Sri Lakshmi Narayana Institute of Medical Sciences

Date: 04.05.2017

From
Dr. Nithanandam
Professor and Head,
Department of Anaesthesia
Sri Lakshmi Narayana Institute of Medical Sciences
Bharath Institute of Higher Education and Research
Puducherry

To
The Dean,
Sri Lakshmi Narayana Institute of Medical Sciences
Puducherry

Sub: Request for Permission to conduct value-added course: Research Methodology

Dear Sir,

With reference to the subject mentioned above, the department proposes to conduct a value-added course titled RESEARCH METHODOLOGY for undergraduates from July- December 2017. We solicit your kind permission for the same.

Kind Regards

Dr. NITHANANDAM. S

FOR THE USE OF DEANS OFFICE

Names of Committee members for evaluating the course.

The Dean: Dr JAYALAKSHMI

The HOD. Dr.NITHANANDAM. S

The Expert: Dr JALAKANDAN

The committee has discussed about the course and is approved.

Dean Subject Expert HOD

OFFICE OF THE DEAN

Sri Lakshmi Narayana Institute of Medical Sciences

OSUDU, AGARAM VILLAGE, VILLIANUR COMMUNE, KUDAPAKKAM POST,
PUDUCHERRY - 605 502.
(Recognised by Medical Council of India, Ministry of Health letter No. U/1201/2/249/2005-ME (P -II) dt. 11/07/2011)
[Affiliated to Bharath University, Chennai - TN]

Circular

06.06.2017

Sub: **Organizing Value-added Courses: Research Methodology - reg**

With reference to the above mentioned subject, it is to bring to your notice that Sri Lakshmi Narayana Institute of Medical Sciences, **Bharath Institute of Higher Education and Research**, is organizing **"_RESEARCH METHODOLOGY"** course. The course content is enclosed below."

The application must reach the institution along with all the necessary documents as mentioned. The hard copy of the application should be sent to the institution by registered/ speed post only so as to reach on or before 15/06-2017. Applications received after the mentioned date shall not be entertained under any circumstances.

Dean

Encl. Copy of Course content

COURSE PROPOSAL

Course Title: **HOSPITAL INFECTION CONTROL**

Course Objective:

1. To enable the students to learn about understanding what is research, what are the different types of clinical studies, to know how to frame a research question and understand various steps involved in conducting a clinical study.

2. To familiarize and update themselves with ongoing research activities in different subjects.

Course Outcome:

On successful completion of the course the students will have skill in framing research questions and to conduct any clinical research of their choice

Course Audience: II year MBBS students

Course Coordinator: Dr S NITHIANANDAM

Course Faculties with Qualification and Designation:

1 Dr Nithianandam-Professor and HOD

2 Dr. Jalakandan-Associate Professor

Course Curriculum/Topics with schedule (Min of 30 hours)

S.No	Date	Topic	Time	Hours	FACULTY
1	08.07.2017	Introduction to HR methods	2-4PM	2	Dr Nithianandam
2	15.07.2017	Definition and role of research	2-4PM	2	Dr. Jalakandan
3	22.07.2017	Objective of research	2-4PM	2	Dr Nithianandam
4	29.07.2017	Research question framing	2-4PM	2	Dr. Jalakandan
5	05.08.2017	Literature review methodology	2-4PM	2	Dr Nithianandam
6	12.08.2017	Proposal submission to scientific committee	2-4PM	2	Dr. Jalakandan
7	19.08.2017	Proposal submission to ethical committee	2-4PM	2	Dr Nithianandam
8	26.08.2017	Randomization / blinding	2-4PM	2	Dr. Jalakandan
9	02.09.2017	Data collection and entry	2-4PM	2	Dr Nithianandam
10	09.09.2017	Statistical analysis for calculating p value	2-4PM	2	Dr. Jalakandan
11	16.09.2017	Decoding data analysis	2-4PM	2	Dr Nithianandam
12	23.09.2017	Discussion of findings with literature support	2-4PM	2	Dr. Jalakandan
13	30.09.2017	Strength/ weakness of study implication	2-4PM	2	Dr Nithianandam
14	07.10.2017	References: vancouver style	2-4PM	2	Dr. Jalakandan
15	14.10.2017	Publications	2-4PM	2	Dr Nithianandam

REFERENCES:

1) Research methodology :An introduction, Wayne Goddard, Stuart Melville, Juta and Company Ltd, 2004

2) Case study: A strategic research methodology, Khairul Baharein Mohd Noor, American journal of applied sciences 5(11),1602-1604,2008.

3) Fundamental of research methodology and statistics ,Yogesh Kumar Singh, New Age International, 2006.

VALUE ADDED COURSE

1. Name of the program & Code

RESEARCH METHODOLOGY, ANAES 05

2. Duration & Period

30 hrs: July 2017- December 2017

3. Information Brochure and Course Content of Value Added Courses

Enclosed as Annexure- I

4. List of students enrolled:

Enclosed as Annexure- II

5. Assessment procedures:

Multiple choice questions- *Enclosed as Annexure- III*

6. Certificate of Participation:

Enclosed as Annexure- IV

7. No. of times offered during the same year:

1 Time JULY 2017-DEC 2017

8. Year of discontinuation: 2018

9. Summary report of each program year-wise

Value Added Course- July 2017- December 2017					
Sl. No	**Course Code**	**Course Name**	**Resource Persons**	**Target Students**	**Strength & Year**
1	ANAES 05	RESEARCH METHODOLOGY	DR. JALAKANDAN	II MBBS	20

10. Course Feed Back

Enclosed as Annexure- V

RESOURCE PERSON **COORDINATOR**

DR. JALAKANDAN **Dr S NITHIANANDAM**

ANNEXURE I

RESEARCH METHODOLOGY

1. Introduction to human research

Introduction

Scientific research on humans includes investigation of the human body and behavior and the effect of various medications and treatments on humans. Research takes place in a laboratory, at home, or in a medical office of hospital.

Controversy surrounds discussion of the permissible ways to do human research and the nature of the proper relationship between researchers and subjects.

Categorizing Human Research

A traditional distinction in the natural sciences (for example, physics and chemistry) is between pure research and applied research, which mirrors a similar distinction between pure science and applied science. Pure research is done only to advance knowledge, while applied research tries to find solutions to specific problems or apply scientific knowledge to the development of technology to use in the world.

Scientists doing human research do both, but the type of research most likely in a clinical setting is applied research. Medical researchers often test new drugs and treatments to find out if they are safe and effective. Among such research trials, a commonly-held distinction is between therapeutic and nontherapeutic research. Therapeutic research is intended to benefit some or all of the specific research subjects (at least it is hoped it will). Nontherapeutic research is intended to increase knowledge and may

benefit individuals in the future who take the medication or treatment in question, for instance, but the research is not intended to benefit the specific research subjects. The research subjects in therapeutic research will likely be suffering from some disease that the treatment being tested might help or cure. This is probably not the case in nontherapeutic research.

Moral Problems with Previous Research

Some research done in the past is now universally condemned as having harmed and wronged the subjects. Enemy soldiers were experimented on during the Second World War by various countries, notably Nazi Germany and Japan. The Nazi doctor Joseph Mengele carried out immoral experiments on civilians, harming and killing them in the process.

A number of things were obviously immoral about the Nazi experiments, including the facts that subjects were not free to refuse to participate and that researchers took little or no precautions against harming subjects during the research. In fact, some research seemed intent on measuring what happened when subjects were intentionally harmed. And some research seemed more the result of perverse and sadistic tendencies among Nazi researchers than for any meaningful scientific purpose.

Though not comparable to the Nazi research atrocities, the history of human research in the United States is not completely blame free. The famous “Tuskegee Syphilis Experiment” of 1932-1972 deceived and harmed African-American males in Alabama. There are numerous other examples of research on human subjects in the United States now commonly considered to have been immoral. Common problems were the anticipated harming of subjects, subjecting subjects to risks without their

informed consent, and outright deception of subjects about the nature of the research and whether or not they were receiving treatment.

As a result of the above research abuses various corrective measures were taken and standards were created, including the Nuremberg Code, the Helsinki Declaration, the Belmont Report, and the use of institutional review boards. The Nuremberg Code stresses the need to inform human subjects of the nature of the research, disclose any risk of harm, avoid unneeded risk to the subjects, and obtain voluntary consent from the subjects. The research must be justified by aiming to benefit society, and some levels of harm to subjects cannot be justified no matter how noble the aim. The Helsinki Declaration carries on the tradition of the Nuremberg code and adds that subjects and their rights must be treated with respect. The well-being of the subjects takes precedence over the goals of the research. In contrast to Nuremberg, Helsinki allows possible exceptions to the requirement of obtaining voluntary consent from the subjects. Research might be done on minors and those with mental impairments, for example, where the whole population under study cannot give consent, but proxy consent must be obtained from guardians. To safeguard the subjects, ethical review committees should be used.

The Belmont Report in the United States in the 1970's highlights three important principles to guide medical care of patients (therapy) and biomedical research on subjects: respect for persons, beneficence, and justice. Respect for persons incorporated what is now known as respect for autonomy (freedom of choice), and beneficence (doing good, benefiting the subject) included what is now known separately as non-maleficence (refraining from harming the subject). Though the same principles guide how physicians treat patients and how researchers should treat subjects,

the Belmont Report recognizes that “medical or behavioral practice” (therapy) is different than research. The former provides diagnosis, prevention, and therapy to benefit specific individuals, while research only need contribute to knowledge in general. Both contexts should be governed by the principles, including that of beneficence. But some critics believe the Belmont Report does not clarify sufficiently whether and how research must or may not benefit the specific research subject.

Conflicts Between Therapy and Research

Stemming from the work of the Belmont Report, the ethicists Beauchamp and Childress popularized the relevance of the principles of respect for autonomy, beneficence, non-maleficence, and (distributive) justice for both clinical practice and medical research. The common view became that the behaviors of both physicians providing treatment and researchers conducting trials should be governed by these principles, even though therapy and research have different goals. So when trying to map out ethical research, thinkers tried to adapt principles that were more commonly thought of as applying to medical practice. Sometimes they had to be interpreted slightly differently for this to work.

To some extent it is understandable one might try to use the same principles. Not all research trials are done in a lab by scientists -- physicians treating patients may at the same time be carrying out clinical research trials on those patients. This is a common way to test the safety and efficacy of new medications and other medical treatments and of course is done only with the consent of the patients. Many trials done by physicians on their patients fall under the category of therapeutic research because the patients have a disease the tested treatment might help or cure.

But it has by now become apparent to some thinkers that perhaps slightly different moral principles are needed for health research than are needed for healthcare practice. Some believe there is a conflict between the two roles the provider is forced to assume in that they may demand conflicting obligations of the provider. The role of therapist demands the provider provide the best possible treatment for a patient. This is commonly held to be implied by the principle of beneficence, here "specificbeneficence" because it applies to a specific patient. On the other hand, as a researcher, even in therapeutic research, the provider may be forced to give a patient less than the best possible treatment. (The duty of beneficence in the research context usually is interpreted to mean not that the researcher provide the best possible treatment for the specific subject, but only that the research in general be intended to benefit humanity.) Hence the provider as therapist will be at war with the provider as researcher.

This situation may come about in a common form of research known as a randomized controlled trial (RCT). In such a trial a new drug, for instance, is tested either against the existing standard of care or against a "dummy" pill, a placebo. (The placebo is considered the "gold standard" for such trials.) The research subject is not told which treatment they are getting – the new drug or the alternative. Now if the patient gets a placebo, and in fact it is not as good as the new drug, then the patient gets less than the best treatment. If instead the trial pits the new drug against the existing standard of care, and the patient receives either one, when the other one is better, then the patient still gets less than the best treatment. But recall that the physician, as therapist, is obligated to always give the patient the best treatment.

There seem two ways to look at this problem. One way is to claim it is not a real problem because of the doctrine of “equipoise.” The other way is to allow that there is a problem and to locate the problem in the fact that therapy is not research, even therapeutic research, the two endeavors should not have the same set of moral principles to guide them, and as long as a physician tries to use patients for research trials there will be a conflict.

Equipoise is a state of balance between options, or a neutrality or suspension of judgment because the evidence does not favor one side or the other. Some thinkers believe that if the physician claims equipoise (“theoretical” equipoise) or the medical community claims equipoise (“clinical” equipoise) then this absolves the physician from the charge of not providing the best available treatment for their patients when those patients are research subjects in a clinical trial. In such a trial, the physician personally and/or the medical community as a whole does not know whether the new drug, for instance, is really better or worse than the standard of care or than a placebo. So it is not as if the physician is intentionally giving the patient less than the best treatment. The patient may get the new drug or what it is tested against, and no one knows which one is better.

Others claim that citing equipoise does not solve the problem in all possible situations. If the drug is tested against a placebo, the fact is that some of the patients will get the placebo, but also consider there may have been a third alternative, the existing standard of care, and those patients would have received that if they were not in the trial. The standard of care is likely better than the placebo. So if the patients get the placebo in the trial instead of getting the standard of care, then in fact the physician is not

giving those patients the best treatment possible. Furthermore, there is the possibility that the new drug is worse than the standard of care, meaning that in a trial testing the new drug against the standard of care (instead of a placebo) there is the possibility the patient does not receive the best available treatment. But when a physician takes on a patient the physician incurs an obligation to provide the best possible care, not guide the patient into an experiment that puts the patient at risk of receiving less or even of being harmed by the treatment in the hope that they will be lucky enough to get a cure.

The unsettling thought of a patient who as a research subject gets less than the standard of care is a reason the World Medical Association has called for using the standard of care instead of placebos in such clinical trials. Some thinkers believe equipoise is unrealistic to expect anyway. If the new drug is being tested on people, it must have shown some promise in earlier studies already. So how can one suspend judgment about whether it is likely to be better?

Those who reject the equipoise argument believe the problem is that the goal of therapy is not the goal of research, even therapeutic research. The physician is in conflict about the two roles. The physician's obligation is to the patient, the researcher's obligation is to gaining knowledge through the research. In therapeutic research a patient might hope to receive a newly discovered superior treatment, but that is not the goal of the research trial.

There is nothing morally wrong about using placebos in research because research is not therapy. Any help the research subject gets from the treatment is incidental. (Miller and Brody.)

The Therapeutic Misconception?

Researchers talk of the “therapeutic misconception.” This occurs when despite cautions from the researcher to the subject that the goal of the research is primarily scientific knowledge and the treatment the subject receives is not intended as therapy, many patients develop the belief that the treatment is going to help them. The patient can even come to believe the primary purpose of the research is to treat them.

Physicians and researchers ponder studies showing that the therapeutic misconception is widespread. But what is perhaps ironic is that researchers and ethicists wonder why this happens when in fact physicians and other researchers themselves talk of “therapeutic research” and researchers are often physicians whose research subjects are their very own patients who are coming to them for treatment. Is it any wonder a subject with an illness participating in medical research being done by their own physician hopes and begins to believe that the treatment is going to help them?

Could researchers be expecting too much of their subjects? Why would anyone volunteer as a research subject anyway? Some people are genuinely altruistic and willing to accept considerable risk for the sake of science, and other people value the small compensation for time and trouble that some research subjects receive, but aside from that, the only motivation to participate is some version of the therapeutic misconception.

If you are ill, why accept possibly significant risk except because the treatment just might be a cure for the disease you have? The therapeutic misconception helps recruit research subjects.

New Principles of Medical Research

Some researchers and ethicists believe the four traditional principles of biomedical ethics are more suited to the physician-patient relationship than

the researcher-subject relationship. For example, Emanuel, Wendler, and Grady propose the following as principles for research:

1. The research must have scientific or social value
2. The research must be scientifically valid
3. The selection of subjects must be fair
4. The research benefits and risks must be in a favorable ratio
5. The research should be subject to independent review
6. The research subjects must provide informed consent
7. The research subjects must be treated with respect

2.Definition and role of research

Analysis of Existing Data or Specimens

If you're using coded private information, data, or specimens, NIH will consider your research to involve human subjects unless it meets both of the following conditions:

- You are not collecting samples by interacting or intervening with living people.
- None of the investigators, collaborators, or co-authors have access to any information (data or biospecimens) that can re-identify subjects.

Toolkit for Analysis of Existing Data

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Observational Studies

In an observational study, the investigator simply records observations and analyzes data, without administration of an intervention or alteration of the care people receive. These studies may focus on risk factors, natural history, variations in disease progression or disease treatment without

delivering an intervention. They often assess specific health characteristics of the enrolled human subjects by collecting medical/dental history, exposure, or clinical data; obtaining biospecimens (e.g., for biomarker or genomic analyses); or obtaining photographic, radiographic or other images from research subjects.

Toolkit for Observational Studies

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Interventional Studies

In an interventional study, the investigator manipulates the subject or the subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. The NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions.

3. Objectives of research

Different types of clinical research are used depending on what the researchers are studying. Below are descriptions of some different kinds of clinical research.

Treatment Research generally involves an intervention such as medication, psychotherapy, new devices, or new approaches to surgery or radiation therapy.

Prevention Research looks for better ways to prevent disorders from developing or returning. Different kinds of prevention research may study medicines, vitamins, vaccines, minerals, or lifestyle changes.

Diagnostic Research refers to the practice of looking for better ways to identify a particular disorder or condition.

Screening Research aims to find the best ways to detect certain disorders or health conditions.

Quality of LifeResearch explores ways to improve comfort and the quality of life for individuals with a chronic illness.

Genetic studies aim to improve the prediction of disorders by identifying and understanding how genes and illnesses may be related. Research in this area may explore ways in which a person's genes make him or her more or less likely to develop a disorder. This may lead to development of tailor-made treatments based on a patient's genetic make-up.

Epidemiologicalstudies seek to identify the patterns, causes, and control of disorders in groups of people.

An important note: some clinical research is "outpatient," meaning that participants do not stay overnight at the hospital. Some is "inpatient," meaning that participants will need to stay for at least one night in the hospital or research center. Be sure to ask the researchers what their study requires.

Phases of clinical trials: when clinical research is used to evaluate medications and devices

Clinical trials are a kind of clinical research designed to evaluate and test new interventions such as psychotherapy or medications. Clinical trials are often conducted in four phases. The trials at each phase have a different purpose and help scientists answer different questions.

- **Phase I trials**

  Researchers test an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.

- **Phase II trials**

  The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- **Phase III trials**

  The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
- **Phase IV trials**

  Post-marketing studies, which are conducted after a treatment is approved for use by the FDA, provide additional information including the treatment or drug's risks, benefits, and best use.

Examples of other kinds of clinical research

Many people believe that all clinical research involves testing of new medications or devices. This is not true, however. Some studies do not involve testing medications and a person's regular medications may not need to be changed. Healthy volunteers are also needed so that researchers can compare their results to results of people with the illness being studied. Some examples of other kinds of research include the following:

- A long-term study that involves psychological tests or brain scans
- A genetic study that involves blood tests but no changes in medication
- A study of family history that involves talking to family members to learn about people's medical needs and history.

Diagnostic Trials: This type of research seeks to find better ways to identify and diagnose diseases and other medical conditions. Work in this area is critically important, in that correct and early diagnosis of problems is a key to achieving successful treatments

2. Screening Trials: Screening trials test various methods and ways of identifying and detecting particular health conditions. New diagnostic screening approaches provide widespread public health benefits. Medical research studies are held to prove or disprove new screening techniques which could be used to diagnose current or new disorders.

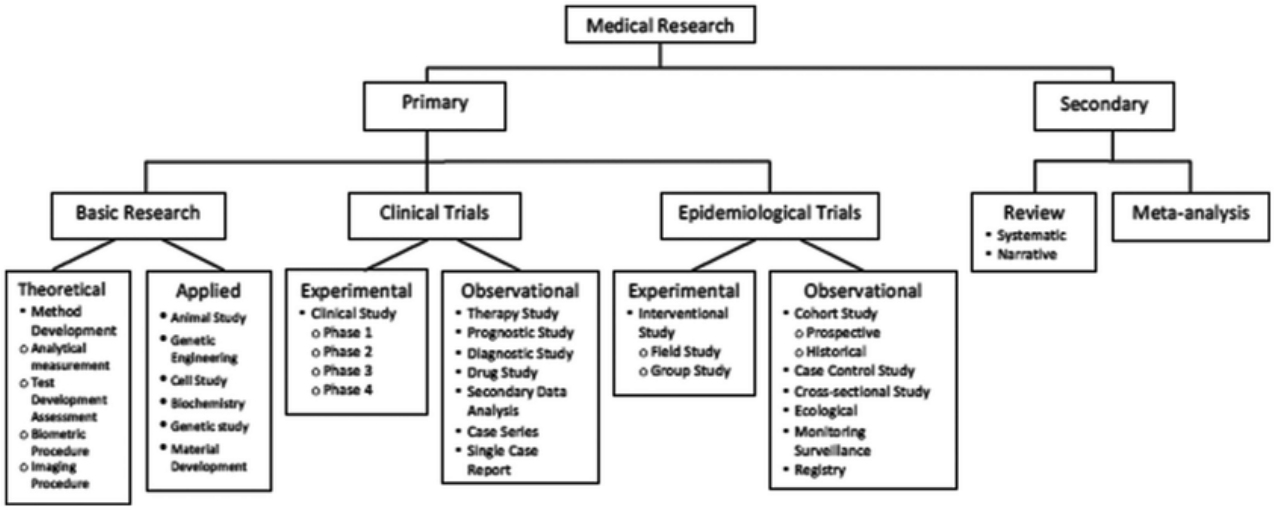
3. Prevention Trials: Prevention is always preferred to treatment, so new methods and approaches to preventing diseases and disorders are constantly being scrutinized and tested. Medical research studies may include the use of new medicines, lifestyle changes, or vaccines. These new approaches are essential in that, generally, preventing a disorder is the best outcome for a patient, and it is cost-effective.

4. Treatment Trials: When people think of medical research studies, they think of treatment trials. This type of medical research study involves testing new treatments, including new medications and vaccines, new approaches and tools for treatment of various diseases and disorders, or use of drug combinations for fighting a particular disease. This type trial is one of the most important of all trial types as new medications and vaccines are made available to the public via these trials. Many of the trials being carried out by DM Clinical Research fall in this category.

5. Behavioral Trials: Many of our modern lifestyle practices and habits lead to difficulties and disorders. Change of lifestyle practices and behavioral modifications often result in great benefits to patients. Certain activities are known to be linked to certain diseases such as smoking and lung cancer.

It’s well-known that by quitting smoking, an individual reduces their chances of contracting lung diseases and cancers

6. Quality of Life Trials: This type of medical research trial tests ways to improve the comfort and well-being of people who are suffering from a variety of diseases and disorders. These trials may include methods of pain



management and recovery protocols.

4.Research question framing

5. Literature review methodology

As the phrase suggests, the Seven-Step Model of the CLR comprises seven steps: (a) Step 1: Exploring Beliefs and Topics; (b) Step 2: Initiating the Search; (c) Step 3: Storing and Organizing Information; (d) Step 4: Selecting/ Deselecting Information; (e) Step 5: Expanding the Search to Include One or More MODES (Media, Observation(s), Documents, Expert(s), Secondary Data); (f) Step 6: Analyze and Synthesize Information; and (g) Step 7: Present the CLR Report. These seven steps

are multidimensional, interactive, emergent, iterative, dynamic, holistic, and synergistic.

professional beliefs, knowledge, and experiences) to explore initial key terms associated with this topic to inform their information searches (Step 1). Further, lit- erature reviewers should explore potential information databases, and then, once appropriate databases have been identified, they should search these databases to explore information about the topic and to identify the most appropriate key terms to help focus the search (Step 2). Literature reviewers also should explore what information to select and what information to deselect (Step 4) and expand the search by incorporating one or more of the five MODES (Step 5). While making their journeys to and through Step 5—the final step of the Exploration Phase—literature reviewers should explore how to store and to organize information.

The second phase, Interpretation, involves liter- ature reviewers interpreting the selected information that they extracted via the previous five steps. This interpretation occurs through analysis and synthesis pathways. As the word suggests, this interpretation phase is interpretive because it is the culmination of the analysis, evaluation, and interpretation of selected information sources, which are then syn- thesized, leading to what Tashakkori and Teddlie (1998) refer to as meta-inferences, which represent inferences from each information source that are combined into a coherent narrative.

The third and final phase, Communication, involves literature reviewers disseminating their lit- erature reviewer reports to the appropriate audience. This dissemination might take the form of a presenta- tion that is delivered via Acting (e.g., performance ethnography wherein the literature review

report is performed via dramatic representations such as plays), Visually (e.g., via drawings, paintings, photographs, videos, multimedia), Orally (e.g., presenting the liter- ature review report in class; presenting the literature review report as part of a thesis/dissertation defense; presenting the literature review report at a research conference by itself, or as part of the presentation of a primary research report), or, most importantly, in Writing (e.g., via a class assignment, thesis/disser- tation chapter, research article, book chapter, blog, website, or Internet-based social bookmarking ser- vice)—with the printed and/or digital form of the literature review report being stored somewhere (e.g., library, bibliographic database, website). Typically,

the goal here is to make the research report avail- able to one or more others, thereby contributing to the cycle of knowledge generation.

Using the Seven-Step Model to Inform Primary Research

As seen in Figure 3.4, the Seven-Step Model can be applied to any or all of the 12 components of a primary research report: problem statement, back- ground, theoretical/conceptual framework, research question(s), hypotheses, participants, instruments, procedure, analyses, interpretation of the findings, directions for future research, and implications for the field. The following sections provide an over- view of these applications.

Problem Statement

An effective (i.e., research-worthy) problem statement (also called the statement of the problem) is the description of a current and important challenge (i.e., problem) that is confronted by researchers and/ or practitioners for which there are no adequate solutions available from the extant literature. Further, a research-worthy problem statement should make clear the nature and scope of the problem that has been identified.

More specifically, the problem statement is a section in a research report that contains the topic for the study, the research problem within this topic, a justification for the problem based on past research and practice, deficiencies or shortcomings of past research or practical knowledge, and the importance of addressing the problem for diverse audiences (Creswell, 2002, p. 650). Clearly, to obtain “a justification for the problem based on past research” and to identify “deficiencies or shortcomings of past research,” a Comprehensive Literature Review is needed.

Background

It should be obvious that a literature reviewer needs to provide adequate background information to be able to write the literature review section of a primary research report. Thus, we do not need to provide a further explanation here as we hope it is implied!

Methodology of the Literature Review 57

Tool: Overview of the Seven-Step Model

Figure 3.3 illustrates the flow of the Seven-Step Model. This figure also reflects the exploration, interpretation, and communication phases.

As you can see from this figure, Step 3 (Storing and Organizing Information) plays a pivotal role in the literature review process because every selected information source needs to be stored and organized, at least initially. Thus, as can be seen, arrows go from Step 2, Step 4, and Step 5 to Step 3, which indicates that information obtained during Step 2, Step 4, and Step 5 must be stored and organized. Also, arrows go from Step 3 to Step 4, Step 5 (i.e., via Step 4), and Step 6, which indicates that information obtained in previous stages should be stored and organized

before moving to Step 4, Step 5, and Step 6. In the following chapters, you will learn about each of the seven steps to conduct the CLR.

Exploration Phase

Step 1

Exploring Beliefs and Topics

Step 2

Initiating the Search

Step 3

Storing and Organizing Information

Step 4

Selecting/ Deselecting Information

Step 5

Expanding the Search (MODES)

Interpretation Phase

Step 6

Analyzing/ Synthesizing Information

Communication Phase

Step 7

Presenting the CLR Report

Applying Concepts

As we outlined in Chapter 1, before the literature review begins, the literature reviewer must determine whether the goal of the literature review is as an end in itself (i.e., as a stand-alone study) or as a study to inform primary research. If the goal is as an end in itself, then the Seven-Step Model will only be used to generate the literature review report (e.g., for written communication, for oral communication). However, if the goal of the

literature review is to inform primary research, then the literature reviewer should undertake a series of literature reviews, as needed, throughout the conduct of the primary research.

Tool: Seven-Step Model to Inform Primary Research Areas

Figure 3.4 presents how the Seven-Step Model might be used to inform the various components of the primary research study.

The Comprehensive Literature Review PROCESS

Background

Problem Statement

Research Question(s)

Participants

Instruments

Procedure

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Z□□

□□a primary research report

Theoretical/Conceptual Framework

As noted by Lester (2005), a theoretical framework guides the research process via the use of formal theory “developed by using an established, coherent explana- tion of certain sorts of phenomena and relationships”

(p. 458). In contrast, a conceptual framework is “an argument that the concepts chosen for investigation, and any anticipated relationships among them, will be appropriate and useful given the research problem under investigation” (p. 460). Virtually all quantitative, qualitative, and mixed research studies are driven, a

6. Proposal submission to scientific committee

Format of submission of Research Project to Institutional Ethics Committee (IEC)

S.No.

1.

Title of the Research Project

2.

Name, designation & address of Principal Investigator/Supervisor

3.

Name, designation & address of CoInvestigators

4.

Name, designation & address of Coinvestigators

5.

Name of the department(s) where research/study will be carried out

6.

Details of the centers involved in multicentre study (applicable to multicentric studies only)

7.

Name & address of Funding Agency

Intramural/Extramural

8.

Details of the budget

9.

Objective(s) of the study

10.

Rationale of conducting the study

11.

Methodology

12.

Does the project involve :

a. Clinical trial with new drug(s)/device(s)
approved by DCGI.

b. Clinical trial with existing
drug(s)/device(s) approved by DCGI.

c. Traditional medicine(s) (Ayurvedic/
Unani/ Homeopathic/ Tribal System).

d. Animals will be used. (if YES, refer to
IECA)

e. None of the above.

(if“a” is yes, kindly provide details/evidence of experimental & clinical safety of the drug(s)/device(s))

13.

Does the project involve :

Samples from human (if yes than what is the type of sample

Animal Work

Celllines

Recombinant Technology

Genetic Information (if yes than explain their ethical concerns)

14.

Are there any anticipated risk(s) during the course of the study (procedural/adverse drug reaction or any other).

(If”yes”, please provide details along with management/compensation of the risk factors).

15.

Does this proposal has clearance from any other scientific committee/agency – (If “yes”, kindly furnish the details)

16.

Conflict of interest of any investigator (If “yes”, please furnish details.

17.

Consent form from the patient (if required than provide the consent form format)

Synopsis of the proposal (format is attached below)

Attach this as a separate annexure

Undertaking / declaration from the Principle Investigator

Attach this as a separate annexure

Intellectual Property Rights (IPR) declaration (format is attached below)

Attach this as a separate annexure

Date : ..... Signature of Principal Investigator/Supervisor

Title:

Principal Investigator:

INTRODUCTION : (BRIEFLY IN A PARAGRAPH)

REVIEW OF LITERATURE: (BRIEFLY IN A PAGE WITH PROPER REFERENCES) METHODOLOGY DESCRIBING THE POTENTIAL RISKS AND BENEFITS: EXPECTED OUT COME AND ETHICAL ISSUES IF THERE IS ANY:

7.Proposal submission to ethical committee

protocol'

Research protocol: part 1

Project summary

Like the abstract of a research paper, the project summary, should be no more than 300 words and at the most a page long (font size 12, single spacing). Provided preferably on a separate page, it should summarize all the central elements of the protocol, for example the rationale, objectives, methods, populations, time frame, and expected outcomes. It should stand on its own, and not refer the reader to points in the project description.

General information

- Protocol title, protocol identifying number (if any), and date.
- Name and address of the sponsor/funder.
- Name and title of the investigator(s) who is (are) responsible for conducting the research, and the address and telephone number(s) of the research site(s), including responsibilities of each.
- Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the research

Rationale & background information

The Rationale specifies the reasons for conducting the research in light of current knowledge. 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 is the equivalent to the introduction in a research paper and it puts the proposal in context.

It should answer the question of why and what: why the research needs to be done and what will be its relevance. 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.

References (of literature cited in preceding sections)
References can also be listed at the end of Part 1.

Study goals and objectives
Goals 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.

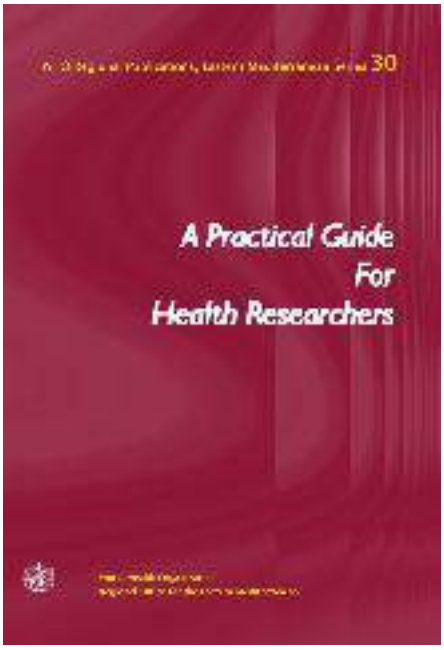
Study design
The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology. The design of the study should include information on the type of study, the research population or the sampling frame, and who can take part (e.g. inclusion and exclusion criteria, withdrawal criteria etc.), and the expected duration of the study

Note: The same study can be described in several ways, and as complete a description of the study as possible should be provided. For example, a

study may be described as being a basic science research, epidemiologic or social science research, it may also be described as observational or interventional; if observational, it may be either descriptive or analytic, if analytic it could either be cross-sectional or longitudinal etc. If experimental, it may be described as a controlled or a non controlled study. The link below provides more information on how to describe a research study.

Guidelines on submitting research proposals for ethics review

Guidance for submissions of documents



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Methodology

The methodology section is the most important part of the protocol. 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. If multiple sites are engaged in a specified protocol, methodology should be standardized and clearly defined.

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.

Safety considerations

The safety of research participants is foremost. Safety aspects of the research should always be kept in mind and information provided in the protocol on how the safety of research participants will be ensured. This can include procedures for recording and reporting adverse events and their follow-up, for example. It is useful to remember that even administering a research questionnaire can have adverse effects on individuals.

Follow-up

The research protocol must give a clear indication of what follow up will be provided to the research participants and for how long. This may include a follow u, especially for adverse events, even after data collection for the research study is completed.

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.

Quality assurance

The protocol should describe the quality control and quality assurance system for the conduct of the study, including GCP, follow up by clinical monitors, DSMB, data management etc.

Expected outcomes of the study

The protocol should indicate how the study will contribute to advancement of knowledge, how the results will be utilized, not only in publications but also how they will likely affect health care, health systems, or health policies.

Dissemination of results and publication policy

The protocol should specify not only dissemination of results in the scientific media, but also to the community and/ or the participants, and consider dissemination to the policy makers where relevant. Publication policy should be clearly discussed- for example who will take the lead in publication and who will be acknowledged in publications, etc.

Duration of the project

The protocol should specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken.

Problems anticipated

This section should discuss the difficulties that the investigators anticipate in successfully completing their projects within the time frame stipulated and the funding requested. It should also offer possible solutions to deal with these difficulties.

Project management

This section should describe the role and responsibility of each member of the team

Ethics

The protocol should have a description of ethical considerations relating to the study. This should not be limited to providing information on how or from whom the ethics approval will be taken, but this section should document the issues that are likely to raise ethical concerns. It should also describe how the investigator(s) plan to obtain informed consent from the research participants (the informed consent process).

Informed consent forms

The approved version of the protocol must have copies of informed consent forms (ICF), both in English and the local language in which they are going to be administered. However translations may be carried out after the English language ICF(s) have been approved by the ERC. If the research

involves more than one group of individuals, for example healthcare users and healthcare providers, a separate specifically tailored informed consent form must be included for each group. This ensures that each group of participants will get the information they need to make an informed decision. For the same reason, each new intervention also requires a separate informed consent form.

Research protocol: part 2

Budget

The budget section should contain a detailed item-wise breakdown of the funds requested for, along with a justification for each item.

Other support for the project

This section should provide information about the funding received or anticipated for this project from other funding organizations.

Collaboration with other scientists or research institutions

Links to other projects

Curriculum Vitae of investigators

The CV of the Principal investigator and each co-investigators should be provided. In general each CV should not be more than one page, unless a complete CV is specifically requested for.

Other research activities of the investigators

The Principal investigator should list all current research projects that he/she is involved in, the source of funding of those projects, the duration of those projects and the percentage of time spent on each.

Financing and insurance

Financing and insurance if not addressed in a separate agreement, and where relevant should be described.

8. Randomisation and blinding

Chapter 11Randomization, blinding, and coding

Go to:

1. Introduction to randomization, blinding, and coding

As discussed in Chapter 4, the random allocation of participants in a trial to the different interventions being compared is of fundamental importance in the design of investigations that are conducted to produce the highest-quality evidence of any differences in the effects of the interventions. Only if the units to which the interventions are applied (for example, individuals, households, or communities) are randomized between the interventions under study and the study is of a sufficient size is it possible to be confident that differences in the outcome measures of the trial among those in the different intervention groups are due to the effects of the interventions, rather than to underlying differences between the groups. Randomization should ensure that any potential confounding factors, whether known or unknown, are similarly distributed in each of the intervention groups and

therefore cannot bias the comparisons of outcome measures between the groups.

Randomization, if done properly, eliminates the possibility of subjective influence in the assignment of individuals to the different intervention groups. Sometimes ‘pseudo-randomization ’methods are employed in trials for reasons of convenience such as alternate assignment of the different interventions to successive trial entrants or allocation based upon the date of birth or date of entry (with, say, one intervention being assigned to those reporting on even dates and another to those reporting on odd dates). However, proper randomization is superior to any systematic method of allocation, and these other methods should be avoided, unless there are very compelling reasons for using them. With systematic allocation, it is possible for the investigator, and sometimes the participant, to know in advance the group to which a participant will be allocated, and this may introduce conscious or unconscious bias into the allocation procedure. For example, such knowledge may affect the investigator’s judgement as to whether or not an individual is eligible for entry into a particular trial. For this reason, it is essential that the randomization is done (or the randomization allocation is revealed to the investigator) only *after* it has been ascertained both that an individual is eligible for entry into a trial and also that he or she is prepared to participate in the trial, no matter which intervention is assigned.

As (Schulz 1995) pointed out, the success of randomization depends on two interrelated processes. The first entails generating a sequence by which the participants in a trial are allocated between intervention groups. To ensure unpredictability of that allocation sequence, it should be generated by a random process. The second process *allocation*

concealment shields those involved in a trial from knowing upcoming assignments in advance, so that investigators cannot change who gets the next assignment, potentially making the comparison groups less equivalent and thus biasing the measurement of the effects of the intervention.

In this chapter, various ways are described in which interventions may be randomly assigned among trial participants. The simplest method, if there are two intervention groups, is by using a procedure which is equivalent to tossing a coin to decide the allocation for each individual unit. This can either be done literally, or an equivalent procedure may be simulated using a table of random numbers or by using a computer to generate random numbers, as described in Section 2.1. In large trials, the use of such a simple randomization procedure is highly likely to ensure that there are nearly equal numbers of units allocated to the different intervention groups and the distribution of potentially confounding factors will be similar in all groups. However, if the total number of units in a study is small, such an assignment procedure may result by chance in the compositions of the different intervention groups being markedly different with respect to factors that may affect the outcome measures in the trial, or markedly unequal numbers of participants may be recruited to each intervention group. Such imbalance may arise by chance as, for example, it is possible that, if a coin is tossed ten times, it will come down heads, say, only twice. In fact, the chance that it will come down exactly heads five times and tails five times is only about 25%. For trials involving several hundreds of participants or more, any such imbalance is likely to be small and can be taken into account in the analysis of the trial. In a small trial, imbalance may make the trial more difficult to interpret, and it is advisable to design the randomization procedure to ensure balance. For this purpose, ‘restricted ’or

‘blocked ’randomization (see Section 2.2) can be used to ensure balance in group sizes. Blocked randomization also helps to achieve balance on time sequence and, in multicentre trials, study site. Stratum-matched designs (see Section 2.3) can be employed to produce balance in the composition of the groups, with respect to those variables on which the matching is based.

The techniques described in Sections 2 and 3 may be used whether the intervention is assigned to communities or to individuals. However, when communities are randomized, as in cluster randomized trials, the number of randomization units (communities) may be relatively small (often 20 or less), and more sophisticated methods of randomization have been devised to reduce sources of potential bias in the allocation of interventions in such trials. These methods are summarized in Section 3.

Whenever possible, intervention studies should be both randomized and *double-blind*, i.e. neither the participants nor the investigator should know to which group each participant has been allocated. This guards against biases that may result from knowledge of the intervention affecting the way an individual behaves, is treated, or is monitored during the trial, or assessed during, or at the end of, the trial. Blinding is discussed in Section 4. In Section 5, there is a discussion of coding systems for recording intervention allocation that may be used in trials.

Go to:

2. Randomization schemes for individual participants

2.1. Unrestricted randomization

Simple random allocation of individuals between the different intervention groups is carried out most conveniently by using a computer. For example, in Microsoft Excel, the instruction ‘= RANDBETWEEN(1,3) ’will produce a

random number between 1 and 3, i.e. each of the numbers 1, 2, or 3 has an equal chance of being generated. The equivalent of tossing a coin is = RANDBETWEEN(1,2). Some calculators also have a key which generates a random number on the display (usually a decimal number between 0 and 1, so that, for example, the equivalent of coin tossing would be to allocate a number less than 0.5000 as ‘heads ’and a number 0.5000 or greater as ‘tails’).

In large trials, it is common for a centralized randomization system to be used. When an investigator has decided that a participant meets the entry criteria for a trial, and the participant has given informed consent to be randomized to one of the trial interventions, the investigator telephones, or sends a text, to a central office to give the identification details for the participant, and the office then tells, or texts, the investigator to which intervention the participant has been randomly assigned or, in the case of a double-blind trial, the code for the intervention that should be administered to the participant. Systems are now commonly used whereby this process has been automated and does not require an individual to answer the telephone in the central office or for a similar automated procedure to be followed over the Internet. The advantage of this method of intervention assignment is that there is no way in which the investigator can influence the randomization procedure, and if, for example, the investigator decides not to allocate an intervention to a participant after knowing the random assignment, there is a central record of this.

For investigators who cannot set up access to a procedure for remote randomization, a frequently used alternative procedure is for a set of opaque, sealed, and numbered envelopes to be prepared, containing the intervention allocations (or possibly even the actual interventions if these

are, for example, drugs). The envelopes are opened in numerical sequence, as each new person is entered into the trial. Entry criteria must be checked and eligibility satisfied before an envelope is opened, in order to exclude the possibility that the decision to accept a subject into the trial is influenced by the knowledge of the group to which he or she would be allocated. For large trials, the use of envelopes may be too cumbersome. Coding systems and alternative procedures appropriate for use in the case of ‘double-blind ’designs are discussed in Section 5.

Where the study product (for example, drug, vaccine) package is individually numbered and labelled (and randomization has been done before the numbering and labelling and where there is an indistinguishable placebo or control intervention), randomization may simply be achieved by registering each new recruit and assigning them the number on the product package.

In some circumstances, it may be better to design the randomization system, such that it is completely transparent to participants that a random allocation process is being used. A trial may be more acceptable if the trial population is involved in the randomization procedure. For example, in a trial in Ghana, the allocation of insecticide-impregnated bed-nets was randomized, such that, in some communities, all households received a bed-net immediately and, in other communities, the distribution of nets was deferred until a later time (Binka et al., 1996). At a public meeting involving all of the trial communities, the name of each community was written on a slip of paper. All the slips were put in a bucket, and a child was asked to draw some of the slips from the bucket to determine which communities received the bed-nets first. By using this procedure, it was apparent that the allocation was random and that no favouritism was operating. The

fairness of the procedure was demonstrated to the population by the fact that, by chance, the community in which the area chief resided was not selected for early bed-net allocation (much to the surprise of the population)! (Fred Binka, personal communication.)

Unrestricted randomization is often employed in large trials, as it is likely that any imbalance between the intervention groups with respect to risk factors for the occurrence of the outcomes of interest will tend to even out. Furthermore, it is possible to adjust for any residual imbalance during the analysis of the study without important loss of statistical power.

2.2. Restricted randomization

Although an unrestricted randomization procedure should lead to approximately equal numbers of participants in each group, this is not guaranteed. For example, there is more than a 5% chance that, if 20 participants are allocated to one of two groups at random, six or fewer may be allocated to one group, and 14 or more to the other. A better balance is achieved by using a ‘restricted randomization ’procedure, also called ‘blocked randomization ’or ‘randomization with balance’. This procedure ensures equal numbers in each group, after there have been a fixed number of allocations. For example, the allocation procedure might be designed in blocks of ten, such that, in every ten allocations, five are to one group and five to the other. The total number of intervention groups must be a multiple of the size of the blocks.

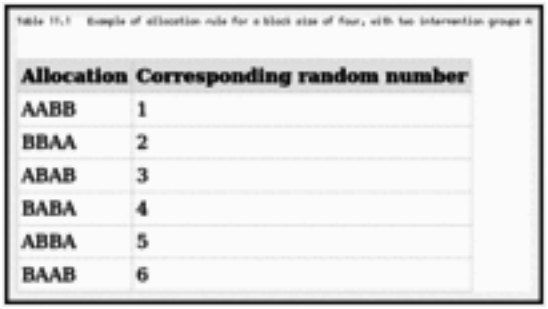
In order to minimize the possibility that an allocation can be deduced from previous allocations, the block size should not be too small (in particular, it should not be two!), and, if possible, it should not be known to the investigator responsible for the administration of the interventions. Indeed, as far as possible, those giving the interventions should not be aware that

blocking has been carried out, or, if the block size is a fixed number, the person giving the intervention would know in advance what the intervention allocation of the last individual or group in the block would be. Another safeguard is to use several different block sizes for allocating interventions in a trial. For example, in a trial with two arms, the block size might be varied, at random, between eight, ten, and 12.

Two different procedures for carrying out restricted randomization are described in Sections 2.2.1 and 2.2.2, one appropriate for small block sizes and the other appropriate for larger block sizes, say eight or more.

2.2.1. Small block sizes

If two interventions, say A and B, are to be allocated using a block size of, say four, it is possible to list all the different possible combinations of the allocations that will yield two As and two Bs. This is illustrated in Table 11.1. A number is allocated to each combination, and a random number is chosen to select a particular allocation.



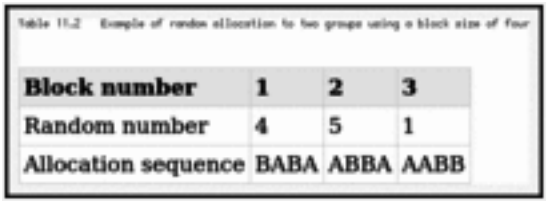
Allocation	Corresponding random number
AABB	1
BBAA	2
ABAB	3
BABA	4
ABBA	5
BAAB	6

Table 11.1

Example of allocation rule for a block size of four, with two intervention groups A and B.

The selection of each random number (between 1 and 6) generates four intervention allocations. Thus, if the random numbers 4, 5, and 1 are

generated, these yield a list of twelve intervention allocations (to be assigned to participants in sequence) (Table 11.2).



Block number	1	2	3
Random number	4	5	1
Allocation sequence	BABA	ABBA	AABB

	Table 11.2 Example of random allocation to two groups using a block size of four.

2.2.2. Larger block sizes

Listing all possible combinations of allocations within a block becomes unmanageable, as the block size increases. For example, with a block size of ten, there are 252 different possible combinations, each yielding five participants in each of two intervention groups A and B. An alternative approach is necessary therefore. Suppose the block size is to be 12 and six allocations are to be made to group A and six to group B. Random numbers between 1 and 12 are generated, until six different numbers in that range have been generated (numbers that duplicate a previous one are ignored). Algorithms are easily available on the Internet to generate such random numbers. (For example, at <http://www.random.org/integers>, it is straightforward to generate X random integers between Y and Z where the user inserts values for X, Y, and Z.) Thus, we might request six random numbers between 1 and 12 and obtain 1, 2, 4, 7, 11, and 12. Then, the first, second, fourth, seventh, eleventh, and twelfth participants within the block are allocated to one of the interventions, say A, and the other

participants to B. The complete sequence for the block of 12 is shown in Table 11.3.

Table 11.3 Example of random allocation to two groups using a block size of 12

Participant	1	2	3	4	5	6	7	8	9	10	11	12
Intervention	A	A	B	A	B	B	A	B	B	B	A	A

		Table 11.3

Example of random allocation to two groups using a block size of 12.A similar procedure, with a different set of random numbers, is used to allocate interventions in the next block (i.e. 13 to 24), and so on.

In general, it is better to choose block sizes which are not too large, in order to reduce the risk of a long sequence of individuals being allocated to the same intervention. A maximum block size of 12 is suggested.

2.3. Stratified randomization

If different subgroups of participants, say males and females, have different background rates of disease, it may be desirable to design the allocation procedure such that the interventions are equally divided in each subgroup. This may be achieved though ‘stratified ’randomization. The population is stratified, for example, by sex or by age group, and the allocation of the interventions is carried out separately in each stratum.

Stratification may be based on more than one factor. For example, there may be a separate allocation of interventions in each of a number of different age–sex groups. The greater the number of strata, the more complex the organization of the randomization is; in general, the number of strata should be kept small. Separate randomization lists will have to be

maintained for each stratum. This may be achieved by using different sets of coloured envelopes, packages, or sticky labels for each stratum.

Stratified randomization should be considered if it is known that there are large differences in disease risk between different groups of individuals in a trial (or in response to treatment in the case of a therapeutic trial) and if it is possible to place individuals in strata corresponding to different levels of risk prior to entry to the trial. The objective of stratification is to try to include in each stratum those at similar risk of disease (or response to treatment) and to randomize between interventions separately within each stratum. In multicentre trials, randomization is often stratified on study site.

Go to:

3. Randomization schemes for community or group-based interventions

As discussed in Chapter 4, trial designs have been increasingly employed in recent years, in which the unit of allocation of the intervention is a community or group, rather than an individual. These cluster randomized trials may involve the randomization of communities that can be quite large; consequently, the number of communities that can be included in a trial is often relatively small and may be of the order of 20 communities or fewer. If a method of simple unrestricted randomization is used to allocate interventions to communities, there is a reasonably high chance that there may be differences between the two groups of communities, unrelated to the interventions, that may bias the measurement of the effects of the intervention. It is common therefore to employ some method of restricted randomization in the allocation of interventions to communities (see also Chapter 4, Section 4.2).

3.1. Matched-pairs design

A matched-pairs design is a special case of stratified randomization, in which the strata are each of size two. Communities are matched into pairs, the pairs being chosen so that the two communities in a pair are as similar as possible with respect to potential confounding variables; in the absence of any intervention, the two communities would be expected to have similar incidence rates of the disease or other outcome under study. One member of each pair is assigned at random to one intervention group and one to the other. Similar matching procedures can be employed when there are more than two intervention groups. For example, with three groups, matched triplets would be employed.

Recent research on the design of cluster randomized trials has indicated that, although matched-pairs randomization remains a valid study design, other methods of randomization, such as stratified randomization or constrained (restricted) randomization, discussed in Sections 3.2 and 3.3, may generally be more appropriate design strategies (Hayes and Moulton, 2009). The major reason for this is because, if a trial is designed as a matched-pairs study, then it must be analysed as such. In technical terms, pairing reduces the number of ‘degrees of freedom ’that are available in the statistical comparison of the outcome measures in the intervention and comparison communities, compared to an unmatched design. This has little consequence if the number of communities is large, but, if the number is small, as is typically the case, then matching reduces the statistical power of a trial to detect an intervention effect of a given size (unless the matching factors are very closely correlated with the outcome).

3.2. Stratified design

For the reasons outlined, unrestricted randomization in a cluster randomized trial may lead to imbalance with respect to potential

confounding factors between the different comparison arms of the trial, unless the number of clusters is very large. Pair matching of communities is one way of attempting to overcome this problem to ensure better balance between the arms of the trial, but this strategy may be associated with a substantial loss of statistical power. An intermediate alternative is to adopt a *stratified*, rather than a matched-pairs, design. A stratified design involves the grouping of communities into a number of strata, based on the expected rate of disease in the absence of the intervention. For example, in a study on malaria, communities with high transmission intensity would be put into the same stratum, and those with low transmission intensity would be put into a different stratum. The communities within each stratum are then randomly allocated between the different intervention arms of the trial.

In practice, it is often challenging to decide which communities should go into the same stratum. If there are baseline rates available for the disease under study from surveillance or from a previous study, then these may provide a reasonable guide as to the expected rates in the different communities in the absence of the interventions. However, the rates of some diseases may vary substantially from year to year, and what happened in the past may not be a very good guide for what will happen in the future. Quite commonly, such rates are not available, and the investigator has the alternative of conducting a pre-trial study to estimate disease rates in each community or, based on ecological and epidemiological considerations, of making some estimate of what the rates might be. The first of these options adds to the cost of the study, whereas there may be considerable uncertainties regarding the utility and accuracy of the second approach. A fuller discussion of these issues is given in (Hayes and Moulton 2009).

A stratified design is associated with less loss of statistical power than a matched-pairs design and will assist in making the communities in the different arms of the trial more comparable with respect to potential confounding factors. There may still remain some imbalance with respect to these factors, but it is possible to adjust for this in the analysis of the trial, provided, of course, the relevant confounding factors have been measured. Methods for the analysis of cluster randomized trials and the adjustment for confounding factors are beyond the scope of this book and will generally require the input of a specialist statistician.

(Hayes and Moulton 2009) suggest that, in practical situations, it is likely that the use of three or four strata will provide most of the advantages provided by pair matching, such that communities can be very accurately paired with respect to expected disease rates during the trial. With respect to the choice of the number of strata, these authors suggest that there should be no more than two strata if there are six or fewer clusters per arm, and no more than three strata if there are 7–10 clusters per arm.

3.3. Constrained randomization design

A further method of controlling for confounding is to adopt a method known as *constrained* or *restricted* randomization. Consider a trial to be conducted in 12 communities, six of which will be allocated to the intervention under test, the remaining six serving as control communities. Using a simple unrestricted randomization design, six communities would be selected at random to receive the intervention, and the other six would serve as controls. By chance, it might happen that the six intervention communities all turn out to be close to a major highway, and the six control communities are all more distant from the highway. If the disease we are studying might be related to proximity to the highway (for example, HIV infection rates

show this characteristic in some situations), then we may be rather unhappy with this particular selection of intervention communities, as there would be a priori reasons for believing there would be differences in disease rates, irrespective of the effect of the intervention we wanted to test. In these circumstances, we might reject the initial random selection of communities and select another set of random numbers to determine which our intervention communities are. While this strategy may not seem unreasonable, it is clearly dangerous to allow an investigator to override a randomization procedure if he or she does not like the result!

Constrained randomization designs aim to exclude from consideration random allocations that result in unsatisfactory imbalance between communities in the intervention and control arms. In the study already outlined, involving 12 communities, there are 924 possible different allocations of which communities comprise the six in which the intervention will be applied. Conceptually, we could imagine examining each of these possible allocations and deciding which of them we would be happy with and which would cause us concern. Suppose there were, for example, 400 for which there seemed to be a reasonable balance of confounding factors between the putative intervention and control communities. We could restrict our consideration of possible allocations to these 400, and choose one of these at random to be the one that was actually used in the trial. This is the basic principle of the constrained or restricted randomization design.

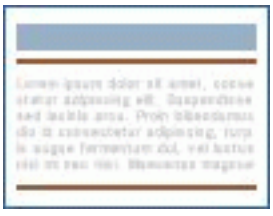
Examining all 924 possible allocations would be a considerable undertaking and would be even more difficult if the total number of communities was more than 12. It is therefore necessary to seek some more automated method of deciding which randomizations are acceptable. In practice, what

is done is to define some key variables for which we wish to achieve reasonable balance across the intervention and control arms. These key variables are then compared in each of the possible randomizations, and a rule is set up to exclude a randomization if the difference between the key variables in putative intervention and control arms is more than some specified amount. Thus, the selection of ‘acceptable ’randomizations can be programmed into a computer, so that the selection is done automatically once the acceptability criteria for balance between the intervention and control communities have been defined.

The procedure described as a modification of simple unrestricted randomization can also be incorporated into a stratified design, so that there is a selection of acceptable possible randomizations within each stratum.

Both stratification and restricted randomization can be used to achieve good balance (avoid confounding), but stratification *also*aims to reduce between-cluster (within-stratum) variation, and hence to increase power and precision.

An example of the use of restricted randomization in the design of a trial of an adolescent sexual health intervention carried out in Tanzania (Hayes et al., 2005) is given in Box 11.1.



			Box 11.1

Use of restricted randomization in a community randomized trial of an adolescent sexual health intervention in Tanzania.Go to:

4. Blinding

Whenever possible, neither the participants nor the investigators should know to which intervention group each participant belongs until after the end of the trial. Such ‘double-blind ’designs (both the investigator and the participants are blind to the knowledge of who have received each intervention) eliminate the possibility that knowing to which intervention an individual is allocated may affect the way the individual behaves, is treated, or is monitored during the trial, or the way an individual is assessed at the end of the trial. Sometimes, a double-blind trial is not possible, and a ‘single-blind ’design might be used, in which the investigator knows to which group a participant belongs, but the participant does not.

‘Blinded ’designs are especially important when those in one of the groups under comparison are given an intervention that is expected to have no effect on the outcome of interest. To maintain blindness in these circumstances, a placebo should be used, if possible, which should look and smell as similar as possible to the intervention itself (and have a similar taste if it is being given orally). Sometimes, an identical-looking placebo cannot be obtained, and, in these circumstances, the investigator and the participants should be kept blind to which treatment is the active one. While this may be the best that can be done in some trials, it is generally undesirable. Either the participants or the investigator may form a view as to which the active treatment is (possibly erroneously), and this may affect differentially the amount of other care given to the participants or the likelihood that a participant reports apparently beneficial or harmful effects. For example, there is evidence that the colour of a tablet may affect the

perceived action of a drug and seems to influence the effectiveness of a drug in some situations (de Craen et al., 1996).

For some interventions, it may be possible to preserve blindness in the initial phase of a trial, but this may be more difficult later. For example, in placebo-controlled studies of ivermectin against onchocerciasis, it was found that some participants were able to guess that they had received an active drug, rather than a placebo, because of the effect of ivermectin on other helminth infections, such as *Ascaris*, through the passage of worms in their stools, whereas those receiving placebo rarely experienced this effect. In placebo-controlled trials of BCG vaccination, most of those who have received BCG develop a lasting scar, whereas those who have received placebo do not. The possible bias that this might induce in the assessment of whether or not a participant developed leprosy, following vaccination, was overcome in a trial in Uganda by covering the vaccination site with sticking plaster for all participants before each clinical examination (Brown and Stone, 1966).

For some intervention trials, in which the unit of randomization is the community, the use of a placebo is straightforward and is no different, in principle, from the situation for an individually randomized trial. This was the case, for example, in a cluster randomized trial to assess the impact of regular vitamin A supplementation on child mortality. Those in the control communities received supplementation with an inert liquid that was administered in such a way that it was indistinguishable from the administration of vitamin A (Ghana VAST Study Team, 1993). For some interventions, however, a suitable placebo may be impossible to find. What would be a suitable placebo for an improved water supply and sanitation programme in a village, for example?

Go to:

5. Coding systems

In some circumstances, it may be necessary to break the intervention code for an individual. This might arise, for example, if a severe adverse event becomes manifest and the treatment for it may be influenced by knowledge of what intervention the individual received. The coding system which is used to record which individuals received which intervention should be designed, such that, if it is necessary to break the code for one individual, the blindness of the investigator, with respect to the interventions received by other trial participants, should be preserved. For example, if one intervention is coded A and the other B, breaking the code for one individual effectively breaks the code for all participants (if the investigator knows who has received A and who has received B). The use of a single code for each intervention is generally a poor design. It is better to have a unique code for each participant and to have a separate list linking participant numbers with the intervention allocated, or to have only a very small number of participants sharing the same code number. For example, in a BCG trial in South India for tuberculosis prevention, ampoules (each containing several doses of vaccine) were packed in boxes of three. Each box held three vials containing one of two different vaccine doses or a placebo preparation. The three ampoules were randomly coded 1, 2, and 3. The vaccine received by a participant was coded in the trial records by a combination of the box number and the ampoule number (TuberculosisPrevention Trial Madras, 1979). If it had been necessary to break the vaccine code for an individual, it would only have been broken for those participants who received vaccine from the same ampoule in the same box.

The randomization list should usually be prepared in advance of the trial, and the codes assigned by someone other than the PI. If the intervention is a drug or a vaccine, the manufacturer may agree to supervise the packaging and coding, but the allocation procedure should be overseen, and the code should be held during the trial by a disinterested party. Often, the code is held by the data safety and monitoring committee (see Chapter 7, Section 4). It is also worth checking, for a random sample of the drugs or vaccines, that the codes are correct and errors have not been made in the packaging.

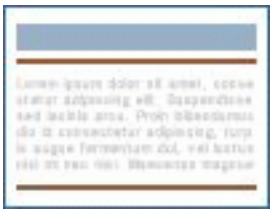
5.1. Individual allocations

Suppose two interventions are to be allocated between 200 individuals. A good coding scheme would be to choose 100 random numbers between 1 and 200 and allocate these codes for intervention A, say, and allocate the other 100 for intervention B (there may also be some ‘blocking ’within the total group of 200, say in blocks of size ten; see Section 2.2). When an intervention is allocated to the 127th patient in the trial, they would be given the drugs in envelope number 127, and this would be noted in their trial record. A master list of the interventions corresponding to each number would be kept in a secure place by a third party not directly connected with the trial. If it were necessary to break the code for an individual patient, the third party could do this without revealing any of the other codes to the investigator. Only at the end of the trial would the list be released to the investigator for the analysis of the results of the trial.

5.2. Group allocations

If a trial involves many thousands of participants, it may be logistically too complicated to allocate a separate treatment code number to each participant, though this will depend upon the circumstances, and, in some

cases, having thousands of individual codes poses no problem. An alternative approach is to use a fixed, but not too small, number of codes for the different interventions. If there are *N* participants in the trial and C codes for the interventions, then breaking the code for one participant would break the codes for N/C in total. For example, the coding system used for a vaccine trial in Venezuela is given in Box 11.2. In this trial, 998 different codes were used (499 for one vaccine and 499 for the other) for about 30 000 participants. Breaking the code for one individual would break it for about 30 others (Convit et al., 1992).



				Box 11.2

Assignment of check letter for three-digit vaccine code.A simpler system might be required if participants had to be given the same intervention on a number of occasions. A method that was used in a trial of ivermectin against onchocerciasis in Sierra Leone was to allocate 20 codes for ivermectin or placebo treatments (A, B, C, D, and so on) (Whitworth et al., 1991). The drugs were taken to the field in 20 tins, with the code letters on them (ten of which contained ivermectin, and ten contained placebo tablets), and participants were allocated to one of the 20 codes at random. If a participant was allocated, say to code E, then each time they were treated, the dose was taken from tin E. About 1000 patients were included in the trial, so that breaking the code for one individual would have also broken it for 1000/20 = 50 others. A similar system was used in a trial of a

pneumococcal vaccine in The Gambia, which involved many thousands of participants, and each participant was scheduled to receive three doses of the vaccine at different times (Cutts et al., 2005).

With either individual or group allocations, it is helpful if the intervention codes are on removable sticky labels that can be affixed to an individual's form, thus minimizing the likelihood of recording errors. Where possible, the coding system should be devised so that transcription errors in recording may be detected. How this was achieved in the leprosy vaccine trial in Venezuela is illustrated in Box 11.2. More commonly now, bar codes are used to identify interventions in trials using drugs or vaccines, and, provided that suitable computer systems are set up, this should eliminate the possibility of transcription errors.

Go to:

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9. Data collection and entry

Data collection, data entry, and analysis

Internet-based data collection

The SDMC licenses an advanced survey software package, DatStatIllume, that can manage all aspects of internet-based surveys, including e-mailing invitations to potential study participants, sending reminder emails, and reporting results. The software supports programming surveys with complex skip patterns, multiple drafts, and frequent changes of survey instruments. Survey responses and survey administration variables (e.g., date of completion, time to complete, number of items presented, number of items answered, etc.) are easily extracted and exported to other programs for analysis. Illume also incorporates robust data security safeguards, ensuring compliance with HIPAA requirements and other laws and regulations governing privacy of health and other personal information. The SDMC also serves as the DFCI institutional support group for REDCap Survey software.

Mail, telephone, and in-person data collection

SDMC staff offer extensive experience with all aspects of traditional data collection processes. Tailoring the route of mail delivery can have a significant impact on response rates among certain populations, and the

Core can advise you on the optimal method of survey delivery via the various mail routes available. Core staff will assemble all materials for paper surveys, assure proper identification with code assignment to appropriate pieces, and collate and mail the survey. Core staff will also track survey completions/opt-outs and perform subsequent waves of mailings to non-responders according to the research protocol. Response statistics are maintained and available to investigators throughout the process.

Medical record review and abstraction

SDMC staff can obtain relevant demographic and clinical study data via medical record review, working closely with investigators to tailor data collection efforts to the specific needs of each study. Record review is offered as a stand-alone service (i.e., to an investigator looking to correlate biological data with clinical risk factors and outcomes) or as a complement to projects involving survey methods.

Data entry

The SDMC offers advanced capabilities for efficient and accurate data entry with quality assurance measures that ensure a clean data set prior to analysis. For some projects, data entry is conducted through automated form scanning using ReMark OCR software.

Data analysis

The Core provides investigators with descriptive statistical reports as well as univariate and bivariate statistical analyses. The Core maintains Wincross software that produces timely data reports, including sub-group analysis and statistical testing. The Core also works with biostatisticians to preparing and develop datasets in SAS and SPSS for advanced statistical analysis.

Training and oversight

The SDMC is available to provide training and oversight of project staff involved in data collection, data entry, quality assurance, reporting, and other tasks related to the implementation of both interventional and observational research involving survey data collection.

10. Statistical analysis for calculating p value of significance

Introduction to Statistical Analysis Types

Statistical Analysis is the science of collecting, exploring, organizing, exploring patterns and trends using one of its types i.e. Descriptive Type (for describing the data), Inferential Type(to generalize the population), Prescriptive, Predictive, Exploratory and Mechanistic Analysis to answer the questions such as, “What might happen?”, “What should be done?”, and “Why”, etc. Due to this most of the business relies on these statistical analysis results to reduce the risk and forecast trends to stay in the competition.

Different Types of Statistical Analysis

Given below are the types of statistical analysis:

- Descriptive Type of Statistical Analysis
- Inferential Type of Statistical Analysis
- Prescriptive Analysis
- Predictive Analysis
- Causal Analysis
- Exploratory Data Analysis
- Mechanistic Analysis

1. Descriptive Type of Statistical Analysis

Descriptive statistical analysis as the name suggests helps in describing the data. It gets the summary of data in a way that meaningful information can be interpreted from it. Using descriptive analysis, we do not get to a conclusion however we get to know what in the data is i.e. we get to know the quantitative description of the data.

For instance, consider a simple example in which you must determine how well the student performed throughout the semester by calculating the average. This average is nothing but the sum of the score in all the subjects in the semester by the total number of subjects. This single number is describing the general performance of the student across a potentially wide range of subject experiences.

Whenever we try to describe a large set of observations with a single value, we run into the risk of either distorting the original data or losing any important information. The student average won't determine the strong subject of the student. It won't tell you the specialty of the student or you won't come to know which subject was easy or strong. In spite of these limitations, Descriptive statistics can provide a powerful summary which may be helpful in comparisons across the various unit.

There are two types of statistics that are used to describe data:

- **Measures of central tendency:** In this, a single value attempts to describe the data by using its central position with the given set. They are also classified as a summary set. In order to get the central value, they use averaging(mean), median or mode.
- **The measure of spread:** In this, the data is summarized by describing how well the data is spread out. For example, if the mean score of 100 students is 55 then there will be students whose score

will be less than 55 or more than 55. Which means their score will be spread out in a way that their mean is 55. To describe the spread, we can use either of the statistical technique i.e. range, quartiles, variation, standard deviation, and absolute deviation.

2. Inferial Statistics

The group of data that contains the information we are interested in is known as population. Inferential Statistics is used to make a generalization of the population using the samples. Where the sample is drawn from the population itself. It is necessary that the samples properly demonstrate the population and should not be biased. The process of achieving these kinds of samples is termed as sampling. Inferential Statistics comes from the fact that the sampling naturally incurs sampling errors and is thus not expected to perfectly represent the population.

There are two types of Inferential Statistics method used for generalizing the data:

- Estimating Parameters
- Testing of Statistical Hypothesis

The above two are the main types of statistical analysis.

3. Prescriptive Analysis

“What should be done?” Prescriptive Analysis work on the data by asking this question. It is the common area of business analysis to identify the best possible action for a situation. Its whole idea is to provide advice that aims to find the optimal recommendation for a decision-making process. It is related to descriptive and predictive analysis. The descriptive analysis describes the data i.e. what has happened, and predictive analytics predicts what might happen prescriptive analysis find the best option among the available choice.

Techniques used in the prescriptive analysis are simulation, graph analysis, business rules, algorithms, complex event processing, and machine learning.

4. Predictive Analysis

“What might happen?” Predictive analysis is used to make a prediction of future events. It is based upon the current and historical facts. It uses statistical algorithm and machine learning techniques to determine the likelihood of future results, trends based upon historical and new data and behavior. Business is implementing predictive analytics to increase the competitive advantage and reduce the risk related to an unpredictable future. The main users of predictive analysis are marketing, financial service, online service providers and insurance companies. Techniques used in Predictive analysis are data mining, modeling, A.I., etc.

5. Causal Analysis

“Why?” CausalAnalysis helps in determining why things are the way they are. Since the current business world is full of events that might lead to failure, Causal Analysis seeks to identify the reason for it. It tries to get the root cause, i.e. the basic reason why something can happen. This is a common technique used in the IT industry for the quality assurance of the software. And industries that address major disasters.

6. Exploratory Data Analysis

It is an Exponential to the inferential statistics and is mostly used by the data scientists. It is an analytical approach that focuses on identifying patterns in the data and figure out the unknown relationships. The purpose of Exploratory Data Analysis is to get check the missing data, find unknown relationships and check hypotheses and assumptions. It shouldn’t be used alone as it only provides a birds-eye view of the data and gets some insight

into it. It is the first step in data analysis that should be performed before the other formal statistical techniques.

7. Mechanistic Analysis

Mechanistic Analysis plays an important role in big industries. Though it is not among the common type of statistical analysis methods still it's worth discussing. It is used for understanding the exact changes in the given variable that leads to the other variables. It works on the assumption that the given system gets affected by the interaction of its internal component. It does not consider external influence. It is useful in a system containing clear definitions like biological science.

Conclusion

In this article, we understood the different types of statistical analysis methods. There is a vast career in this field. Businesses from hotels, clothing designs, music stores, vendors, marketing and even politics rely heavily on the data to stay ahead. Other fields include Medical, Psychologist, etc. Since data on its own can be helpful Statistical Analysis helps in gaining the insight.

11.Decoding data analysis

Coding Qualitative Data: How to Code Qualitative Research (Updated 2020)

AI & NLPFeedback Analysis

Authored by AlyonaMedelyan, PhD – Natural Language Processing & Machine Learning

How many hours have you spent sitting in front of Excel spreadsheets trying to find new insights from customer feedback?

You know that asking open-ended survey questions gives you more actionable insights than asking your customers for just a numerical Net Promoter Score (NPS). But when you ask open-ended, free-text questions, you end up with hundreds (or even thousands) of free-text responses.

How can you turn all of that text into quantifiable, applicable information about your customers 'needs and expectations? By coding qualitative data.

Keep reading to learn:

- What coding qualitative data means (and why it's important)
- Different methods of coding qualitative data
- How to manually code qualitative data to find significant themes in your data

What is coding in qualitative research?

Coding is the process of labeling and organizing your qualitative data to identify different themes and the relationships between them.

When coding customer feedback, you assign labels to words or phrases that represent important (and recurring) themes in each response. These labels can be words, phrases, or numbers; we recommend using words or short phrases, since they're easier to remember, skim, and organize.

Coding qualitative research to find common themes and concepts is part of thematic analysis, which is part of qualitative data analysis. **Thematic analysis**extracts themes from text by analyzing the word and sentence structure.

What is qualitative data analysis?

Qualitative data analysis is the process of examining and interpreting qualitative data to understand what it represents.

Qualitative data is defined as any non-numerical and unstructured data; when looking at customer feedback, qualitative data usually refers to any verbatim or text-based feedback such as reviews, open-ended responses in surveys, complaints, chat messages, customer interviews, case notes or social media posts

For example, NPS metric can be strictly quantitative, but when you ask customers why they gave you a rating a score, you will need qualitative data analysis methods in place to understand the comments that customers leave alongside numerical responses.

Types of qualitative data analysis

1. Content analysis: This is the most common example of qualitative data analysis. It refers to the categorization, tagging and thematic analysis of qualitative data. This can include combining the results of the analysis with behavioural data for deeper insights.
2. Narrative analysis: Some qualitative data, such as interviews or field notes may contain a story. For example, the process of choosing a product, using it, evaluating its quality and decision to buy or not buy this product next time. Narrative analysis helps understand the underlying events and their effect on the overall outcome.
3. Discourse analysis: This refers to analysis of what people say in social and cultural context. It's particularly useful when your focus is on building or strengthening a brand.
4. Framework analysis: When performing qualitative data analysis, it is useful to have a framework. A code frame (a hierarchical set of

themes used in coding qualitative data) is an example of such framework.

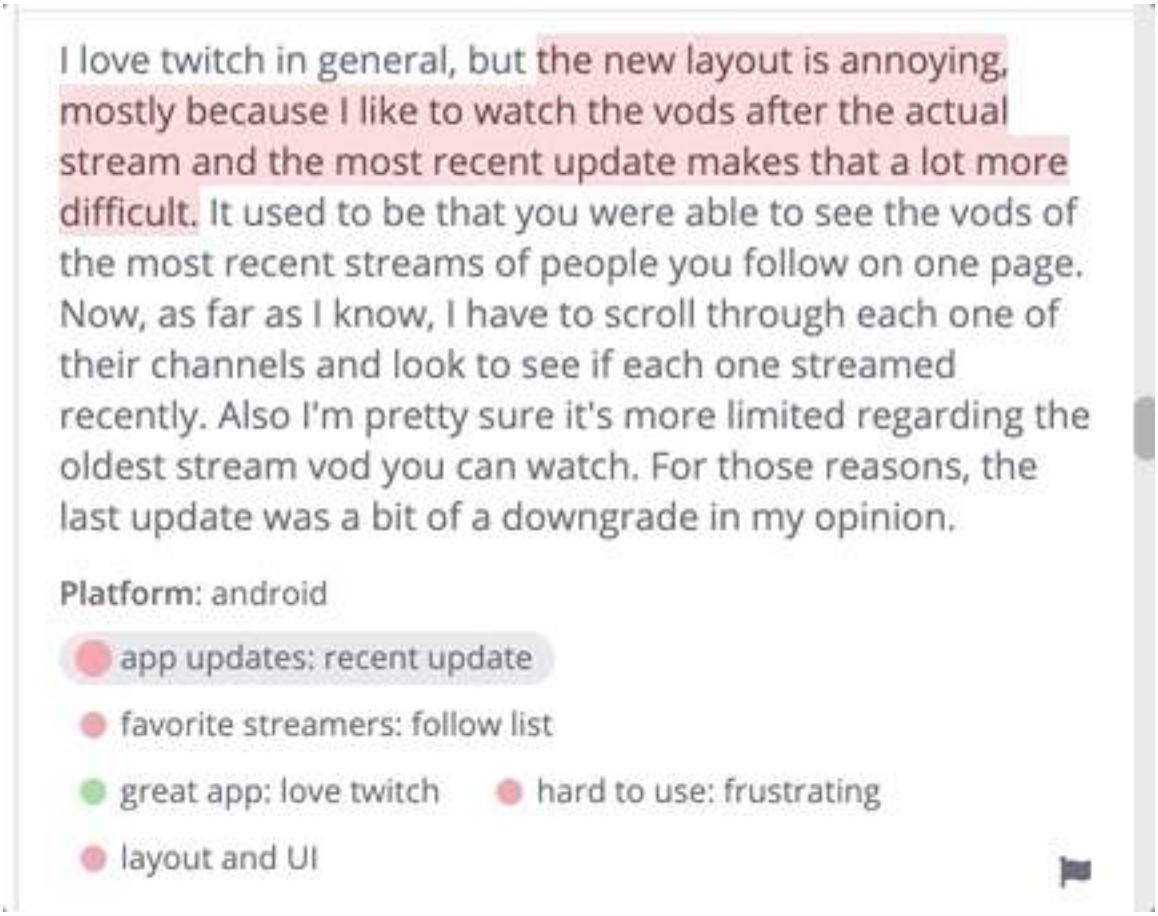
5. Grounded theory: This method of analysis starts by formulating a theory around a single data case. Therefore the theory is “grounded ’ in actual data. Then additional cases can be examined to see if they are relevant and can add to the original theory.

Qualitative data analysis software

Advances in natural language processing& machine learning have made it possible to automate the analysis of qualitative data, in particular content and framework analysis

While manual human analysis is still popular due to its perceived high accuracy, automating the analysis is quickly becoming the preferred choice. Unlike manual analysis, which is prone to bias and doesn’t scale to the amount of qualitative data that is generated today, automating analysis is not only more consistent and therefore can be more accurate, but can also save a ton of time, and therefore money.

The most commonly used software for automated qualitative data analysis is text analytics software such as Thematic.



Qualitative data analysis example: Thematic categorizes qualitative data into themes

Why is it important to code qualitative data?

Coding qualitative data makes it easier to interpret customer feedback. Assigning codes to words and phrases in each response helps capture what the response is about which, in turn, helps you better analyze and summarize the results of the entire survey.

Researchers use coding and other qualitative data analysis processes to help them make data-driven decisions based on customer feedback. When you use coding to analyze your customer feedback, you can quantify the

common themes in customer language. This makes it easier to accurately interpret and analyze customer satisfaction.

Automated vs. Manual coding of qualitative data

Methods of coding qualitative data fall into two categories: automated coding and manual coding.

You can automate the coding of your qualitative data with thematic analysis software. Thematic analysis and qualitative data analysis software use machine learning, artificial intelligence (AI), and natural language processing (NLP) to code your qualitative data and break text up into themes.

Thematic analysis software is autonomous, which means…

- You don't need to set up themes or categories in advance.
- You don't need to train the algorithm — it learns on its own.
- You can easily capture the "unknown unknowns" to identify themes you may not have spotted on your own.

…all of which will save you time (and lots of unnecessary headaches) when analyzing your customer feedback.

Recently, thematic analysis software has been categorised as Unified Data Analytics.

What is thematic coding?

Thematic coding, also called thematic analysis, is a type of qualitative data analysis that finds themes in text by analyzing the meaning of words and sentence structure.

When you use thematic coding to analyze customer feedback for example, you can learn which themes are most frequent in feedback. This helps you understand what drives customer satisfaction in an accurate, actionable way.

To learn more about how thematic analysis software helps you automate the data coding process, check out this article.

How to manually code qualitative data

For the rest of this post, we'll focus on manual coding. Different researchers have different processes, but manual coding usually looks something like this:

1. Choose whether you'll use deductive or inductive coding.
2. Read through your data to get a sense of what it looks like. Assign your first set of codes.
3. Go through your data line-by-line to code as much as possible. Your codes should become more detailed at this step.
4. Categorize your codes and figure out how they fit into your coding frame.
5. Identify which themes come up the most — and act on them.

Let's break it down a little further…

Deductive coding vs. inductive coding

Before you start qualitative data coding, you need to decide which codes you'll use.

What is Deductive Coding?

Deductive coding means you start with a predefined set of codes, then assign those codes to the new qualitative data. These codes might come from previous research, or you might already know what themes you're interested in analyzing. Deductive coding is also called concept-driven coding.

For example, let’s say you’re conducting a survey on customer experience. You want to understand the problems that arise from long call wait times, so you choose to make “wait time” one of your codes before you start looking at the data.

The deductive approach can save time and help guarantee that your areas of interest are coded. But you also need to be careful of bias; when you start with predefined codes, you have a bias as to what the answers will be. Make sure you don’t miss other important themes by focusing too hard on proving your own hypothesis.

What is Inductive Coding?

Inductive coding, also called open coding, starts from scratch and creates codes based on the qualitative data itself. You don’t have a set codebook; all codes arise directly from the survey responses.

Here’s how inductive coding works:

1. Break your qualitative dataset into smaller samples.
2. Read a sample of the data.
3. Create codes that will cover the sample.
4. Reread the sample and apply the codes.
5. Read a new sample of data, applying the codes you created for the first sample.
6. Note where codes don’t match or where you need additional codes.
7. Create new codes based on the second sample.
8. Go back and recode all responses again.
9. Repeat from step 5 until you’ve coded all of your data.

If you add a new code, split an existing code into two, or change the description of a code, make sure to review how this change will affect the

coding of all responses. Otherwise, the same responses at different points in the survey could end up with different codes.

Sounds like a lot of work, right? Inductive coding is an iterative process, which means it takes longer and is more thorough than deductive coding. But it also gives you a more complete, unbiased look at the themes throughout your data.

Categorize your codes with coding frames

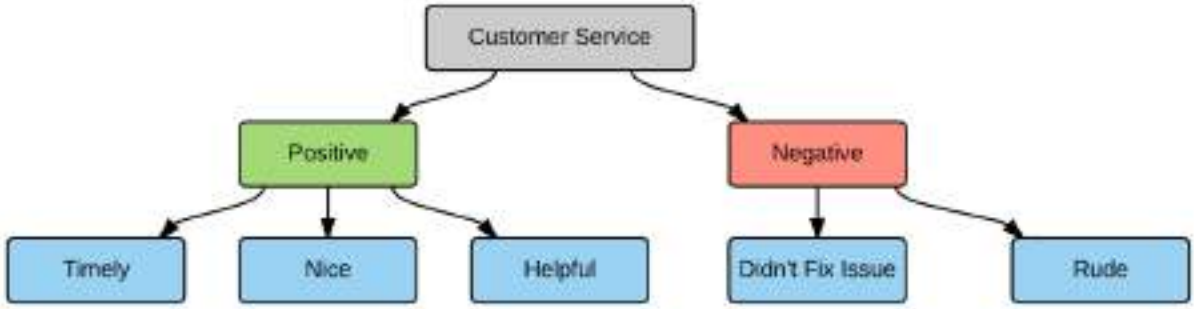
Once you create your codes, you need to put them into a coding frame. A coding frame represents the organizational structure of the themes in your research. There are two types of coding frames: flat and hierarchical.

Flat Coding Frame

A **flat coding frame** assigns the same level of specificity and importance to each code. While this might feel like an easier and faster method for manual coding, it can be difficult to organize and navigate the themes and concepts as you create more and more codes. It also makes it hard to figure out which themes are most important, which can slow down decision making.

Hierarchical Coding Frame

Hierarchical frames help you organize codes based on how they relate to one another. For example, you can organize the codes based on your customers ’feelings on a certain topic:



Hierarchical Coding Frame example

In this example:

1. The top-level code describes the topic (customer service)
2. The mid-level code specifies whether the sentiment is positive or negative
3. The third level details the attribute or specific theme associated with the topic

Hierarchical framing supports a larger code frame and lets you organize codes based on organizational structure. It also allows for different levels of granularity in your coding.

Whether your code frames are hierarchical or flat, your code frames should be flexible. Manually analyzing survey data takes a lot of time and effort; make sure you can use your results in different contexts.

For example, if your survey asks customers about customer service, you might only use codes that capture answers about customer service. Then you realize that the same survey responses have a lot of comments about your company's products. To learn more about what people say about your products, you may have to code all of the responses from scratch! A flexible coding frame covers different topics and insights, which lets you reuse the results later on.

Tips for coding qualitative data

Now that you know the basics of coding your qualitative data, here are some tips on making the most of your qualitative research.

Use a codebook to keep track of your codes

As you code more and more data, it can be hard to remember all of your codes off the top of your head. Tracking your codes in a codebook helps keep you organized throughout the data analysis process. Your codebook can be as simple as an Excel spreadsheet or word processor document. As you code new data, add new codes to your codebook and reorganize categories and themes as needed.

Make sure to track:

- The label used for each code
- A description of the concept or theme the code refers to
- Who originally coded it
- The date that it was originally coded or updated
- Any notes on how the code relates to other codes in your analysis

Create high-quality codes

Your codes should do these 4 things:

1. **Cover as many survey responses as possible.** The code should be generic enough to apply to multiple comments, but specific enough to be useful in your analysis. For example, “Product” is a broad code that will cover a variety of responses — but it’s also pretty vague. What about the product? On the other hand, “Product stops working after using it for 3 hours” is very specific and probably won’t apply to many responses. “Poor product quality” or “short product lifespan” might be a happy medium.

2. **Avoid commonalities.** Having similar codes is okay as long as they serve different purposes. “Customer service” and “Product” are different enough from one another, while “Customer service” and “Customer support” may have subtle differences but should likely be combined into one code.
3. **Capture the positive and the negative.** Try to create codes that contrast with each other to track both the positive and negative elements of a topic separately. For example, “Useful product features” and “Unnecessary product features” would be two different codes to capture two different themes.
4. **Reduce data — to a point**. Let’s look at the two extremes: There are as many codes as there are responses, or each code applies to every single response. In both cases, the coding exercise is pointless; you don’t learn anything new about your data or your customers. To make your analysis as useful as possible, try to find a balance between having too many and too few codes.

Group responses based on themes, not wording

Make sure to group responses with the same themes under the same code, even if they don’t use the same exact wording. For example, a code such as “cleanliness” could cover responses including words and phrases like:

- Clean
- Tidy
- Dirty
- Dusty
- Looked like a dump
- Could eat off the floor

Having only a few codes and hierarchical framing makes it easier to group different words and phrases under one code. If you have too many codes, especially in a flat frame, your results can become ambiguous and themes can overlap. Manual coding also requires the coder to remember or be able to find all of the relevant codes; the more codes you have, the harder it is to find the ones you need, no matter how organized your codebook is.

Make accuracy a priority

Manually coding qualitative data means that the coder's cognitive biases can influence the coding process. For each study, make sure you have coding guidelines and training in place to keep coding reliable, consistent, and accurate.

One thing to watch out for is definitional drift, which occurs when the data at the beginning of the data set is coded differently than the material coded later. Check for definitional drift across the entire dataset and keep notes with descriptions of how the codes vary across the results.

If you have multiple coders working on one team, have them check one another's coding to help eliminate cognitive biases.

Conclusion: 6 main takeaways for coding qualitative data

Here are 6 final takeaways for manually coding your qualitative data:

1. Coding is the process of labeling and organizing your qualitative data to identify themes. After you code your qualitative data, you can analyze it just like numerical data.
2. Inductive coding (without a predefined code frame) is more difficult, but less prone to bias, than deductive coding.
3. Code frames can be flat (easier and faster to use) or hierarchical (more powerful and organized).

4. Your code frames need to be flexible enough that you can make the most of your results and use them in different contexts.
5. When creating codes, make sure they cover several responses, contrast one another, and strike a balance between too much and too little information.
6. Consistent coding = accuracy. Establish coding procedures and guidelines and keep an eye out for definitional drift in your qualitative data analysis.

12.Discussion of the findings with literature support

Reporting and discussing your findings

This page deals with the central part of the thesis, where you present the data that forms the basis of your investigation, shaped by the way you have thought about it. In other words, you tell your readers the story that has emerged from your findings. The form of your chapters should be consistent with this story and its components.

Contents:

Find the story in your data

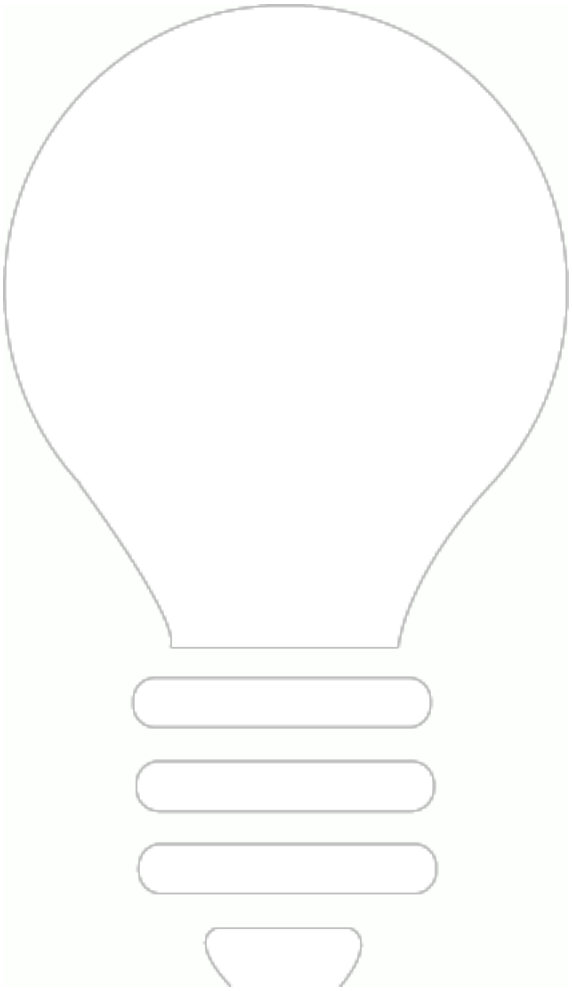
For many kinds of research, the main work of interpretation cannot be done until most of the data has been collected and analysed. For others, the data

already exists (in the form of archival documents or literary texts, for example), and the work of interpreting it begins much earlier in the research process.

Whatever kind of research you are doing, there comes a moment when your head is full of ideas that have emerged from your analysis. Ideally, you will have written them down as they came to you. Now you have to convert that mass of material and ideas into a written text that will make sense to a reader, and do justice to your findings.

Finding your focus

How will you decide which aspects of your findings are the most interesting and important? It is useful to remind yourself what the task of writing up research is all about:



Tip

…the major task of writing [about our research] involves working out how to make contextually grounded theoretical points that are viewed as a contribution by the relevant professional community of readers.
(Golden-Biddle & Locke, 1997, p. 20)

That is, in your thesis you need to make points that are:

- contextually grounded (based on your data)
- theoretical (related to relevant theory)

- viewed as a contribution by the relevant professional community of readers (they add something to the current body of research or theory)

These points must fit into a framework that makes a coherent story of your findings.

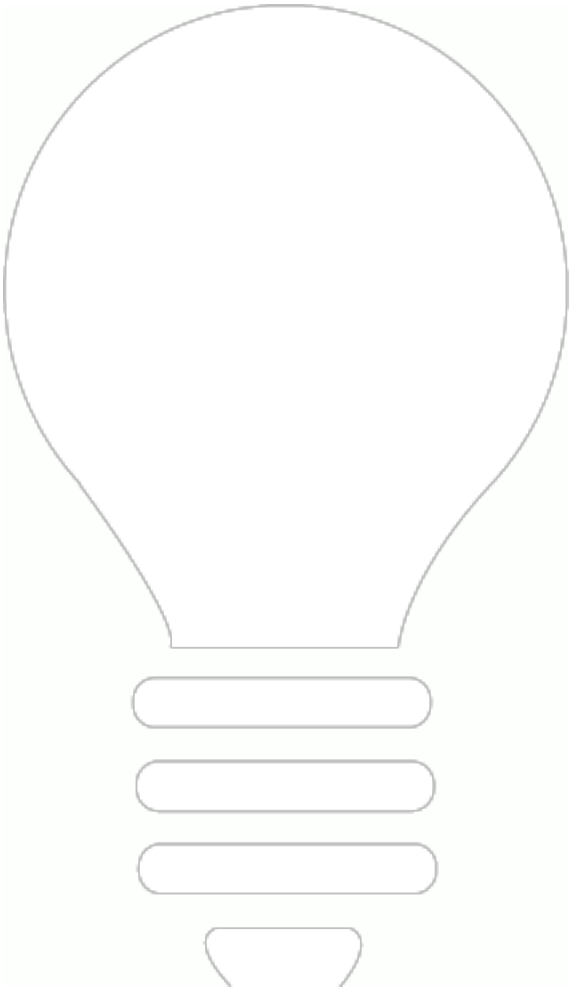
What have you learnt from your data?

The first step is to clarify for yourself what you know now, as a result of your research. David Evans and Paul Gruba (2002, p.112) remind us that our minds continue to work on problems when we aren't thinking about them consciously. So it is worth finding out what conclusions your brain has reached while you were collecting and analysing your data. Evans and Gruba suggest you try these techniques:

Activity

1. Write down all the things you know now that you didn't know when you started the research. Use a single sentence for each item. (At this point, don't worry about whether they relate to your aims or research questions.)
2. Sort the sentences into groups. Give each group a heading. Now check the headings against your research question(s). Do all the headings relate to the research question(s)? Do the questions need refining?
3. Use these groups and headings to make a plan of the points you want to make in your discussion.

Making lists works well for some people, but not for others. Another technique you can use to unlock your unconscious thought processes is **freewriting**.



Freewriting definition

Freewriting on a topic means taking a fresh piece of paper or opening a new word-processor document and writing anything that comes into your head on that topic for a limited time. It must be in whole sentences and you must not stop. If you have nothing to write, write 'I have nothing to write'. This is writing to think. It probably won’t produce text you can use in your thesis, but it might help to clarify your ideas and show you ways to structure your argument.

Activity

1. Write about your data for 5 minutes. You don't have to show what you write to anyone.
2. Stop.
3. Now read over what you've written. Have you learnt anything? Is there anything there you want to develop further? You could try highlighting key words, or identifying any points that need further investigation.

Three kinds of story: macrostructures for a thesis

The way you present the analysis and interpretation of your data sits within a wider thesis framework, which can itself be thought of as a story (adapted from Silverman, 2005, p. 242-43):

- **the hypothesis story** (this is the standard framework for theses in the empirical sciences)
    - state your hypotheses
    - test them
    - discuss the implications
- **the analytic story** (a common framework for theses in the social sciences)
    - What are the key concepts you have used in this study?
    - How do your 'findings' shed light on these concepts and, through them, on the substantive topics you studied?
    - What, therefore, has become of your original research problem and the literature regarding it?
- **the mystery story**
    - starts from empirical examples
    - develops the questions by discussing them
    - gradually leads the reader to interpretations of the material and to more general implications of the results.

The big picture

The challenge for every thesis writer is to hold the detail of the data in focus without losing sight of the big picture of the research. This is why reporting data analysis is not enough; you need to:

- establish the connections between the patterns that emerge from your analysis and your research questions
- relate those connections to the existing research and theory

in order to make clear your contribution to knowledge in the field.

Present your findings

This page and the next, on reporting and discussing your findings, deal with the core of the thesis. In a traditional doctoral thesis, this will consist of a number of chapters where you present the data that forms the basis of your investigation, shaped by the way you have thought about it. In a thesis including publication, it will be the central section of an article.

For some fields of study, the presentation and discussion of findings follows established conventions; for others, the researcher's argument determines the structure. Therefore it is important for you to investigate the conventions of your own discipline, by looking at journal articles and theses.

Every thesis writer has to present and discuss the results of their inquiry. In these pages we consider these two activities separately, while recognising that in many kinds of thesis they will be integrated. This section is concerned with presenting the analysis of the results of data analysis.

There is a great deal of disciplinary variation in the presentation of findings. For example, a thesis in oral history and one in marketing may both use interview data that has been collected and analysed in similar ways, but the way the results of this analysis are presented will be very different because the questions they are trying to answer are different. The presentation of results from experimental studies will be different again. In all cases, though, the presentation should have a logical organisation that reflects:

- the aims or research question(s) of the project, including any hypotheses that have been tested

- the research methods and theoretical framework that have been outlined earlier in the thesis.

You are not simply describing the data. You need to make connections, and make apparent your reasons for saying that data should be interpreted in one way rather than another.

Structure

Each chapter needs an introduction outlining its organisation.

Examples

Chemical Engineering PhD thesis:

In this Chapter, all the experimental results from the phenomenological experiments outlined in Section 5.2 are presented and examined in detail. The effects of the major operating variables on the performance of the pilot filters are explained, and various implications for design are discussed. The new data may be found in Appendix C.

Literature PhD thesis:

The principal goal of the vernacular adaptor of a Latin saint's life was to edify and instruct his audience. In this chapter I shall try to show to what extent our texts conform to vernacular conventions of a well-told story of a saint, and in what ways they had to modify their originals to do so, attempting also to identify some of the individual characteristics of the three poems.

After that, the organisation will vary according to the kind of research being reported. Below are some important principles for reporting experimental, quantitative (survey) and qualitative studies.

Experimental studies

The results of experiments are almost always presented separately from discussion.

- Present results in tables and figures
- Use text to introduce tables and figures and guide the reader through key results
- Point out differences and relationships, and provide information about them
- Include negative results (then try to explain them in the Discussion section/chapter)

Quantitative studies

There are generally accepted guidelines for presenting the results of statistical analyses of data about populations or groups of people, plants or animals. It is important that the results be presented in an informative way.

- Demographic data that describe the sample are usually presented first.
- Remind the reader of the research question being addressed, or the hypothesis being tested.
- State which differences are significant.
- Highlight the important trends and differences/comparisons.
- Indicate whether the hypothesis is supported or not.

You can read more about reporting quantitative results in the next section, Reporting conventions.

Qualitative studies

The presentation and discussion of qualitative data are often combined.

Qualitative data is difficult to present neatly in tables and figures. It is usually expressed in words, and this results in a large quantity of written material, through which you must guide your reader.

Structure is therefore very important.

Try to make your sections and subsections reflect the themes that have emerged from your analysis of the data, and to make sure your reader knows how these themes evolved. Headings and subheadings, as well as directions to the reader, are forms of signposting you can use to make these chapters easy to navigate.

You can read more about reporting qualitative results in the next section, Reporting conventions.

What to include

For all types of research, decisions about what data to include are important.

- Include what you need to support the points you need to make. Be guided by your research questions(s) and the nature of your data.
- Make your selection criteria explicit.
- More detail can be provided in an appendix. Evans and Gruba (2002) offer some good advice: 'Include enough data in an appendix to show how you collected it, what form it took, and how you treated it in the

process of condensing it for presentation in the results chapter.' (p. 105)

Reporting conventions

Reporting conventions differ according to whether the data involved is quantitative or qualitative.

Quantitative data

The purpose of the results section of the thesis is to report the findings of your research. You usually present the data you obtained in appropriate figures (diagrams, graphs, tables and photographs) and you then comment on this data.

Comments on figures and tables (data commentary) usually have the following elements:

- a**location element**
- a**summary** of the information presented in the figure
- a**highlighting statement** to point out what is significant in all the data presented (eg trends, patterns, results that stand out).

Data commentary element example

Instructions: Click on the highlighted data elements in the example below.

Table 5 shows the most common modes of computer infection in Australian businesses. As can be seen in the table, home disks are the most frequent source of infection.

Activity: Data commentary element example

Instructions: Click on the text below to identify the location element, summary and highlighting statement.

The influents to filter A and B were analysed fully on a number of occasions, and the averaged results are presented in Table 6.1. It can be seen from the table that the wastewaters from plants A and B and of similar composition.

Sometimes a reduced location element is used which gives only the table or figure number in brackets after the highlighting statement.

Examples:

- The ranges of metal atom concentrations for the two precipitate types were found to overlap (Table 6)
- Quantitative analysis revealed some variation in the composition of the rods in the various exservice samples (Figure 7 and Table 5).

Commentary on results may include:

- explanations
- comparisons between results
- comments on whether the results are expected or unexpected
- comments about unsatisfactory data.

Dealing with "Problems"

The difference between expected and obtained results	**may be due to**	the incorrect calibration of the instruments.
This discrepancy	**can be attributed to**	the small sample size.
The anomaly in the observations	**can probably be accounted for**	by a defect in the camera.

The lack of statistical significance	**is probably a consequence of**	weaknesses in the experimental design.
The difficulty in dating this archeological site	**would seem to stem from**	the limited amount of organic material available.

(Adapted from Swales & Feak, 2004, p. 138).

If you are discussing your findings in a separate chapter or section, limit your comments here to the specific results you have presented.

Past or present tense?

Location element	present tense	*…the averaged results are presented in Table 6.1.* *Table 5 shows…*
Summary of procedure	past tense	*The influents to filter A and B were analysed fully on a number of occasions,…*
Results of analysis	past tense	*The ranges of metal atom concentrations … were found to overlap.*

Comments	present t tense	*This discrepancy can be attributed to the small sample size.*

Qualitative data

The reporting of qualitative data is much less bound by convention than that of quantitative data. The data itself usually consists of words, from written documents or interview transcripts (but may include images), which have been analysed in some way, often into themes. In reporting the data, it is generally important to convey both the themes and some of the flavour of the actual words.

The data needs to be connected back through the layers of detail to the overarching research question it relates to. This can be done through the introductions to carefully-structured sections and subsections. Individual data extracts can be connected back into this structure through a process of 'tell-show-tell'.

Click on the highlighted text below to read the comments.

Example from a Doctor of Education thesis:

6.4.3 Themes from the Interview Data

In analysing the interview data, two themes emerged which will be discussed in this section. These themes were: the complexity and

challenges of working with families and the professional satisfaction and challenges of program planning for children in preschool or childcare.

For each of these graduates, their work with children was clearly the area of their professional lives that was bringing the most satisfaction, although there were some challenges identified. In the interviews, the data reveal that they were all seeking ways to improve their pedagogy and achieving success in different ways…

Angela suggested that in her second year of teaching she had changed in that she was programming in a "more child oriented" way. She discussed this change:

One of the things I've changed is this idea of herding children through the Kinder day: they go from indoor play to snack time to the mat and so on. How I do it now is that I have a lot of different things happening at once. I'll have a small group on the mat and there might be some children sitting down and having a snack and there's still some children in home corner playing.

These comments seem to provide evidence that Angela is growing professionally for two reasons. First, the ability to identify changes in her program suggests to me that she has deeper pedagogical knowledge gained through critical reflection on her practice, and second, there is congruence between her expressed beliefs and the practice she describes.

Discuss your findings

In the discussion of your findings you have an opportunity to develop the story you found in the data, making connections between the results of

your analysis and existing theory and research. While the amount of discussion required in a thesis may vary according to discipline, all disciplines expect some interpretation of the findings that makes these connections.

Research question

In your discussion you must draw together your research question and your own research results. If the discussion is in a self-contained chapter or section you will need to briefly summarise the major findings that come from the research and relate them to what you originally proposed to find out.

If your research is testing a hypothesis, you need to answer these questions:

- Do your research findings support your initial hypothesis? Why and how?
- Do your findings only support the hypothesis in part? Why and how?
- Do your findings disprove your hypothesis? Why and how?
- What else do your findings tell you, over and above what you initially set out to investigate?

Relation to other research

Since one of the requirements of a doctorate is to make a contribution to knowledge, it is essential to show how your results fit in with other work that has been done in your field.

- Point out the agreements and disagreements between your data and that of others.

- In presenting your own interpretation of the results, consider the strengths and weaknesses of alternative interpretations from the literature.

Implications

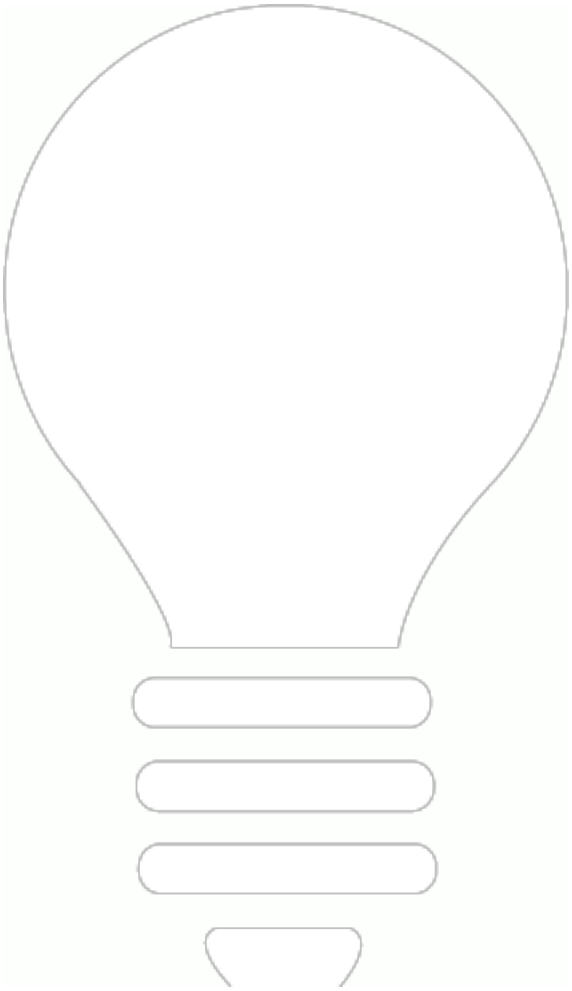
Another aspect of making clear the contribution of your research is to draw out the implications of your findings. Depending on the nature or your research, these will probably be related to:

- current theory
- technical applications
- professional practice

Writing your discussion

The skill in writing a successful discussion is in moving backwards and forwards between others' research and your own research, making it clear:

- which has been done by other people
- which has been done by you
- **and** how they complement each other.



Tip

Remember that you are dealing with three different issues and the three must be clearly differentiated for the reader.

Some techniques to differentiate your own research from previous research in your writing (these are suggestions, not rules, and your best guide is to see how other writers in your discipline do this):

Use the first person to describe your findings.	*My data shows...*
Consistently use ‘this’ to refer to your own research and refer to previous research by name, place or time.	*This study...* *The findings of this research...* *Smith and Geva found that...* *A previous study in Belgrade...*
Make reference to similarities or differences in approach or findings.	*Similar research carried out in the 1980s showed that...*
Use the **presentperfect** tense to highlight the recent relevance of your research in comparison with earlier research, referring to it in the **simple past**.	*This study **has shown** a prevalence rate of 2.5 which is greater than that **found** by Smith and Geva in their Belgrade study…*

Using cautious language

Discussing results and drawing conclusions involves making claims about interpretation, significance and applicability. This is done within a research tradition where existing knowledge is always being modified in the light of

new results. As a researcher, you are expected to distinguish carefully between:

- knowledge you are sure of because you have reliable evidence for it
- other knowledge you are less sure of
- other knowledge you think is only within the realms of possibility

Therefore, very strong claims, like the one below, are rare in academic writing

Reducing fat intake lowers the risk of heart disease.

A claim like this, which implies that the statement is true in every case, cannot be supported with evidence. Claims should therefore be specific and precise, and the level of certainty must match the level of evidence.

There are many methods used in academic writing to qualify a claim:

1. Indicate the degree of probability (note how the claim progressively weakens):

Reducing fat intake **lowers** the risk of heart disease.

Reducing fat intake **could/might lower** the risk of heart disease.

Reducing fat intake **may lower** the risk of heart disease.

2.Distance yourself a) from the claim:

Reducing fat intake **appears** to lower the risk of heart disease.

It seems that reducing fat intake lowers the risk of heart disease.

Some researchers suggest that reducing fat intake lowers the risk of heart disease.

or b) from the data, by showing its limitations:

Some studies indicate that reducing fat intake lowers the risk of heart disease.

For this age group , reducing fat intake lowers the risk of heart disease.

In most of the cases studied , reducing fat intake lowered the risk of heart disease.

3. Use a qualifying verb:

Reducing fat intake **tends** to lower the risk of heart disease.

Reducing fat intake **contributes** to lowering the risk of heart disease.

4. In practice, a combination of these methods is often used:

The majority of studies indicate that for this age group, reducing fat intake contributes to lowering the risk of heart disease.

References

Evans, D., &Gruba, P. (2002). *How to Write a Better Thesis* (2nd ed.). Melbourne University Press.

Golden-Biddle, K., & Locke, K. (1997). *Composing Qualitative Research*. Sage Publications.

Silverman, D. (2005). *Doing Qualitative Research: A Practical Handbook* (2nd ed.). Sage Publications.

Swales, J. M., &Feak, C. B. (2004). *Academic Writing for Graduate Students* (2nd ed.). University of Michigan Press

It is **certain** that It is **very probable/ highly likely** that It is **likely** that It is **possible** that It is **unlikely** that	→	reducing fat intake lowers the risk of heart disease.

13. Strength and weakness of study implications

Quantitative Research

There are many researches taking place, which results into the evolution of something new and unique. Traditional Marketing Research have two options to conduct their research: Quantitative and Qualitative method. Quantitative research is dependent on the creation of Hypothesis followed by accurate analysis of the statistics in order to understand and explain the research findings. It focuses more on the quantity of things and their statistical patterns. Using the number it comes to an analysis so as to come to a conclusion. Quantitative research method has proven to be beneficial in the following ways

- It provides an allowance on the formulation of statistically sound
- Quantitative data provides a macro view with all the required details and comparatively larger samples.
- Larger sample sizes enable the conclusion to be generalized.
- Evaluation of the multiple data sets can be done at once and that too at a faster pace and accurately.

- This method is called to be appropriate when there is a need of systematic and standardised comparisons.
- The manual implementations of ideas can be automated completely which can save time.

↬Weaknesses of Quantitative Data

- Quantitative Method reveals what and to what extent but often fails to answer more on why and how.
- This type of research requires the model performance to be monitored on constant basis in order to ensure its compliance with the original hypotheses.
- The impression of homogeneity in a sample may turn out to be fake in this method.
- This method involves limited number of Quants supply and also involves complex disciplines which are hard to master.

♦ Qualitative Research

It is more focused on exploring the issues, understanding the actual problem and enabling oneself to answer all the questions. Qualitative Research Method is more dependent on deriving the value of variables in their natural setting. The data via this method is collection by asking open ended questions and serving with the direct quotations. Qualitative can be beneficial in the following ways

- All the problems and the topics covered under this research are in detail.
- This method majorly focuses on small groups which ultimately do not require more expenses when compared to quantitative research.

- On the emergence of new developed information and findings, the revision, direction and framework of the data can be done easily quickly.
- The data is collected from a small group which bounds it to be universal for a large population.
- The data with this method is collected based on genuine efforts and gives a clear vision on what can be expected.

↬Weaknesses of Qualitative Research

- As the data is collected for a small group, due to which assumptions cannot be made beyond the small group of people.
- It becomes difficult to demonstrate, maintain and assess the rigidity of the data.
- Collection of statistical data is not easy and cannot be done solely by using this method.
- As the data is in big quantity, analysis and interpretation of the data takes much time.
- The responses of the subjects might be affected as the researchers are bound to be present during the process of data gathering.

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14. Reference Vancouver style

This section contains introductory guides to some common reference styles.

Writers themselves seldom choose which reference style to use; students need to comply with the guidelines issued by their departments and those who write for publication will have to follow the publisher's guidelines.

The AWELU guides to specific reference styles cover some of the main reference systems. For more detailed and discipline-specific information, writers will need to consult the style manual of the specific reference style.
It should also be noted that departments and publishers often adapt reference styles and that guidelines therefore can differ in some respects.

- APA
- Documentary note style
- Harvard
- IEEE
- MLA
- Vancouver

Reference list: General notes

Please check with your faculty for any specific referencing or formatting requirements

- References are listed in numerical order, and in the same order in which they are cited in text. The reference list appears at the end of the paper.
- Begin your reference list on a new page and title it 'References'.
- The reference list should include all and only those references you have cited in the text. (However, do not include unpublished items such as correspondence.)
- Use Arabic numerals (1, 2, 3, 4, 5, 6, 7, 8, 9).
- Abbreviate journal titles in the style used in the NLM Catalog.
- Check the reference details against the actual source - you are indicating that you have read a source when you cite it.
- Be consistent with your referencing style across the document.

Example of a reference list

References

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Referencing Appendices

Referencing your own appendicesin your own text:

- Your appendix does not need to be referenced. It is enough to signpost it the body of your work, for example: (See Appendix A).
- If you created your own appendix, and you've cited references, then number the references within the appendix consecutively in sequence with your written text and include them in your reference list.

Referencing appendices not written by you:

- If the appendix was not written by you then place the numbered citation, in sequence with the rest of the text, at the end of the appendix and include the full reference in your reference list.

VALUE ADDED COURSE

RESEARCH METHODOLOGY

Annexure II

STUDENT ENROLMENT LIST (JULY-DEC 2017)

S.No	University no	Name of the student	Year / CRRI	Signature
1.	U16MB331	MONISHA .S	II nd	
2.	U16MB332	MONISHA .M	II nd	
3.	U16MB333	MONISHDEVI .N	II nd	
4.	U16MB334	MOUNIKA .A	II nd	
5.	U16MB335	MOUNIKA.B	II nd	
6.	U16MB336	MUHAMMAD SHEBIN	II nd	
7.	U16MB337	MUSKAAN SHAMIM	II nd	
8.	U16MB338	MUSULURI SHYAM SINDHU	II nd	
9.	U16MB339	NAMITA YADAV	II nd	
10.	U16MB340	NAMRATA GHORAI	II nd	
11.	U16MB341	NANDU ARAVIND	II nd	
12.	U16MB343	NEELU.S.P	II nd	
13.	U16MB342	NEITOUNUO MARY PIENYII	II nd	
14.	U16MB344	NIKITA VERMA	II nd	
15.	U16MB345	NISHA AGRAWAL	II nd	
16.	U16MB346	NOUNETSHUNUO KEJO	II nd	
17.	U16MB347	PALAYULLA VALAPPIL VARUN	II nd	
18.	U16MB348	PARTHASARATHY .S	II nd	
19.	U16MB349	PATIL NAMRATA YASHANAND	II nd	
20.	U16MB350	PAVETHRA .A	II nd	

RESOURCE PERSON

DR.JALAKANDAN

COORDINATOR

Dr S NITHIANANDAM

Annexure III

MCQ : RESEARCH METHODOLOGY

1) Which of the following must be considered while measuring occurrence of a disease?
   a) The number of people affected by the disease
   b) The population size from which the cases of disease arise
   c) The length of the time the population is followed
   d) All of the above

2) Is most useful for evaluating the impact of prevention program
   a) Point prevalence
   b) Period prevalence
   c) Case fatality
   d) Incidence

3) A measure that reflects severity of an acute infectious disease
   a) Case fatality ratio
   b) Incidence rate
   c) Prevalence
   d) Mortality rate

4) Before initiating a study involving primary data collection, the Principal Investigator must ensure that various approvals are obtained. Which of the following approval is absolutely mandatory?
   a) Scientific committee approval
   b) Ethics committee approval
   c) Technical committee approval
   d) Regulatory authority approval

5) Which of the following disciplines contribute to health research?
   a) Bio-medical research
   b) Biostatistics
   c) Social science research
   d) All of the above

6) Which of the following best describes a study done in a laboratory setting using animals?
   a) Translational research
   b) Bench-based research
   c) Theoretical research
   d) Preventive research

7) Which of the following review is NOT essential before initiating a clinical trial?
   a) Scientific review
   b) Peer review
   c) Regulatory review
   d) Ethics review]

8) Which of the following is NOT a type of study design?
   a) Qualitative study
   b) Observational study
   c) Retrospective study
   d) Translational study

9) A researcher wants to study the relationship betweenCOVID-19 infection in pregnancy and birth weight. Currently, there is no evidence on this topic .Which of the following options is the scope of this health research?
   a) Verifying and confirming known information
   b) Getting additional or new information
   c) Evaluating ongoing programs
   d) All of the above

10) Which of the following is NOT a critical consideration in planning a health research?
   a) Adequate justification
   b) Clear and focused research question
   c) Standard case definitions
   d) Financial gain

11) Identify the CORRECT statement about implementation of a research
   a) Research findings must be approved by the funder
   b) Research finding must be error free
   c) Adequate sample size is a prerequisite
   d) Pilot study can be done during data analysis stage

Moskan Shanwen

Annexure III

6/10

MCQ : RESEARCH METHODOLOGY

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8/10

Annexure III

Pathobiology. 8

MCQ : RESEARCH METHODOLOGY

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d) Pilot study can be done during data analysis stage

Annexure V

Student Feedback Form

Course Name: **RESEARCH METHODOLOGY**

Subject Code: **ANAES 05**

Name of Student: _____ Roll No.: _____

We are constantly looking to improve our classes and deliver the best training to you. Your evaluations, comments and suggestions will help us to improve our performance

Sl. NO	Particulars	1	2	3	4	5
1	Objective of the course is clear					
2	Course contents met with your expectations					
3	Lecturer sequence was well planned					
4	Lectures were clear and easy to understand					
5	Teaching aids were effective					
6	Instructors encourage interaction and were helpful					
7	The level of the course					
8	Overall rating of the course	1	2	3	4	5

*** Rating: 5 – Outstanding; 4 - Excellent; 3 – Good; 2– Satisfactory; 1 - Not-Satisfactory**

Suggestions if any:

Annexure V

Student Feedback Form

Course Name: **RESEARCH METHODOLOGY**

Subject Code: **ANAES 05**

Name of Student: NANITHA YADAV Roll No.: 016MB339

We are constantly looking to improve our classes and deliver the best training to you. Your evaluations, comments and suggestions will help us to improve our performance

Sl. NO	Particulars	1	2	3	4	5
1	Objective of the course is clear					✓
2	Course contents met with your expectations				✓	
3	Lecturer sequence was well planned			✓		
4	Lectures were clear and easy to understand			✓		
5	Teaching aids were effective				✓	
6	Instructors encourage interaction and were helpful			✓		
7	The level of the course				✓	
8	Overall rating of the course	1	2	3	4	5

^ **Rating: 5 – Outstanding; 4 - Excellent; 3 – Good; 2– Satisfactory; 1 - Not-Satisfactory**

Suggestions if any:

Need more Teaching

Annexure V

Student Feedback Form

Course Name: **RESEARCH METHODOLOGY**

Subject Code: **ANAES 05**

Name of Student: HOLISHA. N Roll No.: 16HB332

We are constantly looking to improve our classes and deliver the best training to you. Your evaluations, comments and suggestions will help us to improve our performance

Sl. NO	Particulars	1	2	3	4	5
1	Objective of the course is clear					
2	Course contents met with your expectations					
3	Lecturer sequence was well planned					
4	Lectures were clear and easy to understand					
5	Teaching aids were effective					
6	Instructors encourage interaction and were helpful					
7	The level of the course					
8	Overall rating of the course	1	2	3	4	5

*** Rating: 5 – Outstanding; 4 - Excellent; 3 – Good; 2– Satisfactory; 1 - Not-Satisfactory**

Suggestions if any:

Good Arrangement are Required

Date: 04.12.2017

From
Dr. Nithianandam
Professor and Head,
Department of Anaesthesia
Sri Lakshmi Narayana Institute of Medical Sciences
Puducherry

To
The Dean,
Sri Lakshmi Narayana Institute of Medical Sciences
Puducherry

Sub: Completion of value-added course: RESEARCH METHODOLOGY

Dear Sir,

With reference to the subject mentioned above, the department has conducted the value-added course titled: Research Methodology in July- Dec 2017 for 20 students. We solicit your kind action to send certificates for all the participants, whose name list is attached with this letter. Also, I am attaching the photographs captured during the conduct of the course.

Kind Regards,

Dr.Nithianandam

Encl: Certificates

Photographs

Sri Lakshmi Narayana Institute of Medical Sciences

Affiliated to Bharath Institute of Higher Education & Research

Deemed to be University under section 3 of the UGC Act 1956

CERTIFICATE OF MERIT

This is to certify that __MOUNIKA .A____ has actively participated in the Value Added Course on Research Methodolgy held during July - December 2017 Organized by Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry - 605 502. India.

Dr.J.ELAKANDAN
RESOURCE PERSON

Dr. NITHIANANDAM S
COORDINATOR

Sri Lakshmi Narayana Institute of Medical Sciences

Affiliated to Bharath Institute of Higher Education & Research

(Declared to be Deemed to be University under section 3 of the UGC Act 1956)

CERTIFICATE OF MERIT

This is to certify that NANDU ARAVIND_____ has actively participated in the Value Added Course on Research Methodolgy held during July - December 2017 Organized by Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry- 605 502. India.

Dr.JALAKANDAN
RESOURCE PERSON

Dr. NITHANANDAM S
COORDINATOR


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