Summary: Introduction to Medical Research Methods

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Key objectives

الكلام الي لونه أخضر فهو حكي الدكتور أما الحكي الي عليه نجمة فهو حكي سلايد موجود عند الدكتور و مش موجود بالملف

- To discuss approaches for transferring ideas into a structured research question
- To assist students in development of good research question
- To provide students with skills for conducting a comprehensive and structured literature review
- To providing good understanding of the duties of the research team
- To provide an overview of the research authorship policies



Research is a term used liberally for any kind of investigation that is intended to uncover interesting or new facts.

Researech

- Research is either discovery of new facts or fresh interpretations. For example, if you
 know the risk factor forcing heart disease and we need to look at the prevalence of
 these risk factors, we know these risk factors and we are looking just for distribution of
 these risk factors OR assessment of the known facts or principles. For example, we need
 to look for a new medication and we need to do clinical trial to see whether the new
 medication is better than existing medication.
- It is a systematic investigation to develop or contribute to generalizable knowledge.
- Research is an organized and systematic way of finding better answers to questions.

Research

• A key thing in research that is

- We can't improve any clinical practice, the health care system for the whole community, the innovation new medications or combination medications to look at the outcomes of patients without research. We need to assist the gap areas improvement and to work on them. After we identify these gaps, we can work on through different clinical trials or community trials to improve these gaps.
- Research is vital for the understanding of the problems that affect individuals, communities or health systems.
 - For example, if you want to conduct any cross- sectional study clinical trial you need to do it in a systematic way throughout a certain pathway through according to the study.
- It allows for systematic and scientific assessment or evaluation of problem and provides knowledge that allows for change to occur- change that improve the quality of health and health care.
- No organization or health institution can grow or develop without the use of research.

Research

- The basic function of research is to answer why and how of a phenomenon,
- but searching answers to
 - what,
 - when,
 - how much, etc., is also part of research endeavours.

All these questions when we have the different study designs for for example, descriptive case control, cross- sectional studies. We start to answer these questions and to build hypothesis for analytical studies like the case control and to look for the outcomes and to assess the the interventions we needs to do clinical trials. So, we ask these questions throughout the different study design

Medical Research

- The goal of *medical research* is to improve health, and the purpose is to learn how systems in human body work, why we get ill, and how to get back to health and stay fit, and how to prevent illnesses.
- It is a systematic process to better determine etiology, patho-physiology, epidemiology, distribution of risk factors diagnosis, therapy, prognosis and prevention.

So, it's the foundation of improved medical care

- Research is the very foundation of improved medical care.
- It can also provide evidence for policies and decisions on health development.

 In any country, to improve the health care system we need to look for example prevalence,

In any country, to improve the health care system we need to look for example prevalence, incidence of illnesses to set priorities. In country X for example, if we have a major issue (complication of type 2 diabetes), without knowing the management of this problem and the types of the complication, we can't work on prevention and control of this problem in this country

Areas of Research

- Problem(s) discovery, finding
- Impact of the problem
- Epidemiology of the problem: Size, etiology / risk factors
- Pathogenesis
- Management
- Prevention

Study methods: steps in medical research science

- It's known to be a systematic study that follows a certain patterns to get the results so this step by step approach and produces testable results
- Thus scientific research must follow a step by step pathway that foster clarity and a void the problem of multiplicity.
- We call this study methodology. We have the study design where we describe the patient, the size of the study (primary, secondary), what are the tools we use in our research, what is the sample size, skill analysis plan.

Research Methods

- Research Methods are the tools and techniques for doing research.
- It covers all the steps from planning to carry out research till dissemination of the results.

 So when conduct any study a survey, cross sectional study, clinical trial and course

Valid approach: it's the correct approach of conducting these steps \P

study, we need the describe in the methodology, the tools and techniques that we are following in our study. For example, if you are conducting a study in diff sites in Jordan, for all investigators, research assistant, coordinators to conduct the study following the same approach, we need to have in writing the study methods within the study protocol(who are the patients to be included and what are the including criteria, who should be excluded as excluded criteria). For example, testing for different biochemical test, we need to write the kit used for the analysis, the machine used for the analysis, the approach for collecting samples, how we store the samples, how we transfer the samples. Everything should be in writing there to ensure that we are following systematic approach throughout the study and this is a valid approach.

STEPS IN MEDICAL RESEARCH

- Identify the problem
- ... Collect and evaluate existing information
- III. Make your research team
- IV. Formulate research objectives and hypotheses
- v. Identify study subjects
- vi. Think of the design
- VII. Write the proposal and protocol
- VIII. Develop the tools
- ix. Identify Study sites
- x. Get the necessary permission (Institutional, ethical, etc.)

Epidemiological studies

Clinical observation

Descriptive studies

Analytical studies

Experimental studies

Variation Association Association

The medical studies start form clinical observation, you at your practice in the future can observe something based on that you can provide for example a case report or case series for a group patients with certain characteristics and you start to build hypothesis and then you have a large study through cross- section study to show the association or the prevalence of these factors that you have observed then you can link the risk factor you have observed through analytical studies, case control...... to see whether a positive agent or not . And you can follow that by experimental studies for prevention of these factors

The Human Papilloma Virus vaccine (HPV vaccine), the story of this vaccine came from professor Howen,He was diagnosed with cervical cancer, he start linking this virus with this cancer- there is NO relation, they tell him. He didn't stop at this point. He initially published case series about the HPV and cervical cancer and then he conducted a cross- sectional study. He compared women with cervical cancer what was the prevalence of HPV virus positivity and he compared them with the group of women coming to the same hospital with other illnesses to look at the prevalence of theses HPV virus positive or cervical worst. And he also had a group from the community and he showed that patient with cervical cancer had the high prevalence of HPV. Then, he conducted an retrospective cohort study and he showed a high relative risk for the HPV correlation with cervical cancer and he proved that cervical cancer and HPV is a cause for cervical cancer through analytical studies. He didn't stop at this point, he worked with one pharmacal companies for vaccine. HPV vaccine is given in many countries especially western countries for prevention HPV and prevention of cervical cancer. He won Nobel prize. So if he stopped at the point where he observed patients with cervical cancer positive for HPV and listen to his colleagues that is there no relation, he didn't achieve this Nobel prize and he become a partner in this huge project that has prevented tens of thousands of cervical cancer cases.



Many medication were taken out from the market because it is observed very moderate- severe drug adverse reactions and they confirmed that through case series that these adverse reactions were due to certain medications new in the market and they were taken completely from the markets, so these observations managed to prevent severe complications for many patients worldwide.

Moving from research idea to a feasible research project

Literature review: Is the key for the success of your research project

First thing that we need to ask

Hås it been investigated?

What has been done in this field?

Questions to be answered in this field?

It's very important, sometimes we might find the project was or the idea was investigated ,but the study was conducted/ not strong enough to generalize the result from that study. So we can look at the limitations of that published study and based on that we can repeat our project.

As investigator, you need also to know more about what has been done in this field, what are the questions to be answered in this field.

What is a research question?

- The researcher asks a very specific question and tests a specific hypothesis.
- Broad questions are usually broken into smaller, testable hypotheses or questions.

You will have experience with time, how you can transfer this broad question into a specific question that can be tested

Often called an objective or aim, though calling it a question tends to help with focusing the hypothesis and thinking about how to find an answer

You need to look at the aims of objectives of your project and what you need to answer throughout this study.

What characterizes a good question?

- Well-conceptualized
- Relevant
- Direct and clear
- Focused
- Includes all components (main concepts)

IDENTIFY THE PROBLEM

to select

- relevance and applicability for improving health in one way or the other,
- interest and expertise of you and your collaborators, and
- the feasibility of completing the work with available resources, time, subjects, tools, etc.
- (prioritization)

Sometimes we have ideas for large prospective studies ,but the problem is budget and the resources needed for this project

How to focus your question?

- Literature search for previous evidence: focus on reviews, recent updates...etc.
- Discuss with colleagues
- Attend scientific meetings
- Narrow down the question time, place, group

ALWAYS KEEP ASKING

What answer do you expect to find?

Moving from research idea to research question

- Think about how your research:
 - * may resolve theoretical questions in your area
 - * may develop better theoretical models in your area
 - * may identify new risk factors for a disease
 - * may change current management plans



Why should I formulate a structured research question?

- * To point you in a specific direction (narrowing your scope/focus to ask a manageable question)
- * To identify the main concepts of your question
- * To help build your literature search strategy
- To improve your information retrieval
- * To be able to evaluate the usefulness/appropriateness of the information retrieved

It's very impressive that we collect data that is relevant to our project and we can utilize data and the result dissemination

Hypothetical Research Question

- Your belief(s) or observations:
 People who take Vitamin C regularly are less exposed to upper respiratory tract infections
 - Vitamin C intake could reduce risk of upper respiratory tract infections
- Your hypothesis
 Does Vitamin C regular intake prevent upper respiratory tract infections

IDENTIFY THE PROBLEM



Convert the problem to specific questions that require answer.



The question must pass the —so what? | test.



Throughout the literature review

A good research question is backed up by theoretical considerations. \mathcal{I}

The biological possibility is that the outcomes of your research can be justified through the understanding the pathophysiology of that it.



If you are investigating the role of a particular type of diet in urological malignancies, it is helpful to consider why that type of diet can alter the risk of this cancer. Biological plausibility gives a definite edge.

→ Affect the kidney , the bladder. We need to understand the pathophysiology of the human body so we can do research and these factors.

Clinical example:

- Too broad: How do you control infection?
 - This topic is so broad that you'd have difficulty wading through all of the results.
- **Too narrow**: At the Jordan University Hospital Neonatal Intensive Care Unit, what is the best way to control infections among preterm infants?
- This question is so specific that there probably hasn't been anything published on that specific location regarding that specific population.

 We know that there are many factors to control infections and it might not be feasible to look at the all these factors at one time. So, Just right: In the NICU, JUH, what is the effect of hand washing on infection control compared with hand sanitizers, over 6 months? This is something we quantify/ compare two approaches and we

compare two approaches and we have a period of time and we have the site of this study.

Frameworks for Research Questions

Applying a framework when developing a research question can help to identify the key concepts and determine inclusion and exclusion criteria.

PICo:	Population/Participants, phenomenon of Interest, Context
PICO(S):	Patient/Problem, Intervention, Comparison, Outcome, (Study design)
PECO(S):	Patient/Problem, Exposure, Comparison, Outcome, (Study design)
PESICO:	Person, Environment, Stakeholders, Intervention, Comparison, Outcome
PIPOH:	Population, Interventions, Professionals/Patients, Outcome, Healthcare Setting
<u>PS:</u>	Population, Situation
SPICE:	Setting, Perspectives, Intervention, Comparison, Evaluation

▶ We need to have to write in your question what's the patient / who is the patient / what's the problem/ what's the intervention/ are we conducting a comparison/ what's the outcome of our study / what's our study design

P (Patient, Population, Problem)	I (Intervention)	C (Comparison)	O (Outcome)
How would I describe a group of patients similar to mine?	What main interventions, prognostic factors or exposure are you considering?	What is the main alternative to compare with the intervention?	What can you hope to accomplish, measure, improve or effect?
In:	Does:	Versus:	Result in:
Otherwise healthy children	exposure to in utero smoking/nicorine	children not exposed to in utero nicotine	increased risk of learning disabilities?
In:	Does:	Versus:	Result in:
Primary school children	school-based physical activity	no school-based physical activity	a decrease in obesity

PICOT

- ▶ PICOT is a mnemonic that helps you remember the key components of a well-focused question. It stands for:
- P = Patient, Population or Problem
- I = Intervention, Prognostic Factor, or Exposure
- C = Comparison (optional)
- O = Outcome
 - **T** = Time

This example will be helpful for you to understand, how we can develop research questions

Intervention/therapy

Control

- In <u>Population</u> (P), what is the effect of <u>Intervention</u>(I) on <u>Outcome</u> (O) compared with <u>group</u> (C) within <u>Period</u> of time(T)?
- In the aged population, what is the effect of exercise programs on accidental falls, as compared with no exercise? So, we have an intervention here and we have the standard layout of the questions

Etiology Population
A history of childhood
Are ____ (P) who have asthma (I) at ____ (Increased/decreased) risk for/of COPD (O) compared with ____ (P) with/without ____ (C) over ____ (T)?

Are adult smokers with a history of childhood asthma at increased risk of COPD compared to adult smokers with no history of asthma?

We want to compare different test and we have worked in medical screening

- Diagnosis or diagnostic test on assessment of different screen test and in population based screening
 - Are (is) Test (I) more accurate in diagnosing For the (C) for Second (O)? (P) compared with (P) compar
- Is the combination of fasting glucose with Hemoglobin A1C test more valid for screening for type II diabetes as compared with fasting blood sugar levels?

Studies have proven that fasting glucose combination with Hemoglobin A1C the best screen test for type 2 diabetes compared with the single test (the fasting glucose only/ the hemoglobin A1C only) because we can detect Pyrex diabetes with high sensitivity and high specificity

Prevention

- For Population (P) does the use of _____ (I) reduce the future risk of _____ (O) compared with ____ (C)?
- For people with type 2 diabetes, does zinc supplementation reduce the future risk of foot ulcers compared with placebo? So, we have here prevention of foot ulcer that is one of the complication of type 2 diabetes and we can ask the question this way

We can follow these structures (diagnosis / therapy/ intervention/ etiology) and make a good research questions

Prognosis/Predic	tions		
Does(P) over	_ (I) influence (T)?	(O) in patients who hav	'e
In adults with osted predict the rate of future.		nin D levels in the bloods	stream
Meaning OR quality of	life		
How do (T)?	(P) diagnosed with	(I) perceive	(O)
How do cancer pat during and after chem	ients diagnosed with ald notherapy? This one of the co	opecia perceive their sel	f-esteem cer survivors

Public Health:

These models are helpful actually in clinical practice in the management and ideas related to treatment ,interventions and epidemiology and also they are very helpful in public health studies. So, we can follow the same approach .

for example, population we have people with permanent residence in Jordan intervention hypertension comparison respondent without hypertension, what the outcome would be cardiovascular disease or cardiovascular mortality cross- sectional study to look at the complications. So, comparing the cardiovascular mortality between patient with hypertension and those without hypertension in Tordan

- PICO(T) is commonly used to formulate research questions, sometimes referred to as 'PI/ECO' (Population/participants, Intervention/Exposure, Comparison, Outcome). The PI/ECO structure can be readily amended for different question types:
 - A simple example might be:
 - Population / participants: People with permanent residence in Jordan
 - Intervention (or Exposure): Hypertension
 - Comparison: Respondents without hypertension
 - Outcomes: Cardiovascular disease or cardiovascular mortality
 - Types of studies: Cross-sectional, Longitudinal

Based on the outcomes of this study, we can look at the importance of control blood pressure and reducing cardiovascular mortality

Public Health: Formulating Research Questions

Underdeveloped question:

What interventions help against smoking vaping in youth?

Refined research question:

What strategies help prevent e-cigarette use in adolescents?

Literature review

Is the key we need to see what has been done. We aren't repeating others work so there is no value for the study and even if there has been work, there are limitations for this work, we can justify our study

Literature review is required through your Most of the journals these days they ask the authors to write

research:

in the discussion paragraph or two on the limitations of their work and how we can make it better. This is very helpful for

- It helps to choose topic your students to develop your studies design and to conduct the study at better standards than the previous ones.
- Prevents from duplicating work
- Refine your problem
- Formulate objectives
- Familiar with various methodology investigate the same area of research

That have been conducted to

Provide argument why is it needed

(justification)

Sometimes, we write the last paragraph in our proposal due to lake of large for example clinical trial on the effect of certain medication or prevention of renal failure for example or prevention of complication of IHD or no large study conducted to look at the burden of certain infections in paediatrics. The previous studies were small and not representative, therefore we need to repeat throughout the large representative study

Literature review

Critical appraisal mean that what are the strength of the published work, the study was large, the study design was well conducted or well structured. What are the limitations of that study. So, critical appraisal doesn't mean that we just show the limitations no we show the strength of weakness or limitation of that published study.

Writing a literature review lets you gain and demonstrate skills in two areas

- information seeking: the ability to scan the literature efficiently, using manual or computerized methods, to identify a set of useful articles and books
- critical appraisal: the ability to apply principles of analysis to identify unbiased and valid studies.



Literature Review: Bring clarity and focus to your research problem So, we can have focus questions through the literature review in the field.

- The process of reviewing the literature helps you to understand the subject area better and thus helps you to conceptualise your research problem clearly and precisely.
- It also helps you to understand the relationship between your research problem and the body of knowledge in the area.

Literature Review b. Improve your methodology:

A literature review tells you: cancer surveillance, and we have done this through the region.

For example, we are assessing the quality of life

- If others have used procedures and methods similar to the ones that you are proposing? We can look at the questionnaires or tools used for assessment of quality of life, which one is more valid, and we can follow the same questionnaire or tool in our study.
- Which procedures and methods have worked well for them?
- III. What problems they have faced with them?

What were the problems that they faced throughout the study? How can we counteract these problems in our project?

Thus you will be better positioned to select a methodology that is capable of providing valid answer to your research questions.

> So we can improve our methodology based on reading the literature review in this field.

Literature Review Broaden your knowledge base in your research area: Many times we had in mind to conduct research for certain objectives. After reviewing the literature, reason, publication, we changed the objectives.

It ensures you to read widely around the subject area in which you intend to conduct your research study.

- As you are expected to be an expert in your area of study, it helps fulfill this expectation.
- It also helps you to understand how the findings of your study fit into the existing body of knowledge.

No way to have more or better outcomes from the project.



Literature Review Contextualize your findings:

- 1. How do answers to your research questions compare with what others have found?
- What contribution have you been able to make in to the existing body of knowledge?
- 3. How are your findings different from those of ~ others?
- For you to be able to answer these questions, you need to go back to your literature review.
- It is important to place your findings in the context of what is already known in your field of enquiry.

This is very important, the discussion of our results. When we conduct the project, complete analysis, and we try discussion, we need to show how compare our results with others and how we can, what are the differences and how we can utilize the outcome of the study.

Literature Review

- Search for existing literature:
- To effectively search for literature in your field of enquiry, it is imperative that you have in mind at least some idea of broad subject area and of the problem you wish to investigate, in order to set parameters for your search.

Literature Review

- 1. books
- 2.Journals
- 3. Medical databases: PubMed, Medline..etc.
- 4. Other publications:

(reports, census, surveys etc)

5. Other Internet search

(scientific evidence based sites or sites of official

medical bodies)

We always, we only follow scientific evidence based sites or sites of shared medical bodies. Other sites are not acceptable at all from the, in the medical community. You are a medical student, Whether you are conducting research as student or in the future, please avoid, never ever use any internet research outside the scientific evidence based sites or sites of shared medical bodies.

Literature Review

We always refer to books to understand the pathphysiology of different illnesses . instances, to look at the medical symptoms, signs, etc. The main issue of the utilizing the books is that there are a few years between the completion of the book and between publications.

BOOKS

- comprise a central part of any bibliography.
- Advantage-material published generally is of good quality and the findings are integrated with other research to form a coherent body of knowledge.
- Disadvantage-material is not completely up to date, as it can take a few years between the completion of a work and publication in the form of a book. So most of the knowledge, especially if we are looking at the

treatment of different illnesses, I always recommend not to use the book as a reference because there are two to three years between the preparation of the work and the literature and the publication of the book.

Literature Review

Another major issue that we are seeing these days is the open access journals without solid peer review process. someone will come to you with publication showing you this impact of 'big impact' of this medication control of type two diabetes or hypertension.

JOURNALS

- Journals provide you with the most up-todate information
- Be careful with open access journals without solid peer review process

You need to read the paper carefully and to see the journal, whether it's open access peer review or not, you need to read the paper and see whether you can do a good critical appraisal, whether you can apply it in your practice or not. And this is really dangerous because there are many journals that you can publish to them now within few minutes, they give you acceptance and publish your work. But the quality and validity and utilization of the work is very bad.

Resources

- Pubmed
- Popline
- CDC
- Google Scholar Google Scholar, it's not rigid. They don't have the system, same as PubMed or popline.

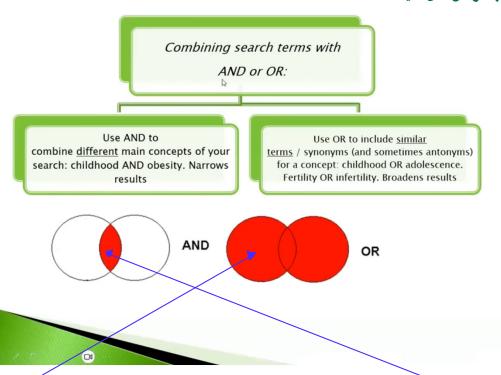
 But we can also sometimes utilize if we read the paper carefully, and we see that

what are the limitations of that paper.

- **UN**
 - WHO
 - emro
 - UNICEF
 - UNICEF Jordan
 - UNDP
 - UNEP UNFPA/ UNAIDS/ UN women
- DHS
- NICE,UK



هاى الصفحة بالفيديو شرحها أوضح، من دقيقة 36



In pubmed, we have some orders to combine research and OR or , and mean this area. For example, adults with type 2 diabetes, in this circle, adults with type 2 diabetes, we have only adults with type 2 diabetes here.

Say here, patients with hypertension or diabetes. This is the two groups we include in the search.



This mean that this Star will mean that will include all the publication Where we can find the word hypothyroid until the deep. So this one be included and papers with hypothyroidism and hypothyroid Will be included. So this is a broader than this one

Pregnancy sometime we said that I'm pregnant sometime pregnancy. So In the search we might find pregnant women or pregnancy during pregnancy So how we can combine pregnant with pregnancy? So we can look at each other that and looked up hypothyroidism in pregnant women or in pregnant during pregnancy We go back to the or so if you have three or four this will lead to the search six So the outcomes of this three or four means that any publication that included the term pregnancy or the term pregnant . So both groups will be included . Hypothyroidism and hypothyroid the same or will means that the two seconds will be included. So we have a Hypothyroidism and hypothyroid in search five or Three or four so you have two groups here. First group & second group ,how little one outcome but now we need to look at Search hypothyroidism and pregnant or pregnancy at the same time we combine five and six So if you have here the hypothyroidism Publication hypothyroidism they include publications and during pregnancy, adults , pediatrics all the groups will be in the second. We only are interested in the group of if you have this is Publication for pregnancy. We are interested only in the group that is located here between the two circles ,this mean that only publication that included pregnancy or pregnant women and Hypothyroid or hypothyroidism

Please practice this more and more so we can sometimes you have for example here hypothyroidism and here during pediatric age groups or elderly or adult population. When you Feel yourself have more skills in the literature review and the research, please go to the Cochrane library. There are many publications, sometimes we find for certain medication different publications out there. The Cochrane library in summary they will Do a review for these clinical trials looking at the same And in different populations looking at the same outcome utilizing the same medication. They will combine the papers together to lead to a meta analysis Or the differences between the publications they will do what we call systematic review and we will cover in this in one lecture. Sometimes where there are large studies clinical trials or cross-section studies and the outcomes of the or cohort study and the outcome these studies are Very important and they will change the science Also, the Cochrane library will do a critical appraisal a valid one for these publications to tell us in the medical community to utilize or not utilize the outcome of these studies. So if you have a paper approved by the Cochrane library whether it's systematic review meta analysis or any any type of studies design, You can be confident that this is a good study and you can utilize the outcome this study.

up to date start to do reviews on different topics utilizing different publications and If You want to look at quick review as student you can also go to the up-to-date, But please always remember that you need to start with pubmed search and to build your skills in literature review of in pubmed and you can utilize other databases like the up-to-date.

Sometimes we have information that you can't find the pubmed. for example if I want to look at the population distribution Jordan by age group we go to the the Different international website like the address program for the USA that different websites official website that we can utilize to get some data or outcome set and surveys or studies or Relations distribution and we can utilize them in our self and our work

Literature Review

- Develop a theoretical framework:
- In writing about such information you should start with the general information, gradually narrowing down to the specific.

Literature Review

Review the literature selected:

- start reading them critically to pull together themes and issues that are associated.
- If you do not have a theoretical framework of themes in mind to start with, use separate sheets of paper for each article or book.

When we start to write the literature review in the introduction of our proposal, we start with general information and drive you narrow down to come to the area of research.



As we mentioned earlier, it's very important that we do critical appraisal for the papers that we are utilizing in the literature review. We look at the area strength and if the paper has certain limitations.

Literature Review

- Writing up the literature reviewed:
- In order to provide theoretical background to your study:
- -List the main themes that have emerged while reading literature.
- -Convert them into subheadings.
- These subheadings should be precise, descriptive of the theme in question, and follow a logical progression.
- under each subheading, record the main findings with respect to the theme in question, highlighting the reasons for and against an argument if they exist, and identify gaps and issues.

Sometimes we start with the main headings and subheadings so we can do the structure for the literature review, and based on that we start to add information. The key thing that we need from the literature review section is that we need to show the reader that what knowledge and ideas have been established, what are their strengths and weaknesses, and why we need to do this stuff.

How to start and end the literature review/introduction part

- Starting with:
- Common illness: burden, epidemiology and complications, current clinical guidelines and recommendations
- b. Rare or uncommon condition: definition

End with:

Key limitation or areas of need, your question, aim of your study, 2 lines on your study design and your study population.

In the journey to move from the search question to the proposal, I collect information from who is the population? What kind of information do I need?Do we need to have simple questionnaire or ready-to-use questionnaire like quality of life or clinical scores? How much information do I need?

From a research question to a proposal
We should not give a scientific approval or ethical approval for a study that is asking for too much information that the authors will

We should not give a scientific approval or ethical approval for a study that is asking for too much information that the authors will not utilize. How we can reach the whole population represented in the sample? Please, as students, this is the first lecture on this research methodology.

who am I collecting information from?

- what kinds of information do I need?
- how much information will I need? how will I use the information?
- How to reach the whole population or a representative sample
- how will I minimise chance/bias/confounding?
- how will I collect the information ethically?

Please avoid the convenience sample throughout your career. Unfortunately, many research projects in developing countries have been conducted waste of time, waste of resources. People just will look, find the easy way that they will go for the sample that is there the available sample and that's it. For example, we want to have a study on the patient satisfaction with Jordan University. When we go today find the patient there at the emergency department exit and we do the interview. We want to do a study for example, complication type 2 diabetes we'll go to the endocrine clinic today and find, for example, 50, 100 patients we look at the complication rate and say that complication rate, for example, type 2 diabetes in Jordan will be, for example, 30%. The study is not representative and that's why we'll have a whole session throughout the module on the sampling technique. Please, as a rule of thumb you should not do a study without proper sampling. We must avoid convenience sample in our projects and this will introduce us to the next question. How will I minimize the chance of bias complication factors and discuss this in details in different study designs? How will I collect information ethically? You want to have an interview of patients, look at the reforms, take sample from them you should have ethical approval and constant form. If

the patient agree to participate then you can collect the study. If they don't constant you should not enroll the patient.

We will also have a session on the key component of the search proposal. What is the research problem description of this problem? Why is it important? What is the key literature review and papers that in the field? What is the methodology and how we can utilize the outcomes to improve the science or to improve the health

Key components of research proposal:

- · A description of the research problem.
- An argument as to why that problem is important.
- A review of literature relevant to the research problem.
- A description of the proposed research methodology.
- A description of how the research findings will be used and/or disseminated.

Key steps in conducting medical research

- Answers relevant questions
 - ✓ Public health problem: Important?
 - ✓ Study question: relevant to the problem?
 - ✓ Objectives: consistent with the study question?
 - ✓ Study design: achieves objectives?
 - ✓ Your sample is representative?
 - ✓ Power of the study: sufficient?
 - ✓ Public health impact of the findings?

So key steps in conductive research public important public health problem is a study question relevant to the problem what are the objectives of your study? What is the study design? Is your sample representative? Power study is a subject sample size and what is the public health impact of the findings? We discuss all these questions when we talk about the different studies designs in this module.



Do we need to repeat previously conducted project?

▶ Epidemiological data

We did not proceed with many projects, simply because there were conducted with valid approach with minor limitations.

Weak study will be repeated!

Clinical trials: Special population, applied the outcomes at your patients but documented different findings in response or adverse drug reactions

Do we need to repeat previously conducted project, the answer will be, for example, if you have cross-section study, look at the prevalence. We had different ideas to do different studies in the region here. We did not proceed with them simply because they were conducted with valid approach and minimum limitation. But if the study was done at one site, for example, or at one place or one village, and this type of evaluation were not representative, we can say these are the limitations of that study and we need to do a representative study with a large sample, or maybe there were limitations of the outcome system or the concern areas, then we can repeat the study. Clinical trials, there are hundreds of thousands of new medications in the popline. We cannot repeat every clinical trial. We hope to participate as an arm within multi-center studies in Jordan or in the region. But the only way to repeat a large, demands-controlled clinical trial, either with one, for example, a study were conducted to look at the control of type 2 diabetes. We might need to repeat the study for a patient with a real impairment, for example. Or we utilize the outcomes of that clinical trial on our patients here in Jordan, and we found that outcomes were different in terms of the efficacy of the medication or the incidence of adverse reaction. Then we have proven that, for example, in our population in Jordan, based on cross-section study, the prevalence of adverse reaction were, for example, 40% compared with the clinical trial that was conducted with only 10%. We started with different hypotheses. For example, we might need a smaller dose in Jordan, or we might need to compare this new medication with the alternative medication that we are using in Jordan. So in this case, you cannot repeat a clinical trial, but we cannot repeat just for the sake of repeating the study.

Possible Bias

- Bias in the literature or in a review of the literature is a distortion of the available information in such a way that it reflects opinion or conclusions that do not represent the real situation.
- Common types of bias:
 - Playing down controversies and differences in own study
 - Restricting references to those that support view of the author
 - Drawing far reaching conclusions from preliminary results

Sometimes people, they are looking at certain ideas or hypothesis and they're trying only to utilize papers that are in the direction of the author. During the COVID pandemic, there are different medications, such as natalizumab, It was used actually for prevention of the autoimmune storm and it had a good effect actually on the reduction of mortality by 30-35%. The large mass control trial was in favor of using this medication. While there are some small studies, they do not have the power to prove or disprove that the medication would be helpful in reduction of the immortality of COVID patients.

Some authors started to conduct proposals or tried reviews and they only looked at the small studies that showed no benefit or the study because the small sample size failed to show a difference and tried to build a hypothesis based on that study where the medication was not effective. But if they had a scientific approach, looking at the large studies, regular studies, different studies, then they can wait until they can see out from their side whether it's the other value or not.



References

THE BIBLIOGRAPHY

- The bibliography should give a clear, complete description of the sources that were used while preparing the report.
- Vancouver style
 - http://www.library.uq.edu.au/training/citation/van couv.pdf
- APA 5
 - http://psych.utoronto.ca/users/reingold/courses/r esources/handouts_apa/Citing6.pdf

References

Reference List

- Articles:
 - Name (surname followed by initials)of the author (s)
 - Name of the article
 - Journal volume, year, volume, pages

Books

- Author
- Title
- Edition, place, publisher, year, pages
- If chapter in book:
- · Title of chapter, editors

Internet:

- Beside the above internet link
- The date of loading, of access

Also, as a medical student who are writing assignments, proposals, different things, you need to have good references. You need to know or to follow certain references' style and to be good in writing references for your work. When you publish our work, each journal will ask you to follow certain references' style. As a student, if you don't have a limitation, you can follow the style that you prefer to use while there are certain guidelines at the university, at the journal, you need to follow these guidelines.

Plagiarism is a major issue on the scientific world. I've seen proposals, people just look at the summary or publication, cut paste from different parts and add it to the proposal. And this is plagiarism. To avoid plagiarism, first of all, you need to reference from where you have obtained this information. Even if you add the number for your reference, 2, 3, and you have just cover-based the contents, this is not acceptable. If you have something cover-based, you need to have a quotation and you have a limitation within your proposal. You should not exceed according to the guidelines of the university or the general, sometimes 10%, sometimes 20%. You should not avoid just cover-based from the, even if you reference the information that you are using. The right approach for you as a medical student to start paraphrasing of another person's spoken written words. We have abstract, we have full paper, we need to write it in your own words. This will take time. Maybe the first proposal will take you a week time to rewrite different paragraphs and take it from here and there. But as you practice more, I can assure you that you can write the introduction within 3 hours time or at least one day, or maximum one day. But please, as a medical student, as a future doctor, as a future scientist, please start to paraphrase the outcomes of different research studies. And we'll have also a session in the practical to show you how we can have different abstracts or publication, how we can rewrite it in our own words.

Plagiarism

- Plagiarism is using others' ideas and words without clearly acknowledging the source of that information.
- To avoid plagiarism, you must give credit whenever you use
 - another person's idea, opinion, or theory;
 - any facts, statistics, graphs, drawings—any pieces of information—that are not common knowledge;
 - quotations of another person's actual spoken or written words; or
 - paraphrase of another person's spoken or written words.

Plagiarism

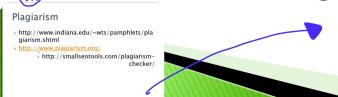
- Strategies for Avoiding Plagiarism
- 1. Put in **quotations** everything that comes directly from the text especially when taking notes.
- 2. **Paraphrase**, but be sure you are not just rearranging or replacing a few words.
- 3. Check your paraphrase against the original text to be sure you have not accidentally used the same phrases or words, and that the information is accurate.

Plagiarism

Common facts that can be found in your space are likely to be known by other people. You don't need to recommend this fact. However, you must recommend the facts that are not generally known or writers that interpret the facts.

Terms You Need to Know

- Common knowledge: facts that can be found in numerous places and are likely to be known by a lot of people.
 - You do not need to document this fact.
 - However, you must document facts that are not generally known and ideas that interpret facts.
- Quotation: using someone's words. When you quote, place the passage you are using in quotation marks, and document the source according to a standard documentation style.
- Paraphrase: using someone's ideas, but putting them in your own words.
 - Although you use your own words to paraphrase, you must still acknowledge the source of the information.



The good thing, there are different websites and databases that you can upload your proposal and will give you the percentage of the plagiarism or the quotation that you have used from the analytics. But please, when you transfer, always remove the references when you upload your work into these programs because it will read it as plagiarism. So please always avoid adding the references in the manuscript or the proposal that you are checking through these websites. The search

objectives are what you are going to achieve in your research.

Set Research Objectives

The research objective is a statement which clearly describes what the researcher(s) aims to achieve from a research.

It should be broken down between (1) a general objective and (2) specific objectives.

Remember:

A good research needs to be both <u>relevant</u> AND <u>methodologically sound!</u>

And you build the outcomes for your study based on the objectives. I want to assess the burden of type 2 diabetes in Jordan. This is the aim. I want to measure the prevalence of type 2 diabetes in Jordan. The outcome will be calculation of the prevalence. So I want to look at to identify those types of diabetes in Jordan. I want to compare the prevalence of type 2 diabetes between males and females. These are the objectives that you can look at the outcomes.





Research objectives

Introduction

Research objectives are concise statements that outline the specific goals and aims of a research study. They provide a clear and focused direction, guiding the research process and helping researchers address the main questions or hypotheses of their investigation.



•••••

and clear aims on you. After having a good research questions, and clear aims, and you have the literature review, the next step after selecting the right studies line is having a good research objectives because they'll be the basis of your outcomes and this is how we can utilize the outcome for your study. We need to formulate clear and concise statement and the objectives.



Components Of Research Objectives

Effective research objectives consist of specific, measurable, achievable, relevant, and time-bound (SMART) components, providing clarity and guiding the research study toward desired outcomes and focused investigation.

VERY IMPORTANT



We are measuring the prevalence of type 2 diabetes among other populations in Jordan. So it's specific that we are looking at type 2 diabetes and we are measuring the prevalence of something we can do and we can achieve and everything, and within the study objective.

National Study on RSV epidemiological, clinical and financial burden in Jordan among children younger than 5 years of age

Aim: The aim of this study is to provide an assessment of the epidemiology, health and economic burden of Respiratory syncytial virus (RSV) infections in Jordan amongst hospitalized children under 5 years of age.

Objectives:

- To examine the epidemiology of RSV infections in children under than 5 years of age.
- To assess the proportion of RSV virus epidemiology compared with other common respiratory infections based on the PCR results.
- 3. To assess the severity of RSV infections amongst hospitalized patients in Jordan.
- 4. To assess the risk factors for RSV infection.
- 5. To quantify the direct and indirect medical along with societal costs of RSV infections amongst hospitalized patients in Jordan.

Research team

- Team Members
- A group of individuals working toward a common goal: that's what a research team is all about.
- In this case, the shared goal between team members is the successful research, data analysis, publication and dissemination of meaningful findings.
- There are key roles that must be laid out BEFORE the project is started, and the "Project Lead", namely the Principal Investigator must provide all the resources and training necessary for the team to successfully complete its mission.

Principal Investigator (PI):

- 1. this is the person ultimately responsible for the research and overall project.
- He needs to to ensure that the team members have the information, resources and training they need to conduct the research.
- He is also the final decision maker on any issues related to the project.
- Some projects have more than one PI, so the designated individuals are known as Co-Principal Investigators.
- PIs are also typically responsible for writing proposals and grant requests, and selecting the team members.
- They report to their employer, the funding organization, and other key stakeholders, including all legal as well as academic regulations.
- The final product of the research is the article, and the PI oversees the writing and publishing of articles to disseminate findings.

Sub-Investigator (Sub-I) / Co-Investigator (Co-I)

The Sub-Investigator/Co-Investigator may perform all or some of the PI functions, but they do not accept primary responsibility for the research study.

The sub-investigator/co-Investigator is under the supervision of the PI and is responsible for performing study—related procedures and /or to make important study-related decisions in compliance with the ethical conduct of the study.

Project or Research Director/manager

- This is the individual who is in charge of the day-to-day functions of the research project, including protocol for how research and data collection activities are completed.
- Mainly appointed in large observational studies and in clinical trials
- The Research Director/Manager directs directly to the PI and works very closely with him/her.
- Specifically, this individual assist the PI in the supervision of the project, direct any protocol as needed, acts as the manager of the team in regards to time, duties and budget, and evaluates the progress of the project.
- The Research Director/manager also makes sure that the project is in compliance with all guidelines, including governmental and institutional review board regulations.
- They also usually assist the PI in writing the research articles related to the project, and report directly to the PI.

3. Research Assistant:

- This individual, or individuals, perform the day-to-day tasks of the project, including collecting data, maintaining equipment, follow up samples collection and analysis, etc.
- Typically, the research assistant has the least amount of experience among the team members.
- Research Assistants usually report to the Research Associate/Project Coordinator, and sometimes the Statistician.

4. Biostatistician:

- This is the individual who analyzes any data collected during the project.
- Sometimes they just analyze and report the data, and other times they are more involved in the organization and analysis of the research throughout the entire study.
- Their primary role is to make sure that the project produces reliable and valid data, and significant data via analysis methodology, sample size, etc.
- The Statistician reports both to the Principal Investigator and the Research Director.
- Research teams may include people with different roles, such as clinical research specialists, interns, student researchers, lab technicians, grant administrators, and general administrative support staff.

Defining the Role of Authors and Contributors

1. Why Authorship Matters

- Authorship confers credit and has important academic, social, and financial implications.
- Authorship also implies responsibility and accountability for published work.
- It always recommended to make a clear plan in the study protocol on the authorship order with conditions for changing this order
- Because authorship does not communicate what contributions qualified an individual to be an author, some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research.

1. Why Authorship Matters

- Editors are strongly encouraged to develop and implement a contributorship policy.
- Such policies remove much of the ambiguity surrounding contributions, but leave unresolved the question of the quantity and quality of contribution that qualify an individual for authorship.

And many times, unresolved issues have been because there was nothing in writing between their research team for the authorship. Who should be included in the authorship? Who should not? What is the order of each of their research team?

If you have something planned in mind, please write it down and ensure that all the research team and co-authors agree and sign for this plan.

2. Who Is an Author?

- Authorship be based on the following 4 criteria:
- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- 2. Drafting the work or reviewing it critically for important intellectual content; AND
- 3. Final approval of the version to be published; AND
- 4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
- In addition to being accountable for the parts of the work done, an author should be able to identify which co-authors are responsible for specific other parts of the work.
- In addition, authors should have confidence in the integrity of the contributions of their co-authors.

2. Who Is an Author?

- All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors.
- Those who do not meet all four criteria should be acknowledged.
- These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work.
- Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

So they have scientific contribution to the work that's conducted. If you have, for example, someone help you from the lab analysis, someone help you in the project conduct or collection of some forms or some data, and they are not entitled to be co-authors, please acknowledge them. In the acknowledgments section, please write down, we thank this person for their, and you write what they did for the study.

Coauthors

- The individuals who conduct the work are responsible for identifying who meets these criteria and ideally should do so when planning the work, making modifications as appropriate as the work progresses.
- We encourage collaboration and co-authorship with colleagues in the locations where the research is conducted.
- It is the collective responsibility of the authors, not the journal to which the work is submitted, to determine that all people named as authors meet all four criteria.

We encourage collaboration and co-authorship, but please ensure that everyone should have certain duties and they fulfill these duties.

Coauthors

- If agreement cannot be reached about who qualifies for authorship, the institution(s) where the work was performed should be asked to investigate.
- The criteria used to determine the order in which authors are listed on the byline may vary, and are to be decided collectively by the author group and not by editors.
- If authors request removal or addition of an author after manuscript submission or publication, journal editors should seek an explanation and signed statement of agreement for the requested change from all listed authors and from the author to be removed or added.

The corresponding author

- The corresponding author is the one individual who takes primary responsibility for communication with the journal during the manuscript submission, peer-review, and publication process.
- The corresponding author typically ensures that all the journal's administrative requirements, such as providing details of authorship, ethics committee approval, clinical trial registration documentation, and disclosures of relationships and activities are properly completed and reported, although these duties may be delegated to one or more co-authors.

The corresponding author

Corresponding author is the one who will communicate the journals or with the body's responsible for dissemination of the results. Sometimes the principal investigator or sometimes the PI, the principal investigator allocate one of the research team to be in charge of the corresponding to the journal. And this person will do the application of the manuscript to the journal and all administrative requirements such as providing tiers with authorship, ethics committee approval, all information with other authors, etc. Should be available throughout the submission and baby process and be in touch with the journal until the paper is published. And also after publication, they should be responsible for responding to any questions from the readers worldwide.

- The corresponding author should be available throughout the submission and peer-review process to respond to editorial queries in a timely way, and should be available after publication to respond to critiques of the work and cooperate with any requests from the journal for data or additional information should questions about the paper arise after publication.
- Although the corresponding author has primary responsibility for correspondence with journals



Large multi-author group

- When a large multi-author group has conducted the work, the group ideally should decide who will be an author before the work is started and confirm who is an author before submitting the manuscript for publication.
- All members of the group named as authors should meet all four criteria for authorship, including approval of the final manuscript, and they should be able to take public responsibility for the work and should have full confidence in the accuracy and integrity of the work of other group authors.
- > They will also be expected as individuals to complete disclosure forms.

Large multi-author group

- Some large multi-author groups designate authorship by a group name, with or without the names of individuals.
- When submitting a manuscript authored by a group, the corresponding author should specify the group name if one exists, and clearly identify the group members who can take credit and responsibility for the work as authors.



And you can find, add a link to the 30 people involved in that project. An original brain diseases group, research group. You might have 30 people there and you need to agree within the 30 people how we can acknowledge their names and the order of these names and to have a link to other names. Sometimes the journal has an limitation of six or eight authors to be included and we have 20 or 30 people there. We add it as research group. So sometimes the author, the journal find only the name of the group instead of the name of the individuals.

3. Non-Author Contributors

- Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged.
- Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading.