*you need to have atleast 2-3 pap. by graduation.

Summary: Introduction to Medical Research Methods
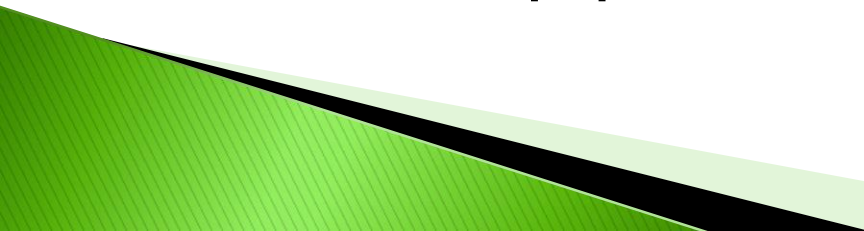
Munir Abu-Helalah MD MPH PhD
Associate Professor, Consultant of Epidemiology and Preventive Medicine
Department of Family and Community Medicine
School of Medicine
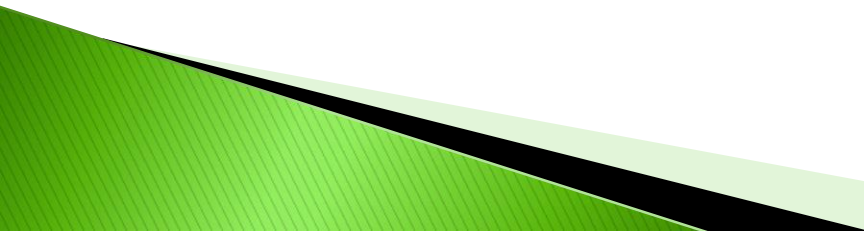Jordan University

Key objectives

- 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

Researech

- 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.

\# systemic = certain pathway / study protocol.

Research

- Research is vital for the understanding of the problems that affect individuals, communities or health systems.

- It allows for a 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.

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, diagnosis, therapy, prognosis and prevention.

- Research is the very foundation of improved medical care.

- It can also provide evidence for policies and decisions on health development.

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 is known to be a **systematic** study that follows a pattern and produces testable results.

▸ Thus scientific research must follow a **step-by-step** pathway that foster clarity and avoids the problem of multiplicity.

▸ We call this **Study Methodology**

*we follow a step by step pathway that fosters clarity & avoids the problem of multiplicity.

*this slide was taken from the video.

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.

*for ex. if you are conducting a study in diff. sites in Jordan, all the researchers will be following the same approach.

STEPS IN MEDICAL RESEARCH

I. Identify the problem

II. 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.)

The Birth of Science

Epidemiological studies

start with

Clinical observation

Descriptive studies

Analytical studies

Experimental studies

Variation

Association

Association

for ex you notice a group of patients with certain characteristics, then you start to build hypothesis & then you do a larger study through a cross-section study to show the prevalence of these factors that you have observed.

then you can link the risk factors that you have observed through analytical studies (case control study) to see wether it's a positive agent or not. & you can follow that with experimental studies for prevention of these agents.

Moving from research idea to a feasible research project

▸ Literature review:

Has it been investigated?
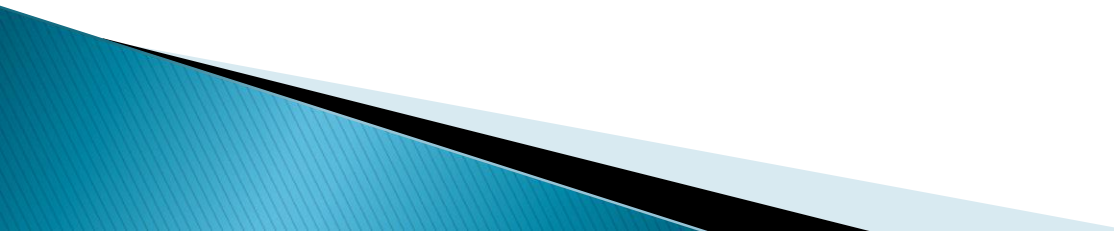
What has been done in this field?

Questions to be answered in this field?

* literature view is the key for the success of your research project.
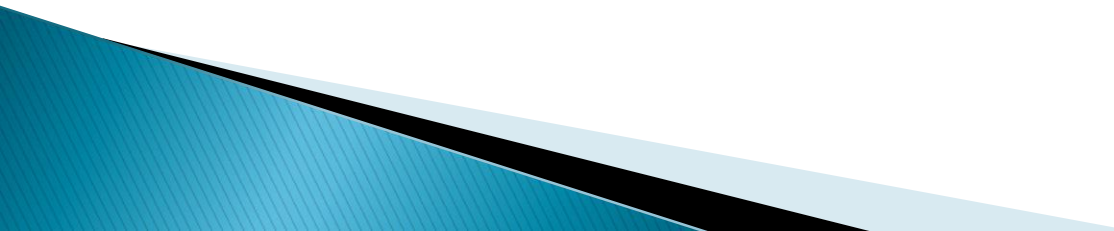
* sometimes we find out that that the idea was investigated but the study that was conducted wasn't good enough to generalize the result from that study.

So we can look at the limitations of that study & based on that we can repeat our project.

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.

- 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

What characterizes a good question?

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

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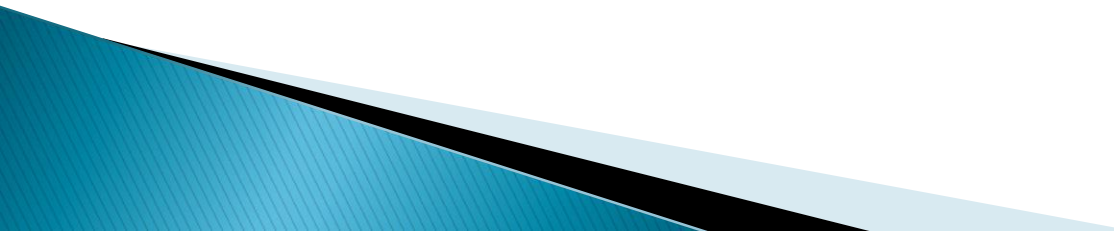
▸ to select
- relevance and applicability for improving health in one way or the other,
- interest and expertise of you and your collaborators, and
- the feasibility of completing the work with available resources, time, subjects, tools, etc.
- *(prioritization)*

How to focus your question?

▸ Literature search for previous evidence: focus on reviews, recent updates…etc.

literature review helps a lot with this.

▸ Discuss with colleagues
▸ Attend scientific meetings

based on those we can narrow down our question.

▸ Narrow down the question – time, place, group

▸ 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

*A structured research question will help us to identify the main concepts of our question & to build our main literature search strategy.

Hypothetical Research Question

*this slide was taken from the video.

▸ 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.

A good research question is backed up by theoretical considerations.

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.

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.

- **Just right**: In the NICU,JUH, what is the effect of hand washing on infection control compared with hand sanitizers, over 6 months?

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
PS:	Population, Situation
SPICE:	Setting, Perspectives, Intervention, Comparison, Evaluation

always start with these Qs until graduation.

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: Otherwise healthy children…	Does: exposure to in utero smoking/nicorine…	Versus: children not exposed to in utero nicotine…	Result in: increased risk of learning disabilities?
In: Primary school children	Does: school-based physical activity	Versus: no school-based physical activity	Result in: 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

▸ **Intervention/therapy**

  ▸ In _____(P), what is the effect of _____(I) on _____(O) compared with _____(C) within _____ (T)?

  ↳period of time of need.

▸ In the aged population, what is the effect of exercise programs on accidental falls, as compared with no exercise?

▸

 Etiology

  ▸ Are _____ (P) who have _____ (I) at ____ (Increased/decreased) risk for/of_____ (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?

▸ **Diagnosis or diagnostic test**

▸ Are (is) _____ (I) more accurate in diagnosing _____ (P) compared with _____ (C) for _____ (O)?

▸ 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?

Prevention

▸ For _____ (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?

▸ **Prognosis/Predictions**

 ▸ Does _____ (I) influence _____ (O) in patients who have _____ (P) over _____ (T)?

▸ In adults with osteoarthritis, does low vitamin D levels in the bloodstream predict the rate of future hip fractures?

▸ **Meaning**

 ▸ How do _____ (P) diagnosed with _____ (I) perceive _____ (O) during _____ (T)?

▸ How do cancer patients diagnosed with alopecia perceive their self-esteem during and after chemotherapy?

Public Health:

▸ 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

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

Literature review is required through your research:

- It helps to choose topic
- Prevents from duplicating work
- Refine your problem
- Formulate objectives
- Familiar with various methodology
- Provide argument why is it needed (justification)

*we see what has been done so we aren't repeating other peoples' work.

* most journals these days ask research- ers for discussion; 1 or 2 paragraphs on the limitations of their work & how they can make it better. Other ppls discussi- ons can help us cond- uct better studies.

Literature review

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.

*critical appraisal shows that our study was large, designed will & was well conducted.

*critical appraisal doesn't only show the limitations, it also shows the weaknesses & strength of those limitations.

Literature Review:
Bring clarity and focus to your research problem

▸ 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:

we should have focused questions in our lit·review.

- A literature review tells you:

I. If others have used procedures and methods similar to the ones that you are proposing?

II. Which procedures and methods have worked well for them?

III. What problems they have faced with them?

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

lit·review = improved me-thodology chance.

Literature Review
Broaden your knowledge base in your research area:

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.

Literature Review
Contextualize your findings:

1. How do answers to your research questions compare with what others have found?
2. 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.

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)

Literature Review

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.

Literature Review

JOURNALS

- Journals provide you with the most up-to-date information

- **Be careful with open access journals without solid peer review process**

*journals are dangerous
cuz some of them directly
publish work. (the quality
of the work could be bad).

Resources

- Pubmed
- Popline
- CDC
- Google scholar → they don't have a specific system, yet they can be handy.
- UN
  - WHO
    - emro
  - UNICEF
    - UNICEF Jordan
  - UNDP
  - UNEP
    UNFPA/ UNAIDS/ UN women
- DHS
- NICE,UK

* the doctor wanted us to start our lit.review utilizing pubmed.

* the doctor said that papers published by "cochrane library" are good.

* "up to date" is also a good source. however for now it's better if we use pubmed.
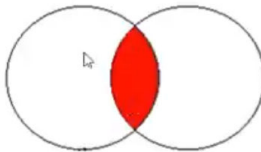
*this slide was taken from the video.

* the doctor was teaching us how to use pubmed & he used this to explain to us how to search. (explanation starts from min 39-43.30 in the video)
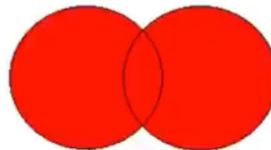
Combining search terms with AND or OR:

Use AND to combine **different** main concepts of your search: childhood AND obesity. Narrows results

Use OR to include **similar** terms / synonyms (and sometimes antonyms) for a concept: childhood OR adolescence. Fertility OR infertility. Broadens results

AND

OR

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

▸ *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.

Literature Review

▸ A literature review is an account of what has been published on a topic by accredited scholars and researchers.

▸ In writing the literature review,
  ◦ your purpose is to convey to your reader what knowledge and ideas have been established on a topic,
  ◦ and what their strengths and weaknesses are.

▸ the literature review must be defined by a guiding concept

How to start and end the literature review/introduction part

*we start with general info. then gradually narrow down to come to the area of research.

▸ Starting with:

a. 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 introductory part we always start with the key limitation of the published studies & the areas of need. (ex. in jordan there were no studies about this topic, therefore we need to conduct a large cross-sectional study at representative sites in JD to look at the epidemology & risk).

From a research question to a proposal

▸ 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?

we'll discuss later.

↳ *you should have ethical approval & consent from the patient.*

✳ we should try avoiding convenient samples throughout our career.

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?

Sometimes we need to remake clinical trials, when our patients have found different outcomes.

ex: we might need smaller doses of a medication in Jordan in comparison with the alternative medication that we are using in Jordan so in this case we can repeat a clinical trial.

* we don't just repeat clinical trials without need.

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

— if the study was done at one site (ex at one village) & the study population wasn't representative, we can consider it a limitation & repeat the study.

Sometimes we need to remake clinical trials, when our patients have found different outcomes.
ex: we might need smaller doses of a medication in jordan in comparison with the alternative medication that we are using in jordan so in this case we can repeat a clinical trial.
* we don't just repeat clinical trials without need

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

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/vancouv.pdf
- APA 5
  - http://psych.utoronto.ca/users/reingold/courses/resources/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
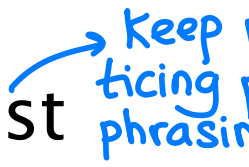- The date of loading, of access

Plagiarism

*to avoid it you need to use reference. It is still not acceptable to copy & paste info & add it's reference, you shouldn't exceed 10-20% of copied info. in your research.

*any copied info should be put in qoutation marks, & the better approach is paraphrasing content.

- 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.

→ Keep practicing paraphrasing.

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

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.

Plagiarism

▸ http://www.indiana.edu/~wts/pamphlets/plagiarism.shtml

▸ http://www.plagiarism.org/

 ▸ http://smallseotools.com/plagiarism-checker/

* these websites can give you the % of plagiarism or qoutation in a research.

*always remove the references when you upload work into these programs.

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 **relevant** AND **methodologically sound**!

*After having good research questions & clear aims & a lit. review & after selecting the right study design we have to have good research objectives cuz they'll be the basis of our outcomes & this is how we can utilize the outcome of our studies.

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.
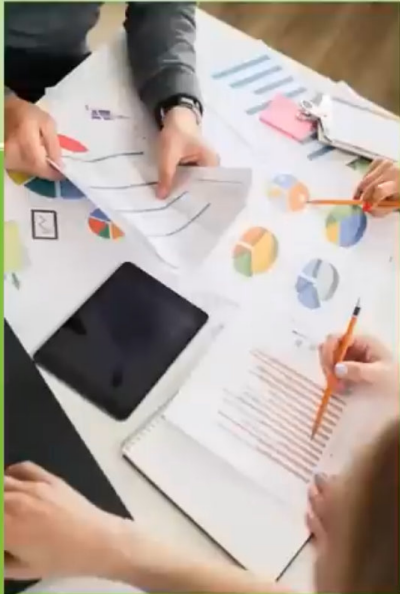
Components Of Research Objectives

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.

Crafting research objectives

Crafting research objectives involves formulating clear and concise statements that define the specific goals and outcomes to be achieved through the research study.

ex: measuring the prevalence of type 2 diabetes among adult population in Jordan.

measurable + achievable   specific

so, it is measurable, specific & achievable & within the study objectives we can identify the duration.

important!

SMART

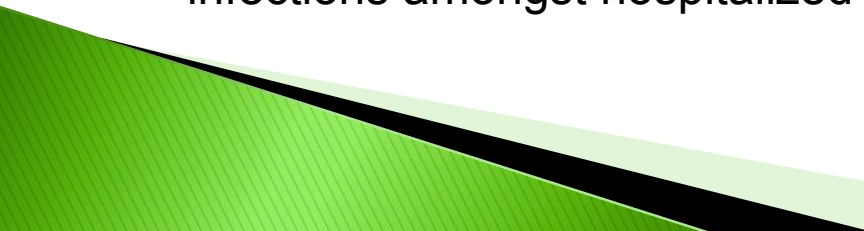| **Specific**	**Measurable**	**Achievable**	**Relevant**	**Time-bound**
State what you'll do	Provide a way to evaluate	Within your scope	Makes sense within your job function	State when you'll get it done
Use action words	Use metrics or data targets	Possible to accomplish, attainable	Improves the business in some way	Be specific on date or timeframe

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:

1. To examine the epidemiology of RSV infections in children under than 5 years of age.
2. 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. *→ from the scientific & legal point of view.*

▸ 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)

#Sometimes 2 people will have a good contribution to the study & both of them will have a very important role in execution of the study.

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. *(make sure that consent forms are signed by the investigators of the sight & by the participants).*

▸ They also usually assist the PI in writing the research articles related to the project, and report directly to the PI. *they assist PI in the supervision of the study like:. (how the samples r processed, are they collected as planed, are we obtaining the results of the analysis, r the medications given to the patient as planed, r the research assistants conducting their work as expected, what is the process of the study etc...).*

 # they also look at the budget, time, duties & help in the evaluation of the project's progress.

3. Research Assistant: *sometimes we also call them coordinators.

▸ 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. (they are like us; students).

▸ 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.
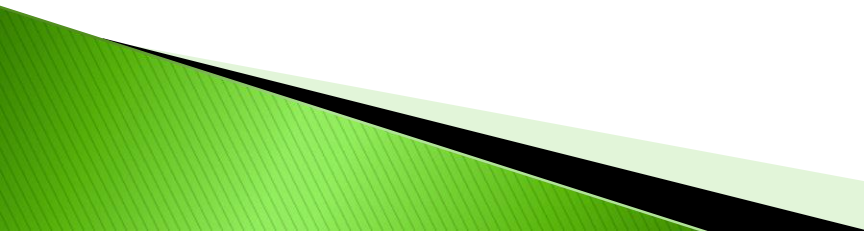
*it is very important to have a plan for the authorship to ensure that at the end of the study all the co-authors & researsh team are satisfied with the outcome of the study

* cuz many times issues occur about the authorship issue.

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.

2. *Who Is an Author?*

- Authorship be based on the following 4 criteria:

1. 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. *if anyone helped you write their names in the acknowledgments.*

▸ 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.

Coauthors

please ensure that everyone has certain duties & that they fulfill them.

▸ 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.
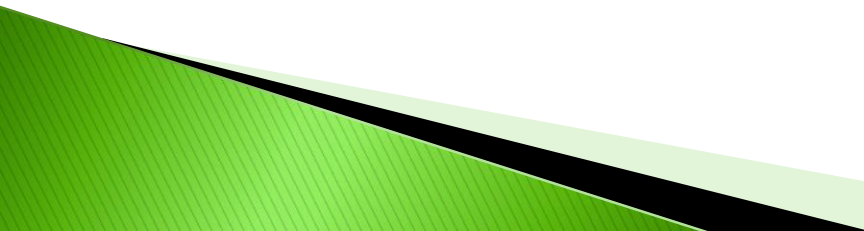
Coauthors

▸ 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.

*they will do the application of the manuscript of the journal & all other administrative require-ments.

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

- 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.

*ex. A National diabetes research group that has 30 authors → we should add the link to the 30 ppl involved

* some journals have an author no. limit so they will add the name of the group instead.

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.