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Scientific Medical Research

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↳ In this sheet, we will go through chapters 4,5, and 6

▪ Chapter 4

- ⊗ After identifying a general research topic, the researcher needs to develop a **specific research goal** and a **workable research plan**.
- ⊗ It is time for the researcher to choose her/his study-approach. This classification is based on the way of gathering/collecting data.

Research approach	Study plan
Primary (Collect and analyze new data)	<ul style="list-style-type: none">• New data will be collected from individuals.
Secondary (Analyze existing data)	<ul style="list-style-type: none">• An existing data set (or data extracted from existing records) will be statistically analyzed.• The researcher can extract from her/his own previously published researches (primary data resource), or basically can extract data from someone's else researches.
Tertiary (Review and synthesize the literature)	<ul style="list-style-type: none">• The existing literature will be reviewed.

⊗ Obviously, every single approach has its own advantages and limitations:

1. In the primary approach, the researcher has freedom in selecting **the topic, design, measuring tool and etc.** However, she/he might struggle in recruiting participants.
2. **Secondary research** approach has one main advantage which is related to the **“cost and time effectiveness”**. Since someone else has already collected the data, the researcher does not need to invest any money, time, or effort into data collection. But it also has its own limitations because the researcher has to find a **valid resource** and the study question is **restricted based on the viable data**.

3. The limitation of a literature review lies in the **necessity of finding all relevant studies**. In this situation, the researcher has to take in consideration the **possible fees** of these articles → cost considerations.

FIGURE 4-2 Key Considerations

Study Approach	Key Questions to Ask
• Collection and analysis of new data	• What are possible source populations? • Will it be possible to recruit enough participants?
• Analysis of existing data	• What are possible sources of usable data files? • What questions can be explored with the available data?
• Review of the literature	• Does the researcher have access to adequate library resources? • Can the researcher reasonably expect to acquire <i>all</i> of the needed articles?

- How to pick your approach? Let's consider this example:

↳ During the on-going COVID-19 pandemic, collecting primary data has become more difficult than ever, due to the challenges created by the disease itself like international /local travel restrictions and social distancing practices that had an impact on the process of collecting the data, since collecting primary data usually involves traveling and interacting with people. Also, insecurity and other health risk factors can affect this phase of research. In this case, secondary (but valid) data can provide sufficient information to guide the research process.

- conceptual and theoretical frameworks:

↳ The theoretical framework provides a general representation of relationships between things in a general phenomenon describing key relationships. It describes a broader relationship between things.

↳ The conceptual framework, on the other hand, is much more specific; it illustrates key relationships between EDPs [Exposure, Disease, Population] that will be evaluated during the study. Statistically speaking, the conceptual framework describes the relationship between specific variables identified in the study.

Example:

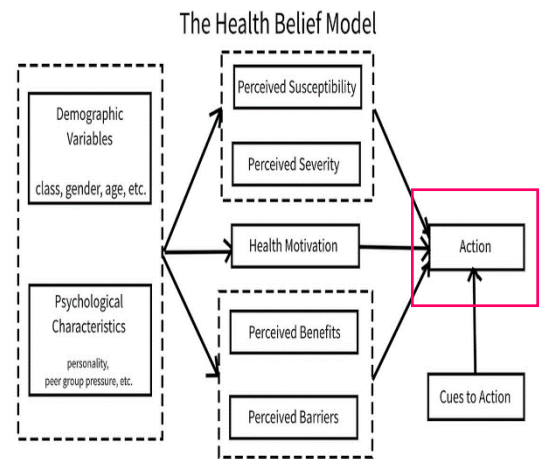
Theoretical Framework: Stimulus elicits response.

Conceptual Framework: New teaching method improves students' academic performance.

Notice that the theoretical framework basically differs from the conceptual framework in terms of scope. The theoretical framework describes a broader relationship between things. When stimulus is applied, response is expected. The conceptual framework is much more specific in defining this relationship. The conceptual framework specifies the variables that have to be explored in the investigation. In this example, the variable "teaching method" represents stimulus while the "students' academic performance" represents the response.

⊗ The Health Belief Model (HBM)- a theoretical framework:

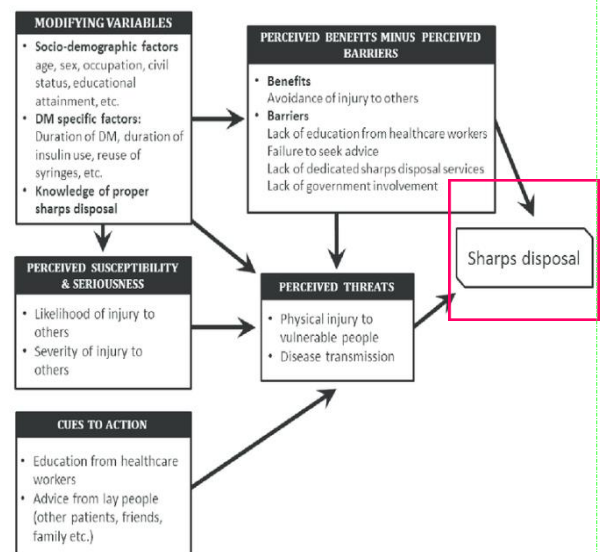
- ↳ a tool that scientists use to try and predict health behaviors. The model was based on an assumption that people fear diseases, and that health actions are motivated in relation to the degree of fear. The Health Belief Model can be a helpful way to design interventions (actions) that can improve both individual and public health.
- ↳ Notice that this framework DOES NOT define the variables.



⊗ Conceptual framework

This particular conceptual framework is based on the Health Belief Model. In this model, it is believed that people adopt preventive behaviors (actions → sharps disposal) against diseases only if they perceive they are at risk of the disease and believe in the usefulness of the preventive behaviors.

- ⊗ You can see how variables are identified specifically in this model and the action is precise (sharp disposal).
- ⊗ These frameworks are not common in medical research, they're more common in nursing, social science, and educational research.



⊗ Study goal and specific objectives:

↳ After choosing the study approach, the researcher should select the study goal, and at least three specific objectives, specific aims, or hypotheses (e.g. we expect from the group that took the experimental drug to have lower blood pressure values compared to the control group) that arise from the main study goal and represent steps toward answering the main study question.

Example

Goal: To assess the impact of lead poisoning on school performance in kindergarten students in southeast Michigan.

The three specific objectives for this study might be:

1. To measure the prevalence of high blood lead levels in a random sample of kindergarten students in Southeast Michigan.
2. To determine whether children in the that sample with high blood lead levels have lower scores in academic tests than children with lower blood lead levels.
3. To estimate the total impact of high blood lead levels on kindergarten performance in Southeast Michigan by applying the rates in the sample population to the total population of the region (results comparison).

FIGURE 4-3 Examples of Study Goals

- To describe the incidence or prevalence of a particular exposure or disease in one well-defined population
- To assess the perceived health-related needs of a community
- To compare the levels of exposure or disease in two or more populations
- To identify possible risk factors for a particular disease in a population
- To test the effectiveness of a new preventive intervention, diagnostic test, assessment method, therapy, or treatment
- To evaluate whether an intervention shown to be successful in one population is equally successful in a second population
- To examine the impact of a program or policy
- To synthesize or integrate existing knowledge

⊗ Some studies aim to compare the levels of exposure to a certain element and the probability of disease, e.g. Increased incidence of cancer after exposure to ionizing radiation, also specific populations can be studied (e.g. Residents who are frequently exposed to Radon).

❁ Scientific papers list the study goal and specific objectives in the last paragraph of the introduction section.

❁ Checklist for success:

Any good research project is:

1. Feasible or *do-able* (The research question is, in general, *possible to answer*). A research should be feasible in terms of time, availability of subjects, and money.
infeasible research question: What is the prevalence of **ALL** cancer types in the Jordanian population?
2. Interesting (the researcher should be interested in the research topic in order to convince the readers in his results).
3. Novel (the research generates **new** evidence that serves the needs of the population).
4. Ethical (DOING NO HARM, for example in drugs clinical trials, it is unethical to inject the causative agent in participants in order to assess the drug role in eliminating the pathogen).
5. Relevant.

FIGURE 4-4 Questions Essential to the Success of the Project

Area	Questions
Purpose and significance	<ul style="list-style-type: none"> • What will the study contribute? • What will be new and noteworthy about the study? • Can the importance and necessity of this project be justified? • How will the study enhance the body of knowledge in its discipline? • Who will benefit from the study besides the researcher? • How will the study help individuals and/or communities live healthier lives? • How might the study contribute to improving health practices and/or policies?
Scope and feasibility	<ul style="list-style-type: none"> • Is the scope of the intended project reasonable and manageable—neither too broad nor too narrow? • Can the proposed study question actually be answered? • Can the researcher answer the proposed study question?

FIGURE 4-4 (continued)

Area	Questions
Capacity and collaborators	<ul style="list-style-type: none"> • Does the researcher have the knowledge and skills needed to conduct the study? • Does the researcher have access to collaborators who have the expertise needed for the project? (See Chapter 5 for information on assembling a support team.)
Money and materials	<ul style="list-style-type: none"> • Are there adequate financial resources to conduct the study? • Does the researcher have access to equipment, space, and other physical requirements? • Given the resources available, can the researcher reasonably expect to conduct a scientifically rigorous and valid study?
Time	<ul style="list-style-type: none"> • Does the researcher have the time to conduct this study? • Does the researcher have the time to make this an excellent study that does not waste health resources?
Population or data	<ul style="list-style-type: none"> • If the plan is to collect new data from individuals, does the researcher have access to a reasonable source population and an adequate number of participants? • If the plan is to analyze existing data or to write a review paper, does the researcher have access to a reasonable existing data set and/or to an extensive library collection?
Ethics	<ul style="list-style-type: none"> • Will the researcher be making good use of the resources available? • Has the researcher considered the relevant ethical issues, especially those related to the collection and use of individual-level data? (See Chapter 21 for the ethical issues that should be considered.) • Is the researcher prepared to conduct culturally appropriate and scientifically rigorous research?
Target audience	<ul style="list-style-type: none"> • Who is likely to be interested in the findings? • Is the resulting paper likely to be publishable?

⊗ Chapter 5

↳ Scientific research is rarely completed by one person working alone, even if the lead investigator may spend many hours working independently on various aspects of a project.

⊗ Why is it better to have multiple co-authors?

They say “two heads are better than one” which reflects that people working in groups are more likely to do the job better than they would if working alone. Sometimes, one author prefers to work on literature reviews, while another one is good in data collection and a third one is good in data analysis, so it makes sense to specialize everybody in writing articles. Also, funding agencies play a big role; because these agencies have limited funds that they want to distribute among as many researchers as possible.

- It is helpful to assemble a team of collaborators who can help ensure that the project conducted is:
 1. Scientifically valid.
 2. Ethical and cultural appropriate (e.g. a research about the effectiveness of school-based sex education might be considered culturally inappropriate in our region, that is why researchers should be aware of the special features of their own culture as well as the cultures of those participating in the project.)
 3. Time and cost efficient.

⊗ Mentorship:

↳ New investigators benefit from mentorships by several experienced researchers with different areas of expertise. For students, the first step is identifying a professor or other experienced researcher to serve as a mentor. For early career professionals, one or more senior colleagues may be willing to serve as mentors.

Lead researcher: the researcher who will do the majority of the work.
Senior researcher: an experienced researcher who guides the work of a newer investigator.



⊗ **Middle authors:** Ones who are not listed first or last in the order of coauthors.

⊗ **Co-authorship vs acknowledgment:**

- A **co-author** is any person who has made a significant contribution to an article. They also share responsibility and accountability for the results. While individuals who have contributed to the article (e.g. technical assistance, writing assistance, translation... which significantly contributed to developing the article, etc.), but who do not meet the criteria for authorship should be listed by name in an **'Acknowledgments'** section.



- Some assistants may ask to be paid by hour to help the researcher as non-co-author, while others may waive the fee but request co-authorship in return for their efforts.

⊗ **Finding research mentors:**

- **Research mentorship:** formal/informal relationship in which an experienced mentor offers professional development advice and guidance to a less experienced mentee.
- Sometimes a new investigator does not have a choice about who will supervise the project, because the supervisor is assigned by the academic program director.

- Others who do not have research requirements have to seek out their own supervisors and mentors for their projects. (researchers in JU are free to choose their own mentors).
- How to identify a good match when seeking mentorship?
 - a. Asking colleagues, classmates, professors, and others about experienced researchers who might be helpful mentors.
 - b. Searching the profiles of researchers at the new investigator's institution to see who is actively conducting and publishing research on relevant topics.
 - c. E-mailing the individuals identified as potential mentors to share a CV and request an in-person meeting to discuss possible research collaboration opportunities.
- ⊗ Mentors might ask for co-authorship, others who don't earn co-authorship should be thanked in the acknowledgment section (after asking them for permission).
- ⊗ The mentor-mentee relationship:
 - ↳ The investigator should not agree on mentorship until he/she understands several points:
 1. The potential mentor's availability.
 2. How does the mentor communicate? The mentor's preferred frequency and style of communication (such as how often e-mails will be exchanged and how often telephone calls or in-person meetings will be scheduled).
 3. What roles the mentor agrees to take on?
 4. What resources does the mentor agree to provide?
 5. What expectations does the mentor have of the mentee.
- ⊗ What mentees need to do?
 1. Communicate often.
 2. Ask questions.
 3. Complete assigned tasks on time.
 4. Be honest (don't fabricate things).
 5. Maintain meticulous (detailed and precise) records.
 6. Express gratitude.

⊗ Professional development:

↳ Don't rely on one person to provide professional development and mentoring. Engage yourself in professional development activities:

1. Participate in journal clubs that read and discuss recently published research articles.
2. Become active in professional organizations.
3. Attend and present at research conferences.
4. Enroll in training programs (for example statistical courses are a crucial part of the general training received by new researchers).

⊗ Chapter 6:

↳ Decisions about co-authorship should be made early in the research process.

- Most researchers serve as “middle” co-authors before moving into lead authors for the first time.
- anyone who is contributing to a project and wants to be considered for inclusion in the authorship list should have a conversation with the lead author **as early as possible** in the research process.
- Lead authors should construct the list of coauthors for a report, poster, or a paper. All decisions about co-authorship should be transparent and clear, and they should be communicated to all contributors, both who are expected to earn co-authorship and those who will be acknowledged but not considered coauthors.

⊗ Authorship criteria:

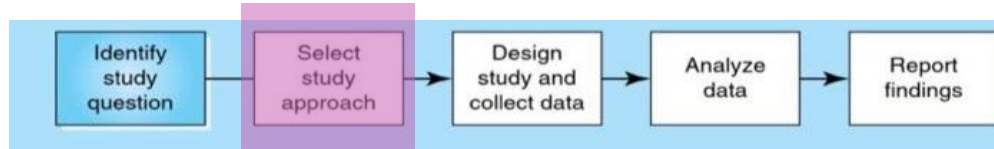
↳ The international committee of medical journal editors (ICMJE) has established criteria for authorship in the health sciences. To earn co-authorship, **all of the four following criteria must be met:**

1. Substantial contributions to conception and design of the study and/or data collection, analysis, or interpretation.
2. Drafting and/or critically revising the intellectual content of the manuscript.
3. Approve the final manuscript to be submitted.
4. Accept responsibility for the integrity of the paper.

- According to the previous criteria, a person who conducts interviews for the project but does not contribute further would not be eligible for authorship. However, an interviewer who also writes a paragraph for the discussion section would meet authorship criteria.
- ⊗ No **gift authorship**, in which someone is given honorary co-authorship without having significantly contributed to the work.
- ⊗ No **ghost authorship**, which is essentially the opposite of honorary authorship. That is when someone entails a significant contribution to a manuscript without acknowledgment of that contribution.
- ⊗ Authorship order:
 - ↳ The first author (**lead author**) is the person who was the most involved in writing the manuscript. **Middle authors** are listed in order from greatest to least contribution or alphabetically by family name or per agreement. The **senior author** (supervising author) is often listed last [not every paper has a senior author].
- ⊗ Decisions about authorship
 - ↳ In order to avoid last-minute debates over which individuals have made important contributions to a research project, it is helpful to decide ahead of time what the roles and responsibilities of each member of the research team will be and how they will earn co-authorship if that is the intended outcome.

Authorship decisions can be very stressful, why?

- Publications are an important metric of success in the science and academia, and authorship is often the **only reward** for the time put in the project.
- Usually it takes between five to seven years for assistant professors to become associate professors. It is a long process, involving some sort of review, which usually evaluates a professor's **publications, research, and teaching**.



Good Luck