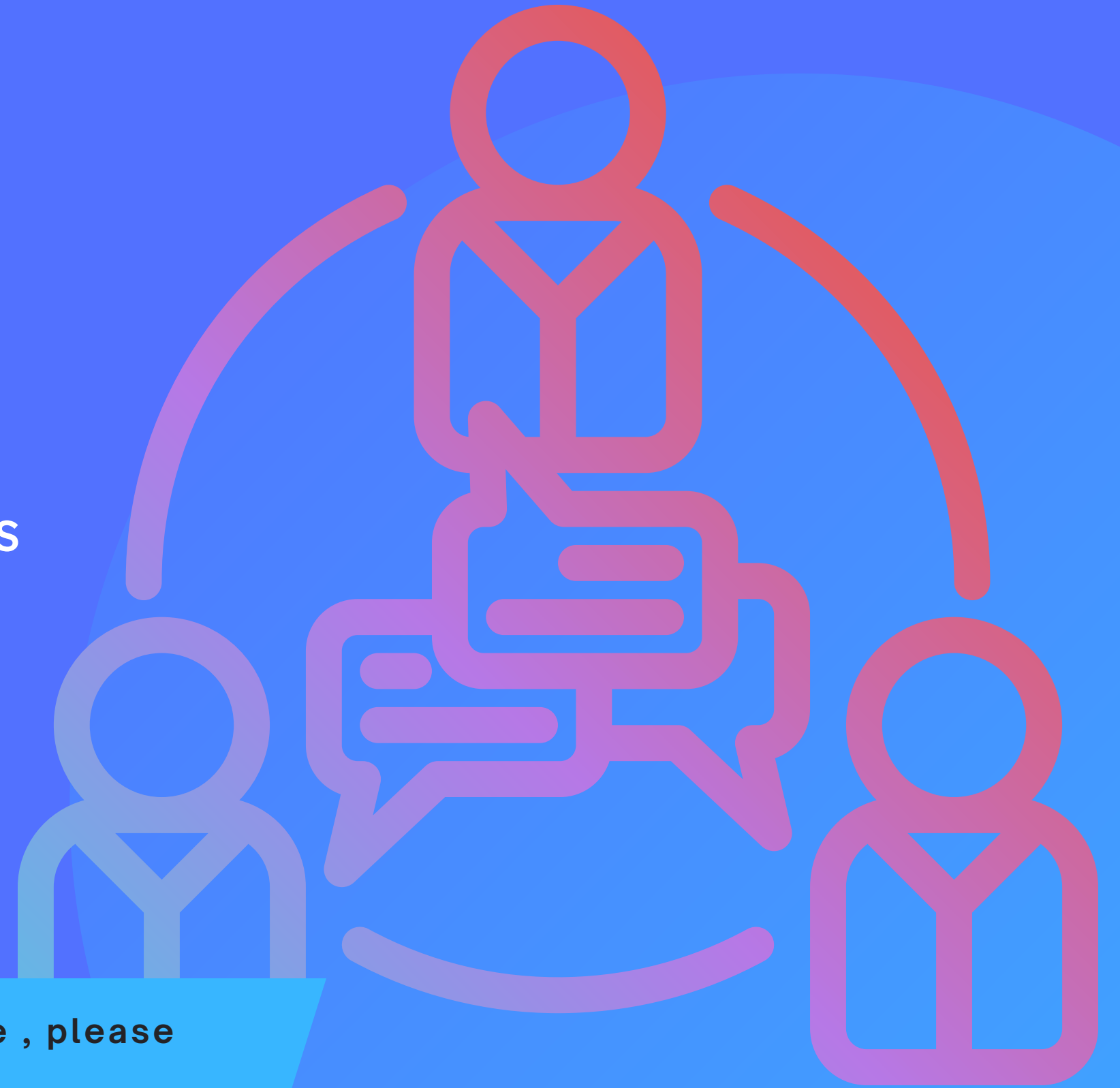Yarmouk University

Community Medicine

Lec. 2 - Practical Research Methods

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SCRIPT

If you come by any mistake , please kindly report it to shaghafbatch@gmail.com

Introduction to research and responsible conduct of research

COMMUNITY MEDICINE (MED 410)

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KEY STEPS IN THE RESEARCH PROCESS

- Define Research Problem :finding and Formulating research Question of our topic

- Literature Review
- Development of Formulate Hypothesis
- Preparing the Research Design
- Data Collection
- Data Analysis
- Presentation and summary of data
- Reporting the Result

Finding and formulating research question

Do green sweets make people

Notes about the previous Q :

1) who is the ppl Category mentioned in the Q ?. _ adult or children
2) Green Colored sweets compared to which Colore of Sweets ?
3) Sweets taste compared to which taste?
4) How can I do this study?
5) How can I measure the happiness?

   a) Shall I do a Comparision before and after eating the green Sweet?

   b) Shall I take a random sample ?

taking a random sample is the most scientific way to measure happiness because:

1) it's more representive
2) It decreases the selection bias.

Measuring the happiness of everyone who eats green sweets

Getting some of you to eat a green sweet and then measuring your happiness

Measuring the happiness of a random sample of those who ate a green sweet, and those who did not

Getting some of you to eat a green sweet and some of you not to, and then measuring your happiness

Do green sweets make people happy?

compared to what?

compared to ...?

Do green sweets make people happy?

Do green sweets make people happy?

compared to ...?

Do green sweets make people happy?

compared to ....?

Do green sweets make people happy?

Compared to ....?

Do green sweets make people happy?

Do green sweets make people happy?

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Do green sweets make people happy?

Do green sweets make people happy?

Do green sweets make people happy?

Formulating the question

While formulating the Q we Should focus on Some Imp topics:

1) The words in the Q
2) Identify the target population ? Is the population can be accessed   easily ?
3) Looking for a new specific variables,, can find them from the Previous research about the same subject the research .   (Literature Review)

Literature Review: overview of previously published works on a specific topics

Question formulation

▶ You need a clear question. It might change during the planning, but you hope it won't change during conduct.

▶ Each word in the question is important. Does it narrow or broaden your literature review?

▶ From here identify
  ▶ Keyword
  ▶ Patient population/ Target population
  ▶ Other specific variables from your study

PICO

- **P**atient/ **P**opulation/ **P**roblem
- **I**ntervention(s)
- **C**omparison(s)/ **C**ontrol
- **O**utcome(s)

- Strategy for framing a "foreground" (searchable) research question
- Framework to formulate a focused question and facilitate the literature search
- Breaking the question into four components will facilitate the identification of relevant information

Scenario

▶ Judy has had a bad throat for a few days and its making her feel miserable. She goes to her primary care practice wanting some antibiotics. However, her provider isn't sure whether there's any benefit prescribing them.

What's the evidence?

From the scenario, what Qs ??
1) Can we use AB to treat sore throat?
2) Is there any benefit for AB to patient with sore throat ?

Focused question

- **P**: sore throat
- **I**: antibiotics
- **C**: no antibiotics
- **O**: symptom relief

- Are antibiotics effective in relieving symptoms of sore throat?

	Patient or Problem	Intervention (a cause, prognostic factor, treatment, etc.)	Comparison Intervention (if necessary)	Outcomes
Tips for Building **Research Q related to PICO**	Starting with your patient, ask "How would I describe a group of patients similar to mine?" Balance precision with brevity	Ask "Which main intervention am I considering?" Be specific.	Ask "What is the main alternative to compare with the intervention?" Again, be specific.	Ask "What can I hope to accomplish?" or "What could this exposure really affect?" Again, be specific
Example	"In patients with heart failure (**target**) from dilated cardiomyopathy who are in sinus rhythm …t"	"… would adding anticoagulation with warfarin to standard heart failure therapy …"	"… when compared with standard therapy alone …"	"… lead to lower mortality or morbidity from thromboembolism. Is this enough to be worth the increased risk of bleeding?"

	Patient or problem	Intervention	Comparison intervention	Outcomes
	Describe a group of patients similar to your own	What intervention are you considering	What is the main alternative to the intervention	What do you hope to accomplish with the intervention
	"In elderly patients with congestive heart failure…	…does treatment with spironolactone…	…when compared with standard therapy alone…	…lead to a decrease in hospitalization"

In every study we have to describe population and report if there is a selection bias .

- Selection bias: selection ppl and data in non randomized way, so It's true,but not representive .
- To avoid the selection bias we should select the population in a random way.

When forming your question using PICO, consider what type you are asking (**therapy**, **prevention**, **diagnosis, prognosis, etiology)**

Question Type	Patient Problem or Population	Intervention or Exposure	Comparison or Control	Example Outcome Measures
Therapy (Treatment)	Patient's disease or condition.	A therapeutic measure, eg., medication, surgical intervention, or life style change.	Standard care, another intervention, or a placebo.	Mortality rate, number of days off work, pain, disability.
Prevention	Patient's risk factors and general health condition.	A preventive measure, e.g., A lifestyle change or medication.	Another preventative measure OR maybe not applicable.	Mortality rate, number of days off work, disease incidence.
Diagnosis	Specific disease or condition.	A diagnostic test or procedure.	Current "reference standard" or "gold standard" test for that disease or condition.	Measures of the test utility, i.e. sensitivity, specificity, odds ratio.
Prognosis (Forecast)	Duration and severity of main prognostic factor or clinical problem.	Usually time or "watchful waiting".	Usually not applicable.	Survival rates, mortality rates, rates of disease progression.
Etiology (Causation)	Patient's risk factors, current health disorders, or general health condition.	The intervention or exposure of interest. Includes an indication of the strength/dose of the risk factor and the duration of the exposure.	Usually not applicable.	Survival rates, mortality rates, rates of disease progression.

Comparsion usually not applicable , why we don't remove this part ?

- We use it sometime for description, such as in COVID-19 , I just want to describe ppl who have it .

- So , PICO for describe .

Asking the Right Question: Specifying Your Study Question

Creating the final study question is a formal and iterative process:

▶ You create an initial study question by answering questions, defining parameters, getting feedback from colleagues, and conducting a limited literature search.

▶ Then you refine your question and define major aspects of your study by using a Patients, Intervention, Comparison, and Outcomes (PICO) table for treatment and diagnostic studies.

▶ By taking the time to complete these steps, you will have a good structure for your research study and will be able to proceed to the next part, a literature review.

The Process of Creating an Effective Study Question

▶ **Step 1**: Draft a Preliminary Study Question (general question)

▶ **Step 2**: Focus Your Study Question

▶ **Step 3**: Complete a PICO Table

▶ **Step 4:** Refine Study Question and Conduct Preliminary Literature Search

▶ **Step 5**: Consider Additional Questions

▶ **Step 6**: Perform a More Complete Literature Search (our key to next lec.)

Step 1: Draft a Preliminary Study Question

▶ The first step is to draft a simple clinical question you would like to answer or a hypothesis you would like to explore.

▶ What do you think the answer to that clinical question might be?

▶ Why do you think it may be important to evaluate this question?

Step 2: Focus Your Study Question

▶ Now you can start the process of focusing your question.

▶ Example of creating a preliminary study question:

  ▶ Suppose you are interested in several treatments for cervical myelopathy

  ▶ Table 1 shows an example of progressing from a broad study question to one that is more focused.

  ▶ Note that in creating a more focused study question, we have been more specific on aspects of the diagnostic condition (myelopathy due to spondylosis) and the patient population

Table 1 Improving study question focus

STEP BY STEP

Study question too broad	Study question somewhat more answerable	Study question with improved focus
What is the comparative effectiveness of laminoplasty versus laminectomy and fusion? Two We compare in general between two operations.	What is the comparative effectiveness of laminoplasty versus laminectomy and fusion for adults with cervical myelopathy? We focus in ADULTS patients.	What is the comparative effectiveness of laminoplasty versus laminectomy and fusion for adults with myelopathy due to spondylosis in the cervical spine? We select in more specific way about adults with myelopathy due to spondylosis in cervical

Step 3: Complete a PICO Table

▶ Add specifications to your study question using a PICO table to further refine it.

▶ While the more focused study question above is an improvement, there are some additional questions you should ask:

   ▶ What types of patients and pathologies do you want to study or exclude from the study?

   ▶ What variations of the treatments or interventions do you want to consider or exclude from the study?

   ▶ What specific outcomes or complications are the most important to measure and evaluate?

- The PICO system provides a framework for further refinement based on these questions.

- A PICO table will help you to consider what should be included in your study and what should not be included.

- Your final PICO table is an aid to (**IMPORTANT**)

  - further refine your study question

  - define inclusion and exclusion criteria

  - highlight the interventions and outcomes you will measure

  - provide the groundwork for a focused literature search.

Consider the following issues when creating your PICO table:

- Patients:

- Intervention:

- Comparison:

- Outcomes:

Patients:

- Consider factors related to the condition,

  - demographics (e.g., age, gender),

  - behaviors (e.g., smoking),

  - medical history (e.g., previous treatment, medications, general health factors, comorbidities),

  - factors associated with treatment selection (e.g., severity or location of condition),

  - and other factors that might be relevant to treatment selection or outcomes.

- For most studies, it is important to define a fairly homogeneous patient population, especially if there are any factors that might influence the outcome other than the intervention you are evaluating.

- For example, note that in the PICO table, we are including patients with spondylosis and excluding patients with ossification of the posterior longitudinal ligament (OPLL). If the condition itself (spondylosis or OPLL) can influence the outcome, it is better to restrict the study population to one condition.

- However, keep in mind that **a restricted study population can limit bias in your study** yet will also limit the generalizability of your findings to a patient population in a clinical setting.

Intervention:

▶ Make sure you specify variations of the procedures (e.g., approach, number of levels, use of specific devices, grafting) as being included or excluded.

▶ If there are variations of the procedure that could influence results, think carefully about their inclusion

Comparison:

▶ Specify the alternative treatment to which the intervention is compared.

▶ Again, are there variations that should be **excluded**?

Outcomes:

▶ Be specific and aim for the most important outcomes. They can be

  ▶ patient-reported (e.g., pain, function, quality of life)

  ▶ clinical outcomes (e.g., nonunion, complications, reoperation, death).

▶ List the primary outcome of interest first; this outcome provides the focus for your study, the data collection, and the sample-size estimate.

▶ Then list secondary outcomes that might provide valuable contributions to your overall study results

Example of a PICO (Patients, Intervention, Comparator, Outcomes) table for formulating a study question

	Inclusion	Exclusion (**I don't want them and I have to mention that in my study**).
Patients What patient group do you want to include?	Symptomatic adults with cervical myelopathy due to spondylosis	Patients under 18 years of age • Ossification of the posterior longitudinal ligament (OPLL) • Tumor • Trauma • Infection • Deformity
Intervention What surgical treatment, procedure, or implants are you interested in?	Cervical laminoplasty	
Comparison What is the comparison treatment?	Cervical laminectomy and fusion	
Outcomes What outcomes are you interested in (e.g., pain, function)?	• Japanese Orthopaedic Association (JOA) recovery rate (primary outcome) • Neck Disability Index (NDI) • Neck or arm pain • SF-36 • Complications, including CSF leakage, dural tear, and C5	• Radiographic outcomes • Economic, cost-effectiveness

Step 4: Refine Study Question and Conduct Preliminary Literature Search (pubMed , Google scholar)

▶ Now you can use your completed PICO table to refine your study question and to conduct a quick preliminary literature search.

▶ **It is important to find out**

  ▶ what is currently known and not known about your research topic

  ▶ what has already been published on this topic

  ▶ what gaps exist that your research can fill

    ▶ a type of intervention that has not been studied

    ▶ a particular group of patients who have not previously been included in studies

    ▶ an outcome that has not been measured but is important to patients.

- This initial literature search helps you hone your study question further and may help you determine if it is realistic to answer in a single, focused study.

- The PICO framework is also helpful for getting feedback from potential co-investigators/colleagues to further refine your study question.

Step 5: Consider Additional Questions

► By this point, you should have not only a solid study question, but at least a preliminary idea of how you might approach answering it, and there are some additional questions to consider for another round of refinement.

► **To be more specific in your study focus, consider these additional questions:**

   ► What might constitute a clinically meaningful improvement?

   ► What time frame will be important? Are you looking at outcomes that are short-term or long-term to evaluate the effects?

   ► Is there a specific hypothesis that you would like to test?

► After considering the questions above, you can refine your study question further (►Table 3)

Table 3: Final study question

In symptomatic adults with cervical myelopathy due to spondylosis, does laminoplasty improve the severity of myelopathy (as measured by the JOA recovery rate) compared with laminectomy and fusion at 12 months?

or, more specifically

In symptomatic adults with cervical myelopathy due to spondylosis, does laminoplasty lead to a minimum 75% JOA recovery rate (from baseline to 12 months) more frequently than after laminectomy and fusion?

Step 6: Perform a More Complete Literature Search

▶ Now that you have created a clear, focused, answerable study question and a PICO table as the framework for your study, you can proceed to a more complete literature search.

▶ It is important to solidify your understanding of

  ▶ what is known about your research topic

  ▶ what gaps in knowledge need to be filled

  ▶ what is the best study design to answer your study question.

Assignment 1 (Group):

▶ **PICO format**: *Develop a focused clinical question using the PICO format on any epidemiological area of interest to you. Clearly articulate your clinical question.*

▶ The group should clearly designate one topic that is of greatest interest for further exploration. This area is to be developed into searchable question for further exploration