Medical Research Summary

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- What the doctor focused on
- Important topics
- Past papers

Lecture 1

Research allows for a systematic and scientific assessment or evaluation of problem and provides knowledge that allows for change to occur, the basic function of research is to answer why, how, what, when, and how much.

Areas of research: Problem discovery, finding, Impact of the problem, Epidemiology of the problem, Pathogenesis, Management, Prevention.

Methodology: step-by-step pathway that foster clarity and avoids multiplicity.
Methods: are the tools and techniques for doing research.

Epidemiological studies begin with **clinical observations** → **descriptive study** (such as a case report or a case series) to help you formulate a hypothesis → expand to a larger **descriptive study** (cross-sectional study) to examine the prevalence → you can perform **analytical studies**, such as case-control or cohort studies → you may also carry out **experimental studies** aimed at preventing the identified factors.

Moving from a research **idea** to a research **question**:

How to select the ides (prioritizing)? **Relevance**, your **interest**, **feasibility**

How to focus your ideas? **Literature review**, **narrow** down the question by time or place

What is a research question? The researcher asks a very specific question and tests a specific hypothesis. Often called **objective** or **aim**.

What characterizes a good question? **Well-conceptualized**, **relevant**, **direct**, **focused**

Finally, how to move from an idea to a question? Think about how your research: **resolve**, **develop**, **identify** new risk factors, **change** management plans. Identify the main concept and point in a specific direction.

Framework for research question:

PICOT: Patient, Population or Problem/ Intervention, Prognostic Factor, or Exposure/ Comparison (optional)/ Outcome/ Time (most used framework in public health).
*Others: PICo, PICO, PECO, PESICO, PIPOH, PS, SPICE

Literature review helps to: choose topic, Prevents duplicating work, Refine your problem, Formulate objectives, be Familiar with various methodology, Provide justification.
Literature review lets you gain **skills** in two areas: **information seeking**, **critical appraisal**.

Sources for literature review:

1. **Books:** good quality, not Up To Date
2. **Journals:** most up to date information, but be careful with open access journals

3.Medical databases (PubMed): 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.
4. publications (reports, surveys)
5. internet search

In writing your **literature review:**
1.Identify key themes from the literature.

2.Create clear, descriptive subheadings that follow a logical flow.

3.Under each subheading, **summarize** the main findings, highlighting any opposing views and identifying gaps or issues.

4. start the introduction (literature review) as follows:

Common illness:
burden, epidemiology and complications, current clinical guidelines and recommendations.

Rare or uncommon condition:
definition

5. End with: Key limitation of the published studies or areas of need, your question, aim of your study, only 2 lines on your study design and your study population.

6. avoid bias, like restricting references to those that support view of the author.

Do we need to **repeat** previously conducted projects?

Epidemiological Data:
Projects with a valid approach and minor limitations do not require repetition. Weak studies, however, should be revisited and repeated.

Clinical Trials:
Repeat study but focus on special populations and apply findings to your patients. Document differences in responses or adverse drug reactions observed in clinical practice.

Bibliography (references): should give clear description of used sources: **Vancouver style, APA style**

Plagiarism: using others' ideas and words **without clearly acknowledging** the source of that information.
To **avoid** plagiarism, you must **give credit** whenever you use (put in quotations), or **Paraphrase**.

Terms you need to know regarding **plagiarism**:
Common knowledge: facts that can be found in numerous places and are likely to be known by a lot of people.

Quotation: using someone's words.

Paraphrase: using someone's ideas but putting them in your own words.

The research objective: a statement which clearly describes what the researcher aims to achieve from a research, and it should be broken down between (1) a **general objective** and (2) **specific objectives**.

Effective objectives consist of **specific, measurable, achievable, relevant, and time-bound components. "SMART"**

Research team: A group of individuals working toward a common goal.
Research Team Goal: Collaborative effort to conduct, analyze, publish, and share meaningful findings.

1. Principal Investigator (PI):
•Leads the project scientifically and legally.
•Provides resources, training, and oversees decision-making.
•Writes proposals, selects team members, and manages publication.
•Reports to stakeholders and ensures regulatory compliance.
•Responsible for the research and overall project

2. Sub/Co-Investigator:
•May preform some of the PI functions, but they don't accept responsibility.
•Under the supervision of the PI, make important study-related decisions in compliance with the ethical conduct of the study.

3. Research Director/Manager:
•In large observational studies or clinical trials
•Supervises daily operations**, time, budget**, and compliance.
•Aids in **protocol** adjustments and research article preparation.
•makes sure that the project is in compliance with all guidelines (IRB)

4. Research Assistant:

•Handles data collection, equipment, and sample processing.
•Reports to coordinators or statisticians.
•Least amount of experience

5. Statistician:

•Ensures robust and valid data analysis.
•Manages study design, sample size, and reporting.
•Reports to PI and research manager.

6. Authorship:

•Based on substantial contribution, intellectual input, final approval, and accountability.
•Clear authorship order must be pre-established.
•Contributors not meeting authorship criteria should be acknowledged.
•Implies responsibility of published work.

7. Corresponding Author:

•Manages journal **communication**, **peer-review and submission processes.**
•Ensures compliance with publication requirements.

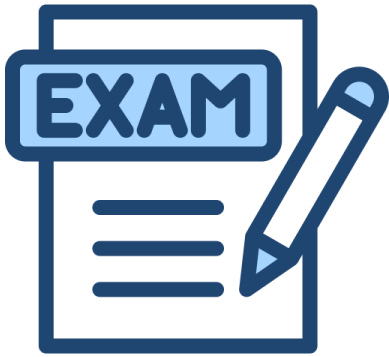
Large Research Groups:

•Authorship may be assigned to a group name, with clear identification of contributors.
•Non-author contributors should be acknowledged with their roles specified.

acknowledgment:

•Contributors not qualifying for authorship (e.g., funding acquisition, administrative support) should be acknowledged, with consent obtained.

Past Papers



1. In designing research questions, PICOT model refers to : (E-Learning Question)
A) Population, Intervention, Comparison, Objective, time
B) Patient, Intervention, Comparison, Outcome, Time
C) Patient, Inclusion criteria, comparison, outcome, Time
D) Population, Inclusion criteria, Comparison, outcome, Time
E) Patient, Intervention, Control group, outcomes, and time

2. Responsibility for communication with the journal during manuscript submission, peer-review and publication process?
A) Principal investigator
B) Co-Author
C) Biostatistician
D) Research assistance
E) Research manager

3. Individual assist the PI in the supervision of the project, direct any protocol as needed, duties and budget?
A. Principal investigator
B. Co-Author
C. Biostatistician
D. Research assistance
E. Research manager

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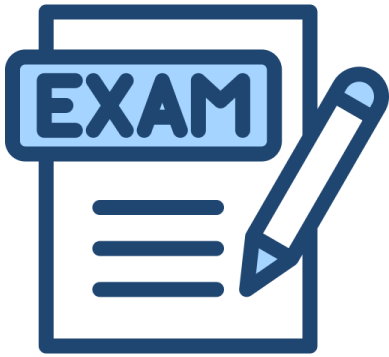

4. The letter “M” stands for in objective components?
A. Manipulating
B. Meaningful
C. Measurable
D. Methodological

5. In designing research questions, PICO(s) model refers to:
A. Patient/Problem, Intervention, Comparison, Outcome
B. Patient/Problem, Exposure, Comparison, Outcome,
C. Person, Environment, Stakeholders, Intervention, Comparison, Outcome
D. Setting, Perspectives, Intervention, Comparison, Evaluation

6. In research team, 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 is: (E-learning)
A. Research Assistant
B. Principle Investigator
C. Co-principle Investigator
D. Project Manager
E. Co-investigator

7. The best way to avoid plagiarism is?

Answer: B/B/E/C/A/D/ Quotation and paraphrasing

Lecture 2 (Introduction to Study Design)

Study Design: a specific plan or protocol for conducting the study, which allows the investigator to translate the conceptual hypothesis into an operational one, and achieve your objectives in a scientific way

Types of Studies:

1.Uncontrolled Assignment (Observational Studies):
-Involves observing patients without intervening, commonly used by epidemiologists to generate hypotheses

A.Descriptive:
-provides insight, data, and information about the course or patterns, it involves:
I.Survey: Uses questionnaires to gather information on topics like quality of life, attitudes, and knowledge from large groups
II.Cross-sectional study: Assesses a group at a specific time to evaluate disease prevalence and risk factors
III.Case report: Detailed study of an individual patient's experience
IV.Case series: Similar to case reports but focuses on a group of patients with a common condition
V.Ecological study: Examines population-level correlations

B. Analytical:
-Used to test cause-effect relationship, it involves:
I.Cohort (Prospective):Track groups with and without risk factors overtime to assess disease incidence
II.Case-Control (Retrospective): Compare individuals with disease (Cases) to those without (control),ideal for rare diseases

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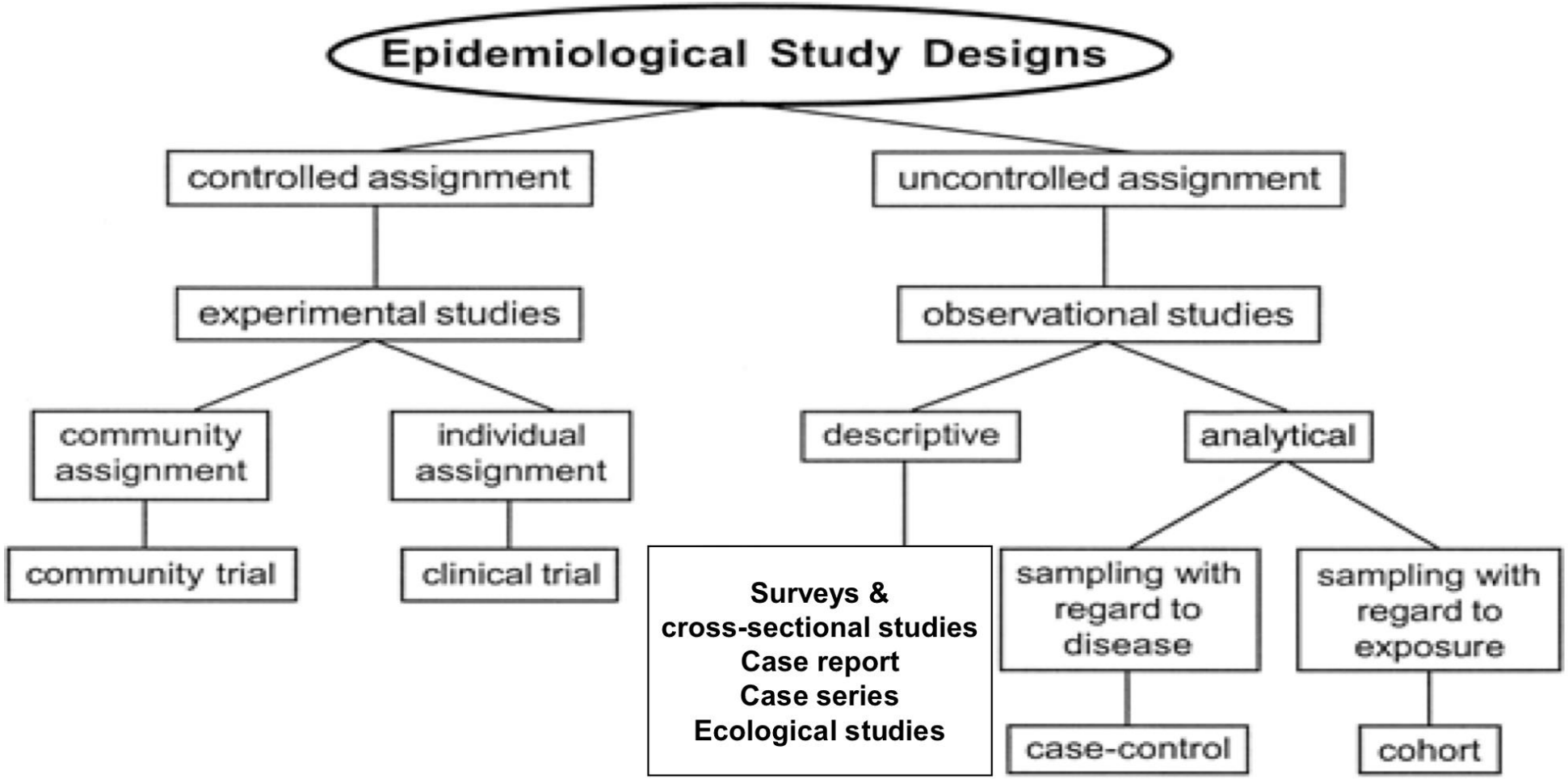
2. Controlled Assignment (Experimental Studies):
-Involves intervention

A.Individual/Clinical Trial: Compare a new treatment with placebo or standard care to evaluate effectiveness
B. Community Trial: Similar to clinical trial, but applied to the whole community

Prospective studies are less susceptible to bias & confounding than retrospective studies.

Comparison of Retrospective and Prospective Approaches	
Retrospective	**Prospective**
Inexpensive to conduct	Expensive to conduct
Completed in a shorter time period	Completed over a longer time period
Easier to access a larger number of subjects	More difficult to access subjects and usually requires a larger number of subjects
Allows results to be obtained more quickly	Exposure status and diagnostic methods for disease may change
Useful for studying exposures that no longer occur	Loss of subjects from the study over time may be substantial
Information and data may be less complete and inaccurate	Information and data may be more complete and accurate
Subjects may not remember past information	Direct access to study subjects enhances reliability of data



Source: Waning B, Montagne M: *Pharmacoepidemiology: Principles and Practice*: http://www.accesspharmacy.com

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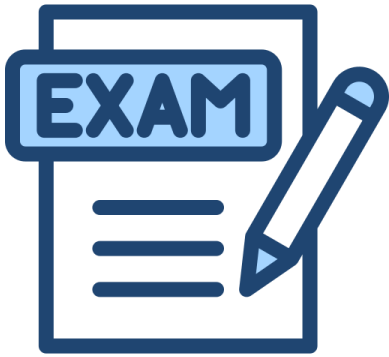

1. One of the followings is an analytical study design (E-learning):

A. Case Control study
B. Community clinical trial
C. Case series
D. Survey
E. Randomized clinical trial

Answer: A

Lecture 3 (Surveys)

A survey may be defined as a collection of information from all individuals or a sample of individuals chosen to be representative of the population from which the are drawn

Non-experimental, based on self reported info rather than observation or analysis, representative, single point in time, more in-depth information that surveillance, expensive, time consuming.

Types of information collected: Morbidity prevalence, mortality, risk factors, behaviors, knowledge, attitude, evaluation of people's precipitation of things, lab test. Data can be:

Primary:
where the investigator is the first to collect the data (medical examinations, interviews, observations).
Advantage: less measurement error, suits objectives of the study better.
Disadvantage: costly, may not be feasible.

Secondary:
where the data is collected by OTHERS, for other purposes that those of the current study.
Individual records (medical / employment);
group records (census data, vital statistics)

Classifying survey methods:

1. By **method of communication**: **Personal Interviews/ Telephone interviews/ Self-administered interviews**

2. By **degree of structure and disguise:**

Structured disguised	**Structured undisguised**	**Unstructured disguised**	**Unstructured undisguised**
↓	↓	↓	↓
Close ended questions, purpose of data collection is **not told** to respondents	**Close** ended questions, purpose of data collection is **known** to respondents	**Open** ended questions, purpose of data collection is **not told** to respondents	**Open** ended questions, purpose of data collection is **known** to respondents

3. By **time frame (Temporal classification)**

a) **Cross-sectional surveys**: data collected at a single point in time
b) **Longitudinal surveys**: data collected at different points in time

Range of uses of survey: **Patients, Health professionals, Relatives and carers, General public and selected subgroups, Health care facilities.**

Advantages:
Easy, generalizable, Large amount of info, fast, inexpensive, accurate in comparison to cost (**Efficient**).

Standardized, structured questionnaire minimizes interviewer bias.

Efficiency:
measured as a ration of accuracy to cost

Disadvantages:
More difficult to collect in-depth information, large sources of error, communication problems.

Survey **design** steps:
Describe the **group of interest** ➢ Obtain a list of **possible participants** ➢ Decide on **sample size** ➢ Select the **methods of sampling**

Stakeholders: all those individuals who would have an interest in the questions you are asking and the results obtained.

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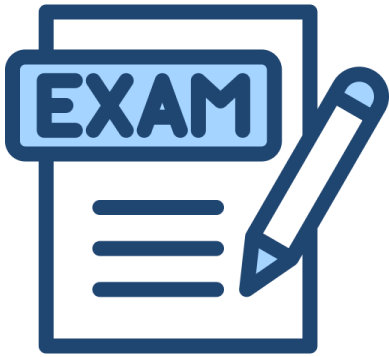


1.All those individuals or bodies who would have an interest in the questions you are asking and the results obtained (E-learning):

A. Research team
B. Ethics Committee
C. Research Committee
D. Stakeholders
E. Coauthors

Answer: D

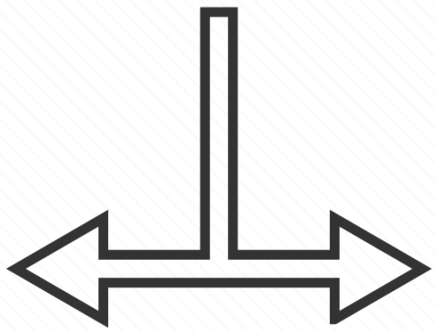
Lecture 4 (Questionnaires)

Questionnaire: A series of questions designed to gather information (data collection) on a certain subject from a respondent through interviews or completed questionnaires

Case report form: A different data collection tool which depends only on medical records, also called Chart review form

-However, it's common we use a combination of both questionnaires & case report form

Structure Interviews → Question are given in a rigid sequence, considered base of **quantitative studies**



Unstructured Interviews → resembles a conversation, used in **qualitative data**

Advantages of Questionnaires:

Ideal for gathering **standardized, straightforward information** from large samples focusing on what rather than why or how

Widespread reach in **low cost**

Straightforward Analysis

Used to collect **quantitative data**

Low pressure on respondents especially in self-completed questionnaires

Reduce interview bias

Limitations:

Superficial, **lacks depth** of meaning

Cannot establish **cause-effect** relationships

Relies on self-reports, not actual behaviour

Ignores environmental **context**

Low response rates may cause **bias**

Unsuitable for poor literacy, impairments, or young children

wording can heavily influence answers, **misunderstandings** cannot be corrected

Types of Questionnaires:

1.Face to Face (Personal)/Interviewer-administred

Advantages:
Participation of illiterates, Clarification, Complete responses, and **Higher response rate**

Disadvantages:
More Time & resources needed (**Expensive**), Interview **bias**, sensitivity & privacy issues

2.Self-Completed:

Advantages:
Cheap & easy, completed at respondent's convenience, preserves confidentiality, **No** interview **bias**

Disadvantages:
viable of literates, misunderstanding & no control by interviewer, **time delay**, **Low response rate**

3.Telephone:

Advantages:
Medium cost, **Medium** response rate, **Wide** coverage

Disadvantages:
Short interview, only viable for those with **phones**

Types of Questions:

1. **Open-ended**: Answer in the respondent's own words
2. **Close-ended**: Respondents choose predetermined options (Yes/No,…)
3. **Screening/Filter**: Ensure respondents meet the criteria

	Close-ended Questions	**Open-Ended Questions**
Examples	Two choices,Multiple choices,Checklist,numerical, ranking, rating	What? Why? How?, "Please describe your experience with the service"
Advantages	**Easier** for participants to respond, **Standardization**, **Statistical analysis** & interpretation are **easier**	**Greater** range of response, **creativity**, unanticipated results
Disadvantages	Questions & options **may not be appropriate, or relevant**	**Longer** time, variety of responses, **statistical analysis & interpretation are more difficult**

Sensitive Questions (Often lead to lower response rates), Strategies to ask sensitive questions:

Question order: Neutral then sensitive, **be casual** when asking to make it sound like his behavior is normal and everybody is doing it, **Longer questions** (Only used with sensitive question), **Reassure** anonymity & confidentiality and never ask identities, Try **self-completion** approach.

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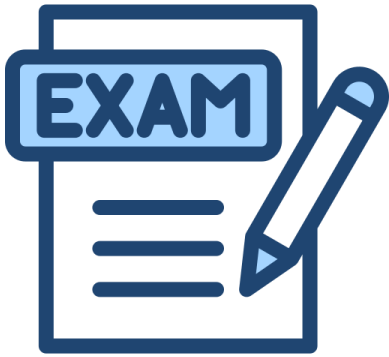

1.For the method of data collection in surveys, the followings are advantages for face-to-face interviews when compared with self-completed questionnaires, EXCEPT (E-learning):

A. Clarification of ambiguities
B. Low response rate
C. Quick answers
D. Less incomplete responses
E. Participation of illiterate people

Answer: B

Lecture 5 (Question Wording)

Tips for question wording:

1.Make sure everyone interprets the questions the same way

2.Be aware of reference frame

3.Avoid leading (Suggestive) questions: (e.g "Does smoking increase the risk of cancer by 30%?")

Right approach ✅:

Make the question open-ended or give them more choices to choose right answer from: (10%, 30%, 50%, or 70%)

4.Avoid Threatening questions: (e.g "Do you have any knowledge of subclinical hypothyroidism?)

Right approach ✅:

-Ask in a non-threatening way "How do you rate your knowledge subclinical hypothyroidism?" , and add scaled options

-It is also possible to test their level of knowledge by using a medical question, e.g:

Thyroid function tests results for patients with subclinical hypothyroidism include:

1.High TSH & Low Free Thyroxine 2. Low TSH & Low Free Thyroxine

3. High TSH & Normal Free Thyroxine 4. High TSH & High FT4

5.Avoid Complex questions: for example if you're asking about multiple procedures & variables , organize components into a table

6. Avoid Double-barreled questions (e.g Have you had pain in you head or shoulder last month) , the responder might have had pain in only one of them, instead split them into separate questions

7. Avoid double-negative questions (e.g Don't you think it's not important to exercise regularly?)

8.Avoid pitfalls, jargon, abbreviations, or slang

9.Be aware of social-desirable phrases (Sensitive Questions)

10.Make sure questions are applicable to all respondents: By targeting our respondents

11.All responses are mutually exclusive: No two options are the same or too similar

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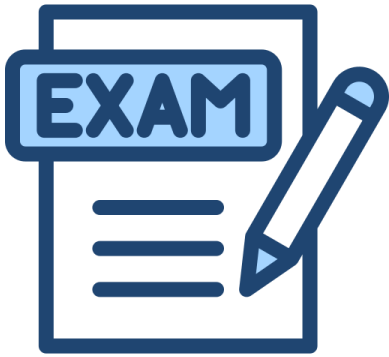


1.You have been selected to be a reviewer for a survey questionnaire, you need to make a decision about the following question (E-learning):
Do you know anything about prediabetes?
Your decision about this question is to:
A. Keep it as it is
B. Delete it

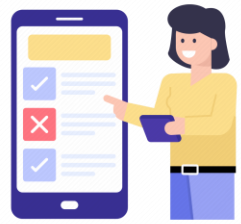
2.Inactivity increases risk for cancer by 10%?
A. Delete question
B. Keep question
C. Edit question

3.Fizzy drinks and junk food are bad for health. highly agree, agree, neutral, disagree,highly disagree.
What should you do for this question?
A. Delete the question
B. Edit the question
C. Keep the question
D. Edit question and answers

Answer: B/C/ A (not sure)

Lecture 6 (Questionnaires and survey design)

A well-designed questionnaire is **short**, **simple**, **good appearance**, **relevant (easy to collect, summarize, analyze)**, **minimized** sources of **bias**



Typology of a questionnaire: determine type of questions to include, wording, coding, grouping, structure and layout.

Structure of a questionnaire:

1. Identification
2. Introduction: who are we and usefulness of the study.
3. Instructions: guidance for interviewers or responders, reduce bias and improve reliability.
4. Questions
   - **Order**: easy then difficult, general then particular, group by topic, be aware of ordering effects, door-opener questions should be simple, closed, non-offending and demographic
   - **Format:** adjust to respondents, define key words, put the options don't know and don't want to answer
5. Conclusion

Steps to design a questionnaire:

1.Define aims and objectives.

2. Define variables to be collected: are you trying to identify attitudes, needs, behaviors? Translate them into **variables** that can be **measured**, define the role of each variable (**predictor, confounder, outcome**).

3. Review the literature: identify related surveys and validated data collection instruments.

4. Compose a draft: write more questions that will be included in the final draft, place important questions in the first half.

5. Revise: shorten the set of questions, ensure the flow in natural, test them with a variety of respondents.

6. Assemble the final questionnaire: at the top, clearly state: The **purpose** of the study, **how** the data will be used, **instructions** on how to fill out the Questionnaire, your policy on **confidentiality.**

Group related questions under headings, **arrange** to stimulate recall, use a format that **ensures unbiased results**.

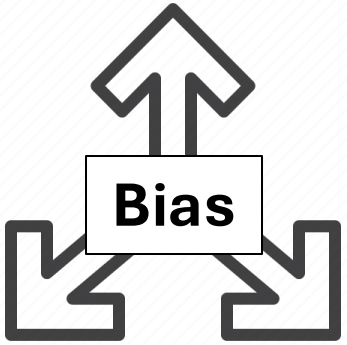
Ethical issues: leave the decision on requiring a consent form to the **Institutional Review Board committee,** each question needs to be linked to the research objectives.

Pilot: distribute questionnaire to a small group of30-50 persons of your target population, to evaluate questions and order. Even modest pretesting can avoid costly errors.

You can include a protocol when administering your questionnaire to maximize response rate.

*How to **reduce** bias?
Structured questionnaire, **high** response rate, **piloting**, **training** of interviewers

Recall bias
Cases more likely to remember than **controls**



Observer bias
Different interviewers – **different** interpretations
Different interpretation of similar questions

Non-response bias
telephone interviews

Techniques for **maximizing response rate**:
Keep questionnaire **short**, ensure **confidentiality** and **anonymity**, **good** design, **sponsorship**, **incentives.**

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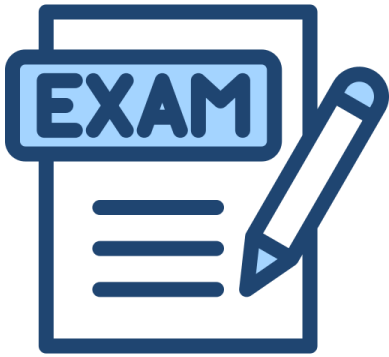


1.You will conduct a study on complications of type II Diabetes Mellitus in Jordan in Amman, Irbid and Maan. One of the following groups should be included in the pilot phase (E-learning):

A. An expert in the field
B. 30 Patients with type II DM in Irbid
C. Endocrinologists from different sites
D. Primary healthcare workers in Irbid
E. Your colleagues

Answer: B

Lecture 7 (Ready To Use Questionnaires)

Definitions:

Instrument: A questionnaire, interview or simple test (or combination of these), used to measure and quantify health or disease status

Domain: An area or realm, one particular aspect within a broad assessment

Measure: A score, generally from a series of items designed to quantify some particular domain

Item or indicator: A single item, (e.g one question in a questionnaire)

Scale: A simple test to quantify broad or single aspect of health using a numerical estimate from visual or numerical range

Classification of questionnaire or scale:

1.Generic questionnaires

2.Disease/population specific questionnaire: Higher acceptability than Generic questionnaires

3.Dimension specific scales/questionnaire: Study a particular aspect of health (e.g Depression inventory, Functional ability)

	Generic Questionnaire	**Disease or population specific Questionnaire**
Population	Large range of populations & Healthcare problems	Particular population or patients groups
Use	Permit comparisons between populations and in the same group before and after an intervention	quantify the severity of individual symptoms or the impact of a disease on a person's overall quality of life
Limitations	1. may be insensitive for subtle but important changes (Less responsive than disease-specific) 2. should be validated across a spectrum of different groups of people	1. Not available for all diseases 2. Lengthy & detailed 3. Limited role in comparisons

For a tool to be **valid,** it must be **precise**, **reliable**, detect meaningful clinical differences & sensitive to changes, easy to use, and acceptable to the target population.
Questionnaires need to be adapted to study population's language, education, occupation, ethnic group, sensitive issues.

These are concepts that you need to **understand & memorize**: 

Concept	Comment
1. Validity	Ability to measure what it supposed to measure.
a.Face validity	Refers to the investigators' subjective assessment of the questionnaire: a reasonable measure and items appears to be measuring what they intend to measure
b. Cotent validity	More systematic and comprehensive assessment than the face validity . It examines that extent to which items on a questionnaire covers all aspects that they intend to measure.
C.Construct validity	Construct: hypotheses are generated, then the questionnaire is tested to determine if it reflect these hypothesis. There two types of construct validity: 1. Criterion validity: the extent that the results match with the pre-existing tools..[3] 2. Concurrent: when the new measure is administered at the same time with the pre-existing one
D. Convergent validity	The measure is correlated positively with other methods that measure the same concept.
E. Sensitivity (detection rate)	Proportion of actual cases. For example patients with clinical depression who score positive on measurement tool for depression
F. Specificity	It is the discriminative ability of a measure. Ie the proportion of people who are not cases and test negative on the measure

Concept	Comment
2.Responsiveness	Ability of an instrument to be responsive to actual changes that occurs over period of time.
3. Administration	Easy
4. Length	Not too long or too short.
5. Cost	Not expensive to obtain or to administer
6. Precision:	Ability to detect small changes
7. Reliabiliy:	The extent to which a measure yields the same number or score each time it is administered.
a.Internal consistency	A test for the homogeneity and extent to which items are correlated within the same scale or domains in the scale. Cronbach's alpha gives an estimate of reliability based on all possible correlations between all items in the scale. Researchers have regarded that 0.7 is the minimum acceptable level for internal consistency. [1,2]
Test-retest reliability	Relationship between scores obtained by the same person on two or more separate occasions. Kappa coefficient is used to test nominal data (ranging from -1 to 1,(0) if the agreement is not better than chance, negative if worse than chance and (1)if there is perfect agreement.

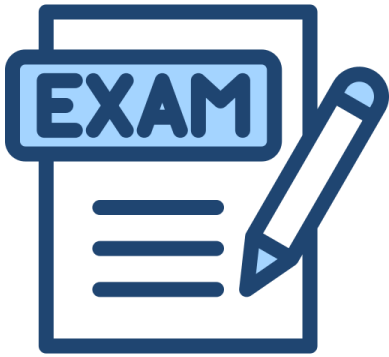
Measures of *reliability* of a new instrument		
Measure	**Concept measured**	**How measured**
Internal consistency	A test for the homogeneity, the extent to which the items within a domain (which broadly should measure the same thing) are correlated.	Cronbach's alpha, an average of the correlation coefficients between all items. Takes values between 0 and 1. A low value (<0.50) indicates that an item does not come from the same conceptual domain[5], a value of 0.7 has been judged the minimum acceptable level for internal consistency[6]. Split half reliability: correlation of two summary scores (for example from odd- and even-numbered questions in a questionnaire)
Test-retest reliability	Relationship between scores obtained by the same person on two or more separate occasions.	Kappa correlation coefficient: Takes values between -1 and 1. A score of 1 indicates perfect agreement, 0 is the extent of agreement expected from chance, a negative score indicates worse agreement than would occur by chance

These were mentioned in the previous tables but with extra information for understanding, I recommend you reviewing them 📖

Measures of *validity* of a new instrument

Measure	Concept measured	How measured
Face validity	The investigators' subjective assessment of the instrument; whether it appears to be measuring what it is intended to measure and whether each indicator is a reasonable one	Judgement (superficial)
Content validity	The extent to which the items in an instrument covers all aspects of the attribute to be measured. More systematic and comprehensive assessment than face validity	Judgement
Criterion validity	Validating an instrument by comparing it with a currently accepted reference measure[6]	Correlation coefficient, correlating the measure with some other accepted "criterion", ideally a gold standard[6]
Concurrent validity	Term for criterion validity when the two scales are administered at the same time; used when attempting to replace an existing scale with a new one that has some advantage (eg simplicity)	
Construct validity	Validating a new instrument by developing a hypothetical prediction of its performance, relevant where the variable of interest is abstract and cannot be directly observed[1]	For example a questionnaire for use in jaundice, measuring the extent of itching and excoriation, should show improvement when serum bilirubin decreases[1]
Two subtypes:		
Convergent validity	The measure is correlated positively with other methods accepted as measuring the same concept	Correlation coefficient
Divergent or discriminant validity	Lack of correlation with variables that measure a different unrelated topic	Correlation coefficient

Past Papers 👨‍🏫



1.All the followings are limitations for disease specific questionnaires, Except (E-learning):

A. They may be insensitive to subtle but important changes in status with respect to a specific disease.
B. They have limited role in comparisons with other conditions or with the general population.
C. They may be lengthy and detailed.
D. They are not available for all diseases.

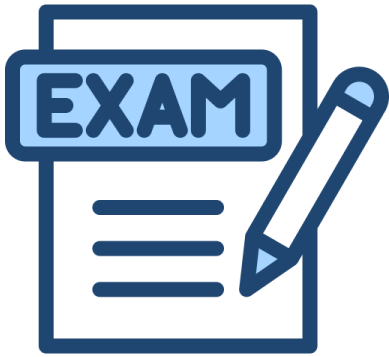
2.Which of the following about disease specific questionnaire is incorrect?

A. They are not available for all diseases
B. Expected to achieve lower acceptability than generic measures
C. They might be lengthy and detailed
D. They have limited role in comparing with other conditions or with the general Population

3.Test for homogeneity and extent to which items are correlated within same scale is?

A. Reliability
B. Precision
C. Test-retest reliability
D. Internal consistency
E. Validity

Past Papers 👨‍🏫

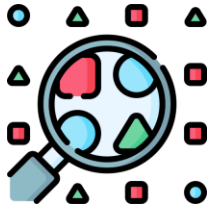


4.Validating an instrument by comparing with currently accepted reference is called?

A. Convergent validity
B. Content validity
C. Criterion validity
D. Divergent validity
E. Validity

Answer: A/B/D/C

Lecture 8 (sampling techniques)



Sampling is a process by which we study a small part of a population to make judgments about that population.

A study unit may be a person, a health facility, a prescription, or other such unit.

The study population (reference population) is the collection of the entire population of all possible study units.

A representative sample has all the important characteristics of the population from which it is drawn.

A sampling frame is a list of all the available units in the study population, if it exists, probability sampling is used.

Sampling techniques

Nonprobability sampling
Less representative and less valid

Probability sampling
More representative and valid

Convenience sampling
Study units are the ones that happen to be available.
Least representative method

Quota sampling
Different categories of sample units are included to ensure that the sample contains units from all these categories.
The sample is not a random sample and therefore the sampling distributions of any statistics are unknown

Most used sampling techniques in health surveys

Complete survey of each unit in the population

Probability sampling: **cluster**

Probability sampling: **systemic**

Probability sampling

1.Simple random sampling

Make a numbered list of all units ⇒ **decide** sample size ⇒ **choose** by lottery method
Each element in the population has an **equal probability** of selection

2.Systemic sampling

Units are selected from a list of all units by using a **regular interval**, starting from a random sampling starting point.
sampling interval = number of units desired / sample size.

3.Stratified sampling

Used when the reference population contains clearly **different sub-populations**, which should be considered separately. sample frame is sorted into two or more groups. These different strata (groups) are sampled either randomly or systematically.

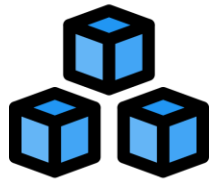
4.Cluster sampling

Dividing the population into **subgroups** called clusters (not as homogeneous as strata), **randomly sampling clusters**, then selecting a random sample of people in each cluster. (a group of sample units is selected together)

Advantages of **cluster** sampling: **easy** and **simple** to use.
Disadvantages: sample selected may be **less representative**, so, double sample size when using cluster sampling.

Stratification	Clustering
• Divide population into groups different from each other: sexes, races, ages • Sample randomly from each group • Less error compared to simple random • More expensive to obtain stratification information before sampling Less feasible than clustering	• Divide population into comparable groups: schools, cities • Randomly sample some of the groups • More error compared to simple random • Reduces costs to sample only some areas or organizations More feasible but less representative when compared with stratified sampling

5.Multistage sampling: the methods described above can be combined. Two-stage sampling, three-stage sampling, etc..



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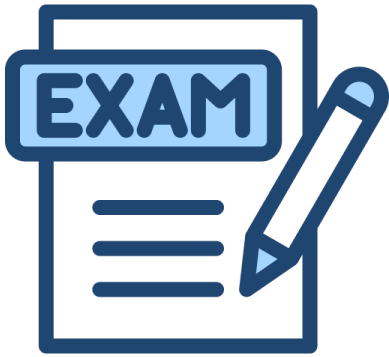


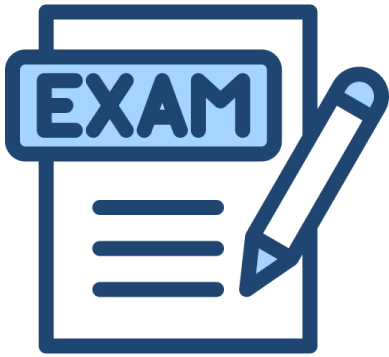
1.You are conducting a study on prevalence of complications rate among adult hypertensive patients in Jordan, you went to the cardiac center and collected a sample of 50 males and 50 females diagnosed with hypertension, this non-probability sampling technique that we should avoid in our research is called (E-learning):

A. Quota Sampling
B. Convenient Sampling
C. Stratified sampling
D. Cluster sampling

2.A group of researchers went to hospital to choose a sample of male and females who came in that day and meet the criteria of the investigator, what is the type of sampling?

A. Convenience
B. Clustering
C. Systemic
D. Quota
E. Stratified

Past Papers



3.A sample was taken by Choosing 16 districts in a country from 56 then choosing 32 healthcare facilities then randomly select 3 villages in Irbid, Amman and Karak, this type of sampling is called?

A. Clustering
B. Stratification
C. Random sampling
D. Systemic sampling
E. Quota

Answer: A/A/A

Lecture 9 (Case Report & Case Series)

Observational studies (Descriptive & Analytical): No intervention
Provides information about disease patterns or drug use problems by various characteristics of person, place, and time, used to generate hypothesis

Descriptive Studies: uncover and portray the occurrence of the condition (without determining the causes).
in this Lecture we will talk about two types of these studies:

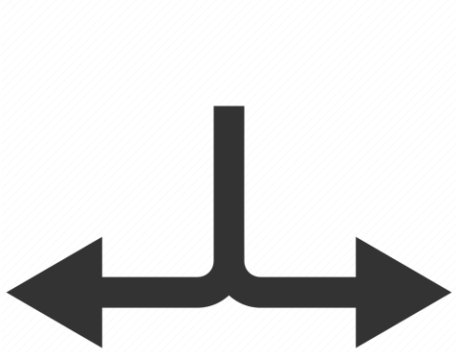
1. Case Report:
detailed report by one or more clinicians of the profile of a single patient about unusual medical occurrences, new diseases, and adverse effects from drug therapies & is the most common type of published study

Applications:
finds unusual disease features or drug effects that **lead to the formulation a new question or hypothesis.**

challenge–rechallenge data to help establish causality, indicating a potential relationship.

2. Case Series: collection of similar cases, considered as a special type of case report.

Applications:
Provide key to sound case control and cohort studies and trials.
Identifies unusual features for new research questions or **hypotheses**
Routine surveillance activities (accumulated case reports) may **suggest emergence** of new diseases



Limitations:
CANNOT estimate Incidence or prevalence
Without Population size, All cases registered, period of data collection
No control group for comparison

Case Series

Clinical Case Series

- Usually, a coherent and consecutive set of cases of a disease (or similar problem)
- are of value in epidemiology for: Studying symptoms,Creating case definitions, Clinical education, and research

Population Case Series/Natural History & Spectrum

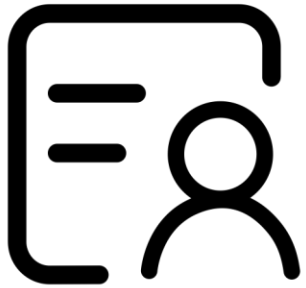
- a systematic extension of this series but which includes additional cases
- build up a picture of the natural history of a disease

Disease Registry (Special form of case series): defined both as the act of recording or registering and as the record or entry itself.

Patient registries: a system that uses observational study methods to collect uniform data to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, that serves a predetermined scientific, clinical, or policy purpose

Types of registries: **Mortality** registry, **Research patient** registry: Supports clinical trials, **Disease or condition** registries, **Service, intervention, device** registry (e.g BMT registry, biosimilars registry).

Applications:



Recruit patients for trials and study diseases.
Monitor treatment effectiveness, safety, and quality.
Analyze population behavior, disease patterns, and progression.
Address care disparities and improve processes.
Support research through analysis, reporting, and pharmacovigilance.
Identify high-need sub-groups and assess intervention outcomes.

Coverage of registry:

Hospital or clinical based: not used to measure the **incidence**
National: Excellent for calculation of **incidence**

Registries vs. RCTs (randomised clinical trials):

RCTs: Therapeutic **Efficacy**
Registries: Therapeutic **effectiveness** (Safety, Generalizability)
Key Difference: Registries Do Not Randomize

Real World Evidence Analysis: Analysis of defined patient cohorts under "real life" conditions (including all comorbidities, AEs & SAEs incl.)

Customized Real World Evidence Analysis: Application and treatment results of various drugs in clinical routine

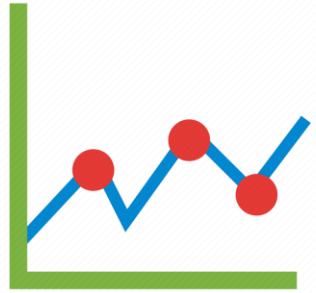
Components of Disease registry

Personal domain: Describe patients demographics, medical history, health status

Exposure domain: Describes **patient's experience** with the disease, medication, device, procedure and other treatments
Baseline **assessment** and **samples** (bioback)

Outcomes domain: Describe patients primary & secondary endpoints

Lecture 10 (Ecological, cross-sectional studies)



Ecological studies: studies in which information on individual members of the population groups are not obtained. Existing statistics are used to compare the mortality or morbidity experience of one or more populations with some overall index exposure. Avoid making inappropriate conclusions from ecologic data (**ecological fallacy**).

Ecological studies are the first identified strong relationships between **disease** and **behavior**.

The unit of analysis is some **aggregates** of individuals, defined by **time** or **place,** then determine if units with high exposure are associated with high frequency of disease.

Data has already been **collected,** measure of association is **correlation coefficient *r*** (a measure of how linear the relationship is between the exposure and outcome).

Advantages:

Quick, cheap, generate new **hypothesise**, and identify new **risk factors**.

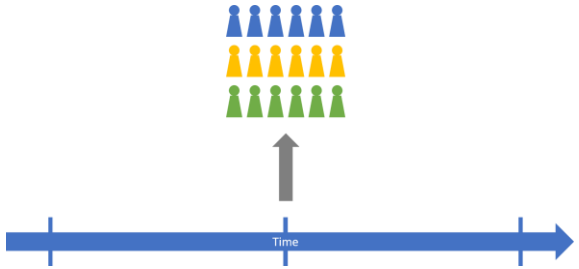
Disadvantages:

Confounding factors, **can't link** exposure to disease and can't reflect association in individuals, **masks** complicated relationship as it uses average exposure.

Cross-sectional study (prevalence studies): studies of total populations or population groups in which information is collected about the present and past characteristics, behaviors, or experiences of individuals. **Prevalencee rates can be determined.**

Emphasis is on **differences** between groups at **one point** in time. No sampling of individuals based on exposure or outcome.

Often used as an **initial exploration of a hypothesis.**



Advantages:

A single data collection **(cheap and quick).**

Effective in identifying **chronic** diseases

Useful when investigating exposures **which do not change** e.g genetic characteristics.

Provide information and data useful for the **planning** of health services.

All variables are only collected **once**, **Standard** measures used.

Sample size **depends** on the question

Disadvantages:

Not suitable for rare disease or diseases of short duration (communicable diseases).

Difficult to **separate** cause and effect.

Seasonal variations of disease are not well represented

Unable to measure **incidence**

Associations identified may be **difficult to interpret**.

Susceptible to **bias**

Exposure	Outcome		Total
	Yes	No	
Yes	a	b	a + b
No	c	d	c + d
Total	a + c	b + d	a + b + c + d

Prevalence of outcome in exposed = a / a + b

Prevalence of outcome in non-exposed = c / c + d

Prevalence Rate Ratio (PRR) = $= \frac{a / a + b}{c / c + d}$

Chemotherapy	Outcome		Total
	With pain	Without pain	
Yes	664	556	1220
No	879	1088	1967
Total	1543	1644	3187

Prevalence of pain among chemotherapy = 664/ 1220 = 54.4%

Prevalence of pain among no chemotherapy = 879 / 1967 = 44.7%

Prevalence Rate Ratio (PRR) = = 54.4 / 44.7 = 1.22

Lecture 11 (Cohort Studies)

Analytical studies: Aim to study cause-effect relationship (no intervention)

Cohort (follow-up) Studies: studies in which people are identified and grouped with respect to whether they have been exposed to a specific factor or not (e.g exposure: Smoking→outcome: Lung cancer)

The groups are followed up over time to determine whether the incidence of a particular disease occurs or not. neither the exposed nor the unexposed groups have the disease of interest at the beginning.

Purposes: descriptive (measures of **frequency**), analytic (measures of **association**).

The best observational study for establishing cause-effect relationships.

Prevention and intervention measures can be tested and affirmed or rejected.

In cross-sectional studies, rare diseases cannot be effectively studied to determine their magnitude because identifying enough cases would require an extremely large sample size. **To assess the burden or magnitude of a rare disease or one with a short duration, cohort studies are more appropriate.**

Steps in study design:

Clear research **question** → Define **sample size** and follow-up **period** → Choose **representative, disease-free** participants → Ensure **accurate** exposure info → **Compare** similar groups and measure outcomes.

Subjects should not be excluded from subsequent analysis because of any change in exposure status during follow-up. Exposure may be **acute, chronic**, or **intermittent**.

Multiple comparison groups may **reinforce the validity** of findings

If **losses** to follow-up are significant during the study, then the **validity of the results** can be seriously affected.

Strengths:

examine **multiple** health outcomes associated with a **single** risk factor

calculate the **incidence**

determining the **relative risk** and **risk ratio**

Establish **temporal relationships** (confident that exposure came before the disease).

Good for **rare** exposures

Not open to bias as much as other types of study

Provide information on **multiple** exposures (but limited).

consider **seasonal variation**

Limitations:

Not efficient for **rare diseases**

Large sample, **expensive** and **time-consuming**

Drop-out biases, Changes over time in diagnostic methods, exposures, or study population may also lead to biase.

Locating subjects and developing tracking systems can be **difficult**.

Cannot test current hypotheses

Healthy Worker Effect:
Workers have lower death rates than the general population because severely ill and disabled individuals are typically excluded from employment.

Types of cohort:

Birth cohort : all individuals in a certain geographic area born in the same period (usually a year)

Inception cohort: all individuals assembled at a given point based on some factor, e.g. where they live or work

Exposure cohort: individuals assembled as a group based on some common exposure

Retrospective cohorts: uses information on prior exposure and disease status, all the events in the study have occurred, thus, faster and costs less.
But it relies on patients recall and existing records. (follow-up was completed in the past).
Might be the only feasible cohort type in **exposures that no longer occur.**

Ambidirectional Cohort: data collected both **retrospectively** and **prospectively** on the same cohort to study short and long-term effect of exposure.

Nested case-control study: Case-control within a cohort study

Analysis:

Collect and analyze data by subgroups based on exposure → calculate and compare subgroup rates → use **relative risk** and **attributable risk fractions** for cohort data.

Midpoint analysis: when, at a defined point in time in the study, all data collected to that point are analyzed so a decision can be made to stop or continue the study.

	Disease Present	Disease absent	
Exposure Present	a	b	a+b
Exposure absent	c	d	c+d
Total	a+c	b+d	a+b+c+d

	Bacteriuria		
	Yes	No	Total
OC use			
Yes	27	455	482
No	77	1831	1908
Total	104	2286	2390

Data from D. A. Evans et al., Oral contraceptives and bacteriuria in a community-based study. *N. Engl. J. Med.* 299:536, 1978.

Risk in the exposed=(a)/(a+b)
Risk in the non exposed=(c)/(c+d)

$$\textit{Relative Risk}\,(RR) = \frac{a/(a+b)}{c/(c+d)}$$

$$\text{Relative Risk}\,(RR) = \frac{27/482}{77/1908} = 1.4$$

Measuring the association between risk factor and diseases

Relative risk

$$\text{Relative Risk } (RR) = \frac{\text{Risk in the exposed}}{\text{Risk in the non exposed}}$$

- **RR=1**
  There is no association between exposure and disease.
- **RR>1**
  Exposure is associated with an *increase* of the frequency of the disease.
- **RR<1**
  Exposure is associated with a *decrease* of the frequency of the disease.

The value of the RR reflects the magnitude of the association between exposure and disease.

Preventive fraction

If the exposure is preventive $I_{exposed} < I_{unexposed}$

$$PF = \frac{I_{\text{unexposed}} - I_{\text{exposed}}}{I_{\text{unexposed}}}$$

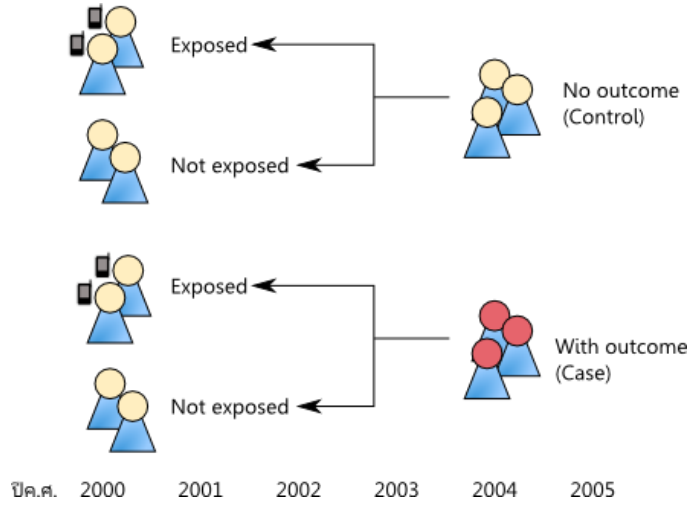
Ischaemic heart disease (IHD) as a disease outcome and exercise as a preventative exposure.

	IHD risk
Exercise	2/100
No exercise	8/100

$$PF = \frac{8/100 - 2/100}{8/100} = 0.75$$

Lecture 12 (Case-Control)

Case-Control (Retrospective): a group of people with a particular disease (the cases) are compared with a group of people without the disease (the controls). The purpose of the comparison is to determine whether, in the past, the cases have been exposed more (or less) often to a specific factor than the controls, and is the **most common analytic design**.



Key features of the design:

1.Comparability: Cases and controls must come from the same population, with cases having the disease and controls disease-free, but both sharing similar characteristics like age and gender. Selecting appropriate cases (eligibility) and controls (representativeness).
2.Specific case definition: The most important step in case-control study

Data collection methods:
A. Subjective (more common): questionnaires and interviews
B. Objective: Preferred for reducing bias, such as case-note reviews (medical records) or **using biomarkers (the most objective mean for characterizing exposure)**

Strengths:

Ideal for **rare diseases** or conditions with **long latency periods**

Allows testing of **multiple** risk factors for a **single** disease

Efficient in **time** and **cost**, requiring **smaller** sample sizes than cohort studies

Can test current hypotheses

Limitations:

Not suitable for **rare exposure**

Prone to **biases** (selection and recall)

Unable to measure **incidence or prevalence**

Cannot establish **causality**

Controls may **not** be **representatives**

Incomplete Past records

No **absolute risk** estimates

Confounding factor:

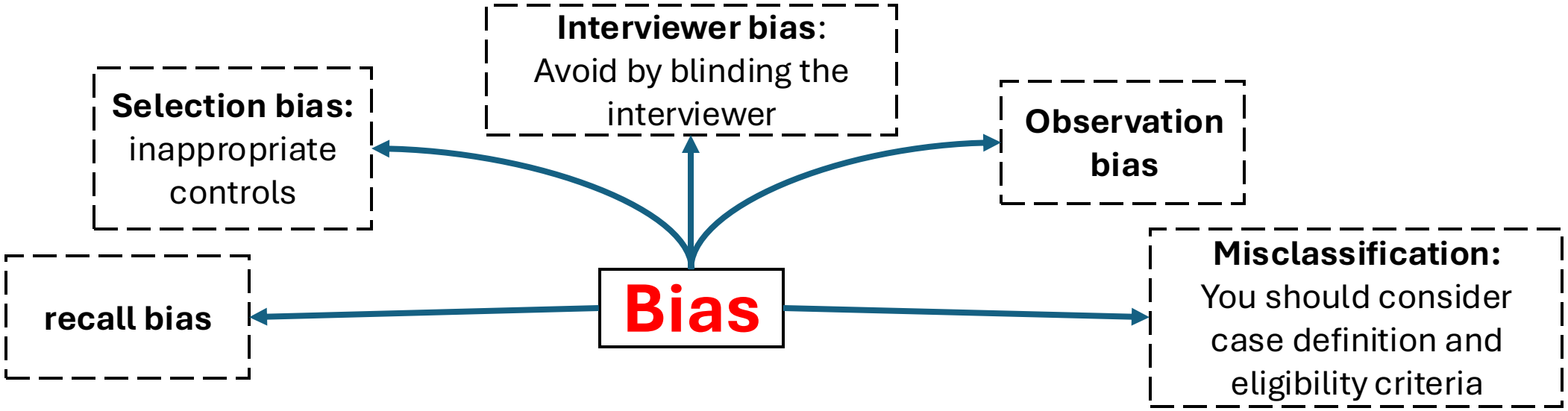
A factor associated with the exposure and **independently** affects the risk of developing the outcome, but **not an intermediate** link in the causal chain between the exposure and the outcome

-Identifying and adjusting for confounders (e.g., smoking in alcohol studies) is **crucial** for valid results.

-Matching controls **helps** reduce confounding and bias, but **special analysis** techniques are required (e.g., matched pair analysis).

Bias:

Any systematic error that results in an incorrect estimate of the association between exposure and risk of outcome



Selecting Cases and Controls:

1.Case Selection: clear eligibility and exclusion criteria based on disease presence.

2.Control Selection: drawn randomly from same population as cases, Multiple control groups may be used.

3.Matching: ensures cases and controls are comparable (pair matching)

4.Control-to-Case Ratio: 1:1 ratio is the optimal when the number of available cases and controls is large and the cost of obtaining information from both groups is comparable, **BUT the Best number of cases-to-control is 4:1**

Ratios up to 4:1 may be used to increase study power, but exceeding this is not recommended.

Data Analysis: Data collection and analysis are based on whether the case-control study involves a matched or unmatched design. The measure used typically in case-control studies is the **odds ratio**

Odds Ratio (OR): Commonly used to assess the strength of association between exposure and disease

Case-control study

	Disease Present	Disease absent	
Exposure Present	a	b	a+b
Exposure absent	c	d	c+d
Total	a+c	b+d	a+b+c+d

Odds of being ill in exposed=a/b
Odds of being ill in non exposed =c/d
Odds ratio (OR)=Odds in exposed/Odds in non exposed
= OR=(a/b)/(c/d)

$$Odds\ Ratio(OR) = \frac{ad}{cb}$$

Data from a case-control study of current oral contraceptive (OC) use and myocardial infarction in premenopausal female nurses

	Myocardial infarction		
	Yes	No	Total
Current OC use			
Yes	23	304	327
No	133	2816	2949
Total	156	3120	3276

Data from L. Rosenberg et al., Oral contraceptive use in relation to non-fatal myocardial infarction. *Am. J. Epidemiol.* 111:59, 1980.

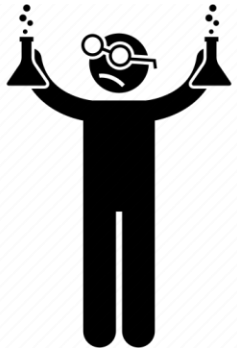
$$OR = \frac{23 \times 2816}{304 \times 133} = 1.6$$

Women who were current OC users had a risk of MI 1.6 times that of nonusers

Lecture 13 (Experimental Studies)

Controlled Assignments (Experimental Studies): A study in which a population is selected for a planned trial of a regimen, whose effects are measured by comparing the outcome of the regimen **(new treatment)** in the **experimental** group versus the outcome of another regimen **(standard care if exist or placebo)** in the **control** group.

They aim to compare outcomes between experimental and control groups, **divided into:**



1. Individual Assignment (Clinical Trial):

A. Treatment Trials: Focused on curing or managing **diseases**
B. Preventive Trials: Aimed at disease prevention in **healthy** populations

2. Community Trials: Applied to entire communities rather than individuals

Key Features of Study Design
1.Manipulation of the study factor (exposure)
2.Randomization: random allocation of subjects to treatment groups or control groups **ensuring each subject has an equal chance,** otherwise it's unethical to do the trial
-Manipulation & Randomization differentiate experimental study design from observational studies
3.Blinding: Ideally both patients and the observers should be blind in order to reduce bias

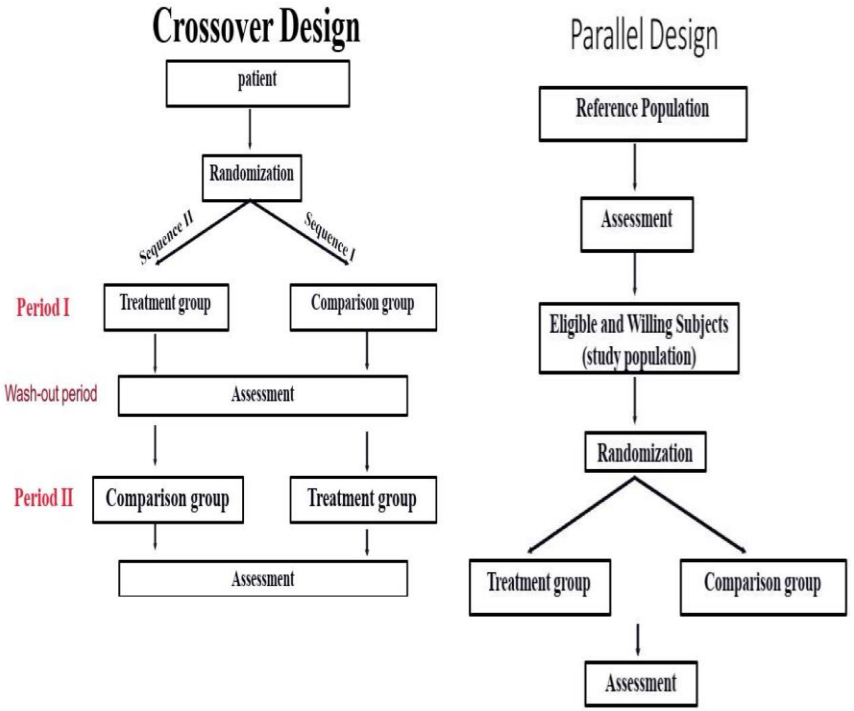
Clinical Trials:

Individuals with disease are **randomly** allocated into experimental or control groups. Types of clinical trials:

A. Randomized **(Gold Standard)** or Non-randomized **(should be avoided)**

B. Single-Center (e.g at one hospital) or Multi-Center

Designs of Clinical Trial	Parallel Design	Crossover Design
Sample Size	**Large**	**Small**
Treatments	**One** treatment for short period	**Multiple** treatments for long period (due to washout period)
Concept	Each group receives a different treatment then results are compared after a period of time	The first group receives Treatment A, while the second group receives Treatment B for a set period. Afterward, both groups undergo a washout period before switching treatments



Clinical trial choice of design depends on: research questions, goals, funding, existing knowledge, disease occurrence, latent period duration, data availability, and resources

Common Challenges:

1.Small sample size & Failed randomization: lead to bias and weak studies
2.Loss to follow-up: Lost participants should not be excluded from analysis, as understanding the reasons for their withdrawal is essential for accurate interpretation of results.

Advantages:

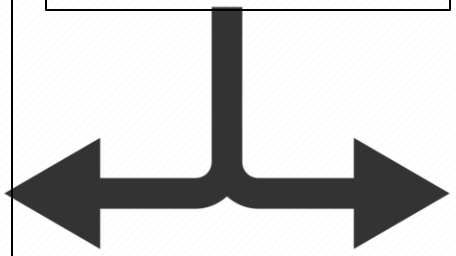
-Assess drugs, surgery, services

-**Most definitive method** to determine if a treatment is effective

-**Stronger evidence** of the outcome compared to observational design

-**Determine** whether experimental treatments are **safe and effective under "controlled environments",** especially when the margin of expected benefit is doubtful/ narrow

Clinical Trials



Disadvantages:

-**Expensive**, **Long-term** follow up (possible loss of participants)

-**Compliance** of patients

-**Large** Trials may affect statistical power

-Requires **treatment on basis** (in part) of **scientific rather than medical** factors. Thus, patients may make some sacrifice

Placebo: Substance which resembles the treatment under investigation
Sham Control: Faked surgical intervention with the patient's perception of having had a regular operation

Adverse effect: An incident in which harm resulted to a person receiving health care
- Some adverse effects can be known from earlier trials
- If we have in Phase 0, I or II serious Adverse events, **we should not proceed to phase III**

Need for Blinding: Open, Single (Participant), Double (Participant & Investigator), Triple (include biostatistician)

Purpose of Control Groups

1.Distinguishing Treatment Effects: Separates outcomes caused by the treatment from those due to other factors, like:
Natural Disease **Progression** (spontaneous recovery), **Placebo** Effect, Effect of **Other Treatments**

2.Fair Comparisons & Informative Results :
Comparison with Approved Treatments, ensures new treatments are evaluated relative to existing standards, avoiding overestimation of effectiveness

Phases of Clinical Trials (very important topic in past papers):

-**Preclinical**: Animal studies
Objective: Determine Toxicity & Bioavailability

-**Phase I**: In few **healthy individuals** (10-40)
Objective: evaluate a drug's metabolism, pharmacokinetics, side effects with increasing dose, while gathering early effectiveness data to inform phase II studies

-Phase II: Effectiveness in small group of **patients**
Objective: identify the target patient population, assess drug effectiveness, evaluate **short-term** side effects & associated risks, and establish dosing ranges for phase III

-Phase III: Rigorous testing, large randomized controlled, possibly blinded
Objective: additional information about effectiveness and safety needed to evaluate the overall benefit-risk relationship, and provide an adequate basis for physician labeling

-Phase IV: Post-marketing surveillance with long-term follow-up
Objective: Drug's efficacy & safety in new age groups, races, other types of patients, and detect rare adverse reactions

Surrogate endpoints: indirect measures used in clinical trials to predict the long-term effects of a treatment without waiting for the actual outcomes, used in therapeutic exploratory trials
-Used with caution in confirmatory trials
–Uses: An alternative to ideal trial to save time & resources, address questions or endpoints

Ethical Considerations in Clinical Trials:
1.Defining Patients: Diagnostic features and Eligibility (Inclusion & Exclusion criteria)

2. Placebo Use: It's unethical to use placebo if there's a proven treatment. Only Acceptable if there is no proven treatment or standard care

3.Randomization:
A medical doctor should prioritize what they believe is best for their patient (Two MDs may ethically treat same patient quite differently), however:
A. If an MD is confident about the superiority of a particular treatment, they should not participate in the trial, as this may conflict with the principles of randomization.
B. If there is uncertainty about which treatment is better, randomization ensures each patient has an equal chance of receiving any of the therapies under investigation. This promotes fairness and maintains ethical standards in clinical practice
C. Bayesian Adaptive Designs: These designs adapt based on accumulating trial data, increasing the likelihood of assigning patients to the treatment that appears more effective

Preventive Trials:
-Require a larger sample than treatment trial(more expensive)
-In rare diseases preventative studies, it's more efficient to study those of higher risk
-**An introduction to community trials** (if the preventative is applied to a whole community)

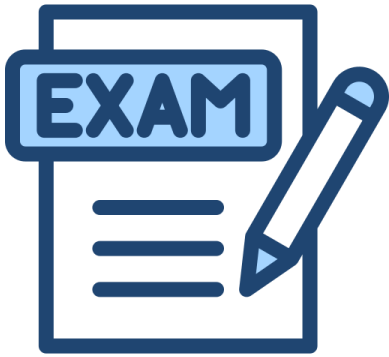
Community Trials:
-Determine the potential benefit of new policies and programs
-Community refers to a defined unit, e.g., a county, state, or school district. They are randomized and followed over time
-Example:Increasing fluoride level within acceptable limits in all drinking water sources in Aqaba, while no change of fluoride levels in Irbid.

Meta Analysis & Systematic Review:
-Meta-analysis provides the highest level of evidence in research, followed by systematic reviews and then clinical trial

1.Meta analysis: A method to combine results from multiple clinical trials into a single finding when there is **NO heterogeneity** between the studies. This approach generates a unified outcome that represents the combined result.

2.Systematic Review:A method to present results from multiple studies separately, typically in tables, when there is significant heterogeneity between the studies, preventing data combination.

Past Papers



All questions regarding study design were grouped together here

1.The main limitation for case series (E-learning):

A. Difficult to generate case definition based on them
B. Cannot assess symptoms and signs
C. Generation hypothesis
D. No comparison group

2.The best number of controls to cases in case control studies (E-learning):

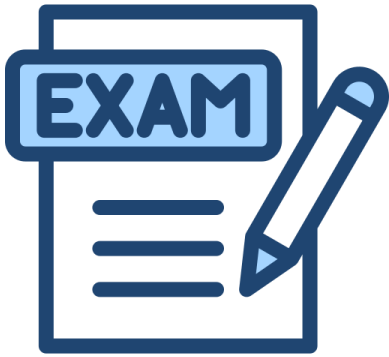
A. 4 to 1
B. 1 to 1
C. 3 to 1

3.Studying correlations in incidence of type ll diabetes mellitus and coffee drinking according to world data from different countries can be achieved quickly through (E-learning):

A. Cohort study
B. Ecological study
C. Cross-sectional study
D. Case report

Answer: D/A/B

Past Papers



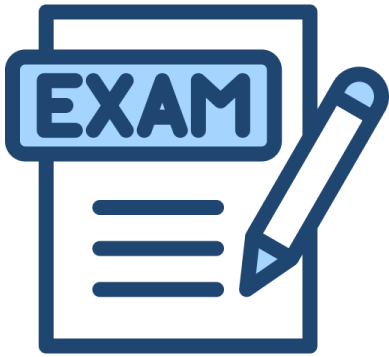
4.To study risk factors of rare disease, we need to conduct (E-learning):
A. Case control study
B. Cohort study
C. Cross-sectional study

5.Studies consist of animal experiments that determine bioavailability and toxicity of drug is (E-learning):
A. Phase I
B. Preclinical
C. Phase II
D. Phase IV
E. Phase III

6.Gathers additional information about effectiveness and safety?
A. Preclinical
B. Phase I
C. Phase II
D. Phase III
E. Phase IV

Answer: D/B/D

Past Papers

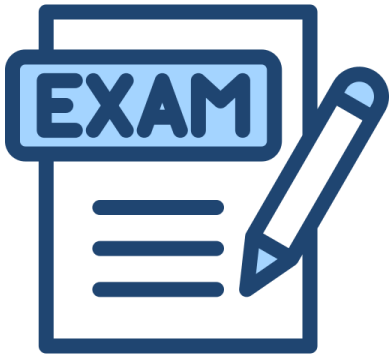


7. A controlled trial of approved treatment with long term follow up?
A. Preclinical
B. Phase I
C. Phase II
D. Phase III
E. Phase IV

8. Determines whether a therapy has potential using few sick patients?
A. Preclinical
B. Phase I
C. Phase II
D. Phase III
E. Phase IV

Answer: E/C

Past Papers



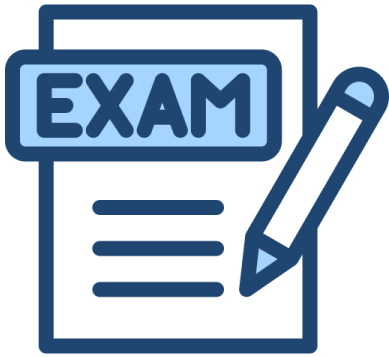
9.When the drug is given to healthy people to estimate toxicity?
A. Preclinical
B. Phase I
C. Phase II
D. Phase III
E. Phase IV

10.Choose the correct regarding the cross-sectional study?
A. Can measure the incidence
B. Not ideal for seasonal fluctuations
C. Suitable for communicable diseases of short duration

11.To identify accurately the population that can benefit from the drug?
A. Preclinical
B. Phase I
C. Phase II
D. Phase III
E. Phase IV

Answer: B/B/C

Past Papers



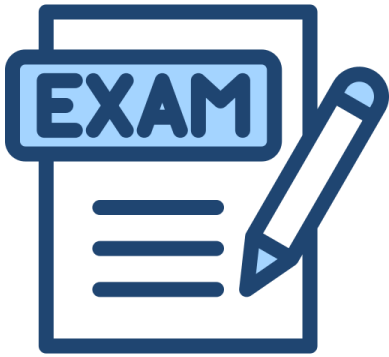
12.All the following are characteristics of case control except?
A. Able to study diseases with long latency
B. It is a retrospective study
C. Not suitable for rare exposure
D. Suitable for rare disease
E. It can measure the incidence

13.The registry is a special for ?
A. Case report
B. Case series
C. Case control
D. Cohort
E. Ecological

14.The study of low fibers intake as a risk factor for diabetes?
A. Cohort
B. Case report
C. Case series
D. Case control
E. Ecological

Answer: E/B/A

Past Papers



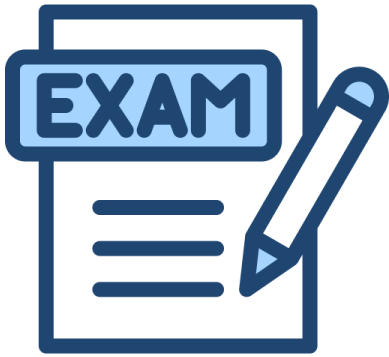
15.To study the burden of acute infection?
A. Incidence of disease in cohort
B. Incidence of disease in cross sectional
C. prevalence of disease in cohort
D. prevalence of disease in cross sectional

16.To study the burden of common chronic disease?
A. Incidence of disease in cohort
B. Incidence of disease in cross sectional
C. prevalence of disease in cohort
D. prevalence of disease in cross sectional

17.The highest evidence in medical research is coming from?
A. Case report
B. Clinical trial
C. Meta analysis and systematic review
D. Case control
E. Cohort

Answer: A/D/C

Past Papers 👨‍🏫



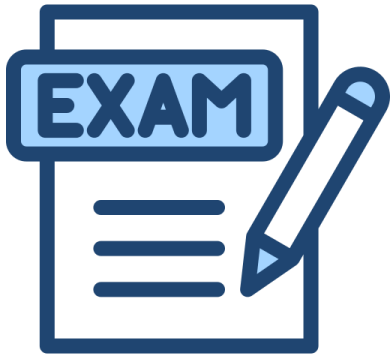
18.Which of the following can't be retrospective?
A. Cohort
B. Randomized clinical trials
C. Case report
D. Case series
E. Case control done

19.Best used to study multiple diseases with a risk factor?
A. Cohort
B. Case report
C. Case series
D. Case control
E. Ecological

20.To investigate an outbreak of food poisoning you should use which study design?
A. Cohort
B. Case report
C. Case series
D. Case control
E. Ecological

Answer: B/A/D

Past Papers



21.The odd ratio is present in which study design?
A. Cohort
B. Case report
C. Case series
D. Case control
E. Ecological

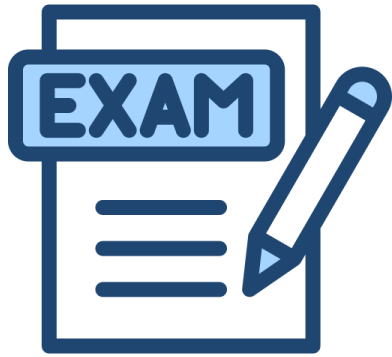
22.The relative risk is present in which study design?
A. Cohort
B. Case report
C. Case series
D. Case control
E. Ecological

23.The study of 2 antibiotics for Urinary tract infections is?
A. Cross-over study
B. Parallel study

24.The study of bronchial asthma drug on a group of patients then give them the current drug is?
A. Cross-over study
B. Parallel study

Answer: D/A/B/A

Past Papers



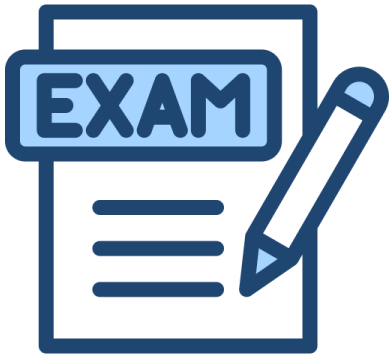
25.The most important step in case control is?
A. Selecting control
B. Selecting case
C. analysis of data
D. Specify the case definition

26.Compare the presence of modifiable risk factor of residents of Aqaba and Irbid?
A. Cohort
B. Case report
C. Case series
D. Case control
E. Ecological

27.All of the following about cohort are true except?
A. More bias than case control
B. More bias than case series
C. More bias than ecological studies

Answer: D/E/A

Past Papers



28. In Evidence Based Medicine (EBM) the strongest scientific evidence comes from (E-learning):

A. Experimental studies
B. Meta-analysis and systematic reviews
C. Case Control studies
D. Cohort studies
E. Cross-sectional studies

Answer: B

Lecture 14 (Proposal design)

Key steps in conducting a medical research:

Inform interested parties → **Write the proposal** → Obtain ethical approval → Secure funding → Register under the Data Protection Act → Develop data processing → Pilot all stages → Review the design.

Proposal is crucial to check if your objectives can be **achieved**, prevent **failure**, and obtain **funds**. The **outline** of the proposal should look like this:

Presentation, Background and justifications, Objectives and research questions → Methods → Ethical considerations → Project management → Timetable → Resources → References → Appendices

1.Presentation, Background and justifications, Objectives and research questions:

A. **presentation:** title, investigators, proposal summary, centers.

B. **Introduction:** sets the scene, **define** the program or healthcare problem, summarize existing work (**literature review**), highlight knowledge gaps, **justify** the study's urgency, and state **aims and objectives**.

Aims and objectives

Aims: subjective statement to describe what you wants to achieve by conducting this study

Objectives: something you can measure or assess

Literature review

Start from **general** to **specific,** ensure you reviewed key articles from **Jordan**, the **region** and **worldwide.**

Write down your objectives then **provide the review for each objective**

Last paragraph should contain **summary** and **justifications** of the study.

2.Methods:

Study **design**, Study **setting** : community based or healthcare (hospital or clinic)

Primary **outcomes** and Secondary outcomes: should reflect the primary and secondary objectives.

Study **population**, Inclusion **Criteria**, Exclusion criteria

Sampling technique, **Sample size**, **Study tool/data collection methods** Example: For questionnaires, if a total score will be calculated, **validity** and **reliability** data are required.

Justifications for investigations used, example: because it is the most sensitive markers

In Clinical trial, **Randomization** and **blinding**,

Ethical Consideration: Inform Consent, if needed

Confidentiality, **References**

Statistical analysis plan: data **cleaning**, **timing** (during study or after?)

Organize data by objectives with dummy tables, moving from general to specific, and applying appropriate statistical tests like Chi-Square, t-test, regression, and P-values.

Why do a data analysis plan?

Prevents collection of data that will not be used
Prevents failure to collect crucial information
Better estimates of sample size for analysis of subgroups

Pilot studies, pre-testing: No study should ever proceed without a test

Validity (limitations, weaknesses): Identification of potential sources of biases (confounding, selection bias, information bias) and how to deal with them.

3. Ethical considerations: informed consents, confidentiality and anonymity.

4. Project management: participating institutes and persons, responsibilities and tasks of each partner, quality assurance, data ownership

5. Timetable: planning, organizing, pilot study, final study

6. Resources: keep budget reasonable, detailed, justified.

7. References: only put key articles, follow the recommended style

8. Appendices (methodological): questionnaire, variables, forms of informed consent.

Tips for specific studies

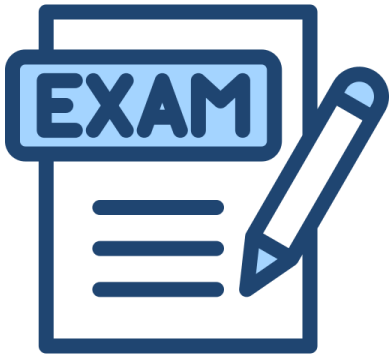
Survey
Develop preliminary skeleton table, begin with simple deceptive statistics, piloting

Case control
Case definition, control definition, data analysis plan

Cohort studies
Set the sample size, the follow-up period (immediate, short term and long term).
Put measures in place to reduce loss to follow up if possible.
general population (whole area or representative sample) and special groups (selected by occupation, profession, or specific exposure to agents).

Cohort studies
What are the proposed methods for protecting against sources of bias.
What is the likely rate of loss to follow-up?

Past Papers



1.When we selected a ready to use questionnaire for our study such as pain scale, quality of life score, clinical score, we need to provide the validity and reliability of this questionnaire in the methods section (E-learning):

- True
- False

Answer: True

Lecture 15 (Introduction to Ethics in Medical Research)

Essential aspects when conducting a research:

1.Proposal Writing Methodology:
-Requires agreeing on the doses for each medication, defining inclusion and exclusion criteria, and identifying the primary and secondary outcomes of the study
-Use Gold Standard methods like RCTs

2.Ethical Considerations in Clinical Trials:
-Ensure human protection, confidentiality, and minimize harm
-Research aims to benefit participants while guaranteeing safety

Ethical Approval:

-Approval from an Institutional Review Board (IRB) is mandatory before conducting research
-Conducting Researches without IRB approval is unethical & illegal
-Approval types:
1.Expedited Approval: For minimal risk studies (e.g., surveys without sensitive data).
2.Full Review: For higher-risk studies (e.g., clinical trials, invasive procedures like blood sampling)

Informed Consent: A legally-effective, voluntary agreement that is given by a prospective research participant.

A.Participation: must be voluntary & participants should be comprehensive.
-Normal compensation (e.g Transportation) is ethical
-Excessive compensation/**undue influence** (Influence by rewards) is unethical

B.Special Populations and Vulnerabilities:

1.Children and Vulnerable Groups:
-Require surrogate consent & Children must provide assent alongside guardian consent
-Tailor ethical protections to the needs of cognitively impaired individuals, terminally ill patients, or those in compromised positions

2.Prisoners:
Participation must be free of coercion (Influence by threats), undue influence (e.g parole decisions)

C.Disclosure:
Researchers must inform participants about:
1.**Purpose** of study, **risks** and **benefits**, **Confidentiality** measures ,**Compensations** in case of injury & Contact **info**.
2. Right to **withdraw** without consequences, **alternatives** to the research protocol.

D. Special Cases:

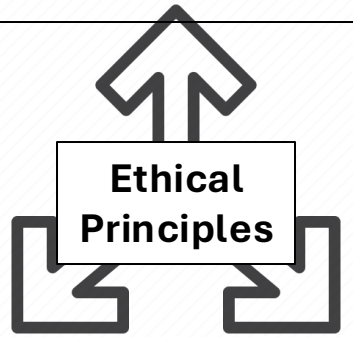
- **De-identified Data**: Consent is not required if the data contains no identifiers and the research involves no direct interaction with participants, However secondary analysis still requires IRB approval.

- **Biological Samples**: Consent forms must include a clause allowing the use of samples for future research, without identifying participants (using coded data) ensuring confidentiality is maintained.

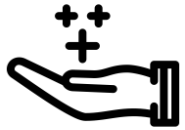
1.Risk: The likelihood of harm, which may be physical, psychological, social, or economic
Studies involving greater risks demand more rigorous monitoring and oversight

2.Benefit: represents the potential to enhance health outcomes or contribute to scientific knowledge.

Autonomy & Respect
Investigators should Respect participants' rights to make decisions.



Beneficence:
Maximize potential benefits and minimize risks or harm **(Belmont Principle)**



Justice
Ensure fair treatment, equitable distribution of risks and benefits, and inclusivity in research design

Participant Selection and Justice:

1.Equity and Inclusion:

- Participants should represent the population
- **Stratification in Sampling** based on prevalence rates (e.g., include more women for conditions affecting women disproportionately)

2.Fairness in Selection:

- Avoid exploiting vulnerable populations or selecting participants based solely on availability.
- Ensure fair distribution of risks and benefits among groups.

3.Balancing Equity and Equality: Treat individuals fairly (equity) rather than identically (equality).

In Poorly Designed Studies, if there is a mid-study protocol change, this require **IRB approval**

Data Analysis Ethics:

-No statistically significant different result must be published

-It is essential to investigate reasons for participant dropouts (e.g., adverse reactions), as failure to document adverse events can lead to inaccurate approvals, risking public safety

Blinding and Controls in Research:

1.Blinding: Single, Double, Triple.
- Some studies (e.g., surgical interventions) may not allow blinding

2.Controls
-Use appropriate control groups (e.g., active controls, randomized assignment, crossover design)
-Avoid historical controls (controls from previous studies) due to potential biases

Data Management and Reporting:

1.Privacy and Confidentiality: anonymity using coded or de-identified data, and store data securely and limit access.

2.Transparency and Publication:
- Avoid overstating benefits or creating false hope
- Publish all findings, including non-significant results, to maintain scientific integrity.
- Register clinical trials (e.g. at clinicaltrials.gov) to ensure transparency and accountability.

International Codes & Ethical Guidelines:

A. Nuremberg Code (1947): Permissible Medical Experiments Section, which included 10 directives for human experimentation:

1. Voluntary Consent **2. Necessity and Relevance**

3. Preceding Animal Trials: Human experimentation should only occur after sufficient animal testing

4. Avoidance of Suffering

5. Prohibition of High-Risk Experiments: Experiments with foreseeable risks of death or severe injury must not be conducted.

6. Risk-Proportionate to Importance **7. Minimizing Risks** **8. Qualified Investigators**

9. Right to Withdraw: Participants must have the freedom to withdraw from the experiment at any time.

10. Mandatory Termination: if the experiment becomes unsafe or poses serious harm to participants

B. Modern Guidelines: Adhere to WHO and local regulations, emphasizing global ethical standards.

Lecture 16 (Research Ethics and Good Clinical Practice)

Historical Context:

1.The Nuremberg Code (1947)

2.Declaration of Helsinki (1964)
-“In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.”

The Six Key Principles:

1.Integrity, Quality and Transparency of Research
2.Informed Participation:
Participants should typically receive clear and comprehensive information about the research, with exceptions only in specific contexts.
3.Confidentiality
4.Voluntary Participation
5.Avoiding Harm
6.Independence : Research must remain independent, with any conflicts of interest or partiality openly explicit

British Psychology Society (BPS) Code of Human Research Ethics:

1.Respect for the Autonomy and Dignity of Persons:
-Upholding moral rights, including privacy, self-determination, and fairness.
-Ensuring valid consent, confidentiality, and equitable treatment in research.

2.Scientific Value:
-contribute meaningfully to knowledge.
-Avoiding poorly executed research, which wastes resources and risks misleading outcomes.

3.Social Responsibility:
-Recognizing psychology's role within society and the collective responsibility for human and non-human welfare.

4.Maximizing Benefit and Minimizing Harm

Institutional Review Board/ Ethical Review Board/ Independent Ethics Committee (IRB/ERB/IEC): Reviews, approves, and monitors clinical research to protect human subjects.
Composed of at least 5 members & at least one scientist and one non-scientist : medical scientists, ethicists, legal experts, laypersons (Community-presenting members), subject experts according to the application, and possibly external chairs to ensure impartiality

The IRB may include consultants in their discussions to meet requirements for expertise or diversity, but only actual IRB members may vote.
IRB members may not vote on their **own** projects

-Responsibilities include:
1. Reviewing study protocols, consent forms, and participant recruitment strategies.
2. Ensuring equitable participant selection and minimizing risks relative to benefits.
3. Addressing conflicts of interest and monitoring for amendments or adverse events.

4. **Risk-Benefit Ratio:**
   A. must make sure that physical risk is not disproportionate to the benefits.

   B. When physical risks are minimal, IRBs ensure that psychological and social risks, such as stigma or discrimination, are not significant. Studies must not label participants in ways that harm their reputation, employability, or insurability.

The IRB should collect the following documents:

1. Trial protocols and amendments
2. Written informed consent forms and updates
3. Subject recruitment materials (e.g., advertisements)
4. Written information for subjects
5. Investigator's Brochure (IB)
6. Available safety information
7. Payment and compensation details for subjects
8. Investigator's current CV or proof of qualifications

Projects requiring Ethical Approval: Human participants, Use of the 'products' of human participants, or work done on humans, and animal part

Post study→ Notify the IRB upon study completion and provide a detailed report of the findings & Ensure that participants have access to the study results & continuous service after the trial.

Good Clinical Practice (GCP): Internationally recognized standards which ensure research is conducted ethically and data is credible (Authorities such as Food & Drug Administration work under GCP Guidelines)

Research must adhere to the **Declaration of Helsinki** and national/international standards.
Focuses on participant safety. Includes protocol adherence, monitoring, and investigator qualifications.
Researchers are encouraged to obtain and renew GCP certification **every two years** for compliance and global research eligibility.

The Core of Consolidated GCP Guidance (13 Principles):

1. **Clinical trials** must align with ethical principles rooted in the Declaration of Helsinki.
2. **Risk-Benefit Analysis**: Initiate and continue trials only if the benefits justify the foreseeable risks and inconveniences.
3. **Subject Rights Priority:** Prioritize the rights, safety, and well-being of trial subjects above scientific and societal interests.
4. **Scientific Validity:** Ensure trials are scientifically sound, backed by sufficient preclinical and clinical data, and described in clear, detailed protocols.
5. **Data Adequacy**: Ensure investigational products are supported by sufficient non-clinical and clinical information to justify the proposed trial
6. **Protocol Adherence**
7. **Qualified Medical Oversight:** Guarantee that medical care and decisions for participants are managed by qualified physicians or dentists.
8. **Competence in Execution:** All personnel involved in the trial must be qualified through education, training, and experience for their tasks.
9. **Informed Consent:** Obtain freely given, informed consent from every subject prior to participation, ensuring understanding and voluntariness.
10. **Accurate Data Management:** Record, handle, and store all trial information to allow accurate reporting, interpretation, and verification.
11. **Confidentiality**
12. **Product Integrity:** Manufacture, handle, and store investigational products in accordance with Good Manufacturing Practice (GMP) standards and use them per the approved protocol.
13. **Quality Systems:** Implement systems and procedures to assure quality across all trial aspects.

Benefits:

-A requirement for access to participants
-A requirement to comply with Research Excellence Framework (REF) to obtain funding (e.g ESRC)
-Researcher training and professional reputation.
-Product development for public health improvements (e.g., pharmaceuticals)

Research Ethics

Challenges and Risks in Research:

-Informed Consent: special consideration for minors
-Some may require Police Clearance
-Deception
-Need for debriefing
-Right to withdraw
-Confidentiality
-Safety and risk

Coded Private Information and Human Subject Research:

-Research with coded private information or specimens does not involve human subjects if:

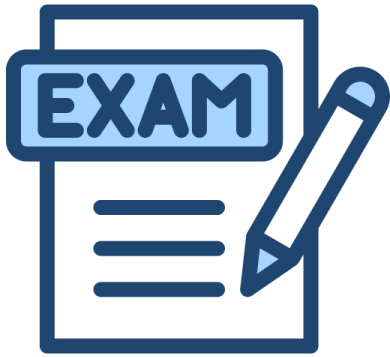
A. The private information or specimens were not collected directly from living individuals specifically for the current research project through interaction or intervention

B. When The investigator(s) cannot easily determine the identity of the individuals associated with the coded private information or specimens.

Example: You are an investigator proposing to use data from a colleague's database to conduct secondary analyses. Your colleague will provide coded data for your proposed studies, and you and he enter into an agreement by which he will keep the key to the code and will have no other involvement in the research. Does this study involve human subjects?

Ans: No, the data is coded and the investigator cannot readily ascertain the identity of individuals, and the colleague (who holds the key to the code) is not otherwise involved in the research

Past Papers 👩‍🏫



1.The minimum number for IRB committee members (E-learning)?

A. 7
B. 3
C. 2
D. 5

2.When we conduct phase 0 clinical trial, do we need to apply for IRB approval (E-learning)?

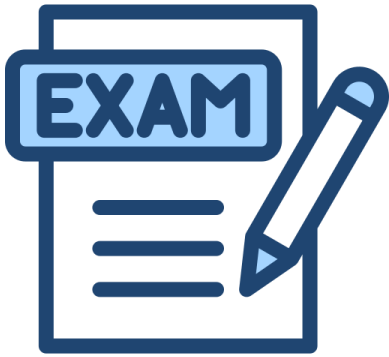
- No, we do not need to apply because the study is on animals not humans
- Yes, we need to apply for IRB approval

3.You will conduct a survey on knowledge of medical students about medical research, do you need to apply for an IRB approval (E-learning)?

- Yes, I need to apply for an IRB approval. The IRB committee will decide on the consent form. Whether or not I need to use it.
- No, I will not. It is a simple survey. No IRB approval and no consent form.

Answer: D/Yes/Yes

Past Papers 👨‍🏫



4.An offer of an excessive, unwarranted, inappropriate reward in order to obtain compliance is?
A. Coercion
B. Undue influence
C. Compensation
D. Autonomy
E. Benefits

5.Incorrect about good clinical practice (GCP) is?

Answer: B/ mainly focused on human rights in a cohort study

Lecture 17 (how to write a scientific paper)

Scientific writing: A precise way to explain what you did, what you found, and why it matters (clarity).

Journal impact:

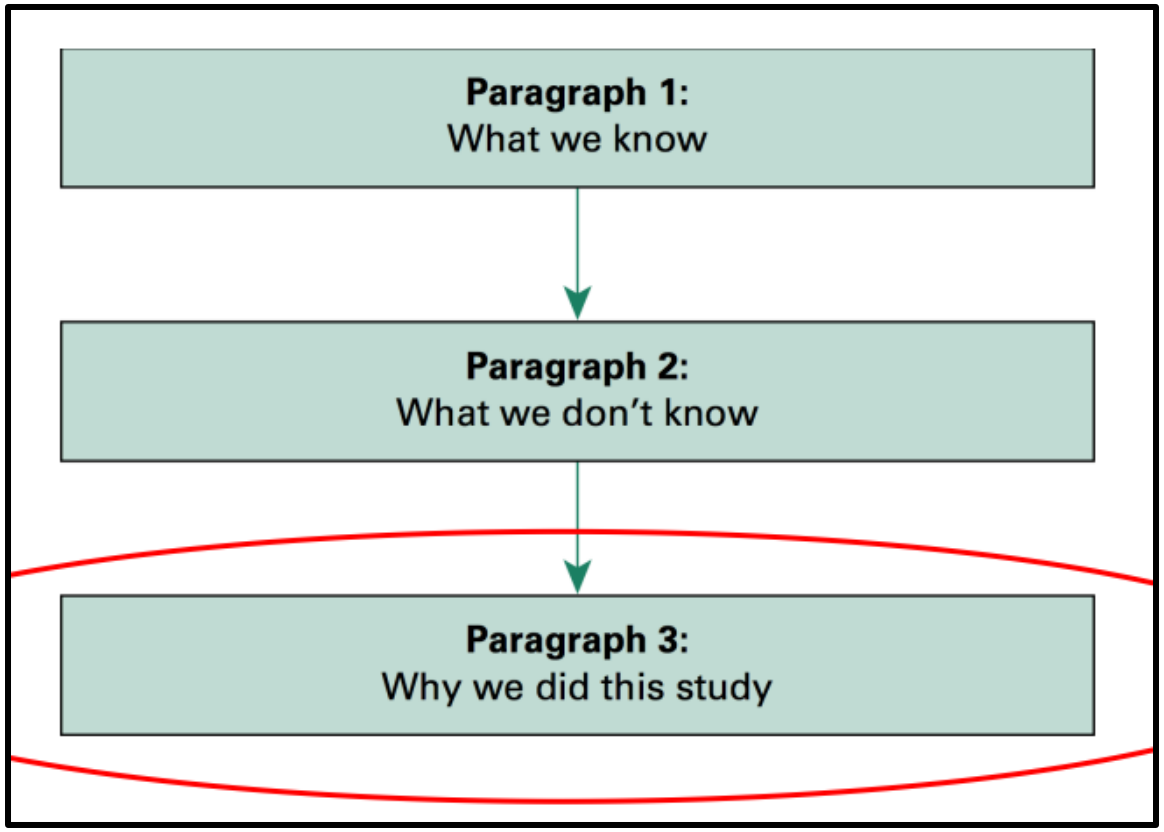
How to choose **which journal**? See if it matches your paper's topic, **impact factor**.
"**Very high impact**" journals only accept minority of papers, in addition to a lot of review, revision and publication.

Impact factor: A measure of the **frequency** with which the 'average article' in a journal has been **cited** in a particular year, it helps evaluate journal's importance.
Impact factor >5 considered very good.

Before submitting a paper, make sure your paper is short, clear, and can be understood.

1.Introduction: draw audience in, target journal specific audience, identify gaps in knowledge, end with question/hypothesis.

Be clear about what the problem you are addressing is and how your study proposes to answer this



2.Methods: Describe how you obtained your results in a way that others could replicate them, include: Study design/ Participants/ Sample size calculation/ Define exposures and outcomes/ Statistical analysis/Ethical approval.

3.Results: organize it around tables and figures, use past tense, state facts with no interpretation, **one paragraph per table or figure.**

No need to repeat background information.

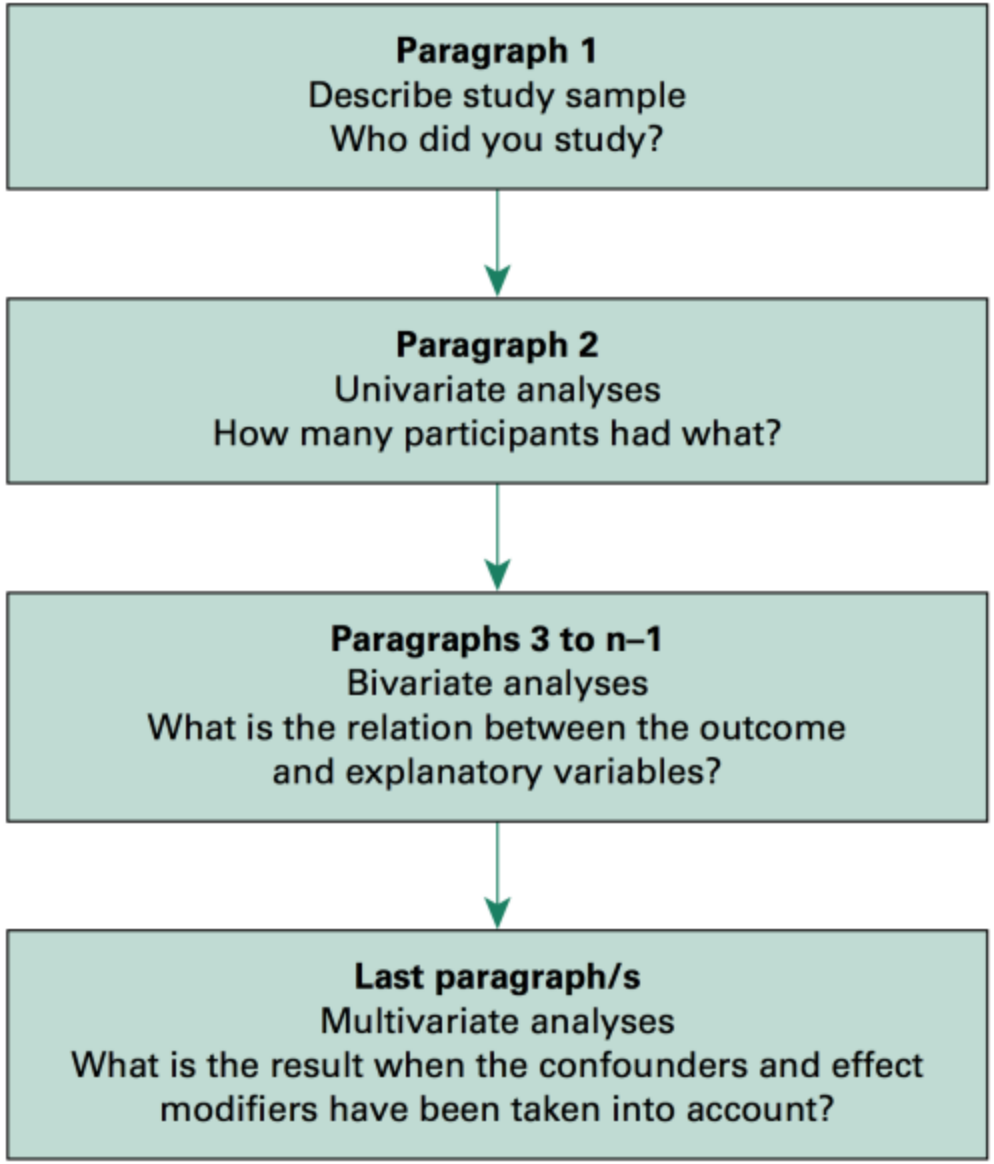
Regression analysis: just shown table for the statistically significant predictors.
If none is significant: just write few lines

First paragraph: starts with **key characteristics** and number of participants (gender, age). First table should be baseline characteristics.

Second paragraph: figure or table showing the primary outcome (key findings).

Other paragraphs: other outcomes, objectives, or analysis.

Last paragraph: we usually keep it for the multivariate analysis



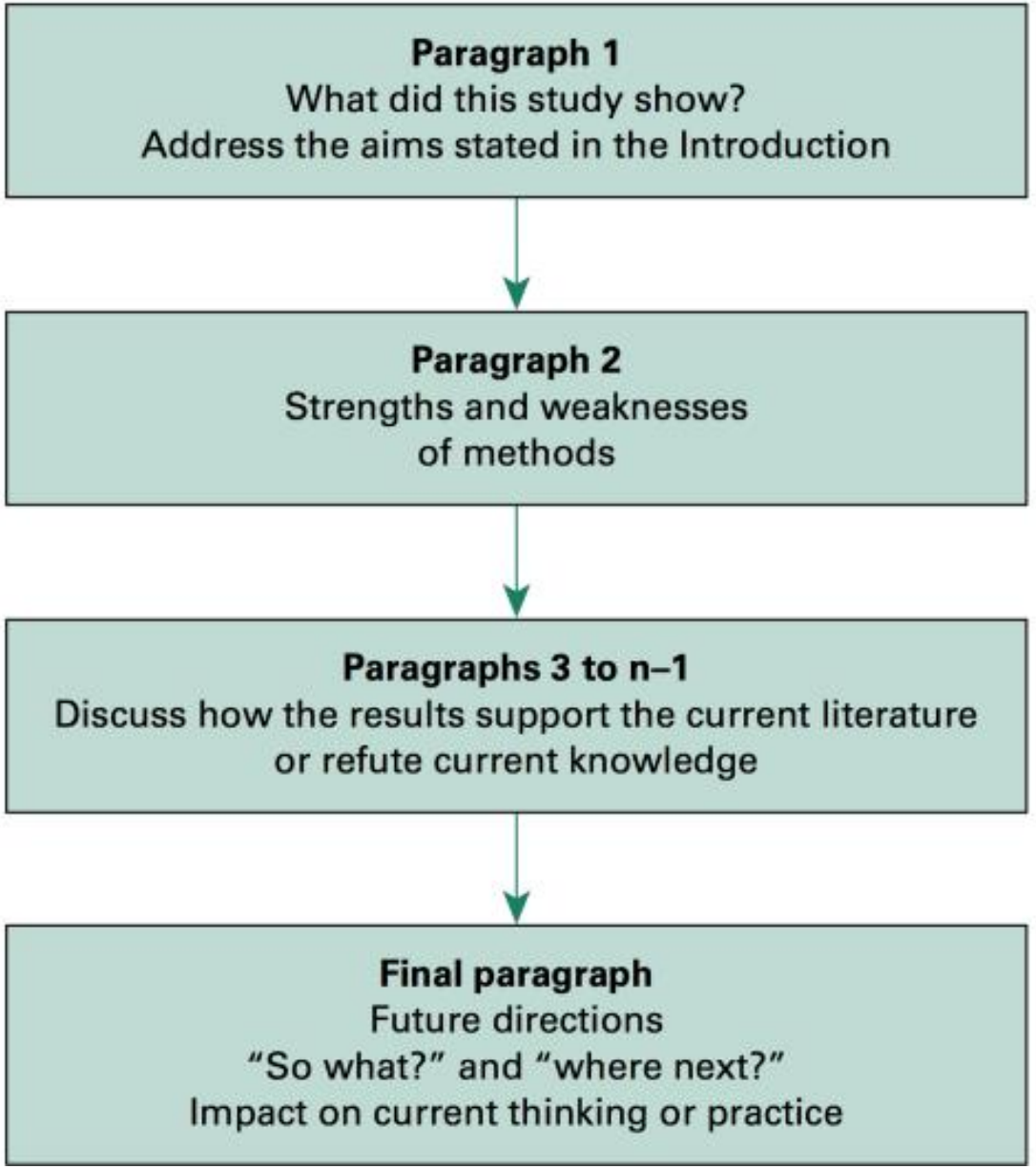
4.Discussion: Be **bold**, explain precisely what you have found and explain

First paragraph: what this study showed, answer question/hypothesis (**key findings**).

Second and third paragraphs: strengths and **weaknesses**, **compare** your findings with existing literature.
Implications of findings, **other** findings of your study.

Last paragraph: reemphasize the key finding and provide some key **directions**. Then we write the **conclusion** and **recommendations**.

Try to **avoid** concluding that "further research is needed"



5. Abstract:

Only convey the most interesting and important parts of your work , most journals require you structure the abstract, limit to 250 words (MEDLINE limit).

It's a minipaper:

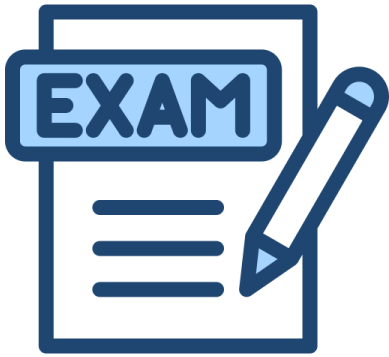
Introduction (usually 1-2 sentences)

Methods (often **longest** part)

Results (supported by data and p values, can be the longest part especially in cross-sectional studies)

Discussion/conclusion (limited to concluding statement)

Past Papers 👨‍🏫



1.The first paragraph of the discussion should include (E-learning):

A. Key finding
B. Reason of the study
C. study key limitations
D. main strength of the study

2.The first paragraph in the discussion should include (E-learning):

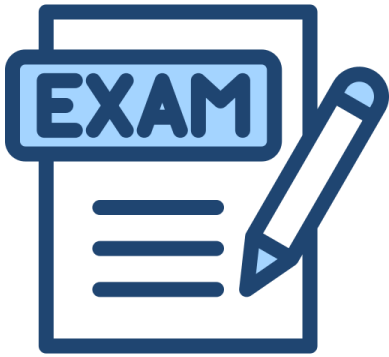
A. summary of the main result the study according to the primary outcome
B. Background results
C. Key recommendation

3.The first paragraph in result section is:

A. Main strength of study
B. State significant results according to the primary outcome
C. Reason of the study
D. Main study limitations

Answer: A/A/B

Past Papers 👨‍🏫



4.The first paragraph of results shows?

A. Univariate analysis

B. Bivariate analysis

C. Multivariate

D. Describes number of patients and their characteristics

E. Key limitations

Answer: D