Lecture 1

Research Known as:

1. systematic investigation to develop or contribute to generalizable knowledge. → (testable result)
   Research is an organized and systematic way of finding better answers to questions,inprove the quality of health and health care and understand phenomen to find the solution of problems.

2. It is a systematic process to better determine etiology, patho-physiology, epidemiology, diagnosis, therapy, prognosis and prevention

Methods

Research Methods are the tools and techniques for doing research.

prioritization

the feasibility of completing the work with available resources, time, subjects, tools, etc.

سؤال امتحان

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

information seeking: the ability to scan the literature efficiently, using manual or computerized methods, to identify a set of useful articles and books

critical appraisal: the ability to apply

principles of analysis to identify unbiased and valid studies.

Literature review :

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

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

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

Bias in the literature or in a review of the literature is a distortion of the available information in such a way that it reflects opinion or conclusions that do not represent the real situation.

Common types of bias:
◦ Playing down controversies and differences in own study
◦ Restricting references to those that support view of the author
◦ Drawing far reaching conclusions from preliminary result

The bibliography should give a clear, complete description of the sources that were used while preparing the report.

Plagiarism is using others' ideas and words without clearly acknowledging the source of that information.
Strategies for Avoiding Plagiarism
1. Put in quotations everything that comes directly from the text especially when taking notes.
2. Paraphrase, but be sure you are not just rearranging or replacing a few words.
3. Check your paraphrase against the original text to be sure you have not accidentally used the same phrases or words, and that the information is accurate.
Quotation: using someone's words. When you quote,

place the passage you are using in quotation marks,
and document the source according to a standard
documentation style.
 Paraphrase: using someone's ideas, but putting them
in your own words.
◦ Although you use your own words to paraphrase, you must
still acknowledge the source of the information.

Introduction

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

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

Team Members
 A group of individuals working toward a common goal: that's what a
research team is all about.

Principal Investigator (PI): Postpeper

this is the person ultimately responsible for the research and overall project

PIs are also typically responsible for writing proposals and grant requests, and selecting the team members.

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

may perform all or some of the PI
functions, but they do not accept primary responsibility for the research study

under the supervision of the PI and is
responsible for performing study–related procedures and /or to make important
study-related decisions in compliance with the ethical conduct of the study

Project or Research Director/manager

in charge of the day-to-day functions of the research
project, including protocol for how research and data collection activities are
completed.

also makes sure that the project is in compliance

with all guidelines, including governmental and institutional review board regulations.

3. Research Assistant:

individual, or individuals, perform the day-to-day tasks of the project, including collecting data, maintaining equipment, follow up samples collection and analysis, etc.

4. Biostatistician:

This is the individual who analyzes any data collected during the project.
 Sometimes they just analyze and report the data, and other times they are more involved in the organization and analysis of the research throughout the entire study.

Authorship confers credit and has important academic, social, and financial implications.
1)Authorship also implies responsibility and accountability for published work
2)Editors are strongly encouraged to develop and implement a contributorship policy.
3)All those designated as authors should meet all four criteria for authorship,

Coauthors

and all who meet the four criteria should be identified as authors
The individuals who conduct the work are responsible for identifying who meets these criteria and ideally should do so when planning the work, making modifications as appropriate as the work progresses.

The corresponding author

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

a **large multi-author group** has conducted the work, the group ideally should decide who will be an author before the work is started and confirm who

3. Non-Author Contributors

is an author before submitting the manuscript for publication

meet fewer than all 4 of the above criteria for authorship
should not be listed as authors, but they should be acknowledged

Second lecture

A study Design

is a
specific plan or protocol
for conducting the study,
which allows the
investigator to translate
the conceptual hypothesis
into an operational one.

a. Descriptive
Case reports and case series
Descriptive analysis (Person place time)
Ecological (correlational)
Surveys and Cross-sectional studies
b. Analytical
Case Control
Cohort

Descriptive studies attempt to uncover and portray the occurrence of the condition or problem.provide insight, data, and information about the course or patterns of disease or drug use problems in a population or group

analytical studies determine the

causes of the condition or problem.test cause–effect relationships, and they usually rely on the generation of new data.

Surveys

1. 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 draw.

other types of studies

① Retrospective

related backward to Measure risk factors or protective one related exposures without comes. Colonic Cancer, breast Cancer.

مثال يجي عنا مريض سرطان نسأل عن الوراثة كان سترب يدخن يلعب رياضة بوكل وجبات سريعة وغيرها الآن مرحلي / حتى على مستوى الجينات والاقارب العقارب.

② Prospective

only the developing of disease related risk factor or protective one. "During studing period."

Researches of corona virus when pandemic happen والي how effect related smokers and Non-Smokers

1.

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

(2) Non-experimental research design used primarily to measure characteristics of a population

 A research method based on self reported information from participants rather than on observations or measurements taken by researchers

Sources include: medical examinations, interviews, observations, etc.

Advantage: less measurement error, suits objectives of the study better.

Disadvantage: costly, may not be feasible

Classifying Survey Research Methods

1. By method of communication.

a) Personal Interviews

b) Telephone interviews

c) Self-administered interviews

2. By degree of structure and disguise.

a) Structured disguised

b) Structured undisguised

c) Unstructured disguised

d) Unstructured undisguised

3. By time frame (Temporal classification).

a) Cross-sectional surveys

b) Longitudinal surveys

By degree of structure and disguise

Disguised (indirect): When the purpose of the data collection is not told to the respondents and asked in indirect manner

Undisguised (direct): purpose of data collection is known to respondents.

Temporal Classification of Survey Research

1. Cross-sectional studies: studies in which various segments of a population are sampled and data collected at a single point in time. (also to measure prevalence of certain factors or diseases)
2. Longitudinal studies: studies in which data are collected at different points in time

 Focus on personal and demographic characteristics, illness and health related habits
 These surveys may also examine frequencies of disease and other characteristics may be examined in relation to age, sex, location, education, etc

ADVANTAGES OF SURVEYS

Good survey measures must be grounded on sound theory and conceptual definitions
Can complete structured questions with many stakeholders within a relatively short time frame.
✓ Can be completed by telephone, mail, fax, or in-person.
✓ It is quantifiable and generalizable to an entire population if the population is sampled appropriately.
✓ interviewer bias.Standardized, structured questionnaire minimizes
Tremendous volume of information can be collected in short period of time.
✓ Speed: faster data collection than other methods
✓ Cost: relatively inexpensive data collection
✓ Accuracy
✓ Efficiency: measured as a ration of accuracy to cost, surveys are generally very efficient data collection methods

Disadvantages of survey

More difficult to collect a comprehensive understanding of respondents' perspective (in-depth

information) compared to in-depth interviews or focus groups.

➢ Survey error: Potentially large sources of error in Surveys

➢ Communication Problems - Each of the different communication survey methods has its own unique problem

Definition of Questionnaire

A series of questions designed to gather information on a certain subject from a respondent

#Related to case report:

A Case Report Form is a document recording all the patient clinical information (past medical history, diagnosis, investigations, treatment, complications, finance data) based form their medical records/files, as required by the study protocol.

*In case of ready to use questionnaires, to collect relevant additional data such as demographics and predictors of response such as socioeconomic status and medical history

 Questionnaire to assess outcomes in clinical trials and other research methodology

 To collect data on variables relevant to research methodology such as predictors of response to treatment.

Structured versus unstructured

▪ In a structure interview each question is clearly defined and given a rigid sequence.

▪ An unstructured interview resembles a discussion with the interviewer leading it.

Important:! متى نستعمل هاظ الاشي؟

There is a large sample

 You want fairly straightforward information

 You want standardized data from identical

questions and preferably in the presence of

a reference manual

Strength:

#Reach respondents in widely dispersed locations
 Can be relatively low cost in time and money
 Relatively easy to get information from people quickly
 Standardised questions
 Analysis can be straight-forward and responses pre-coded
 Low pressure for respondents
 Lack of interviewer bias in case of selfadministered questionnaires

Types of Questionnaires

1. Face to face (personal) interview

Advantages
◦ participation of illiterate people
◦ clarification of ambiguities
◦ quick answers
 Disadvantages
◦ interviewer bias
◦ needs more staff resources
◦ difficult for sensitive issues
◦ Time needed
#expensive🤑

2. Self-completed questionnaire

Mailed

Completed by respondent
► Requires literate respondent
► Variable completeness of answers
► Low-cost
► Low response rate
► No instructions or check on incomplete responses: Instructions cancer be provided but incomplete response is still a limitation

1)Self administration

 Self-administered questionnaire (as opposed to interviewer administered) requires:

▪ More instruction for respondent
▪Clear-cut, unequivocal wording
▪ More pre-coded questions
▪A separate coding sheet for analysis

Advantages

 cheap and easy to administer
 preserves confidentiality
 completed at respondent's convenience
 not influenced by interviewer

 Disadvantages

 low response
 questions can be misunderstood
 no control by interviewer
 only literate persons
 time delay (post

2)Telephone interviews

Wide coverage rate
► Standardization depends on interviewer
► Medium cost: lower cost than personal interviews
► Can be conducted quickly
► Miss those without a telephone or at work
► Interviews have to be kept short
► Medium response: better response rate than mailed questionnaire

Sampling techniques

► The population is all the members of the

group you are researching (e.g., all youth in our city)
► The sample is the selection of the population who will be asked questions
► To generalize is to state that what you say about your sample can be applied to the rest of the population

General limitations of questionnaires

 Can be superficial - difficult to capture the richness of meaning
 Information is not causal - cannot attribute cause-effect relationships
 Information is self-report - which does not necessarily reflect actual behavior
 Cannot deal with context - information is collected in isolation of environment
Low response rate and consequent bias and confidence in results
 Unsuitable for some people
Misunderstandings cannot be corrected

Types of Questions

A.Open-end questions

 No predetermined responses given
 Able to answer in own words
 Useful exploratory research and to generate ideas
 Flexible
 Requires skill in asking questions and interpreting results
 Answers can lack uniformity and be difficult to analyze
More demanding and time-consuming for respondents

 More difficult to analyze and interpret

Example: “Please describe your ideal boss.”

 Advantages

◦ Allows a much greater range of responses

◦ Allows for creativity

◦ May find unanticipated results

 Disadvantages

◦ Statistical analysis is very difficult

◦ Large variety of responses

◦ Takes much longer

◦ Interpretation of results is more difficult

B. Close ended questions

 Respondent selects a response from those provided on the questionnaire

 Less time consuming and easier for respondent

 Requires more effort to develop questions

 May oversimplify an issue

 Response categories must be inclusive and non-overlapping (i.e., mutually exclusive

Two-choice

Multiple choice

Checklist

Numerical

Ranking

Rating

Advantages:

1. Easier for participants to respond
2. Standardization
3. Easy to count and analyse
4. Easy to interpret

- Disadvantages:

1. May not have catered for all possible answers
2. Questions may not be relevant or important
3. Answer options can influence responses

Screening or Filter Questions:

are used to ensure respondents included in the study are those that meet the pre-determined criteria of the target population.

SENSITIVE QUESTIONS

- Researchers sometimes ask sensitive questions in surveys.
- Respondents are often hesitant to answer sensitive items, so item non-response on these questions is normally higher than for other questions in a survey.
- Some respondents may even stop taking the survey because a sensitive question turns them off from the process.

It is generally not a good idea to start the survey with any question that touches on something private.

1. If the respondent chooses to stop the survey once he or she reaches the sensitive questions, you still have the respondent's answers to all questions beforehand, which you can use for other analyses.
2. The respondent works through the easy, unthreatening questions, he or she may feel as though trust is being established, and will be more likely to answer the question asking the sensitive information.

هاد صح؟ لا

Don't Use in your research: ① abbreviation ✗ ② Specific Q "Firstly" ✗ ③ Jargons ✗ ④ "Self-Confidence" ✓ ⑤ "be Kind" ✓ ⑥ Complex Q ✗ ⑦ "Use Indirect Questions to get information" ✓ ⑧ "Just smile" ☺

Third lecture :questionnaire design

- Clarify the nature of the research problem and objectives.
- Develop research questions to meet research objectives.
- Define target population and sampling frame.
- Determine sampling approach, sample size, and expected response rate.
- Make a preliminary decision about the method of data collection.

- it's just have good appearance, simple and short.
- logical, too easy.
- Minimizing of Bias - *How to select the type of Questionnare?

1. Determine the types of questions to include and their order.
2. Check the wording and coding of questions.
3. Decide on the grouping of the questions and the overall length of the questionnaire.
4. Determine the structure and layout of the questionnaire.

*Structures of Questionnare?

1 Identification

2 Interview introduction (A) (Who/Why/Where/HOW)

(B) usefulness of study should be clear to all respondents

(C) Lenght of Interview.

3 Instructions on how to answer

Minimise potential sources of bias

- Guide for Interviewers
- Guide for Respondents in self-administered questionnaires

Interviewer guidance manual helps to reduce bias and to improve reliability

Related On presentation.

Clear and consistent

▯ adequate space to answer

◦ large font size

◦ appropriate page breaks

▯ avoid

▯ messy layouts

▯ too many and fancy logos

Question order related from general(simple)➡️➡️difficult(specific)

"Door-opener"first question

◦ Simple

◦ Closed format

◦ Relevant to main subject

◦ Non-offending

◦ Demographic but personal questions

وبعيد ونزيد نحاول قدما نقدر نوصل ل formكويس ومفهوم للأسئلة في بدايه النقاش

Responding audience

4 Questions

5 Conclusion تذكر انك دكتور كيوت اشكر الي قابلتهم بالبحث

Step 1: Define the aims of the study

بدك تحدد الهدف من البحث الي انت عامله عشان تزبط كل امورك غير الخطة الي انت واضعها للكتابه للبحث!

Set at point of your questionnaire and the problem that you want to study (one sentence per point)

Set the target population

Step 2: Define the variables to be collected

Write a detailed list of the information to be collected and the concepts to be measured in the study.

Translate these concepts into variables that can be measured.

Define the role of each variable in the statistical analysis:

- Predictor
- Confounder
- Outcome

Step 3: Review the literature

Review current literature to identify related surveys and data collection instruments that have measured concepts similar to those related to your study's aims.
Proceed with caution if using only a subset of an existing questionnaire as this may change the meaning of the scores.

Step 4: Compose a draft :

Determine the mode of survey administration: face-to-face interviews, telephone interviews, self-completed questionnaires, computer-assisted approaches.
increase response on the important measures even in partially completed surveys.
 Make sure questions flow naturally from one to another.

Step 5: Revise

Shorten the set of questions for the study.
 If a question does not address one of your aims, discard it.
 Refine the questions included and their wording by testing them with a variety of respondents.

Step 6: Assemble the final questionnaire [1]:

Just decide about your information based on computer analysis or your analysis.

- [ ] About ethical ethics all in the lecture 8 I think!😎#
- [ ] **Pilot Test:** Pilot it with the target group and as you

intend to

Evaluate and modify on basis of pilot

an evaluation of the specific questions, format, question.

 sequence and instructions prior to use in the main survey.

 Pilot testing is a crucial step in conducting a survey. Even modest pretesting can avoid costly errors.

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 Concurrent validity	Validating an instrument by comparing it with a currently accepted reference measure[5] 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)	Correlation coefficient, correlating the measure with some other accepted "criterion", ideally a gold standard[6]

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.

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

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 w… not cases and test negative on the measure

6

Definitions of terminology used in ready to use questionnaires selection	
Instrument	A questionnaire or interview or simple test (or some 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, eg 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

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**

* After piloting you should administered it & Conduct survey including Protocol for & Maximizing response rates.

Bias

Systematic difference in the response measurement.

- 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

How to reduce bias

Structured questionnaire

- Ensure high response rate
- Pretesting and piloting
- Training of interviewers

A. Generic questionnaires:

It should be always considered that these measures are less responsive changes in health when compared with disease specific questionnaires.

Limitations:

- They may be insensitive to subtle but specific disease.

important changes in status with respect to a

- They should be validated across a spectrum

B. Disease or population specific questionnaires:

They are designed to target particular population or patients group.

Such as angina pectoris, asthmatic patients and diabetes millitus.

C. Dimension specific scales/questionnaires:

These focus on particular aspects of health

- The Beck depression inventory is an example
- Some questionnaires measure functional ability; the Barthel index and Townsend's disability scale are examples.

Appropriateness: of the measure to the question or issue of concern

- Correspondence between the content of the measure and goals of the study
- Evidence in relevant populations of:

Reliability, Validity, Responsiveness

If no previous evidence, you need to assess them

For translated questionnaires, the translated version should be validated.

▪ Practical considerations:

Mode of administration

 Time to administer

 Language

 Respondent burden

 Availability of supporting materials

Exclusion criteria: exclusion of subject with psychological conditions. Sometimes it is secondary to the condition.

Validity: question measure what you claim it measures

 Reliability: results are reproducible or consistent with similar

Lecture 4

Studying design

Just specific plan or tool or protocol for conducting study, which allows the investigator to translate the conceptual hypothesis into Operational one.

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

* types or selection of sample :

▪Probability sample survey

•Systematic sampling

oRecord reviews

oStudies of health care workers

•Cluster sampling

oUsed in surveys of widely dispersed populations

Very important definitions:

* A study unit may be a person, a health facility, a prescription, or other such unit.
* *The study population*, sometimes called the reference population, is the collection of the entire population of all possible study units. Again, this population may be people, health facilities, prescriptions or other such 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 of the available units in the study population. If a complete listing is available, the sampling frame is identical to the study population. The method of sampling depends on whether there is a sampling frame available. If a sampling frame exists, or if it can be created, probability sampling is used. If there is none available, probability samplings cannot be used

using non-probability methods is likely to be less representative than a probability sampling and so study results are less valid.

*Non probability Sampling:

1. Convenience Sampling

is a method by which, for convenience sake, the study units that happen to be available at the time of data collection are selected in the sample. This is the least representative sampling method.

2.Quota sampling

is a method by which different categories of sample units are included to ensure that the sample contains units from all these categories. For example, a quota sample of patients from a health center that might included 10 patients with diabetes, 10 with diarrhea, and 10 with malaria.

* Types of Probability samples:

Simple Random Sampling-1

a) Make a numbered list of all units in the reference population from which you will select the sample (for example, a list of all the health

centers in the country).
b) Decide on the size of the sample (say 20 facilities).
c) Choose the facilities to include by a lottery method. (For example the numbers of all the facilities can be placed in a box and drawn, a random number table can be used, or random numbers can be generated using a spreadsheet or calculator.)

* Random numbers to select elements from an ordered list .

2. Systematic Sampling

In systematic sampling, sample units are selected from a numbered list of all units in the study population by using a regular interval, starting from a random sampling starting point.

To calculate the sampling interval,

•Determine the total number of units in the population

* Sample Interval = $\frac{\text{num. of Unit}}{\text{Desired Samp. Size}}$

3. Stratified Sampling

Stratified sampling is used when the reference population contains clearly different sub-populations, which should be considered separately. the sample frame (the list of the overall population) is sorted into two or more groups. These different strata (groups) may then be sampled either randomly or systematically.

▪Basis for grouping must be known before sampling
▪Select random sample from within each group

Advantages:

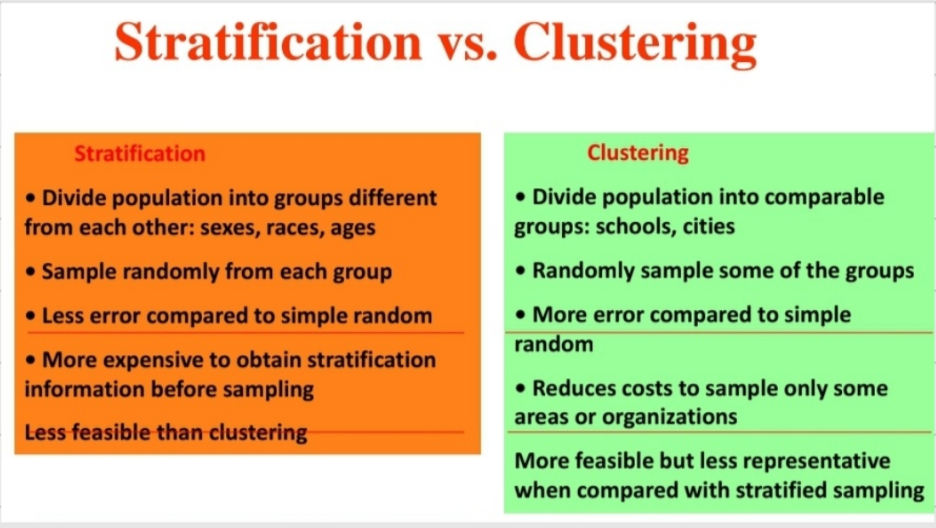
▪Basis for grouping must be known before sampling
▪Select random sample from within each group
Reducing the error compared simple Random sampling.

4. ***Cluster Sampling***

▪ Cluster sampling: Dividing the population into subgroups called clusters (not as homogeneous as strata), randomly sampling clusters, and then possibly selecting a random sample of people in each cluster.

Advantages and disadvantages

▪The main advantage of cluster sampling is that the method is easy to use
and often logistically simpler to organize.
▪The disadvantageis that the samples selected may be less representative especially when the number of clusters selected is small. As a rough guide, double the sample size if cluster sampling is used.



5. Multistage Sampling

In multistage sampling, the methods described above can be combined. For example, we might wish to select 32 health facilities in a country containing 56 districts, each of which contains a number of health facilities. From the 56 districts, 16 districts would first be selected. In each district two health facilities would then be randomly selected. This would be two-stage random sampling.

Lecture5:Descriptive studies

Introduction

Provides information about disease patterns or drug use problems by various characteristics of person, place, and time.

• It also is used by epidemiologists to generate hypotheses regarding The causes of disease or drug use problems.

Observational epidemiology only descriptive and analytical one.

Descriptive studies: provide insight, data, and information about the course or patterns of disease or drug use problems in a population or group.

• ***Analytical studies*** are used to test cause–effect relationships, and they usually rely on the generation of new data.

Case report. **Vs.** ***Case series***

Single patient only report one clinicans Related one history ~ groups "number of patients" ~ Description of Cases. ~ many Clinicans ~ given Diseases

✱Clinician finds ***unusual features of a disease or effects of a drug, or the patient's medical history, that lead to the formulation of a new research question or hypothesis.***

#case report: 🥲

The most common type of study published in the medical literature.

Advantages

They note unusual medical occurrences, identify new diseases, and describe adverse effects from drug therapies.

administration of a drug (the challenge) might be suspected of producing a specific symptom (side effect or adverse reaction).

• Administration of the drug can be stopped to observe whether the side effect or adverse reaction diminishes.

• If it does, then administration of the drug can be resumed (the rechallenge) to observe whether the effect returns, suggesting a possible relationship between the two events.

£case series:🍲

Usually a coherent and consecutive set of cases of a disease (or similar problem) which derive from either the practice of one or more health care professionals or a defined health care setting, e.g. a hospital or family practice.

*Advantiges:

1.Helps professionals can build up a picture of the natural history of a disease.
2.systematic extension of this series but which includes additional cases
3.Add breadth to the understanding of the spectrum and natural history of disease.

#Dis Advantiges :

1)Usually we cannot estimate the prevalence or incidence rate.
Example:
Breast cancer registry in Jordan: We cannot provide prevalence rates without
1. Population size
2. Time- period of data collection
3. All cases of breast cancer are registered

2)without controlling groups

Notes:
Case-series **can provide the key to sound case control and cohort studies and trials.**
• Design of a case-series is conceptually simple
• Defines a disease or health problem to be studied and sets up a ***system for capturing data on the health status and related factors in consecutive cases.***

Registry(definition):

1. ***as the act of recording or registering and as the record or entry itself.***
2. ***can refer to both programs that collect and store data and the records that are so created.***

Just special form of Case series.

3. [an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s)]."

Disease Registry can provide data to:

•Describe **the patient population**
•**Identify patient sub-groups having the most need**
•Identify **who is in the sub-groups**
•**Show** the 'reach' of **intervention programs**
•**Show the outcomes of intervention programs**
• **Pharmacovigilance: supports reporting of ADRs**

#Types of Registries

■**Mortality registry**
• An important thing to know about your patients
■***Research Patient Registry***
• Clinical Trials
■**Disease or Condition Registries**
• disease or condition as the inclusion criterion.
Disease or condition registries use the state of a particular
• sclerosis registry, bleeding disorders.
One disease or group of diseases: Cancer registry, multiple
■**Service, intervention, device registry**
[BMT registry, Biosimilars registry Patient R]

Coverage:

Hospital or clinic based: Do not use for calculating incidence
• **Local**
• **Regional**
• **National: Excellent for calculation of incidence if there is a valid and reliable surveillance system in place.**
• **International .**

Registries VS RCT's

• ***RCT***
• Best for assessment of
therapeutic efficacy
• ***Registry***
• Therapeutic effectiveness
• Safety/harm of therapy

• Generalizability to populations

• ***Key Difference***

• ***Registries do not randomize***

Regestries Uses in:

1) Observe the Course of Disease.
2) Understand Variations "Treatments, Outcomes".
3) Factors → Prognosis, Quality of life.
4) Health Care system Quality.
5) minoter safety and assess effectiveness.

Second part :

Components of Regestries:

1)Personal domain:

"• Consists of data that describe the patient, such as information on patient demographics, medical history, health status, and any necessary patient identifiers."

2)Exposure domain:

"Describes the patient's experience with the disease,medication, device, procedure, or service of interest to the registry. "

• Exposure can also include other treatments that are known to influence outcome but are not necessarily the focus of the study, so that their confounding influence can be adjusted for in the planned analyses.

• Baseline assessment and storage of samples

3)Outcome domain:

"Consists of information on the patient outcomes that are of interest to the registry".

• This domain should include both the primary endpoints and any secondary endpoints that are part of the overall registry goals.

Ecological studies:

Are studies in which information on the characteristics and/or exposures of individual members of the population groups are generally not obtained. Existing statistics are used to compare the mortality or morbidity experience of one or more populations with some overall index exposure. care is needed to avoid the 'ecological fallacy' where inappropriate conclusions are made from ecologic data.

*Usage:

1. describe disease or drug use problems in relation to some factor of interest.
2. *Ecological studies are the first identified strong relationships between disease and behavior.*
3. In ecological studies the unit of *analysis is some aggregate individuals rather than individual persons*.
4. ▪Geographic areas or time period are *often used asa basis for defining aggregates .*
5. ▪The analysis centers on *determining whether the ecological units with a high frequency of exposure are also unit with a high frequency of disease (+ve correlation) or a low frequency of disease (- ve correlation)*
6. related between exposures and outcomes "association" in Population Rather than endiviuals.
7. Related Corelation Coefficent (rs).
8. Linear relation ex VS OC -

#ADVANTAGES:-

1. *An ecological study is quick and cheap to conduct.*
2. *It can generate new hypotheses.*
3. *It can identify new risk factors.*

Disadvantages:

1. It is unable to control for confounding factors. This is often referred to as 'ecological fallacy', where two variables seem to be correlated but their relationship is in fact affected by cofounding factor(s).
2. It cannot link exposure with disease in individuals as those with disease may not be expose.
3. Its use of average exposure levels masks more complicated relationships with disease.
4. Its units of study are populations not individuals. Therefore, the disease rates linked with population characteristics and the association observed at group level

does not reflect association at individual level.

Cross-sectional studies (prevalence):

Are studies in which a defined population is surveyed and their disease or exposure status determined at one point in time.

▪*The prevalence rates of disease in the whole population as well as in those with and without the exposure under investigation can be determined.*
▪*Cross-sectional studies are generally not suitable for a disease which is rare or of short duration as few people will have the disease at any one point in time.*
Cross-sectional studies are generally not suitable for a disease which is rare or of short duration as few people will have the disease at any one point in time.

Usage:

*1)*Emphasis is on differences between groups at one point in time.
2)• They provide a one-time glimpse at the study population, showing the relative distribution of conditions, diseases, and injuries—and their attributes—in a group or population.
3)• Point prevalence versus Period prevalence.
4)*More effective in identifying chronic diseases and problems*
5)• Less effective in identifying communicable diseases of short incubation periods and short durations.
6)provide health care system and medical program.
*7)*Assessment of the burden of diseases or healthcare programs leads to setting priorities at the organization,local or national levels.
8)They are based on a sample of the whole population and don't rely on individuals presenting themselves for medical treatment.

#Exposure and outcome are assessed simultaneously among individuals in a defined population, thus at one point in time
• No sampling of individuals based on a exposure or an outcome

Advantages:

Relatively quick
• Data on all variables is only collected once.
• Sample size depends on the question
• Standard measures used
• Prevalence estimated
• The prevalence of disease or other health related characteristics are important in public health for assessing the burden of disease in a specified population and in planning and allocating health resources.
• Good for descriptive analyses and for generating hypotheses

Disadvantages:

They cannot show cause–effect relationships.
Difficult to determine whether the outcome followed exposure in time or exposure resulted from the outcome.
• If the sample is not representative, results are representative only of the individuals who participate in the studyExample prevalence of sickle cell anaemia in the Easter region of the KSA does not represent the who country.
• Not suitable for studying rare diseases or diseases with a short duration.
• Unable to measure incidence
• Associations identified may be difficult to interpret.
• Susceptible to bias due to low response and misclassification

Lecture6:analytical studies:

Cohort study(prospective one)

Are studies in which people are identified and grouped with respect to whether or not they have been exposed to a specific factor.

▪ The groups are followed up over time to determine whether the incidence of a particular disease is any greater (or less) in the exposed group than in the nonexposed group.

▪The starting point is *the risk factor!*

#Primary purposes:

Descriptive (measures of frequency)

– To describe the incidence rates of an outcome over time, or to describe the natural history of disease.

▪ *Analytic (measures of association)*

– To analyze associations between the rates of the outcomes and risk factors or predictive factors.

the best observational one for establishing cause–effect relationships.
• Prevention and intervention measures can be tested and affirmed or rejected.
• Cohort studies consider seasonal variation, fluctuations, or other changes over a longer period.
• Objective measures of exposure, such as biological markers, are preferred over subjective measures.

Strenghts(Advantages):

1)We can measure incidence of disease in exposed and unexposed groups

2)• Can get a temporal (time related) sequence between exposure and outcome as all individuals must be free of disease at the beginning of the study.

3)• Good for looking at effects of rare exposures.

4)• Allows for examination of multiple effects/diseases of a single exposure.

5)• Not open to bias as much as other types of study

6)• Direct calculation of the risk ratio or relative risk is possible.

7)• Provide information on multiple exposures

Limitation (Disadvantages):)

• Not efficient for rare diseases
• Can be expensive and time-cosuming
• Large sample
• Drop-out biases

If study goes over many years, can get considerable loss to follow up. This can 'dilute' results or lead to bias, and therefore the validity of result can be seriously affected

• Locating subjects, developing tracking systems, and setting up examination and testing processes can be difficult.
• Changes over time in diagnostic methods, exposures, or study population may lead to biased results.

***Good note:

• **Rare disease**: we conduct case control study starting with cases.

• **Rare risk factor**: we conduct a cohort study starting with rare risk factors.

Measurement of risk

$$Risk\ (R) = \frac{\text{No of people becoming ill during the period of observation}}{\text{No of people exposed at the beginning of the period}}$$

It is proportion (0 - 1)

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

- **RR=5** means that the probability to develop the disease in the exposed is 5 times the probability to develop it in the non exposed

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.

Preventive fraction

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

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

Steps "Cohort Study"

1. *Exposed and unexposed subjects must be free of the outcome of interest at the start of the study and equally susceptible to developing the outcome during the course of the study.(selection of subjects).* A
2. *Frequency of examination and duration of follow-up depend on the type of exposure and the outcome under investigation.*
3. *The degree of surveillance should be similar in exposed and unexposed groups.*
4. *Both groups should be accessible and available for follow-up.*
5. *• Multiple comparison groups for exposed subjects chosen in differentways may reinforce the validity of findings.*

Notes:

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

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

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

- e.g. smokers
- e.g. radiation

4)healthy worker effect:(pastpaper)

phenomenon of workers usually exhibiting overall death rates lower than those of the general population due to the fact that the severely ill and disabled are ordinarily excluded from employment.

*****Original cohort study is prospective but it can be retrospective one.how?!

Uses information on prior exposure and disease status.

- All of the events in the study have occurred and conclusions can be drawn more rapidly.
- Costs can be lower
- May be the only feasible one for studying effects from exposures that no longer occur, such as discontinued medical treatments.
- The main disadvantage of a retrospective cohort study is that the investigator must rely on existing records or subject recall.

***Ambidirectional Cohort:

Data collected both retrospectively and prospectively on the same cohort to study short and long term effect of exposure.

***Loss during follow up:

Following subjects over a long period of time can lead to a variety of problems.

- Dropouts and losses of subjects to follow-up are major problems in cohort studies.
- Subjects may move away or leave the study for other reasons, including deaths from other causes than the disease under investigation.
- If losses to follow-up are significant during the study, then the validity of the results can be seriously affected.

***Changing in exposure status:

It is also possible for exposure status to change during the course of the study.

• The exposure under study may be subject to variation over time.

***Analysis:

based on exposure, are divided according to variables of interest, like analysis in a cross-sectional study.

• Rates for subgroups are then calculated and compared.

• Data from cohort studies are analyzed in terms of relative risk and attributable risk fractions.

**Midpoint analysis:

Occurs 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.

Case Control study:(Retrospective Study)

Are studies in which a group of people with a particular disease (the cases) are compared with a group of peoplewithout 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.

- This type of study is done to identify factors that could be responsible for the development of a disease or drug use problem.

Designed to assess association between disease occurrence and exposures (e.g., causative agents, risk factors) suspected of causing or preventing the disease.

Compare exposure to risk factors in both groups

• Able to look at many different possible risk factors

• Able to study diseases with a long latency period

• Most common analytic study design seen in the medical literature today

In general, **the cases included in a case-controlstudy include people with one specific disease only.**

▪But, a case-control study ***can provide information on a wide range of possible exposures that could be associated with that particular disease.***

▪Useful for the study of rare diseases

▪Not suitable for the study of rare exposure(only cohort).

▪Relatively small and inexpensive

▪Takes *a relatively short time to complete*

▪*Can test current hypotheses*

▪*Cannot measure disease incidence*

challenges:

- *Selecting case*s
- Eligibility
- *Selecting controls*
- Representativeness
- *Exposure assessment*
- Accurate

Comparability: *Two groups must be as similar to each other as possible so selection of controls is very important. Controls must be as similar as possible to cases – except that they do not have the outcome (disease)*

(ادعو لزميلنا بالرحمه والمغفرة لنا ولكم الاجر ان شاء الله😢)

***Strengths:**

- *Suited to study disease with long latency periods, but can be used in outbreaks investigations.*
- *Optimal for rare diseases*
- *Efficient in terms of time and costs: relatively quick and inexpensive.*
- *Allows for evaluation of a wide range of possible causative factors that might relate to the disease being studied.*
- *Odds ratio estimated*

***Limitation:**

• *Very susceptible to bias (especially selection and recall bias) as both the disease and the exposure have already occurred when participants enter the study. Cases and controls might not be representative of the whole population.*
• *We cannot calculate incidence or prevalence rate of disease*
• *We cannot be certain that exposure came before disease*
• *Choice of controls difficult*
• *Controls do not usually represent non-exposed population*
• *Past records incomplete*
• *No absolute risk estimates*

• *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):*** *odds of a particular exposure among people with a specific condition divided by the corresponding odds of exposure among people without the condition under study*(سؤال امتحان)

Q)How to make this??

1)Selecting Cases and Controls

• *Identification and collection of cases involves specifying the criteria for defining a person as a case—in other words, as having the disease (also called case definition).*
• This definition *consists of a set of criteria, also called eligibility criteria, for inclusion in the study. There also are criteria for exclusion from the study.*

How??

*1)*Controls are chosen from the source population.
• The source population is usually defined by geographic area. It is important to select controls so that participation does not depend on exposure.

2)source of control:

The ideal situation is a random sample from the same source population as the cases.

- *Investigators may use more than one control group.*
- *Controls can be selected* by sampling: The general population in the same community; *the hospital community* (patients in the same hospital); individuals who reside in the same block or neighborhood; and spouses, siblings, or associates (schoolmates, co-workers) of the cases.

3)matching cases and controls:

Matching is a popular approach to control for confounding and selection bias in case-control studies.

- ***Matching cases and controls helps to ensure that these groups are similar with respect to important risk factors, thereby making casecontrol comparisons less subject to confounding or selection bias.***

Bias:(pastpaper)

Bias is any systematic error in an epidemiological study that results in an incorrect estimate of the association between exposure and risk of the outcome.

- *Selection bias*: inappropriate controls
- Observation bias
- *Subject and recall bia*s: eg recall bias of mothers with cerebral palsy babies
- *Interviewer bias*: blind if possible
- Misclassification

****Confounding:

A confounding factor is one that is associated with the exposure and that independently affects the risk of developing the outcome, but that is not an intermediate link in the causal chain between the exposure and the outcome under study.

How many controls?

- **control-to-case ratio is 1 : 1**
  is the optimal when the number of available cases and controls is large and the cost of obtaining information from both groups is comparable
- **control-to-case ratio is 1 : n**
  When the number of cases is limited or when the cost of obtaining information is greater for cases or controls

- **As the number of controls per case increases, the power of the study also increase**

- **It is not recommended that this ratio increase beyond 4 : 1**

Odds Ratio

The word "odds" means the chances of an event to happen. The Odds of an event is the *ratio* of the event to happen over the event not to happen.

$$Odds(A) = \frac{probability(A\ happens)}{probability(A\ does\ not\ happen)} = \frac{prob(A)}{1 - prob(A)}$$

$$prob(A) = \frac{Odds(A)}{1 + Odds(A)}$$

Odds Ratio (OR)

$$OR = \frac{\text{Odds of exposure}_{cases}}{\text{Odds of exposure}_{controls}}$$

The use of matching usually requires special analysis techniques (e.g. matched pair analyses and conditional logistic regression).

Lecture 7:Experimental Study Design:

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 in the experimental group versus the outcome of another regimen in the control group.

*Different from observational designs by the fact that there is manipulation of the study factor (exposure), and randomization (random allocation) of subjects to treatment (exposure) groups.

*ليست أحنا بنروح لحد النوع من الدراسة

Limitations of theory, Previous disasters,Spontaneous improvements And mportance of small effects.

*****Clinical Trials:**

Individuals with particular disease are randomlly allocated into experimental or control groups. randomization is used to ensure that both groups are comparable with respect to all other factors except for the one under investigation.

(3/4from our exam in this topic in this lecture)

The experimental group is given the agent being tested and the control group is given either an agent in current use or a placebo.

Ideally both patients and the observers should be 'blind'to the treatment being given. This in order to reduce bias.

Are studies of the effect of a specific treatment onpatients who already have a particular disease.

▪*They are used to evaluate the efficacy of a preventive or therapeutic agent in the treatment or prevention of a disease.*

**Why we choose clinical trials??

Most definitive method to determine whether a treatment is effective.
Provide the stronger evidence of the effect, with maximum confidence and assurance.

Determine whether experimental treatments are safe and effective under "controlled environments" (as opposed to "natural settings "in observational designs.

RCT DISADVANTAGES

*Large trials (may affect statistical power)
• Long term follow-up (possible losses)
• Compliance
• Expensive
• Public health perspective ?
• Possible ethical questions
• As above, may take a long time.
• Must be ethically and laboriously conducted.
• Requires treatment on basis (in part) of scientific rather than medical factors. Patients may make some sacrifice.🤦

**Clinical trial stages:

1)Preclinical:Animal study

Biochemical and pharmacological research.
•Animal Studies :Consists of animal studies that determine the toxicity and bioavailability of a drug. Studies involving animal matrices such as rabbit serum, monkey urine, dog or rat plasma, are all examples of preclinical studies.

2)Phase I Trials:given to healthy people

Determine the metabolism and pharmacologic activities of the drug in humans
• Side effects associated with increasing doses
• Early evidence on effectiveness
• Obtain sufficient information about the drug's pharmacokinetics and pharmacological effects to permit the design of well-controlled and scientifically valid phase II clinical studies.

3)Phase II Trials:given to patients (sick one)

Initial clinical assessment: determines whether a therapy has potential using a few very sick patients.

The primary objectives of phase II studies are:

- *Identify accurately the patient population that can benefit from the drug.*
- *Evaluate the effectiveness of a drug based on clinical endpoints for a particular indication.*
- *Determine the dosing ranges and doses for phase III studies*
- *Common short-term side effects*
- *Risks associated with the drug.*

4)Phase III Trials:given to risk group

Rigorous testing: large randomized controlled, possibly blinded, experiments.

The primary objectives of phase III studies are:

- *Gather an additional information about effectiveness and safety needed to evaluate the overall benefit-risk relationship of the drug.*
- *provide an adequate basis for physician labeling*

5)Phase IV Trials:follow up the effect of drugs

Post-marketing surveillance: a controlled trial of an approved treatment with long-term follow-up of safety and efficacy.

The primary objectives of phase IV studies are:

- *Provide additional details required to learn more about a drug's efficacy and/or safety profile.*
- *Study new age groups, races, and other type of patients.*
- *Detect and define of previously unknown or inadequately.*

***Types:*

- *Randomized,Non-Randomized,Single-Center,Multi-Center and Phase I, II, III, IV Trials.*

**Patients assigned at random to either treatment(s)or control.

- Considered to be "Gold Standard"

[Definitions]:"بصمج بصمج سؤال امتحان "

- *Single Blind Study: A clinical trial where the participant does not know the identity of the treatment received.*
- *Double Blind Study: A clinical trial in which neither the patient nor the treating investigators know the identity of the treatment being administered.*
- *Triple Blind study: Biostatisticians is also blinded*

Placebo:• Used as a control treatment

1. An inert substance made up to physically resemble a

treatment being investigated .
2. Best standard of care if "placebo" unethical
3. "Sham control": Faked surgical intervention with the patient's perception of having had a regular operation.

• Adverse event:An incident in which harm resulted to a person receiving health care.

"Surrogate Endpoint"

*Response variables used to address questions often called endpoints.

*Surrogates used as alternative to desired or ideal clinical response to save time and/or resources.

#Preventive #trial🤓(Related Vaccine)

The risk of developing any particular disease among the people who are free from disease is small. Because of this, preventive trials usually require a greaternumber of subjects than clinical trials, and are therefore more expensive.

More difficult when disease rare and is expensive way to establish research.

should be given so that the individuals who do and do not receive the preventative are as comparable as possible. This is often difficult.

▪In some types of trials the preventative have to be administered to communities rather than individuals,

e.g. water fluoridation to prevent dental caries

&Community trials:

community participates in a behavioral intervention, nutritional intervention, a screening intervention, etc

• Intervention: Any program or other planned effort designed to produce changes in a target population.

• Community refers to a defined unit, e.g., a county, state, or school district.

• Communities are randomized and followed over time.
• Determine the potential benefit of new policies and programs.

Tip: محاضرة الاخلاقيات هي آخر محاضرة شرحتها عشان تكون الأخيرة
وفقكم الله ادعو لأخينا المتوفى بالرحمة والمغفرة فالدوام ولك بمثله.
Good Look bros😘😎🤠

Lecture 8+10+11: (same ideas just focus 🤓)

Think about your research moving to proposal/Ideas/Question(specific one)😉
may resolve theoretical questions in your area.
* may develop better theoretical models in your area.
* may identify new risk factors for a disease
* may change current management plans

First one presentation:
(العنوان، بأيش بحثت ،العناوين الاساسيه من المقارنات وغيرها)
Second one Introduction:
Sets the scene for the proposed study by:
▯ Start with definition of the program or by a general statement about the burden of common healthcare problems.
▯ Briefly describe work in the area
▯ Outlines the gap in knowledge which require further research
▯ this section should explain why there is an urgent need for the new study.
▯ Write your aims and objectives ▯ Please read the sample document.
Aims is subjective statement to describe what you wants to achieve by conducting this study
▯ Objectives: something you can measure or assess
Third one is literature review نفس الي مكتوب بالمحاضرة الأولى
*first paragraph about risk factors and the main area of exposure.
*second paragraph +third one about previous studies about this topic.
*last paragraph about purpose of research and many results.

Fourth one is method same as before in lecture 2.

Fifth one ethical consideration.(in the ethics lecture)

Sixth one is project management.

Participating institutes and persons
Responsibilities and tasks of each partner
Quality assurance
✓compliance with protocol
+problem identification
✓distribution and maintenance of material
Data ownership

Eight one time related .

Planning ,writing ,testing ,organising ,collection of data analysis and presentation .

Ninth one Resources.
Available and requested one's.

Seventh one😅 reference related"paraphase and quotation".

Tenth one Appendices "Methodological appendices,Questionnaires, Variable list with definitions,introductory letters to study participants and Forms for informed consent."

***Steps in survey:** كل الاردن عارفينها بدون تكرار كل الحب لكم 😇😍*

هسا ركزو معي كل جمله 90%عليها سؤال:

Impact factor: ***A measure of the frequency with which the 'average article' in a journal has been cited in a particular year.***

•Helps evaluate a journal's relative importance, especially compared to others in the same field,***Impact factor >5 considered very good.***

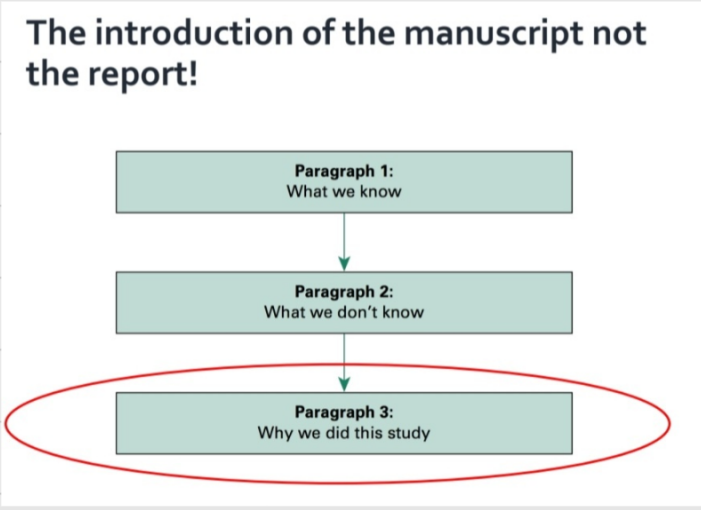
Writing scientific:*A precise way to explain what you did, what you found, and why it matters.*

Instructions to Authers:Make sure your paper conforms exactly to the journals specifications

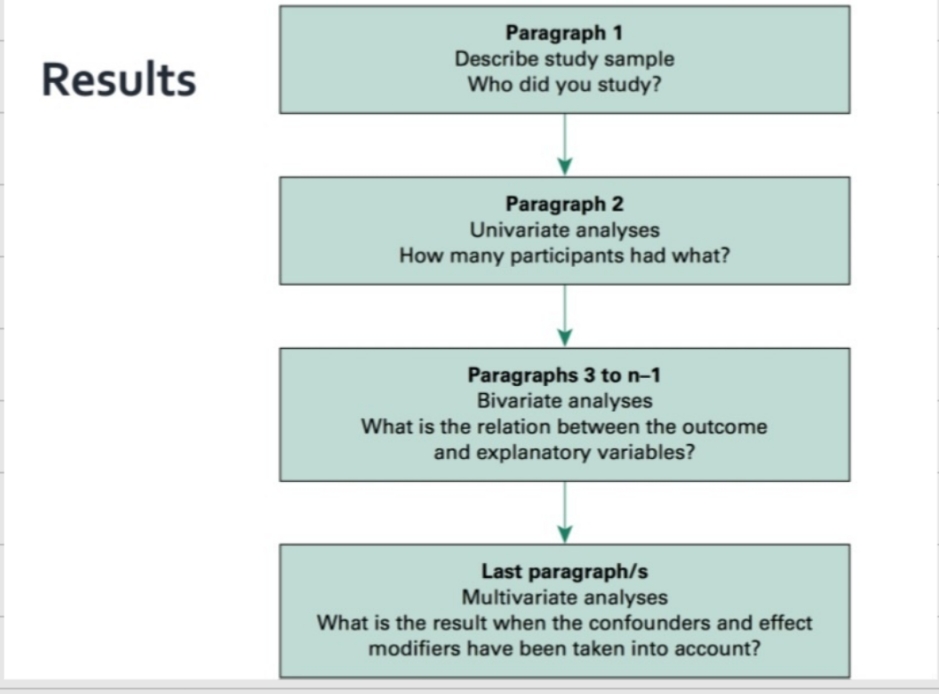
The Introduction:

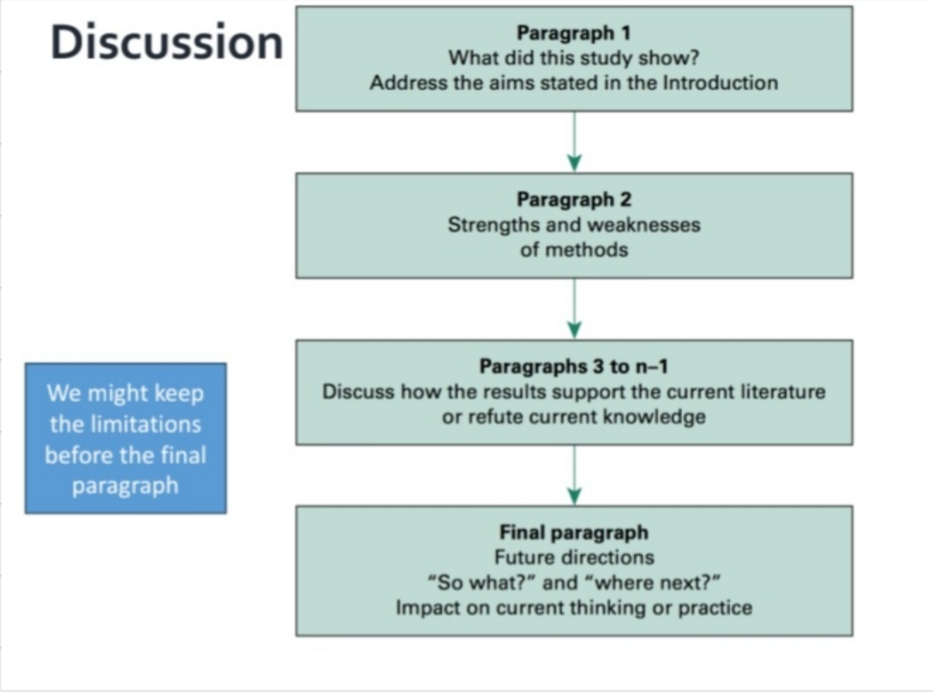
Draw audience in; be provocative,Target journal specific audience, Identify gaps in knowledge,End with question/hypothesis.

*Decide on the level of background information needed; do not just repeat the obvious first line you have read in every paper.
*Be clear about what the problem you are addressing is and how your study proposes to answer this.



*Methods:Describe how you obtained your results in a way that others could replicate them (use CONSORT, STROBE or similar structure).
Result:احفظو الرسمه





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)*
- *Results are supported by data and p values*
- *Interpretation of findings is clearly stated in the conclusion*

بسم الله الرحمن الرحيم الله افتح بوجهنا الخير والبركة آخر محاضرة ركزو عليها كثير بتخبط وفقنا ووفقكم الله اخوتنا😇😇

😭 لانتسو اخوكم من الدعاء فإنه يسأل الان.

Lecture 9 :Ethics in medical research

It's critical to recognize the importance of appropriate statistical analysis.
 Statistical approaches should be developed as part of the study design.
 If possible, hypotheses should be well defined in advance.

No statistically significant different is an important result and must be published.

1)Efficacy: maximum response achievable from an applied ordosed agent.

In therapeutic studies, both efficacy of the interventions and their safety are generally studied simultaneously but the designmay focus on one or the other.

Risk is defined as the probability of physical, psychological, social, or economic harm occurring as a result of participation in a research study.

Both the probability and magnitude of possible harm in human research may vary from minimal to considerable.

**Minimal harm:(pastpaper)*

"that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests ".

[Risk above this standard is more than minimal (moderate, maximal) and that imposes limitations on the conduct of the research and increases the requirements for monitoring.]

Increased risk should be accompanied by the probability of appropriately increased benefits.

***Benefits:**

Benefit applies to the potential of the research treatment to ameliorate a condition or treat a disease.

- *This can apply to an individual participant or to a population.*
- *In research as in clinical medicine, results cannot be guaranteed but, as a consequence of prior work, a benefit may appear to be a reasonable expectation.*

#The investigator should always distinguish between research and treatment and never lure the patient into participating in hopes of remission or cure.

**Difference between risk and benefit Ratio:*

A main role of IRBs is to determine the risk versus benefit ratio for clinical studies.

- They must make sure that the physical risk is not disproportionate to the benefits.
- When the physical risk is minimal they must determine that psychological and social risks such as stigma are not important.
- It is not ethical to conduct a study in which an individual or a group is labeled so as to be stigmatized or to be made less employable or insurable.

Controls,diffention:

are research participants who receive an inactive treatment or stay on standard treatment

- *In most trials they are selected by computer lottery from the group of eligible candidates with the condition under. study.*

Normal control: research participants who do not have the condition under study.

Historical control:are subjects from prior studies or observational investigations whose data are compared with those of the current participants used for years of controlling in hiding factors related control.

They often produce biases because the research population rarely duplicates the historical population.

Blinding refers to a process whereby the participant does not know whether he/she is receiving an active agent or a similar appearing inactive substance or mock procedure,investigators who analyze components of a study without knowing the identity and treatment of the participant.

Double Blinding:a process whereby neitherthe investigator nor the participant knowswhich agent the participant is receiving.

Triple blinding:blind the statisticans.

*في حاله كان الدواء خطير وله آثار جانبية كثيرة مابزبط هيك اشي.

A placebo is an inactive version of atreatment identical in appearance to the real thing.

**Standard of care :*

1)This term applies to the expected care in the medical community as a whole.

2)The current expectation is that controls will be treated at the level of the Western standard of care, not the indigenous standard.

In selection of subject population They must be selected and dealt with on the basis of the three principles of Human Research, Autonomy, Beneficence and Justice.

**In mean of protection only child's ,less than 18 years old and pregnancies.*

**Autonomy is understood to mean that becoming a research subject is a totally voluntary act (related only prospective and rare cases of retrospective).*

**Individuals must be fully informed and understand what they are signing up for.(honest ,trust,respect)*

**This section became known as the Nuremberg Code and was the first international code of research ethics.*

**Coercion*

"Influencing an individual decision about whether or not to do something by using explicit or implied threats (loss of good standing in job, poor grades, etc.)"

Undue Influence

"An offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance" "excessive compensation"

Compensation is meant to reimburse research participants for their time, research-related inconveniences and/or research-related discomforts.

Compensation is ***not*** a benefit of the research.

Informed Consent :

legally-effective, voluntary agreement that is given by a prospective research participant following comprehension and consideration of all relevant information pertinent to the decision to participate in a study.

Voluntariness :

Individuals' decisions about participation in research should not be influenced by anyone involved in conducting the research: "...consent must be freely given or truly voluntary."

Comprehension:

Individuals must have the mental or decisional capacity to understand the information presented to them in order to make an informed decision about participation in research.

Disclosure :

This disclosure must be made in such a way that it provides a reasonable person the information she or he would need in order to make an informed decision.

Related to purpose of study,Any reasonably foreseeable risks to the individual ,Potential benefits to the individual or others, Alternatives to the research protocol , The extent of confidentiality protections for the individual , Compensation in case of injury due to the protocol,Contact information for questions regarding the study, participants' rights, and in case of injury andThe conditions of participation, including right to refuse or withdraw without penalty.

prohibit:Inducements of any kind to terminate a pregnancy.

Beneficence:

Two general rules have been articulated as complementary expressions of beneficent actions:

- Do no harm.
- Maximize possible benefits and minimize possible harms.

**The challenge inherent in applying the Belmontprinciple of beneficence is how to determine when potential benefits outweigh considerations of risks and vice versa.

Privacy means being ”.“free from unsanctioned intrusion

- ***Confidentiality*** relating to an individual, means holding unless secret the individual all information gives consent permitting disclosure.

IRBs determine:***(Institutional review boards)***

the acceptability of proposed research in terms of institutional commitments and regulations,applicable law, and standards of professional conduct and practice ”

Also known as an Independent Ethics Committee (IEC) or Ethical Review Board (ERB)is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects .

Justice (definition):

1)Justice requires that individuals and groups be treated fairly and equitably in terms of bearing the burdens and receiving the benefits of research.

2)Justice relates to access to research of all relevant populations Specifically including age, ethnicity, gender and preexisting conditions.

To treat“ *equitably* ”means to *treat fairly*;

◦ To treat“ *equally* ”means to *treat in exactly the same way.*

informed consent process must that potential research participantsThe disclose sufficient information to ensure

“In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.” (😁قالها الحكيم هيلسنكي)

Scientific Value:

Research should be designed, reviewed and conducted in a way that ensures its quality, integrity and contribution to the development of knowledge and understanding.

Respect for the Autonomy and Dignity of Persons:

Adherence to the concept of moral rights is an essential component of respect for the dignity of persons.

Social Responsibility

The discipline of psychology, both as a science and a profession, exists within the context of human society.

Maximising Benefit and Minimising Harm(pastpaper)

... psychologists should consider all research from the standpoint of the research participants, with the aim of avoiding potential risks to psychological well-being, mental

health, personal values, or dignity.

Chair: Preferably from outside the Institution.
Member secretary: from the same organization or institute.

Where ethical approval is deemed unnecessary a disclaimer may be signed by researcher (and supervisor).

Full Procedure
1)Complete Full Approval form
2)Attach consent form, information sheet and additional material e.g. questionnaires.

Approved subject to amendments –supervisor confirms with Chair of FEP
***Not Approve**d – major revisions and resubmit

Good Clinical Practice (GCP) is defined as a '*standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are rotected'*

*1)Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirements.

*2)Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks

3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society

4 The available non clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial .

5 Clinical trials should be scientifically sound, and described in a clear, detailed protocol

6 A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favorable opinion

7 The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist

8 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective tasks

9 Freely given informed consent should be obtained from every subject prior to clinical trial participation

10 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification.

11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements.

12 Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol .

13 Systems with procedures that assure the quality of every aspect of the trial should be implemented.

بيجي عليهم سؤال واحد أو سؤالين بالامتحان اذا بدكاش علامه السؤالين او السؤال لاتدرسهم لانهم طوال شوي وبوخذو وقت افهمهم فهم بس ويعطيكم العافيه لاتنسونا من دعائكم 😇

Done by

Ahmad-Shawabkeh..