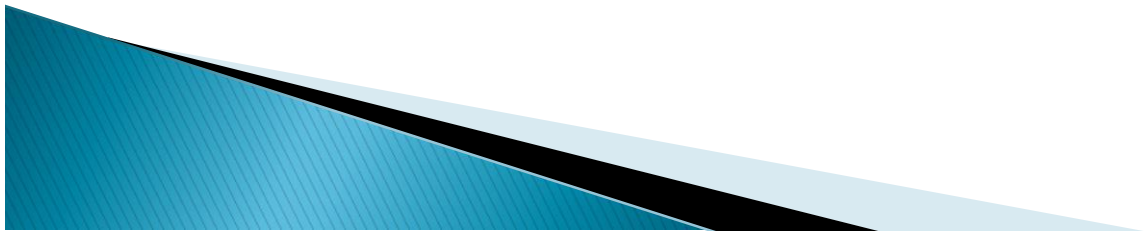
Research-mid

Doctor: Munir Abu-Helalah

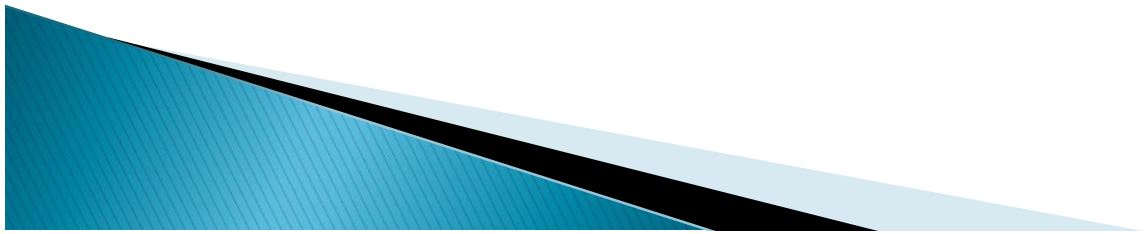
Proposal design

- **Dr Munir Abu-Helalah**
- MD,MPH,PHD
- Associate Professor of Epidemiology and Preventive Medicine



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



Literature review

- Start from general to specific
- Ensure that you have reviewed key articles from Jordan, the region and worldwide that is matching your study objectives.

- The best practical way: write down your objectives then provide the review for each objectives
- Objective 1: to measure the prevalence of tobacco smoking in Jordan
- Objective 2: To measure the proportion of smokers who failed to quit smoking and its predictors

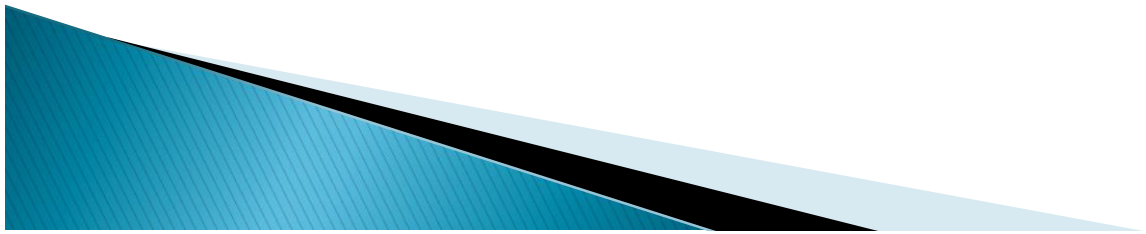
First section of the literature review: The first paragraph: will be about smoking risk and burden in Jordan, the region or developing countries and then in western countries

Second section: Then 2-3 paragraphs will be on previous studies from Jordan have shown that the prevalence of cigarettes smoking in Jordan among males… females..

The third section: previous studies have shown that good proportion of smokers tried to quit smoking. For example a study from the KSA…

This study from Saudi showed that nicotine withdrawal symptoms were the key predictors of failure to quit.

We continue with other objectives then we reach the last paragraph of the literature review: this should contain summary and justifications of the study – see next slide



Last paragraph of the literature review example 1:

- In summary, previous studies have shown that smoking rates are high in Jordan. No national study have been conducted for the last 5 years at representative sites on the tobacco smoking rates among males and females at representative sites in Jordnan. There is limited data on vape smoking rates in Jordan. It is proposed to conduct a national cross-sectional study on tobacco rates in Jordan covering cigarettes, waterpipe and vape smoking amongst adult at representative sites in Jordan.

Methods

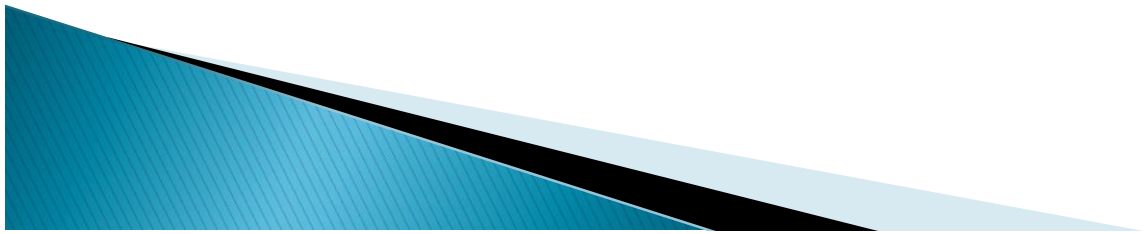
- **Study design:** Example: A cross-sectional online survey questionnaire will be conducted
- **Study setting : community based or healthcare (hospital or clinic)**
- **Primary outcomes and Secondary outcomes**
- **Study population**
- **Inclusion Criteria, Exclusion criteria**
- **Sampling technique: Multistage sampling technique starting with ……..**
- **Study tool/data collection methods** Example: information about (Questionnaire or clinical score):
- For questionnaires, if a total score will be calculated, validity and reliability data are required. This is required for clinical scores.
- Justifications for investigations used. TSH as a screening tool for hypothyroidism because it is the most sensitive markers for hypothyroidism with low false positive rates.
- **Clinical trial:** **Randomization and blinding , Study arms**
- **Sample size and Statistical analysis plan**
- **Ethical Consideration:** Inform Consent, if needed: justify whether or not it is needed
- **Confidentiality**
- **References**

4. Methods

Data analysis

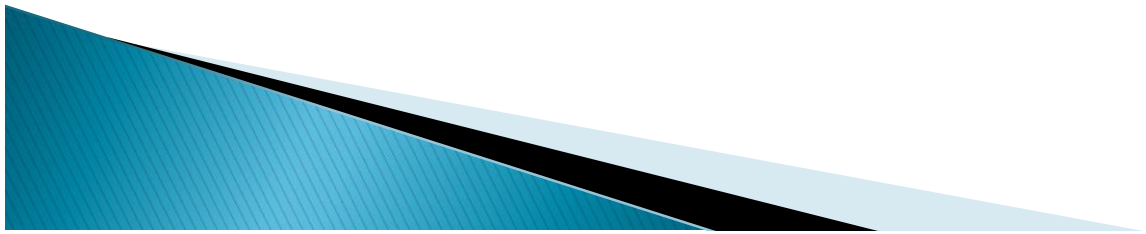
- Validation and data cleaning
  - ✓timing: during study or later

- Data analysis plan
  - ✓structured in terms of the specific objectives
  - ✓dummy tables
  - ✓from general to specific
  - ✓when to use Chi-Square, t-test, regression analysis, P-values



Why a data analysis plan ?

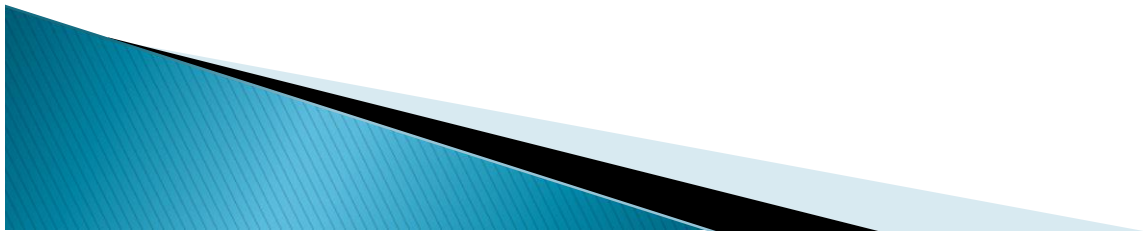
- Prevents collection of data that will not be used
- Prevents failure to collect crucial information
- Better estimates of sample size for analysis of sub groups



4. Methods

Pilot studies, pre-testing

- No study should ever proceed without a test
- Describe how to test
  - ✓Feasibility of sampling
  - ✓Data collection, measurement methods
  - ✓Questionnaire



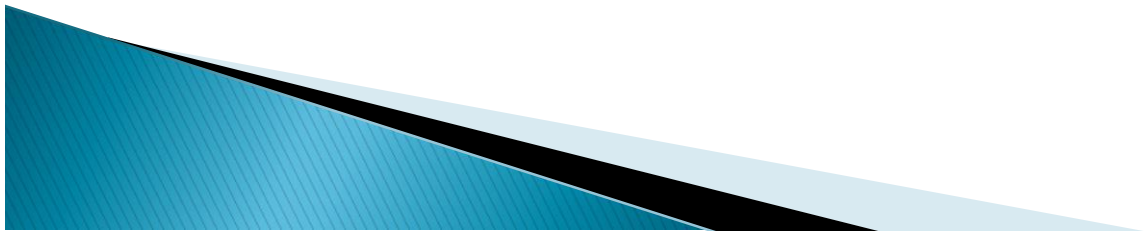
4. Methods

Validity (limitations, weaknesses)

- Identification of potential sources of biases
  - ✓confounding
  - ✓selection bias
  - ✓information bias
- How to deal with them
  - ✓In design
  - ✓In analysis

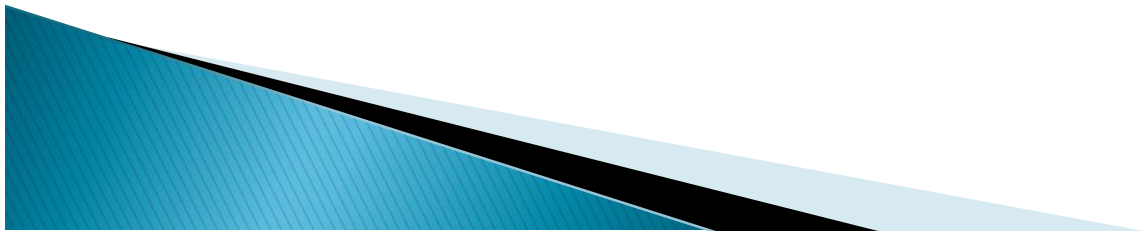
5. Ethical considerations

- Informed consent
- Confidentiality, anonymity?
- Data storage and protection
- Ethical review committee
- Data protection inspectorate



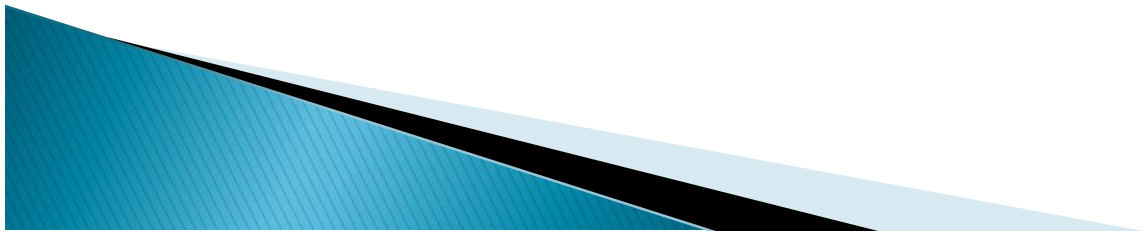
Protocol design for cases control studies:

I. Background
II. Research Question
III. Research Design
IV. Case definition and selection
V. Control definition and selection



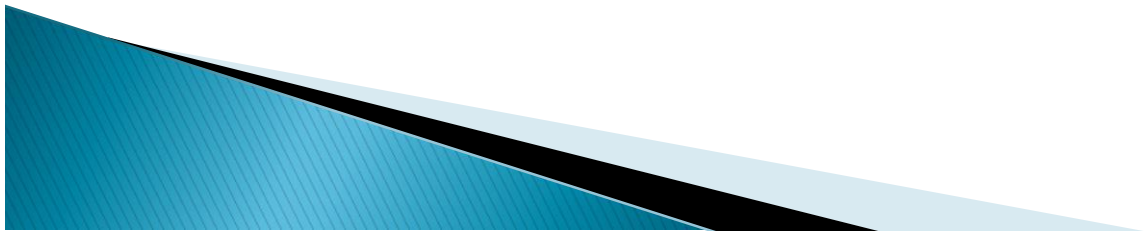
Protocol design for cases control studies:

VI. Informed consent and confidentiality
VII. Resources Needed
VIII. Study conduct
IX. Sample size calculations
X. Data analysis plan
X. Budget
XI. References



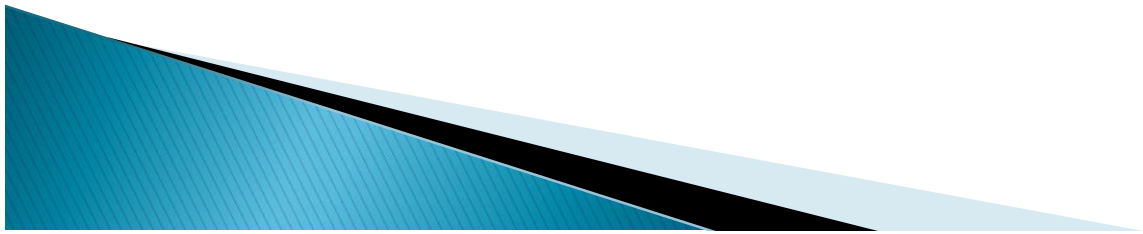
Design of cohort studies

1. Research question must be clear
2. Set the sample size
3. Set the follow-up period (immediate, short term and long term)
4. Specify study group Sample must be representative of the population you are studying
5. All participants should be free of the outcome (disease) at the beginning of the study
6. Must be able to get correct information about exposure status easily
7. Measure the outcome
8. Comparison group must be as similar as possible to exposed group
9. Put measures in place to reduce loss to follow up if possible



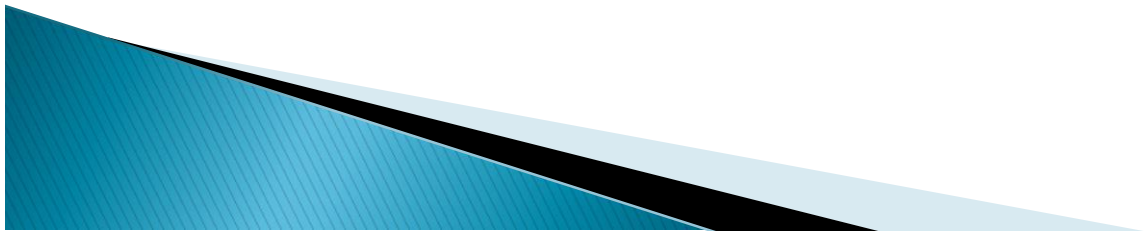
General consideration while selecting cohorts

- Both the cohorts are free of the disease.
- Both the groups should equally susceptible to disease
- Both the groups should be comparable
- Diagnostic and eligibility criteria for the disease should be defined well in advance.



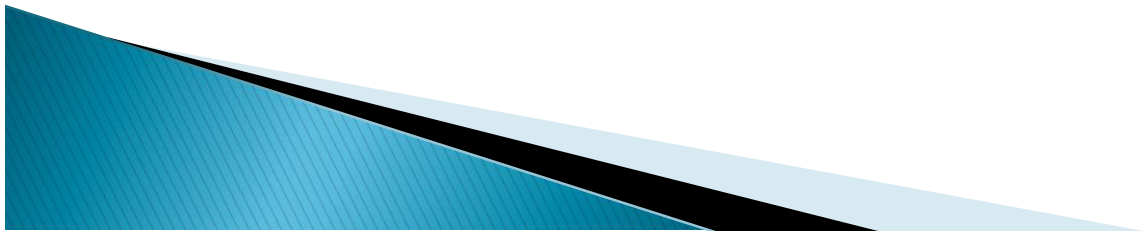
Elements of cohort study

- Selection of study subjects
- Obtaining data on exposure
- Selection of comparison group
- Follow up
- Analysis



Cohort studies
Selection of study subjects

- General population
  - Whole population in an area
  - A representative sample
- Special group of population
  - Select group
    - occupation group / professional group (Dolls study)
  - Exposure groups
    - Person having exposure to some physical, chemical or biological agent
      - e.g. X-ray exposure to radiologists



Clinical trials

- Give a brief summary of the proposed trial
- Hypotheses.
- What is the proposed trial design?
- What are the proposed outcome measures?
- What are the planned inclusion/exclusion criteria?