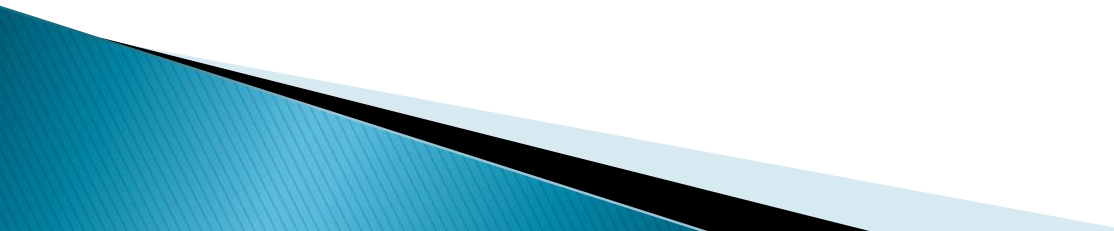


Proposal design

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

Key components of research proposal:

- A description of the research problem.
 - An argument as to why that problem is important.
 - A review of literature relevant to the research problem.
 - A description of the proposed research methodology.
 - A description of how the research findings will be used and/or disseminated.
- 

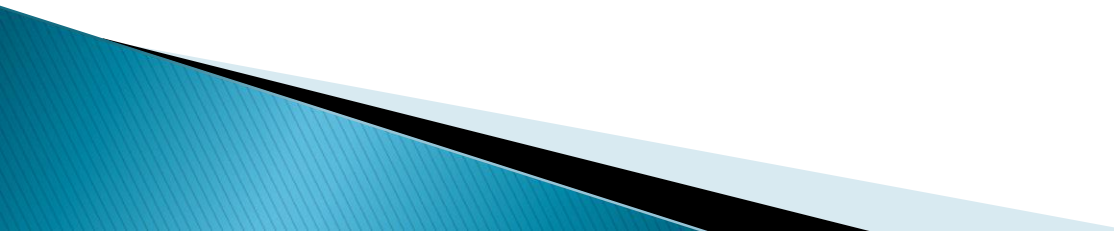
Moving from research idea to a proposal

- ▶ Literature review:

Has it been investigated?

What has been done in this field?

Questions to be answered in this field?



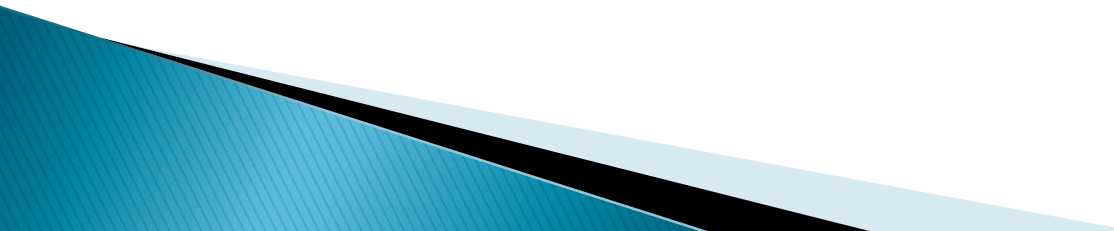
Key steps in conducting medical research

- Answers relevant questions
 - ✓ Public health problem: Important?
 - ✓ Study question: relevant to the problem?
 - ✓ Objectives: consistent with the study question?
 - ✓ Study design: achieves objectives?
 - ✓ Power of the study: sufficient?
 - ✓ Public health impact of the findings?

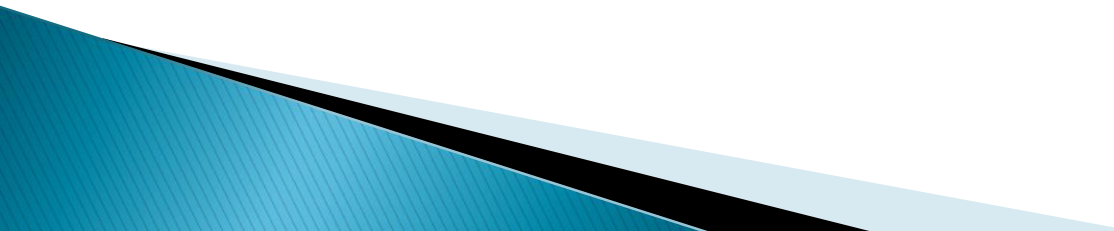
Refine your question

- ▶ **What is the question being asked? What is the purpose or objective of the of study**


Moving from research idea to research question

- ▶ Think about how your research:
 - * 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
- 

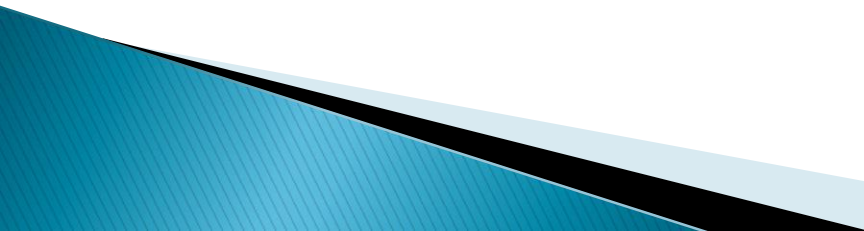
Key steps in conducting medical research

- ▶ Inform interested parties
 - ▶ Write the proposal
 - ▶ Obtain ethical approval
 - ▶ Obtain funding
 - ▶ Register under the data protection act
 - ▶ Develop the data processing
 - ▶ Pilot all stages
 - ▶ Review the design
- 

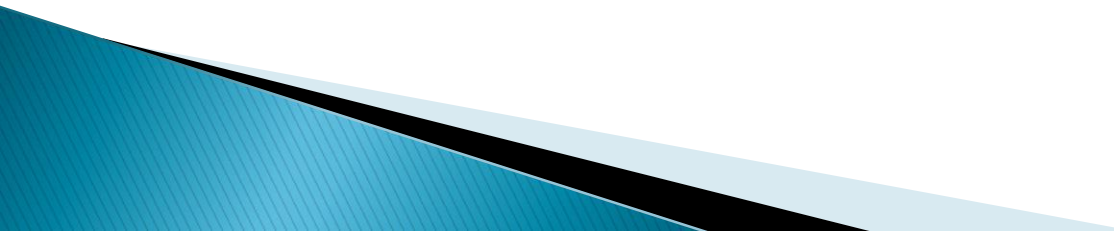
Proposal outline

1. Presentation
 2. Background and justifications
 3. Objectives and research questions
 4. Methods
 5. Ethical considerations
 6. Project management
 7. Timetable
 8. Resources
 9. References
 10. Appendices
- 


Study proposal: Why?

- ▶ To check if the objectives can be achieved
 - ▶ To check the feasibility of the study
 - ▶ Prevents failure to collect crucial information
 - ▶ Lays down the rules for all partners
 - ▶ To obtain approval of ethical committee(s)
 - ▶ Application for funds
 - ▶ Makes it much easier to write article
- 

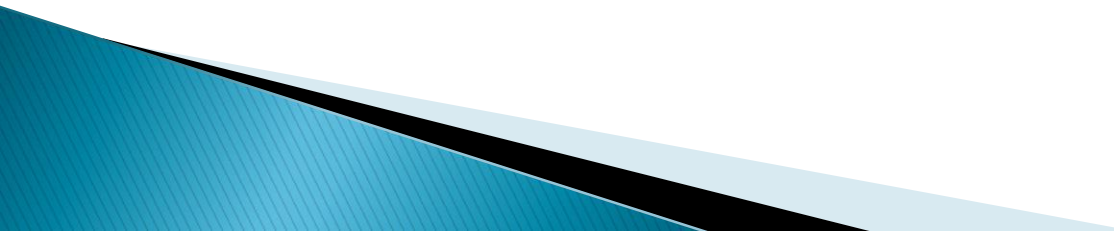
Study proposals: How to start ?

- ▶ Get good examples
 - ▶ Get ideas from similar published studies
 - ▶ Use a checklist of items to include
 - ▶ Get the requested format
(grant application)
 - ▶ Share ideas with colleagues
- 

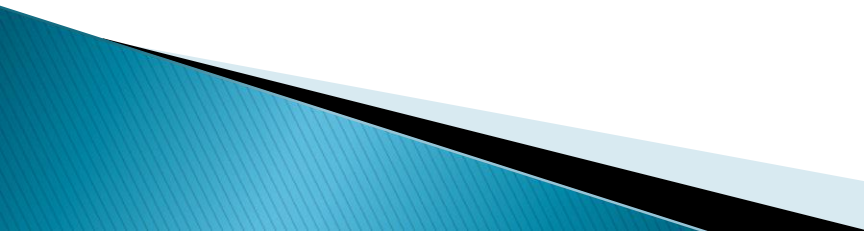
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- 

1 .Presentation

- ▶ Title
 - ▶ Investigators
 - ▶ Main centres
 - ▶ (Steering committee)
 - ▶ Summary of the Proposal
- 

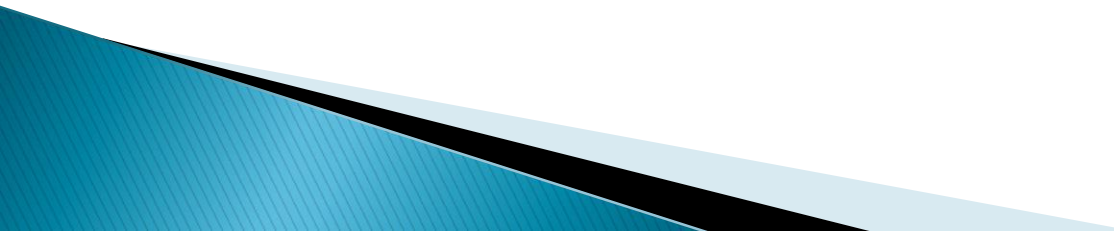
Introduction

- ▶ 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
- 

Sample introduction

- ▶ Please read the sample document

Aims and objectives

- ▶ Aims is 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 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 Jordan. 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.

Last paragraph of the literature review example 1:

- ▶ In summary, previous studies have shown that smoking rates are high in Jordan. Studies conducted in Jordan over the last five years had several limitations such as lack of national representations, not covering vape and waterpipe smoking, and the limitations of the age criteria. 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.

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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

▶ Study design

- ✓ what design will be used?
(cohort, case-control, cross-sectional...)
- ✓ brief justification

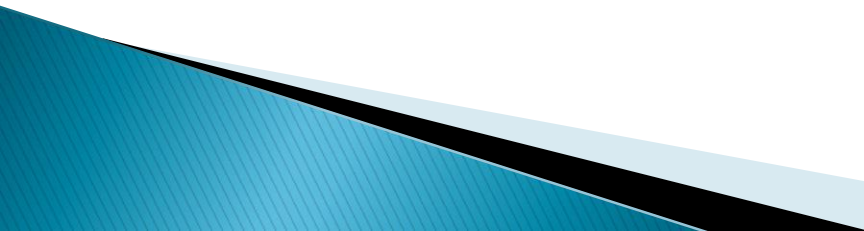
Primary and secondary outcomes: based on your research objectives

- Eligibility criteria:
Inclusion and exclusion criteria

▶ Study population

- ✓ appropriateness for study objectives
- ✓ accessibility, co-operation, follow up, representativeness
- ✓ criteria for inclusion and exclusion
- ✓ description of mechanisms of recruitment

4. Methods

- ▶ Sampling design
 - ✓ Frame: district, household, persons,...
 - ✓ method: random, cluster, stratified,...
 - ✓ randomisation procedures
 - ✓ replacement procedures (in case of refusal)
 - ▶ Sample size
 - ✓ sample size and power calculations based on principal objective
- 

4. Methods

Data required

- ▶ Selection and definition

example:

smoking: definition, quantification, categories

lung cancer: case definition, definition of a control

- ▶ Items to be measured and how (scales used)

4. Methods

Data collection

- ▶ How?

 - ✓ Interview, observation, record review

- ▶ By whom?

 - ✓ interviewers: selection, training

 - ✓ level of supervision

- ▶ Tools?

 - ✓ questionnaires, recording materials (forms)

 - ✓ questionnaires: self or interviewer administered, face to face or telephone interview

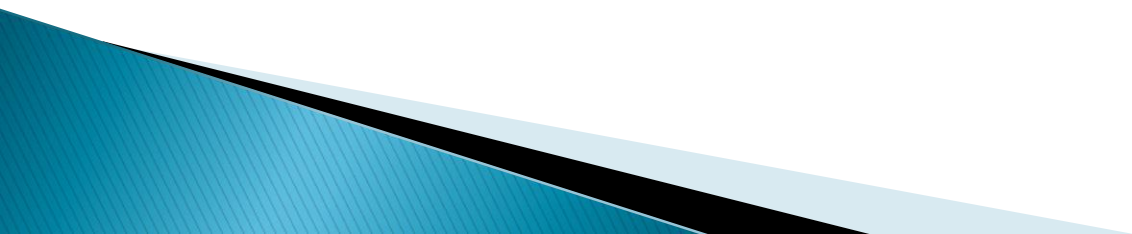
- ▶ Blind data collection?

- ▶ Procedures for taking samples

Study tool

3.2. Study Tool

A structured Arabic questionnaire consisting of five sections on socio-demographic characteristics, knowledge, Perceptions, uptake rate, and predictors of Uptake was used. It was constructed through the combination of items from reliable and valid questionnaires (AlMusailhi et al., 2019; Henninger et al., 2013; Hu. Yu et al., 2017). backward - forward translation of the Questionnaire was done by medical and social experts.



4. Methods

Data handling

▶ Data coding

- ✓ during data collection, afterwards?
- ✓ by whom?

▶ Data processing

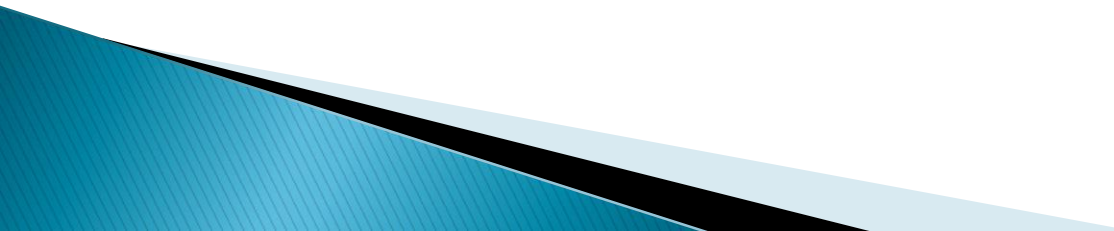
- ✓ manually, by computer
- ✓ software, hardware
- ✓ data entry:
 - during the study, afterwards?
 - order of entry screen and structure of data base
 - single entry, double entry?

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 ?

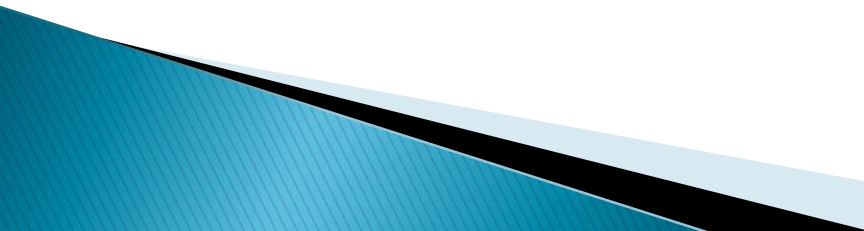
- ▶ Prevents collection of data that will not be used
 - ▶ Prevents failure to collect crucial information
 - ▶ Better estimates of sample size for analysis of sub groups
- 

Example

- ▶ *Plan for statistical analysis*
- ▶ Analysis was conducted using SPSS software version 19.0 (SPSS Inc., Chicago, IL, USA). In addition to calculating the quality of life scores, data on the predictors of the quality of life scores were collected through a standardized interview questionnaire and a clinical chart review form. The interview questionnaire and chart review forms covered socioeconomic variables, histopathological findings, the stage and grade of colorectal cancer, treatment and current medical conditions.
- ▶ Student's t-test was used to compare the means of continuous variables for two groups and one-way analysis of variance was used to compare the means of continuous variables for three or more groups (Bland, 2000).
- ▶ Multiple linear regressions were used to relate the quality of life scores to their predictors. A stepwise selection method was used to select the best regression model with alpha-to-enter of 0.05 and alpha-to-remove of 0.1.
- ▶ Predictors included in the regression model were classified into four groups:
- ▶ *i)* Social and economic indicators: Age, city, age at diagnosis, marital status, place of living (with husband, family, others or alone), literacy, level of education, husband's education, employment status, average monthly family income (JD), number of children under 18 at home and smoking history.
- ▶ *ii)* Medical indicators: Presence of chronic diseases, family history of cancer, number of pregnancies and if had reached menopause.
- ▶ *iii)* Clinical indicators: cancer site (sigmoid including all other colon non-rectal sites, rectum including anorectal tumors and rectosigmoid tumors on junction between rectum and sigmoid colon), use of stoma, stage at diagnosis, pathological type, differentiation, tumor size at histological examination, recurrence since baseline, extent of disease, type of surgery, surgical margin, chemotherapy and its duration, radiation therapy and its duration, palliative chemotherapy and palliative radiotherapy.
- ▶ *iv)* Psychosocial indicators: receiving psychological counseling after diagnosis, participation in a psychosocial support program, having suffered from traumatic events prior to the diagnosis with colorectal cancer, having suffered from traumatic events after diagnosis irrelevant to colorectal cancer, history of a diagnosis of depression, history of a diagnosis of anxiety, presence of current social problems causing major stress to the patient's life, presence of any financial difficulties that affect the patient's life and well-being and the total HADS score.

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

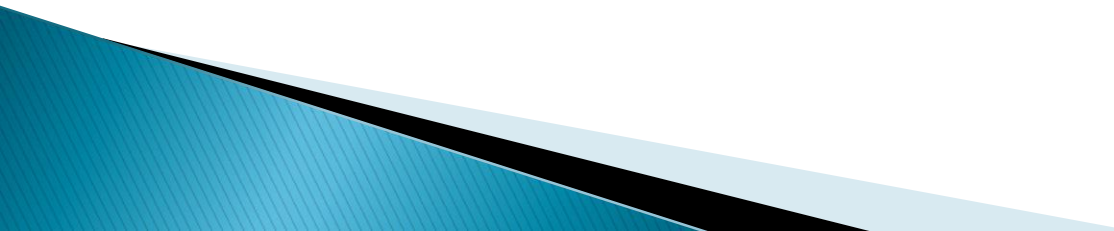
Validity (limitations, weaknesses)

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

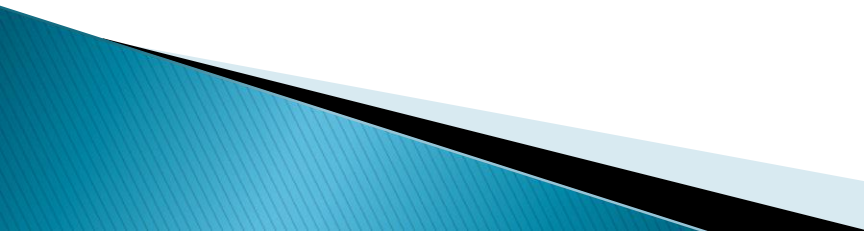
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5. Ethical considerations

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

6. 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
- 

7. Timetable

Planning/organisation of the study

- ▶ questionnaire design, recruitment, purchases
- ▶ permission
- ▶ obtain funding

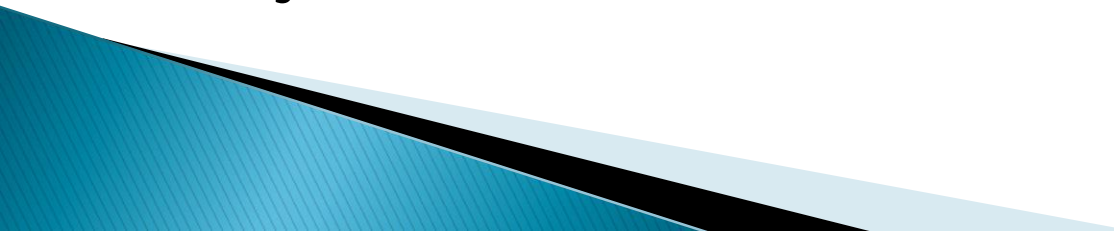
“Pilot study”

- ▶ testing of methods and questionnaires
- ▶ adjust procedures as result of pilot

Final study

- ▶ data collection
- ▶ analysis
- ▶ presentation of results and write up

8. Resources

- ▶ Extent of this section will depend on target audience
 - ▶ Specify
 - ✓ available sources
 - ✓ requested sources
 - ▶ Keep budget
 - ✓ reasonable
 - ✓ detailed
 - ✓ well justified
- 

9. References

- ▶ Limit number of references to key articles
 - ▶ Follow recommended style
- 

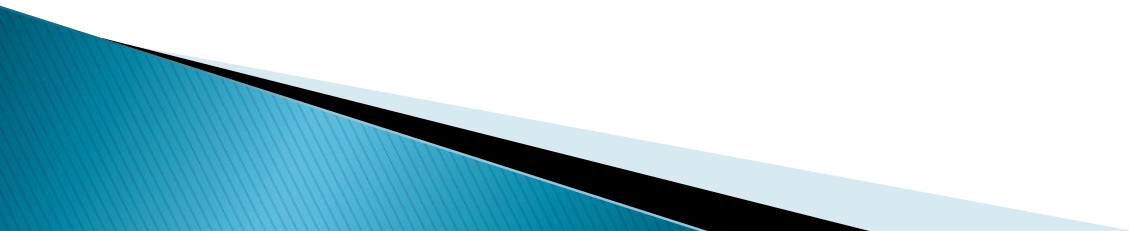
10. Appendices

- ▶ (Methodological appendices)
- ▶ Questionnaires
- ▶ Variable list with definitions
- ▶ Introductory letters to study participants
- ▶ Forms for informed consent

.....



Critically appraise your proposal



Part 2

Proposal writing

Tips for specific study designs

Steps in conducting a survey

- ▶ **Step 1: Determine the objectives of your study**
- ▶ **Step 2: Determine the exposure and outcome variables and**
 - ▶ **decide how you will define them**
- ▶ **Step 3: develop preliminary “skeleton” tables**
- ▶ **Begin with simple descriptive characteristics**
- ▶
- ▶ **Step 4: determine:**
 - ▶ **Who will be the study subjects**
 - ▶ **Methodology**
 - ▶ **Sample size**
- ▶ **Step 5: design a questionnaire**
- ▶ **Pretesting and then Piloting**

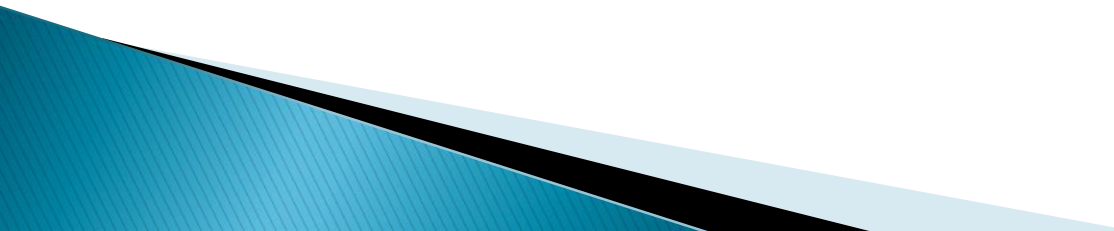
Steps in conducting a survey

- ▶ **Step 6: Establish a sampling plan for data collection and**
 - ▶ **work out the logistics**
- ▶ **Step 7: Determine the personnel needs**
- ▶ **Step 8: Field test the questionnaire in the population in**
 - ▶ **which it is to be used and determine whether there are operational problems**
- ▶ **Step 9: Develop instruction manuals for survey personnels**
- ▶ **Step 10: select and train the personnel to be used**
 - ▶ **to collect the data**

Steps in conducting a survey

- ▶ **Step 11: Develop check list of materials needed for field work**
- ▶ **Step 12: collect the data**
- ▶ **Step 13: Edit your data to determine errors in collection, coding,**
 - ▶ **transcription, or data entry**
- ▶ **Step 14: do the data analysis**
- ▶ **Step 15: interpret your data**
- ▶ **Step 16: Writing up**
- ▶

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

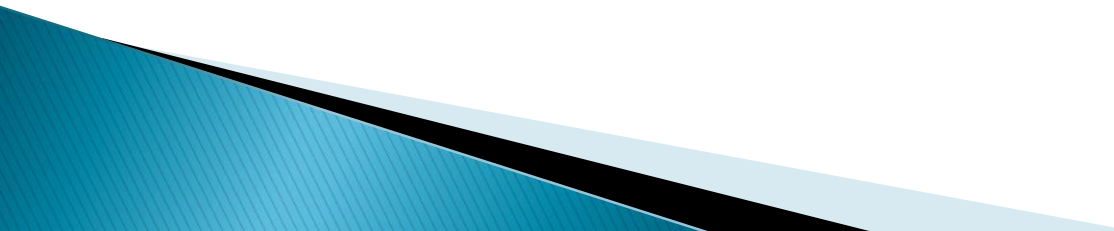
X. Data analysis plan

X. Budget


XI. References



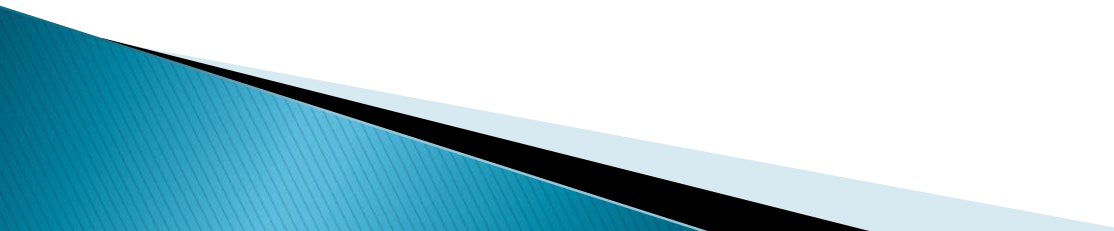
Design of cohort studies

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
- 

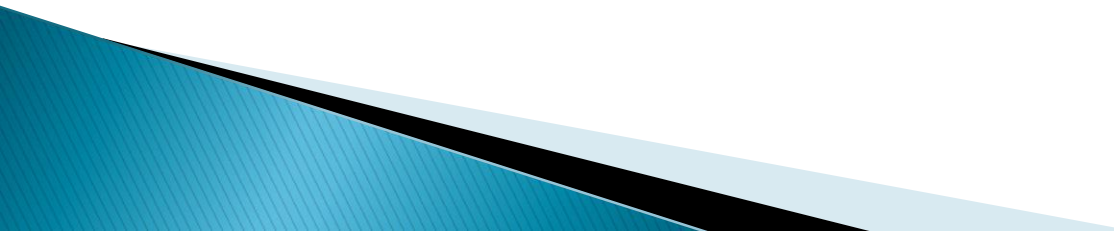
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General consideration while selecting cohorts

- 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

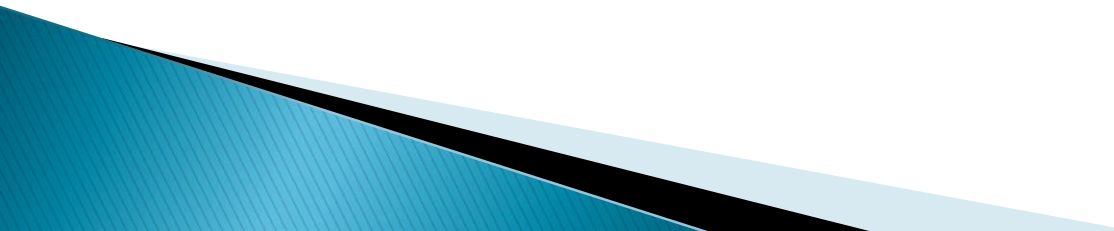
- ▶ Selection of study subjects
 - ▶ Obtaining data on exposure
 - ▶ Selection of comparison group
 - ▶ Follow up
 - ▶ Analysis
- 

Cohort studies

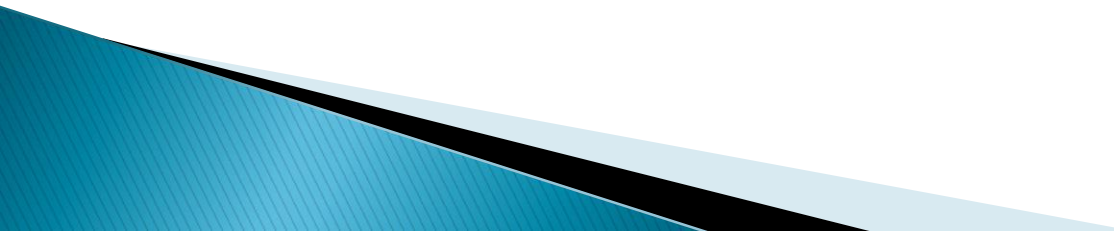
Selection of study subjects

- ▶ 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?
- 

Clinical trials

- ▶ **What is the proposed sample size?**
 - ▶ **How many centres will be involved?**
 - ▶ **What is the planned recruitment rate?**
 - ▶ **What are the practical arrangements for allocating patients to trial groups?**
 - ▶ **What are the planned trial interventions?**
 - ▶ **What is the proposed duration of treatment?**
- 

Clinical trials

- ▶ What are the proposed methods for protecting against sources of bias?
 - ▶ What is the proposed frequency and duration of follow up?
 - ▶ How will the outcome measures be measured at follow-up?
 - ▶ Give details of the planned analyses.
 - ▶ Are there likely to be any problems with compliance?
 - ▶ What is the likely rate of loss to follow-up?
 - ▶ Consent and ethical approval
 - ▶ Budget
 - ▶ Time plan
 - ▶ References:
- 