
MEDICAL RESEARCH
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Color code

- Slides
- Doctor
- Additional info
- Important

Proposal design

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Good afternoon, everyone. Today, we will discuss proposal design, focusing on two main parts. The first part will cover the components of a proposal, including the *Introduction* section required for your applied project.

The second part will focus on different study designs and tips specific to each. For example, in cohort studies, we need to address the parts of the proposal unique to this design, such as a section on participant follow-up and strategies to ensure adherence. In clinical trials, additional elements need to be included, such as randomization, blinding, study treatments, and other related aspects.

In summary, the first part of this lecture will provide a general framework for designing proposals applicable to any study. The second part will offer tailored tips for specific study designs.

Key components of research proposal:

- A description of the research problem. In the introduction
- 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?

We want to conduct a cross-sectional study on the prevalence of hypertension in Jordan. If a national study has been conducted recently at representative sites, we should avoid repeating the study in the same locations, as this work has already been done. For example, if a previous study was conducted in Mafraq on the prevalence of hypertension, and we lack sufficient data or no national study has been conducted, we could justify the need for a new study. Alternatively, if there were limitations in the previous study, this would also provide justification for repeating the research.

It is crucial to emphasize the importance of a thorough literature review. This helps address various questions and ensures we learn from the experiences of others. By examining the limitations of previous studies and considering their primary and secondary outcomes, we can ensure our project is comprehensive and builds effectively on prior research.

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

If I want to examine the prevalence of a risk factor, I would conduct a cross-sectional study. However, if I aim to study new risk factors for a disease, an analytical study, such as a cohort or case-control study, would be more appropriate. For common diseases, a cohort study is suitable, whereas for rare diseases, a case-control study is preferred.

If the goal is to change the management plan, a clinical trial would be required. In summary, the selection of the study design depends entirely on the research question being addressed.

Key steps in conducting medical research

- Inform interested parties — The stakeholders
- Write the proposal
- Obtain ethical approval — For example, we now have platforms like the WHO or NIH websites to register your project and ensure that you publish the data in accordance with your proposal.
- Obtain funding
- Register under the data protection act
- Develop the data processing — Analysis plan
- Pilot all stages
- Review the design — I want to conduct a cohort study with 10,000 subjects. However, before starting with the full sample, I need to conduct a pilot study with 30-50 participants at a single site.

Proposal outline

Components of proposal

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

Proposal outline

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1.Presentation

The first page of your proposal

- Title
- Investigators
- Main centres
- (Steering committee) In large studies
- Summary of the Proposal 1 page

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

This is the presentation we meant. In the first section of the proposal, we sometimes include the introduction within the literature review, along with the background information. Other times, similar to the format we use for research methods, we write the introduction separately, followed by the literature review.

The purpose of the introduction is to provide a brief description of the work conducted in the area, outline the objectives and aims, and highlight the value of the study.

Sample introduction

- Please read the sample document

Introduction

1.1. Background

Seasonal Influenza (SI) is caused by airborne influenza viruses that affect the respiratory system mainly between fall and early Spring. The virus has a wide range of clinical manifestations from mild to severe complications, especially among high-risk groups (infants, the elderly, patients with chronic diseases, pregnant women, as well as people with immune diseases). In pregnant women, Influenza infections are more severe when compared with influenza infections amongst non-pregnant women (Hu et al., 2017).

Influenza infection affects pregnant women's respiratory, immune, and cardiovascular systems, leading to a high risk for cardiopulmonary hospitalization. Studies have shown that cardiopulmonary hospitalization rates due to influenza is around 3, 6, and 10 per 10,000 women among pregnant women in their first, second, and third trimesters, respectively, as compared with approximately 2 per 10,000 women-months among nonpregnant women during influenza season (Neuzil et al., 1998).

The effect of influenza infection is not limited to the pregnant mother, but it also poses a threat to the fetus, although transmission of the virus to the fetus through the placenta is rare (Rasmussen et al., 2012). Exposure to influenza infections during the first trimester of pregnancy increases the risk of any congenital abnormality two times more than that rates for pregnant unexposed to influenza (Luteijn et al., 2014).

Influenza vaccine is routinely recommended in the north hemisphere in October each year and can be given anytime between September and November. It can protect pregnant women and their newborns from influenza-related morbidity and mortality. The protection extends to infants under six months by transmitting antibodies from mother to fetus through the placenta (Descamps et al., 2020).

The uptake and acceptance of the influenza vaccine among pregnant women in the Middle East remain unknown. Few studies have been published about pregnant women's awareness and uptake of the influenza vaccine. They have shown that the rate of pregnant women receiving influenza vaccine during their current pregnancy ranges between 4.6% and 19.8% (AlMusailhi et al., 2019; Dhaouadi et al., 2022; Mayet et al., 2017).

Previous studies revealed poor awareness and knowledge about influenza infections burden and influenza vaccines among pregnant women in the Middle East.

Very few participants from the Middle East believed that the influenza vaccine is safe during pregnancy, while a large proportion of participants believed that it could be dangerous for pregnant women, fetuses, and newborns. It was also reported that participants believed that the vaccine causes birth defects, and ,therefore, pregnant women should avoid all types of vaccinations. (AlMusailhi et al., 2019; Dhaouadi et al., 2022).

However, no published studies from Jordan on the uptake, knowledge, attitudes and perceptions towards seasonal influenza vaccine during pregnancy

1.2. **Primary Goal** to reduce the burden of influenza infections during pregnancy in Jordan by improving influenza vaccine uptake during pregnancy

1.3. . Objectives

1.3.1. Primary Objective

- To measure the uptake rate of influenza vaccine during pregnancy at representative sites in Jordan

1.3.2. Secondary objectives

- To assess knowledge about influenza and influenza vaccines uptake during pregnancy.
- To identify predictors of influenza vaccine uptake and barriers to uptake during pregnancy.
- To assess attitudes and perceptions of pregnant women toward influenza vaccine uptake.

1.4. Significance of the Study

This study will assess the uptake rate, knowledge, attitudes, beliefs, and barriers related to influenza vaccines among pregnant women in Jordan. The results will help policy makers to design and implement an effective program and strategic plan for improving the uptake rate of influenza vaccine during pregnancy with an overall gaol of reducing morbidity and mortality due influenza infections during pregnancy.

This introduction addresses the uptake of the influenza vaccine, as well as the knowledge, attitudes, and barriers during pregnancy in Jordan. We begin with an overview of seasonal influenza, emphasizing its significance and impact. Subsequently, we discuss the importance of influenza during pregnancy, focusing on its effects on both the pregnant woman and the fetus.

Next, we examine the timing of vaccination, the process of receiving the vaccine, and the uptake of the vaccine during pregnancy. We reference several studies from the Middle East, summarizing previous research on knowledge and barriers to vaccine uptake. Notably, there is a scarcity of studies published in the Middle East, and no studies from Jordan specifically addressing the uptake, attitudes, and perceptions toward the influenza vaccine during pregnancy. This gap underscores the necessity of our proposed cross-sectional study to assess the uptake rate, barriers, knowledge, and attitudes toward the influenza vaccine among pregnant women in Jordan.

In research, it is essential to distinguish between goals and objectives. The goal is a subjective, overarching aim that is not easily measurable, whereas objectives are specific and measurable. The primary goal of this study is to reduce the burden of influenza infections during pregnancy in Jordan by improving vaccine uptake. The key objective is to measure the uptake rate of the flu vaccine during pregnancy. Secondary objectives include assessing the knowledge and attitudes of pregnant women toward the influenza vaccine in Jordan.

We also include a paragraph discussing the public health importance of this issue. In some reports and manuscripts, the introduction is combined with the literature review. For the purposes of this module's report, we will have a separate introduction, followed by a literature review. Initially, we will discuss the influenza vaccine, then proceed to other relevant aspects, providing a summary of the influenza vaccine during pregnancy and justifying the need for this study. Subsequently, we will outline the aims and objectives.

All these points will be elaborated upon in detail in the literature review. The primary and secondary objectives are central to the literature review, as the outcomes of the study should align with these objectives. For instance, if the objective is to measure the uptake rate, the corresponding outcome will be the measurement of the influenza vaccine uptake rate. Secondary outcomes may involve examining knowledge about the influenza vaccine during pregnancy, identifying predictors of influenza uptake, and assessing attitudes and perceptions of pregnant women toward influenza vaccine uptake.

The literature review should encompass all these aspects, including uptake rates globally, in developing countries, and within the region, as well as previous studies from Jordan concerning influenza. It should also cover research assessing knowledge about influenza and influenza vaccine uptake, along with the results of these studies. For example, regression analyses may reveal that factors such as education level, income, and health status are predictors of influenza vaccine uptake during pregnancy. Additionally, the review should examine studies that assess barriers, as well as those related to attitudes and perceptions.

By structuring the literature review around these objectives, we ensure a comprehensive and focused analysis that directly supports the aims of our study.

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

We aim to conduct a study on the epidemiology of tobacco smoking in Jordan. Our goal is to assess the burden and magnitude of smoking rates in the country.

The objectives of the study will focus on measurable and quantifiable outcomes. Specifically, we aim to determine the prevalence of tobacco smoking rates among adults in Jordan, categorized by gender.

Literature review

We need to start the literature review by moving from general to specific topics. For example, we will begin by discussing the overall impact of tobacco smoking on health. Then, we will focus on specific aspects, such as the uptake rates or smoking rates among adults, including different types of smoking, such as cigarette smoking, water pipe smoking, and vaping.

- 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

Tobacco has a major impact on the health of the population. Smoking has been recognized as a risk factor for many illnesses, such as ischemic heart disease, cancer, and complications of diabetes.

Second section: Then 2-3 paragraphs will be about the first objectives 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.

With 50% of the participants reported this as the reason for failure to quit smoking

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

So, we need to have a structure for the literature review. We start with a general comment about the topic, then we need to include the objectives, and we need to cover each objective in the literature review.

The last paragraph of the literature review should be the justification and a summary of your study.

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.

This can be used in the last paragraph of your literature review

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.

So, we either say no studies were conducted, or there were small studies conducted, but they had limitations. We need to justify this in the last paragraph and summarize the limitations. For example, the previous studies did not cover vaping or waterpipe smoking, or the age criteria were limited (e.g., people aged 30 to 50, not all adults). The study was conducted in samples from Irbid or Aqaba and not the whole country. This is why we need to conduct our proposed national cross-sectional study on tobacco rates in Jordan. If there had been a good previous study with no limitations, there would be no need for us to do the study.

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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**

Any successful proposal should include all these items. We need to ensure that these elements are present in any study proposal, as they serve as a roadmap for developing a strong proposal. Always make sure to include these items first, then proceed to write the study proposal.

- **Study design:** Example: A cross-sectional online survey questionnaire will be conducted
- I'm looking at the risk factors of ischemic heart disease or cancer, for example, studying the incubation risk factors for cancers in Jordan, the study design should be analytical. For common diseases, a cohort study is appropriate, while for rare diseases, a case-control study is more suitable. Therefore, we need to specify that the study design is a case-control study if we are assessing the risk factors of conditions like Parkinson's disease or epilepsy. However, if we are examining the prevalence of smoking in Jordan, a cross-sectional study should be used.

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

If we are conducting a study on the complication rate of type 2 diabetes in patients visiting the hospital, outpatient clinic, or primary healthcare center, or if we are studying the smoking rates of the general population in a community-based study, the setting should be community-based for the latter. For the community-based study, we may use face-to-face or door-to-door approaches to gather data from the general population. However, if we are focusing on patients from hospitals or clinics, the setting should be healthcare facility-based, such as hospitals or outpatient clinics.

- **Primary outcomes and Secondary outcomes**
- It should reflect the primary and secondary objectives. I want to assess my objective, which is to assess the quality of life of diabetic patients. The primary outcome should be measuring diabetes-related scores or questionnaires, or using the short-form survey SF36 to assess the quality of life of diabetic patients.
- **Study population**
- Am I going to include the adult population living in Jordan, aged 18-100, or 18-79?
- **Inclusion Criteria, Exclusion criteria**
- Exclusion criteria: People who are not permanently resident in Jordan, as we cannot have accurate smoking rates for those not living permanently in Jordan.

- **Sampling technique: Multistage sampling technique starting with ……..**

We need to describe the sampling technique. I am going to follow a multistage sampling technique. Firstly, we will stratify Jordan into three regions: middle, north, and south. Then, for each city, such as Irbid representing the north of Jordan, we will stratify it into areas: middle, north, south, and the center of Irbid city. Afterward, we will visit different parts of northern Irbid and select a sample from specific streets. We will use either systematic sampling or simple random sampling. For example, from a sample of 100 flats in a particular area, we will choose 10 households using systematic or simple random sampling.

For a study on diabetic patients in eastern Irbid, if we have 30 healthcare centers, we will use cluster sampling. We will randomly select three or four centers and then stratify the sample by gender. The sample will then be selected using either random or systematic sampling. We always ensure that we avoid convenience sampling, as it is non-probability sampling.

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

to assess newly diagnosed cases subclinical cases and also to assess the degree of control of known cases we need to have in the data collection section justification for our our tool
I'm assessing quality of life for the general population Jordan I'm using SF 36 this questioner is validated translated to Arabic il has sensitivity of for example 8% reliability of 90% I need to justify why I'm using this tool I'm using certain questionnaire for assessment of quality of life of diabetic patients I need to write down that this tool has been validated for patient with type two diabetes sensitivity and specificity is for example 70 or 80% will not accept less than 8 less than 80% just say 80 and 90% this is the validity reability and we need to show data about validity as references for that then we are using this tool in Arabic language this questioner has been validated for using Arabic language and we need to add the reference for that I'm using this blood test in my methodology for measurement for example hypotheism I need to write that TSH is the most sensitive screen marker for hypothyrodism sensitivity is 99% is 95% so the study tool data collection methods I need to justify the tools I'm using my questionnaire tools I'm using for assessment of the outcomes I'm using this questionnaire because validated for you so this group of patients it's validated for using Arabic for example I'm having this blood test in my cross-section study because this is the most sensitive tool for this disease I'm using Pain Scale for assessment or symptoms and or signs scores for clinical evaluation I need to justify that these tools have been validated if you have methodology for a clinical trial we need write about randomization how we maintain the blinding what are the study outcomes

- **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
  We need to write that we have obtained or will obtain the
  IRB approval from the central committee/ Jordan FDA
  / hospital/ your School of Medicine
- **Confidentiality**
- We will maintain and store the data by ensuring confidentiality. For example, when taking blood samples, we will use a patient code instead of names or national ID numbers to ensure that participants' identities remain anonymous. We will also include relevant information, such as the date of birth, but will not associate it directly with identifiable information to protect participants' privacy.
- **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)

For example, the QLQ-C30, which is a validated tool for assessing the quality of life in cancer patients, will be used. I need to gather background information about age, gender, education level, medical history, and drug history, as these factors could be predictors of the total score and quality of life. Additionally, I will need a chart review form to gather information about the stage of cancer and the treatments the patient has received. This information can be obtained from their medical files through the chart review form.

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.

NOTE we have to add reference

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.

The statistical analysis plan outlines the approach you will follow for analyzing your study data. If you are using SPSS, you need to mention that in your study. For example, you should specify that SPSS will be used and describe the statistical tests you plan to conduct, such as chi-square tests, p-values, and t-tests. These details should be included to describe the analysis. For instance, you might analyze the smoking rate differences between males and females or across different regions of Jordan. Additionally, regression analysis will be used to identify predictors of smoking in Jordan. All these items should be summarized in the statistical analysis plan.

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

If my questionnaire measures smoking rates, we start by asking about smoking initially. We conduct pre-testing by giving the questionnaire to an expert, a family member, or a colleague to review the questions. Once it is ready, we proceed with a pilot study. As mentioned previously, piloting is necessary to review the questionnaire with the target group, which will be the same as our study population. For example, I have studied the prevalence rates of smoking in Amman, Irbid, and Al-Karak. In Al-Karak, I will take a sample of 30 subjects and give them the questionnaire to identify any points missing or unclear to the study participants and to assess the duration of the interview. I plan to conduct face-to-face interviews or have the participants self-complete the questionnaire, depending on the piloting results.

4. Methods

For example, I am using the Zulewski score (a clinical score) for hypothyroidism. I need to mention that this questionnaire tool, which combines symptoms and signs of hypothyroidism, is valid for use in patients with hypothyroidism.

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? And IRB will be obtained
- Data storage and protection
- Ethical review committee
- Data protection inspectorate

We, as investigators, should not decide whether a consent form is required; this is the responsibility of the IRB committee. However, I always encourage avoiding a consent form when conducting studies on opinions, attitudes, or beliefs, as long as we are not collecting blood samples, medical information, or reviewing patient files—there is no need for a consent form in such cases. On the other hand, if any investigations are involved, such as measuring the patient's blood pressure, collecting blood samples, or reviewing medical notes, a consent form is necessary. Additionally, if you are interviewing a patient with cancer, you need to obtain their consent, especially if you intend to review their medical notes or examine details about the types of surgery, chemotherapy, or radiotherapy they have received.

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

Sometimes we have a project management section in the proposal. For example, there will be a project manager who supervises the study and assists the PI, and to add, it is not always we have this project management.

7. Timetable

The first two months will be dedicated to approvals and preparation for the study. From month three to month nine, fieldwork will be conducted. Months 10 and 11 will focus on data analysis, and the final month, month 12, will be allocated for the dissemination of results and publications.

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

…..

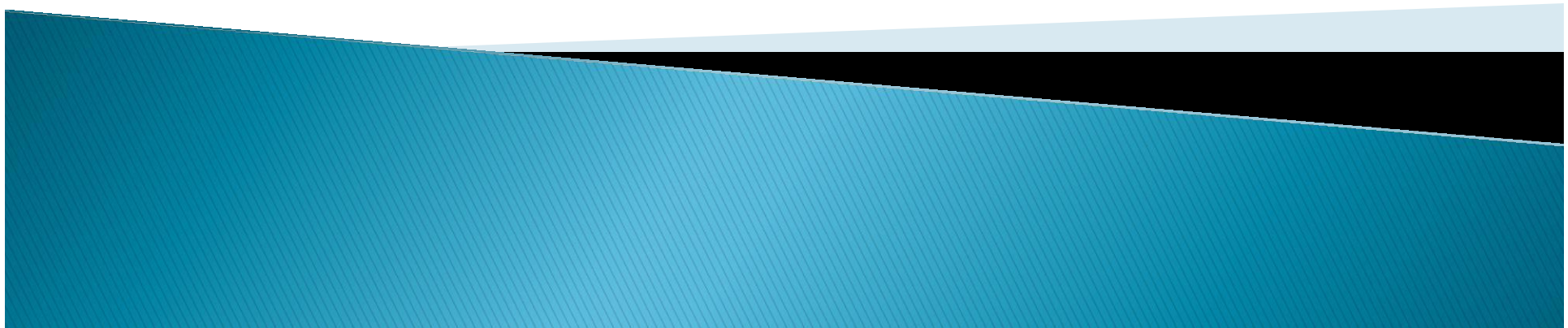
Critically appraise your proposal

A key factor for a successful proposal is conducting a critical appraisal of your own proposal. We need to revisit the methodology section to ensure that the right study design has been selected with proper justification. It is important to clearly define the primary and secondary outcomes and ensure that the tools used in the study are valid and reliable. Additionally, the proposal must address aspects related to IRB approval, sampling techniques, statistical analysis, and sample size calculation. All these items should be included, and we should be satisfied with the proposal before finalizing it.

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

If you have a survey about attitudes and beliefs towards influenza vaccination, breast cancer screening, or smoking cessation, and then we have the structure of the survey, we need to ensure in the end of the proposal that we have pre-testing and piloting of the study questionnaire. The key thing also in the survey is the selection of the sampling technique.

Steps in conducting a survey

In the proposal, we need to state that we have a research coordinator who received training on the study questionnaire. Piloting was conducted under supervision before starting data collection. Additionally, we need to include in the methodology that an instruction manual was developed for the study, the team was trained on this manual, and it was distributed to them.

- 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

the key thing in case control studies, case definition and also how we identity the cases and the controls and we need to avoid the interviewer bias try minimize the recall bias in the study and selection bias so you need to have a clear case definition and control definition in 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
XI. Budget
XII. References

We might also include blinding of the investigators in the case-control studies to avoid interviewer bias.

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

Key things

The study will assess the smoking risk factor for type 2 diabetes over a duration of 10 to 20 years. This duration has been chosen to account for the gradual onset of type 2 diabetes, which typically develops over time. The exact duration will be based on the progression of the disease observed during the study.

Participants will be divided into two groups: smokers (exposure group) and non-smokers (non-exposure group). Smoking status will be determined through self-reported history. To ensure that participants are free from type 2 diabetes or any glucose impairment at baseline, we will ask both the exposure and non-exposure groups about their history of diabetes or any impairments in their glucose function tests. Blood samples will be collected from them to assess their glucose profile and detect any impairments.

At baseline, all participants should have normal glucose function tests. We will ensure that both the exposure and non-exposure groups are comparable at baseline in terms of their health status, with no prior history of diabetes or glucose dysfunction.

To reduce the risk of loss to follow-up, participants will be seen regularly. During the first two months of the study, participants will be seen every other week. Afterward, follow-up visits will be scheduled every three months, and then every six months. Throughout the study, participants will be contacted regularly via emails, WhatsApp messages, and phone calls to encourage participation and ensure they remain engaged in the study.

Protocol 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

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.

Both groups should be free of the disease at baseline and equally susceptible to it. This means that, at baseline, without considering the risk factors, both groups should be comparable except for their exposure status. For example, if we are studying the incidence of type 2 diabetes or hypothyroidism, we must have clear diagnostic criteria with justification for those criteria. These diagnostic criteria should define how type 2 diabetes or hypothyroidism is identified and confirmed in the study population.

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

Another key aspect of the cohort study is the sampling technique: how we are going to select the study population and how we are going to identify smokers and non-smokers within the population.

Clinical trials

- Give a brief summary of the proposed trial
- Hypotheses.
- What is the proposed trial design?

  Is it a parallel design or a crossover design?
  Is it triple-blind, double-blind, or single-blind?

- 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?
- Is it a single-center study in Jordan, a multi-center study in Jorda
- What is the planned recruitment rate?
- I need to have the study for one year with, for example, 30 patients per month.
- What are the practical arrangements for allocating patients to trial groups?
- We need to describe the randomization process to ensure that each participant in the clinical trial has an equal chance to be included in different study groups.
- What are the planned trial interventions?
- What is the proposed duration of treatment?

And follow up

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:

إِنَّ اللَّهَ وَمَلَائِكَتَهُ يُصَلُّونَ عَلَى النَّبِيِّ ۚ يَا
أَيُّهَا الَّذِينَ آمَنُوا صَلُّوا عَلَيْهِ وَسَلِّمُوا تَسْلِيمًا

VERSIONS	SLIDE #	BEFORE CORRECTION	AFTER CORRECTION
V1→ V2			
V2→V3			

امسح الرمز و شاركنا بأفكارك لتحسين أدائنا !!