# BASIC GUIDELINES FOR MEDICAL RESEARCHES

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**First Edition**

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# Preface

Medical research is an important aspect of healthcare, as it helps to improve our understanding of diseases and their treatments. By understanding the different types of medical research and study designs, researchers can design and conduct high-quality studies that can help to improve patient outcomes. Medical students face great difficulty in conducting research work as a part of the academic requirements, especially the fourth stage, for the reason of time shortage, and routine work. Consequently, not all students can master the steps of scientific research work, which may create a defect in their background, which leads to a shortcoming in their future work as physicians and researchers. So, bringing guidelines in the research methodology of medicine is critically needed to lead under and postgraduate students in executing such work; which is considered a fundamental item in the curriculum and physician career.

# Objectives of This Book

To help medical students to carry out research in a scientific way while saving time, and effort and building out their experience with a minimum of teacher help. This book puts in the hands of the researcher all the information and steps he\she needs, during the process of conducting research, as well as writing the results that he/she reaches scientifically i.e., how to perform research or to write a manuscript. So, the goal is to provide a succinct practical guide, not to prepare a comprehensive reference book, and beginners in the field of health research should look at different sources the list of references listed at the end of the book if they want to be fully aware of the various aspects of the research process.

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I am grateful to my college (College of Medicine, University of Mosul) with all its staff who guided me with knowledge and support throughout my life whether as a student or a faculty member. Thanks to my family who supported me during the period of my writing, and special thanks to my husband Dr. Mohammad Yousif Mohammad.

# Dedication

To the spirit of my mother who encouraged me during her life.

# Understanding The Research Process

As a doctor, and at whatever time, if one wants to discover the impact of certain disease on his/her community, realize the effect of a new drug on patients; or wants to evaluate the effects of certain measures on the population at large or even on the small groups in the community, so a research work should take place

Research is the systematic collection, analysis, and interpretation of data to answer a certain question or to solve a problem.

It is a process for acquiring new knowledge in a systematic approach involving diligent planning and interventions for the discovery or interpretation of the new-gained information. (1)

It is worth noting, that the ultimate goal of research work, is to improve control of disease\diseases through both prevention and treatment that will prevent deaths and disability and will enhance the quality of life of those who have developed a serious illness. (2)

# Contents

# Chapter 1

## Introduction to Health Research

# 1. Introduction to the general classification of health and medical research

## How to Carry out Research Work

The researcher should be aware of different categories of health research to be able to make a better choice of study design that helps to answer the questions of concern**.**

## 1-1 Categories of Health Research

Health research is any research that ultimately aims to improve human health. It has a wider term than medical research. It may include, but not limited to, biology, physiology, pharmacology, chemistry, engineering, biotechnology, epidemiology, medicine, psychology, nursing, allied health, population studies, IT, mathematics, economics, and health services research. The Health Research Classification System (HRCS) is based on the World Health Organization (WHO) International Classification of Diseases (ICD) codes which cover all areas of disease and ill health. It is a framework used to classify health research in a standardized manner providing a more detailed breakdown of health research domains which allows for a more precise analysis of research activities and funding allocation in the field of health research.

The Health Research Classification System (HRCS) includes the following:

1-1-1 Blood which includes Hematological diseases, anemia, clotting (including thromboses and venous embolisms) and normal development and function of platelets and erythrocytes

1-1-2 Cancer and neoplasms which includes all types of neoplasms, including benign, potentially malignant, or malignant cancer growths. This includes leukemia and mesothelioma.

1-1-3 Cardiovascular Coronary heart disease, which includes diseases of the vasculature and circulation including the lymphatic system, and normal development and function of the cardiovascular system.

1-1-4 Congenital disorders which include physical abnormalities and syndromes that are not associated with a single type of disease or condition including Down's syndrome and cystic fibrosis.

1-1-5 Ear which includes deafness and normal ear development and function.

1-1-6 Eye which includes diseases of the eye and normal eye development and function.

1-1-7 Infection which includes diseases caused by pathogens, acquired immune deficiency syndrome, sexually transmitted infections and studies of infection and infectious agents.

1-1-8 Inflammatory and immune system which includes rheumatoid arthritis, connective tissue diseases, autoimmune diseases, allergies and normal development and function of the immune system

1-1-9 Injuries and accidents which include fractures, poisoning and burns.

1-1-10 Mental health which includes depression, schizophrenia, psychosis and personality disorders, addiction, suicide, anxiety, eating disorders, learning disabilities, autistic spectrum disorders and studies of normal psychology, cognitive function, and behavior.

1-1-11 Metabolic and endocrine which includes metabolic disorders (including Diabetes) and normal metabolism and endocrine development and function. This includes all research on the pineal, thyroid, parathyroid, pituitary and adrenal glands.

1-1-12 Musculoskeletal Osteoporosis which includes osteoarthritis, muscular and skeletal disorders and normal musculoskeletal and cartilage development and function.

1-1-13 Neurological which includes dementias, transmissible spongiform encephalopathies, Parkinson's disease, neurodegenerative diseases, Alzheimer's disease, epilepsy, multiple sclerosis and studies of the normal brain and nervous system.

1-1-14 Oral and gastrointestinal which includes inflammatory bowel disease, Crohn's disease, diseases of the mouth, teeth, esophagus, digestive system including liver and colon, and normal oral and gastrointestinal development and function.

1-1-15 Renal and urogenital which includes kidney disease, pelvic inflammatory disease, renal and genital disorders, and normal development and function of male and female renal and urogenital system

1-1-16 Reproductive health and childbirth fertility which includes contraception, abortion, in vitro fertilization, pregnancy, mammary gland development, menstruation and menopause, breast feeding, antenatal care, childbirth and complications of newborns.

1-1-17 Respiratory which includes asthma, chronic obstructive pulmonary disease, respiratory diseases and normal development and function of the respiratory system.

1-1-18 Skin which includes dermatological conditions and normal skin development and function.

1-1-19 Stroke Include both ischemic stroke (caused by blood clots) and hemorrhagic stroke (caused by cerebral/intracranial hemorrhage).

1-1-20 Generic health relevance which includes research applicable to all diseases and conditions or to general health

and well-being of individuals. Public health research, epidemiology and health services research that is not focused on specific conditions. Underpinning biological, psychosocial, economic or methodological studies that are not specific to individual diseases or conditions.

1-1-21 Disputed an etiology and other diseases which include conditions of unknown or disputed an etiology (such as chronic fatigue syndrome/myalgia encephalomyelitis), or research that is not of Generic Health Relevance and not applicable to the top 19 specific health categories with specific pathological / physiological determinants. (3)

## 1-2 Types of Medical Research and its Classification

Classification of Medical Research

Medical research is a vital field of study that aims to understand the causes, treatments, and prevention of various health conditions. It can be broadly categorized into two types: primary and secondary research. (4) Primary research involves collecting and analyzing new data to answer a specific research question, while secondary research involves synthesizing existing data to draw new conclusions or insights.

### 1.2.1 Primary Researches

Primary medical research refers to original research conducted to generate new knowledge in the field of medicine and

healthcare. It involves the collection of data, experimentation, and analysis to answer specific research questions or test hypotheses. It can be classified into three categories as basic research, clinical and epidemiological research.

***1-2-1-1 Basic Research*:** Basic research, also known as fundamental research, focuses on understanding the fundamental mechanisms that underlie disease and health. This type of research often takes place in a laboratory setting and involves studying cells, tissues, and organisms at a molecular or cellular level. Basic research aims to develop a better understanding of how the body works and to identify new targets for drug development. It is an essential component of medical research, as it lays the foundation for future clinical research. It is classified into two main classification applied research and method development.

A- applied research which includes

1- Animal study

2- Biochemistry

3- Cell study

4- Genome

5- Pharmacogenetics

B- Method Development

***1.2.1.2 Clinical Research***: This is the second type of primary research involving research that tests medical interventions in human subjects to evaluate their safety and effectiveness.

Clinical research can be classified into several subdivisions

A- Observational research which includes:

- Therapy study without intervention
- Prognostic study
- Diagnostic study
- Therapy study with drug intervention
- Secondary data analysis
- Case series
- Single Case report

B- Experimental study

This includes clinical study which is subdivided into:

- Phase I study
- Phase II study
- Phase III study
- Phase IV study

Each phase is focusing on different aspects of drug development. Phase I trials are the first stage of testing a new drug, and they typically involve a small group of healthy volunteers to assess the drug's safety. Phase II trials expand on the

findings of Phase I, and they typically involve a larger group of patients with the condition being studied. Phase III trials are the final stage of testing before a drug is approved for use, and they involve large-scale studies to assess the drug's effectiveness and safety in a diverse population. Phase IV trials are conducted after a drug has been approved and are designed to monitor its long-term safety and effectiveness.

#### *1.2.1.3 Epidemiological Research:*

Epidemiological research is concerned with understanding the distribution and determinants of health and disease in populations. It involves the study of the incidence, prevalence, and risk factors associated with various health conditions. Epidemiological research can be used to identify patterns of disease and to develop interventions to prevent or manage these conditions. It can also be used to evaluate the effectiveness of health interventions in real-world settings. It is considered the "fundamental science" of prevention. Identification of populations at elevated risk, identification of the cause(s) of their increased risk(s), and analysis of the costs and advantages of removing or lowering exposure to the causal factor are all results of interpreting the findings of epidemiologic studies. The difficulties include drawing reliable conclusions from the data produced by epidemiologic studies, ensuring appropriate and understandable dissemination of the findings and their interpretations to decision-

makers and the general public, and resolving ethical issues that develop as a result of epidemiology's close relationship to human health and clinical and public health policy. Besides, epidemiology is used in evaluating both health services and programs for screening and early detection of diseases. (5)

The epidemiological studies can be divided into two major categories:

#### 1.2.1.3.1 Qualitative Research

Qualitative research is a structured way of collecting and analyzing data obtained from different sources. It involves collecting and analyzing non-numerical data (e.g., text, video, or audio) to understand concepts, opinions, or experiences. (6)

There are six common types of qualitative research: **phenomenological, narrative, ethnographic, grounded theory, historical, case study, and action** research.(7) (8)

#### 1.2.1.3.2 Quantitative Research

Quantitative Research is the process of collecting and analyzing numerical data.

Types of study design that are included in Quantitative research are:

1. Observational research
2. Experimental research

#### 1.2.1.3.2.1 Observational research

This type of research design allows the researchers to observe and analyze the behaviors, characteristics, or outcomes of a group of people or phenomena without any intervention. In other words, observational studies are non-experimental, meaning that the researchers do not manipulate any variables, but rather observe what is already happening.

Observational studies can provide valuable insights into the relationships between various factors and outcomes, especially when experimental studies are not feasible or ethical. For example, it may not be possible or ethical to conduct a randomized controlled trial to study the effects of smoking on health outcomes, but observational studies can provide valuable information in this area.

One of the major advantages of observational studies is that they can be conducted relatively quickly and inexpensively, especially compared to experimental studies. Additionally, they can provide valuable information on rare events or conditions that might not be possible to study through experimental methods.

However, observational studies also have several limitations. One major limitation is the potential for bias. Since researchers are not controlling any variables, they cannot guarantee that the observed relationships are causal, and other factors may be

confounding the results. Additionally, there is a risk of selection bias, where the participants selected for the study may not be representative of the broader population.

Despite these limitations, observational studies remain an important tool for researchers in a variety of fields, from medicine to social sciences. By carefully designing and conducting these studies, researchers can gain valuable insights into the complex relationships between different variables and outcomes, and ultimately improve our understanding of the world around us. Observational study is subdivided to:

- Descriptive study
  - Case study report
  - Case series
  - Ecological study
  - Cross-sectional study
  - Naturalistic observation
- Analytic study
  - Case-control
  - Cohort study
  - Analytic cross-sectional
  - Nested case-control study

**Types of Observational Study:**

➢ **Descriptive Observational Study:**

This type of studies includes case reports, case series, cross-sectional studies, and ecological studies, which merely describe one or more variables in a sample or population.

- **Case Reports and Case Series**

Case reports and case series are key hypothesis-generating tools, especially when they are simple, inexpensive, and easy to conduct in the course of busy clinical settings. However, the lack of a comparison group is a major disadvantage. Furthermore, external validity (generalizability) is limited, given the biased selection of cases (all identified in clinical practice) because it is through careful observation by physicians and other healthcare providers of what they see during their clinical practice. Such individual-level observation can be documented in a case report, describing a particular clinical phenomenon in a single patient, or in a case series, that describes more than one patient with similar problems. It includes a description of one case or series of cases that have common characteristics as they are identified in clinical practice.(9)

- **Ecological Studies**

An ecological study looks at the characteristics, behaviors, or outcomes of groups or populations rather than individuals. This

study focuses on the comparison of groups, rather than individuals; thus, individual-level data are missing on the joint distribution of variables within groups. (10) It is the first approach in determining whether an association exists. Odd study of group researchers uses ecological studies to investigate how different factors (e.g., environmental, economic, social) may influence health outcomes in different populations. For example, the higher consumption of oral contraceptive pills in one country is correlated with a higher percentage of breast cancer. However, it does not reveal that those women who develop breast cancer are truly the consumers of the oral contraceptive pills and that leads to the **ecologic fallacy** –which means that an error in statistical inference that occurs when conclusions are drawn about individuals based on group-level data. It is the assumption that the relationship observed between variables on a group level will hold true for individuals within that group.

- **Cross-Sectional Studies**

A cross-sectional study is a type of observational study that collects data at a single point in time. Researchers collect data on the characteristics, behaviors, or outcomes of a group of individuals or phenomena at a particular point of time. For example, a cross-sectional study might gather information about the prevalence of a particular disease in a given population.

It is un-expensive, easy, common study design used to measure the association between an exposure and a disease, condition, or outcome within a defined population.(11) It is a type of observational study, that involves analyzing information about a population at a specific point in time. Typically, these studies are used to measure the prevalence of health outcomes and the characteristics of a population.

Both exposure and disease outcomes are determined simultaneously for each study participant. It is described as if we take a snapshot of a certain population at a certain point in time but with no temporal sequence between the exposure and the disease. In this case, the researcher does not know which starts first the disease or the exposure. For example, finding the prevalence of prevalent cases of liver cirrhosis among alcohol consumers would not explore the role of other causes or past exposure to alcohol but would not allow the role of past alcohol use, or other causes, to be explored. In this type of study, recall bias is one of the important disadvantages, especially during investigating about past events.

Cross-sectional studies may involve special data collection, including questions about the past and for that, it is very susceptible to recall bias.

Naturalistic Observation**:** Naturalistic observation is a type of observational study where researchers observe individuals in their

natural environment without interfering with their behavior. Naturalistic observation is commonly used in psychology and anthropology research.

➢ **Analytic Observational Study**

Analytic studies attempt to quantify a relationship or association between two variables – an exposure and an outcome. These include case-control, cohort, and analytic cross-sectional design.

- **Case-Control Studies**

In a case-control study, researchers compare individuals with a particular condition or disease (cases) to those who do not have the condition or disease (controls) and then try to elicit a history of exposure in each group. Researchers then look for differences between the two groups to identify potential risk factors for the condition or disease via the calculation of an odds ratio. Thus, these are backward-direction studies (looking from outcome to exposure) and are always retrospective (the outcome must have occurred when the study starts). (12) Typically, cases are identified from hospital records, death certificates, or disease registries. This is followed by the identification and enrolment of controls. Case-control studies are often cheap and need less time. It is useful for hypothesis generation but bias is a major problem in this study. Potential Biases in Case-Control Studies maybe from

selection bias, sources of cases, selection of controls information bias, and problems of recall.(13)

- **Cohort study:**

In a cohort study, researchers select a group of individuals who share a common characteristic or experience (e.g., all born in a particular year). These participants have to be free of the outcome at baseline. The presence or absence of the risk factor (exposure) in each subject is recorded over time to see how their characteristics or outcomes change. Cohort studies can be either prospective (where the researchers select the cohort and follow them forward in time as the outcome has not occurred at the start of the study, or retrospective where the researchers look back at historical data to identify the cohort as the outcome has occurred at the start of the study. For an exposure to be causative, it must precede the outcome. In a cohort study, the temporal relationship is present. Therefore, the relative risk, attributable risk, and attributable risk ratio of the factor under the study are calculated, as shown in Figures 6 and 7

However, large epidemiologic cohort studies often need to follow several thousand subjects longitudinally. Assembling detailed information for all cohort members may take a long time and result in enormous cost. To reduce cost and achieve the same goal as a cohort study, several alternative study designs have been proposed. Some of them such as nested case-control and case-

cohort study designs are particularly practical in studying rare diseases.

- **Nested case-control study:**

For many research questions, the nested case-control design potentially offers impressive reductions in costs and efforts of data collection and analysis compared with the full cohort approach, with relatively minor loss in statistical efficiency. As cases of a disease that occur in a defined cohort are identified and, for each, a specified number of matched controls is selected from among those in the cohort who have not developed the disease by the time of disease occurrence in the case. (14)

This can be illustrated by the following example:

Consider a hypothetical prospective cohort study among 89,949 women from whom the investigators took blood samples and froze them at baseline for possible future use. After following the cohort for 12 years the investigators wanted to investigate a possible association between the pesticide DDT (dichloro-diphenyl-trichloroethane) and breast cancer. Since they had frozen blood samples collected at baseline, they had the option of having the samples tested for DDT levels. If they had done this, the table below shows what they would have found.

| | Br. Cancer | No Br. Cancer | Total Exposed |
|---|---|---|---|
| DDT high | 0,360 | 13,276 | 13,636 |
| DDT low | 1,079 | 75,234 | 76,313 |
| Column Totals | 1,439 | 88,510 | 89,949 |

If they had had this data, they could have calculated the risk ratio as follows:

RR = (0,360/13,636) / (1,079/76,313) = 1.87

However, the cost of analyzing each sample for DDT was $20, and to analyze all of them would have cost close to $1.8 million. So, like the previous study, the exposure data was very costly.

Although this was a prospective cohort study, *we could regard the cohort as a source population and conduct a case-control study drawing samples from the cohort*. We could, for example, analyze the blood samples on all of the women who had developed breast cancer during the 12 years follow up and on 2,878 randomly selected samples from the women without breast cancer (i.e., twice as many controls as cases). This would be described as a **nested case-control study**, i.e., nested within a cohort study.

The results might have looked like this:

| | **Br. Cancer** | **No Br. Cancer** | **Total Exposed** |
|---|---|---|---|
| DDT high | 0,360 | 0,432 | Unknown |
| DDT low | 1,079 | 2,446 | Unknown |
| Column Totals | 1,439 | 2,878 | |

Odds Ratio = (a/c) / (b/d) = (0,360/1,079) / (0,432/2,446)

= 1.89 during the 12 years follow up study

So, they could achieve an odds ratio that is very close to what the risk ratio would have been at a much lower cost: (1,439+2,878) x $20 = $86,340.(15)

While a nested case-control study design involves the selection of several healthy controls for each case, typically from those still under observation at the time when the case developed the disease. It is an efficient design that can be embedded within an existing cohort study or randomized trial. However, nested case-control studies have some limitations:

1) Inefficiency due to the alignment of each selected control subject to its matched case.
2) When there is more than one disease outcome considered, strict implementation of the nested case-control design requires the

selection of a new set of controls for each distinct disease outcome.

Therefore, case-cohort study designs were proposed as an alternative to the nested case-control study design. A major advantage of the case-cohort design is the ability to study several disease outcomes using the same sub-cohort. Figure (1) The defining feature of the case-cohort design is the presence of 2 subject groups within a large patient cohort: a sub-cohort and a case group.(16), (17)The case group includes all cohort members that develop an outcome of interest during a period of follow-up after cohort formation.(18) This outcome may be defined as an illness or condition, such as a treatment complication, a failure to respond to treatment, or a disease recurrence. The sub-cohort is a sample of the entire cohort selected at random, without regard to case definition or future outcomes.(19) (20)A subset of individuals may thus become a case within the sub-cohort. Importantly, multiple independent case groups can be compared with the common sub-cohort within a single study. The random selection of the sub-cohort also allows for its use as a comparison group for investigating multiple outcomes in 1 study.

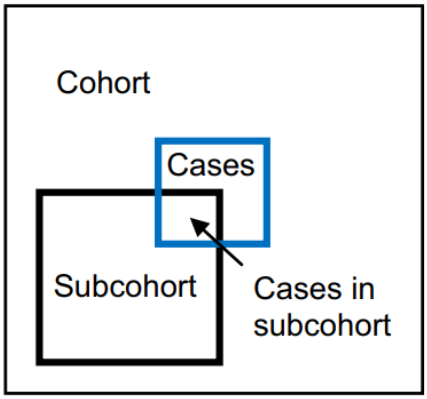


**Figure 1 (Case-Cohort design)**(21)

Under this situation, two control groups need to be sampled under the nested case-control design while a case-cohort design only requires one sub-cohort which is used to evaluate for example the effect of smoking for both diabetes and lung cancer.

**Analytic cross-sectional study**

It is a type of quantitative, non-experimental research design. These studies seek to "gather data from a group of subjects at only one point in time(22). This kind of study design usually uses surveys or questionnaires to gather data from participants to measure the association between an exposure and a disease, condition, or outcome within a defined population.

**1.2.1.3.2.2. Experimental (Interventional) research**

This is the second type of quantitative research design and it includes the introduction of new drugs, experiments, and tests on

the subjects to obtain results. The study can be tailored to answer a specific research question.(23)

There are two main types of experimental research:

- **Randomized controlled trials (RCTs):**

These studies are considered the gold standard for evaluating the effectiveness of an intervention. Participants are randomly assigned to either an intervention group or a control group, as appeared in figure (2).The intervention group receives the treatment being tested, while the control group receives a placebo or standard treatment. Researchers can then compare the outcomes in the two groups to determine the effectiveness of the intervention. It is placed at the top of the list of levels of evidence in evidence-based medicine. This ensures providing the most definitive evidence regarding the impact of the exposure or intervention on the outcome (24)

The randomized trial is the gold standard for evaluating the efficacy of therapeutic, preventive, and other measures in both clinical medicine and public health. It is defined as a prospective scientific experiment that involves human subjects in whom treatment is initiated for the evaluation of a therapeutic intervention. RCTs involve randomly assigning participants to different groups, with each group receiving a different treatment or intervention. The groups are then compared on the outcome

variable of interest to determine if there is a significant difference between them.(25)

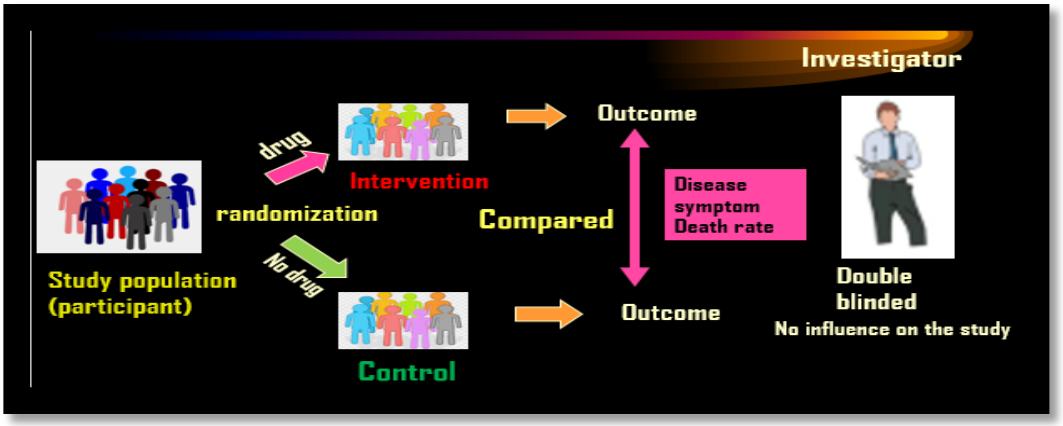


**Figure (2): Demonstration of Interventional Design.**

There are different subgroups of RCT depending on the study design, namely Active Control, Placebo Control, Multiple arms, Clustered randomized, Adaptive design, and Platform. However, because of its randomization process and follow-up duration; these kinds of studies require teamwork and are regarded as the most expensive study design used in epidemiology. Other disadvantages of RCT are a high dropout of participants when the intervention has undesirable side effects or there is little motivation to stay in the control arm. Besides, ethical considerations may indicate that a research question cannot be investigated using the RCT design.

There are different ways of measuring the independent and dependent variables in a study, and the choice of the design will

depend on the research questions, the resources available for the study, and the nature of the variables being studied. There are six types of these designs that can be used in a variety of research studies, including experimental and non-experimental studies.

1. Independent Groups Design: In this design, participants are randomly divided into two or more separate groups, with each group receiving a different treatment or condition. The goal is to compare the effects of each treatment or condition on the outcome variable. This design is efficient but may have issues with participant differences. (26)
2. Repeated Measures Design (Cross-Over Design): In this design, the same participants are measured multiple times, under different conditions or treatments. This reduces the need for more participants but may have order effects.(27)
3. Matched Pairs Design: In this design, participants are matched based on certain characteristics and then randomly assigned one member of each pair to a different treatment or condition. This controls participants differences but is limited in the number of pairs that can be formed.(28)
4. Within-Subjects Design: In this design, the same participants are measured multiple times under the same conditions, then changing conditions and measure again. This allows for a

comparison of results within the same participants but may have carry-over effects (29).

5. Factorial Design: In this design, the effects of two or more independent variables on the outcome variable are examined. This allows for the examination of how different factors interact with each other but requires a larger sample size.(30)
6. Quasi-Experimental Design: In this design, a comparison is made between groups, but it cannot randomly assign participants to different conditions or treatments. This design is useful when random assignment is not possible, but may have issues with internal validity.(31)

- Non-randomized controlled trials: These studies involve assigning participants to either an intervention group or a control group, but the assignment is not random. These studies can still be useful for evaluating the effectiveness of an intervention, but there is a higher risk of bias compared to RCTs.

Overall, the choice of study design depends on the research question, available resources, and ethical considerations. Researchers must carefully consider the strengths and limitations of each study design to ensure that their research is of high quality and can contribute to improving patient outcomes.

### 1-2-2 Secondary research

Secondary medical research involves the analysis, synthesis, and interpretation of existing data and research findings. It typically does not involve the collection of new data but instead relies on previously published primary research. Secondary research is valuable for summarizing, synthesizing, and drawing new conclusions from a body of existing knowledge. It is also known as desk research. This type of research is often used to evaluate the effectiveness of medical interventions, identify gaps in the literature, and inform the development of new research studies. Those could be systematic reviews, meta-analyses, and scoping reviews.

Secondary research can take many forms, but the commonest types related to medicine are Systematic review and Metanalysis.

- **Systematic Review**

A systematic review attempts to organize empirical evidence that fits pre-specified eligibility criteria to answer a specific research question. The key characteristics of a systematic review are a clearly stated set of objectives with pre-defined eligibility criteria for studies. Through this review, a careful examination of books, scholarly articles, and any other sources relevant to a particular issue, area of research, or theory will be done and this provides a description, summary, and critical evaluation of these works about the research problem being investigated. A

systematic search attempts to identify all studies that meet the eligibility criteria; an assessment of the validity of the findings of the included studies (e.g., through the assessment of the risk of bias); and a systematic presentation and synthesis of the attributes and findings from the studies used. (32)

Systematic methods are used to minimize bias, thus providing more reliable findings from which conclusions can be drawn and decisions be made than the traditional review method.

- **Meta-analysis**

It is a subset of a systematic review. A meta-analysis is a statistical analysis that combines the results of multiple scientific studies. (33) Meta-analyses have been performed when multiple scientific studies are addressing the same question, with each study reporting measurements that are expected to have some degree of error. It is a quantitative, formal, epidemiological study design used to systematically assess the results of previous research to derive conclusions about that body of research. Typically includes randomized control trials; however, it can use cohort or case-control studies. Outcomes from a meta-analysis may include a more exact estimate of the effect of treatment or risk factors for disease, or other outcomes, than any individual study contributing to the pooled analysis.(34) Generally, it has a special software program that performs the pooling effect of these studies.

# Chapter 2

## Research Methodology: Guidelines for Research Conduction

## 2. Steps of Research Conducting

Medical research involves several steps, and each step is critical to ensuring the validity and reliability of the research. Here are the steps of doing medical research:

1. Identify the research questions: The first step is to identify the research questions or hypotheses. This involves a thorough review of the literature to determine what is already known about the topic and identify gaps in knowledge. The research questions should be specific, measurable, and relevant to clinical practice.
2. Develop the research plan: Once the research questions have been identified, the next step is to develop a research plan. This includes determining the study design, sample size, data collection methods, and statistical analysis plan. The research plan should be detailed and include a timeline for each step of the study.
3. Obtain ethical approval: Before any research can be conducted, ethical approval must be obtained from an institutional review board (IRB) or ethics committee. The IRB or ethics committee will review the research plan to ensure that it meets ethical standards and protects the rights and welfare of the study participants.

4. Recruit participants: Once ethical approval has been obtained, participants must be recruited for the study. Depending on the study design, participants may be recruited from a specific population, such as patients with a particular disease or condition, or the general population.
5. Collect data: Data collection methods will depend on the study design and research questions. This may include surveys, interviews, medical record reviews, or laboratory tests. It is important to ensure that the data is collected in a standardized and consistent manner to reduce bias.
6. Analyze data: Once the data has been collected, it must be analyzed using appropriate statistical methods. This may involve descriptive statistics, such as means and standard deviations, or inferential statistics, such as t-tests or regression analysis. The analysis plan should be specified in advance in the research plan.
7. Interpret results: After the data has been analyzed, the results must be interpreted in the context of the research question and previous research. This involves drawing conclusions from the data and determining the implications for clinical practice.
8. Communicate results: The final step is to communicate the results of the research to others. This may involve publishing the results in a peer-reviewed journal, presenting the results at

a conference, or disseminating the results through other means. It is important to ensure that the results are communicated clearly and understandably to maximize their impact.

## 2-1 Research Questions

Researchers can develop a research question or hypothesis that is relevant, feasible, and liable to be answered through research. This is an important first step in conducting high-quality medical research. Developing a research question or hypothesis is a critical first step in conducting medical research which expresses what the research project aims to address. Here are some steps to follow when developing a research question or hypothesis:

1. Review the literature: Conduct a thorough review of the literature to determine what is already known about the topic. This will help identify gaps in knowledge and areas where further research is needed.
2. Identify a specific topic: Once you have reviewed the literature, identify a specific topic that you are interested in studying. This topic should be relevant to clinical practice and should have a clear research question or hypothesis.
3. Consider the scope of the study: Determine the scope of the study based on the available resources, time, and feasibility. This will help ensure that the study is manageable and can be completed within the available timeframe.

4. Develop the research questions or hypotheses: The research questions or hypotheses should be specific, measurable, and relevant to clinical practice. It should also be testable and liable to be answered through research. For example, a research question could be: "Does physical activity reduce the risk of type 2 diabetes in overweight adults?"
5. Refine the research questions or hypotheses: Once the research questions or hypotheses have been developed, refine them to ensure that it is clear and concise. This may involve rephrasing the questions or hypotheses or adding additional details to these questions.
6. Consider ethical considerations: Consider any ethical considerations related to the research questions or hypotheses. This may involve ensuring that the study does not harm participants, obtaining informed consent, and maintaining confidentiality.
7. Seek feedback: Seek feedback from colleagues, mentors, or other experts in the field to ensure that the research questions or hypotheses are sound and can be answered through research.

- Now, three questions should be answered:

- What is the research question?
- Why such data should be collected?
- From whom such data should be collected?

Indicators outcomes that are generated must be measurable (using either qualitative or quantitative data)

"An outcome is something that you can track to measure data on your research question" Outcomes should be feasibly measurable (quantitative), like age, weight, blood pressure, hemoglobin level, …etc. or qualitative like attitude by special scale, or just yes or no answers.

**Defining the research question clearly will help in the determination of an appropriate research design that answers the questions.**

## 2-2 Research Aim & Objectives

Research aims and objectives are critical components of any research study. They define the purpose and scope of the research and guide the direction of the study. Here are some details on developing the research aims and objectives:

### ➢ Research Aim:

The research aim is the overarching goal of the study, and it should be a concise statement that defines the purpose of the research. It should be broad enough to encompass the entire study, but specific enough to provide a clear focus. A well-written research objective should be:

- Clear and concise
- Specific and measurable

- Relevant to the research question
- Aligned with the research questions or hypotheses
- Realistic and achievable

For example, a research aim might be "to investigate the effect of physical activity on blood glucose levels in patients with type 2 diabetes."

➢ **Research objectives:**

Research objectives are specific goals or statements that articulate what a research study intends to achieve. They serve as a roadmap for the research, guiding the researcher in terms of what needs to be investigated, measured, and analyzed. Example "To assess the effectiveness of a new drug in reducing blood pressure in patients with hypertension over a 6-month period."(35)

There are different types of research objectives that can be used, use the specific objectives to describe how a researcher can achieve research's general goal. The specific objectives should meet SMART criteria:

- Specific research objectives should be clearly written and leave no room for confusion. This can help researcher keep objectives specific, narrow and focused.
- Measurable: It is essential for the objectives to be measurable to achieve goal.

- Achievable: Objectives should be realistically achieved to help researcher avoid getting overwhelmed by unrealistic expectations.
- Relevant: Make objectives relevant to the research overall goals. This can help researcher stay motivated and on track throughout research project.
- Time-based: Researcher can establish deadlines to help him/her keep research process on track.

Objectives should be stated using action verbs that are specific enough to be measured, for example: to compare, to calculate, to assess, to determine, to verify, to evaluate, to describe, to explain, etc. Avoid the use of vague non-active verbs such as: to appreciate, to understand, to study, etc., because it is difficult to evaluate whether they have been achieved.

## 2-3 Research Design

Selecting the appropriate research design is critical for any research study, as it affects the validity and reliability of the results obtained. There are several types of study design that researchers can use, including cross-sectional studies, cohort studies, case-control studies, and randomized controlled trials. (See details page). Each design has its strengths and limitations, and researchers must carefully choose the appropriate design based on their research questions and objectives. (36)

There are some important considerations when selecting a research design.

1. The research design should be tailored to address the specific research questions and objectives in a manner that is feasible and efficient.
2. Type of data: The type of data to be collected is also a critical factor in determining the research design. Qualitative data, such as open-ended responses, observations, and interviews, are typically collected through exploratory research designs, whereas quantitative data, such as numerical data, are collected through descriptive and inferential research designs.
3. Research participants: The characteristics of the research participants, such as their age, sex, socio-economic status, and cultural background, should also be considered when selecting a research design. The research design should be appropriate for the target population and should take into account any potential biases that may arise from the sample selection process.
4. Time and budget constraints: The time and budget available for the research study can also influence the choice of research design. For example, a longitudinal study that requires multiple data collection points over an extended period may be more costly and time-consuming than a cross-sectional study.

5. Ethical considerations: Informed consent, confidentiality, and the use of sensitive information, should also be considered according to the study design. The research design should be appropriate for the ethical considerations of the research study, and any potential ethical issues should be addressed.
6. Available resources: The availability of resources, such as equipment, software, and personnel, can also impact the choice of research design. For example, a research study that requires advanced statistical analysis may require specialized software and personnel with expertise in statistical analysis.

In principle, medical research is classified into primary and secondary research. While secondary research summarizes available studies in the form of reviews and meta-analyses. (Figure 2)

**2-4 Research Title**

After formulating research questions, the aim of the study and the decision of study design has been made; choosing a good title for a research study is an important step in the research process. A title should be concise, informative, and capture the essence of the research. Here are some tips on how to choose a title for a research study:

1. Identify the main focus of the research: The title should indicate the main focus of the research. This can be achieved by

including keywords or phrases that accurately describe the study's topic, methodology, or population.

2. Keep it concise: A title that is too long can be confusing and difficult to read. Aim for a title that is brief, yet descriptive. Typically, titles should be no longer than 15 words.
3. Use active verbs: Active verbs can make a title more engaging and dynamic. For example, instead of "The Effects of Exercise on Heart Health," consider "Exercise Improves Heart Health in Older Adults."
4. Be specific: Avoid vague or general titles that don't provide enough information about the research. Instead, use specific details to make the title more informative and interesting.
5. Consider the target audience: The title should be appropriate for the intended audience. For example, a title for a research study aimed at a scientific audience may be more technical than a title for a general audience.
6. Review similar studies: Look at the titles of similar studies to get inspiration and ideas. However, be sure to avoid duplicating titles or using titles that are too similar to existing research.
7. the originality of the research can be checked by using the VOS viewer version 1.6.19, released on January 23, 2023, which is available for download and can limit the search for the area of the researcher’s country.

## 2-5 Data Collecting tools

To answer a research question, there are many potential sources of data. The amount of data collected for the study should be sufficient. A common mistake is collecting too much data without knowing what will be done with it. Researchers should identify essential data elements and eliminate those that may seem *interesting* but are not central to the study hypothesis, so the data needs to be justified.

There are two main categories for data collection;

**2.5.1 Primary Data:** is newly collected data, the researcher constructs a questionnaire that can be used in collecting the primary data either alone or in combination with other primary sources of data like collecting participants' biometrics (blood pressure, weight, blood tests, etc.) or even through hospital and ambulatory medical records. (37) The data used to fill-out the questionnaire can be collected through different methods:

**1. Direct Interviews**

An interview is a conversation in which one participant asks questions and the other provides answers. Interviews work best for small groups and help the researcher understand the opinions and feelings of respondents.

**2. Focus groups**

A focus group is a small group of people who have an informal discussion about a particular topic, or health problem. The researcher selects participants with similar interests, gives them topics to discuss, and records what they say.

Focus groups can help the researcher better understand the results of a large-group quantitative study and they have advantages for researchers in the field of health and medicine. (38)For example, a survey of 1,000 respondents may help the researcher spot trends and patterns, but a focus group of 10 respondents will provide additional context for the results of the large-group survey. In one quantitative analysis, the researcher may need to meet more than one focus group and continue until no new answers can be taken from the respondents.

**3. Observation**

Observation involves watching participants or their interactions with specific products or objects. It is a great way to collect data from a group when they are unwilling or unable to participate in interviews — children are a good example.

4. **Patient self-reported data:** The sensitivities of patient and family self-reported information are much higher than conventional data sources currently used by disease

surveillance systems like chief complain or diagnostic procedure that is usually used in clinical records.(39)

5. **Proxy/informant information:** A proxy is an individual who provides reports on behalf of, or about, a patient, beneficiaries, or nursing home residents.(40)

### *2.5.1.1 Questionnaire*

Designing a questionnaire requires careful planning and consideration of the research objectives and target audience. The questionnaire tool can be used to collect information either through direct face-to-face interviews, or via distributing the questionnaire to the participants, through online, by mail, or by phone.

For constructing a well-designed questionnaire, the researcher must carefully prepare the questionnaire in order to be able to collect qualified information that could answer the research questions.

#### 2.5.1.1.1 Types of Questionnaires

There are two major types of questionnaires:

**A-Structured Questionnaires**

A structured questionnaire is used to collect quantitative data. This type of questionnaire is designed in such a way that it collects intended and specific information.

**B-Unstructured Questionnaires**

This type of questionnaire is used to collect qualitative information. Simply put, the questions here are more open-ended. **Example: What do you think the cause of increase violence in the community?**

**2.5.1.1.2 Steps in Questionnaire Development**

There are certain steps that should be followed in designing the questionnaire.

- ❖ Step 1: What problem or need is to be addressed?
- ❖ Step 2: Reviewing the relevant literatures.
- ❖ Step 3: Reviewing what to evaluate.
- ❖ Step 5: Developing relevant questions.

1. Decide the information required.
2. Define the target respondents.
3. Choose the method(s) of reaching your target respondents.
4. Decide on question content.
5. Develop the question wording.
6. Put questions into a meaningful order and format.
7. Check the length of the questionnaire.(41)

- ❖ Step 6: Conducting preliminary study (pilot study) to refine wording and content.
- ❖ Step 7: Applying analysis for the selected questions.(42)

### 2.5.1.1.3 Formats of the Questions:

►***Open-Ended Questions***: These are questions that allow respondents to provide their own answers. These questions that cannot be answered with a "yes" or "no" response. Open-ended questions are a fundamental tool in qualitative researches in which interrogation questioning is the form of regular, informal conversation, with little preparation and arrangement for questions. They require the respondents to elaborate on their points. Open-ended questions help to see things from respondent's perspective. When designing open-ended questions, consider the following:

- Use clear and concise language.
- Be specific about what information you are looking for.
- Avoid leading questions or biasing language.
- Provide enough space for respondents to write their answers.

Example: "What do you think about mask wearing in protection of Covid 19?

The answers require effort to categorize them and theme creation for data analysis purposes later on.

►***Close-Ended Questions***: These are questions that provide respondents with a set of predefined answer choices. When designing closed-ended questions, consider the following tips:

- Keep the number of answer choices to a minimum (3-5 choices are usually sufficient).

- Use mutually exclusive answer choices to avoid confusion.
- Avoid using "don't know" or "not applicable" as an answer choice unless it is truly necessary.
- Consider using a Likert scale to measure attitudes or opinions.

Close-ended questions could be as:

•**Dichotomous Questions**, which offer only two response choices, Yes or No.

•**Multiple-choice Questions**, that give respondents several choices.

•**Ranking Questions**, here the respondent ranks the response options listed on a continuum basis in order of preference.

•**Checklist Questions**, the participant has the freedom to choose one or more of the response options available.

The questionnaire can be self-administered as the respondents can apply it. The self-applied questionnaire method is inexpensive and has little exposure to the bias of the interrogator. It can be carried out by mail or via the internet through Google Forms or can be distributed to the participants to fill out independently. Sometimes, the failure rate may be too high which may affect the results or the answers may also be incomplete.

### 2.5.1.1.4 Validity and Reliability

Two significant elements that can influence the accuracy and applicability of study findings are the validity and reliability of the methods employed to collect data.

**Validity** describes the accuracy of the information gathered to answer the research questions.(43) Validity guarantees that the information gathered accurately depicts the phenomenon or idea being measured. The main types of validity namely; face validity, content validity, construct validity, criterion validity with its subtypes of various forms of validity tests are given in (figure 2)

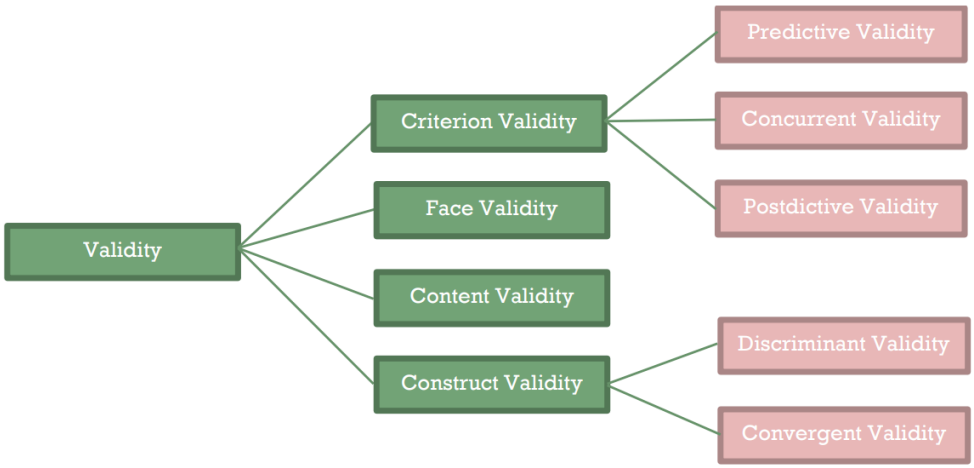


**Figure 3 Main and subtypes of various forms of validity tests**(44)

**Face validity:** It is the degree to which a measure appears to be related to a specific construct, in the judgment of nonexperts such as test takers and representatives of population of

concern. (45)In order to examine the face validity, the dichotomous scale can be used with categorical option of "Yes" and "No" which indicate a favorable and unfavorable item respectively. Unfortunately, face validity is arguably the weakest form of validity and many would suggest that it is not a form of validity in the strictest sense of the word. (46)

**Content validity** is defined as "the degree to which items in an instrument reflect the content universe to which the instrument will be generalized"

In general, content validity involves evaluation of a new survey instrument in order to ensure that it includes all the items that are essential and eliminates undesirable items. (47)The judgmental approach to establish content validity involves literature reviews and then follow-ups with the evaluation by expert judges or panels. The content validity ratio (CVR) is then calculated for each item by employing Lawshe (1975) 's method, which is a linear transformation of a proportional level of agreement on how many "experts" within a panel rate an item "essential," calculated in the following way:

$$\mathrm{CVR} = \frac{n_e - (\frac{N}{2})}{\frac{N}{2}}$$

where CVR is the content validity ratio, ne is the number of panel members indicating "essential," and N is the total number of

panel members. The final evaluation to retain the item based on the CVR depends on the number of panels.

Table 1 shows the guideline for the valid value of CVR for the evaluated item to be retained.

**Table 1: Validity and Reliability of the Research Instrument: How to Test the Validation of a Questionnaire/Survey in a Research (46)**

| Number of Panelist | Minimum values |
|---|---|
| 5 | 0.99 |
| 6 | 0.99 |
| 7 | 0.99 |
| 8 | 0.75 |
| 9 | 0.78 |
| 10 | 0.62 |
| 11 | 0.59 |
| 12 | 0.56 |
| 13 | 0.54 |
| 14 | 0.51 |
| 15 | 0.49 |
| 20 | 0.42 |
| 25 | 0.37 |
| 30 | 0.33 |
| 35 | 0.31 |
| 40 | 0.29 |

**Construct validity:** It refers to how well the concept, idea, or behavior is constructed into a functioning and operating reality that can be translated into causal relationship. It has two subdivisions: convergent validity which tests the constructs that are expected to be related are, in fact, related, and discriminant validity which tests constructs that should have no relationship do not, in fact, have any relationship. (48)

**Criterion Validity:** Criterion or concrete validity is the extent to which a measure is related to an outcome. It measures how well one measure predicts an outcome for another measure. There are different types of criterion validity namely, concurrent validity, predictive, and postdictive validity.(45)

**Reliability** refers to the consistency and stability of the data that was gathered. A trustworthy data-gathering technology should deliver consistent results throughout time, under various circumstances, with various researchers or participants. (49) A scale is said to have high internal consistency reliability if the items of a scale "hang together" and measure the same construct (49,50) The most commonly used internal consistency measure is the Cronbach Alpha coefficient. Sometimes for the easiest use of calculation of reliability and consistency of the results, a researcher simply can apply test-retest total agreement between two responses as in the following example:

In a study, 10 participants were included to determine the presence of smoking as a predisposition for asthmatic attacks.

| | | **test** | | |
|---|---|---|---|---|
| | | **+ve smoking** | **-ve smoking** | **Total** |
| Re-test | +ve smoking | 8 | 0 | 8 |
| | -ve smoking | 1 | 1 | 2 |
| | Total | 9 | 1 | 10 |

By applying the equation

Reliability index (percent agreement) = total agreement /total number of responses x 100 (2) (51)

9/10x100= 90% agreement.

A good questionnaire should be able to establish high reliability and validity to produce correct information concerning a particular topic. This can be done through certain steps:

1. Pilot testing: Before using a data collection tool in a study, it is important to pilot-test it with a small group of participants to identify any issues or inconsistencies. This will help to identify any problems with the tool and improve the validity and reliability of the data collected.(52)
2. Standardization: To ensure consistency and reliability, researchers should standardize the data collection process. This includes ensuring that all participants receive the same

instructions and administer the tool under the same conditions.(53)

3. Training and supervision: Research assistants and interviewers should be trained and supervised to ensure that they understand the data collection tool and the study procedures. This will help to minimize errors and inconsistencies in data collection.(54)

4. Randomization: To ensure the validity of the study results, randomization should be used wherever possible. This will help to ensure that the study participants are representative of the population being studied, reducing bias in the results.(6)

5. Data cleaning: Data cleaning is the process of checking and correcting errors in the collected data. This process should be done before data analysis to ensure that the data is reliable and accurate. (55)

6. Questionnaire (Test-retest) reliability: This involves giving the questionnaire to the same group of respondents at a later point in time and repeating the research. Then, comparing the responses at the two-time points. This type of reliability test has a disadvantage caused by memory effects. If the respondents respond to the questions in the way they remembered answering them the first time, it may provide the researcher with artificial reliability.(56)

7. Questionnaire Validity: This measures the degree of agreement between the results or conclusions gotten from the research questionnaire with the real world as mentioned earlier (57); measure the different component of the questionnaire to ensure that results truly assess the real problem.

8. Use multiple methods: Use multiple methods of data collection, such as surveys, interviews, and observations, to cross-validate the results and **improve the validity** and reliability of the data.(58)

9. Ensure confidentiality: Ensure that the data collected is kept confidential and anonymous, to encourage honest and accurate responses from participants. This helps to improve the validity and reliability of the data.(52,59–61)

***2.5.1.2 Hospital and ambulatory medical records****:* It can be a rich source of data. A wide range of public and commercial data gathering tools are utilized in the health care services such as hospitals, private doctors' records, and health insurance data. These tools include administrative enrollment and billing records, health surveys, and medical history and records, language, ethnicity, and racial data are gathered. Health information technology (Health IT) may have the potential to improve the collection and exchange of data.(37)

***2.5.1.3 Collection of biological materials***: Collecting biological materials as well as various imaging modalities, from the study participants are increasingly being used in clinical research. They need to be performed under standardized conditions, and ethical implications should be considered. It can be used alone or in combination with a questionnaire.

### 2.5.2 Secondary data-collection methods

Secondary data collection involves retrieving already available data from sources other than the target population. When working with secondary data, the researcher doesn't "collect" data; instead, they consult secondary data sources.

Secondary data sources are broadly categorized into published and unpublished data. As the names suggest, published data has been published and released for public or private use, while unpublished data comprises unreleased private information that researchers or individuals have documented. Some examples of secondary data sources:

1. **Online journals, records, and publications**
2. **Government records and publications**
3. **Business and industry records**
4. **Newspapers**
5. **Unpublished sources like** diaries, letters, reports, records. However; it can often be unreliable.

Secondary data already exists; where it has already been published or complied as resembling Disease-specific Registries, Public Health Data, government statistics, World Health Organization data… etc., or even Local hospital or clinic statistics on any number of topics.(62)

## 2-6 Ethical Considerations

After setting all the outlines of the research under question and how to be conducted, getting the agreement for data collection is needed. All research involving humans or animals must be conducted in accordance with the ethical principles embodied in the current nature of the Declaration of Helsinki of the World Medical Association (63) (Appendix)

All individuals involved in the conduct of any experiment must be fully aware of, and comply with moral principles, including the principles of beneficence, non-maleficence, and respect.

Research should base on a thorough knowledge of the scientific background; a careful assessment of risks and benefits has a reasonable likelihood of benefiting study subjects and be conducted appropriately by trained researchers using approved protocols and subject to independent ethical review and oversight by a properly convened panel.

The protocol should address ethical issues and indicate that it is in accordance with the Helsinki Declaration. Research should be discontinued if the available information indicates that the original considerations are no longer satisfactory.

Steps must be taken to ensure that the confidentiality of records has been taken, either by restricting access to them or by replacing patient identities with token numbers. The principle of confidentiality means “that the collection of information in qualitative research is based on mutual trust”.

Observational studies generally do not require any intervention beyond asking questions and performing routine medical examinations. Sometimes laboratory tests or x-rays are performed, and these studies do not pose any physical risks to the subjects, although they may cause inconvenience to them.

Perhaps psychosocial harm is more painful to the person than physical harm.

Here are some of the ethical considerations that researchers need to take into account (64):

1. Informed consent: Researchers must obtain informed consent from study participants, meaning they must provide all the necessary information about the study and allow participants to make an informed decision about their willingness to participate.

2. Confidentiality: Researchers must maintain the confidentiality of study participants' personal information and ensure that their data is kept secure and not shared with anyone who is not involved in the study.
3. Privacy: Researchers must ensure that participants' privacy is protected during the study and that their personal information is not disclosed without their consent.
4. Minimizing harm: Researchers must minimize the potential harm or discomfort that participants may experience during the study and take steps to address any harm that may occur.
5. Fairness: Researchers must ensure that their studies are fair and that they do not discriminate against any participant based on their race, sex, age, or any other personal characteristic.
6. Debriefing: Researchers must debrief participants before the study, providing them with information about the study's purpose, results, and any potential implications for them.
7. Institutional Review Board (IRB): Researchers must obtain approval from an Institutional Review Board (IRB) before conducting their study to ensure that it adheres to ethical standards and principles.

By taking these ethical considerations into account, researchers can ensure that their studies are conducted in a manner that is respectful, responsible, and just.

## 2-7 Study Participants

Establishing inclusion and exclusion criteria for study participants is a standard, required practice when designing high-quality research protocols. (65)

### 2-7-1 Inclusion Criteria

Inclusion criteria are defined as the key features of the target population that the investigators will use to answer their research question. (66)It means a set of criteria that should be fixed for individuals to be included in the study. Do not forget to think carefully about all aspects of the problem and be creative when deciding who can provide the best information. For example, all females of reproductive age will be included in the study, and so on.

### 2-7-2 Exclusion Criteria

Some people who are eligible but have certain criteria that may affect the outcome of interest should be excluded from the study e.g., studying the effect of supplement use on post-menopausal women, in this condition, young premenopausal women should not be included in data collection.

### 2-7-3 Assigning Study Participants to Groups

Assigning study participants to groups is an essential step in many research studies. This process involves dividing participants into different groups based on various factors, such as

demographic information, medical history, or specific characteristics relevant to the study's research questions. The primary objective of this process is to ensure that the study groups are comparable in terms of these factors so that any differences observed in the study outcomes can be attributed to the intervention or treatment being tested.

The process of assigning participants to groups can be done using different methods, depending on the study's design and the nature of the research question. Some common methods include:

1. Randomization: This method involves randomly assigning participants to different study groups. This is considered the gold standard method for assigning participants to groups as it minimizes the risk of selection bias and ensures that the groups are similar in terms of known and unknown confounding factors.
2. Stratification: This method involves dividing participants into subgroups based on specific factors, such as age, sex, or disease severity, and then randomly assigning them to different study groups. This method ensures that the study groups are comparable in terms of these specific factors.
3. Matching: This method involves selecting pairs of participants who are similar in terms of specific characteristics, such as age, sex, or disease severity, and then randomly assigning one

participant from each pair to different study groups. This method ensures that the study groups are comparable in terms of these specific characteristics.

4. Quasi-experimental designs: In some cases, it may not be possible to randomly assign participants to different groups. In such cases, researchers may use quasi-experimental designs, such as pretest-posttest designs, to assign participants to groups based on their exposure to a particular intervention or treatment.

Regardless of the method used to assign participants to groups, it is important to ensure that the process is transparent and well-documented.

This helps to minimize the risk of bias and ensures that the study's findings are reliable and valid. Additionally, it is important to consider ethical considerations when assigning participants to groups, such as ensuring that participants are fully informed about the study and that their consent is obtained before assigning them to a particular group.

In experimental or interventional research, the assigning of participants to an intervention or experimental group should be done through the blinding method, often referred to as masking, which is used to reduce bias in the study outcomes. It entails not telling participants, researchers, or both, about the intervention or

treatment group. This helps to guarantee that participant or researcher expectations or prejudices does not affect the study's findings.

Different types of blinding methods can be used in experimental or interventional studies, depending on the study design and the nature of the intervention. The most common types of blinding methods include:

1. Single-blind: In a single-blind study, either the participants or the researchers are unaware of which group they belong to. For example, in a drug trial, the participants may be unaware of whether they are receiving the drug or a placebo, while the researchers know which group each participant belongs to.
2. Double-blind: In a double-blind study, both the participants and the researchers are unaware of which group they belong to. This helps to minimize the risk of bias, as neither the participants nor the researchers can influence the study outcomes based on their expectations or biases.
3. Triple-blind: In a triple-blind study, in addition to the participants and researchers being blinded, the statisticians analyzing the data are also blinded to the group assignments. This helps to ensure that the statistical analysis is not influenced by knowledge of the group assignments.

Blinding is an important technique in experimental or interventional studies, as it helps to ensure that the study's outcomes are not influenced by the expectations or biases of the participants or researchers. However, blinding may not always be possible, especially in studies where the intervention is obvious or where it is difficult to blind the participants or researchers. In such cases, researchers may need to use other methods, such as randomization or stratification, to minimize bias and ensure that the study's outcomes are reliable and valid. See diagram (1) which describes the randomized control trail (RCT).

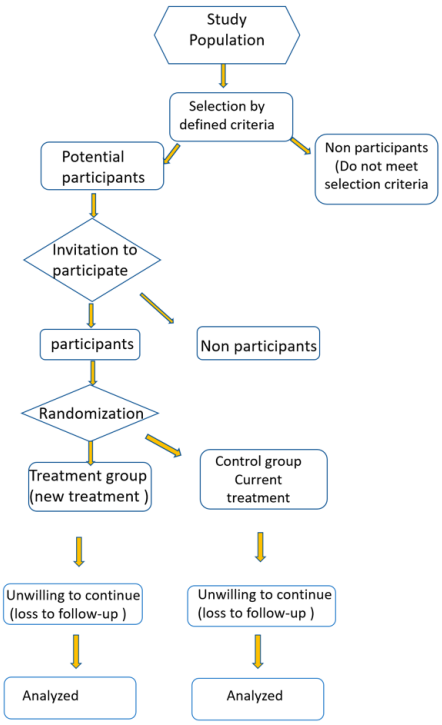


**Diagram 1: Methods of selection groups of participants to treatment and control group (67)**

## 2-8 Sampling Methods and Techniques

Sampling techniques are a crucial aspect of research design and are used to select a representative sample from a larger population. The sample selected must be representative of the population to ensure that the findings of the study are valid and reliable and accurately reflect the characteristics of the community from which it was withdrawn, that is; to be a microsome of this community. It can be used to eliminate a cause that may affect the study's creditability. There are two main categories of sampling techniques: probability and non-probability sampling.

### 2-8-1 Types of Sampling Methods

Sampling in market action research is of two types – probability sampling and non-probability sampling. Let's take a closer look at these two methods of sampling.

***2.8.1.1 Probability Sampling*:** Probability sampling is a sampling technique where a researcher sets a selection of a few criteria and chooses members of a population randomly. All the members have an equal opportunity to be a part of the sample with this selection parameter.

### Types of Probability Sampling

There are four types of probability sampling techniques:

**I-Simple Random Sampling:**

It is one of the best probability sampling techniques that helps in saving time and resources. It is a reliable method of obtaining information where every single member of a population is chosen randomly, merely by chance. Each individual has the same probability of being chosen to be a part of a sample. This method is often used when the population is homogenous and the sample size is small.

For example, in an organization of 500 employees, each of the 500 employees has an equal opportunity of being selected. Previously, randomization was done manually, using a table of random numbers, now it is usually performed using a computer program.

**II- Systematic Sampling:**

This method is used to choose the sample members of a population at regular intervals. It requires the selection of a starting point for the sample and sample size that can be repeated at regular intervals. This type of sampling method has a predefined range, and hence this sampling technique is the least time-consuming.

For example, a researcher intends to collect a systematic sample of 500 people in a population of 5000. He/she numbers each element of the population from 1-5000 and will choose every

10th individual to be a part of the sample (Total population/ Sample Size = 5000/500 = 10).

**III -Stratified Random Sampling:**

It is a sampling method where the population (or sampling frame) is divided into sub-populations or strata, according to some common characteristic. A simple random sample is selected from each strata for sampling.

For example, a researcher looking to analyze obesity among primary schools in the city, he will start by dividing cities into zones and then from each zone choose a random sample from schools, then from each school chooses a random sample from classes, and then he chooses random sample from students of each class.

This type of sampling provides benefits of reducing sample bias, diverse population, and creates an accurate sample.

**IV-Cluster Sampling: -**

By this method, the entire population is divided into sub-population called clusters that represent a population. Clusters are identified according to geographic differences or naturally occurring divisions. This makes it very simple for a survey creator to derive effective inferences from the feedback (10). Each of the clusters should ideally be mini-representations of the population

as a whole, keeping in mind that these clusters are non-homogenous.

For example, if the Ministry of Health intends to evaluate the number of Covid -19 vaccinated people in Iraq, it will divide Iraq into its governorates and from each governorate can indicate the number of vaccinated versus non vaccinated, even in each governorate from each local authority can determine the number of people that are vaccinated more in compares to other zone area.

Cluster sampling and stratified sampling have similar techniques. However, cluster sampling is non homogenous in characteristics while the stratified sample is homogenous, both of them can be used simultaneously in research. For example, in a study of mental health among high school students, school can be chosen by cluster sampling technique then class grade can be determined by stratified sampling technique.(68)

**V- Multistage Sampling:** Multistage sampling is a sampling method that combines two or more sampling techniques. This method is often used when the population is large and diverse, and the researcher wants to obtain a representative sample that is logistically feasible. For example, the researcher may use cluster sampling to select geographic locations and then use simple random sampling to select individuals within each location.(6,69–71) For example if a researcher wants to study the effect of oil extraction factory pollution on the Iraqi

population, so Iraq can be divided in to 8 zones, from each zone a city is selected, these cities' squares can nominated by numbers and by simple random selection the researcher can choose the squares that should be visited to take the samples from the population. Each square can be further undergoing simple random sampling by numbering the houses and every fifth house, for example, can be taken for the purpose of the study.

### *2.8.1.2 Non-Probability Sampling*

In non-Probability Sampling, the researcher chooses members for research at random. This sampling method is not a fixed or predefined selection process. This makes it difficult for all elements of a population to have equal opportunities to be included in a sample.

**Types of non-Probability Sampling**

The non-probability method involves a collection of feedback based on a researcher or statistician's sample selection capabilities and not on a fixed selection process. There are different types:

**I-Convenience Sampling:**

This method is dependent on the ease of access to subjects such as surveying customers at a mall or passers-by on a busy street. It is usually termed convenience sampling, because of the

researcher’s ease of carrying it out and getting in touch with the subjects. Researchers have nearly no authority to select the sample elements, and it’s purely done based on proximity and not representativeness. This non-probability sampling method is used when there are time and cost limitations in collecting feedback. In situations where there are resource limitations such as the initial stages of research, convenience sampling is used. For example, if you are investigating why leprosy patients do not always present for medication, it would seem more "convenient" and more useful to select those patients, relatives, and staff involved in the leprosy program. A random sample of the whole community may not provide you with a single person with leprosy.

**II-Judgmental or Purposive Sampling:**

Purposive sampling is formed at the discretion of the researcher. Researchers purely consider the purpose of the study, along with the understanding of the target audience. For instance, when researchers want to understand the thought process of people interested in studying for their master’s degree. The selection criteria will be: “Are you interested in doing your masters in …?” and those who respond with a “No” are excluded from the sample.

**III-Snowball Sampling:**

It is a sampling method that researchers apply when the subjects are difficult to trace. For example, it will be extremely challenging to survey shelter less people or illegal immigrants. In such cases, using the snowball theory, researchers can track a few categories to interview and derive results. Researchers also implement this sampling method in situations where the topic is highly sensitive and not openly discussed—for example, surveys to gather information about HIV and Aids.

**IV-Quota Sampling:**

The selection of members in this sampling technique happens based on a pre-set standard. In this case, as a sample is formed based on specific attributes, the created sample will have the same qualities found in the total population. It is a rapid method of collecting samples.

Non-probability sampling is used to create a hypothesis, exploratory research, and when there are budget and time constraints.

In conclusion, the choice of sampling method depends on several factors, including the research design, research question, and population of interest. It is important to select a sampling method that will ensure that the sample is representative of the population to avoid biased results. The appropriate sampling

method should be selected based on the research design and the available resources.

### 2-8-2 Sample Size

The size of the sample has to be pre-determined, analytically approached, and sufficiently large to represent the population.(72) It is the process of determining the number of participants or observations needed to achieve a specific level of statistical power and accuracy in the study. In general, a larger sample size is better for obtaining accurate results, but it can also be more costly and time-consuming to collect and analyze data from a larger sample.

Including a larger sample would lead to a wastage of resources, the risk that the true treatment effect may be missed due to heterogeneity of a large population, and would be time-consuming. If a study is too small, it will not provide a suitable answer to the research questions.

It is very important to understand that different study designs need different methods of sample size calculation and one formula cannot be used in all designs.(73)

It is now easy to calculate the desired sample size with the help of statistical computer software or even online, searching each study design calculation method and applying immediately the available parameters according to each design that will be used; is an effective method in calculating sample size.

When selecting a sample size for a research study, several factors must be taken into account. These factors include the research questions, study design, statistical analysis plan, available resources, and ethical considerations.

One of the primary factors that influence sample size selection is the research questions. The complexity of the research questions and the level of precision needed to answer it determine the sample size required. For instance, a study that aims to investigate the prevalence of a particular health condition in a population will require a larger sample size than a study that aims to investigate the relationship between two variables.

The study design also plays a critical role in sample size selection. For instance, the sample size required for a randomized controlled trial (RCT) is typically larger than that required for a cross-sectional study. RCTs require larger sample sizes because they involve the randomization of participants into treatment and control groups, which increases the statistical power needed to detect differences between the groups.

The statistical analysis plan is another vital consideration in sample size selection. The type of statistical analysis to be performed, the level of significance, and the effect size will all impact the required sample size. A larger sample size is needed to achieve greater statistical power and to detect smaller effects.

The resources available to conduct the study, including time, funding, and personnel, can also influence sample size selection. A larger sample size may require more resources, which may not be feasible for some studies. In such cases, researchers may need to compromise on sample size or adjust their study design.

Finally, ethical considerations are also essential when selecting a sample size. Researchers must ensure that their study is not underpowered, which could lead to inconclusive or misleading results. At the same time, they must also ensure that the sample size is not unnecessarily large, as this could expose participants to undue risk or inconvenience

## 2.9 Data Coding

Data coding is a serious step in research analysis, in both quantitative and qualitative research. It involves the systematic categorization and labeling of data to identify themes, patterns, and relationships in the data. Data coding is a key process that helps researchers to organize and make sense of large volumes of data.

The following are the steps to perform data coding in research analysis:

1. Familiarize yourself with the data: Before starting the coding process, it is essential to become familiar with the data. Read through the data several times to get a general sense of the

content and identify any patterns or themes that may be present.

2. Create a coding scheme: Based on the research question and the data collected, develop a coding scheme or a set of categories to code the data. The coding scheme should be comprehensive and include all relevant categories to ensure that all data is accurately coded.

3. Apply the coding scheme to the data: Once the coding scheme has been developed, apply it to the data. This involves reading through the data and assigning codes to each piece of data that fits into a particular category.

4. Check for consistency: As you code the data, check for consistency in your coding. Ensure that each piece of data is coded appropriately and consistently throughout the data set.

5. Refine the coding scheme: As you code the data, you may need to refine the coding scheme by adding or revising categories. Refining the coding scheme is an iterative process that requires constant monitoring and revision.

6. Analyze the coded data: Once all the data has been coded, analyze the coded data to identify themes, patterns, and relationships. This involves summarizing the data by category and identifying commonalities and differences among the categories.

7. Interpret the results: Finally, interpret the results of the data analysis. Identify key findings and conclusions based on the coded data and relate them to the research question.

Codes could be numeric number such as starting with 0,1, 2 …. etc.

For example: if one starts to take data from the respondents and the question is about the sex of the participant, the answer will be either male or female, by that the code for the male is 0 and the female is 1 or vice versa. This coding should be fixed in one of the questionnaire forms to be used as a reference paper later on when one will decide to enter data into the analyzing program like SPSS or Excel worksheet. Another example: In asking about the presence or absence of certain disease like hypertension, the answer will be yes or no; by that, the coding will be 1 for yes and 0 for no and the reverse is true. By this method, all information in the questionnaire is translated to numerical values that will be used in the analysis process. Sometimes, the questions are coded by themselves, for example: How many times do you eat vegetables per week? The answer will be 0, 1,2,3 …. etc. and here no code is needed and it will be used as such. The same can be done in creating a theme for qualitative research.

## 2-10 Data Analysis

Data analysis refers to the process of inspecting, categorizing, transforming, and modeling data to discover useful information, draw conclusions, and support decision-making. After the coding has been completed, enter collected data into suitable software that will perform data analysis. The type of software used to analyze data can be SPSS, Excel, Google form, etc. At this level, one can ask for help from the statistician to finalize the results that help in data exploration, which involves examining the data to identify patterns, trends, and relationships with its significance.

### 2-10-1 Types of data analysis

### 2-10-2 Risk calculation in research

Risk calculation is an essential part of the research, especially when it involves human participants. It is crucial to identify, evaluate, and manage potential risks to ensure the safety and well-being of study participants. The process of risk calculation involves analyzing the possible harms and benefits of the study and taking steps to minimize or eliminate the risks involved.

According to the International Conference on Harmonization (ICH) guidelines, risk calculation involves assessing the probability and severity of harm to the study participants, as well

as the likelihood and magnitude of the potential benefits of the study (1). The guidelines recommend that risk assessment be performed throughout the entire research process, from protocol development to data analysis, to ensure that risks are continually evaluated and managed.

In research involving human participants, risk calculation is typically conducted during the ethics review process. Institutional Review Boards (IRBs) and Ethics Committees (ECs) are responsible for reviewing research proposals and ensuring that the potential risks are adequately addressed (2).

The odds ratio and relative risk are two commonly used measures in epidemiology to evaluate the strength of association between an exposure and an outcome. (74) The odds ratio (OR) is a measure of the ratio of the odds of an outcome occurring in the exposed group to the odds of the same outcome occurring in the unexposed group. The relative risk (RR) is a measure of the ratio of the risk of an outcome in the exposed group to the risk of the same outcome in the unexposed group.

The odds ratio is commonly used in case-control studies, where the outcome is already present, and the odds of exposure are compared between cases and controls. The relative risk is commonly used in cohort studies, where the exposure is known at the beginning, and the risk of developing the outcome is compared between exposed and unexposed groups.(75)

Both measures can be calculated using 2x2 contingency tables (Table 3), where the rows represent the exposure status (exposed or unexposed) and the columns represent the outcome status (present or absent).

**Table (3) example of 2x2 contingency table**

| **Disease status** / **Risk status** | **Disease present** | **Disease absent** |
|---|---|---|
| Exposure present | a | b |
| Exposure absent | c | d |

The formula for calculating the odds ratio is:

$OR = (a/b) / (c/d)$

where a is the number of exposed cases, b is the number of exposed non-cases, c is the number of unexposed cases, and d is the number of unexposed non-cases.

The formula for calculating the relative risk is:

$RR = (a/(a+b)) / (c/(c+d))$

where a is the number of exposed cases (diseased), b is the number of exposed non-cases (not diseased), c is the number of unexposed cases (diseased), and d is the number of unexposed non-cases (not diseased).

Both measures can be interpreted as the ratio of the risk or odds of the outcome in the exposed group compared to the

unexposed group. If the OR or RR is greater than 1, it suggests a positive association between exposure and outcome, while an OR or RR less than 1 suggests a negative association.(76)

### 2-10-3 P-Value and Significance of The Results

The estimation of P-values is a crucial aspect of statistical analysis in research. It represents the probability of obtaining results as extreme or more extreme than the observed data, assuming the null hypothesis is true. A P-value less than the predefined alpha level (usually 0.05) indicates that the results are statistically significant and unlikely to occur by chance.

The significance of p-value estimation lies in its ability to guide researchers in making decisions about whether to reject or accept a null hypothesis. In research, the null hypothesis is a statement that there is no significant relationship or difference between two variables or groups. It is typically denoted as "H0" and is the default hypothesis that researchers aim to reject or disprove. Rejecting the null hypothesis suggests that there is evidence of a significant relationship or difference between the variables while failing to reject the null hypothesis means that there is not enough evidence to conclude that there is a significant relationship or difference. However, it is important to note that the p-value is just one component of statistical analysis and should not be solely relied upon to draw conclusions. Other factors, such as

effect size and sample size, should also be taken into consideration.(77)

### 2-10-4 Bias and Confounding Factors

Bias is a major consideration in any type of epidemiologic study design. It is defined as “any systematic error in the design, conduct, or analysis of a study that results in a mistaken estimate of an exposure’s effect on the risk of disease.” A thorough understanding of bias and how it affects study results is essential for the practice of evidence-based medicine. (78) There are different types of bias that could inevitably occur when performing research. As appeared in Figure 4

***-Pre-trial bias***

It includes errors in study design and patient recruitment as selection bias or channeling bias, which occurs when patient prognostic factors or degree of illness orders the study cohort into which patients are placed. For that, it is important to clearly define both risk and outcomes and to have standardized protocols for data collection.

**-Bias during the clinical trial**

The information bias can cause an error in the measure of exposure or outcome. Many subtypes of information bias can occur, including interviewer bias, chronology bias, recall bias,

patient loss to follow-up, bias from the misclassification of patients, and performance bias.

- *Bias after a trial*

Citation bias is when the researchers and trial sponsors may be unwilling to publish unfavorable results, believing that such findings may negatively reflect on their abilities or the efficacy of their product.

Confounding occurs when an observed association is due to three factors: the exposure, the outcome of interest, and a third factor that is independently associated with both the outcome of interest and the exposure. For example, there is a relationship between coffee and cancer of the pancreas. Thus, searching for a possible relationship between coffee drinking and pancreatic cancer, smoking is a known risk factor for pancreatic cancer adding that smoking is associated with coffee drinking. All these biases affect the validity of the findings and should be assessed and, if possible, eliminated.

As appear in Figure 5

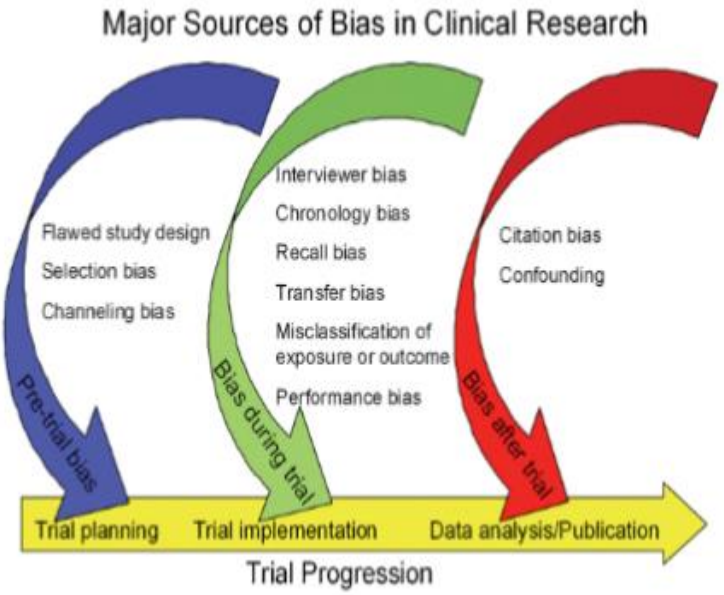


**Figure 4: Types of bias.(78)**

## Interact

"When the incidence rate of disease in the presence of two or more risk factors differs from the incidence rate expected to result from their individual effects." as defined by MacMahon (19). The effect can be greater than what one would expect (positive interaction, synergism) or less than what one would expect (negative interaction, antagonism). The problem is to determine what one would *expect* to result from the individual effects of the exposures.

## Matching

A major concern in conducting a case-control study is that cases and controls may differ in characteristics or exposures other

than the one that has been targeted for study. If more cases than controls are found to have been exposed, one may be left with the question of whether the observed association could be due to differences between the cases and controls in factors other than the exposure being studied.

For example, in a study on the relationship of smoking with lung cancer, for each case of lung cancer enrolled, one control with similar age and sex is enrolled. This would reduce the risk of confounding by age and sex – the factors used for matching. Sometimes, the number of controls per case may be larger (e.g., two, three, or more). These are used to increase the power of the study.

# Chapter 3

# The Writing Process

## 3. Writing A Manuscript

A manuscript typically consists of several sections, each of which serves a specific purpose. The different sections of a manuscript are often referred to as divisions.

**Major manuscript parts**

- **Abstract**
- **Introduction**
- **Methods**
- **Results**
- **Discussion**
- **Conclusions**
- **Recommendations**
- **Financial support**
- **Conflict of interest**
- **Acknowledgment**
- **References**
- **Appendix**

### 3-1 Summary or Abstract

An abstract provides an overview of the main points and conclusions of the study. It is typically the first section of an article that readers will encounter, and it should be written with special care to ensure that it effectively communicates the main ideas of the paper, for that reason, it should be the last section to

be written. It is a self-sufficient, short, powerful statement that describes a larger body of work. (79)

It includes a simple background of the subject under study followed by the aim of the study and a summary description of the methods that have been followed. Then, the researcher should provide data that answers a research question and describes the most important data with numbers and statistics. Finally, conclusions should mention the important points concluded from the research. A good abstract can communicate results most efficiently and unambiguously. (80) Abbreviations should be avoided and only be used after they have been indicated. There are two ways of writing the abstract, either as one paragraph or as the IMRD section as background, aim or objective, methods, main results, and conclusion. In many papers, they determine that the total number of words in the abstract should not exceed 250 words. Some other journals determine that the upper limit is 150 words. It is very important to include the most important words (the "keywords") in the title and the research for appropriate indexing purposes and retrieval from search engines and scientific databases. (81) Such keywords come after the abstract. In abstract writing, the originality of the work must be mentioned by carefully chosen direct wording.

## 3.2 Introduction

In this section, the researcher gives a simple review of the subject under study by searching articles and/or books. The introduction introduces the subject, emphasizes the research questions or hypotheses, and states the value/significance of the investigation. Definitions should be given, besides terms in the format of paragraphs and at the end of each paragraph; references should be shown either following the Vancouver style or Harvard style which are the commonest ways of writing the references. (See reference section). In writing a thesis, more extensive information about the subject of interest should be set up including recent evidence-based research. (82) An introduction essentially has three main elements:

1- The background of the research topic.
2- Justification of why this research is carried out and what gap of knowledge it will fill.
3- Aims of the study and specific objectives of research under concern.(83)

The Introduction offers the research question(s) which will be answered in the subsequent sections of the paper.(84)

## 3.3 Methods

In this division, a description of the steps that have been followed in carrying out the research of interest should be given. It

describes how the study was conducted, including the participants, materials, and procedures used. It should provide enough details for other researchers to replicate the study. A basic understanding of the methodology is essential to have a reliable, repeatable, and clinically acceptable outcome. (1) Each research method division should contain the following subdivision:

### 3.3.1 Ethical Consideration in Research

It is an assertion that ethical considerations are an integral part of the research process. (see ethical consideration mentioned earlier) It is started by getting approval from the department responsible for conducting the research. Then, followed by approval from the ethical committee at the College and /or the ethical committee of the Health Directorate in which the research will be conducted in its geographical areas.

After proceeding with the research steps, informed consent from the participants in the research should be taken in private, after discussing the scientific value of the planned research as mentioned earlier.

### 3.3.2 Study Participants

This subdivision is based on the characteristics of the participants in the study. For example, researchers may divide their study participants into different groups based on age, sex, ethnicity, occupation, or health status.

Choosing study participants will follow the inclusion and exclusion criteria mentioned earlier in section I.

### 3.3.3 Study Setting:

Study setting is based on the location or environment where the study takes place. For example, researchers may conduct studies in clinical settings, schools, workplaces, or communities.

### 3.3.4 Study Design:

Study design is based on the overall approach and structure of the study. For example, researchers may use experimental, observational, or survey designs, among others.

### 3.3.5 Study Period:

Study period is based on the duration of the study. For example, researchers may conduct cross-sectional studies that collect data at a single point in time or longitudinal studies that collect data over an extended period.

### 3.3.6 Data Collection Tool:

Data collection tool is based on the specific methods and instruments used to collect data. For example, researchers may use surveys, interviews, focus groups, or observations to collect data. The questionnaire is the most popular type of collecting data that can be used in different types of medical research. (85)

### 3.3.7 Data Analysis:

Data analysis is based on the techniques and methods used to analyze the data collected in the study. For example, researchers may use descriptive statistics, inferential statistics, content analysis, or grounded theory analysis to analyze their data.

During the description of data analysis, the type of software used to analyze the data like SPSS, Excel, Google form,...etc. should be mentioned. Adding to that, the type(s) of statistical analysis tests used whether T-test, Z- test, regression analysis, ANOVA, etc. should be stated with the level of precision as P value to be considered significant at the level of 0.05. It is worth noting that these subdivisions are not mutually exclusive, and researchers may use multiple subdivisions within a single study, depending on the research questions and objectives. Additionally, each subdivision has its strengths and weaknesses, and researchers should carefully consider which subdivision is best suited to their research questions and goals.

## 3.4 Results

The results division presents the findings of the study logically and clearly to the audience. To achieve that, the following should be taken into consideration:

1. Organizing the data: Before presenting results, the data should be organized logically. This will help in identifying key

patterns and trends and also make it easier for the audience to follow the findings.

2. Starting with a summary: Begin the division of the result with a summary of the main findings of your study. This can help orient the reader and provide context for the more detailed results that follow. Text is the principal method for explaining findings, outlining trends, and providing contextual information.

3. Using visuals: Visuals such as graphs, charts, and tables are a great way to present complex data in a way that is easy to understand. (86) Make sure to choose the right type of visual for your data and use colors that are comfortable to look at. Keep in mind that journal editors and reviewers or readers look at these presentations before reading the whole article, choosing between sentences, tables, or figures to ensure that readers find it easy to understand, to assist the author(s) presenting data in a way that would catch the reader's eye, hold his/her interest and enhance his/her understanding. (87) Moreover, in some situations, tables, graphs, and figures can present certain types of information (including complicated relationships and sequences of events) more clearly and in less space than the same information would require in sentence form. (88)

4. Using descriptive statistics: Use descriptive statistics, such as means, standard deviations, and percentages, to summarize your data. Make sure to clearly label your tables and figures and provide appropriate titles and captions.
5. Explaining the findings: It is important to not just present data but to also give short comments of what it means. Make sure to highlight any key findings or trends and explain their significance. If there is a statistical analysis performed, it is preferred to mention at the bottom of the tables or graphs the types of tests that have been used.
6. Using simple language: While it may be tempting to use technical jargon, it is important to use language that is easy for your readers to understand. Avoid using acronyms or terms that may not be familiar to the readers.
7. Be concise: Focus on the most important findings and avoid getting bogged down in details that may not be relevant to the readers.

Overall, presenting research results can be challenging; each table, figure or graph should have a short description of its content from 1 to 3 lines according to its content. In these lines, the researcher presents the most important findings. No interpretation (discussion) of the results should be given at this stage but it should be delayed to be explained in the discussion section.

## 3.5 Discussion

A discussion section is an essential component of a research paper that provides an opportunity for researchers to interpret and analyze their results, contextualize them in the broader literature, and draw conclusions based on their findings. The Discussion is the hardest section of a scientific article to write, as cognitive skills need to put the findings of the study in their properly written sentences of debate. (89). The main topic should be emphasized without going into much detail. Its place, and importance among other studies should be indicated. However, during this procedure studies should be presented in a logical sequence (i.e., from past to present, from a few to many cases), and aspects of the study contradicting those of studies should be underlined. Results without any supportive evidence or equivocal results should be mentioned with a suitable explanation. Besides numerical values presented in the results section should not be repeated unless required. For that, the main function of the discussion is to answer the research question(s) assembled in the introduction and to interpret the results by discussing the implications of the findings and what they mean in the broader context of the field. Compare the results with previous research in the field. Discuss similarities and differences between current findings and those of other studies, and explain why these differences might exist. One should also consider any gaps in the literature that his/her study helps to

fill. Any unexpected or significant results should be highlighted and their importance should be explained. It is also important to consider mentioning any limitations, weaknesses, and strengths in comparison to other studies. Not all findings can be agreed with results from other works; negative findings or opposite findings can be so important that could be presented and a suitable explanation could be given for that. For example, if the percentage of obesity is common among 11-15 years old children, this can be explained either by giving a self-explanation like it could be due to decreased physical activity nowadays or supported results from other researchers who discovered similar findings can be given (or added) and by mentioning the reference that the findings have taken from. A certain number will be given at the end of the paragraph (Vancouver style) or the author's name with the year (Harvard style), to be mentioned in detail in the list of references at the end of the manuscript in the references section, (see reference section).

Generally, the length of the ‘Discussion’ section should not exceed the sum of other sections (introduction, material and methods, and results), and it should be completed within 6–7 paragraphs. Each paragraph should not contain more than 200 words, and hence words should be counted repeatedly. The ‘Discussion’ section can be generally divided into 3 separate

paragraphs. 1) Introductory paragraph, 2) Intermediate paragraphs, 3) Concluding paragraph. (90)

The introductory paragraph contains the main idea of performing the study in question. It starts with an undebatable sentence, and proceeds with a part addressing the following questions as 1) On what issue we have to concentrate, discuss or elaborate? 2) What solutions can be recommended to solve this problem? 3) What will be the new, different, and innovative issue? 4) How will our study contribute to the solution of this problem. An introductory paragraph in this format is helpful to accommodate the reader to the rest of the Discussion section. However, summarizing the basic findings of the study in the first paragraph is generally recommended.(91)

In the last paragraph of the Discussion section “strong points” of the study should be mentioned using “constrained”, and “not too strongly assertive” statements. Indicating limitations of the study will reflect objectivity of the authors, and provide answers to the questions that arise among reviewers. On the other hand, in the last paragraph, future directions or potential clinical applications may be emphasized. (90)

## 3.6 Conclusions and Recommendations

**3.6.1 Conclusions Outline** Based on the results and discussion, conclusions can be drawn about the research question(s) and hypotheses tested. It is important to be careful not to overstate the findings or make claims that are not supported by the data. Conclusions can also serve as a basis for continuing research, creating new ideas to resolve an issue emphasized in the paper, and offering advice(s) for the next step that could be done. (92,93) In general the conclusion should:

- restate the hypotheses or research questions
- restate the major findings
- inform the reader about the contribution the study has made to the existing literature
- highlight any limitations of your study
- state future directions for research/recommendations

The conclusion should NOT:

- introduce new arguments
- introduce new data
- fail to include the research question(s)
- fail to state the major results(94,95)

### 3.6.2 Recommendations outlines

Recommendations should directly respond to key findings arrived at through data collection and analysis. This includes the suggestion of specific interventions or strategies to address the issues and constraints identified by the research analysis. They also identify any areas that need further investigation. It can visualize the next step that should be done by the health authority to take note of the health situation and may try to improve it. As a rule of thumb, try to limit the recommendation to only the most relevant future recommendations: ones that stem directly from the work. While it is possible to have multiple recommendations for each research conclusion, it is also acceptable to have one recommendation that is connected to more than one conclusion.(96)

## 3.7 Supplementary (Accessories)

### 3.7.1 Conflict of Interest:

A conflict of research interest occurs when researcher's interests or biases interfere with their ability to conduct unbiased and impartial research. Conflicts of interest can arise in many ways, including financial incentives, personal relationships, institutional affiliations, or other factors that may influence the researcher's ability to maintain objectivity.

A conflict of interest can have serious implications for the integrity and credibility of the research. It can compromise the validity of the research findings and undermine public trust in the research process. It can also have legal and ethical implications, particularly in cases where the research involves human subjects.(97)

To avoid conflicts of research interest, researchers need to be transparent about their affiliations, financial interests, and personal relationships. This can include disclosing any conflicts of interest in research publications, presentations, or other communications. It may also involve recusing oneself from certain research activities if a conflict of interest arises. One common form of conflict of research interest is a financial conflict of interest. For example, if a researcher is receiving funding from a company that stands to benefit from the results of their research, it could create a conflict of interest. Similarly, if a researcher has a financial interest in a product or service being studied, their findings may be biased in favor of that product or service.

Another form of conflict of interest is personal relationships. For example, if a researcher is studying a drug that is being developed by a close friend or family member, it could create a conflict of interest. Similarly, if a researcher is romantically involved with a study participant, it could compromise their ability to remain objective and unbiased.(98)

### 3.7.2 Acknowledgments

Acknowledgments are an important part of any research project. They allow researchers to recognize the contributions of individuals and organizations who have provided support and assistance throughout the research process.

It typically appears at the end of a research paper but at the beginning of the thesis, and it can include a wide range of people and entities. For example, researchers may acknowledge funding agencies that provided financial support for the project, or institutions that provided resources such as laboratory space or equipment. They may also acknowledge colleagues who provided input or feedback on the research, or participants who took part in the study.

Acknowledgments can also be used to express gratitude to family and friends who provided emotional support during the research process. Researchers may wish to acknowledge individuals who provided administrative or technical assistance, such as librarians, statisticians, or editors.

When writing acknowledgments, it is important to be specific and clear about the contributions of each person or organization. Researchers should use formal language and follow appropriate conventions for acknowledging different types of support. For example, they may use phrases such as "I would like to thank" or

"I am grateful to" when acknowledging individuals or organizations.

It is also important to ensure that all individuals or organizations that contributed to the research are acknowledged. This includes individuals who may have provided support in less obvious ways, such as through informal conversations or mentorship.(99)

### 3.7.3 Financial Support

Financial support is a critical component of conducting research. To carry out any research project, funding is essential to cover expenses related to equipment, materials, participant compensation, and other associated costs. Financial support can come from a variety of sources, including government agencies, private foundations, corporations, and universities.(100)

One of the most common sources of financial research support is government funding. Government agencies such as ministry of health in collaboration with the World Health Organization provide grants to support research in a variety of fields that are important to the general public. These grants can cover a wide range of expenses, including equipment and supplies, travel expenses, and salaries for researchers and staff.

Private foundations are another important source of financial research support. Foundations such as the Bill and Melinda Gates

Foundation and the Ford Foundation provide funding for research in specific areas, such as public health, education, and environmental science. Private corporations also provide funding for research, particularly in areas that are relevant to their business interests.

Universities themselves often provide financial research support. Faculty members can apply for internal grants to support their research projects, and universities may also offer funds for graduate students to conduct their research.

In addition to providing financial support, funding agencies, and foundations may also offer support in other forms, such as mentorship, networking opportunities, and access to specialized resources. For example, the NSF provides resources such as the Research.gov website, which offers tools and resources for researchers to manage their grants and collaborate with others in their field.

All these types of support or fund should be mentioned in the research to resolve any conflict of interest. Sometimes no funding is applied, and here the researcher may include a statement like "There are no financial conflicts of interest to disclose." (101)

### 3.8 References

The reference section, also known as the bibliography, is a crucial component of any research paper or academic document.

This section lists all of the sources that were used to inform the research and support the arguments made in the paper.

The purpose of the reference section is to provide readers with the necessary information to locate and verify the sources used in the research. Besides, referencing allows the researcher to acknowledge the contribution of other writers and researchers in the work. (102)This includes the author's name, the title of the work, the publication date, and other relevant information, such as the publisher, page numbers, and the URL for online sources. It's important to note that the reference section should be formatted according to the appropriate citation or reference style. A reference style is a set of guidelines used to format and organize references in a consistent and standardized manner. There are several reference styles, each with its own set of rules and requirements. Here are some of the most common types of reference styles used in medical writing:

### 3.8.1. Reference style

#### *3.8.1.1 Vancouver Style*:

This referencing style is heavily used in the health and biomedical sciences citation style and it is based on a numbered system.(103) In this style, sources are cited in the text using a number in brackets that corresponds to the reference list at the end of the article. The reference list includes the full details of the

source, including the author's name, the title of the article, journal name, volume, and page numbers.

#### *3.8.1.2 Harvard Style:*

The Harvard referencing style is an author-date system, similar to the APA style. In this style, sources are cited in the text using the author's surname and the year of publication, and the reference list is arranged alphabetically by the author's surname. However, the Harvard style also includes the title of the article, the journal name, volume, and page numbers in the reference list.

#### *3.8.1.3 APA Style:*

The American Psychological Association (APA) style is another commonly used referencing style in medical writing. It is an author-date system, where sources are cited in the text using the author's surname and the year of publication. The reference list is then arranged alphabetically by the author's surname and includes the full details of the source, including the title, journal name, volume, and page numbers.

#### *3.8.1.4 AMA Style:*

The American Medical Association (AMA) referencing style is used mainly in medical and scientific writing. It is based on a numbered system, where sources are cited in the text using superscript numbers. The reference list is then arranged numerically and includes the full details of the source, including

the author's name, the title of the article, journal name, volume, and page numbers.

**Let's get some detail about the commonest references style**

**Vancouver style:**

It is a numbered referencing style consisting of:

- Citations to someone else's work in the text, indicated by the use of a number
- A sequentially numbered reference list at the end of the document provides full details of the corresponding in-text references.

Insert an in-text citation: when your work has been influenced by someone else's work, for example: when you directly quote someone else's work, when you paraphrase someone else's work

**Basics of in-text citation**

A number is allocated to a source when it is cited in the text. If the source is referred to again, the same number is used. Arabic numerals (1,2,3,4,5,6,7,8,9) should be used.

Either curved bracket (), square [], or superscripts can also be used rather than brackets, e.g.,...was discovered. [1,3]

Reference numbers are generally placed outside or after full stops and commas and punctuation must be consistently applied to the whole document.

A secondary source, or indirect citation, occurs when the ideas of one author are published in another author's work, and the original work could not be accessed. Cite the author of the work you have read and also include this source in your reference list.

**Citing more than one reference at a time**

The preferred method is to list each reference number separated by a comma, or by a dash for a sequence of consecutive numbers. There should be no spaces between commas or dashes for example: (1,5, 6-8).

**Reference List**

References are listed in numerical order, and in the same order in which they are cited in the text. The reference list appears at the end of the paper. The references list should be on a new page with a clear title (References)

The reference list should include all and only those references that have been cited in the text using Arabic numerals (1, 2, 3, 4, 5, 6, 7, 8, 9).

The general principles for capitalization, space, layout, and punctuation in print and electronic articles are listed here.

- Type the author's last name, then no more than two initials (full stop).
- If there are multiple authors, provide all of their names, separating each with a comma and a space.

- List all authors for publications with between one and six writers. List the first six authors of any articles with more than six authors before adding "et al."
- Authors' name start with a capital letter and the first word of the article title are capitalized.
- Journal names are shortened.
- Use a semi-colon after the date.
- Shorten the months to their first three letters (no full stop).
- Write the volume number (without a space) then).
- Give the volume number (no space) followed by the issue number in brackets.
- Abbreviate page numbers where possible, e.g., 123-29.

**Digital Object Identification (DOI) and URLs**

The digital object identifier (DOI) is a unique identifier and should be provided in the reference where it is available.

Here are some examples

Printed articles

**Article with 1 to 6 authors:**

Author AA, Author BB, Author CC, Author DD. Title of article. Abbreviated title of the journal. Date of publication YYYY Mon DD; volume number (issue number): page numbers.

**Article with more than 6 authors:**

Author AA, Author BB, Author CC, Author DD, Author EE, Author FF, et al. Title of article. Abbreviated title of the journal. Date of publication YYYY Mon DD; volume number (issue number): page numbers.

**Electronic journal article**

Author AA, Author BB. Title of article. Abbreviated title of Journal [Internet]. Date of publication YYYY MM [cited YYYY Mon DD]; volume number (issue number): page numbers. Available from: URL

**Electronic journal article with DOI**

Author AA, Author BB, Author CC, Author DD, Author EE, Author FF. Title of article. Abbreviated title of Journal [Internet]. Year of publication [cited YYYY Mon DD]; volume number (issue number): page numbers. Available from: URL DOI

**Books and book chapters**

Enter the author's surname, followed by no more than 2 initials.

- Give all authors' names and separate each by a comma and a space.
- Enter all authors' names in the order in which they appear in the source.

- Only the first word of the article title and words that normally begin with a capital letter is capitalized.
- For book chapters abbreviate page numbers to (p.) e.g., p. 12-25. Where appropriate abbreviate thus: p. 122-8.
- For electronic books include the DOI (Digital Object Identifier) if it is given and place it after the URL (web address).

-Book:

a.) Print book: Author AA. Title of book. edition [if not first]. Place of Publication: Publisher; Year of publication. Page number.

b.) Electronic book: Author AA. Title of the web page. Place of Publication: Sponsor of Website/Publisher; Year Published [cited YYYY Mon DD]. Pages. Available from: URL DOI: (if available)

Example: Carlson BM. Human embryology and developmental biology. 4th ed. St. Louis: Mosby; 2009. 541 p.

-Chapter in a book:

a.) In an edited book: Author AA, Author BB. Title of chapter. In: Editor AA, Editor BB, editors. Title of book. # edition. Place of Publication: Publisher; Year of publication. p. [page numbers of chapter].

b.) In an edited electronic book: Author AA, Author BB. Title of chapter. In: Editor AA, Editor BB, editors. Title of the book

[Internet]. Place of publication: Publisher's name; Year of publication. [cited YYYY Mon DD]. p. #. [page or chapter number/s]. Available from: URL DOI [if available]

**Government and Other Reports**

- Enter author's surname, followed by no more than 2 initials.
- Give all authors and separate each by a comma and a space.
- Where the author is an organization, quote the full name of the organization, omitting the word "The" if preceding the name. Follow the name with the country of origin in parenthesis () using only the two-letter country code.

If there are no authors, only editors, list all editors, followed by a comma and the word editor(s).

**Government reports example:**

Author AA, and Author BB. Title of report. Place of publication: Publisher; Date of publication. A total number of pages. Report No.

**Article from Online Reference Work**

Title of encyclopedia [Internet]. Place of publication: Publisher; year. Title of the article; [updated YYYY Mon DD; cited YYYY Mon DD]; [# of pages/screens]. Available from: URL

Web page:

a.) homepage: Author/organization’s name. Title of the page [Internet]. Place of publication: Publisher's name; Date or year of publication [updated yr. month day; cited yr. month day]. Available from: URL

b.) part of the website: Title of the homepage [Internet]. Place of publication: Publisher's name; Date or year of publication. Title of specific page/part; 4

**-Harvard Reference Style and APA The American Psychological Association Style:**

**Basics: In-Text**

It is a type of reference that is used in writing for referencing, both in the text and in a reference list at the end. It gives the last name of the author(s) and the year of publication, as illustrated in table (1).

Every author whose name comes in the text must also be listed in the references with full details of the source given in, and every work included in the references list must also be cited in the main text. As following:

**Table (1) methods of writing in text reference according to Harvard style**

| Number of authors | In-text citation example |
|---|---|
| **1 author** | (Davis, 2019) |
| **2 authors** | (Davis and Barrett, 2019) |
| **3 authors** | (Davis, Barrett, and McLachlan, 2019) |
| **4+ authors** | (Davis *et al.*, 2019) |

If No Author: use the organization responsible for the post in place of the author. If not, use the title in italics: (*A guide to citation*, 2017, pp. 189-201). (104)

Another general different rule is the same as the Vancouver style (explained earlier).

**Reference List**

A Harvard references list must:

- be on a separate sheet at the end of the document.
- be organized alphabetically by author's name, unless there is no author then it is ordered by the source title
- if there are multiple works by the same author these are ordered by date, if the works are in the same year they are ordered alphabetically by the title and are allocated a letter (a, b, c, etc.) after the date.

- be double-spaced: there should be a full, blank line of space between each line of text.
- contains full references for all in-text references used.

**AMA Style: It** is a variation of the Vancouver system devised by the American Medical Association (AMA). AMA is an author-number style, which means a number is placed in the text to correspond to the author's name(s) in the reference list, which are listed numerically in order of appearance same as Vancouver style list of references.(105)

### 3.8.2 Technological Way of Inserting References

Any writer, researcher, or student who wants to credit sources for their work must learn how to properly include references in a Word document. Thankfully, there are numerous technological tools available to make adding references to documents in Word simpler. Each paragraph in the research taken from a source needs to be referred to its source whether it is a medical rule, fact or historical data, published paper…. etc.

One of the most popular and efficient ways to insert references in Word is by using reference management software. Either through word document plugin software or by some added software as **EndNote** 

**, Mendeley** 

**, and Zotero** 

. These tools allow users to create a

library of references, organize them into folders, and automatically insert them into Word documents.

To use reference management software, the first step is to create an account and download the software. Once installed, users can import references from online databases, such as Google Scholar or Web of Science, or manually add references to their library. Most reference management software also provides the option to generate citations and bibliographies in various citation styles, such as APA, MLA, or Chicago.

After creating a library of references, the next step is to insert them into a Word document. Most reference management software provides a Word plugin that integrates with Word and allows users to insert references with just a few clicks. Users can also customize their citations and bibliographies by choosing the citation style, adding or removing fields, and formatting the text.

Another technological way of inserting references in Word is by using the built-in citation feature in Word. This feature allows users to create a list of sources and citations within a document, and then generate a bibliography at the end of the document. To use this feature, users can click on the "References" tab in Word and select "Insert Citation." Word will prompt users to choose a citation style and then fill out the necessary information for the citation. Users can also add sources to their bibliography by clicking on "Bibliography" and selecting the desired format.

Furthermore, the researcher can create an account on PubMed and NCBI websites. Then, in the search bar write the searching item desired to search, then the list of articles on specific subjects will appear. The researcher chooses any one of the citations desired and then clicks on the send to at the bottom in the right upper corner, one of the options is (to send to the bibliography). Here the citation will plugin Microsoft Word

These programs allow researchers to choose the kind of reference from the above menu whether it is a journal, book, report, etc. Besides, manual adding of references is available by providing information about authors' names, titles, journals, dates, volumes, and pages, with the DOI site. All these will be added to the researcher's bibliography and when the work is finished, one can insert the bibliography in the reference section of the research by clicking the insert bibliography icon in the toolbar. Reference style should be chosen earlier, whether Vancouver style, APA, or Harvard style. **(see reference part)**

### 3.9 Appendix

The appendix is a supplementary section that is used to provide additional information and data that support the main content of the paper. This section is located at the end of the research paper and is usually numbered separately from the main body of the text.

The purpose of the appendix section is to present information that is too detailed or lengthy to be included in the main body of the paper but is still relevant to the study. This may include raw data, calculations, sample questionnaires, graphs, charts, images, or any other materials that support the arguments made in the paper, e.g., listing the questionnaire items or radiological features and so on.

### 3.10 Artificial Intelligence in Research

Artificial intelligence (AI) has revolutionized the field of research by providing researchers with powerful tools for analyzing large amounts of data and generating insights that were previously impossible to obtain. AI has the potential to transform many aspects of research, including hypothesis generation, data analysis, and even the development of new experimental methods.

One of the most significant applications of AI in research is in data analysis. AI algorithms are particularly effective at identifying patterns and correlations in large datasets, allowing researchers to extract insights that might otherwise be overlooked. AI can also be used to develop predictive models that can help researchers forecast outcomes and identify potential areas for further study.

Another area where AI is having a significant impact on research is in the development of new experimental methods. AI

algorithms can be used to analyze complex datasets and identify areas where new experiments may be needed. Additionally, AI can help researchers design experiments that are more efficient and effective, reducing the time and resources required to achieve results.

Examples of AI are chatbot, Chat GPT which can assist users in a variety of tasks, such as answering questions, providing recommendations, or carrying out simple tasks.

# Chapter 4

## Publishing the Research

## 4. Publishing Research:

After finishing the research and writing the results, publishing it in a local or national journal is required. Choosing the appropriate journal to submit your research work can be a crucial decision in the academic world. The right journal can increase the researcher's visibility, credibility, and impact, while the wrong one can hurt the research chances of getting published and reaching the appropriate audience. (106)The following steps can be followed to help in choosing the right journal for publishing the research:

1. Determine the research objectives: Before start looking for journals, one needs to have a clear understanding of the research objectives, the scope of the study, and the target audience. This will help in identifying the appropriate journals that cover topics and readership that are relevant to the research.
2. Review similar articles: Look for articles similar to the current research and check the journals where they were published. This will give the researcher an idea of the types of journals that publish similar research and help in identifying potential journals that might be interested in the work, or simply can use the following sites to help in the searching process by typing the research name and abstract and the site will provide a list with the most appropriate journals. These common sites are:

- **Clarivate:**
- **http://mjl.clarivate.com/home**
- **Elsevier:**
- **http://journalfinder.elsevier.com**
- **Springer:**
- **http://journalsuggester.springer.com**
- **Edanz:**
- **https://edanz.com/journal-selector**
- **Jane:**
- **http://jane.biosemantics.org/index.php**

3. Evaluate the journal's reputation and impact factor: The reputation and impact factor of a journal can affect the visibility and credibility of the research. The impact factor is a measure of how frequently articles from a particular journal are cited in other research papers. Journals with a high impact factor are considered more prestigious and can boost your academic profile. However, you should also consider other factors such as the quality of peer review and the relevance of the journal to the research.(107,108)
4. Check the submission guidelines: Before submitting the research paper to a journal, check their submission guidelines carefully. Some journals have specific formatting and length requirements, and failing to adhere to these guidelines can lead

to rejection. It is also important to check the journal's policies on open access, copyright, and publication fees.(109)

5. Consider the publication timeline: The publication timeline can also be a factor to consider. If the researcher needs the research to be published quickly, they should look for journals with a short publication timeline. However, some prestigious journals may take longer time to publish the research but offer higher visibility and impact.(110,111)

The journal should be a peer-reviewed journal and/ or have an impact factor or a cite score. Making sure that the research subject is within the scope of the chosen journal and do not rush in publishing in journals that could be predatory.

# Chapter 5

## Samples of Medical Research

## 5.Examples of medical research

### The following are examples of some research design application

Research 1 (112)represents the application of primary research, a cross-sectional study type of design with sampling. It represents an example of different research sections beginning with title, authors, abstract, introduction, methods, analysis, results, discussion with its limitation and strengthening aspects, conclusions and recommendations, acknowledgments, funding, ethics approval and consent to participate, competing interests and references with Vancouver style.

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Conflict and Health

RESEARCH Open Access

# Reproductive health in humanitarian settings in Lebanon and Iraq: results from four cross-sectional studies, 2014–2015

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**Abstract**

**Background:** Reproductive health is an important component of humanitarian response. Displaced women need access to family planning, antenatal care, and the presence of a skilled birth attendant at delivery. Since the beginning of the Syrian conflict in 2011, Lebanon and Iraq have been hosting large numbers of refugees, thereby straining local capacities to provide these services. In order to identify salient health needs, Médecins Sans Frontières conducted a survey in several sites hosting refugees and internally displaced persons across the region. Here we describe the reproductive health profile of Syrian refugees, Iraqi displaced persons, and vulnerable Lebanese and their use of services.

**Methods:** We conducted four cross-sectional surveys in 2014–2015 in two sites in Lebanon and two sites in Iraq. Depending on the site, two-stage cluster sampling or systematic sampling was intended, but non-probability methods were employed at the second stage due to implementation challenges. We collected information on overall health (including reproductive health) and demographic information from heads of households on the basis of a standardized questionnaire. Pearson chi-square tests were used to compare proportions, and generalized linear models were used to calculate odds ratios with regard to risk factors. All analyses were performed using the survey suite of commands in Stata version 14.1.

**Results:** A total of 23,604 individuals were surveyed, including 5925 women of childbearing age. Overall, it was reported that 7.5% of women were currently pregnant and 12.8% had given birth within the previous 12 months. It was reported that pregnancy was unplanned for 57% of currently pregnant women and 66.7% of women who had delivered in the previous year. A slight majority of women from both groups had accessed antenatal care at least once. Amongst women who had delivered in the previous year, 84.5% had done so with a skilled birth attendant and 22.1% had had a cesarean section. Location and head of household education were predictors of unplanned pregnancy in multivariable analysis. Head of household education was also significantly associated with higher uptake of antenatal care.

**Conclusions:** Considering the large number of pregnant women and women having recently delivered in these settings, addressing their sexual and reproductive health needs emerges as a crucial aspect of humanitarian response. This study identified unmet needs for family planning and high cesarean section rates at all sites, suggesting both lack of access to certain services (contraception, antenatal care), but also over-recourse to cesarean section. These specific challenges can impact directly on maternal and child health and need today to be kept high on the humanitarian agenda.

**Keywords:** Refugees, Family planning, Pregnancy, unplanned, Prenatal care, Delivery, obstetric, Cesarean section, Iraq, Lebanon, Syria

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Iraq, Lebanon, Syria

## Background

Sexual and reproductive health (SRH) is a challenging issue in the Middle East and the subject has attracted relatively little academic attention over the past 40 years. As a result, the SRH profile of women living in the Middle East, and specifically Syrian women, is not fully described. Before the conflict, Syria enjoyed a well- functioning health system [1]. A survey had shown that 42% of women aged 15 to 49 years were using modern contraceptives [2]. The average fertility rate at the time was 3.8, with around a third of pregnancies stated to be unintended (whether unplanned or unwanted) [3]. Ter- mination of pregnancy (ToP) was allowed only if the mother was at risk of death [4], and the rate of induced abortion was estimated at 3.9% in 2006, although previous studies had found much higher figures [3]. Overall trends in SRH are similar in neighboring countries such as Lebanon, Iraq, and Jordan, where many Syrian refugees are currently living [5–10].

In a conflict and refugee context, it is well known that women and children are at highest risk of adverse health outcomes [1]. In March 2015, the United Nations Popu- lation Fund estimated that nearly half a million Syrian women (both in Syria and hosting countries) were pregnant and that more than 70,000 of them would experience complications associated with pregnancy and/or delivery [11]. Many Syrian families (approxi- mately 5.3

million registered refugees) have relocated to neighboring countries, primarily Turkey (3.3 million), Lebanon (1.5 million), Jordan (655,000), Egypt (500,000), and Iraq (246,000) according to the latest available figures [12].

Specifically in Lebanon, due to the continuous influx of displaced people and refugees, the existing health structures were extremely burdened [13]. Gaps in critical health services included key areas such as SRH. Since November 2011, Médecins Sans Frontières (MSF) has been providing free primary care assistance to Syrian refugees in a number of locations in Lebanon, including the treatment of acute and chronic diseases and reproductive health. These services are offered to Syrian refugees (irrespective of registration status), Lebanese and Palestinian refugees from Syria, and the Lebanese host community.

In Iraq, it is widely known that health services are under stress [14, 15], but to our knowledge no specific study has systematically investigated this problem.

In 2014, concerned notably by these populations' needs for greater care of chronic conditions, MSF conducted a general health assessment in a selection of its project sites both in Lebanon and Iraq where the organization was also operating to help Syrian refugees and Iraqi displaced persons. Here we describe the repro- ductive health profile of all women of reproductive age

(in surveyed households) in Bekaa and Tripoli (Lebanon), and Kirkuk and Dohuk (Iraq), their use of services, and their most salient needs. For a map of the region, see Fig. 1.

## Methods

Four cross-sectional surveys were conducted between February 2014 and April 2015 in four sites (Bekaa, Tripoli, Kirkuk, and Dohuk). Our surveys looked at three different study populations (Syrians, Iraqis, Lebanese). In Bekaa, we wished to sample from the Syrian refugees who had migrated from Syria to Lebanon within the 3 years prior to the survey. In Tripoli, the sample included mainly the hosting Lebanese population who were neither refugees nor IDPs, but did include also some Syrians. In Kirkuk and Dohuk (Iraq), our sample was taken among those displaced during the second wave of displacement which had occurred 12 months prior to the survey. Setting also differed by site with populations living in camps, informal tented settlements, and houses/apartments in both urban and rural areas as follows: a) in Bekaa the majority of respondents lived in urban and rural areas of Baalbek, West Baalbek, Arsal, Zahle, Bar Elias, Al Marj, Majda Anjar, and surrounding villages with some respondents in informal tented settle- ments, b) in Tripoli respondents were in the urban set- tings of Bab al Tabanneh and Jabal Mohsen; c) in Kirkuk respondents were living in Kirkuk city and the surround- ing areas, or the Yahyawah and Laylan camps, and d) in Dohuk

city and surrounding areas respondents residing in as well as in informal tented settlements and camps.

## Survey and sampling methodology

### Sampling

The survey was designed to utilize two-stage cluster sampling in three of the survey sites (Bekaa, Dohuk, Kirkuk), which included both camps and informal tented settlements. In each site, clusters were identified from sampling frames based on existing data from UNHCR, UNICEF or other NGOs active in the area, and were sampled with probability proportional to size. Systematic sampling was attempted in the second stage; however, due to logistical constraints it is possible that non- probability sampling methods, such as convenience sampling were used at some clusters to identify the first dwelling in the second stage of sampling. In Tripoli, an attempt was made to systematically sample households in the urban communities of Bab al Tabanneh and Jabal Monsen. However, non-probability sampling methods may have been used to identify the first household. Sampling intervals differed by site, and the interviewers proceeded to every fourth (Tripoli) or sixth dwelling (elsewhere) from the selected starting point.

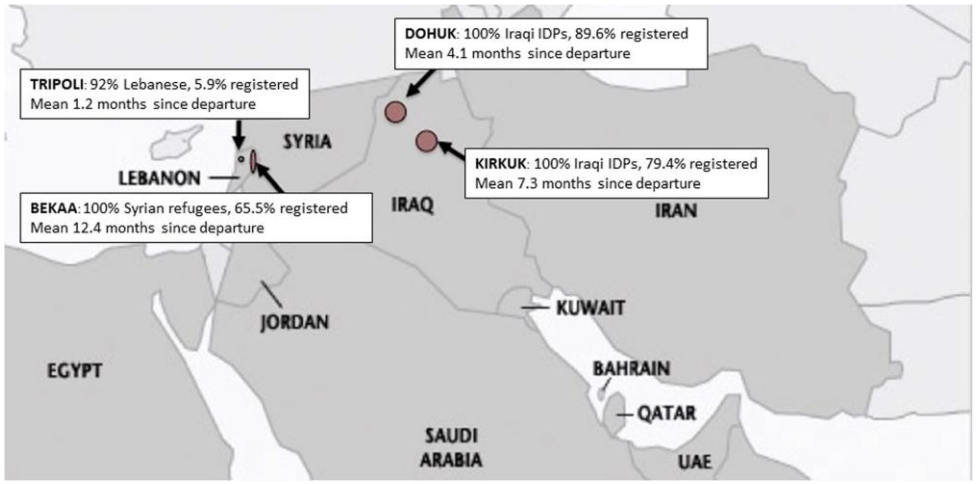


Fig. 1 Map of the

## Questionnaire

The questionnaire was broad in scope, covering demographic information, morbidity and mortality, vaccination coverage, sexual and reproductive health, and access to health care. Questions were drawn from instruments used by the investigators for previous sur- veys of refugee health in collaboration with the Centers for Disease Control and Prevention and the World Health Organization, and translated into Arabic. A stan- dardized questionnaire was used at all sites and the head of household or household representative (husband, wife, widow/mother-in-law or other) was interviewed for information on all members of households. Data was collected both on paper and electronically.

## Analysis

The survey was initially designed to look at a broad range of health issues and this article will concentrate on SRH. The

present analysis focuses on two groups of interest among women of reproductive age (15 to 49 years): women who reported being currently pregnant and women who reported having given birth in the previous 12 months. The main reproductive health out- comes of interest were: unplanned pregnancy, antenatal care, skilled birth attendant at time of delivery, and cesarean section. We combined the four sites to explore risk factors and determinants of these four outcomes among the two groups of women, using site and demo- graphic variables as explanatory factors. Note that the question on unplanned pregnancy was not systematically asked for currently pregnant women in Bekaa, and this

site was excluded from the analysis of this outcome among currently pregnant women. Sample means and proportions were used to estimate their respective popu- lation counterparts. Note also that these survey percent- ages take into account weighting and refer to the estimated underlying population and not the survey sample. Pearson chi-square tests were used to compare proportions, and generalized linear models were used to calculate odds ratios. Multivariable models for all out- comes were adjusted for demographic variables (age, head of household, education) and information on refu- gee status (time since departure from home, registration as refugee or IDP, and shelter type). Available obstetric or reproductive health information differed for the two groups of women, and when available the following variables were included in adjusted models: for currently pregnant women: intention to conceive and

gestational age; for women having delivered in the previous year: intention to conceive, birth location, and previous cesarean section. All analyses were performed using the survey suite of commands in Stata version 14.1 which takes the sampling methodology into account.

## Results

### Overall results

The total surveyed population consisted of 23,604 individuals in 4444 households including 5925 women between 15 and 49 years of age ("women of childbearing age", WCA) [Table 1]. A total of 4115 survey respon- dents reported on 5925 women of childbearing age; the survey respondent was a woman of childbearing age in

**Table 1 Survey population by site**

| | Bekaa | | Tripoli | | Duhok | | Kirkuk | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | n | % |
| Total survey population | 6363 | 27.0 | 3022 | 12.8 | 7628 | 32.3 | 6591 | 27.9 | 23,604 | 100% |
| Women[a] | 3282 | 51.6 | 1492 | 49.4 | 3783 | 49.6 | 3228 | 49.0 | 11,785 | 50.0 |
| Women 15–49 years[b] | 1548 | 47.2 | 830 | 55.6 | 1861 | 49.2 | 1686 | 52.2 | 5925 | 50.3 |
| Current pregnancy[c] | 211 | 13.7 | 31 | 3.7 | 97 | 5.2 | 106 | 6.29 | 445 | 7.5 |
| Delivery in last year[c] | 294 | 19.0 | 47 | 5.7 | 235 | 12.6 | 184 | 10.9 | 760 | 12.8 |

[a]percentage of total population by site; [b]percentage of women by site [c]percentage of women 15–49 years by site

58.5% of households ($n$ = 2406). There was a median of one WCA per household (IQR 1–2, range 1–7); 72.1% ($n$ = 2965) of respondents reported only one WCA and 11.1% ($n$ = 455) reported on three or more. Overall, respondents reported that 445

(7.5%) women were preg- nant and 760 (12.8%) had given birth within the previous 12 months. For a majority of women in both groups, their pregnancy was said to be not wanted “at the time” or “at all”. This held for 57.5% ($n$ = 140; 95% CI 47.9–66.7) of currently pregnant women in Tripoli, Dohuk and Kirkuk and 66.7% ($n$ = 496; 95% CI 59.3–73.4) of women who had delivered in the previous year in all four sites.

Regarding currently pregnant women in all sites, 61.3% (95% CI: 55.3–67.0) ($n$ = 270) had had at least one antenatal visit. The presence of a skilled birth attendant at delivery was high (85.4, 95% CI 81.0–88.0) ($n$ = 632), as was the proportion of cesarean sections (22.1, 95% CI 18.8–25.4), in women who had delivered in the last year ($n$ = 168).

The average age for women of reproductive age was 28 years, and differed significantly by site, ranging from

26.6 in Duhok to 29.7 in Tripoli ($p < 0.001$, Table 2). Overall education was low in this group: 38% ($n$ = 325) of household heads reported no formal education, and this ranged from 60.2% in Duhok to 19.5% in Tripoli ($p < 0.05$). Time since departure from home and propor- tion of people registered as refugees or IDPs with the UNHCR differed by site, reflecting the different stages of the refugee crisis (Fig. 1). Percentages of currently pregnant women and women having given birth in the previous 12 months were highest in Bekaa and lowest in Tripoli

[Table 1]. Appropriate antenatal care was lowest in Duhok with just over a third of women accessing antenatal care according to WHO and MSF recommen- dations, i.e. at least four visits before delivery [Table 2].

Unplanned pregnancy did not differ significantly by site amongst women who had delivered in the previous year, and was reported by 66.7% overall. However, amongst currently pregnant women, this proportion was lower in Tripoli than in other sites, where one third of women reported unplanned pregnancy compared to 66% of women who reported the same in Kirkuk ($p = 0.07$).

Although the proportions of deliveries in the presence of a skilled birth attendant was high for women overall, the proportions differed significantly by site, from 93.4% in Bekaa to 71.9% in Duhok, $p < 0.001$ [Table 2].

Nearly a third of women had delivered by cesarean section, with the exception of Dohuk where this figure was 12.8% (95% CI: 9.9–16.4).

## Risk factor analysis

### *Currently pregnant women*

In the multivariable model of unplanned pregnancy, only site remained a significant predictor such that women in Kirkuk had higher odds of unplanned pregnancy (OR % 14.08, 95% CI 3.89–

50.99) than women in Tripoli (data not available for Bekaa) (Table 3).

In terms of antenatal care, head of household educa- tion and intention to conceive were predictive of at least one ANC visit in multivariable analysis. Women living in a household where the head of household had sec- ondary education had greater odds of ANC compared to those with no education (OR: 4.80, 95% CI 1.7–13.5). And women who reported that their pregnancy was not intended ("not at all") had less than half the odds of reporting any ANC than women who said their preg- nancy was planned (OR 0.43 95% CI 0.21–0.89).

**Women who had delivered in the previous 12 months**

For women who had delivered in the previous year, liv- ing with a head of household who had university education was associated with lower odds of unplanned pregnancy (OR 0.44, 95% CI 0.19–0.98) than a head of household with no education (Table 4).

Location of delivery was a significant predictor of skilled birth attendance in multivariable analysis, such that women who had given birth in the survey site (i.e., the area to which they had been displaced) had more than triple the odds of presence of a skilled attendant compared to those who had given birth in their home region (OR 3.55, 95% CI 1.94–6.49). Site was associated

with the presence of a skilled birth attendant, such that women in Tripoli had much lower odds of presence of a skilled birth attendant at delivery (OR 0.12)

**Table 2 Socio-demographic characteristics and sexual and reproductive health outcomes for women of reproductive age by survey site Characteristics Bekaa (*n* = 1548) Tripoli (*n* = 830) Duhok (*n* = 1861) Kirkuk (*n* = 1686) Total (*n* = 5925)**

| | svy % | 95% CI | svy % | 95% CI | svy % | 95% CI | svy % | 95% CI | svy % | 95% CI | *p*-val[5] |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Age (mean) | 28.2 | 27.8–28.5 | 29.7 | 28.4–31.1 | 26.6 | 26.2–27.0 | 28.2 | 27.6–28.9 | 28.0 | 27.6–28.4 | < 0.001 |
| Head of HH without education | 36.9 | 29.8–44.7 | 19.5 | 3.6–61.5 | 60.2 | 53.8–66.4 | 25.6 | 16.6–37.2 | 38.2 | 31.0–46.0 | 0.038 |
| Time since departure (mean months) | 12.5 | 11.4–13.7 | 1.2 | 0–3.4 | 4.1 | 4.0–4.3 | 7.3 | 6.5–8.2 | 6.0 | 5.2–6.7 | < 0.001 |
| UNHCR registration | 65.5 | 57.6–72.7 | 5.9 | 0.68–36.8 | 89.6 | 80.3–94.8 | 79.4 | 62.9–89.8 | 68.3 | 62.1–74.4 | < 0.001 |
| HH size (mean) | 5.9 | 5.7–6.2 | 5.5 | 4.3–6.6 | 6.8 | 5.7–7.8 | 5.7 | 5.4–5.9 | 6.4 | 5.6–6.5 | 0.15 |
| Delivered in survey site region | 60.4 | 50.0–70.0 | 95.7[#] | 84.1–99.0 | 46.8 | 40.3–53.4 | 53.3 | 44.7–61.7 | 57.5 | 37.7–47.4 | < 0.001 |
| Previous caesarean section | 28.3 | 22.2–34.4 | 31.8 | 15.4–48.2 | 13.0 | 16.7–19.4 | 16.3 | 11.3–21.3 | 20.4 | 16.3–24.4 | 0.003 |
| Gestational age (mean weeks)[b] | 19.9 | 18.7–21.1 | 20.0 | 13.9–26.1 | 22.9 | 20.7–25.1 | 11.9 | 10.1–13.8 | 18.9 | 17.3–20.5 | < 0.001 |
| SRH Outcomes Unplanned pregnancy[a,c] | 67.0 | 60.0–73.8 | 61.7 | 21.3–90.1 | 68.9 | 63.3–74.1 | 70.1 | 45.4–86.9 | 66.7 | 59.3–73.4 | 0.85 |
| Unplanned pregnancy [b,c] | – | – | 32.2 | 18.5–50.0 | 61.9 | 54.4–68.7 | 66.0 | 38.3–85.9 | 57.5 | 47.9–66.7 | 0.07 |
| Antenatal care[b] | 62.9 | 52.0–72.5 | 87.1 | 75.4–93.7 | 44.3 | 30.6–59.0 | 64.2 | 56.1–71.5 | 61.3 | 55.3–67.0 | < 0.001 |
| Appropriate ANC[b,d] | 56.4 | 46.1–66.1 | 74.2 | 63.9–78.6 | 35.1 | 24.8–46.9 | 62.3 | 54.1–69.8 | 54.3 | 49.0–59.6 | < 0.001 |
| Skilled birth attendance[a] | 93.4 | 90.8–95.3 | 91.5 | 70.3–98.0 | 71.9 | 63.1–79.3 | 89.7 | 83.1–93.9 | 85.4 | 81.0–88.0 | < 0.001 |
| Caesarean section[a] | 29 | 23.3–35.5 | 27.3 | 9.9–56.1 | 12.8 | 9.9–16.4 | 25.5 | 20.8–31.0 | 22.1 | 18.8–25.4 | 0.043 |

[a]among women with delivery in last 12 months (*N* = 294 in Bekaa, *N* = 47 in Tripoli, *N* = 235 in Dohuk, *N* = 184 in Kirkuk, *N* = 760 in total); [b] among women currently pregnant (*N* = 211 in Bekaa, *N* = 31 in Tripoli, *N* = 97 in Dohuk, *N* = 106 in Kirkuk, *N* = 445 in total); [c]Unplanned pregnancy = reported that pregnancy either unwanted or not wanted at this time (aka unmet need for family planning),[d] at least one visit by 26 weeks- at least 2 visits by 32 weeks and at least 3 visits by 38 weeks- and 4 visits over 38 weeks. [5]Pearson chi square test for categorical variables- adjusted Wald test for continuous variables (within survey suite of commands). # *n* = 47 women

*Svy* Survey, *CI* Confidence interval, *UNHCR* United Nations High Commissioner for Refugees, *HH* Household, *SRH* Sexual and reproductive health, *ANC* Antenatal care 95% CI 0.02–0.67) than women in Bekaa (no evidence for a difference in the other sites).

The proportion of women delivering by cesarean section was high overall at 22.1% across the four sites, and factors associated with a higher odds of a cesarean a previous cesarean (OR 17.54 95% CI 8.89–34.59) and delivery at survey site compared to home region (1.91, 95% CI 1.29–2.84).

## Discussion

The results of this survey highlight three components of SRH requiring improvement: 1) proportions of un- planned pregnancies are overall high; 2) access to ante- natal care is suboptimal; 3) proportions of cesarean sections are significantly above the recommended limits.

**We shall discuss each of these points separately.**

### High proportions of unplanned pregnancies

The question of unplanned pregnancy remains a sensi- tive issue. Worldwide, around 40% of pregnancies are thought to be unintended [16]. In 2009 it was estimated that one in three pregnancies was unintended in the Middle East and North Africa

region [3]. However, many women may be reluctant to state that their pregnancy was unplanned and/or may change their view once the child is born. Thus, data on unintended pregnancies cannot be considered as thoroughly reliable. It is clearthat Syrian, Iraqi and vulnerable Lebanese women have, at best, experienced ruptures in contraceptive stocks or, at worst, have no access to modern contraceptive methods for prolonged periods. It is known that unin- tended pregnancies are associated with a range of phys- ical and psychological risks including reduced access to antenatal care, greater risk-taking behaviors (such as smoking), low birth weight for the baby, and even maternal death [17]. Indeed in our survey, we found that women who did not intend to get pregnant were less likely to access ANC at all. Risk factors for unplanned pregnancy in our survey were linked to site, with higher proportions being reported in Iraq. Why this is so is not clear and would require further investigation. Sexual vio- lence, for instance, is more prevalent in conflict/displacement situations than in stable circumstances and this can contribute to higher unintended pregnancy rates. There have been numerous reports of sexual vio- lence in the present Syrian crisis, both in Syria and in host countries, even given the strong cultural reluctance and fear to talk about such subjects [18–20]. Another fact to consider is that early marriage has emerged as a

"coping strategy" for families with young girls [21]: it is hoped that married teenage women will be thus better protected and provided for. However, early marriage can be associated with poorer knowledge of family planning methods, higher maternal risks, and poorer pregnancy

**Table 3 Predictors of unplanned pregnancy and ANC use in currently pregnant women in all sites combinedUnplanned pregnancy[a] ANC use**

| | OR | 95% CI | aOR | 95% CI | OR | 95% CI | aOR | 95% CI |
|---|---|---|---|---|---|---|---|---|
| Site Bekaa | – | | | | 1.0 | | 1.0 | |
| Tripoli | 1.0 | | 1.0 | 1.0 | 3.99 | 1.61–9.88 | 1.53 | 0.26–9.11 |
| Dohuk | 3.41 | 1.53–7.59 | 2.69 | 0.22–33.61 | 0.47 | 0.22–0.99 | 0.54 | 0.11–2.59 |
| Kirkuk | 4.08 | 1.05–15.89 | 14.08 | 3.89–50.99 | 1.06 | 0.60–1.85 | 0.96 | 0.33–2.83 |
| Age (years) 15–19 | 1.0 | | 1.0 | 1.0 | 1.0 | | 1.0 | |
| 20–29 | 0.94 | 0.22–4.04 | 0.97 | 0.34–2.75 | 1.21 | 0.61–2.40 | 1.14 | 0.41–3.15 |
| 30–39 | 1.28 | 0.38–4.38 | 1.49 | 0.54–4.10 | 0.98 | 0.41–2.34 | 1.02 | 0.32–3.30 |
| 40–49 | 1.79 | 0.18–18.17 | 1.22 | 0.09–16.28 | 0.69 | 0.17–2.91 | 0.87 | 0.21–3.54 |
| Head of household education None | 1.0 | | 1.0 | 1.0 | 1.0 | | 1.0 | |
| Primary | 0.91 | 0.57–1.44 | 1.23 | 0.66–2.28 | 1.52 | 0.90–2.59 | 0.87 | 0.49–1.54 |
| Secondary | 0.51 | 0.18–1.42 | 0.56 | 0.19–1.66 | 3.68 | 1.48–9.17 | 4.80 | 1.70–13.52 |
| University | 0.34 | 0.08–1.46 | 0.3 | 0.09–1.01 | 4.69 | 1.47–14.93 | 2.68 | 0.98–7.28 |
| Trimester First (week 1–12) | 1.0 | | 1.0 | 1.0 | 1.0 | | 1.0 | |
| Second (week 13–27) | 1.21 | 0.50–2.93 | 1.2 | 0.59–2.41 | 1.11 | 0.69–1.80 | 1.05 | 0.60–1.81 |
| Third (week 28–36) + | 1.37 | 0.32–5.78 | 2.09 | 0.58–7.57 | 1.16 | 0.62–2.16 | 1.51 | 0.78–2.92 |
| Intention Planned | | | | | 1.0 | | 1.0 | |
| Not now | | | | | 0.81 | 0.49–1.33 | 1.10 | 0.71–1.71 |
| Not at all | | | | | 0.32 | 0.15–0.69 | 0.43 | 0.21–0.89 |
| Shelter type Own or rent house | 1.0 | | 1.0 | 1.0 | 1.0 | | 1.0 | |
| House occupied for free | 2.22 | 0.75–6.57 | 0.98 | 0.26–3.69 | 0.53 | 0.27–1.04 | 1.11 | 0.45–2.73 |
| Unfinished building | 1.72 | 0.59–5.00 | 0.79 | 0.12–5.06 | 0.26 | 0.07–0.93 | 0.74 | 0.17–3.21 |
| Other shelter type | 2.41 | 1.17–4.99 | 1.28 | 0.28–5.87 | 0.23 | 0.12–0.46 | 0.65 | 0.16–2.62 |
| Camp / ITS | 4.38 | 2.32–8.29 | 0.99 | 0.12–8.21 | 0.31 | 0.16–0.59 | 0.96 | 0.39–2.34 |
| Time since leaving home < | 1.0 | | 1.0 | 1.0 | 1.0 | | 1.0 | |

| | OR | 95% CI | aOR | 95% CI | OR | 95% CI | aOR | 95% CI |
|---|---|---|---|---|---|---|---|---|
| 3 months | | | | | | | | |
| 3–5 months | 4.82 | 2.44–9.52 | 1.26 | 0.14–11.11 | 0.2 | 0.07–0.56 | 0.41 | 0.11–1.53 |
| 6–11 months | 3.71 | 1.00–13.79 | 0.45 | 0.11–1.76 | 0.31 | 0.11–0.87 | 0.29 | 0.06–1.39 |
| > 12 months | 1.41 | 0.32–6.32 | 0.86 | 0.35–2.13 | 0.43 | 0.18–1.03 | 0.67 | 0.19–2.43 |
| UNHCR registration | 2.53 | 1.03–6.22 | 0.93 | 0.17–4.98 | 0.64 | 0.37–1.09 | 1.45 | 0.64–3.29 |

[a]Unplanned pregnancy includes only Tripoli- Dohok- Kirkuk. *ITS* Informal tented settlement, *UNHCR* United Nations High Commissioner for Refugees,*HH* Household, *SRH* Sexual and reproductive health, *ANC* Antenatal care

outcomes [22, 23]. Finally, beyond pregnancies occurring from unwanted sexual relations, it is not clear whether more women dread becoming pregnant in a refugee context or whether some women are having children in order to "compensate" for lives lost during the war; this ambiguity of attitude towards pregnancy has been noted in many other contexts [24]. Unfortunately, we were not able to examine these important factors in the context of our survey.

## Suboptimal access to antenatal care

After having recommended four antenatal visits for pregnant women, the WHO speaks now of at least eight "contacts" with a health care provider during pregnancy with a view to preventing health problems for both

mother and child [25]. Prenatal care includes tetanus vaccination, screening for and treatment of infections, and identification of early warning signs of complica- tions. Reaching this goal in a refugee situation can be challenging. However, lack of antenatal care is associated with a higher risk of complex

deliveries and health issues for both mother and child [26, 27]. In our survey, we saw that coverage by at least one antenatal care visit was highest in Tripoli (nearly 75%) – which was the first location where MSF intervened – and lowest in Dohuk (35%). Women who had planned their pregnancy were more likely to access ANC, than those who stated their pregnancy was unintended, underscoring the need for family planning. Clearly, the target of eight visits with a health care provider during pregnancy is far from being

**Table 4 Predictors of unplanned pregnancy, skilled birth attendance and caesarean section in women who delivered in the last 12 months in all sitesUnplanned pregnancy Skilled birth attendance Caesarean section**

| | OR | 95% CI | aOR | 95% CI | OR | 95% CI | aOR | 95% CI | OR | 95% CI | aOR | 95% CI |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Site Bekaa | 1.0 | | 1.0 | | 1.0 | | 1.0 | | 1.0 | | 1.0 | |
| Tripoli | 0.93 | 0.15–5.72 | 1.94 | 0.62–6.11 | 0.76 | 0.16–3.59 | 0.12 | 0.02–0.67 | 0.92 | 0.26–3.24 | 0.23 | 0.02–2.73 |
| Dohuk | 1.29 | 0.85–1.95 | 0.92 | 0.33–2.60 | 0.18 | 0.11–0.31 | 0.38 | 0.09–1.62 | 0.36 | 0.24–0.54 | 0.18 | 0.08–0.44 |
| Kirkuk | 1.36 | 0.46–4.03 | 1.5 | 0.61–3.68 | 0.61 | 0.31–1.20 | 0.74 | 0.32–1.73 | 0.84 | 0.56–1.25 | 1.3 | 0.74–2.28 |
| Age (years) 15–19 | 1.0 | | 1.0 | | 1.0 | | 1.0 | | 1.0 | | 1.0 | |
| 20–29 | 1.39 | 0.75–2.58 | 1.16 | 0.56–2.41 | 0.61 | 0.24–1.58 | 0.75 | 0.26–2.16 | 1.25 | 0.78–2.01 | 1.15 | 0.59–2.25 |
| 30–39 | 1.91 | 0.84–4.36 | 1.63 | 0.80–3.31 | 0.35 | 0.15–0.83 | 0.43 | 0.15–1.27 | 1.14 | 0.63–2.04 | 1.19 | 0.55–2.56 |
| 40–49 | 2.79 | 0.98–7.93 | 1.97 | 0.72–5.36 | 1.06 | 0.31–3.61 | 1.23 | 0.23–6.45 | 1.45 | 0.54–3.85 | 1.16 | 0.38–3.50 |
| Head of HH educ. None | 1.0 | | 1.0 | | 1.0 | | 1.0 | | 1.0 | | 1.0 | |
| Primary | 0.74 | 0.48–1.14 | 0.79 | 0.53–1.17 | 3.13 | 1.70–5.77 | 1.65 | 0.79–3.41 | 2.23 | 1.38–3.59 | 1.04 | 0.54–2.00 |
| Secondary | 0.52 | 0.25–1.09 | 0.60 | 0.29– | 3.81 | 1.28–11.36 | 2.1 | 0.58– | 2.03 | 1.04– | 1.03 | 0.40–2.70 |

| | OR | 95% CI | aOR | 95% CI | OR | 95% CI | aOR | 95% CI | OR | 95% CI | aOR | 95% CI |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | 1.24 | | | | 7.58 | | 3.96 | | |
| University | 0.42 | 0.16–1.10 | 0.44 | 0.19–0.98 | 6.19 | 1.28–29.90 | 3.17 | 0.68–14.80 | 2.1 | 0.99–4.49 | 1.05 | 0.32–3.45 |
| Intention Planned | | | | | 1.0 | | 1.0 | | 1.0 | | 1.0 | |
| Not now | | | | | 0.82 | 0.37–1.84 | 1.07 | 0.46–2.46 | 0.61 | 0.41–0.91 | 0.47 | 0.26–0.88 |
| Not at all | | | | | 0.61 | 0.27–1.40 | 1.2 | 0.46–3.14 | 0.93 | 0.53–1.61 | 0.91 | 0.51–1.60 |
| Birth in survey site region | 0.66 | 0.40–1.09 | 0.71 | 0.47–1.06 | 4.07 | 2.40–6.88 | 3.55 | 1.94–6.49 | 1.84 | 1.34–2.53 | 1.91 | 1.29–2.84 |
| Previous CS | 1.26 | 0.68–2.34 | 1.45 | 0.84–2.52 | 2.07 | 1.14–3.75 | 1.35 | 0.66–2.74 | 16.23 | 9.29–28.36 | 17.54 | 8.89–34.59 |
| Shelter type Own/rent house | 1.0 | | 1.0 | | 1.0 | | 1.0 | | 1.0 | | 1.0 | |
| House for free | 0.95 | 0.35–2.55 | 0.89 | 0.34–2.32 | 0.24 | 0.07–0.76 | 0.59 | 0.11–3.03 | 0.74 | 0.35–1.57 | 1.09 | 0.46–2.61 |
| Unfinished bldg. | 2.25 | 0.67–7.51 | 2.14 | 0.63–7.25 | 0.21 | 0.07–0.61 | 0.42 | 0.12–1.47 | 0.44 | 0.24–0.81 | 1.4 | 0.67–2.94 |
| Camp / ITS | 1.42 | 0.62–3.23 | 1.59 | 0.68–3.69 | 0.2 | 0.07,0.62 | 0.56 | 0.15–2.13 | 0.42 | 0.21–0.84 | 1.48 | 0.73–3.01 |
| Other | 1.33 | 0.54–3.27 | 1.13 | 0.52–2.43 | 0.97 | 0.14–6.50 | 0.67 | 0.19–2.35 | 0.68 | 0.39–1.18 | 0.71 | 0.46–1.11 |
| Time since leaving home < 3 months | 1.0 | | 1.0 | | 1.0 | | 1.0 | | 1.0 | | 1.0 | |
| 3–5 months | 1.64 | 0.35,7.77 | 1.79 | 0.53–6.12 | 0.11 | 0.03–0.44 | 0.12 | 0.01–1.62 | 0.4 | 0.19–0.85 | 0.71 | 0.32–1.59 |
| 6–11 months | 1.51 | 0.29,7.84 | 1.85 | 0.66–5.22 | 0.35 | 0.09–1.42 | 0.16 | 0.02–1.30 | 0.75 | 0.36–1.57 | 0.38 | 0.21–0.70 |
| > 12 months | 1.41 | 0.30,6.60 | 2.32 | 0.68–7.94 | 0.53 | 0.18–1.52 | 0.16 | 0.03–0.84 | 0.65 | 0.36–1.18 | 0.32 | 0.18–0.57 |
| UNHCR registration | 1.19 | 0.61–2.30 | 0.86 | 0.48–1.51 | 0.95 | 0.52–1.72 | 1.94 | 0.99–3.79 | 0.62 | 0.36–1.06 | 0.87 | 0.54–1.40 |

*ITS* Informal tented settlement, *UNHCR* United Nations High Commissioner for Refugees, *HH* Household, *SRH* Sexual and reproductive health

met, but even if one considers the former WHO target of four antenatal care visits (which is more realistic in this context), coverage remains suboptimal. This is interesting given that a similar study conducted soon after ours found that 89% of

Syrian women in Lebanon had sought ANC with an average of six visits [25].

**High proportions of cesarean sections**

Cesarean section rates in Syria and Lebanon were high before the Syrian crisis, with estimates of up to 35% in Lebanon and 45% in Syria [28]. Cesarean section is not a minor event and carries risks for both mother and child. The WHO estimates that between 5 and 15% of deliver- ies at a population level necessitate the procedure, and states that there is no evidence of benefit to the mother or child of a medically unnecessary procedure [29, 30]. In the present context, with an average of 22.1% of cesarean sections for women having delivered in the pre- vious year across all four sites, we are clearly over the limit. Another study in Lebanon found that around one- third of Syrian women had had a cesarean section [31]. The question is: are they medically necessary? In our survey, the strongest predictor of a cesarean section was a previous cesarean section. It has been reported that currently in Syria some health care professionals suggest cesarean section to expectant mothers so that, in unstable conditions, they can plan their delivery. Several studies have found higher cesarean section rates in conflict settings [28, 32]. A survey in 2013 found that up to 41% of deliveries in the Bekaa Valley were by cesarean section, in spite of the fact that most women said they preferred vaginal birth [28]. We found a

lower percent- age of cesarean sections (29%) in the same area at around the same time. Medical considerations aside, the UNHCR covers 75% of costs associated with delivery, such that when there is a cesarean section families may have to pay up to the equivalent of 500 euros for the extra 25% [33].

**Limitations & generalizability**

Our study has several limitations. To begin with, the uncertainty surrounding the use of probability sampling methods in the second stage of sampling in Bekaa, Dohuk and Kirkuk, as well as for the selection of the starting household in Tripoli, suggests that the sampled respondents may not be representative of the refugees or IDPs living in these sites, and results may be biased. Secondly, our survey was not designed specifically to address reproductive health issues, but was a general health assessment at one point in time in a constantly evolving and complex environment. Third, we identified many differences among survey sites, but were unable fully to explore the reasons for these differences. At a pro- grammatic level, we could not examine how differences in

service provision would have affected service use between sites. Also we lacked information on important individual level determinants of our outcomes, e.g. we did not include questions on parity, miscarriage or stillbirth (for which there is a known lack of data [1]), marital status, or age at marriage. It would have

likewise been valuable to address questions of sexual violence (including intra- partner violence) both as an outcome in itself and as a determinant of service use; however, this subject is associated with such stigma (and even danger for the woman admitting to it) [18], that to include it in the questionnaire would probably have been counterproductive. Also, we did not delve into the issue of depression/anxiety during pregnancy and postpartum which, in an insecure setting, might affect more women than in non-conflict circum- stances [34]. A final but important limitation to our study is the fact that the respondent to the health assessment questionnaire was not always the woman herself (justified by the fact that the survey was not restricted to SRH). Only in the case of households where the survey respond- ent was a woman of childbearing age and where there was only one woman of childbearing age can we be sure that the woman was reporting on herself, which occurred for 1782 (30%) of women. While this would probably not have affected the reporting of outcomes such as birth and skilled delivery to an important degree, it may well have affected questions relating to pregnancy and especially to unintended pregnancy, and might have biased also the re- sults of risk factor analysis. The exclusion of the Bekaa site from the analysis of unintended pregnancy among currently pregnant women may also limit the generalizability of the results on unmet need for family planning among currently

pregnant Syrian refugees. Despite these limita- tions, this is to our knowledge one of the only studies to concentrate on reproductive health needs of Syrian and Iraqi displaced women using systematic survey methods and a large sample. Thus we feel our main findings are ro- bust and likely apply to Syrian and Iraqi displaced women in other host countries as well as to vulnerable Lebanese.

## Conclusions

Since the 1990s, sexual and reproductive health has been increasingly integrated into humanitarian re- sponses [34, 35]. The minimal initial service package for reproductive health introduced a set of priorities for agencies providing medical care in emergencies in the late 1990s and included making sure that contra- ceptives and condoms are freely available, and provid- ing clean delivery kits and a 24/7 referral system for obstetric emergencies [35]. While aid agencies provide care according to international standards, they often operate within host country national guidelines, which can particularly affect sensitive issues such as family planning and delivery care [36].

Problems associated with reproductive health are be- ing compounded by a series of interacting risk factors including poor access to family planning, unintended pregnancies, suboptimal access to antenatal care, and over-recourse to cesarean sections. It would be interest- ing to conduct further research examining

trends over time and looking notably at Syrian women in other host countries. But even in the absence of this information, as the refugee crisis evolves, it is clear that women have real needs which – if unmet – can critically affect their physical health and psychosocial wellbeing as well as that of their children. It is not unlikely that the chal- lenges we describe here can be observed also in similar migrant populations [37, 38]. While more data may be desirable in order to fine-tune intervention strategies, it is crucial to place sexual and reproductive health needs – and in particular adequate antenatal care, family plan- ning, and safe termination of pregnancy – high on the agenda of aid agencies. This is all the more true today, in a context where massive numbers of Syrian refugees maybe returning (voluntarily or involuntarily) to their home country with unknown levels of access to care.

**Abbreviations**

ANC: Antenatal Care; IDP: Internally Displaced Person; MSF: Médecins Sans Frontières; NGO: Non Governmental Organization; SRH: Sexual Reproductive Health; ToP: Termination of Pregnancy; UN: United Nations; UNHCR: United Nations High Commission for Refugees

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## Authors' contributions

MAB: contextualized survey results, identified needs for further analysis, conducted literature search, drafted and revised all manuscripts. RN: analyzed survey results, contributed to manuscript drafts. ZG: Survey Field Coordinator, assisted in data cleaning& contributed to manuscript drafts. IC: Contributed to the analysis design and reviewed final drafts. NS: Contributed to first and subsequent drafts of manuscript: overall conception and contextualization and interpretation of results. All authors read and approved the final manuscript.

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Availability of data and materials

The data can be made available upon reasonable demand.

Ethics approval and consent to participate

This study was approved by the MSF Ethical Review Board.

## Consent for publication

The authors of this study have consented to its publication in Conflict and Health.

## Competing interests

The authors declare that they have no competing interests.

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# Maternal deaths averted by contraceptive use: an analysis of 172 countries

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## Abstract

**Background:** Family planning is one of the four pillars of the Safe Motherhood Initiative to reduce maternal death in developing countries. We aimed to estimate the effect of contraceptive use on maternal mortality and the expected reduction in maternal mortality if the unmet need for contraception were met, at country, regional, and world levels.

**Method:** We extracted relevant data from the Maternal Mortality Estimation Inter-Agency Group (MMEIG) database, the UN World Contraceptive Use 2010 database, and the UN World Population Prospects 2010 database, and applied a counterfactual modelling approach (model I), replicating the MMEIG (WHO) maternal mortality estimation method, to estimate maternal deaths averted by contraceptive use in 172 countries. We used a second model (model II) to make the same estimate for 167 countries and to estimate the effect of satisfying unmet need for contraception. We did sensitivity analyses and compared agreement between the models.

**Findings:** We estimate, using model I, that 342,203 women died of maternal causes in 2008, but that contraceptive use averted 272,040 (uncertainty interval 127,937-407,134) maternal deaths (44% reduction), so without contraceptive use, the number of maternal deaths would have been 1·8 times higher than the 2008 total. Satisfying unmet need for contraception could prevent another 104,000 maternal deaths per year (29% reduction).

**Interpretation:** Numbers of unwanted pregnancies and unmet contraceptive need are still high in many developing countries. We provide evidence that use of contraception is a substantial and effective primary prevention strategy to reduce maternal mortality in developing countries.

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# APPENDIX

# Appendix

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

**General Principles**

3. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient's best interest when providing medical care.”

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.
6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.
8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.
9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimizes possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professionals.

13. Groups that are underrepresented in medical research should be provided with appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not

adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

**Risks, Burdens and Benefits**

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimize the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

**Vulnerable Groups and Individuals**

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

**Scientific Requirements and Research Protocols**

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

**Research Ethics Committees**

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

**Privacy and Confidentiality**

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the

study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for

involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent, to remain in the research, must be obtained as soon as possible from the subject or a legally authorized representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

**Use of Placebo**

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

a. Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

b. Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

c. When the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

**Post-Trial Provisions**

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

**Research Registration and Publication and Dissemination of Results**

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of the research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

**Unproven Interventions in Clinical Practice**

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.