



#### **Presented by:**

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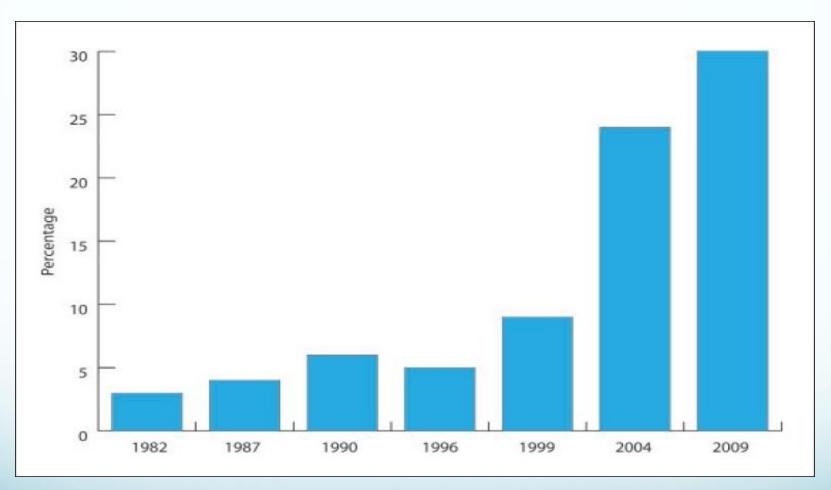
# Session Objectives



### Students will be able to

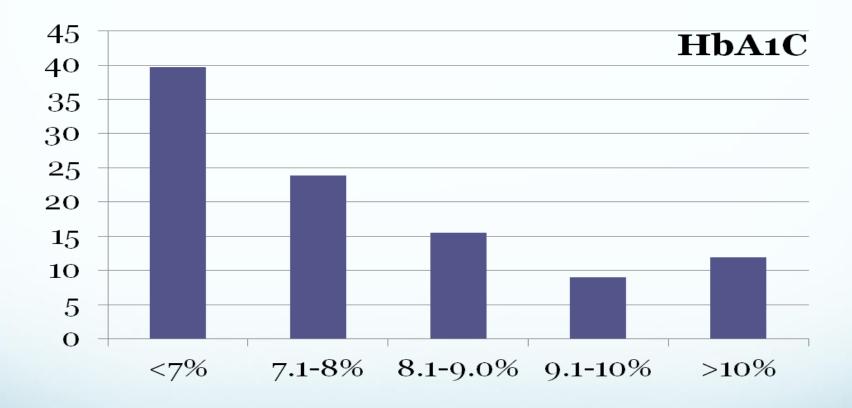
- Learn formulation of research question
- 2. Differentiate between goals & objectives
- Define the specific objectives in terms of the stated problem
- Describe the study hypotheses

# Prevalence of diabetes mellitus (DM) in a Saudi community



Ref: Prevalence of diabetes mellitus (DM) in a Saudi community. Ann Saudi Med. 2011 Jan-Feb;31(1):19-23

# Glycemic control in diabetic patients KKUH January –December 2009



Glycemic control in diabetic patients KKUH January –December 2009, Al-Rowais NA Saudi Pharmaceutical Journal (2014) 22, 203-206

# What research questions come to your mind?



How to reduce the prevalence of DM?

How to increase, well controlled HbA1c?

# What other research questions can arise?



All the stated responses will lead towards the goal of reducing the impact of DM in Saudi Arabia and each research question will be answered by stating clear objectives

## Ask following questions initially



- Do I have, time for this topic at this point during my course?
- Is this really the burning topic for me?
- Will this be worth it?
- Is this a major and relevant public health problem or is it too mysterious?
- Are my goals/objectives too big? Am I covering too much?
- Will available methods answer my questions?
- What are the ethical and human subject issues here?

# Research Question



A well-defined and specific research question is the key for making decisions about study design and population and subsequently what type of data will be collected and analyzed.

# Research Question



- ✓ It should be a single sentence in the form of a question.
- ✓ It should be clear, unambiguous and specific

## What is a Research Question



## Often begins with a general concern

- Examples:
- Should women take hormones to prevent bone loss?
- Can a vegetarian diet reverse cardiovascular disease?
- Can diabetic patients be taught to control their blood glucose levels?



## What is a Research Question I



Must be narrowed to measurable and can able to do research

#### **Examples:**

- Is taking estrogen associated with a lower risk of osteoporosis in women 60+?
- Does a plant-based diet reduce serum cholesterol levels in patients with cardiovascular disease?
- Can a structured intensive diabetes education program help patients with type 2 diabetes control their blood glucose levels?

# How & from where to get ideas to formulate a research question?



- Be inspired by observing people & practices, by attending seminars, conferences, & symposia
- Review local, national, and regional problems
- Discuss, collaborate and get input from your colleagues
- Read about the topic, reviews, & research done; to find out gaps in existing knowledge (Literature search)

# Requirements

- What are the items required to support feasibility of my research question?
- Your background knowledge reflects in the question
- Background information (critical appraisal) stated in intro/background section





# Subject knowledge



- Familiarity with the subject helps define an appropriate research question for a study.
- Questions arise out of a perceived knowledge deficit within a subject area or field of study. (pathways of current knowledge and uncertainty)
- The challenge in developing an appropriate research question, is in determining which uncertainties could or should be studied and also rationalizing the need for their investigation.

## What goes in the research question?

- Disease or condition of interest
- Population
- Intervention to be tested
- Comparison group(s) -- placebo? Existing treatment?
- Outcome measures



# Sample research question (I)



#### Interest:

Should women take hormones to prevent bone loss?

## Research question:

Does taking estrogen after menopause reduce the likelihood of bone density loss in women over 60 years of age, compared to women not taking estrogen?

# Sample research question (2)



#### Interest:

Can a vegetarian diet reduce cardiovascular disease?

## Research question:

Does an entirely plant- based (vegan) diet reduce blood serum cholesterol levels in men over 50 years old with lipid levels > ... compared to a meat- based diet?

# Sample research question (3)



#### Interest:

Can diabetic patients be taught to control their blood glucose levels?

## Research question:

Can a structured intensive diabetes education program help adult patients with Type 2 diabetes control their blood glucose levels, compared to patients receiving standard instructions?

# Types of Research Questions



- ✓ Descriptive: describing a group, exploring
- ✓ Relational: associations between two variables in a group
- ✓ Comparable: associations between two or more variables (differences) in two or more groups (Causality / prediction / intervention)

# Examples of Research questions (Descriptive)



What is the level of knowledge of "Biostatistics" among 3<sup>rd</sup> year medical students?

Is drug "A" better than drug "B" in the management of hepatic failure in patients with Cirrhosis?

Is alcoholism related to the development of Cirrhosis liver?

# Examples of Research questions (Relational)



Is concentration of blood cholesterol directly related to dietary intake of saturated fat in Saudi population?

(hereditary?/ dietary/ metabolic ? Reasons in Saudi Population could differ from other settings)

# Examples of Research questions (Comparable)



 Does daily saturated fat intake by persons with hypercholesterolemia differ from persons with normal cholesterol range in Saudi population?

## **Evaluation of Research Question**

- How good and appropriate is the idea?
- Critique appropriateness of your Question
- Merit of your question
- Relationship of proposal to problem



## **Good research question**



- Feasible
- Interesting
- Novel
- Ethical
- Relevant

# FINER criteria: a good research question



#### F Feasible

- Adequate number of subjects
   Adequate technical expertise
- Affordable in time and money Manageable in scope

#### I Interesting

• Getting the answer intrigues investigator, peers & community

#### N Novel

• Confirms, refutes or extends previous findings

#### **E** Ethical

Amenable to a study that institutional review board (IRB) will approve

#### R Relevant

To scientific knowledge

To clinical and health policy

To future research

# Research Objectives



# **Goals and Objectives**

Goals / Objectives





## **Goals and Objectives**



#### **Goals**

It describes the aim of the work in broad terms (Over a longer time period)

## **Objectives**

These are more specific and relate directly to research question.

They may be divided into two types:

- Primary objectives → (bound to be achieved)
- Secondary objectives → (by the way)

# Research Goal & Objectives



- The goal (aim) and objectives must be stated at the very beginning of the study, since they will guide the investigator during the process of formulating research questions and hypothesis.
- They will also help in the prioritization process.
- They will enable the reader or consumer of the work to judge whether the investigator had achieved these objectives or not.

# Research Objectives



### The research objectives should be:

- Closely related to the research question
- Covering all aspects of the problem
- Very specific
- Ordered in a logical sequence
- Stated in <u>action verbs</u> that could be evaluated e.g. to describe, to identify, to measure, to compare, etc.
- Achievable, taking into consideration the available resources and time
- Mutually exclusive, with no repetitions or overlaps

# **SMART Objectives**



- Specific
- Measurable
- A Achievable
- Relevant
- Time-bound

# Research Objectives



Properly formulated, specific objectives will:

- facilitate the development of your research methodology
- help to orient the <u>collection</u>, <u>analysis</u>, <u>interpretation</u> and utilization of data.

# Examples of Research Objectives



▼ To study whether SNP markers are associated with obesity and hypertension phenotypes.

√ To assess the general population knowledge & attitude towards Organ donation

√ To identify the risk factors for Type-II diabetes



## Example



#### Goal:

To reduce risk of cardiovascular diseases in Saudi population by developing evidence based interventions

#### Question (I)

Is dietary intake of saturated fats over the past xx weeks related to hypercholestrolemia in Saudi adult population?

#### Question (2)

Is dietary intake of saturated fats over a period of xx months is associated with risk of coronary heart disease in Saudi adult population



# Example



#### Objective (I)

To determine the daily intake of saturated fats in the past 4 weeks in Saudi adults

#### Objective (2)

To determine the relationship of dietary intake of saturated fats and blood levels of low density lipoprotein (LDL) in Saudi adults

### Objective (3)

To determine the association of dietary intake of saturated fats and intimal thickness of coronary artery in Saudi adults

# Research Hypothesis



# Research Hypothesis



"Research hypothesis is a statement of the research question in a measurable form"

# Research Hypothesis



- A hypothesis can be defined as a prediction or explanation of the relationship between one or more <u>independent variables</u>
   (PREDISPOSING/RISK FACTORS) and one <u>dependent variable</u>
   (OUTCOME/CONDITION/DISEASE)).
- A hypothesis, in other words, translates the problem statement into a precise, clear prediction of expected outcomes.
- It must be emphasized that hypotheses are not meant to be disorganized guesses, but should reflect the depth of knowledge, imagination and experience of the investigator.



# Hypothesis formulation

This is based on existing knowledge, deriving it through critical reading of literature and facts

### **Descriptive:**

It is hypothesized that average daily intake of saturated fat in Saudi adult population is more than 20% of the recommended intake when measured by xxx test and yyy standards to define dietary saturated fat intake.



# Hypothesis formulation

### Objective:

To determine the relationship of dietary intake of saturated fats and intimal thickness of coronary artery

#### Hypothesis:

It is hypothesized that > 20% of recommended saturated fat intake in Saudi population will be associated with 50% increased intimal thickness of coronary artery when compared to the normal intimal thickness measured by XYZ

# Hypothesis (Examples)



- We hypothesize that standard care plus new intervention (additional drug) will be superior to standard care alone in reducing CVD mortality by 30% among patients with preexisting heart disease.
- We hypothesize that prophylaxis with inhaled drug A will be superior to oral preparation of drug B in preventing acute exacerbation of reactive airway disease by 20%.
- We hypothesize that low birth weight is an independent risk factor for type II diabetes.

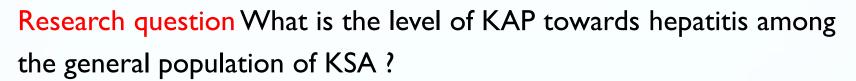
# Examples



### Example 1: (KAP Study)

Area Community medicine

Topic Communicable diseases- hepatitis



Goal To contribute to the reduction of hepatitis in KSA through studying general population perceptions about the disease

Objective To assess the knowledge, attitudes and practice of the general population towards hepatitis in KSA.

Hypothesis It is hypothesized that the knowledge, attitudes and practice of the general population towards hepatitis in KSA is less than 50%.



### Example 2: (Cross sectional study)



Area Psychiatry

Topic Body Dysmorphic Disorders (BDD)

Research question What is the prevalence of BDD among female medical students in Riyadh?

Goal To contribute, by finding the prevalence of BDD and its associated factors in Saudi females

Objective To Quantify the prevalence of BDD among female medical students

Hypothesis It is hypothesis that, the prevalence of BDD among female medical students is around 10%.

# Example 3: (Interventional Study)



Area Cardiology

Topic Ischemic heart disease (IHD)

Goal To contribute to prevention of IHD

Research question Does hypocholesterolemic agent "A" decrease the risk of MI?

Primary objective To determine the effect of reducing LDL on the occurrence of MI

Secondary objective: To describe the side effects of lowering LDL

Hypothesis The risk of MI among patients treated with hypocholesterolemic agent "A" is lower than the risk among patients not treated with hypocholesterolemic agents

### **Summary**



- I. Perform a systematic literature review to increase knowledge for the topic
- 2. Learn about current trends and advances on the topic.
- Seek careful input from experts, mentors, colleagues and collaborators
- 4. Use the FINER criteria in the development of the research question.
- 5. Develop clear and well-defined objectives using SMART criteria
- 6. Ensure that the research question and objectives are answerable, feasible and relevant.
- 7. Develop the testable research hypotheses from the research question.

### References



 Stephen B Hulley. Designing Clinical Research. 3<sup>rd</sup> Edition . Wolters Kluwer Health Lippincott Williams and Wilkins 2007.

 Daniel P Schuster & William J Powers. Translational and Experimental Clinical Research. Introduction: Lippincott Williams and Wilkins 2005.

 Cummings SR, Browner WS, and Hulley SB. "Conceiving the research question." In Hulley SB, Cummings SR, Browner WS, Grady D, Hearst N, and Newman TB. Designing Clinical Research.
 2nd edition. Philadelphia: Lippincott Williams & Wilkins, 2001.

Fletcher RH, Fletcher SW, Wagner EG. Clinical Epidemiology: the essentials. 3rd edition.
 Baltimore: Williams and Wilkins, 1996.

Sackett DL, Haynes RB, Guyott GH, Tugwell, P. Clinical Epidemiology: a basic science for clinical medicine. 2nd edition. Boston: Little, Brown and Company, 1991.

