1- Which type of errors in pharmacoepidemiology research design is this and how it can be minimized: “An error in the estimation of the association between the exposure and the disease which occurs because of a design flaw. It is not intentional error, but error that systematically occurs because of a problem with the study design.”

**Systematic error**

It can be minimized through:

1. Careful research design
2. Appropriate adjustment during data analysis.

2- A study to assess the association of diabetes and smoking compared a group of hospitalized individuals with diabetes (cases) with a group of volunteer individuals without diabetes (controls) who were full-time employees of the same hospital where the cases were identified. The results from this study reported, for the first time in the literature, a strong association between diabetes and smoking.

What type of bias may be present?

**Selection bias.**

3- To determine whether baldness causes coronary heart disease (CHD) in men, a hypothetical cohort study was conducted. The epidemiologist in charge of the study recruited 10,000 bald men and 10,000 men with hair into the study and followed all of them for 10 years to determine whether they developed CHD.

The investigator thought that the results might be confounded by age. What is meant by "confounded by age"? In addition, what are the requirements for confounders?

It may be that bald men are older on average than hairy men and that older men are also more likely than younger men to get CHD. If this were the case, there would be an association between age and the disease (CHD) and
between age and the exposure (baldness). Therefore, age would be a confounder.

1. Variable must be risk factor for disease
2. Variable must be associated with exposure under study
3. Can not be in the causal pathway (not a stage or process in the disease)

4- What are the properties of Drug Utilization Review (DUR) studies?

1. Quantify drug use
2. Assess the appropriateness of therapy
3. Time limited

5- When DUR detect a problem what are the possible interventions that can be done?

1. Formulary deletions of the drug,
2. Restriction of a medication for use in particular circumstances,
3. Restriction of a medication for use by certain specialties.

6- What are the three major Types of Adverse Experiences in pharmacovigilance?

1. An adverse experience (AE) is any adverse event associated with the use of a drug or biological product in humans, whether or not considered product related
2. An unexpected adverse experience means any AE that is not listed in the current labeling for the product.
3. A serious adverse experience is any AE occurring at any dose that results in any of the following outcomes: death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability /incapacity, or congenital anomaly/birth defect.

7- What are the MedWatch goals?

1. To increase awareness of drug, device, and other medical product induced disease and the importance of reporting

2. To clarify what should (and should not) be reported. Health professionals are asked to limit reporting to serious AEs

3. To make it as easy as possible for a health professional to report directly to the agency.

4. To provide feedback to health professionals about new safety issues involving medical products.