Introduction to epidemiology

Epidemiological Study Design Challenge

Designing Epidemiological Studies: A Step-by-Step Guide

This guide outlines the seven essential steps for designing any robust epidemiological study. Each group must follow these steps for their assigned topic.

Step 1: Define the Research Question (PICO)

- Population: Who are you studying?
- Intervention (or Exposure): What is the factor of interest?
- Comparison: What is the comparison group?
- Outcome: What is the health-related event?

Step 2: Select the Study Design

Choose the most appropriate design and justify your choice (e.g., Cohort, Case-Control, RCT, Cross-Sectional, Descriptive).

Step 3: Define Study Participants (Sampling)

- Set clear Inclusion Criteria and Exclusion Criteria.
- Determine the Sampling Method (how participants are selected).

Step 4: Define Exposure and Outcome Measurements

Clearly define how the Exposure (e.g., diet, vaccine) and the Outcome (e.g., disease diagnosis) will be accurately and objectively measured.

Step 5: Address Potential Biases and Confounding

- Identify at least **two** specific potential **Biases** (e.g., Recall Bias, Selection Bias) and how you will minimize them.
- Identify at least **two** specific **Confounders** (factors associated with both the exposure and outcome) and how you will control for them (e.g., Restriction, Matching, Statistical Adjustment).

Step 6: **Statistical Analysis Plan (SAP)**

This dictates how data will be used to test the hypothesis and must be designed *before* data collection.

- Data Management & Description: Define procedures for data cleaning, handling missing data (e.g., imputation), and the descriptive statistics (e.g., means, proportions) used to summarize the sample.
- Primary Effect Measures: Define the main statistical tool and measure of association:
  - Case-Control: Odds Ratio (OR), often using Logistic Regression.
  - Cohort/RCT: Relative Risk (RR) or Incidence Rate Ratio (IRR), often using Survival Analysis (e.g., Cox Regression) for time-to-event outcomes.
  - Ensure all estimates are reported with a 95% Confidence Interval (CI).
- Confounding Control: Specify the multivariate regression model (e.g., Logistic, Cox, or Linear Regression) that will be used to simultaneously adjust for the primary confounders identified in Step 5.
- Subgroup and Sensitivity Analysis: Pre-specify any planned subgroup analyses (i.e., analyzing the effect in a specific subset of the population) and sensitivity analyses to test if the primary results are robust to changes in methodological definitions.

Step 7: Consider Ethics, Logistics and results dissemination

Consider: Ethical Review necessity (e.g., Informed Consent) and major logistical challenges (e.g., funding, duration). Where will you publish your work? Who else will you share your results with, community, local government?

Part 2: The Challenge

Each group is assigned a high-impact public health topic and a specific epidemiological challenge focus.

Group	Topic	Epidemiological Challenge Focus
1/ A	Malaria	Intervention/Efficacy: Design an RCT to test a new preventative measure.
2/ B	Tuberculosis	Risk Factors/Cohort: Design a Prospective Cohort Study to

	(TB)	assess risk of drug resistance.
3/ C	**Obesity**	Prevalence/Correlates: Design a Cross-Sectional Study to measure prevalence and associated factors.
4/ D	**Contraceptives**	Association/Rare Outcome: Design a Case-Control Study to link use to a specific rare adverse event.
5/ E	**HIV/AIDS**	Behavioral/Longitudinal: Design a Cohort Study to evaluate the impact of adherence programs.
6/ F	**Lassa Fever / NTDs/snake bite**	Descriptive/Outbreak: Design a Descriptive Study (Case Series or Surveillance Protocol) for a suspected outbreak.

Part 3: Study Proposal Summary

Each group must prepare a 7 **- minute presentation** summarizing their study design based on the seven steps.