

Question 4

Create a statistical analysis plan:

Objectives: *To assess whether there is an association between current smoking status and preterm delivery in pregnant women in country X. Secondary, to evaluate previous smoking status and preterm delivery.*

Hypotheses: *Smoking increases the risk of preterm delivery.*

Data sources and primary variables:

Data sources: questionnaire handed out at first prenatal care visit, regarding smoking status and smoking history. Variables measured at first prenatal care visit regarding age, blood pressure and weight. National birth register recording preterm deliveries between gestational week 24⁰ and 37⁰.

Primary variables: Current smoking status: yes / no

Preterm delivery: deliveries between gestational week 24⁰ and 37⁰

Secondary variables: Smoking history: never / previously / still smoking

Age

Weight

Previous preterm delivery

Marital status

Educational status

Blood pressure

Eligibility criteria for participants: *all pregnant women in country X.*

Statistical software: *Statistical software R, version 3.5.0.*

Question 5

Create a good data management plan for the project:

Questionnaire design:

- Current smoking status: yes/no
- Previous smoking status: used to smoke/never smoked
- Marital status: married/unmarried/divorced
- Educational status

Birth registry:

- Premature deliveries between gestational weeks 24⁰ and 37⁰
- Previous preterm delivery

Data collection:

- Questionnaire handed out at first prenatal care visit regarding current and previous smoking status – data will be entered into the registry by the clinician.
- Age, weight, blood pressure measured and entered by the clinician at the first visit.

Data storage:

Data will be stored according to the law.

Archiving:

The data should be well organized and self-descriptive.