Severe Malaria in Children Under five years in Homabay County: Incidence, Risk factors and Preventive Interventions

Introduction to Epidemiology I

Group I

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Research Question

1. Does Samuel-45 vaccine reduce the incidence of severe malaria in children under five years compared to placebo group?

Study Design

Randomised Control Trial

- We want to evaluate our new intervention (Samuel-45 vaccine).
- We used RCT because we want to determine the cause-and-effect relationship between our intervention(Samuel-45) and our outcome.
- Because we are choosing randomly it helps to reduce bias and confounders.

Participants

Inclusion Criteria

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This is healthy children only under five years with their parents/guardian in Homabay county.

Exclusion Criteria

- Children who are older than five years.
- Children outside homabay
- Children who have received prior Malaria vaccine
- Those allergic to the substance in the vaccine
- Participants in another study and those who are sickle cells

Sampling Techniques

Cluster Sampling

- We are considering a very large geographical area.
- Because it supports a high quality follow up.
- High external validity.
- Time and cost-efficient.

Define Exposure and Outcome Measurements

Exposure Measurement

- Samuel-45 Vaccine
  - Number of dosage.
  - Amount of dosage (In terms of millimeters)
  - Number of children we will give the dose.

Outcome

- Anaemia and Parasitemia
  - Laboratory test by using blood samples.
  -

Bias and Confounders

Bias

- Selection Bias
  - By using the cluster Sampling well.
  - Ensure high participation rates through community mobilization.
- Loss to Follow-up Bias
  - Track migration and deaths carefully.
  - Maintain active follow-up through phone calls, home visits.

Confounders

- Age
  - Adjust for age in the statistical analysis using multivariable regression
  - Stratify participants by age group during randomization (e.g., 6–11 months, 12–59 months).
- Use of Insecticide-Treated Nets
  - Consider stratifying clusters by Insected - treated nets coverage before randomization

Statistical Analysis

Data Management & Cleaning

- Begin by checking for duplicate records, inconsistent entries, and out-of-range values.
- Address missing data using appropriate imputation techniques(Excel, R, python).
- Generate descriptive statistics to summarize baseline characteristics before analysis.

Primary Effect Measures

- Compute Relative Risk (RR) or Incidence Rate Ratio (IRR) to compare study groups.
- Apply Cox Regression when outcomes involve time-to-event follow-up.
- Present all effect estimates with corresponding 95% Confidence Intervals.

Confounding control and sensitivity Analysis

Confounding Control

- Fit a multivariable regression model (Cox regression) to adjust for confounders.
- Include primary confounders identified earlier in the study design.

Subgroup & Sensitivity Analyses

- Conduct pre-specified subgroup analyses (by age group or exposure level).
- Perform sensitivity checks to evaluate whether results remain stable under different assumptions.

Step 7: Ethics, Logistics & Results Dissemination

Ethical Considerations

- Ethical Review approval from IRB and informed consent from caregivers.
- Protection of confidentiality and child safety.

Logistical Considerations

- Funding needs, staffing, and study duration.
- Coordination with local health facilities and CHWs.

Results Dissemination

- Publication in peer-reviewed journals like European Journal of medical research.
- Sharing findings with the community and county health authorities.