



The Childhood Acute Illness Network

Template Statistical Analysis Plan

Version Control	Update after any change
Version 1.0	SAP created by xxxx on [date]
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1. Background

[Provide brief background to the proposed study. Maximum of one page]

2. Objectives

2.1 General objective

[What is the general objective]

2.2 Specific objectives

[List the study objectives]

3. Study Design

[Provide brief study design, one paragraph]

3.1 Setting

[Provide one paragraph of study settings]

3.2 Participants

[Who are participants to be included in the analysis?]

3.2.1 Inclusion criteria

[List inclusion criteria of the participants included]

3.2.2 Exclusion criteria

[Provide any exclusion criteria]

3.3 Variables

3.3.1 Outcomes

[Explain the outcome variable (s)]

3.3.2 Exposures

[Explain all the exposure variables to be examined in the analysis]

3.3.3 Potential confounders and effect modifiers

[Explain any potential confounders and how they will be addressed in the analysis like the anthropometric stratification]

3.4 Bias

[Outline any consideration for bias and explain how they were avoided or will be addressed in analysis e.g selection bias due to the enrolment strata was addressed through use of inverse weights]

3.5 Study Size

[Provide the rationale for sample size including the number of participants to be included in the analysis]

3.6 Quantitative variables

[List and explain how quantitative variables will be handled e.g growth z scores will be categorised <-3 (SAM), -3 to -2 (MAM) and \geq -2 (not wasted)]

4. Statistical methods

[Provide the statistical methods to be used following a logical order. For example;

- How numbers of individuals at each stage of study will be reported, consider adding a flow chart.
- What methods will be used to summarise characteristics of study participants.
- How attrition from the study, missing data and follow-up time (cohort studies) will be reported.
- Methods to be used to report outcome data.
- Methods to report univariate and adjusted measure of effect.
- For any regression models, explain the rationale for the choice of regression model, methods of feature selection for variables to be included in multivariable models, methods of assessing performance of regression models.
- Any methods to assess sensitivity, sub-analysis or effect modifications.]

References