Clinical Research Methods
KUHeS, Blantyre, Malawi, September 2021

Session 8 practical Statistical Analysis Plans

Prepared by: Marc Henrion from original material by Mavuto Mukaka

Version and date: v3.0 16th September 2021

Support material (printed or electronic)

1. SICS-I SAP v1.0 (pdf)

2. ART outcomes in Blantyre (AOB) SAP v1.1 (pdf)

3. MARVELS Feasibility SAP v1.3 (pdf)

4. ICH E9 guidelines

5. RSS Code of Conduct

6. ASA Ethical guidelines

Exercise 1 (group)

Review and discuss example SAPs:

1. Clinical Trials / intervention studies
    a. CRYPTOFAZ v3.0 (only up on screen; led by facilitator)
    b. SICS-I v1.0
    c. MARVELS Feasibility v1.3

2. Observational studies
    a. ART Outcomes (AOB) in Blantyre v1.1

Exercise 2 (individual)

Develop a statistical plan for your own study.

Hints:

a. Clearly state the research question, hypotheses, study aims (general) and study objectives (specific).
b. Describe the study design.
c. Write a summary on the variables which will be included in the baseline characteristics
d. Provide a dummy study profile / flowchart / CONSORT diagram.
e. Provide dummy tables indicating variables and statistics which will be summarized for baseline characteristics (demographic data summary).
f. Describe (in detail) the statistical methods which will be used e.g. chi-squared test, logistic regression, linear regression, t-test, etc. State the variables which will be analysed. State any variables which will be adjusted for in your analyses. State how results will be summarized / presented (e.g. will you provide 95% confidence intervals for odds ratios, hazard ratios etc. (confidence intervals are recommended wherever applicable). State the level of significance e.g. 5%. You may also state software. This helps you to know in advance whether the software you intend to use is capable of analyzing your intended analyses!
g. Provide table and / or figure shells for the primary analysis. (NB. For the sake of this practical, you will not have the time to generate figure mock-ups, but you can state what kind of figures you plan to use.)
h. Similarly provide statistical methods and variables for the secondary outcomes. Provide table & figure mock-ups for these.

Examples of CONSORT diagram and table mock-ups.

Fig 1.: Study profile for ……..

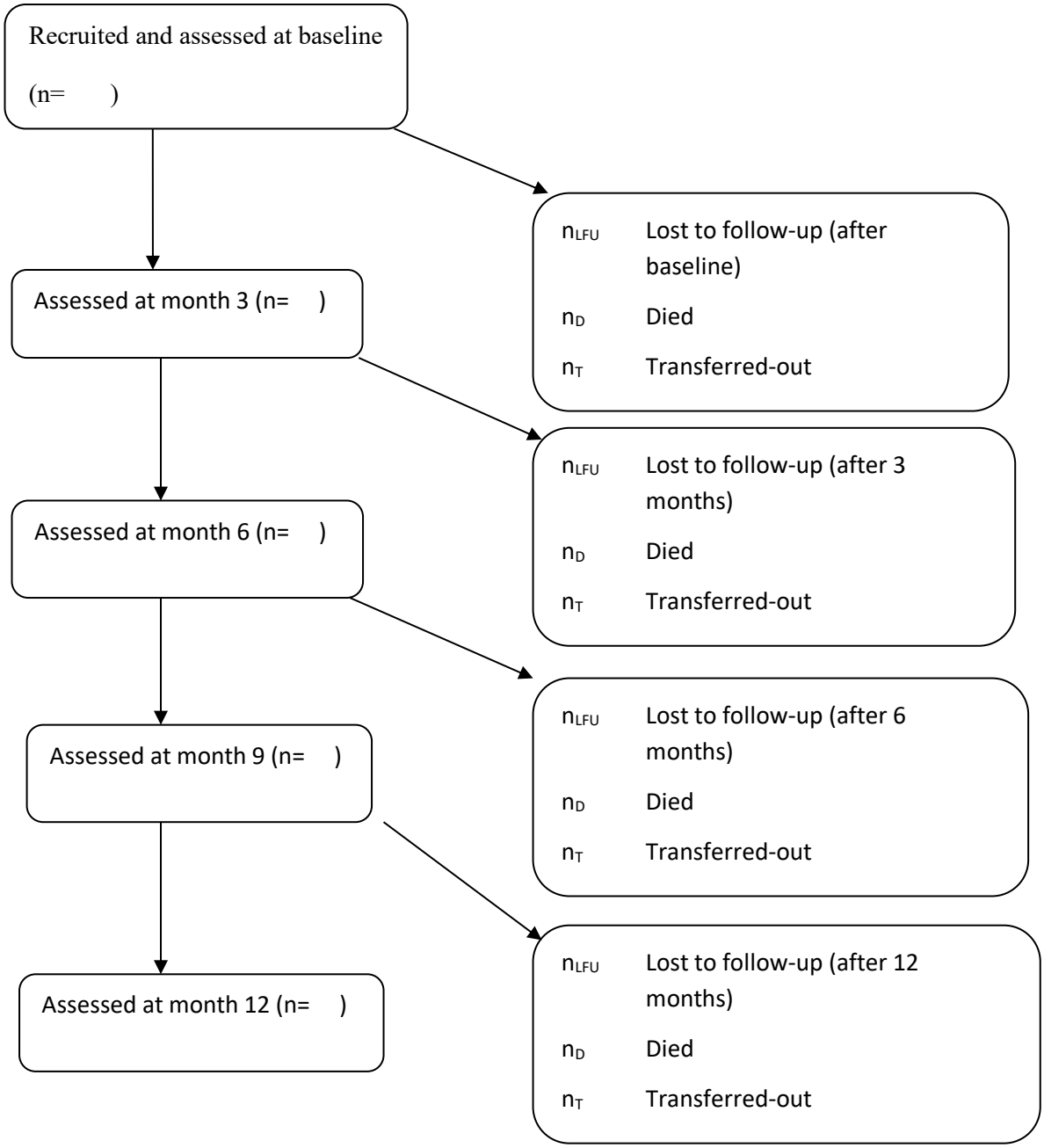

Table 1 Baseline characteristics of subjects in the study by HIV status

Variable (units/statistic)	Category /Statistic	HIV infected	HIV uninfected	Total
Sex (no. (%))	Male			
Age (units)	Mean			
	sd			
	Range			
Haemoglobin (g/dl)	Mean			
	sd			
	Missing			
Malaria parasites (no. (%))	None			
	+			
	++			
	+++ or more			

TB history (no. (%))	Yes			
	No			
	Missing			
TB type (no. (%))	Pulmonary			
	Extra-pulmonary			
	Missing			
Current TB treatment	Yes			
	No			
	Missing			
GCS (no. (%))	<8			
	≥15			

Table 2: Summary statistics and univariate comparisons of the features of CM and TBM in HIV positive patients

	Cryptococcal	Tuberculous	p value
Clinical Features			
Glasgow Coma Score (/15)[b]			
Headache duration (days)[b]			
Fever duration (days)[b]			
Temperature (°C)[c]			
Neck stiffness (%)[a]			
Laboratory investigations			
CD4 count (x10^6 cells)[b]			
Haemoglobin (g/dl)[c]			
Opening pressure (mm H_2O)[b]			
Peripheral WBC (x10^9 cells)[b]			
CSF investigations			
CSF WBC (cells/µl)[b]			
% CSF lymphocytes[b]			
% CSF polymorphs[b]			

[a] Percentage; [b] Median & Interquartile Range; [c] Mean & standard deviation

Table 3: Multivariable logistic regression analysis of admission data for HIV positive cases

	β-coefficient	Odds ratio (95% CI)	p-value
Opening Pressure			
Neck stiffness (yes)			
CSF WBC			
GCS total			
Presence of fever(yes)			
constant			