
Analytical Plan for Reliability of prehospital ultrasound in helicopter emergency transfers: cross-sectional study

DOCUMENT: SAP-2023-026-HK-v01

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2023-08-22

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Analytical Plan for Reliability of prehospital ultrasound in helicopter emergency transfers: cross-sectional study

Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

- CI: confidence interval

2 CONTEXT

2.1 Objectives

To assess the inter-rater reliability of ultrasound measures of a mobile device used in helicopter emergency transfers.

2.2 Hypotheses

The three measures are reliable across raters.

3 DATA

3.1 Raw data

The original data base had 15 variables collected on 242 observations.

3.2 Analytical dataset

After the cleaning process 7 variables were included in the analysis. The total number of observations excluded due to incompleteness and exclusion criteria will be reported in the analysis. Table 1 shows the structure of the analytical dataset.

Analytical Plan (SAP)

Table 1 Analytical dataset structure after variable selection and cleaning.

id	qa_hk	qa_mv	interpretation_hk	interpretation_mv	acceptability_hk	acceptability_mv
1						
2						
3						
...						
N						

All variables in the analytical set were labeled according to the raw data provided and values were labeled according to the data dictionary for the preparation of production-quality results tables and figures.

4 STUDY PARAMETERS

4.1 Study design

Cross-sectional study, based on routine records.

4.2 Inclusion and exclusion criteria

N/A

4.3 Exposures

Two expert raters (HK and MV).

4.4 Outcomes

Specification of outcome measures (Zarin, 2011):

1. (Domain) Ultrasound evaluation
2. (Specific measurement) QA Score, Interpretation and Acceptability
3. (Specific metric) End-value
4. (Method of aggregation) Proportion of inter-rater agreement

Primary outcome

Inter-rater agreement in QA Score, Interpretation and Acceptability of prehospital ultrasound images.

4.5 Covariates

N/A

5 STATISTICAL METHODS

5.1 Statistical analyses

5.1.1 Descriptive analyses

The measurement profile will be described as counts and proportions (%). The distributions of measurements' characteristics will be summarized in tables and visualized in exploratory plots.

The agreement will be described as proportions. Cohen's kappa coefficient will be calculated and described for each measurement.

5.1.2 Inferential analyses

The CI of the kappa coefficient will be calculated and described. All comparisons between raters will be performed as univariate analyses. Differences in distribution of binary measures will be assessed with the McNemar test.

5.1.3 Statistical modeling

N/A

5.1.4 Missing data

No missing data imputation will be performed. All evaluations will be performed as complete case analyses. Missing data counts and proportions will be reported in tables.

5.2 Significance and Confidence Intervals

All analyses will be performed using the significance level of 5%. All significance hypothesis tests and confidence intervals computed will be two-tailed.

5.3 Study size and Power

N/A

5.4 Statistical packages

This analysis will be performed using statistical software R version 4.3.0.

6 OBSERVATIONS AND LIMITATIONS

Recommended reporting guideline

The adoption of the EQUATOR network (<http://www.equator-network.org/>) reporting guidelines have seen increasing adoption by scientific journals. All observational studies are recommended to be reported following the STROBE guideline (von Elm et al, 2014).

In particular when a retrospective study is conducted using hospital records, it is recommended that the RECORD extension of the STROBE guideline is considered (Benchimol et al, 2015).

7 REFERENCES

- **SAR-2023-026-HK-v01** – Reliability of prehospital ultrasound in helicopter emergency transfers: cross-sectional study
- Zarin DA, et al. The ClinicalTrials.gov results database – update and key issues. N Engl J Med 2011;364:852-60 (<https://doi.org/10.1056/NEJMsa1012065>).
- Gamble C, et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA. 2017;318(23):2337–2343 (<https://doi.org/10.1001/jama.2017.18556>).
- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. Int J Surg. 2014 Dec;12(12):1495-9 (<https://doi.org/10.1016/j.ijsu.2014.07.013>).
- Benchimol EI, Smeeth L, Guttman A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM; RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement. PLoS Med. 2015 Oct 6;12(10):e1001885 (<https://doi.org/10.1371/journal.pmed.1001885>).

8 APPENDIX

This document was elaborated following recommendations on the structure for Statistical Analysis Plans (Gamble, 2017) for better transparency and clarity.

8.1 Associated analyses

This analysis is part of a larger project and is supported by other analyses, linked below.

Effect of prehospital ultrasound on the time of helicopter emergency transfers: cross-sectional study

<https://philsf-biostat.github.io/SAR-2023-027-HK/>

8.2 Availability

All documents from this consultation were included in the consultant's Portfolio.

The portfolio is available at:

<https://philsf-biostat.github.io/SAR-2023-026-HK/>