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

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Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

- CI: confidence interval
- pRBC:
- SD: standard deviation

2 CONTEXT

2.1 Objectives

To determine the effect of a mobile ultrasound device on the time of care in helicopter emergency transfers.

2.2 Hypotheses

The time of care in the ultrasound group is comparable to the non-intervention group.

3 DATA

3.1 Raw data

The raw data was received on two tables separating the two groups of exposed and non-exposed (see section 4.3). Since the ID started at 1 in both tables, each corresponding ID was prepended by E or U to allow for the identification of individuals from the source data. The two tables were merged into a single one following a standardized column naming scheme, which is herein called the raw data table.

The original data base had 16 variables collected on 439 observations.

3.2 Analytical dataset

After the cleaning process 15 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.

Table 1 *Analytical dataset structure after variable selection and cleaning.*

id	exposure	outcome	age	gender	type_transfer	type_call	air_ground	rbc	vasopressor	fluids	intubation	disposition	specialty	year
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

Ultrasound vs non-ultrasound.

4.4 Outcomes

Specification of outcome measures (Zarin, 2011):

1. (Domain) Emergency care
2. (Specific measurement) Time at the scene (minutes)
3. (Specific metric) End-value
4. (Method of aggregation) Mean

Primary outcome

4.5 Covariates

- Age
- Gender
- Type of transfer
- Type of call
- Air ground?
- pRBC
- Vasopressor
- Fluids during flight
- Intubation
- Disposition
- Specialty call

5 STATISTICAL METHODS

5.1 Statistical analyses

5.1.1 Descriptive analyses

The epidemiological profile of the study participants will be described. Demographic and clinical variables will be described as mean (SD) or as counts and proportions (%), as appropriate. The distributions of participants' characteristics will be summarized in tables and visualized in exploratory plots.

5.1.2 Inferential analyses

All inferential analyses will be performed in the statistical models (described in the next section).

5.1.3 Statistical modeling

Two linear regression models will be fitted to evaluate the effect of the usage of ultrasound (Section 4.3) in the time of care (section 4.4), while adjusting for the available covariates (section 4.6). The first model will adjust for all covariates using all data available. Since the data for the control group was only available for a single year, a second model will be fit matching the same time period for both groups to mitigate the risk of bias.

The sensitivity analysis planned is intended to look for evidence of bias in the study sample. If the estimates obtained from both datasets differ by a large amount, selection bias will be assumed to be present and the period-matching estimates will be reported as the less biased estimate for the true effect.

We don't plan to test for interactions.

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

Risk of bias

There is the risk of selection bias in the study sample. Data from the exposed span the period between 2018 to 2023, whereas the unexposed group only has observations from 2022. This is important especially considering that the critical period of the COVID-19 pandemic was included only in the exposed group. The sensitivity analysis planned is intended to look for evidence of bias in the study sample. If the estimates obtained from both datasets differ by a large amount, selection bias will be assumed to be present and the period-matching estimates will be reported as the less biased estimate for the true effect.

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-2023-027-HK-v01** – Effect of prehospital ultrasound on the time of helicopter emergency transfers: cross-sectional study
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- 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).
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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.

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

https://philsf-biostat.github.io/SAR-2023-026-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-2023-027-HK/