Analytical Plan for Effect of healthcare interventions on the average number of ER visits: cross-sectional study

DOCUMENT: SAP-2023-013-DB-v01

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Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

- CI: confidence interval
- CV: coefficient of variation
- ER: emergency room
- SD: standard deviation

2 CONTEXT

In the context of Hospital Quality, there is an incentive to reduce the number of unnecessary ER visits that patients might need. This study explores whether a set of interventions performed by the nursing department are associated with an effect on the average number of ER visits.

2.1 Objectives

To assess whether the use of various nursing interventions in healthcare are associated with a change in the average number of emergency care visits by patients in Atrium Health Cabarrus hospital.

2.2 Hypotheses

When each intervention under investigation is used there is an effect on the average number of ER visits.

3 DATA

3.1 Raw data

The original data base had 24 variables collected on 26 observations.

3.2 Analytical dataset

A new variable for the outcome (section 4.4) will be calculated as the change from baseline in average number of ER visits, for each study participant. Variables not included in the analyses will be dropped.

After the cleaning process 17 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 *Analytical dataset structure after variable selection and cleaning.*

id	age	sex	baseline	end	outcome	insurance	pcp	reminders	education	para	community	programs	transport	bridge	tele	meds
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, with multiple concurring interventions.

4.2 Inclusion and exclusion criteria

N/A

4.3 Exposures

Participants enrolled in the study were targeted by ten interventions, and some participants might have received more than one intervention.

1. **pcp**: Appointment made fo PCP or specialists
2. **reminders**: Reminders via phone call or text
3. **education**: Education
4. **para**: Referral to community paramedicine or home health
5. **community**: Connection to availible community resources
6. **programs**: Referral to existing disease specific navigation programs
7. **transport**: Transportation arrangement to and from appointments
8. **bridge**: Urgent care utilization as a bridge to primary care
9. **tele**: Telepresence at specified appointments
10. **meds**: Medication and pharmacy

4.4 Outcomes

Specification of outcome measures (Zarin, 2011):

1. (Domain) Hospital Quality
2. (Specific measurement) Number of ER visits
3. (Specific metric) Change from baseline
4. (Method of aggregation) Average

Primary outcome

Average number of ER visits.

4.5 Covariates

No adjustment for covariates will be performed in this analysis.

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. Given the small sample size of the study, the variability will be additionally interpreted with the CV. The distributions of participants' characteristics will be summarized in tables and visualized in exploratory plots.

5.1.2 Inferential analyses

The observed effect of each exposure is defined as the difference between the exposed and unexposed groups. All comparisons between groups will be performed as univariate analyses, for each exposure defined in section 4.3. The outcome defined in section 4.4 will be compared between groups with the independent t test with Welch correction.

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 4.2.1.

6 OBSERVATIONS AND LIMITATIONS

Study design

The exposures are not mutually exclusive and there was no definition on how participants would be allocated to each available intervention or combination of interventions. Additionally, there was no comparator group where study participants either received none of the interventions under investigation, or have only received the standard of care. Furthermore the allocation to exposures was not balanced. It appears that the intention for this project is to do an exploratory analysis of data the was already available, either on medical records or collected for a different protocol. Since the data made available was not collected according to a protocol designed to test a hypothesis of clinical/healthcare relevance, this analysis will only be able to offer exploratory value on the data collected, assuming an observational study design that attempts to detect association instead of causality. As such, any observed effects should be interpreted with caution, as there should be a high risk of bias and confounding.

As the scope of the research inquiry lies within Healthcare Quality it can be recommended that in future studies a protocol is developed to test a hypothesis with a well-defined and relevant comparator group and the hospital database be queried for data under a balanced design. If the desired hypothesis is to test whether or not of interventions have a causal effect in the outcome, it is recommended that a randomized controlled trial design is used, instead of an observational design. If an exploratory study is still helpful, a protocol could be written to find patterns in ER visits.

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-2023-013-DB-v01** – Effect of healthcare interventions on the average number of ER visits: 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).
- Benchimol EI, Smeeth L, Guttmann 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 Availability

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

The portfolio is available at:

https://philsf-biostat.github.io/SAR-2023-013-DB/