Analytical Plan for Prevalence of knee implant loosening in patients with prior surgery in a German hospital

DOCUMENT: SAP-2022-032-JF-v01

From: Felipe Figueiredo **To:** Jens Freitag

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Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

- CI: confidence interval
- OR: odds ratio
- PR: prevalence ratio

2 CONTEXT

In **SAR-2021-002-JF-v02** the average survival time of knee implants was estimated. After that retrospective cohort was analyzed, aggregated counts of previous surgery were made available, and this analysis will investigate whether or not this exposure is a significant risk factor for loosening.

2.1 Objectives

Calculate the prevalence of knee prosthesis loosening in patients with prior history of knee surgery in Helios Klinikum Berlin-Buch, Germany.

2.2 Hypotheses

Patients with prior knee surgery have a higher prevalence of implant loosening than controls.

3 DATA

3.1 Raw data

The original data was already aggregated into counts of exposure and outcome. No individual information was available on these patients (see Observations).

3.2 Analytical dataset

N/A

4 STUDY PARAMETERS

4.1 Study design

This is a case-control study, based on hospital records.

4.2 Inclusion and exclusion criteria

N/A

4.3 Exposures

Exposure will be defined as having a previous knee surgery.

4.4 Outcomes

Specification of outcome measures (Zarin, 2011):

1. (Domain) Knee arthroplasty
2. (Specific measurement) Implant loosening
3. (Specific metric) End value
4. (Method of aggregation) Frequency of implant loosening

Primary outcome

Cases will be defined as the patient experienced a knee implant loosening event.

4.5 Covariates

N/A

5 STATISTICAL METHODS

5.1 Statistical analyses

5.1.1 Descriptive analyses

The counts of exposures and outcomes will be described in frequency and proportion (%), and summarized in a 2x2 contingency table. Prevalence in exposed and unexposed will be reported.

5.1.2 Inferential analyses

The distributions of participants' characteristics will be summarized in contingency tables. The measure of effect will be assessed with the OR. The measures of association between exposure and outcome will be assessed with the PR, as an additional measure. Both the point estimates and the CI around the estimates will be calculated using the Wald method.

Significance will be tested and interpreted from the Wald CI for all measures. Additionally the chi-squared test will be calculated for the OR, without Yates' continuity 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.

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

Aggregated sample data

No individual-level data was available for this analysis. This means that we cannot control for confounding either in regression models or stratified analyses. It is recommended that this be reported as a limitation of the study, since it raises the risk of bias of the study.

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-2022-032-JF-v01** – Prevalence of knee implant loosening in patients with prior surgery in a German hospital
- **SAR-2021-002-JF-v02** – Implant failure rates in a knee prosthesis sub-population of the Helios Klinikum Berlin-Buch hospitals
- 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).
- 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).

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.

Implant failure rates in a knee prosthesis sub-population of the Helios Klinikum Berlin-Buch hospitals

https://philsf-biostat.github.io/SAR-2021-002-JF/

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-2022-032-JF/