

## Template for POSE Secondary Analysis detailed application

Study TITLE:	<b>Peri-interventional Outcome Study in the Elderly (POSE): European, multi-centre, prospective observational cohort study</b>
Study PROTOCOL #:	V 2.0, 14.06.18
Clinicaltrials.gov identifier:	NCT03152734
Chief Coordinating Investigator	Prof. Dr. med. Mark Coburn, Department of Anaesthesiology and Intensive Care Medicine, University Hospital Bonn, Bonn, Germany
Deputy Study Coordinator	PD Dr. med. Ana Kowark, Department of Anaesthesiology and Intensive Care Medicine, University Hospital Bonn, Bonn, Germany
To:	POSE Steering Committee
Re:	Proposal secondary analysis
Date:	10-11-2022

*Dear investigators.*

*Please fill the form below, which will help the steering committee of the POSE study to decide upon eligibility of your proposal to serve as POSE secondary analysis.*

*The proposal details should have max: 3 pages!*

*Regarding publication; authors must agree **not** to submit their secondary analysis before the main POSE manuscript is published. This statement should be added to the application*

### 1. Applicant details:

- 1.1. Name of Hospital: University Hospital RWTH Aachen
- 1.2. City, Country: Aachen, Germany
- 1.3. Centre #: 049-001
- 1.4. Last Name, First Name Local investigator: Grüßer, Linda
- 1.5. Email address Local investigator: [lgruesser@ukaachen.de](mailto:lgruesser@ukaachen.de)
- 1.6. Working position Local investigator: Clinician scientist

## 2. Proposal details:

- 2.1. Title: Characteristics and outcomes of elderly patients undergoing in- versus outpatient surgery in Europe
- 2.2. Rationale for study: The peri-interventional period may present a considerable stressor for elderly patients: Age-related changes often combined with comorbid conditions lead to an increased surgical risk in this age group.<sup>1-4</sup> Besides survival, improvement of functioning is a major goal for caregivers. Little is known about differences in elderly outpatients versus inpatients. Information on baseline characteristics, mortality rates, and functional and cognitive outcomes may provide insights for improved perioperative care and may also affect a patient's decision to undergo a specific procedure.
- 2.3. Hypothesis: We hypothesize that characteristics and outcomes of elderly outpatients differ from inpatients.
- 2.4. Study design: Observational study. Secondary analysis.
- 2.5. Study population: all POSE patients
- 2.6. Primary endpoints: overall 30-day mortality, change in functional and cognitive outcome in outpatients versus inpatients
- 2.7. Secondary endpoints: complications in outpatients versus inpatients, patient pathways (referring facility and discharge destination),
- 2.8. Methods and Statistics: This is a secondary analysis of the prospective observational multicentre POSE study, which included 9497 consecutively recruited patients aged 80 years and older undergoing any kind of surgical or nonsurgical procedures under anaesthesia in Europe.<sup>5</sup> Ethical approval was obtained or waived for each participating centre. Data was collected and managed as previously described.<sup>5</sup> This secondary analysis will include all patients in the cleaned and closed POSE database. A patient will be defined as outpatient when the length of hospital stay is <1 day. All statistical analysis will be performed using the R Language and Environment for Statistical Computing<sup>6</sup>. Descriptive statistics of baseline and surgery characteristics, mortality, and change in functional and cognitive status will be performed. Categorical variables will be presented as number (% of total sample) and continuous variables as median [interquartile range] and mean  $\pm$  standard deviation respectively. Kaplan-Meier estimates with 95% confidence intervals will be used to describe the 30-day mortality up to 30 days. Changes in functional and cognitive status will be analysed using (quasi-)Poisson and ordinal logistic regression. Models will be adjusted for the following baseline characteristics: Age, sex, American Society of Anesthesiologists classification, kind of referring facility, multimorbidity, timed up and go test, history of falls, application of premedication, severity of surgery, urgency of surgery, surgical category, anaesthesia technique. Associations between outpatient vs. inpatient status and covariates

will be analysed in an explorative manner by a regularized logistic regression model. Multiple imputation will be used to handle missing data.

### 2.9 References:

1. Turrentine FE, Wang H, et al. Surgical risk factors, morbidity, and mortality in elderly patients. *J Am Coll Surg* 2006; **203**:865-77.
2. Gajdos C, Kile D, et al. Advancing age and 30-day adverse outcomes after nonemergent general surgeries. *J Am Geriatr Soc* 2013; **61**:1608-14.
3. Bailes BK. Perioperative care of the elderly surgical patient. *AORN J* 2000; **72**:186-207; quiz 18-21, 23, 25-6.
4. Lin HS, Watts JN, et al. Frailty and post-operative outcomes in older surgical patients: a systematic review. *BMC Geriatr* 2016; **16**:157.
5. Peri-interventional outcome study in the elderly in Europe: A 30-day prospective cohort study. *Eur J Anaesthesiol* 2022; **39**:198-209.
6. R Core Team (2022). R: A Language and Environment for Statistical Computing. R Foundation for Statistical Computing, Vienna, Austria. <https://www.R-project.org/>.

### 3. Administrative plan:

3.1 Expected timeline to perform the secondary analysis after receipt of the data (in months): We expect to perform the data analysis and manuscript preparation within 6 months after data receipt. Presentation to the SC, review and further adjustments are expected to take 2 months. We plan to submit within 8 months.

3.2 Publication plan (including authorship plan): To be published in an international journal. Authors: Linda Grüßer, Mark Coburn, Matthias Schmid, Rolf Rossaint, Sebastian Ziemann, Ana Kowark, researcher(s) who fulfil ICMJE criteria for authorship (Vancouver convention); POSE investigators (full list to be listed in acknowledgements/supplements according to POSE regulations on authorship). All authors agree to submit this secondary analysis after the main POSE manuscript is published.

3.3 Funding (please include here any funding or financial guarantees for conduction of this secondary analysis): POSE Research Group

Date 10/11/2022



Signature of the Principal Applicant