|  |  |
| --- | --- |
| Title of Study or Project: | *Please limit Cover Sheet to one page.* |
| Primary Institution: |  |
| Primary Author: |  |
| Co-Authors: |  |
| Statistician(s): |  |
| Type of Study: | << Exploratory / Retrospective Observational / Prospective Trial >> |
| IRB Number/Status: | <<IRB Number>> / <<Approved / Pending>>  ☐ IRB specifies that dataset accessed is a *limited* data set (i.e. not de-identified) |
| Hypotheses / Aims: | *Gain MPOG insight*: *consider reviewing:*   * *“****MPOG Research Process Overview****”* * *“****Developing a Research Proposal****”*   *available as* [*Tips & Tricks Modules*](https://mpog.org/tipsandtricks/) *on the MPOG website* |
| Number of Patients/Participants: |  |
| Power Analysis: |  |
| Proposed statistical tests/analyses: |  |
| Resources (Brief summary of resources for data collection, personnel, financial): |  |

**Introduction (target 300-500 words; limit 750 words)**

*Advanced user tip: consider writing the Introduction and Methods, exactly as intended for submission to target journal (links to Instructions for Authors can be found here:* [*Anesthesiology*](http://anesthesiology.pubs.asahq.org/public/instructionsforauthors.aspx)*,* [*BJA*](https://www.elsevier.com/journals/british-journal-of-anaesthesia/0007-0912/guide-for-authors)*,* [*JAMA*](https://jamanetwork.com/journals/jama/pages/instructions-for-authors)*,* [*A&A*](https://journals.lww.com/anesthesia-analgesia/_layouts/15/1033/oaks.journals/informationforauthors.aspx)*).*

What is the significance of the clinical problem being addressed?

Text

What current gaps exist in the understanding of this problem?

Text

How will this project address this gap and advance clinical care and/or research knowledge?

Text

What are the primary (and secondary if applicable) aim(s) / hypothes(es)?

Text

# Methods

*Gain MPOG insight*: *consider reviewing “****Developing a Research Question Answerable with MPOG Data****” available as* [*Tips & Tricks Modules*](https://mpog.org/tipsandtricks/) *on the MPOG website.*

Study Design

Text, to include:

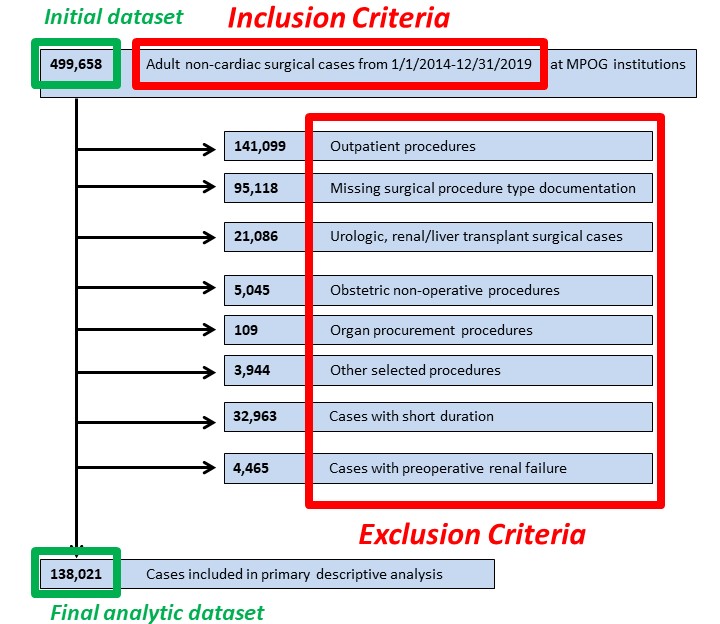
* Type of study (e.g. exploratory, retrospective, prospective, etc.)
* IRB statement
* Statement on reporting guidelines. Please review the [EQUATOR Network](https://www.equator-network.org/reporting-guidelines/) and determine the appropriate guidelines for reporting your proposal. Several common examples include:
  + For observational studies (i.e. cohort, case-control, and cross-sectional studies) using routinely collected health data (i.e. MPOG data), please acknowledge that you have referenced the [RECORD statement](#RECORD) extension to the STROBE guidelines, and that your proposal is in accordance with the checklist
  + For clinical prediction models, please acknowledge that you have referenced the [TRIPOD guidelines](#TRIPOD) and that your proposal is in accordance with the checklist
  + For systematic reviews and meta-analysis, please acknowledge that you have referenced the [PRISMA guidelines](#_PRISMA_Checklist) and that your proposal is in accordance with their checklist
  + For quality improvement studies, please acknowledge that you have referenced the [SQUIRE guidelines](#SQUIRE) and that your proposal is in accordance with the checklist

Study Population

*Gain MPOG insight*: *consider reviewing “****Using DataDirect for Self-Serve Data Access****” available as* [*Tips & Tricks Modules*](https://mpog.org/tipsandtricks/) *on the MPOG website.*

Text, to include:

* Date range
* Participating institutions
* Study population
  + **Inclusion criteria** – defines which cases/patients are included in the dataset for the study team’s analyst to work with (analogous to the number of patients screened at the start of a CONSORT flow diagram; see example figure below)
    - When defining a study date range, note that start dates earlier than Jan 1st, 2014 have less consistent data quality compared to more recent dates; and that end dates later than 3 months before the current date may have lower rates of data completeness; study queries extending beyond these boundaries are not recommended if study remains adequately powered.
    - To further improve data quality and completeness, consider using a starting population such as “Intraoperative Research Standard”, “Perioperative Research Standard”, or “Outcome Research Standard”; details on what qualifies for each starting population are defined in [MPOG DataDirect](https://datadirect.mpog.org/Main).
  + **Exclusion criteria** – applied by study team’s analyst to refine the queried cohort into a final analytic dataset (analogous to final population analyzed within a CONSORT flow diagram; see example figure below)
* Estimated sample size, as determined by [MPOG DataDirect](https://datadirect.mpogresearch.org/Main) query using Cohort mode, or preliminary query of any other data source involved.



**Illustrative Example Figure:** Demonstration of Inclusions vs. Exclusions,

and Initial Dataset vs. Final Analytic Dataset

Primary outcome

Text

Secondary outcome(s), if applicable

Text

Data source

Text

* Please indicate which data source(s) you anticipate using for your retrospective analysis. Please be as specific as possible.
* For the vast majority of PCRC proposals, stating “MPOG database” is sufficient for this section
  + If you anticipate using other data sources, please state how you propose to link them to the pooled (limited) MPOG dataset.

Exposure Variable

Text, to include a description of the exposure variable of interest

* Please provide as specific a definition as possible
* For exposure variables previously studied, consider providing references justifying your choice of definition

Covariates

*Gain MPOG insight*: *consider reviewing “****Transforming Raw Data into Clinical Inferences: Phenotypes****” available as* [*Tips & Tricks Modules*](https://mpog.org/tipsandtricks/) *on the MPOG website.*

Text, to include a description of covariates to be queried (for descriptive purposes or for multivariable adjustment).

* Consider use of a simple table
* Please be specific—i.e. stating “comorbidities” is not sufficient, instead list “diabetes, hypertension, coronary artery disease”, etc.
* If using terms which lack a generally-agreed upon definition (i.e. intraoperative hypotension), please define what criteria you would use to define this event (i.e. a systolic blood pressure of less than 90 mm Hg over a five-minute epoch)
* All covariates described should be consistent with what the study team specifies in the [*Query Specification*](#Query_Specification)forms.

Statistical analysis

*Gain MPOG insight*: *consider reviewing “****Statistics for Large Database Research****” available as* [*Tips & Tricks Modules*](https://mpog.org/tipsandtricks/) *on the MPOG website.*

Text, with consideration given to (where applicable):

* Proposed statistical software to be used
* Partitioning of cohorts (e.g. derivation/validation, if applicable)
* Specific univariate testing (e.g. Student’s t-test, Mann-Whitney U test)
* Specific multivariable testing (e.g. logistic / linear regression)
  + *Fixed effects versus mixed effects models*: if developing a multivariable model, consider MPOG institution as a random effect in a mixed effects model
* Methods for assessing and handling collinearity (e.g. variance inflation factor, Pearson correlations)
* p-value threshold for significance
  + For studies with extremely large sample sizes, consider a strong p-value (e.g. p <0.01 or <0.005) rather than traditional p <0.05
  + For studies with multiple independent tests performed, consider a method to control for multiple comparisons (e.g. Bonferonni correction, Benjamini-Hochberg procedure)
* Methods for performing internal and external validation
  + Internal validation – e.g. bootstrapping
  + External validation – e.g. model performance within validation cohort
* Methods for assessing effect size (e.g. adjusted odds ratios, confidence intervals)
* When applicable, consider a strategy for handling baseline differences between cases/patients with and without the exposure of interest
* When applicable, consider methods for model/variable selection

Note, answers such as “will be performed”, “will be done by statistician”, etc. are not adequate. Please consult with a statistician for assistance in completing this section if necessary

Sensitivity / Secondary subgroup / Secondary outcome analyses

Text

* If performing sensitivity analyses, please describe
* If performing analyses of subgroups of the study population, please describe
* If measuring secondary outcomes, please indicate how these will be analyzed separately

Power analysis

Text

* Please consult your team’s statistician for assistance in completing this section.
* Please include your *a priori* estimation of what constitutes a clinically meaningful effect size, and the sample size necessary to detect such an effect size.
  + Example: “*For purposes of this study, we considered a reduction in complication rates from 20% to 10% to be a clinically meaningful exposure. At a power level of 80%, we determined 4,958 patients would be necessary to detect such a reduction, at a significance level α = 0.05.”*

Handling of missing or invalid data

* For MPOG studies, common methods for handling missing data include a complete case analysis, mean/median substitution, and/or multiple imputation.
  + A summary of these techniques [is provided here](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3668100/).
* For MPOG studies, common methods for handling invalid data include:
  + Artifact reduction for physiologic monitoring – see **Appendix 1** at end of template
  + Rejection of outlier values – as described in multiple MPOG phenotypes; examples:

|  |  |
| --- | --- |
| **MPOG Phenotype** | **Valid Range** |
| [Weight (kg)](file:///C:\Users\mathism\Google%20Drive\PGY-8%20(Assistant%20Professor)%20Years\MPOG%20-%20Research%20Director\PCRC%20Process%20Documents\%09https:\collations.mpogresearch.org\Detail.aspx%3fname=Weight%20(kg)) | 0.5 – 250 kg |
| [Height (cm)](file:///C:\Users\mathism\Google%20Drive\PGY-8%20(Assistant%20Professor)%20Years\MPOG%20-%20Research%20Director\PCRC%20Process%20Documents\%09https:\collations.mpogresearch.org\Detail.aspx%3fname=Height%20(cm)) | 12.70 – 243.85 cm (5-96 inches) |
| [Anesthesia Duration (minutes)](https://collations.mpogresearch.org/Detail.aspx?name=Anesthesia%20Duration) | 0 – 2,160 minutes (0 – 36 hours) |

Preliminary Single Center Data

* Please describe summary characteristics from a test data download of the study team’s local, single-center data, as relevant to the proposed research.
* Please describe any obstacles encountered with the quality of the test data, and strategies to mitigate these obstacles.

Areas for discussion/known limitations

* If applicable, include several points that you wish to discuss at the PCRC meeting. This will help MPOG reviewers provide targeted feedback regarding questions/concerns you may already have with the proposed manuscript.

**References**

Text

**Query Specification**

*Gain MPOG insight*: *consider reviewing “****Using DataDirect for Self-Serve Data Access****” available as [Tips & Tricks Modules](https://mpog.org/tipsandtricks/) on the MPOG website*.

* Using [MPOG DataDirect](https://datadirect.mpogresearch.org/Main), please develop multiple query specification forms, which enable the MPOG developer team to provide the necessary data for analysis of the research proposal.
* These query specification forms include:
  + Data elements to determine inclusion criteria (as would be used to describe the initial set of eligible patients within a flow diagram)
  + Data elements comprising the final analytic dataset: including exclusion criteria, exposure variables, outcome variables, and covariates
* Through the use of MPOG DataDirect, the study team should identify an MPOG Query ID, and provide this in the PCRC Proposal Submission Checklist
* As a separate document to accompany this PCRC proposal, a query specification table – as automatically generated via DataDirect – must be provided by the study team.

# RECORD Statement

**The RECORD statement – checklist of items, extended from the STROBE statement, that should be reported in observational studies using routinely collected health data.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Item No.** | **STROBE items** | **Page #** | **RECORD items** | **Page #** |
| **Title and abstract** | | | | | | |
|  | 1 | (a) Indicate the study’s design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found |  | RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included.  RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract.  RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract. |  |
| **Introduction** | | | | | | |
| Background rationale | 2 | Explain the scientific background and rationale for the investigation being reported |  |  |  |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses |  |  |  |
| **Methods** | | | | | | |
| Study Design | 4 | Present key elements of study design early in the paper |  |  |  |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |  |  |  |
| Participants | 6 | *(a) Cohort study* - Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up  *Case-control study* - Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls  *Cross-sectional study* - Give the eligibility criteria, and the sources and methods of selection of participants  *(b) Cohort study* - For matched studies, give matching criteria and number of exposed and unexposed  *Case-control study* - For matched studies, give matching criteria and the number of controls per case |  | RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided.  RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided.  RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage. |  |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. |  | RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided. |  |
| Data sources/ measurement | 8 | For each variable of interest, give sources of data and details of methods of assessment (measurement).  Describe comparability of assessment methods if there is more than one group |  |  |  |
| Bias | 9 | Describe any efforts to address potential sources of bias |  |  |  |
| Study size | 10 | Explain how the study size was arrived at |  |  |  |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why |  |  |  |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding  (b) Describe any methods used to examine subgroups and interactions  (c) Explain how missing data were addressed  (d) *Cohort study* - If applicable, explain how loss to follow-up was addressed  *Case-control study* - If applicable, explain how matching of cases and controls was addressed  *Cross-sectional study* - If applicable, describe analytical methods taking account of sampling strategy  (e) Describe any sensitivity analyses |  |  |  |
| Data access and cleaning methods |  | .. |  | RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population.  RECORD 12.2: Authors should provide information on the data cleaning methods used in the study. |  |
| Linkage |  | .. |  | RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided. |  |
| **Results** | | | | | | |
| Participants | 13 | (a) Report the numbers of individuals at each stage of the study (*e.g.*, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed)  (b) Give reasons for non-participation at each stage.  (c) Consider use of a flow diagram | ***N/A for PCRC*** | RECORD 13.1: Describe in detail the selection of the persons included in the study (*i.e.,* study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram. | ***N/A for PCRC*** |
| Descriptive data | 14 | (a) Give characteristics of study participants (*e.g.*, demographic, clinical, social) and information on exposures and potential confounders  (b) Indicate the number of participants with missing data for each variable of interest  (c) *Cohort study* - summarise follow-up time (*e.g.*, average and total amount) | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| Outcome data | 15 | *Cohort study* - Report numbers of outcome events or summary measures over time  *Case-control study* - Report numbers in each exposure category, or summary measures of exposure  *Cross-sectional study* - Report numbers of outcome events or summary measures | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included  (b) Report category boundaries when continuous variables were categorized  (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| Other analyses | 17 | Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| **Discussion** | | | | | | |
| Key results | 18 | Summarise key results with reference to study objectives | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias |  | RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported. |  |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| **Other Information** | | | | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based |  |  |  |
| Accessibility of protocol, raw data, and programming code |  | .. |  | RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code. |  |

\*Reference: Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, the RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLoS Medicine* 2015; in press.

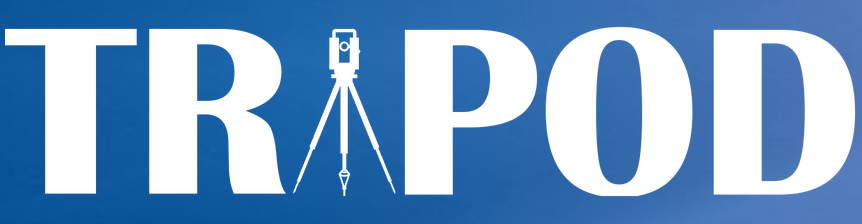
\*Checklist is protected under Creative Commons Attribution ([CC BY](http://creativecommons.org/licenses/by/4.0/)) license.

# PRISMA Checklist

|  |  |  |  |
| --- | --- | --- | --- |
| **Section/topic** | **#** | **Checklist item** | **Reported on page #** |
| **TITLE** | | |  |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. |  |
| **ABSTRACT** | | |  |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | (N/A for PCRC) |
| **INTRODUCTION** | | |  |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. |  |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). |  |
| **METHODS** | | |  |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. |  |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. |  |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. |  |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. |  |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). |  |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. |  |
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. |  |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. |  |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). |  |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis. |  |
| Risk of bias across studies | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). |  |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. |  |
| **RESULTS** |  |  |  |
| Study selection | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | (N/A for PCRC) |
| Study characteristics | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | (N/A for PCRC) |
| Risk of bias within studies | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | (N/A for PCRC) |
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | (N/A for PCRC) |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | (N/A for PCRC) |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | (N/A for PCRC) |
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | (N/A for PCRC) |
| **DISCUSSION** |  |  |  |
| Summary of evidence | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | (N/A for PCRC) |
| Limitations | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). |  |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | (N/A for PCRC) |
| **FUNDING** |  |  |  |
| Funding | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. |  |

*From:*  Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

**TRIPOD Checklist**: Prediction Model Development and Validation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/Topic** | **Item** |  | **Checklist Item** | **Page** |
| **Title and abstract** | | | | |
| Title | 1 | D;V | Identify the study as developing and/or validating a multivariable prediction model, the target population, and the outcome to be predicted. |  |
| Abstract | 2 | D;V | Provide a summary of objectives, study design, setting, participants, sample size, predictors, outcome, statistical analysis, results, and conclusions. | (N/A for PCRC) |
| **Introduction** | | | | |
| Background and objectives | 3a | D;V | Explain the medical context (including whether diagnostic or prognostic) and rationale for developing or validating the multivariable prediction model, including references to existing models. |  |
| 3b | D;V | Specify the objectives, including whether the study describes the development or validation of the model or both. |  |
| **Methods** | | | | |
| Source of data | 4a | D;V | Describe the study design or source of data (e.g., randomized trial, cohort, or registry data), separately for the development and validation data sets, if applicable. |  |
| 4b | D;V | Specify the key study dates, including start of accrual; end of accrual; and, if applicable, end of follow-up. |  |
| Participants | 5a | D;V | Specify key elements of the study setting (e.g., primary care, secondary care, general population) including number and location of centres. |  |
| 5b | D;V | Describe eligibility criteria for participants. |  |
| 5c | D;V | Give details of treatments received, if relevant. |  |
| Outcome | 6a | D;V | Clearly define the outcome that is predicted by the prediction model, including how and when assessed. |  |
| 6b | D;V | Report any actions to blind assessment of the outcome to be predicted. |  |
| Predictors | 7a | D;V | Clearly define all predictors used in developing or validating the multivariable prediction model, including how and when they were measured. |  |
| 7b | D;V | Report any actions to blind assessment of predictors for the outcome and other predictors. |  |
| Sample size | 8 | D;V | Explain how the study size was arrived at. |  |
| Missing data | 9 | D;V | Describe how missing data were handled (e.g., complete-case analysis, single imputation, multiple imputation) with details of any imputation method. |  |
| Statistical analysis methods | 10a | D | Describe how predictors were handled in the analyses. |  |
| 10b | D | Specify type of model, all model-building procedures (including any predictor selection), and method for internal validation. |  |
| 10c | V | For validation, describe how the predictions were calculated. |  |
| 10d | D;V | Specify all measures used to assess model performance and, if relevant, to compare multiple models. |  |
| 10e | V | Describe any model updating (e.g., recalibration) arising from the validation, if done. |  |
| Risk groups | 11 | D;V | Provide details on how risk groups were created, if done. |  |
| Development vs. validation | 12 | V | For validation, identify any differences from the development data in setting, eligibility criteria, outcome, and predictors. |  |
| **Results** | | | | |
| Participants | 13a | D;V | Describe the flow of participants through the study, including the number of participants with and without the outcome and, if applicable, a summary of the follow-up time. A diagram may be helpful. | (N/A for PCRC) |
| 13b | D;V | Describe the characteristics of the participants (basic demographics, clinical features, available predictors), including the number of participants with missing data for predictors and outcome. | (N/A for PCRC) |
| 13c | V | For validation, show a comparison with the development data of the distribution of important variables (demographics, predictors and outcome). | (N/A for PCRC) |
| Model development | 14a | D | Specify the number of participants and outcome events in each analysis. | (N/A for PCRC) |
| 14b | D | If done, report the unadjusted association between each candidate predictor and outcome. | (N/A for PCRC) |
| Model specification | 15a | D | Present the full prediction model to allow predictions for individuals (i.e., all regression coefficients, and model intercept or baseline survival at a given time point). | (N/A for PCRC) |
| 15b | D | Explain how to the use the prediction model. | (N/A for PCRC) |
| Model performance | 16 | D;V | Report performance measures (with CIs) for the prediction model. | (N/A for PCRC) |
| Model-updating | 17 | V | If done, report the results from any model updating (i.e., model specification, model performance). | (N/A for PCRC) |
| **Discussion** | | | | |
| Limitations | 18 | D;V | Discuss any limitations of the study (such as nonrepresentative sample, few events per predictor, missing data). |  |
| Interpretation | 19a | V | For validation, discuss the results with reference to performance in the development data, and any other validation data. | (N/A for PCRC) |
| 19b | D;V | Give an overall interpretation of the results, considering objectives, limitations, results from similar studies, and other relevant evidence. | (N/A for PCRC) |
| Implications | 20 | D;V | Discuss the potential clinical use of the model and implications for future research. | (N/A for PCRC) |
| **Other information** | | | | |
| Supplementary information | 21 | D;V | Provide information about the availability of supplementary resources, such as study protocol, Web calculator, and data sets. |  |
| Funding | 22 | D;V | Give the source of funding and the role of the funders for the present study. |  |

\*Items relevant only to the development of a prediction model are denoted by D, items relating solely to a validation of a prediction model are denoted by V, and items relating to both are denoted D;V. We recommend using the [TRIPOD Checklist](http://www.equator-network.org/reporting-guidelines/tripod-statement/) in conjunction with the TRIPOD Explanation and Elaboration document.

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| Revised **Standards for QUality Improvement Reporting Excellence** (**SQUIRE 2.0**) publication guidelines | | |  |
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| **Notes to authors** | | |
| ▸ The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare. | | |
| ▸ The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). | | |
| ▸ A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. | | |
| ▸ Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. | | |
| ▸ The SQUIRE glossary contains definitions of many of the key words in SQUIRE. | | |
| ▸ The explanation and elaboration document provides specific examples of well-written SQUIRE items and an in-depth explanation of each item. | | |
| ▸ Please cite SQUIRE when it is used to write a manuscript. | | |
|  | | |  |
| **Text section and item name** | | **Page/line no(s).** |
|  | | **info is located** |
| **Title and abstract** | |  |
| 1. **Title** | |  |
| Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centredness, timeliness, cost, efficiency and equity of healthcare). | |  |
|  | |  |
| 2. **Abstract** | |  |
| a. Provide adequate information to aid in searching and indexing. | | (N/A for PCRC) |
| b. Summarise all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions. | | (N/A for PCRC) |
|  | |  |
| **Introduction: Why did you start?** | |  |
| 3. **Problem description** - Nature and significance of the local problem. | |  |
| 4. **Available knowledge** - Summary of what is currently known about the problem, including relevant previous studies. | |  |
| 5. **Rationale** - Informal or formal frameworks, models, concepts and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s) and reasons why the intervention(s) was expected to work | |  |
| 6. **Specific aims** - Purpose of the project and of this report. | |  |
|  | |  |
| **Methods: What did you do?** | |  |
| 7. **Context** - Contextual elements considered important at the outset of introducing the intervention(s). | |  |
| 8. **Intervention(s)** | |  |
| a. Description of the intervention(s) in sufficient detail that others could reproduce it. | |  |
| b. Specifics of the team involved in the work. | |  |
| 9. **Study of the intervention(s)** | |  |
| a. Approach chosen for assessing the impact of the intervention(s). | |  |
| b. Approach used to establish whether the observed outcomes were due to the intervention(s). | |  |
| 10. **Measures** | |  |
| a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions and their validity and reliability. | |  |
| b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency and cost. | |  |
| c. Methods employed for assessing completeness and accuracy of data. | |  |
| 11. **Analysis** | |  |
| a. Qualitative and quantitative methods used to draw inferences from the data. | |  |
| b. Methods for understanding variation within the data, including the effects of time as a variable. | |  |
| 12. **Ethical considerations** - Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest. | |  |
|  | |  |
| **Results: What did you find?** | |  |
| 13. **Results** | |  |
| a. Initial steps of the intervention(s) and their evolution over time (eg, time-line diagram, flow chart or table), including modifications made to the intervention during the project. | | (N/A for PCRC) |
| b. Details of the process measures and outcomes. | | (N/A for PCRC) |
| c. Contextual elements that interacted with the intervention(s). | | (N/A for PCRC) |
| d. Observed associations between outcomes, interventions and relevant contextual elements. | | (N/A for PCRC) |
| e. Unintended consequences such as unexpected benefits, problems, failures or costs associated with the intervention(s). | | (N/A for PCRC) |
| f. Details about missing data. | | (N/A for PCRC) |
|  | |  |
| **Discussion: What does it mean?** | |  |
| 14. **Summary** | |  |
| a. Key findings, including relevance to the rationale and specific aims. | | (N/A for PCRC) |
| b. Particular strengths of the project. | | (N/A for PCRC) |
|  | |  |
| 15. **Interpretation** | |  |
| a. Nature of the association between the intervention(s) and the outcomes. | | (N/A for PCRC) |
| b. Comparison of results with findings from other publications. | | (N/A for PCRC) |
| c. Impact of the project on people and systems. | | (N/A for PCRC) |
| d. Reasons for any differences between observed and anticipated outcomes, including the influence of context. | | (N/A for PCRC) |
| e. Costs and strategic trade-offs, including opportunity costs. | | (N/A for PCRC) |
|  | |  |
| 16. **Limitations** | |  |
| a. Limits to the generalisability of the work. | |  |
| b. Factors that might have limited internal validity such as confounding, bias or imprecision in the design, methods, measurement or analysis. | |  |
| c. Efforts made to minimise and adjust for limitations. | |  |
|  | |  |
| **Conclusions** | |  |
| a. Usefulness of the work. | | (N/A for PCRC) |
| b. Sustainability. | | (N/A for PCRC) |
| c. Potential for spread to other contexts. | | (N/A for PCRC) |
| d. Implications for practice and for further study in the field. | | (N/A for PCRC) |
| e. Suggested next steps. | | (N/A for PCRC) |
|  | |  |
| **Other information** | |  |
| 18. **Funding** - Sources of funding that supported this work. Role, if any, of the funding organisation in the design, implementation, interpretation and reporting. | |  |
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| *Ogrinc G, et al. BMJ Qual Saf 2015;0:1–7. doi:10.1136/bmjqs-2015-004411* | |  |
| *Downloaded from http://qualitysafety.bmj.com/ on January 2, 2017* | |  |

**Appendix 1: Intraoperative Blood Pressure Monitoring, Signal Processing, and Arterial Blood Pressure Artifact Reduction**

* For arterial line waveform data or non-invasive blood pressure monitoring data, when simultaneous values are recorded, the higher of the two MAP values will be used.
* When blood pressure monitoring is non-continuous during a case (e.g. non-invasive blood pressure measurements, or arterial line disconnected), blood pressure will be assumed constant and equal to the previous measurement if within five minutes from the most recent measurement; if five minutes or greater from any blood pressure measurement value, blood pressure will be presumed unknown and treated as missing data.
* Additional blood pressure monitoring artifact reduction will be performed as follows:

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| --- | --- |
| **Artifact Elimination Strategy** | **Rules/Logic** |
| Provider Marked Artifacts | Marked as artifact in real-time by the provider |
| Artifact from arterial line clamping, damping, or flushing; or cuff under external pressure | SBP > 200 AND PP < 50 |
|  | SBP > 150 and SBP ≤200 AND  PP < 30 |
|  | SBP ≥ 100 AND SBP ≤ 150 AND PP < 15 |
|  | SBP < 100 AND PP < 10 |
| Artifact from arterial line or cuff transducing signal but disconnected from patient | SBP ≤ 10 OR DBP ≤ 10 |
|  | SBP = DBP = MAP |
|  | MAP < 0 |
|  | MAP ≥ 140 |
|  | If any BP is marked as artifact, then all BP measurements for that time will be marked as artifact |

*SBP = Systolic Blood Pressure; DBP = Diastolic Blood Pressure; MAP = Mean Arterial Pressure; PP = Pulse Pressure (SBP-DBP). If artifact other than provider-marked, is detected for SBP, DBP, or MAP for a specific reading, then all three blood pressure values are marked as an artifact.*