VA Male OP Project – RISK FACTOR STUDIES, Quality Measurement

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First Author: _____
(Last Name Only)

STUDY PARTICIPATION

The study sample represents the population of interest on key characteristics, sufficient to limit potential bias to the results.

Yes .....❑
Partly .....❑
No .....❑
Unsure .....❑

*Population of interest is adequately described for key characteristics
*Sampling frame and recruitment are adequately described, including methods to identity the sample (number and type used, e.g., referral patterns in health care), period of recruitment, and place of recruitment (setting and geographic location).
*Inclusion and exclusion criteria are adequately described (e.g., including explicit diagnostic criteria or "zero time" description).
* There is adequate participation in the study by eligible individuals.
*The baseline study sample (i.e., individuals entering the study) is adequately described for key characteristics.

STUDY ATTRITION

Loss to follow-up (from sample to study population) is not associated with key characteristics (i.e., the study data adequately represent the sample), sufficient to limit potential bias.

Yes .....❑
Partly .....❑
No .....❑
Unsure .....❑

*Proportion of study sample completing the study and providing outcome data is adequate.
*Attempts to collect information on participants who dropped out of the study are described.
*Reasons for loss to follow-up are provided.
*Participants lost to follow-up are adequately described for key characteristics.
*There are no important differences between key characteristics and outcomes in participants who completed the study and those who did not.

PROGPROGNOSTIC FACTOR MEASUREMENT

The prognostic factor of interest is adequately measured in study participants to sufficiently limit potential bias.

Yes.....❑
Partly.....❑
No .....❑
Unsure.....❑

*A clear definition or description of the prognostic factor measure is provided (e.g., including dose, level, duration of exposure, and clear specification of the method of measurement.)
*Continuous variables are reported or appropriate (i.e., not data-dependent) cut-points are used.
*The prognostic factor measure and method are adequately valid and reliable to limit misclassification Bias (e.g. may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall).
*Adequate proportion of the study sample has complete data for prognostic factors.
*The method and setting of measurement are the same for all study participants.
*Appropriate methods are used if imputation is used for missing prognostic factor data.

OUTCOME MEASUREMENT

The outcome of interest is adequately measured in study participants to sufficiently limit potential bias.

Yes.....❑
Partly.....❑
No .....❑
Unsure.....❑

*A clear definition of the outcome of interest is provided, including duration of follow-up and level and extent of the outcome construct.
*The outcome measure and method used are adequately valid and reliable to limit misclassification bias (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and confirmation of outcome with valid and reliable test.)
*The method and setting of measurement are the same for all study participants.

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CONFOUNDING MEASUREMENT AND ACCOUNT

Important potential confounders are appropriately accounted for, limiting potential bias with respect to the prognostic factor of interest.

Yes ..... ❑
Partly ..... ❑
No ..... ❑
Unsure ..... ❑

*All important confounders, including treatments (key variables in conceptual model), are measured.
*Clear definitions of the important confounders measured are provided (e.g., including dose, level and duration of exposures).
*Measurement of all important confounders is adequately valid and reliable (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall.)
*The method and setting of confounding measurement are the same for all study participants.
*Appropriate methods are used if imputation is used for missing confounder data.
*Important potential confounders are accounted for in the study design (e.g., matching for key variables, stratification, or initial assembly of comparable groups.)
*Important potential confounders are accounted for in the analysis (i.e., appropriate adjustment).

ANALYSIS

The statistical analysis is appropriate for the design of the study, limiting potential for presentation of invalid results.

Yes ..... ❑
Partly ..... ❑
No ..... ❑
Unsure ..... ❑

*There is sufficient presentation of data to assess the adequacy of the analysis.
*The strategy for model building (i.e., inclusion of variables) is appropriate and is based on a conceptual framework or model.
* The selected model is adequate for the design of the study.
*There is no selective reporting of results.