

Appendix III: Risk of bias instruments used for the assessment of risk of bias of studies that investigated the effect of a decision-aid on the intention of the men to undergo screening.

Modified version of Cochrane Risk of Bias Tool and modified version of International Patient Decision Aid Standards instrument (IPADSi) v3 of the recent systematic review of Riikonen *et al.* (2018) has been used.

Modified version of Cochrane Risk of Bias Tool

1) Randomization

a) Was the allocation sequence adequately generated?

Definitely yes	Probably yes	Probably no	Definitely no
(low risk of bias)			(high risk of bias)

The use of a random component should be sufficient for adequate sequence generation. This could be achieved by allocating interventions using methods such as repeated coin-tossing, throwing dice or dealing previously shuffled cards. If the allocation was by telephone or Internet, the randomization was done through a computer system.

Examples of low risk of bias: Referring to a random number table; Using a computer random number generator; Coin tossing; Shuffling cards or envelopes; Throwing dice; Drawing of lots; Minimization with or without a random element.

Examples of high risk of bias: Sequence generated by odd or even date of birth; Sequence generated by some rule based on date (or day) of admission; Sequence generated by some rule based on hospital or clinic record number; Allocation by judgement of the clinician; Allocation by preference of the participant; Allocation based on the results of a laboratory test or a series of tests; Allocation by availability of the intervention.

If they say “randomized” and give no more information regarding sequence generation, the process was probably low risk of bias, so, answer “Probably yes”.

b) Was allocation adequately concealed?

Definitely yes	Probably yes	Probably no	Definitely no
(low risk of bias)			(high risk of bias)

Examples of possible low risk of bias: Sequentially numbered drug containers of identical appearance; Sequentially numbered, opaque, sealed envelopes.

Examples of high risk of bias allocation generation techniques: Using an open random allocation schedule (e.g. a list of random numbers); Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); Alternation or rotation; Date of birth; Case record number; Any other explicitly unconcealed procedure.

Cochrane instructions:

- Use of telephone, web-based, independent research assistant, or pharmacy-controlled randomization → Central randomization
- Allocation by minimization → Central randomization
- Use of envelopes but at least one of the 3 descriptors or an equivalent (sequentially numbered, opaque, sealed) missing → Envelopes, other
- Use of a list of random numbers, a randomization table → Open random allocation schedule
- Use of alternation, rotation, date of birth, day of the week, or case record number → Quasi-randomized
- Explicitly described as concealed but no concealment method described → Concealed, no method described
- Explicitly described as not concealed → Not concealed
- No mention of a concealment method or of concealment at all → Not reported

Examples of low risk of bias allocation concealment techniques: Central allocation (including telephone, web-based, and pharmacy-controlled, randomization);

If they say “randomized” and give no more information regarding allocation concealment, the process was probably high risk of bias, so, answer “Probably no”.

2) Blinding. Was knowledge of the allocated interventions adequately prevented?

a) Were data collectors blinded?

Definitely yes	Probably yes	Probably no	Definitely no
(low risk of bias)			(high risk of bias)

If questionnaires were self-administered, patients were the data collectors. If questionnaires were interviewer-administered, the interviewers were the data collectors. Data collectors are those who abstracted the data from the medical records.

If the questionnaire were self- or interviewer-administered, you only answer “Definitely yes” or “Probably yes” if there was indication that the patients or the interviewers did not know that the information they got was decision aid. Otherwise it is “Definitely no” or “Probably no”.

For data collectors for abstracting the data from the medical records answer “Probably yes” unless there is some specific indication otherwise.

b) Were data analysts blinded?

Definitely yes	Probably yes	Probably no	Definitely no
(low risk of bias)			(high risk of bias)

Answer “Probably no” unless there is some specific indication implying that data analysts were blinded.

3) Missing data:

a) Screening choice

b) Other outcomes

Definitely yes

Probably yes

Probably no

Definitely no

(low risk of bias)

(high risk of bias)

Risk of bias was considered high if more than 5% of data was missing.

Modified version of International Patient Decision Aid Standards instrument (IPDASi) v3

1) SCREENING AIM: The decision support technology describes what the test is designed to measure.

We answered “yes” if the use of test informed by decision support technology was designed to measure whether man has prostate cancer.

2) TRUE POSITIVE: The decision support technology includes information about the chances of having a true positive test result.

We answered “yes” if the decision support technology included quantitative information about the chances of having prostate cancer when test was positive. If the decision support technology gave probability of positive test, and if it also gave the probability of having prostate cancer among those with positive test, we answered "yes".

3) TRUE NEGATIVE: The decision support technology includes information about the chances of having a true negative test result.

We answered “yes” if the decision support technology included quantitative information about the chances of not having prostate cancer when test was negative. If the decision support technology gave probability of negative test, and if it also gave the probability of not having prostate cancer among those with negative test, we answered “yes”.

4) FALSE POSITIVE: The decision support technology includes information about the chances of having a false positive test result.

We answered “yes” if the decision support technology included quantitative information about the chances of not having prostate cancer when test was positive. If the decision support technology gave probability of positive test, and if it also gave the probability of not having prostate cancer among those with positive test, we answered “yes”.

5) FALSE NEGATIVE: The decision support technology includes information about the chances of having a false negative test result.

We answered “yes” if the decision support technology included quantitative information about the chances of having prostate cancer when test was negative. If the decision support technology gave probability of negative test, and if it also gave the probability of having prostate cancer among those with negative test, we answered “yes”.

6) NEXT STEPS IF POSITIVE: If the test detects the condition or problem, the decision support technology describes the next steps typically taken.

We rated as “yes” if the decision support technology informed that typical steps after positive test include repeating the test and referral to urologist if still positive or direct referral to urologist for further examination, which typically includes prostate biopsy. If prostate biopsies were not mentioned, we rated as “no”.

7) NEXT STEPS IF NEGATIVE: The decision support technology describes the next steps if the condition or problem is not detected.

We rated as “yes” if the decision support technology informed that typical steps include either repeating the test at some time in the future, or no planned testing in future.

8) CHANCES OF DISEASE: The decision support technology describes the chances that the disease is detected with and without the use of the test.

We answered “yes” if the decision support technology described the chances that prostate cancer was detected with and without the use of test properties (=screening) or impact of test on outcomes.

9) The decision support technology presents the consequences of screening versus not screening on the outcomes of interest:

- a. IMPACT ON MORTALITY:** We answered “yes” if the decision support technology described the screening effect on overall or prostate cancer specific mortality.
- b. HARMS OF SCREENING:** We answered “yes” if the decision support technology described the chances that screening may lead to erectile dysfunction, urinary incontinence, and bowel problems. If 2/3 were mentioned, we gave points.