



12 questions to help you make sense of cohort study

How to use this appraisal tool

Three broad issues need to be considered when appraising a cohort study:

- **Are the results of the study valid?** (Section A)
- **What are the results?** (Section B)
- **Will the results help locally?** (Section C)

The 12 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is “yes”, it is worth proceeding with the remaining questions.

There is some degree of overlap between the questions, you are asked to record a “yes”, “no” or “can’t tell” to most of the questions. A number of prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

There will not be time in the small groups to answer them all in detail!

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(A) Are the results of the study valid?

Screening Questions

1. Did the study address a clearly focused issue?

Yes

Can't tell

No

HINT: A question can be 'focused' In terms of

- The population studied
- The risk factors studied
- The outcomes considered
- Is it clear whether the study tried to detect a beneficial or harmful effect?

2. Was the cohort recruited in an acceptable way?

Yes

Can't tell

No

HINT: Look for selection bias which might compromise the generalisability of the findings:

- Was the cohort representative of a defined population?
- Was there something special about the cohort?
- Was everybody included who should have been included?

Is it worth continuing?



Detailed questions

3. Was the exposure accurately measured to minimise bias?

Yes

Can't tell

No

HINT: Look for measurement or classification bias:

- Did they use subjective or objective measurements?
- Do the measurements truly reflect what you want them to (have they been validated)?
- Were all the subjects classified into exposure groups using the same procedure

4. Was the outcome accurately measured to minimise bias?

Yes

Can't tell

No

HINT: Look for measurement or classification bias:

- Did they use subjective or objective measurements?
- Do the measures truly reflect what you want them to (have they been validated)?
- Has a reliable system been established for detecting all the cases (for measuring disease occurrence)?
- Were the measurement methods similar in the different groups?
- Were the subjects and/or the outcome assessor blinded to exposure (does this matter)?

5. (a) Have the authors identified all important confounding factors? Yes Can't tell No

List the ones you think might be important, that the author missed.

(b) Have they taken account of the confounding factors in the design and/or analysis? Yes Can't tell No

List:

HINT: Look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors

6. (a) Was the follow up of subjects complete enough? Yes Can't tell No

(b) Was the follow up of subjects long enough? Yes Can't tell No

HINT: Consider

- The good or bad effects should have had long enough to reveal themselves
- The persons that are lost to follow-up may have different outcomes than those available for assessment
- In an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort?

(B) What are the results?

7. What are the results of this study?

HINT: Consider

- What are the bottom line results?
 - Have they reported the rate or the proportion between the exposed/unexposed, the ratio/the rate difference?
 - How strong is the association between exposure and outcome (RR,)?
 - What is the absolute risk reduction (ARR)?
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8. How precise are the results?

HINT: Look for the range of the confidence intervals, if given.

9. Do you believe the results?

Yes Can't tell No

HINT: Consider

- Big effect is hard to ignore!
- Can it be due to bias, chance or confounding?
- Are the design and methods of this study sufficiently flawed to make the results unreliable?
- Bradford Hills criteria (e.g. time sequence, dose-response gradient, biological plausibility, consistency)

(C) Will the results help locally?

10. Can the results be applied to the local population?

Yes

Can't tell

No

HINT: Consider whether

- A cohort study was the appropriate method to answer this question
- The subjects covered in this study could be sufficiently different from your population to cause concern
- Your local setting is likely to differ much from that of the study
- You can quantify the local benefits and harms

11. Do the results of this study fit with other available evidence?

Yes

Can't tell

No

12. What are the implications of this study for practice?

HINT: Consider

- One observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making
- For certain questions observational studies provide the only evidence
- Recommendations from observational studies are always stronger when supported by other evidence