

CRITICAL APPRAISAL SKILLS PROGRAMME

Making sense of evidence about clinical effectiveness



12 questions to help you make sense of cohort study

General comments

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

Are the results of the study valid?

What are the results?

Will the results help locally?

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 those two is "yes", it is worth proceeding with the remaining questions.
- There is a fair degree of overlap between several of the questions.
- You are asked to record a "yes", "no" or "can't tell" to most of the questions.
- A number of italicised hints are given after each question. These are designed to remind you why the question is important. 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? <i>HINT: A question can be focused in terms of?</i> <ul style="list-style-type: none">• the population studied• the risk factors studied• the outcomes considered• is it clear whether the study tried to detect a beneficial or harmful effect?	Yes <input type="checkbox"/>	Can't tell <input type="checkbox"/>	No <input type="checkbox"/>
2 Did the authors use an appropriate method to answer their question? <i>HINT: Consider</i> <ul style="list-style-type: none">• is a cohort study a good way of answering the question under the circumstances?• did it address the study question?	Yes <input type="checkbox"/>	Can't tell <input type="checkbox"/>	No <input type="checkbox"/>

Is it worth continuing?

Detailed Questions

3 Was the cohort recruited in an acceptable way? <i>HINT: We are looking for selection bias which might compromise the generalisability of the findings:</i> <ul style="list-style-type: none">• Was the cohort representative of a defined population?• Was there something special about the cohort?• Was everybody included who should have been included?	Yes <input type="checkbox"/>	Can't tell <input type="checkbox"/>	No <input type="checkbox"/>
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<p>4 Was the exposure accurately measured to minimize bias?</p> <p><i>HINT: We are looking for measurement or classification bias:</i></p> <ul style="list-style-type: none"> • <i>Did they use subjective or objective measurements?</i> • <i>Do the measures truly reflect what you want them to (have they been validated)?</i> • <i>Were all the subjects classified into exposure groups using the same procedure?</i> 	<p>Yes <input type="checkbox"/></p> <p>Can't tell <input type="checkbox"/></p> <p>No <input type="checkbox"/></p>
<p>5. Was the outcome accurately measured to minimize bias?</p> <p><i>HINT: We are looking for measurement or classification bias:</i></p> <ul style="list-style-type: none"> • <i>Did they use subjective or objective measurements?</i> • <i>Do the measures truly reflect what you want them to (have they been validated)?</i> • <i>Has a reliable <u>system</u> been established for detecting all the cases (for measuring disease occurrence)?</i> • <i>Were the measurement methods similar in the different groups?</i> • <i>Were the subjects and/or the outcome assessor blinded to exposure (does this matter)?</i> 	<p>Yes <input type="checkbox"/></p> <p>Can't tell <input type="checkbox"/></p> <p>No <input type="checkbox"/></p>
<p>6 A, Have the authors identified all important confounding factors?</p> <p>List the ones you think might be important, that the author missed.</p> <p>B. Have they taken account of the confounding factors in the design and/or analysis?</p> <p><i>HINT:</i></p> <ul style="list-style-type: none"> • <i>Look for restriction in design, and techniques eg modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors</i> 	<p>Yes <input type="checkbox"/></p> <p>Can't tell <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/></p> <p>Can't tell <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>List:</p>

<p>7. A. Was the follow up of subjects complete enough?</p> <p>B. Was the follow up of subjects long enough?</p> <p>HINT:</p> <ul style="list-style-type: none"> • <i>The good or bad effects should have had long enough to reveal themselves</i> • <i>The persons that are lost to follow-up may have different outcomes than those available for assessment</i> • <i>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?</i> 	<p>Yes</p> <input type="checkbox"/>	<p>Can't tell</p> <input type="checkbox"/>	<p>No</p> <input type="checkbox"/>
	<p>Yes</p> <input type="checkbox"/>	<p>Can't tell</p> <input type="checkbox"/>	<p>No</p> <input type="checkbox"/>

B/ What are the results?

<p>8 What are the results of this study?</p> <p>HINT:</p> <ul style="list-style-type: none"> • <i>What are the bottom line results?</i> • <i>Have they reported the rate or the proportion between the exposed/unexposed, the ratio/the rate difference?</i> • <i>How strong is the association between exposure and outcome (RR,)?</i> • <i>What is the absolute risk reduction (ARR)?</i> 	
<p>9. How precise are the results?</p> <p>HINT:</p> <ul style="list-style-type: none"> • <i>Size of the confidence intervals</i> 	
<p>10. Do you believe the results?</p> <p>HINT:</p> <ul style="list-style-type: none"> • <i>Big effect is hard to ignore!</i> • <i>Can it be due to bias, chance or confounding?</i> • <i>Are the design and methods of this study sufficiently flawed to make the results unreliable?</i> • <i>Consider Bradford Hills criteria (eg time sequence, dose-response gradient, biological plausibility, consistency).</i> 	<p>Yes</p> <input type="checkbox"/> <p>Can't tell</p> <input type="checkbox"/> <p>No</p> <input type="checkbox"/>

C/ Will the results help me locally?

<p>11. Can the results be applied to the local population?</p> <p><i>HINT: Consider whether</i></p> <ul style="list-style-type: none"><i>• The subjects covered in the study could be sufficiently different from your population to cause concern</i><i>• Your local setting is likely to differ much from that of the study</i><i>• Can you quantify the local benefits and harms?</i>	<p>Yes <input type="checkbox"/></p> <p>Can't tell <input type="checkbox"/></p> <p>No <input type="checkbox"/></p>
<p>12. Do the results of this study fit with other available evidence?</p>	<p>Yes <input type="checkbox"/></p> <p>Can't tell <input type="checkbox"/></p> <p>No <input type="checkbox"/></p>

One observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making.

However, for certain questions observational studies provide the only evidence.

Recommendations from observational studies are always stronger when supported by other evidence.