# Question of prognosis – Advanced critical appraisal

## 1. Are the objectives of the study clearly stated?

The main question being addressed should be clearly stated. The question will often be expressed in terms of a simple relationship but may not fit a PICO question. The Title, Abstract, or final paragraph of the Introduction should clearly state the question.

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Comments: Question:

## 2. Was the sample of patients representative, well-defined, and at a similar point in the course of disease?

Look in ‘Patients and Methods’ for a description of how the patient sample was selected. Check that the researchers applied a definition of the target disorder in the inclusion criteria. Did they select their sample from a tertiary hospital setting or the community? Are all patients at the same point in their disease, as duration of disease may relate to prognosis?

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## 3. Was follow-up sufficiently complete and was it long enough?

The Methods and Results sections will tell you how follow-up was conducted, and how long participants were followed up for. A flow diagram may show loss to follow up. Would follow up have allowed sufficient time for the outcome of interest to occur? Loss to follow-up may not be random and may be related to either an adverse or a good outcome. The study may have performed a ‘sensitivity analysis’ to investigate the effects of loss to follow up – the investigators may re-analyse the data assuming that patients lost to follow up all had the outcome of interest. This can help define the consequences of loss to follow-up on the study results.

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## 4. Were objective and unbiased outcome criteria used?

The Methods section should provide a clear definition of the criteria for the outcome of interest. This is simpler with clear outcomes such as death. Where the outcome requires clinical judgement (e.g. Assessment of disability) then criteria for that outcome should be rigorously defined and preferably validated, or assessors should be blinded to whether the patient had a potential prognostic factor.

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## 5. Was there adjustment for important prognostic variables?

If the prognosis of two groups of patients are compared, their clinical characteristics should be similar at baseline, or statistical adjustments should be made in the analysis for prognostic variables. Adjustment should also be made for treatments which may confound the study outcomes.

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Comments:

## 6. Did the study have a sufficiently large sample size?

Larger samples usually mean more precise results. An online sample size calculator is available at [http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize](http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize)

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Comments:

**What are the results?**
7. How have the outcomes over time been quantified?

This may be expressed as the likelihood of an event in x years, odds ratio, relative risk, or displayed as a ‘time to event’ curve. This type of curve shows how the chance of the event occurring changes over time. A survival curve is one type of time to event curve, but time to any event may be graphed.

This paper: Yes ☐ No ☐ Unclear ☐
Comments:

Odds ratio (OR):

The ratio of the odds of disease in an exposed group over the odds of disease in an unexposed group. The ratio will be greater than 1 if the exposure is harmful, less than 1 if the exposure is protective, and equal to 1 if the exposure carries no risk. The odds ratio is used for case-control studies and it is a useful estimate of the risk ratio if the risk of disease in the study population is low (e.g., less than 5%).

Relative risk (RR)
The ratio of risk in an exposed group to risk in an unexposed group. The ratio will be greater than 1 if the exposure is harmful, less than 1 if the exposure is protective, and equal to 1 if the exposure carries no risk.

8. How precise are the estimates of likelihood?

A 95% confidence interval should be given so that the reader can determine the precision of the result.

This paper: Yes ☐ No ☐ Unclear ☐
Comments:

9. Are the results discussed in relation to existing knowledge, and is the discussion biased?

The discussion should place results into a clinical context and the authors conclusions should be justified by the study results.

This paper: Yes ☐ No ☐ Unclear ☐
Comments:

10. Were the study patients and their management similar to those in my practice?

Can you generalise the study population to your patient? Would your patient have been included in the study? Are they in the same setting? Do they have the same severity of disease?

This paper: Yes ☐ No ☐ Unclear ☐
Comments:

11. What level of evidence does this paper give?

Can you assign a Level of Evidence using the Oxford CEBM Levels of Evidence hierarch?

Level of Evidence:
Comments:

12. Are the results useful in patient management in your practice?

Does this paper answer your clinical question, or have you changed your question to suit the available literature? Are there important geographical differences in disease? Is the treatment the same?

This paper: Yes ☐ No ☐ Unclear ☐
Comments:

13. How would I clearly express the results to a colleague or my patient?

What am I looking for?

Can you extract data that helps you describe the study findings to a patient or colleague in plain English? Can you perform EBM calculations to help you do this? Can you put a NNT, ARR, RRR or NNH into a sentence for your patient?

This paper: Yes ☐ No ☐ Unclear ☐
EBM calculation:

Sentence: