



Literature Critique Criteria

Tabular form for studies of prognostic factors

Criterion	Green	Yellow	Red	Comments
Well-specified hypothesis of which prognostic variables are being tested	There is a clear statement that a particular measurable factor is being studied to determine whether it is associated with at least one clinical outcome which matters to patients, with specifications of end points, cut-off values, and subsets of patients			
Study population is described	The source, inclusion criteria, diagnostic criteria, stage of disease, time of origin, and co-morbidities are described in the methods section, and was sampled in a way which represents the patient population of interest; an inception cohort (with new onset of disease) is included, with fewer than 15% who cannot be			



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	evaluated due to missing data			
Method of measurement of prognostic factor is described clearly enough to be reproduced	The prognostic factor has been measured using methods which have been described in other studies, and the distribution of its measured values have been ascertained in both healthy and in patient populations			
Follow-up is sufficiently complete to capture the distribution of disease outcomes in the source population	Participants who completed the follow-up do not differ in key characteristics from those who did not complete the entire period of follow-up			It is preferable not to judge this by prespecified percentages (e.g., 80% completion) when the important consideration is whether attrition introduces bias
Outcome assessment can be interpreted in terms of what is important to patients	Outcome is described in terms which include method of measurement, length of follow-up, and is measured with the same instrument and setting for all study participants			
Confounders are accounted for in the analysis	Variables which may influence the outcome are measured (dose,	Only one factor is presented as a prognostic factor	Univariate models are presented, but no mention of	Prognostic factors are commonly associated with



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	level, length of exposure, etc), and there is an accounting for which variables were included in the analysis model	(univariate model), with mention of, but no adjustment for, possible confounders	potential confounders is reported	additional factors which need to be adjusted for and which may strongly influence the estimate of the strength of the prognostic factor
Data presentation facilitate the process of examining the progress of the study cohort	A flow diagram, displaying the number of participants at each stage of the follow-up, with reasons for attrition given at every stage of the study period			
The estimated effect of the prognostic factor on the outcome is presented with confidence intervals in terms which are appropriate for the study question	Logistic regression or Cox regression are used to estimate the odds ratios between the prognostic factor and the outcome, and the selection and the order of entering variables is specified in advance	Logistic or Cox regression are used to estimate odds ratios between prognostic factors and outcomes, but stepwise (forward or backward) regression is used	No regression model for estimating odds ratios is presented	Stepwise regression is fine for exploratory studies of prognostic factors, but the regression coefficients are likely to be inflated; for confirmatory studies, the variable entry needs to be specified in advance (likely derived from exploratory studies)
If laboratory measurements are used as prognostic factors, intra- and inter-				



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laboratory reproducibility of assays is reported				

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