

## A framework for assessing the internal validity of articles describing prognostic factor studies

| Study feature                                  | Qualities sought  |
|--|---|
| Sample of patients                             | <ul style="list-style-type: none"> <li>Inclusion criteria defined</li> <li>Sample selection explained</li> <li>Adequate description of diagnostic criteria</li> <li>Clinical and demographic characteristics fully described</li> <li>Representative</li> <li>Assembled at a common (usually early) point in the course of their disease</li> <li>Complete</li> </ul> |
| Follow-up of patients                          | <ul style="list-style-type: none"> <li>Sufficiently long</li> </ul>   |
| Outcome  | <ul style="list-style-type: none"> <li>Objective</li> <li>Unbiased (e.g. assessment blinded to prognostic information)</li> <li>Fully defined</li> <li>Appropriate</li> <li>Known for all or a high proportion of patients</li> </ul>   |
| Prognostic variable                            | <ul style="list-style-type: none"> <li>Fully defined, including details of method of measurement if relevant</li> <li>Precisely measured</li> <li>Available for all or a high proportion of patients</li> <li>If relevant, cut-off point(s) defined and justified</li> </ul>  |
| Analysis                                       | <ul style="list-style-type: none"> <li>Continuous predictor variable analysed appropriately</li> <li>Statistical adjustment for all important prognostic factors</li> </ul>   |
| Intervention subsequent to inclusion in cohort | <ul style="list-style-type: none"> <li>Fully described</li> <li>Intervention standardised or randomised</li> </ul>  |

Source: Altman *et al.*<sup>37</sup>