7. Variables: Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.

Example ‘‘Only major congenital malformations were included in the analyses. Minor anomalies were excluded according to the exclusion list of European Registration of Congenital Anomalies (EUROCAT). If a child had more than one major congenital malformation of one organ system, those malformations were treated as one outcome in the analyses by organ system (...) In the statistical analyses, factors considered potential confounders were maternal age at delivery and number of previous parities. Factors considered potential effect modifiers were maternal age at reimbursement for antiepileptic medication and maternal age at delivery’’ .

Explanation

Authors should define all variables considered for and included in the analysis, including outcomes, exposures, predictors, potential confounders and potential effect modifiers. Disease outcomes require adequately detailed description of the diagnostic criteria. This applies to criteria for cases in a case-control study, disease events during follow-up in a cohort study and prevalent disease in a cross-sectional study. Clear definitions and steps taken to adhere to them are particularly important for any disease condition of primary interest in the study. For some studies, ‘determinant’ or ‘predictor’ may be

appropriate terms for exposure variables and outcomes may be called ‘endpoints’. In multivariable models, authors sometimes use ‘dependent variable’ for an outcome and ‘independent variable’ or ‘explanatory variable’ for exposure and confounding variables. The latter is not precise as it does not

distinguish exposures from confounders. If many variables have been measured and included in

exploratory analyses in an early discovery phase, consider providing a list with details on each variable in an appendix, additional table or separate publication. Of note, the International Journal of Epidemiology recently launched a new section with ‘cohort profiles’, that includes detailed information on what was measured at different points in time in particular studies . Finally, we advise that authors declare all ‘candidate variables’ considered for statistical analysis, rather than selectively reporting only those included in the final models (see also item 16a).