 





|  |  |  |
| --- | --- | --- |
| Question number | Item | Information |
| 1 | Relevance | Can the research question be addressed with the database used? |
| 2 | Reliability and Validity | Have the reliability and validity of the data been described? Data cleaning/checking mentioned? |
| 3 | Linkages | Did the authors provide information on the merging of databases, if more than one database was used? |
| 4 | Eligibility | Have the authors described the type of data used to determine member eligibility? Mostly based on diagnosis. |
| 5 | Data analysis plan | Governmental or nonprofit funding imply a data analysis plan. An explicit statement is necessary in all other situations. |
| 6 | Design selection | Why did the authors chose for retrospective database research and not another research design? |
| 7 | Research design limitations | Did the authors mention potential research design limitations (often to be found in the limitation section)? |
| 8 | Treatment effect | N/A |
| 9 | Sample selection | Do the readers have a clear idea about who is included and who is excluded? Did the authors describe the steps to derive the final sample? |
| 10 | Eligibility | Is there any notion of the sample's coverage status? Coverage status can impact health care utilization. |
| 11 | Censoring | N/A |
| 12 | Operational definitions | e.g. what is a hospitalization? Which patients are meant with 'univentricular patients'? Etc.. |
| 13 | Definition validity | Did the authors provide a rationale for the definition or did they strenghten their decission with literature? E.g. 32nd Bethesda Conference. |
| 14 | timing of outcome | N/A |
| 15 | Event capture | Does the data capture all outcome information? E.g. hospitalization in a single center study: the patient can have been hospitalized in another hospital as well. |
| 16 | Disease history | N/A |
| 17 | Resource valuation | Applicable if the study reported costs. E.g. prices adjusted to a reference year, costs mentioned must match the choosen perspective. |
| 18 | Control variables | N/A |
| 19 | statistical model: rationale for model or method used | E.g. elaboration on why chi square has been used (little elaboration is sufficient). |
| 20 | Influential cases | E.g. results all cases versus results outliers? Or results with and without ASD/PFO. |
| 21 | Relevant variables | Did the authors consider a minimum of confounders (disease severity, age, sex, etc..)? |
| 22 | Testing statistical assumptions | Notion of testing for heterogeneity,Shapiro-Wilkon, etc..? |
| 23 | Multiple testing | If analyses of multiple groups are carried out, are the statistical tests adjusted to reflect this? Most studies take a p-value of 0.05 as cut-off, independent of how many tests are performed. |
| 24 | Model prediction | Applicable if the authors utilized multivariate statistical techniques. Did the authors mentioned R2, AIC, BIC to describe the model's fit? |
| 25 | Theoretical Basis (=link with literature) | Did the authors link their results with the existing literature? |
| 26 | Practical versus Statistical significance | Both adressed in the discussion section? Clinical and economical value. |
| 27 | Generalizability | Did the authors indicate on which population the results are applicable? |