Pediatrics Journal Club Literature Critique Form

**Article title and journal:**

**Study objectives:**

**Hypothesis:**

**Outcome measures (**dependent variables**):**

|  |  |
| --- | --- |
| MethodsDesign type \_ Observational  \_ Case-control \_ Cohort \_ Experimental \_ Cross-over \_ Other: \_\_\_\_\_\_\_\_\_\_ | Design features  Randomized no yes: Blinded no yes: (single or double) Prospective or Retrospective Controlled no yes : |

**Sample:** Number of data points or sample size (n) \_\_\_\_\_\_\_\_\_\_

Inclusion criteria:

Exclusion criteria:

Treatment (independent variables):

Sampling type: \_\_ convenience \_ consecutive \_ randomized \_ systematic \_\_other:

**Data type:** \_\_nominal (named ie yes, no) \_\_ordinal (ordered, numbers) \_\_\_interval (specific differences)

**Introduction**

Did the study address a clearly focused issue?

Is the reasoning for conducting the trial provided and appropriate?

Was the objective/hypothesis clearly stated and appropriate?

**Patient selection**

Describe each treatment group and indicate number (n) for each:

Did the protocol receive IRB approval? Did the subjects give informed consent?

Was the spectrum of patients representative of the population who will receive the test in practice?

Was the recruitment process described and appropriate?

Were selection criteria (inclusion/exclusion) clearly described and appropriate?

Could the selection of patients have introduced bias?

Where the groups similar at the start of the study?

Where the controls appropriate (placebo, active or historical controls . . .)?

**Study design and Method**

Did the authors use an appropriate method to answer their question?

Describe randomization, blinded vs open-labeled, design (parallel/crossover).

Are the population studied (are the groups well defined), intervention and outcomes well described and appropriate?

Is the sample large enough to produce significant results?

What are the limitations of the study design (unable to randomize or blind, limited experience of the provider/center, etc)?

If the study involves treatment, does the study clearly describe how, why and when treatment was modified between groups?

Are the groups treated equally aside from experimental interventions (the only difference is the study intervention)?

Is this a multicenter study? If so, are the results comparable for all sites?

**Statistics**

Was a power analysis done and appropriate?

What statistical analysis was used?

Are the statistics used appropriate for the data?

What are the confidence intervals? P values?

**Results**

Are potential sources of bias accounted for (e.g. selection bias)?

Are the results discussed consistent with data presented on tables/graphs? Are the results clearly presented?

Were the variables presented appropriate to answer the study question? Are there any variables that should have been included but were not?

Is the primary outcome well defined?

Were all the patients enrolled accounted for at the conclusion of the study (excluded, withdrawn, etc)?

Based on the study design, methodology, statistical power, etc, are the overall study effects due to the intervention? Could there be other factors influencing the results?

Does the study answer the question asked?

How could the study be redesigned to better answer the question asked?

Were adverse effects of treatment, limitations to the study, and intention to treat discussed?

**Conclusions**

Is the study biased?

Where the study results compared to similar previous trials?

Are conclusions supported by the data?

Are the benefits worth the potential harms and costs?

Were all clinically important outcomes considered?

Does it affect your practice?