

## **CRITICAL APPRAISAL OF AVAILABLE EVIDENCE**

From: "Introduction to evidence-based medicine" by M. Offringa, W.J.J. Assendelft and R.J.P.M. Scholten  
Checklists from the Cochrane library

ARTICLE: .....

### **SHORT DESCRIPTION OF STUDY**

Type of study (According to level of evidence)	1. a) Systematic review / meta-analysis ( <i>table I</i> ) b) Randomized controlled trial ( <i>table II</i> ) 2. a) Systematic review of cohort studies or case-control studies ( <i>table III</i> ) b) Cohort study or case-control study ( <i>table IV or V</i> ) c) "Outcome research" (i.e. descriptive study) 3. Patient series or case report 4. Expert opinion
Patients (and controls)	
Vaccination	
Medications used	
Primary outcome measures	
Secondary outcome measures	

### **VALIDITY** (see appendix table I-IV for validity assessment of included studies)

Is this study valid? Yes / Moderate / No (*including case reports and expert opinions*)

### **RELEVANCE**

Are results applicable to juvenile patients? Yes / Possible / No / Unknown

### **RESULTS**

Outcome safety	Patients: Controls: Influence medication:
Outcome immunogenicity	Patients: Controls: Influence medication:

### **CONCLUSION**

Safety:

Immunogenicity:

Influence medication:

Are the effects significant and relevant?:

## APPENDIX: TABLES FOR VALIDITY ASSESMENT

Table I

**VALIDITY (SYSTEMATIC REVIEW OF RANDOMISED CONTROLLED TRIALS)**

1	Is the research question properly formulated?	Yes / No / Unknown
2	Is the literature search accurate?	Yes / No / Unknown
3	Is the selection of literature accurate?	Yes / No / Unknown
4	Is the critical appraisal of included articles accurate?	Yes / No / Unknown
5	Is data extraction accurately described?	Yes / No / Unknown
6	Are important features of included trials accurately described?	Yes / No / Unknown
7	Is heterogeneity between studies handled accurately?	Yes / No / Unknown
8	Is statistical pooling correctly performed?	Yes / No / Unknown
Based on the above: <b>WAS THIS REVIEW VALID?</b>		Yes / Moderate / No

Remarks:

Table II

**VALIDITY (RANDOMISED CONTROLLED TRIAL)**

1	Was a method of randomisation performed?	Yes / No / Unknown
2	Was the treatment allocation concealed?	Yes / No / Unknown
3	Were the groups similar at baseline regarding important prognostic indicators?	- Yes - No, corrected in analysis - No, not corrected in analysis - Unknown
4	Were the groups, apart from the intervention, treated similarly?	Yes / No / Unknown
5	Were eligibility criteria specified?	Yes / No / Unknown
6	Was the outcome assessor blinded?	Yes / No / Unknown
7	Was the care provider blinded?	Yes / No / Unknown
8	Was the patient blinded?	Yes / No / Unknown
9	Was follow-up complete? (i.e <20% loss to follow-up)	Yes / No / Unknown
10	Were point estimates and variability measures presented for the primary outcome?	Yes / No / Unknown
11	Did the analysis include an intention-to-treat analysis?	Yes / No / Unknown
Based on the above: <b>WAS THIS STUDY VALID?</b>		Yes / Moderate / No

Remarks:

*Table III*

<b>VALIDITY (SYSTEMATIC REVIEW OF OBSERVATIONAL STUDIES)</b>		
1	Is the research question properly formulated?	Yes / No / Unknown
2	Is the literature search accurate?	Yes / No / Unknown
3	Is the selection of literature accurate?	Yes / No / Unknown
4	Is the critical appraisal of included articles accurate?	Yes / No / Unknown
5	Is data extraction accurately described?	Yes / No / Unknown
6	Are important features of included trials accurately described?	Yes / No / Unknown
7	Is the meta-analysis correctly performed?	Yes / No / Unknown
Based on the above: <b>WAS THIS REVIEW VALID?</b>		Yes / Moderate / No
Remarks:		

*Table IV*

<b>VALIDITY (COHORT STUDY)</b>		
1	Are the study groups clearly defined?	Yes / No / Unknown
2	Was selection bias sufficiently prevented?	Yes / No / Unknown
3	Was exposition to vaccination accurately measured?	Yes / No / Unknown
4	Were outcome measures clearly defined and accurately analyzed?	Yes / No / Unknown
5	Was outcome assessment blinded for exposition to vaccination?	Yes / No / Unknown
6	Was the follow-up period sufficient to measure outcome?	Yes / No / Unknown
7	Was selective loss-to-follow-up sufficiently prevented?	Yes / No / Unknown
8	Were important confounders identified and corrected for?	Yes / No / Unknown
Based on the above: <b>WAS THIS STUDY VALID?</b>		Yes / Moderate / No
Remarks:		

*Table V*

<b>VALIDITY (CASE CONTROL STUDY)</b>		
1	Was the patient group clearly defined?	Yes / No / Unknown
2	Was the control group clearly defined?	Yes / No / Unknown
3	Was selection bias sufficiently prevented?	Yes / No / Unknown
4	Was exposition to vaccination accurately measured?	Yes / No / Unknown
5	Was exposition to vaccination assessed blinded for disease status?	Yes / No / Unknown
6	Were important confounders identified and corrected for?	Yes / No / Unknown
Based on the above: <b>WAS THIS STUDY VALID?</b>		Yes / Moderate / No