

Appendix B – Data extraction form, level and grading of evidence tables

Table B1: Checklist for appraising the quality of studies of interventions*

<p>Box 6.1</p> <p>Checklist for appraising the quality of studies of interventions*</p> <p>1. Method of treatment assignment</p> <p>a. Correct, blinded randomisation method described OR randomised, double-blind method stated AND group similarity documented</p> <p>b. Blinding and randomisation stated but method not described OR suspect technique (eg allocation by drawing from an envelope)</p> <p>c. Randomisation claimed but not described and investigator not blinded</p> <p>d. Randomisation not mentioned</p> <p>2. Control of selection bias after treatment assignment</p> <p>a. Intention to treat analysis AND full follow-up</p> <p>b. Intention to treat analysis AND <15% loss to follow-up</p> <p>c. Analysis by treatment received only OR no mention of withdrawals</p> <p>d. Analysis by treatment received AND no mention of withdrawals OR more than 15% withdrawals/loss-to-follow-up/post-randomisation exclusions</p> <p>3. Blinding</p> <p>a. Blinding of outcome assessor AND patient and care giver</p> <p>b. Blinding of outcome assessor OR patient and care giver</p> <p>c. Blinding not done</p> <p>4. Outcome assessment (if blinding was not possible)</p> <p>a. All patients had standardised assessment</p> <p>b. No standardised assessment OR not mentioned</p> <p><small>*Source: modified from I Chalmers, Cochrane Handbook; available on the Cochrane Library CDROM</small></p>

*Source: National Health and Medical Research Council (NHMRC). How to review the evidence: systematic identification and review of the scientific literature. Canberra: NHMRC, 1999: p.45

Table B2: Classifying size of the effect*

Ranking	Clinical importance of benefit
1	A clinically important benefit for the full range of plausible estimates The confidence limit closest to the measure of no effect (the 'null') rules out a clinically unimportant effect of the intervention
2	The point estimate of effect is clinically important BUT the confidence interval includes clinically unimportant effects
3	The confidence interval does not include any clinically important effects
4	The range of estimates defined by the confidence interval includes clinically important effects BUT the range of estimates defined by the confidence interval is also compatible with no effect, or a harmful effect

* Source: National Health and Medical Research Council (NHMRC). How to use the evidence: assessment and application of scientific evidence. Canberra: NHMRC, 2000: p.23.

Table B3: Classifying the relevance of the evidence*

Ranking	Relevance of the evidence
1	Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.
2	Evidence of an effect on a surrogate outcome that has been shown to be predictive of patient-relevant outcomes for the same intervention.
3	Evidence of an effect on proven surrogate outcomes but for a different intervention.
4	Evidence of an effect on proven surrogate outcomes but for a different intervention and population.
5	Evidence confined to unproven surrogate outcomes.

* Source: National Health and Medical Research Council (NHMRC). How to use the evidence: assessment and application of scientific evidence. Canberra: NHMRC, 2000: p.28.

Table B4: NHMRC Levels of evidence for intervention studies*

Intervention	Level of evidence
A systematic review of level II studies	I
A randomised controlled trial (RCT)	II
A pseudo-randomised controlled trial (eg. alternate allocation or some other method)	III-1
A comparative study with concurrent controls: <ul style="list-style-type: none"> • Non-randomised, experimental trial • Cohort study • Case-control study • Interrupted time series with a control group 	III-2
A comparative study without concurrent controls: <ul style="list-style-type: none"> • Historical control study • Two or more single arm study • Interrupted time series without a parallel control group 	III-3
Case series with either post-test or pre-test/post-test outcomes	IV

* Source: NHMRC Additional levels of evidence and grades for recommendations for developers of guidelines. Pilot program 2005. NHMRC, 2005 (<http://www.nhmrc.gov.au/consult/index.htm>).

Table B5: Grades of recommendations*

Grade of recommendation	Description
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

* Source: NHMRC Additional levels of evidence and grades for recommendations for developers of guidelines. Pilot program 2005. NHMRC, 2005 (<http://www.nhmrc.gov.au/consult/index.htm>).

Table B6. The data extraction form used in this review*

STUDY DETAILS				
Reference:				
Affiliation/source of funds:				
Study design:		Location/setting:		
Intervention: Sample size		Comparator: Sample size		
Patient characteristics:				
Length of follow-up:		Outcomes measured:		
INTERNAL VALIDITY				
Allocation concealment:	Comparison of study groups:	Blinding:	Treatment/measurement bias:	Large scale safety study:
Overall quality assessment (descriptive):				

RESULTS				
Safety outcome measures:	Intervention group (n/N)	Control group (n/N)	Measure of effect/effect size (95% CI)	
Efficacy outcome measures:	Intervention group (n/N)	Control group (n/N)	Measure of effect/effect size (95% CI)	

Clinical importance of all above outcomes:	Relevance of all above outcomes:
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EXTERNAL VALIDITY
Generalisability:
Applicability:
Comments

*Data extraction forms for each included study are available on request from <http://immunise.health.gov.au/>