

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

Table B1. 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:		
EXTERNAL VALIDITY				
Generalisability:				
Applicability:				
Comments				

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

Study quality was assessed using a descriptive approach based on the following criteria (from ‘Minimum requirements for formulating NHMRC evidence-based guidelines’):

INTERNAL VALIDITY (QUALITY ASSESSMENT)

Enter the following details about the study:

Allocation: The method used to assign patients to treatment or control groups (eg. coin toss, random number table, computer-generated random numbers, sealed envelopes). Also indicate whether the allocation list was concealed (eg. computerised random number generation, administered from a central trial office, assigned locally)

Comparison of groups: The results of the group analysis, noting any clinically or statistically significant differences between the groups at study inception

Blinding: Whether the participants, outcome assessors and (if different) investigators were blinded to the group allocation

Maintenance/treatment: Indicate whether, aside from the experimental treatment, the groups were treated and measured the same

Follow up: The proportion of participants that were followed up and whether all participants were analysed according to the group to which they were initially allocated, regardless of whether or not they dropped out, fully complied with the treatment, or crossed over and received the other treatment (‘intention to treat analysis’ – ITT)

Overall: Describe your assessment (in words) of the overall quality of the study. Is the study quality good enough that you have confidence in the results?

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>).