

Safety and effectiveness of acellular pertussis vaccination during pregnancy: a systematic review

Additional file 1:

Figure S1: Systematic review on safety and effectiveness of pertussis vaccination in pregnancy; flowchart selection of included studies

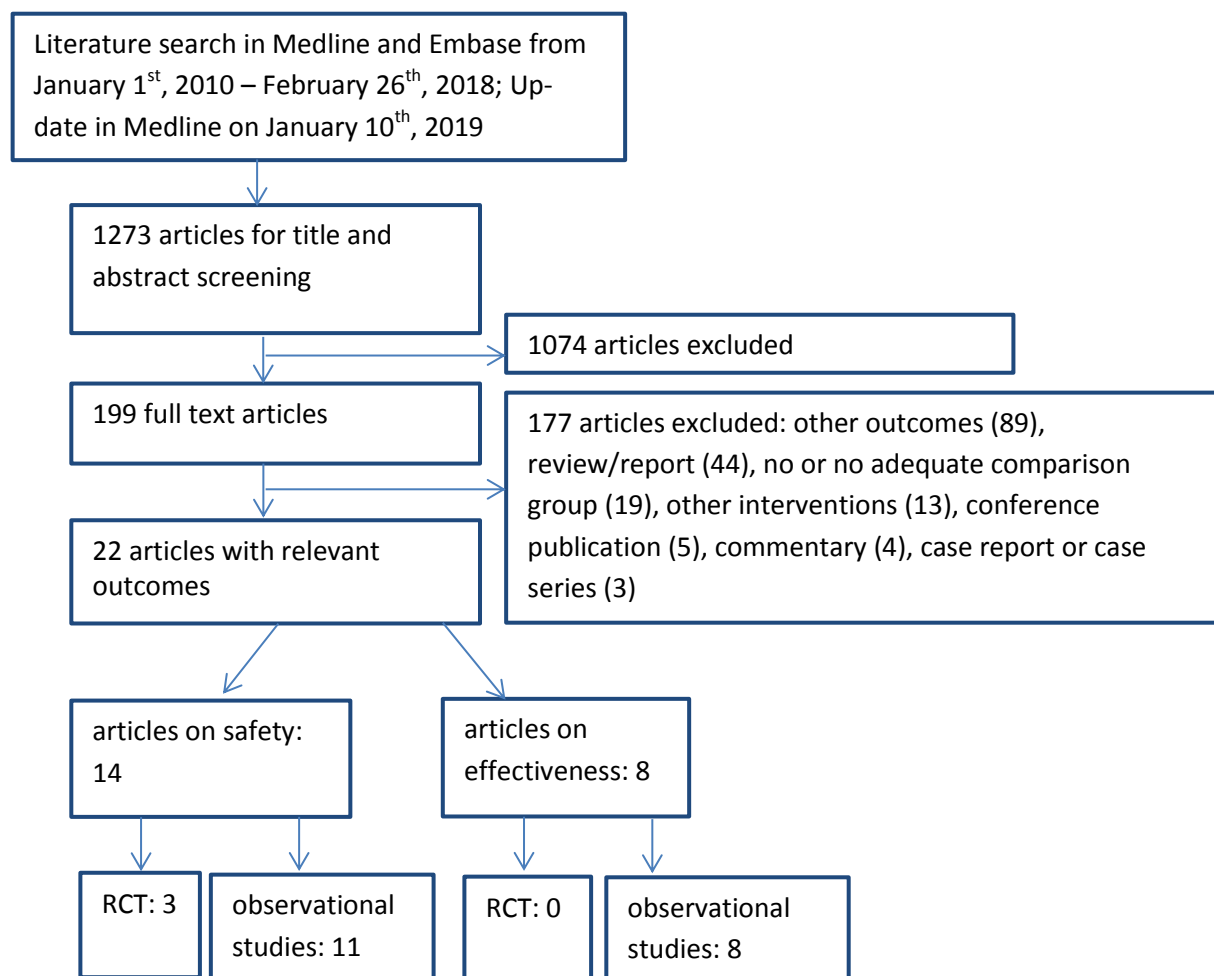


Table S1: Systematic review on safety and effectiveness of pertussis vaccination in pregnancy; excluded studies

Reason for exclusion: other outcomes (n=89)
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Reason for exclusion: review/report (n=44)
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Table S2: Systematic review on safety and effectiveness of pertussis vaccination in pregnancy; results of the risk of bias (ROB) assessment in studies on safety and effectiveness outcomes

ROB for safety outcomes

RCTs (Cochrane ROB tool)	Sequence generation	Allocation concealment	Blinding	Selective outcome reporting	Incomplete outcome	Other sources of bias	Summary	
Hoang et al., 2016 [1]	moderate	unclear	unclear	unclear	unclear	high	high	
Munoz et al., 2014 [2]	low	low	low	low	low	low	low	
Halperin et al., 2018 [3]	low	low	low	low	low	moderate	moderate	
Observational studies (Robins-I tool)	Bias due to confounding	Bias in selection of participants into the study/analysis	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of reported result	Summary
Berenson et al., 2016 [4]	serious	serious	serious	serious	serious	serious	moderate	serious
DeSilva et al., 2016 [5]	serious	serious	serious	moderate	serious	moderate	moderate	serious
DeSilva et al., 2017 [6]	serious	serious	serious	low	serious	serious	moderate	serious
Donegan et al., 2014 [7]	critical	serious/critical	moderate/serious	moderate/serious	serious	moderate	moderate	critical
Griffin et al., 2018 [8]	serious	moderate	serious	low	moderate	serious	low	serious
Kharbanda et al., 2014 [9]	serious	serious	serious	low	serious	serious	moderate	serious
Kharbanda et al., 2016 [10]	critical	critical	moderate	low	serious	moderate	serious	critical
Layton et al., 2017 [11]	serious	serious	moderate	serious	low	serious	moderate	serious
Maertens et al., 2016 [12]	critical	serious	serious	serious	serious	serious	low	critical
Morgan et al., 2015 [13]	serious	moderate	moderate	low	low	moderate	mod./serious	serious
Shakib et al., 2013 [14]	serious	serious	unclear	low	low	moderate	moderate	serious

ROB for effectiveness outcomes

Observational studies (Robins-I tool)	Bias due to confounding	Bias in selection of participants into the study/analysis	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of reported result	Summary
Amirthalingam et al., 2014 [15]	serious	moderate	low	low	low	low	low	serious
Amirthalingam et al., 2016 [16]	serious	unclear	low	low	low	low	low	serious
Baxter et al., 2017 [17]	moderate	unclear	low	low	unclear	low	low	moderate
Becker-Dreps et al., 2018 [18]	serious	moderate	moderate	low	low	moderate/serious*	moderate	serious
Bellido-Blasco et al., 2017 [19]	moderate	moderate	low	low	low	low	low	moderate
Dabrera et al., 2018 [20]	serious	moderate	low	low	unclear	low	low	serious
Saul et al., 2017 [21]	moderate	moderate	low	low	moderate	low	low	moderate
Skoff et al., 2017 [22]	moderate	serious	low	low	moderate	low	low	serious

*serious for "pertussis", moderate for "inpatient pertussis"

Table S3: Systematic review on safety and effectiveness of pertussis vaccination in pregnancy; GRADE Evidence profile

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias (ROBINS-I for NRS)	Inconsistency	Indirectness	Imprecision	Other considerations	Pertussis vaccination during pregnancy	No vaccination	Relative (95% CI)	Absolute		
VE: Pertussis in infants <3 months (cohort studies) (assessed with: lab-confirmed pertussis)												
1 (Amirthalingam et al., 2016 [16])	observational study	serious ¹	no serious inconsistency	no serious indirectness	no serious imprecision	none	35/243 (14.4%)	49327/72538 (68%) ²	VE 91 (88 to 96)	0 more per 1000 (from 1000 more to 1000 more) ³	⊕⊕○○ LOW	CRITICAL
VE: Pertussis in infants <3 months (case-control studies) (assessed with: lab-confirmed pertussis)												
2 (Bellido-Blasco et al. [19], 2017 [19]; Saul et al., 2017 [21])	observational studies	moderate ⁴	serious ⁵	no serious indirectness	no serious imprecision	none	70 cases 114 controls		VE ranged from 69 to 91	-	⊕⊕○○ LOW	CRITICAL
								0%		-		
VE: Hospitalization (timing of exposure 3 months; assessed with: lab-confirmed pertussis)												
1 ⁶ (Saul et al., 2017 [21])	observational study	moderate	no serious inconsistency	no serious indirectness	no serious imprecision	none	37 cases 37 controls		VE 94 (59 to 99)	-	⊕⊕⊕○ MODERATE	CRITICAL
								0%		-		
VE: Pertussis related death during first year of life (assessed with: lab. confirmed pertussis)												
1 (Amirthalingam et al., 2016 [16])	observational study	serious ¹	no serious inconsistency	no serious indirectness	no serious imprecision	none	1/11 (9.1%)	158/232 (68.1%)	VE 95 (79 to 100)	1000 more per 1000 (from 1000 more to 1000 more)	⊕⊕○○ LOW	CRITICAL

Fever >38°C after vaccination (assessed with: medically attended fever in 3 days post vaccination)												
1 ⁷ (Kharbanda et al., 2016 [10])	observational studies	serious ⁸	no serious inconsistency	no serious indirectness	no serious imprecision	none	15/53885 (0.03%)	6/109253 (0.005%)	RR 2.16 (1.7 to 2.8) ⁹	64 more per 1,000,000 (from 38 more to 99 more)	⊕⊕OO LOW	IMPORTANT
							alternative scenarios:	double the observed risk: 0.010%		116 more per 1,000,000 (from 70 more to 180 more)		
								Four times the observed risk: 0.02%		232 more per 1,000,000 (from 140 more to 360 more)		
Preterm birth (assessed with: <37 weeks of gestation)												
3 ¹⁰ (Kharbanda et al., 2014 [9]; Berenson et al., 2016 [4]; Griffin et al., 2018 [8])	observational studies	serious ¹¹	no serious inconsistency	no serious indirectness	serious ¹²	none	-	0%	RR ranged from 0.68 to 1.03	-	⊕OOO VERY LOW	CRITICAL
Stillbirth												
4 (Berenson et al., 2016 [4]; Donegan et al., 2014 [7]; Morgan et al. [13], 2015 ; Shakib et al., 2013 [14])	observational studies	serious ¹³	no serious inconsistency	no serious indirectness	no serious imprecision	none	-	-	RR ranged from 0.36 to 0.85	-	⊕⊕OO LOW	CRITICAL
								0%		-		
Pre-eclampsia (assessed with varying definitions)												
2 ¹⁴ (Kharbanda et al., 2014 [9]; Layton et al., 2017 [11])	observational studies	serious	no serious inconsistency	no serious indirectness	no serious imprecision	none	-	-	RR ranged from 0.96 to 1.09	-	⊕⊕OO LOW	CRITICAL
								0%		-		
Low birth weight (assessed with: <2500g)												
1 ¹⁵ (Berenson et al., 2016)	observational	serious	no serious	no serious	no serious	none	61/1109	59/650	RR 0.76 (0.51 to	22 fewer per 1000 (from 44	⊕⊕OO	CRITICAL

[4])	study		inconsistency	indirectness	imprecision		(5.5%)	(9.1%)	1.14)	fewer to 13 more)	LOW	
							alternative scenarios:	5%		12 fewer per 1000 (from 25 fewer to 7 more)		
								15%		36 fewer per 1000 (from 74 fewer to 21 more)		
Chorioamnionitis (assessed with: ICD9, ICD10, others)												
6 ¹⁶ (Kharbanda et al., 2014 [9]; Berenson et al., 2016 [4]; Layton et al., 2017 [11]; Griffin et al., 2018 [8]; DeSilva et al., 2017 [6]; Morgan et al., 2015 [13])	observational studies	serious ¹³	no serious inconsistency	no serious indirectness	no serious imprecision	none	637/11351 (5.6%)	5329/97265 (5.5%)	RR ranged from 1.1 to 1.53	-	⊕⊕○○ LOW	IMPORTANT
Malformations (assessed with: varying definitions)												
2 ^{15,17} Berenson et al., 2016 [4]; DeSilva et al., 2016 [5])	observational studies	serious ¹³	no serious inconsistency	no serious indirectness	no serious imprecision	none	-	-	RR ranged from 0.8 to 0.98	-	⊕⊕○○ LOW	CRITICAL
								0%		-		
NIC (assessed with: NICU admission in 30 days post-delivery or not defined)												
1 (Layton et al., 2017 [11])	observational study	serious ¹³	no serious inconsistency	no serious indirectness	no serious imprecision	none	6996/80217 (8.7%)	42904/543906 (7.9%)	RR 1.0 (0.97 to 1.03)	0 fewer per 1000 (from 2 fewer to 2 more)	⊕⊕○○ LOW	CRITICAL
							alternative scenarios:	3%		0 fewer per 1000 (from 1 fewer to 1 more)		
								10%		0 fewer per 1000 (from 3 fewer to 3 more)		

Neonatal death (assessed with: Neonatal death within 7 days of delivery or not defined)												
2 (Morgan et al., 2015 [13]; Donegan et al., 2014 [7])	observational studies	very serious ¹⁸	serious ¹⁹	no serious indirectness	no serious imprecision	none	-	-	RR ranged from 0.16 to 1	-	⊕○○○ VERY LOW	CRITICAL
								0%		-		
Sepsis												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

¹ Use of screening method for calculation of VE; serious ROB

² Crude estimate only, because screening method was used.

³ Cannot be calculated since screening method was used

⁴ Both rated as moderate RoB.

⁵ Wide range of effect estimates in the studies

⁶ Case-control study with lowest risk of bias (Saul et al.) was used here. One additional case-control study (Skoff et al.) and one cohort study (Becker-Dreps et al.) had higher risk of bias.

⁷ Largest cohort study with control group for this outcome (based on VSD data; Kharbanda, 2016)

⁸ RoB was rated serious because only an unadjusted estimate was reported.

⁹ Crude ratio effect estimate (95% CI); authors do not present adjusted results, only for composite outcome

¹⁰ Three cohort studies (Kharbanda et al., Berenson et al., Griffith et al.) with confounder-adjusted estimates.

¹¹ All 3 were rated serious risk of bias.

¹² Adjusted effects varied and partly included 1.0

¹³ Serious RoB in all studies due to various categories

¹⁴ Three cohort studies reported confounder-adjusted estimates.

¹⁵ One study with plausible background rate and confounder-adjusted estimate.

¹⁶ 5 cohort studies reported confounder-adjusted estimates.

¹⁷ Two studies with confounder-adjusted estimates.

¹⁸ Only crude estimates reported.

¹⁹ very low case numbers, very wide 95% CIs

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