

## **Supplemental Material: Systematic Review of Published Meta-Analyses of Vaccine Safety**

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# Systematic Review of Published Meta-Analyses of Vaccine Safety

## Supplemental Material

S1. Data extracted from the publications.

The following variables were extracted from the papers and were recorded in an excel spreadsheet.

Table S1. Data extracted from the publications.

<b>Variable</b>	<b>Description</b>
<b>ID</b>	Unique identification number
<b>Author</b>	First author's last name
<b>YearPubl</b>	Year of publication
<b>Citation</b>	Article citation
<b>MASafety</b>	Was Meta-analysis of Safety conducted?
<b>SystRevSaf</b>	Was Systematic Review of Safety conducted?
<b>Included</b>	Does the study satisfy the inclusion criteria?
<b>RCTonly</b>	Does the Meta-analysis include only RCT?
<b>NonRCTIncl</b>	Were non-RCT studies, such as observational studies, included?
<b>IPDMA</b>	Is the Meta-analysis Individual Participant Data (IPD) Meta-analysis?
<b>Vaccine</b>	Vaccine (descriptive) that was studied
<b>VaccineClass</b>	Vaccine (brief) class. E.g. Influenza, HPV, etc.
<b>Control</b>	What was the control group (if any) in the studies included in the Meta-analysis /review?

<b>PopulDesc</b>	Description of the population
<b>PopulAge</b>	Population age
<b>SafetyOutcomes</b>	List of the safety outcomes that were evaluated
<b>AIIAE</b>	Was "Any AEs" a safety endpoint that was analyzed/reviewed?
<b>AIISAE</b>	Was "Any SAEs" a safety endpoint that was analyzed/reviewed?
<b>Reactogenicity</b>	Was Reactogenicity analyzed/reviewed in the publication?
<b>UnsolicitedAE</b>	Were Unsolicited AEs analyzed/reviewed in the publication?
<b>SpecificAE</b>	Was a specific AE, such as Guillain-Barré syndrome (GBS), abortion, etc. analyzed/reviewed?
<b>NInclStud</b>	Number of studies that were included in the Meta-analysis /Systematic review
<b>MAMethod</b>	Meta-analysis method(s) that was/were used
<b>RandomEffects</b>	Was the Random effects method for Meta-analysis used?
<b>FixedEffects</b>	Was the Fixed effects method for Meta-analysis used?
<b>OtherMethods</b>	Other (than random or fixed effects Meta-analysis) methods that were used
<b>Heterogen</b>	Was heterogeneity assessed?
<b>EffectType</b>	How was the effect defined?
<b>ReasonNoMA</b>	For publications that are not included, what is the reason(s) for not conducting Meta-analysis?

<b>Concern</b>	Was a safety concern (such as significant SAE) concluded?
<b>Quality</b>	What method was used (if any) for assessment of the quality of the included studies?

Abbreviations: AE – Adverse Events; SAE – Serious Adverse Events;

## S2. Included Publications Characteristics

Table S2. Select characteristics for each included publication.

Publication	RCTs only included	Vaccine	Population	Safety Outcomes	N Incl. Studies	Meta- Analysis Method
Vadlamudi et al. (2019)	Yes	PCV13	Adults age>50	local AEs; systemic AEs; all cause mortality	5	random effects
Arbyn et al. (2018)	Yes	HPV; HPV2; HPV4	Young women (ages 15-26) or mid-adult (ages 24-45)	local AEs; systemic; SAE; deaths; pregnancy outcomes	26	random effects
Badurdeen et al. (2019)	No	BCG vaccine (given <=7 days after birth)	Infants who Are preterm and/or have low birth weight	local AEs; systemic AEs; mortality	7	random effects ( Mantel- Haenszel*)
Genovese et al. (2018)	No	HPV2; HPV4	Children; Adults (ages 9- 26)	Autoimmune diseases	6	random effects; fixed effects
Tricco et al. (2018)	Yes	herpes zoster live attenuated vaccine	Adults (age>50)	local AEs; systemic AEs; SAE; withdrawal as a	11	Bayesian MA; Network MA;

				result of AE; pIMD; deaths		random effects
Zheng et al. (2018)	Yes	Adjuvanted H7N9 influenza vaccines	Healthy Adults (≥18)	local AEs; systemic AEs	6	Mantel- Haenszel fixed effects
Baay et al. (2018)	Yes	vaccines using the adjuvants AS01, AS02, AS03, or MF59	Adults (age>50)	local AEs; systemic AEs; SAE; unsolicited AE; pIMD; deaths	24	random effects
Mouchet et al. (2018)	No	HPV	Children; Adults	central demyelination; multiple sclerosis, optic neuritis or GBS	10	inverse variance random effects model
Mulley et al. (2018)	No	All vaccines against infectious pathogens	Solid-organ transplant recipients	de novo donor- specific anti- human leukocyte antibodies; allograft rejection; allograft loss	9	random effects
Yin et al. (2018)	No	2-dose varicella vaccine/MMR V	Healthy children	local AEs; systemic AEs	6	random effects; Mantel- Haenszel

						fixed effects
Flacco et al. (2018)	Yes	multicomponent meningococcal serogroup B vaccine (4CMenB)	Children; Adolescents	local AEs, systemic AEs, mild-to-moderate AEs, SAE	16	random effects; individual data random effect logistic regression
Xu et al. (2018)	Yes	Staphylococcus aureus vaccines (S. aureus four-antigen (SA4Ag) and three-antigen (SA3Ag) vaccines)	Adults	local AEs; systemic AEs; severe local reactions; severe systemic reactions	3	fixed effects; random effects
Malisheni et al. (2017)	Yes	Live Attenuated Tetravalent Dengue vaccine (CYD-TDV)	Children	Immediate AEs; SAE; local AEs; systemic AEs; unsolicited AEs	7	random effects; fixed effects
Costa et al. (2017)	Yes	HPV9 vaccine	Women	local AEs; systemic AEs	3	fixed effects;

						random effects
Ogawa et al. (2017)	Yes	HPV vaccine (2vHPV, 4vHPV or 9vHPV)	Women	local AEs; systemic AEs; Unsolicited symptoms	9	random effects (Mantel-Haenszel*)
Teo et al. (2017)	Yes	oral whole-cell mono-bacterial NTHi vaccine	Adults with COPD or chronic bronchitis	AEs; death	5	fixed effects; random effects (Mantel-Haenszel*)
Badawi et al. (2017)	Yes	Lyme disease vaccine	Adults	local AEs; Systemic AEs	7	random effects
Zhao et al. (2017)	Yes	Outer surface protein A (OspA) vaccine	All	local AEs; Systemic AEs	3	fixed effects; random effects
Velazquez et al. (2017)	Yes	RV5 (RotaTeq); RV1 (Rotarix)	Infants in Latin American countries	SAEs; death; intussusception	3	fixed effects (Mantel-Haenszel); random effects
Godoi et al. (2017)	Yes	dengue vaccine (Dengvaxia)	All in dengue endemic regions	local AEs; Systemic AEs; SAEs	9	random effects



Setiawan et al. (2017)	Yes	HPV vaccine	Women in Asian countries	local AEs; Systemic AEs	8	random effects
Ciapponi et al. (2016)	Yes	PCV10	Children (age<5)	local AEs; Systemic AEs; SAEs	4	Mantel-Haenszel fixed effects
Guo et al. (2016)	Yes	Pandemic Influenza H5N1 Avian Influenza vaccine (AIV)	Adults	local AEs; Systemic AEs	5	random effects (Mantel-Haenszel)
Duan et al. (2017)	No	PCV in preterm infants	Infants	local AEs; Systemic AEs	4	fixed effects; random effects
Moa et al. (2016)	Yes	Inactivated Quadrivalent Influenza vaccine (QIV)	Adults	local AEs; Systemic AEs	4	random effects (inverse variance weight)
Huang et al. (2016)	No	Influenza vaccine	Systemic lupus erythematosus (SLE) patients	local AEs; Systemic AEs;	11	random effects (inverse variance weight)

Bigaeva et al. (2016)	Yes	vaccines adjuvanted with QS-21 or ISCOMATRIX	Non-healthy subjects	local AEs; Systemic AEs;	9	random effects (Mantel-Haenszel*)
Liao et al. (2016)	No	Influenza vaccine	Systemic lupus erythematosus (SLE) patients	All AEs	6	fixed effects; random effects (Mantel-Haenszel*)
Stassijns et al. (2016)	Yes	adjuvanted vaccines using AS01, AS02, AS03, MF59	Infants; Children	local AEs; Systemic AEs; SAEs; unsolicited AEs; AEs of special interest (Convulsions; Meningitis)	26	random effects
Mansour-Ghanaei et al. (2016)	Yes	acellular pertussis vaccine (DTaP)	Children	All AEs	6	random effects; fixed effects
Ma et al. (2015)	Yes	MMRV vaccine	Children	local AEs; Systemic AEs; unsolicited AEs; SAEs	13	random effects; Mantel-Haenszel fixed effects

Pileggi et al. (2015)	Yes	intradermal Influenza vaccine	Immuno- compromised patients	local AEs; Systemic AEs	4	random effects (D- L); Mantel- Haenszel fixed effects
Polyzos et al. (2015)	No	Inactivated Influenza vaccine (trivalent or monovalent)	Maternal subjects	congenital malformations; major congenital defects	15	random effects (D- L)
Pileggi, Mascaro et al. (2015)	Yes	intradermal Influenza vaccine	Elderly subjects (age>=60)	local AEs; Systemic AEs	13	random effects (D- L); Mantel- Haenszel fixed effects
Li-Kim-Moy et al. (2015)	No	inactivated seasonal Trivalent Influenza Vaccine (TIV) administered intramuscular ly	Healthy Children	fever, febrile convulsions; SAEs	15	random effects (D- L)
Leung et al. (2015)	Yes	MMRV vaccine	Healthy Children	local AEs; Systemic AEs;	10	random effects; Mantel-

				rash; febrile seizure		Haenszel fixed effects
Wang et al. (2015)	Yes	JEV vaccines: JEV-I (PHK); JEV-I (Vero); JEV-L	Asia-Pacific area Infants; Children	AEs	6	random effects; fixed effects
Coelho et al. (2015)	Yes	HPV4	Children; Adults (ages 9- 26)	local AEs; Systemic AEs;	5	Mantel- Haenszel (fixed effects)
Li et al. (2014)	No	JEV vaccine	All	local AEs; Systemic AEs; AEs; Treatment- emergent AEs; SAEs	7	fixed effects; random effects
Bratton et al. (2015)	No	Influenza vaccine	Influenza vaccination during pregnancy or immediately prior to conception	spontaneous abortion; stillbirth	7	random effects (D- L)
Couto et al. (2014)	Yes	HPV	Women (age >16)	SAEs	14	fixed effects; random effects

						(Mantel-Haenszel*)
da Costa et al. (2014)	Yes	recombinant and tetravalent dengue vaccine (CYD-TDV)	Children; Adults	local AEs; Systemic AEs; SAEs; unsolicited AEs; unsolicited allergic reactions	7	fixed effects; random effects
Udell et al. (2013)	Yes	influenza vaccine	High risk population	major adverse cardiovascular events; cardiovascular mortality; all-cause mortality; other individual cardiovascular events	6	random effects (Mantel-Haenszel*) ; fixed effects; Yusuf-Peto
Ruiz-Aragon et al. (2013)	Yes	PCV13	Infants	local AEs; Systemic AEs	9	random effects (D-L)
Thompson et al. (2013)	Yes	PCV13	Infants; toddlers	local AEs; Systemic AEs; SAEs; AEs	13	mixed effects model with random treatment effect.

Salmon et al. (2013)	No	influenza A (H1N1) 2009 monovalent vaccine	All	GBS	6	self-controlled risk-interval design using Poisson distribution model
Marra et al. (2013)	Yes	intradermal Influenza vaccine	Adults	local AEs; Systemic AEs	13	random effects (inverse variance weight)
Bar-On et al. (2012)	Yes	DTP-HBV-HIB vaccine	Healthy infants (age <2 years)	local AEs; Systemic AEs; SAEs	18	fixed effects; random effects (Mantel-Haenszel)
Fabrizi et al. (2012)	Yes	adjuvanted HBV recombinant vaccine	Patients with chronic kidney disease	AEs	10	fixed effects; random effects (D-L)

Manzoli et al. (2011)	No	Pandemic Influenza A 2009 (H1N1) Vaccines	Healthy subjects	local AEs; Systemic AEs; SAEs	34	random effects; Mantel-Haenszel (fixed effects)
Beyer et al. (2011)	Yes	inactivated influenza vaccines: split virus vaccine (SPL); aqueous subunit vaccine (SU); virosomal subunit vaccine (VIR); or MF59-adjuvanted subunit vaccine (adjSU)	Primed populations	local AEs; Systemic AEs;	13	random effects (D-L)
Lu et al. (2011)	Yes	L1 VLP-based HPV vaccines	Non-pregnant women (ages 15-44)	SAEs; injection-related SAEs	7	fixed effects
Manzoli et al. (2009)	Yes	avian influenza A H5N1 vaccine	Healthy adults who had not been	local AEs; Systemic AEs;	13	random effects; Mantel-

			previously vaccinated with H5			Haenszel (fixed effects)
Beyer et al. (1998)	Yes	Influenza Subunit (SU) Vaccines	All	local AEs; Systemic AEs;	13	random effects (D-L)
Fraser et al. (2007)	Yes	Typhoid fever vaccines	Children; Adults	local AEs; Systemic AEs;	7	random effects
Rambout et al. (2007)	Yes	HPV vaccine	Women (ages 15-26)	SAEs; death	6	Peto OR fixed effects
Kretzschmar et al. (2006)	No	smallpox vaccine	All	postvaccinal encephalitis; death	12	Bayesian methods
Durier et al. (2006)	No	HIV lipopeptides vaccines	Adults	local AEs; Systemic AEs; SAEs	8	IPD logistic regression adjusted for factors
Jefferson et al. (2004)	No	aluminium-containing DTP vaccines	Children (age $\leq 16$ )	local AEs; Systemic AEs;	3	fixed effects; random effects
Engels et al. (1998)	No	Typhoid fever vaccines	All	local AEs; Systemic AEs; Missed school or work	10	random effects



Jefferson et al. (2003)	No	pertusis or DTP vaccine	Healthy individuals (age <=15)	local AEs; Systemic AEs;	11	Mantel-Haenszel; random effects; fixed effects; Peto OR for rare events
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\*Random effects (Mantel-Haenszel) refers to the random effects method based on the Mantel-Haenszel method implemented in the RevMan software by the Cochrane Collaboration.

Abbreviations: AE – Adverse Event; COPD - Chronic Obstructive Pulmonary Disease; DTP - diphtheria, pertussis, tetanus; GBS - Guillain-Barré syndrome; HBV – Hepatitis B Virus; HIB - Haemophilus influenzae type B; HIV - Human Immunodeficiency Virus; HPV – Human Papillomavirus; IPD – Individual Participant Data; JEV - Japanese encephalitis vaccine; MMRV - measles, mumps, rubella, varicella; NTHi - Nontypeable Haemophilus influenzae; OR – Odds Ratio; PCV - pneumococcal conjugate vaccine; pIMD - Potentially Immune Mediated Disease; RCT – Randomized Controlled Trial; SAE – Serious Adverse Events;

### S3. References of the included studies

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