Data Abstraction Form-Controlled Trials and Head-to-Head Cohort Comparisons

Study Details & Participation Information

Country

Study Design (CHECK ONE)

- Cohort study (comparing at least 2 cohorts)
- Controlled clinical trial
- Other (please specify)

Sample Size - Total

Length of follow-up

Mean Units

Range from to Units

Year study was conducted

to

Age

Mean Units

Range from to Units

Gender % Female

Pregnant Patients %

yes no

Trimester

First Second Third

Race and ethnicity (CHECK ALL THAT APPLY) %

White

Latino

Asian/PI

Black / African American

Native American

Other

Not reported

Medical Condition

- ☐ Asthma
- ☐ Cancer
- ☐ HIV
- ☐ Inflammatory Bowel Disease
- ☐ Lupus
- ☐ Multiple Sclerosis
- ☐ Premature babies
- ☐ Rheumatoid Arthritis
- ☐ Sickle Cell Anemia
- ☐ Transplant patients (Specific Type) _____
- ☐ Other 1 (Specify) _____
- ☐ Other 2 (Specify) _____
- ☐ None / not reported

Quality Assessment

McMaster Quality Assessment Scale for Harms (McHarm)	**RATING**
1. Were the harms PRE-DEFINED using standardized or precise definitions?	○ Yes ○ No ○ Unsure Clear Response
2. Were SERIOUS events precisely defined?	○ Yes ○ No ○ Unsure Clear Response

McMaster Quality Assessment Scale for Harms (McHarm)	RATING
3. Were SEVERE events precisely defined?	○ Yes ○ No ○ Unsure Clear Response
4. Were the number of DEATHS in each study group specified OR were the reason(s) for not specifying them given?	○ Yes ○ No ○ Unsure Clear Response
5. Was the mode of harms collection specified as ACTIVE?	○ Yes ○ No ○ Unsure Clear Response
6. Was the mode of harms collection specified as PASSIVE?	○ Yes ○ No ○ Unsure Clear Response
7. Did the study specify WHO collected the harms?	○ Yes ○ No ○ Unsure Clear Response
8. Did the study specify the TRAINING or BACKGROUND of who ascertained the harms?	○ Yes ○ No ○ Unsure Clear

McMaster Quality Assessment Scale for Harms (McHarm)	RATING
	Response
9. Did the study specify the TIMING and FREQUENCY of collection of the harms?	○ Yes ○ No ○ Unsure Clear Response
10. Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	○ Yes ○ No ○ Unsure Clear Response
11. Did the authors specify if the harms reported encompass ALL the events collected or a selected SAMPLE?	○ Yes ○ No ○ Unsure Clear Response
12. Was the NUMBER of participants that withdrew or were lost to follow-up specified for each study group?	○ Yes ○ No ○ Unsure Clear Response
13. Was the TOTAL NUMBER of participants affected by harms specified for each study arm?	○ Yes ○ No ○ Unsure Clear Response
14. Did the author(s) specify the NUMBER for each TYPE of harmful event for each study group?	○ Yes ○ No ○ Unsure

McMaster Quality Assessment Scale for Harms (McHarm) **RATING**

Clear Response

15. Did the author(s) specify the type of analyses undertaken for harms data?

- Yes
- No
- Unsure

Clear Response

Vaccine Group 1

Sample Size

Enter all that apply:

- DTap
- Haemoph. Influen. type b (Hib) protein conjugate
- Hepatitis A
- Hepatitis B
- Human papillomavirus (HPV)
- Influenza (inactived)
- Influenza (live)
- Influenza - monovalent H1N1
- Measles, mumps, rubella (MMR)
- Meningococcal conjugate
- Meningococcal polysaccharide
- Pneumococcal conjugate (PC7 vs PCV13)
- Pneumococcal polysaccharide PSV23 – (23-valent polysaccharide

vaccines)

- ☐ Polio (inactivated only)
- ☐ Rotavirus
- ☐ RotaTeq (RVS)
- ☐ Rotarix (RV1) (also known as RIX4414)
- ☐ Td
- ☐ Tdap
- ☐ Varicella
- ☐ Zoster
- ☐ Routine Vaccines
- ☐ Other Vaccine (please specify)

Brand Name(s)

Manufacturer

Age

Units

to

Formulation

Dose 1 *Timing* *Units* *Dosage* *Units*

Dose 2 *Timing* *Units* *Dosage* *Units*

Dose 3 *Timing* *Units* *Dosage* *Units*

Dose 4 *Timing* *Units* *Dosage* *Units*

Dose 5 *Timing* *Units* *Dosage* *Units*

Adjuvants

- ☐ ASO 4
- ☐ Aluminum
- ☐ Adjuvant Free
- ☐ Not reported
- ☐ Other

Preservatives

- ☐ Thimerisol
- ☐ Phenol
- ☐ Preservative Free
- ☐ Not reported
- ☐ Other

Delivery route

- ☐ Intradermal
- ☐ Intramuscular
- ☐ Intravenous
- ☐ Intranasal
- ☐ Oral
- ☐ Other (please specify)

Adverse Events

Adverse Event	#	%	System Category	Severity
# of patients with any AE				
Any Severe Adverse Event				

Adverse Event	#	%	System Category	Severity

Vaccine Group 2

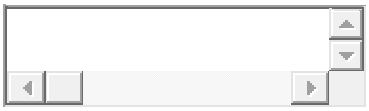
Sample Size

Enter all that apply:

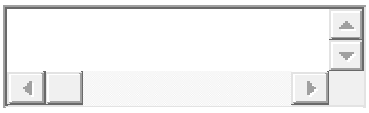
- ☐ DTap
- ☐ Haemoph. Influen. type b (Hib) protein conjugate
- ☐ Hepatitis A

- ☐ Hepatitis B
- ☐ Human papillomavirus (HPV)
- ☐ Influenza (inactived)
- ☐ Influenza (live)
- ☐ Influenza - monovalent H1N1
- ☐ Measles, mumps, rubella (MMR)
- ☐ Meningococcal conjugate
- ☐ Meningococcal polysaccharide
- ☐ Pneumococcal conjugate (PC7 vs PCV13)
- ☐ Pneumococcal polysaccharide PSV23 – (23-valent polysaccharide vaccines)
- ☐ Polio (inactivated only)
- ☐ Rotavirus
- ☐ RotaTeq (RVS)
- ☐ Rotarix (RV1) (also known as RIX4414)
- ☐ Td
- ☐ Tdap
- ☐ Varicella
- ☐ Zoster
- ☐ Routine Vaccines
- ☐ Other Vaccine (please specify)

Brand Name(s)



Manufacturer

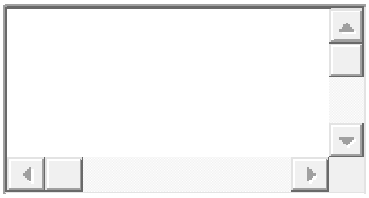


Age

Units

to

Formulation



Dose 1 *Timing* *Units* *Dosage* *Units*

Dose 2 *Timing* *Units* *Dosage* *Units*

Dose 3 *Timing* *Units* *Dosage* *Units*

Dose 4 *Timing* *Units* *Dosage* *Units*

Dose 5 *Timing* *Units* *Dosage* *Units*

Adjuvants

ASO 4

- ☐ Aluminum
- ☐ Adjuvant Free
- ☐ No reported
- ☐ Other

Preservatives

- ☐ Thimerisol
- ☐ Phenol
- ☐ Preservative Free
- ☐ Not reported
- ☐ Other

Delivery route

- ☐ Intradermal
- ☐ Intramuscular
- ☐ Intravenous
- ☐ Intranasal
- ☐ Oral
- ☐ Other (please specify)

Adverse Events

Adverse Event	#	%	System Category	Severity
# of patients with any AE				
Any Severe Adverse Event				

Adverse Event	#	%	System Category	Severity

Adverse Event	#	%	System Category	Severity

Vaccine Group 3

Sample Size

Enter all that apply:

- ☐ DTap
- ☐ Haemoph. Influen. type b (Hib) protein conjugate
- ☐ Hepatitis A
- ☐ Hepatitis B
- ☐ Human papillomavirus (HPV)
- ☐ Influenza (inactived)
- ☐ Influenza (live)
- ☐ Influenza - monovalent H1N1
- ☐ Measles, mumps, rubella (MMR)
- ☐ Meningococcal conjugate
- ☐ Meningococcal polysaccharide
- ☐ Pneumococcal conjugate (PC7 vs PCV13)
- ☐ Pneumococcal polysaccharide PSV23 – (23-valent polysaccharide vaccines)
- ☐ Polio (inactivated only)
- ☐ Rotavirus
- ☐ RotaTeq (RVS)
- ☐ Rotarix (RV1) (also known as RIX4414)

☐ Td

☐ Tdap

☐ Varicella

☐ Zoster

☐ Routine Vaccines

☐ Other Vaccine (please specify)

Brand Name(s)

Manufacturer

Age

Units

to

Formulation

Dose 1 *Timing* *Units* *Dosage* *Units*

Dose 2 *Timing* *Units* *Dosage* *Units*

Dose 3 *Timing* *Units* *Dosage* *Units*

Dose 4 *Timing* *Units* *Dosage* *Units*

Dose 5 *Timing* *Units* *Dosage* *Units*

Adjuvants

- ☐ ASO 4
- ☐ Aluminum
- ☐ Adjuvant Free
- ☐ No reported
- ☐ Other

Preservatives

- ☐ Thimerisol
- ☐ Phenol
- ☐ Preservative Free
- ☐ Not reported
- ☐ Other

Delivery route

- ☐ Intradermal
- ☐ Intramuscular
- ☐ Intravenous

☐ Intranasal

☐ Oral

☐ Other (please specify)

Adverse Events

Adverse Event	#	%	System Category	Severity
# of patients with any AE				
Any Severe Adverse Event				

Adverse Event	#	%	System Category	Severity

"Unvaccinated" Comparison Group

Sample Size

☐ Placebo

☐ Routine Vaccines

☐ Nothing

☐ Other (please specify)

If Placebo, does it include the same adjuvants, preservatives, formulations as the active group?

☐ Yes

☐ No

(if no, please specify)

☐ Unsure

Adverse Events

Adverse Event	#	%	System Category	Severity
# of patients with any AE				
Any Severe Adverse Event				

Adverse Event	#	%	System Category	Severity

COMMENTS / NOTES: