

## **Vaccine Safety Full-Text Inclusion Screening**

### **Background:**

- Very important background paper (REFERENCE MINE BELOW, HIT SUBMIT)
- Mechanistic study (REFERENCE MINE BELOW, HIT SUBMIT)

### **Excludes:**

- Exclude-Participants (animal or in-vitro study) -
- Exclude-Outcome (no information on presence or absence of AE)
- Exclude-Language (not English)
- Exclude-Design, (no comparison of interest, case report, case series)
- Exclude-Other
- Exclude-Conference Abstract
- Exclude-Already included in IOM report
- Exclude- IOM exclusion

### **Needs Discussion** (bring to meeting)

- ENTER REASON, THEN SUBMIT

**Special interest studies where all groups were vaccinated (if one group got only "routine vaccines" go to next bold item)**

**\*We were going to research these issues of special interest to the TEP, but were unable due to resource constraints\***

- Pregnant women vs non-pregnant group
- High dose influenza vs other dose, in elderly
- Interdermal vs intramuscular administration of influenza vaccine
- Pneumococcal conjugate vaccine 13 (PCV13) vs Pneumococcal conjugate vaccine 7 (PCV7)
- Inactivated polio vaccine (IPV) vs Oral polio vaccine (OPV)
- Live attenuated influenza vaccine (LAIV) vs Trivalent influenza vaccine (TIV)
- Tetanus, diphtheria, acellular pertussis (Tdap) vs Tetanus, diphtheria (Td)
- Meningococcal conjugate vaccine (MCV4) vs meningococcal polysaccharide vaccine five (MPSV)
  
- Study of vaccine group vs. unvaccinated (or "routine vaccines") group (controlled trials, cohort studies comparing two groups)**
- Multivariate risk factor study (simultaneously analyzing more than 1 risk factor), case-control study (people with AE versus not), and self controlled studies**

**Vaccines**

**(Study with human participants)**

- DTaP
- Haemoph. Influen. type b (Hib)
- Hepatitis A
- Hepatitis B

- Human papillomavirus (HPV)
- Influenza (inactivated)
- Influenza (live)
- Measles, mumps, rubella (MMR)
- Meningococcal conjugate
- Meningococcal polysaccharide
- Pneumococcal conjugate
- Pneumococcal polysaccharide
- Polio (inactivated only)
- Rotavirus
- Td
- Tdap
- Varicella
- Zoster
- None of the above (REJECT)

**Population (check all that apply)**  
**(Study with human participants)**

- Children (under age 12)
- Adolescents (12-18)
- Adults

- Elderly (65 and up)
- Immunocompromised only
- Pregnant

**Calculated Exclusion (Vaccine and Population Combination)**

- Exclude - No Relevant Groups (STOP SCREENING, HIT SUBMIT)
- Include - At least one relevant group

**Vague:** Vague Study with no information which adverse event was assessed (“safe”, “no AE occurred”)

- Vague

**NOTES:**

(i.e. where are the safety data if not in the results, special concerns):



**Reference Mining:**

- Which references should be ordered