Supplementary Table 1: Trials included in Hib conjugate vaccine review, detailed information

Study details	*Participant characteristics*	*Schedule A / schedule B / schedule C*	*Schedule A population characteristics*	*Schedule B population characteristics*	*Schedule C population characteristics*	*Outcomes*	
						Mortality	*Immunological*
Belgium[1]							
Location: Belgium **Recruitment dates:** October 1994 to March 1995 **Hib vaccine:** PRP-T, Act-HIB, Pasteur Mérieux Connaught **Pertussis vaccine:** aP (2 compontent), brand name not stated, Pasteur Mérieux, Connaught **Funding:** Pasteur Mérieux Connaught	**Inclusion criteria:** healthy infants, Belgian, aged 2 months (22 weeks) with informed written consent from the parents or legal guardian **Exclusion criteria:** none reported	**A:** 3, 4, 5 +b12-14 **B:** 3, 4, 5 +b12-14 **C:** 2, 4, 6 **Additional information:** **A:** DTaP at 3, 4, 5, 12-14 combined **B:** DTaP at 3, 4, 5, 12-14m, separate **C:** DTaP at 2, 4, 6, separate	**N=**54* **Mean age at randomization (SD):** 2 (0.5) **Mean age at vaccination (SD):** 1st dose: 3.0 (0.1) 2nd dose: 4.0 (0.1) 3rd dose: 5.0 (0.2) Booster:14.0 (0.7) **Gender (M/F):** 32/22 (59% M)	**N=** 49* **Median age at randomization (SD):** 2 (0.5) **Mean age at vaccination (SD):** 1st dose: 3.0 (0.1) 2nd dose: 4.0 (0.1) 3rd dose: 5.0 (0.2) Booster: 13.8 (0.6) **Gender (M/F):** 27/25 (50% M)	**N=** 54* **Mean age at randomization (SD):** 2 (0.5) **Mean age at vaccination (SD):** 1st dose: 2.1 (0.2) 2nd dose: 4.0 (0.2) 3rd dose: 5.9 (0.2) No booster **Gender (M/F):** 22/32 (41% M)		✓
Canada1[2]							
Location: Canada **Recruitment dates:** Not stated **Hib vaccine (booster):** PRP-T, PENTA (combined DPT-IPV/PRP-T), Pasteur Mérieux Connaught **Pertussis vaccine:** Not stated if wP or aP, assume wP given trial date, PENTA, Pasteur Mérieux Connaught **Funding:** Pasteur Mérieux Connaught	**Inclusion criteria:** healthy children, written consent from a parent or legal guardian, completed a study of primary immunization with a DPT-IPV/PRP-T combination vaccine **Exclusion criteria:** any contraindication to receipt of PENTA or MMR vaccines, impairment of immune responsiveness, prior infection with any of the agents targeted by PENTA or MMR vaccines; receipt of any other DPT, polio or Hib vaccine apart from in the earlier study; receipt of blood products within 3 months, receipt of any other vaccine within 2 weeks	**A:** 2, 4, 6 + b18 **B:** 2, 4, 6 + b15 **C:** 2, 4, 6 + b12 **Additional information:** All children had previously received 3 doses of PENTA (combined DPT-IPV/PRP-T) at 2, 4, 6 months and received a PENTA booster in this study. All received MMR vaccine at 12 months.	**N=** 82 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR† **Gender (M/F):** NR	**N=** 85 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR† **Gender (M/F):** NR	**N=** 86 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR† **Gender (M/F):** NR		✓

Study details	*Participant characteristics*	*Schedule A / schedule B / schedule C*	*Schedule A population characteristics*	*Schedule B population characteristics*	*Schedule C population characteristics*	*Outcomes*	
						Mortality	*Immunological*
Canada2[3-7]							
Location: Canada **Recruitment dates:** Study performed in 2000 to 2001 **Hib vaccine:** PRP-T, Act-HIB, Sanofi Pasteur **Pertussis vaccine:** aP (5 component) Quadracel, Sanofi Pasteur. **Funding:** Sanofi Pasteur	**Inclusion criteria:** healthy toddlers, 12 months of age, who had completed a routine three-dose primary series with DTaP-IPV//PRP-T combination vaccine (Pentacel) by eight months of age **Exclusion criteria:** history of neurologic disorder, confirmed pertussis, chronic underlying disorder; known or suspected hypersensitivity to any component of the study vaccine; impaired immunologic function or receipt of immunosuppressive therapy or immunoglobulins; and prior immunization with a fourth dose of diphtheria, tetanus, pertussis, H. influenza type b conjugate, or poliovirus vaccine)	**A:** 3p +b18 **B:** 3p +b17 **C:** 3p +b16 **D:** 3p +b15 **Additional information:** Primary and booster doses were combined DTaP-IPV and PRP-T vaccines. Varicella and MMR vaccines offered upon study entry at 12 months of age to those who had not received them.	**N=** 438 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** Primary: NR Booster: 18.3 (0.3) **Gender (M/F):** 213/225 (47% M) **Schedule D:** **N=** 445 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** Booster:15.4 (0.3) **Gender (M/F):** 215/230 (48% M)	**N=** 450 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** Primary: NR Booster:17.4 (0.3) **Gender (M/F):** 222/228 (49% M)	**N=** 449 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** Primary: NR Booster:16.4 (0.3) **Gender (M/F):** 211/238 (47% M)		✓
Canada3[8]							
Location: Canada **Recruitment dates:** 2003 **Hib vaccine:** PRP-T, Pentacel, Sanofi Pasteur **Pertussis vaccine:** aP (5 component) Pentacel, Sanofi Pasteur **Funding:** Wyeth Pharmaceuticals	**Inclusion criteria:** healthy children who had completed a study of 3-dose primary PCV7 vaccination, with a final blood sample for serology obtained at 7–8 months of age, informed consent from parents **Exclusion criteria:** none stated.	**A:** 2, 4, 6 +b18 **B:** 2, 4, 6 +b15 **Additional information:** All received DTaP-IPV combined with Hib and offered routine MMR at 12 months. **A and B:** primary PCV doses either 2, 4, 6 or 3, 5, 7. Booster doses of PCV given at the same time but separately from Hib.	**N=** 167 **Mean age at randomization based on time beyond birthday (SD):** 6.3 (0.3) **Mean age at vaccination (SD):** Primary: NR Booster:18.3(0.3) **Gender (M/F):** 98/69 (59% M)	**N=** 168 **Median age at randomization based on time beyond birthday (SD):** 3.3 (0.3) **Mean age at vaccination (SD):** Primary: NR Booster**:** 15.3 (0.3) **Gender (M/F):** 100/68 (59.5% M)			✓

Study details	*Participant characteristics*	*Schedule A / schedule B / schedule C*	*Schedule A population characteristics*	*Schedule B population characteristics*	*Schedule C population characteristics*	*Outcomes*	
						Mortality	*Immunological*
Chile1[9, 10]							
Location: Chile **Recruitment dates:** October to December, 1995 **Hib vaccine:** PRP-T, ActHib, Pasteur Mérieux Connaught PRP-HbOC, HibTiter, Wyeth-Lederle **Pertussis vaccine:** **Funding:** Children's Vaccine Initiative (WHO, Geneva, Switzerland), National Institute of Allergy and Infectious Disease	**Inclusion criteria:** healthy infants born at full term with a birth weight of 2500 g or more, written, informed consent from parent or guardian **Exclusion criteria:** contraindication to receiving DTP vaccine, major chronic or congenital diseases, or known immunological disorders	**A:** 2, 4, 6 (PRP-T) **C:** 4, 6 (PRP-T) **B:** 2, 4, 6 (PRP-HbOC) **D:** 4, 6 (PRP-HbOC) **Additional information:** PRP given to all at 12 months of age (results after PRP not eligible for this review. Fractional dose groups also not eligible	**N=** 78 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR **Schedule D:** **N=** 78 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR	**N=** 79 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):**NR **Gender (M/F):** NR	**N=** 78 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR		✓
Chile2[11]							
Location: Chile **Recruitment dates:** December 20, 1995 to April 2, 1996 **Hib vaccine:** PRP-T, ActHIB, Pasteur Mérieux Connaught **Pertussis vaccine:** aP (2 compontent), brand name not stated, Pasteur Mérieux Connaught **Funding:** Pasteur Mérieux Connaught	**Inclusion criteria:** healthy 2 month-old infants (±4 weeks) planning to receive primary care at the selected health centres for the complete study period, informed consent from parents or guardian **Exclusion criteria:** known or suspected disease; previous vaccination against diphtheria, tetanus, pertussis, Hib or polio; <37 weeks of gestation; birth weight <2500g; known contraindication to receiving DTP, PRP-T or IPV vaccines	**A:** 3, 5, 7 +b12 **B:** 3, 5, 7 +b12 **C:** 3, 5, 7 +b12 **D:** 2, 4, 6 +b12 (separate) **E:** 2, 4, 6 +b12 (combined) **Additional information:** All children received MMR and DTaP combined with Hib vaccine at 12 months. **A, B, C, D, E**: received DTaP at 2, 4, 6 **B, C, D, E:** received IPV at 2, 4, 6 (B separate, others combined with DTaP), OPV at 7, 13 **A:** OPV at 2, 4, 6, 13	**N=**NR(710 total in study)* **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR. **Schedule D:** **N=**NR(710 total in study)* **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR.	**N=**NR(710 total in study)* **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR. **Schedule E:** **N=**NR(710 total in study)* **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR.	**N=**NR(710 total in study)* **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR.	✓	✓

Study details	*Participant characteristics*	*Schedule A / schedule B / schedule C*	*Schedule A population characteristics*	*Schedule B population characteristics*	*Schedule C population characteristics*	*Outcomes*	
						Mortality	*Immunological*
China1[12-14]							
Location: China **Recruitment dates:** NR **Hib vaccine:** PRP-T, Pentacel, Sanofi Pasteur **Pertussis vaccine:** aP (2 component) in combined schedules) Pentaxim, Sanofi Pasteur aP (1 component) in separate schedule, brand name not stated, Wuhan Institute of Biological Products **Funding:** Sanofi Pasteur	**Inclusion criteria:** children who had completed the primary vaccination study and had informed consent from parents or legal representatives **Exclusion criteria:** participation in another clinical trial in the 4 weeks preceding the trial inclusion, immunodeficiency, immunosuppressive therapy, hypersensitivity to vaccine components, chronic illness; receipt of blood products	**A:** 3, 4, 5 +b18-20 (combined) **B:** 3, 4, 5 +b18-20 (separate) **C:** 2, 3, 4 +b18-20 (combined) **Additional information:** **A and C:** DTaP-IPV combined with Hib **B:** DTaP, Hib, IPV separately 3, 4, 5, 18-20	**N=** 264 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Overall gender based on N=792 (M/F):** 393-444/348-399 (49.6–56% M).	**N=** 264 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Overall gender based on N=792 (M/F):** 393-444/348-399 (49.6–56% M).	**N=** 264 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Overall gender based on N=792 (M/F):** 393-444/348-399 (49.6–56% M).	✓	✓
China2[15, 16]							
Location: China **Recruitment dates:** Study period: March 24 to November 19, 2010 **Hib vaccine:** PRP-T, Infanrix-Hib or Infanrix-IPV+Hib, GlaxoSmithKline **Pertussis vaccine:** aP (3 component), Infanrix-Hib or Infanrix-IPV+Hib, GlaxoSmithKline **Funding:** GlaxoSmithKline	**Inclusion criteria:** healthy infants 60-90 days old, born after a gestation period of 36 to 42 weeks, written informed consent from the parents **Exclusion criteria:** previous or intercurrent diphtheria, tetanus, pertussis, poliomyelitis and/or Hib disease or vaccination, current febrile illness or axillary temperature > 37.0°C or other moderate to severe illness within 24 hours of study vaccine administration	**A:** 3, 4, 5 (DTaP-IPV combined) **B:** 2, 3, 4 (DTaP-IPV combined) **C:** 2, 3, 4 (DTaP combined, IPV separate) **Additional information:**	**N=** 324 **Mean age at randomization (SD):** NR **Mean age vaccination (SD):** 3.3 (0.3) **Gender (M/F):** 147/177 (45.4% M).	**N=** 330 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** 2.3 (0.3) **Gender (M/F):** 155/175 (47% M).	**N=** 330 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** 2.3 (0.3) **Gender (M/F):** 141/189 (43% M).	✓	✓

Study details	*Participant characteristics*	*Schedule A / schedule B / schedule C*	*Schedule A population characteristics*	*Schedule B population characteristics*	*Schedule C population characteristics*	*Outcomes*	
						Mortality	*Immunological*
Europe[17-22]							
Location: Austria, Germany, Greece **Recruitment dates:** August 2007 to October 2008 **Hib vaccine:** Booster: PRP-T, Infanrix-hexa; GlaxoSmithKline **Pertussis vaccine:** aP (3 component), Infanrix-hexa, GlaxoSmithKline **Funding:** GlaxoSmithKline	**Inclusion criteria:** healthy children between 12 and 23 months, documented evidence of 3-dose primary vaccination with DTaP, hepatitis B, IPV and Hib vaccines completed at least 180 days previously **Exclusion criteria:** immunosuppression, previous receipt of any meningococcal vaccine or booster vaccination against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis or Hib, a past history of disease due to meningococcus, or receipt of blood products	**A:** 3p‡ +b13 **B:** 3p‡ +b12 **C:** 3p‡ +b12 (MenACWY-TT, separate at 12) **D:** 3p‡ **Additional information:** **A:** MenACWY-TT at 12 months. DTaP combined with Hib at 13 months **B:** MenACWY-TT at 13 months. DTaP combined with Hib at 12 months **C:** MenACWY-TT, separate at 12 months, DTaP combined with Hib at 12 months **D:** MenC conjugate at 12 months	**N=** 220 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** Booster dose: 15(3.3) **Gender (M/F):** 114/106 (51.8% M) **Schedule D:** **N=** 127 **Median age at randomization:** NR **Mean age at vaccination (SD):** Booster dose: 14.6(3.0) **Gender (M/F):** 66/61 (52% M)	**N=** 224 **Median age at randomization (SD):** NR **Mean age at vaccination (SD):** Booster dose: 14.9(3.17) **Gender (M/F):** 105/119 (46.9% M)	**N=** 224 **Median age at randomization (SD):** NR **Mean age at vaccination (SD):** Booster dose: 14.6(3.01) **Gender (M/F):** 113/109 (50.9% M)	✓	✓

Study details	*Participant characteristics*	*Schedule A / schedule B / schedule C*	*Schedule A population characteristics*	*Schedule B population characteristics*	*Schedule C population characteristics*	*Outcomes*	
						Mortality	*Immunological*
France[23, 24]							
Location: France **Recruitment dates:** 1995 to 1996 **Hib vaccine:** PRP-T, Hexavac, Aventis Pasteur **Pertussis vaccine:** aP (2 component), Hexavac, Aventis Pasteur. **Funding:** Not stated, likely Aventis Pasteur	**Inclusion criteria:** healthy Infants already enrolled in the trial initiated for the investigational vaccine and who had received primary immunisation under schedules 2, 4, 6 and 2, 3, 4 in the study **Exclusion criteria:** none stated	**A:** 2, 4, 6 + b15-17 **B:** 2, 3, 4 + b15-17 **Additional information:** DTaP-HepB-IPV combined with Hib at each dose	**N=** 258 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR	**N=** 258 **Median age at randomization (SD):** NR **Mean age at vaccination (SD):**NR **Gender (M/F):** NR			✓
Gambia1[25-28]							
Location: The Gambia **Recruitment dates:** January 1 to December 31, 1985 **Hib vaccine:** PRP-OMP, PedvaxHib, Merck Sharp & Dohme **Pertussis vaccine:** Not given as part of trial. Not stated if wP or aP, assume wP given trial date. No brand name or manufacturer stated **Funding:** Merck Sharp & Dohme	**Inclusion criteria:** children living in the area of the health center, informed consent from mothers **Exclusion criteria:** none stated	**A:** 2, 4 **B:** 1, 3 **C:** No doses **Additional information:** Other routine EPI vaccinations received but not as part of study.BCG and oral polio vaccines at 1 month of age and DTP and oral polio vaccines at 2, 3, and 4 months. Assume DTP given separately from Hib **C:** No control vaccine	**N=** 95 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR	**N=** 99 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR	**N=** 90 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** no Hib **Gender (M/F):** NR		✓

Study details	*Participant characteristics*	*Schedule A / schedule B / schedule C*	*Schedule A population characteristics*	*Schedule B population characteristics*	*Schedule C population characteristics*	*Outcomes*	
						Mortality	*Immunological*
Gambia2 [29]							
Location: The Gambia **Recruitment dates:** 1990 **Hib vaccine:** PRP-T, ActHib, Pasteur Mérieux **Pertussis vaccine:** Not given as part of trial. Not stated if wP or aP, assume wP given trial date. No brand name or manufacturer stated **Funding:** Pasteur Mérieux	**Inclusion criteria:** Not stated **Exclusion criteria:** none stated	**A:** 2, 4 **B:** 1, 3 **C:** No doses **Additional information:** All children had EPI routine vaccination (not specified). Assume DTP separate from Hib	**N=** 43 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR	**N=** 45 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR	**N=** 40 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** NR		✓
Guatemala [30]							
Location: Guatemala **Recruitment dates:** March 1998 to August 1999 **Hib vaccine:** PRP-T, Hiberix, GlaxoSmithKline **Pertussis vaccine:** wP (combined schedule), Tritanrix, GlaxoSmithKline wP (separate schedule), Brand name and manufacturer not clearly stated **Funding:** GlaxoSmithKline	**Inclusion criteria:** healthy infants ≥6 weeks of age **Exclusion criteria:** known allergic reaction to any of the vaccine components, immunodeficiency, major congenital defects, serious illness, seizure disorders, history of blood product transfusions, or previous immunizations (except oral polio or Bacillus Calmette-Guerin vaccine)	**A:** 2, 4, 6 **B:** 7, 9 (+b12) **Additional information:** All children had OPV at 2, 4, 6 and MMR at 9-12. **A:** Hib combined with DTwP and HepB **B:** DTwP at 2, 4, 6months. HepB given separately from Hib at 7, 9 months. Also received Hib and HepB vaccines at 12 months but no data provided after 12 month dose	**N=**325[§] **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** 238/176 (57.5% M)	**N=**106[§] **Median age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** 56/50 (53% M)			✓

Study details	*Participant characteristics*	*Schedule A / schedule B / schedule C*	*Schedule A population characteristics*	*Schedule B population characteristics*	*Schedule C population characteristics*	*Outcomes*	
						Mortality	*Immunological*
Netherlands[31]							
Location: The Netherlands **Recruitment dates:** March 1993 to September 2, 1994 **Hib vaccine:** PRP-T, brand name not stated, Pasteur Mérieux **Pertussis vaccine:** wP, brand name not stated, Pasteur Mérieux **Funding:** Chief Inspectorate of Health Care, Netherlands	**Inclusion criteria:** children born in February and March 1993, living in the Rotterdam cluster or in Apeldoom, written informed consent by the parents **Exclusion criteria:** None stated	**A:** 3, 4, 5 +b11 (DTwP-IPV combined) **B:** 3, 4, 5 +b11 (DTwP-IPV separate) **C:** 6, 7+b13 **Additional information:** All children had MMR at 14 months.**A:** DTwP-IPV at 3, 4, 5, 11 in a combined injection. **B, C:** DTwP-IPV at 3, 4, 5, 11 as a separate injection.	**N=**180 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** 94/86 (52% M)	**N=**181 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** 102/79 (56% M)	**N=**182 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Gender (M/F):** 104/78 (57% M)		✓
Niger[32]							
Location: Niger **Recruitment dates:** January to November 1995 **Hib vaccine:** PRP-T, brand name not stated, Pasteur Mérieux **Pertussis vaccine:** Not stated if wP or aP, assume wP given trial date. Brand name not stated, Pasteur Mérieux **Funding:** Supported by the French Ministry of Cooperation and the WHO Global Program on Vaccines	**Inclusion criteria: c**hildren between the ages of four and twelve weeks, informed consent from the parents **Exclusion criteria:** none stated	**A:** 1.5, 2.5, 3.5 **B:** 2.5, 3.5 **C:** No doses **Additional information:** All children had BCG and OPV at birth, DTP (combined with Hib when Hib given) and OPV at 1.5, 2.5, 3.5; measles and yellow fever at 9 months. **C:** Men A/C polysaccharide vaccine at 1.5, 3.5 months	**N=** 59 **Mean age at randomization:** NR **Overall mean age at vaccination (range):** 1st visit:1.9(0.9-2.8) 2nd visit:3.0(2.1-5.1) 3rd visit: 4.2(3.0-6.8) **Overal gender (M/F):** 93/87 (52% M).	**N=** 62 **Mean age at randomization:** NR **Overall mean age at vaccination (range):** 11st visit:1.9(0.9-2.8) 2nd visit:3.0(2.1-5.1) 3rd visit: 4.2(3.0-6.8) **Overal gender (M/F):** 93/87 (52% M).	**N=** 59 **Mean age at randomization:** NR **Overall mean age at vaccination (range):** No Hib **Overal gender (M/F):** 93/87 (52% M).		✓

Study details	*Participant characteristics*	*Schedule A / schedule B / schedule C*	*Schedule A population characteristics*	*Schedule B population characteristics*	*Schedule C population characteristics*	*Outcomes*	
						Mortality	*Immunological*
Sweden[33, 34]							
Location: Sweden **Recruitment dates:** November 19, 1994 to April, 1995 **Hib vaccine:** PRP-T, ActHIB, Pasteur Mérieux Connaught **Pertussis vaccine:** aP (2 component), brand name not stated, Pasteur Mérieux Connaught **Funding:** Pasteur Mérieux Connaught, Göteborg Medical Society, the Medical Faculty of Göteborg University; the County Hospital of Norra Älvsborg	**Inclusion criteria:** healthy term infants, with a birth weight of at least 2500 g, who were recruited with written informed consent of parents at the age of 2m +/-2 weeks at routine visits to Child Health Centers (CHC) **Exclusion criteria:** none stated.	**A:** 2, 4, 6 +b13 **B:** 3, 5 +b12 **Additional information:** Both groups received DTaP-IPV in combination with Act-HIB in one injection.	**N=**118 **Median age at randomization (SD):** NR **Mean age at vaccination (SD):** NR but 98.8% of doses given within range stipulated in protocol **Gender (M/F):** NR	**N=**118 **Median age at randomization (SD):** NR **Mean age at vaccination (SD):** NR but 98.8% of doses given within range stipulated in protocol **Gender (M/F):** NR		✓	✓
Turkey[1]							
Location: Turkey **Recruitment dates:** October 1994 to March 1995 **Hib vaccine:** PRP-T, Act-HIB, Pasteur Mérieux Connaught. **Pertussis vaccine:** aP, brand name not stated, Pasteur Mérieux, Connaught **Funding:** Pasteur Mérieux Connaught	**Inclusion criteria:** healthy infants, Belgian, aged 2 months with informed written consent was obtained from the parents or legal guardian of each child **Exclusion criteria:** none reported	**A:** 3, 4, 5 +b12-14 (DTaP combined) **B:** 3, 4, 5 +b12-14 (DTaP separate) **C:** 2, 4, 6 (DTaP separate) **Additional information:** **A:** DTaP at 3, 4, 5, 12-14,combined **B:** DTaP at 3, 4, 5, 12-14, separate syringe. **C:** DTaP at 2, 4, 6 in a separate syringe.	**N=** 74* **Mean age at randomization:** 2 (0.5) **Mean age at vaccination (SD):** 1st dose: 3.0 (0.2) 2nd dose: 4.1 (0.3) 3rd dose: 5.1 (0.3) Booster: 13.4 (1.1) **Gender (M/F):** 50/34 (60% M)	**N=** 78* **Median age at randomization:** 2 (0.5) **Mean age at vaccination (SD):** 1st dose: 3.0 (0.1) 2nd dose: 4.0 (0.2) 3rd dose: 5.1 (0.4) Booster: 13.5 (1.1) **Gender (M/F):** 41/42 (49% M)	**N=** 81* **Median age at randomization:** 2 (0.5) **Mean age at vaccination (SD):** 1st dose: 2.1 (0.2) 2nd dose: 4.0 (0.3) 3rd dose: 5.9 (0.3) No booster **Gender (M/F):** 51/32 (61% M)		✓

Study details	*Participant characteristics*	*Schedule A / schedule B / schedule C*	*Schedule A population characteristics*	*Schedule B population characteristics*	*Schedule C population characteristics*	*Outcomes*	
						Mortality	*Immunological*
USA1[35]							
Location: USA **Recruitment dates:** August 8, 1991 to June 19, 1992 **Hib vaccine:** PRP-OMP, VaxHib, Merck & Co. PRP-HbOC, HibTiter, Praxis Biologics **Pertussis vaccine:** Not stated if wP or aP, assume wP given trial date. Brand name and manufacturer not stated **Funding:** National Institute of Allergy and Infectious Diseases	**Inclusion criteria:** healthy two month old infants with informed consent of parent or guardian and scheduled to receive routine immunization **Exclusion criteria:** none stated	**A:** 2 (PRP-OMP), 4, 6 (HbOC) **B:** 2 (HbOC), 4, 6 (PRP-OMP) **C:** 2, 4, 6 (HbOC) **D:** 2, 6 (PRP-OMP) **E:** 2, 4 (PRP-OMP) **Additional information:** DTP, OPV and MMR given to all groups "according to published guidelines". All children received unconjugated PRP vaccine at 15m. **D:** Placebo at 4m **E:** Placebo at 6m	**N=**36[¶] **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Overall gender (M/F):** 140/117 (55% M) **Schedule D:** **N=**36 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Overall gender (M/F):** 140/117 (55% M)	**N=**35[¶] **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Overall gender (M/F):** 140/117 (55% M) **Schedule E:** **N=**39 **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Overall gender (M/F):** 140/117 (55% M)	**N=**96[¶] **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Overall gender (M/F):** 140/117 (55% M)		✓
USA2 [36]							
Location: USA **Recruitment dates:** NR **Hib vaccine:** PRP-T, ActHib, Pasteur Merieux HbOC, HibTiter, Lederle-Praxis Biologics **Pertussis vaccine:** Not stated if wP or aP, assume wP given trial date. Brand name and manufacturer not stated **Funding:** National Institutes of Health and Connaught Laboratories	**Inclusion criteria:** healthy infants, 0 months of age with signed informed consent from a parent **Exclusion criteria:** infants of a gestational age of less than 37 weeks, receipt of any blood product, known or suspected impairment of neurologic function, acute febrile illness, severe congenital defect or major organ dysfunction, known maternal immunodeficiency or human immunodeficiency virus infection	**A:** 2, 4, 6 (PRP-T) **B:** 2, 4, 6 (HbOC) **C:** 0, 2, 4, 6 (HbOC) **Additional information:** All children received regularly scheduled childhood immunizations including HepB, DTP, and OPV concurrently as separate injections at 2, 4, 6. **A and B:** DT at birth	**N=**NR (total in all groups 150)* **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Overall, gender (M/F):** 49% M	**N=**NR (total in all groups 150)* **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** 3rd:6.7 Other doses NR **Overall, gender (M/F):** overall 49% M	**N=**NR (total in all groups 150)* **Mean age at randomization (SD):** NR **Mean age at vaccination (SD):** NR **Overall, gender (M/F):** overall 49% M		✓

Study details	*Participant characteristics*	*Schedule A / schedule B / schedule C*	*Schedule A population characteristics*	*Schedule B population characteristics*	*Schedule C population characteristics*	*Outcomes*	
						Mortality	*Immunological*
USA3[37, 38]							
Location: USA **Recruitment dates:** NR **Hib vaccine:** PRP-OMP, PedvaxHIB, Merck Sharp & Dohme **Pertussis vaccine:** Not described **Funding:** Supported, in part, by National Institute of Allergy and Infectious Diseases, National Institutes of Health, Connaught Laboratories, Inc. and Merck Sharp & Dohme	**Inclusion criteria:** healthy children from paediatric clinics in Missouri and Illinois with informed parental consent and with a physical examination performed prior to each immunization **Exclusion criteria:** history of a serious reaction to any previous vaccination, suspicion of underlying immunodeficiency. Vaccination deferred if history of fever within the previous 72 hours vaccination within the previous week	**A:** 2-6, 4-8 **B:** 2-6, 3-7 **Additional information:** No other vaccines described.	**N=** 27 **Mean age at randomization (SD):** 1st dose: 4.1 (1.6) 2nd dose: 6.1 (1.6) **Overall mean age at vaccination (SD):** 3.6(1.5) **Overall gender at randomization (M/F):** 33/21 (61% M)	**N=** 27 **Median age at randomization (SD):** 1st dose: 3.2 (1.3) 2nd dose: 4.2 (1.3) **Overall mean age at vaccination (SD):** 5.1(1.8) **Overall gender at randomization (M/F):** 33/21 (61% M)			✓

Legend:

aP - acellular pertussis vaccine; BCG - Calmette-Guérin Bacillus; combined – Hib vaccine mixed in same syringe as other vaccines; DTP - diphtheria, tetanus, pertussis vaccine; DTaP - diphtheria, tetanus, acellular pertussis vaccine; DTwP - diphtheria, tetanus, whole cell pertussis vaccine; EPI: Expanded Program on Immunization; FHA - filamentous hemagglutinin; FIM - fimbriae; Hib – Haemophilus influenzae type b vaccine; m - months; MenACWY-PsACWY - quadrivalent meningococcal polysaccharide (groups A, C, Y, and W135) conjugate vaccine; MenA-TT-PsA-TT - MenA meningococcal conjugate vaccine; MMR - measles, mumps, rubella vaccine MMRV - measles, mumps, rubella, varicella vaccine; NR - Not reported; OPV - oral polio vaccine; p - primary course; PCV5: 5 valent pneumococcal conjugate vaccine; PCV7: 7-valent pneumococcal conjugate vaccine; PRP - polyribosylribitol phosphate; PRP-HbOC - PRP conjugated to diphtheria toxin CRM 197; PRP-OMP - PRP conjugated to outer membrane protein of Neisseria meningitidis; PRP-T - PRP conjugated to tetanus toxoid; wP - whole cell pertussis vaccine; separate – Hib vaccine not given in same syringe as other vaccines (other vaccines given at same or different time from Hib vaccine).

* Number of children vaccinated. Number of randomized children not reported.

† Authors state the intended schedule immunization was met for each child with only 2 single exceptions

‡Type of conjugate vaccine in primary schedule (3p) not specified.

§ Group A includes 164 Ladino and 161 Native Indian participants; Group B includes 47 Ladino and59 Native Indian participants.

¶ Number of children followed-up. Numbers randomized to each group not reported. Total number randomized 497

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