ICAN
Informed Consent Action Network

None of the vaccine doses the CDC recommends for routine injection into children were licensed by the FDA based on a long-term placebo-controlled trial

Type	Doses	Age Injected	Brand	Company[1]	Control	Placebo?	Safety Review After Injection[2]	Long	Source	Note
HepB	3	Birth 1M 6M	Recombivax HB	M	None	NO	5 days	NO	Package insert at § 6.1	Note that to license a vaccine for children, the FDA relies upon the clinical trial conducted with children, not adults, because as the FDA explains, "It's important that the public recognize that, because young children are still growing and developing, it's critical that thorough and robust clinical trials of adequate size are completed to evaluate the safety and the immune response to a … vaccine in this population. Children are not small adults[.]"
			Engerix B	G	None	NO	4 days	NO	Package insert at § 6.1	
DTaP	15	2M 4M6M 15M 4Y	Infanrix	G	DTP	NO	30 days		Package insert at § 6.1	DTP was also not licensed based on a placebo controlled trial and it increases mortality. The 6-month Daptacel trial had no control, 1,454 children and "[w]ithin 30 days following any dose of DAPTACEL, 3.9% subjects reported at least one serious adverse event."
			Daptacel	S	DT or DTP	NO	Up to 2 months + 1 trial 6 months	NO	Package insert at § 6.1	
PCV	4	2M 4M 6M 12M	Prevnar 13, PCV-13	P	Prevnar 7	NO	6 months	NO	Package insert at § 6.1	Prevnar 7 trial's control was an "[i]nvestigational meningococcal group C conjugate vaccine." In Prevnar 13 trial, "[s]erious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar 7 recipients." In Vaxneuvance trial, "serious adverse events…were reported by 9.6% of VAXNEUVANCE recipients and by 8.9% of Prevnar 13 recipients" but deemed "safe" because "no notable patterns or numerical imbalances between vaccination groups." Prevnar 20 had similar result split into "serious adverse events" and "newly diagnosed chronic medical conditions."
			Vaxneuvance PCV-15	M	Prevnar 13	NO	6 months	NO	Package insert at § 6.1	
			Prevnar 20, PCV-20	P	Prevnar 13	NO	6 months	NO	Package insert at § 6.1; Clinical Review	
IPV	4	2M4M 6M 4Y	IPOL	S	None	NO	3 days	NO	Package insert at 14-17	IPOL is very different than the polio vaccine created by Jonas Salk in the 1950s (used until 1960s). Hence, trials of Salk's vaccine from the 1950s were not relied upon to license IPOL.
Hib	3 or 4	2M 4M 6M 12M	ActHIB	S	HepB	NO	30 days	NO	Package insert at § 6.1; Basis of Approval at 8	Within 30 days of injection in the ActHIB trial, 3.4% experienced a serious adverse event but "[n]one was assessed by the investigators [Sonafi] as related to the study of vaccines." Lyophilized PedvaxHIB vaccine, used as the control for Liquid PedvaxHIB, was tested in a trial in which controls were given placebo, OPV, and DTP but there is no indication Lyophilized PedvaxHIB was ever licensed.
			Hiberix	G	HibTITER or other vaccine	NO	31 days	NO	Package insert at § 6.1; Clinical review at 20-21	
			Liquid PedvaxHIB	M	Lyophilized PedvaxHIB	NO	3 days	NO	Package insert at 6-8	
RV[3]	2 or 3	2M 4M 6M	Rotarix	G	Dextran, Sorbitol, Amino Acids, Dulbecco's Modified Eagle Medium, and Xanthan	NO	31 days + 1 year for intussusception	NO	Package insert at § 6.1; Clinical review at 23-24	"[T]here were 68 (0.19%) deaths following…ROTARIX…and 50 (0.15%) deaths following placebo…. The most common…cause…was pneumonia…observed in 19 (0.05%) recipients of ROTARIX and 10 (0.03%) placebo recipients." Its clinical review admits "[t]he placebo consisted of all components of Rotarix, but without any RV particles." The package insert for RotaTeq similarly admits its "placebo" contains multiple ingredients as seen to the left.
			RotaTeq	M	Polysorbate-80, Tissue Culture Medium, Fetal Bovine Serum, and Sodium Phosphate	NO	42 days + 1 year for intussusception	NO	Package insert at § 6.1; Clinical reports at 445 etc.	
Covid19	3	6M 7M 10M	Comirnaty	P	Placebo	YES	6 months	NO	Package insert at § 6.1	Comirnaty licensed for only 12+ (Spikevax, Moderna, only 18+). Placebo controls unblinded and most vaccinated during the trial. All data 16+ is combined but 12-15 data is separate, had 1,131 vaccinated children, and one participant shows how this trial was conducted.
Flu	19	6M 7M Yearly	Various	Various	Flu shots change annually without any clinical trial	NO	Flu shots change annually without any clinical trial	NO	CDC 22-23 Flu Shots; FDA Flu Shots	The trials of the original flu shot formulations for children also did not have a placebo control (see pp. 13-14) even though some adult trials did. The one inhaled influenza vaccine had a placebo but, again, it changes every year and is not safety tested in any trial.
MMR	6	12M 4Y	M-M-R-II	M	None	NO	42 days	NO	Clinical reports	M-M-R-II trials totaled only 834 children and a third developed gastrointestinal issues and a third respiratory issues. In Priorix trial, both vaccine groups had high rate of serious adverse events, emergency room visits, and new chronic diseases (e.g., autoimmune disorders, asthma, type I diabetes, celiac, and allergies). See Table 6 of the Supplementary Materials.
			Priorix	G	M-M-R-II	NO	6 months	NO	Package insert at § 6.1; Sup materials at 12	
VAR	2	12M 4Y	Varivax	M	45 mg of neomycin per milliliter	NO	70 days	NO	Package insert at § 6.1; Merck study at 2; Clinical reports	One controlled trial with 956 children, half Varivax and half neomycin, and one trial with 32 vaccinated and another 29 vaccinated 8 weeks later, during which the first group had double the ear infections and 50% more respiratory infections.
HepA	2	12M 18M	Havrix	G	Engerix-B	NO	6 months	NO	Package insert at § 6.1	Trials for both occurred at the same time when there was no licensed Hep A vaccine and hence no excuse for not using a placebo control. It is also startling Engerix-B, see above, was the control for Havrix, and an injection of cyto-and-neuro toxic substances, AAHS and thimerosal, were used as a control for Vaqta instead of a saline injection.
			Vaqta	M	AAHS and Thimerosal	NO	42 days	NO	Package insert at § 6.1; Merck study at 454	
Tdap	3	11Y	Adacel	S	Td, for adults	NO	6 months	NO	Package insert at § 6.1	Due to reactions, Tdap (Adacel) given at 11Y has 12.5 times less diphtheria toxoid (25Lf v 2LF) and 10 times less pertussis toxin (25mcg v 2.5mcg) than DTaP (Infanrix) given to babies.
			Boostrix	G	Decavac or Adacel	NO	6 months	NO	Package insert at § 6.1	
HPV	2 or 3	9Y 9 ½Y	Gardasil 9	M	Gardasil 4 (see note)	NO	1 month in five trials, 6 months in one trial, and 4 years in one trial		Clinical review at 17-19	Gardasil 9 trial gave 306 people placebo after full series of Gardasil 4. In Gardasil 4's trial, controls received aluminum adjuvant, AAHS, except 320 people labeled "Saline Placebo" that actually received all vaccine ingredients except antigens and AAHS. Across trials, 2-3% receiving vaccine or aluminum adjuvant (used to induce autoimmunity) had a suspected autoimmune disorder.
Men4	2	11Y 16Y	Menactra	S	Menomune	NO	6 months	NO	Package insert at § 6.1	Incredibly, the safety section of the package insert for Menomune lists the trial in which it was used as a control for the trial of Menactra. This provides another good example of the safety pyramid scheme in which Menomune is licensed without a placebo-controlled trial and then used as the control to license Menactra; Menactra is then used as the control to license Menveo; and then Menveo is used as the control to license MenQuadfi. What is the actual safety profile? Putting aside the limited 6-month safety period, it is unknown since Menomune's safety baseline was never established in a placebo-controlled clinical trial.
			Menveo	G	Menactra or other vaccine	NO	6 months	NO	Package insert at § 6.1	
			MenQuadfi	S	Menveo or other vaccine	NO	6 months	NO	Package insert at § 6.1	
MenB	0 or 2	10Y+ if indi-cated	Bexsero	G	See note	NO	30 days	NO	Summary basis at 14-15; Clinical review at 40	Bexsero's controls injected with aluminum hydroxide and, in one trial with 120 adolescents, saline injection followed by injection of Menveo and hence FDA labels this an "active control," not a "placebo control" trial. Trumenba's trials had no placebo control group other than 12 people in a dose ranging phase II study; otherwise, the controls were injected with Gardasil+placebo, dTaP-IPV+placebo, HepA+placebo, or Menactra+Adacel+placebo.
			Trumenba	P	See note	NO	30 days in 3 trials + 11M in 2 trials	NO	Summary basis at 4; Clinical review at 9-10	
PPSV23	0 to 2	2Y+ if indi-cated	Pneumovax 23	M	See note	NO	See note	NO	FDA documentation	Licensed for children 2 years and older but there is no indication that there was any clinical trial involving anyone younger than 16 years of age that the FDA relied upon to license this vaccine. See all FDA documentation for this vaccine linked.
DEN	0 or 3	6Y+ prior infected endemic areas	Dengvaxia	S	Placebo	YES	5 years	YES	Statistical review at 10; Package insert at 4	Finally, a longer-term placebo-controlled trial (35k+ children). Children under 6 had severe harm and death – harms the above trials would likely miss – and older children "not previously infected are at increased risk for severe dengue." Hence, it is only given in endemic areas (not in U.S.) to children 6+ who had dengue (Note: 5 years insufficient for vaccine for babies.)

[1] M=Merck; G=GSK; S=Sanofi; P=Pfizer.
[2] Note that for many trials with "6 months," the review was typically around 30 days after injection with a phone call at 6 months.
[3] Note that RV is given by oral drops and one influenza vaccine is given by nasal spray.

Updated: October 18, 2023