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[1] | Age Injected[2] | Brand | Company[3] | Control | Placebo? | Safety Review After Injection[4] | Long term? | 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 4M 6M 15M 4Y | Infanrix | G | DTP | NO | 30 days | | Package insert at § 6.1 | DTP was also not licensed based on placebo controlled trial and it increases mortality.<br><br>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 | 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 "Investigational meningococcal group C conjugate vaccine." In Prevnar 13 trial, "Serious 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 | 2M 4M 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."<br><br>Lyophilized PedvaxHIB vaccine, used as the control for Liquid PedvaxHIB, was tested in a trial in which controls were injected with lactose, aluminum adjuvant, and thimerosal but there is no indication Lyophilized PedvaxHIB was ever licensed. |
| | | | Hiberix | G | ActHIB | 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 | 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 "The 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. | |
| Covid-19 | 13 | 5Y 6Y-17Y | Comirnaty | P | Placebo | YES | 6 months | NO | Package insert at § 6.1 Clinical Review at 36 | Comirnaty placebo controls were unblinded and most were vaccinated during the trial. The trial for ages 12-15 had 1,131 vaccinated children, and at least one participant suffered a profound injury. |
| | 19 | 6M 8M 1Y-17Y | Spikevax | Mo | Placebo | YES | 51-71 days | NO | Package insert at § 6.1 FDA Briefing at 10 | Spikevax placebo controls were unblinded and mostly vaccinated during the trial. Depending on the age group, the median duration of blinded safety follow-up was 51 to 71 days. |
| Flu | 19 | 6M 7M 1Y-17Y | Various | Various | Flu shots change annually without any clinical trial | NO | Flu shots change annually without any clinical trial | NO | CDC 25-26 Flu Shots; FDA Flu Shots | Also, the trials of the original flu shot formulations for children 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 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 that Engerix-B, see above, was the control for Havrix, and an injection of cyto-and-neuro toxic substances, AAHS (aluminum hydroxide) 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 | NO | Clinical review at 17-19 | Gardasil 9 trial gave 306 people placebo after full series of Gardasil 4. In Gardasil 4 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. |

[1] Total of 64 doses if a child receives the minimum number through age 18 of the routine recommended vaccines on the 2025 CDC Immunization Schedule, excluding Covid-19 vaccine.
[2] Note that RV is given by oral drops and one type of influenza vaccine is given by nasal spray.
[3] M=Merck; Mo=Moderna; G=GSK; S=Sanofi; P=Pfizer.
[4] Note that for many trials with "6 months," the review was typically around 30 days after injection with a phone call at 6 months.

Updated: August 5, 2026

| Type | Doses[5] | Age Injected[6] | Brand | Company[7] | Control | Placebo? | Safety Review After Injection[8] | Long term? | Source | Note |
|---|---|---|---|---|---|---|---|---|---|---|
| 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 control trial and then used as the control to license Menactra, then Menactra is 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 | 16Y 16.5Y 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 and otherwise the controls were injection of 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 | |
| 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, only given to 6+ who had dengue in endemic areas (not in U.S.) (Note: 5 years insufficient for vaccine for babies.) |

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