Randomization — Randomized (n= 154)

Allocation

Pregnant women allocated and received $DTaP_5$-IPV (n= 77)

Pregnant women allocated and received $DTaP_3$-IPV (n= 77)

Non-randomized control group of women enrolled postnatally (n= 44, of which 19 from Infanrix hexa study)

47 infants born to 45 women (2 sets of twins)

Follow-Up

Infants born to DTa_5P-IPV vaccinated mothers (n=79; includes 2 sets of twins)

Followed up at 2 months: n= 74

Followed up at 3 months: n= 70

Followed up at 4 months: n= 69

Followed up at 5 months: n=67

Followed up at 12 months: 65

Followed up at 13 months: n= 63

Lost to follow-up (n=16) (Did not return for study visits, moved away from area or vaccines given by primary care provider)

Infants born to DTa_3P-IPV vaccinated mothers (n=80, includes 3 sets of twins)

Followed up at 2 months: n= 70

Followed up at 3 months: n= 63

Followed up at 4 months: n= 63

Followed up at 5 months: n=63

Followed up at 12 months: 61

Followed up at 13 months: n= 61

Lost to follow-up (n= 19): (Did not return for study visits, moved away from area or vaccines given by primary care provider)

Followed up at 2 months: n= 46

Followed up at 3 months: n= 46

Followed up at 4 months: n= 46

Followed up at 5 months: n= 45

Followed up at 12 months: n= 44

Followed up at 13 months: n= 44

Lost to follow-up (n= 19): (Did not return for study visits, moved away from area or vaccines given by primary care provider)

Analysis

Included in analysis at birth: n=53

Matched maternal and infant blood samples for placental transfer calculations: n= 52

Included in analysis at 2 months: n= 70

Included in analysis at 5 months: n= 65

Included in analysis at 13 months: n= 63

Excluded from analysis if insufficient sample volume

Included in analysis at birth: n= 57

Matched maternal and infant blood samples for placental transfer calculations: n= 52

Included in analysis at 2 months: n= 62

Included in analysis at 5 months: n= 62

Included in analysis at 13 months: n= 61

Excluded from analysis if insufficient sample volume

Included in analysis at 2 months: n= 27*

Included in analysis at 5 months: n= 45

Included in analysis at 13 months: n= 44

* 2 month blood samples not collected from infants in the Infanrix hexa study

Excluded from analysis if insufficient sample volume