Vaccination Site and Risk of Local Reactions in Children 1 Through 6 Years of Age

WHAT’S KNOWN ON THIS SUBJECT: Previous evaluations of local reactions after the fifth diphtheria-tetanus-acellular pertussis (DTaP) vaccine in children 4 to 6 years of age have revealed that vaccination in the thigh is associated with a lower risk of local reactions compared with vaccination in the arm.

WHAT THIS STUDY ADDS: Among children 12 to 35 months of age, injection of DTaP vaccine in the thigh is associated with a lower risk of local reactions compared with vaccination in the arm.

abstract

OBJECTIVE: Our objective was to assess whether the occurrence of medically attended local reactions to intramuscularly administered vaccines varies by injection site (arm versus thigh) in children 1 to 6 years of age.

METHODS: This is a retrospective cohort study of children in the Vaccine Safety Datalink population from 2002 to 2009. Site of injection and the outcome of medically attended local reactions were identified from administrative data.

RESULTS: The study cohort of 1.4 million children received 6.0 million intramuscular (IM) vaccines during the study period. The primary analyses evaluated the IM vaccines most commonly administered alone, which included inactivated influenza, hepatitis A, and diphtheria-tetanus-acellular pertussis (DTaP) vaccines. For inactivated influenza and hepatitis A vaccines, local reactions were relatively uncommon, and there was no difference in risk of these events with arm versus thigh injections. The rate of local reactions after DTaP vaccines was higher, and vaccination in the arm was associated with a significantly greater risk of this outcome compared with vaccination in the thigh, both for children 12 to 35 months (relative risk: 1.88 [95% confidence interval: 1.34–2.65]) and 3 to 6 years of age (relative risk: 1.41 [95% confidence interval: 0.84–2.34]), although this difference was not statistically significant in the older age group.

CONCLUSIONS: Injection in the thigh is associated with a significantly lower risk of a medically attended local reaction to a DTaP vaccination among children 12 to 35 months of age, supporting current recommendations to administer IM vaccinations in the thigh for children younger than 3 years of age. Pediatrics 2013;131:283–289

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KEY WORDS
diphtheria-tetanus-acellular pertussis vaccines, injections, intramuscular, vaccine safety, children

ABBREVIATIONS
ACIP—Advisory Committee on Immunization Practices
CI—confidence interval
DTaP—diphtheria-tetanus-acellular pertussis
ICD-9-CM—International Classification of Diseases, Ninth Revision, Clinical Modification
IM—intramuscular
MCO—managed care organization
RR—relative risk
VSD—Vaccine Safety Datalink

(Continued on last page)
Current recommendations of the US Advisory Committee on Immunization Practices (ACIP) indicate that intramuscular (IM) vaccinations given to children 3 years of age and older should be administered in the deltoid, and for toddlers aged 12 months to 2 years the anterolateral thigh muscle is preferred, but the deltoid can be used if the muscle mass is adequate. Available evidence indicates that in actual practice there is variability in choice of vaccine injection sites for children and that the risk of local reactions after vaccination can vary by injection site. Two previous evaluations of local reactions after the fifth diphtheria-tetanus-acellular pertussis (DTaP) vaccine, given to children 4 to 6 years of age, have revealed that vaccination in the arm is associated with a higher risk of local reactions compared with vaccination in the thigh.

There are few data on the relationship between site of vaccination and risk of local reactions to other IM vaccines recommended for children and to earlier doses of DTaP vaccine. To further evaluate the association between site of vaccination and risk of medically attended local reactions, we conducted a retrospective cohort study of IM vaccinations administered to children 1 to 6 years of age in the Vaccine Safety Datalink (VSD) population.

**METHODS**

This study was conducted in the VSD population. The VSD is a collaborative project between the Centers for Disease Control and Prevention and 10 managed care organizations (MCOs) in the United States that was established in 1991 to monitor and evaluate vaccine safety. The VSD collects data, including information on demographics, health plan enrollment, vaccinations, and medical encounters, on more than 9 million MCO members annually. The VSD MCOs participating in this study included Group Health (Seattle, WA), Harvard Pilgrim Health Care (Boston, MA), HealthPartners (Minneapolis, MN), Kaiser Permanente Colorado (Denver, CO), Kaiser Permanente Northwest (Portland, OR), Marshfield Clinic (Marshfield, WI), Northern California Kaiser Permanente (Oakland, CA), and Southern California Kaiser Permanente (Los Angeles, CA).

The study cohort included children enrolled at a participating VSD MCO who were at least 1 and not more than 6 years of age during the study period of 2002 through 2009. Among the study cohort, all vaccinations given on or after the first birthday and before the seventh birthday, and given during the study period, were identified from the VSD data files, and vaccines were categorized by type of administration (IM, subcutaneous, oral, or intranasal). For each vaccination, information collected from the VSD data files included the child’s age in months at the time of vaccination, date of vaccination, and, where applicable, site of injection (arm or thigh). Less commonly administered combination vaccines, for example hepatitis A and hepatitis B combination vaccine, were not included in the analyses.

To account for body habitus, the child’s height and weight recorded within 3 months of the vaccination date were obtained, when available, from data recorded in the electronic health records of the participating MCOs. BMI was calculated based on identified valid height and weight indicators. Biologically implausible extreme values were identified by using World Health Organization age and gender standardized BMI percentile thresholds and excluded. BMI was included in regression models as a 3-category variable, with BMI cutoff points established a priori corresponding to 25th and 85th percentiles (by age and gender) according to the World Health Organization Child Growth Standards. The outcome event of a medically attended local reaction was identified by using methods employed in the previous VSD study of medically attended local reactions to the fifth DTaP vaccine. In that study, medically attended local reactions were first presumptively identified by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes assigned to visits occurring within 4 days of the vaccination visit, and those presumptive events were then confirmed by chart review. In that study, the diagnosis code algorithm was highly predictive of confirmed medically attended local reactions; 83% of events presumptively identified by diagnosis codes were confirmed by chart review. Therefore, in this study, the outcome definition is based on that ICD-9-CM code algorithm, without confirmatory chart review.

Accordingly, the outcome of a medically attended local reaction after an IM vaccination was defined by an ICD-9-CM diagnosis code of cellulitis (682.3, 682.6, and 682.9), limb swelling (729.81), pain in limb (729.5), allergy unspecified (995.3), other unspecified disorder of skin (709.8), unspecified disorder of skin and subcutaneous tissue (709.9), lymphadenitis (289.3, 683, and 785.6), infection after infusion or vaccination (999.3), serum reaction (999.5), complications of medical care (999.9), or adverse effect of a medication or biologic substance (995.2) assigned to an outpatient medical encounter on the day after vaccine administration (day 1) through day 5. As in the previous study, to exclude preexisting conditions, presumptive cases defined by these criteria who also had an ICD code for cellulitis, limb swelling, pain in limb, unspecified skin disorders, allergy unspecified, or lymphadenitis (289.3, 682.3, 682.6, 682.9, 683, 709.8, 709.9, 729.5, 729.81, 785.6, and 995.3) assigned
on the day of vaccination or within the previous 30 days were excluded.

**Statistical Analysis**

The primary analyses evaluated IM vaccines administered alone, that is, without other concomitant vaccines. These analyses allowed the most straightforward assessment of the association of injection site and risk of local reactions. Secondary analyses evaluated the risk of local reactions in children who received exactly 2 vaccines on a given day, both of which were administered IM and both of which were given either in the arm or the leg. For example, among children who received a hepatitis A vaccine and an inactivated influenza vaccine on the same day, the risk of local reactions in the children who received both vaccines in the arm was compared with that in children who received both vaccines in the leg. Children who were given 1 vaccine in the arm and 1 in the thigh were excluded because the location of the local reaction could not be determined from the diagnosis codes, and so in those cases the occurrence of the reaction could not be linked to the injection site.

Evaluations of the relationship of injection site (arm versus thigh) with risk of the outcome of local reactions were based on relative risks (RRs) and 95% confidence intervals (CIs) from adjusted Poisson regression models by using robust SEs estimated using generalized estimating equations to account for within-child correlation of outcomes. Subanalyses stratified by age groups and BMI percentiles to further explore the relationship of patterns of injection to adverse events were conducted. The analyses were conducted by using Stata 12.0 (Stata Corp, College Station, TX).

**RESULTS**

The study cohort included 1.4 million children enrolled in the 8 participating MCOs when they were 1 to 6 years of age and during the study period of 2002 through 2009. That cohort received 9.3 million vaccinations during the study period, of which 6.0 million were administered intramuscularly. Of those, 5.6 million vaccines had a site of administration recorded as arm or leg.

The primary analyses evaluated the IM vaccines most commonly administered alone (without other concomitant vaccinations), which included inactivated influenza and hepatitis A and DTaP vaccines. The characteristics of children identified as receiving those vaccines without other concomitant vaccines are shown in Table 1. For each of the 3 vaccine types, the proportion of vaccines administered in the arm versus the thigh increased with age (Fig 1).

For inactivated influenza and hepatitis A vaccines, medically attended local reactions were relatively uncommon, and there was no difference in risk of these events by site of injection (Table 2). The risk of local reactions after a DTaP vaccine given without other concomitant vaccines was several fold higher than with influenza and hepatitis A vaccines. Among the study population of children 1 to 6 years of age, administration of DTaP vaccine in the arm was associated with a significantly higher risk of this outcome compared with administration in the thigh (RR: 1.88 [95% CI: 1.42–2.49]).

In analyses stratified by age, among children 12 to 35 months of age, the rate of injection site reactions after DTaP vaccination was significantly higher with arm than with thigh administration, whereas among the smaller subgroup...
of children 3 to 6 years of age, the rate of injection site reactions was also higher with arm than with leg administration, but this difference was not statistically significant. Rates of local reactions after DTaP vaccine were significantly higher in the older versus the younger age group, for both arm and thigh injections. The risk of a local reaction after a DTaP vaccine did not vary by gender.

To evaluate the possible influence of BMI on the association of injection site and risk of local reactions, analyses restricted to the subgroups of children for whom BMI on the date of vaccination could be calculated were conducted. Among those subgroups, there was essentially no difference in the results of multivariable models that included or did not include BMI, suggesting that BMI is not a confounder in the association of injection site and risk of local reactions (Table 3). In a multivariable model including a binary variable for BMI ≥ 85th percentile for age that also adjusted for age, gender, MCO, and injection site, BMI ≥ 85th percentile was independently associated with a higher risk of a local reaction after DTaP vaccine (RR: 1.56 [95% CI: 1.09–2.23]). In analyses stratified by BMI (< or ≥ 85th percentile), the association of arm vaccination and risk of a local reaction after DTaP vaccination was similar in the 2 strata (<85th percentile RR: 1.91 [95% CI: 1.06–3.43], ≥85th percentile RR: 2.59 [95% CI: 1.11–6.05]).

Analyses of children who received 2 IM vaccinations on the same day, with both given either in the arm or in the thigh, also revealed a generally higher rate of medically attended local reactions with combinations that included a DTaP vaccine. Among children who received a DTaP vaccine together with another vaccine, there was a trend toward a higher risk of local reactions when both vaccines were given in the arm versus the thigh, and this association was statistically significant for the DTaP plus hepatitis A vaccine combination (Table 4). In contrast, when the vaccine combination did not

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**TABLE 2** Association of Site of Vaccination and Risk of a Medically Attended Local Reaction After Receipt of Inactivated Influenza, DTaP, or Hepatitis A Vaccine Without Other Concomitant Vaccinations, by Age Group

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Vaccine</th>
<th>Injection Site</th>
<th>Number of Vaccines</th>
<th>Number of Outcomes</th>
<th>Rate of Outcomes per 10,000 Vaccinations</th>
<th>RR of Local Reactions</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>RR</td>
<td>95% CI</td>
</tr>
<tr>
<td>1–6 y</td>
<td>Inactivated influenza</td>
<td>Thigh</td>
<td>397 237</td>
<td>373</td>
<td>9.4</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm</td>
<td>535 539</td>
<td>524</td>
<td>9.8</td>
<td>1.08</td>
<td>0.92–1.28</td>
</tr>
<tr>
<td></td>
<td>DTaP</td>
<td>Thigh</td>
<td>72 795</td>
<td>184</td>
<td>25.3</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm</td>
<td>18 715</td>
<td>125</td>
<td>66.8</td>
<td>1.88</td>
<td>1.42–2.49</td>
</tr>
<tr>
<td></td>
<td>Hepatitis A</td>
<td>Thigh</td>
<td>427 373</td>
<td>300</td>
<td>7.0</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm</td>
<td>388 442</td>
<td>270</td>
<td>6.9</td>
<td>1.09</td>
<td>0.91–1.30</td>
</tr>
<tr>
<td>12–35 mo</td>
<td>Inactivated influenza</td>
<td>Thigh</td>
<td>286 257</td>
<td>265</td>
<td>9.3</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm</td>
<td>97 924</td>
<td>92</td>
<td>9.4</td>
<td>1.00</td>
<td>0.77–1.29</td>
</tr>
<tr>
<td></td>
<td>DTaP</td>
<td>Thigh</td>
<td>68 007</td>
<td>154</td>
<td>22.8</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm</td>
<td>8799</td>
<td>49</td>
<td>50.0</td>
<td>1.88</td>
<td>1.34–2.65</td>
</tr>
<tr>
<td></td>
<td>Hepatitis A</td>
<td>Thigh</td>
<td>315 187</td>
<td>230</td>
<td>7.3</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm</td>
<td>147 713</td>
<td>111</td>
<td>7.5</td>
<td>1.05</td>
<td>0.85–1.32</td>
</tr>
<tr>
<td>3–6 y</td>
<td>Inactivated influenza</td>
<td>Thigh</td>
<td>110 980</td>
<td>108</td>
<td>9.7</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm</td>
<td>437 615</td>
<td>432</td>
<td>9.9</td>
<td>1.13</td>
<td>0.89–1.43</td>
</tr>
<tr>
<td></td>
<td>DTaP</td>
<td>Thigh</td>
<td>4788</td>
<td>30</td>
<td>62.7</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm</td>
<td>8916</td>
<td>76</td>
<td>85.2</td>
<td>1.41</td>
<td>0.84–2.34</td>
</tr>
<tr>
<td></td>
<td>Hepatitis A</td>
<td>Thigh</td>
<td>110 802</td>
<td>70</td>
<td>6.3</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm</td>
<td>241 439</td>
<td>159</td>
<td>6.6</td>
<td>1.20</td>
<td>0.89–1.63</td>
</tr>
</tbody>
</table>

* In model adjusting for month of age, gender, and MCO.
include a DTaP vaccine, there was no evidence of an increased risk of a medically attended local reaction with arm administration.

DISCUSSION

In this study, we used the unique data resources of the VSD to evaluate the association between injection site and risk of medically attended local reactions to IM vaccines commonly given to children 1 to 6 years of age. In evaluations of IM vaccines given alone, we found that local reactions occurred more frequently after a DTaP vaccine than after an inactivated influenza or hepatitis A vaccine and that injection of a DTaP vaccine in the arm was associated with a significantly higher risk compared with administration in the thigh, whereas there was no association of injection site and risk of a local reaction for the other 2 vaccine types. A higher risk of local reactions with arm administration of DTaP vaccine was also suggested by the results of analyses of vaccine combinations that included a DTaP vaccine.

The current ACIP recommendations, which were adopted in 2011, state that IM vaccines given to children 3 years of age and older should be administered in the deltoid, and for toddlers aged 12 months to 2 years the anterolateral thigh muscle is preferred, but the deltoid can be used if the muscle mass is adequate.1 Before that, the recommendations of the ACIP and the American Academy of Pediatrics stated that the deltoid muscle was the preferred site for IM vaccinations given to children 1 year of age and older.10,11 Our results indicate that there was inconsistent adherence to those recommendation during our study period of 2002 through 2009, as, across all sites, only a minority of children 12 to 36 months of age who received DTaP vaccine alone received the vaccine in the arm, and even among 3- and 4-year-old children, at least 20% received the vaccine in the thigh.

Our results support the current preference for thigh administration of IM vaccinations to children 12 to 35 months of age, particularly for DTaP vaccine. Among this age group, arm administration of DTaP vaccine was associated with a nearly twofold increase in risk of a medically attended local reaction compared with thigh administration, although the absolute risk of this outcome was relatively uncommon, occurring in less than 1% of vaccinated children.

Our results, and those of previous studies, also suggest that a similar benefit may be derived from thigh administration of DTaP vaccine to children 3 to 6 years of age (an age group with a higher risk of medically attended local reactions after DTaP vaccine than that in the 12- to 35-month-old age group). Among the 3- to 6-year age group, we found a trend toward an increased risk of a medically attended injection site reaction with arm administration of DTaP vaccine. This is consistent with the results of a previous VSD evaluation of medically attended local reactions to the fifth DTaP, which revealed that that injection in the arm was associated with an approximately two-fold increase in the risk of that outcome.5 Our findings are also consistent with those of a prospective study that followed 1315 children after their fifth DTaP vaccination and collected information on the presence and severity of local reactions from daily study diaries completed by parents.2 In that study, children vaccinated in the arm were significantly more likely to have local reactions characterized by any degree of redness at the injection site (65% vs 40%) and at least 5 cm of redness at the injection site (38% vs 6%) but were no more likely to complain of pain in the vaccinated limb (53% vs 48%) than children vaccinated in the thigh. Together, these findings suggest that, for DTaP vaccine, the preference for thigh administration should extend to children through 6 years of age. As in those previous studies, we also found that higher BMI

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**TABLE 3** Association of Site of Vaccination and Risk of a Medically Attended Local Reaction Following Receipt of Inactivated Influenza, DTaP, or Hepatitis A Vaccine Without Other Concomitant Vaccinations, Among the Subgroup of Children for Whom BMI at the Date of Vaccination Could be Determined, in Models Unadjusted and Adjusted for BMI

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Injection Site</th>
<th>Number of Vaccines</th>
<th>Number of Outcomes</th>
<th>Rate of Outcomes per 10 000 Vaccinations</th>
<th>RR of Local Reactions&lt;sup&gt;a&lt;/sup&gt;</th>
<th>95% CI</th>
<th>RR of Local Reactions&lt;sup&gt;b&lt;/sup&gt;</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inactivated influenza</td>
<td>Thigh</td>
<td>195 036</td>
<td>203</td>
<td>10.4</td>
<td>Referent</td>
<td>—</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Arm</td>
<td>187 255</td>
<td>220</td>
<td>11.7</td>
<td>1.01</td>
<td>0.79–1.28</td>
<td>1.00</td>
<td>0.78–1.28</td>
</tr>
<tr>
<td>DTaP</td>
<td>Thigh</td>
<td>34 414</td>
<td>54</td>
<td>26.4</td>
<td>Referent</td>
<td>—</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Arm</td>
<td>51 684</td>
<td>43</td>
<td>83.2</td>
<td>2.15</td>
<td>1.33–3.48</td>
<td>2.13</td>
<td>1.31–3.44</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>Thigh</td>
<td>164 103</td>
<td>118</td>
<td>7.2</td>
<td>Referent</td>
<td>—</td>
<td>Referent</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Arm</td>
<td>81 127</td>
<td>61</td>
<td>7.5</td>
<td>1.16</td>
<td>0.82–1.63</td>
<td>1.16</td>
<td>0.82–1.62</td>
</tr>
</tbody>
</table>

<sup>a</sup> In model adjusting for month of age, gender, and MCO.

<sup>b</sup> Defined as a categorical variable (<25th percentile, ≥25th and <85th percentile, and ≥85th percentile) based on World Health Organization child growth standards.
was associated with an increased risk of a local reaction, independent of injection site, age, and gender, possibly due to inadequate IM penetration in children with higher BMI.

There are limitations of this study that should be considered when interpreting the findings. We identified local reactions on the basis of ICD-9-CM codes assigned to medical encounters, and so our capture of medically attended local reactions was likely not 100% complete, and we did not validate the reactions by medical record review, and so some events were likely misclassified. Information on height and weight was not available for the majority of the study population and so the relationship between BMI and risk of a local reaction could only be evaluated in the subgroup with this information. We also could not evaluate children who received multiple vaccinations concomitantly in both the arm and the thigh. Lastly, among our study population, providers may have elected to vaccinate in the arm or thigh based on local standards and practices. When we controlled for the characteristics we could define in multivariable models, the association of arm injection site with a significantly higher risk of medically attended local reactions persisted, but it is possible that bias may have influenced the findings.

**CONCLUSIONS**

Local reactions are the most common adverse events after vaccination, but relatively little is known regarding factors that influence the risk of these reactions. Our findings indicate that injection in the thigh is associated with a significantly lower risk of a medically attended local reaction to DTaP vaccination among children 1 to 2 years of age, supporting current recommendations for thigh administration of IM injections in this age group.

**REFERENCES**


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**TABLE 4** Association of Site of Vaccination and Risk of a Medically Attended Local Reaction After Receipt of 2 IM Vaccines in the Arm Compared With Receipt of the Same Combination of 2 IM Vaccines in the Thigh, Without Other Concomitant Vaccinations

<table>
<thead>
<tr>
<th>Vaccine Combination</th>
<th>Injection Site for Both Vaccines</th>
<th>Number of Episodes</th>
<th>Number of Outcomes</th>
<th>Rate of Outcomes per 10 000 Episodes</th>
<th>RR of Local Reactions</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP + Hepatitis A</td>
<td>Thigh</td>
<td>48 095</td>
<td>101</td>
<td>21.0</td>
<td>Referent</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Arm</td>
<td>9411</td>
<td>51</td>
<td>54.2</td>
<td>2.13</td>
<td>1.44–3.15</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>DTaP + PCV7</td>
<td>Thigh</td>
<td>25 693</td>
<td>52</td>
<td>20.2</td>
<td>Referent</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Arm</td>
<td>3473</td>
<td>8</td>
<td>23.0</td>
<td>1.15</td>
<td>0.55–2.42</td>
<td>.7</td>
</tr>
<tr>
<td>DTaP + Hib</td>
<td>Thigh</td>
<td>18 735</td>
<td>27</td>
<td>14.4</td>
<td>Referent</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Arm</td>
<td>2192</td>
<td>7</td>
<td>31.9</td>
<td>2.07</td>
<td>0.83–5.17</td>
<td>.1</td>
</tr>
<tr>
<td>DTaP + inactivated influenza</td>
<td>Thigh</td>
<td>12 050</td>
<td>11</td>
<td>9.1</td>
<td>Referent</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Arm</td>
<td>1638</td>
<td>4</td>
<td>24.4</td>
<td>2.02</td>
<td>0.47–8.72</td>
<td>.3</td>
</tr>
<tr>
<td>Hepatitis A + inactivated influenza</td>
<td>Thigh</td>
<td>67 112</td>
<td>52</td>
<td>7.7</td>
<td>Referent</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Arm</td>
<td>34 516</td>
<td>24</td>
<td>7.0</td>
<td>0.89</td>
<td>0.53–1.51</td>
<td>.7</td>
</tr>
<tr>
<td>Hepatitis A + PCV7</td>
<td>Thigh</td>
<td>14 845</td>
<td>21</td>
<td>14.3</td>
<td>Referent</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Arm</td>
<td>4444</td>
<td>6</td>
<td>13.5</td>
<td>0.81</td>
<td>0.28–2.29</td>
<td>.7</td>
</tr>
<tr>
<td>Hepatitis A + Hib</td>
<td>Thigh</td>
<td>8209</td>
<td>10</td>
<td>12.2</td>
<td>Referent</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Arm</td>
<td>2147</td>
<td>2</td>
<td>9.3</td>
<td>1.16</td>
<td>0.26–5.11</td>
<td>.8</td>
</tr>
</tbody>
</table>

**Hib**, Haemophilus influenzae type b vaccine; PCV7, 7 valent pneumococcal conjugate vaccine.

* In model adjusting for month of age and gender.

(Continued from first page)

Dr Jackson conceptualized and designed the study, developed the protocol, interpreted the results, and drafted the initial and final articles; Mr Peterson created the programming instructions for data collection, cleaned the study data, performed the statistical analyses, interpreted the results, reviewed and revised the article, and approved the final article as submitted; Dr Nelson provided oversight and statistical consultation for the data collection and analytic methods, interpreted the results, reviewed and revised the article, and approved the final article as submitted; Dr Marcy assisted in the development of the protocol, supervised data collection at his site, critically reviewed the article, and approved the final article as submitted; Dr Naleway assisted in the development of the protocol, supervised data collection at her site, critically reviewed the article, and approved the final article as submitted; Dr Nordin assisted in the development of the protocol, supervised data collection at his site, critically reviewed the article, and approved the final article as submitted; Dr Donahue assisted in the development of the protocol, supervised data collection at his site, critically reviewed the article, and approved the final article as submitted; Dr Marcy assisted in the development of the protocol, supervised data collection at his site, critically reviewed the article, and approved the final article as submitted; Dr Hambidge assisted in the development of the protocol, supervised data collection at his site, critically reviewed the article, and approved the final article as submitted; Ms Balsbaugh assisted in the development of the protocol, supervised data collection at her site, critically reviewed the article, and approved the final article as submitted; Dr Baxter assisted in the development of the protocol, supervised data collection at his site, critically reviewed the article, and approved the final article as submitted; Ms Marsh created the data collection programs, performed data checks and data cleaning, critically reviewed the article, and approved the final article as submitted; Mr Madzwi reviewed the data collection programs, performed initial testing of those programs, received the data from sites and performed checks for errors and accuracy, critically reviewed the article, and approved the final article as submitted; and Mr Weintraub reviewed the original study concept, reviewed draft protocols and assisted in the development of the study, critically reviewed the article, and approved the final article as submitted.

The findings and conclusions in this report are those of the authors, and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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