Background
The safety of live attenuated influenza vaccine (LAIV) has been evaluated in several clinical trials and a community-based open-label study.1• LAIV was initially approved in the United States in 2003 for eligible individuals 5–17 years of age; the age indication was lowered to include children as young as 7 years in 2007. • As part of a postlicensure commitment to the US Food and Drug Administration, Medimmune conducted a postlicensure evaluation of the safety of LAIV in 60,000 LAIV recipients 5–49 years of age, including approximately 20,000 individuals in each of 3 age cohorts (5–8, 9–17, and 46–49 y). • LAIV is also approved in other countries for use in eligible individuals aged 2–17 years. • As part of a postlicensure commitment to the US Food and Drug Administration, Medimmune conducted a postlicensure evaluation of the safety of LAIV in 60,000 recipients 5–49 years of age, including approximately 20,000 individuals in each of 3 age cohorts (5–8, 9–17, and 46–49 y).

Objective
To evaluate the postlicensure safety of LAIV among US children aged 5–8 and 9–17 years.

Methods
Safety data were prospectively collected from a Kaiser Permanente Health Plan in California. The analysis population included 43,702 subjects 5–17 years of age who received 47,611 doses of LAIV (42,862 subjects in LAIV Doses 5–8 and 8,749 subjects in LAIV Doses 9–17). All MAEs and SAEs through 42 days postvaccination and all hospitalizations and deaths for rare events potentially related to LAIV were included. Specific events included in the study are listed in Table 1. All MAEs were categorized into MedDRA system organ class (SOC), preferred term (PT), and MedDRA high level term (HLT) categories. Effectiveness was determined by comparing events in LAIV recipients with TIV recipients in the TIV control column. Certain events were assessed within 2 postlicensure years of LAIV, and other events were not assessed owing to limited postlicensure follow-up in this population.

Results
In the analysis population, 43,702 subjects 5–17 years of age were vaccinated with LAIV, 7 vaccinated with TIV, and no unvaccinated children. Within the analysis population, 43,702 subjects 5–17 years of age were vaccinated with LAIV, 7 vaccinated with TIV, and no unvaccinated children. All MAEs and SAEs through 42 days postvaccination and all hospitalizations and deaths for rare events potentially related to LAIV were included. Specific events included in the study are listed in Table 1. All MAEs were categorized into MedDRA system organ class (SOC), preferred term (PT), and MedDRA high level term (HLT) categories. Effectiveness was determined by comparing events in LAIV recipients with TIV recipients in the TIV control column. Certain events were assessed within 2 postlicensure years of LAIV, and other events were not assessed owing to limited postlicensure follow-up in this population.

Conclusions
This postlicensure surveillance study evaluated the safety of LAIV in children aged 5–17 years through a structured retrospective chart review. LAIV was not associated with an increase in any safety signal compared with TIV recipients. This study did not identify any unexpected significant adverse events associated with LAIV in children aged 5–17 years received LAIV from October 2003–March 2008; comparators were multiple non randomized controls, including self-control, matched unvaccinated controls, and matched TIV recipients. Subjects were matched based on sex, age, and previous healthcare use. Children at high risk for those with underlying medical conditions for whom LAIV was not recommended were excluded from analysis. MAEs were identified in the clinic, emergency department, and hospital. All MAEs and SAEs through 42 days postvaccination and all hospitalizations and deaths through 6 months postvaccination were analyzed (Table 1).

Table 1. Characteristics of Subjects Receiving Doses in All Analyses
<table>
<thead>
<tr>
<th>Type of Analysis</th>
<th>Within-Cohort</th>
<th>Comparison With Unvaccinated Controls</th>
<th>Comparison With TIV Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAIV Doses 5–8</td>
<td>23,528 (44.1)</td>
<td>25,245 (47.3)</td>
<td>27,546 (52.0)</td>
</tr>
<tr>
<td>LAIV Doses 9–17</td>
<td>23,362 (43.8)</td>
<td>25,245 (47.3)</td>
<td>27,546 (52.0)</td>
</tr>
</tbody>
</table>

• Individual MAEs that were significantly increased or decreased after LAIV were organized by organ class in a 2-dimensional heat map (Figure 1).
• Statistical significance was assigned without multiplicity adjustment.

Specifically, no increase in asthma or wheezing events were seen after vaccination with LAIV. LAIV was not recommended) were excluded from analysis. Within-Cohort

References
4. Frangiscos Sifakis, PhD, MPH, Frangiscos Sifakis, PhD, MPH, 1
5. Roger Baxter, MD, Roger Baxter, MD, 1
6. Kaiser Permanente Vaccine Study Center, Oakland, CA 94619, USA
7. Medimmune, LLC, Gaithersburg, MD
10. 38 (0.1)

• The incidence rates of SAEs were low and not significantly higher or lower in LAIV recipients relative to control groups in any comparisons.
• 2 SAEs (Bell palsy [n=2] and nonspecific paralytical spell [n=1]) were considered possibly related to LAIV.
• In children 9–17 years of age, Bell palsy occurred in 2 children vaccinated with LAIV, 7 vaccinated with TIV, and no unvaccinated children. The rate of hospitalization was low and not significantly higher or lower in LAIV recipients relative to control groups in any comparison.
• 3 deaths occurred within 180 days postvaccination; all were considered unrelated to LAIV.

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