patients dispensed prescriptions for oxycodone ER during the study, with no significant change after the labeling change (Wilcoxon-Mann-Whitney test; \( P = .48 \)).

**Discussion** | Our analysis demonstrates that the approval of pediatric labeling for OxyContin in children 11 years of age and older was not associated with an increase in the number of children dispensed oxycodone ER in the outpatient setting, and that such dispensing occurs at extremely low levels, particularly when viewed in the context of overall oxycodone ER dispensing. However, clinicians for this limited population of pediatric patients can now rely on age-appropriate prescribing information derived from clinical studies, and they need not base patient selection and dosing on clinical judgment alone. More research is needed to examine the long-term effect of pediatric labeling of opioids, including changes in prescription dosages, changes in prescribing of opioids that lack pediatric labeling, and the risks for subsequent misuse of prescription opioids.

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**Drafting of the manuscript:** All Authors. Critical revision of the manuscript for important intellectual content: All Authors. Statistical analysis: Xu, Cruz. Administrative, technical, or material support: Lurie. Study supervision: Staffa, Lurie.

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**Vaccination Coverage Rates and Factors Associated With Incomplete Vaccination or Exemption Among School-age Children Based in Public Schools in New York State**

Gaps in intentional and unintentional vaccination coverage persist and appear to be associated with socioeconomic factors that often drive social and geographic clustering.1–3 Nonmedical exemptions to school vaccination requirements are rising nationally and in New York State (NYS).4 In states, including NYS, that only allow religious and medical exemptions, the association between socioeconomic characteristics and vaccination coverage and exemptions is unknown. The objective of this study was to assess vaccination coverage rates and
Factors associated with either incomplete vaccination or exemptions among school-age children in NYS public schools outside of New York City.

Methods | Children entering kindergarten through 12th grade in NYS between the academic years 2010-2011 and 2013-2014 were required to have at least 3 doses of diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine, 3 doses of poliovirus vaccine, 2 doses of measles-mumps-rubella (MMR) vaccine, 3 doses of hepatitis B vaccine, and a single dose of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) booster for 6th grade. The primary outcome measures were annual vaccination coverage and religious exemptions among children in grades K through 12. School immunization assessment survey results were obtained via the Freedom of Information Act from the NYS Department of Health. School district-level vaccination coverage and exemption data among public schoolchildren for 4 academic years (2010-2011 to 2013-2014) were matched to sociodemographic information obtained from the American Community Survey. The analyses were restricted to the 95% of school districts with matched data available from the survey. For each school district, the median percentage vaccination coverage and exemptions (medical or religious) were calculated. The 1% to 99% ranges were calculated to remove the effect of a few outliers. The Wilcoxon rank sum test was used to assess for trend across academic years. Poisson regression with robust error estimates was used to determine the association between rates of exemptions and underimmunization with districts’ income, education, and race distributions. The study met the criteria for exempt research. Therefore, State University of New York Upstate Medical University Institutional Review Board approval and informed consent were not required.

Results | The number of reporting districts and schools ranged from 699 districts (2978 schools) in 2010-2011 to 695 districts (2878 schools) in 2013-2014. The median coverage for each mandated vaccine and the complete immunization series remained above 99% for the reported period overall. Most districts and individual schools maintained greater than 95% coverage for individual vaccines and the complete immunization series, while only 2.7% (18 of 661) of districts reported less than 95% coverage (Table 1). Among schools with less than 95% coverage, 85.5% (5089 of 5951) of missed vaccines were unintentional and unrelated to exemptions. Exemptions are uncommon in NYS public schools. From the 2010-2011 to 2013-2014 academic years, the median religious and medical exemption rates increased from 0.26% to 0.39% (P < .05) and 0.08% to 0.12% (P > .05), respectively. Children in districts with lower socioeconomic status were less likely to have received the complete series of required vaccines. While religious exemptions are rare, districts with larger income, more education, and greater percentage of residents of white race had significantly higher rates of religious exemptions (Table 2).

Discussion | Public schools in NYS have high vaccination coverage, with current state immunization policies permitting only religious or medical exemptions. While religious exemptions are associated with higher socioeconomic status, the effect of these exemptions is small compared with unintended underimmunization, which disproportionately occurs in the economically challenged districts. The primary study limitation is the dependence on school immunization reports due in the fall semester, thus excluding immunizations completed after October. Public health practitioners should continue to enforce effective vaccination exemption policies and carefully examine barriers to vaccination among children in poorer school districts.

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Table 2. Vaccination Exemptions and Underimmunization for Public Schoolchildren, New York State, 2013-2014 Academic Year

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Children With Medical Exemption</th>
<th>Children With Religious Exemption</th>
<th>Children With Underimmunization for Complete Immunization Series</th>
<th>Children With Underimmunization for Measles-Mumps-Rubella Vaccine</th>
<th>Children With Underimmunization for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Of Persons Older Than 25 y With a Bachelor’s Degree or Higher</td>
<td>0.20 (0.19-0.22)</td>
<td>0.58 (0.56-0.60)</td>
<td>1.23 (1.20-1.26)</td>
<td>1.01 (0.98-1.04)</td>
<td>0.92 (0.89-0.94)</td>
</tr>
<tr>
<td>% Of Children Participating in the Free Lunch Program</td>
<td>0.20 (0.19-0.21)</td>
<td>0.63 (0.61-0.64)</td>
<td>1.35 (1.32-1.37)</td>
<td>1.10 (1.08-1.13)</td>
<td>1.00 (0.99-1.03)</td>
</tr>
<tr>
<td>% Of Households With Children</td>
<td>0.14 (0.12-0.17)</td>
<td>0.90 (0.85-0.97)</td>
<td>1.88 (1.80-1.97)</td>
<td>1.61 (1.54-1.70)</td>
<td>1.43 (1.35-1.50)</td>
</tr>
<tr>
<td>% Of White Race</td>
<td>0.14 (0.08-0.13)</td>
<td>0.21 (0.18-0.25)</td>
<td>3.46 (3.32-3.61)</td>
<td>2.12 (2.11-2.13)</td>
<td>1.16 (1.08-1.25)</td>
</tr>
<tr>
<td>% Of Black Race</td>
<td>0.13 (0.09-0.16)</td>
<td>0.44 (0.39-0.49)</td>
<td>1.10 (1.03-1.18)</td>
<td>0.99 (0.92-1.07)</td>
<td>0.81 (0.75-0.88)</td>
</tr>
</tbody>
</table>

*Values represent the rate (number of children attending school districts with the characteristic designated per 100 children in those school districts) expressed as a percentage. Rates were determined using Poisson regression with robust error estimates. Schools within New York City were excluded because they report vaccination coverage and exemptions as a single school district; therefore, the substantial heterogeneity of socioeconomic status in New York City makes these data uninformative. Sociodemographic data were obtained from the 2013 American Community Survey 5-y estimates. Multivariable analysis identified the following 3 statistically significant factors: percentage of persons older than 25 y with a bachelor’s degree or higher, percentage of households with children, and percentage of black race. All other factors were not statistically significant once the model was adjusted for these 3 factors due to the highly correlated nature of the measures. The adjusted estimated percentages of religious exemptions for the levels of these factors were similar to the unadjusted estimates presented in the table.

1. Diphtheria and tetanus toxoids and acellular pertussis vaccine includes children who might have been vaccinated with diphtheria and tetanus toxoids vaccine or diphtheria vaccine, tetanus toxoids, and pertussis vaccine.

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Author Contributions: Dr Nadeau had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Nadeau, Shaw. Acquisition, analysis, or interpretation of data: All authors. Drafting of the manuscript: Nadeau, McNutt. Critical revision of the manuscript for important intellectual content: McNutt, Shaw.

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Additional Contributions: Ellen Darabaner, MLS (Samaritan Medical Center, Watertown, New York), provided librarian assistance and expertise. Allison Krug, MPH (Artemis Biomedical Communications LLC, Bainbridge Island, Washington), contributed editorially to the manuscript, for which she received hourly compensation.

Close follow-up in children with acute otitis media initially managed without antimicrobials

According to several national guidelines, close follow-up is required if initial observation without antimicrobial agents is chosen for the management of acute otitis media (AOM) in children.1-4 The aim of this study was to examine whether close follow-up with reexamination is needed for children with AOM initially managed without antimicrobial agents who have symptomatic improvement during the first week after diagnosis, as assessed by their parents.

Methods | This study is part of a project examining diagnostics and treatment of AOM (Clinicaltrials.gov identified NCT00299455).5 Children aged 6 to 35 months with acute symptoms and parental suspicion of AOM were eligible. Acute otitis media was diagnosed from March 16, 2006, to December 5, 2008, excluding June and July of each year, with the use of stringent criteria and children were randomized in a double-blind fashion to receive either a combination of amoxicillin, 40 mg/kg per day, and clavulanate potassium, 5.7 mg/kg per day, divided into 2 daily doses, or placebo for 7 days. The scheduled visits were 48 to 72 hours and 1 week after the day of the diagnosis of AOM; additional visits were arranged on any other day by parental request. At each visit, the physician examined the child and recorded signs as seen on pneumatic otoscopy as completely resolved, better, no improvement, worse, or perforation of the tympanic membrane. Correspondingly, at each visit, parents assessed their child’s overall condition as healthy, better, no improvement, or worse.

In our analysis, we included 158 patients who received placebo and divided them into 2 groups. The group with symptomatic improvement (n = 104) included children whose overall condition improved within 48 to 72 hours and did not deteriorate within 1 week of diagnosis, according to assessment by their parents. The group with symptomatic failure (n = 54) included children whose overall condition did not improve within 48 to 72 hours or deteriorated within 1 week of diagnosis, according to assessment by their parents.

Results | Of the 104 children with symptomatic improvement, 3 (2.9%) developed worse signs or perforation of the tympanic membrane as seen on otoscopy, 15 (14.4%) showed no improvement, and 86 (82.7%) showed improvement or complete resolution of signs as seen on otoscopy (Table). Of the 54 children with symptomatic failure, 16 (29.6%) developed worse signs or perforation of the tympanic membrane as seen on otoscopy, 26 (48.1%) showed no improvement, and 12 (22.2%) showed improvement or complete resolution of signs as seen on otoscopy. Perforation of the tympanic membrane was seen in 2 children with symptomatic improvement and in 3 children with symptomatic failure. In children with symptomatic improvement, the odds ratio for the worsening (including perforation of the tympanic membrane) of signs as seen on otoscopy during the 1-week follow-up was 0.07 (95% CI, 0.02-0.26).

Discussion | Our results indicate that the resolution of signs of AOM as seen on otoscopy seems to be related to the child’s overall symptomatic condition. When parents assessed their child’s symptomatic condition as improving, otoscopic signs worsened in only 3 children (2.9%), including 2 children with perforation of the tympanic membrane. Thus, it appears that in children with symptomatic improvement, a routine follow-up visit may not be needed and a telephone call between the physician and parents would be sufficient to ensure the child’s well-being. Even the telephone call might be unnecessary if the physician considers the parents to be independently reliable to assess their child’s overall condition. However, when a child has symptomatic failure, parents should contact the physician, who will reexamine the child if there is any suspicion of toxic effects. Alternatively, parents of a child

Table. Development of Signs Seen on Otoscopy During Follow-up at 1 Week

<table>
<thead>
<tr>
<th>Signs as Seen on Otoscopya</th>
<th>No. (%)</th>
<th>Children With Symptomatic Improvement (n = 104)</th>
<th>Children With Symptomatic Failure (n = 54)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worse or perforation of the tympanic membraneb</td>
<td>3 (2.9)</td>
<td>16 (29.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No improvement</td>
<td>15 (14.4)</td>
<td>26 (48.1)</td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Completely resolved or better</td>
<td>86 (82.7)</td>
<td>12 (22.2)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a Signs seen on otoscopy were recorded before the 1-week visit in 4 children with symptomatic improvement and in 36 children with symptomatic failure owing to the cessation of the study drug.
b Perforation occurred in 2 children (aged 16 and 22 mo) with symptomatic improvement and in 3 children (aged 10.16, and 25 mo) with symptomatic failure. In children with symptomatic improvement, the perforation was diagnosed on a scheduled follow-up visit 48 h after the day of diagnosis with acute otitis media. The parents had not noticed any ear discharge and they assessed their child’s overall condition as better than it had been at the time of diagnosis.