Trends in Otitis Media–Related Health Care Use in the United States, 2001-2011

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IMPORTANCE Otitis media (OM) is a leading cause of pediatric health care visits and the most frequent reason children consume antibiotics or undergo surgery. During recent years, several interventions have been introduced aiming to decrease OM burden.

OBJECTIVE To study the trend in OM-related health care use in the United States during the pneumococcal conjugate vaccine (PCV) era (2001-2011).

DESIGN, SETTING, AND PARTICIPANTS An analysis of an insurance claims database of a large, nationwide managed health care plan was conducted. Enrolled children aged 6 years or younger with OM visits were identified.

MAIN OUTCOMES AND MEASURES Annual OM visit rates, OM-related complications, and surgical interventions were analyzed.

RESULTS Overall, 7.82 million unique children (5.51 million child-years) contributed 6.21 million primary OM visits; 52% were boys and 48% were younger than 2 years. There was a downward trend in OM visit rates from 2004 to 2011, with a significant drop that coincided with the advent of the 13-valent vaccine (PCV-13) in 2010. The observed OM visit rates in 2010 (1.00/child-year) and 2011 (0.81/child-year) were lower than the projected rates based on the 2005-2009 trend had there been no intervention (P < .001). Recurrent OM (≥3 OM visits within 6-month look-back) rates decreased at 0.003/child-year (95% CI, 0.002-0.004/child-year) in 2001-2009 and at 0.018/child-year (95% CI, 0.008-0.028/child-year) in 2010-2011. In the PCV-13 premarket years, there was a stable rate ratio (RR) between OM visit rates in children younger than 2 years and in those aged 2 to 6 years (RR, 1.38; 95% CI, 1.38-1.39); the RR decreased significantly (P < .001) during the transition year 2010 (RR 1.32; 95% CI, 1.31-1.33) and the postmarket year 2011 (RR 1.01; 95% CI, 1.00-1.02). Tympanic membrane perforation/otorrhea rates gradually increased (from 3721 per 100 000 OM child-years in 2001 to 4542 per 100 000 OM child-years in 2011; P < .001); the increase was significant only in the older children group. Mastoiditis rates substantially decreased (from 61 per 100 000 child-years in 2008 to 37 per 100 000 child-years in 2011; P < .001). Ventilating tube insertion rate decreased by 19% from 2010 to 2011 (P = .03).

CONCLUSIONS AND RELEVANCE There was an overall downward trend in OM-related health care use from 2001 to 2011. The significant reduction in OM visit rates in 2010-2011 in children younger than 2 years coincided with the advent of PCV-13. Although tympanic membrane perforation/otorrhea rates steadily increased during that period, mastoiditis and ventilating tube insertion rates decreased in the last years of the study.

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Otitis media (OM) is the most common disease seen in pediatric practice, a leading cause of health care visits, and the most frequent reason children consume antibiotics or undergo surgery.\(^1\) By their third birthday, 80% of children will have experienced 1 or more episodes of OM, and more than 40% will have had 3 or more episodes.\(^4\) Reported OM ambulatory visits in US children younger than 2 years were 1244 visits per 1000 child-years in 2004,\(^5\) and 80% of those visits resulted in an antibiotic prescription.\(^2\) Otitis media also has a high socioeconomic impact worldwide.\(^6,^7\) In the United States, an estimated $4 billion is spent yearly on OM-related healthcare.\(^5,^6\)

During the previous decade, considerable medical progress has been made in OM prevention. Among the major interventions are conjugate vaccines against *Streptococcus pneumoniae*, a major pathogen of acute OM (AOM). In the United States, 7-valent pneumococcal conjugate vaccine (PCV-7) was licensed in 2000. Routine PCV-7 vaccination was associated with significant OM visit rate reduction as well as a decrease in ventilating tube (VT) insertion related to recurrent and chronic OM.\(^8,^9\) The pneumococcal population has changed since the widespread use of PCV-7, with nonvaccine serotypes in the nasopharynx increasing among both asymptomatic carriers and patients with OM in a process termed serotype replacement.\(^11,^12\) These changes mandated new vaccines with broader coverage. In March 2010, the 13-valent vaccine (PCV-13) was licensed for use among US children aged 6 weeks and more than 40% will have had 3 or more episodes.\(^4\) Recent OM episodes with a primary diagnosis of OM: 381.X (nonsuppurative OM and eustachian tube disorder), 382.X (suppurative and unspecified OM), or 384.X (acute myringitis, unspecified). Any OM visits occurring within 14 days after the initial OM visit (index date) were considered as follow-up visits, and the OM episode was counted only once. For each eligible OM visit, estimated age and sex were extracted. Patients with recurrent OM were defined as having 3 or more OM episodes within a 6-month look-back from the index date. Follow-up visits were excluded, and multiple episodes within 6 months in the same patient were counted only once.

We also studied OM-related complications that were diagnosed within 21 days following the index date: tympanic membrane (TM) perforation (ICD-9 code 384.2), otorrhea (388.6), and acute mastoiditis (383.X). Because TM perforations may be hard to visualize, we combined them with otorrhea into one category, assuming that pus drainage in the external ear within 3 weeks of OM diagnosis indicates TM perforation due to middle ear inflammation. Other complications included meningitis (ICD-9 code 320.9), intracranial abscess (324.X), sigmoid vein thrombosis (325.X), and facial nerve palsy/disorder (767.5, 351.8, and 351.9). These complications were grouped into one category because of their rarity.

Methods

Study Design and Data Source

We analyzed claims data from a large US managed health care plan to estimate time trends in OM visit rates and related complication rates in children aged 6 years or younger. The health insurance claims database (Clinformatics Data Mart; Ingenix; Eden Prairie, MN) consists of de-identified records from outpatient, inpatient, and enrollment data sets representing information on approximately 48 million enrollees for the period 2001-2011. Fully privately insured patients compose the majority in this database, which also includes some eligible Medicare and Medicaid patients. The age distribution for enrollees younger than 20 years well reflects the US distribution of this age group (28% vs 27%). The percentage of continuously insured enrollees ranges from 15% (>48 months) to 81% (>6 months). The male to female ratio is evenly distributed, and the location of the health plans represents the US commercially insured population distribution, with 22% in the northeastern states; 30%, north-central; 30%, southern; and 18%, western in the database compared with 20%, 25%, 34%, and 21% in the US population distribution, respectively (2006).\(^14\) The study period encompassed dates of service from January 1, 2001, to December 31, 2011. The study was approved by the institutional review board of The University of Texas Medical Branch.

Patient Identification

We used the *International Classification of Diseases, Ninth Revision (ICD-9)*, to identify children aged 6 years or younger who had health care visit claims with a primary diagnosis of OM: 381.X (nonsuppurative OM and eustachian tube disorder), 382.X (suppurative and unspecified OM), or 384.X (acute myringitis, unspecified). Any OM visits occurring within 14 days after the initial OM visit (index date) were considered as follow-up visits, and the OM episode was counted only once. For each eligible OM visit, estimated age and sex were extracted. Patients with recurrent OM were defined as having 3 or more OM episodes within a 6-month look-back from the index date. Follow-up visits were excluded, and multiple episodes within 6 months in the same patient were counted only once.

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Statistical Analysis

For each year, we summarized the age and sex distribution of enrollees using descriptive statistics and calculated overall OM visit rates per child-year and rates by age group (<2 and 2-6 years). Otitis media visit rates during 2001-2011 were plotted. Joinpoint regression analysis (Joinpoint Regression Program, version 3.5; National Cancer Institute; http://surveillance .cancer.gov/joinpoint/), a statistical modeling technique that explains the relationship between 2 variables by means of a segmented linear regression, was used to identify the time point at which the trend had changed significantly.\(^15\)

To further evaluate PCV-13 efficacy, we calculated the projected OM visit rates in 2010 (transition year, when PCV-13 was introduced) and 2011 (postmarket year, when PCV-13 was used routinely) for children from birth to 6 years based on the 2005-2009 trend (premarket years, when only PCV-7 was fully in use). The difference between the projected and the observed rates was attributed to the PCV-13 intervention.

Because OM peak incidence is at age 1 to 2 years,\(^16\) we performed an ecologic study comparing OM visit rates in the premarket years with the 2010 and 2011 rates for 2 age groups (<2 years).
Results

Baseline Characteristics

During the 11-year study period, nearly 7.82 million unique children aged 6 years or younger contributed nearly 5.51 million child-years. Characteristics of the study population are reported in Table 1. The mean number of children per year was 710,943. Overall, 52% were boys. Children younger than 2 years composed 48% of the study population.

Overall OM Incidence

Table 2 reports the number of OM visits (OM as primary diagnosis) by year and visit rates by age group. Overall, there were 6.21 million visits with a primary OM diagnosis. There were more boys diagnosed with OM than girls (ie, 57% vs 43% in 2001; P < .001 [data not shown]), and children younger than 2 years had more OM visits compared with children aged 2 to 6 years (ie, in 2001, 1.69/child-year in children <2 years vs 0.98/child-year in children aged 2-6 years; P < .001).

Figure 1 illustrates the trend for OM visit rates during 2001-2011.13,18-21 Joinpoint analysis detected 3 segments with significant changes in the overall OM visit rates trend (2001-2003, 2004-2009, and 2010-2011). The OM visit rates increased at 0.04/child-year annually in 2001-2003, decreased at 0.02/child-year annually in 2004-2009, and decreased more sharply at 0.14/child-year annually in 2010-2011 (Figure 1A). The overall trend was more influenced by children aged 2 to 6 years because of their higher proportion in the study population (Figure 1B, Table 1). For children younger than 2 years, the group with the highest OM incidence, Joinpoint analysis detected 2 segments with a significant change in OM visit rate trend. Although OM visit rates decreased at 0.03/child-year annually during 2001-2009, a more prominent decreased rate of 0.27/child-year annually was observed in 2010-2011 (P < .001) (Figure 1C). The significant change points detected in Figure 1A around 2004 and 2010 are concordant with the expected effects of the interventions noted in the figure.

Recurrent OM visit rates decreased gradually during the study years. Joinpoint analysis found significant change in
OM-Related Complications and Surgical Interventions

Figure 2 shows the OM-related complications and surgical interventions during the study period. Within 21 days after the index date, TM perforation/otorrhea was the most common complication. The TM perforation/otorrhea rates increased significantly during 2001-2009, with a mean annual increase of 81.3 cases per 100 000 OM child-years (95% CI, 62.5-100.1; \( P < .001 \)).

When the data were analyzed by age group, TM perforation/otorrhea rates in children younger than 2 years were stable during 2001-2011, and the rates in children aged 2 to 6 years increased annually by 80.3/100 000 child-years (95% CI, 57.0-103.6; \( P < .001 \)).

The overall trend for children aged 0-6 years was more influenced by those aged 2-6 years because of their higher proportion in the study population. During 2010-2011 (after 13-valent pneumococcal conjugate vaccine [PCV-13] licensure), children younger than 2 years had a significantly greater decrease in OM visit rates than did children aged 2 to 6 years (0.27/child-year vs 0.09/child-year decrease, respectively; \( P < .001 \)).

American Academy of Pediatrics (AAP) guidelines for OM diagnosis and treatment were published in 2004; influenza vaccine (Inf Vac) recommendations were made to vaccinate children by age group: 6 to 23 months (2004); 6 to 60 months (2007); and 6 months to 18 years (2008); recommendation to routinely vaccine children with PCV-13 occurred in 2010.
tions were stable, with no significant changes during the study period (P = .40). Overall, there was an increased trend in myringotomy and/or VT insertion rates during 2001-2008 (annual increase of 463 per 100,000 child-years; 95% CI, 179-815; P = .02) and then a decreased trend in 2009-2011 (annual decrease of 1635 per 100,000 child-years; 95% CI, 534-2737; P = .03) (Supplement[eTable]).

PCV-13 Effect on OM Visit Rates
To determine the effect of PCV-13 on OM visit rates, we compared the downward trend in children younger than 2 years (routinely vaccinated with PCV) with the trend in children aged 2 to 6 years from 2005 to 2011. During the premarket years (2005-2009), transition year (2010), and postmarket year (2011), primary OM visit rates in children younger than 2 years were 1.38, 1.22, and 0.82/child-year compared with rates of 0.99, 0.92, and 0.81/child-year in children aged 2 to 6 years, respectively (Figure 3). Although there was a stable RR between OM visit rates in children younger than 2 years and in those aged 2 to 6 years in the premarket years, with an RR of 1.38 (95% CI, 1.38-1.39), the RRs between these 2 age groups were decreased significantly during the transition year and the postmarket year (P < .001): RRs were 1.32 (95% CI, 1.31-1.33) in 2010 and 1.01 (95% CI, 1.00-1.02) in 2011.

Discussion
Our analysis of nationwide data from a large US insurance claims database for an 11-year period during the post-PCV era found a substantial decrease in OM visit rates in children from birth to 6 years, particularly among children younger than 2 years in 2010-2011. In parallel, there was a larger decrease in recurrent OM rates in these years. The more recent decrease coincided with PCV-13 administration in this age group. To our knowledge, this is the first study to determine OM-related health care use trends since the marketing of PCV-13. Along with the decreased OM visit rates, mastoiditis diagnoses and...

Since PCV-7 became available in 2000, there has been other medical progress made toward prevention of OM and attempts to reduce OM overdiagnosis. In 2004, the American Academy of Pediatrics (AAP) released a clinical practice guideline that specified the criteria for diagnosis of AOM, with the aim to increase diagnostic accuracy and reduce AOM overdiagnosis. The guideline also included an observation option without antibiotic use in the initial management. Healthcare providers may have felt less pressure to diagnose and treat AOM knowing that watchful waiting is an acceptable option. The temporary decrease in OM visit rates observed in 2004 may have been partly attributable to a short-term effect of the AAP practice guidelines published that year. However, recent evidence suggested low adherence to these guidelines: after their publication, the rate of OM visits without antibiotic prescribing did not change significantly, and the observed OM visit reduction was only mild. Routine influenza vaccine was recommended in 2004, 2006, and 2008 for children aged 6 to 23 months, 2 to 5 years, and all children, respectively. Influenza vaccination has been shown to reduce AOM associated with influenza, but the effect of the vaccine on AOM prevention varies from year to year depending on the prevalence of influenza in each season and the efficacy of the vaccine to prevent the circulating influenza strains. The larger the epidemic, the more efficacious are the “good-match” vaccines in preventing influenza and influenza-associated AOM. The reduced trend in OM-related health care use shown in the present study may be the result of the combined impact of all these developments, including the use of PCV-13 since 2010. The AAP has released the 2013 AOM clinical practice guidelines with more stringent diagnostic criteria. It also expanded the group of young children whose care may be managed by initial observation. Hence, OM-related health care use may be further reduced in the next several years because of these developments.

Our results showing a downward trend in OM visit rates were derived from a very large database. The observed reduction in OM visit rates in the PCV-13 transition year and the post-market year in routinely vaccinated children (aged <2 years) was significantly lower than the projected rate. This strongly supports the expected effect of PCV-13 in preventing OM in the first year of its introduction. The reduction in OM visit rates observed in children younger than 2 years in the first year after PCV-13 introduction (Figure 1C) was similar to the reported decline in OM visit rates in that age group in the first years after PCV-7 introduction. Several studies have predicted PCV-13 efficacy on the expected decline in the proportion of children colonized with S pneumoniae who would develop pneumococcal OM. Even after taking serotype replacement into account, the modeling predicted that PCV-13 will further decrease pneumococcal OM substantially within just a few years after its introduction. Our data extended only to the second year of PCV-13 use. There is a need to continue monitoring PCV-13 efficacy in preventing OM over time.

Otitis media is a common childhood disease that is associated with mild to serious complications. We found an upward trend in OM-associated TM perforation/otorrhea cases over time resulting from increased rates in older children (2–6 years). However, the upward trend began in 2002 and continued through 2011. We did not detect a significant increase specifically from 2004 after the publication of the 2004 AAP clinical practice guideline that introduced withholding antibiotic therapy in certain cases of AOM in older children as an option. The reason for this upward trend was unclear; antibiotic resistance and withholding antibiotic could partly contribute to this result. In any event, the incidence rate of OM-associated TM perforation/otorrhea is still within the previously reported incidence rate of 3% to 7%. Acute mastoiditis is an inflammatory process that results almost exclusively from OM. The most common bacterial cause of mastoiditis in children is S pneumoniae, even after the PCV-7 years. With antibiotic use and overall improvements in health care, mastoiditis currently complicates less than 0.01% of OM cases, and the annual incidence of mastoiditis dropped to 1.2 to 3.8 per 100 000 children in the developed world. Although some studies reported decreased rates after PCV-7 introduction, others found no change or even an increase in mastoiditis rates. We found stable mastoiditis rates between 2001 and 2008, with a downward trend from 2009 to 2011. The steeper decrease occurred after PCV-13 introduction in 2010 in parallel to the decrease in OM visit rates.

Insertion of VTs, with or without adenoidectomy, has been proved to be effective for preventing recurrent OM in children. Both the AAP and the American Academy of Pediatrics.
Otolaryngology-Head and Neck Surgery clinical practice guidelines\(^6\)–\(^7\)\(^2\) recommend VT insertion for recurrent OM (defined as either ≥3 episodes in 6 months or ≥4 episodes in 12 months). Ventilating tube insertion is also indicated in symptomatic middle ear effusions, which are mostly considered to be late sequelae of OM. We found a significant upward trend between 2001 and 2008, with a precipitous drop from 2009 to 2011. This suggests that PCV-13 had efficacy in the 19% reduction of myringotomy and/or VT insertion within the first year after its introduction. Previous reports\(^8\) have shown that PCV-7 reduced VT insertions by 20.1% across several years. Further follow-up studies will be required to confirm this effect of PCV-13.

There are limitations of our study. First, our data came from a privately insured population; OM health care use could be somewhat different from populations in other databases, such as uninsured or Medicaid populations. Other limitations include those common to population-based health outcomes research using claims data. Second, because of the nature of our database, we did not have a way to verify the accuracy of OM diagnosis. Third, individual data on PCV immunization status or recognized risk factors for OM were not available. In stead, we performed an ecologic study, which is considered the design of choice to evaluate the impact of interventions when it is not possible to rule out or control for secular trends. Because the policy impact is evaluated for an entire defined population regardless of the individual vaccination status, ecologic studies can avoid such a selection bias. The overall national PCV vaccination coverage among children aged 19 to 35 months in 2007-2011 was 90% to 93% for 3 or more doses and 75% to 84% for 4 or more doses.\(^9\)\(^2\)\(^4\) Vaccination rates in our privately insured population likely are as good, if not higher. The transition period between PCV-7 and PCV-13 during 2010 was rapid, taking place within only a few months. By the autumn of 2010, most of the PCV vaccinations administered to children in the United States were PCV-13.\(^4\)\(^4\) Therefore, our results in the first postmarketing year in children younger than 2 years may reflect the PCV-13 effect. Finally, we were unable to obtain accurate data on antibiotic use during OM visits because the data were from health insurance claims. Currently, antibiotic prescriptions can be filled inexpensively at discount or grocery stores. Health insurance is often not claimed for these prescriptions, yielding inaccurate data for antibiotic use.

In summary, data from a large US insurance claims database have shown a continuous downward trend in OM-related health care use from 2001 to 2011. The advent of PCV-13 in 2010 resulted in a significant further reduction of OM visit rates, especially in the PCV-13-vaccinated population. Although the diagnosis of mastoiditis decreased in the past few years and VT insertion procedures decreased significantly in 2009-2011, there was an upward trend in OM-associated TM perforation/otorrhea. Because S pneumoniae serotype may change with continued use of PCV-13, further studies are needed to assess the long-term effects of PCV-13 on the reduction of OM and its related morbidities.

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Study concept and design: Marom, Tan, Wilkinson, Freeman, Chonmaitree.

Acquisition of data: Marom, Tan, Wilkinson.

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