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Non-adherence to Guideline Recommendations for Tympanostomy Tube Insertion in Children Based on Mega-database Claims Analysis

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Abstract

Objective—To estimate the non-adherence rate of pressure-equalization tube placement in the preceding three-year period before release of the 2013 American Academy of Otolaryngology Head and Neck Surgery Foundation (AAO-HNSF) clinical practice guideline (CPG).

Study Design—Analysis of the Truven Health MarketScan® Research Databases 2010–2012.

Subjects and Methods—Medical claims data from 2010–2012 were analyzed. Children aged 12 years and younger with otitis media (OM) related diagnoses were identified. Adherence and non-adherence rates for OM and PET placement were analyzed using administrative codes extrapolated from the key action statements (KAS) of the CPG. KASs were aggregated to estimate the overall non-adherence and determine areas for quality improvement.

Results—A total of 9,726,411 visits with OM associated codes in 3,710,730 children were identified. 2.9% (80,451/3,239,700) were considered non-adherent to KAS 1 because a code for PET placement occurred with a first episode of OME less than 3 months duration. 52.1% (14,534/27,913) underwent PET placement for OME of 3 months duration and had a concurrent hearing loss code. In those without hearing loss that underwent PET placement, 48.3% (52,921/109,583) had a diagnosis code indicating risk for speech, language, or learning problems. For each KAS, we found heterogeneity of computed non-adherence rates by region, age, and season.

Conclusion—Pre-guideline dissemination, we found low to moderate rates of non-adherence to guideline recommendation. Deeper analysis of mega-databases could provide better insights for measurement of guideline adherence. The expansion of administrative and clinical databases provides a unique opportunity to investigate the impact of CPGs.

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Keywords

AAO-HNSF clinical practice guidelines; MarketScan; Otitis media; tympanostomy tubes; guideline compliance

Introduction

Otitis Media (OM) is the most frequent diagnosis for which children present to the pediatrician and the leading reason for childhood antimicrobial prescriptions.¹ Pressure-equalization (tympanostomy) tube (PET) insertion is the most commonly performed ambulatory surgical pediatric procedure in the United States.² OM has a high socioeconomic impact, with an estimated cost of 4 billion dollars per year.³

Published guidelines exist on management of acute otitis media (AOM) and otitis media with effusion (OME).^{4,5} However, no guidelines prior to 2013 provided specific indications for PET insertion. Two studies^{6,7} suggested that most PET placements were inappropriate based on criteria derived from expert consensus. These authors concluded that many PET insertions were inappropriate due to short duration of OME (mean < 30 days). They determined that nearly 50% of cases were inappropriate or equivocal even when known risk factors were taken into account. In response to this lack of clarity on best practices for surgical management of OME, The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) convened a multidisciplinary group in 2012 to develop an evidence-based clinical practice guideline (CPG) for the specific indication of placement of PET in children.² The AAO-HNSF CPG contains 12 individual KAS that have relevance to compliance, best practice, and opportunities for quality improvement.

We used Truven Health MarketScan® Research Database (3 years 2010–12) to determine the non-adherence of PET placement in children by KAS (Table 1). This guideline builds upon itself to provide recommendations for healthcare providers to manage OME based on duration as well as *risk factors and sequelae of OME*. We hypothesized that a significant percentage of PET insertions considered inappropriate for effusion duration < 90 days (KAS #1) would be significantly reduced once the KAS were examined as an integrated and comprehensive management guide. Integration of all the KAS allows behavioral, balance, and speech language delay to be modifiers of the recommendation for PET insertion. We also sought to identify opportunities for quality improvement in the care of patients with OM. Close examination of nonadherence rates can serve as the baseline to examine changes after dissemination and implementation of the new guideline on PETs.²

Methods

Data used for the analysis was extracted from the 2010–2012 Truven Health MarketScan® Commercial Claims and Encounters Research Databases (©2012 Truven Health Analytics Inc., All Rights Reserved) (“MarketScan”) licensed by and accessed via a collaboration between the AAO-HNSF and the NIDCD-funded CHEER Network. The data contained in our Truven subset of data included: emergency department (ED), inpatient (IP), outpatient/clinic (OP), prescription drug (RX) claims of employees and dependents covered by a

selection of large employers, private and public health plans, and government and public organizations.⁸

Case Selection

Our coding strategy was derived from the KAS of the guideline, vetted by the senior author (Witsell) with the investigative team and reviewed by the PET CPG primary author (Rosenfeld). International Classification of Diseases, ninth revision (ICD-9) codes were queried for patients 12 years and younger with at least one OM claim (Figure 2) from any clinic visit between January 1, 2010, and December 31, 2012. We used a bracketing strategy for code selection (Table 1), to reduce errors if clinicians used non-specific coding (eg, coded for OME but not concurrent hearing loss). The Duke University Health System Institutional Review Board granted the study exemption from further review.

Statement Definitions

The following definitions were used for each KAS and were applied to extract data from the 2010–2012 MarketScan® to assess adherence to the correspondingly numbered KAS (Table 1).

For KAS 1–5, an episode of OME was defined as a series of visits with OM codes where the time between visits was <6 months. Duration of episode was computed as the time between first visit and last visit. “First visit” = no preceding diagnosis of OM for 6 months or more. “Last visit” = no subsequent diagnosis of OM for 6 months. Patients with tympanic membrane perforation or otorrhea at first visit were excluded.

KAS 1 OME of Short Duration—An episode met the criteria for PET placement if the duration of episode was 3 months or longer (chronic OME). If a PET placement code was found within 3 months of first visit, the episode was labeled non-adherent.

KAS 2 Hearing Testing—In patients with an episode of OME 3 months or longer, adherence was defined as a hearing test performed between 3 and 6 months after first visit.

KAS 3 Chronic Bilateral OME with Hearing Difficulty—For patients who had an episode of OME for 3 months or longer with a hearing test and a hearing loss code 3 to 6 months after first visit, adherence was defined as PET placement within 6 months of the earliest date of hearing loss code.

KAS 4 Chronic OME with Symptoms—For patients with an episode of OME 3 months or longer who received PET without documented hearing test or hearing loss codes, but with a potentially related complicating symptom (balance (vestibular) problems, poor school performance, behavioral problems, and ear discomfort), adherence was defined as having a code for at least one of the symptoms above.

KAS 5 Surveillance of Chronic OME—For patients who had OME for 3 months or longer and did not receive PET, adherence was defined as presence of a code for OM within 6 months prior to the date of a hearing loss or structural abnormality code suggesting appropriate surveillance.

KAS 6 and 7 Recurrent AOM with and without Effusion—An episode of AOM was defined as a series of visits with an AOM-related code where the time between visits was < 30 days. Determining the physical presence of middle ear effusion was not possible from this dataset; therefore, hearing loss was used as a surrogate marker. Candidates for tubes had 3 or more separate well-documented AOM episodes in 6 months, or at least 4 separate well-documented AOM episodes in 12 months with at least 1 in the past 6 months. Adherence for statement 6 was defined as no PET insertion within 6 months of the last visit for AOM if no hearing loss code at last visit. Adherence for statement 7 was defined as PET insertion within 6 months of the last visit for AOM if hearing loss code at the last visit.

KAS 8 & 9 Tubes and At-risk Children—(Patients who are at risk for speech, language, or learning problems from OM because of baseline sensory, physical, cognitive, or behavioral factors). The guideline specifically mentions permanent hearing loss, speech delay, autism, syndromes/craniofacial disorders, blindness, cleft palate, developmental delay. For statement 8, patients with an episode of OM of any duration were assessed for the above conditions. For statement 9, patients with an episode of OM for 3 months or longer who received PET without documented hearing difficulties were assessed for the presence of the above conditions. Adherence was defined as having one baseline sensory, physical, cognitive or behavioral factor within 6 months prior to getting PET.

KAS 11 Acute Tympanostomy Tube Otorrhea—Patients who had a code for PET and AOM and/or otorrhea were assessed for receipt of topical and/or oral antibiotics within one month of the otorrhea code using MarketScan REDBOOK generic identification numbers. Adherence was defined as topical antibiotics prescribed within 1 month of an otorrhea code. Non-adherence was defined as oral antibiotics prescribed within 1 month of the otorrhea code, with exceptions if the patient had the following conditions as listed in the guideline: cellulitis of the pinna or adjacent skin bacterial infection, severe infection, immune compromised. There are no codes for otorrhea that worsens despite topical antibiotics, cost considerations, or inability to administer topical antibiotics.

For all statements, data on gender, age, seasonal and regional variations were extracted. Perioperative education regarding tube care and water precautions (statements 10 and 12, respectively) could not be assessed using the database.

Each statement was analyzed in a descriptive fashion by tabulating frequencies and rates of compliance according to age, month of first visit, geographic region, and plan type. Where indicated, the Pearson chi-square test was used to compare frequencies of compliance between specified groups.

All analyses were performed using SAS version 9.4 (Cary, NC). All statistical tests were two-sided and a p-value < 0.05 was considered statistically significant.

Results

Analysis of statements pertaining to tympanostomy tube placement

A total of 9,726,411 visits with codes associated with OM in 3,710,730 patients age 0–12 were identified. After excluding tympanic membrane perforations and otorrhea at first visit, a total of 3,239,700 episodes of OME in 2,692,742 patients remained.

2.9% of patients (80,451) had PET placement for an episode of OME less than 3 months duration and were classified as non-adherent to KAS 1 (Table 1). When viewed by episode (patients could have >1 episode), 2.5% (82,576) episodes were not in adherence with KAS 1. Non-adherent episodes occurred in more males than females (59% vs 41%). Patients age 2 and younger had a disproportionately higher number of episodes and non-adherence management ($P<0.0001$) (Figure 2, Table 2). Significant increases in non-adherence were noted in winter and southern regions ($P<0.0001$) (Table 2; Figure 3).

52.1% of patients who had OME for over 3 months with hearing loss (14,534 of 27,913) were adherent to KAS 3. In those without hearing loss who underwent PET placement 24.1% (109,583) had a symptom that was attributable to OME (KAS 4); 12.4% were at risk for speech, language, or learning problems (KAS 9).

4.5% of analyzed patients were at risk for speech, language, or learning problems [(KAS 8) (107,038 of 2,372,828)].

When the PET placement criteria were explored sequentially, the overall non-adherence rate dropped from 2.9% to 1.5%. Additionally, when exclusions for patients who were classified as “*OME for 3 months with no hearing loss*” were applied, non-adherence dropped from 23.1 % to 12% (Figure 1).

KAS 6 and 7 address management for patients with recurrent AOM without and with MEE. 106,221 patients had recurrent AOM. 22.4% of those had no hearing loss code (our surrogate for middle ear effusion) at last visit and yet underwent PET placement, which is not adherent to KAS 6. 44.2% of patients with AOM and MEE at last visit underwent PET placement within 6 months of last visit, which is considered adherent with KAS 7.

Analysis of statements pertaining to medical management

The CPG recommends that patients with chronic OME have an audiogram and, if PET are not placed, are followed. 13.5% (81,442 of 603,785) episodes of OME >3 months duration were associated with a hearing test between 3 and 6 months of first visit (KAS 2). 14.5% episodes of chronic OM (episode lasting > 3 months) did not undergo PET placement and 6.0% of these patients had at least one code for hearing loss or structural abnormalities. 91.6% of this group remained under surveillance for complications of OME as recommended in KAS5.

For patients who received PET and had a subsequent code for otorrhea, 18.7% (16,242 of 86,947) were prescribed topical or oral antibiotics within 1 month of an otorrhea code. Most (95.4%) of these patients were given topical antibiotics and complied with KAS 11. 754

patients were prescribed oral antibiotics; 34.9% of these also had a code for concurrent infection or history of being immunocompromised.

Discussion

Our analysis of a large healthcare claims database (MarketScan) shows high compliance and low non-adherence to the AAO-HNSF CPG for PET insertion in OME.² We used a retrospective-prospective analysis approach and tracked patients from the index diagnosis to the index event for each guideline statement. We considered the direction of the guideline statement; each provided recommendations regarding what action should or should not be considered adherent to its described purpose.

Our analysis differs significantly from previous studies and is relevant when comparing the interpretation of physician adherence with PET indications.^{6,7} The availability of comprehensive national claims metadata enables new analytic strategies to evaluate US healthcare practices broadly. Our rationale for using this approach is that aggregated metadata from the EHR is used to inform policy and initiatives. These new “big data” analytic capabilities and strategies are 1) timely yet retrospective, 2) link to episodes of care and associated cost, and 3) could be powerful tools to assess changes in practice resulting from new validated research and/or policy.

Previous studies evaluated tympanostomy tube insertion using criteria derived from expert consensus guidelines on management of otitis media. The analytic strategy in these studies begins with the index event and looks retrospectively for clinical and diagnostic evidence to support appropriateness assessment. In the Kleinman et. al. study, a sampling strategy of all cases of proposed tympanostomy tube insertion was used to evaluate appropriateness.⁶ Keyhani et al. selected a population of patients who received PET and performed retrospective analysis of data for one year to determine appropriateness of the procedure.⁷

Kleinman and Keyhani concluded that the majority of tympanostomy tube insertions were inappropriate. They based their conclusion on a scoring algorithm stratified by hearing status and antibiotic treatment.

In both studies, the OM disease management guideline evaluated PET insertion appropriateness. Our study used a PET intervention guideline to evaluate disease management (non-adherence assessment).

Further, the population considered in their analyses was fundamentally different from ours. Our denominator was patients coded with OM while they used the patients who underwent PET insertion. Our approach frames non-adherence of PET indications within the context of all OME patients. Our analysis strategy could be considered the negative of previous authors; we evaluated when **not** to place PET (KAS1) and management when hearing loss is **not** present (KAS3). Most of subsequent KAS qualify the above to arrive at the estimate of episodes of care that did not meet criteria based upon our available information.

Our results show low estimates of non-adherence of PET placement within the studied population of pediatric patients with OME. Of note is that our overall population estimate of

patients who received PET is similar and supports the published estimates of PET insertion (5.1% vs 6%).

We also examined gender, age, seasonal and regional variations to determine whether these factors affected the rate of OM or influenced PET placement. Our finding of increased episodes of OM in children age 2 and younger is consistent with other studies,³ as is our finding that non-adherence was higher in the South.¹

Analysis of the 12 KAS in a stepwise fashion revealed the impact of the qualifying KAS that should be considered in the assessment of non-adherence. A stepwise analysis of coded diagnoses adjusted the non-adherence rate downward significantly. These qualifying KAS included known risk factors and associations with OM such as developmental delay, delayed speech and language development,⁵ other symptoms such as vestibular problems or chronic ear pain (Figure 1).

Two KAS that related specifically to medical management/evaluation showed potential opportunities for quality improvement. Only 13.5% of OME episodes >3 months duration had an associated hearing test (KAS 2). Most patients with otorrhea had a prescription for topical antibiotics (95.4%). However, about two-thirds of patients who received oral antibiotics did not have a coded comorbid condition or diagnosis other than otitis media.

There are several unique and important features in this study, including the use of a large national database with information from millions of patient encounters. We analyzed both episodes of care and individual patients which enabled the retrospective prospective study design, and we examined non-adherence based upon disease management of a population of patients rather than a subpopulation that received PET. Results from the latter strategy can be biased towards lack of compliance and are not as generalizable to the greater population of patients with otitis media.

Although the *overall percentage* of non-adherence in our study is small (5.1% combined non-adherence for 137,113/2,692,742 patients), the burden of disease is great and translates to 137,113 procedures over the time period of the study. With the estimated cost of PET placement at \$2,700, the total direct cost is over \$370 million.

Limitations of this study include the presence of physician coding variability and inability to directly determine important physical exam findings such as the presence of a middle ear effusion. Additionally, we had to define an episode of care to frame the analysis of non-adherence. We used the definitions set forth in the guideline; some required subjective assessment and relational logic to determine the most proximal surrogate code for the specified finding or action. This is most apparent in KAS 10 and 12, which give guidance on education and expectations as well as water precautions. We could not evaluate these statements since our database does not contain these variables, nurse notes, or patient education tasks.

We hope that studies like ours can help both the developers of evidence based guidelines and EHR vendors improve patient care and documentation by providing an integrated disease-specific “code set.” This code set should approximate the true state of care more accurately,

improve quality through coding, and potentially facilitate integration and translation of research and evidence into best clinical practice. Despite its limitations, analysis of this mega-database allowed for determination of non-adherence metrics and assessment of how the KAS of the clinical practice guideline interact.

Conclusion

A mega-database can be used to explore practice patterns and measure guideline non-adherence. Analysis of the MarketScan databases revealed low rates of non-adherence in regards to PET placement. Our stepwise KAS analysis strategy allowed qualifying KAS in assessment of the overall non-adherence rate. There were performance gaps identified in our study pertaining to audiological evaluation of patients with OM >3 months as well as antibiotic therapy in treatment of otorrhea. Despite the low non-adherence rate for placement of tympanostomy tubes, there remain opportunities for quality improvement and better resource management. Similar analyses of data collected after the publication of the 2013 AAO-HNSF CPG are needed to determine the impact of the guideline on clinical practice. We believe that non-adherence evaluation within the population of interest is a valid, generalizable, and important analysis strategy for evaluating disease management at a policy and health services research level.

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Figure 1.

Adherence rates for tympanostomy tube placement after accounting for comorbid conditions and modifying factors specified in the KAS.

Figure 2.
Distribution of OM episodes based on age.

Geographic Region	Division	States included	Mean (SD)	Median (Q1, Q3)	Minimum (%)	Maximum (%)
Northeast	New England	CT, MA, ME, NH, RI, VT	2.0% (0.5)	2.0% (1.7, 2.3)	1.1	2.5
	Middle Atlantic	NJ, NY, PA	1.7% (0.5)	1.4% (1.3, 2.3)	1.3	2.3
North Central	East	IL, IN, MI, OH, WI	2.8% (0.3)	2.8% (2.7, 2.8)	2.3	3.3
	West	IA, KS, MN, MO, NE, ND, SD	3.6% (0.5)	3.8% (3.2, 3.9)	2.7	4.4
South	Atlantic	DC, DE, FL, GA, MD, NC, SC, VA, WV	2.5% (0.5)	2.5% (1.9, 3.0)	1.7	3.1
	East	AK, KY, MS, TN	4.1% (1.0)	4.2% (3.3, 5.0)	3.1	5.1
	West	AR, LA, OK, TX	4.1% (1.0)	4.2% (3.3, 4.9)	2.8	5.3
West	Mountain	AZ, CO, ID, MT, NV, NM, UT, WY	2.6% (1.0)	2.5% (1.9, 3.4)	1.2	4.0
	Pacific	AK, CA, HI, OR, WA	1.7% (0.8)	2.0% (1.4, 2.1)	0.5	2.6

Figure 3.

Distribution of non-adherent tympanostomy tube placement (OM < 3 months) based on geographic region. The means in the table are calculated at the regional level. (Map created using SAS software.)

ICD9 codes used for OM claim

381.	00	381.	3
	01		4
	02		
	03	382.	00
	04		9
	05		
	06		
	10		
	19		
	20		
	29		

Figure 4.
ICD9 codes used for OM claim.

Table 1

Key action statements (KAS) from the 2013 AAO-HNSF CPG are in the left hand column. The population and codes used in the analysis of each KAS are in the corresponding right hand column.

KAS#	Key Action Statement (KAS)	MarketScan surrogate	# patients studied	# patients adherent	% adherence
1	OME OF SHORT DURATION: Clinicians should not perform tympanostomy tube insertion in children with a single episode of OME of less than 3 months' duration, from the date of onset (if known) or date of diagnosis (if onset is unknown).	Population included patients age 0–12 who had at least one visit with OM codes. Those with otitis media with effusion (OME) or tympanic membrane perforation at first visit were excluded. PET placement assessed with CPT code.	2,692,742	2,612,291	97.0%
2	HEARING TESTING: Clinicians should obtain an age-appropriate hearing test if OME persists for 3 months or longer OR prior to surgery when a child becomes a candidate for tympanostomy tube insertion.	Population from KAS 1 with OM episode greater than 3 months was assessed for presence of hearing test	603,795	81,442	13.5%
3	CHRONIC BILATERAL OME WITH HEARING DIFFICULTY: Clinicians should offer tympanostomy bilateral tube insertion to children with bilateral OME for 3 months or longer AND documented hearing difficulties	Population from KAS 1 with OM episode greater than 3 months was assessed for hearing loss by presence of hearing test. PET placement assessed with CPT code	27,913	14,534	52.1%
4	CHRONIC OME WITH SYMPTOMS: Clinicians may perform tympanostomy tube insertion in children with unilateral or bilateral OME for 3 months or longer (chronic OME) AND symptoms that are likely attributable to OME that include, but are not limited to, balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, or reduced quality of life.	Population from KAS 1 with OM episode greater than 3 months without hearing loss was assessed for presence of symptoms: balance problems, poor school performance, ear discomfort. No codes for quality of life. PET placement assessed with CPT code	109,583	26,360	24.1%
5	SURVEILLANCE OF CHRONIC OME: Clinicians should reevaluate, at 3- to 6-month intervals, children with chronic OME who do not receive tympanostomy tubes, until the effusion is no longer present, significant hearing loss is detected, or structural abnormalities of the tympanic membrane or middle ear are suspected.	Population from KAS 1 with OM episode greater than 3 months were assessed for hearing loss code or structural abnormality code. The presence of a code for OM within 6 months prior to the hearing loss or structural abnormality code was used as a surrogate for surveillance	27,929	25,590	91.6%
6	RECURRENT AOM WITHOUT MEE: Clinicians should not perform tympanostomy tube insertion in children with recurrent acute otitis media who do not have MEE in either ear at the time of assessment for tube candidacy.	Population included patients with AOM-related code. Hearing loss was used as a surrogate for effusion. PET placement assessed with CPT	105,327	81,717	77.6%
7	RECURRENT AOM WITH MEE: Clinicians should offer bilateral tympanostomy tube insertion in children with recurrent AOM who have unilateral or bilateral MEE at the time of assessment for tube candidacy.	Same as statement 6 above	894	395	44.3%
8	AT RISK CHILDREN: Clinicians should determine if a child with recurrent AOM or with OME of any duration is at increased risk for speech, language, or learning problems from otitis media because of baseline sensory, physical, cognitive, or behavioral factors (see Table 2).	Population included patients from KAS 1 who had codes for permanent hearing loss, speech delay, autism, syndromes/craniofacial disorders, blindness, cleft palate, developmental delay.	107,038/2,372,828	n/a	n/a
9	TYMPANOSTOMY TUBES AND AT-RISK CHILDREN: Clinicians may perform tympanostomy tube insertion in at-risk children with unilateral or bilateral OME that is unlikely to resolve quickly as reflected by a type B (flat) tympanogram or persistence of effusion for 3 months or longer.	Same as statement 8 above. PET placement assessed with CPT codes	109,583	13,554	12.4%

KAS#	Key Action Statement (KAS)	MarketScan surrogate	# patients studied	# patients adherent	% adherence
10	PERIOPERATIVE EDUCATION: In the perioperative period, clinicians should educate caregivers of children with tympanostomy tubes regarding the expected duration of tube function, recommended follow-up schedule, and detection of complications.	Cannot be assessed	n/a	n/a	n/a
11	ACUTE TYMPANOSTOMY TUBE OTORRHEA: Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics, for children with uncomplicated acute tympanostomy tube otorrhea.	Patients with PET were assessed for AOM and/or otorrhea and whether they received antibiotics. A list of exceptions for oral antibiotics included cellulitis of pinna, bacterial infection, severe infection, immunocompromised	Topical: 16,242 Oral: 754	Topical: 15,488 Oral: 263	Topical: 95.4% Oral: 34.9%
12	WATER PRECAUTIONS: Clinicians should not encourage routine, prophylactic water precautions (use of earplugs or headbands; avoidance of swimming or water sports) for children with tympanostomy tubes.	Cannot be assessed	n/a	n/a	n/a

Table 2

Comparison of non-adherent tympanostomy tube placement (OM < 3 months) in children ages two and younger versus children over age two, winter versus summer months, and the South versus other regions of the United States (P<0.0001)

	Non-adherent	Adherent	Total
Age > 2	38,453	1,916,569	1,955,022
Age 2	44,123	1,240,555	1,284,678
Winter (Dec–Feb)	30,870	1,086,678	1,117,548
Summer (Jun–Aug)	9,897	423,018	432,915
Southern region of US	35,821	1,153,348	1,189,169
All other regions of US	46,755	2,003,776	2,050,531