



A Pathway to Value-Based Care of Chronic Rhinosinusitis Using a Claims Database

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Objective: To construct a comprehensive picture of the typical chronic rhinosinusitis (CRS) patient in the United States including the demographics, comorbidities, and geographic prevalence. The study will also identify the diagnostic and treatment regimens, their cost, and pattern of use for both medically and surgically managed patients.

Study Design: Historical cohort study utilizing private and public payer databases.

Methods: Medical claims data from the Truven Health MarketScan Research Databases from the years 2010 to 2012 for patients with acute rhinosinusitis (ARS) and CRS 18 and older were analyzed.

Results: There were 54 million unique patients in the databases from 2010 to 2012. Approximately 8 million had at least one diagnosis of ARS and 298,337 had a diagnosis of CRS. Females represented 63.7% of patients with ARS and 59.4% with CRS. Medicare patients represented 6.7% of the ARS population and 10.2% of the CRS population. The mean cost of a CRS episode for those commercially insured was \$1024 and \$762 in Medicare. CRS patients underwent diagnostic procedures including diagnostic endoscopy (55.1%), cultures (23.6%), sinus CT scan (82.1%) and MRI (0.2%). Endoscopic sinus surgery (ESS) was performed on 14.4% of those patients with CRS. Change in frequency of medication use from the 6 months prior to ESS to the 6 months post-ESS yielded a reduction in total costs of 34.2% or \$3.9 M. The most commonly operated sinuses (with or without septoplasty on same day as ESS) were the maxillary (94%/76.1%); followed by ethmoid (82.1%/66.6%); frontal (38.8%/35.1%); and sphenoid (28.5%/28.1%). In total, 16.6% had one sinus operated on, 39.1% had two, 24.6% had three, and 18.7% had four sinuses operated on.

Conclusions: This data paints a much clearer understanding of the current medical and surgical management. This study confirms the previously described “value proposition” for the surgical management of those CRS patients refractory to medical management.

Key Words: CRS demographics, comorbidities, cost, surgical management, diagnosis.

Level of Evidence: 4

INTRODUCTION

The healthcare system in the United States is transitioning away from volume-driven treatment to the quality, outcome-based care necessary to control the runaway costs that currently account for 18% of the GDP.¹ Fully understanding the current state of disease management and the factors contributing to the present situation is essential. This complex analysis requires a precise characterization of the disease process in question; the different therapeutic options currently utilized to treat the problem; the

effectiveness and cost of these treatments; and an adequate data set from which to draw conclusions.

The Center for Disease Control (CDC)² estimated that 12.1% of the population or 29.4 million people had some form of sinusitis, and an additional 8.2% or 20.1 million people suffered from hay fever or allergic rhinitis, in the United States in 2015. The national expenditure on healthcare services 2015 spending estimate of \$3.2 trillion or 18.1% of GDP, with a trajectory towards 25% of the GDP in 2030, is not sustainable. Scientific construction of working disease models to research, by which to determine and promote “best practices,” appropriate use, and delivery of true “value” to our patient population, requires that we understand common disease processes and existing therapeutic practices to a depth and breadth that provides us a platform to build upon. Chronic rhinosinusitis (CRS) is such a disease process as it is currently recognized to affect a broad portion of the population in the United States. Estimated prevalence of CRS ranges from 5% to 16%,^{3–6} however it is difficult to determine definitively because of lack of precision in defining and recording this diagnosis. CRS is a disease process that requires long-term management as opposed to an expectation of routine cure. Despite many papers on the subject, there is considerable anecdotal variation in detailing the current diagnostic patterns, medical treatment

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regimens, surgical management (including postoperative care), cost burden of CRS, and the expected long-term maintenance cost of the disease.^{7–12}

The goal of this study is to look further at the prevalence of both ARS and CRS through a large payer database including both commercial and Medicare patients, and to develop a better understanding of the typical patient with CRS and how they are currently being diagnosed and treated. We looked at geographic distribution along with common comorbidities seen with these diseases and attempt to detail diagnostic and treatment regimens and their frequency currently in use. We compared costs of medical management to that of surgical management, both initially and on an ongoing basis. Additionally, we identified patterns of surgical treatment and their costs, both initially and post-operatively. Finally, we will describe the frequency of the acute exacerbations of CRS in those patients treated both medically and surgically. The compilation of these data will help inform payer-related issues, current knowledge gaps, and perhaps more importantly how we can structure our data collection utilizing administrative, clinical, and outcome-related measures to get to the desired patient result at an affordable cost. This in turn will allow us to recommend opportunities to define an increased “value” using state-of-the-art management of this chronic disease.

METHODS

Data used for the analysis were extracted from the 2010–2012 Truven Health MarketScan Research Databases (2017, Truven Health Analytics Inc.) licensed by and accessed via a collaboration between the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) and the National Institute on Deafness and Other Communication Disorders–funded CHEER network. The data contained in our Truven subset included the following: inpatient, outpatient/clinic, and prescription drug claims of employees and dependents covered by a selection of large employers, private, and public health plans, and government and public organizations (Truven, 2017). The Duke University Health System Institutional Review Board granted the study exemption from further review.

ARS and CRS Case Selection

Using the International Classification of Diseases, ninth revision (ICD-9), patients age 18–64 with at least one ARS (461.x) or CRS (473.x) claim and Medicare patients ≥65 years of age were selected to form the base population. Modeled after the CRS study utilization by Bhattacharyya et al. (2010),¹³ claims-based ICD-9 and current procedural terminology (CPT) code sequences were used to further define the CRS analysis population (Fig. 1). Three exclusion criteria were also implemented. If any of the CRS records had a concurrent diagnosis of cystic fibrosis (277.00–277.09); acute fungal sinusitis (117.9); and/or Samter’s Triad of nasal polyposis (471.0, 471.9), in the first visit of a CRS “episode,” then that patient was excluded from the CRS analysis population

Medically managed patients meeting the CRS definition in Figure 1 had an initial diagnosis on or after January 1, 2011 to ensure these were both new CRS cases (ie, had a prior minimum 3-month clean period) and to allow for adequate follow-up; they were distinguished from surgically managed patients in that they had no record of undergoing ESS. Surgically managed patients meeting the CRS definition in Figure 1 had to have received surgery between January 1, 2011 and September 30, 2011 in order to allow for prior clean period, a 90-day healing period (October–December 2011), and adequate follow-up time period. Acute exacerbations among medically managed CRS patients were defined as a post-CRS (initial diagnosis of January 2011, or later) Evaluation and Management (E&M) visit associated with a CRS or ARS diagnosis code as well as a prescription of antibiotics within 2 days of the E&M visit. Acute exacerbations among surgically managed CRS patients were defined as a post-endoscopic sinus surgery (ESS) (only considering surgeries occurring during January 1, 2011 through December 31, 2011 to allow for a 90-day healing period and adequate follow-up), E&M visit associated with a CRS or ARS code, as well as a prescription of antibiotics within 2 days of the E&M visit. Only E&M visits occurring at least 90 days after the ESS were considered.

Endoscopic Sinus Surgery Case Selection

Among the CRS patients defined previously, we defined a sub-population of CRS patients who underwent endoscopic sinus surgery (ESS). ESS was defined using procedure codes defined in Figure 1.

Drug Definition

A combination of MarketScan Therapeutic Classes (THERCLS) and/or in some cases CPT codes was utilized to define drug categories (Table I).

Financial Analyses

For accurate cost summaries, ARS and CRS claims records were pulled from the inpatient services dataset if the respective ICD-9 code was listed as the primary diagnosis (PDX); for outpatient services, the first diagnosis field was checked (DX1) as there was no PDX field in the outpatient services dataset. The same approach was used for procedures. The cost figures presented in this study represent gross payments made to providers after the submitted charges were reduced by noncovered services and pricing reduction based on contracted fee schedules which varied based on the individual payer.

Statistical Analysis

All analyses were conducted in a descriptive fashion using SAS version 9.4 (Cary, North Carolina). Our intention is to describe the characteristics and treatment patterns of a large sample of patients diagnosed with CRS in a meaningful way such that, for example, patterns might emerge from the data. As our sample size was large

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|--|
| <p>Defining CRS:</p> <ol style="list-style-type: none"> Two CRS diagnoses (473.x) within 12 weeks of one another and an intervening CT scan (CPT 70486 or 76380). Two CRS diagnoses (473.x) within 12 weeks of one another and intervening nasal endoscopy (CPT 31231). Initial diagnosis of either septal deviation (470) or chronic rhinitis (472.0), a follow-up diagnosis for CRS (473.x) within 12 weeks, and an intervening CT scan (CPT 70486 or 76380). Initial diagnosis of either septal deviation (470) or chronic rhinitis (472.0), a follow-up diagnosis for CRS (473.x) within 12 weeks, and an intervening nasal endoscopy (CPT 31231). Initial diagnosis of allergic rhinitis (477.x), a follow-up diagnosis for CRS (473.x) within 12 weeks, and an intervening CT scan (CPT 70486 or 76380). Initial diagnosis of allergic rhinitis (477.x), a follow-up diagnosis for CRS (473.x) within 12 weeks, and an intervening nasal endoscopy (CPT 31231). <p><i>If a patient satisfies more than one of the 6 claims-based definitions, then we keep the record that occurred first.</i></p> <p>Coding definitions: Balloon Sinus Ostial Dilation: 31295, 31296, 31297 E&M: 99201-99205, 99211-99215, 99241-99245, 99024 (post-op) ESS: 31254-31256, 31267, 31276, 31287-31288 Septoplasty: 30520 Turbinate Surgery: 30130, 30140, 30801, 30802, 30930 Nasal endoscopy, debridement, epistaxis, and unlisted: 31231, 31237, 31238, 31299</p> |
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Fig. 1. Defining the Chronic Rhinosinusitis Population.

(N~300,000), we did not want to rely on P-values to claim support for results of no practical significance.

RESULTS

There were approximately 54 million unique patients 18 years of age and older identified in the MarketScan Commercial Claims and Encounters

TABLE I.
Rx Crosswalk to MarketScan Therapeutic Classes and CPT Codes.

| RX | THERCLS |
|--|--|
| Antihistamines and comb | 1, 236, 240 |
| Antibiotics | 4, 6, 7, 9-12, 16, 17, 20, 133-137, 190, 194 |
| Anticholinergic agents | 24 |
| Sympathomimetic; decongestants | 27, 28, 145 |
| Irrigating solutions | 126, 132 |
| Mucolytics, cold comb | 129, 130 |
| Anti-inflammatory agents; nasal steroids | 138, 195 |
| Adrenals and comb* | 166 |
| Leukotriene modifiers | 248 |
| Allergy (shots) | CPT 95115, 95117, 95120, 95125 |
| Allergy (serum prep) | CPT 95165 |

*Hormones and other synthetic substances to include Beclomethasone, Betamethasone, Budesonide (and comb), Cortisone, Dexamethasone (and comb), Fludrocortisone, Flunisolide, Fluticasone (and comb), Hydrocortisone, Methylprednisolone, Mometasone, Prednisolone, Prednisone, Triamcinolone

database from January 1, 2010 through December 31, 2012 representing 48,075,296 commercially insured patients (90.2%) and 5,236,593 Medicare patients (9.8%). Of these, 8,035,265 (14.9%) had at least one ARS-related claim. This represented 93.3% commercial payers (CP) and 6.7% Medicare (MC) beneficiaries. The majority (67.6%) had only one ARS claim, whereas 18.9% had two ARS claims and the remaining 13.5% had three or more claims. The ARS population for CP was 63.9% female and 36.1% male with a mean age of 42. The MC population of ARS patients was 61.3% female and 38.7% male with a mean age of 73. In terms of geographic distribution of CP ARS claims, the South had the highest prevalence (45.5%), followed by the North Central (23.8%), the Northeast (16.8%), and the West (14%). In the MC population, the highest prevalence was also the South (38.3%) followed by North Central (29.5%), West (16.3%), and the Northeast (16%). Otolaryngologists saw only 1.8% of these patients with an ICD-9 coded claim for ARS.

A total of 298,337 (0.6%) unique patients had at least one ICD-9 related claim for CRS as defined in our criteria for inclusion. This was made up of 89.8% in the CP market and 10.2% in the MC population. There was a 59.9% female predominance having a CRS related claim in the commercial market and a 54.6% female predominance having a CRS related claim in the Medicare population. Geographic distribution for CRS showed the prevalence to be highest in the South (36.7% CP, 32.8% MC) followed by the Northeast (23.9% CP, 23.6% MC), the North Central (23.3% CP, 23% MC) and the West (16.1% CPA, 20.7% MC). Otolaryngologists submitted 47.5% of the claims for patients with an ICD-9 diagnosis related claim

TABLE II.
Characteristics of ARS and CRS Cohorts by Data Source.

| Characteristic | Acute Rhinosinusitis (N = 8,035,265) | | Chronic Rhinosinusitis (N = 298,337) | |
|---------------------------------------|---|-----------------------------|---|---------------------------|
| | Commercial (N = 7,499,183) | Medicare (N = 536,082) | Commercial (N = 267,843) | Medicare (N = 30,494) |
| Age at Diagnosis (yr.) | | | | |
| N | 7,499,183 | 536,082 | 267,843 | 30,494 |
| Mean (SD) | 42.0 (12.7) | 72.8 (6.7) | 44.0 (12.4) | 72.7 (6.6) |
| Median (25th, 75th) | 43 (32, 53) | 71 (67, 77) | 45 (34, 54) | 71 (67, 77) |
| Min, Max | 18, 64 | 65, 112 | 18, 64 | 65, 102 |
| Gender | | | | |
| Male | 2,705,714/7,499,183 (36.08%) | 207,284/536,082 (38.67%) | 107,338/267,843 (40.07%) | 13,860/30,494 (45.45%) |
| Female | 4,793,469/7,499,183 (63.92%) | 328,798/536,082 (61.33%) | 160,505/267,843 (59.93%) | 16,634/30,494 (54.55%) |
| Geographic Region | | | | |
| Northeast | 1,224,254/7,306,549 (16.76%) | 82,742/518,075 (15.97%) | 62,598/261,624 (23.93%) | 7,037/29,841 (23.58%) |
| North Central | 1,736,371/7,306,549 (23.76%) | 152,724/518,075 (29.48%) | 60,963/261,624 (23.30%) | 6,858/29,841 (22.98%) |
| South | 3,323,609/7,306,549 (45.49%) | 198,388/518,075 (38.29%) | 96,058/261,624 (36.72%) | 9,774/29,841 (32.75%) |
| West | 1,022,315/7,306,549 (13.99%) | 84,221/518,075 (16.26%) | 42,005/261,624 (16.06%) | 6,172/29,841 (20.68%) |
| Insurance Plan Type | | | | |
| Comprehensive | 96,236/6,808,072 (1.41%) | 189,850/510,380 (37.20%) | 3,689/243,408 (1.52%) | 10,321/29,121 (35.44%) |
| Exclusive Provider Organization (EPO) | 168,547/6,808,072 (2.48%) | 4,658/510,380 (0.91%) | 8,477/243,408 (3.48%) | 474/29,121 (1.63%) |
| Health Maintenance Organization (HMO) | 662,630/6,808,072 (9.73%) | 56,439/510,380 (11.06%) | 23,646/243,408 (9.71%) | 3,228/29,121 (11.08%) |
| Point of Service (POS) | 431,075/6,808,072 (6.33%) | 13,422/510,380 (2.63%) | 16,640/243,408 (6.84%) | 819/29,121 (2.81%) |
| Preferred Provider Organization (PPO) | 4,888,725/6,808,072 (71.81%) | 242,725/510,380 (47.56%) | 172,886/243,408 (71.03%) | 14,134/29,121 (48.54%) |
| POS with capitation | 31,339/6,808,072 (0.46%) | 874/510,380 (0.17%) | 1,349/243,408 (0.55%) | 56/29,121 (0.19%) |
| Consumer Directed Health Plan (CDHP) | 313,344/6,808,072 (4.60%) | 1,714/510,380 (0.34%) | 9,211/243,408 (3.78%) | 61/29,121 (0.21%) |
| High Deductible Health Plan (HDHP) | 216,176/6,808,072 (3.18%) | 698/510,380 (0.14%) | 7,510/243,408 (3.09%) | 28/29,121 (0.10%) |

for CRS. Descriptive data is provided in more detail in Table II.

The mean cost attributed to CRS cost among Commercial and Medicare populations is \$1023.82 and \$761.72, respectively. The median (Q1, Q3) CRS costs are Commercial: \$635.10 (\$406.50, \$1029.77) and Medicare: \$427.20 (\$297.90, \$639.39).

Documentation of the comorbidities among the 298,337 patients with a CRS-related claim has some limitations in that typical claims contain four or fewer diagnoses. The MarketScan data as displayed in Tables IIIA A–C ranks the comorbidities as follows: allergic rhinitis (43.1%), headache (15.2%), asthma (7.3%), reflux (4.9%), and Chronic Obstructive Pulmonary Disease (COPD) (3%). The frequency of smoking (1.1%) is probably not accurately reflected in that this data, as it is not a commonly used billing diagnosis for either ARS or CRS. In the CP population, the top three comorbidities were allergic rhinitis (≥ 2 visits, 17.4%), headache (≥ 2 visits, 4%), and asthma (≥ 2 visits, 2.8%); versus the top three in the

MC population—allergic rhinitis (≥ 2 visits, 12.9%), followed by COPD (≥ 1 visit, 5%), and diabetes (≥ 1 visit, 4.8%) (Table IIIB). Of patients seen in Otolaryngology, 19.1% had at least one of the comorbidities assessed, versus 37.7% of patients seen in other specialties (Table IIIC).

Of the 298,337 unique patients with a CRS-related diagnosis, the majority had at least one diagnostic procedure during the 3-year window of the study. In the group having a procedure, 55.1% had flexible or rigid endoscopy, 23.6% had cultures taken, 82.1% had a CT scan of the sinuses, and 0.2% had an MRI of the sinuses. In those patients who underwent ESS ($n = 42,937$), with the exception of CT scan, diagnostic testing occurred more frequently—66.3% had a flexible or rigid endoscopy, 31.9% had cultures taken, 90.7% had a CT scan of the sinuses, and 0.3% had a MRI of the sinuses (Table IVA). The frequency and distribution of the aforementioned tests are detailed in Tables IVB. Of those patients that had procedures, the vast majority of patients only had

TABLE IIIA.
Comorbidities Among the CRS Study Population Overall
Frequency—Patients with at Least One Comorbidity.

| Comorbidity | Frequency (%) |
|-------------------|-----------------|
| Allergic Rhinitis | 128,555 (43.1%) |
| Asthma | 21,800 (7.3%) |
| Aspirin Allergy | 342 (0.1%) |
| COPD | 8934 (3.0%) |
| Smoking | 3254 (1.1%) |
| Diabetes | 9401 (3.2%) |
| Headache | 45,323 (15.2%) |
| Reflux | 14,759 (4.9%) |
| No Comorbidities | 127,375 (42.7%) |

The denominator is the number of CRS patients (N = 298,337).
Comorbidities are tabulated within the 12-week time window that defines inclusion in the claims-based CRS population.

one (Table IVC). However, the proportion of patients with two or more of each procedure is as follows: flexible or rigid endoscopy (20.9%), cultures (7.9%), CT scan of the sinuses (15.7%), and MRI (0.01%).

Table V presents the patterns of surgical treatment for CRS. 14.4% (42,937/298,337) of CRS patients in the database underwent ESS. These patients were categorized into those that also had septoplasty same day as ESS (n = 21,395) or pre- or post-ESS (n = 1,835), those that did not have septoplasty (n = 19,707) and those who had turbinate surgery same day as ESS (n = 21,562) or pre- or post-ESS (n = 2,306) or those that did not (n = 19,069). In the group of 21,395 that had ESS and septoplasty on same day, 94% had maxillary, 82.1% had ethmoid surgery, 38.8% had frontal surgery, and 28.5% had sphenoid surgery. In those patients having septoplasty on same day, 16.6% had only one sinus operated on, 39.1% had two sinuses operated on, 24.6% had three

TABLE IIIB.
Comorbidities Among the CRS Study Population According
to Data Source.

| Comorbidity | Commercial (N = 267,843) | Medicare (N = 30,494) |
|---------------------------------------|-----------------------------|--------------------------|
| Allergic rhinitis (at least 2 visits) | 46,527 (17.4%) | 3942 (12.9%) |
| Allergic rhinitis (at least 4 visits) | 12,335 (4.6%) | 1049 (3.4%) |
| Asthma (at least 2 visits) | 7508 (2.8%) | 891 (2.9%) |
| Asthma (at least 4 visits) | 1776 (0.7%) | 220 (0.7%) |
| Aspirin allergy (only 1 visit) | 269 (0.1%) | 34 (0.1%) |
| COPD (at least 1 visit) | 4786 (1.8%) | 1511 (5.0%) |
| Diabetes (at least 1 visit) | 4635 (1.7%) | 1461 (4.8%) |
| Headache (at least 2 visits) | 10,808 (4.0%) | 819 (2.7%) |
| Headache (at least 4 visits) | 888 (0.3%) | 71 (0.2%) |
| Reflux (at least 2 visits) | 2673 (1.0%) | 462 (1.5%) |
| Reflux (at least 4 visits) | 216 (0.1%) | 34 (0.1%) |

Comorbidities are tabulated within the 12-week time window that defines inclusion in the claims-based CRS population.

Comorbidities with multiple visit counts are not mutually exclusive categories.

TABLE IIIC.
Comorbidities among the CRS Study Population According to
Provider Type.

| Comorbidity | Otolaryngology (N = 135,205) | Other Specialty (N = 149,698) |
|---------------------------------------|---------------------------------|-------------------------------------|
| Allergic rhinitis (at least 2 visits) | 15,583 (11.5%) | 32,605 (21.8%) |
| Allergic rhinitis (at least 4 visits) | 3034 (2.2%) | 9835 (6.6%) |
| Asthma (at least 2 visits) | 923 (0.7%) | 7110 (4.7%) |
| Asthma (at least 4 visits) | 158 (0.1%) | 1759 (1.2%) |
| Aspirin Allergy (only 1 visit) | 64 (0.0%) | 225 (0.2%) |
| COPD (at least 1 visit) | 1777 (1.3%) | 4257 (2.8%) |
| Diabetes (at least 1 visit) | 2081 (1.5%) | 3738 (2.5%) |
| Headache (at least 2 visits) | 4256 (3.1%) | 6733 (4.5%) |
| Headache (at least 4 visits) | 236 (0.2%) | 671 (0.4%) |
| Reflux (at least 2 visits) | 1159 (0.9%) | 1812 (1.2%) |
| Reflux (at least 4 visits) | 52 (0.0%) | 185 (0.1%) |

Comorbidities are tabulated within the 12-week time window that defines inclusion in the claims-based CRS population.

The "Otolaryngology" and "Other Specialty" groups denote the provider of each CRS patient on the first date of the claims-based criteria satisfied. The "Otolaryngology" group contains patients who may have seen more than one provider (in addition to an Otolaryngologist) on the same day. The "Other Specialty" group contains patients who did not see an Otolaryngologist on the particular date that satisfied the claims-based criteria. A total of 13,434 (4.5%) of patients had missing provider information and are not included in this table.

Comorbidities with multiple visit counts are not mutually exclusive categories.

sinuses operated on, and 18.7% had all four of the sinuses operated on. The patient population that had ESS and no septoplasty had 76.1% that underwent maxillary surgery, 66.6% of the patients undergoing ethmoid surgery, 35% had frontal surgery, and 28.1% had sphenoid surgery. Within this group, 16.2% had one sinus operated on,

TABLE IVA.
Summary of Diagnostic Regimens and Procedures
Associated with CRS.

| Population | Regimen/ Procedure | Total No. Patients (%)* | Total No. Procedures |
|---|----------------------------|----------------------------|-------------------------|
| All CRS patients (N = 298,337) | Flexible & rigid endoscopy | 164,299 (55.07%) | 293,253 |
| | cultures | 70,333 (23.58%) | 117,258 |
| | CT scan of sinuses | 244,827 (82.06%) | 308,117 |
| All CRS patients who underwent ESS (N = 42,937) | MRI of sinuses | 643 (0.22%) | 695 |
| | Flexible & rigid endoscopy | 28,484 (66.34%) | 65,628 |
| | cultures | 13,684 (31.87%) | 23,930 |
| | CT scan of sinuses | 38,925 (90.66%) | 53,214 |
| | MRI of sinuses | 115 (0.27%) | 131 |

The time frame for these tabulations is January 1, 2010 through December 31, 2012.

*Denominator is the number of patients in the specified group (ie, N = 298,337 and N = 42,937).

TABLE IVB.
Timing of Diagnostic Regimens and Procedures Associated with CRS Patients Undergoing ESS Population.

| Group | Total No. Procedures (%)* |
|---|---------------------------|
| Patients who underwent flexible and rigid endoscopy (N = 28,484 patients and 65,628 procedures) | |
| Procedure occurred prior to ESS | 27,190 (41.43%) |
| Procedure occurred on same day as ESS | 403 (0.61%) |
| Procedure occurred post ESS | 38,035 (57.96%) |
| Patients who received cultures (N = 13,684 patients and 23,930 procedures) | |
| Procedure occurred prior to ESS | 8721 (36.44%) |
| Procedure occurred on same day as ESS | 5448 (22.77%) |
| Procedure occurred post ESS | 9761 (40.79%) |
| Patients who underwent a CT scan (N = 38,925 patients and 53,214 procedures) | |
| Procedure occurred prior to ESS | 46,097 (86.63%) |
| Procedure occurred on same day as ESS | 1064 (2.00%) |
| Procedure occurred post ESS | 6053 (11.37%) |
| Patients who underwent a MRI (N = 115 patients and 131 procedures) | |
| Procedure occurred prior to ESS | 73 (55.73%) |
| Procedure occurred on same day as ESS | 1 (0.76%) |
| Procedure occurred post ESS | 57 (43.51%) |

*Denominator is the total number of procedures within each group.

30.2% had two sinuses operated on, 21.6% had three sinuses operated on, and 16.1% had all four sinuses operated on. In the group that had ESS and turbinate surgery on same day, 93.6% had maxillary sinus surgery, 81.4% had ethmoid surgery, 39.3% had frontal sinus surgery, and 28.3% had sphenoid sinus surgery. The ESS and turbinate surgery on same day group had 17% undergoing surgery on one sinus, 38.6% having two sinuses done, 24.7% had three sinuses done, and 18.6% had all four sinuses operated on. Balloon Sinus Ostial Dilatation (BSOD) (CPT 31295/6/7) was performed in addition to ESS on 5.3% of the patients that had septoplasty on same day and 5.7% of the patients who did not have septoplasty. Polyps were noted in 3.7% of patients having ESS with the septoplasty on same and 65.4% of patients with no septoplasty performed. Surgical pathology specimens were ordered within 10 days of ESS in 79.5% of patients undergoing ESS with septoplasty on same day and 65.7%

of those patients undergoing ESS without septoplasty. Cultures were ordered in 9.8% of patients undergoing ESS with septoplasty on same day and 26.9% of patients undergoing ESS without septoplasty.

Costs associated with medical management of the CRS patients who underwent ESS both before and after surgery were also assessed. Costs were documented for the 6 months immediately prior to the procedure, the 45 days immediately following the procedure, and 6 months following the completion of the 45-day postoperative period. We compared the use of antihistamines and combination products, antibiotics, decongestants, anti-inflammatory agents (ie, nasal steroids), leukotriene modifiers, and others. All medications in this study were verified by prescription billing. During the years included in this study, the only nasal steroid available OTC was Nasacort (October 2013). Table VI presents the volumes of patients and costs by therapeutic category. The average cost reflects the average cost for patients who filled a prescription in that therapeutic class versus the average cost for that therapeutic class across all CRS patients.

When compared to the pre-op 6-month period, antihistamine use dropped 31.1% in the first postoperative period (0 to 45 days), 54.2% in the second postoperative period (45 to 225 days), and the overall cost dropped 50.9%. Antibiotic usage dropped 17.8% in the first postoperative period, 49.2% in the second, and overall cost dropped 62.9%. Anticholinergic agents dropped 64.7% in postoperative period one, 37.2% in the second period, and overall cost dropped 25.4%. Decongestants dropped 66.5% in the first period, 38.3% in the second period, and overall cost dropped 34.5%. Anti-inflammatory agents (ie, nasal steroids) dropped 48.9% in the first period, 40.7% in the second, and overall cost dropped 36.3%. Adrenals and combination medications dropped 44% in the first postoperative period, 56.8% in the second, and overall cost dropped 20.7%. Finally, leukotriene modifiers dropped 38.6% in the first postoperative period, 14.2% in the second, and overall cost dropped 22.4%. Across all medications, overall cost dropped 34.2% or \$3.9 M.

The average cost of the ESS procedures varied by the place of service as follows:

- Inpatient, hospital outpatient, ambulatory surgery center (STDPLAC = 21, 22, 23, 24), \$3,973 (N = 38,782);
- Office (STDPLAC = 11), \$1,114 (N = 26,676); and

TABLE IVC.
Distribution of Per-Patient Diagnostic Regimens and Procedures Associated with CRS.

| No. Procedures | Flexible and Rigid Endoscopy | Cultures | CT Scan of Sinuses | MRI of Sinuses |
|----------------|------------------------------|------------------|--------------------|------------------|
| Zero | 134,038 (44.93%) | 228,004 (76.42%) | 53,510 (17.94%) | 297,694 (99.78%) |
| One | 101,994 (34.19%) | 46,898 (15.72%) | 197,967 (66.36%) | 601 (0.20%) |
| Two | 33,090 (11.09%) | 13,699 (4.59%) | 36,299 (12.17%) | 35 (0.01%) |
| Three | 14,094 (4.72%) | 4996 (1.67%) | 7256 (2.43%) | 5 (0.00%) |
| Four | 6656 (2.23%) | 2114 (0.71%) | 2060 (0.69%) | 1 (0.00%) |
| Five or more | 8465 (2.84%) | 2626 (0.88%) | 1245 (0.42%) | 1 (0.00%) |

Denominator is the CRS study population (N = 298,337).

TABLE V.
Patterns of Surgical Treatment for CRS.

| Treatment | Septoplasty Same Day as ESS (N = 21,395) | No Septoplasty (N = 19,707) | Septoplasty Pre or Post ESS (N = 1835) | Turbinate Same Day as ESS (N = 21,562) | No Turbinate (N = 19,069) | Turbinate Pre or Post ESS (N = 2306) |
|--|--|-----------------------------|--|--|---------------------------|--------------------------------------|
| Sinus Surgeries: | | | | | | |
| Ethmoid | | | | | | |
| No. patients | 17,565 (82.10%) | 13,131 (66.63%) | 539 (29.37%) | 17,561 (81.44%) | 12,997 (68.16%) | 675 (29.27%) |
| Age (median [Q1, Q3]) | 43 (32, 53) | 48 (37, 58) | 46 (33, 55) | 43 (32, 53) | 48 (37, 58) | 45 (34, 55) |
| Male (% no. patients) | 9263 (52.74%) | 5941 (45.24%) | 290 (53.80%) | 8890 (50.62%) | 6279 (48.31%) | 322 (47.70%) |
| Maxillary | | | | | | |
| No. patients | 20,119 (94.04%) | 14,998 (76.10%) | 597 (32.53%) | 20,187 (93.62%) | 14,783 (77.52%) | 751 (32.57%) |
| Age (median [Q1, Q3]) | 42 (32, 53) | 48 (37, 58) | 45 (33, 55) | 42 (32, 53) | 48 (37, 58) | 46 (34, 55) |
| Male (% no. patients) | 10,541 (52.39%) | 6596 (43.98%) | 313 (52.43%) | 10,156 (50.31%) | 6939 (46.94%) | 354 (47.14%) |
| Frontal | | | | | | |
| No. patients | 8309 (38.84%) | 6899 (35.01%) | 305 (16.62%) | 8472 (39.29%) | 6655 (34.90%) | 390 (16.91%) |
| Age (median [Q1, Q3]) | 43 (33, 54) | 49 (38, 59) | 45 (34, 55) | 43 (33, 54) | 49 (37, 59) | 46 (35, 56) |
| Male (% no. patients) | 4587 (55.21%) | 3394 (49.20%) | 161 (52.79%) | 4565 (53.88%) | 3385 (50.86%) | 188 (48.21%) |
| Sphenoid | | | | | | |
| No. patients | 6091 (28.47%) | 5545 (28.14%) | 233 (12.70%) | 6103 (28.30%) | 5488 (28.78%) | 277 (12.01%) |
| Age (median [Q1, Q3]) | 44 (33, 54) | 49 (38, 58) | 46 (33, 55) | 44 (33, 54) | 49 (38, 58) | 46 (33, 56) |
| Male (% no. patients) | 3284 (53.92%) | 2629 (47.41%) | 129 (55.36%) | 3180 (52.11%) | 2720 (49.56%) | 137 (49.46%) |
| Number of sinuses treated: | | | | | | |
| One Sinus (any one of the above) | | | | | | |
| No. patients | 3555 (16.62%) | 3186 (16.17%) | 110 (5.99%) | 3664 (16.99%) | 3046 (15.97%) | 144 (6.24%) |
| Age (median [Q1, Q3]) | 42 (32, 52) | 49 (37, 58) | 41 (31, 53) | 41 (32, 52) | 49 (38, 59) | 43 (32, 53) |
| Male (% no. patients) | 1793 (50.44%) | 1191 (37.38%) | 50 (45.45%) | 1775 (48.44%) | 1202 (39.46%) | 65 (45.14%) |
| Two sinuses (any two of the above) | | | | | | |
| No. patients | 8356 (39.06%) | 5944 (30.16%) | 228 (12.43%) | 8316 (38.57%) | 5909 (30.99%) | 288 (12.49%) |
| Age (median [Q1, Q3]) | 42 (32, 52) | 48 (36, 58) | 44 (33, 54) | 42 (32, 52) | 48 (36, 58) | 44 (33, 54) |
| Male (% no. patients) | 4223 (50.54%) | 2414 (40.61%) | 107 (46.93%) | 3972 (47.76%) | 2645 (44.76%) | 122 (42.36%) |
| Three sinuses (any three of the above) | | | | | | |
| No. patients | 5259 (24.58%) | 4261 (21.62%) | 148 (8.07%) | 5321 (24.68%) | 4161 (21.82%) | 199 (8.63%) |
| Age (median [Q1, Q3]) | 43 (32, 54) | 49 (38, 59) | 45 (34, 55) | 43 (32, 53) | 49 (38, 59) | 45 (34, 56) |
| Male (% no. patients) | 2760 (52.48%) | 1979 (46.44%) | 83 (56.08%) | 2700 (50.74%) | 2029 (48.76%) | 100 (50.25%) |
| Four sinuses (all four of the above) | | | | | | |
| No. patients | 4010 (18.74%) | 3179 (16.13%) | 166 (9.05%) | 4016 (18.63%) | 3144 (16.49%) | 194 (8.41%) |
| Age (median [Q1, Q3]) | 44 (33, 54) | 48 (37, 58) | 46 (33, 55) | 44 (33, 54) | 48 (37, 57) | 47 (33, 55) |
| Male (% no. patients) | 2289 (57.08%) | 1651 (51.93%) | 95 (57.23%) | 2243 (55.85%) | 1686 (53.63%) | 98 (50.52%) |
| Specific Combinations of Two Procedures*: | | | | | | |
| Maxillary and ethmoid | | | | | | |
| No. patients | 7650 (91.55%) | 4983 (83.83%) | 190 (83.33%) | 7537 (90.82%) | 5019 (84.65%) | 229 (76.33%) |
| Age (median [Q1, Q3]) | 42 (32, 52) | 47 (36, 57) | 46 (32, 54) | 42 (31, 52) | 47 (36, 58) | 44 (33, 53) |
| Male (% no. patients) | 3900 (50.98%) | 2018 (40.50%) | 96 (50.53%) | 3615 (47.96%) | 2277 (45.37%) | 101 (44.10%) |
| Ethmoid and frontal | | | | | | |
| No. patients | 114 (1.36%) | 277 (4.66%) | 13 (5.70%) | 127 (1.53%) | 252 (4.25%) | 22 (7.33%) |
| Age (median [Q1, Q3]) | 44 (36, 55) | 50 (38, 60) | 39 (33, 55) | 44 (34, 53) | 51 (39, 62) | 47 (39, 54) |
| Male (% no. patients) | 69 (60.53%) | 132 (47.65%) | 5 (38.46%) | 71 (55.91%) | 123 (48.81%) | 10 (45.45%) |
| Ethmoid and sphenoid | | | | | | |
| No. patients | 116 (1.39%) | 178 (2.99%) | 7 (3.07%) | 110 (1.33%) | 175 (2.95%) | 6 (2.00%) |
| Age (median [Q1, Q3]) | 46 (35, 57) | 51 (39, 60) | 35 (24, 60) | 43 (34, 58) | 51 (40, 60) | 35 (19, 57) |
| Male (% no. patients) | 42 (36.21%) | 61 (34.27%) | 3 (42.86%) | 40 (36.36%) | 61 (34.86%) | 2 (33.33%) |
| Frontal and sphenoid | | | | | | |
| No. patients | 18 (0.22%) | 31 (0.52%) | 0 (0.00%) | 21 (0.25%) | 26 (0.44%) | 2 (0.67%) |
| Age (median [Q1, Q3]) | 40 (31, 48) | 53 (41, 59) | | 40 (30, 48) | 53 (45, 60) | 66 (58, 73) |
| Male (% no. patients) | 12 (66.67%) | 10 (32.26%) | | 12 (57.14%) | 9 (34.62%) | 1 (50.00%) |

(Continues)

TABLE V.
Continued

| Treatment | SeptoplastySame Day as ESS(N = 21,395) | NoSeptoplasty (N = 19,707) | SeptoplastyPre or Post ESS(N = 1835) | TurbinateSame Day as ESS(N = 21,562) | NoTurbinate (N = 19,069) | TurbinatePre or Post ESS(N = 2306) |
|--|--|----------------------------|--------------------------------------|--------------------------------------|--------------------------|------------------------------------|
| Other Areas of Interest: | | | | | | |
| Balloon | | | | | | |
| No. patients | 1130 (5.28%) | 1126 (5.71%) | 0 (0.00%) | 1266 (5.87%) | 949 (4.98%) | 94 (4.08%) |
| Age (median [Q1, Q3]) | 42 (33, 53) | 48 (36, 57) | | 43 (33, 53) | 49 (37, 58) | 46 (36, 55) |
| Male (% no. patients) | 573 (50.71%) | 494 (43.87%) | | 623 (49.21%) | 431 (45.42%) | 40 (42.55%) |
| Polyp | | | | | | |
| No. patients | 781 (3.65%) | 12,880 (65.36%) | 1654 (90.14%) | 881 (4.09%) | 11,790 (61.83%) | 2065 (89.55%) |
| Age (median [Q1, Q3]) | 46 (34, 56) | 49 (38, 59) | 43 (32, 53) | 45 (34, 55) | 50 (39, 60) | 43 (33, 54) |
| Male (% no. patients) | 515 (65.94%) | 5759 (44.71%) | 876 (52.96%) | 551 (62.54%) | 5495 (46.61%) | 1058 (51.23%) |
| Pathology ordered within 10 days of ESS | | | | | | |
| No. patients | 17,007 (79.49%) | 12,938 (65.65%) | 381 (20.76%) | 16,864 (78.21%) | 12,975 (68.04%) | 487 (21.12%) |
| Age (median [Q1, Q3]) | 43 (32, 53) | 49 (37, 59) | 44 (31, 55) | 43 (32, 53) | 49 (37, 59) | 45 (34, 54) |
| Male (% no. patients) | 9022 (53.05%) | 5924 (45.79%) | 210 (55.12%) | 8623 (51.13%) | 6286 (48.45%) | 247 (50.72%) |
| Cultures ordered | | | | | | |
| No. patients | 2105 (9.84%) | 5294 (26.86%) | 343 (18.69%) | 2212 (10.26%) | 5124 (26.87%) | 401 (17.39%) |
| Age (median [Q1, Q3]) | 46 (35, 56) | 49 (38, 58) | 45 (33, 55) | 46 (35, 56) | 49 (38, 59) | 45 (34, 55) |
| Male (% no. patients) | 1104 (52.45%) | 2111 (39.88%) | 157 (45.77%) | 1101 (49.77%) | 2128 (41.53%) | 164 (40.90%) |

Sinus procedures in each row are summarized across columns (Septoplasty, Turbinate surgery) as follows: occurring same day as Septoplasty/Turbinate; occurring on or after ESS (among those with no Septoplasty/Turbinate); occurring on or after ESS (among those with Septoplasty/Turbinate occurring before or after ESS).

Septoplasty and Turbinate surgery groups are not mutually exclusive groups.

*Denominator is any two sinus procedures as listed in the "Number of Sinuses Treated" section of the table.

- Other (STDPLAC = all other values not listed above), \$1,622 (N = 1055).

Table VII describes the subsequent management frequency of visits for patients on medical therapy for CRS. The medically managed patients were quantified based on visits during which an antibiotic was prescribed within 2 days following that appointment and tracked for 6 months. Of the 255,400 unique patients being managed medically, the average number of visits per patient seen for CRS declined by >50% over the 6-month study period from 1.2 visits per patient in month 1 to 0.55 in month 6 (1.2¹, 1.01², 0.85³, 0.66⁴, 0.56⁵, 0.55⁶). However, when the cohort is limited within each month to patients with at least one visit, the average number of visits was relatively constant and averaged 1.73 in the first month and 1.63 in month 6 (1.73¹, 1.72², 1.72³, 1.65⁴, 1.6⁵, 1.63⁶).

Table VIIIA presents the patterns of care in surgically managed CRS patients. Across all procedures (except epistaxis among patients with ≥1 visit), the average number of visits per patient increased in the 6-month period to the procedure and decreased in the 6-month period post-procedure as follows: Nasal endoscopy (0.5[-6] → 1.66[-1]; 0.88[+1] → 0.54[+6]); debridement (0.52[-6] → 1.71[-1]; 0.68[+1] → 0.43[+6]); and epistaxis (0.45[-6] → 1.32[-1]; 0.73[+1] → 0.14[+6]). When the cohort is limited within each month to patients with at least one visit, the same pattern is present: Nasal endoscopy (1.51[-6] → 2[-1]; 1.72[+1] → 1.60[+6]); debridement (1.49[-6] → 2.01[-1]; 1.6

[+1] → 1.52[+6]); and epistaxis (1.67[-6] → 1.45[-1]; 1.45[+1] → 1.5[+6]).

Table VIIIB presents the patterns of care in the post-ESS surgical cohort. In the nasal endoscopy group 7826 unique patients had postoperative nasal endoscopy in the 6-month postoperative period, or 18.2% of the 42,937 patients who underwent ESS (average of 1.76 per patient). The total number of unique surgically managed patients with a record of undergoing ONLY nasal endoscopy in the postoperative period is 4450 of 42,937 (10.4%) at any time.

There were 11,278 unique patients who underwent debridement in the 6-month postoperative period, or 26.3% of the original ESS group (average of 1.78 per patient). The total number of unique surgically managed patients with a record of undergoing ONLY a debridement is 6320 of 42,937 (14.7%) at any time. Additionally, 25 (0.06%) of the initial 42,937 unique patients had visits to control epistaxis and one of the initial 42,937 unique patients had an unlisted procedure in the 6-month postoperative period.

Finally, we looked at the frequency of acute infectious exacerbations of CRS patients following initial diagnosis of CRS. First, the medically managed CRS patients (n = 255,400) were studied (Tables IXA, IX B). An acute exacerbation was defined as a post-CRS E&M visit that was associated with a CRS or ARS diagnosis code as well as a prescription of antibiotics within 2 days of the E&M visit. In the second group, we studied surgically managed CRS patients (n = 42,937) (Tables XA, X B). An acute

TABLE VI.
Average Cost Per-Patient for Sinus-Related Health Care Utilization Endoscopic Sinus Surgery Population.

| Group | Previous 6 Months | | | Procedure t = 0 to Day 45 | | | Post-Op 6 Months | | | Change pre 6 to post 6 months |
|--|----------------------------|--------------|--------------|----------------------------|--------------|-------------|----------------------------|--------------|-------------|-------------------------------|
| | No. Patientst [†] | Average Cost | Total Cost | No. Patientst [†] | Average Cost | Total Cost | No. Patientst [†] | Average Cost | Total Cost | |
| Prescription Drugs | | | | | | | | | | |
| Antihistamines and Comb | 5,137 | \$99 | \$508,563 | 3,540 | \$37 | \$130,980 | 2,354 | \$106 | \$249,524 | (\$259,039) |
| Antibiotics | 26,505 | \$149 | \$3,949,245 | 21,789 | \$59 | \$1,285,551 | 13,453 | \$109 | \$1,466,377 | (\$2,482,868) |
| Anticholinergic Agents | 712 | \$303 | \$215,736 | 251 | \$225 | \$56,475 | 447 | \$360 | \$160,920 | (\$54,816) |
| Sympathomimetic Agents: Decongestants | 5,026 | \$129 | \$648,354 | 1,686 | \$106 | \$178,716 | 3,100 | \$137 | \$424,700 | (\$223,654) |
| Irrigating Solutions | 152 | \$36 | \$5,472 | 364 | \$33 | \$12,012 | 199 | \$49 | \$9,751 | \$4,279 |
| Mjcolytics, Cold Comb | 16 | \$72 | \$1,152 | 11 | \$52 | \$572 | 13 | \$114 | \$1,482 | \$330 |
| Anti-Inflammatory Agents: Nasal Steroids | 15,527 | \$120 | \$1,863,240 | 7,934 | \$81 | \$642,654 | 9,207 | \$129 | \$1,187,703 | (\$675,537) |
| Adrenals and Comb | 16,298 | \$132 | \$2,151,336 | 9,120 | \$94 | \$857,280 | 7,047 | \$242 | \$1,705,374 | (\$445,962) |
| Leukotriene Modifiers | 2,959 | \$425 | \$1,257,575 | 1,818 | \$216 | \$392,688 | 2,540 | \$384 | \$975,360 | (\$282,215) |
| Procedures | | | | | | | | | | |
| Allergy Shots | 1,402 | \$108 | \$151,416 | 1,721 | \$60 | \$103,260 | 2,325 | \$165 | \$383,625 | \$232,209 |
| Serum Prep | 1,424 | \$467 | \$665,008 | 1,113 | \$373 | \$415,149 | 2,079 | \$457 | \$950,103 | \$285,095 |
| Overall Change in Cost | 75,158 | \$152 | \$11,417,097 | 49,347 | \$83 | \$4,075,337 | 42,764 | \$176 | \$7,514,919 | (\$3,902,178) |

[†]Indicates the number of unique patients who filled a prescription for the given therapeutic class (or had the given procedure) in the respective time window. These numbers serve as the denominators for each calculation.

Note: All prescription drug records were pulled according to therapeutic class only. No other filtering mechanism was applied.

TABLE VII.
Patterns of Care in Medically Managed CRS Patients.

| Patient Group | Month Post-CRS Diagnosis* | No. Patients [†] | Ave. No. Visits (Total Visits) [‡] |
|--|---------------------------|---------------------------|---|
| Among all patients | Month 1 | 255,400 | 1.20 (306,868 visits) |
| Among patients with at least one visit | | 177,086 | 1.73 (306,868 visits) |
| Among all patients | Month 2 | 255,400 | 1.01 (258,603 visits) |
| Among patients with at least one visit | | 150,323 | 1.72 (258,603 visits) |
| Among all patients | Month 3 | 255,400 | 0.85 (216,993 visits) |
| Among patients with at least one visit | | 126,256 | 1.72 (216,993 visits) |
| Among all patients | Month 4 | 255,400 | 0.66 (169,675 visits) |
| Among patients with at least one visit | | 103,045 | 1.65 (169,675 visits) |
| Among all patients | Month 5 | 255,400 | 0.56 (143,923 visits) |
| Among patients with at least one visit | | 90,016 | 1.60 (143,923 visits) |
| Among all patients | Month 6 | 255,400 | 0.55 (141,410 visits) |
| Among patients with at least one visit | | 86,492 | 1.63 (141,410 visits) |

*Calculations are based on the first date that a patient satisfied the claims-based criteria for inclusion in the CRS population.

[†]Indicates the denominator for each calculation.

[‡]Evaluation & management visits: CPT 99201-99205, 99211-99215, 99241-99245, 99024 (post-op).

infectious exacerbation of CRS is defined as a post-ESS E&M visit following a ninety-day healing period that was associated with a CRS or ARS diagnosis code as well as a prescription for antibiotics written within 2 days of the E&M visit.

In the medically managed group there were a total of 122,417 acute exacerbations among 67,616 (26.5% of those medically managed CRS patients) unique patients. The average per-patient exacerbation was 1.81 (SD = 1.33). A total of 39,056 patients had one exacerbation, 15,490 patients had two exacerbations, 6730 patients had three exacerbations, 3146 had four exacerbations, and 3194 had five or more exacerbations. In the post ESS group, there were 9123 exacerbations among 4971 unique patients (11.6% of the surgically managed patients). The 4971 unique patients that had an exacerbation averaged 1.84 exacerbations (SD = 1.38). A total of 2865 patients had one exacerbation, 1138 patients had two exacerbations, 467 patients had three exacerbations, 233 patients had four exacerbations, and 268 patients had five or more exacerbations during the study period.

DISCUSSION

The Truven Health MarketScan Commercial Claims and Encounters database contained roughly 54 million

TABLE VIII.
Patterns of Care in Surgically Managed CRS Patients.

| Patient Group | Month Pre/ Post ESS | Pre-ESS Time Frame | | Post-ESS Time Frame | |
|--|------------------------|--------------------|--|---------------------------|--|
| | | No. Patients* | Ave. No. Visits (Total Visits) [†] | No. Patients [‡] | Ave. No. Visits (Total Visits) [‡] |
| Nasal endoscopy | | | | | |
| Among all patients with procedure | Month 1 | 4450 | 1.66 (7,384 visits) | 4450 | 0.88 (3,928 visits) |
| Among patients with at least one visit | | 3684 | 2.00 (7,384 visits) | 2289 | 1.72 (3,928 visits) |
| Among all patients with procedure | Month 2 | 4450 | 1.34 (5,981 visits) | 4450 | 0.72 (3,223 visits) |
| Among patients with at least one visit | | 3346 | 1.79 (5,981 visits) | 2027 | 1.59 (3,223 visits) |
| Among all patients with procedure | Month 3 | 4450 | 0.90 (4,022 visits) | 4450 | 0.61 (2,706 visits) |
| Among patients with at least one visit | | 2482 | 1.62 (4,022 visits) | 1736 | 1.56 (2,706 visits) |
| Among all patients with procedure | Month 4 | 4450 | 0.61 (2,715 visits) | 4450 | 0.60 (2,688 visits) |
| Among patients with at least one visit | | 1762 | 1.54 (2,715 visits) | 1732 | 1.55 (2,688 visits) |
| Among all patients with procedure | Month 5 | 4450 | 0.51 (2,288 visits) | 4450 | 0.57 (2,520 visits) |
| Among patients with at least one visit | | 1562 | 1.46 (2,288 visits) | 1608 | 1.57 (2,520 visits) |
| Among all patients with procedure | Month 6 | 4450 | 0.50 (2,211 visits) | 4450 | 0.54 (2,386 visits) |
| Among patients with at least one visit | | 1462 | 1.51 (2,211 visits) | 1489 | 1.60 (2,386 visits) |
| Debridement | | | | | |
| Among all patients with procedure | Month 1 | 6320 | 1.71 (10,781 visits) | 6320 | 0.68 (4,287 visits) |
| Among patients with at least one visit | | 5374 | 2.01 (10,781 visits) | 2672 | 1.60 (4,287 visits) |
| Among all patients with procedure | Month 2 | 6320 | 1.39 (8,777 visits) | 6320 | 0.59 (3,725 visits) |
| Among patients with at least one visit | | 4862 | 1.81 (8,777 visits) | 2454 | 1.52 (3,725 visits) |
| Among all patients with procedure | Month 3 | 6320 | 0.89 (5,628 visits) | 6320 | 0.52 (3,295 visits) |
| Among patients with at least one visit | | 3470 | 1.62 (5,628 visits) | 2149 | 1.53 (3,295 visits) |
| Among all patients with procedure | Month 4 | 6320 | 0.60 (3,764 visits) | 6320 | 0.50 (3,170 visits) |
| Among patients with at least one visit | | 2485 | 1.51 (3,764 visits) | 2091 | 1.52 (3,170 visits) |
| Among all patients with procedure | Month 5 | 6320 | 0.51 (3,199 visits) | 6320 | 0.44 (2,794 visits) |
| Among patients with at least one visit | | 2212 | 1.45 (3,199 visits) | 1868 | 1.50 (2,794 visits) |
| Among all patients with procedure | Month 6 | 6320 | 0.52 (3,296 visits) | 6320 | 0.43 (2,740 visits) |
| Among patients with at least one visit | | 2205 | 1.49 (3,296 visits) | 1803 | 1.52 (2,740 visits) |
| Epistaxis control | | | | | |
| Among all patients with procedure | Month 1 | 22 | 1.32 (29 visits) | 22 | 0.73 (16 visits) |
| Among patients with at least one visit | | 20 | 1.45 (29 visits) | 11 | 1.45 (16 visits) |
| Among all patients with procedure | Month 2 | 22 | 1.68 (37 visits) | 22 | 0.64 (14 visits) |
| Among patients with at least one visit | | 18 | 2.06 (37 visits) | 11 | 1.27 (14 visits) |
| Among all patients with procedure | Month 3 | 22 | 0.50 (11 visits) | 22 | 0.55 (12 visits) |
| Among patients with at least one visit | | 9 | 1.22 (11 visits) | 8 | 1.50 (12 visits) |
| Among all patients with procedure | Month 4 | 22 | 0.64 (14 visits) | 22 | 0.41 (9 visits) |
| Among patients with at least one visit | | 8 | 1.75 (14 visits) | 6 | 1.50 (9 visits) |
| Among all patients with procedure | Month 5 | 22 | 0.73 (16 visits) | 22 | 0.55 (12 visits) |
| Among patients with at least one visit | | 8 | 2.00 (16 visits) | 8 | 1.50 (12 visits) |
| Among all patients with procedure | Month 6 | 22 | 0.45 (10 visits) | 22 | 0.14 (3 visits) |
| Among patients with at least one visit | | 6 | 1.67 (10 visits) | 2 | 1.50 (3 visits) |
| Unlisted sinus procedure | | | | | |
| Among all patients with procedure | Month 1 | 1 | 1.00 (1 visits) | 1 | N/A (0 visits) |
| Among patients with at least one visit | | 1 | 1.00 (1 visits) | 0 | N/A (0 visits) |
| Among all patients with procedure | Month 2 | 1 | 2.00 (2 visits) | 1 | N/A (0 visits) |
| Among patients with at least one visit | | 1 | 2.00 (2 visits) | 0 | N/A (0 visits) |
| Among all patients with procedure | Month 3 | 1 | N/A (0 visits) | 1 | 1.00 (1 visits) |
| Among patients with at least one visit | | 0 | N/A (0 visits) | 1 | 1.00 (1 visits) |
| Among all patients with procedure | Month 4 | 1 | N/A (0 visits) | 1 | 1.00 (1 visits) |
| Among patients with at least one visit | | 0 | N/A (0 visits) | 1 | 1.00 (1 visits) |

(Continues)

TABLE VIIIA.
Continued

| Patient Group | Month Pre/ Post ESS | Pre-ESS Time Frame | | Post-ESS Time Frame | |
|--|------------------------|--------------------|--|---------------------------|--|
| | | No. Patients* | Ave. No. Visits (Total Visits) [†] | No. Patients [‡] | Ave. No. Visits (Total Visits) [§] |
| Among all patients with procedure | Month 5 | 1 | N/A (0 visits) | 1 | N/A (0 visits) |
| Among patients with at least one visit | | 0 | N/A (0 visits) | 0 | N/A (0 visits) |
| Among all patients with procedure | Month 6 | 1 | 1.00 (1 visits) | 1 | N/A (0 visits) |
| Among patients with at least one visit | | 1 | 1.00 (1 visits) | 0 | N/A (0 visits) |

*For pre-ESS and post-ESS calculations, the sample size for each procedure group is the number of unique patients with the given procedure in the 6 months following ESS.

[†]Indicates the denominator for each calculation.

[‡]Evaluation & management visits: CPT 99201-99205, 99211-99215, 99241-99245.

[§]Evaluation & management visits: CPT 99024, 99201-99205, 99211-99215, 99241-99245.

unique patients 18 years of age and older who were studied for 3 years which is the equivalent to over 160 million patient years being studied of which 90.2% were commercially insured and 9.8% on Medicare. Our findings in this population indicated that 14.9% of unique patients had a diagnosis of ARS during the three-year study and 0.6% of the unique patients had a diagnosis of CRS. The widely published range²⁻⁴ of prevalence for CRS is 2% to 16%. This study is considerably below the estimates of most prior publications. The designation of CRS in our study is based on diagnostic billing codes after each unique patient had already been seen and a physician-assigned diagnosis established. We also used a very "tight" definition of CRS. This contrasts with national survey and self-reported estimates.^{14,15} We required two CRS diagnosis within 12 weeks of another and an intervening CT scan or nasal endoscopy. These are similar criteria to those used by Bhattacharya.¹³ A possible explanation for the decreased prevalence would be the length of time that the revised classification of CRS had been in use. The more specific requirements likely had a progressive adoption period. Previous studies that utilized unselected populations based on administrative data and health surveys typically rely on self-reported diagnoses. This strategy would naturally tend to overestimate patients with CRS.

This may account for the significant differential in the prevalence statistics quoted in the literature.¹⁴⁻¹⁶ In turn, this influences the cost attributed to CRS on a broad basis and possibly lead to significant overestimation of the cost burden of this disease. Our data confirms the female predominance in both the commercial population and the Medicare population for both ARS and CRS.

TABLE VIIIB.

Patterns of Care in Surgically Managed CRS Patients Procedure Counts Post-ESS.

| Post-Operative Month | No. Nasal Endoscopies | No. Debridements | No. Epistaxis Control | No. Unlisted Sinus |
|----------------------|-----------------------|------------------|-----------------------|--------------------|
| Total (Months 1-6) | 7826 | 11,278 | 25 | 1 |
| Month 1 | 4085 | 9268 | 21 | 1 |
| Month 2 | 1779 | 1329 | 4 | 0 |
| Month 3 | 710 | 347 | 0 | 0 |
| Month 4 | 508 | 158 | 0 | 0 |
| Month 5 | 423 | 97 | 0 | 0 |
| Month 6 | 321 | 79 | 0 | 0 |

The number of unique patients with each procedure in the six months post-ESS is as follows: Nasal endoscopy (N = 4,450), Debridement (N = 6,320), Epistaxis control (N = 22), Unlisted sinus procedure (N = 1).

TABLE IXA.

Frequency of Acute Exacerbations of CRS in Medically Managed Patients.

| Date | E&M Visits at any time after CRS Diagnosis | | E&M Visits at least 21 Days after CRS Diagnosis | |
|----------------|--|---------|---|---------|
| | No. Exacerbations | Percent | No. Exacerbations | Percent |
| 01/2011 | 763 | 0.62 | 75 | 0.07 |
| 02/2011 | 1961 | 1.60 | 1006 | 0.93 |
| 03/2011 | 2839 | 2.32 | 1883 | 1.74 |
| 04/2011 | 2783 | 2.27 | 2078 | 1.92 |
| 05/2011 | 3073 | 2.51 | 2446 | 2.26 |
| 06/2011 | 3016 | 2.46 | 2475 | 2.29 |
| 07/2011 | 2591 | 2.12 | 2181 | 2.02 |
| 08/2011 | 3402 | 2.78 | 2907 | 2.69 |
| 09/2011 | 4089 | 3.34 | 3624 | 3.35 |
| 10/2011 | 4741 | 3.87 | 4204 | 3.89 |
| 11/2011 | 5754 | 4.70 | 5111 | 4.73 |
| 12/2011 | 6964 | 5.67 | 6261 | 5.79 |
| 01/2012 | 7024 | 5.74 | 6222 | 5.76 |
| 02/2012 | 7517 | 6.14 | 6621 | 6.13 |
| 03/2012 | 6620 | 5.41 | 5896 | 5.46 |
| 04/2012 | 5884 | 4.81 | 5352 | 4.95 |
| 05/2012 | 5875 | 4.80 | 5330 | 4.93 |
| 06/2012 | 5155 | 4.21 | 4765 | 4.41 |
| 07/2012 | 4867 | 3.98 | 4469 | 4.14 |
| 08/2012 | 5915 | 4.83 | 5434 | 5.03 |
| 09/2012 | 6481 | 5.29 | 6079 | 5.63 |
| 10/2012 | 7817 | 6.39 | 7286 | 6.74 |
| 11/2012 | 8381 | 6.85 | 7951 | 7.36 |
| 12/2012 | 8923 | 7.29 | 8415 | 7.79 |
| Total N | 122,417 | | 108,071 | |

TABLE IXB.
Per-Patient Distribution of Acute Exacerbations of CRS in Medically Managed Patients.

| No. Exacerbations | E&M Visits at any time after CRS Diagnosis | |
|-------------------------------------|--|--------------------|
| | No. Patients | No. Patients |
| 1 | 39,056 | 34,539 |
| 2 | 15,490 | 13,608 |
| 3 | 6730 | 5977 |
| 4 | 3146 | 2752 |
| 5 or more | 3194 | 2832 |
| Total N | 67,616 | 59,708 |
| Average No. Per-Patient (SD) | 1.81 (1.33) | 1.81 (1.33) |

Patients living in the southern United States were most likely to experience both ARS and CRS followed by those living in the north central portion of the country. This is also consistent with other reports studying the same diseases.^{17,18} Interestingly, only 1.8% of patients with ARS were treated by otolaryngologists. This did not include acute exacerbations of CRS. Otolaryngologists accounted for 47.5% of all patient visits for CRS.

These statistics highlight both opportunity and responsibility for otolaryngology. The clear majority of sinus related disease is taken care of by non-

TABLE XA.
Frequency of Acute Exacerbations of CRS in Surgically Managed Patients.

| Date | E&M Visits at least 90 Days after ESS Surgery | |
|----------------|---|---------|
| | No. Exacerbations | Percent |
| 04/2011 | 74 | 0.81 |
| 05/2011 | 157 | 1.72 |
| 06/2011 | 208 | 2.28 |
| 07/2011 | 242 | 2.65 |
| 08/2011 | 338 | 3.70 |
| 09/2011 | 423 | 4.64 |
| 10/2011 | 513 | 5.62 |
| 11/2011 | 628 | 6.88 |
| 12/2011 | 666 | 7.30 |
| 01/2012 | 603 | 6.61 |
| 02/2012 | 648 | 7.10 |
| 03/2012 | 504 | 5.52 |
| 04/2012 | 483 | 5.29 |
| 05/2012 | 470 | 5.15 |
| 06/2012 | 392 | 4.30 |
| 07/2012 | 349 | 3.83 |
| 08/2012 | 365 | 4.00 |
| 09/2012 | 432 | 4.74 |
| 10/2012 | 512 | 5.61 |
| 11/2012 | 550 | 6.03 |
| 12/2012 | 566 | 6.20 |
| Total N | 9123 | |

TABLE XB.
Per-Patient Distribution of Acute Exacerbations of CRS in Surgically Managed Patients.

| No. Exacerbations | E&M Visits at any time after CRS Diagnosis | |
|-------------------------------------|--|--|
| | No. Patients | |
| 1 | 2865 | |
| 2 | 1138 | |
| 3 | 467 | |
| 4 | 233 | |
| 5 or more | 268 | |
| Total N | 4971 | |
| Average No. Per-Patient (SD) | 1.84 (1.38) | |

otolaryngologists. As the health system moves toward best practice and best value care paradigms, otolaryngology has a duty to the public as well as their colleagues to lead in the development of data-driven outcome standards of care for both ARS and CRS. This can be done through Clinical Practice Guidelines, appropriate measures development, clinical research projects, advanced data analytics, development of clinical pathways, incorporation of patient reported outcomes measures, identification of true outcome measures and product effectiveness surveillance through expanding data sources such as clinical data registries. The widespread dissemination of the resultant clinical information to all provider groups as well as affected patients.

The most common comorbidities associated with CRS were allergic rhinitis, headache, asthma, reflux, diabetes, and COPD. The inherent limitation in this methodology of collecting information through payment-related databases is that not all related conditions are included in the submitted claims as relevant ICD diagnoses to that particular visit. Unfortunately, we have no alternative way to pull that information out of the claims records in an unselected population. As registries mature and data dictionaries are refined, we will be able to track this data much more accurately. Specifically, in this study it is highly likely that headache, reflux, and smoking are underreported based on the limitations of four diagnoses per claim typical for most payers. However, when looking at CRS and the common respiratory diseases including allergic rhinitis, asthma, and COPD, this patient population demonstrated that 53.4% of the unique CRS patients also had one of the previously mentioned respiratory diseases (allergic rhinitis, asthma, or COPD). Among the unselected population of approximate 54 million unique patients, 23.8% of the patients had one of the respiratory diseases mentioned above. Even with the issue of potential underreporting certain comorbidities, the fact that well over half of these CRS patients had a significant comorbidity relative to the general population is telling and consistent with other publications.¹⁹

The definition of CRS for this study required two CRS diagnoses within 12 weeks of one another with an intervening CT scan or nasal endoscopy with or without septal deviation. Additionally, an initial diagnosis of

allergic rhinitis with a follow-up diagnosis of CRS within 12 weeks with an intervening CT scan or diagnostic nasal endoscopy qualified a patient for inclusion. CRS patients who underwent surgical management had a higher percentage of diagnostic endoscopy (66.3% vs. 55.1%), sinus cultures (31.9% vs. 23.6%) and CT scans of the sinuses (90.7% vs. 82.1%) than those who did not have ESS. In that group, 40.9% of the ESS patients had both a CT scan and diagnostic sinus endoscopy prior to surgery. This data demonstrates a consistent pattern of diagnostic testing that is being followed in the preoperative workup of patients with CRS, confirming the condition with diagnostic endoscopy and/or a CT scan of the sinuses prior to a surgical procedure.²⁰ It is somewhat surprising that roughly one third of the patients undergoing ESS did not have a preoperative sinus endoscopy. However, the standard at the time dictated a CT scan or sinus endoscopy and there was considerable issue with precertifications at the time of the study. Since this study did not access any clinical data, it is also possible some of the endoscopies performed were not billed.

There were 42,937 patients (14.4%) who underwent at least one endoscopic surgical procedure for the treatment of their CRS with or without septoplasty or septoplasty. Most of the patients (83.4%) that had a septoplasty on the same day as ESS had surgery on two or more sinuses (maxillary, ethmoid, sphenoid, frontal). The most common combination was two sinuses and a septoplasty being done at the same time. This is consistent with CRS being a wide-field, regional disease and mirrors recent Medicare billing screens (as propagated in American Medical Association Relative Value Update Committee process) that identified multiple sinus combinations performed together more than 75% of the time together. This screen resulted in four new endoscopic CPT codes based on the frequencies they are performed together. The median age of patients undergoing sinus surgery on one sinus without septoplasty was 49 years old and those having sinus surgery on same day as septoplasty was 42 years old. One other interesting finding in this group of patients involved those with polyps. Patients who did not have a septoplasty were 18 times more likely to have polyps removed than those that had a septoplasty on same day as ESS. Additionally, they were also three times more likely to have cultures ordered. It is unclear as to the causative nature of these findings.

All the patients undergoing ESS were followed for medical management based on prescriptions filled 6 months before surgery, during a 45-day healing phase and for the subsequent 6 months following that. In this study antihistamine use, antibiotic use, anticholinergic agent use, decongestant usage, anti-inflammatories (nasal steroid spray and oral steroids), adrenals and combination medications and leukotriene modifiers all dropped in both the postoperative healing period of 45 days and the subsequent 6 months. The largest declines were seen in adrenals and combination medicine (56.8%), antibiotic usage (49.2%), anti-inflammatory agents (40.7%), decongestants (38.3%), and anticholinergic agents (37.2%). This reflects both the overall volume of patients utilizing these medications. The highest

overall cost reductions were antibiotics (62.9%), followed by antihistamines (50.9%) and anti-inflammatory agents (36.3%), yielding a total cost reduction across all drug categories of 34.2% or \$3.9 M. These results mirror other studies showing similar reductions.²¹⁻²⁶ Our look at cost effectiveness is intended to address whether the surgery defrays the additional costs and quality metrics associated with management of disease. Our assessment specifically focused on metrics such as utilization and costs of prescription drug therapies, and office visits. We did not analyze the actual costs of the surgical procedure itself or patient-reported outcomes, both of which fit into the effectiveness equation, but require a longer period economically delineate their value. Admittedly, this follow-up period of 7.5 months is short and no conclusion for long-term trends can be made from this data.

We further studied episodes of acute exacerbation of CRS in both the medically managed and surgically manage patients. 26.5% of those CRS patients managed medically had at least one acute exacerbation requiring antibiotic therapy during the period of study. The average number of exacerbations per unique patient was 1.81 (SD = 1.33). The medically managed seemed to plateau in terms of improvement in the fourth month.

In those patients managed surgically with ESS, only 11.6% of those patients suffered acute exacerbation following the healing period. This group averaged 1.84 (SD = 1.38) exacerbations. An area of continued concern among the various payers has been the utilization of postoperative debridement. The data from this study quantified postop diagnostic endoscopy, debridement and control of epistaxis. Diagnostic nasal endoscopy was performed on 10.4% of the 42,937 patients who underwent ESS, endoscopic debridement was performed on 14.7% of the original group cohort undergoing ESS and an additional 0.06% needed control of epistaxis. Pre-ESS visits increase in the 6 months up until surgery and then decrease in the 6 months post-ESS. This data calls into question personal communications with medical directors of several prominent insurance carriers in the United States indicating that there is a pervasive overutilization of these procedures. Again, the follow-up period for these patients is inadequate to make long-term predictions, but these findings suggest a decreased disease burden for the majority of patients as well as decreased cost. The period for follow-up in this study is also inadequate to determine the economic value (either positive or negative) when factoring in the cost of the procedure. There are multiple elements to be considered when fully evaluating the cost structure and treating sinus disease.²⁷⁻²⁹ These involve care both by otolaryngologists and other healthcare professionals.³⁰ Information gained from this study will help guide future analysis of CRS from both a cost and quality standpoint.

CONCLUSION

This study has succeeded in presenting a greater characterization of CRS and how it fits in as a chronic disease in the United States. This claims-based study has confirmed some of the previously described demographics

of CRS including age, sex, and geographic location. The prevalence of both ARS and particularly CRS in this data set is considerably less than previously published studies representing unselected populations. The most likely explanation lies in the definition of CRS used in our study. This study clearly demonstrates the presence of unified airway disease in CRS. The utilization of various diagnostic testing for CRS appears to be consistent with recommendations and diagnostic criteria established in the literature. The effectiveness of surgical management of CRS is confirmed in the short-term follow-up of 7.5 months both in terms of frequency and cost. The post-operative management regimens are consistent with healing as we understand it. Antibiotic usage, postoperative visits, nasal endoscopy, and debridement show significant decrease in utilization over the healing period of 6 months. This data reinforces the current reasonable utilization of the various treatment tools available for CRS and does not demonstrate the excessive use of endoscopy and debridement as some suggest.

Even though this data demonstrates a decreased frequency of visits and cost of medications following ESS, the portion of the “value equation” missing is only obtained through the integration of clinical data including expanded patient reported outcomes through validated instruments. The next step to truly discovering appropriate value is the incorporation of the clinical data from the office, hospital, and ASC settings with administrative data through widespread clinical situations as one sees in Clinical Data Registries. The high percentage of CRS patients with other airway disease would warrant exploration of the creation of “grouper” type bundles for these patients since their outcomes are interrelated with the various individual diseases.³¹ Additionally, reviewing the cost data reminds us that we must be diligent in the utilization of costly new technology and account for the cost-benefit ratio that each brings. This data confirms the need for widespread educational efforts both in terms of the diagnosis of the disease, but also the “best practice” treatment of sinus disease among the diverse group of providers treating these patients. Finally, this project highlights the need for better standardization of disease definition when that data is used to formulate treatment regimens and calculate costs.

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