

## BACKGROUND

- CRS with and without nasal polyps (CRSwNP and CRSsNP) is a common and serious chronic inflammatory condition with diagnostic symptoms including nasal congestion/obstruction, rhinorrhea, facial pain/pressure, and reduction/loss of smell.<sup>1</sup>
- The symptoms of CRS often extend beyond the sinonasal region. Extrasinal manifestations include fatigue, bodily pain, problems with sleep, and depression.<sup>1</sup>
- The burden of disease attributable to CRS with and without nasal polyps is substantial. CRS has been shown to impair quality of life (QoL) to a degree similar to other serious illnesses (CHF, COPD, and Parkinson's disease), and the overall annual economic burden of CRS in the United States was estimated at \$22 billion (direct and indirect costs) in 2014.<sup>2,3</sup>
- The estimated prevalence of CRS is high, but specific estimates vary (range, 15-40 million) and are often derived from administrative health care databases, where data are collected for billing purposes rather than from primary population sources.
- Epidemiologic research using administrative databases may be subject to surveillance bias and may have inherent limitations, including overrepresentation (or underrepresentation) of procedures with financial incentives (or disincentives) and other sources of systematic bias. Furthermore, these databases often lack data (e.g., patient QoL) and may have limits on generalizability due to homogeneous populations.<sup>4,5</sup>
- This population-based survey was conducted to better characterize the prevalence and burden of illness in the US adult population with symptoms of CRS, including CRSwNP and CRSsNP.

## METHODS

- Population survey of 10,336 US adults was randomly drawn from a representative general panel of 4.3 million. Patient selection was not weighted based on any specific patient characteristics or toward any subpopulations.
- Panel participants were sourced through a variety of approaches, including Web sites, e-mail, phone, online communities, and social networks.
- Information collected included nasal symptoms (including CRS diagnostic symptom criteria); frequency, duration, and severity/bother of nasal symptoms; and health care use and treatments.

### Patient-Reported Data Included

- General health symptoms
- CRS-defining symptoms in past 12 months
- Physician-diagnosed conditions
- Duration of nasal symptoms and medication use in past 12 months to treat nasal symptoms
- Presence or absence of diagnosed nasal polyps

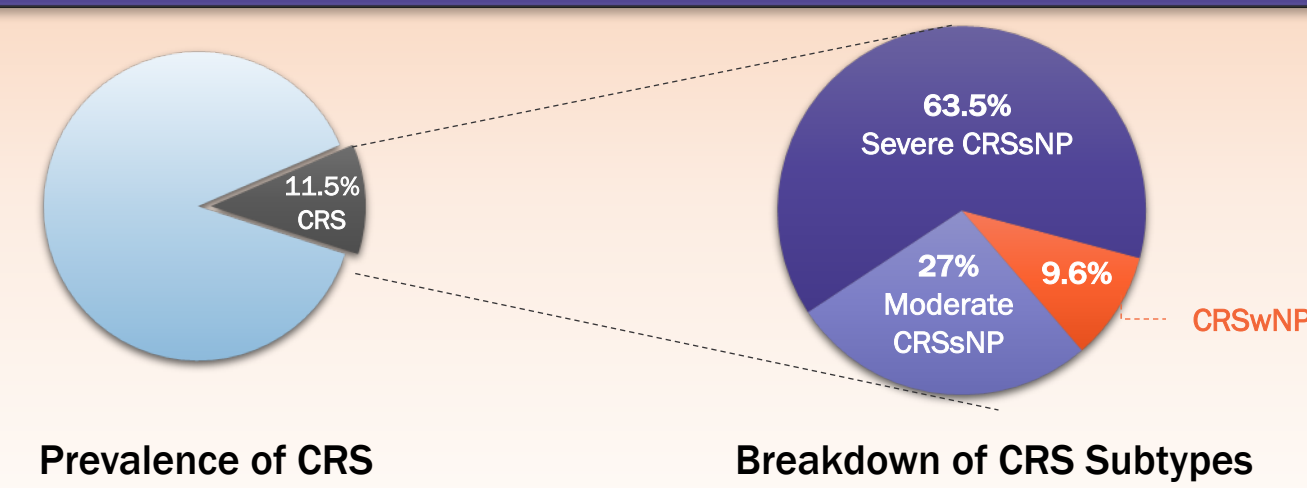
### Criteria to Assess Disease Severity

- Severity of the diagnosed condition in past 12 months
- Severity of symptoms on a typical day in past 12 months
- Burden ("Bother") of symptoms
- Use of intranasal steroid for >60 days in past 12 months
- Number of flares in past 12 months
- Use of oral steroid for symptom control in past 12 months

- Participants reporting sufficiently severe and chronic symptoms were categorized into CRS subgroups based on self-reported symptoms and severity during the last year (at least 2 of the 4 defining CRS symptoms, with duration of more than 8 consecutive weeks, with congestion/obstruction or rhinorrhea required to be one of the symptoms).

- Survey respondents were closely representative of the US adult population in terms of geographic distribution (including USDA climate zones), socioeconomic status, age, education, and comorbid illnesses (hypercholesterolemia, diabetes, hypertension, asthma, and allergies) when compared with known distributions (eg, US Census).<sup>6,7</sup>
- Approximately 11.5% of respondents self-reported symptoms meeting diagnostic symptom criteria for CRS and were defined as CRS patients for this analysis. Of these respondents, 9.6% reported having received a diagnosis of nasal polyps (Figure 1).

Figure 1. Prevalence of CRSwNP and Moderate-Severe CRSsNP



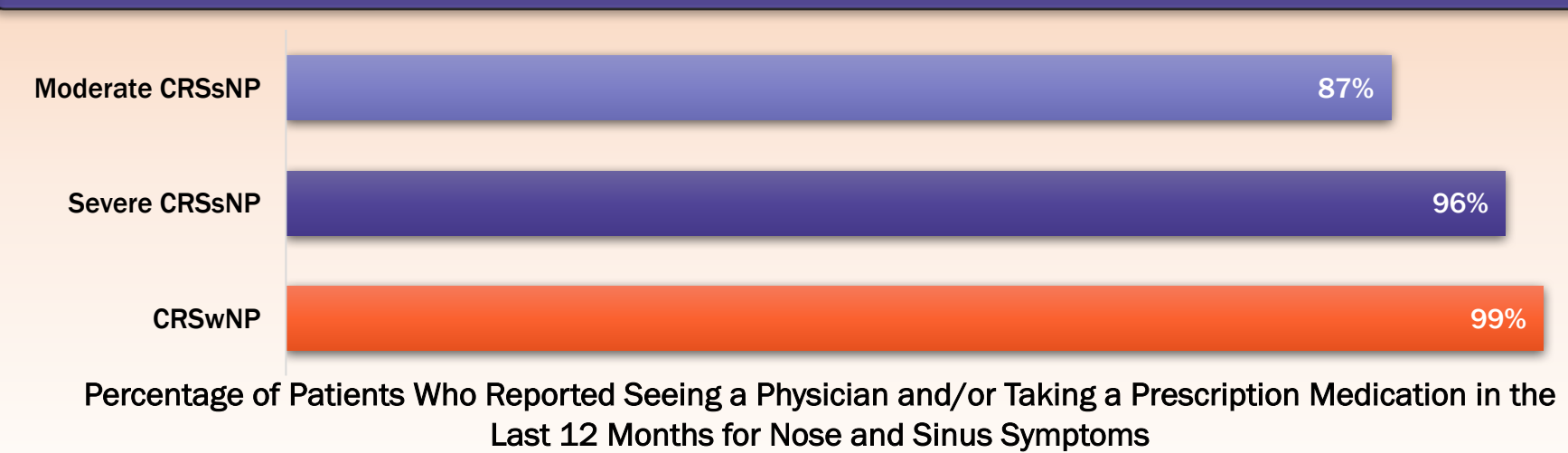
- A substantial number of CRS patients reported prior medical or surgical interventions for their CRS symptoms; more than half of CRSwNP patients reported prior nasal surgery for their nose and sinus symptoms (Table 1).

Table 1. Patient-Reported Medication and Surgical History

Characteristic	CRSwNP	Severe CRSsNP	Moderate CRSsNP
Surgery for nose, sinus—ever (%)	52.2%	14.7%	12.8%
Surgery for nose, sinus in past 12 mo (%)	8.0%	2.0%	0.3%
Treated with intranasal steroids for nose, sinus in past 12 mo (%)	92.5%	86.3%	88.9%
Oral steroids used for nose, sinus in past 12 mo (%)	71.2%	36.3%	31.4%

- The majority of CRSsNP patients and almost all CRSwNP patients have seen a doctor for their symptoms and/or have taken a prescription medicine for their symptoms within the past 12 months (Figure 2).

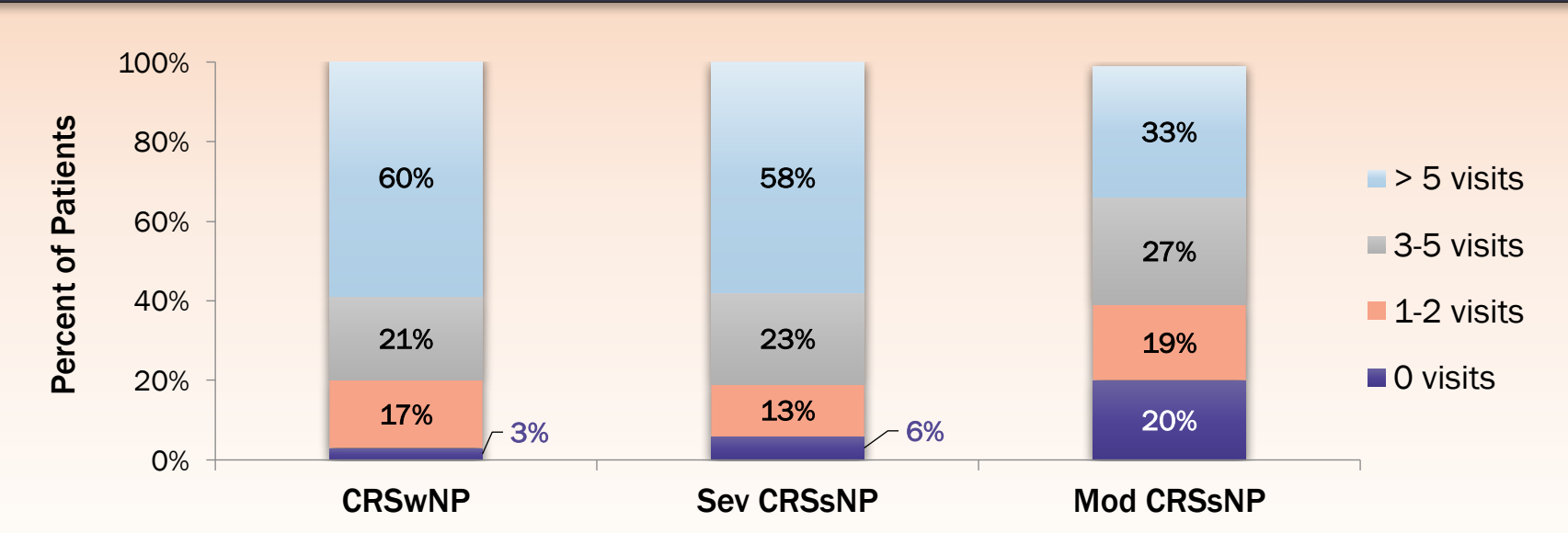
Figure 2. Health Care Utilization in the Last 12 Months



- Most CRS patients report having seen a doctor 5 or more times in the past 12 months for their nose and sinus symptoms, including both "flare-ups" and regular office visits (Figure 3).

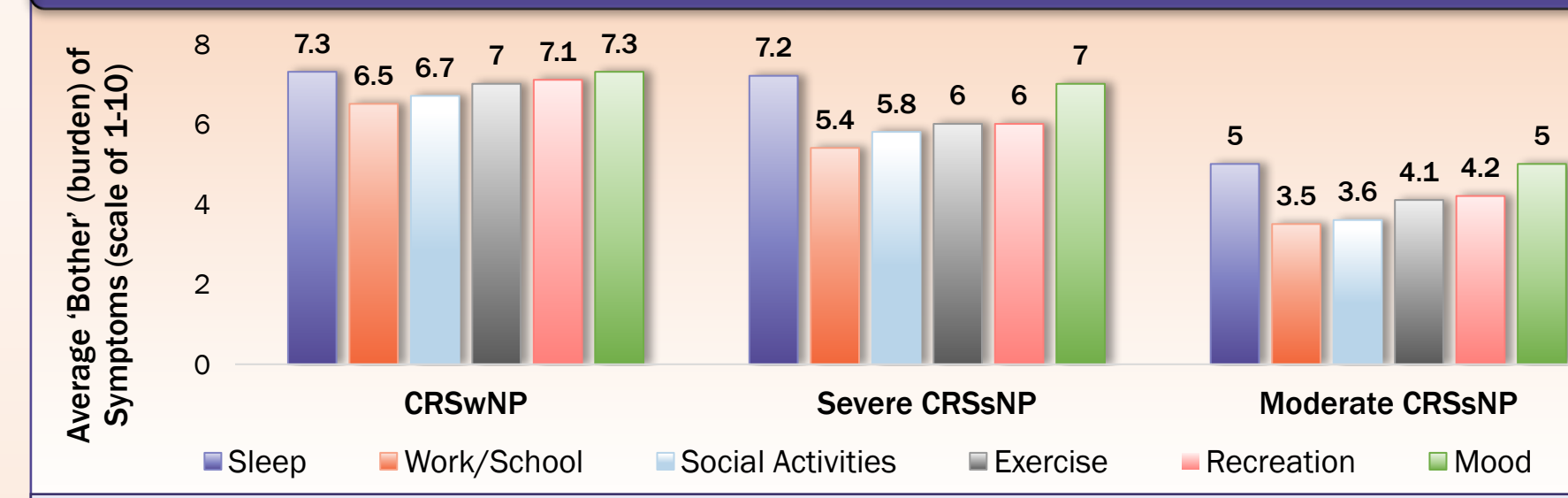
## RESULTS

Figure 3. Physician Visits in Last 12 Months for Nose and Sinus Symptoms



- The frequency of defining CRS symptoms was similar in CRSwNP and CRSsNP, except that patients with polyps and those with severe CRSsNP reported higher rates of facial pain/pressure (60%-65%) and loss of smell/taste (46%-56%). Nasal congestion/obstruction (94%-97%) and drainage (89%-92%) were the most frequently reported core symptoms.
- Disease exacerbations (flare-ups) were reported to be frequent (CRSwNP, 75%; CRSsNP, 78%). Only 54% believed their symptoms were controlled, and 79% were concerned about flare-ups.
- CRS symptoms adversely impact multiple areas of daily life, as reported by patients, despite available treatment options. Adverse effects were greatest on sleep and mood, and notable on work/school, social activities, exercise, and recreation (Figure 4).

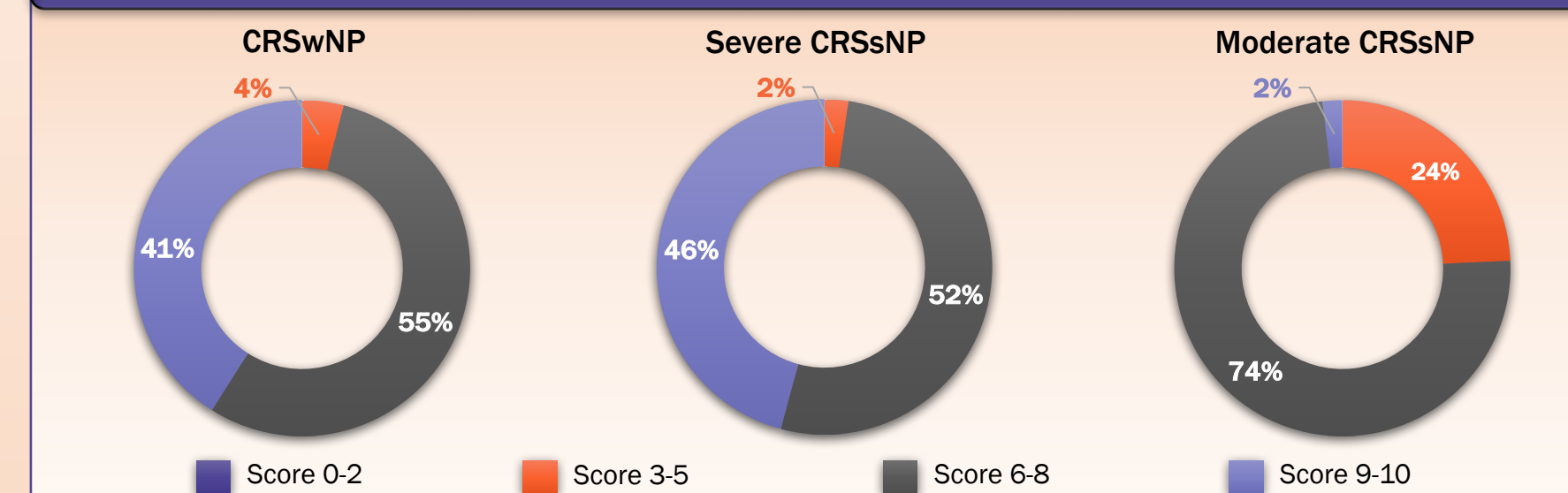
Figure 4. Impact of Symptoms on Daily Activities



Patients were asked: In the past 12 mo., when you had these symptoms, on a typical day, how much did these affect you in the following areas? Use 0-10 scale, where 0 means "not at all" and 10 means "completely."

- Despite all available treatment interventions, 41% of CRSwNP and 46% of severe CRSsNP patients report that they remain "extremely" affected by symptoms (score 9-10/10; Figure 5).

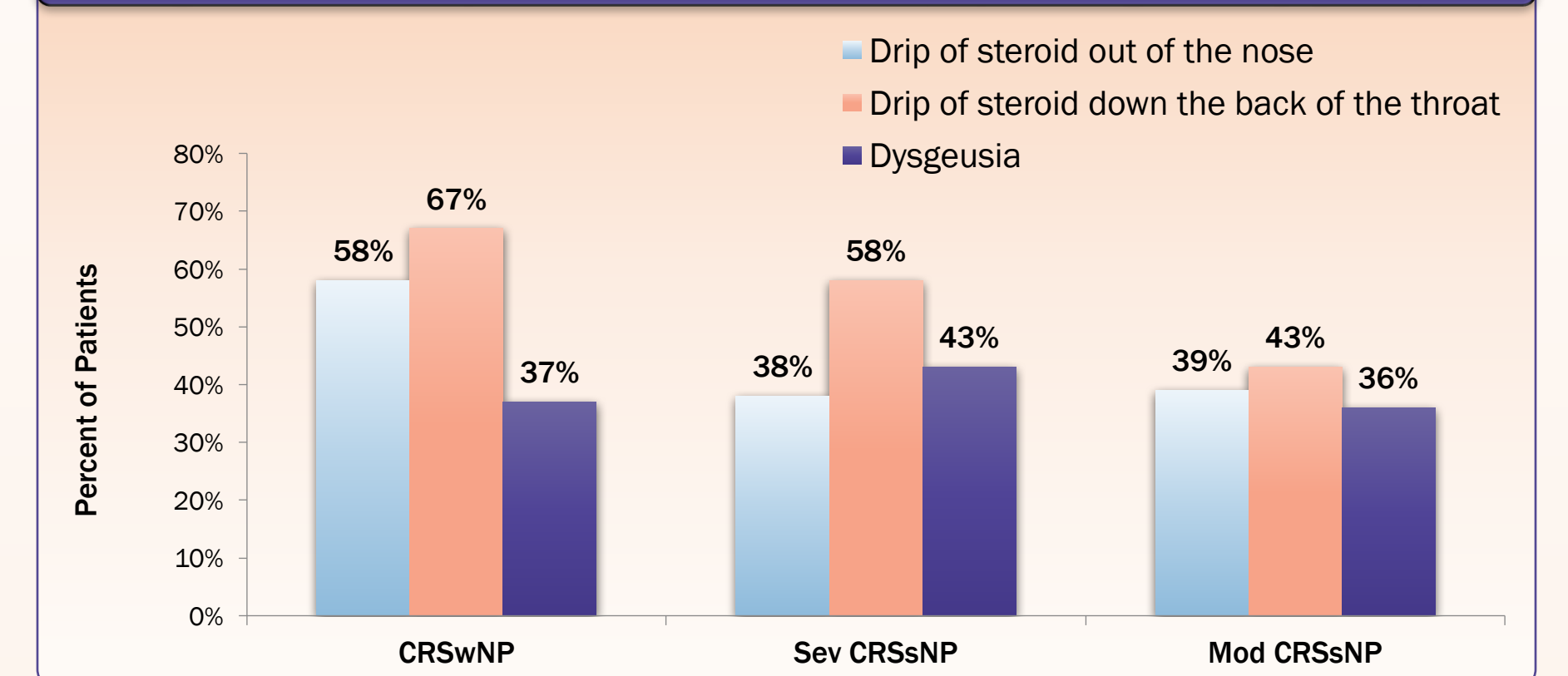
Figure 5. Severity ("Bother") of Symptoms, Including Patients on Treatment



In the past 12 mo, how bothersome have your symptoms been overall? Use 0-10 scale, where 0 means "no bother at all" and 10 means "extremely bothersome."

- A large majority (~60%-90%) of patients with CRSwNP (87%), severe CRSsNP (86%), or moderate CRSsNP (63%) using intranasal corticosteroids (INS) report being frustrated with the inadequate symptom relief produced by their current INS spray.
- Many CRS sufferers who use conventional INS report experiencing loss of drug due to drip out of the nose (38%-58%) or down the throat (43%-67%), or having dysgeusia (36%-43%) (Figure 6).

Figure 6. Loss of Topical Steroid From the Nose (Drip, Drainage, and Dysgeusia)



## CONCLUSIONS

- This large, population-based, representative survey extends our understanding of the prevalence and burden of illness associated with symptoms of CRS with or without polyps.
- This primary, population-based survey suggests a high population prevalence of symptoms of CRS (11.5%), which is generally consistent with other estimates reported in the literature.
- Many CRS patients with or without polyps continue to report suffering significant symptoms, despite reporting high rates of doctor visits and use of currently available medications.
- INS are first-line treatment for CRS with or without polyps, but a large majority of patients are dissatisfied with current intranasal steroid sprays, primarily due to inadequacy of symptom relief. Patients also report other problems with current nasal spray delivery, such as loss of drug to "drip-out" and dysgeusia.
- CRS symptoms are common and create serious patient burden, both on quality of life and health care resource utilization. Common first-line treatments are most often unsatisfactory. This indicates a role for more and/or improved treatment options to better meet patient needs.

### REFERENCES

- Orlandi RR, Kingdom TT, Hwang PH, et al. *Int Forum Allergy Rhinol*. 2016;6(6):suppl 1:S22-S209.
- Smith KA, Orlandi RR, Rudnik L. *Laryngoscope*. 2015;125(7):1547-1556.
- Soler ZM, Wittenberg E, Schlosser RJ, Mace JC, Smith TL. *Laryngoscope*. 2011;121(12):2672-2678.
- Haut ER, Pronovost PJ, Schneider EB. *JAMA*. 2012;307(24):2589; author reply 2589-2590.
- Gandhi SK, Salmon W, Kong S, Zhao SZ. *JMCP*. 1999;5(3):215-222.
- Hamilos DL. *J Allergy Clin Immunol*. 2011;128(4):693-707.
- Centers for Disease Control and Prevention. Summary Health Statistics: National Health Interview Survey, 2014. Table A-2.