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Executive Summary

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# Clinical Practice Guideline: Improving Nasal Form and Function after Rhinoplasty

## Executive Summary

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### Abstract

**Objective.** Rhinoplasty, a surgical procedure that alters the shape or appearance of the nose while preserving or enhancing the nasal airway, ranks among the most commonly performed cosmetic procedures in the United States, with >200,000 procedures reported in 2014. While it is difficult to calculate the exact economic burden incurred by rhinoplasty patients following surgery with or without complications, the average rhinoplasty procedure typically exceeds \$4000. The costs incurred due to complications, infections, or revision surgery may include the cost of long-term antibiotics, hospitalization, or lost revenue from hours/days of missed work.

The resultant psychological impact of rhinoplasty can also be significant. Furthermore, the health care burden from psychological pressures of nasal deformities/aesthetic shortcomings, surgical infections, surgical pain, side effects from antibiotics, and nasal packing materials must also be considered for these patients. Prior to this guideline, limited literature existed on standard care considerations for pre- and postsurgical management and for standard surgical practice to ensure optimal outcomes for patients undergoing rhinoplasty. The impetus for this guideline is to utilize current evidence-based medicine practices and data to build unanimity regarding the peri- and postoperative strategies to maximize patient safety and to optimize surgical results for patients.

**Purpose.** The primary purpose of this guideline executive summary is to provide evidence-based recommendations for clinicians who either perform rhinoplasty or are involved in the care of a rhinoplasty candidate, as well as to optimize patient care, promote effective diagnosis and therapy, and reduce harmful or unnecessary variations in care. The target audience is any clinician or individual, in any setting, involved in the management of these patients. The target patient population is all patients aged

≥15 years. The guideline is intended to focus on knowledge gaps, practice variations, and clinical concerns associated with this surgical procedure; it is not intended to be a comprehensive reference for improving nasal form and function after rhinoplasty. Recommendations in this guideline concerning education and counseling to the patient are intended to include the caregiver if the patient is <18 years of age.

**Action Statements.** The Guideline Development Group made the following *recommendations*: (1) Clinicians should ask all patients seeking rhinoplasty about their motivations for surgery and their expectations for outcomes, should provide feedback on whether those expectations are a realistic goal of surgery, and should document this discussion in the medical record. (2) Clinicians should assess rhinoplasty candidates for comorbid conditions that could modify or contraindicate surgery, including obstructive sleep apnea, body dysmorphic disorder, bleeding disorders, or chronic use of topical vasoconstrictive intranasal drugs. (3) The surgeon, or the surgeon's designee, should evaluate the rhinoplasty candidate for nasal airway obstruction during the preoperative assessment. (4) The surgeon, or the surgeon's designee, should educate rhinoplasty candidates regarding what to expect after surgery, how surgery might affect the ability to breathe through the nose, potential complications of surgery, and the possible need for future nasal surgery. (5) The clinician, or the clinician's designee, should counsel rhinoplasty candidates with documented obstructive sleep apnea about the impact of surgery on nasal airway obstruction and how obstructive sleep apnea might affect perioperative management. (6) The surgeon, or the surgeon's designee, should educate rhinoplasty patients before surgery about strategies to manage discomfort after surgery. (7) Clinicians should document patient satisfaction with their nasal appearance and with their nasal function at a minimum of 12 months after rhinoplasty.

The guideline development group made *recommendations against* certain actions: (1) When a surgeon, or the surgeon's designee, chooses to administer perioperative antibiotics for rhinoplasty,

he or she should not routinely prescribe antibiotic therapy for a duration >24 hours after surgery. (2) Surgeons should not routinely place packing in the nasal cavity of rhinoplasty patients (with or without septoplasty) at the conclusion of surgery.

The panel group made the following statement an *option*: (1) The surgeon, or the surgeon's designee, may administer perioperative systemic steroids to the rhinoplasty patient.

### Keywords

rhinoplasty, septorhinoplasty, functional or cosmetic surgery or nose surgery, nasal valve, nasal surgery, nasal deformity, nasal obstruction, nasal injury

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### Introduction

Rhinoplasty—a surgical procedure that alters the shape or appearance of the nose while preserving or enhancing the nasal airway—ranks among the most commonly performed cosmetic procedures in the United States, with >200,000 procedures reported annually.<sup>1</sup> As facial cosmetic enhancement has become more routine and considered socially acceptable, the procedure has increased in popularity in the United States and around the world.<sup>2</sup> In Latin American countries, rhinoplasty is the most commonly performed facial cosmetic procedure.<sup>2</sup>

Rhinoplasty is more than just a cosmetic procedure because it often seeks to enhance function by improving nasal respiration and relieving obstruction that is either congenital or acquired. This dual role is reflected in the following qualifying statements to the term *rhinoplasty* as used in this guideline (see **Tables 1** and **2** for additional word definitions used in the guideline):

- Rhinoplasty is defined as a surgical procedure that alters the shape or appearance of the nose while

preserving or enhancing the nasal airway. The change in appearance may be a consequence of addressing a functional abnormality (eg, deviated caudal septum, nasal valve compromise) and for cosmetic purposes (eg, an incidental cosmetic procedure).

- The primary reason for surgery can be aesthetic, functional, or both and may include adjunctive procedures on the nasal septum, nasal valve, nasal turbinates, or paranasal sinuses.
- When these adjunctive procedures, however, are performed without an impact on nasal shape or appearance, they do not meet the definition of rhinoplasty and are therefore excluded from further consideration in this guideline—for example, septoplasty alone without an incidental or intended cosmetic component.

As increasing numbers of rhinoplasty procedures are performed, it is important to reduce surgical morbidity, promote appropriate therapy, engage patients in their care, and coordinate care effectively. There does not exist, however, any standard in this regard for counseling rhinoplasty patients, evaluating comorbid conditions (eg, bleeding disorders, obstructive sleep apnea [OSA], body dysmorphic disorder [BDD]), or assessing surgical outcomes or for the perioperative use of steroids, antibiotics, intranasal packing, or pain medications.

Despite the popularity and importance of rhinoplasty, there are currently no evidence-based multidisciplinary clinical practice guidelines to assist clinicians and patients in preoperative consultation, planning care, and working together through shared decision making to optimize clinical outcomes. This guideline was created to address this need, and the remainder of the introduction briefly highlights some of the clinical decisions that confront clinicians.

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The clinical practice guideline is not intended as the sole source of guidance in managing candidates for rhinoplasty. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not absolute. Guidelines are not mandates. These do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology—Head and Neck Surgery Foundation emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

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**Table 1.** Definitions of Words Used in the Guideline.

Rhinoplasty	Rhinoplasty is a surgical procedure that alters the shape or appearance of the nose while preserving or enhancing the nasal airway. The primary reason for surgery can be aesthetic, functional, or both and may include adjunctive procedures on the septum, turbinates, or paranasal sinuses. (When these adjunctive procedures, however, are performed without an impact on nasal shape or appearance, they do not meet the definition of rhinoplasty used in this guideline.)
Aesthetic	Concerned with beauty or the appreciation of beauty.
Body dysmorphic disorder	Psychiatric disorder consisting of distressing or impairing preoccupation with nonexistent or slight defects in one's appearance.
Cosmetic	Relating to treatment intended to restore or improve appearance.
Rhinitis	Inflammation of the mucus membranes of the nose, frequently caused by infection or allergic reaction. It typically manifests with symptoms of nasal itching, increased mucus drainage, congestion, or postnasal drainage.
Obstructive sleep apnea	Sleep disorder involving at least 5 obstructive respiratory events per hour (detected during an overnight sleep study).
Nasal cycle	The often unnoticed alternating partial congestion and decongestion of the nasal cavities in humans and other animals. It is a physiologic congestion of the nasal turbinates due to selective activation of the autonomic nervous system on 1 side of the nose.
Anterior rhinoscopy	Examination of the anterior part of the nose, including the inferior turbinate, the septum, and the nasal valves.
Nasal packing	Nasal packing is material, either removable or absorbable, placed inside the nose to promote hemostasis, structural support, and reduction of scar formation. Traditional nasal packs include ribbon gauze, expandable nonbiodegradable pads, and nonstick dressing material. <sup>44</sup> There are many newer types of packing that are biodegradable. Silastic stents or nasal splints and custom-cut sheeting are not considered packing.

**Table 2.** Nasal Anatomy Definitions.

Upper lateral cartilage	The lateral cartilage piece of the nose, triangular in shape, meeting with the nasal bones superiorly and the lower lateral cartilages inferiorly and fusing with the septum in the midline.
Lower lateral cartilage	Thin flexible plate of cartilage folded on itself and situated just below the upper lateral cartilage. It makes up the medial and lateral wall of the nostril.
Internal nasal valve	Refers to the area bordered by the upper lateral cartilage laterally, the septum medially, the head of the inferior turbinate, and the floor of the nose.
External nasal valve	Refers to the area bordered by the lateral limb of the lower lateral cartilage laterally, the medial limb of the lower lateral cartilage and the septum medially, and the floor of the nose.
Nasal septum	Wall of cartilage and bone that runs down the middle of the nose, dividing it into left and right nasal passages.
Nasal turbinates	Long narrow curved shelves of bone covered in mucus membrane and protruding into the nasal passage.

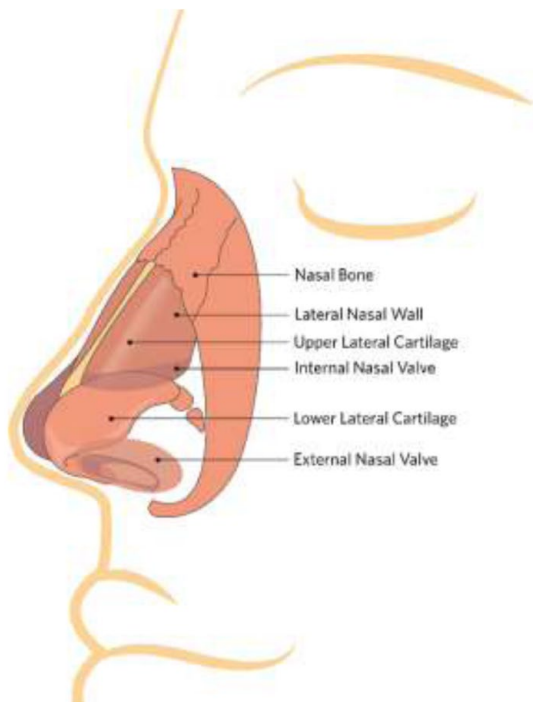
### *Rhinoplasty Controversies and Challenges*

Variability in rhinoplasty goals and techniques exists, depending on factors such as patient preference and facial features. Myriad anatomic problems addressed by rhinoplasty exist, including dorsal humps, bulbous nasal tips, twisted noses, tip rotation, nasal valve compromise, and projection concerns, to name a few. However, a growing body of evidence supports methods to optimize care in the perioperative period regardless of the particular anatomy corrected or technique used. Specific areas to expand the evidence base, which may support less variability in care, include the preoperative physical and psychosocial evaluation; the perioperative medication administration for bleeding, swelling, infection, and pain; and the use of supporting materials, such as nasal grafts and

splints, among others.<sup>3-7</sup> Furthermore, opportunities exist to optimize the pre- and postoperative management of patients with OSA, a unique rhinoplasty patient population.<sup>8</sup>

The rhinoplasty procedure can be of tremendous benefit toward improving self-esteem for those with concerns about their nasal appearance. However, physicians consulting preoperatively with patients for rhinoplasty must consider patient expectations and motivations.<sup>9-11</sup> BDD, a disorder where patients have obsessive ideas about their appearance out of proportion to their actual deformity, manifests commonly with nasal concerns.<sup>12,13</sup> Patients with BDD are best served with other treatments as opposed to surgery.<sup>5</sup> Furthermore, given the intent of rhinoplasty to change nasal appearance, rhinoplasty surgeons must be cautious to thoroughly understand patients' desires for the procedure. Preoperative patient photographs may be reviewed with patients,

## Anatomy of the Nose



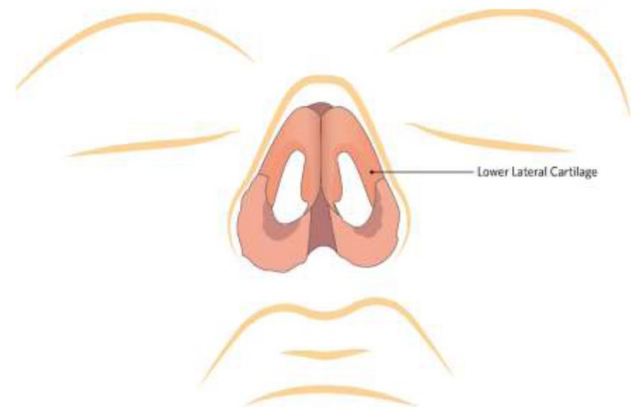
**Figure 1.** Anatomy of the nose: oblique view.

and image morphing may be useful to understand their desires.<sup>14</sup> However, it must be emphasized that the results shown in morphing are those that are desired but not guaranteed.

For the preoperative physical examination, the rhinoplasty surgeon should thoroughly evaluate the skin quality, cartilage strength and position, nasal airway, and surrounding facial features. Skin quality varies by thickness and presence of sebaceous tissue, which affect the result based on ability to show underlying cartilaginous detail. A thorough examination via anterior rhinoscopy can reveal nasal components, including the presence or absence of caudal nasal obstruction (eg, septal deflection), while an endoscopic examination can reveal more posterior airway findings. **Figures 1-4** provide illustrations of several views of the anatomy of the nose.

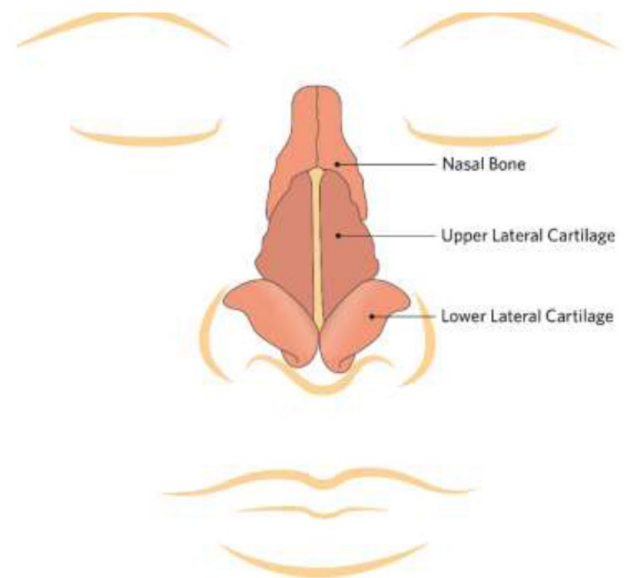
Rhinoplasty, particularly with an external surgical approach involving elevation of the soft tissue flap, may result in postoperative soft tissue edema, with patients noting the presence of a “swollen nose.” The swollen appearance may persist as a source of patient and surgeon dissatisfaction for weeks or months, depending on the type of procedure and the individual skin thickness. Methods described to minimize postoperative edema include intra- and postoperative administration of steroids.<sup>3,6,15</sup> Postoperative pain from rhinoplasty remains a concern and possible deterrent to surgery for prospective patients. Studies assessing advances in the procedure, including pre- and intraoperative administration of analgesics, resulted in lower postoperative pain scores and less postoperative pain medication consumption.<sup>4,16</sup> Other studies evaluated the postoperative utilization of intranasal

## Anatomy of the Nose



**Figure 2.** Anatomy of the nose: base view.

## Anatomy of the Nose



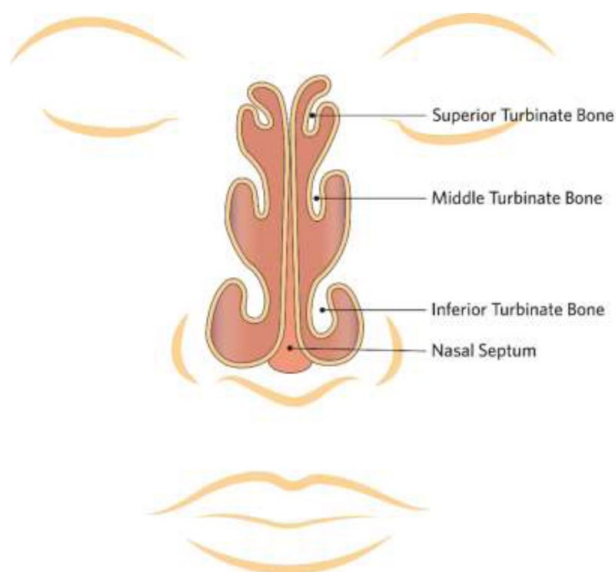
**Figure 3.** Anatomy of the nose: frontal view—I.

packing and external nasal splints—a current source of variability among rhinoplasty surgeons and a source of anxiety among patients.<sup>7</sup> While the risk of postoperative infection after rhinoplasty is generally low, perioperative antibiotics may minimize the risk of postoperative infection after rhinoplasty, though questions persist surrounding duration.<sup>17,18</sup>

### **Guideline Purpose**

The primary purpose of this guideline executive summary is to provide evidence-based recommendations for clinicians who either perform rhinoplasty or are involved in the care of a rhinoplasty candidate, as well as to optimize patient care, promote

### Anatomy of the Nose



**Figure 4.** Anatomy of the nose: frontal view—2.

effective diagnosis and therapy, and reduce harmful or unnecessary variations in care. The target audience is any clinician or individual, in any setting, involved in the management of these patients. The target population is all patients aged  $\geq 15$  years. The guideline is intended to focus on knowledge gaps, practice variations, and clinical concerns associated with this surgical procedure; it is not intended to be a comprehensive reference for improving nasal form and function after rhinoplasty. Recommendations in this guideline concerning education and counseling to the patient are also intended to include the caregiver, particularly if the patient is  $< 18$  years of age.

Currently, variations in the goals and techniques used in rhinoplasty procedures exist. They are influenced by myriad factors that include the patient's preferences and facial features and the psychosocial effects and potential patient burden, pre- and postoperatively. This is the first evidence-based clinical practice guideline developed to address rhinoplasty with the goal of providing clinicians and those involved in the management of these patients with a logical framework to improve patient care by using a specific set of focused recommendations based on an established and transparent process that considers levels of evidence, harm-benefit balance, and expert consensus.<sup>19</sup> These recommendations may also be used to develop performance measures and identify avenues for quality improvement. The topics and issues considered in the development of this guideline are categorized by National Quality Strategy (NQS) for the improvement of health care and are included as an online appendix (see Appendix 1 in the online version of the article).

### Health Care Burden

Rhinoplasty provides the opportunity for direct surgical intervention to correct nasal deformities and anatomic variations

to alleviate nasal airway obstruction and to improve overall nasal shape and aesthetics. According to the American Society of Plastic Surgeons' annual plastic surgery report, rhinoplasty/nose reshaping ranked second on the list of the 5 most common cosmetic surgeries, with approximately 217,000 procedures performed.<sup>1</sup> Of those, 162,000 (75%) rhinoplasty procedures were performed on women, with the most common (32%) age range being 20 to 29 years.

Ponsky et al found that of 100 patients screened prior to rhinoplasty, the male:female ratio was 20:80, with an average age of 37 (range, 15-64).<sup>20</sup> The majority of the cases presenting with subjective nasal obstruction (78%) required concomitant septal (90%) and turbinate (81%) surgery. Total expenditures on rhinoplasty in 2014 exceeded just over US\$1 billion and was third only to breast augmentation and fillers.

### Psychopathology and Rhinoplasty

There is a high potential burden or risk taken by both the patient and the surgeon when cosmetic surgery is performed on patients with preexisting psychopathology or BDD, regardless of surgical outcome. A high incidence of predisposing psychopathology has been identified among patients desiring rhinoplasty.<sup>21</sup> Because rhinoplasty significantly alters the appearance of patients ("type change"), they may require more psychological support than with other surgery. Interestingly, most patients who found benefit from rhinoplasty continue to notice the effects even 5 years after surgery, with reported improvement in social relationships<sup>21</sup>; however, patient dissatisfaction after surgery carries an additional burden, even if the surgeon considered the surgery objectively successful.

Individuals with BDD, or dysmorphophobia, account for approximately 5% of all patients desiring rhinoplasty, which is the most common surgical procedure received by patients with BDD. They are typically young, depressive, and anxious, and they usually focus on minor, even nonexistent, deformities of the nose. They tend to feel generally unattractive; they are frequently preoccupied with the appearance of multiple body areas, believing that they look deformed or ugly; and they are usually dissatisfied with the outcome of cosmetic procedures, including rhinoplasty.<sup>22</sup> These patients may live in social isolation and have unreasonable expectations for postoperative changes in quality of life. Honigman et al reviewed the literature on psychological and psychosocial outcomes for individuals undergoing cosmetic rhinoplasty to address whether it improved psychological well-being and psychosocial functioning and whether there are identifiable predictors of an unsatisfactory psychological outcome.<sup>22</sup> They concluded that patients generally appeared satisfied with the outcome, although some exhibited transient and lingering psychological disturbance.

Factors associated with poor psychosocial outcome after rhinoplasty include being young and male and having unrealistic preoperative expectations, previous unsatisfactory cosmetic surgery, minimal preoperative deformity, and a motivation for surgery based on personal relationship issues, as well as a history of depression, anxiety, or personality

disorder.<sup>23</sup> Preoperative BDD was also found to be a predictor of poor outcome, warranting prescreening of individuals in cosmetic surgery settings. It is desirable to identify such patients before the operation.<sup>5</sup>

### Cost and Complications

While it is difficult to calculate the exact economic burden incurred by rhinoplasty patients following surgery with or without complications, the average rhinoplasty procedure typically exceeds \$4000, not including anesthesia, operating room facilities, and other related expenses.<sup>1,24</sup> The costs incurred due to complications, infections, or revision surgery may include long-term antibiotics, hospitalization, or lost revenue from hours/days of missed work. The resultant psychological impact can also be significant and in many ways immeasurable.

From a surgical perspective, the burden of postoperative wound infection or other complication has been reported as 2%.<sup>20</sup> Factors that may influence these complications include surgeon experience, choice of graft or suture materials, and comorbid conditions such as smoking or diabetes, which can lead to poor wound healing. Ponsky et al reported that most common rhinoplasty procedures include osteotomy, cephalic trim, dorsal nasal hump removal, and alar base resection.<sup>20</sup> Autologous cartilage grafts from the septum, ear, or rib are the most common graft materials. These are most commonly placed at the alar rim as spreader grafts, alar batten grafts, or columella strut grafts, while interdomal or transdomal sutures were the most common suture technique. Winkler et al reported a postoperative infection rate of 2.8% (19 of 662 cases) in cases with alloplastic implants.<sup>25</sup>

To minimize the incidence of postoperative infection, surgeons frequently prescribe antibiotics after rhinoplasty despite lack of standard criteria.<sup>26</sup> Many studies reported very low rates of local soft tissue infection (0.48%-0.6%) after septorhinoplasty among patients who were not given prophylactic antibiotics.<sup>27-29</sup> Of the estimated 220,000 rhinoplasties performed per year in the United States, rhinoplasty surgeons reported that approximately 91% routinely use antibiotics.<sup>1</sup> Of that entire percentage, nearly 34% use antibiotics regularly for prophylaxis, while 37% decide on prophylaxis on a case-by-case basis, with 20% using antibiotics for long or contaminated cases. Additionally, a study conducted by Grunebaum and Reiter found that 49% of surgeons use antibiotics postoperatively for >24 hours, 43% give 1 dose, and 11% continue the regimen for 24 hours after surgery.<sup>30</sup> These data suggest that antibiotics may be prescribed more than needed in approximately 100,000 rhinoplasty cases. This may further contribute to the risks of microbial resistance and/or untoward patient side effects, such as rash, gastrointestinal sequelae, and *Clostridium difficile* colitis, and it may increase patient morbidity.

### OSA and Rhinoplasty

A major ongoing health care burden often related to nasal and upper airway obstruction is OSA, common in adults and defined as increased events of obstructive breathing during sleep. In a random sample of individuals aged 30 to 60 years,

the prevalence of OSA—defined by an apnea-hypopnea index >5 events/hour—was 9% in women and 24% in men.<sup>31</sup> OSA contributes to a substantial economic burden on society, with potential costs attributed to diagnosis and treatment, diminished quality of life, medical consequences, motor vehicle accidents (estimated to cost \$15.9 billion in 2000), and occupational losses.<sup>32</sup> The estimated annual cost of treating the medical sequelae of OSA is \$3.4 billion in the United States.<sup>32</sup>

Post-rhinoplasty, the burden of managing OSA can be challenging. For patients using nasal continuous positive airway pressure (CPAP) devices preoperatively, clinicians must consider the utility of nasal packing, wound care, and the timing to reinstatement of CPAP use. In a recent survey of 407 rhinoplasty surgeons, many of them reported temporarily suspending CPAP after nasal surgery, typically for a period of 1 to 2 weeks.<sup>33</sup> In the same study, many surgeons reported suspending CPAP postoperatively with minimal complications. The lack of uniformity on OSA screening preoperatively and the reintroduction of postoperative CPAP poses a potential health burden on the patient.

### Methods

This guideline was developed with an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm, as outlined in the third edition of “Clinical Practice Guideline Development Manual: A Quality-Driven Approach for Translating Evidence into Action.”<sup>19</sup> The Guideline Development Group (GDG) consisted of 16 panel members representing experts in advanced practice nursing, plastic surgery, consumer advocacy, facial plastic and reconstructive surgery, otolaryngology, otology, psychiatry, plastic surgery, rhinology, and sleep medicine.

### Literature Search

An information specialist conducted 3 literature searches from May 2015 through December 2015, using a validated filter strategy, to identify clinical practice guidelines, systematic reviews, and randomized controlled trials (RCTs). The search terms used were as follows:

((rhinoplasty OR rhinoplasties OR septorhinoplasty OR septorhinoplasties OR ((functional OR cosmetic) AND (“nasal surgery” OR “nose surgery”))) (“nasal valve” AND airflow) OR “nasal valve repair” OR “nasal valve surgery”) (((rhinoplasty OR rhinoplasties OR septorhinoplasty OR septorhinoplasties OR ((functional OR cosmetic) AND (“nasal surgery” OR “nose surgery”))) (“nasal valve” AND airflow) OR “nasal valve repair” OR “nasal valve surgery”)).

These search terms were used to capture all evidence on the population, incorporating all relevant treatments and outcomes.

The English-language searches were performed in multiple databases: HSTAT, AHRQ, BIOSIS Previews, CAB Abstracts, AMED, EMBASE, GIN International Guideline Library, Cochrane Library (Cochrane Database of Systematic Reviews, DARE, HTA Database, NHS EED), Australian National

Health and Medical Research Council, New Zealand Guidelines Group, SIGN, TRIP Database, NICE Evidence (includes NHS Evidence ENT & Audiology and National Library of Guidelines), CMA Infobase, National Guideline Clearinghouse, PubMed Search, Web of Science, and the Cumulative Index to Nursing and Allied Health Literature.

The initial English-language search identified 21 clinical practice guidelines, 116 systematic reviews, and 171 RCTs published in 2005 or later. Systematic reviews were emphasized and included if they met quality criteria of (1) clear objective and methods, (2) an explicit search strategy, and (3) valid data extraction. RCTs were included if they met the following quality criteria: (1) trials involved study randomization; (2) trials were described as double blind; and (3) trials denoted a clear description of withdrawals and dropouts of study participants. Additional evidence was identified, as needed, with targeted searches to support needs of the GDG in writing sections of the guideline text. After duplicates, irrelevant references, and non-English-language articles were removed, we retained 0 guidelines, 25 systematic reviews, and 48 RCTs. In certain instances, targeted searches were performed by GDG members to address gaps from the systematic searches, identified in writing the guideline from November 2015 through July 2016. These additional searches yielded 1 additional clinical practice guideline and 4 additional systematic reviews. Therefore, in total, the evidence supporting this guideline includes 1 guideline, 22 systematic reviews, and 19 randomized controlled trials.

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the 16 months devoted to guideline development ending in August 2016, the group met twice, with in-person meetings following the format previously described<sup>34</sup> and with use of electronic decision-support software (BRIDGE-Wiz; Yale Center for Medical Informatics, New Haven, Connecticut) to facilitate creating actionable recommendations and evidence profiles.<sup>35</sup> Internal electronic review and feedback on each guideline draft were used to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.<sup>36</sup>

American Academy of Otolaryngology—Head and Neck Surgery Foundation staff used the Guideline Implementability Appraisal and Extractor to appraise adherence of the draft guideline to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation.<sup>37</sup> Guideline panel members received summary appraisals in February 2016 and modified an advanced draft of the guideline. The final guideline draft underwent extensive external peer review. Comments were compiled and reviewed by the panel's chair and co-chairs and a modified version of the guideline was distributed and approved by the guideline development panel. A scheduled review process will occur at 5 years from publication or sooner if new compelling evidence warrants earlier consideration.

## Classification of Evidence-Based Statements

Guidelines are intended to produce optimal health outcomes for patients, to minimize harms, and to reduce inappropriate

variations in clinical care. The evidence-based approach to guideline development requires the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in **Tables 3** and **4**.<sup>38-40</sup>

Guidelines are not intended to supersede professional judgment but, rather, may be viewed as a relative constraint on clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a “strong recommendation” than a “recommendation.” “Options” offer the most opportunity for practice variability.<sup>40</sup> Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. They must also operate within their scope of practice and according to their training. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.<sup>40</sup> Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline panel sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the panel was to be transparent and explicit about how values were applied and to document the process.

## Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American Academy of Otolaryngology—Head and Neck Surgery Foundation. Potential conflicts of interest for all panel members in the past 2 years were compiled and distributed before the first conference call. After review and discussion of these disclosures,<sup>41</sup> the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established “stake” in an issue.<sup>42</sup>

## Guideline Key Action Statements

Each evidence-based statement is organized in a similar fashion: an evidence-based key action statement in bold, followed by the strength of the recommendation in italics. Each key action statement is followed by an “action statement profile” of aggregate evidence quality, level of confidence in the evidence, benefit-harm assessment, and statement of costs. Additionally, there is an explicit statement of any value judgments, the role of patient preferences, clarification of any intentional vagueness by the panel, exceptions to the statement, any differences of opinion, and a repeat statement of the



Table 3. Aggregate Grades of Evidence by Question Type.<sup>a</sup>

Grade	CEBM Level	Treatment	Harm	Diagnosis	Prognosis
A	I	Systematic review <sup>b</sup> of randomized trials	Systematic review <sup>b</sup> of randomized trials, nested case-control studies, or observational studies with dramatic effect	Systematic review <sup>b</sup> of cross-sectional studies with consistently applied reference standard and blinding	Systematic review <sup>b</sup> of inception cohort studies <sup>c</sup>
B	2	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies <sup>c</sup>
C	3-4	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonrandomized controlled cohort or follow-up study (postmarketing surveillance) with sufficient numbers to rule out a common harm. case series, case-control, or historically controlled studies	Nonconsecutive studies; case-control studies; or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study; control arm of a randomized trial; case series or case-control study; poor-quality prognostic cohort study
D	5	Case reports, mechanism-based reasoning, or reasoning from first principles	Case reports, mechanism-based reasoning, or reasoning from first principles		
X	N/A	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm.			

Abbreviations: CEBM, Oxford Centre for Evidence-Based Medicine; N/A, not applicable.

<sup>a</sup>Adapted from Howick and coworkers.<sup>39</sup>

<sup>b</sup>A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

<sup>c</sup>A group of individuals identified for subsequent study at an early uniform point in the course of the specified health condition or before the condition develops.

strength of the recommendation. Several paragraphs subsequently discuss the evidence base supporting the statement. An overview of each evidence-based statement in this guideline can be found in **Table 5**.

For the purposes of this guideline, *shared decision making* refers to the exchange of information regarding treatment risks and benefits, as well as the expression of patient preferences and values, which result in mutual responsibility in decisions regarding treatment and care.<sup>43</sup> In cases where evidence is weak or benefits are unclear, the practice of shared decision making—again, where the management decision is made by a collaborative effort between the clinician and an informed patient—is extremely useful. Factors related to patient preference include, but are not limited to, absolute benefits (numbers needed to treat), adverse effects (number needed to harm), cost of drugs or procedures, and frequency and duration of treatment.

## Key Action Statements

**STATEMENT 1: COMMUNICATING EXPECTATIONS: Clinicians should ask all patients seeking rhinoplasty about their motivations for surgery and their expectations for outcomes, should provide feedback on whether those expectations are a realistic goal of surgery, and should document this discussion in the medical record. *Recommendation based on observational studies, with a preponderance of benefit over harm.***

### Action Statement Profile

- **Quality improvement opportunity:** Avoid poor surgical outcomes for patients with unrealistic expectations (NQS domains: patient safety; patient and family engagement)
- **Aggregate evidence quality:** Grade C, based on observational studies with a preponderance of benefit over harm
- **Level of confidence in evidence:** Low because of limited evidence
- **Benefits:** Promote realistic expectations of achievable surgical outcomes, avoid surgery among patients with unrealistic expectations, better align clinician and patient expectations, promote enhanced communication, identify underlying psychiatric disorders (eg, BDD), promote patient satisfaction
- **Risk, harm, cost:** Patient anxiety, time spent in assessing and counseling the patient
- **Benefit-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** Perception by the GDG that expectations are not always fully considered before rhinoplasty and that explicitly assessing expectations could help improve outcomes and potentially avoid surgery in patients with unachievable goals
- **Intentional vagueness:** The specifics of the discussion are left to the discretion of the patient and clinician
- **Role of patient preferences:** None

**Table 4.** Guideline Definitions for Evidence-Based Statements.

Statement	Definition	Implication
Strong recommendation	A strong recommendation means that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits, in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). <sup>a</sup> In some clearly identified circumstances, strong recommendations may be made on the basis of lesser evidence, when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means that the benefits exceed the harms (or that the harms exceed the benefits, in the case of a negative recommendation) but that the quality of evidence is not as strong (grade B or C). <sup>a</sup> In some clearly identified circumstances, recommendations may be based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means either that the quality of evidence that exists is suspect (grade D) <sup>a</sup> or that well-done studies (grade A, B, or C) <sup>a</sup> show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives. Patient preference should have a substantial influencing role.

<sup>a</sup>American Academy of Pediatrics classification scheme.<sup>40</sup>

- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

**STATEMENT 2: COMORBID CONDITIONS: Clinicians should assess rhinoplasty candidates for comorbid conditions that could modify or contraindicate surgery, including OSA, BDD, bleeding disorders, or chronic use of topical vasoconstrictive intranasal drugs.** *Recommendation based on observational studies, with a preponderance of benefit over harm.*

#### Action Statement Profile

- Quality improvement opportunity: Identify known and potentially unknown comorbid conditions that could result in poor outcomes or complications if not detected prior to surgery (NQS domain: patient safety)
- Aggregate evidence quality: Grade C, based on observational studies with a preponderance of benefit over harm
- Level of confidence in evidence: High
- Benefits: Reduce surgical complications, identify opportunities to optimally prepare patients for surgery, better counsel patients regarding surgical risk, avoid surgery in poor candidates
- Risk, harm, cost: Time spent in assessing for comorbid conditions, false-positive results from screening surveys, making the patient self-conscious
- Benefit-harm assessment: Preponderance of benefit over harm

- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

**STATEMENT 3: NASAL AIRWAY OBSTRUCTION: The surgeon, or the surgeon's designee, should evaluate the rhinoplasty candidate for nasal airway obstruction during the preoperative assessment.** *Recommendation based on observational studies, with a preponderance of benefit over harm.*

#### Action Statement Profile

- Quality improvement opportunity: Call explicit attention to an aspect of rhinoplasty planning that could be overlooked and identify unrelated causes of nasal airway obstruction (NQS domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade C, based on observational studies with a preponderance of benefit over harm
- Level of confidence in evidence: High
- Benefits: Avoid overlooking nasal airway obstruction; refine the surgical plan; identify deviated nasal septum, nasal valve collapse, or both; identify non-anatomic causes of obstruction, including inflammatory disorders, neoplastic disorders, and obstructing adenoids
- Risk, harm, cost: Cost and adverse events of diagnostic procedures (endoscopy, imaging), time spent

**Table 5.** Summary of Evidence-Based Statements.

Statement	Action	Strength
1. Communicating expectations	Clinicians should ask all patients seeking rhinoplasty about their motivations for surgery and their expectations for outcomes, should provide feedback on whether those expectations are a realistic goal of surgery, and should document this discussion in the medical record.	Recommendation
2. Comorbid conditions	Clinicians should assess rhinoplasty candidates for comorbid conditions that could modify or contraindicate surgery, including obstructive sleep apnea, body dysmorphic disorder, bleeding disorders, or chronic use of topical vasoconstrictive intranasal drugs.	Recommendation
3. Nasal airway obstruction	The surgeon, or the surgeon's designee, should evaluate the rhinoplasty candidate for nasal airway obstruction during the preoperative assessment.	Recommendation
4. Preoperative education	The surgeon, or the surgeon's designee, should educate rhinoplasty candidates regarding what to expect after surgery, how surgery might affect the ability to breathe through the nose, potential complications of surgery, and the possible need for future nasal surgery.	Recommendation
5. Counseling for obstructive sleep apnea patients	The clinician, or the clinician's designee, should counsel rhinoplasty candidates with documented obstructive sleep apnea about the impact of surgery on nasal airway obstruction and how obstructive sleep apnea might affect perioperative management.	Recommendation
6. Managing pain and discomfort	The surgeon, or the surgeon's designee, should educate rhinoplasty patients before surgery about strategies to manage discomfort after surgery.	Recommendation
7. Postoperative antibiotics	When a surgeon, or the surgeon's designee, chooses to administer perioperative antibiotics for rhinoplasty, he or she should <i>not</i> routinely prescribe antibiotic therapy for a duration >24 hours after surgery.	Recommendation against
8. Perioperative steroids	The surgeon, or the surgeon's designee, may administer perioperative systemic steroids to the rhinoplasty patient.	Option
9. Nasal packing	Surgeons should <i>not</i> routinely place packing in the nasal cavity of rhinoplasty patients (with or without septoplasty) at the conclusion of surgery.	Recommendation against
10. Outcome assessment	Clinicians should document patient satisfaction with their nasal appearance and with their nasal function at a minimum of 12 months after rhinoplasty.	Recommendation

in evaluating the patient, potential for focusing attention on incidental or asymptomatic findings

- **Benefit-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** Perception by a majority of the GDG that early evaluation for nasal airway obstruction could identify opportunities to surgically improve the airway during rhinoplasty that may have been overlooked if not explicitly assessed prior to surgery
- **Intentional vagueness:** The method of evaluating for nasal airway obstruction is left to the discretion of the clinician
- **Role of patient preferences:** Limited, primarily concerns the choice of tests or procedures beyond the basic physical examination
- **Exceptions:** None

- **Policy level:** Recommendation
- **Differences of opinion:** Minor differences regarding the inclusion of nasal function versus nasal obstruction in the key action statement resulted in a panel vote: 8 members of the GDG voted to include nasal obstruction; 3 voted to include nasal function; and 1 did not have an opinion.

**STATEMENT 4: PREOPERATIVE EDUCATION:** The surgeon, or the surgeon's designee, should educate rhinoplasty candidates regarding what to expect after surgery, how surgery might affect the ability to breathe through the nose, potential complications of surgery, and the possible need for future nasal surgery. *Recommendation based on observational studies on the benefits, in general, of the value of education and counseling, with a preponderance of benefit over harm.*

### Action Statement Profile

- Quality improvement opportunity: To facilitate shared decision making regarding the need for surgery and surgical outcomes (NQS domain: patient and family engagement)
- Aggregate evidence quality: Grade C, based on observational studies on the benefits, in general, of the value of education and counseling, with a preponderance of benefit over harm
- Level of confidence in evidence: High
- Benefits: Facilitate shared decision making, promote realistic expectations, promote informed consent, identify unrealistic expectations, improve quality of care and outcomes
- Risk, harm, cost: Time spent with education, patient anxiety
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

**STATEMENT 5: COUNSELING FOR OSA PATIENTS:**  
**The clinician, or the clinician's designee, should counsel rhinoplasty candidates with documented OSA about the impact of surgery on nasal airway obstruction and how OSA might affect perioperative management.** *Recommendation based on systematic reviews or randomized and observational studies with preponderance of benefit over harm.*

### Action Statement Profile

- Quality improvement opportunity: To facilitate informed patient decisions and coordinate care for optimal surgical outcomes (NQS: patient safety; care coordination)
- Aggregate evidence quality: Grade B, systematic reviews or randomized and observational studies regarding the positive impact of rhinoplasty on OSA (reduced CPAP pressures, enhanced CPAP compliance, lower apnea-hypopnea index); Grade C, observational studies on the benefits, in general, of counseling on shared decision making
- Level of confidence in evidence: High
- Benefits: Increase awareness of beneficial effects of rhinoplasty on CPAP compliance and use, increase awareness of rhinoplasty as a means to reduce severity of OSA, facilitate shared decision making, facilitate coordination of care (primary care clinician, sleep medicine specialist, anesthesiologist, surgeon), plan more effectively for perioperative management
- Risk, harm, cost: Time spent counseling, increased patient anxiety

- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: Minor regarding the need to include a separate statement about counseling for rhinoplasty candidates with OSA: 8 members of the GDG voted in favor of a statement; 5 members thought that an additional statement was unnecessary.

**STATEMENT 6: MANAGING PAIN AND DISCOMFORT:**  
**The surgeon, or the surgeon's designee, should educate rhinoplasty patients before surgery about strategies to manage discomfort after surgery.** *Recommendation based on studies of the value of education and counseling, with a preponderance of benefit over harm.*

### Action Statement Profile

- Quality improvement opportunity: To facilitate informed patient decisions and coordinate care for optimal management of pain and discomfort (NQS domains: patient and family engagement; clinical process/effectiveness)
- Aggregate evidence quality: Grade C, observational studies on the benefits, in general, of the value of education and counseling, with a preponderance of benefit over harm
- Level of confidence in evidence: Medium because of the indirectness of evidence and need to extrapolate from other pain management studies
- Benefits: Establish expectations regarding pain and discomfort, increase patient satisfaction, decrease need for postoperative calls to physician office, raise awareness of intraoperative and postoperative strategies to reduce pain and discomfort, reduce patient anxiety
- Risk, harm, cost: Time spent counseling
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of patient education in promoting optimal outcomes
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

**STATEMENT 7: POSTOPERATIVE ANTIBIOTICS:**  
**When a surgeon, or surgeon's designee, chooses to administer perioperative antibiotics for rhinoplasty, he or she should *not* routinely prescribe antibiotic therapy for a duration >24 hours after surgery.** *Recommendation against*

prescribing based on RCTs and systematic reviews, with a preponderance of harm over benefit.

### Action Statement Profile

- **Quality improvement opportunity:** Reduce antibiotic prescribing after rhinoplasty and promote antibiotic stewardship (NQS domain: patient safety)
- **Aggregate evidence quality:** Grade B, RCT trials and systematic reviews with a preponderance of harm over benefit
- **Level of confidence in evidence:** Medium, based on indirectness of evidence about benefits beyond 24 hours and absence of evidence concerning benefits of antibiotic prophylaxis for rhinoplasty patients
- **Benefits:** promote selective use of antibiotics after surgery (reducing induced bacterial resistance), reduce antibiotic adverse effects, reduce cost
- **Risk, harm, cost:** Potential for infection in patients who might have benefited from >24 hours of antibiotic therapy but did not receive it
- **Benefit-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** Perception by the GDG that antibiotics are commonly prescribed after rhinoplasty despite a lack of evidence to consistently support benefits of administering antibiotics beyond a single intraoperative dose or >24 hours after surgery; a desire to avoid reflex, or automatic, prescribing of antibiotics after 24 hours
- **Intentional vagueness:** The word “routine” is used to avoid setting a legal standard of care and to reflect that there may be individual patient situations that warrant antibiotic prescribing
- **Role of patient preferences:** Small
- **Exceptions:** Revision surgery, complicated rhinoplasty, patients receiving nasal implants, patients with postoperative nasal packing, patients with baseline nasal colonization with MRSA (methicillin-resistant *Staphylococcus aureus*), extensive cartilage grafting, immunocompromised patients, concurrent medical condition requiring antibiotics (eg, rhinosinusitis)
- **Policy level:** Recommendation against
- **Differences of opinion:** None

**STATEMENT 8: PERIOPERATIVE STEROIDS: The surgeon, or the surgeon’s designee, may administer perioperative systemic steroids to the rhinoplasty patient.** *Option based on systematic review of RCTs with limitations and a balance of benefits and harms.*

### Action Statement Profile

- **Quality improvement opportunity:** Promote awareness of the benefits and risks of systemic steroids, engage patients in shared decisions, emphasize a need for future research to increase our confidence in

the effect of perioperative steroids on the rhinoplasty patient (NQS domains: patient safety; clinical process/effectiveness)

- **Aggregate evidence quality:** Grade B, based on systematic review of RCTs with limitations and a balance of benefits and harms
- **Level of confidence in evidence:** Low, because of small randomized trials with heterogeneity in drug dosing, administration, and assessment of clinical outcomes; low precision in systematic review pooled estimates of treatment effect
- **Benefits:** Reduced periorbital ecchymosis and edema, reduced discomfort, less postoperative nausea and vomiting
- **Risk, harm, cost:** Cost, adverse events of systemic steroids (which include bone weakening, avascular necrosis of the femur, adverse effect on diabetes, nervousness/anxiety, etc), potential impact on wound healing
- **Benefit-harm assessment:** Balance of benefits and harms
- **Value judgments:** None
- **Intentional vagueness:** The specifics of dosing and timing of steroid administration are at the discretion of the clinician
- **Role of patient preferences:** Moderate role in deciding whether or not to receive steroids
- **Exceptions:** Patients for whom systemic steroids are contraindicated
- **Policy level:** Option
- **Differences of opinion:** None

**STATEMENT 9: NASAL PACKING: Surgeons should not routinely place packing in the nasal cavity of rhinoplasty patients (with or without septoplasty) at the conclusion of surgery.** *Recommendation against, based on systematic reviews and RCTs with a preponderance of harm over benefit and a lack of studies regarding the benefits of nasal packing after rhinoplasty.*

### Action Statement Profile

- **Quality improvement opportunity:** Improve patient comfort and outcomes by avoiding routine nasal packing in the absence of documented benefits (NQS domains: patient safety; clinical process/effectiveness)
- **Aggregate evidence quality:** Grade C, based on systematic reviews and RCTs with a preponderance of harm over benefit
- **Level of confidence in evidence:** Low, due to lack of studies
- **Benefits:** Improved patient comfort, decreased pain after surgery, avoiding additional risk of toxic shock syndrome, decreased patient anxiety, improved nasal airway, avoiding respiratory compromise, improved CPAP compliance in patients with OSA

- **Risk, harm, cost:** Risk of epistaxis
- **Benefit-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** Perception by the GDG that nasal packing is frequently used after rhinoplasty despite no published evidence documenting benefits but significant evidence of potential harms; perception by the GDG that the use of nasal packing, in general, is declining among rhinoplasty surgeons and that, when packing is used, it is limited to 24 hours
- **Intentional vagueness:** The word “routinely” is used to avoid establishing a legal precedent and to allow clinicians discretion to identify patients who might benefit from nasal packing on an individualized basis
- **Role of patient preferences:** Moderate, the patient may have strong preferences about nasal packing that create an opportunity for shared decision making
- **Exceptions:** Patients with epistaxis that requires packing for control; patients with complex unstable nasal fractures that require packing for stability; patients with a known bleeding/clotting disorder
- **Policy level:** Recommendation against
- **Differences of opinion:** None regarding the recommended action but some concern on whether a simple cotton ball or other temporary object in the nasal vestibule after nasal surgery could be misconstrued as packing

**STATEMENT 10: OUTCOME ASSESSMENT: Clinicians should document patients’ satisfaction with their nasal appearance and their nasal function at a minimum of 12 months after rhinoplasty.** *Recommendation based on observational studies, with a preponderance of benefit over harm.*

#### Action Statement Profile

- **Quality improvement opportunity:** Incorporate patient-reported outcome measures in rhinoplasty surgery, empower the patient to express satisfaction and communicate with the clinician (NQS domains: patient and family engagement; clinical process/effectiveness)
- **Aggregate evidence quality:** Grade C, based on observational studies with a preponderance of benefit over harm.
- **Level of confidence in evidence:** Medium based on limited evidence concerning the optimal time frame to assess outcomes and the wide range of outcome measurements available
- **Benefits:** Empower the patient to communicate meaningful outcomes and express unmet expectations, provide feedback information on patient satisfaction to the surgeon, call explicit attention to the importance of assessing both cosmetic and function outcomes, identify patients who might benefit from additional counseling or management, identify causes of nasal obstruction unrelated to the original rhinoplasty that could be managed and corrected

- **Risk, harm, cost:** Time spent assessing outcomes, administrative burden of outcome measurements
- **Benefit-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** The content experts in the GDG felt that 12 months was the minimal acceptable time for a reasonable stable outcome assessment of nasal appearance. While earlier assessment and documentation may be useful for counseling, the final assessment should ideally be done at  $\geq 12$  months
- **Intentional vagueness:** The method of assessing satisfaction is not specified and is at the discretion of the clinician; the precise timing of the final outcome assessment is not specified but should be no sooner than 12 months
- **Role of patient preferences:** Small
- **Exceptions:** None
- **Policy level:** Recommendation
- **Differences of opinion:** None

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## Supplemental Material

Additional supporting information is available in the online version of the article.

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