*Running title: Consensus CRS disease control criteria*

ORIGINAL CONTRIBUTION

**Consensus criteria for chronic rhinosinusitis disease control: an international Delphi Study**

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**SUMMARY**

**Background:** Chronic rhinosinusitis (CRS) disease control is a global metric of disease status for CRS. While there is broad acceptance that it is an important treatment goal, there has been inconsistency in the criteria used to define CRS control. The objective of this study was to identify and develop consensus around essential criteria for assessment of CRS disease control.

**Methods:** Modified Delphi methodology consisting of three rounds to review a list of 24 possible CRS control criteria developed by a 12-person steering committee. The core authorship of the multidisciplinary EPOS 2020 guidelines was invited to participate.

**Results:** Thirty-two individuals accepted the invitation to participate and there was no dropout of participants throughout the entire study (3 rounds). Consensus essential criteria for assessment of CRS control were: overall symptom severity, need for CRS-related systemic corticosteroids in the prior 6 months, severity of nasal obstruction, and patient-reported CRS control. Near-consensus items were: nasal endoscopy findings, severity of smell loss, overall quality of life, impairment of normal activities and severity of nasal discharge. Participants’ comments provided insights into caveats of, and disagreements related to, near-consensus items.

**Conclusions:** Overall symptom severity, use of CRS-related systemic corticosteroids, severity of nasal obstruction, and patient-reported CRS control are widely agreed upon essential criteria for assessment of CRS disease control. Consideration of near-consensus items to assess CRS control should be implemented with their intrinsic caveats in mind. These identified consensus CRS control criteria, together with evidence-based support, will provide a foundation upon which CRS control criteria with wide-spread acceptance can be developed.

**INTRODUCTION**

 Control of a disease implies that disease manifestations and how they impact the patient are at acceptable levels.1 Because it does not necessarily imply resolution, control is an important and commonly used metric of disease status and treatment response for incurable, chronic conditions.2 For decades, the concept of disease control has been used in this manner for the assessment of asthma, with control being explicitly recognized as the goal of asthma treatment.3-5 Disease control is also used in the assessment of—and as a goal of treatment for—allergic rhinitis.6 The concept of control has similarly been proposed as an important goal of treatment for chronic rhinosinusitis (CRS).7

 The concept of control has been historically applied to CRS by clinicians, investigators and patients in a manner indicating the extent to which manifestations of CRS are within acceptable limits and with control serving as the goal of treatment.8,9 The exact criteria by which CRS control is judged, in contrast, has been inconsistent. The first formally proposed criteria for assessment of CRS control was by the 2012 European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS).10 These criteria, which have largely been preserved in EPOS 2020, captured multiple dimensions of CRS, including not only patients’ symptom severities but also the need for systemic corticosteroids and antibiotics as well as the presence of diseased mucosa on nasal endoscopy.10,11 Currently, at least fifteen different sets of criteria have been used to date in the scientific literature to assess CRS control.8 The lack of consistency in the criteria for such an important outcome measure and global metric of CRS disease status represents a significant problem for the field, both from the perspective of patient care and scientific investigation.

 Several factors may explain the lack of consistently used criteria for CRS control. One important factor is that no CRS control guideline has been developed with specific attention to broad consensus building around the individual criterion. Even the EPOS CRS control criteria were developed as expert opinion without a formal consensus determination. In this study, we therefore sought to determine and build formal consensus around the criteria that are deemed most essential for assessment of CRS control, engaging the authorship of the multidisciplinary EPOS guidelines as participants. We believe that the findings of this study, which identify criteria broadly agreed upon to be essential for the assessment of CRS control, together with evidence-based support, will provide a foundation upon which CRS control criteria with wide-spread acceptance can be developed.

**MATERIALS AND METHODS**

***Study design***

 This study was designed with the primary objective of developing consensus around the criteria that are essential in determining CRS disease control using modified Delphi methodology. Because the first proposed criteria for the assessment of CRS disease control were in the EPOS guidelines, a multidisciplinary position paper on CRS, this study was designed to be implemented within the context of the EPOS authorship. A steering committee was organized consisting of the study organizers (ARS and CH), the EPOS 2020 steering committee, any EPOS authors involved in the development of the EPOS CRS control criteria, as well as one patient advocate from the EPOS 2020 authorship group—a total of 12 steering committee members. The steering committee developed a long list of statements, each summarizing a specific criterion for the assessment of CRS control. This long list was then presented to all participants as possible options for CRS control criteria. Participants, who were invited from the core EPOS 2020 authorship group, were then asked to participate in a modified Delphi process to develop consensus around criteria essential for the assessment of CRS control.

***Modified Delphi process***

 The design of the modified Delphi process was established by the steering committee prior to study commencement to be consistent with fundamental elements of Delphi methodology (anonymity, iterative, controlled feedback) and methodology used in prior studies and consensus statements.12,13 The modified Delphi process was implemented electronically in REDCap through the University of Cincinnati and was specifically designed to have three rounds. All core EPOS 2020 authors and steering committee were invited to participate. Although invitations were made as “an author of the 2020 EPOS guidelines to participate,” quasi-anonymity was maintained by not sharing who ultimately participated or individual-level scores/data. In each round, participants were asked to rate their agreement with each statement from the long list identifying a specific CRS disease manifestation as essential to the assessment of CRS control on a 9-point Likert scale (agreement score): strongly disagree (1), disagree (3), neutral (5), agree (7), and strongly agree (9). To minimize the risk of presentation bias, statements were presented to participants in four different possible orders, each of which represented a random shuffling of the order in which statements were finalized by the steering committee. In every round, a text box for each statement was provided in which comments could be made by the participant. Participants were instructed that these comment boxes reflected their opportunity to provide feedback, express their reasoning for their agreement scores and/or sway the opinion of their fellow participants. At the end of the first round, participants were also provided with a text box in which they could recommend additional CRS disease manifestations for inclusion in the subsequent Delphi rounds. Participants were given 3 weeks to complete each round.

At the end of each round, cumulative group-level results (agreement scores and comments) for each statement were compiled and sent to each participant; each participant was also provided with their own agreement scores for each statement so they could directly compare their ratings with group-level results. Participants were then asked to return any additional comments to the organizers. Participant comments were incorporated, where deemed appropriate, into the implementation of later rounds of the modified Delphi. There are many ways that consensus has been defined in Delphi methodology,13 from which our *a priori* definition of consensus for a statement after each round was developed as: a mean agreement score of ≥7 or ≤3, with less than 10% of participants as outliers (defined as having agreement score >2 Likert points away from the mean). When a statement reached consensus, it was no longer considered in subsequent rounds. “Near consensus” was defined as reaching the mean agreement score criteria for consensus but not the outlier criteria.

***Assumptions, definitions, and instructions to participants***

 Prior to commencement of the study, the steering group agreed upon several assumptions and definitions that would establish the context of the modified Delphi process for all participants. CRS disease control was broadly defined as the extent to which CRS disease manifestations are within acceptable limits and achievement of CRS control was recognized as the goal of treatment. The steering group also developed additional specific instructions that were given to all participants prior to commencement of the modified Delphi, which are described in the “Delphi instructions for study participants” section of the Supplemental Materials.

***Statistical Analysis***

 All analyses were performed using the statistical software package R ([www.r-project.org](http://www.r-project.org)).14 Standard descriptive statistics (mean, standard deviation [SD], median and range) were calculated. Stability of participants’ responses from one round to the next was calculated based on descriptive statistical analyses of changes in agreement scores for each item as well as a 2-way mixed effects intraclass correlation coefficient (ICC).15 Consistency of agreement scores from round to round was deemed to be moderate (0.50 ≤ ICC < 0.75), good (0.75≤ ICC < 0.90) or excellent ( 0.90 ≤ ICC).15

**RESULTS**

***List development***

 A long list of possible CRS criteria was developed by the steering committee through a pre-planned process including meetings and discussion among the steering committee. The details of this process are described in the “Long list development” section of the Supplemental Materials. After completion of this process, a final list of 24 items was generated (**Table 1**).

***Delphi results***

 Of the 41 individuals who were invited to participate, 32 agreed to participate in the first round. This consisted of 29 otolaryngologists, 2 patient advocates and 1 general practitioner. Invitations were sent for Round 1 in January 2023, for Round 2 in March 2023, and for Round 3 in May 2023.

The agreement scores for each statement after Round 1 of the modified Delphi are shown in **Table 2** and **Figure 1**. The overall symptom severity score, the need for systemic corticosteroids for CRS in the prior 6 months, the severity of nasal obstruction and the patient’s assessment of their own CRS control (patient-reported CRS control) all reached consensus as essential for the assessment of CRS control. The overall symptom severity score had the highest mean agreement score (mean: 8.4, median: 9) while patient-reported control was the only item reaching consensus with no outliers (**Table 2**).

After Round 1, CRS disease manifestations reaching near consensus as essential for the assessment of CRS control included nasal endoscopy findings, overall QOL, impairment of normal activities, smell loss, nasal discharge, and sleep impairment. Participants’ comments from Round 1 related to these near consensus items are provided in **Supplemental Table 1**. No additional statements were added to the long list for subsequent rounds based on participants’ feedback after round 1.

 All 32 individuals who participated in the first round of the modified Delphi also participated in the second round. The agreement scores for each statement after Round 2 of the modified Delphi are shown in **Table 3** and **Figure 2**. No statement reached consensus in Round 2 as essential for the assessment of CRS control. CRS disease manifestations reaching near consensus were smell loss, nasal endoscopy findings, overall QOL, impairment of normal activities, and nasal discharge. Participants’ comments from Round 2 related to these near consensus items are provided in **Supplemental Table 2**. From Round 1 to Round 2, the mean change in agreement scores over all items was 1.4 points (SD: 1.6 points) in either direction, with a median change of 1 point. From Round 1 to Round 2, there was at least moderate consistency (ICC≥0.50) in how participants rated 14 out of the 20 statements (**Table 4**).

All 32 individuals who participated in the first and second rounds of the modified Delphi also participated in the third round, so there was no dropout in participation throughout the entire study. The agreement scores for each statement after Round 3 of the modified Delphi are shown in **Table 5** and **Figure 3**. Similar to Round 2, no statement reached consensus in Round 3 as essential for the assessment of CRS control. CRS disease manifestations reaching near consensus in Round 3 were nasal endoscopy findings, smell loss, overall QOL, impairment of normal activities, and nasal discharge. Participants’ comments from Round 3 related to these near-consensus items are provided in **Supplemental Table 3**. From Round 2 to Round 3, the mean change in agreement scores over all items was 1.1 points (SD: 1.4 points) in either direction, with a median change of 1 point. From Round 2 to Round 3, there was at least moderate consistency (ICC≥0.50) in how participants rated 16 out of the 20 statements (**Table 6**).

***Items reaching consensus and near consensus***

Through three rounds of the modified Delphi, consensus was reached on the following items as being essential in the assessment of CRS control: overall symptom severity score, the need for systemic corticosteroids for CRS in the prior 6 months, the severity of nasal obstruction and patient-reported CRS control. Consensus on these items was reached during the first round, while items reaching near consensus—nasal endoscopy findings, smell loss, overall QOL, impairment of normal activities, and nasal discharge—were remarkably consistent across all three rounds (**Table 7**). Across the three rounds, participants’ ratings demonstrated good or excellent consistency for nasal discharge (ICC=0.92) and nasal endoscopy (ICC=0.78), but moderate consistency for smell loss (ICC=0.52), overall QOL (ICC=0.72) and activity impairment (ICC=0.56). Participants’ comments at each round (**Supplemental Tables 1-3**) offer insights into reasons why near consensus statements did not reach formal consensus.

**DISCUSSION**

 Inconsistency in the application of a concept or terminology in healthcare or science can slow and prevent its adoption by promoting confusion, misunderstanding and miscommunication among patients, healthcare providers and researchers. The inconsistent application of the disease control concept to CRS has suffered in this manner and the consequent underutilization of CRS disease control is especially problematic because it has been broadly identified as an important outcome measure.16 It may be postulated that more common usage of this important global outcome measure could arise from development of criteria that are supported by both evidence and broad consensus for their essential place in the assessment of CRS control. While studies have been performed to identify the relative significance of individual CRS disease manifestations to CRS control, no study has yet sought to determine and develop formal consensus around the CRS disease manifestations that are deemed most essential by key stakeholders in the assessment of CRS control. In this study we used Delphi methodology to develop and identify formal consensus among the core authors of the multidisciplinary EPOS guidelines around the essential criteria of CRS control. We found that overall symptom severity, the use of systemic corticosteroids for CRS, severity of nasal obstruction, and patients’ own assessments of their CRS control (patient-reported CRS control) achieved formal consensus as essential criteria in the assessment of CRS control. Although not reaching formal consensus, nasal endoscopy findings, overall QOL, activity impairment and the severities of smell loss and nasal discharge reached near-consensus as essential criteria for the assessment of CRS control.

 Previous studies have suggested that a significant degree of consistency among key stakeholders—physicians and patients—may exist for what CRS control means and how it is assessed. For example, there is overlap in nasal symptom severity as one of the most important CRS control determinants for both physicians and patients.17,18 Among patients, providers and researchers, there is consistency in considering the achievement of CRS control as the goal of treatment.8,9 Among rhinologists of different backgrounds, there is remarkable consistency in how patients’ CRS control is judged and consistency in the CRS disease manifestations that are most associated with their control assessments.19 These results demonstrate that consistency in the concept of CRS control exists among key stakeholders and that the active pursuit of consensus CRS control criteria is achievable.

 In this study, we identify several CRS disease manifestations that have consensus as essential criteria for the assessment of CRS control and they include overall symptom severity, the severity of nasal obstruction, CRS-related systemic corticosteroid usage, and patient-reported CRS control. Consensus around these CRS control criteria is supported by prior studies establishing their importance as CRS outcome measures and targets of treatment. Symptom burden is the most significant CRS disease manifestation that affects patients, as well as how they perceive their CRS and their treatments.18,20 To that end, overall symptom severity was developed to assess global CRS symptom burden,21 validated to be reflective of patients’ perception of their CRS as mild, moderate and severe,22 and correlates with EPOS guideline-based classification of CRS control.23 In fact, CRS symptom burden is tightly associated with how patients assess their own CRS control,24 with nasal symptoms—especially nasal obstruction— as the disease manifestation most dominantly associated with how patients assess their own CRS control.17,18,25 Nasal obstruction severity in particular is a primary determinant of how physicians assess CRS disease control.17,19 Our determination of consensus around the need for systemic corticosteroids as a CRS control criteria is also consistent with known practice patterns. CRS-related oral corticosteroid usage is associated with how physicians assess CRS control,17-19 and this practice is supported by evidence. CRS-related systemic corticosteroids usage has been shown to be an important outcome measure reflective of CRS disease burden26,27 and a source of risk for morbidity from corticosteroid-associated adverse outcomes.28,29 Patient-reported CRS control was the only item that reached consensus with no outliers, which is consistent with the importance placed on it in a recent study showing patient-reported CRS control to be the factor most associated with how rhinologists assess CRS control.19 Patient-reported CRS control has been previously validated as an outcome measure reflective of CRS disease burden and QOL.30 Because it directly reflects the patient’s perspective of their disease, it has been proposed for inclusion in CRS control assessment as a means of better aligning patient perspectives with physician-derived guidelines.31

 We also identified several CRS disease manifestations that reached near consensus as essential criteria for CRS control. The significance of diseased mucosa on nasal endoscopy as a CRS control criterion—and by direct extension an independent target of treatment—has historically been a source of controversy. Previous studies have shown that nasal endoscopy findings have a weak—or no—correlation with patients’ CRS symptom burden.32-36 Studies have also shown that the nasal endoscopy criterion rarely changes the EPOS-based CRS control classification, while additionally serving as a primary source of discordance with how patients view their own CRS control.23,31 In contrast to these perspectives, at least one study has shown that nasal endoscopy findings may have an especially important role in CRS control assessment when it is unclear whether symptoms are correctly being attributed to CRS by providing objective evidence of active disease.19 This point was reflected in comments made by our study participants. Other comments echoed the theme that diseased mucosa on nasal endoscopy is a predictor of worsening of symptoms and disease status in the future, although study participants who disagreed with this view commented on the lack of evidence to support the assertion. The diagnostic symptoms of smell loss and nasal discharge, both of which have been established to be important to CRS patients as targets of treatment,20 also did not reach full consensus as essential CRS control criteria. While the severity of nasal discharge has been shown to be a strong determinant of both patient-reported and rhinologist-assessed CRS control, the severity of smell loss has not.17,19,37 Comments from participants pointed out that the smell loss may often be secondary and redundant to severe nasal obstruction and discharge, that smell loss may be most important for only the subset of patients with nasal polyps, or that permanent smell loss may occur in the setting of CRS without necessarily being an indicator of the active disease process. In contrast to the significance placed on nasal discharge severity in prior studies of CRS control,17,19,37 comments made against nasal discharge as an essential CRS control criterion indicated primary objections to the inclusion of post-nasal drainage. Although post-nasal drainage has been reported to be a very common symptom of CRS,38 participants’ comments have argued for the non-specificity of post-nasal drainage, which may also be caused by other conditions. Activity impairment, which has been included in at least one CRS control assessment tool,17 also did not reach full consensus as essential. Its significance as a reflection of QOL was mentioned in comments both as evidence for its essentiality as well as its redundancy to other criteria (and hence its non-essentiality). Another point raised was that previously described associations of CRS-related productivity loss or activity impairment with emotional disturbance may indicate it is not necessarily a direct manifestation of CRS.39-41 Interestingly, the need for short-term CRS-related antibiotics, and the severity of facial pain and sleep disturbance—all of which are included EPOS CRS control criteria—did not even reach near consensus. While CRS-related antibiotics have previously been considered an indirect measure of acute exacerbations of CRS,42 comments by Delphi participants indicated disagreement with its inclusion due to the lack of evidence to support short-term antibiotics as a treatment for CRS.43 Comments by Delphi participants also raised concerns about the non-specificity of facial pain and sleep disturbance, which while important to CRS could also be confounded by other comorbidities.44-46

 Our study has important implications for the future development of CRS control criteria and guidelines, the success of which will depend on broad acceptance of the contents. The results of our study now illustrate for the first time, consensus around essential criteria for the assessment of CRS control. Moreover, we also demonstrate quantitatively the degree of agreement around other possible CRS control criteria. In particular, for criteria reaching near-consensus, we have demonstrated not only the general state of opinions regarding their importance but also reasons for discrepancies in participants’ opinions, all of which may provide opportunities for further study as well as provide avenues for reconciling disagreements about their inclusion in CRS control criteria.

 This study should be interpreted within the constraints of its limitations. While the core EPOS authorship reflects a multidisciplinary group, the backgrounds of those who participated were heavily skewed towards otorhinolaryngology. Although the explicit views of CRS patients on CRS control have been studied qualitatively in the past,9 only two CRS patients participated in this Delphi study. Moreover, only one general practitioner participated while other stakeholders such as pulmonologists were not represented. Our study did not consider the means (e.g. scales) for measuring CRS control criteria. This was an intentional aspect of our study design in order to focus the consensus building around the criteria for CRS control. Our modified Delphi methodology also did not include any live or in-person discussions, which may have increased the chances that consensus would be reached for more statements. However, the intentional omission of live discussion in our design was to maintain anonymity and for the practical consideration of difficulty in assembling a quorum of participants. Finally, our modified Delphi was designed specifically to have 3 rounds rather than being open-ended, with study completion determined by strict stopping criteria defining stability in the lack of consensus for each item. While strict and formal stopping criteria may have more greatly ensured a true lack of consensus where consensus was not achieved, the performance of this study in an open-ended manner related to number of rounds may have led to dropout and ultimately the artificial achievement of consensus through attrition of participants.

**CONCLUSIONS**

 Despite the many definitions by which CRS control has been assessed, there is remarkable consistency among key stakeholders in the individual criteria that are essential in the assessment of CRS control. Consensus CRS control criteria include overall symptom severity, the need for systemic corticosteroids, nasal obstruction severity and patient-reported control. Near-consensus essential criteria—which have cogent arguments for and against—include nasal endoscopy findings, severity of smell loss, severity of nasal discharge, activity impairment and overall QOL. The identification of these consensus and near-consensus CRS control criteria will allow more focused investigation to support their incorporation into a broadly accepted definition for CRS control.

**AUTHORSHIP CONTRIBUTION**

ARS and CH: concept of study, study design, steering group member, collection of data, analysis of results, write up of manuscript, critical review of all contents.

WJF, VJL, PWH, RCK, SR, STS, MBS, JM, PG, and TT: steering group member, study design, performance of the study, critical review of all results and manuscript.

IA, WTAL, FMB, AC, NAC, JC, LDG, MD, RJH, LK, AK, BNL, CM, CMP, DR, RJS, BAS, TLS, PVT, and LZ: performance of the study, critical review of all results and manuscript.

**CONFLICTS OF INTEREST**

The authors declare that they have no conflicts of interests regarding the publication of this paper.

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**Table 1. Statements presented to participants for consensus in the assessment of CRS control**

|  |
| --- |
| Assessment of Overall Symptom Severity attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of Overall Quality of Life attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of Severity of Nasal Obstruction attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of Severity of Nasal (anterior/post-nasal) Discharge attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of Severity of Smell Loss attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of Severity of Facial Pain/Pressure attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of Severity of Ear Discomfort (fullness/pressure/pain) attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of Severity of Impaired Sleep attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of Severity of Emotional/Mood Disturbance attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of use of short-course antibiotics (used for antibacterial properties) for CRS within the last 6 months is essential for the routine assessment of CRS control. |
| Assessment of use of long-term antibiotics (e.g. macrolides, used for anti-inflammatory properties) within the last 6 months for CRS is essential for the routine assessment of CRS control. |
| Assessment of use of systemic corticosteroids within the last 6 months for CRS is essential for the routine assessment of CRS control. |
| Assessment of use of steroid-eluting stents within the last 6 months for CRS is essential for the routine assessment of CRS control. |
| Assessment of use of biologics within the last 6 months for CRS is essential for the routine assessment of CRS control. |
| Assessment of prior endoscopic sinus surgery is essential for the routine assessment of CRS control. |
| Assessment of the extent of prior endoscopic sinus surgery is essential for the routine assessment of CRS control. |
| Assessment of nasal endoscopy findings (e.g. presence of edema, nasal polyps, or drainage) are essential for the routine assessment of CRS control. |
| Assessment of radiographic/imaging findings of the paranasal sinuses are essential for the routine assessment of CRS control. |
| Assessment of the degree to which CRS interferes with a patient’s ability to perform normal activities (e.g. at work/school/home) is essential for the routine assessment of CRS control.  |
| Assessment of occurrence of an Acute Exacerbations of CRS within the last 6 months is essential for the routine assessment of CRS control. |
| Assessment of the severity of lower airway symptoms (e.g. hyperresponsiveness or asthma exacerbation) that is associated with their CRS is essential for the routine assessment of CRS control. |
| The patient’s self-assessment of their own CRS control is essential for the routine assessment of CRS control. |
| Assessment of occurrence or future risk of CRS-related medication side effects is essential for the routine assessment of CRS control. |
| Assessment of occurrence of orbital or intracranial complications of CRS is essential for the routine assessment of CRS control. |

**Table 2. Agreement scores for items in Round 1 of Delphi**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item** | **Mean score** | **Median** | **Range** | **# of outliers****(>2pts from mean)** |
| ***1. Overall symptom severity***  | ***8.4*** | ***9*** | ***3 – 9*** | ***1*** |
| ***2. Systemic corticosteroids*** | ***8.3*** | ***9*** | ***5 – 9*** | ***2*** |
| ***3. Nasal obstruction*** | ***8.1*** | ***9*** | ***3 – 9*** | ***3*** |
| ***4. Patient-reported control*** | ***7.9*** | ***8*** | ***7 – 9*** | ***0*** |
| 5. Nasal endoscopy findings | 7.8 | 9 | 3 – 9 | 4 |
| 6. Overall QOL | 7.8 | 9 | 3 – 9 | 6 |
| 7. Impairment of normal activities | 7.5 | 8 | 3 – 9 | 6 |
| 8. Smell loss | 7.4 | 8 | 3 – 9 | 7 |
| 9. Nasal discharge | 7.1 | 7 | 3 – 9 | 6 |
| 10. Sleep impairment | 7.1 | 7 | 4 – 9 | 9 |
| 11. Occurrence of AECRS | 6.9 | 7 | 3 – 9 | 14 |
| 12. Facial pain/pressure | 6.7 | 7 | 1 – 9 | 9 |
| 13. Severity of lower airway symptoms | 6.7 | 7 | 3 – 9 | 13 |
| 14. Short course antibiotics | 6.5 | 7 | 1 – 9 | 14 |
| 15. Use of biologics | 6.5 | 7 | 1 – 9 | 18 |
| 16. Long-term antibiotics | 6.1 | 7 | 1 – 9 | 8 |
| 17. Emotional/mood disturbance | 6.1 | 6.5 | 1 – 9 | 12 |
| 18. Occurrence/future risk of med side effects | 6.1 | 6.5 | 1 – 9 | 14 |
| 19. Prior ESS | 5.8 | 5.5 | 1 – 9 | 18 |
| 20. Ear discomfort | 5.5 | 5.5 | 1 – 9 | 13 |
| 21. Occurrence orbital/intracranial complications | 5.5 | 6 | 1 – 9 | 23 |
| 22. Extent of prior ESS | 5.3 | 5 | 1 – 9 | 18 |
| 23. Steroid-eluting stents | 4.3 | 5 | 1 – 9 | 11 |
| 24. Radiographic/imaging findings | 4.0 | 3 | 1 – 9  | 15 |

\*Items sorted according to agreement score

\*\*Rows in bold and italics reached full criteria for consensus

\*\*\*Shaded rows reached mean score criteria for consensus

**Table 3. Agreement scores for items in Round 2 of Delphi**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item** | **Mean score** | **Median** | **Range** | **# of outliers****(>2pts from mean)** |
| 1. Smell loss | 7.6 | 8 | 3 – 9 | 4 |
| 2. Nasal endoscopy findings | 7.2 | 8 | 1 – 9 | 6 |
| 3. Overall QOL | 7.1 | 8 | 1 – 9  | 6 |
| 4. Impairment of normal activities | 7.1 | 7 | 2 – 9 | 6 |
| 5. Nasal discharge | 7.0 | 7 | 3 – 9 | 7 |
| 6. Occurrence of AECRS | 6.7 | 7 | 3 – 9 | 11 |
| 7. Short course antibiotics | 6.4 | 7 | 2 – 9 | 9 |
| 8. Facial pain/pressure | 6.4 | 7 | 1 – 9 | 14 |
| 9. Sleep impairment | 6.2 | 7 | 2 – 9 | 14 |
| 10. Severity of lower airway symptoms | 6.1 | 7 | 1 – 9 | 12 |
| 11. Use of biologics | 6.0 | 7 | 1 – 9 | 18 |
| 12. Long-term antibiotics | 5.7 | 6.5 | 1 – 9 | 16 |
| 13. Emotional/mood disturbance | 5.5 | 6 | 1 – 9 | 15 |
| 14. Ear discomfort | 4.7 | 5 | 1 – 8 | 12 |
| 15. Occurrence/future risk of med side effects | 4.5 | 3 | 1 – 9 | 19 |
| 16. Occurrence orbital/intracranial complications | 4.5 | 4 | 1 – 9 | 21 |
| 17. Prior ESS | 4.4 | 4 | 1 – 9 | 17 |
| 18. Extent of prior ESS | 3.8 | 3 | 1 – 9 | 16 |
| 19. Steroid-eluting stents | 3.6 | 3 | 1 – 9 | 11 |
| 20. Radiographic/imaging findings | 3.6 | 3 | 1 – 9 | 12 |

\*Items sorted according to agreement score

\*\*Shaded rows reached mean score criteria for consensus

**Table 4. Comparison of agreement scores between Round 1 and Round 2**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item** | **Mean change\* (SD)** | **Median change\*** | **Range of change\*** | **ICC\*\*** |
| 1. Smell loss | 1.1 (1.3) | 1 | 0 – 6 | 0.60 |
| 2. Nasal endoscopy findings | 1.1 (1.4) | 1 | 0 – 7  | 0.68 |
| 3. Overall QOL | 1.1 (1.4) | 1 | 0 – 6  | 0.69 |
| 4. Impairment of normal activities | 1.1 (1.3) | 1 | 0 – 5 | 0.65 |
| 5. Nasal discharge | 0.6 (0.9) | 0 | 0 – 3  | 0.85 |
| 6. Occurrence of AECRS | 1.5 (1.7) | 1 | 0 – 6 | 0.35 |
| 7. Short course antibiotics | 1.7 (1.5) | 2 | 0 – 6 | 0.43 |
| 8. Facial pain/pressure | 1.7 (1.3) | 2 | 0 – 4 | 0.46 |
| 9. Sleep impairment | 1.7 (1.9) | 1 | 0 - 6  | 0.28 |
| 10. Severity of lower airway symptoms | 1.0 (1.3) | 1 | 0 – 5  | 0.74 |
| 11. Use of biologics | 1.4 (1.7) | 1 | 0 – 6  | 0.68 |
| 12. Long-term antibiotics | 1.6 (1.8) | 1 | 0 – 8  | 0.41 |
| 13. Emotional/mood disturbance | 1.6 (1.6) | 1 | 0 – 6  | 0.54 |
| 14. Ear discomfort | 1.7 (1.6) | 1 | 0 – 6  | 0.40 |
| 15. Occurrence/future risk of med side effects | 1.8 (1.8) | 1.5 | 0 – 6  | 0.67 |
| 16. Occurrence orbital/intracranial complications | 1.5 (1.5) | 1 | 0 – 6  | 0.79 |
| 17. Prior ESS | 1.9 (2.1) | 2 | 0 – 8  | 0.54 |
| 18. Extent of prior ESS | 1.8 (1.9) | 1.5 | 0 – 8  | 0.64 |
| 19. Steroid-eluting stents | 1.4 (1.3) | 1.5 | 0 – 5 | 0.65 |
| 20. Radiographic/imaging findings | 1.5 (1.3) | 2 | 0 – 4  | 0.64 |

\*Absolute value of change, with a participant’s change in score in either direction (increasing or decreasing) considered the same

\*\*ICC = intraclass correlation coefficient, 2-way mixed effects model

**Table 5. Agreement scores for items in Round 3 of Delphi**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Statement** | **Mean score** | **Median** | **Range** | **# of outliers****(>2pts from mean)** |
| 1. Nasal endoscopy findings | 7.7 | 9 | 1 - 9 | 5 |
| 2. Smell loss | 7.6 | 8 | 1 - 9 | 4 |
| 3. Overall QOL | 7.4 | 8 | 3 – 9  | 5 |
| 4. Impairment of normal activities | 7.4 | 7.5 | 3 - 9 | 6 |
| 5. Nasal discharge | 7.2 | 8 | 3 - 9 | 6 |
| 6. Occurrence of AECRS | 6.8 | 7 | 1 - 9 | 11 |
| 7. Sleep impairment | 6.7 | 7 | 3 – 9  | 10 |
| 8. Facial pain/pressure | 6.2 | 7 | 1 – 9  | 10 |
| 9. Severity of lower airway symptoms | 6.1 | 6.5 | 1 – 9  | 13 |
| 10. Emotional/mood disturbance | 6.0 | 6 | 2 – 9  | 15 |
| 11. Use of biologics | 5.8 | 6 | 1 – 9  | 19 |
| 12. Short course antibiotics | 5.8 | 7 | 1 - 9 | 17 |
| 13. Long-term antibiotics | 5.7 | 7 | 1 – 9  | 32 |
| 14. Prior ESS | 5.2 | 5 | 1 – 9  | 22 |
| 15. Ear discomfort | 5.1 | 5 | 1 – 9  | 16 |
| 16. Occurrence/future risk of med side effects | 5.0 | 5 | 1 – 9  | 19 |
| 17. Occurrence orbital/intracranial complications | 4.6 | 4.5 | 1 – 9  | 18 |
| 18. Extent of prior ESS | 4.1 | 3 | 1 – 9  | 32 |
| 19. Steroid-eluting stents | 3.8 | 3 | 1 – 9  | 13 |
| 20. Radiographic/imaging findings | 3.4 | 3 | 1 – 9  | 11 |

\*Items sorted according to agreement score

\*\*Shaded rows reached mean score criteria for consensus

**Table 6. Comparison of agreement scores between Round 2 and Round 3**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item** | **Mean change\* (SD)** | **Median change\*** | **Range of change\*** | **ICC\*\*** |
| 1. Nasal endoscopy findings | 0.5 (0.4) | 0 | 0 – 7  | 0.82 |
| 2. Smell loss | 1.2 (1.7) | 1 | 0 – 8  | 0.36 |
| 3. Overall QOL | 1.2 (1.2) | 1 | 0 – 4 | 0.68 |
| 4. Impairment of normal activities | 1.3 (1.6) | 1 | 0 – 7  | 0.44 |
| 5. Nasal discharge | 0.7 (0.9) | 0 | 0 – 2 | 0.83 |
| 6. Occurrence of AECRS | 1.5 (1.8) | 1 | 0 – 6 | 0.37 |
| 7. Sleep impairment | 1.4 (1.5) | 1 | 0 – 5  | 0.49 |
| 8. Facial pain/pressure | 1.1 (1.5) | 0 | 0 – 6  | 0.63 |
| 9. Severity of lower airway symptoms | 0.9 (1.3) | 0.5 | 0 – 5 | 0.75 |
| 10. Emotional/mood disturbance | 1.4 (1.3) | 1 | 0 – 6  | 0.63 |
| 11. Use of biologics | 1.0 (1.1) | 1 | 0 – 4  | 0.84 |
| 12. Short course antibiotics | 1.2 (1.8) | 0 | 0 – 6  | 0.53 |
| 13. Long-term antibiotics | 1.2 (1.5) | 1 | 0 – 5  | 0.71 |
| 14. Prior ESS | 1.6 (1.8) | 1 | 0 – 7 | 0.63 |
| 15. Ear discomfort | 1.3 (1.3) | 1 | 0 – 4 | 0.64 |
| 16. Occurrence/future risk of med side effects | 1.3 (1.6) | 1 | 0 – 6 | 0.70 |
| 17. Occurrence orbital/intracranial complications | 0.5 (0.7) | 0 | 0 – 2  | 0.95 |
| 18. Extent of prior ESS | 1.0 (1.1) | 1 | 0 – 4  | 0.83 |
| 19. Steroid-eluting stents | 1.1 (1.5) | 0 | 0 – 5  | 0.63 |
| 20. Radiographic/imaging findings | 0.9 (1.3) | 0  | 0 – 4 | 0.74 |

\* Absolute value of change, with a participant’s change in score in either direction (increasing or decreasing) considered the same

\*\*ICC = intraclass correlation coefficient, 2-way mixed effects model

**Table 7. Top scoring statements reaching consensus**

|  |
| --- |
| **Statements reaching full consensus criteria** |
| Assessment of Overall Symptom Severity attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of use of systemic corticosteroids within the last 6 months for CRS is essential for the routine assessment of CRS control. |
| Assessment of Severity of Nasal Obstruction attributed to CRS is essential for the routine assessment of CRS control. |
| The patient’s self-assessment of their own CRS control is essential for the routine assessment of CRS control. |
| **Statements close to consensus (reaching mean agreement score criteria but not full criteria)** |
| Assessment of nasal endoscopy findings (e.g. presence of edema, nasal polyps, or drainage) are essential for the routine assessment of CRS control. |
| Assessment of Severity of Smell Loss attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of Overall Quality of Life attributed to CRS is essential for the routine assessment of CRS control. |
| Assessment of the degree to which CRS interferes with a patient’s ability to perform normal activities (e.g. at work/school/home) is essential for the routine assessment of CRS control.  |
| Assessment of Severity of Nasal (anterior/post-nasal) Discharge attributed to CRS is essential for the routine assessment of CRS control. |

**FIGURES LEGENDS**

**Figure 1.** Box-and-whisker plots of agreement scores for each statement for the first round of the Delphi. Items reaching consensus are shaded/highlighted in dark grey. Items meeting mean score criteria—but not full criteria—for consensus are shaded/highlighted in light grey.

**Figure 2.** Box-and-whisker plots of agreement scores for each statement for the second round of the Delphi. Items meeting mean score criteria—but not full criteria—for consensus are shaded/highlighted in light grey.

**Figure 3.** Box-and-whisker plots of agreement scores for each statement for the third round of the Delphi. Items meeting mean score criteria—but not full criteria—for consensus are shaded/highlighted in light grey.