

Disease control in chronic rhinosinusitis: a qualitative study of patient perspectives*

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Abstract

Background: The definition of disease control in chronic rhinosinusitis (CRS) is an active area of study. However, investigations have not engaged CRS patients in how they think about disease control. This study seeks to understand the patient perspective on CRS disease control.

Methods: Qualitative phenomenological study using constant comparative methodology was applied. The research team conducted 10, one-on-one interviews with CRS patients ranging from 22 to 55 minutes in length. The content of the interview protocol was determined through iterative discussion amongst all authors. Two authors served as coders to identify recurrent themes. Themes were analyzed for meaning and conclusions were summarized.

Results: Three recurring themes determined from patients were that (1) use of the terminology “control” adequately represents this phenomenon, (2) components of control could be classified into four main themes relating to CRS symptomatology, exacerbation of comorbid disease, quality of life and acute exacerbations of CRS, and (3) when patients deem their CRS is uncontrolled they are more willing to escalate their treatment to include escalating their daily maintenance regimen, seeking otolaryngology referral, taking rescue medication or undergoing endoscopic sinus surgery.

Conclusions: CRS patients consider their daily symptoms, the severity and frequency of CRS exacerbations, impact on quality of life as well as exacerbation of comorbid disease when thinking about their disease control. Disease control is a goal of treatment for patients and uncontrolled disease motivates patients to seek further treatment. Physicians should explore all components of CRS control when considering disease status and need for further treatment.

Key words: chronic rhinosinusitis, disease control, patient perspective, qualitative study, quality of life, sinonasal symptoms, acute exacerbations, sinus infections, asthma, productivity

Introduction

In the management of chronic diseases when cure is not an option, the goal of treatment is instead to achieve disease control. Disease control can be described as the degree to which manifestations of the disease process are acceptable⁽¹⁾. The concept of disease control has been a well-established treatment goal and topic of research in chronic airway diseases such as asthma and allergic rhinitis, but is still relatively new in chronic rhinosinusitis (CRS). A possible definition for CRS disease control was first pro-

posed in the 2012 European Position Paper on Chronic Rhinosinusitis and Nasal Polyps (EPOS) and reiterated by EPOS 2020, however this definition is based entirely on consensus expert opinion^(2,3). Since this introduction, the definition and concept of CRS disease control has been an active area of study⁽⁴⁻⁷⁾. Derivation of a comprehensive definition for CRS disease control is an important long term goal because clear criteria of CRS disease control-as the ultimate goal for treatment of CRS⁽¹⁾-may be used by primary care practitioners, allergists, otolaryngolo-

gists and rhinologists alike to ensure a minimal level of care of CRS patients. As a global metric of disease burden, CRS disease control is likely to include elements of various CRS disease manifestations. The ultimate downstream consequences of CRS disease manifestations include quality of life (QOL) detriment and costs to society related to healthcare and lost productivity^(3,8-11). The most prominent manifestation of CRS is the chronic symptomatology associated with CRS and which is also the primary driver of decreased QOL^(12,13). However, CRS has many other disease manifestations including the occurrence of acute exacerbations of CRS (AECRS)^(14,15) and exacerbation of pulmonary disease^(16,17).

Previous work has suggested that, on the whole, the physician's view of CRS disease control may be different than the patient's view⁽⁴⁾, with patients primarily focusing on their sinonasal symptoms^(4,18,19). However, to date, no study has comprehensively characterized the different perspectives of patients in relation to their CRS disease control. It is not even known how well the concept of disease control resonates with patients. Because any definition of CRS disease control should be developed with input from patients, who are primary stakeholders, as well as healthcare providers, we sought to comprehensively characterize the perspectives of CRS patients with respect to CRS disease control. We used a qualitative study design, which included interviewing CRS patients and analyzing the transcripts of those interviews for recurring themes. We sought to understand how CRS patients view the concept of disease control and what CRS disease manifestations do patients consider, in determining their degree of CRS disease control. We believe that the results of this study could directly inform the development of future CRS disease control measures and definitions.

Methods

Study participants

This study was approved by the Institutional Review Board of the University of Cincinnati College of Medicine. Adult patients (18 years and older) with a diagnosis of CRS based on consensus criteria⁽²⁰⁾ who spoke English and were able to communicate over telephone were recruited to be in the study. Due to small sample size, care was taken to select a balanced representation of participants from multiple demographic categories (such as gender, race and socioeconomic status). Informed consent was obtained. Exclusion criteria included diagnosis of cystic fibrosis, vasculitis, sarcoidosis and immunodeficiency. Patients were recruited from a tertiary care rhinology practice by a separate research coordinator to offset any potential power dynamic or undue influence the treating physician may have on their patients. Basic demographic information including age and gender were obtained. Clinical characteristics including smoking status, history of nasal polyps, comorbid asthma and allergy confirmed by skin prick test were recorded. The 22-item sinonasal outco-

mes test (SNOT-22) and Lund Kennedy (LK) endoscopic score from the last clinic visit were recorded for each participant.

Study design

Qualitative phenomenological study using constant comparative methodology was applied. The content of the interview protocol was determined through iterative discussion amongst the entire research team, and a standardized script consisting of semi-structured questions was developed. Ten, one-on-one interviews with participants that ranged in duration from 22 to 55 minutes in length were conducted between patients and a member of the research team. To avoid a power differential that may confound participant responses, the interviewer (V.W.) was not the treating physician. Conversations were recorded and transcribed, removing all patient identifiers. Two of the authors (M.T. and K.M.P.) served as coders and a codebook was created and used to identify recurrent themes.

Data analysis

Descriptive statistics were used to summarize the participant demographics and clinical characteristics. The first five interviews were performed, transcribed and coded. The team then met to discuss recurring themes and whether data saturation was met. At this time, data saturation was felt to be met for some themes, while others required more clarification. The interview protocol was further supplemented, and five more interviews were conducted by the same author with five new participants. The interviews were then transcribed and coded. Through iterative discussion among the research team, themes were analyzed for meaning and conclusions drawn.

Results

Demographics and clinical characteristics

There were 10 participants, 6 females and 4 males, with an average age of 52.2 years (Standard Deviation = 15.7). Seven participants had CRS with nasal polyps. Six participants had comorbid asthma, and 7 participants had aeroallergen hypersensitivity. No participants were smokers. The mean SNOT-22 score was 49.1 (Standard Deviation [SD] = 16.7). The mean LK endoscopic score was 6.4 (SD = 3.9).

Terminology/definition

We first gave our participants a working definition of chronic disease control as "the degree to which all manifestations of disease are within acceptable limits". We then explored the word control and asked our participants to further define this concept based on their lived experience with CRS.

Regarding terminology, most participants felt the word control was the correct word to use stating that the word itself is understandable across a range of backgrounds and education levels.

"I like the control concept. The idea of controlling the syndrome or the disease makes sense to me. When [my doctor] talked to me during our appointments, it makes perfect sense that we're attempting to control a chronic condition."

"I think control makes sense. It's similar to when you have your asthma under control. So, I think the word control people would understand."

Moreover, the participants felt that the word control can cover a range of levels from uncontrolled to well controlled. Participants stated:

"Control covers the entire spectrum. It can either be really well controlled or it can be poorly controlled."

"Yeah, that would certainly be a good part of the definition of control because it may be less controlled sometimes, and more controlled most of the time."

Speaking the control concept's very essence, participants summarized their ideas of controlled disease as

"Where I don't really notice it."

"It means that it's something bearable, it's not affecting you negatively. That's what control means to me; not having any negative affect, it's bearable or tolerable."

Discussing the concept of control further, participants acknowledged the likely heterogeneous, patient-dependent nature of disease control. Specifically, participants explained the word acceptable in the definition of disease control is useful as it lets control to be somewhat individualized to a person's tolerance.

"What was acceptable to me may not be acceptable to somebody brand new to this."

"I guess each person is a little different in the opinion of what's an acceptable limit."

One participant also aptly pointed out acceptable may be different from the viewpoint of the patient versus the physician.

Components of control

We next asked participants to discuss what components of their CRS they considered when deciding if their disease was controlled or acceptable. We identified four recurrent overarching categories of CRS disease manifestations that participants considered when evaluating if their disease was controlled.

These categories of CRS disease manifestations included sino-nasal symptom burden, acute exacerbations of CRS, comorbid pulmonary disease exacerbation, and quality of life impact. For example,

"I would consider the number of infections per year. The severity of the infection and the length of time that the infection lasts. If my infection leads to an asthma attack. On a day-to-day basis, the things like how much congestion I have and drainage. If I have discomfort like sinus headaches or other sorts of sinus pain. How much it disrupts my life, my work, things like that."

"I attribute control to reducing the number of sinus infections, but also improving breathability, reducing congestion, increasing quality of life. All those would be under control."

These categories were then further explored in the interviews.

Symptom burden

"If I can smell and taste. I don't have pressure or anything. Then it's okay."

"It [control] means being able to breathe. I feel like I'm constantly congested, and when I speak, it sounds stuffy all the time. And I have lots of post-nasal drip. It's just this, obviously, chronic thing. It would feel kind of liberating to have control."

"You're never going to feel a hundred percent better, but at least somewhat better to where you feel like you're not totally weighed down by your symptoms."

Acute exacerbations of chronic rhinosinusitis

"So when it was less well-treated I would miss work frequently because I would have serious infections. I would have to repeatedly go to the doctor multiple times per year because of these infections. So it was back and forth to the doctor, taking a lot of antibiotics which is probably not good cumulatively. So my general well-being, it was not good when I was suffering from a lot of infections frequently. It made me tired. It made me not feel good. It affected my mood and my quality of life."

"[well controlled] is not having the junk in your nose and not having to be on prednisone or antibiotics repeatedly"

"I think quality of life is a big overarching concern and probably also long term medical considerations from repeat infections. It's probably not good to have repeated infections. I'm sure it's not good for your body to constantly be dealing with infections like that. I think that's what I would weigh is the quality of life"

and the long term effects of repeated infections and costs.”

Exacerbation of comorbid pulmonary disease

“Acceptable limits would be being able to survive, being able to breathe without a life-threatening asthma attack or discomfort.”

“My asthma is always worse when my sinuses are bad. If I want asthma control, I have to have sinus control.”

“Repeated coughing or wheezing tell me my sinuses are bad, not controlled”

Quality of life impact

“I worry about how it [poor control of CRS] impacts my work”

“Is it causing you difficulties in day-to-day tasks and sleeping at night? Those can all be part of a definition of what controlled means”

“I had about a year period where I couldn't functionally work out because of my sinuses. So I had about 30 to 40 pounds of weight gain while working, which in my career is very bad. Since I've been controlled, I can work out again and I've lost 35 to 40 of it back off. It's been a major improvement.”

Disease control is a goal of treatment for patients

Most participants described a similar arc of treatment escalation that they pursued in order to gain control of their CRS. Once control was achieved, participants perform a maintenance treatment regimen which keeps their disease in control. For example,

“...once I started on my rinses with the steroids, my symptoms have been stable. I have avoided surgery so far and hope to never have to have sinus surgery”

“It means if I didn't take daily meds, I was having a problem with it. You know, with my daily meds, I'm controlling it”

“The infections, they kept reoccurring, so I was concerned about having to keep taking antibiotics and steroids. That became a problem and influenced my decision to have surgery because I know it's not good to take too many antibiotics.”

“I mean, now that I've been made aware that my quality of breathing can improve, I don't feel like it's controlled. If you would've asked me this maybe two months ago, I would've been like, “Yeah, it's totally under control,” like, “I got this. I just have to take all these medicine type things.” But now that I'm

aware that there are other treatment methods that I could use, or other treatments that could happen to me to help me breathe better, I don't feel like it's controlled.”

“Yes. Sometimes I think that I am fixing sinus infections myself because I'm rinsing and doing all these things. And I feel like, “Okay, it looked like it had infection. Now, it looks better.” So, then I just go along. But this one was so chronic, and it seemed to be getting worse. So, that was the reason I went in to see the doctor. I felt like I probably needed medication, and my rinsing wasn't going to help anymore.”

Participants often described a ladder of treatment escalation that first involved using over-the-counter medications and saline irrigations, then going to see a physician, which could be their primary care physician (PCP), an Urgent Care physician or an otolaryngologist. For some patients, a visit to the PCP or Urgent Care usually preceded escalation to visiting their otolaryngologist, highlighting the important of general practitioners in the care of CRS ⁽²¹⁾. Beyond seeking out professional medical care, participants described starting or modulating prescription medications to further escalate treatment, occasionally having to take rescue medications, and then either taking adjunct medications or pursuing endoscopic sinus surgery based on this concept of control.

Discussion

A definition of disease control in CRS was derived based on expert opinion and first proposed in EPOS in 2012 and updated in 2020 ^(2,3). In these guidelines, control is defined as “a disease state in which the patient does not have symptoms, or the symptoms are not impacting quality of life” ⁽³⁾. EPOS proposes assessing control based on the clinical status of the patient over the prior month and includes assessment of nasal blockage, nasal drainage, facial pain/pressure, decreased sense of smell, sleep disturbance, and need for rescue medications, with nasal endoscopy findings considered/incorporated when available. Based on these factors, a provider can then rate a patient's CRS as controlled, partly controlled or uncontrolled and then escalate, de-escalate or maintain treatment accordingly ⁽³⁾. This is particularly important since the majority of healthcare visits for CRS are to providers who are general practitioners ⁽²¹⁾. Notable to the EPOS criteria for CRS disease control is that the document did not consider or incorporate the perspectives of CRS patients, who certainly comprise a key stakeholder in how control is defined in this disease which primarily has a QOL impact on the patient. In this study, we therefore studied the patient perspective on CRS disease control using qualitative methodology to add context and richness to the concept of disease control in CRS.

Our results show that CRS patients understand the word control.

Likewise, the term resonates with them as a reflection of the underlying construct, and they feel comfortable using this terminology when communicating with their health care provider about their CRS disease control. There was consensus amongst patient perspectives that in well controlled CRS, the manifestations of the disease are acceptable, tolerable, and bearable. Moreover, well controlled CRS did not have a meaningful impact on completing daily tasks such as going to work or school. Through our interviews, we found that which specific elements of CRS that must be acceptable to achieve control is to some degree patient-specific and that providers and patients may have different perspectives on what is tolerable. Furthermore, we found that patients are able to, and do incorporate several different CRS disease manifestations when judging if their CRS is controlled. These different disease manifestations include chronic sinonasal symptomatology, severity and frequency of AECRS, impact on comorbid pulmonary disease and the overall QOL detriment that is experienced. Finally, patients described what they were willing to do, to achieve control of their CRS. This process usually involved escalation of treatment until control was achieved. Patients describe a progression from starting with over-the-counter regimens, to seeking care from a healthcare provider (e.g., primary care doctor, urgent care, or otolaryngologist) and then starting on a daily medication regimen. Based on the factors described above, patients felt their disease was either controlled or not, in which case they moved on to either adjuvant medical therapy, such as biologics, or went on to get endoscopic sinus surgery.

Previous studies of CRS disease control have focused on identifying the dominant determinants of how patients have rated their CRS disease control but have never delved into an open-ended discussion with patients about their perspectives on CRS disease control as we have done in this study. For example, patient-reported CRS control has been shown to be strongly correlated with the downstream consequences of CRS such as decreased general quality of life⁽²²⁾ and lost productivity⁽²³⁾. Previous studies have also shown that the nasal symptoms of CRS are the dominant determinants of patient-reported CRS disease control^(4,19,24). The correlation between patient-reported CRS control and sinonasal symptoms is so strong that the burden of CRS symptoms has been shown to be an accurate predictor of how controlled patients assess their CRS to be⁽²⁵⁾. Amongst nasal symptoms of CRS, nasal obstruction and nasal drainage have been shown to be most dominantly associated with patient-reported CRS disease control, with olfactory dysfunction appearing to be largely redundant to nasal obstruction and nasal drainage⁽¹⁸⁾. While these previous studies have identified the most dominant and consistent determinants of how patients rate their level of CRS disease control, our current study shows that there is a rich heterogeneity with respect to how the

various manifestations of CRS may impact patient-perceived CRS disease control.

Our results have important implications for communication between the healthcare provider and the CRS patient. Previous work has shown there may be discordance between a patient and physician's perspective of CRS disease control⁽⁴⁾. Because CRS disease control is an individualized concept, and may be different based on the perspective of the stakeholder, i.e. patient or the health care provider, it is particularly important to explicitly discuss specific CRS disease manifestations beyond sinonasal symptomatology, such as frequency of AECRS, exacerbation of comorbid pulmonary disease and QOL decrease when treatment decisions are being made. This may better align treatment goals between patients and their providers and help patients achieve control. At the same time, our study also highlights that while certain dominant factors, such as nasal symptoms of CRS, may have a significant impact on patient-reported CRS disease control, there are also many patient-specific determinants of control which emphasizes the need to specifically ask patients for input into their degree of CRS disease control. Recently, we've shown that a single question to measure patient-reported CRS disease control is a valid measure of CRS disease burden⁽⁷⁾. Our results here suggest that a patient-centered assessment of CRS disease control, for example asking patients to report their level of CRS control, may be an important component of future measures of CRS disease control.

This study should be viewed in the context of its limitations. All participants interviewed were recruited from a tertiary care rhinology clinic and likely have a greater burden of disease which may bias their perspective. Furthermore, participants were recruited and interviewed by an associate of their treating physician. Because of this, participants may have felt some coercion to participate (despite being counseled there were no consequences to declining) and answer questions the way they think their doctor wanted them to answer instead of their honest opinion (despite being counseled there were no clinical implications based on their answers). Future study may benefit from recruiting patients outside of the physician's own patient population and amongst all disease severity. Nevertheless, this is the first study reporting patient perspectives on CRS disease control and therefore provides the basis for further study.

Conclusion

CRS patients understand the concept of control with respect to their CRS and the terminology resonates with them as a reflective of the underlying construct. CRS patients consider several CRS disease manifestations including their daily symptoms, the severity and frequency of AECRS, the impact on their quality of life as well as exacerbation of comorbid pulmonary disease

when thinking about their disease control. Moreover, uncontrolled disease does motivate patients to seek further treatment. Physicians should explore all these components of CRS disease control with their patients when considering disease status and need for further treatment. Moreover, patient perspectives should be considered in definitions of CRS disease control.

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Authorship contribution

VW: collection of data, analysis of results, write up of manuscript, critical review of all contents; MT: collection of data, analysis of results, write up of manuscript, critical review of all contents; AAT: concept of study, write up of manuscript, critical review of all contents; ARS: concept of study, collection of data, analysis of results, write up of manuscript, critical review of all contents; KMP: concept of study, collection of data, analysis of results, write up of manuscript, critical review of all contents.

Conflict of interest

The authors declare that there are no conflicts of interests regarding the publication of this paper.

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References

- Sedaghat A, Hopkins C. Chronic rhinosinusitis disease control as a metric for guiding treatment. *Rhinology* 2020; 58:193.
- Fokkens WJ, Lund VJ, Mullol J et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2012. *Rhinol Suppl* 2012; 23:1-298.
- Fokkens WJ, Lund VJ, Hopkins C et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2020. *Rhinology* 2020; 58:1-464.
- Sedaghat AR, Hoehle LP, Gray ST. Chronic rhinosinusitis control from the patient and physician perspectives. *Laryngoscope Invest Otolaryngol* 2018; 3:419-433.
- Kohli P, Soler ZM, Storck KA, Shahangian A, Banglawala SM, Schlosser RJ. Responsiveness and reliability of the Sinus Control Test in chronic rhinosinusitis. *Rhinology* 2017; 55:39-44.
- Little RE, Schlosser RJ, Smith T et al. Disease control after surgery for chronic rhinosinusitis: prospective, multi-institutional validation of the Sinus Control Test. *Int Forum Allergy Rhinol* 2021; 11:106-114.
- Phillips KM, Houssein FA, Singerman K, Boeckermann LM, Sedaghat AR. Patient-reported chronic rhinosinusitis disease control is a valid measure of disease burden. *Rhinology* 2021; 59(6):545-551.
- Hoehle LP, Phillips KM, Speth MM, Caradonna DS, Gray ST, Sedaghat AR. Responsiveness and minimal clinically important difference for the EQ-5D in chronic rhinosinusitis. *Rhinology* 2019; 57:110-116.
- DeConde AS, Soler ZM. Chronic rhinosinusitis: Epidemiology and burden of disease. *Am J Rhinol Allergy* 2016; 30:134-139.
- Wahid NW, Smith R, Clark A, Salam M, Philpott CM. The socioeconomic cost of chronic rhinosinusitis study. *Rhinology* 2020; 58:112-125.
- Lourijsen ES, Fokkens WJ, Reitsma S. Direct and indirect costs of adult patients with chronic rhinosinusitis with nasal polyps. *Rhinology* 2020; 58:213-217.
- Hoehle LP, Phillips KM, Bergmark RW, Caradonna DS, Gray ST, Sedaghat AR. Symptoms of chronic rhinosinusitis differentially impact general health-related quality of life. *Rhinology* 2016; 54:316-322.
- Speth MM, Hoehle LP, Phillips KM, Caradonna DS, Gray ST, Sedaghat AR. Changes in chronic rhinosinusitis symptoms differentially associate with improvement in general health-related quality of life. *Ann Allergy Asthma Immunol* 2018; 121:195-199.
- Phillips KM, Hoehle LP, Bergmark RW, Caradonna DS, Gray ST, Sedaghat AR. Acute Exacerbations Mediate Quality of Life Impairment in Chronic Rhinosinusitis. *J Allergy Clin Immunol Pract* 2017; 5:422-426.
- Phillips KM, Barbarite E, Hoehle LP, Caradonna DS, Gray ST, Sedaghat AR. Clinical Traits Characterizing an Exacerbation-Prone Phenotype in Chronic Rhinosinusitis. *Otolaryngol Head Neck Surg* 2019; 161:890-896.
- Phillips KM, Talat R, Caradonna DS, Gray ST, Sedaghat AR. Quality of life impairment due to chronic rhinosinusitis in asthmatics is mediated by asthma control. *Rhinology* 2019; 57:430-435.
- Banoub RG, Phillips KM, Hoehle LP, Caradonna DS, Gray ST, Sedaghat AR. Relationship between chronic rhinosinusitis exacerbation frequency and asthma control. *Laryngoscope* 2018; 128:1033-1038.
- McCann AC, Trope M, Walker V et al. Olfactory Dysfunction is not a Determinant of Patient-Reported Chronic Rhinosinusitis Disease Control. *Laryngoscope* 2021; 131:E2116-e2120.
- Snidvongs K, Heller GZ, Sacks R, Harvey RJ. Validity of European position paper on rhinosinusitis disease control assessment and modifications in chronic rhinosinusitis. *Otolaryngol Head Neck Surg* 2014; 150:479-486.
- Rosenfeld RM, Piccirillo JF, Chandrasekhar S et al. Clinical practice guideline (update): adult sinusitis. *Otolaryngol Head Neck Surg* 2015; 152:S1-s39.
- Bhattacharyya N. Contemporary Incremental Healthcare Costs for Chronic Rhinosinusitis in the United States. *Laryngoscope* 2021; 131:2169-2172.
- Gray ST, Hoehle LP, Phillips KM, Caradonna DS, Sedaghat AR. Patient-reported control of chronic rhinosinusitis symptoms is positively associated with general health-related quality of life. *Clin Otolaryngol* 2017; 42:1161-1166.
- Campbell AP, Hoehle LP, Phillips KM, Caradonna DS, Gray ST, Sedaghat AR. Symptom control in chronic rhinosinusitis is an independent predictor of productivity loss. *Eur Ann Otorhinolaryngol Head Neck Dis* 2018; 135:237-241.
- Banglawala SM, Schlosser RJ, Morella K et al. Qualitative development of the sinus control test: a survey evaluating sinus symptom control. *Int Forum Allergy Rhinol* 2016; 6:491-499.
- Gray ST, Phillips KM, Hoehle LP, Caradonna DS, Sedaghat AR. The 22-item Sino-Nasal Outcome Test accurately reflects patient-reported control of chronic rhinosinusitis symptomatology. *Int Forum Allergy Rhinol* 2017; 7:945-951.

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QUESTIONNAIRE

Participant # _____, Phase 1

Interviewer: _____

Date: _____

Phase 1 Interview Questions:

Warmup:

How is your CRS?

Control – Phase 1

- 1) What does it mean for your CRS to be controlled?
- 2) So when we talk about CRS control, we mean, “the degree to which all manifestations of a disease are within acceptable limits.”
 - i. Based on that, would you change your definition of control?
 - ii. What does acceptable limits mean to you?
- 3) How can we, as physicians, ask about this concept of control? For example, does the term control make sense, or should we use different terminology?

Symptoms & perception of control:

What elements of CRS go into your judgement of control? (Con, S)

- A) Symptoms? What kinds of symptoms? (Con, S)
 - a. No right or wrong here – don’t agree unless you actually experience it?
 - b. Sleep?
 - c. Mood?
- B) Elaborate on any CRS manifestations to understand exactly what element is being weighed to judge control

Quality of life/activity interference:

How has living with CRS affected you? (Con, V)

What makes a good week with your CRS? (Con, M)

What makes a bad week with your CRS? (Con, M)

What’s the most challenging part of living with CRS? (Con, V)

How does productivity or activity avoidance play a role in your judgement of CRS control? (Con, S)

Has CRS ever affected your relationships? (friends/family) ...How so? (Con, M)

Treatment options & perception of control:

What steps do you take to try to control your CRS? (Con, V)

How do you deal with a bad CRS week? (Con, M)

How do antibiotics and need for prednisone play a role in control? Medications in general? Surgery? (Con, S)

(ie if you have zero symptoms but you have to take prednisone or antibiotics all the time, would that be something you're happy with?)

Do you use any notion of control to inform how you take medications? Would you? (Con, S)

(#9) What factors would you (and should we) consider in making a decision about how much medication we give you (or offer surgery)? (Con, S)

Do you think these factors (in #9) or your judgement of disease control has changed over time? (Con, S)

Exacerbation - Phase 1

1) What does having a CRS exacerbation or flare mean to you?

2) If you could define a CRS exacerbation or flare in one sentence, what would it be?

3) So when we talk about an Acute Exacerbation of CRS, we mean, "worsening of symptoms that gets better either on its own or with medication." How can we, as physicians, communicate and ask about this concept of AECRS?

i. What do you call this? Is flare or exacerbation a better term (or something else)?

Symptoms:

What bothers you the most when your CRS is bad? (Ex, V)

What symptoms do you experience during an AECRS? [Prompt about nasal, pain/pressure, sleep if not brought up] (Ex, S)

What is your worst symptom? (Ex, M)

What is the easiest symptom do deal with? (Ex, M)

Does an AECRS affect anything else about your health besides your nose/sinuses? (Ex, S)

Does your sleep ever get affected by an exacerbation? ...How so? (Ex, M)

Does your mood ever get affected by an exacerbation? ...How so? (Ex, M)

How do you differentiate an AECRS from your normal symptoms?

Do your normal symptoms have some day-to-day variability and if so, how do you differentiate the AECRS from normal variation? Is an AECRS any change in symptoms? How does duration play a role in whether you experience an AECRS? (Ex, S)

Compare/contrast AECRS to a sinus infection (Ex, S)

Quality of life/activity interference:

What's your top priority when your CRS is bad/flared? (Ex, V)

How does an AECRS affect your day-to-day life? Are there functional consequences? (Ex, S)

Is there anything that you can't do when your CRS is bad? (Ex, V)

*What would it take for you to miss work due to an AECRS? (Ex, S)

Has an exacerbation ever affected your school/job? ...How so? (Ex, M)

Seeking Care:

How do you decide when it's time to seek medical care for CRS? (Ex, V)

Treatment:

What do you do when your CRS flares? (Ex, V)

Are there certain medications that you use? Prescription or over the counter? (M&S)

Participant # _____, Phase 1

Interviewer: _____

Date: _____

Demographics:

Age: _____

Gender: male female nonbinary

Smoking: never active previous (quit >10 yrs ago) previous (quit <10 yrs ago)

Asthma: yes no

Allergies: yes no

Polyps: yes no

Education: What is your highest degree attained? _____
(high school, associate, bachelor, graduate)

Thoughts on Interview (memo):

Participant # _____, Phase 1

Interviewer: _____

Date: _____

Phase 2 Interview Questions:

Warmup:

How is your CRS?

Control – Phase 2

- 4) What does it mean for your CRS to be controlled?
- 5) So when we talk about CRS control, we mean, “the degree to which all manifestations of a disease are within acceptable limits.”
 - i. What does acceptable limits mean to you?
 - ii. Based on that, would you change your definition of control?
 - iii. We have heard people express their CRS is “controlled” or “not controlled”. Do you feel your disease is like this, or is there more of a range?”
- 6) How can we, as physicians, ask about this concept of control? For example, does the term control make sense, or should we use different terminology?

Components of control:

- 7) What elements of CRS go into your judgement of control? (Start open ended)
 - B) Symptoms? What kinds of symptoms?
 - a. Does symptom severity or frequency impact your judgement on whether your disease is controlled?
 - C) Do the severity or frequency of sinus infections impact your perception of disease control?
 - D) Do you have problems with your lungs (ex asthma, bronchitis, COPD)?
 - a. If so, does your CRS impact your lung disease?
 - b. Do you incorporate how CRS impacts your lungs when thinking about how well your CRS is controlled?
 - E) How does productivity or activity avoidance play a role in your judgement of CRS control?
 - F) When thinking about CRS control, do you factor in how CRS impacts your life? If so how? (start open ended)
 - a. Quality of life
 - b. Mood
 - c. Sleep
 - d. Social Relationships
 - G) "What time frame are you thinking about when you're considering your "current" level of disease control? (Days, weeks, months)
 - H) "If we use your reported "current level" of control to make treatment decisions, would you want us to consider a longer time frame? Why or why not?"

Treatment options & perception of control:

- 8) What steps do you take to try to control your CRS? (Con, V)
 - a. Would you consider taking more medicine (either over the counter or prescription)?
 - i. How do antibiotics and need for prednisone play a role in control? (ie if you have zero symptoms but you have to take prednisone or antibiotics all the time, would that be something you're happy with?)
 - b. What causes you to call the doctor (either urgent care, PCP or ENT) to get better control of your CRS?
 - c. Would you consider having surgery or if you have already had surgery, what prompted you to decide to undergo surgery?
- 9) What factors would you (and should we) consider in making a decision about how much medication we give you (or offer surgery)?

Exacerbation - Phase 2

Transition Sentence: Next, I want to focus our conversation specifically on acute exacerbations of CRS.

- 4) What does having a CRS exacerbation or flare mean to you?
- 5) So when we as doctors talk about an Acute Exacerbation of CRS, we mean, "worsening of symptoms that gets better either on its own or with medication." How can we communicate and ask about this concept of AECRS?
 - i. What do you call this? Is flare or exacerbation a better term (or something else)?

Impact on Patient:

- 6) What bothers you the most when you are having a flare? (start open ended)
- 7) What symptoms do you experience during an AECRS? [Prompt about nasal, pain/pressure, sleep if not brought up]
- 8) Does an AECRS affect anything else about your health besides your nose/sinuses? (start open ended)
- 9) Does your sleep ever get affected by an exacerbation? ...How so? (Ex, M)
- 10) Does your mood ever get affected by an exacerbation? ...How so? (Ex, M)
- 11) Are your lung problems (if you have any) impacted by an exacerbation? .. how so?
- 12) How does an AECRS affect your day-to-day life? Are there functional consequences? (Ex, S)
- 13) What would it take for you to miss work due to an AECRS? (Ex, S)

Drilling down on AECRS

- 14) How do you differentiate an AECRS from your normal symptoms?
- 15) Do your normal symptoms have some day-to-day variability and if so, how do you differentiate the AECRS from normal

variation? Is an AECRS any change in symptoms? How does duration play a role in whether you experience an AECRS?

16) Compare/contrast AECRS to a sinus infection

17) What is the natural history of your exacerbations/flares?

Treatment:

18) How do you decide when it's time to seek medical care for your CRS exacerbation?

a. Is it the severity?

b. Is it the duration?

c. Is it because your life is being impacted (missing work, social interactions)?

19) What do you do when your CRS flares? Do you have a process or plan?

Participant # _____, Phase 1

Interviewer: _____

Date: _____

Demographics:

Age: _____

Gender: male female nonbinary

Smoking: never active previous (quit >10 yrs ago) previous (quit <10 yrs ago)

Asthma: yes no

Allergies: yes no

Polyps: yes no

Education: What is your highest degree attained? _____
(high school, associate, bachelor, graduate)

Thoughts on Interview (memo):