

# Patient-reported outcome measures for adult chronic rhinosinusitis: A systematic review and quality assessment

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**Background:** With a focus on patient-centered care, there is increasing policy interest in patient-reported outcome measures (PROMs) to inform improvements in health care delivery. Given the importance of understanding patient-reported outcomes during the management of chronic rhinosinusitis (CRS), PROMs will play an essential role in informing and tailoring the right intervention to the right patient.

**Objective:** The objective of this systematic review was to identify and assess the quality of PROMs being used for adults with CRS.

**Methods:** A systematic review of Ovid MEDLINE (R) (1947-May 2015), Embase, and the Cochrane databases was performed using the following key terms: ["chronic" AND "\*sinusitis"] AND [PROM OR patient reported outcome measure\* OR quality of life OR questionnaire OR survey OR valid\* OR develop\*]. An unlimited truncation strategy (placement of \*) was used to capture all variations of terms used. The quality of each PROM was assessed and reported using standardized criteria from the CONsensus-based Standards for the selection of health status Measurement INstruments checklist.

**Results:** A total of 15 PROMs validated for use in adult patients with CRS were identified. Fourteen instruments were specific to adults with CRS, and one was a generic quality-of-life instrument (EuroQol five-dimensional questionnaire [EQ-5D]). There was significant variation in the quality of development and reporting of psychometric properties. Overall, the highest quality validated PROMs for adults with CRS were (1) the 22-item Sinonasal

Outcome Test (19 points), (2) the Questionnaire of Olfactory Disorders (14 points), (3) the Sinusitis Control Test (14 points), and (4) the EQ-5D (13 points). Most of the PROMs were developed for research purposes such as determining changes in health-related quality of life or symptoms after an intervention as opposed to improving clinical decision making.

**Conclusions:** Based on quality assessment, the 22-item Sinonasal Outcome Test, the Questionnaire of Olfactory Disorders, and the Sinusitis Control Test provided the highest quality CRS-specific PROMs, whereas the EQ-5D provided the highest quality generic quality-of-life instrument. Future CRS PROMs will need to incorporate clinical domains that assess common comorbid diseases along with patient values and preferences to improve clinical decision making. (*J Allergy Clin Immunol* 2015;136:1532-40.)

**Key words:** Chronic rhinosinusitis, sinusitis, patient-reported outcome measure, quality of life, systematic review, evidence-based medicine

With efforts to improve the value of health care, there is increasing focus on improving the patient-centeredness of health care delivery.<sup>1,2</sup> At the core of improving patient-centered care is transitioning away from the old paradigm of medicine that "one-size fits all" and instead delivering the right intervention to the right patient. In 2010, the Patient-Centered Outcomes Research Institute was developed to promote and support research focused on outcomes that are meaningful and important to patients.<sup>3</sup> Given that physicians are on the front lines of patient care, it is important that we take the lead and provide policymakers with the information necessary to make appropriate decisions on patient-centered health care delivery.

Patient-reported outcome measures (PROMs) are essential to assess whether or not clinicians are improving the health of patients. As opposed to *objective measures* (ie, laboratory, radiologic, and endoscopic outcomes) or *performance-based measures* (ie, readmission rates, complication rates, or mortality rates), PROMs capture the aspects of care that result in tangible improvements in patient health status, productivity, and overall well-being. Several health care systems around the globe have focused on PROMs as a vehicle to measure and improve the value of care.<sup>4-6</sup> For example, health care providers participating in certain accountable care organizations in the United States will have to provide evidence that the care they have delivered has produced value to the patients as reported by PROMs.<sup>4</sup> PROMs will also be an essential component used to benchmark the performance of health providers and link remuneration to evidence of patient outcomes.<sup>7</sup> Given the trend toward incorporating PROMs into health care delivery, it is imperative to critically assess the quality of current instruments.

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*Abbreviations used*

- COS: Core Outcome Set
- CRS: Chronic rhinosinusitis
- EQ-5D: EuroQol five-dimensional questionnaire
- HRQOL: Health-related quality of life
- PROM: Patient-reported outcome measure
- QOD: Questionnaire of Olfactory Disorders
- SCT: Sinusitis Control Test
- SNOT-20: 20-Item Sinonasal Outcome Test
- SNOT-22: 22-Item Sinonasal Outcome Test

Chronic rhinosinusitis (CRS) is a ubiquitous chronic inflammatory disease that primarily affects patients' health-related quality of life (HRQOL)<sup>8</sup> and daily productivity.<sup>9</sup> Furthermore, patients are often faced with several treatment options<sup>10</sup> and the degree of HRQOL impairment has been demonstrated to be the primary driver of patient treatment decisions<sup>11,12</sup> as well as being an important tool to inform patients about the expected outcomes after treatment.<sup>13,14</sup> Given the importance of understanding

patient-reported outcomes during the management of CRS, PROMs will play an essential role in informing and tailoring the right intervention to the right patient. The objective of this systematic review was to identify and assess the quality of validated PROMs being used for adults with CRS. The goal is to inform policymakers about the most promising PROMs capable of improving the value of care and identify limitations to improve upon for future PROM development.

**METHODS**

For the purposes of this article, a PROM will be defined as any instrument that measures outcomes reported directly by patients about how they function or feel in relation to a health condition and its therapy, without interpretation of the patients' responses by a clinician or anyone else.<sup>15</sup>

**Search strategy**

A primary and secondary literature search was performed during June 2015. The searches aimed to systematically identify all published literature evaluating validated PROMs for CRS. Two reviewers (L.R. and Z.M.S.)

**TABLE I.** Definitions for PROM quality assessment ratings

Properties	Performance domain	Definition	Minimal acceptable level of quality
Development properties	Prestudy hypothesis	Expected quantitative outcomes provided before analysis	+ + if explicitly reported
	Measurement aim	The purpose(s) of the PROM is provided: Discriminatory, Evaluative, or Predictive	+ if not explicitly stated but implied by reading the study; + + if explicitly reported
	Appropriateness	The content of the PROM specifically addresses patients with CRS	+ if PROM validated using old CRS diagnostic criteria; + + if PROM validated using current guideline-based CRS diagnostic criteria
	Concepts	The concepts being measured are defined (ie, functional status, health state preference, or overall HRQOL)	+ if some of the following 4 outcomes reported: Items, Domains, Response, Scoring; + + if all 4 reported
	Item selection	Item selection reflects areas important to the patient population (ie, patients involved in item selection)	+ if only 1 group involved (either patients or clinicians involved); + + if both patients and clinicians involved in item selection
	Interpretability	The degree to which one can assign qualitative meaning to quantitative scores	+ if mean scores (with measure of variation; SD or 95% CI) presented for at least 4 relevant subgroups of patients; + + if MCID explicitly defined
Psychometric properties	Reproducibility (ie, test-retest reliability)	Stability of the PROM over time; assessed by administering the PROM to respondents on 2 occasions and quantifying the correlation between each test	+ if test retest reliability score of $\geq 0.70$ -0.90 + + if retest reliability score of $>0.90$
	Internal consistency	The correlation for which different items in a PROM measure the same underlying construct	+ Cronbach $\alpha$ score between 0.70 and 0.90; + + if score $>0.90$
	Responsiveness	Ability of the PROM to detect clinically significant change over time; assessed by comparing scores before and after an intervention of known efficacy	+ if effect size (ie, difference between means divided by SD) between 0.2 and 0.8; + + if $SDC < MIC$ OR $MIC$ outside of limits of agreement OR responsiveness ratio $> 1.96$ OR area under ROC curve $\geq 0.70$ OR effect size $> 0.8$
	Criterion validity	The extent to which scores on a particular PROM relate to a criterion standard	+ + if correlation with criterion standard $\geq 0.70$
	Floor/ceiling effects	Ability of the PROM to measure accurately across the full spectrum of a construct	+ + if $<15\%$ of the respondents achieve the highest or lowest possible scores
	Acceptability	Reflects the patients' willingness to complete the PROM and impacts on quality of the data	+ $<15\%$ of incomplete data or nonresponse; + + if $<5\%$ incomplete data
	Feasibility	The time, energy, monetary cost, or personnel required by patients or those administering the PROM	+ Reasonable time ( $<10$ min) and resources to collect; + + short time ( $<5$ min), easy to collect/analyze the data statistically

MCID, Minimal clinically significant change; MIC, minimal important change; ROC, receiver operating characteristics; SDC, smallest detectable change.

**TABLE II.** Summary of validated PROMs for adult patients with CRS

PROM	Abbreviation	Type
Chronic Sinusitis Survey <sup>23</sup>	CSS	HRQOL
31-Item Rhinosinusitis Outcome Measurement <sup>24</sup>	RSOM-31	HRQOL
Rhinosinusitis Disability Index <sup>25</sup>	RSDI	HRQOL
16-Item Sinonasal Outcome Test <sup>26</sup>	SNOT-16	HRQOL
20-Item Sinonasal Outcome Test <sup>27</sup>	SNOT-20	HRQOL
Rhinosinusitis Symptom Inventory <sup>28</sup>	RSI	Symptom score
Rhinosinusitis Quality of Life survey <sup>29</sup>	RhinoQoL	HRQOL
The Rhinosinusitis Task Force symptom score <sup>30</sup>	RSTF	Symptom score
22-Item Sinonasal Outcome Test <sup>31</sup>	SNOT-22	HRQOL
Sinonasal 5-item Questionnaire <sup>32</sup>	SNQ	Sinusitis screen
Dysfonctionnement Nasal Chronique Questionnaire <sup>33</sup>	DyNaChron	HRQOL
Questionnaire of Olfactory Disorders <sup>34</sup>	QOD	HRQOL
Adelaide Disease Severity Score <sup>35</sup>	DSS	HRQOL
EuroQoL five-dimensional questionnaire <sup>36</sup>	EQ-5D	Generic QOL/ Health state utility
Sinusitis Control Test <sup>37</sup>	SCT	CRS-specific control

QOL, Quality of life.

independently performed 2 searches to optimize the identification of all relevant literature.

The primary search involved searching Ovid MEDLINE (R) (1947-May 2015), Embase, Cochrane Central register of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts and Reviews of Effects, Health Technology Assessment, and National Health Service Economic Evaluation Database. The following 2 search strategies were combined: ["chronic" AND "\*sinusitis"] AND [PROM OR patient reported outcome measure\* OR quality of life OR questionnaire OR survey OR valid\* OR develop\*]. An unlimited truncation strategy (placement of \*) was used to capture all variations of terms used.

A secondary literature search included the National Institutes of Health Patient Reported Outcome Measurement Information System database.<sup>16</sup> Studies published in the gray literature were sought by searching the term *sinusitis* using the [Greylit.org](http://www.greylit.org) database.<sup>17</sup> In addition, reference lists of all identified studies were examined to ensure that all relevant studies were captured. References were managed in an EndNote library (EndNote version X5, Thomson Reuters, Calif).

Translations for each PROM were identified using the search strategy: [translat\* OR adapt\* OR culture\* OR valid\*] AND [PROM-specific terms (eg, chronic sinusitis survey OR CSS)]. Studies using each PROM were identified by using the search strategy: [chronic AND \*sinusitis] AND [PROM-specific terms]. Only applications of the PROM to evaluate patients with CRS (ie, clinical trials or observational cohorts) were considered. The limitation of this search is that articles using an outcome but not reporting the PROM by name in the abstract will have been missed.

### Inclusion and exclusion criteria

Abstracts from the primary and secondary searches were assessed using the following inclusion criteria: (1) adults ( $\geq 18$  years old), (2) study population has CRS,<sup>18-20</sup> and (3) study reporting the validation of a PROM. Exclusion criteria included (1) studies evaluating mixed sinusitis populations (ie, acute and chronic rhinosinusitis), (2) letters or editorials, (3) clinician-based outcome measures (ie, endoscopy or computed tomography measures), and (4) studies evaluating children ( $< 18$  years old).

Decisions for study inclusion were undertaken independently by 2 reviewers (L.R. and Z.M.S.), with disagreements resolved through discussion and, when necessary, by consultation with a third reviewer (C.H.). After the initial abstract review, a full-text review was performed and studies were once again reviewed for final inclusion.

### Quality assessment

Before the use of any PROM in a clinical setting, the instrument should be rigorously tested to ensure that the properties and outcomes accurately reflect the disease being evaluated. The quality of each PROM for adults with CRS was assessed using the quality assessment criteria by Terwee et al<sup>21</sup> and the CONSensus-based Standards for the selection of health status Measurement Instruments checklist.<sup>22</sup> Specifically, the psychometric performance for the development, reliability, validity, and practical properties for each PROM were evaluated and graded according to minimal acceptable level of quality recommendations (Table I).<sup>21</sup> A final quality score was provided for each PROM using the following calculation: each "+" provided 1 point toward the overall quality score, and each "-" resulted in the subtraction of 1 point from the overall quality score. After the first round of independent quality assessment by the 2 reviewers (L.R. and Z.M.S.), any disagreements were resolved by discussion and a final ranking was achieved by consensus.

## RESULTS

### Search outcomes

Our search identified a total of 38 studies involved in the development and validation of a PROM for CRS (Fig 1). After reviewing the full text of the 38 studies along with review of references from included studies, 15 unique PROMs that have been validated for use in the adult population with CRS were included in the final analysis (Table II).<sup>23-37</sup> There were no disagreements about which studies to include in the final quality assessment.

### PROM characteristics for CRS

The general characteristics for each of the 15 PROMs for CRS are outlined in Table III. A qualitative description of each PROM is provided in the Appendix in this article's Online Repository at [www.jacionline.org](http://www.jacionline.org). Fourteen of the PROMs are CRS-specific instruments,<sup>23-35,37</sup> whereas the EuroQoL five-dimensional questionnaire (EQ-5D)<sup>38</sup> is the only generic instrument that has been validated in the CRS population.<sup>37</sup>

### Quality appraisal

The quality scoring of PROM development and psychometric performance are outlined in Tables IV and V. Overall, the highest quality validated PROMs for adult CRS were (1) the 22-item Sinonasal Outcome Test (SNOT-22) (19 points), (2) the Questionnaire of Olfactory Disorders (QOD) (14 points), (3) the Sinusitis Control Test (SCT) (14 points), and (4) the EQ-5D (13 points). The Rhinosinusitis Quality of Life instrument had 11 points, and then there were 5 studies tied with 10 points: the Chronic Sinusitis Survey, the 31-Item Rhinosinusitis Outcome Measure, the Rhinosinusitis Disability Index, the 20-item Sinonasal Outcome Test (SNOT-20), and the Dysfonctionnement Nasal Chronique Questionnaire. Table VI summarizes the development, psychometric, and overall quality scores for each PROM validated for CRS. Although there were occasional disagreements in quality assessment for particular domains after the first round of ratings, the disagreements were the result of

**TABLE III.** Characteristics for CRS-specific PROMs

PROM	Year developed	No. of patients in validation study	No. of questions	No. of domains	Score range	Domains assessed	Mode of administration	Time to complete (min)
CSS <sup>23</sup>	1995	104	6	2	0-100	CRS symptoms Medication use	Self	5
RSOM-31 <sup>24</sup>	1995	142	31	7	0-155	Nasal Eye Ear Sleep General Emotional Functional	Self	15
RSDI <sup>25</sup>	1997	87	30	3	0-120	Physical Functional Emotional	Self	5-10
SNOT-16 <sup>26</sup>	1999	47	16	0	0-48	NA	Self	5
SNOT-20 <sup>27</sup>	2002	102	20	0	0-100	NA	Self	5
RST <sup>28</sup>	2003	322	20	3	0-100	CRS symptoms Medication use Work and Social	Self	5
RhinoQoL <sup>29</sup>	2005	49	17	3	0-100	Symptom severity Bothersomeness Impact scale	Self	7
RSTF symptom score <sup>30</sup>	2007	201	14	0	0-140	NA	Self	3
SNOT-22 <sup>31</sup>	2009	2803	22	0	0-110	Rhinologic Extranasal rhinologic Ear/facial Psychological Sleep	Self	7
SNQ <sup>32</sup>	2009	59	5	0	5-35	NA	Self	<2
DyNaChron Questionnaire <sup>33</sup>	2012	759	78	6	0-780	Nasal obstruction Anterior rhinorrhea Posterior rhinorrhea Sense of smell difficulty Facial pain Cough	Self	15
QOD <sup>34</sup>	2012	102	25	3	0-57	Negative items Positive items Social items	Self	7-10
Adelaide DSS <sup>35</sup>	2013	48	6	2	0-32	Symptoms HRQOL	Self	<2
EQ-5D <sup>36,38</sup>	2015	350	15	5	0-100	Mobility Self-care Usual activity Pain/discomfort Anxiety/depression	Self	<2
SCT <sup>37</sup>	2015	50	4	3	0-16	Symptoms Productivity Rescue medication use	Self	1

CSS, Chronic Sinusitis Survey; DSS, Disease Severity Score; DyNaChron, Dysfonctionnement Nasal Chronique Questionnaire; NA, not available/applicable; RhinoQoL, Rhinosinusitis Quality of Life questionnaire; RSDI, Rhinosinusitis Disability Index; RSI, Rhinosinusitis Severity Inventory; RSOM-31, 31-item Rhinosinusitis Outcome Measurement; RSTF, Rhinosinusitis Task Force; SNOT, Sinonasal Outcome Test; SNQ, Sinonasal 5-item questionnaire.

minor misinterpretations and were resolved with a discussion without needing a third reviewer.

### Characteristics of PROM utilization

As of August 15, 2015, the SNOT-20 instrument had the largest number of published studies using it as the primary outcome (n = 111) and the second largest number of validated translations (n = 5). The SNOT-22 instrument had the largest number of validated translations (n = 10) and had the second largest number

of published studies using it as the primary outcome (n = 75 studies). Given that the SNOT-22 instrument assesses 2 additional symptom scores specific to CRS (nasal obstruction and smell), it has been recommended over SNOT-20.<sup>19</sup> Table VII summarizes the utilization characteristics for each PROM validated for CRS.

Aside from the original validation study, SNOT-16,<sup>39</sup> the EQ-5D,<sup>40</sup> and SNOT-20<sup>41</sup> each had an additional study validating the instrument in English. SNOT-22 had 3 additional

**TABLE IV.** Development property scores for CRS PROMs

PROM	Prestudy hypothesis	Measurement aim	Appropriateness for CRS	Concepts reported	Item selection	Interpretability
CSS <sup>23</sup>	0	+	+	+	+	0
RSOM-31 <sup>24</sup>	0	+	+	++	++	++
RSDI <sup>25</sup>	0	+	-	++	+	+
SNOT-16 <sup>26</sup>	0	+	-	-	+	+
SNOT-20 <sup>27</sup>	0	+	-	+	++	+
RSI <sup>28</sup>	0	+	+	+	-*	0
RhinoQoL <sup>29</sup>	0	+	+	++	+	+
RSTF symptom score <sup>30</sup>	0	+	+	++	+	0
SNOT-22 <sup>31</sup>	0	++	++	++	+	++
SNQ <sup>32</sup>	0	++	-	+	+	+
DyNaChron Questionnaire <sup>33</sup>	0	+++*	-	++	++	-
QOD <sup>34</sup>	0	++	+	+++*	+	+
Adelaide DSS <sup>35</sup>	0	+	++	+	+	+
EQ-5D for CRS <sup>36</sup>	0	++	+	++	++	++
SCT <sup>37</sup>	0	+	++	++	++	+

If not reported, score of "0"; minimal acceptable rating, score of "+"; better than the minimal acceptable rating, score of "++"; reported with worse than minimal acceptable rating, score of "-."

CSS, Chronic Sinusitis Survey; DSS, Disease Severity Score; *DyNaChron*, Dysfonctionnement Nasal Chronique Questionnaire; *RhinoQoL*, Rhinosinusitis Quality of Life questionnaire; *RSDI*, Rhinosinusitis Disability Index; *RSI*, Rhinosinusitis Severity Inventory; *RSOM-31*, 31-item Rhinosinusitis Outcome Measurement; *RSTF*, Rhinosinusitis Task Force; *SNOT*, Sinonasal Outcome Test; *SNQ*, Sinonasal 5-item questionnaire.

\*There was a disagreement between independent reviewers after the first rankings (final score based on the consensus after discussion).

**TABLE V.** Psychometric property scores for CRS PROMs

PROM	Reproducibility (test-retest reliability)	Internal consistency	Responsiveness	Criterion validity	Floor/ceiling effect	Acceptability	Feasibility
CSS <sup>23</sup>	+	+	0	0	0	++	++
RSOM-31 <sup>24</sup>	0	++	0	0	0	+	-
RSDI <sup>25</sup>	+	++	0	0	0	0	++
SNOT-16 <sup>26</sup>	0	+	+	0	0	0	+
SNOT-20 <sup>27</sup>	+	+	+	+	0	+	+
RSI <sup>28</sup>	0	+	0	0	0	0	+
RhinoQoL <sup>29</sup>	-	+	++	+	0	0	++
RSTF symptom score <sup>30</sup>	0	0	0	-	0	0	+
SNOT-22 <sup>31</sup>	++	++	++	0	0	++	++
SNQ <sup>32</sup>	+	0	0	0	0	0	++
DyNaChron Questionnaire <sup>33</sup>	+	++	0	0	++	++	-
QOD <sup>34</sup>	++	++	0	++	0	0	+
Adelaide DSS <sup>35</sup>	0	0	0	-	+++*	0	0
EQ-5D for CRS <sup>36</sup>	0	0	+	-	0	++	++
SCT <sup>37</sup>	0	0	0	++	0	++	++

If not reported, score of "0"; minimal acceptable rating, score of "+"; better than the minimal acceptable rating, score of "++"; reported with worse than minimal acceptable rating, score of "-."

CSS, Chronic Sinusitis Survey; DSS, Disease Severity Score; *DyNaChron*, Dysfonctionnement Nasal Chronique Questionnaire; *RhinoQoL*, Rhinosinusitis Quality of Life questionnaire; *RSDI*, Rhinosinusitis Disability Index; *RSI*, Rhinosinusitis Severity Inventory; *RSOM-31*, 31-item Rhinosinusitis Outcome Measurement; *RSTF*, Rhinosinusitis Task Force; *SNOT*, Sinonasal Outcome Test; *SNQ*, Sinonasal 5-item questionnaire.

\*There was a disagreement between independent reviewers after the first rankings (final score based on the consensus after discussion).

studies validating its use in English-speaking patients with CRS.<sup>42-44</sup>

## DISCUSSION

This systematic review identified 15 PROMs validated for adults with CRS. The quality assessment demonstrated that SNOT-22, the QOD, and the SCT show promise as being useful PROMs for adults with CRS and contained the highest quality of development and psychometric properties. Furthermore, each of the top 3 PROMs evaluate different aspects of CRS such as HRQOL/symptoms (SNOT-22), olfaction (QOD),

and CRS disease control (SCT). However, the context was primarily used in research settings to quantify changes after an intervention and further investigation is required to validate these PROMs used in clinical settings to inform clinical decision making. The EQ-5D represents a high-quality validated generic quality-of-life instrument for CRS. The most common methodologic flaw during PROM development was the inclusion of patients with mixed sinusitis and failure to apply guideline-based criteria for CRS appropriate to the year of development. The most common psychometric performance flaws were the lack of defining the floor/ceiling effect, poor assessment of criterion validity, and lack of assessing patient

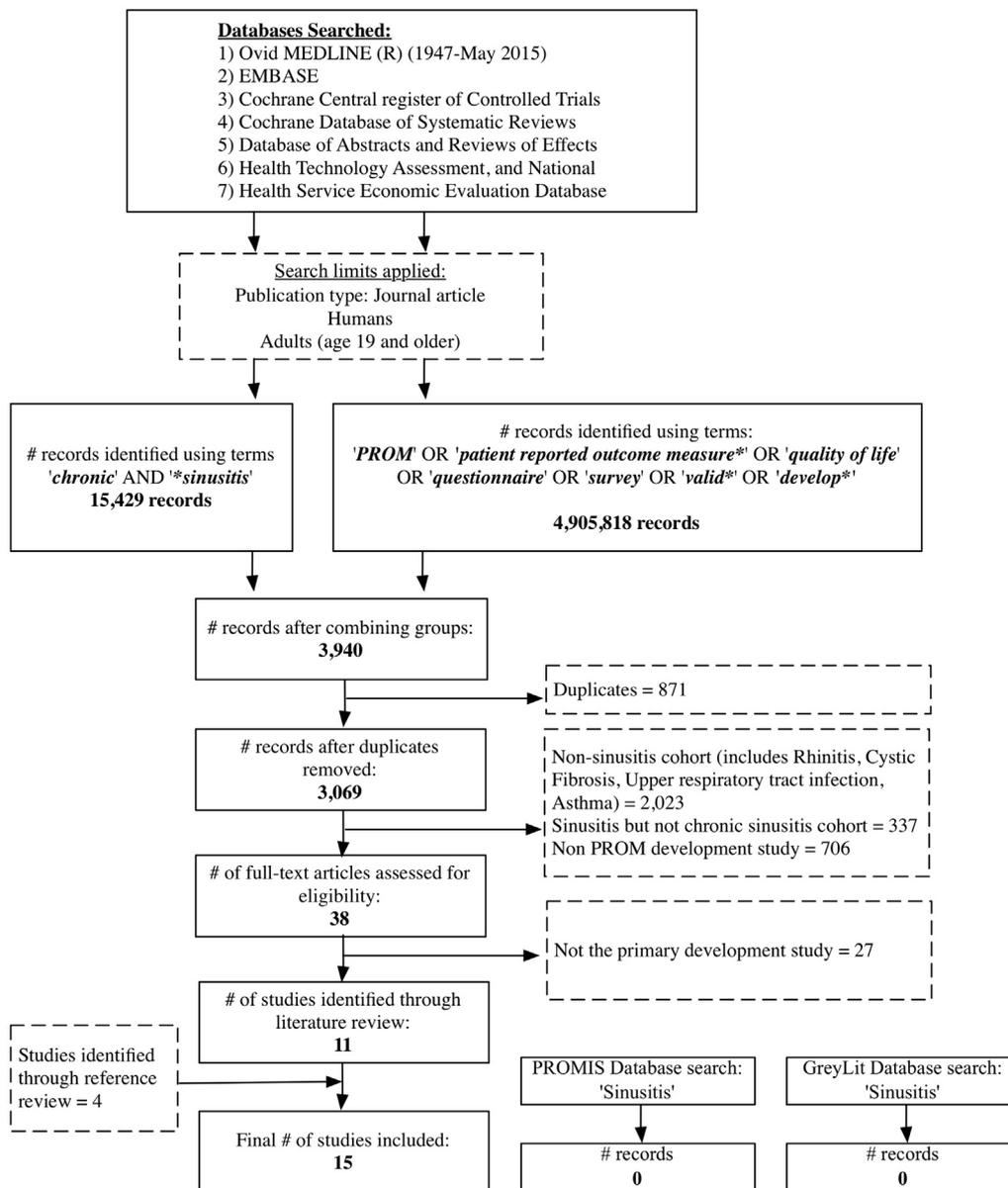


FIG 1. Search strategy for CRS PROMs.

acceptability. All PROMs appraised in this systematic review lacked domains to assess patient values and preferences for certain management options and lacked items to assess the impact of common comorbid diseases such as asthma and allergic rhinitis. These limitations represent areas to improve upon for future instrument development.

Patients are commonly faced with making decisions regarding their care despite incomplete understanding of their individual outcomes and risks. Specifically, patients with CRS who have persistent symptoms and reduced HRQOL, despite appropriate initial medical therapy, have a difficult decision to either continue with medical therapy or choose to undergo surgery. Given that both therapeutic approaches are appropriate and effective in the correctly selected patient, there is a need to improve how we inform patients about their outcomes, so that they can make a

decision that reflects their preferences rather than the physician's preference. To address this issue, there is increasing interest in using PROMs to measure disease burden from the perspective of the patient, which can then be used to match the right treatment to the right patient.<sup>1-3</sup>

Despite strong validation and use in the research setting, there are 2 primary limitations of current PROMs for CRS that limit their use in clinical settings. First, there is a lack of items that assess patient preferences and value judgments for certain treatment options, such as continued medical therapy or surgery. Although physicians try to act in the patients' best interest, physician values may be biased and differ from those of the patient. To move PROMs beyond just the research setting (ie, used to measure the change in outcomes after an intervention), development should begin to incorporate value judgments and

**TABLE VI.** Summary of quality scores for each PROM

PROM	Development score	Psychometric score	Overall quality score
CSS <sup>23</sup>	4	6	10
RSOM-31 <sup>24</sup>	8	2	10
RSDI <sup>25</sup>	5	5	10
SNOT-16 <sup>26</sup>	1	3	4
SNOT-20 <sup>27</sup>	4	6	10
RSI <sup>28</sup>	2	2	4
RhinoQoL <sup>29</sup>	6	5	11
RSTF symptom score <sup>30</sup>	5	0	5
SNOT-22 <sup>31</sup>	9	10	19
SNQ <sup>32</sup>	4	3	7
DyNaChron Questionnaire <sup>33</sup>	4	6	10
QOD <sup>34</sup>	7	7	14
Adelaide DSS <sup>35</sup>	6	1	7
EQ-5D for CRS <sup>36</sup>	9	4	13
SCT <sup>37</sup>	8	6	14

CSS, Chronic Sinusitis Survey; DSS, Disease Severity Score; DyNaChron, Dysfonctionnement Nasal Chronique Questionnaire; RhinoQoL, Rhinosinusitis Quality of Life questionnaire; RSDI, Rhinosinusitis Disability Index; RSI, Rhinosinusitis Severity Inventory; RSOM-31, 31-item Rhinosinusitis Outcome Measurement; RSTF, Rhinosinusitis Task Force; SNOT, Sinonasal Outcome Test; SNQ, Sinonasal 5-item questionnaire.

patient preferences that can help improve the patient-centeredness of CRS care. Without measuring patient preferences and incorporating patient judgments, PROMs for CRS will continue to have limited value in clinical decision making. Second, there is a lack of items that assess the impact of common comorbid diseases such as asthma and allergic rhinitis. Given that more than 50% of the patients with CRS suffer from comorbid asthma or allergic rhinitis,<sup>45-47</sup> future PROMs may consider incorporating items that address the impact of comorbid disease control in addition to CRS. Given that there is significant redundancy in the items assessed for each PROM developed for CRS, future instruments should begin focusing on incorporating novel items that assess patient preferences and comorbid diseases, which would improve the clinical applicability of using PROMs during the management of CRS.

Although current PROMs for CRS lack some important “patient-centered” items, SNOT-22 has shown promise not only for research (used as the primary outcome in >70 outcome studies; Table VII) but also in clinical settings. For example, 2 studies have demonstrated how physicians can use the baseline SNOT-22 score to predict treatment selection for CRS,<sup>11,12</sup> while 2 recent studies demonstrated that baseline SNOT-22 scores can be used to inform patients about their expected HRQOL outcomes after sinus surgery.<sup>13,14</sup> SNOT-20 was moderately ranked for overall quality and had the largest volume of published studies using it as a primary outcome (n = 111; Table VII); however, this instrument does not evaluate 2 very important symptoms for CRS (nasal obstruction and smell), which reduces its content validity and has therefore been recommended against for use in patients with CRS.<sup>19</sup> Several of the PROMs had relatively strong “Development” properties but lacked important “Psychometric” properties during the validation (Table VI). The quality of a PROM would ideally be viewed in the context of the overall score because major deficiencies in either the development or psychometric properties could negatively affect the accuracy of outcome measurement.

With the goal to improve the quality of outcomes research and facilitate the combination of data using meta-analysis, the wide variety of PROM choices for adults with CRS represent a challenge to researchers. To overcome this challenge, there is a trend to define a “Core Outcome Set” (COS) for both research and clinical settings.<sup>48</sup> The COS would include a minimum data set that should form the basis of clinical trials and routine practice that would help reduce heterogeneity in outcome reporting and reduce variation in clinical decision making. Development of a COS involves 2 distinct stages: the first determines what should be measured and the second how best to measure it. Determining which outcomes to measure typically involves several important stakeholders in health care (including physicians, health care providers, policymakers, and patients) and uses a Delphi process to repeatedly rank the importance of different outcome measures for inclusion in the COS until consensus is reached.<sup>48</sup> Once core outcomes have been identified, the second stage in COS development addresses how, and this systematic review will help inform this stage by detailing those instruments with proper development and psychometric validity that include the core outcomes of interest.

The primary limitation of this systematic review is the potential to miss a validated PROM for adults with CRS using our search strategy. The identification of validation studies for full-text review depended on abstract review of more than 3000 studies. Poor reporting and inadequate abstract description may have led to missing PROM validation studies for CRS. However, the independent review performed in duplicate and the use of PROM-related search terms have been used in previously published systematic reviews for PROMs<sup>49,50</sup> and would limit the risk of missing important instruments. Another potential limitation of the quality assessment is the subjectivity involved in several of the rankings. To minimize this risk, the quality assessment was performed independently in duplicate by 2 authors (L.R. and Z.M.S.) with any disagreements settled by a third reviewer (C.H.) if needed. Despite these inherent limitations, this study is strengthened by the robust systematic review process, use of a validated PROM quality assessment tool, and consultation with experts in PROM development and outcomes research for adult CRS.

## Conclusions

This systematic review identified 15 validated PROMs for use in adult patients with CRS. Based on the quality of development and reporting of psychometric performance, SNOT-22, QOD, and SCT provided the highest quality CRS-specific PROMs while the EQ-5D provided a high-quality generic quality-of-life instrument. Future PROMs will need to incorporate domains that assess patient values and preferences to further assist in clinical decision making.

**Clinical implications: PROMs are essential to assess whether or not clinicians are improving the health of patients with CRS. Results from this systematic review have demonstrated that current PROMs developed for CRS have variable quality and lack important items that assess common comorbid diseases along with patient values and preferences, which may assist in improving clinical decision making.**

**TABLE VII.** Summary of CRS PROM utilization characteristics

PROM	No. of validated translations	Validated translations	No. of additional validation studies in English	No. of published studies using PROM
CSS <sup>23</sup>	2	Chinese, Norwegian	0	45
RSOM-31 <sup>24</sup>	0	None	0	8
RSDI <sup>25</sup>	0	None	0	35
SNOT-16 <sup>26</sup>	1	French	1	5
SNOT-20 <sup>27</sup>	5	Chinese, Portuguese, Japanese, German, Chilean Spanish	1	111
RSI <sup>28</sup>	0	None	0	11
RhinoQoL <sup>29</sup>	1	French	0	1
RSTF symptom score <sup>30</sup>	0	None	0	4
SNOT-22 <sup>31</sup>	10	Portuguese, French, Spanish, Greek, Persian, Portuguese, Lithuania, Danish, Czech, Sinhalese	3	75
SNQ <sup>32</sup>	0	None	0	1
DyNaChron Questionnaire <sup>33</sup>	0	None	0	1
QOD <sup>34</sup>	0	None	0	2
Adelaide DSS <sup>35</sup>	0	None	0	2
EQ-5D <sup>36,38</sup>	126*	See Web site*	1	3
SCT <sup>37</sup>	0	None	0	0

CSS, Chronic Sinusitis Survey; DSS, Disease Severity Score; DyNaChron, Dysfonctionnement Nasal Chronique Questionnaire; *RhinoQoL*, Rhinosinusitis Quality of Life questionnaire; *RSDI*, Rhinosinusitis Disability Index; *RSI*, Rhinosinusitis Severity Inventory; *RSOM-31*, 31-item Rhinosinusitis Outcome Measurement; *RSTF*, Rhinosinusitis Task Force; *SNOT*, Sinonasal Outcome Test; *SNQ*, Sinonasal 5-item questionnaire.

\*Translations available on the EQ-5D Web site ([www.euroqol.org](http://www.euroqol.org)).

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## APPENDIX. QUALITATIVE DESCRIPTION OF PROMs VALIDATED FOR CRS

The Chronic Sinusitis Survey<sup>E1</sup> is a 6-question survey designed to measure sinusitis-specific symptoms and medication use within the preceding 8-week period (score range, 0-100). Lower total and subscale scores indicate a greater impact of CRS on HRQOL.

The 31-Item Rhinosinusitis Outcome Measurement<sup>E2</sup> is a self-administered 31-item survey that evaluates 7 domains: nasal, eye, ear, sleep, and general, emotional, and functional problems. Pretreatment items are ranked using a 5-category “bothersome” scale according to the degree of disturbance they receive in their life as a result of CRS. Higher scores imply a greater impact of CRS on HRQOL.

The Rhinosinusitis Disability Index<sup>E3</sup> is a 30-question survey comprising 3 individual subscales to measure the impact of sinus disease on the physical, functional, and emotional domains on a continuum (score range, 0-120). Higher total and subscale scores represent a greater impact of CRS on HRQOL.

The 16-item Sinonasal Outcome Test<sup>E4</sup> was developed to provide a quick and easy PROM for patients with CRS. Items are ranked using a 4-point Likert scale to provide a total score between 0 and 48.

SNOT-20<sup>E5</sup> was developed as a modification of the RSOM survey. It asks patients to rank the severity of 20 symptoms using a 6-point Likert scale and rank the importance of their symptoms. Outcomes from this metric include a total symptom score from 0 to 100 and the list of their top 5 symptoms. Guidelines have recommended against the use of SNOT-20 as a PROM in patients with CRS because of the lack of questions on nasal obstruction and sense of smell.

The Rhinosinusitis Symptom Inventory<sup>E6</sup> evaluates the CRS Task Force major and minor symptoms on a 6-point Likert scale (0 indicates symptom absent; and 5, symptom very severe) on the basis of symptoms experienced in the preceding 3 months. Furthermore, it documents medication use, physician office visits, and work absence directly related to CRS. Higher scores imply greater impact of disease on HRQOL.

The Rhinosinusitis Quality of Life survey<sup>E7</sup> is a 17-item survey that evaluates 3 domains: symptom frequency, bothersomeness, and impact scale. Individual item scores are ranked from 0 (worse possible health status) to 100 (best possible health status). Lower total scores imply a greater impact of CRS on HRQOL.

The Rhinosinusitis Task Force symptom score<sup>E8</sup> questionnaire was developed as a validated tool for clinicians to assess symptom-based outcomes of CRS. Using a 0 (absence of symptom) to 10 (maximum severity) visual analog scale (VAS), patients are instructed to rank their 5 major (facial pain/pressure, facial congestion, nasal obstruction/blockage, nasal discharge/purulence, and altered sense of smell) and 7 minor (headache, fever [nonacute], halitosis, fatigue, dental pain, cough, and ear pain) Rhinosinusitis Task Force symptoms. Two additional rankings of either 0 or 10 are provided by the clinician from an examination indicating either fever (acute) and purulence on examination.

SNOT-22<sup>E9</sup> is an outcome measure applicable to both sinonasal conditions and surgical treatments (score range, 0-110). Derived from SNOT-20, it removed the ranking of top 5 most bothersome symptoms, and 2 questions were added to measure nasal blockage and sense of taste/smell. Higher total scores on SNOT-22 imply greater impact of CRS on HRQOL.

The Sinonasal 5-item questionnaire<sup>E10</sup> was developed to screen for chronic sinusitis. It evaluates 5 domains: sinus infection, nasal obstruction, allergy symptoms, emotional distress, and activity limitations. Each domain consists of various symptom clusters and uses a 1 (none of the time) to 7 (all of the time) scale to provide a mean domain score. There is a single VAS HRQOL question that is ranked from 0 (worst) to 10 (perfect).

The Dysfonctionnement Nasal Chronique Questionnaire<sup>E11</sup> was developed to evaluate the specific physical and psychosocial consequences of specific nasal symptoms, independent of CRS. The questionnaire is composed of 78 questions divided into 6 domains. Each question is answered using a 0 (no impact) to 10 (unbearable impact) scale, and patients need to respond only to those questions that deal with conditions they suffered from.

The short-form QOD<sup>E12</sup> has been validated to evaluate the impact of olfactory dysfunction on HRQOL in patients with CRS. It is composed of 25 items divided into 3 general domains: negative items (degree to which patients are suffering), positive items (how well patients are coping with olfactory dysfunction), and social items (measure how credible the patients responses are). Items are ranked from 0 (none) to 3 (severe), and the sum of scores from all 3 domains are calculated to a maximum score of 57 points.

The Adelaide Disease Severity Score<sup>E13</sup> was developed as a shorter alternative to SNOT-22. This metric asks patients to rank the 5 common task force symptoms (nasal obstruction, rhinorrhea, postnasal drip, headache/facial pain, and smell dysfunction) using a 0 (none) to 5 (severe) Likert scale. In addition to the 5 symptom items, there is 1 VAS HRQOL question with scores ranking from 0 (no effect) to 7 (maximal effect). The sum from each symptom question plus the single HRQOL question provides a maximum score of 32.

The EQ-5D is a generic measure of a patient's preference for living in a particular health state. It been recently validated in the CRS population and provides health state utility values capable of generating quality-adjusted life-years.<sup>E14,E15</sup> The EQ-5D contains 5 attributes: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression.<sup>E15,E16</sup> Each attribute has 3 possible states, which provides 245 possible health states. Utility scores were measured for each health state using the time trade-off technique.<sup>E17</sup>

The SCT<sup>E18</sup> was recently developed to assess the degree of CRS control. The SCT differs from HRQOL metrics in that it does not assess the patients' perception of disease impact but rather how well the CRS is controlled using current medical therapies at a specific point in time. The survey involves 4 questions, 3 of which are answered using a 5-point Likert scale and 1 dichotomous no (score = 0) or yes (score = 4) question. The outcomes categorize patients into 3 groups: well-controlled (overall score, 0-3), partially controlled (overall score, 4-11), and poorly controlled (overall score, 12-16).

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