# Validity and Reliability of the French Short Version of the Questionnaire of Olfactory Disorders-Negative Statements (sQOD-NS)

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Céline Leclercq, MD<sup>1</sup>, Carlos M. Chiesa-Estomba, MD, MS<sup>2,3</sup>, Mihaela Horoi, MD<sup>1</sup>, Serge D. Le Bon, MD<sup>1</sup>, Stephane Hans, MD, PhD, MS<sup>2,4</sup>, Lea Distinguin, MD, MS<sup>2,4</sup>, Younes Chekkoury-Idrissi, MD<sup>2,4</sup>, Marta P. Circiu, MD<sup>2,4</sup>, Mohamad Khalife, MD<sup>2,5</sup>, Sven Saussez, MD, PhD<sup>1,2,6</sup>, and Jérôme R. Lechien, MD, PhD, MS<sup>1,2,4,6</sup>

## Abstract

**Objective:** To develop a French Short Version of the Questionnaire of Olfactory Disorders-Negative Statements (Fr-sQOD) to assess the quality of life impairments of patients with olfactory dysfunction (OD). **Methods:** Patients with OD and controls were enrolled from 2 academic centers. Individuals completed the Fr-sQOD, an OD visual analog scale severity, and the French version of the sinonasal outcome tool-22 (SNOT-22). Cronbach  $\alpha$  was used to measure the internal consistency of Fr-sQOD. The reliability and the external validity of Fr-sQOD were assessed through a test-retest approach and by correlating Fr-sQOD with SNOT-22 scores, respectively. The external validity was assessed by correlation analysis between Fr-sQOD and the result of an assessment of the severity of OD on a visual analog scale. **Results:** Eighty patients completed the evaluations. The internal consistency was adequate (Cronbach  $\alpha$  .96), and the test-retest reliability was high in the entire cohort ( $r_s = 0.877, P < .001$ ). The correlation between Fr-sQOD total scores and the severity of OD was moderate but significant ( $r_s = -0.431$ ; P = .001) supporting an acceptable external validity. **Conclusion:** The Fr-sQOD is a reliable and valid self-administered tool in the evaluation of the impact of OD on quality of life of French-speaking patients.

## Keywords

anosmia, smell, olfaction, tool, clinical, quality of life

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#### **Corresponding Author:**

Jerome R. Lechien, MD, PhD, MS, Department of Otolaryngology–Head & Neck Surgery, Foch Hospital, School of Medicine, UFR Simone Veil, Université Versailles Saint-Quentin-en-Yvelines (Paris Saclay University), Paris 92151, France. Email: jerome.lechien@umons.ac.be



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<sup>&</sup>lt;sup>1</sup> Department of Otolaryngology–Head and Neck Surgery, CHU Saint-Pierre, Université Libre de Bruxelles, Brussels, Belgium

<sup>&</sup>lt;sup>2</sup> Research Committee of the Young-Otolaryngologists of the International Federations of Oto-rhino-laryngological Societies (YO-IFOS), San Sebastian, Spain

<sup>&</sup>lt;sup>3</sup> Department of Otorhinolaryngology–Head & Neck Surgery, Hospital Universitario Donostia, San Sebastian, Spain

<sup>&</sup>lt;sup>4</sup> Department of Otolaryngology–Head & Neck Surgery, Foch Hospital, School of Medicine, UFR Simone Veil, Université Versailles Saint-Quentin-en-Yvelines (Paris Saclay University), Paris, France

<sup>&</sup>lt;sup>5</sup> Department of Otorhinolaryngology–Head & Neck Surgery, EpiCURA Hospital, Baudour, Belgium

<sup>&</sup>lt;sup>6</sup> Department of Human Anatomy and Experimental Oncology, School of Medicine, Research Institute for Health Sciences and Technology, University of Mons (UMons), Mons, Belgium

## Introduction

Olfactory dysfunction (OD) affects one-fifth of the general population.<sup>1</sup> Recently, anosmia has been identified as a key symptom of the coronavirus disease 2019 (COVID-19),<sup>2,3</sup> indicating the current need for standardized olfactory-specific quality of life (QOL) patient-reported outcome questionnaires. In 2012, Simopoulos et al developed the Questionnaire of Olfactory Disorders-Negative Statements (QOD-NS) composed by 17 items measuring olfactory-specific QOL.<sup>4</sup> This questionnaire is well used in clinical practice around the world and presents high validity and reliability properties.<sup>4</sup> Questionnaire of Olfactory Disorders-Negative Statement evaluates the OD impact on QOL, through social, anxiety, annovance, and eating-related problem questions. Recently, Mattos et al developed a short version of QOD-NS (sQOD-NS) composed of 7 items, with excellent validity and reliability properties.<sup>5</sup> To date, sQOD-NS is only validated in English and Spanish.<sup>6</sup> There is no validated sQOD-NS version for French-speaking countries that include more than 400 million inhabitants. The aim of this study is to develop a French Short Version of the Questionnaire of Olfactory Disorders-Negative Statements (Fr-sQOD).

## Methods

The study protocol was approved by the Institutional Ethics Committee ( $n^{\circ}$  CHUSP20032020). Patient electronic informed consent was obtained.

# Translation of Fr-sQOD

A multidisciplinary team composed of 2 otolaryngologists, a psychologist, a statistician, and a linguist worked on the French adaptation of sQOD-NS (Fr-sQOD-NS). The Fr-sQOD-NS was translated from the US version by the linguist. Experts of the team were native French speakers. Before the validation, the Fr-sQOD-NS was sent to 10 patients to detect potential misunderstanding(s). The final version of Fr-sQOD is available in Table 1.

Patients with OD were enrolled from March 2020 to June 2020 from the Departments of Otolaryngology-Head & Neck Surgery of Foch Hospital (Paris, France), CHU Saint-Pierre (Brussels, Belgium), and EpiCURA Hospital (Baudour, Belgium). Patients developed OD during the pandemic of COVID-19. There were 47 males and 33 females with a mean age of  $40.8 \pm 12.6$  (ranged from 15 to 83 years old). A control group of healthy individuals was composed with a mean age of  $37.7 \pm 15.7$  (range 18 to 70 years old). Individuals with severe neurological diseases limiting the understanding of the study protocol, history of chronic OD, or those who were not native French speaker were excluded. Eighty patients with demonstrated anosmia or hyposmia and 100 healthy individuals (62 males) completed the study. The characteristics of patients are reported in Table 1. The diagnosis of COVID-19 was performed through nasal swabs and reverse transcriptasepolymerase chain reaction.

French Version				
	Tout à fait d'accord	D'accord	Pas d'accord	Pas du tout d'accord
Les changements dans ma perception des odeurs m'isolent socialement	0	I	2	3
Mon trouble de l'odorat a un impact négatif sur mes activités sociales quotidiennes	0	I	2	3
Mon trouble de l'odorat me rend plus irritable	0	1	2	3
A cause de mon trouble de l'odorat, je vais moins au restaurant ou manger à l'extérieur		I	2	3
A cause de mon trouble de l'odorat, je mange moins qu'avant (perte d'appétit)		1	2	3
A cause de mon trouble de l'odorat, je dois faire davantage d'efforts pour me relaxer	0	I	2	3
J'ai peur de ne jamais pouvoir m'habituer à mon trouble de l'odorat	0	I	2	3

English version

	Agree	Partly agree	Partly disagree	Disagree
The changes in my sense of smell make me feel isolated	0	I	2	3
Because of the changes in my sense of smell, I have problems with taking part in activities of daily life	0	I	2	3
The changes in my sense of smell make me feel angry	0	I I	2	3
Because of the changes in my sense of smell, I go to restaurants less often than I used to	0	I	2	3
Because of the changes in my sense of smell, I eat less than I used to or more than I used to	0	I	2	3
Because of the changes in my sense of smell, I try harder to relax	0	I	2	3
I am worried that I will never get used to the changes in my sense of smell	0	I	2	3

<sup>a</sup>The Short version of Questionnaire of Olfactory Disorders-Negative Statements in French.

## Olfactory and Nasal Evaluations

Nasal complaint evaluation was performed using the French version of the sinonasal outcome tool-22 (SNOT-22).<sup>7</sup> Patients and controls fulfilled subjective evaluations of olfaction based on olfactory and gustatory questions of the smell and taste component of the National Health and Nutrition Examination Survey.<sup>8</sup> Psychophysical olfactory evaluations were performed with Sniffin-Sticks tests (Medisense), which is a standardized and validated evaluation using 16 smell pens. The patient had to choose the adequate term describing the smell between 4 given options.<sup>9</sup> The total score ranges from 0 (complete anosmia) to 16 (no olfactory disorder). Regarding results, 3 categories were defined: normosmia (score between 12 and 16), hyposmia (score between 9 and 11), and anosmia (score <9).<sup>9</sup>

## Validity, Reliability, and Responsiveness to Change

The Fr-sQOD-NS was completed twice over 2-day period (test-retest reliability) to assess the internal consistency (Spearman correlation coefficient). Internal consistency was evaluated with Cronbach  $\alpha$  for the 7 items of the tool. External validity was assessed by correlation analysis between Fr-sQOD-NS and the result of an assessment of the QOL impact of OD through a visual analog scale, ranging from 0 (=no QOL impact) to 4 (=severe QOL impact) using Spearman correlation coefficient. The sQOD-NS scores were compared between patients and healthy patients to measure internal validity (Mann-Whitney *U* test.). Because Fr-sQOD-NS is not a clinical tool aiming to detect pathology but a QOL questionnaire, we did not assess the normative value of Fr-sQOD-NS.

## Statistical Analyses

The statistical analyses were performed with Statistical Package for the Social Sciences for Windows (SPSS version 22.0; IBM Corp). A level of significance of P < .05 was used. The difference in Fr-sQOD-NS scores between patients and healthy individuals was evaluated with the Mann-Whitney U test. Spearman correlation coefficient was used to perform the different correlation analyses (test–retest reliability, external validity).

## Results

A total of 80 patients with hyposmia or anosmia completed the evaluations. The epidemiological and clinical characteristics of patients are available in Table 2. There were respectively 72, 6, and 2 patients with mild, moderate, and severe forms of the COVID-19 according to the World Health Organization classification.<sup>10</sup> The most prevalent general symptoms in COVID-19 patients were fatigue, headache, and myalgia. Prevalent otolaryngological symptoms were nose congestion, anterior rhinorrhea, and postnasal drip. Among the cohort of patients with OD, there were 49 anosmic and 31 hyposmic patients according to Sniffin-Sticks tests (Table 3). The mean Fr-SNOT-22 score of patients was 36.6 (Table 3).

#### Table 2. Patient Characteristics.

Outcomes	Ν	%
Age (mean, range)	40.8 ± 12.6 (15-83)	
Sex		
Male	33	41.25
Female	47	58.75
Comorbidities		
Diabetes	4	5.00
Hypertension	6	7.50
Hypothyroidism	6	7.50
Allergic rhinitis	6	7.50
Renal insufficiency	I	1.25
Hepatic insufficiency	0	0
Respiratory insufficiency	0	0
Cardiologic affections	3	3.75
Neurologic affections	0	0
Reflux	11	13.75
Asthma	8	1
Depression	I	1.25
General symptoms		
Fever	15	18.75
Cough	31	38.75
Expectorations	33	41.25
Myalgia	21	26.25
Arthalgia	28	35
Chest pain	19	23.75
Inappetence	32	40
Diarrhea	23	28.75
Abdominal pain	12	15
Nausea and vomiting	8	I
Headache	42	52.5
Fatigue	51	63.75
Otolaryngological symptoms		
Nasal congestion	41	51.25
Anterior rhinorrhea	33	41.25
Postnasal drip	29	36.25
Odynophagia	15	18.75
Dysphagia	9	11.25
Dysphonia	17	21.25
Otalgia	20	25
Facial pain/pressure	16	20
Dyspnea	19	23.75

The Cronbach  $\alpha$  value was .955 for the 7 items of Fr-sQOD-NS, indicating high internal consistency. The test–retest reliability was high for total scores ( $r_s = 0.877$ , P < .001) and moderate-to-high for all item scores (Table 4). The correlation between Fr-sQOD-NS total score and the visual analog scale OD assessment was moderate but significant ( $r_s = -0.431$ ; P = .001), suggesting high external validity. Concerning internal validity, the mean score of Fr-sQOD-NS was significantly higher in patients compared with controls (Table 5).

## Discussion

The high prevalence of anosmia and hyposmia in COVID-19<sup>11,12</sup> and the risk of reinfection and second anosmia episodes<sup>13</sup> make the development of QOL patient-reported outcome

SNOT-22 outcomes	Mean $\pm$ SD
Need to blow nose	1.56 <u>+</u> 1.39
Nasal blockage	1.69 <u>+</u> 1.44
Sneezing	1.49 <u>+</u> 1.31
Runny nose	1.52 <u>+</u> 1.39
Cough	1.49 <u>+</u> 1.50
Postnasal discharge	1.14 ± 1.36
Thick nasal discharge	0.66 $\pm$ 1.11
Ear fullness	0.73 <u>+</u> 1.13
Dizziness	0.87 <u>+</u> 1.36
Ear pain	0.76 <u>+</u> 1.19
Facial pain/pressure	0.80 ± 1.33
Decreased sense of smell/taste	4.06 <u>+</u> 1.32
Difficulty falling asleep	1.48 <u>+</u> 1.66
Wake up at night	1.80 <u>+</u> 1.64
Lack of good night's sleep	2.00 <u>+</u> 1.69
Wake up tired	2.37 <u>+</u> 1.73
Fatigue	$2.62 \pm 1.62$
Reduced productivity	2.35 <u>+</u> 1.73
Reduced concentration	2.17 <u>+</u> 1.66
Frustrated/restless/irritable	1.82 <u>+</u> 1.60
Sad	1.92 ± 1.60
Embarrassed	1.79 <u>+</u> 1.70
Total SNOT-22	36.56
Sniffin-Sticks tests (mean)	7.67
Anosmic (number, %)	49 (61)
Hyposmic (number, %)	31 (39)
Cacosmia (number, %)	34 (43)
Phantosmia (number, %)	17 (21)
Self-reported taste disorders	27 (34)
Time of development of OD	
Before other symptoms	3 ( 7)
In the same time of other symptoms	21 (28)
After other symptoms	42 (55)

Abbreviations: OD, olfactory disorder; SD, standard deviation; SNOT-22, sinonasal outcome tool-22.

Table 4. Test-Retest Reliability Analysis.<sup>a</sup>

Fr-sQOD-NS items	r <sub>s</sub>	P value
Item 1: Feeling isolated	0.873	<.001
Item 2: Problems with daily activities	0.859	<.001
Item 3: Feeling angry	0.779	<.001
Item 4: Going less to restaurants	0.763	<.001
Item 5: Eating less	0.775	<.001
Item 6: Harder to relax	0.790	<.001
Item 7: Worried	0.778	<.001
Total score	0.877	<.001

Abbreviations: Fr-sQOD-NS, French Short Version of the Questionnaire of Olfactory Disorders-Negative Statement; r<sub>s</sub>, Rho Spearman.

<sup>a</sup>The correlation analysis between Fr-sQOD-NS day 0 and Fr-sQOD-NS day 2 according to Spearman correlation test.

questionnaires important. The initial version of QOD-NS was time-consuming with these 17 items, and consequently, the development of a reliable and valid short version makes sense. In this study, we developed a French version of sQOD-NS that reports

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 Table 5. Comparison of sQOD-NS Between OD Patients and Healthy Individuals.

	Patients		Controls		
sQOD-NS items	Mean	SD	Mean	SD	P value
Item 1: Feeling isolated	2.00	0.93	1.97	0.96	.849
Item 2: Problems daily activities	1.85	0.97	1.84	1.01	.942
Item 3: Feeling angry	1.79	1.06	1.82	1.01	.843
Item 4: Going less to restaurants	1.56	1.20	1.56	1.20	.994
Item 5: Eating less	1.74	1.08	1.65	1.10	.625
Item 6: Harder to relax	2.09	0.80	2.07	0.87	.926
Item 7: Worried	1.07	1.10	1.52	1.20	.008
Total score	11.95	5.66	12.43	6.60	.039

Abbreviations: Fr-sQOD-NS, French Short Version of the Questionnaire of Olfactory Disorders-Negative Statement; OD, olfactory dysfunction; SD, standard deviation.

high internal consistency regarding the Cronbach  $\alpha$  value (.955). The internal consistency value of the Fr-sQOD-NS is comparable to the value of the original paper of Simopoulos et al who reported a Cronbach  $\alpha$  of .88.<sup>4</sup> In the Spanish version of sQOD-NS, Chiesa-Estomba et al<sup>14</sup> found a Cronbach  $\alpha$  of .861, which was also comparable to ours.<sup>6</sup>

In the same vein, the test–retest reliability of Fr-sQOD-NS, also named external reliability, was high for total scores ( $r_s = 0.877, P < .001$ ) and moderate-to-high for item scores. In the original version of QOD-NS, Simopoulos et al reported adequate external reliability of QOD-NS since they did not find significant differences between the values of the initial (test) and the second (retest) fulfill of QOD-NS (P = .567).<sup>4</sup> However, the result comparison between our studies is still limited because they used a different statistical approach to assess the external reliability. The comparison with the Spanish study is not possible because the authors did not provide external reliability analysis.

The Fr-sQOD-NS total score of OD patients was significantly lower than the score of healthy individuals (P = .039), indicating good internal validity. Concerning the item scores, only the item 7 ("I am worried that I will never get used to the changes in my sense of smell.") was significantly lower in OD patients compared with controls. According to our data, this item is probably the most relevant to report the fear of patients about the risk to not recover olfaction and the related significant negative impact on QOL. Our internal validity findings are comparable to those of Simopoulos et al who compared the QOD-NS values of anosmic, hyposmic, and normosmic in order to evaluate the internal validity. The authors found that the value of QOD-NS of normosmic individuals was significantly higher than those of hyposmic and anosmic.<sup>4</sup>

Currently, there is a lack of patient-reported outcome questionnaires focusing on olfactory QOL impairment. For this reason, we assessed the external validity through a correlation analysis between sQOD-NS and a visual analog scale describing OD QOL impairment. Then, the correlation analysis reported moderate but significant association ( $r_s = -0.431$ ; P = .001), suggesting high external validity. We did not evaluate external validity through a correlation analysis with SNOT-22 because many COVID-19 patients are known to be free of nasal complaints.<sup>15,16</sup> The comparison of our data of external validity with the other studies is still limited because Simopoulos et al only assessed the external validity of QOD-positive statements and not QOD-NS, while Chiesa-Estomba et al did not report such analysis.<sup>6</sup>

The main limitation of this study is the low number of patients and the focus on individuals with COVID-19. Indeed, OD in COVID-19 is probably related to neurological mechanisms, leading to total loss of smell (anosmia) in the high majority of cases. The features of patients with neurological post-viral anosmia may be different from the OD of patients with chronic rhinosinusitis with nasal polyps or other rhinological common diseases. In that way, the properties of sQOD-NS would be different for these types of patients. Moreover, some items of sQOD-NS involved social habits of individuals. During the pandemic, many European governments have imposed lockdown in some regions, modifying the social habits of populations, which may impact the patient responses. The strength of this study is the realization of psychophysical olfactory evaluations, allowing the confirmation of OD.

## Conclusion

The Fr-sQOD-NS is a short, reliable, and valid selfadministered tool for the evaluation of the impact of OD on the QOL of French-speaking patients.

#### Authors' Note

Jerome Lechien and Sven Saussez have equally contributed to this work and should be regarded as joint senior authors. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Electronic informed consent was obtained from all individual participants.

## **Declaration of Conflicting Interests**

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## **ORCID** iDs

Céline Leclercq https://orcid.org/0000-0003-1151-611X Carlos M. Chiesa-Estomba https://orcid.org/0000-0001-9454-9464 Sven Saussez https://orcid.org/0000-0002-3655-1854 Jérôme R. Lechien https://orcid.org/0000-0002-0845-0845

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