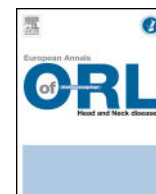




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Mini-review

French-language questionnaires in ENT: Inventory and review

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INFO ARTICLE

Keywords :

Questionnaires
 Patient-Reported Outcome Measures (PROMs)
 ENT

ABSTRACT

Objective. – Patient-Reported Outcome Measures (PROMs) are now an integral part of clinical and academic practice in ENT, and it is essential to have tools with a validated French version. However, there are no guidelines on ENT questionnaires available in French or those that could have transcultural adaptation. **Methods.** – The present study, under the auspices of the ENT National Professional Council and the French Society of ENT, inventoried PROMs, for each super-specialty and pathology, meeting one of the following inclusion criteria: validated French version, not translated but used internationally (i.e., translated into other languages and widely cited since 2017), or subjectively deemed useful by experts in the super-specialty in question.

Results. – In total, 103 questionnaires were identified. To encourage and accompany their intercultural adaptation and statistical validation, this article presents the rationale and methodology of such an undertaking.

Conclusion. – PROMs either already validated in French or which it would be useful to translate were inventoried. The methodology of translation and validation to guarantee reliability and relevance is presented.

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1. Introduction

Questionnaires are now an essential means of assessing the patient's experience, without the investigator's subjective bias interfering. Patient-Reported Outcome Measures (PROMs) have been developed for use at several levels: economic, institutional, and clinical. The number of questionnaires available in ENT has also multiplied, becoming increasingly specific [1].

Sponsored by the French ENT National Professional Council (CNPORL), a work group of the scientific commission of the French Society of ENT and Head and Neck Surgery (SFORL) was set up to inventory and support health questionnaires in ENT. The first step was to identify the PROMs and collate those validated in French. The research reported here was conducted between December 2022 and March 2023 (since when, new data may have come in). For each super-specialty, 1 or 2 experts were appointed to select available questionnaires identified on bibliographic search and consultation with the relevant association or scientific society. Inclusion criteria comprised: existence of a validated French translation, OR questionnaire used internationally, translated into other languages and

cited in PubMed since 2017, OR other questionnaire for which a French version would be useful in the experts' opinion. The secondary aim was to provide a theoretical framework for PROMs and practical recommendations for their transcultural adaptation.

2. Results

2.1. Inventory of ENT PROMs

Tables of the selected questionnaires in each super-specialty and the associated references are shown in the present Appendices (Supplementary materials).

The 103 PROMs identified were divided into 7 categories: 28 for otology and audiophonology (Appendix 1), 18 for pediatric ENT (Appendix 2), 22 for laryngo-phoniatrics (Appendix 3), 16 for oncology and head-and-neck surgery (Appendix 4), 5 for rhinosinusology (Appendix 5), 10 for facial plastic surgery (Appendix 6), and 6 generic (Appendix 7).

2.2. Use of PROMs

In the late 1980s, a need to be able to assess health subjectively emerged in two fields: public health, and clinical trials [2]. With this increasing concern for subjective health as experien-

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ced by the patient, the question arose as to how to measure it, and thus Patient-Reported Outcome Measures (PROMs) came to be developed. The first study using self-assessed quality of life as a main endpoint in assessing tolerance was published in 1985 [3]. Its success contributed to the setting up of a work group by the Food & Drug Administration (FDA), which, in 2000, defined PROMs as reports on the patient's health status coming directly from the patient, without interpretation of the patient's response by a clinician or any other third party. The result can be measured in absolute values (e.g., the severity of a symptom, sign or disease state) or as change from a prior measurement. In clinical trials, PROMs can be used to measure the impact of a medical intervention on one or more concepts: i.e., what is measured, such as a symptom or group of symptoms, the effects on a function or group of functions, or a group of symptoms or functions taken to measure the severity of a state of health [4].

The impact of a disease is not directly proportional to its symptoms, and many cognitive and environmental factors (e.g., occupational) can affect experience. Two persons with the same pathology may show very different degrees of disability. PROMs to measure quality of life improve communication between doctor and patient, focusing discussion on these issues [5,6]. Academically, patient self-assessment is now a key criterion for the efficacy of a medical intervention, whether for functional, esthetic or oncologic purposes [7]. Assessment of the efficacy of surgery is greatly enhanced by measuring quality of life pre- and post-operatively so as to improve comparison of symptoms [8]. Surgery often suffers from the lack of any direct comparator, as double-blinding is impossible and randomized controlled trials would often be difficult or unethical, especially when methodology requires a sham procedure [8,9].

Likewise, clinical trials for market authorization for new drugs increasingly use PROMs [10,11]. They are now an integral part of treatment efficacy assessment in medico-economic studies, as advocated by the French Health Authority (HAS) in its methodology reports (notably, EQ-5D; https://www.has-sante.fr/jcms/r_1499251/fr/choix-methodologiques-pour-l-evaluation-economique-a-la-has) [12]. In parallel, Patient-Reported Experience Measures (PREMs) have also been developed for questionnaires assessing the experience of care as reported by the patient, such as satisfaction with the care pathway [13]. PREMs are more particularly used for assessing quality of care at healthcare organization level rather than in clinical practice, and may be general or focused on a specific issue [14].

2.3. General and population-specific issues

2.3.1. Objectives

The International Society for Quality of Life Research (ISOQOL) defines several types of objective for Health-Related Quality of Life (HRQOL) instruments [15–17]: snapshots of individual quality of life; comparison of quality of life between pathologies (i.e., relative impact of the pathologies); change in quality of life over time (therapeutic trials, observational studies); predicting the progression of quality of life; and application in daily clinical practice on a case-by-case basis, aiming to involve the patient more actively in management [18].

2.3.2. General versus specific PROMs

Generic questionnaires are designed to assess all dimensions of HRQOL, and can be applied in any population, including healthy subjects [19]. One great advantage is to be able to compare quality of life impact between different pathologies. However, they cannot measure the different dimensions of a given pathology and tend to lack sensitivity in measuring change or treatment impact on quality of life in a specific pathology [19–21].

Specific PROMs address particular dimensions of a disease or a treatment and are more detailed, generally making them more sensitive to clinical changes [20,22]. Disease-specific PROMs are thus better able to highlight differences between different therapies [23].

In designing a scientific study, questionnaire selection is very important. One solution is to use both a specific and a general questionnaire, so far as the patient responders allow.

2.3.3. Specificities in pediatric and other populations

One of the main problems in pediatrics is that children below a certain age have a limited capacity for self-assessment. Children are deemed able to respond to a self-report questionnaire as of the age of 8 [24]. Earlier ages require proxy-assessment: e.g., by a relative or teacher [25]. Proxy-assessments are also known as Observer-Reported Outcomes (ObsRO). After 8 years of age, the relative merits of self versus proxy-assessment is a matter of debate, and differences seem to emerge between the perceptions of the proxy and the child, especially for the emotional aspects of quality of life. These discordances do not correlate with the child's age or gender [19,26].

Parents tend to overestimate their child's quality of life. This can be seen by studying "response-shift bias", comparing proxy-assessments prospectively before intervention and retrospectively after; the latter is often found to be lower than the former, as clinical improvement highlights the previous poor quality of life [27]. Having the two perspectives provides a wider view of the impact of pathology on the child [21], but requires more work for the investigator, patient and proxy.

ISPOR (the International Society for Pharmacoeconomics and Outcomes Research) taskforce developed several guidelines for pediatric quality of life assessment [28,29]: use of PROMs according to patient age; use of proxies as needed; design of specific pediatric instruments; design of instruments according to age, with adapted vocabulary or images; and special attention to transcultural issues. The Taskforce pointed out that it is doubtless impossible to set age brackets matching every situation. Even so, it set an age threshold of 5 years for self-assessment in whatever situation, and age brackets of < 5, 5–7, 8–11 and 12–18 years [29]. Also, a questionnaire designed for a broad age range tends to be less sensitive to changes in phases of life such as the transition to adolescence [30]. Two factors explain the importance of age brackets: cognitive development, and the importance of setting a comprehensible context. Questions suited to a given age bracket may show very poor statistical performance in another, in which the context may not be understood [31]. These issues likewise hinder pediatric use of questionnaires designed for adults.

These types of problem found in pediatrics can also arise in adults. Notably, subjects with cognitive or developmental disorder can find self-assessment problematic, despite quality of life and subjective assessment of symptoms being central to management [32]. It is vital to take these difficulties into account in designing a self-report instrument, which cannot be entirely replaced by proxy report [33]. Questionnaires assessing cognitive disorders as such usually take account of these aspects [34], but there are usually no questionnaires for completely distinct pathologies in such populations: e.g., the impact of tinnitus on quality of life in Alzheimer patients [34]. Management of patients with mental disorders also requires particular precautions: British National Health Service (NHS) guidelines for PROMs and mental illness highlighted, among other features, the importance of accompaniment and motivation (<https://www.rcpsych.ac.uk/improving-care/nccmh/service-design-and-development/proms-cmh-ig>).

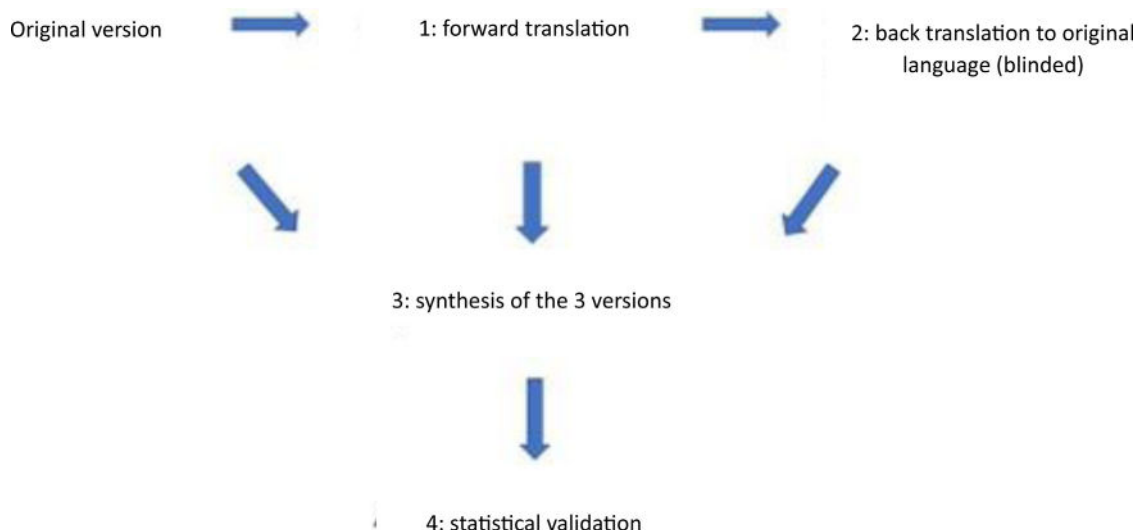


Fig. 1. Steps in transcultural adaptation and validation of a questionnaire.

2.4. Collection and analysis issues

In a 2018 report of the role of quality of life in the assessment of health technologies, the French Health Authority stressed various points for improving practices [35]:

- quality of collection: clinicians may still be reticent about PROMs, which involve extra work for them and for their patients, leading to missing data;
- statistical analysis: statistical methods exist and have been widely reported [36], but analysis of PROM data often lacks rigor (e.g., control of first-order risk and management of missing data);
- interpretation of results: this can be difficult, whence the need for tools to help with interpretation of PROM results, assessing clinical relevance in terms of minimal important difference [37].

2.5. Transcultural adaptation and validation

The first step in any research plan involving questionnaire assessment is to see whether there is a relevant instrument for which a French version has been validated. A large number of scales have been translated without any proper validation study for the French version. Using a non-validated scale can seriously undermine the validity of the results of a study. Marshall et al. analyzed results from 300 randomized trials of psychiatric drugs, and found that studies using non-validated scales showed 40% greater probability of reporting efficacy than those using validated scales [38]. The rate was one-third for non-drug studies, highlighting the major risk of bias [38].

When there are no validated instruments for the topic in question, there are two options: creating an original questionnaire, or adapting a questionnaire that exists in another language. Creating a new questionnaire is a long, rigorous and costly business, and raises the problem of comparison with other studies of the same issue using other instruments. Streiner et al. (Health measurement scales: a practical guide to their development and use) recommended not creating new scales if at all possible, arguing that the proliferation of questionnaires hinders research.

In most cases, a scale can be found, either already translated into French but not validated, or available in another language and eligible for transcultural adaptation. Also, it may be possible to modify a scale designed for a similar purpose, which would be easier than starting from scratch [39,40]. Before beginning adap-

tation, copyright status has to be checked, and it is advisable to seek the permission (or even collaboration) of the original author [39,41]. International guidelines such as those of the International Test Commission aim to standardize questionnaire adaptation methodology; scientific journals may indeed require point-by-point adhesion to such guidelines [42]. So far as possible, it is recommended to use the COSMIN guidelines of the EQUATOR network to structure the validation study [43].

2.5.1. Translation process

Questionnaire adaptation is not just a matter of translation [39], but involves several types of “equivalence”, as described by Herdman et al. [44]:

- conceptual equivalence: a given factor studied in two populations may be interpreted quite differently depending on the culture in question. For example, the concept of “family” varies greatly between cultures, from nuclear family to extended family;
- item equivalence: the questions have to be suited to the population and its way of life. For example, a question about lawnmower noise will not have the same significance in an urban as in a rural population;
- semantic equivalence: the level of language has to be suitable, with turns of phrase that are understandable for all the target population. The easiest way of getting a question understood should be used whenever possible;
- operational equivalence: the format, instructions and mode of administration have to be coherent;
- measurement equivalence: statistical performance has to be comparable between the two versions so that the measurements can be compared.

The most widely used method of translation is the forward-backward technique [39–41], which amplifies any errors and mistranslations, so as to be able to correct them (Fig. 1).

The scale is translated and adapted into French, independently by at least two bilingual native French speakers (who do not need to be ENT specialists or even health professionals). The two French versions are harmonized by the two translators, alongside an investigator, to produce the “forward” version. This is then back-translated into the original language by two bilingual translators, ideally native speakers of the original language, blind to the original version and to one another. The two versions are again harmoni-

zed by the two translators, alongside an investigator, to produce the “backward” version. The translators and the two investigators compare the backward and the original version, to correct any linguistic or cultural inexactitudes, and produce the final French version. At the end of this forward-backward translation process, there are several means of further refining the translation.

Assessment by experts in the relevant field is useful, and a simple 1–5 item-to-item score of translation quality identifies room for improvement. Readability can be assessed quite easily using formulae based on word length, phrase number, etc. [45] that are readily found and can be implemented directly online, but are not always suited for analyzing questionnaire items, as distinct from the introductory text. Finally, a pilot study on a small number of patients and/or control subjects is very helpful for further refinement before cohort implementation.

2.5.2. Statistical validation

Non-validated questionnaires and translations are an important source of bias and should be avoided as much as possible [38]. Statistical validation is an essential step for designing a new questionnaire, for any new translation and for any significant change, such as reducing the number of items [41,46]. It requires a prospective study in a cohort of patients. Various parameters can and should be studied, the most important being test reliability and validity (which can be assimilated to relevance) [46]. Reliability involves several concepts: firstly, item homogeneity is essential for interpretation, and can be measured by several techniques using correlations between items (e.g., internal coherence on Cronbach's alpha), and between items and total score (item-total correlation: ITC) [47,48]. After homogeneity, comes reproducibility. Depending on what is being studied, this maybe, and usually is, reproducibility over time (test-retest), or else inter- or intra-operator reproducibility, etc. [49]. These assessments generally use intraclass correlation (ICC) or correlation coefficients.

Questionnaires need to be not only reliable but also relevant. Here again, several methodological concepts shed light on the question, which is sometimes known as “construct validity”: i.e., that the questionnaire is indeed exploring the issue one wishes to investigate. Convergence validity is based on correlating test results with those of another questionnaire considered as a gold-standard comparator. However, there are usually no directly comparable scales (if there were, there would be no need for a new one!), and this approach is of limited use. Using generic questionnaires as comparators can be helpful [50]. A clinical parameter, such as biology results, weight, hearing threshold, etc., may be identified as correlating with quality of life and thus be used as a comparator, but this approach is limited by the poor correlations between quality of life and objective parameters in most pathologies. Lastly, discrimination performance between target and control populations, ideally with matching, is a strong methodological element in most studies, determining diagnostic thresholds by ROC curves.

A validation study for a translated questionnaire comprises a target cohort (who may fill out the questionnaire at two time points to assess reproducibility) and, usually, a control cohort serving as comparator. This allows, at least, a validity test (discrimination performance), homogeneity assessment and reproducibility assessment. The requisite number of cases and controls can, if possible, be taken from other validation studies of the same questionnaire, for example in other languages, or from questionnaires of comparable length and complexity.

2.5.3. Adaptation of an adult questionnaire to a pediatric population

There is no set age threshold for applying an adult questionnaire to a pediatric population. The ISPOR report [29] gave several

good practice recommendations for using and adapting adult questionnaires in pediatric settings (see Appendices, supplementary materials) and suggested that 12 was the lowest age for self-assessment. However, this obviously depends on the complexity of the questionnaire and its semantics [51].

3. Discussion

Use of PROMs in studies in ENT has increased exponentially in the last decade: 10-fold between 1994 and 2013 [1]. The present study inventoried the most widely used validated PROMs and those deemed useful by experts in each super-specialty. We present a theoretical and practical framework for transcultural adaptation of questionnaires, to promote such studies.

Although the study involved several experts, it may not be exhaustive and some relevant questionnaires may have slipped through our net. The study period was December 2022 to March 2023, and new questionnaires may have emerged in the interval up to publication.

For greater efficiency, we advise teams wishing to develop questionnaires or to undertake transcultural validation to contact the scientific commission of the French Society of ENT (SFORL: s.gargula@sforl.org), so as to avoid duplication.

4. Conclusion

PROMs enable the patient's point of view to be taken on board and have become a crucial part of assessment in health fields, both for patient management in clinical practice and for designing scientific studies. Using statistically validated French-language scales is essential, to limit bias inherent to subjective instruments. Translation and validation of a PROM involves precise steps to guarantee reliability and relevance.

Disclosure of interest

The authors declare that they have no competing interest.

Funding

The study received no funding, from public or private bodies.

Acknowledgments

The authors thank Pr Vincent Darrouzet, President of the CNP ORL and of the SFORL during the study period, and Pr Vincent Couloigner, Secretary General of the SFORL, for their initiative and support in setting up this project;

Dr Virginie Woisard (CHU de Toulouse) for her contribution in listing PROMs in laryngo-phoniatrics;

Ms Natacha Heutte (CHU de Caen) for her contribution in listing PROMs in oncology and head and neck surgery;

Pr Thomas Radulesco for his contribution in listing PROMs in facial plastic surgery;

Pr François Simon for his contribution in listing PROMs in pediatric ENT;

and Pr Roger Jankowski for his contribution in listing PROMs in rhino-sinusology.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.anorl.2024.07.007](https://doi.org/10.1016/j.anorl.2024.07.007).

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