The Otology Questionnaire Amsterdam: a generic patient reported outcome measure about the severity and impact of ear complaints. A cross-sectional study on the development of this questionnaire.

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Objective: Development of the Otology Questionnaire Amsterdam (OQUA); a patient reported outcome measure (PROM), measuring the severity and impact of ear complaints of patients visiting an ENT surgeon.

Design: Multicenter, cross-sectional study. Phase 1: qualitative research. In depth interviews (N=16) to identify relevant types of ear complaints and to formulate items. Pilot study of the first and second draft of the OQUA (N=32, N=39). Phase 2: quantitative research. Field-testing of the OQUA (N=352). Item reduction based on inter-item correlation, factor analysis and expert opinion.

Setting: Two secondary and two tertiary ENT clinics.

Participants: Patients over the age of sixteen visiting an ENT surgeon with an ear complaint.

Main outcome measures: Phase 1: meaning units and frequency of selected descriptions. Phase 2: inter-item correlation, factor loading and Cronbach’s Alpha (α).

Results: Phase 1: eight relevant types of ear complaints were identified: earache, pressure in ear, hearing loss, tinnitus, otorrhoea, itch, dizziness and loss of taste. Phase 2: factor analysis generated a factor ‘impact’ (α = 0.913). The current version of the OQUA consists of 34 items, covers eight types of ear complaints and consists of two constructs: complaints and impact.

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Conclusion: The OQUA is a generic, otologic PROM designed to evaluate the severity of ear complaints and their impact on patients lives.

Introduction
Like in many disciplines in medicine, in the domain of otolaryngology it is crucial that relevant and validated measurement instruments are available for the monitoring of disease progression and treatment effectiveness. Along with the increased focus on patient-centered medicine, the interest in subjective measurement of complaints has increased. Subjective measurements can provide valuable information about the way patients are experiencing their complaints and can be used in addition to objective tests like audiometric data. A useful tool in assessing subjective complaints is a patient reported outcome measure (PROM). Usually this is a questionnaire completed by the patient. Over the years, many PROMs about ear complaints have been developed. Currently, the use of these PROMs in the ENT clinic is limited. This might be due to the fact that most of the existing PROMs are either symptom-specific (SSQ and THI) or disease-specific (COMQ-12 and MDPOSI). However, patients visiting an ENT surgeon often report multiple ear complaints simultaneously. The use of multiple questionnaires per patient seems impractical in the outpatient clinic. Therefore, a PROM that addresses all relevant types of ear complaints is desirable in the outpatient clinic.

This paper describes the development of the Otology Questionnaire Amsterdam (OQUA), a generic PROM addressing the severity of ear complaints and their impact on daily life. The OQUA can be used in the outpatient ENT clinic.

Materials and methods
Ethical considerations
The study protocol was assessed by the Medical Ethics Review Committee of VU University Medical Center, Erasmus Medical Center, Isala and Amstelland hospital which led to the decision that the Medical Research Involving Human Subjects Act did not apply to this study. Written informed consent was obtained prior to study participation. All questionnaires were completed anonymously.

Participants
Patients visiting an ENT surgeon with an ear complaint were recruited in two secondary (Isala and Amstelland hospital) and two tertiary (VU University Medical Center and Erasmus Medical Center) clinics, all located in the Netherlands. Patients were eligible to participate if they were sixteen years and over, had an ear complaint, were not known to have a learning disability or cognitive impairment and had a good written understanding of the Dutch language, which was the dominant used language in the research setting.

Study design
This cross-sectional study consisted of two phases; formulation and selection of items based on qualitative analysis (phase 1) and selecting the definite set of items based on quantitative psychometric analyses (phase 2). The development of the OQUA was based on the guidelines provided in 'Measurement in medicine'. All statistical analyses were performed using SPSS Statistics v.22.0.

Phase 1: formulation and selection of items.
A. Interviews. Semi-structured interviews (N=16) were conducted to generate content and to identify relevant types of ear complaints. Patients were asked to describe their ear complaints and how these affected their daily lives. Qualitative content analysis was used to extract meaning units. Based on these meaning units, items were formulated (OQUA-v1). OQUA-v1 contained 34 items about several ear complaints.

B. Pilot study 1. The first draft of a measurement instrument needs to be tested in a small sample of patients (e.g. 15-30 persons) of the target population to test the acceptability and relevance of all items of the questionnaire. Therefore, the OQUA-v1 was pilot tested (N=32) to identify which ear complaints were rated relevant to patients and to select descriptions of ear complaints that best described the complaints as experienced by patients. Each item contained different descriptions of a specific ear complaint, which were all formulated based on patients' descriptions that were collected during patient interviews. For each item, the description that was selected most frequently was identified. Items were formulated based on these most selected descriptions. This resulted in OQUA-v2.
C. Expert opinion. An expert panel including specialists in ear and hearing (N=4) critically examined the content of OQUA-v2. Based on their input, adaptations were made. They also discussed the feasibility in the outpatient clinic and decided on adequate response scales that should be used. Visual Analogue Scales (VAS) and Likert scales were chosen. A VAS is a continuous line of variables with a clear begin and end point, like ranging from 'no pain' to 'extreme pain'. The patient has to drag or click the line to the point that resembles their complaint the most. This scale was chosen to measure the severity of complaints because it allows a precise measurement. A 5-point Likert scale is a 5-answer multiple choice scale that measures a discrete variable and was chosen to measure frequency and impact of complaints because it enables us to quantify data that is difficult to quantify. A 5-point Likert scale ranging from '(almost) never' to '(almost) always' was used to quantify the frequency of complaints. A 5-point Likert scale ranging from 'strongly disagree' to 'strongly agree’ was used to quantify the impact of complaints. Medical students and people without any medical knowledge discussed the content of OQUA-v2 to identify questions that were unclear or ambiguous. Based on these results, items were reformulated by our expert panel which resulted in OQUA-v3.

D. Pilot study 2. After substantially adjusting the questionnaire, it is recommended to perform another pilot study in a new sample of the target population (again 15-30 persons). Hence, OQUA-v3 was piloted (N=39) to assess the comprehensibility of the reformulated items using think-aloud interviews. Items that were perceived unclear or ambiguous were reformulated in OQUA-v4.

Phase 2: definite selection of items.
Field-testing of OQUA-v4 was conducted (N=352) to perform quantitative analyses. The number of completed questionnaires required to perform proper field-testing equals seven times the number of items on the questionnaire. Quantitative analysis consisted of the following steps:
A. Missing values (missings) and distribution of the scores. First, the percentage of missings for each item was determined. Items with <3% missings were considered acceptable, items with >15% missings were considered unacceptable. Second, each item’s score distribution was examined. The items with VAS scales were checked for a normal distribution using a Q-Q plot, histograms with a normal distribution curve and the significance in the Kolmogorov-Smirnov test. For items presenting normally distributed scores the mean and SD were calculated to examine the distribution of the scores. For items presenting non-normally distributed scores the median and interquartile range were calculated. The distribution of the scores of items with a Likert scale was examined by determining how frequently each response option was selected.
B. Inter-item correlation. An inter-item correlation matrix was created. Items with low correlations (<=0.2) with any of the other items were removed. Items correlating highly (>0.9) with any of the other items were checked for being identical.
C. Explorative factor analysis (EFA). EFA was conducted to gain insight in the factor structure of the OQUA and to examine possibilities for item reduction. EFA serves to identify a set of latent variables (i.e. factors) underlying the items. A condition to perform EFA is that responses are normally distributed. Generalized least squares were used to correct for non-normally distributed data. The number of relevant factors was determined based on factors with an eigenvalue >1 and the 'elbow' in the scree plot. Orthogonal rotation (i.e. Varimax) was used to rotate the component matrix. After orthogonal rotation, items were grouped into factors based on their factor loading. A minimum loading of 0.5 was taken as a threshold. Cronbach’s Alpha was used to examine the coherency within a factor (i.e. items within a factor should represent a common latent variable). A value between 0.70 and 0.90 was considered acceptable.

Chart 1. The number of participants in the various phases of the study.

Results
Patient characteristics
Table 1 presents the patient characteristics of the study samples in the various phases.

Table 1. Patient characteristics in the various phases of the study.

Study results
Phase 1: formulation and selection of items.
A. Interviews. Eight relevant types of ear complaints were identified; earache, pressure in ear, hearing

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loss, tinnitus, otorrhoea, itch, dizziness and loss of taste. In addition, several descriptions of these ear complaints were collected. Based on these data, 34 multiple-choice-items were formulated in OQUA-v1.

**B. Pilot study 1.** The results of pilot study 1 showed that patients experienced multiple ear complaints simultaneously (chart 2). Based on the 34 selected descriptions, 34 items were formulated in OQUA-v2.

**C. Expert opinion.** The expert panel provided feedback on OQUA-v2 and this resulted in the addition of 16 items. For example, an item about loss of taste was added because the expert panel stated this is an important side effect of ear surgery.

**D. Pilot study 2.** The results of pilot study 2 confirmed that patients experienced multiple ear complaints simultaneously (chart 2). Based on think-aloud interviews, some items were reformulated. The 50 items of OQUA-v4 are listed in table 2.

### Chart 2
Percentage of experienced ear complaints in the various phases of the study. Each bar represents an ear complaint as a percentage of the total number of patients in that study. Patients had the ability to tick multiple complaints. The total percentage in each phase is above 100, which shows that multiple patients experienced multiple ear complaints simultaneously.

### Table 2
50-Item version of the OQUA (translated into English, original language Dutch).

**Phase 2: definite selection of items.**

**A. Missings and distribution of the scores.** Overall, there were few missings (N=45, 0.3%), obtained from 26 (7%) respondents. All scores on the VAS items showed non-normal distributions. Scores on all items (VAS and Likert scale) were assessed as being sufficiently distributed by our expert panel (i.e. every response option was selected by a substantial number of respondents).

**B. Inter-item correlation.** All items showed an inter-item correlation of >0.2 with at least one other item. None of the items showed an inter-item correlation >0.9 with any other item.

**C. Explorative factor analysis.** EFA of OQUA-v4 generated 11 relevant factors with an eigenvalue >1. The scree-plot showed no obvious ‘elbow’. Therefore, we decided to retain 11 factors. Two of these factors had no items with a factor loading >0.5. All items were grouped into the nine remaining factors which were then labelled; eight factors related to severity and frequency of complaints and one factor related to impact. Most factors related to severity and frequency of complaints consisted of only two or three items per factor and had a low (<0.70) value of Cronbach’s Alpha.

Both parts of the questionnaire (complaints and impact) can be seen as separate constructs. The complaints-part represents a formative model: items do not necessarily correlate with each other. The impact-part represents a reflective model: a change in the observed variables is caused by a change in the construct. Each item in a reflective model is interchangeable. Factor analysis should only be applied to a reflective model. Hence, item reduction of the complaints-scale was conducted based on expert opinion.

**Complaints-scale.** Items were critically reviewed by the expert panel. Seven items were removed because they did not seem to measure what they were supposed to measure or were found irrelevant (item no. 6, 22, 30, 32, 33, 35 and 38). Nine items about hearing loss were replaced by five items from an existing, validated and broadly used questionnaire; the ‘Amsterdam Inventory for Auditory Disability and Handicap’. These items have proved to cover the different aspects in hearing (e.g. speech intelligibility in noise and in quiet, localization, detection and discrimination of sounds). One item for every aspect of hearing loss was used. Three items about popping of the ear were combined into one item (‘my ear pops’).

**Impact-scale.** EFA was conducted with the 12 items of the impact-scale. EFA generated two factors with an eigenvalue >1. The scree plot showed an obvious ‘elbow’ after the first factor. Therefore, EFA was repeated using one factor. All 12 items showed a factor loading >0.5. This factor was labelled as ‘impact’. This factor showed a high Cronbach’s Alpha (α = 0.913) which proves the coherency of items within this factor. Three items were removed based on expert opinion because they did not seem to measure what they were supposed to measure (item no. 44, 46 and 49). After deleting these items this factor still showed a high Cronbach’s Alpha (α = 0.908).

Based on the above analyses, the final version of OQUA was created. It consists of 34 items (figure 1).

**Figure 1.** 34-Item version of the OQUA (translated into English, original language Dutch).
Discussion

Comparisons with other studies
To our knowledge, only one generic otologic PROM has been described in the English literature; the 'Cambridge Otology Quality of Life Questionnaire' (COQOL). The COQOL is a 24-item questionnaire and was designed to quantify the quality of life of patients attending otology clinics. An important difference between the COQOL and the OQUA is that the COQOL was designed to measure the construct 'quality of life', presented as one sum score or 24 separate item scores. The OQUA measures two constructs; 'complaints' and 'impact'. The scores on the complaint-part are presented graphically per complaint and the scores on the impact-part are presented as one sum score.

Clinical applicability of the study
The current study presents the development of a Dutch generic PROM addressing ear complaints and their impact on daily life. The OQUA was developed, pilot-tested and field-tested in a large group of ENT patients. The final version consists of 34 items, measuring eight types of ear complaints and the impact of ear complaints on daily life. The advantages of the OQUA are various: graphical representation of severity of complaints, easy to use in the outpatient clinic and easy comparison of patients' perspectives of complaints and impact of these complaints before and after intervention. The OQUA can be used in addition to objective measurements so that it can be used to optimize otologic care. Further research is required to determine OQUA's minimally important change.

Strength and weakness of the study
Following the guidelines of COSMIN, the required steps to develop a questionnaire were taken in the various phases of the study. The study population represented a heterogeneous group by including participants of different ages, experiencing different types of ear complaints and an even distribution of male and female participants. Another positive feature of this study is that there were only few missings (<0.3%). Moreover, the missings were obtained from few respondents (7%) and were distributed over various items. This suggests that missings were not caused by poor formulation of an item.
A limitation of this study is that the origin of the participants was not evenly distributed across clinics. Fifty-eight participants (74%) in phase 1 and 303 participants (86%) in phase 2 originated from a tertiary clinic. This may have led to a selected display of distributions of complaints within the study population. However, every type of ear complaints was sufficiently represented in the study population. Another limitation of this study is the fact that the OQUA contains eight items answered by a VAS. Previous research has shown that not every patient, in particular the elder patient, is able to complete a VAS correctly. This was also observed in the current study. However, almost no problems occurred when the OQUA was completed digitally. Therefore, it is preferred to complete the OQUA digitally.

Further research
Before implementation, the reliability and validity of the OQUA need to be investigated. In addition, OQUA's format will be further developed so that scores of different ear complaints can be presented graphically, which will give a quick overview of each patient's complaints. To optimize the comparison of patients' perspectives before and after an intervention a third construct should be added next to complaints and impact, namely 'benefit and satisfaction'. The OQUA has the potential to provide the scores on all three parts of the questionnaire (complaints, impact and benefit & satisfaction) separately. We aim to examine OQUA's test-retest reliability and responsiveness in future research.

Conclusion
The development of a generic otologic PROM covering all relevant ear complaints is presented. This generic questionnaire can be very useful as many patients with an ear complaint report multiple ear complaints simultaneously. The OQUA addresses eight types of ear complaints and contains items about impact in a 34-item questionnaire. The OQUA is based on thorough analyses including in depth interviews, think-aloud interviews, pilot studies and field-testing. Further studies will focus on validity, reliability, the optimization of graphical representation and satisfaction & benefit scores.

Conflict of interest
None to declare.

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Tables

Table 1. Patient characteristics in the various phases † of the study.

| Characteristics   | Phase 1A: Interviews | Phase 1B: Pilot study 1 | Phase 1D: Pilot study 2 | Phase 2: Field-testing |
|-------------------|----------------------|-------------------------|-------------------------|------------------------|
| Number of patients| 16                   | 32                      | 39                      | 352                    |
| Items investigated| 0                    | 34                      | 47                      | 50                     |
| Age, years        | Mean                 | 47                      | 55                      | 48                     | 49                     |
|                   | Range (min.–max.)    | 24–69                   | 20–88                   | 16–76                  | 16–93                  |
| Missing ‡         | 0 (0%)               | 0 (0%)                  | 0 (0%)                  | 0 (0%)                 | 10 (2.8%)              |
| Gender            | Male                 | 7 (44%)                 | 10 (31%)                | 20 (51%)               | 174 (49.4%)            |
|                   | Female               | 9 (56%)                 | 21 (66%)                | 19 (49%)               | 177 (50.3%)            |
| Missing §         | 0 (0%)               | 0 (0%)                  | 0 (0%)                  | 1 (0.3%)               |                        |
| Clinic            | Secondary            | 0 (0%)                  | 29 (91%)                | 0 (0%)                 | 49 (13.9%)             |
|                   | Tertiary             | 16 (100%)               | 3 (9%)                  | 39 (100%)              | 303 (86.1%)            |

† Phase 1C was omitted in table 1 because in this phase only expert opinion was used. No patients were included in this phase.
‡ Missing values are caused by respondents who forgot to fill in their age.
§ Missing values are caused by respondents who forgot to fill in their gender.

Table 2. 50-Item version of the OQUA (translated into English, original language Dutch).

| Items                                                                                           |
|-------------------------------------------------------------------------------------------------|
| **Complaints**                                                                                  |
| 1. Indicate the severity of your earache on the line below.                                     |
| 2. I have an earache.                                                                           |
| 3. When my ear pops, the earache lessens.                                                       |
| 4. Indicate the severity of itching in or on your ear on the line below.                         |
| 5. I have an itch in or on my ear.                                                              |
| 6. It feels as if there is something in my ear.                                                  |
| 7. Indicate the severity of your tinnitus (this can be a hum, murmur, beeping noise, or buzzing sound) on the line below. |
| 8. I hear a hum, murmur, beeping noise, or buzzing sound.                                        |
| 9. Indicate the severity of your hearing loss on the line below.                                 |
| 10. I am sensitive to loud noises.                                                               |
| 11. I have poor hearing.                                                                        |
| 12. I have trouble understanding what people are saying.                                         |
| 13. I have to turn my ‘good’ ear towards someone to understand what they are saying.           |
| 14. I have trouble following conversations that involve several people.                         |
| 15. I have trouble following conversations in noisy rooms.                                      |
| 16. When my ear pops, I can suddenly hear more sounds.                                           |
| 17. The sounds I hear seem far away.                                                             |
| 18. I need to turn up the volume of the television – more than other people do – to understand what is being said. |
| 19. Before an approaching vehicle comes into view, my hearing tells me which direction it is coming from. |
| 20. To me, sounds are like noises heard under water.                                             |
| 21. Indicate the severity of your ear discharge on the line below.                               |
| 22. I have ear discharge.                                                                        |
| 23. Liquid comes out of my ear.                                                                  |
| 24. Pus comes out of my ear.                                                                     |
| 25. Indicate the severity of pressure in your ear on the line below.                             |
| 26. I feel pressure in my ear.                                                                   |
| 27. When my ear pops, it eases the pressure in my ear.                                            |
| 28. Indicate the severity of your dizziness on the line below.                                    |
| 29. I have balance problems.                                                                     |
| 30. In the dark, I have problems with my balance.                                                |
| 31. I feel dizzy.                                                                                |
| 32. I feel light-headed.                                                                        |
| 33. It seems as if the room is spinning.                                                          |
| 34. When I move my head, I get dizzy.                                                             |

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35. When I roll over in bed, I get dizzy.
36. Indicate the severity of your loss of taste on the line below.
37. I have a poor sense of taste.
38. Food tastes just fine.

**Impact**
39. I get irritated due to my ear problems.
40. I get upset due to my ear problems.
41. I have impaired concentration due to my ear problems.
42. I feel depressed due to my ear problems.
43. My ear problems are very tiring.
44. I have difficulty sleeping due to my ear problems.
45. My ability to take part in social activities (hobbies, sport, or leisure-time activities) is limited due to my ear problems.
46. I find telephone conversations difficult due to my ear problems.
47. I have had to modify my daily activities and/or work due to my ear problems.
48. My ear problems make life difficult for me.
49. My ear problems make life difficult for those around me.
50. I am concerned about my problems.

**Key points**
- A generic otologic questionnaire seems the most desirable PROM (compared to disease- or complaint-specific) as many patients visiting an ENT surgeon experience multiple ear complaints simultaneously and the use of several questionnaires next to each other seems unpractical.
- Eight relevant types of ear complaints were identified: earache, pressure in the ear, hearing loss, tinnitus, otorrhoea, itch, dizziness and loss of taste.
- The OQUA is a 34-item questionnaire and contains two subscales: complaints and impact of ear complaints on daily life.
Figures

Chart 1. The number of participants in the various phases of the study.

| Phase 1A: Interviews (N=16) | Phase 1B: Pilot study 1 (N=32) | Phase 1C: Expert opinion (N=4) | Phase 1D: Pilot study 2 (N=39) | Phase 2: Field-testing (N=352) |

Chart 2. Percentage of experienced ear complaints in the various phases of the study. Each bar represents an ear complaint as a percentage of the total number of patients in that study. Patients had the ability to tick multiple complaints. The total percentage in each phase is above 100, which shows that multiple patients experienced multiple ear complaints simultaneously.

- Hearing loss
- Tinnitus
- Otorrhoea
- Pressure in ear
- Itch
- Earache
- Dizziness
- Dizziness
- Loss of taste

Study phases
**Figure 1.** 34-item version of the OQUA (translated into English, original language Dutch).

**Otology Questionnaire Amsterdam**

*Please answer all the questions below. The questions relate to the complaints you have experienced in the past four weeks. If you use hearing aids in daily life, please answer all questions as if you are using them.*

**Complaints**

1. Indicate the severity of your earache on the line below.

   | No earache | Unbearable earache |
   |------------|-------------------|
   | (Almost) never | Sometimes | Regularly | Often | (Almost) always |

2. I have an earache.

3. Indicate the severity of itching in or on your ear to the line below.

   | No itching | Unbearable itch |
   |------------|-----------------|
   | (Almost) never | Sometimes | Regularly | Often | (Almost) always |

4. I have an itch in or on my ear.

5. Indicate the severity of your tinnitus (this can be a hum, murmur, beeping noise or buzzing sound) on the line below.

   | No tinnitus | Unbearable tinnitus |
   |------------|---------------------|
   | (Almost) never | Sometimes | Regularly | Often | (Almost) always |

6. I hear a hum, murmur, beeping noise or buzzing sound.

7. Indicate the severity of your hearing loss on the line below.

   | No hearing loss | Unbearable hearing loss |
   |----------------|------------------------|
   | (Almost) never | Sometimes | Regularly | Often | (Almost) always |

8. Can you hear somebody approaching from behind?

9. Can you hear cars passing by?

10. Can you hear from what corner of a room someone is talking to you being in a quiet house?

11. Can you understand the presenter of the new on TV at a normal volume?

12. Can you follow a conversation between a few people during dinner?

13. I am sensitive to loud noises.

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14. Indicate the severity of your ear discharge on the line below.

| No ear discharge | Unbearable ear discharge |
|------------------|--------------------------|

15. Liquid comes out of my ear.
16. Pus comes out of my ear.

17. Indicate the severity of pressure in your ear on the line below.

| No pressure in ear | Unbearable pressure in ear |
|--------------------|-----------------------------|

18. I feel pressure in my ear.
19. My ear pops.

20. Indicate the severity of your dizziness on the line below.

| No dizziness | Unbearable dizziness |
|--------------|----------------------|

21. I have balance problems.
22. I feel dizzy.
23. When I move my head I get dizzy.

24. Indicate the severity of your loss of taste on the line below.

| No loss of taste | Unbearable loss of taste |
|------------------|--------------------------|

25. I have a poor sense of taste.

Impact

| Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
|-------------------|----------|---------|-------|---------------|

26. I get irritated due to my ear problems.
27. I get upset due to my ear problems.
28. I have impaired concentration due to my ear problems.
29. I feel depressed due to my ear problems.
30. My ear problems are very tiring.
31. My ability to take part in social activities (hobbies, sport or leisure-time activities) is limited due to my ear problems.
32. I have had to modify my daily activities and/or work due to my ear problems.
33. My ear problems make life difficult for me.
34. I am concerned about my ear problems.