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Technical note

Standardized questions in English for estimating tinnitus prevalence and severity, hearing difficulty and usage of healthcare resources, and their translation into 11 European languages

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ABSTRACT

Introduction: Prevalence estimates depend largely on the nature of the question asked to define the presence of the health condition, and the literature on the population burden of tinnitus and hearing difficulties is no different in this respect. The lack of standardized questions for data collection limits comparison across studies and across countries. The purpose of this short Technical Note is to report the first attempt to establish a set of standard questions developed for use in population-based surveys, and their adaptation and translation from English into 11 European languages.

Methods: Four questions and their corresponding response options were adapted from existing population-based surveys to assess tinnitus prevalence, tinnitus symptom severity, use of healthcare resources for tinnitus and hearing difficulty. The translated versions (Bulgarian, French, German, Greek, Italian, Latvian, Polish, Portuguese, Romanian, Russian, and Spanish) were generated using recognized methods to achieve a "world-for-world" translation.

Results: Translated versions were produced with acceptable functional equivalence to the original English-language version, as judged by a small panel of bilingual speakers who participated in the online field testing.

Conclusion: This work is the first of its kind to promote multi-national standardization by creating a set of tools that can readily be used across countries. These are currently being used in a European-wide study of tinnitus prevalence, and have wider application across English- and Spanish speaking countries including the Americas and Oceania.

1. Introduction

Tinnitus is a common symptom associated with the conscious perception of an auditory sensation in the absence of a corresponding external stimulus. For many people, it can severely impact everyday life (Hall et al., 2018a). From a public health perspective, it is important to work out effective prevention and intervention strategies and, for that, an understanding of the tinnitus population burden is required. Three issues are relevant to considerations of estimating population burden of tinnitus: i) wording of the question, ii) separating bothersome from non-bothersome tinnitus, and iii) understanding co-morbid hearing difficulties.

Prevalence studies of tinnitus have mostly been conducted in Western Europe or the USA, but many have had methodological limitations, especially in terms of the lack of an agreed definition of tinnitus and phrasing of appropriate questions asked of

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participants in population surveys (McCormack et al., 2016). A recent systematic review by McCormack and colleagues identified 39 studies which had been conducted to estimate the prevalence of tinnitus in different countries (McCormack et al., 2016). They reported that the overall prevalence of any tinnitus ranged from 5% (Quaranta et al., 1996) to 43% (Gibrin et al., 2013). A widespread variability in the definition of tinnitus is believed to be an important factor in determining this large range in population estimates. Other authors (e.g. Gallus et al., 2015; Nondahl et al., 2004) have also attributed the wide variation in prevalence estimates, beyond what is expected due to demographic differences, to the lack of a standard definition of tinnitus. Indeed, McCormack et al. (2016) identified eight different types of definition of tinnitus, with few studies justifying their choice of wording. The most common wording describing the presence of tinnitus referred to "tinnitus lasting for more than five minutes at a time". This form of tinnitus experience is arguably phenomenologically different from a "clinically significant" tinnitus where the condition hampers an individual's quality of life (Hoekstra et al., 2014). Hence, many epidemiological studies also ask a question about the severity or bothersomeness of tinnitus symptoms. McCormack et al. (2016) found that severity was assessed in under half of studies (16 out of the 39 studies) with the data indicating that the prevalence of bothersome tinnitus ranged from 3% (Michikawa et al., 2010) to 31% (Kim et al., 2015). Again, an important factor to this variability concerns the definition of tinnitus symptom severity. The most common concept of severity considered how bothered, annoyed or worried the person was by their tinnitus, and this wording was used in eight of the studies reviewed by McCormack et al. (2016). However, other studies asked about severity in terms of impact on sleep, concentration, or ability to lead a normal life. Because of this lack of standardization for estimating tinnitus prevalence and severity, it is not possible to pool estimates to understand the global burden of tinnitus, nor to examine differences across countries or world regions. A call to resolve this problem was raised by Gallus et al. (2015) and McCormack et al. (2016).

A second issue is that in population-based surveys it can be useful to distinguish tinnitus in the general population which does not lead to medical help-seeking from tinnitus which affects an individual enough to seek care. The latter has important socio-economic implications. Martinez et al. (2015) specifically defined a 'clinically significant' tinnitus as a condition where the patient has a recording in a general practice or hospital setting of a specific diagnosis or procedure, or referral to a healthcare practitioner. In the absence of an efficient and effective healthcare system such patients can often make repeat appointments, creating a 'revolving door' pattern of healthcare (McFerran et al., 2018). Thus, a clinically significant tinnitus, in which people seek medical help, imposes personnel and financial resource burden on the healthcare system (Goldstein et al., 2015; Maes et al., 2013; Stockdale et al., 2017). This information can easily be captured by a question about the number of appointments for tinnitus-related problems in the past year.

Third, hearing loss is a known major risk factor for developing tinnitus (Nondahl et al., 2002), and hearing loss with tinnitus substantially increases the burden of disability (Salomon et al., 2015). Like tinnitus, hearing loss is a common medical problem. The global prevalence of hearing loss is about 5% (World Health Organization, 2012). Yet, few studies have reported prevalence of hearing loss and tinnitus (and the overlap) in the same population; one example in the UK assessed self-reported hearing difficulty and tinnitus, finding 41% of those reporting at least a slight hearing difficulty also reported experiencing tinnitus (Moore et al., 2017). The prevalence of hearing loss is known to vary across countries, with lower estimates in high-income countries (5%) and higher estimates in middle- and low-income countries of Sub Saharan Africa (16%) and South Asian region (17%) (Stevens et al., 2013). When examining any tinnitus differences across countries, it would therefore be informative to assess prevalence estimates in the context of individual hearing status. For simplicity, population-based surveys would probably rely on self-reported hearing difficulty, rather than hearing loss measured using pure tone audiometry.

2. Rationale

This Technical Note describes the methods we undertook to define a set of standardized questions and corresponding response options suitable for use in population-based surveys for assessing tinnitus, hearing difficulty, and the associated use of healthcare resources. We then extended the international applicability of these questions by translating and adapting them from English into 11 European languages, following good practice methods recently summarized by Hall et al. (2018b). We have implemented these questions in a European-wide population survey that is currently ongoing as a project within the European School on Interdisciplinary Tinnitus Research (ESIT) (Schlee et al., 2017). ESIT seeks to promote multi-national comparability of findings across all major relevant disciplines. The purpose of this population survey is to characterize prevalence within a number of European countries[1] and to conduct the first comparative evaluation across those same countries. The participating countries were selected because of their varied cultural and socio-economic population characteristics, across a reasonably constrained geographical region.

3. Description of the methods

3.1. Description of the original source items

The European-wide population survey comprised four self-report questions and corresponding response options to assess the prevalence of tinnitus, hearing difficulty, tinnitus symptom severity, and tinnitus-related healthcare resource use (Table 1). The questions were adapted from existing survey questionnaires in English by the project team in consultation with two independent academics with relevant experience. The survey included instructions for the interviewer, questions and response options. Collectively, these are referred to as 'items'.

The (English) wording of questions and response options was informed by published work, as far as possible. The four questions were introduced in the following way: "Now we ask you a few questions on hearing problems and on the sensation of noise in the head or in one or both ears, which is a symptom that medical doctors call tinnitus." (Table 1). The first item on **prevalence of tinnitus** used the same core question as the published UK Biobank (question H11: *"Do you get or have you had noises (such as ringing or buzzing) in your head or in one or both ears that lasts for more than five minutes at a time?"*) (UK Biobank, 2011). There was one modification. Our question asked about experience 'over the past year'. The expected benefit from specifying a fixed recall period was to reduce recall bias and to exclude those with just occasional episodes occurring in the distant past. The resulting question therefore incorporated two common aspects in published definitions of tinnitus reported by McCormack et al. (2016); those being "tinnitus lasting for more than five minutes at a time" and "experiencing in the last one year". Response options were the same as the published UK Biobank, but with one modification. In the UK Biobank

[1] Bulgaria, England, France, Germany, Greece, Republic of Ireland, Italy, Latvia, Poland, Portugal, Romania, and Spain.

Table 1
Standardized survey instructions, questions and response options in the source language (English).

General instruction to participants	"Now we ask you a few questions on hearing problems and on the sensation of noise in head or in one or both ears, which is a symptom that medical doctors call "tinnitus""		
	Question-specific instruction to the interviewer	*Question*	*Response options*
Presence of tinnitus	To all adults (i.e., aged ≥ 18 years)	Over the past year, have you had noises (such as ringing or buzzing) in your head or in one or both ears that lasts for more than five minutes at a time?	• Yes, most or all of time •Yes, a lot of the time •Yes, some of the time •No, not in the past year •No, never •Do not know/Prefer not to answer
Tinnitus severity	To participants with current tinnitus	Over the past year, how much do these noises in your head or ears worry, annoy or upset you when they are at their worst?	•Severely •Moderately •Slightly •Not at all •Do not know/Prefer not to answer
Use of healthcare resources for tinnitus	To participants with current tinnitus	Over the past year, have you seen your family doctor, or seen a healthcare professional at a clinic or hospital about problems with noises in your head or ears?	•Yes, 5 or more visits •Yes, from 2 to 4 visits •Yes, just one visit •Not at all •Do not know/Prefer not to answer
Presence of hearing difficulty	To all adults (i.e., aged ≥ 18 years)	Do you currently have any other difficulty with your hearing, such as listening to speech in a noisy situation?	•Yes, cannot hear at all •Yes, severe difficulty •Yes, moderate difficulty •Yes, slight difficulty •No difficulty •Do not know/Prefer not to answer

(2011), one response option is "Yes, but not now, but have in the past". By introducing a fixed one-year recall period into our survey question, this response option no longer made sense and so our survey used the alternative version "No, not in the past year." **Tinnitus symptom severity** also used the same core question as the UK Biobank (question H11a: *"How much do these noises worry, annoy or upset you when they are at their worst?"*, UK Biobank, 2011), but again with the addition of 'over the past year'. Response options were identical to those in UK Biobank.

Regarding **use of healthcare resources for tinnitus,** published studies modelling population-based health care costs have typically used the number of tinnitus-related general practitioner visits and/or hospital visits as a basis for cost estimates of the burden on healthcare resources, and this information has been obtained retrospectively from clinical records (Goldstein et al., 2015; Maes et al., 2013). To our knowledge, there has been no published population survey asking participants a question on use of healthcare resources for tinnitus. In the absence of a published source, we turned to other sources. The Medical Research Council Study of Hearing Difficulties has been partly published (Noble et al., 2012), but includes an unpublished question asking "*Have you ever been to your family doctor or hospital about problems with noises in your ears?",* with response options of *No/Yes visited doctor (GP) only/Yes, visited GP and been referred to hospital*. Our modified version again included the one-year recall period. Revised wording also extended relevant medical specialists to include healthcare professionals at a clinic or hospital. The thinking here was to consider relevance to countries where the distinction between GP and hospital is less well defined than in the UK. To capture information about the degree of resource usage, the response options were modified to specify the actual number of visits. Note that only those respondents reporting tinnitus (be it 'most', 'a lot of' or 'some of the time') were asked about severity and resource use.

All respondents were asked a question about **hearing difficulty**. This question was adapted from an internet-based population study conducted by Moore et al. (2017). The original question asked '*Do you currently have any difficulty with your hearing?*'. Our modified version added the qualifying phrase *'listening to speech in a noisy situation'* to give a context to the self-report. Listening to speech in a noisy situation is a common listening complaint in everyday situations (Vas et al., 2017). Response options were maintained as per the original.

3.2. Translation and cross-cultural adaptation of the survey items

The survey items were written in English and so needed to be translated into Bulgarian, French, German, Greek, Italian, Latvian, Polish, Portuguese, Romanian, Russian and Spanish for use by the interviewers in the population-based survey. The translation process followed the good practice guidelines summarized in Hall et al. (2018b) and illustrated in Fig. 1, and a template document was created specifically for the purpose of recording all of the steps taken. These guidelines were based on common elements among previous well-known guidelines (Acquadro et al., 2008; Beaton et al., 2000; Guillemin et al., 1993; Wild et al., 2005, 2009). The purpose was to produce a final set of items that preserved the same meaning as the original, would be understood by the target population, and would adequately reflect any nuances of the source or target languages. The first relevant step was that of translating the source-language items into the target languages (Hall et al., 2018b). This forward translation was conducted by a commercial market research company (DOXA, Italy), which has partners across all target countries and in-house expertise in translating population-survey items.

For the next stage of back translation, we recruited for each language at least one, and in some cases two, bilingual translators with in-country experience of the target language. The translators were not necessarily topic-specific experts, but they were all briefed on the clinical concepts underlying the health conditions of interest addressed by each item, using concept definitions written in plain language by DAH, with review by the project team (Supplementary Table 1). Each translator used both the target-language item and the corresponding concept definitions to independently create a written translation in English. The back translators were asked to write comments about any words or phrases that were particularly challenging and to suggest an alternative

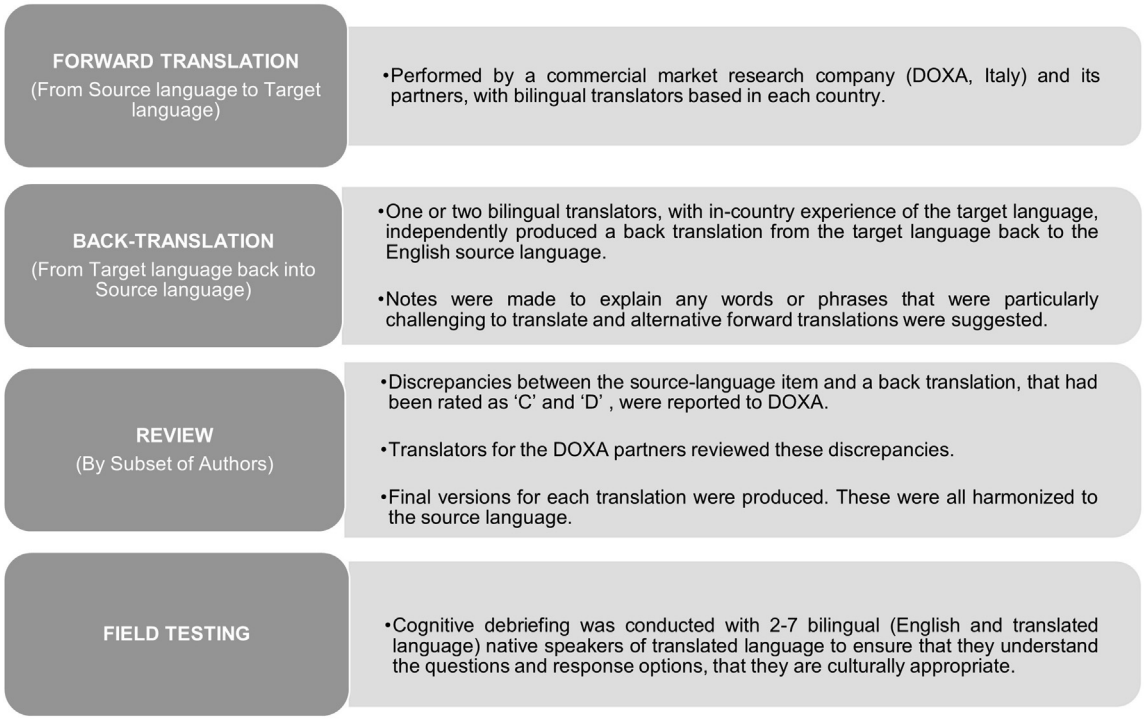

Fig. 1. Steps of the Translation Process: The following scheme shows the order of the translation steps following the good practice guide by Hall et al., (2018b).

forward translation if necessary. One member of the research team then highlighted each word or phrase of the back translation and the source. The discrepancies were classified using an A–D scheme (e.g. Badia and Alonso, 1994; Sanchez-Moreno et al., 2008). Ratings of 'A' or 'B' indicated acceptable conceptual and semantic equivalence between the back-translated and English version even if one or two different words had been used. Ratings of 'C' were acceptable because the items preserved the meaning of the original, but not necessarily with the exact semantic equivalence. Ratings of 'D' indicated unacceptable equivalence, and so following (Hall et al., 2018b), these are the items that required further action. However, in this study, all discrepancies given a rating of 'D' or 'C' were discussed by the project team. Note that for the Latvian version, it proved challenging to find bilingual (Latvian-English) speakers and so the team had to rely on Google translate for the backward translation step. Some of the resulting Latvian back translations were rated 'D', but when these were cross-checked with one native Latvian speaker their opinion was that the original forward translation was understandable in Latvian without any further changes necessary. For all languages, we submitted the resulting set of recommendations to DOXA, who were asked to manage the necessary revisions in order to achieve a final version of the translated items that harmonized with the source language version. One member of the project team coordinated with DOXA to understand what suggested revisions had been incorporated.

3.3. Confirmation that the translated versions are functionally equivalent

Next, we ran a field testing step to ensure that the translated questions and response options were understood by the target population in the same way as the source English language version and adequately reflected any nuances of the target language (Hall et al., 2018b). For most languages, between three and seven bilingual speakers were recruited as participants using purposive sampling. Participants were recruited from our network of colleagues and collaborators, and their social and professional networks. We also reached out to some of the European Federation of Audiology Society (EFAS) country chiefs for their assistance, and to direct us potential participants. The final participant group comprised hearing researchers, clinicians and members of the general public. All had the target language as their mother tongue and none had previously been involved in the back translation process. Unfortunately, despite repeated attempts we were unsuccessful in recruiting Latvian and Romanian bilingual speakers.

A structured short online survey presented the four translated questions and response options. We asked the participants to summarize their interpretation of each question and response option in their own words in English language. This enabled the project team to check equivalence with the original English language version. Participants were also asked to note words or phrases that were either difficult to understand or that might sound awkward colloquially, and provide any recommendations that would make it more culturally appropriate or more acceptable to the general public. The survey had a section where the participants could rate the overall translation using a numerical rating scale from 0 to 100. We did not conduct any field testing on the introductory sentence.

4. Results

The set of standardized questions and response options in their source-language English version are reported in Table 1.

4.1. Translation and cross-cultural adaptation of the survey items

From these, forward translations of each set of questions were created by the market research company and these were then evaluated by the back translators. Based on the comparison between the back translations and the original English-language

version, the translated items which had an acceptable degree of equivalence to the original source were rated as A or B. For the translations of the item on presence of tinnitus, 8 out of 11 translated questions, and 10 out of 11 translated response options were given a rating of A or B. For the translations of the item on tinnitus symptom severity, 5 out of 11 translated questions, and 10 out of the 11 translated response options were rated A or B. For the translations of the item on use of healthcare resources for tinnitus, 10 out of 11 questions, and all of the 11 response options were rated A or B. For the translations of the item on hearing difficulty, 6 out of 11 translated questions and 10 out of 11 response options were rated A or B.

Table 2 reports for the item on presence of tinnitus those cases where there appeared to be some sort of discrepancy between the source and target language versions (i.e., C or D ratings). Table 2 also lists any corresponding suggestions by the back translators and the actions taken; namely reasons for accepting or rejecting those suggestions. The discrepancy related information (i.e., C or D ratings) for the three items on tinnitus symptom severity, tinnitus-related resource use and hearing difficulty are reported in Supplementary Tables 2, 3, and 4, respectively.

Most of the discrepancies arose due to difficulties in striking a balance between preserving the meaning of the original words while at the same time having satisfactory conceptual equivalence, as when developing the final translated versions, we tried to capture the nuances of the target language. We noted that the C and D ratings were most commonly found for the questions and response options on the severity of tinnitus symptoms and the question on hearing difficulty (three translations were rated "D" for both questions). These questions and response options, required further edits in the translated versions in seven and six languages, respectively, out of the 11 translated languages. For example, in the question on tinnitus severity, the three emotional descriptors used to assess tinnitus distress- "worry, annoy or upset", have subtly different meanings in English. A major point of discrepancy was conveying the same emotion in the translated version while preserving the original meaning. For the question on hearing difficulties, a key concept was listening and understanding speech, as against simply hearing it. An important concern in this case was to keep the conceptual alignment without straying excessively from the original wording and question structure.

The final versions of the translated items produced by the market research company are reported in Supplementary Table 5. Some of the minor changes and slight conceptual differences as recommended by the back translators (see Table 2 and Supplementary Tables 2, 3, 4), were not incorporated in the final versions.

4.2. Field testing

The main purposes of this step were to evaluate the likelihood that the translated versions would be understood by the target population in the same way as the source English language version, and how well they reflected any nuances of the source or target languages. Table 3 reports the overall rating scores for the language level and understandability of the translated versions. Although the numbers as such are not necessarily straightforward to interpret, the ratings show general agreement across raters on the quality of

Table 2
Discrepancies and recommendations for question on presence of tinnitus.

Translations of question					
Language of translation	Forward Translation	Rating based on discrepancy	Change recommended	Change implemented	Reasoning
FRENCH	Au cours de l'année passée, avez-vous expérimenté ce type de bruits (sonneries ou bourdonnements) dans votre tête, du côté d'une oreille ou des deux oreilles, qui durent plus de cinq minutes à chaque fois ?	C	Recommend changing 'ce type de bruits' (meaning: this type of noises) to 'un acouphène' (meaning: a tinnitus).	No	Since the original English version question used the term 'noises' not 'tinnitus', the researchers believed the forward translation was good enough.
GREEK	Κατά το περασμένο έτος, αισθανόσασταν θορύβους (όπως κουδούνισμα ή βουητό) στο κεφάλι σας ή σε ένα ή και στα δύο αυτιά που διήρκησε για περισσότερο από πέντε λεπτά τη φορά;	C	The term 'Last year' does not adequately stress the period of time over which participants should consider their response.	Yes	The term 'Over the last year' implies the time frame. In the back-translation, the translator used the term 'last year' which we agreed did not capture the duration of the condition.
PORTUGUESE	No último ano, ouviu ruídos (como campainhas ou zumbidos) dentro da cabeça, ou em um, ou nos dois ouvidos que tenham durado mais de 5 minutos de cada vez?	C	The term 'ringing' seems substituted for 'buzzers'	Yes	The back-translator translated "[…] (como campainhas ou zumbidos)"as "[…] (such as buzzers or buzzing)]. This is slightly different from the original English word "ringing". A closer term in Portuguese was sought.
Translations of response options					
Language of translation	Forward Translation	Rating based on discrepancy	Change recommended	Change implemented	Reasoning
ITALIAN	1. Sì, quasi sempre o sempre 2. Sì, buona parte del tempo 3. Sì, qualche 4. No, non nell'ultimo anno 5. No, mai 6. Non so/Preferisco non rispondere	C	"Most or all of time" in Italian should be "La maggior parte del tempo o tutto il tempo". The researchers preferred to translate it using "quasi sempre o sempre" which means "almost always or always", since this is more comprehensible. The third option in Italian is actually different … in the last version of the questionnaire, it is "Si, qualche volta".	Yes	It was a typing error where some part of the sentence was missed.

Table 3
Evaluation scores of field testing. Scores are between 0 and 100. 'ND' denotes that the field testing was not done.

Languages	Number of individual field testers	Median score	Score range	
			Minimum	Maximum
Bulgarian	3	100	90	100
French	3	80	75	99
German	7	85	70	100
Greek	5	94	75	97
Italian	5	90	85	100
Latvian	0	ND	ND	ND
Polish	3	85	60	90
Portuguese	4	77.5	25	98
Romanian	0	ND	ND	ND
Russian	5	70	60	100
Spanish	5	89	70	89

most of the translated versions. Nevertheless, there were wider differences of opinion across the Polish, Portuguese and Russian raters, with some of those raters giving a quality score of 60 or less. As data collection (for estimating prevalence) was already ongoing for some countries using the translated questionnaires, no edits were made after the field testing step. But the open-text comments for some of the languages are informative for future research.

Polish: The Polish language version was evaluated by three bilingual speakers, none of whom were hearing experts. For the response options in the tinnitus prevalence question, two participants suggested removing the comma after "Nie" in the response option ("*Nie, w ciąguostatniego roku"*). This corresponds in English to "No, not in the past year". Two participants found the word order of the question on use of healthcare resources rather awkward. One summarized the question as: "*If patient seek medical attention (general practitioner, specialist in clinic/hospital) in one-year period because of unpleasant feeling in head or ears*", and noticed that in Polish context, a specialist could be available in ambulatory care as well, and not necessarily in hospital/clinic. The second person suggested changing the word order from "*W ciągu ostatniego roku czy był/a*" to "*Czy w ciągu ostatniego roku był/a*", to better express the time period "over the last one year". For the question on hearing difficulties, all three suggested changing the word "*problem*" to "*problemy*" which is the plural form. Two participants also queried whether the final question assessed difficulty in hearing in general or specifically in a loud environment, since this was not quite clear to them from the question.

Portuguese: The Portuguese language version was evaluated by four bilingual speakers all of whom were hearing experts. One of them thought that, the questions were awkwardly phrased and needed modifications based on whether they were being addressed to the Portuguese population in Portugal or in South American countries such as Brazil, since the translation was a mix of both versions. For example, for the question on tinnitus prevalence, "*ringing or buzzing*" was translated to "*toques ou zumbidos*". But according to the participant, *"'toques" does not directly translate to "rings"" - "toques" also mean "touches""*. For the response options relating to the use of healthcare resources, two participants suggested changing "*Nada*" (meaning *nothing*) to "*Nenhuma vez*" (meaning *not a single time*). For the question on hearing difficulty, one participant commented: *"a person may hear but not understand. If you want to focus on understanding in noise, rephrasing is important"*.

Russian: The Russian language version was evaluated by five bilingual speakers, four of whom were hearing experts. Three participants felt that the questions on tinnitus prevalence and severity of tinnitus symptoms did not sound natural in Russian and were awkwardly phrased. They either suggested alternative versions for the questions or recommended changing part of them. For example, for the prevalence question, the three suggested rephrased alternative versions are as follows:

> *"В течение Последнего года ощущали ли Вы в голове, одном или обоих ушах шум, наЩоминающий звон или свист, ЦродолЖительностью более Цяти минут?"* (meaning: *"During the past year, did you feel a noise resembling a ringing or whistling in the head, one or both ears, lasting more than five minutes?"*); *"В течении Последнего года ощущали ли Вы такие звуки, как шум или свист в голове, в одном или в обоих ушах, которые длились более 5 минут?"* (meaning: *"During the past year, did you feel such sounds as noise or whistling in your head, in one or both ears that lasted more than 5 minutes?"*); and *"В течение Последнего года возникали ли у Вас в голове или в ухе (или в обоих ушах) шумы, ЩохоЖие, наЦример, на звон или свист, которые длились более Цяти минут?"* (meaning: *"During the past year, did you have noises in your head or in your ear (or both ears), similar to, for example, ringing or whistling, which lasted more than five minutes?"*).

Although the ratings given for the other language translations indicated general overall agreement on quality, there did remain some informative comments about how easy the items were to interpret. These are summarized as follows:

Bulgarian: The Bulgarian language version was evaluated by three bilingual speakers, only one of whom was a hearing expert. Two participants thought the question on the severity of tinnitus symptoms could be misleading to some readers. One said: "*I would change the phrasing "problems in your head and ears - (Цроблемите ви в главата или ушите) with problems concerning your tinnitus or ringing in the ears (Цроблеми свързани със шума в ушите или главата)*".

French: The French language version was evaluated by three bilingual speakers, two of whom were hearing experts. Two participants queried whether the question on hearing difficulty was intended to assess hearing per se or speech understanding. One commented: "*the word "écouter" refers to hearing a conversation, if you want to assess if they can understand you should use the term "comprendre"*".

German: The German language version was evaluated by seven bilingual speakers, four of whom were hearing experts. The comments/feedbacks were mainly on the question on the use of healthcare resources and its response options. Four out of the seven participants mentioned that there was no use of the phrase "*hearing problems*" before this question. One participant mentioned "*I think 'Hörprobleme' comes a bit out of the blue … maybe I would leave that out*", and another suggested ""*Hörprobleme" instead of "der Hörprobleme*" because no reference to hearing problems before".

Greek: The Greek language version was evaluated by five bilingual speakers, two of whom were hearing experts. In the English version, the final response option is always "*Do not know/ Prefer not to answer*", but in the Greek version, this was abbreviated *(ΔΞ/ΔΑ)*, and so three participants recommended to use the full form.

Italian: The Italian language version was evaluated by five bilingual speakers, one of whom was a hearing expert. For the question on severity of tinnitus symptoms, three participants suggested using a different translation for the phrase "at their worst" than "*al loro peggio*". There was no consensus on the replacement phrase. The three suggested replacements were – "*nella loro fase piu intensa*", "*nella fase più acuta*" and "*al loro massimo grado di severità*".

Spanish: The Spanish language version was evaluated by five bilingual speakers, including four hearing experts. For the tinnitus

prevalence question, four out of five participants suggested changing "*como sonar o zumbar*" (meaning *"like sound or buzz")* to "*como sonidos o zumbidos*" (meaning "*like sounds or buzzing*"), which is the plural form. The question on hearing difficulties was translated well for three participants, but two of the hearing experts raised a similar query to the one noted by the Polish and French speakers: for example, one said: *"The main problem in patients with hearing loss is not hear in noisy environment but to understand in noisy environment. In Spanish "hear" is "oir" and "understand" is "entender"".*

This constructive feedback identifies further revisions that could potentially be made to the items to enable further improvements towards functional equivalence.

5. Conclusions

We have developed and evaluated a set of four questions and corresponding response options in 12 European languages to provide a standard for use in population-based surveys on tinnitus and hearing loss. To our knowledge, this is the first attempt to create an international standard by applying good practice in the translation and cross-cultural adaptation process that seeks to promote equivalence across populations (Hall et al., 2018b).

5.1. Strengths and limitations

The four survey items closely correspond to well-established questions and response options as used in previous large-scale population studies, and thus we expect that any findings obtained from studies using these items should be broadly comparable to existing published studies. For example, Spankovich et al. (2017) studied the prevalence of tinnitus in the population of the United States using National Health and Examination Survey (NHANES) data from 1999 to 2002. The information derived from the two items on presence and frequency of tinnitus used in NHANES (*"In the past* 12 months*, have you ever had ringing, roaring, or buzzing in your ears?"* and *"How often did this happen?"*) could be roughly approximated to the information derived from our item on tinnitus prevalence (Spankovich et al., 2017). Similarly, in the EuroTrak Survey carried out across Germany, France and UK from 2009 to 2015, *"trouble hearing conversations in a noisy background"* is a component of the degree of hearing loss (Bisgaard and Ruf, 2017).

We regard as a particular strength that our translation and adaptation process extended beyond a simple forward translation to include the further steps of defining the key concepts in each question, back translation, rating equivalence, revising the target language translations, and field testing by native speakers. Our focus was on creating culturally appropriate and easily comprehensible versions, rather than providing verbatim 'word-for-word' translations. The evaluation scores derived from the field testing indicate the quality of the translated survey items was high for Bulgarian, French, German, Greek, Italian, and Spanish. Further, in line with good practice guidelines, we report all comments and revisions made during the process in order to provide transparency in reporting. Given that findings from the field testing indicated that some of the translations could be further improved (especially for Portuguese and Russian), transparency in reporting provides an important basis for other investigators to build on in this regard. The recommendations provided during the field testing are included here to enable further improvements towards functional equivalence.

Comments made during field testing by the French, Polish, and Spanish speakers indicate some degree of uncertainty in how the question on hearing difficulties should be interpreted. Revisiting the source language version (*"Do you currently have any other difficulty with your hearing, such as listening to speech in a noisy situation?")* indicates that the uncertainty most probably arises at source, not during translation. One possibility is that the target audience interprets the question in a way that limits it to only asking about listening to speech in a noisy situation. Some confusion was caused by the fact that 'listening to speech' is not necessarily the same as 'understanding speech'. Although not indicated during field testing, another inherent limitation of using a single question to assess hearing difficulty might be that respondents interpret this question in terms of *hearing difficulty due to tinnitus* rather than *hearing impairment* per se (e.g. Henry et al., 2015).

The main limitation of our work is in the recruitment of participants for the field testing stage. While there is no consensus on the desired sample size in the literature, a review indicates that the sample size generally varies between 5 and 50 (Acquadro et al., 2008). Indeed, Hall et al. (2018b) recommend at least eight native speakers, and up to 20 native speakers for countries where there is regional variation. In the time scale available for the project, and with limited resources, none of the samples reached the numbers recommended by Hall et al. (2018b). Moreover, we could not recruit any Romanian or Latvian speakers, despite targeting our widespread networks of international collaborators and colleagues. However, each translated item was scrutinized and reviewed by multiple persons (the project team and bilingual speakers) in more than one step of the translation process (namely the back-translation and the field testing steps). Owing to this thoroughness of process and relatively high evaluation scores, we can safely conclude that the resultant final versions produced from our work are reasonably well adapted "world-for-world" translations. More extensive field testing is advised before any revisions are made to the wording of the items in order to be confident that the suggestions proposed by our bilingual speakers are acceptable to a reasonably large proportion of the relevant target audience.

5.2. Future research

While all of the survey items are acceptable in their English and translated versions, the findings from the field testing indicate that there is still some room for improvement. As recommended above, future research could consider extending the field testing stage, or as an alternative one could incorporate the comments suggested here, and then reassess participants' interpretation of these items using a larger field testing sample.

Four of the languages selected (Spanish, English, Portuguese and Russian) represent some of the top ten languages which are spoken most across the world. These four languages alone account for more than 1 billion speakers across the globe (e.g. English = 378 million speakers, Spanish = 442 million speakers and Portuguese = 223 million speakers, Russian = 154 million speakers). All the 12 languages combined account for 1.5 billion first-language speakers worldwide (Simons and Fennig, 2018). Although development and field testing was restricted to mainland Europe, these translated versions could potentially be used in other countries, but only as long as investigators first conduct additional field testing to determine whether any revisions are needed to account for national dialects or social and cultural differences. In particular, Spanish and Portuguese as spoken in the Americas differs from that spoken in mainland Europe and so our work presents an important potential for cultural adaptation for use in countries beyond mainland Europe.

5.3. Concluding remarks

This work is a unique attempt to develop standardized survey

items in many different languages, using a rigorous translation process to develop good-quality versions of the questions and response options with acceptable scores confirmed in most cases. The process was somewhat challenging and time consuming given the detailed steps and the number of translated languages. Nevertheless, we believe that the consistency of result made the effort worthwhile. Since the same steps were applied to produce the 11 translated versions from the English original, this work can provide new insights into translating other surveys and questionnaires. Overall, this is an innovative endeavor on tinnitus and hearing difficulty prevalence that we hope will provide relevant results which can be pooled together to infer on global prevalence and facilitate across-country comparisons.

Declaration of interest

All authors declare that there is no conflict of interest.

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Appendix A. Supplementary data

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