Participant Information Sheet

Title of the study
Development and testing of EQ-5D-5L bolt-on descriptors for hearing

Names of researchers

- Chris Sampson, Nadine Henderson, Mike Herdman, Sian Besley, Office of Health Economics (UK)
- Mireia Jofre-Bonet, City University London & Office of Health Economics (UK)
- Katie Page, Brendan Mulhern, University of Technology Sydney (Australia)
- Kim Rand, Maths in Health (Norway)
- Yaling Yang, University of Oxford (UK)

Purpose of this document
We would like to invite you to take part in our research study. Before you decide whether you want to take part, we would like you to understand why the research is being done and what it would involve for you. Please ask our team if you have any questions. You may talk to others about the study if you wish. If there is anything that is not clear, please speak to any of the researchers listed above.

Aims of the project
The EQ-5D is a questionnaire used in health research to describe people's health states. The current version of the EQ- 5D asks respondents about five aspects of health:

- mobility,
- self-care,
- usual activities,
- pain/discomfort, and
- anxiety/depression.

Research has shown that, in some cases, the EQ-5D might not do a good enough job of describing health states because it misses important aspects of health. One condition where this might be the case is hearing-related impairment. We use the term 'impairment' to capture all forms of hearing loss, deafness, tinnitus, and other hearing-related experiences.

In order to improve the EQ-5D, some researchers have suggested adding 'bolt-on' items. These would be extra questions about health added to the existing five (listed above). We are investigating potential bolt-on questions relevant to hearing.

The wording of the questions and the response options is very important because they can affect the way health states are described. The aim of our project is to develop suitable terminology that will capture the effects of hearing impairment. We will use a mix of focus groups, interviews, and a large survey to collect the data we need to design suitable bolt-on items.

Why have I been invited?
You are being invited to take part because you have experience with hearing impairment.

We are inviting people like you to take part in an online discussion group, focus group, and/or one-to-one interview. Up to five online discussion groups will be held for the development of the hearing bolt-on. Each discussion group will include twelve participants. For the interviews, we will invite around 20 people in total.
Two focus groups will be held, each will include between five and twelve participants.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?
If you agree to participate, you may be invited to attend an online discussion group, focus group, or an interview. We need to ensure that online discussion groups, focus groups, and interviews include a range of people with experience of different health conditions and different levels of impairment. Therefore, even if you agree to participate, we cannot guarantee that you will be invited to a session.

All focus groups and interviews will be recorded and transcribed.

What will online discussion groups involve?
Online discussion groups will be accessed through the project website (http://bolt-ons.info). They will be held using bulletin boards (forums). You will be invited to join a session on a prearranged date and provided with guidance on how to contribute. On the agreed date, you will be able to connect throughout the day and will be encouraged to answer questions and to engage with other participants. The group discussion will relate to your experiences of hearing impairment and its impact on quality of life. You will be expected to spend at least 1 hour taking part in the online bulletin boards.

What will interviews involve?
Interviews will be conducted with participants in the UK and Australia, by telephone/video call. Interviewees will be asked to complete an EQ-5D questionnaire including and excluding the hearing bolt-ons. This may be followed by debriefing, whereby the interviewer will ask about how you thought about your answers and whether you had any difficulties in understanding the questions.

Interviews designed for BSL users will be held virtually, using the video conferencing software Zoom. Interviews will not last more than one and a half hours. A BSL interpreter will be present. Discussion will relate to your experiences of hearing impairment and its impact on quality of life. You may be asked to complete a questionnaire asking about your personal circumstances, your health status, and your experience of hearing impairment and to answer examples of quality of life questionnaires including the EQ-5D.

Can I claim expenses?
Participants in our online discussion groups and non-BSL interviews will not be paid an allowance to take part in this study.
Participants in our interviews designed for BSL users will be provided with a £50 online or Highstreet shopping voucher.

What are the possible disadvantages and risks of taking part?
We do not envisage any risk associated with taking part in this research. Conversations about experiences of health problems may be distressing for some participants. However, you will not be asked to speak about specific issues if you are not comfortable doing so.

What are the possible benefits of taking part?
We cannot promise the study will help you but the information we collect from this study may help people like you in future. The research will help us to better understand and measure the impact of hearing impairment and therefore support the provision of effective health care.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the Economics Research Ethics Committee at City, University London. All contact details are given at the end of this information sheet.

Will my taking part in the study by kept confidential?
We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, the data collected for the study will be looked at by authorised persons from The Office of Health Economics; City, University London; University of Oxford; Maths in Health; and University of Technology, Sydney, who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept strictly confidential, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the institutions organising this research will have your name and any other potentially identifiable information removed in order to anonymise the data. Anonymised data may also be stored in data archives for future researchers interested in this area. Recordings will be transferred to an external transcription company.

Your personal data (name, telephone number, email address, address) will be kept for up to one year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). All research data will be kept securely for 9 years. After this time, your data will be disposed of securely. During this time, all

precautions will be taken by all those involved to maintain your confidentiality. Only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What will happen if I don't want to carry on with the study?
Your participation is voluntary, and you are free to withdraw at any time, without giving any reason and without your legal rights being affected. If you withdraw then it may not be possible to erase the information collected so far after 7 days and this information may still be used in the project analysis.

What will happen to the results of the research study?
We aim to publish the results of the study in 2024 and you will be able to obtain a copy of the published results from any member of the research team.

Who is organising and funding the research?
This research is being organised by Office of Health Economics; the University of Technology, Sydney; City, University London; the University of Oxford; and Maths in Health. It is funded by the EuroQol Research Foundation.

Who has reviewed the study?
The research has been reviewed by a Research Ethics Committee, to protect your interests. This study has been reviewed and Approved by the Economics Research Ethics Committee at City, University London.

How can I contact the research team?
If you have any questions about the study, please contact Chris Sampson by email (csampson@ohe.org) or telephone (02077478866).
If you wish to make a complaint about the study on ethical grounds, please contact the Research Ethics Coordinator at City, Dr Dagmara Celik Katreniak, by email (Dagmara.Celik@city.ac.uk).