Standard Operating Procedure

Pre-pilot study
Translation of questionnaires and initial testing (back-translation with feedback)

Table of contents

Revision table

SOP version no.	Date of change	Description of change	Prepared by	Approved and released by
0.1		First draft	Daloha Rodríguez-Molina	
0.2	31.01.2018	Delete redundant info (IDs), add expert for translation revision	Daloha Rodríguez-Molina	
0.3	14.02.2018	Minor changes as per Katja Radon's comments	Daloha Rodríguez-Molina	

1. General Information

1.1. Scope

This document describes the procedure applied to the translation of AWARE questionnaires, as well as the procedures for testing the questionnaires in a real-life setting before piloting the study.

1.2. Purpose

The purpose of this document is to give guidelines for performing the translation of AWARE questionnaires from the English and/or German versions to the Dutch and Romanian versions, as well as to guide on the procedures for testing the questionnaires and obtaining immediate feedback to improve the design of the questionnaires, if needed.

1.3. Definitions and abbreviations

- **SOP:** Standard operating procedure
- **WWTP:** Wastewater treatment plants
- **Critical control point (CCP):** a point, step or procedure at which controls can be applied and a hazard can be prevented, eliminated or reduced to acceptable (critical) levels.
- **Field Blank:** A field blank is a sample that is prepared in the field to evaluate the potential for contamination of a sample by site contaminants from a source not associated with the sample collected (for example air-borne dust or organic vapors which could contaminate a soil sample).
- **Spikes:** Spike samples are used to measure bias due to sample handling or analytical procedures.

1.4. Responsibilities

The responsible researcher:

- Translates all documents needed (questionnaires, invitation letter, informed consent and data privacy documents, etc.) and attaches them to this SOP; *It is important to put special emphasis to the translation to avoid misunderstanding.*
- Recruits eligible subjects;
- Performs interview to eligible subjects;
- Keeps track of the time it takes to fill out the questionnaires;
- Records feedback from participants;
- Improves the translation of questionnaires if needed, based on participants' feedback;
- Archives all collected information;
- Sends the finished interviews and final version of questionnaires to coordinator.

The project leader/head of department:

- Ensures that the responsible researcher has the necessary competences to carry out the task described in this SOP;
- Ensures that the researcher receives appropriate specific training;
- Ensures that work is carried out according to the valid (latest) version of the SOP.

The AWARE team:

- Ensures regular revision of this SOP and initiates its update, whenever needed;
- Requests users of this SOP to give suggestions for improvements/feedback from their experience to make the SOP a living document;
- Ensures that the valid version of this SOP is made available at the AWARE online drive (if private deliverable), and the AWARE webpage (if public deliverable).

1.5. Cautions

The questionnaire responses and the participant's personal data must be kept secure at all times.

2. Summary of method

A well-trained researcher carries out the translation of all documents and questionnaires from English to the target language. The German version of the documents and questionnaires might also be helpful. Instead of a literal translation, the translation process should look for understandability and a natural feeling in the target language. At least two experts on the topic who are also native speakers of the target language should check the translation and provide feedback.

The translated questionnaires and documents are tested in a two-phase procedure: in the first phase, a small number of participants (n = 3) are recruited to read and provide verbal feedback on their understanding of each question. On the second phase, another small number of participants (n = 3) goes through the process of filling out the questionnaires online. They also provide feedback on the understanding of each question, and the online survey functionality.

Once the instruments have been refined and tested for clarity and understandability, it is possible to proceed to the pilot study.

3. Materials

For the first phase of the interviews

- Copy of documents and questionnaire set for each participant
- Original version (English) of documents and questionnaire set as a reference for the researcher
- Feedback form (Appendix A)
- A clock or watch
- Two pens: One for the researcher and a backup pen
- Incentive for participant

For the second phase of the interviews

- Tablet or laptop with an internet connection
- Link to online survey
- Feedback form (Appendix A)
- A clock or watch
- Two pens: One for the researcher and a backup pen
- Incentive for participant

4. Method

The pre-pilot of this study is an iterative process to translate, back-translate, ask for feedback and improve the current version of the questionnaires. Before the interviews, all documents and questionnaires should be translated from the English version to the target language (the German version might be helpful for some questions). The pre-pilot interview procedure is conducted in two phases: the first phase involves participants only reading questions and providing verbal feedback, while the second phase involves participants filling out the questionnaires and testing the online mechanisms.

It is necessary that the interviewer is well trained and knows the instrument for data collection and data entry very well (online survey for second phase). The interviewer remains neutral during the entire interview, and does not react either adversely or approvingly to participant's answers. The interviewer behaves appropriately; does not eat, drink, or chew chewing gum during the interview, speaks politely, and when performing face-to-face interviews the interviewer should also look neat and clean.

5. Procedure description

- **Translation:** The translation of all documents and questionnaires should be made by a well-trained researcher with an English level of at least C1 (C2 is preferable), and native in the target language (either Romanian or Dutch). The translation should convey *the same meaning* as in the original version, even if it is not a literal translation. Take into account any regional cultural predefined formats and nuances. The translated text should feel natural to a native speaker of the target language. After translating the questionnaires, at least two independent experts on the topic and natives in the target language (Romanian, Dutch) have to check the translation and give feedback if needed. Document all feedback and changes if possible.
- **Location for the interviews:** The chosen location for recruiting subjects and performing the interviews should be affiliated to the research or teaching institutions. All necessary permissions should be obtained from responsible authorities before approaching participants. In Germany, the chosen location is the Outpatient Clinic of the Institute for Occupational, Social and Environmental Medicine at the University Hospital of Munich. Eligible subjects will be recruited at the waiting room, and interviews will be performed before or after their medical consultation at the Clinic. An appointment for a later time is not recommended.

- **Inclusion criteria:**
  - ✓ Volunteers
  - ✓ Age > 18 years
  - ✓ Subjects that arrive to the desired location.
- **Exclusion criteria:**
  - × Subjects with high (university) educational degrees
  - × Health-care professionals (doctors, nurses, etc.)
  - × Subjects whose level of the language is < C1
- **Incentives:** Offer participants a 10€ voucher from amazon
- **Total sample size for the pre-pilot:** ~10 eligible subjects per country
- **Procedure to reach the participant:** A participant is reached at the chosen location by the researcher, and is invited to take part in the pre-pilot of the study. If the participant accepts, set up a specific time when the interview will be performed (e.g. in Germany: before or after his or her medical consultation). Specify at place where the interview will take place. If the participant decides not participate, thank him or her and try to recruit another subject.
- **For repeated interviews:** make sure that the same interviewer does not perform all interviews from the same person to avoid interviewer bias.
- **Feedback to other members of the team:** Interviewers may communicate the results from the interview ONLY at the end of each phase.

CCP1: Interviewer bias
Preventive action: use one well-trained interviewer.
Corrective action: make regular checks of the performed interviews and have regular staff meetings to discuss problems.

CCP2: Underreporting
Preventive action: use one well-trained interviewer who will ask the correct probing questions.
Corrective action: make regular checks of the performed interviews and have regular staff meetings to discuss problems.

Before the interviews:
Make sure you have everything ready before the interview: Check materials list (section 3).

5.1. First phase of the interviews

- Use paper questionnaires for this phase.
- Use the feedback form (Appendix A) for this part.

Procedure:

Preparation

1. Ask 3 eligible subjects to participate.

2. Ask the participant to read the informed consent and to describe back what he or she understood.
3. Ask the participant to sign the informed consent.

Main procedure

4. Check what time is it and write it down on the feedback form (Appendix A).
5. Ask each eligible participant to read every question on the questionnaire in a private interview.
6. Ask each participant to explain back each question, i.e. to describe what he or she understood they were being asked.
7. Ask each participant to express if they have difficulties understanding each question.
8. Take notes of any feedback or irregularity (use feedback form, Appendix A).
9. At the end of the interview, write down what time is it on the feedback form (Appendix A), remember to thank the participant, and offer him or her the incentive.

Final actions

10. Evaluate how far is the participant's interpretation of each question from our intended interpretation in the original questionnaire? (Qualitatively)
11. Perform changes to questionnaires if needed, based on participants' feedback.
12. If there are still major changes (in understanding, language, etc.): ask for feedback from other members of the team (if needed), and re-test phase 1 with n = 2 more eligible participants (repeat steps 2-10 of phase 1).
13. If there are not major changes, wrap up preliminary version of the questionnaires and documents, ask for feedback from other members of the team (if needed), and prepare for phase 2.

5.2. Second phase of the interviews

- Use online version for this part (in a tablet/laptop)
- Important: have internet connection
- Use feedback form for this part (on paper; see Appendix A)

Procedure:

Preparation

1. Ask another 3 eligible subjects to participate.
2. Ask the participant to read the informed consent and to describe back what he or she understood.
3. Ask the participant to sign the informed consent.

Main procedure

4. Check what time is it and write it down on the feedback form (Appendix A).
5. Ask each participant to fill out every question in the questionnaire using the online version.
6. Ask each participant to state if there are questions that they did not understand, or where they did not know what to answer, and why.

7. At the end of the interview, write down what time is it on the feedback form (Appendix A), remember to thank the participant, and offer him or her the incentive.

Final actions

8. If there are still major changes (in understanding, filling out, or online mechanism): ask for feedback from other members of the team (if needed), and re-test phase 2 with n = 2 eligible participants (repeat steps 2-7 of phase 2).
9. If there are not major changes, ask for feedback from other members of the team (if needed), wrap up final version of the questionnaires and documents, and send to the coordinator and the rest of the team.

6. Documentation and record keeping

The interviewer must keep a record of everything he/she did during the interview that did not follow the procedures, and if he/she experienced any difficulties in following the procedures as described in this document. This record should be given to the responsible researcher who will report it further to the AWARE team for revision of the SOP.

CCP3: Record keeping

Preventive action: A standardized record form (see Appendix A) should be implemented and shared with the whole working group.

Corrective action: Collect all possible information that was not recorded.

7. Data Backup

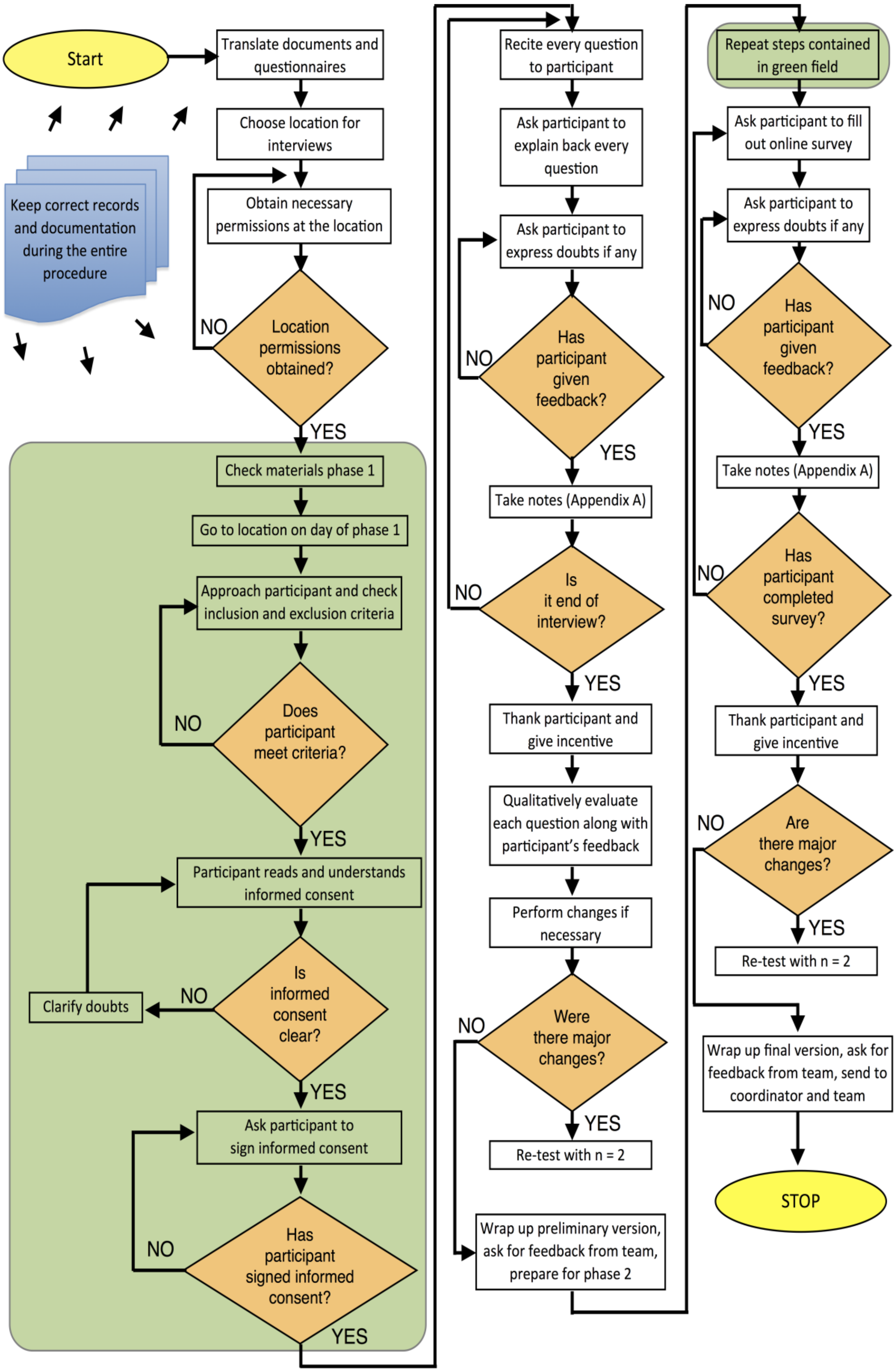
Make a digital back up version of each feedback form for each interview in phase 1. For each participant in phase 2, make sure that there is an online entry for each survey; you can either do this yourself with the local team, or ask the German team to check it. Make a back up file of each digital file. Back up should be done on a daily basis. Filenames should be changed on a daily basis including the date so that we may go back to previous versions easily. Use this format: *YYYYMMDD_filename.extension*. At least one extra copy should be saved on a different hard disc, server, or CD than where the original interviews are saved. The same back up procedure should be followed with the edited interviews. Follow the back up procedures at your institute, if available.

CCP4: Backup

Preventive action: Perform a backup at a regular interval of time. Servers can be set to backup data automatically.

Corrective action: Do a backup when forgotten.

8. Flowchart


Start
Translate documents and questionnaires
Choose location for interviews
Obtain necessary permissions at the location
Location permissions obtained?
NO
YES
Keep correct records and documentation during the entire procedure
Check materials phase 1
Go to location on day of phase 1
Approach participant and check inclusion and exclusion criteria
Does participant meet criteria?
NO
YES
Participant reads and understands informed consent
Is informed consent clear?
NO
Clarify doubts
YES
Ask participant to sign informed consent
Has participant signed informed consent?
NO
YES
Recite every question to participant
Ask participant to explain back every question
Ask participant to express doubts if any
Has participant given feedback?
NO
YES
Take notes (Appendix A)
Is it end of interview?
NO
YES
Thank participant and give incentive
Qualitatively evaluate each question along with participant's feedback
Perform changes if necessary
Were there major changes?
NO
YES
Re-test with n = 2
Wrap up preliminary version, ask for feedback from team, prepare for phase 2
Repeat steps contained in green field
Ask participant to fill out online survey
Ask participant to express doubts if any
Has participant given feedback?
NO
YES
Take notes (Appendix A)
Has participant completed survey?
NO
YES
Thank participant and give incentive
Are there major changes?
NO
YES
Re-test with n = 2
Wrap up final version, ask for feedback from team, send to coordinator and team
STOP

Appendix A. Feedback form

<table>
<tr><td colspan="4">Antibiotic Resistance in Wastewater: Transmission Risks for Employees and Residents around Wastewater Treatment Plants – The AWARE Study</td></tr>
<tr><td colspan="4">Pre-pilot – Feedback form for questionnaire evaluation</td></tr>
<tr><td colspan="2">Collection Date (DD-MM-YYYY):</td><td colspan="2">____ / ____ / _____</td></tr>
<tr><td colspan="2">Participant ID:</td><td colspan="2"></td></tr>
<tr><td>Age:</td><td>Sex:</td><td colspan="2">Highest school degree:</td></tr>
<tr><td>Start time:</td><td></td><td>End time:</td><td></td></tr>
<tr><td colspan="4">Questionnaire collection comments (language, wording, understanding, general feedback):</td></tr>
<tr><td colspan="4">Other comments:</td></tr>
<tr><td colspan="2">Field staff name</td><td colspan="2">Field staff signature</td></tr>
</table>