

Guidance for ASCOT Translation

Introduction

This guidance has been introduced by the ASCOT team to help people interested in translating ASCOT to plan their projects and ensure consistency in the translation process. This is designed to ensure harmonisation across translated versions of ASCOT and capture learning around translations.

ASCOT is a person-reported outcome measure (PROM). Therefore, translation of ASCOT – as with other PROMs – should be conducted in a way that considers **linguistic validation**. This refers to the process of investigating conceptual equivalence, reliability and content validity of translations of PROMs.

The aim of this guidance is to set out the process to be followed for ASCOT translation (linguistic validation). The guidance covers all ASCOT tools except CH4 tool. The CH4 is a complex tool consisting of a number of components. Thus, the methodology presented in this guidance may be adapted to better suit the needs of its planned use. Anyone wishing to translate the CH4 tool should contact the ASCOT team to discuss the translation process and obtain permission for the translation.

Translations developed following this guidance will have the status of ‘official’ and will be accredited by the ASCOT team. Any translations conducted without approval and the appropriate licence, will be deemed as a breach of copyright and Intellectual Property. The copyright holder, the London and South East University Group (LASE), of which the University of Kent is part, reserves the right to take legal action in such situations.

Useful terminology

Project manager: the person overseeing the translation process. Typically, this person is a researcher from the target country who has requested and obtained permission from the ASCOT team and LASE (the copyright holder) to translate ASCOT into the target language. The permission is given in a contract/licence agreement signed by LASE and the authorising body on behalf of the requester (project manager). Ideally, the project manager should be an expert in health and social care economics and/or outcomes research, a native speaker of the target language and fluent in English.

In-country team: the team of researchers in the target country who work with the project manager on the translation and cultural adaptation of the ASCOT measure. They should be

native speakers of the target language and be able to converse in English. They should be researchers in health and social care and/or health economics. The in-country team will be expected to be closely involved in the following stages of the translation process: review of the ASCOT instrument for target country, back translation review, pilot testing, pilot testing review, production of report from the pilot testing (in English), and resolution of queries from developer pilot testing review.

Instrument developer: the person or group of people who developed the instrument being translated, in this case, the ASCOT team.

Target language: the language into which the ASCOT instrument is being translated and linguistically validated.

Source language: the language of the ASCOT instrument; English for the UK.

Linguistic validation: the process of investigating the reliability, conceptual equivalence, and content validity of translations of patient or person-reported outcomes measures (PROMs).

Conceptual equivalence: indicates that an item in a questionnaire measures the same concept in all languages into which this questionnaire has been translated.

Concept elaboration guide: A detailed guide to the instrument typically prepared by the developer team. It documents the intended meaning of each item and response. Attention is paid to wording or concepts that may be understood in multiple ways. This guide is used by the translation team for reference throughout the translation process.

ASCOT Measures

ASCOT is a suite of related measures of social care-related quality of life and care-work related quality of life. Project managers can choose which of the ASCOT measures to translate. Translation licences need to be sought for the tools that will be translated. Translations of multiple tools can be covered by one licence.

In the case where the required tool has not been translated into a target language, but translations in that language already exist for another ASCOT tool, then we would expect the translation process to build on the existing translation, where there is overlap in the tools. The most common example is where ASCOT-SCT4 has already been translated, but the same or another team then wish to translate ASCOT-INT4 or ASCOT-Carer SCT4/INT4.

Principles of the Translation Process

ASCOT has been translated into several languages using methodology based on principles of good practice for translations and cultural adaptations recommended by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

These principles are summarised in the article below:

Wild D, Grove A, Martin M, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translating adaptation. *Value in Health* 2005; 2: 94-104. <https://doi.org/10.1111/j.1524-4733.2005.04054.x>

Following these principles ensures that the result is a robust translation which will measure what the ASCOT tools intend to measure.

Based on our translation experience and considering the COSMIN study design checklist for translations (see [Mokkink et al, 2019](#), pp.29-31), we have adapted the stages set out in Wilde et al (2005). Any translations must adhere to our methodology below.

We will **not** approve AI-led or assisted translation using open AI models or freely available machine learning tools (e.g., Google Translate). ASCOT measures must not be entered into open AI. Any action to do so would breach ASCOT T&Cs.

The ASCOT team do not require the use of a professional translation company, if there is evidence of sufficient expertise and experience of linguistic validation within the in-country team and knowledge and experience held by the project manager. However, even so, there are advantages of engaging with a company with experience of linguistic validation of PROMs. This is a specialised process that requires considerable knowledge, skill and expertise. Where the project manager engages with a professional translation company, they must ensure that the company fulfils our criteria, as specified below:

- Demonstrable experience and expertise in the translation (**linguistic validation**) of standardised PROMs. This can be evidenced by the company's ability to work to the regulatory requirements for linguistic validation set by the US Food and Drug Administration (FDA) and/or European Medicines Agency (EMA)
- Adherence to quality management systems ISO 9001:2015 and ISO 17100:2015
- Adherence to our policy on use of AI in ASCOT translation (see above)
- The ability to conduct the translation following this guidance (please refer especially to Diagram 1 and Table 1)

Project managers can decide whether to conduct the stages of professional review (if needed) and pilot testing independently (i.e., within the project team) or to outsource to a translation company. If the pilot testing is outsourced to the translation company, they must be able to follow the approved methodology (i.e., cognitive testing/cognitive debriefing) with the target social care group for the measure.

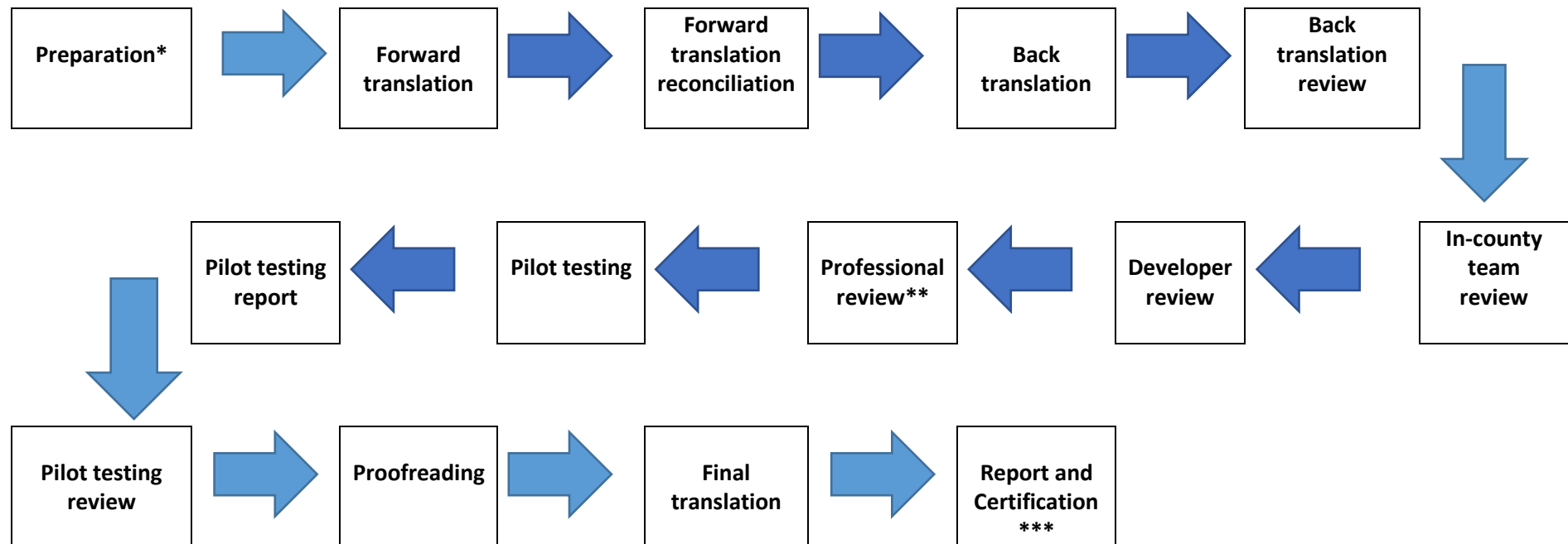
An important aspect of the translation process is the translation review by the instrument developer – the ASCOT team. This work is chargeable. The project manager must obtain an estimate of cost from the ASCOT team. The project manager will be required to sign a contract covering the cost for this work prior to project commencement.

If you wish to translate any of the ASCOT tools, please contact Lizzie Welch from the ASCOT team (e.welch@kent.ac.uk) so that she can advise you regarding existing translations, record your interest in translating the toolkit, provide an estimate of cost for the developer review, and arrange an appropriate licence and contract for the developer review. We require that all project managers discuss their plans for translations with the ASCOT team to ensure that requirements are fulfilled and documented.

Detailed Stages in the Translation Process

The translation must follow the stages outlined in Diagram 1 below (or with adaptation only if approved by the ASCOT team in advance) to be approved and accredited by the ASCOT team as an official translation.

Diagram 1: Stages of translation and cultural adaptation process of ASCOT (adapted from Wild et al, 2005)



* A *concept elaboration guide* will be shared by the ASCOT team with translators/project managers upon completion of the licence agreement.

** This step can be omitted **if** the in-country team are experts in social care and conduct a review of the ASCOT instrument to determine if the terminology is suitable for the social care context of the target country.

*** On completion of the project, a final report of the detail of the translation process should be produced. Where completed by a professional translation company, this should be accompanied by certification of the process. This information will be available to all users of the translated version upon request.

Table 1 below provides more details regarding each stage of the translation process outlined in Diagram 1 (adapted from Wild et al. 2005).

1	Preparation	
1.1	Contact instrument developer	The project manager contacts the instrument developer (Lizzie Welch from the ASCOT team: e.welch@kent.ac.uk) to seek permission to use and translate the instrument. The project manager will be asked to complete one of the standard ASCOT license forms (typically, Form 2). These include questions about the proposed use of the translated measure. The project manager will need to provide an outline plan of how they propose to translate the ASCOT measure(s) with appropriate regard to the process steps and methodology outlined in this guidance. If a professional translation company will be engaged in the work, the project manager will ensure that the company fulfils the criteria and requirements in this guidance. The project manager will provide detail and assurance to the ASCOT team for review and approval. When approved, the project manager obtains an estimate of cost for the translation from the approved translation company. <i>Note:</i> <i>Where engaging with a professional translation company, we recommend that two estimates be obtained: (1) the translation company carries out all translation stages (including pilot testing) (2) the translation company carries out the translation except for cognitive testing (pilot testing) and professional review (if applicable). In option 2, cognitive testing would be conducted by the in-country team. The ASCOT team would assess whether the in-country team would be able to conduct this work based on their experience and level of expertise. This option needs approval from the ASCOT team. If the translation cannot be supported by an in-country team, then the estimate of cost should cover only option 1.</i> The instrument developer (ASCOT team) will then provide a quotation for the cost of their developer review. This cost in in addition to any costs incurred by the project manager, in-country team or payable to the translation company.

1.2	Permission issued	LASE issue a contract for the developer review (ASCOT team review) and a licence agreement covering the intended use of the ASCOT translation. The contract is signed by both parties. Translation work <u>must not</u> commence until the agreement is officially signed.
1.3	Sign contract with the translation company	The project manager signs a contract with the translation company and instructs them to conduct the translation. Translation work may commence.
1.4	Concept elaboration guide shared with translators	The concept elaboration guide is prepared (where no guide currently exists. Most tools already have corresponding guides for translation). The guide is shared by the ASCOT team with the project manager. This describes concepts in the ASCOT instrument, clarifies ambiguities and provides alternatives for difficult or potentially problematic wording. The guide is shared with each translator who are instructed to base their translations on the guidance provided.
1.5	ASCOT instrument review for target country	The in-country team reviews the ASCOT instrument to be translated to check whether the terminology used differs in the target country. The aim is to catch any terminology or concepts specific to the UK that could not be directly translated and to establish alternatives.
2	Forward-translation	
2.1	Development of two (or more) independent forward translations	<i>At least two</i> forward translators carry out independent forward translations of the instrument. Forward translators should have a mother tongue in the target language and be fluent in English. The translators should be instructed to produce translations that will be easily understood by the general lay population. <i>Ideally</i>, one forward translator will have expertise in social care and/or ASCOT social care-related quality of life – the other be naïve to the construct and context (see Mokkink et al, 2019, p.29).
3	Forward translation reconciliation	
	Reconciliation of the forward translations into a single forward translation	The translation company carries out a reconciliation of the forward translations. The forward translations should be compared and reconciled through discussions with the project manager and the in-country team. A reconciled version of the translation is produced.

4	Back translation	
	Back translation of the translated instrument into English.	The reconciled forward translation should be translated back into English by at least two translators, who work independently. The back translators should have English as their mother tongue and be fluent in the target language. The back translators should be naïve to the construct and context of measurement – i.e., they are not experts in social care use or social care-related quality of life (see Mokkink et al, 2019, p.29).
5	Back translation review	
	Review of the back translations against the source language	The translation company and/or project manager and the key in-country person (if applicable) should review the back translations against the English source version to identify any discrepancies or issues. The translation company and/or project manager should address the problematic items or issues and, in liaison with the key in-country person (if applicable), refine the translation. Note: A key in-country person should be recruited if the translation cannot be supported by an in-country team (who are experts in health and social care and/or health economics).
6	In-country team review	
		The in-country team review the translation with particular focus on cultural adaptation and appropriateness. Any queries should be resolved in close cooperation with the translators. The in-country team suggest alternatives to the queried items. They must provide the suggestions, their translations into English and the rationale behind the suggested amendments. This will facilitate the developer review, as the ASCOT team will be able to review the amendments and the reasons behind them, thus reducing the number of queries to the in-country team.
7	Developer review	
		The ASCOT team reviews the back translation focusing on the conceptual equivalence with the source instrument. Any difficult issues are resolved between the ASCOT team, the translation company and the in-country team.

8	Professional review	
		Note: <i>This step only applies when:</i> • <i>The instrument to be translated is ASCOT INT4 or ASCOT-Carer INT4 <u>AND</u></i> • <i>The in-country team and project manager do not have expertise in the social care context of the target country.</i> At least two professionals who work with adults receiving social care services (e.g. social workers, care workers, nurses, etc.) will be invited to review the translation. The review will focus on terminology used to describe social care services and contexts to ensure that it is appropriate, comprehensible and correct for the context. The results should be reviewed and discussing with the in-country investigators.
9	Pilot testing	
	Testing of the translated instrument	During pilot testing, an interviewer conducts interviews with at least 5 (ideally, up to 10) people from the target population. i.e., • ASCOT-SCT4 or INT4 – adults using social care • ASCOT-Carer – unpaid or family carers • ASCOT-Workforce – people working in social care This should apply cognitive testing methods – specifically, ‘think aloud’ with follow-up probes (Willis, 2005). The respondent should be asked to complete the measure and ‘think aloud’ as they do so, to describe what they think the question means, how they come to an answer and how they record the answer. The interviewer will then ask probe questions to explore comprehension, judgement and response – i.e., how people understand questions, weigh up the response options, and then decide upon and record a response. Any issues with comprehension, judgement and response should be recorded with verbatim quotes from respondents.
10	Pilot testing report	
		The results of the pilot testing are reviewed and a brief report prepared by the translation company, project manager and/or in-country team. This should summarize

		any identified issues with comprehension, judgement and response. If necessary, the report is translated into English to allow for review by the ASCOT team.
11	Pilot testing review	
		The report from cognitive debriefing is sent to the ASCOT team for review. The ASCOT team raises any queries with the translation company (if involved) and the project manager. The queries are resolved between parties.
12	Proofreading	
		The final version of the translation is proofread by the translation company, project manager or another independent person.
13	Final translation	
		The final version of the translation is finalised and sent to the ASCOT team.
14	Report and Certification	
		The translation company or project manager produces a report in English describing each stage of the translation process, detailing any issues / difficulties and how they were dealt with, and any other relevant information. The report is sent to the ASCOT team along with certification of the translation by the translation company (if involved). This report will be kept on record and will be available on request as a record of the translation process and quality.

It is recommended that all stages of the translation are carefully documented. Revisions applied between stages should be recorded along with the rationale for decision-making and how the views of different parties were considered. This especially applies to the decisions made at Stages 6 to 9 of the process.

Translation Accreditation

Translations developed using the methodology presented in this guidance and with approval and permission from the ASCOT team will typically satisfy the requirements for an official translation and will be accredited by the ASCOT team.

Any translations conducted not following this guidance and without permission from the ASCOT team and the copyright holder, LASE, will not be permitted and will be treated as breach of copyright. LASE reserves the right to take legal action against anyone who has translated ASCOT instrument into another language without prior consultation with the

ASCOT team and without explicit consent from the ASCOT team and license agreement and contract to cover the ASCOT team's involvement in the developer review.

Ownership and Access to Translated Versions

LASE will typically retain ownership of translated versions of ASCOT. The translation project managers will be allowed to use the translation for the purposes specified in the registration form submitted to the ASCOT team and any subsequent bespoke license agreement/contract. Upon completion of the translation, the ASCOT team will hold the translation and will update the ASCOT website with details of the new the translation. The use of the translations will be free of charge for not-for-profit purposes but will be licensed. Anyone wishing to access the translation will be required to register for a licence via the ASCOT website and agree to terms and conditions, which will form the licence to use the translation. The translation will be shared once the registration has been approved.

We encourage project managers who have overseen the translation process of ASCOT to write a journal article about the translation and cross-cultural adaptation of the measure. The member(s) of the ASCOT team involved in the developer review would typically be invited to be co-authors on such publications.

Translations Without Agreement

Any translations developed applying different methodology (unless expressly discussed and agreement with the ASCOT team) and not formally agreed with the ASCOT team in advance of the translation, will be treated as unofficial translations that are breach of copyright and intellectual property law. As such, they will be subject to legal action by the copyright holder – the LASE.

Disclaimer

The ASCOT tools and the translation process are continually reviewed and updated based on the experiences and results of translating and using ASCOT in research and practice. Therefore, the content of this guidance for translations may change periodically. Please ensure that you follow the most recent version in your translation project. If you are unclear regarding any of the translation process stages outlined in this document, please contact Lizzie Welch (e.welch@kent.ac.uk).