

Guidance for translations of ASCOT

Confidentiality

This document is shared confidentially with individuals considering translating ASCOT and should not be shared with any other parties without explicit consent from the ASCOT team.

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. We also hope that this process will enable us to ensure harmonisation across translated versions and capture learning around translations.

The aim of this guidance is to set out the process that should be followed for all translations of ASCOT. The guidance covers all of the ASCOT tools except the CH3 tool. The CH3 is a complex tool consisting of a number of components. Thus, the translation methodology presented in this guidance may be adapted to better suit the needs of its planned use. Anyone wishing to translate the CH3 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 the approval from the ASCOT Team and the appropriate licence, will be deemed as a breach of copyright and the Intellectual Property. The copyright holder, the University of Kent, reserves the right to take legal action in such situations.

If you have any queries about the process set out in the document or regarding our criteria for the translation company, please contact the ASCOT team.

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 the University of Kent (the copyright holder) to translate ASCOT into the target language. The permission is given in a contract/licence agreement signed by the University of Kent and the authorising body on behalf of the requester (project manager).

Ideally, the project manager should be an expert in social care/health economics, 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 social/healthcare 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.

Developer: 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-reported outcomes (PRO) measures.

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

ASCOT tools

Currently there are six ASCOT tools, known as:

- **SCT4:** This is a self-completion version of ASCOT. All questions covering the ASCOT domains have four response options.
- **SCT4 Easy Read:** This is an easy-read version of the self-completion ASCOT. All questions covering the ASCOT domains have four response options.
- **INT4:** This is an interview version of ASCOT. All questions covering the ASCOT domains have four response options.
- **CH3:** This is a version of ASCOT suitable for use in an institutional environment (e.g. residential care home or nursing home). It consists of a set of tools for observing residents and interviewing staff, residents and relatives. It also consists of a scoring guide.
- **Carer SCT4:** This is a self-completion version of ASCOT for informal carers. All questions covering the ASCOT domains have four response options.

- Carer INT4: This is an interview version of ASCOT for informal carers. All questions covering the ASCOT domains have four response options.

Project managers can choose which of the tools 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 the study 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 (as is the case for INT4 and SCT4).

Process for translation

ASCOT has been translated into a number of 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.

http://www.ispor.org/workpaper/research_practices/PROTranslation_Adaptation.pdf

Following the stages set out in Wild et al (2005) ensures that the result is a robust translation which will measure what the ASCOT tools intend to measure. Based on our translation experience, we have adapted the stages set out in Wilde et al (2005). Any translations must adhere to our methodology which is set out in Diagram 1 and Table 1 below.

The translation company used for the previous translations of ASCOT was Corporate Translations Inc (now called RWS Life Sciences <https://www.rws.com/our-teams/rws-life-sciences/>), please see the ASCOT website for further information (<https://www.pssru.ac.uk/ascot/translations/>) We have chosen to work with RWS because they specialise in the translation and linguistic validation of patient reported outcome (PRO) measures and are certified as meeting the requirements of ISO 9001:2008, ISO 13485:2003 and ISO 17100:2015 for the management of medical translation services.

Project managers can decide to commission RWS Life Sciences or another translation company. When choosing a translation company, project managers must ensure that the company fulfils our criteria, as specified below:

- Adherence to ISPOR recommendations for PRO translations

- Demonstrable experience of translating of PRO measures or social care measures
- Adherence to quality management systems ISO 9001:2008, ISO 13485:2003 and ISO 17100:2015
- The ability to conduct the translation following the methodology described in this guidance (see Diagram 1 and Table 1 below). The ability to pilot the translation in the field with the appropriate social care group (cognitive testing/cognitive debriefing) is of particular importance.

To discuss the suitability of a translation company, prospective translation project managers should contact the ASCOT team at ascot@kent.ac.uk.

A '*concept elaboration guide*', which elaborates on the ASCOT items, has been developed and will be shared with translators/project managers upon completion of the licence agreement.

Project managers can decide whether to conduct the stages of professional review (if applicable) and pilot testing independently or to outsource this work to a translation company. We require that all project managers discuss their plans for translations with the ASCOT team and the translation company to ensure that all requirements are fulfilled and documented.

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

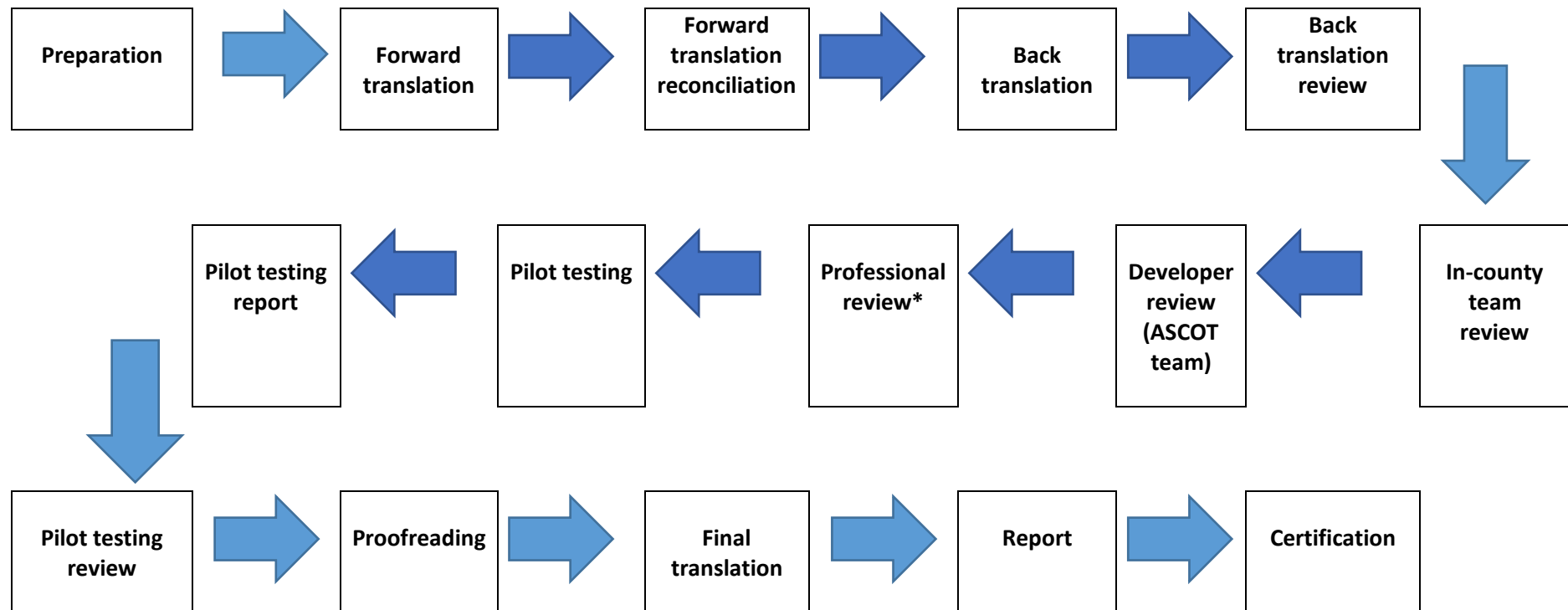
On completion of the project the translation company should provide a final report and certification letter. This information will be available to all users of the translated version.

If you wish to translate any of the ASCOT tools, please contact the ASCOT team (ascot@kent.ac.uk) so that we can advise you regarding existing translations, record your interest in translating the toolkit, provide an estimate of cost for the developer review, and arrange appropriate licence and contract for the developer review.

Stages in the translation process

The translation process must follow the stages outlined in Diagram 1 below as closely as possible to be approved and accredited by the ASCOT team as an official translation.

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



*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, the professional review step can be omitted.

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	<p>The project manager contacts the instrument developer (ASCOT team: ascot@kent.ac.uk) to ask for permission to use and translate the instrument. The ASCOT team requires information regarding the intended use of the proposed translation; the project manager completes a registration form. The instrument developer advises on the translation process and provides a quotation for the cost of the developer review. The project manager searches for an appropriate translation company (making sure that they fulfil criteria specified above) and seeks approval of the translation company from the ASCOT team. When approved, the project manager obtains an estimate of cost for the translation from the approved translation company. If RWS Life Sciences is planned to be commissioned, the ASCOT team will liaise with RWS Life Sciences directly to obtain an estimate of cost. Two estimates should be obtained: (1) the translation company carries out all of the translation stages (including pilot testing) (2) the translation company carries out the translation stages 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 merit, experience and level of expertise. Therefore, this option needs approval from the ASCOT team. The project manager should discuss the two options with the ASCOT team. If the translation cannot be supported by an in-country team, then the estimate of cost should cover only option 1.</p>
1.2	Permission issued	<p>The project manager authorises the translation company. Kent Innovation and Enterprise issue a contract for developer review (ASCOT team consultancy) and a licence agreement covering the intended use of the ASCOT translation. The documentation is signed by both parties. Translation work will not commence until the agreements is officially signed.</p>

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	Concept elaboration guide has been developed by RWS in cooperation with the ASCOT team. The document describes the concepts in the ASCOT instrument, clarifies any 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. Currently there are concept elaboration guides for ASCOT service user INT4 and SCT4, and ASCOT Carer INT4 and SCT4.
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. This is particularly important for translations of INT4 tools. The aim is to catch any terminology or concepts specific to the UK that could not be directly translated and to establish alternatives that will be applicable to the social care provision in the target country.
2	Forward-translation	
2.1	Development of two independent forward translations	Two forward translators carry out independent forward translations of the instrument. The forward translators should be native speakers of the target language and fluent in English. The translators should be instructed to produce colloquial translations that will be easily understood by the general lay population.
3	Forward translation reconciliation	
	Reconciliation of the forward translations into a single forward translation	The translation company carries out a reconciliation of the two forward translations. The two 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 translation should be translated back in to English by two independent translators. The back translators should be native speakers of English fluent in the target language.
5	Back translation review	

	Review of the back translations against the source language	<p>The translation company / project manager and the key in-country person (if applicable) should review the back translations against the English source version to identify any discrepancies.</p> <p>The translation company / project manager should address the problematic items and, in liaison with the key in-country person (if applicable), refine the translation. Key in-country person should be recruited if the translation cannot be supported by an in-country team (who would be experts social/healthcare and/or health economics).</p>
6	In-country team review	
		<p>The in-country team review the translation with particular focus on cultural adaptation.</p> <p>Any queries should be resolved in close cooperation with the translators and the translation company. 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.</p>
7	Developer review	
		<p>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.</p>
8	Professional review	
		<p>The translation company recruit two professionals who work with adults receiving social care to conduct a professional review of the translated instrument. The professionals focus on all interviewer-oriented wording and whether they believe the wording is correct and appropriate for use in the context of the type of instrument (e.g. self-completion or interview). The professionals should be individuals who work professionally with adults receiving social care, e.g. social workers, practitioners, carer workers, etc. The results should be sent to the translation company who</p>

		<p>will review and discuss them with in-country investigators to develop the best possible translation solutions.</p> <p>If the project manager and the in-country team possess expertise in the social care context in the target country, then the professional review can be omitted. This would apply if the in-country team reviewed the source ASCOT instrument to check whether the social care terminology was suitable for the social care context of the target country (see step 1.6).</p>
9	Pilot testing	
	Testing of the translated instrument	<p>There are two options possible in terms of pilot testing; it can be done by the translation company or by the project manager and the in-country team. Translation company should provide an estimate of cost for the two options. During testing, an interviewer conducts interviews with at least 5 adults receiving social care/carers of people receiving social care. The respondents are asked to comment on the response options and any wording that was difficult to understand and suggest alternative wording. Respondents should also be asked to describe in their own words what the wording meant to them. This process is termed cognitive debriefing.</p>
10	Pilot testing report	
		<p>The results of the pilot testing (including respondents' verbatim answers to cognitive debriefing questions) are reviewed by the translation company / project manager and in-country team. A report in English from the cognitive debriefing is produced by the project manager / translation company. If necessary, the report is translated into English (either by the in-country team or the translation company).</p>
11	Pilot testing review	
		<p>The report from cognitive debriefing is sent to the ASCOT team for review. The ASCOT team raises any queries with the translation company and the project manager. The queries are resolved between the three parties.</p>
12	Proofreading	

		The final version of the translation is proofread by the translation company / project manager or an independent person.
13	Final translation	
		The final version of the translation is finalised and sent to the ASCOT team.
14	Report	
		The translation company / 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 and will be shared with any licensed users of the translated instrument.
15	Certificate	
		The translation company produces a letter certifying the translation of the instrument, which is sent to the project manager and the ASCOT team along with the final translation.

Translation accreditation

Translations developed using the methodology presented in this guidance will satisfy the requirements for an official translation and will be accredited by the ASCOT team. To receive accreditation translations will have to be conducted by a translation company which fulfils the criteria specified in the 'Process for translation' on page 3 of this guidance.

Any translations conducted not following this guidance and without permission from the ASCOT team and the copyright holder, the University of Kent, will not be permitted and will be treated as breach of copyright. The University of Kent reserves the right to take legal action against anyone who has developed a translation of any ASCOT instrument into another language without prior consultation with the ASCOT team and without explicit consent from the ASCOT team and the University of Kent (in the form of a licence agreement and contract for developer review).

Ownership and access to the translated versions

As set out in the licence agreement, **the University of Kent / ASCOT team will retain ownership of the 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. Upon completion of the translation, the ASCOT team will hold the translation and will update the ASCOT website with 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 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 on the translated version and its measurement properties. However, we ask that you contact us if you plan to write such an article, as we require that the member(s) of the ASCOT team who was involved in the developer review is an author on any translation publications.

Unofficial and/or not agreed translations

Any translations developed using a methodology different to the recommended methodology described in this guidance and/or not agreed with the ASCOT team, will be treated as unofficial translations and a breach of copyright and intellectual property law. As such, they will be subject to legal action by the copyright holder – the University of Kent.

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 the ASCOT team at ascot@kent.ac.uk.