Translation and Adaptation of the DC/TMD Protocol

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For the Committee for Translations and Protocols
INfORM
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The "Guidelines for Establishing Cultural Equivalency of Instruments", Ohrbach et al,[1] (available on the Consortium website) specifies in detail the recommended steps and procedures for adapting an instrument to another language. This document provides additional information and translation guidance specific to the DC/TMD protocol.

Contents

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A. Components for translation

A completed DC/TMD translation will consist of the following components:

Component	Source
Title page of the translated instrument	Translation template on Consortium website
Contents page	Translation template on Consortium website
Examination Commands. Translation teams will, in general, choose one of these options: • A1 (Complete Examiner Specifications) and A2 (Examination-Related Pain Interview), or • B (Required Examination Commands),	
A1. Complete Examiner Commands	Section 5 Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) Clinical Examination Protocol Ohrbach R, Gonzalez Y, List T, Michelotti A, Schiffman E Instrument Version: June 02, 2013
A2. Examination-Related Pain Interview	Section 6 Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) Clinical Examination Protocol Ohrbach R, Gonzalez Y, List T, Michelotti A, Schiffman E Instrument Version: June 02, 2013
B. Required Examination Commands	Section 8 Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) Clinical Examination Protocol Ohrbach R, Gonzalez Y, List T, Michelotti A, Schiffman E Instrument Version: June 02, 2013
Examination Form [translation not required; if not translated, then English version will be part of the final document]	Section 9 Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) Clinical Examination Protocol Ohrbach R, Gonzalez Y, List T, Michelotti A, Schiffman E Form Version: May 12, 2013
Diagnostic Decision Trees, as based on published criteria [translation not required; if not translated, then English version will be part of the final document]	Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) for Clinical and Research Applications: Recommendations of the International RDC/TMD Consortium Network* and Orofacial Pain Special Interest Group** Schiffman E, Ohrbach R, et al, Journal of Orofacial Pain, 2013 Figure Version: June 8, 2013

Component	Source
Diagnostic Criteria Table, as based on published criteria [translation not required; if not translated, then English version will be part of the final document]	Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) for Clinical and Research Applications: Recommendations of the International RDC/TMD Consortium Network* and Orofacial Pain Special Interest Group** Schiffman E, Ohrbach R, et al, Journal of Orofacial Pain, 2013 Table Version: June 8, 2013
DC/TMD Symptom Questionnaire	Impact Study Research Group Form Version: May 12, 2013
TMD Pain Screener	Gonzalez YM, Schiffman E, Gordon G, Seago B, Truelove EL, Slade G, Ohrbach R. Development of a brief and effective temporomandibular disorder pain screening questionnaire: reliability and validity. *JADA* 142:1183-1191, 2011. Form Version: October 11, 2013
DC/TMD Demographics	Impact Study Research Group Form Version: May 12, 2013
Pain Drawing	Impact Study Research Group Form Version: May 12, 2013
Graded Chronic Pain Scale Version 2.0	Von Korff M. Assessment of chronic pain in epidemiological and health services research: empirical bases and new directions. In: Turk DC, Melzack R, editors. Handbook of Pain Assessment, Third Edition. New York: Guilford Press. 2011. pp 455 – 473. Form Version: May 12, 2013
Jaw Functional Limitations Scale (8-item and 20-item versions)	Ohrbach R, Larsson P, and List T. The Jaw Functional Limitation Scale: Development, reliability, and validity of 8-item and 20-item versions. *J.Orofacial Pain* 22:219-230, 2008. Form Version: May 12, 2013
PHQ-4	Kroenke K, Spitzer RL, Williams JB, and Löwe B. An ultra-brief screening scale for anxiety and depression: the PHQ-4. *Psychosomatics* 50 (6):613-621, 2009. A text-revision of this instrument is posted at http://www.phqscreeners.com/ and incorporated into the final instrument for the Consortium. Form Version: May 12, 2013

Component	Source
PHQ-9	Kroenke K, Spitzer RL, and Williams JB. The PHQ-9: validity of a brief depression severity measure. *Journal of General Internal Medicine* 16 (9):606-613, 2001. A text-revision of this instrument is posted at http://www.phqscreeners.com/ and incorporated into the final instrument for the Consortium. Form Version: May 12, 2013
GAD-7	Spitzer RL, Kroenke K, Williams JB, and Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch.Intern.Med.* 166 (10):1092-1097, 2006. A text-revision of this instrument is posted at http://www.phqscreeners.com/ and incorporated into the final instrument for the Consortium. Form Version: May 12, 2013
PHQ-15	Kroenke K, Spitzer RL, and Williams JB. The PHQ-15: validity of a new measure for evaluating the severity of somatic symptoms. *Psychosom.Med.* 64 (2):258-266, 2002. Form Version: May 12, 2013
Oral Behaviors Checklist	Ohrbach R, Markiewicz MR, and McCall WD Jr. Waking-state oral parafunctional behaviors: specificity and validity as assessed by electromyography. *European Journal of Oral Sciences* 116:438-444, 2008. Ohrbach R et al. Oral Behaviors Checklist: Development and validation. Forthcoming. Form Version: May 12, 2013

B. General Notes on the Translation Process

1. While most extant translated versions of the RDC/TMD available on the website for the International RDC/TMD Consortium Network (www.rdc-tmdinternational.org) were created with only one forward translator, two forward translators will be required for the DC/TMD data collection instruments in order to improve overall translation quality. The two forward translators must work independently with respect to the eventual goal of cultural adaptation of each instrument.
2. The minimal sections of the DC/TMD protocol which must be translated include all components in the above table except for the diagnostic decision trees and the examination recording form.
3. The other components of the DC/TMD protocol (i.e., remainder of the examination specifications, diagnostic decision trees, examination recording forms, scoring rules for Axis I and Axis II components, and summary diagnosis forms) may be translated, depending on time, interest, and needs of the developer of the translated version; whether those parts are translated may depend on English fluency of clinicians who will be using the DC/TMD protocol. As noted in the table, above, the decision trees and the examination form do not require translation, as only professional staff use those instruments. If use of those instruments in the target language is desired, forward translation only can be sufficient.
4. For the final document containing the translated version of the DC/TMD, two face pages should be constructed; the first face page will be in the target language (i.e., non-English), and the second face page will be in English. The face pages identify the lead developer/translator as well as all collaborators. Collaborators include forward translators, back-translator, project coordinator, and reviewer. See example face page for the DC/TMD (as based on Italian) posted on the Consortium web site (www.rdc-tmdinternational.org).

C. Examiner Commands

The language used by the examiner during the examination is a set of operationalized commands that must be translated just as carefully as a self-report instrument; otherwise, the exact behavioural context for subject response during the examination may not be consistent with the intent of the command and may result in non-comparability of data with that obtained in other languages. The DC/TMD examination protocol is intended to be used in both clinical and research settings. In both settings, the nature of the verbal command to a patient or research subject will determine the observed responses and hence data that lead (or not) to a diagnosis. The stated sensitivity and specificity of the common TMDs within the DC/TMD are based on data collected according to reliable

methods; consequently, failure to use the appropriate commands (in English, or correctly translated to another language) will result in false positive and false negative diagnoses. Consequently, translators must be very careful in the translation process to produce examination commands that have the same meaning (which includes the same cultural equivalence) as expressed in the English examination commands. Examiners must then be equally careful to use the culturally equivalent commands when actually conducting the DC/TMD examination.

Nothing in these instructions about rigorous examination commands that carry the same meaning and clarity in all languages should be construed to imply that investigators are not free to add other items to the core protocol, if they wish to empirically test hypotheses about the examination protocol or particular types of findings; again, the emphasis here pertains to adding items. The DC/TMD items, on the other hand must be administered in their current format. Adding an item that is a modification of a standard DC/TMD item is acceptable.

The present set of commands have been extensively field-tested for examiner reliability in several languages (English, Swedish, German, Danish) and have been trial translated into several languages (Dutch, German, Spanish, Swedish) in order to provide assurance that the English language version forms a sufficient and clear base for further translation.

For example, for pain-free opening, the command (in English) could be stated as any of the following versions: “Open as wide as you can, without any pain”, or it might be “Open as wide as possible without pain” or it might be “Open maximally without pain”. While each of these versions in English means approximately the same thing and while each can be translated reasonably accurately to another language, only one construction, the version “Open as wide as you can, without any pain” has been shown to translate well to the conversational forms in other languages and consistent with the intention of the source item as implemented with native English-language speaking individuals. Another example is to “close your teeth completely together”; in one language (at least), the phrase “completely together”, if translated literally, means to the speaker of that language that the teeth should be clenched tightly together, which is not at all a requirement for the valid performance of the particular examination command; hence, the phrase, “…but not clenching” was added as a reminder to the translator that the intent in bringing the teeth completely together is a spatial one, not one that involves any extra force. If other translators find problems with the current wording, they are invited to contact the first author of this document for further review. One intent of the present document is to provide, over time, an FAQ that describes problems encountered by translators of different languages, and to archive the method of resolving the particular problems.

The bias of the research group that refined the verbal examination commands in English is that verbal language used during the examination should be as simple and direct as possible (i.e., make it as clear as you can) in order to foster common-sense understanding on the part of the patient. The form of the language for the verbal examination commands should therefore be regarded as our attempt to provide as clear a statement as possible regarding what the essential operations are in the performance of each examination procedure. We also recognize, however, that the final performance of a command rests upon shared understanding on the part of the patient, and that that understanding often emerges as much from non-verbal communication or ancillary commands which examiners instinctively provide as it does from the formal verbal command. After capturing the essential intent of a command, common-sense usage should be foremost for the translator and user. Translators would do well to remember that verbal language and written language often differ, and for the examiner commands, the requirements and sensibilities of verbal language should prevail.

The translator should consult Parts 2 and 3 of the "Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) Clinical Examination Protocol" for elaboration regarding any particular command in the Complete Specifications (Part 5) that is unclear with regard to the meaning in the source language.

The translator has a choice of two approaches for the translation of the examination commands and procedures:

- To translate only the Required commands (Section 8 of the DC/TMD Examination Protocol) and just the verbal component of the Examination Pain interview (Section 6 of the Protocol); under this approach, everything else that an examiner would say during an examination will be up to the examiner to create based on the intent of the procedure as described in the Complete Specifications of the Examiner Protocol; or
- To translate the Complete Examiner Specifications (Section 5 of the Protocol) and complete Examination Pain Interview (Section 6 of the Protocol); together, these two documents fully operationalize all aspects of the examination procedure.

From our field studies of this protocol, the complete set of specifications provides the comprehensive structure for an examiner to efficiently complete the examination. Which version a translator develops is up to that individual and will often be determined by the setting. For example, translated versions that will be used in university training environments will likely be based on the complete specifications; however, whether the additional verbal text and examiner procedures are translated will often depend on English fluency among the users of the specifications. It is entirely sensible to insert the translated required commands into the otherwise English language version of the

specifications. In contrast, a version used in a primary clinical setting may productively be based only on the required commands. In both instances, however, the examination pain interview must be translated. The verbal component of the Examination Pain Interview is included in the Log B of the Required Commands; the same material accompanied by the explanation also exists as a separate Log B when the complete specifications are translated.

D. Examination Recording Form

The examination form does not require translation, as only professional staff interact with it. However, in some settings, it is desirable to make that language consistent with the verbal language used for data collection. An international version as well as US version is provided; the difference is solely in the numbering of the teeth. The RDC/TMD used the English measurement pounds for specifying palpation force; the DC/TMD has changed to the international kilogram.

E. Diagnostic Decision Trees and Diagnostic Criteria

Decision trees and the diagnostic criteria table are not used by patients, and they consequently do not require translation as far as reliable data collection from the patient is concerned. However, in terms of reliable decision-making by the provider, translation of the decision trees or diagnostic criteria table may be desirable. Because the decision trees are graphical in nature, the translation log for this content does not readily map to the finished product. Suggestions for how to improve this will be gratefully received.

One phrase in the decision trees and diagnostic criteria table may present some problem to non-native speakers of English. In the DC/TMD, Tables containing the diagnostic criteria use the phrase "The pain is not better accounted for by another pain diagnosis" for the myalgia and arthralgia diagnoses, and "Headache not better accounted for by another headache diagnosis" for the Headache attributed to TMD disorder. This phrase, "...not better accounted for by ..." is standard [English language] jargon in many diagnostic taxonomies, but it is often awkward for non-native English speakers to translate. These phrases can be equivalently expressed in English as ““The pain condition is not better explained by another disorder” or “"The pain is not attributed to another pain disorder". Either of these English structures appears to be an easier form of the source language for translation to other languages.

F. DC/TMD Symptom Questionnaire and TMD Pain Screener

The Patient History Questionnaire (PHQ) of the RDC/TMD has been completely revised for the DC/TMD and is renamed Symptom Questionnaire (SQ) in order to more clearly

differentiate it from the PHQ-9 and PHQ-15, where the names pre-existed the development of the DC/TMD.

Notable differences between the RDC/TMD PHQ and the DC/TMD SQ include: focus on Axis I diagnostic requirements (except for the pain chronicity question), placement of all Axis II instruments as a separate set of documents, and placement of demographic questions in a separate document. The modular organization (i.e., separation of Axis II and demographic instruments to their own documents) enhances flexibility in how the DC/TMD protocol can be adapted for specific settings. For example, one setting may wish to use only the Axis II screening instruments, while another setting will use the complete Axis II instruments. One setting may already assess the necessary demographic information through a mandatory clinic registration form, while another setting may need a separate form for research.

The TMD Pain Screener was intended to be a stand-alone screener for use in a variety of settings. Almost all of the scope of the TMD Pain Screener is included in the SQ, but note that the identified anatomical region of interest differs pain-related filter item across the two instruments (item 1 in TMD Pain Screener; items 1 and 3 in DC/TMD SQ). The TMD Pain Screener, in the interest of maximizing specificity in relation to other disorders that can produce TMD-like pain, asks about pain in the jaw or temple area, whereas the DC/TMD SQ, in the interest of being inclusive about possible areas of TMD-like pain and coupled with a clinical examination for confirmation, asks about pain in the jaw, temple, ear, or front of the ear. Whether this difference in wording has substantive consequences remains to be determined by empirical or logical means. In many settings, the DC/TMD SQ will be the sufficient pain history collection instrument, and the TMD Pain Screener will not be needed. In other settings, only the TMD Pain Screener might be needed. Nevertheless, both instruments must be translated in order for the resultant language instrument set be complete for all potential users in that language setting.

G. Demographics

Demographic questions are often asked as part of other registration materials, and hence they are no longer a required part of the PHQ. The user could include them with the PHQ as the first section or as the last section. If they are included as the first section, then the item numbering of the PHQ must be carefully controlled, as the Diagnostic Decision Trees key from the item numbers in the PHQ for the respective criteria by history.

Questions in the Demographic form assessing education, income, marital status, and race/ethnic status need to be carefully revised for each national setting in order to appropriately capture the respective information in a manner that is accurate for that

setting. A literal translation of these items will almost always be incorrect for any setting outside the United States. In making changes to these items, the source item on the Log B for the Demographics form should be revised accordingly.

Additional comments on each aspect of demographics follow:

(1) The types of marital status, and the relevance of each type, are often unique in each setting. Co-habitation, for example, has different meanings in different cultures. Whether relationships of the same sex should be explicitly acknowledged in the way the question is asked depends on local mores and changes across time.

(2) Race/ethnicity on the Demographics form represent the categories considered important for national surveys in the United States, as determined by the US Federal Government. Categories appropriate in other settings will be determined on the basis of a wide range of considerations, including the population local to a particular setting, to theoretically or empirically meaningful distinctions, to national record keeping. In addition, in many settings the ethnicity and race questions, as used in the US, may be collapsed to a single item.

(3) Years of education seem to be based on an approximately equivalent unit throughout the world. At an instrument level, the grouping of the years may well differ (e.g., elementary school may be 4, 5, or 6 years). And, in some countries, the number of years of education do not necessarily map directly to the number of years in other countries due to strong differences in the education programs. Consequently, significant attention in data analysis of this variable is needed even though the raw numerals appear equivalent across settings. The primary response format for the DC/TMD was simplified into blocks of schooling; a translator may wish to retain the actual number of years of education since that measurement method is less ambiguous. Moreover, the lowest level of education in the DC/TMD demographics form is “through high school” due to the very low prevalence in the US of education terminated early (e.g., primary school). How the lowest level of education is represented in a given setting should be determined according to national statistics and prevalence rates in that setting.

(4) Income levels for each bracket should be based on national indices which may represent quartiles. Socioeconomic status is still best measured on the basis of both education and income; in the US, there is also a directory of job classifications, which also permits the inclusion of job status into the computation of SES. If there is such a directory in other countries, the instrument developer might want to consider the inclusion of that kind of item in the Questionnaire if SES is of significant interest.

(5) There are national statistics units which provide classifications of value for these variables. The national statistics unit in The Netherlands has links to similar units in many countries throughout the world; see http://www.cbs.nl/nl/service/links/default.asp#Europa to get started. In general, it can be recommended to use instruments which have been already used in large national health-related surveys. National survey databases should be consulted, if available, in making decisions regarding the levels of importance for the demographic variables.

H. Axis II Instruments

The Axis II instruments fall into two sets: the short set for primarily screening purposes, and the long set for more comprehensive evaluation. From a translation perspective, the short set includes two instruments (PHQ-4, JFLS-8) that are derivative from other instruments in the long set; consequently, translating the long set provides the full information for constructing the instruments in the short set. As a procedural policy, only translations that include the both short and long sets of Axis II instruments of the DC/TMD protocol will be posted on the Consortium website; this principle is consistent with the goal of disseminating in other languages translations of the full DC/TMD protocol. Users will often have other instruments that they wish to add to the set of Axis II instruments for a given setting; other instruments can of course be added, and if these instruments exist as a source language in English, they can also be translated and added to the instrument library on the Consortium website. While we recommend that the long set of Axis II instruments be used, in order to maximally facilitate DC/TMD research, we also recognize that in a given setting, a different instrument (e.g., HADS for depression and anxiety, instead of the PHQ-9 and GAD-7) might be preferred or even required due to various consortia agreements that often exist. As noted in the Guidelines document [1], translation and in particular cultural equivalency of instruments that assess mood and similar constructs can be a complex undertaking.

A developer may also consider retaining the legacy instruments for depression, anxiety, and physical symptoms, as based on the SCL90 and used in the RDC/TMD. Already completed translations may exist of the entire SCL90-Revised (SCL90-R), perhaps also accompanied by psychometric data with regard to reliability and validity; note that the Revised version of the SCL90 is copy-righted, while the original SCL90 is not (and from which the depression and non-specific physical symptoms scales in the RDC/TMD were derived). Data for the construction of a scoring concordance table are currently being conducted, with data collection scheduled to be completed by December 2013; a measurement table will be released (estimate: 2014) which will allow direct comparison of RDC/TMD Axis II legacy data with the new PHQ family instruments.

I. The PHQ Family of Instruments

The PHQ family of instruments comprises PHQ-4, PHQ-9, GAD-7, and PHQ-15. These instruments were derived from the PRIME-MD project, which sought to improve mental health assessment in primary care settings. The specific item content for each of these instruments has undergone text revision since publication, and we have chosen to use the most recent versions of each of these instruments for the Consortium Axis II dataset. If a given setting for DC/TMD implementation needs to be compatible with the version of the instruments initially published, then the translation developer must decide whether to use the published wording or the text-revision. If using the published wording, the Log B for the respective instruments will need to be modified in order to reflect that particular wording.

The PHQ-4, PHQ-9, GAD-7, and PHQ-15 have already been extensively translated as part of Pfizer, Inc.'s research program, and already translated versions are readily available (http://www.phqscreeners.com/). In order to conserve resources and promote cross-domain research, DC/TMD translation groups are therefore encouraged to use the existing translations if the translation is acceptable. Consequently, if an existing translation of any of these instruments is used for a given translation of the DC/TMD, indicate in the translation Log A that an existing translation was used, provide the citation to that version, and attach the translated instrument to Log A. That "translation" would then be complete.

The origin of these translations archived at phqscreeners.com is, however, not clearly stated on the website, and while many have been translated by a professional translation group, it is not clear which ones have been, and we have found items in the PHQ-9, for example, that were translated into another language by an unknown group and which we disagreed with. Consequently, DC/TMD translators are encouraged to consider the available translations of these instruments but to first critically review the translation as well as any published supporting material for the reliability, validity, and cultural equivalence of the translation. Should a DC/TMD translator find problems in the existing translation of one of these instruments, we recommend the following steps:

- Use the translation available via Pfizer for "Translation 1"
- Perform an independent translation from the source Log B ("Translation 2")
- Critically review and synthesize the two translations into a single translation
- If the differences between Translation 1 and Translation 2 are minor and of no substantive consequence in the target language, then use the existing Pfizer-based translation; if the differences are not minor, then note on the translation Log C as a comment (use another color in the synthesis column) that the translation group disagrees with the Pfizer-based version, and briefly explain why.

- The Consortium will convey this information as well as the final Consortium version to the individual who monitors the Pfizer translations, and we will add a note on the Consortium website regarding the presence of differences in our version of the translation vs that on the Pfizer website.

As an official Consortium policy, we encourage collaboration between individuals and groups when difference perspectives emerge regarding the correctness of a translation. However, we contacted Pfizer and they have no formal method in place for resolving differences in translations. Pfizer states that "no permission is required to reproduce, translate, display, or distribute them". We have therefore adopted the above recommendations for translations of the PHQ instruments that will be part of the DC/TMD protocol. As always, the marketplace for science is peer-reviewed journals, and the scientific community through that mechanism decides upon measures, instruments, and data. If a translation developer decides to not use an existing translation of any of these 4 instruments and instead create a new translation, the rationale for this should be briefly stated in the Translation Log A and, if possible, to note which items in the existing translation were considered incorrect.

J. Psychometric Issues

The DC/TMD components encompass a clinical assessment protocol that is actually very complex in terms of the psychometric methods associated with establishing reliability and validity in a cultural context. The types of instruments include examination commands, single item inquiries, checklists (an aggregate of single item inquiries held together by a common theme such as "oral behaviors"), and formal measurement scales (e.g., Graded Chronic Pain, Depression, Anxiety). Each type of instrument has its own standards for assessing reliability and validity. In the following section, "Stages" refers to process stages of development as described in the document, Guidelines for Establishing Cultural Equivalency of Instruments.

1. Clinical DC/TMD examination

- Translation. All verbal commands need to go through Stages I-IV. The recording form (used by the examiner), if translated for data collection, should be reviewed via trial usage. Known problematic areas include:
    - Certain words cause problems, such as "Place your mouth in a comfortable position" where in some languages "mouth" is better translated as "mandible". The pre-testing phase of Stage V in a small group of subjects is important and should be done.
    - The procedures "maximum unassisted opening" and "maximum assisted opening" are also referred to, particularly in the physical therapy domain, as

"active opening" and "passive opening", respectively. However, these terms are not as operationally descriptive as the terms "unassisted" and "assisted". Users should of course use labels that are meaningful in their setting; however, for any publication purposes, adherence to "unassisted" and "assisted" is recommended since these are the formal labels in the DC/TMD.

- The complete examiner specifications includes a left-hand column containing the name of the construct that is operationalized in that row of the table; this construct label is also included in the corresponding Log B. These labels are for reference only by users of the document; translators should adjust the names as needed for clarity.

- Reliability. The primary psychometric methods for verbal commands are bilingual reliability (see Guidelines document for explanation), test-retest reliability, and inter-rater reliability. Such analyses provide evidence for the correctness of the translated verbal commands.
- Validity. Simple face validity of the examination commands can be verified through usage in an examination reliability study; in other words, does the command result in the expected subject behavior or demonstration of the phenomenon. Construct validity of the clinical examination items and diagnoses is a very complex undertaking, and not part of the purview of this document.
- Responsiveness. Not applicable.

2. DC/TMD Symptom Questionnaire
   - Translation. With only few exceptions, all of the items in this instrument contribute to the diagnostic algorithms for the Axis I diagnoses. Readability and adaptation of physical symptom-oriented items are important. The remainder of the Questionnaire can be translated directly, recognizing that some words such as "click", "lock", and "pain" may require special attention. Clinical symptoms relating to mechanical jaw problems seem especially prone to problems in translation and adaptation; this is also true in English.
   - Reliability. The primary psychometric methods for individual items are bilingual reliability (see Guidelines document for explanation) and test-retest reliability.
   - Validity. Simple face validity of the items can be verified through usage in a semi-structured interview or open interview.
   - Responsiveness. Not applicable.

3. Graded Chronic Pain Scale, Version 2.0

- Translation. The GCPS instrument published as part of the RDC/TMD contained errors in contrast to the correct version of the Graded Chronic Pain instrument as published (M. Von Korff, J. Ormel, F. J. Keefe, and S. F. Dworkin. Grading the severity of chronic pain. Pain 50:133-149, 1992). The new version 2.0 includes an additional item, and the wording of all of the questions has been revised. Stages I-V should be performed.
- Reliability. Test-retest assessment is the primary form of analysis that can be done, as internal reliability for this instrument is harder to interpret due to the complex nature of all 8 of the items that comprise the Graded Chronic Pain Scale. Internal consistency of each set of items 2-4 (characteristic pain) and items 6-8 (interference) can readily be done; published data (R. Ohrbach, J. A. Turner, J. J. Sherman, L. A. Mancl, E. L. Truelove, E. L. Schiffman, and S. F. Dworkin. Research Diagnostic Criteria for Temporomandibular Disorders. IV: Evaluation of Psychometric Properties of the Axis II Measures. *J.Orofacial Pain* 24:48-62, 2010) indicate excellent reliability which should serve as an appropriate benchmark for other translations. Additionally, Rasch analysis also yields a clearly reliable measurement scale for each of pain and interference items, when using data collected in the US, but whether this holds true for other countries is as yet unknown and, as such, Rasch (or other IRT) analysis for item reliability may be premature. Moreover, the Chronic Pain Grades 1-4 are derived from a Mokken analysis, and hence customary reliability statistics are not useful for the instrument as a whole.
- Validity. Pain scaling across cultures (i.e., from the characteristic pain items) clearly needs attention via data analysis. However, cultural equivalency should not be based solely on demonstrating the equivalence of pain scores across cultures. This may be a situation where confirmatory factor analysis is the appropriate assessment method for validity.
- Responsiveness. Establishing responsiveness in the context of cultural equivalency of these items is beyond these guidelines. Published data, to date, seem to support the GCPS as a classification instrument rather than a monitoring instrument, and consequently responsiveness may not be a critical analysis for evaluating this instrument.

4. Depression, anxiety, and physical symptoms
   - Translation. The items in these 4 instruments (PHQ-4, PHQ-9, GAD-7, PHQ-15) index traits that clearly require the full set of Stages described in the Guidelines document. DC/TMD translators should note the items comprising the PHQ-9 and GAD-7 instruments require special attention in the translation process. For example, an item referencing “feeling down” may need cultural modification. The

PHQ-4 contains 2 items from the PHQ-9 and 2 items from the GAD-7. If the translator decides to first translate the PHQ-9 and GAD-7, and then later decides to also use the PHQ-4, the appropriate items should be retrieved from the two prior translations; there is no need to do a separate PHQ-4 translation in this instance.

- Reliability. Stages I-V should be followed.
- Validity. Stages I-V should be followed. Moreover, full construct validity in a given culture requires collection of data for assessing formal validity as is commonly used in test development assessment. See Norman and Streiner, Health Measurement Scales, 3rd edition, NY: Oxford University Press, 2003, for suggested methods.
- Responsiveness. Can be tested. Contemporary methods should be used such as those described in Norman and Streiner.

5. Jaw Functional Limitation Scale
   - Translation. These items should be straight-forward. However, the items that start with "Open wide enough to …" refer to opening the mouth, and they can be changed to "Open the mouth wide enough to …" if needed for clarity. The JFLS-8 is a subset of the JFLS-20, and consequently if both instruments are to be translated, then the developer should do the complete translation for the JFLS-20, and then adapt a final JFLS-8 instrument for administration from the JFLS-20 translation.
   - Reliability. The primary psychometric methods for the JFLS are internal reliability for each of the component constructs, test-retest reliability of subscores, and model fit via Rasch analysis.
   - Validity. Confirmatory factor analysis should be considered.
   - Responsiveness. Can be tested. Contemporary methods should be used such as those described in Norman and Streiner.

6. Oral Behaviors Checklist
   - Translation. These items should be straight-forward.
   - Reliability. The primary psychometric methods are bilingual reliability (see Guidelines document for explanation) and test-retest reliability.
   - Validity. Clarification via interview of whether the selected translated term points to the same behavior as intended in the source version is probably the most direct, in order to map the better words for these behaviors to common-sense understanding and labeling of the behavior.

- Responsiveness. Unknown at present.

7. Pain Drawing
   - Translation. The instructions are minimal.
   - Reliability. The primary psychometric method is test-retest reliability for the individual completing the pain drawing.
   - Validity. Clarification via interview of whether the reported body parts on the pain drawing correspond to pain symptoms is probably the most direct. Interpretation of this instrument is, however, complex given that there is no real "score" that emerges.
   - Responsiveness. Unknown at present.

K. Filename conventions and submission of Logs for review

1. Filename conventions. The Translation Team Leader will verify that the filename for each Log follows the correct convention:

   a. For single version of a log:
      i. Format: Log <letter> - <instrument name> - <language>.doc
      ii. Example: "Log A – Symptom Questionnaire – Greek.doc"

   b. For log that has several iterations:
      i. Format: Log <letter><iteration number> - <instrument name> - <language>.doc
      ii. Example: "Log D1 – Symptom Questionnaire – Greek.doc" for first back-translation, and
      iii. Example: "Log D2 – Symptom Questionnaire – Greek.doc" for second corrected back-translation

   c. For Log C, given two forward translations:
      i. Format: : Log <letter> - FT<translator number> - <instrument name> - <language>.doc
      ii. Example 1: "Log C – FT1 - Symptom Questionnaire – Greek.doc" for forward translator #1, and
      iii. Example 2: "Log C – FT2 …" for forward translator #2.

   d. For Log C, when a corrected forward translation is required:
      i. Format: : Log <letter><iteration number> - FT<translator number> - <instrument name> - <language>.doc
      ii. Example 1: "Log C1 – FT1 - Symptom Questionnaire – Greek.doc" for first translation by forward translator #1, and

iii. Example 2: “Log C2 – FT1 …” for second translation by forward translator #1.

2. Logs may be submitted in either .doc or .docx format.

3. Submission of Logs for independent back-translation review.
    a. For each instrument, a completed Log D will be submitted to the independent reviewer.

    b. For each instrument, the reviewer will return a Log E with comments to the Translation Team Leader.

4. Submission of Logs for final administrative review
    a. Administrative review focuses not on the content of the translation, but rather on the adequacy of addressing any concerns in the translation as well as completeness of the documentation itself. Examples of errors or discrepancies that would not be acceptable are: (1) incomplete Section A on a Log; (2) inadequate follow-through of potential cultural problem in a translation as identified by the expert committee; (3) inadequate representation of an expert committee; or (4) missing component on a final instrument for patient administration. An acceptable translation Log should readily demonstrate a complete translation process that meets the requirements of cultural validity for a given target translation.

    b. The Translation Team Leader will submit via email all logs (fully completed Log A – Log H; header row completed for Log I) in .doc or .docx format, as follows:
        i. If the Logs are separate files, then all Logs for one instrument will be submitted as the attachments to a single email message. For example, the minimum translation requirement is 13 instruments, each of which will have a set of Logs; 13 email messages would be submitted for the minimal set of instruments to be translated.
        ii. The logs may be compiled into a .zip file according to the Team Leader preference; if so, the compiled .zip files for all instruments can be submitted as multiple attachments to a single email message. For example, the one email message could contain 13 .zip files, assuming that only the minimal instrument set has been translated. Email servers may impose size limitations on outgoing email, and consequently, the 13 (or more) .zip files may be submitted across more than 1 email message.

    c. For the full set of instruments, the Team Leader will also submit a title page in each of English and the target language, using the title page template

posted on the website. The name of the Translation Team Leader(s) listed on the title page should be consistent with the information in Log A for all of the instruments.

d. The final translated instrument for patient administration, for each source instrument, will be submitted as a separate document, in addition to the instrument being an attachment to Log H.

e. Translation Logs not meeting the stated requirements will be returned for correction.

f. When a DC/TMD translation is approved, the following steps will occur:

    i. The name and email address of the Translation Team Leader(s), as based on the title page, will be posted on the Consortium website as the contact individual(s).

    ii. The names of all members of the Translation Team will be posted on the Consortium website.

    iii. The title pages and each administrative instrument will be aggregated into a .zip file and posted on the Consortium website for public download.

    iv. The Log files will be aggregated into a composite .pdf file and posted on the Consortium website for member-only access.

L. Authorship of a translation

Authorship of a translation should be decided in the same way as for a publication. The title page of the translated instrument set includes the authors' names. Two primary categories are used: translators and collaborators. In this context, a "translator" refers to anyone making a major contribution to the final product; this could be a coordinator who does not actually translate but manages the full project, or it could refer only to those who actually do forward translation (the most restrictive approach). "Collaborators" refers to everyone else involved in the project who makes substantive contributions but not as extensive as that of the "translators". A third category could also be used: "acknowledgments", such as for the expert panel members.

Recognizing contributions should be distinguished from a purchased service (such as a back-translator hired through an agency). Consequently, individuals simply hired to forward or backward translate but who do not contribute to the scientific quality of the translation are often not included as authors. Translation team leaders will make the final decisions regarding how credit is listed on the title page, and the listing can be as

inclusive as needed. As with publications, the web page for the translation will list the email address of the translation team leader (and co-leader, as determined by the team) for inquiries.

Authorship is indicated on the title page, according to rules established for formal document translations. Only this format is permitted for official and approved translations to be posted on the Network website. For example, university logos or other symbols are not permitted for the official release version. Translation teams may of course affix such logos for any internal use or other type of distribution (e.g., as part of a continuing education course) that is clearly anchored to the translator's organization.

Indication of authorship of the translation also extends to the credit assigned to each translated instrument. The final form of each translated instrument must retain the footer as included on the source document. In addition, the translation team is encouraged, but not required, to take credit for the translation of the instrument by including the translator names, as determined by the individuals listed as translators on the title page of the full instrument document.

> For example, the TMD Pain Screener footer on the course document reads as follows:
> Copyright Gonzalez YM. Available at http://www.rdc-tmdinternational.org. Version 11Oct2013. No permission required to reproduce, translate, display, or distribute.
>
> The footer for the Swedish translation would be modified as follows:
> Copyright Gonzalez YM. Translated by Alstergren P, Häggman-Henrikson B, Ekberg EC, Harfelt K, Dahl Nordin S, List T, all at Malmo University. Available at http://www.rdc-tmdinternational.org. Version 11Oct2013. No permission required to reproduce, translate, display, or distribute.
>
> All originally translated instruments (including tables and figures, as appropriate) may be so modified for the official distribution of the approved translation via the Network website, and translation teams are encouraged to include this acknowledgment to their work. Instruments from the PHQ family (PHQ-4, PHQ-9, PHQ-15, GAD-7) that were fully translated by the team would also include the footer with the translator names. If the translations of the PHQ instruments were built on existing translations (that is, the existing translation served as the base but was modified), then the footer should indicate that the translation was modified, for example, "Existing translation was modified by Smith at Malmo University". If the existing translation of the PHQ instruments was retained, without any change by the translation team, then the current footer would remain intact.

M. Preparation of final translation document for Network website

A separate instruction document, “Assembly instructions for translated DC-TMD”, provides the specific instructions for completing the DC/TMD translation document as well as a combined document containing the full examination protocol and Axis-II scoring guidelines. This document is sent separately to translation teams at the appropriate stage of translation completion.

N. References

1. Ohrbach R, Jezewski MA, Bjorner JB et al. Guidelines for Establishing Cultural Equivalency of Instruments. 2013.

O. Updates to this document

2017 Sep 29

- Added Committee members on title page
- Added new sub-section to Section L, regarding insertion of translator names into the footer on each instrument and not allowing logos to be part of the final document.
- Added new section M, “Preparation of final translation document”.
- Updated numbering of prior sections M and N.

2014 Mar 20

- Clarification regarding translation of the examiner specifications; see pages 2 and 7.
- Added information regarding authorship (new section L).

2014 Feb 23

- Clarification that both TMD Pain Screener and DC/TMD Symptom Questionnaire (SQ) must be translated as part of the DC/TMD instrument set.

2014 Jan 04

- The order of the list of instruments to be translated and the contents listing was reversed.
- New section K for filenaming conventions and document submission was added.