Linguistic Validation, Including Cultural Adaptation, of an Updated ADKnowl, Diabetes Knowledge Questionnaire, for International Use

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Audit of Diabetes Knowledge (ADKnowl)

- A 138-item self-administered knowledge measure divided into 33 sections to:
  . Evaluate the knowledge adults with diabetes have of their condition and
  . Determine the aspects of the condition where knowledge needs to be improved to help them manage their diabetes better on an everyday basis.
- Target population: people with Type 1 and 2 diabetes.
- Classification of items:
  . 95 items for all respondents
  . 12 items for respondents using insulin regimen, with or without tablets
  . 3 items for respondents using urine glucose monitoring
  . 11 items for respondents using insulin regimen with at least four injections a day
  . 3 items for respondents using premixed insulin twice a day with or without tablets
  . 7 items for respondents who at least occasionally drink alcohol
  . 7 items for respondents who take tablets, with or without insulin
- Development:
  . Originally developed in UK English by Prof. Clare Bradley in 1993 in consultation with UK diabetologists, diabetes specialist nurses, dieticians and a podiatrist (Speight & Bradley, 2001);
  . Updated for DAFNE trial (Dose Adjustment For Normal Eating) in 2000-2001 (Speight, 2003), again with a multidisciplinary team of diabetes experts;
  . Updated most recently (2009) with a similar team of diabetes experts for an international educational project sponsored by Eli Lilly;
- The linguistic validation in two languages was sponsored by Eli Lilly.

Context

Assessment in an international clinical study of the knowledge adults with diabetes have of their condition.

Need for a reliable, valid and responsive instrument that:

- Facilitates the assessment of what people with diabetes know about their condition to help them improve its management on an everyday basis.
- Is conceptually equivalent across countries and culturally and clinically relevant in the target country.
- Allows for data pooling and comparison across countries.

Countries and Languages harmonised here

Europe

- **Germany** (German)
- **Spain** (Spanish)
- **The UK** (English)

Objectives

- Review the content of the newly updated English version of the diabetes knowledge measure (ADKnowl) developed in UK English to assess its suitability to the current clinical and cultural context of Germany and Spain.
- Finalize the UK English version and produce conceptually equivalent and culturally relevant language versions in German and Spanish.

Methods

A consultant was recruited in Germany and in Spain to co-ordinate and supervise the work described below in the respective country. The expert consultant also recruited translators and patients as required by the methodology outlined below as well as diabetes experts (a diabetologist, diabetes specialist nurse (DSN) and a dietician).

Linguistic Validation Methodology

Original UK English updated 2009

Forward step

- Production of a "list of concepts" by the developer defining the meaning of each item as well as a list of possible and acceptable translation alternatives.
- Production of 2 translations from source language to target languages.
- Meeting with the 2 translators and the consultant.
- Production of a reconciled target language version on the basis of the list of concepts (German V1 and Spanish V1).
- Establishment of a list of questions / comments regarding the original UK version in the light of the German and Spanish translations.

Assessment of the cultural suitability of the original UK version to the context of Germany and Spain

- Discussion of the list of concepts and the reconciled forward translation with the developer, the consultants and the diabetes experts in both countries to assess the measure's suitability for Germany and Spain.
- Update of the original UK English version and of the Spanish and German translations (UK V2, German V2 and Spanish V2).

Backward step

- Production of 2 backward translations of the German and Spanish V2 into English.
- Comparison of the backward translations with the UK V2; discussion of any discrepancies and establishment of a revised version in UK English, German and Spanish (V3).

Cognitive debriefing

- Comprehension test on 8 people with diabetes (2 with Type 1 diabetes, 2 with Type 2 diabetes on medication including insulin, 2 with Type 2 diabetes treated with tablets and diet but no insulin and 2 on diet alone with no diabetes medication), during in-depth face-to-face interviews conducted by the consultant, to determine whether the wording was understood as intended. Because of the detailed discussions around each item, it was considered too burdensome for each patient to complete the whole ADKnowl. Consequently, 4 patients tested the first half of the questionnaire and the remaining 4 the second half.
- Alternative wordings were discussed in the target languages during a "thinking out loud" exercise.
- Establishment of the final target versions and final UK version in the light of cognitive debriefing results. (UK, German and Spanish Final Version (FV)).

Finalisation process

Results and issues encountered

- Results of the process showed that diabetes management differs somewhat across countries. Differences in dietary habits, alcohol use and statutory health care qualifications necessitated some adaptation in the target languages, and sometimes also in the original English, in order to make the measures culturally relevant to context of Germany and Spain.

Example 1: Translation of units of measurement in items 5.3, 12.5 and 13.2

- **Latest English Wording (following UK update work):**
  Item 5.3: *take additional quick-acting insulin if your ketones test positive and your blood glucose is over 10 mmol/L*

  Items 12.5/13.2: *take extra carbohydrate (quick-acting) if your blood glucose is below 6 mmol/L*

Concept
The 3 items used "mmol/L" as the unit of measurement.

Issue
Expert review in Spain and Germany indicated that this unit of measurement was not common in the 2 countries where the reference to "mg/dL" was preferred. Cognitive debriefing however revealed that the original unit of measurement was still in use in parts of former East Germany.

Solution
To facilitate comprehension it was decided to create 2 German versions referring respectively to "mmol/L" and to "mg/dL" and a Spanish version using just the latter unit of measurement.

Example 2: Translation of "cheese and biscuits" in Item 16.5

- **English Item 16.5:** *Cheese and biscuits are usually less fattening than puddings*

True	*False*	*Don't know*
☐	☐	☐

Concept
Respondents are expected to indicate if they think that cheese and biscuits (i.e. often offered as an alternative to dessert in the UK) are less fattening than puddings (i.e. desserts).

Issue
Cheese and biscuits are not traditionally served as an alternative to desserts in Spain, although cheese alone or with bread is commonly eaten in Germany.

Solution
The conceptually equivalent and culturally relevant translation proposed by the German team was "Käse macht normalerweise weniger dick als ein süßer Nachtisch" (Cheese is usually less fattening than a sweet dessert). The final Spanish version referred to "Las personas con diabetes tienen que evitar algunas clases de fruta (por ej., plátanos, uvas o higos)" (People with diabetes should avoid certain types of fruit (e.g. bananas, grapes and figs). This was identified and recommended by the Spanish experts as a common dietary misconception in Spain. These fruits are particularly high in carbohydrate but that does not mean they must be avoided by people with diabetes, so the correct answer is likewise False. Cognitive debriefing confirmed the relevance and acceptability of these cultural adaptations and translation choices in the context of the measure.

Example 3: Translation of alcohol items, glass sizes and units of measurement

- **Extracts from Section 18:**
  ***[Note: 1 unit of alcohol =*
  . ½ pint of ordinary strength (3-4%) beer;
  . 1 small glass (80 ml) of wine (12-13% strength); or
  . a single measure (25ml) of spirits (40% strength)

*18.1 If drinking 3 or more pints** of beer/lager/cider, additional quick-acting insulin could be taken to control blood glucose levels.*

*18.3 If drinking 6 or more units** of alcohol in an evening, long-acting insulin (if taken at bedtime) could be reduced to prevent night-time hypos.*

Concept
Section 18 asks about the balance between alcohol intake and amounts of long- and short-acting insulin.

Issue
Due to the differences in drinking patterns, glass sizes, alcohol strengths and the existence or not of "standard units" between the 3 countries, literal translations, although linguistically possible, would have been inappropriate.

Solution
To achieve equivalence across the 3 countries: (1) some types of drink had to be excluded (either not drunk locally, or equivalents had different sugar contents, e.g. "cider"); (2) the introductory definition for Germany and Spain could not refer to units, which are not widely recognised in Spain and do not exist in Germany; (3) The words pints and units could not be used for Spain and Germany and were translated using locally familiar "glasses" as relevant for each language version. The "glasses" were each pre-defined by quantity (in ml) and alcohol strength (in %).

Conclusion

An internationally acceptable version of the ADKnowl was developed following a rigorous methodology to facilitate international comparison and pooling of data. This project demonstrates the importance of assessing the suitability of the item content of a knowledge measure to the clinical and cultural context of the target countries, as well as the use of a rigorous translation methodology to ensure conceptual equivalence across the different language versions.

General Recommendations

- When developing a new instrument for international use:
  . Beware of idiomatic expressions or references which may cause difficulties in finding suitable equivalents that are cross-culturally appropriate
  . A detailed list of clearly explained concepts, validated by the developers of each instrument, is essential.
  . Use a rigorous translation methodology including the involvement of experts at an early stage in the process and a cognitive debriefing step to identify and solve cultural issues and ensure acceptance by the respondents.
  . Integrate international feedback from and to all target countries early in the process.
  . Be open to modifying the original language version in the interests of clarification and harmonisation.

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For any information on, or permission to use the ADKnowl, please contact Prof. Bradley at C.Bradley@rhul.ac.uk; or go to the website www.healthpsychologyresearch.com

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