

THE EVOLUTION OF LANGUAGE IN CLINICAL OUTCOME ASSESSMENTS: AN ANALYSIS OF SOURCE WORDING UPDATES, TRANSLATION UPDATES, AND THE NEED TO PERIODICALLY ASSESS THE RELEVANCE OF LINGUISTICALLY VALIDATED TRANSLATIONS

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OBJECTIVES

As technology advances, conceptual frameworks evolve, and cultures become more inclusive and diverse, we have seen a significant shift in the recognition and widespread use of certain concepts and terminology among the general population. This can impact the language in Clinical Outcome Assessments (COAs) in various ways as updates to the source and translations may be required to reflect up-to-date vernacular, disease treatment, and lexical/grammatical standards. Consequently, this poster aims to make a case for periodic review of both source and translations of COAs to ensure that patient-facing wording remains current and applicable, in turn ensuring higher-quality data.

METHODS

A selection of COAs used in a variety of therapeutic areas was analyzed to determine the need for linguistic or conceptual updates in both source documents and existing translations. The focus of this review was primarily in three areas: language, concepts and cultural relevance, and medical treatments.

RESULTS

Language and linguistic inclusivity

COAs relating to sexual health provide a rich ground to explore the issue of inclusivity. From 2018 to 2023 in the United Kingdom alone, the number of people identifying as LGB increased from 2.2% of the population to 3.8%¹. As stated by Scott et al. (2024) “to promote inclusion of all people, gender inclusivity should be incorporated into the development of all health surveys”. While this is applicable to the development of new PROs, it is also highly beneficial to review and revise existing questionnaires and forms to ensure inclusivity and better-quality data collection for studies.

One such example is the International Index for Erectile Function (IIEF). The version 1 wording of the IIEF (2005) is heavily influenced by heteronormativity and cisnormativity. Despite the use of the English gender-neutral term ‘partner’ throughout the questionnaire to refer to the respondent’s sexual partner, the form’s definition of the term ‘Sexual intercourse’ is given as “vaginal penetration (entry) of the partner”. This definition effectively excludes respondents who are not heterosexual. Upon review of the version 1 source file, it was determined that the instrument required a wording update to this item to ensure greater inclusivity for gay, bisexual and gender-nonconforming respondents. In the version 2 form the source definition of ‘Sexual intercourse’ is defined as “sexual penetration (entry) of the partner.”

When reviewing for the aforementioned update between v1 and v2 of the IIEF, various instances in the existing translations were detected that also required revisions in order to be applicable for respondents who are not heterosexual. For instance, when reviewing the Romanian (Romania) version 1 existing translation (*Fig. 1*), it was found that in all questions where the source makes reference to the respondent’s sexual partner, the existing translation only referred to a female sexual partner.

Conceptual equivalence and cultural relevance

Working patterns

In the aftermath of the COVID-19 pandemic, working patterns have undergone drastic changes, most notably in the number of people that work primarily from their home (remote working). (*Fig 2*). Of the 6.64 million members of the UK remote workforce, nearly a fifth of these are disabled^{2,3}.

This evolution in working habits should be reflected in COAs to capture accurate data. An example of a potentially outdated notion of working habits is the wording of question 2 of the Work Productivity and Impairment Questionnaire (WPAI) (*Fig 3*).

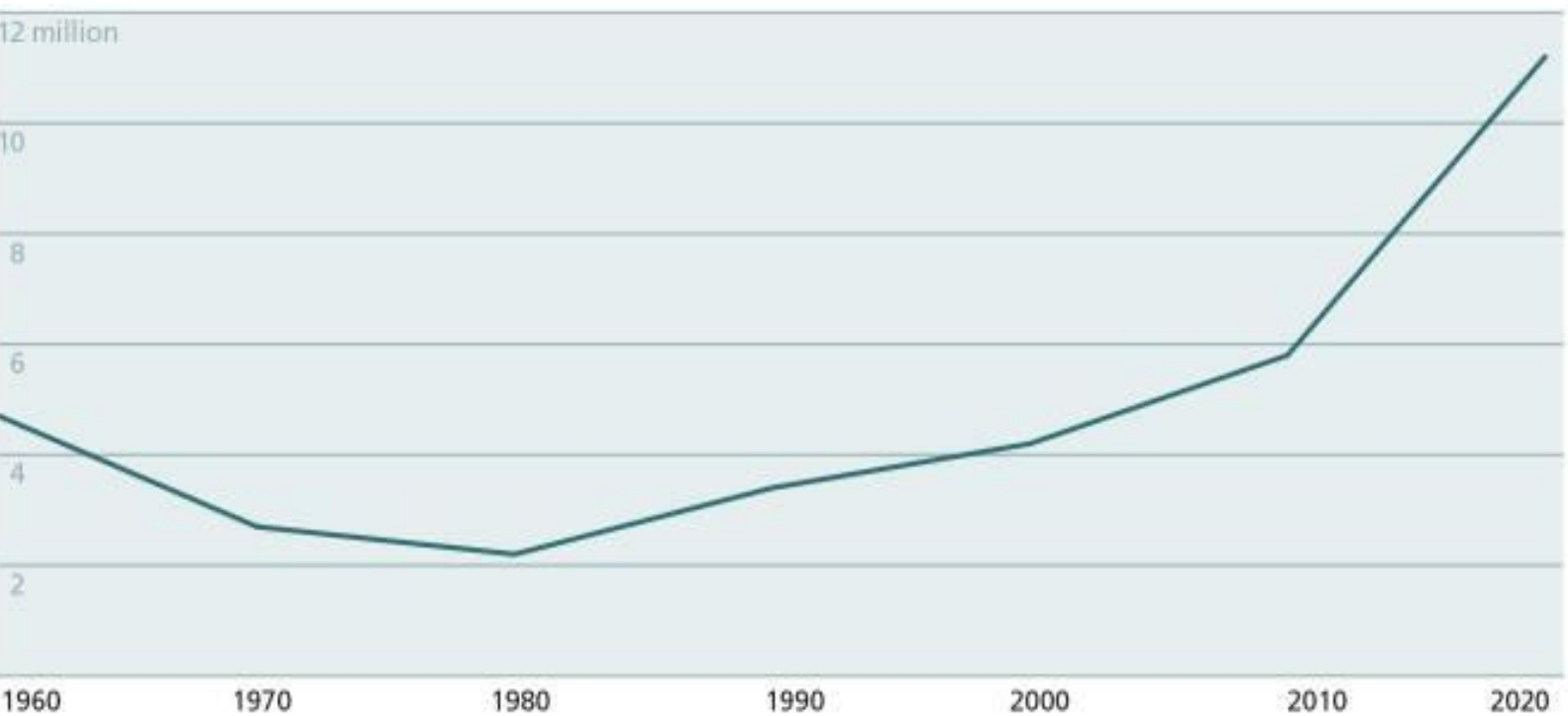
Figure 3: Question 2 from the WPAI questionnaire

2. During the past seven days, how many hours did you miss from work because of problems associated with your health problem? Include hours you missed on sick days, *times you went in late, left early*, etc., because of your health problem. Do not include time you missed to participate in this study.

Figure 1: Question 14 of the IIEF

English Source text	Romanian (Romania) V1	Romanian (Romania) V2	Description of change
14. Over the past 4 weeks how satisfied have you been with your sexual relationship with your partner?	14. În ultimele 4 săptămâni, cât de satisfăcut ați fost de relația sexuală cu partenera dvs.?	14. În ultimele 4 săptămâni, cât de satisfăcut ați fost de relația sexuală cu partenera/partenerul dvs.?	The revision was made from ‘female partner’ to ‘female/male sexual partner’.

Figure 2: Number of people working at home in the US (principal place of work in primary job)⁴



The implication of fixed working hours is a concept which is becoming increasingly outmoded. Moreover, as both working hours and locations have become more flexible, the notion of in-person work according to a traditional ‘9-5’ schedule in a static location is becoming less commonplace. This, together with the concept that salaried/paid employment in this existing instrument is considered to be office work or outside of the home, despite more people than ever performing remote work, means that traditional instruments to measure work impairment and productivity may be less relevant than they used to be, thus serving to demonstrate the importance of conceptually relevant wording in COAs.

Eating patterns

Another example of COA-wording that is not entirely inclusive according to modern cultural standards is the HAQ-DI (Health Assessment Questionnaire-Disability Index). One item in the instrument’s *Eating* domain asks the respondent “Are you able to: Cut your meat?”. It can be argued that it would be advisable to replace ‘meat’ with an alternative foodstuff to be more inclusive for respondents following a plant-based diet. Between 2023 and 2024 in the UK alone, the number of people identifying as vegan increased by 1.1 million to a total of 2.5 million (4.7% of the adult population)⁵. Meanwhile, eleven percent of the Indian population are vegans⁶. While the reasons behind following a plant-based diet may be myriad (for example, religious beliefs, health, secular ethical concerns), in order to ensure inclusivity this should similarly be reflected in patient-facing materials.

Media engagement

Cultural patterns shift over time, with technology acting as an overarching influence. An item used across several HRQOL measures that could benefit from a review to ensure cultural relevance with regards to modern media engagement and consumption is found in the PHQ-9 and QLQ-C30, in items 7 and 20 respectively (*Fig 4*).

Newspaper circulation and print readership have been steadily declining in the last 20 years. In 2019, only 38 per cent of UK adults accessed news via print newspapers and 11 per cent via print magazines, compared with 75 per cent via television, 66 per cent via the internet and 43 per cent via radio (*Fig 5*).

Medical treatment

Medical treatments and standard-of-care continue to evolve as a result of research and development, which should be similarly reflected in disease-specific COA wording. Periodic review of both treatment advances and COA wording in parallel can play a key role in improving patient outcomes. One particular therapeutic area of interest is diabetes; in recent years, continuous glucose monitoring systems, insulin pumps, telemedicine and precision medicine have advanced diabetes management⁸. Some diabetes-specific COAs refer to treatments for the condition (*Fig 6*). This is also seen in other therapeutic areas, such as bronchiectasis.

With the advent of new treatment advances existing text may require revision as COAs benefit from continual review to ensure relevance and that the medical treatments listed are reflective of the current patient reality.

Figure 4: PHQ-9 and QLQ-C30 items

PHQ-9 item 7	7. Trouble concentrating on things, such as reading a newspaper or watching television?
QLQ-C30 item 20	2. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?

Figure 5: Average circulation per issue, UK national newspapers and regional publications⁷

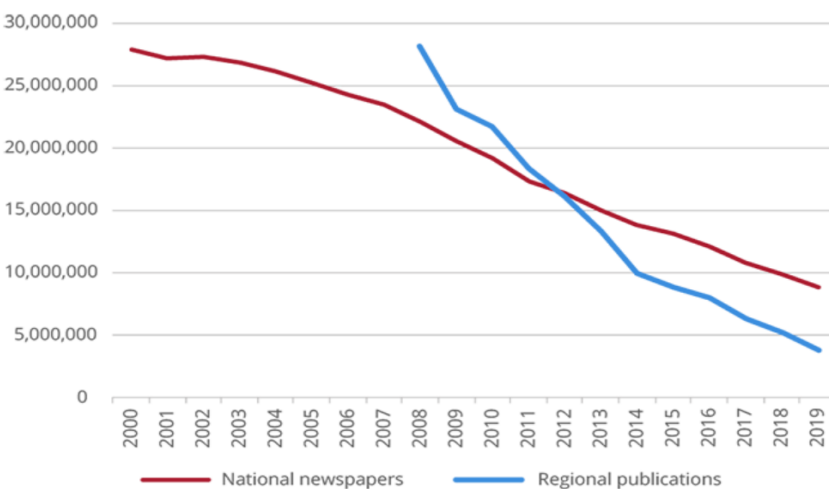


Figure 6: COA items featuring specific treatment options

COA	Medical treatments referred to	Description
QoL-Q Diabetes	“(e.g. injecting insulin [...] using an insulin pump, checking your glucose levels, taking tablets, following a healthy diet)”	In the UK, the National Health Service is in the process of rolling out artificial pancreas systems to patients with type 1 diabetes. The use of the hybrid closed-loop system will mean some people with type 1 diabetes will no longer need to inject insulin but will use technology instead ⁹ .
DTSQ	“...insulin, tablets and/or diet.”	As above.
QoL-B	“Are you currently on any treatments (such as: oral or inhaled medications; a PEP, Acapella® or Flutter® device; chest physiotherapy; or Vest) for bronchiectasis?”	The treatments listed include several devices that are not available in some European countries. A 2024 study determined that only 16% of European patients use devices for airway clearance. The same study revealed that access to specialist respiratory physiotherapy was low throughout Europe, but particularly low in Eastern Europe ¹⁰ . Additionally, not all of the existing treatments for bronchiectasis are available or used in all European countries ¹¹ .

CONCLUSION

In an ever-changing world, language, concepts, and medical treatments similarly change and evolve, and as such a COA and its translations may need to be updated to ensure they remain fit for purpose in the population being assessed. Instrument owners should monitor their libraries and have consistent versioning in place to track source and translation updates. Periodic reviews of existing wording of COAs are highly beneficial in identifying language and concepts that may require revision and updates to remain relevant to contemporary patient populations and to ensure higher quality data collection. Language Service Providers (LSPs) should have documented processes for reviewing and updating existing translations to ensure they remain linguistically, culturally, and conceptually appropriate.

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4 Article refers to the Equality Act 2010 for a definition of what constitutes disability, stating that “You’re disabled under the Equality Act 2010 if you have a physical or mental impairment that has a ‘substantial’ and ‘long-term’ negative effect on your ability to do daily activities.” UK Government (2011). “Definition of disability under the Equality Act 2010”. Gov. UK [Online]. Available at: [https://www.gov.uk/definition-of-disability-under-equality-act-2010#:~:text=you’re%20disabled%20under%20the,not%20apply%20to%20Northern%20Ireland]
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