

Background

Quality of life (QoL) is often poorly defined and most 'QoL' measures are not based on a clear theoretical model. In contrast, the needs-based QoL model (see below) used as the basis for the ASQoL has been applied successfully in the development of numerous disease-specific patient-reported outcome measures.

Patient reported outcome measures (PROMs) are becoming increasingly widely used, especially in clinical trials. Payers now require evidence of **patient benefit** in addition to the efficacy of interventions.

PROMs used in clinical studies are required to have extremely good psychometric properties including reproducibility, construct validity and responsiveness to changes in health status. It is also now widely accepted that **PROMs should also be unidimensional**.

The **needs-based QoL model** is the most operationalised in QoL assessment and research. It considers that the most important aspect of a disease or illness is the impact that impairments and functioning have on patients' ability to meet their needs. For example, a person who is restricted in their ability to walk may become deprived of a number of needs such as their sense of identity, gaining access to exercise and pleasure, participating in work, spending time with friends and family or purchasing essential food.

Hunt SM, McKenna SP. The QLDS:A scale for the measurement of quality of life in depression. *Health Policy* 1992a;22: 307-19.

The ASQoL was first published in 2003 and has been regularly used in clinical studies since that time.

Doward LC, Spoorenberg A, Cook SA, et al. The Development of the ASQoL: A quality of life instrument specific to Ankylosing Spondylitis. *Ann Rheum Dis* 2003; 62: 20-6.

Content for the ASQoL was derived from qualitative interviews conducted with AS patients. Several stages of testing followed the development of a draft version of the measure. These ensured that it was well accepted by patients and that it had good face and content validity, reproducibility and construct validity.

The ASQoL is easy to administer and score and it has been shown to provide a valuable tool for assessing the impact of interventions for AS and for evaluating models of service delivery. The ASQoL takes about four minutes to complete and has excellent scaling and psychometric properties.

Aim

This poster reports on further developments of the ASQoL.

In order to make the measure more available the ASQoL was successfully translated into eight languages. Psychometric properties were excellent for US English, Canadian English, and German and extremely promising for the other languages.

Doward LC, McKenna SP, Meads DM, et al. Translation and validation of non-English versions of the Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire. *Health Qual Life Outcomes* 2007; 2;5:7.

Authors have shown that disease-specific assessment of patient-reported outcomes in AS is more effective than using generic measures. This is because carefully developed disease-specific measures assess all relevant issues and omit others that are not specific to the disease.

Helliwell PS, Marzo-Ortega H, Tennant A: Comparison of a disease-specific and a generic instrument for measuring health-related quality of life in Ankylosing Spondylitis. *Arthritis Rheum* 2002; 46: 3098.

Others have used the ASQoL to investigate specific AS-related issues:

Freeston J, Barkham N, Hensor E, et al. Ankylosing Spondylitis, HLA-B27 positivity and the need for biologic therapies. *Joint Bone Spine*. 2007 Mar;74(2):140-3. Epub 2007 Feb 7.

Stone MA, Pomeroy E, Sengupta R, et al. Assessment of the impact of flares in Ankylosing Spondylitis disease activity using the Flare Illustration. *Rheumatology* 2008; 47: 1213-8.

Interest in the ASQoL has grown **rapidly since the need arose to evaluate the new anti-TNF biological modulators** in the treatment of AS.

Abbott was the first major pharmaceutical company to use the ASQoL when evaluating the impact of **adalimumab**. The company was able to obtain a **QoL label from the FDA** based on data collected with the ASQoL.

van der Heijde DM, Revicki DA, Gooch KL, et al. Physical function, disease activity, and health-related quality-of-life outcomes after 3 years of adalimumab treatment in patients with ankylosing spondylitis. *Arthritis Res Ther* 2009; 11(4): R124. Epub 2009 Aug 17.

Davis JC Jr, Revicki D, van der Heijde DM, et al. Health-related quality of life outcomes in patients with active ankylosing spondylitis treated with adalimumab: Results from a randomized controlled study. *Arthritis Rheum* 2007; 57(6): 1050-7.

This encouraged other companies to use the ASQoL to show the benefits of their products. For example, the measure has been used to evaluate **etanercept** in the treatment of AS.

Marzo-Ortega H, McGonagle D, O'Connor P, Emery P. Efficacy of etanercept in the treatment of the enthesal pathology in resistant spondylarthropathy: a clinical and magnetic resonance imaging study. *Arthritis Rheum* 2001; 44(9): 2112-7.

Marzo-Ortega H, McGonagle D, Haugeberg G, et al. Bone mineral density improvement in spondyloarthritis after treatment with etanercept. *Annals of the Rheumatic Diseases* 2003; 62: 1020-1.

Zhao LK, Liao ZT, Li CH, et al. Evaluation of quality of life using ASQoL questionnaire in patients with ankylosing spondylitis in a Chinese population. *Rheumatol Int* 2007; 27(7): 605-11. Epub 2006 Nov 14.

Abalos-Medina GM, Ruiz-Villaverde G, Sánchez-Cano D, et al [Functional level and quality of life in ankylosing spondylitis, pilot study after 16 weeks TNF blocker treatment]. [Article in Spanish] *Rev Esp Geriatr Gerontol* 2010; 45(6): 331-4. Epub 2010 Nov 13.

Table 1: ASQoL language versions available

Original Development	UK English	US English	Canadian English	Canadian French	Dutch
	French	German	Italian	Spanish	Swedish
Second Wave	Argentinean Spanish	Belgian Flemish	Belgian French	US Spanish	Czech
	Hungarian	Mexican Spanish	Turkish	Polish	NZ English
	Brazilian Portuguese				
Third Wave	Bulgarian	Chilean Spanish	Greek	Croatian	Danish
	Finnish	Swedish for Finland	Hebrew	Korean	Norwegian
	Peruvian Spanish	Philippine Tagalog	Russian	Slovakian	UAE Arabic
	Traditional Chinese-Taiwan	Simplified Chinese-China			

Figure 2: International coverage of the ASQoL

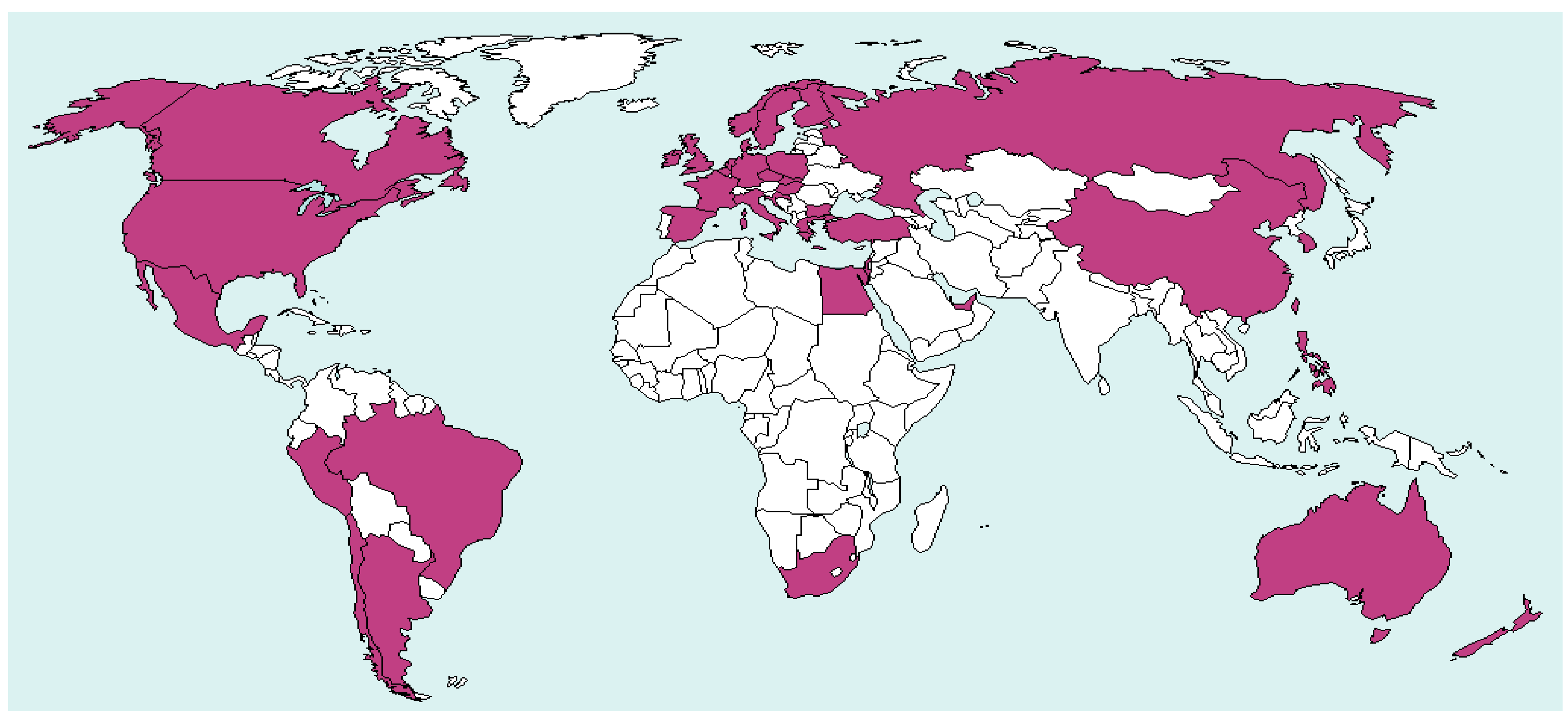


Table 2: ASQoL Test-retest reliability and internal consistency

	Test-retest reliability	Internal consistency (Cronbach's alpha)
UK-English	0.92	0.89
US-English	0.85	0.85
Canadian-English	0.86	0.86
Canadian-French	0.87	0.44
French	0.96	0.81
German	0.77	0.79
Hungarian	0.85	0.87
Italian	0.84	0.87
Dutch	0.91	0.91
Spanish	0.77	0.84
Swedish	0.85	0.81
Turkish	0.96	0.89

Figure 1: Sample page from the ASQoL

Please read each item carefully and tick the **one** response that applies best to you **at the moment**

- My condition limits the places I can go Yes
No
- I sometimes feel like crying Yes
No
- I have difficulty dressing Yes
No
- I struggle to do jobs around the house Yes
No
- It's impossible to sleep Yes
No
- I am unable to join in activities with my friends/family Yes
No
- I am tired all the time Yes
No
- I have to keep stopping what I am doing to rest Yes
No
- I have unbearable pain Yes
No

Conclusions

There are now 37 language versions of the ASQoL available for use.

The ASQoL is currently being used by five major pharmaceutical companies to evaluate new biological therapies for AS. Each of these international clinical trials involves up to 17 different language versions of the measure.

Anyone interested in further validating existing versions of the ASQoL or developing new language versions should contact the authors at the address shown below.

Contact details

Professor S P McKenna, Director of Research and CEO, Galen Research Ltd, Enterprise House, Manchester Science Park, Lloyd Street North, Manchester, M15 6SE, UK.
Tel: +44 (0)161 226 4446
Email: smckenna@galen-research.com