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IMPORTANCE OF DIFFERENTIATING HEALTH STATUS FROM QUALITY OF LIFE

Of nine exhibits in the Quality of Life with Diabetes poster event at the recent European Association for the Study of Diabetes meeting in Jerusalem,¹ five used measures of health status (EQ5D and SF-36) and two others used measures of well-being (W-BQ22). All nine referred to the measures used as quality-of-life measures. The EQ5D² and SF-36³ measure how people feel about their health (physical and mental) and the W-BQ22⁴ measures feelings of depression, anxiety, energy, and positive well-being. If people feel that their health or well-being is poor, they may feel that their quality of life is also impaired, though this is not necessarily the case. The opposite – that just because they feel that their health is excellent and they are not depressed or anxious, their quality of life is excellent – may not be true either.

Efforts to achieve excellent health may damage quality of life, particularly in the management of diabetes. Assessing the impact of treatments on quality of life is important for many reasons, not least because an adverse impact could reduce compliance with therapy. When a health-status measure is used to assess quality of life, the conclusions can be misleading.

Take the UK Prospective Diabetes Study (UKPDS),⁵ for example. It compared the impact, on complications of diabetes, of various pharmacological approaches to improving glycaemic control and blood pressure. Quality of life was one of many outcomes of interest. The investigators' interpretation of their "quality of life" data was that intensifying treatment did not affect quality of life.⁶

A series of questionnaire measures was used in the UKPDS, at a time when no diabetes-specific measures of quality of life were readily available. One questionnaire selected was the two-part "generic" questionnaire, the EQ5D.² The first part of the EQ5D has five questions about mobility, self-care, usual activities, pain, and anxiety. In the second part, patients are asked to give an overall indication of their health state. The EQ5D is one of the bluntest health-status instruments available. It is concerned more with how good or bad participants feel their health to be rather than how good or bad they perceive their life to be.

The EQ5D might reasonably be expected to detect differences between people with or without the major chronic complications of diabetes, but not between people who are following different treatment regimens for diabetes. This pattern was pretty much that of the UKPDS findings, although the EQ5D could detect only significant differences between people with and without macrovascular complications. The lack of difference in EQ5D scores between people with and without microvascular complications indicates the bluntness of the instrument.

The other questionnaires used in the UKPDS were described as “specific”, in that they measured more specific psychological outcomes than did the EQ5D, not that the instruments were “diabetes-specific”. These more specific tools included measures of symptom frequency, cognitive-failure frequency, work satisfaction, and the Profile of Mood States (POMS), which measures six mood states: tension, depression, anger, vigour, fatigue, and confusion. Whether people with intensively-treated diabetes are expected to have more or fewer symptoms than people with less-intensively-treated diabetes will depend on which symptoms are measured. People with less-intensively-treated diabetes might be expected to have more symptoms commonly associated with hyperglycaemia, but perhaps fewer symptoms associated with mild hypoglycaemia, than would people with more-intensively-treated diabetes. 19 of the 40 symptoms included in the symptom measure used in the UKPDS⁷ occurred in excess in treated diabetes; some were associated with hyperglycaemia and some with hypoglycaemia. This measure will not find differences between the treatment groups in the nature and impact of symptoms experienced; it can indicate only the frequency of symptoms, which was similar in both UKPDS groups. The UKPDS researchers also reported data for a small group of controls, people without diabetes, who had significantly fewer symptoms than the patients with diabetes, irrespective of how the latter were treated. The only other significant difference reported between the control and the diabetes groups was that vigour was greater in the controls. Thus, the findings show that, although the questionnaires used could not detect any differences between treatment groups (more intensive *vs* less intensive), both groups were more adversely affected than controls. Furthermore, longitudinal data showed no differences within the groups across time, even though an improvement in health status between diagnosis and follow-up might be expected. This finding was interpreted to mean that there was no reduction in quality of life during treatment. If the instruments used are viewed as measures of health status and symptoms

rather than of quality of life, it becomes rather more surprising that improvements were not found across time.

The UKPDS researchers concluded over-optimistically that “This study showed that there were no detectable differences in quality of life between patients allocated to different therapies. This was confirmed in both the cross-sectional studies and the longitudinal study. Thus the policies were neutral in effect”.⁶ In fact, even with these generic blunt instruments, both diabetes groups had more symptoms than controls, and improvements in health status that might reasonably be expected after diagnosis were not found. Probably both treatment policies were negative in effect and the particular generic measures used were not able to detect differences between treatments.

Treatment group differences might, however, be detected using more sensitive diabetes-specific tools. The first-generation diabetes-specific quality-of-life measure, the DQOL, used in the Diabetes Control and Complications Trial (DCCT), was designed to have four subscales to measure satisfaction, impact, diabetes worry, and social/vocational worry, which are commonly combined to provide a total score.⁸ The satisfaction and impact subscales were sensitive to increasing number or severity of complications and have shown significant differences between type 2 patients treated with insulin, oral agents, or diet alone. Worry subscales and the total score were less sensitive.⁸ Notoriously, the DQOL total scores did not show differences between more-intensively-treated and less-intensively-treated type 1 patients in the DCCT.^{9,10} The lack of difference probably had more to do with injudicious totalling of the many varied items, which were all given equal weight (irrespective of relevance or importance to individual respondents) than to any real lack of impact of intensified treatment on quality of life.¹¹ The DQOL was not available at the start of the UKPDS but would have been unlikely to fare any better in detecting differences between therapies than it did in the DCCT.

Second-generation measures of the impact of chronic disorders on quality of life¹² have been influenced by the work of Hannah McGee and Dick Joyce and their colleagues, who developed the patient-centred SEIQoL interview method of measuring individualised quality of life.^{13,14} The SEIQoL method elicits from each respondent life domains of importance for that individual’s quality of life. These domains are then rated by the respondent for current quality and weighted by the individual’s judgement of their importance in influencing his or

her overall quality of life. Weighted domain ratings are added up to provide a single quality-of-life score.

The generic SEIQoL method has been adapted to questionnaire format and modified to be condition-specific in the assessment of the impact of a chronic disorder on quality of life. The first of these condition-specific questionnaires, the ADDQoL (Audit of Diabetes Dependent Quality of Life) has since been modified for patients with other chronic disorders.¹² In two separate studies,^{15,16} ADDQoL scores have shown greater negative impact of diabetes on the quality of life of insulin-treated patients than on people treated by oral agents and/or diet, as well as greater negative impact of diabetes on quality of life when people have complications. Thus, unlike the EQ5D, a diabetes-specific individualised quality-of-life measure can reveal striking negative effects of intensive treatment of diabetes and of the presence of complications. What the EQ5D revealed in the UKPDS was that respondents' perceptions of their health were only slightly impaired by complications of diabetes and not at all affected by intensified treatment.⁶ EQ5D could tell nothing about the effect of complications or treatment intensification on quality of life. Greater precision is needed in the use of the term "quality of life" if clinicians are not to be misled into thinking that findings based on a health-status instrument indicate that treatments do not damage quality of life when all the data reveal is that treatments do not damage perceived health.

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