Omissions impact measurements of patient-reported outcomes (Letter to the editor)

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Letter to the Editor

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Re: Valderas, J.M., Kotzeva, A., Espallargues, M., Guyatt, G., Ferrans, C.E., Halyard, M.Y., Revicki, D.A., Symonds, T., Parada, A., Alonso, J. (2008). The impact of measuring patient-reported outcomes in clinical practice: a systematic review of the literature. *Quality of Life Research*, 17(1), 179-193.

Dear Editor,

With interest I have read the recent study by Valderas et al. [1]. In their important study, the authors provide a comprehensive compilation of the evidence on the impact of measuring patient-reported outcomes (PRO). However, in this letter, I aim to show to the authors of the systematic review and the readers of *Quality of Life Research* that there are several significant omissions in the study by Valderas et al. [1].

In brief, the two most important inclusion criteria used by Valderas et al. [1] were that studies should have a randomised controlled design and investigate a replicable intervention consisting of administration of a standardized patient-reported outcome with subsequent feedback to health-care professionals versus routine care, without disclosure of PRO.

I am aware of several studies that meet all inclusion criteria that were not included in the systematic review of Valderas et al. [1]. For example, between 1997 and 1999 our diabetes psychology research group conducted a randomised controlled trial to test whether assessment of psychological well-being in an outpatient diabetes care setting had beneficial effects on: (1) psychological well-being; (2) the patient's evaluation of the quality of diabetes care; and (3) glycemic control [2]. Our intervention comprised the measurement and discussion of psychological well-being, a patient reported outcome. Patients randomised to the control group received diabetes care as usual; their PRO was not included in the feedback to the members of the diabetes care team. For the measurement of the PRO, we used a computerised version of the Well-Being Questionnaire (W-BQ12) and the Patient's Evaluation of the Quality of Diabetes Care (PEQ-D) inventory [3–6]. In our study, clinical research staff (diabetes nurses) were responsible for the measurement and discussion of the patient reported outcome. This is in contrast with most of the studies included in the systematic review [1], where the intervention was organised and delivered by research staff.

Furthermore, Maguire et al. [7] have conducted a randomised controlled trial to determine whether counselling by a nurse specialist prevented psychiatric morbidity in a group of breast cancer patients with mastectomy. Seventy-seven patients received standard care and 75 patients were counselled by a nurse, who monitored the psychological well-being of these patients using the Present State Examination (PSE, standardised interview). In this study, the monitoring plus counselling intervention had no effect on mortality, but markedly improved the recognition of those patients who were in need of psychiatric help. At 12–18-month follow-up, there was much less psychiatric morbidity in the counselled group (12%) compared to the control group (39%) [7].

In another randomised controlled trial, the psychological well-being of 461 male patients with a recent myocardial infarction was measured during 1 year on a monthly basis using the General Health Questionnaire [8]. Patients of the McGill University Teaching Hospital were

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interviewed prior to discharge using a semi-structured interview. Those with high distress scores received a variety of supportive and educational nursing interventions aimed at stress reduction. Patients in the control group received standard care. The monitoring group showed greater decline in distress scores than controls and the results of this study also indicated that there were fewer deaths in the intervention group [8]. Results of the 7-year follow-up study [9] suggest that the monitoring intervention group had fewer myocardial infarction recurrences during the years after the programme than the control group. However, the differences in cardiac deaths only existed for 6 months beyond the end of the programme, after which the mortality curves of both groups began to approach each other [9].

Another randomised controlled trial that was not included in the review of Valderas et al. evaluated the effects of a nurse-case managed, multifactorial risk reduction programme on psychological distress in 585 male and female patients with a recent myocardial infarction [10]. In that study, patients were randomised to care as usual or to a programme that included a brief screen for psychological distress with further evaluation if indicated. As expected, psychological distress was significantly lower at follow-up in both groups compared to baseline, but both treatment groups did not differ significantly regarding psychological variables at follow-up [10].

In sum, I believe that the results of several important randomised controlled trials that meet all five inclusion criteria used by Valderas et al. were not included in their recent review. I trust that, if the authors agree with me, they will improve their search method for finding eligible studies and include the studies I have added in the next update of their systematic review.

References

1. Valderas, J. M., Kotzeva, A., Espallargues, M., Guyatt, G., Ferrans, C. E., Halyard, M. Y., Revicki, D. A., Symonds, T., Parada, A., & Alonso, J. (2008). The impact of measuring patient-reported outcomes in clinical practice: a systematic review of the literature. *Quality of Life Research, 17*(1), 179–193.
2. Pouwer, F., Snoek, F. J., Van der Ploeg, H. M., Ader, H. J., & Heine, R. J. (2001). Monitoring of psychological well-being in outpatients with diabetes: effect on mood, HbA1c, and the patient's evaluation of the quality of diabetes care: a randomized controlled trial. *Diabetes Care, 24*, 1929–1935.
3. Pouwer, F., Snoek, F. J., Van der Ploeg, H. M., Heine, R. J., & Brand, A. N. (1998). A comparison of the standard and the computerized versions of the Well-being Questionnaire (WBQ) and the Diabetes Treatment Satisfaction Questionnaire (DTSQ). *Quality of Life Research*, 7, 33–38.
4. Pouwer, F., Snoek, F. J., Van der Ploeg, H. M., Ader, H. J., & Heine, R. J. (2000). The well-being questionnaire: evidence for a three-factor structure with 12 items (W-BQ12). *Psychological Medicine, 30*, 455–462.
5. Pouwer, F., Van der Ploeg, H. M., Ader, H. J., Heine, R. J., & Snoek, F. J. (1999). The 12-item well-being questionnaire. An evaluation of its validity and reliability in Dutch people with diabetes. *Diabetes Care, 22*, 2004–2010.
6. Pouwer, F., & Snoek, F. J. (2002). Patients' Evaluation of the Quality of Diabetes Care (PEQD): development and validation of a new instrument. *Quality and Safety in Health Care, 11*, 131–1366.
7. Maguire, P., Tait, A., Brooke, M., Thomas, C., & Sellwood, R. (1980). Effect of counselling on the psychiatric morbidity associated with mastectomy. *British Medical Journal*, *281*, 1454–1456.
8. Frasure-Smith, N., & Prince, R. (1985). The Ischemic Heart Disease Life Stress Monitoring Progam: impact on mortality. *Psychosomatic Medicine, 47*(5), 431–445.
9. Frasure-Smith, N., & Prince, R. (1989). Longterm follow-up of the Ischemic Heart Disease Life Stress Monitoring Program. *Psychosomatic Medicine, 51*(5), 485–513.
10. Taylor, C. B., Miller, N. H., Smith, P. M., & DeBusk, R. F. (1997). The effect of a home-based, case-managed, multifactorial risk reduction program on reducing psychological distress in patients with cardiovascular disease. *Journal of Cardiopulmonary Rehabilitation 17*(3), 157–162.