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Diabetes is my main area of research. Increasingly, we are seeing measures of psychological outcomes used alongside measures of biomedical outcomes in clinical practice to determine appropriate treatments in diabetes and in evaluating health care. That is a very important step forward towards better management of the condition.

A focus exclusively on biomedical outcomes, and lack of information about the psychological effects of diabetes and its treatment, can be a major obstacle to good decision making by doctors specialising in diabetes care. If, instead of just measuring blood glucose and lipid levels, the physicians obtain information about patient satisfaction, psychological well-being and quality of life, they are in a much better position to work to protect and improve quality of life as well as blood glucose levels. We find that in diabetes, if attention is paid only to blood glucose levels and not to the person's quality of life, efforts to try and improve the blood glucose control are usually doomed to failure. Control of diabetes is not likely to be sustainable in the long term if the person's quality of life is being damaged by these efforts.

It is important for patients and health care professional to make decisions together because they both have expertise to bring to the process. The patients know about themselves, their lifestyles and what they find acceptable or unacceptable, and the physician knows about the treatment options and possible side effects. They need to share that information but this doesn't always happen. One way of helping communication is to include psychological measures alongside the biomedical measures.

Where the development of psychological measures is concerned, diabetes has been very much in the forefront of the field. Measures of quality of life, satisfaction, well-being and health beliefs are included in the *Handbook of Psychology and Diabetes*, which I edited for publication in 1994.¹ More recent measures include the ADDQoL (Audit of Diabetes-Dependent Quality of Life) individualised diabetes-specific measures.² Rather than just imposing a definition of quality of life and deciding for patients what is important to them, the ADDQoL lets the individual decide which domains of life are relevant for his or her quality of life. Patients indicate their relative importance, which is then reflected in the scoring of their responses. Psychological measures provide doctors with important information not otherwise readily available to them.

Clinical trials also provide information of importance to patients and their doctors. But the value of clinical trial data depends on the methods used in the trial, including what patients are told about the treatment in the trial, treatments available outside the trial and the kinds of patients recruited. Trial results can be highly misleading unless these factors are taken into account.

With a conventional randomised control trial, we can find problems when we recruit a subset of patients who are particularly keen to use the new treatment. Often, which patients are actually included in a trial is not given any consideration in interpreting the results of that trial. There may be attempts to include a generalised sample but usually they fail. In the early 1980s, CSII pumps for insulin delivery in diabetes were available only within trials. Trials of CSII pumps tended therefore to attract people who wanted the pump. People who expressly wanted to stay with injections did not take part in randomised clinical trials and those who had a preference for CSII pumps predominated among those recruited. Then, when patients were randomly allocated to the new treatment (CSII pump) or the old (injections), differences were created in the sample. One group was pleased with what it was allocated and another group was disappointed, with reverberating effects throughout the trial. More patients, for example, dropped out if they were disappointed and more patients found the side effects intolerable if they were disappointed.

There are various ways of dealing with the problems of randomised control trials, which have been discussed elsewhere.³ An essential step is to consider patients' preferences when thinking about evaluating a new treatment. Even better, we might go back a step and consider patients' preferences before developing a new treatment. Certainly, patient preferences need to be taken into account and reported in publications of clinical trial outcomes. The outcomes measured in clinical trials need to include not only the biomedical outcomes but also psychological outcomes, including quality of life.⁴

¹*Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in Diabetes Research and Practice*. Clare Bradley, ed., (Switzerland: Harwood Academic Publishers, 1994).

²C. Bradley, 'Measuring Quality of Life in Diabetes', in E.M. Marshall, P.D. Home and R.A. Rizza, eds., *Diabetes Annual 10* (Amsterdam: Elsevier Science, 1996).

³C.R. Brewin and C. Bradley, 'Patient Preferences and Randomised Clinical Trials', *British Medical Journal* 229: 313-315.

⁴C. Bradley, 'Psychological Issues in Clinical Trial Design', *Irish Journal of Psychology*, 1997.