## DAFNE: improved quality of life with intensified treatment is counter-intuitive to many clinicians

6 November 2002

Many of the early rapid responses to the DAFNE trial paper (1) [see bmj.com] claimed that improved quality of life (QoL) resulting from flexible intensified insulin treatment was well established prior to the DAFNE trial (Ullman, 5th Oct; Black, 6th Oct; Chaufan, 12th Oct). However, the only evidence cited was anecdotal.

Early German studies did not measure QoL, patient satisfaction or well-being and the authors gave only passing mention to possible lifestyle benefits in the small print of the methods section: "they should gain a certain 'liberalisation' of lifestyle with respect to exercise and eating schedules" (2, p471). In contrast, Kinga Howorka who, in Vienna, developed Functional Insulin Treatment (3) (similar to the Düsseldorf-derived DAFNE approach) not only acknowledged that this approach enables dietary freedom but also that this "represents the most important factor in the long-term motivation of patients" (4, p23). Unfortunately, both in Düsseldorf and in Vienna, psychological outcomes were measured only after many patients had already adopted the approach and it was routine practice in the clinics concerned. Thus, it was not possible to measure the QoL benefits in those settings. Further, the names used for the two treatment approaches ("structured teaching and treatment programme" and "functional insulin treatment") did not imply any lifestyle benefits. "Dose Adjustment For Normal Eating" indicates short-term benefits to be gained from intensifying treatment and the motto "like what you eat, eat what you like" makes explicit the potential for DAFNE training to improve dietary freedom.

DAFNE clinicians were far-sighted in their desire to evaluate a flexible, intensive approach to insulin treatment in the UK, and in choosing the DAFNE name and motto, but even they were concerned that increased injections and blood glucose monitoring might be too big a price to pay for increased dietary freedom. Many observers of the DAFNE trial have also taken this view. However, our work in developing the ADDQoL (a measure of the impact of diabetes on quality of life) had shown that dietary freedom is the aspect of life which, of all the 18 aspects of life included in the questionnaire, is most negatively impacted by diabetes and its treatment (5,6). Such evidence made us confident that the increased dietary freedom afforded by DAFNE would have major benefits for QoL, despite the need for more injections and blood glucose monitoring. After observing a Düsseldorf training course, DAFNE clinicians were more prepared to accept that DAFNE would not further damage QoL but few expected QoL benefits. In addition, despite Diabetes UK's interest and support, such was their doubt about the acceptability of this approach to UK patients that only the recruitment phase of the DAFNE trial was funded initially. Funding of the main trial was approved only after we had demonstrated that sufficient numbers of participants could be recruited.

Now that DAFNE has been shown to provide significant QoL benefits for adults with type 1 diabetes, it is likely that many more people will be interested in adopting this form of intensive diabetes management. However, these benefits had not been demonstrated empirically prior to the DAFNE trial and were counter-intuitive to many clinicians specialising in diabetes care.

- 1. DAFNE Study Group. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial. British Medical Journal 2002;325:746-749.
- 2. Mühlhauser I, Jörgens V, Berger M, Graninger W, Gurtler W, Hornke L, et al. Bicentric evaluation of a teaching and treatment programme for type 1 (insulindependent) diabetic patients: improvement of metabolic control and other measures of diabetes care for up to 22 months. Diabetologia 1983; 25: 476.
- 3. Howorka K. Functional insulin treatment. 3rd English ed. Berlin: Springer, 2003 in press.
- 4. Howorka K. Functional Insulin Treatment. 2nd English ed. Berlin, Heidelberg, New York: Springer-Verlag, 1996.
- 5. Bradley C, Todd C, Gorton T, Symonds E, Martin A, Plowright R. The development of an individualised questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. Quality of Life Research 1999;8:79-91.
- 6. Bradley C, Speight J. Patient perceptions of diabetes and diabetes therapy: assessing quality of life. Diabetes/Metabolism Research and Reviews 2002;18:S64-S69.