

## **DAFNE: authors' response to electronic letters from 5th October to 22nd October 2002**

29 October 2002

The rapid responses received following the publication of the DAFNE trial reflect the controversy surrounding the current inadequate management of Type 1 diabetes. [1] While it is true that the approach is not novel (Ullman, 5th Oct; Black, 6th Oct; Reed 9th Oct; Chaufan, 12th Oct, Cohen, 22nd Oct), it is new to the UK. The biomedical benefits of this intensified approach had been known for some time in parts of Europe [2,3] but it was unclear whether these could be transferred to a British healthcare setting. Furthermore, the impact on quality of life was unknown, as psychological outcomes were not measured in the early German work.

Several rapid response letters, mostly from pump users or their families - have suggested that this research was redundant or wasteful because of the clear superiority of continuous subcutaneous insulin infusion (CSII) therapy or because carbohydrate counting is already practised to enable a free choice of food (Ullman, 5th Oct; Black, 6th Oct; Reed, 9th Oct; King, 11th Oct). We appreciate the benefits of CSII but, although welcome, they are only used by a minority of people with diabetes. Expense is certainly an issue for some (Rosu, 6th Oct) but many simply dislike the idea of wearing a pump. [4] Consequently, there are few data on the effects of providing all comers with the type of education package routinely offered to would-be pump users without the pump itself. DAFNE was not designed as a replacement for the pump but as an option for people with type 1 diabetes, whatever their method of insulin delivery, enabling them to be free to eat what they like when they like while maintaining optimal blood glucose control.

Among people who have not been trained in DAFNE or related approaches, many use carbohydrate counting to restrict their diet to match prescribed insulin doses with few using it to make major changes in insulin doses to accommodate real dietary freedom. Some individuals have, over time, discovered for themselves how to achieve dietary freedom with carbohydrate counting and insulin adjustment but there is no published evidence that this improves both biomedical and psychological outcomes. Furthermore, we are unaware of evidence that this is undertaken widely. DAFNE is an approach to managing type 1 diabetes that teaches explicitly the skills necessary for insulin adjustment and true dietary freedom.

We would challenge the view that DAFNE encourages people to abandon healthy eating (Hunter, 11th October). DAFNE divorces the decisions about healthy eating from decisions about balancing carbohydrate and insulin. It enables people with Type1 diabetes to have the same choices as those without diabetes, i.e. to choose to eat regularly or to be flexible, and to choose to eat healthily or not.

We agree that improvements in satisfaction with treatment, well-being and quality of life need to be understood in the light of information about the treatment previously recommended to these patients (Ehrlich, 4th Oct). Prior to DAFNE, patients injected on average 3.5 (sd=1.0) times per day (indicating that most followed a basal bolus regimen) rising to 5.3 (sd=0.7) per day after training. We also agree that the separation of basal insulin replacement from meal-related insulin probably contributes to DAFNE's success in controlling blood glucose levels

(Lawrence & Robinson (9th Oct) and Hunter (11th Oct). However, it cannot completely explain the specific improvements in dietary freedom or account for the widespread and highly significant improvements in overall treatment satisfaction and well-being. It is the demonstration of improvements in psychological as well as biomedical outcomes (without the patient having to compromise one in favour of the other) and the potential for this to become mainstream treatment that makes the DAFNE approach novel.

The DAFNE trial was financed by research grants from Diabetes UK and as Jenkins and Nagi (16th Oct) suggest the initial costs of training healthcare professionals to deliver courses may be beyond the current budget of most diabetes centres. However, an economic analysis based upon data from the DAFNE trial and other studies using the Düsseldorf approach (Bagust, personal communication) suggests major cost savings per participant (in terms of anticipated reduction in complications of diabetes associated with improved blood glucose control) in the longer term. We believe that re-designing services around a DAFNE programme would eventually be cost saving although these services probably need to include on-going support for the patients to maintain biomedical and psychological benefits (Hunter 11th Oct; Jenkins & Nagi, 16th Oct; Chantelau 23rd Oct). Much current diabetes care is neither effective nor evidence based, so there may be opportunities to redirect resources.

We appreciate the need to roll out the DAFNE approach and acknowledge concerns about provision of an exclusive service in a few centres in the short term (Hunter, 11th Oct; Jenkins & Nagi, 16th Oct). The Department of Health has already provided funding for a further seven UK centres to be trained to provide and evaluate DAFNE. A temporary quality gap could arise, but we believe that a gradual, quality assured roll-out, which is carefully monitored, will result in a better service for all in the longer term. It is a sad fact that many people struggle with diabetes without having the skills with which to treat it successfully (Hanscombe, 16th Oct; King 19th Oct) and we believe that a DAFNE or similar approach should be available to all adults with Type 1 diabetes. Marked benefits might also be expected in children (Hanscombe 16th Oct) and adolescents though this remains to be investigated. For now, it seems evident that the DAFNE approach offers a step forward in improving the quality of health and quality of life for people with diabetes in the UK.

[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 (insulin-dependent) diabetic patients: improvement of metabolic control and other measures of diabetes care for up to 22 months. *Diabetologia* 1983; 25: 476.

[3] Mühlhauser I, Bruckner I, Berger M, Cheta D, Jörgens V, Scholz V, et al. Evaluation of an intensified insulin treatment and teaching programme as routine management of type 1 (insulin-dependent) diabetes: the Bucharest-Düsseldorf study. *Diabetologia* 1987; 30: 681-690.

[4] Bradley C, Gamsu DS, Moses JL, Knight G, Boulton AJM, Drury J, et al. The use of diabetes-specific perceived control and health belief measures to predict treatment

choice and efficacy in a feasibility study of continuous subcutaneous insulin infusion pumps. *Psychology and Health* 1987; 1: 133-146.