Barriers to following dietary recommendations in Type 2 diabetes

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Abstract

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Aims To evaluate barriers to following dietary recommendations in patients with Type 2 diabetes.

Methods We conducted focus groups and surveys in urban and suburban VA and academic medical centres. For the written survey, a self-administered questionnaire was mailed to a random sample of 446 patients with diabetes. For the focus groups, six groups of patients with diabetes (three urban, three suburban) were conducted, with 6–12 participants in each group. The focus groups explored barriers across various types of diabetes self-management; we extracted all comments relevant to barriers that limited patients' ability to follow a recommended diet.

Results The written survey measured the burden of diabetes therapies (on a seven-point rating scale). Moderate diet was seen as a greater burden than oral agents (median 1 vs. 0, P = 0.001), but less of a burden than insulin (median 1 vs. 4, P < 0.001). A strict diet aimed at weight loss was rated as being similarly burdensome to insulin (median 4 vs. 4, P = NS). Despite this, self-reported adherence was much higher for both pills and insulin than it was for a moderate diet. In the focus groups, the most commonly identified barrier was the cost (14/ 14 reviews), followed by small portion sizes (13/14 reviews), support and family issues (13/14 reviews), and quality of life and lifestyle issues (12/14 reviews). Patients in the urban site, who were predominantly African-American, noted greater difficulties communicating with their provider about diet and social circumstances, and also that the rigid schedule of a diabetes diet was problematic.

Conclusions Barriers to adherence to dietary therapies are numerous, but some, such as cost, and in the urban setting, communication with providers, are potentially remediable. Interventions aimed at improving patients' ability to modify their diet need to specifically address these areas. Furthermore, treatment guidelines need to consider patients' preferences and barriers when setting goals for treatment.

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Keywords diabetes, dietary adherence, barriers, patient preferences, guidelines

Introduction

Type 2 diabetes mellitus (T2DM) is a growing public health and policy concern. Management of diabetes and its complica-

tions are responsible for a disproportionate amount of healthcare costs in the USA, and the prevalence of diabetes is on the rise due to the ageing and increasing average weight of the US population [1–3]. As a result, diabetes has been a major target area for disease management programmes, ranging from the development and dissemination of treatment guidelines to algorithm-based case management [4–8].

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Although medical management is extremely important, self-management is also a major factor in caring for Type 2 diabetes [9]. Many diabetes treatments have met with limited success in general practice and often require patient willingness to collaborate with difficult lifestyle changes. However, despite the crucial importance of adherence to prescribed therapy as part of self-management, there is surprisingly little information on patients' views of and preferences for different therapies.

Dietary modification is a good example. Dietary recommendations often require patients to alter behaviours that have been present for a lifetime, and are based upon strong and entrenched preferences. Regardless, diet is considered a cornerstone for management of Type 2 diabetes and is usually proposed as first-line therapy [10], though it is temporary in most patients [11,12]. This is unfortunate, as the potential benefits of diet are great: weight loss through proper diet and exercise results in improved glycaemic control and possibly reductions in cardiovascular risk and overall mortality [13-16]. Although long-term studies of patients with diabetes have failed to demonstrate sustained weight loss or glycaemic improvements with dietary changes alone [12], few studies have examined the reasons for this failure or how patients view dietary restrictions. We undertook a study designed to evaluate, both quantitatively and qualitatively, barriers to patients' ability to follow self-management recommendations in Type 2 diabetes; this study focuses on barriers to following a prescribed diet.

Methods

Patients were recruited occurred from the primary care population of a large academic medical centre and two VA hospitals. Patients at these facilities were identified as having diabetes using a previously validated algorithm that used either medical systems diagnosis information (for the academic medical centre) or both diagnosis and pharmacy database information [17–19]. They were classified by searching for either a diagnosis of diabetes or prescriptions for oral hypoglycaemic agents, insulin, or glucose monitoring supplies.

The study was conducted in two phases and was approved by the Institutional Review Board (IRB) at each study site. A quantitative survey phase was conducted to determine comparative views of diabetes treatments, and a qualitative phase was conducted to explore patients' views of treatments. For the quantitative phase, a mailed, self-administered 50-question survey was sent to a random sample determined to be eligible through the algorithm above. The survey was conducted anonymously, and informed consent was thus waived by the IRB at both study sites. Patients were excluded from the analysis if they were diagnosed prior to the age of 30 (to minimize the participation of those with Type 1 diabetes). The survey was designed to obtain overall ratings of patient attitudes towards various hypoglycaemic treatments, including different intensities of diet, along with ratings of interventions on specific subscales (pain and interference with usual daily activities). In addition, demographic information, experience with treatments, physician recommendations

for treatments, and self-reported adherence to treatment (using a seven-point scale with 1 = always followed, 4 = followed about half the time, and 7 = never followed) were collected. The validity of the measures was tested through examining whether within-subject comparisons followed logical orders; e.g. was twice-daily insulin consistently viewed as more burdensome than once-daily insulin. We found that in 97% of subjects, the ordering was consistent, and the overall ratings followed a similarly consistent ordering. There are no clear external measures that would serve to test the validity of the questions; indeed, in the case of a straightforward rating of burden measured directly from the patients, comparison with other measures is probably of limited utility. We tested for the internal consistency reliability of overall ratings of burden with the ratings for pain and interference with usual activity. Cronbach's α across these scales ranged from 0.74 for urine testing to 0.88 for insulin twice a day.

Demographic and clinical information was collected via previously validated measures from the Type 2 diabetes Patient Outcomes Research Team [19]. This included data on diabetes treatments and duration, level of complications, provider type and frequency of visits, income, ethnicity, and education.

Because of non-normal distributions of ratings of treatments, simple comparisons between ratings for various hypoglycaemic interventions were analysed using the non-parametric Wilcoxon sign-rank test for paired comparisons. Categorical variables were compared using contingency tables and χ^2 tests of independence. Because of non-normality and heteroscedasticity of residuals, we conducted multivariate analyses using linear regression with robust Huber/White sandwich estimators of variance [20,21]. Results of all analyses were considered statistically significant at a *P*-value of < 0.05.

In the qualitative phase of the study, patients with diabetes were recruited to one of several focus groups. Recruitment was done via flyers posted in the waiting rooms at clinic sites. All focus group participants provided signed informed consent. The primary goals of the focus groups were to have patients express their views towards various aspects of diabetes care and to provide insight into barriers to their ability to follow recommended interventions. This phase was designed to complement the survey and provide a deeper understanding of some of the findings from the quantitative phase. A series of prescripted questions were used to guide the groups and to open the discussion (Table 1). The focus groups were led by a facilitator who had familiarity both with diabetes care and with moderating focus groups. In total, six focus groups were conducted, with 6-12 participants in each. This number of participants is generally big enough to generate a broad range of ideas but small enough to allow active participation from all members [22]. The participants for the first three focus groups were recruited from a suburban setting (Ann Arbor, Michigan); most participants were white. The remaining three focus groups were conducted in an urban setting (Detroit, Michigan); most were African-American. The average duration of each focus group was 2 h; patients were provided with a £14 (\$25) incentive payment to participate.

Each focus group was audiotaped and professionally transcribed. The transcripts were reviewed by a panel of investigators and statements were coded based upon their content (e.g. related to diet, insulin therapy, or oral agents) using Q.S.R.

Table 1 Sample focus group questions

- 1 Please briefly introduce yourself and tell us a little bit about your diabetes, that is, how long have you had diabetes and how is it treated?
- 2 Patients do not always do everything their doctors recommend. Are there things that your doctor has recommended for you but you don't do? Why? 3 What do you do that your doctor has recommended? Why do you do it?
- 4 What are the main problems you have with the treatment you are currently taking, for example, if you are currently taking insulin injections, what are the main problems you have with taking insulin?
- 5 Are there any particular issues involved in taking your treatment that causesyou difficulty or really irritate you?
- 6 Are there any specific events or times when taking your treatment is most bothersome, for example, during holidays or during vacations or trips? 7 Do you feel as if you had a choice about the treatment you are taking for your diabetes?
- 8 If you did have a choice, what factors influenced your decision to take the diabetes treatment you are currently using?
- 9 In what ways does your family help you administer your treatment for diabetes?
- 10 In what ways do they not support you or obstruct your efforts to control your blood sugar?

NUD*ISTTM qualitative analysis software (N5 qualitative data analysis program; Melbourne, Australia; QSR International Pty Ltd. Version 5.0, 2000). The portions of the transcripts that were related to diet were compiled, and the statements reviewed by seven experts in diabetes care; these experts spanned a range of disciplines, including medicine, public health, anthropology, nursing, and education. The experts were asked to identify content areas that reflected major barriers or concerns that patients had regarding their ability to comply with a diabetes diet. These content areas were then independently reviewed by three of the authors (N.S.S., J.T.F., S.S.). These authors then met, and differences and overlap in categories were resolved through consensus; there were no disputed areas after discussion. This process led to identification of 12 major barriers to following recommendations for diet. The content areas indicated by the diabetes experts were tabulated, and statements that typified each area were identified in the transcripts. The analyses of these results were conducted as a whole and stratified by site.

Results

The written survey was mailed to a total of 446 patients, of whom 365 were eligible (of the 81 ineligible subjects, 23 did not have diabetes; 32 were under the age of 30 at diagnosis; 17 addresses were incorrect; and nine were deceased). A total of 197 completed surveys were returned, for a response rate of 54%. The demographics of the population that completed the written survey are presented in Table 2. Analyses of administrative data showed that non-respondents were similar in age, gender and insurance status to respondents.

Ratings of the burden of diet, oral agents, and insulin were collected by asking patients to rate, on a seven-point scale (from 0 = do not dislike at all to 6 = dislike very much) their dislike of treatments. Subjects rated even a moderate diet (a diet with sugar and fat reduction, but minimal calorie reduction) as more burdensome than pills (median burden for diet = 1; IQ range 0–3; median burden for pills = 0, IQ range = 0–1, P = 0.001), but substantially less burdensome than twice-daily insulin injections (median burden for insulin = 4, IQ range = 2–6, P < 0.001). However, a strict diet (a diet with sugar, fat, and calorie reduction aimed at weight loss) was rated as similar to twice-daily insulin injections (median burden = 4, IQ range = 2–6, P = 0.351). The results for ratings of physical

Table 2 Characteristics of survey participants (n = 197)

Age, years (mean \pm SD)	62.1 ± 11.2
Male/female, %	67/33
Median education	13 years (1 year of college)
Median income	£11 300–16 900 (\$20 000–\$29 999)
Race	
White, %	87.6
Black, %	6.5
Other, %	5.9
Current diabetes therapy	
Home glucose monitoring, %	72.6
Moderate diet, %	80.9
(avoidance of sugar and fat)	
Strict diet, %	34.0
(aimed at weight loss)	
Oral agents, %	55.6
Insulin, %	32.5
Average diabetes duration, years	10.5 ± 8.6

pain and interference with usual activities followed similar patterns. Subjects found any treatments that required strict timing of meals burdensome, with a median rating of 4, IQ range 1–6.

We compared the ratings of the burdens of dietary therapy across various demographic groups using robust linear regression. In multivariate analyses, the burden of moderate diet was significantly related to age, with older patients viewing diet as less burdensome than younger patients (for every 10 years older, burden was less by 0.5 on the seven-point scale; P = 0.008). Additionally, the burden of diet was viewed as higher in subjects who had frequent visits to a dietitian (for each visit, burden increased by 0.07 on the seven-point scale; P = 0.029). Caucasian and African-American respondents had similar ratings of dietary restriction; other races were not examined due to small sample sizes. Other variables, including demographics (gender, income and education), along with specific characteristics (duration of diabetes, household support, attendance at diabetes education classes) were not significantly associated with ratings of the burden of a moderate diet.

Patients were also asked to rate, on a seven-point scale, how closely they followed recommendations for prescribed

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therapies. Despite rating diet as less burdensome than insulin, patients were much less likely to report following a diet than taking insulin as prescribed; patients reported following their diet somewhat more than half the time, but always or almost always followed insulin prescriptions (mean rating for diet vs. insulin = 3.2 vs. 1.2, P < 0.001). Patients were also less likely to follow their diet than take oral agents (mean rating = 3.2 vs. 1.3, P < 0.001), but rated following recommendations for oral agents and insulin similarly (mean rating = 1.3 vs. 1.2, P = 0.36).

Focus groups

In the qualitative component of the study, we sought to understand specific barriers to following suggested therapy. We convened six focus groups at two sites. The average age of the focus group participants was 61 years; 97% were men; and 73% had a high-school education or less. In the suburban site, the focus groups were 88% white; in the urban site, the focus groups were 92% African-American. The specific categories of barriers that were identified by the reviewers of the focus group transcripts are outlined in Table 3. The most commonly cited problem was the cost of complying with the diet prescribed for control of Type 2 diabetes. In fact, in reviewing the transcripts, every reviewer identified cost as one of the major concerns of the focus group participants. As most would expect, portion size was frequently mentioned as a limiting factor; patients often felt hungry when complying with prescribed diets. Social and family support was identified as a key area as well; lack of family support was cited as a major factor in difficulty with maintaining diet, while those with strong family support found it easier to adhere to dietary recommendations. Other major topic areas identified by the reviewers were the effect of diet on quality of life; confusion over the proper elements of a diabetes diet; difficulty during holidays/ social occasions; emotional aspects of having to follow the

Table 3 Diet concerns identified by seven reviewers*

Diet Concerns	Score†
Expense	14
Portion size	13
Support/family	13
Quality of life/lifestyle	12
Confusion	10
Difficulty during holidays and special occasions	8
Emotional aspects	8
Good food/bad food	8
Rigid schedule	8
Communication with health professionals	7
Hypoglycaemia	4
Craving	3

*Reviewers had a broad range of expertise and independently evaluated the transcripts for content.

+Score range: 1 (concern identified by one reviewer at one site) to 14 (concern identified by all reviewers at both sites).

diet; a dislike of the food in the diet; and difficulties with the rigid schedule associated with diabetes diet. Representative quotes from the focus group participants are included in Table 4.

The focus group reviewers also evaluated the groups from the suburban (Ann Arbor) and urban (Detroit) site separately. The comparisons between the scoring at each site are shown in Table 5. The primary issue of concern at both sites was the expense of the diet; portion size, quality of life, and family support were also noted as barriers at both sites. However, there were areas that differed substantially between sites, most notably the issue of communication with health professionals, which was a major concern at the urban, but not at the suburban site. Of note, the population at the urban site was predominantly African-American, which may have contributed to this difference. Representative quotes include 'The only thing I got to say about the diet thing is that when you go to a nutritionist, I have not a clue of what they are talking about'. 'You are talking to me and you don't know what my economical position, my economics position, is. You don't know how I am situated. You don't know the community that I live in, but you are talking to me like I am Richie Cunningham of Happy Days and that is the problem that I have with the doctor.' 'You don't take into consideration how much money is available to me, the community that I live in, and the sources, my resources, that is available to me.' 'See, that is where it comes down to these doctors again. They don't understand the community or your upbringing ... It ain't got nothing to do with black or white. I am a southerner man. They cook like this all the time.' Similarly, a rigid schedule was felt to be a major barrier in the urban group, but not in the suburban group.

Discussion

Although dietary modification is considered by many to be the first step in the treatment of Type 2 diabetes, most studies show that the effectiveness of diet is limited and generally non-sustainable. However, there is little information about the specific barriers to following the typically prescribed diet. Many providers see lack of ability to follow a diet as a simple failure of patients' willpower or unwillingness to change longstanding behavioural patterns.

The results from our written survey suggest that patients find even moderate dietary modification to be more cumbersome than taking oral agents; a stricter diet that promotes weight loss (and would be likely to lead to more substantial benefits) is seen as having a burden similar to that of twicedaily insulin injections. While it is not surprising that patients cooperate less with diet than pills given the perceived burden of therapy, they may be less likely to comply with diet than with twice a day insulin injections, given similar views of the burden of therapy. In general, patients appeared to be more likely to cooperate with pharmaceutical diabetes management than with self-care behaviours such as dietary modification or home glucose monitoring.

Table 4 Sample patient quotes about barriers to following a prescribed diet

Cost of therapy

'What they tell you to eat, the stuff that you are supposed to eat that is good for you, most people cannot afford'

'I get \$700 a month. After rent and all, I can't afford to buy the vegetables and some of the things that they are talking about buying' 'My wife and I went down and did an inventory of what it would cost to get the dietetic food ... we spend about \$250 a month now for food for the wife and I. It would have been \$450 the other way ... so we have to buy the cheap stuff'

Portion size

'You couldn't live on that diet ... you have to eat twice as much as they want you to eat'

'The little bit they want you to eat is not enough. I mean my grandkids eat more than that'

'... you are only supposed to have three ounces of meat a day, or was it four? I forget, but all it amounts to is a little piece of meat like this. That is what make makes dieting so hard'

Social/family support

'You can't go over to one sister's house without going over to your baby sister's house, and you are going to eat something. They make you eat' 'Mine are really supportive but it is really their attitude. Like I am a biting dog. Don't get near that, he can't have that, you know' 'I don't know if my wife helps me or not. She came home last night with a chocolate cake and says, you can't have any ... last week, though, she was good. She only bought one peach pie and one pumpkin pie'

Quality of life/lifestyle

'I'm not going to sacrifice everything, what do you want to be a real old man and you can't eat, what the hell, you got to have something in life' 'I feel deprived, I guess is what it is ... I have a tendency to cheat and then I feel bad that I did that'

'If I'm going to be alive today, I am going to eat what I want. Otherwise, there is no sense in being here, if you can't enjoy something about it'

Confusion

Craving

Hypoglycaemia

'They tell me that I'm supposed to have so many portions of this and so many portions of that. ... I have not a clue what portions mean' 'One ounce of this and a half teaspoon of that, 2 g of this, I mean it's crazy ... it confuses you too'

'They put me on diets that I try to follow with, but it is hard and expensive. It is hard ... it is really confusing a lot of the times'

Difficulty during holidays/special occasions

'Holidays are a bad time; I mean summertime, all the time ... in summertime, that cold beer tastes good, that you can't have'

'Thanksgiving and Christmas, the 4th of July, any holiday, because of the barbecue sauce and the sweet potato pies'

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'I find the hardest time is this time of year, Thanksgiving and Christmas'

Diet concerns	Suburban site score†	Urban site score†
Expense	7	7
Portion size	6	7
Support/family	6	7
Quality of life/lifestyle	6	6
Confusion	6	4
Emotional aspects	5	3
Good food/bad food	4	4
Difficulty during holidays and special occasions	3	5
Rigid schedule	2	6
Communication with health professionals	1	6

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*Reviewers had a broad range of expertise and independently evaluated the transcripts for content.

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+Score range: 1 (concern identified by one reviewer) to 7 (concern identified by all reviewers).

The focus group results of our study are particularly revealing, and help to illuminate the barriers, beyond simple dislike, that make it difficult for patients to undertake dietary recommendations. The cost of a diabetes diet was a barrier that was mentioned by every expert who reviewed the focus group transcripts. This is an important finding since minorities and those with lower incomes bear a disproportionate burden of both the prevalence and the complications of Type 2 diabetes [3,23– 25]. Providers, dietitians, and educators need to acknowledge this factor when prescribing a diabetes diet; educational material should focus not only on ways to manage diet properly, but also on ways to do so economically. Some of the other barriers mentioned by patients were expected; limited portions, a decrease in quality of life, a lack of family support, dislike of the foods in the diet, and difficulty during holidays and special occasions were all mentioned as important factors. However, patients did not mention a craving for certain foods as a frequent problem.

Another issue that deserves special attention is the variation in patients' perceptions of communication with health professionals. A finding of our focus groups is that patients in the urban setting (a group that was almost exclusively made up of African-Americans; only one participant was not African-American) felt that communication with their providers was a major barrier to following recommendations for dietary modification. Quotes from the focus group participants strongly suggest a perception that providers are unaware of cultural differences that play a very important role in patients' willingness or ability to comply with prescribed therapy. Improving providers' understanding of these critical issues must be an area of emphasis if we are to design programmes to reduce many of the inequities that are seen in diabetes outcomes.

This study has several limitations. First, it was conducted in selected populations, and thus does not adequately represent a true cross-section of all patients with diabetes. We sought, however, to test a range of participants, including suburban and urban groups. We used flyers and offered a financial incentive to patients, which can produce a recruitment bias. Since the focus groups were conducted in a VA sample, which is a lower income group, they may lead to an overemphasis on cost; however, the burden of diabetes is disproportionately borne by those with lower socioeconomic status and in minority groups. Thus, many of the main lessons about cost and cultural barriers to dietary adherence are likely to apply in many locales. Second, the written survey had a response rate of only 54%. Third, because this is a cross-sectional analysis, the direction of causality cannot be determined for some associations; for example, the finding that patients who have more visits to a dietitian find diet to be more burdensome may be due either to an effect of visit frequency on perceived burden (e.g. diet is judged burdensome because so many dietitian visits are required with it, and in these health systems, a separate visit is often required) or to an effect of diet burden on dietitian visit frequency (e.g. diet burden leads to decreased ability to follow the diet which requires more frequent dietitian visits).

While the findings of this study are important for clinical care, they also have important policy implications. Clinical practice guidelines are set up to standardize care as much as possible, yet they often ignore patients' preferences and cultural, racial, or economic variation that may make following treatment recommendations difficult or impossible. Continuing research into these topics is needed to produce guidelines that meet the needs of patients rather than those of healthcare systems. Policy research also needs to consider these findings carefully. For example, the cost of a diabetes diet is invisible to the healthcare system, yet it is a very real and substantial cost that is borne by patients. Our focus group participants also mentioned that they feel a decreased quality of life when following a diabetes diet. While we did not specifically quantify quality of life, the cost increment and the quality of life decrement should both be considered when trying to set diabetes policy and practice standards.

The burden that treatments for diabetes place on patients is substantial. Understanding the burden of therapy and the barriers to following recommended therapy will allow us to design better treatment programmes and guidelines more consistent with patients' desires and values. Compromise is often required in life, and programs that consider both burden and benefit are those that are most likely to be successful in improving the lives of patients, both in the short and long term.

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References

- 1 *Diabetes in America*, 2nd edn. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 1995.
- 2 American Diabetes Association. Economic consequences of diabetes mellitus in the U.S. in 1997. *Diabetes Care* 1998; 21: 296–309.
- 3 Harris MI, Flegal KM, Cowie CC, Eberhardt MS, Goldstein DE, Little RR *et al.* Prevalence of diabetes, impaired fasting glucose, and impaired glucose tolerance in U. S. adults. The Third National Health and Nutrition Examination Survey, 1988–1994. *Diabetes Care* 1998; 21: 518–524.
- 4 Vijan S, Stevens DL, Herman WH, Funnell MM, Standiford CJ. Sreening, prevention, counseling, and treatment for the complications of type II diabetes mellitus: putting evidence into practice. *J Gen Intern Med* 1997; 12: 567–580.
- 5 Aubert RE, Herman WH, Waters J, Moore W, Sutton D, Peterson BL et al. Nurse case management to improve glycemic control in diabetic patients in a health maintenance organization: a randomized, controlled trial. Ann Intern Med 1998; 129: 605–612.
- 6 Weinberger M, Kirkman MS, Samsa GP, Shortliffe EA, Landsman PB, Cowper PA *et al.* A nurse-coordinated intervention for primary care patients with non-insulin-dependent diabetes mellitus: impact on glycemic control and health-related quality of life. *J Gen Intern Med* 1995; 10: 59–66.
- 7 American Diabetes Association. Standards of medical care for patients with diabetes mellitus. *Diabetes Care* 1994; 17: 616–623.
- 8 American Diabetes Association. Standards of medical care for patients with diabetes mellitus. *Diabetes Care* 1998; 21: S23–S31.
- 9 Goodall TA, Halford WK. Self-management of diabetes mellitus: a critical review [published erratum appears in Health Psychol 1992; 11: 77]. *Health Psychol* 1991; 10: 1–8.
- 10 United Kingdom Prospective Diabetes Study (UKPDS) 13. Relative efficacy of randomly allocated diet, sulphonylurea, insulin, or metformin in patients with newly diagnosed non-insulin dependent diabetes followed for three years. *Br Med J* 1995; **310**: 83–88.
- 11 United Kingdom Prospective Diabetes Study 24. A 6-year, randomized, controlled trial comparing sulfonylurea, insulin, and metformin therapy in patients with newly diagnosed type 2 diabetes that could not be controlled with diet therapy. United Kingdom Prospective Diabetes Study Group. *Ann Intern Med* 1998; **128**: 165–175.
- 12 UK Prospective Diabetes Study (UKPDS) Group. Intensive bloodglucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 1998; **352**: 837–853.
- 13 Barnard RJ, Jung T, Inkeles SB. Diet and exercise in the treatment of NIDDM. The need for early emphasis. *Diabetes Care* 1994; 17: 1469–1472.
- 14 Garcia MJ, McNamara PM, Gordon T, Kannel WB. Morbidity and mortality in diabetics in the Framingham population. Sixteen year follow-up study. *Diabetes* 1974; 23: 105–111.
- 15 Fuller JH, Shipley MJ, Rose G, Jarrett RJ, Keen H. Mortality from coronary heart disease and stroke in relation to degree of glycaemia: the Whitehall study. Br Med J (Clin Res Ed) 1983; 287: 867–870.
- 16 Metz JA, Stern JS, Kris-Etherton P, Reusser ME, Morris CD, Hatton DC *et al.* A randomized trial of improved weight loss with a prepared meal plan in overweight and obese patients: impact on cardiovascular risk reduction. *Arch Intern Med* 2000; 160: 2150– 2158.
- 17 Pogach LM, Hawley G, Weinstock R, Sawin C, Schiebe H, Cutler F et al. Diabetes prevalence and hospital and pharmacy use in the Veterans Health Administration (1994). Use of an ambulatory care pharmacy-derived database. *Diabetes Care* 1998; 21: 368–373.
- 18 Krein SL, Hayward RA, Pogach L, BootsMiller BJ. Department of Veterans Affairs' Quality Enhancement Research Initiative for Diabetes Mellitus. *Medical Care* 2000; 38: I38–I48.

- 19 Hayward RA, Manning WG, Kaplan SH, Wagner EH, Greenfield S. Starting insulin therapy in patients with type 2 diabetes: effectiveness, complications, and resource utilization. *JAMA* 1997; 278: 1663– 1669.
- 20 Huber PJ. The behavior of maximum likelihood estimates under nonstandard conditions. In Anonymous Proceedings of the Fifith Berkeley Symposium in Mathematical Statistics and Probability. Berkeley, CA: University of California Press, 1967; 221–233.
- 21 MacKinnon JG, White H. Some heteroskedasticity consistent covariance matrix estimators with improved finite sample properties. J Econometrics 1985; 29: 305–325.
- 22 Krueger RA. Focus Groups: a Practical Guide for Applied Research, 1st edn. Newbury Park: SAGE Publications, 1988; 27.
- 23 Harris MI. Epidemiological correlates of NIDDM in Hispanics, whites, and blacks in the U.S. population. *Diabetes Care* 1991; 14: 639–648.
- 24 Haffner SM. Epidemiology of type 2 diabetes: risk factors. *Diabetes Care* 1998; **21**: C3–6.
- 25 Chaturvedi N, Stephenson JM, Fuller JH. The relationship between socioeconomic status and diabetes control and complications in the EURODIAB IDDM Complications Study. *Diabetes Care* 1996; 19: 423–430.