The Diabetes Control and Complications Trial (DCCT) has been organized by the National Institutes of Health to answer this important question: Does normalizing blood glucose help to prevent or ameliorate diabetic complications? The largest prospective, randomized study of this problem ever undertaken, it will have 21 centers throughout the United States and Canada. The study will proceed in three phases: a planning phase begun in February 1982 and just completed; a two-year feasibility trial—beginning patient recruitment in April 1983; and the full-scale study, including about one thousand patients over an eight-to-ten-year period.

The feasibility trial has four goals: 1) to recruit patients with Type I (insulin-dependent) diabetes who fulfill the eligibility criteria (see box) and who are willing to be randomized either to a "standard" or an "experimental" therapy; 2) to determine whether a clinically, statistically significant difference in the level of blood glucose control can be maintained between the two groups over a two-year period; 3) to establish the safety, efficacy, and acceptability of the two treatment regimens; 4) to determine whether the biochemical and endpoint measurements outlined can be measured and documented with acceptable precision.

Eligible volunteers will be assigned to either a "standard" or "experimental" treatment group by means of a statistical randomization procedure. Randomization is necessary to limit the impact of any confounding variables that might otherwise be unequally distributed between the two groups. Treatment of patients in both groups will emphasize: 1) avoidance of glycosuria and/or hypoglycemia and ketonuria, and 2) maintenance of normal growth and development and ideal body weight.

The standard treatment regimen is meant to approximate the therapy that most insulin-dependent diabetic patients now receive. It will consist of not more than two injections of insulin daily and an individualized meal plan that provides for the total nutritional needs of the patient. The dietary program will be reinforced by the dietitian every six months. Therapy will also call for home urine tests for glucose three to four times per day, an educational program, and a standard schedule of clinic visits and monitoring procedures every three months.

The experimental treatment regimen is designed to maintain near-normal blood glucose control without significant hypoglycemia. Individuals in this group will receive intensive insulin therapy by continuous subcutaneous infusion that employs a pump (CSII), or by administration of subcutaneous injections of short-acting insulin before each meal, coupled with one or two simultaneous injections of longer-acting insulin (multiple daily injections). The DCCT physician and the individual patient will choose the insulin delivery method. Each patient will perform self-blood-glucose monitoring at least four times each day. The same principles of dietary management as set for the standard group will apply to the experimental group, but will involve a more intensive schedule of follow-up as well as more frequent clinic visits.

Throughout the trial, blood glucose and glycohemoglobin will be used as the primary indicators of overall metabolic control. Diabetic retinopathy will be the primary endpoint measured because it is an early indicator of disease progression and may be affected by blood glucose control.

### DIABETES CONTROL AND COMPLICATIONS TRIAL

#### Basic Eligibility Criteria

- Insulin-dependent diabetic patients between 13 and 40 years old
- Serum creatinine ≤ 1.2 mg/dl
- Glycosylated hemoglobin (A1c) value greater than three standard deviations above the mean of a nondiabetic population (approximately 8%)
- Informed consent from all participants; in addition, informed consent from parent or guardian of participants under 18 years old
- Absence of advanced complications of diabetes, e.g., severe retinopathy or nephropathy

#### Primary Intervention

- No retinopathy as judged by stereo-color fundus photography
- Duration of diabetes, 1-5 years
- Corrected visual acuity of at least 20/25 in both eyes
- Absence of proteinuria

#### Secondary Intervention

- Minimal background retinopathy (at least one microaneurysm in either eye)
- Duration of diabetes, 1-15 years
- Corrected visual acuity of at least 20/32 in both eyes
- Absence of proteinuria
The protocol includes measures for insuring confidentiality of patient information and for patient safety. Mechanisms for insuring quality control and for monitoring performance of all DCCT components on a regular basis include two external and independent advisory groups: the Policy Advisory Group and the Data, Safety, and Quality Review Group.

Basic eligibility criteria are listed in the accompanying box. We encourage anyone interested to contact Fred Whitehouse, MD, Dorothy Kahkonen, MD, or Davida Kruger, RN, MSN, in Metabolic Diseases at Henry Ford Hospital, Detroit, Michigan 48202. The toll free numbers are: 1-800-482-2404 (within Michigan) or 1-800-521-7946 (outside Michigan). Volunteers will be needed.

**Comments on Office Management of the Insulin-Requiring Diabetic Patient: A Preferred Alternative to Hospitalization**

The cost of medical care to the patient and to the community makes thoughtful people pause these days. The issue is complex and not amenable to simplistic answers. However, it is clear that office diagnosis and therapy rather than hospital care will lessen costs to the patient, to third party payors, and to the community. We have addressed this issue as we help our diabetic patients establish metabolic control of their disease and learn to care for themselves.

Office education of the person with diabetes saves hospital days. Ambulatory patients who are well except for the diabetes are easily regulated in an office setting if it is possible to monitor their blood glucose levels. Initiation of insulin therapy or regulation of the blood glucose in those taking insulin is more realistically accomplished in an ambulatory setting. Continuing activities of daily living during this regulation period reinforce independence and responsibility for personal health care. Hospitalization places one in a dependent position where efforts of the health care team often fail to include education in self-care of the diabetes. Table I lists the advantages of office care over hospital care.

A pilot program in diabetic regulation and self-care involving 109 insulin-requiring diabetic patients was held at Henry Ford Hospital in 1979. We found that good diabetic care could be achieved and sustained when these patients completed a five-day office program in self-care instead of being admitted for similar treatment (1). As an outgrowth of this salutary experience, we modified our pilot program to a three-day schedule, following which patients are referred to their physician for further advice. Our program offers 24 hours of contact between the patient and professionals, the diabetes teaching nurse, nutritionists, and physicians. The curriculum includes breakfast and lunch each day with a nutritionist, group sessions with other diabetics helps the individual cope with feelings of separateness, hostility, denial, and grief.

### TABLE I

**ADVANTAGES OF AMBULATORY CARE OVER HOSPITALIZATION**

**Cost Savings:**
- Office management is less expensive than a hospital bed.
- Less time is lost from family and work situations.

**Maintenance of Independence:**
- The patient remains in control and is responsible.

**Individualized Education:**
- Small group sessions make it possible to answer questions as they arise and offer opportunity to identify problem areas.

**Experience of Peer Relationships:**
- Gathering together in a small group at meal times and in educational sessions with other diabetics helps the individual cope with feelings of separateness, hostility, denial, and grief.

During these three days, plasma glucose levels are measured frequently and insulin needs adjusted. After completing the three-day program, patients are given a summary of their expe-
During 1981 and 1982, we enrolled 150 patients in this office program, all of whom fulfilled accepted criteria for hospitalization for uncontrolled diabetes. In January 1983, we reviewed their hospitalization experience subsequent to the three-day program, reasoning that if frequent hospitalization for poorly controlled diabetes were mandatory following the experience of the three-day program, either the quality of the three-day program was inadequate or we were not able to stabilize the diabetes during that short period. Fourteen patients were hospitalized subsequent to the regulation and education experience. Only four admissions of two patients were directly related to poorly controlled diabetes. The other 12 patients required hospital care for acute intercurrent infections, surgical therapy, and treatment of chronic medical problems (Table II).

Experience with our three-day office diabetes regulation and education program confirms our previous experience (1). Cost of hospitalization was spared for 150 patients. Over a period ranging from one to 24 months, only two patients required admission to treat their diabetes.

We interpret this experience as further support of this office approach to regulation and education of insulin-requiring diabetic patients in lieu of hospitalization. We believe this type of care is preferable to inpatient management. Costly hospitalization is avoided without compromising the quality of diabetic care. Close office supervision after the patient has completed the program is necessary until the patient is clinically stable. We hope that third party payors will respond in support of this approach to management of the ambulatory diabetic patient.

Staff Members of the Division of Metabolic Diseases and Clinical Dietetics, Henry Ford Hospital

Reference

Erratum
My editorial on “Heart Valve Surgery at Henry Ford Hospital from a Perspective of Thirty-two Years” in Vol. 30, No. 3, 1982 has an error. I wrote that “No homograft was ever used in a human being at Henry Ford Hospital” (p. 171). It has been brought to my attention that 17 years ago, Dr. Rodman Taber did a series of homograft replacements which eventually reached a total of about 15. The grafts were removed at routine autopsies and sterilized with betapropriolactone. These operations are mentioned in the 1966 and 1967 annual reports of the Division of Thoracic Surgery, which I signed. I apologize to Dr. Taber for this lapse of memory.

Conrad R. Lam, MD  Associate Editor

TABLE II
SUBSEQUENT COURSE OF 150 PATIENTS ENROLLED IN AN OFFICE REGULATION AND EDUCATION PROGRAM

<table>
<thead>
<tr>
<th>Hospitalized</th>
<th>Not Hospitalized</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>136</td>
</tr>
</tbody>
</table>

1. Unrelated to Diabetes Control
2. Related to Diabetes Control