

Community Based Studies of Diabetes Control: Program Development and Preliminary Analysis

Charles Kent Smith, MD, Thomas R. Taylor, MD, PhD, and Michael J. Gordon, PhD
Seattle, Washington
and

The WAMI Family Medicine Collaborative Research Group

In this report are examined the patterns of control of diabetes mellitus achieved by practicing family physicians in small communities in the Pacific Northwest and Alaska. The diabetic patients under study appear to be broadly similar to patients in tertiary care settings, where most studies of diabetes care have been carried out. Motivated, competent family physicians, knowledgeable about tight control of diabetes, appear to have considerable difficulty in maintaining even modest levels of biochemical control. Goals in this study for fasting plasma glucose levels for patients with insulin-dependent diabetes mellitus (IDDM) averaged between 120 and 160 mg/100 ml. Glucose levels actually achieved ranged up to 360 mg/100 ml. A similar though lesser discrepancy was noted for patients with non-insulin-dependent diabetes mellitus (NIDDM), with achieved levels ranging up to 270 mg/100 ml fasting plasma glucose. There were wide individual differences among physicians in management styles and treatment policy, including wide discrepancies in emphasis on diet, use of oral hypoglycemic agents, and insulin use. This diversity is felt to merit further investigation. Collaborative studies of this type with community based physicians are feasible and academically rewarding. Significant research questions can be addressed and answered.

Diabetes mellitus is a major health care problem, with much of the responsibility for long-term care falling on family physicians. In the National Ambulatory Medical Care Survey¹ 53.4 percent of all outpatient visits for diabetes care in the United States were made to general and family physi-

cians. Of over 500,000 encounters in family practices in the State of Virginia,² diabetes mellitus was the seventh most common problem encountered. Similarly, a recent study in the Pacific Northwest region conducted by R. Kirkwood found that diabetes ranked 13th in the set of 50 most common diseases seen by family physicians (personal communication, June 1981). One of the few studies that exist on the ambulatory care of diabetes is that of Williams et al.³ Almost all studies have focused either on a diabetic clinic or a

From the Department of Family Medicine, School of Medicine, University of Washington, Seattle, Washington. Requests for reprints should be addressed to Dr. Charles Kent Smith, Department of Family Medicine RF-30, School of Medicine, University of Washington, Seattle, WA 98195.

tertiary care hospital setting. The study described below is the first phase in a larger research program aimed at moving the observation and study of diabetes and its care into community based ambulatory settings with the active collaboration of the patients' family physicians.

The Impact of Diabetes Mellitus

Of the health problems related to diabetes, those affecting vision and cardiovascular, peripheral vascular, and kidney functions are the most serious. Eighty percent of all diabetics in the 1964-65 Health Interview Survey⁴ had a second chronic condition, and 58 percent had two or more. Diabetes is the tenth main cause of activity limitations according to responses in the 1969 and 1970 Health Interview Survey.⁵ About one in two insulin-dependent diabetics develop kidney failure.⁶ Diabetes accounts for about one quarter of all persons entering end stage renal disease programs. Diabetes is also a major cause of blindness in the United States. One out of every 20 insulin-dependent diabetics becomes blind. Diabetics are about 25 times more likely than nondiabetics to develop blindness, four to six times more likely to develop cataracts, two times more likely to develop glaucoma, and two to four times more likely to be unable to read a newspaper.⁶ Diabetics with high blood pressure had twice the risk of retinal exudates than those without elevated blood pressure.⁷ Finally, diabetes is currently considered by specific disease category to be this nation's fifth leading cause of death. The economic cost of the condition itself is estimated at about \$7 billion annually.⁸ These facts emphasize the impact of diabetes on health care and the critical role played by family physicians in the care of diabetic patients.

Efficacy of Tight Control

In the day-to-day management of diabetes, a vitally important aspect of care is the control of

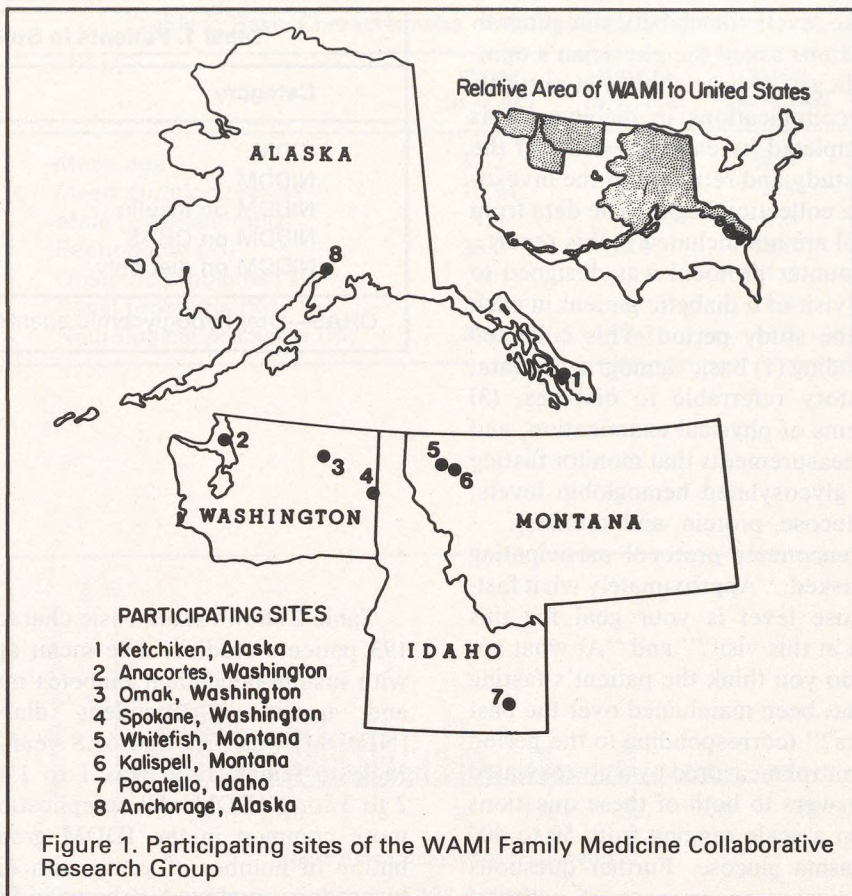
plasma glucose levels. Recently, interest in tight control of plasma glucose levels has increased greatly. Research evidence in general tends to support a causative link between chronic hyperglycemia and the vascular related complications of diabetes.⁹ A related hypothesis is also promoted, namely, that a decreased incidence of microvascular complications is associated with tight control.¹⁰

There seems little doubt that a plausible case can be made for the benefits of strict control in diabetes management. From this follows the problem of how this degree of control can be achieved in large populations of patients. The main approach to stricter control in recent years has been technological, focusing on the use of plasma glucose monitoring¹¹ and insulin delivery devices.¹² Further developments and refinement of these approaches are currently receiving much attention in the literature in the fields of diabetes and general medicine.

The strictly biomedical approach to medical care has much to recommend it. But little is known of the outcome of diabetic care as currently delivered, particularly in community settings. This study is the first in a series aimed at investigating functional, psychosocial, and biomedical outcomes of diabetes care, focusing in particular on management decisions and their role in improving diabetes control.

Research Plan

Two broad directions are being pursued in this research plan. The first, a basic science approach, involves a detailed study of both physician and patient decision making in the day-to-day management of diabetes in non-insulin-dependent diabetics, which is funded by a three-year grant from the National Institutes of Health. The second thrust in the research plan is the development of a community based research consortium of family physicians and other primary care physicians interested in studying the management of diabetes in the community. A desire was expressed by the clinical faculty in the Advanced Family Medicine Clerkship at the University of Washington Medical School to expand their role to encompass collabo-



rative research as well as teaching. In 1979 the desire to promote community based research was crystallized around the issue of diabetes management. This communication, involving patients with both insulin-dependent and non-insulin-dependent diabetes mellitus, is the first report on the project describing its development and presenting the results of preliminary investigations.

Study Methods

The study was conducted with practicing physicians in the states of Washington, Alaska, Mon-

tana, and Idaho (the WAMI region of the Pacific Northwest, Figure 1). Thirty physicians in eight practice locations participated with clinical data reported from seven of the sites; 27 of these physicians were family physicians, and 3 were general internists. The group comprises the faculty of the Advanced Family Medicine Clerkship of the WAMI Program of the University of Washington Medical School.¹³ The participating sites were at Ketchikan and Anchorage, Alaska; Anacortes, Omak, and Spokane, Washington; Whitefish and Kalispell, Montana; and Pocatello, Idaho. In cooperation with the participating physicians, two protocols were developed for the study.

Each physician was asked in the initial protocol to indicate his or her ideal goal and realistic goal

for plasma glucose levels for diabetics in general. Two further questions asked the physician's opinions about the efficacy of tight control in preventing or delaying complications in diabetes. This protocol was completed by each physician at the beginning of the study and returned to the investigators before data collection began. The data from the initial protocol are not included in this report.

A second encounter protocol was designed to be used at every visit of a diabetic patient in each practice during the study period. This collected patient data, including (1) basic demographic data, (2) pertinent history referable to diabetes, (3) some selected items of physical examination, and (4) biochemical measurements that monitor fasting plasma glucose, glycosylated hemoglobin levels, and urinalysis (glucose, protein, and ketones).

Also on this encounter protocol participating physicians were asked, "Approximately what fasting plasma glucose level is your goal for this particular patient at this visit?" and "At what approximate level do you think the patient's fasting plasma glucose has been maintained over the past two to four weeks?" (corresponding to the period of biochemical control measured by a glycosylated hemoglobin). Answers to both of these questions were recorded on a scale ranging from 50 to 400 mg/100 ml of plasma glucose. Further questions were asked concerning an estimate of patients' compliance and the number of management changes made at each visit (along with the reasons for these changes).

Results

Basic Data

The study covered the period from September 1, 1980, to April 1, 1981. During this eight-month period data were collected on 330 encounters with 192 patients by 24 physicians in seven practice locations throughout the Pacific Northwest. Table 1 divides cases into diagnostic groups according to the classification developed by an international work group sponsored by the National Institutes of Health and approved by the American Diabetes Association.¹⁴

Table 1. Patients in Study

Category	Number
IDDM	40
NIDDM	153
NIDDM on insulin	33
NIDDM on OHAS	43
NIDDM on diet only	77
OHAS—Oral hypoglycemic agents	

Table 2 shows some basic characteristics of the 193 patients studied. The mean age for patients with insulin-dependent diabetes mellitus (IDDM) and non-insulin-dependent diabetes mellitus (NIDDM) was 33.2 and 63.8 years, respectively. Male to female ratio was 1 to 1 for IDDM and 2 to 3 for NIDDM. All complications were much more common in the IDDM group. The distribution of number of years with diabetes for the two groups combined is shown in Figure 2; the age distribution of all patients in the study is shown in Figure 3.

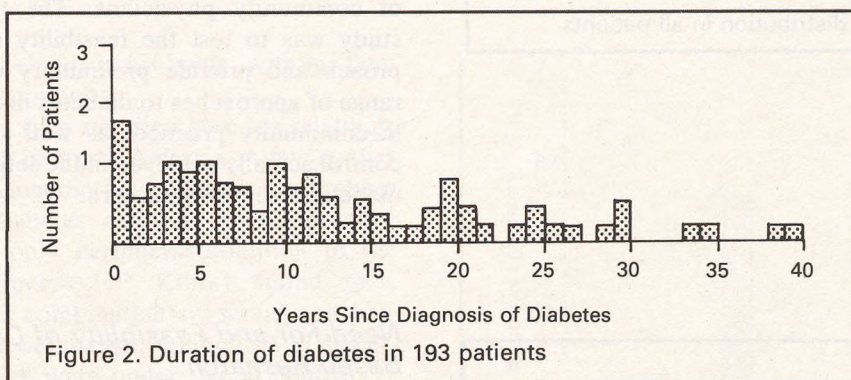
Disease-Treatment Groupings

All patients were categorized into one of four diagnosis-treatment groups as follows: 41 cases were insulin-dependent (IDDM); of those who were not insulin dependent (NIDDM), 32 were treated with insulin, 42 with oral hypoglycemic agents, and 77 with diet alone.

These groups can be compared in several ways; for example, there were no significant differences in the total calories prescribed by physicians among the four groups (mean, 1,650 calories). When comparing the average weight among the four groups, the IDDM patients weighed significantly less ($P = <.001$) than those in all three NIDDM groups. There were no significant differences in weight among the three treatment groups of NIDDM patients ($P = <.001$).

Table 2. Basic Characteristics of All Patients Studied

	IDDM (n = 40)	NIDDM (n = 153)	Total (n = 193)
Mean age	33.2	63.8	58.5
Mean duration (years)	10.94	8.17	8.94
Male to female ratio	1:1	2:3	2:3
Retinopathy (%)	36.0	14.0	18.0
Obstetric problems (%)	5	0	1.0
Renal problems (%)	25.0	6	11.5
Neurological problems (%)	22.0	10.0	12.0



Measurements of the Management Process

Two measures of the patient management process were used in this study. The first was a plasma glucose discrepancy measure (PGD) of the difference between the physician's goal plasma glucose and that actually found at the encounter (Figure 4). In all cases the levels of plasma glucose achieved fell short of the goal. Among all four patient groups the PGD was greatest for the IDDM group and the next greatest for the NIDDM patients treated with diet only. Figure 5 records the distribution of goal plasma glucose levels across all the

encounters in the study (each of which was set at the beginning of the encounter for the individual patient), showing a preponderance of goals at 150 mg/100 ml or less.

The second measure was the number of changes in treatment made at each encounter. In IDDM diabetics, changes were made at 50 percent of the encounters studied; for NIDDM patients on insulin, changes were made at 27.7 percent of the encounters; for NIDDM patients on oral hypoglycemic agents, changes were made at 6.3 percent of the encounters; and for NIDDM patients on diet, changes were made at 18.2 percent of the encounters studied.

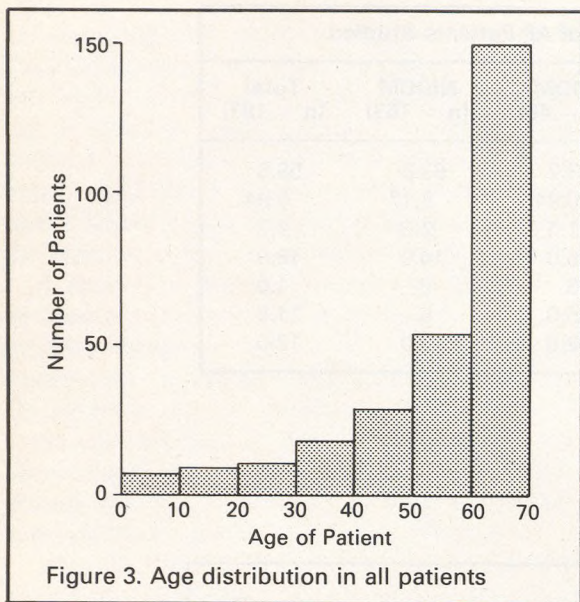


Figure 3. Age distribution in all patients

Individual Differences in Management Styles Among Physicians

A profile of two physicians in the study is shown in Table 3, demonstrating the range of treatment approaches employed by different physicians who care for patients at similar age ranges.

Discussion

The present study represents the first in a planned program of research on diabetes management to be conducted in collaboration with a team of community physicians. The purpose of the study was to test the feasibility of such an approach and provide preliminary data about the range of approaches to diabetes management used in community practices as well as the levels of control actually achieved in the setting where most diabetics receive their care.

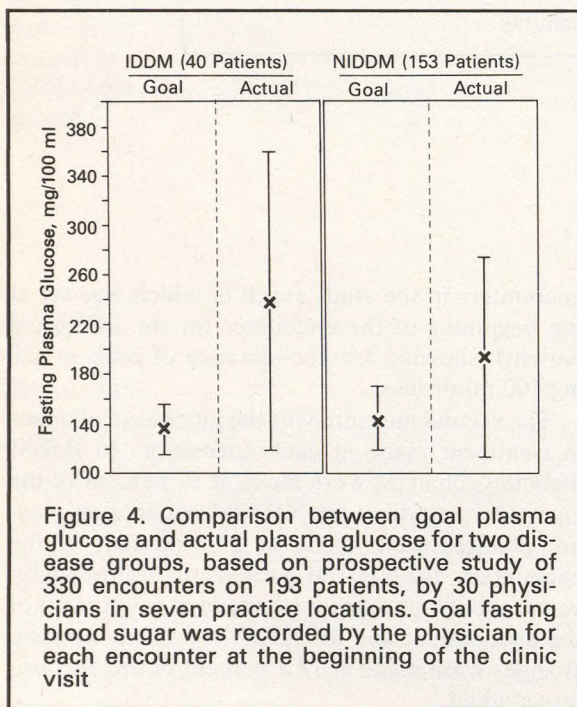


Figure 4. Comparison between goal plasma glucose and actual plasma glucose for two disease groups, based on prospective study of 330 encounters on 193 patients, by 30 physicians in seven practice locations. Goal fasting blood sugar was recorded by the physician for each encounter at the beginning of the clinic visit

Need For and Feasibility of Community Based Research

In 1979 the National Conference on Diabetes brought together 200 experts in the fields of diabetes related research, treatment, control, and education to develop a long-range plan to combat diabetes and make recommendations for the next five years. A major conclusion of the diabetes epidemiology work group was that there was a dearth of epidemiologic research on diabetes. Among the many recommendations for the future study of diabetes was that population based registers for those with insulin-dependent diabetes mellitus be established in selected geographic sites. The work group saw these registers as providing the basis for multiple studies less hampered by selection bias than previous studies.¹⁵ This study represents the earliest phase in a program of establishing just such community based registers of diabetic patients.

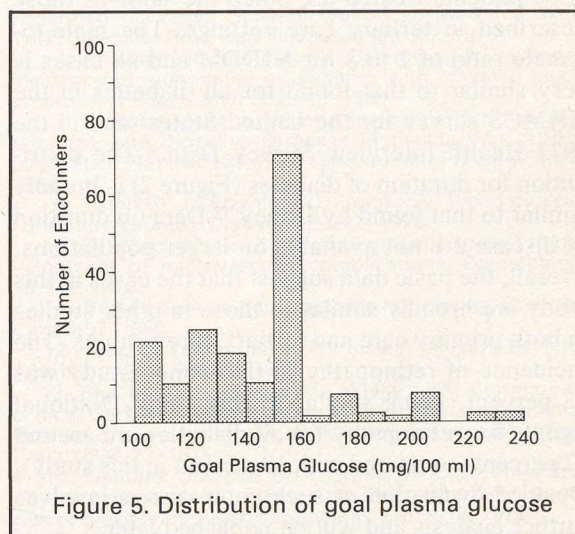
A recent report from the World Health Organization Expert Committee on Diabetes Mellitus¹⁶ emphasized that clinical care of the diabetic should be moved from the diabetic clinic and "put

Physician	Patients			Treatment		
	Number	Age Range (years)	Mean Age (years)	Percent Insulin	Percent OHAS*	Percent Diet Only
A	8	49-75	62	25.0	62.5	12.5
B	37	49-77	63	24.3	2.7	73.0

*OHAS—Oral hypoglycemic agents

firmly where it belongs in his home, with his family and in the community.”

Studies of the type reported here are relatively rare, particularly in North America. A few studies in the United Kingdom have looked in a preliminary way at diabetes care in general practice (although with only peripheral attention to the management process).¹⁷⁻¹⁹ Kratky found that, using a specific combination of social and biochemical criteria of his own, 8 out of the 17 diabetics in his practice were under “good control.”¹⁸ The most relevant study of diabetes control in the community in the United States was that of Williams et al,³ who studied the control of diabetes in four settings: two university medical centers, the office of an internist specializing in diabetes, and a health maintenance organization. They found that good or poor day-to-day control was most closely associated with the age of onset of the disease. Using a classification system of their own for diabetes control, only 17 percent of the patients in the study achieved good control. More recently, Tchobroutsky,²⁰ studying a group of 102 insulin treated diabetics managed in outpatient settings by their own physicians in association with a diabetic specialist, confirmed that only 19 percent of the patients studied had a glycosylated hemoglobin level less than three standard deviations above the normal mean. In other words, control was poor in over 80 percent of the patients studied. Thus the need for collaborative community based studies seems firmly established.



Feasibility of community based studies involves several components, including willingness on the part of community physicians to participate in time consuming meetings to design the study as well as efforts to reorganize office procedures and commitment of practice resources to collection of the required data. The data collection procedures must be implemented with sufficient care to assure that the resulting data will meet accepted stand-

ards of reliability and validity. Further, such studies can only continue if they are sufficiently rewarding to both community collaborators and university based researchers to justify the considerable effort required to carry them out.

The present study involves many more practices than any of the previous studies mentioned above. The practice settings vary from urban to remote rural communities. All physicians participating in this study were board certified and diplomates of the American Academy of Family Physicians or the American College of Physicians actively teaching medical students and residents on a regular basis. This set of physicians can therefore be viewed as a sample of high-level primary medical care providers in a variety of community settings.

The basic data (Table 1) indicate that the diabetic patients treated are much the same as those described in tertiary care settings. The male-to-female ratio of 2 to 3 for NIDDM and all cases is very similar to that found for all diabetics in the NAMCS survey for the United States¹ and in the 1973 Health Interview Survey Data.⁵ The distribution for duration of diabetes (Figure 2) is broadly similar to that found by Doney.¹⁷ Data on duration of disease are not available on larger populations; overall, the basic data suggest that the cases in this study are broadly similar to those in other studies in both primary care and tertiary care settings. The incidence of retinopathy in the Doney study was 13 percent, being similar to this study. National figures for retinopathy for all diabetics are around 17 percent (compared with 18 percent in this study). Detailed evaluation of such comparisons involves further analysis and will be published later.

The correlation between fasting plasma glucose level and glycosylated hemoglobin level in individual patients ranged from $r = .56$ to $r = .74$ in this study, comparing well with (1) a study reported by Aleyassine et al²¹ from Montreal General Hospital Diabetic Center ($r = .55$ to $.70$), (2) a study in a hospital based diabetic clinic in Queensland, Australia, reported by Bartley and Hambling²² ($r = .65$), and (3) a diabetic outpatient clinic in Boston, Massachusetts ($r = .46$).²³ Review of many other similar studies gives comparable figures. This suggests that, even with multiple clinical sites and using several laboratories, the biochemical data in this study are reliable.

Figure 5 suggests that most physicians favor a

plasma glucose goal of less than 150 mg/100 ml. Recently some experts have even suggested that a level of less than 100 mg/100 ml would be needed to prevent complications (Figure 4).

Finally, the range of individual differences among physicians demonstrated in Table 3 emphasizes the need for gathering more baseline data about physician behavior, including the differences in management styles and treatment preferences demonstrated here.

Conclusions

The preliminary findings in this study suggest (1) motivated competent physicians knowledgeable about the value and techniques of tight control of diabetes patients have considerable difficulty in maintaining even modest levels of control, (2) diabetic patients in this study are broadly similar to those patients in tertiary care settings, where most studies of diabetic care have been carried out, (3) wide individual differences exist among physicians in management styles and treatment policies which merit further investigation, and (4) collaborative community based primary care studies of this type are academically rewarding and above all feasible. Important research questions can be posed and answered.

WAMI Participating Clinical Faculty

Washington

Anacortes

Thomas P. Brooks, MD
 Harold R. Clure, MD
 C. Leslie Conway, MD
 Harold L. Eiesland, MD
 C. Richard Kirkwood, MD
 William V. Long, MD
 Wayne G. Ramerman, MD
 Oliver L. Stalsbrotten, MD

Omak

D. James Bone, MD
 Amos P. Bratrude, MD
 John B. Coombs, MD
 Greg L. Ledgerwood, MD

Spokane

Walter W. Balek, MD
 Michael J. Metcalf, MD
 Paul E. Russell, MD

Alaska**Anchorage**

Richard E. Brodsky, MD
 Thomas S. Nighswander, MD

Ketchikan

Ann Black, MD
 Myron E. Bloom, MD
 Thomas L. Conley, MD
 Hilbert J. Henrickson, MD
 David E. Johnson, MD

Montana**Kalispell**

George H. Gould, MD
 J. Jerome Wildgen, MD

Whitefish

Ronald A. Miller, MD
 Wilfred S. Miller, MD

Idaho**Pocatello**

Michael S. Baker, MD
 Howard Katz, MD
 Dennis Minjster, MD
 Sam J. W. Romeo, MD
 Jack P. Summers, MD
 David Wise, MD

University of Washington

William R. Phillips, MD, Coordinator
 Mark Hegewald, medical student
 Margaret Bangs, medical student

Acknowledgments

This paper was supported in part by the Predoctoral Training Grant of the Department of Family Medicine,

School of Medicine, University of Washington (2D15 PE 8000) and the Student Research Program of the University of Washington.

References

- Office visits for diabetes mellitus. National ambulatory medical care survey: United States, 1977. In National Center for Health Statistics (Hyattsville, Md): Advance Data from Vital and Health Statistics, No. 57. DHEW publication No. (PHS) 79-1250. Government Printing Office, 1980
- Marsland DW, Wood M, Mayo F: Content of family practice: Part I: Rank order of diagnosis by frequency. *J Fam Pract* 3:37, 1976
- Williams TF, Martin DA, Hogon MD, et al: The clinical picture of diabetic control studied in four settings. *Am J Public Health* 57:441, 1967
- Characteristics of persons with diabetes. United States—July 1964-June 1965. In National Center for Health Statistics (Hyattsville, Md): Vital and Health Statistics, series 10, No. 40. PHS publication No. 1000. Government Printing Office, 1967
- Limitation of activity due to chronic conditions: United States—1969-1970. In National Center for Health Statistics (Hyattsville, Md): Vital and Health Statistics, series 10, No. 80. DHEW publication No. (HSM) 73-1506. Government Printing Office, 1973
- Cahill GF Jr: Diabetes mellitus. In Rubenstein E, Federman DD (eds): *Scientific American Medicine*. New York, Scientific American Illustrated Library, 1979
- Knowler WC, Bennett PH, Ballintine EJ: Increased incidence of retinopathy in diabetics with elevated blood pressure. *N Engl J Med* 302:645, 1980
- Diabetes Mellitus. National Institute of Arthritis, Metabolism, and Digestive Diseases (Bethesda, Md). DHHS publication No. (NIH) 80-1982. Government Printing Office, 1980
- Cahill GF Jr, Etwiler DD, Freinkel N: Blood glucose control in diabetes. *Diabetes* 25:237, 1976
- Tchobroutsky G: Relation of diabetic control to development of microvascular complications. *Diabetologia* 15:143, 1978
- Symposium on home glucose monitoring. *Diabetes Care* 3:57, 1980
- Felig P, Tamborlane WV: Insulin delivery devices. *Ann Intern Med* 93:627, 1980
- Phillips TJ, Swanson AG, Wiegert HT: Community clinical clerkships for educating family medicine students: Process of development (a WAMI progress report). *J Fam Pract* 1(3/4):23, 1974
- National Diabetes Data Group (NDDG): Classification and diagnosis of diabetes mellitus and other categories of glucose intolerance. *Diabetes* 28:1039, 1979
- Harris M: Diabetes epidemiology work group, national conference on diabetes: Research needs in the epidemiology of diabetes. *Am J Epidemiol* 113:105, 1981
- WHO Expert Committee on Diabetes Mellitus: *Lancet* 2:217, 1980
- Doney BJ: An audit of the care of diabetics in a group practice. *J R Coll Gen Pract* 26:734, 1976
- Kratky AP: An audit of the care of diabetics in one general practice. *J R Coll Gen Pract* 27:536, 1977
- Wilkes E, Lawton EE: The diabetic, the hospital and primary care. *J R Coll Gen Pract* 30:199, 1980
- Tchobroutsky G, Charitanski D, Blouguet Y, et al: Diabetic control in 102 insulin-treated outpatients. *Diabetologia* 18:447, 1980
- Aleyassine RJ, Gardiner RJ, Tonks DB, Koch P: Glycosolated haemoglobin in diabetes mellitus. *Diabetes Care* 3:508, 1980
- Bartley DC, Hambling TE: Hemoglobin A1C in diabetes mellitus. *Aust NZ J Med* 9:49, 1979
- Dunn DJ, Cole RA, Soeldner JS, Gleason RE: Reproducibility of hemoglobin A1C and sensitivity to various degrees of glucose intolerance. *Ann Intern Med* 91:390, 1979