

Improving Clinical Effectiveness

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Introduction

The abstracts in this section represent published studies of diabetes care improvement interventions. The studies were identified by a literature search conducted by the Center for Health Studies at the Group Health Cooperative of Puget Sound. Approximately 150 studies were identified, and about 90 were eliminated due to obvious flaws in study design. The Health Care Financing Administration (HCFA) and its Clinical Area Support Peer Review Organization (CASPRO) for diabetes, the Texas Medical Foundation (TMF), recruited an expert panel to review the remaining studies for inclusion in this compendium.

Each study was reviewed by two reviewers who recommended whether or not to include the study in the Compendium. If the two reviewers disagreed, there was a third review. TMF provided the reviewers with a rating tool which was a modification of a tool developed by the Centers for Disease Control and Prevention (CDC) to rate immunization interventions. Inclusion/exclusion criteria were based on a study's methodology including:

- Appropriate study design;
- Sampling methods and sample size;
- Controlling or describing bias and confounders;
- Validity of measures;
- Reliability of measurement;
- Appropriate statistical methods; and
- Statistically significant and meaningful results.

The reviewers did not rate the studies on generalizability to “average” health care settings, feasibility, nor cost. It is the responsibility of the readers to make these judgments when considering applying the interventions in their own health care settings. The review tool is available in the appendix.

Sixty-three studies were reviewed; 24 were accepted and 23 were rejected after two reviews. For those with disagreements between the first two reviewers, 8 were accepted and 8 were rejected after the third review. There was an agreement rate of 74.6% between the first two reviewers. Thirty-two studies are included in the Compendium.

There are two summary tables preceding the abstracts. The first table is a general summary of each study and the second table categorizes each study's interventions.

The second table's intervention categories come from a model of chronic disease care developed by the Center for Health Studies at the Group Health Cooperative of Puget Sound in Seattle, Washington. The categories are:

- **Self-management support:** this includes educational and psycho-social support for the patient and family in living with and treating a chronic disease. Examples include providing patient education in a clinic, using community health workers, using culturally sensitive materials, and using technology such as video tapes and computer touch screens.
- **Delivery system design:** rather than merely adding interventions to a physician's workload, prevention and care processes can be redesigned. Health care team members should have clear, complementary roles and aspects of care can be delegated by physicians to other professionals such as nurses, pharmacists, and health educators. Examples of changing delivery system design include implementing a nurse case management program, using a nurse or podiatrist to perform foot exams, or using a multi-disciplinary team to manage the care of diabetic inpatients.
- **Decision support:** health care professionals must have current scientific information on how to best treat their patients. This information is usually found in the medical literature and in evidence-based practice guidelines. How this information is provided is also important. Numerous studies have shown that methods such as feedback from an opinion leader or academic detailing are more effective than traditional continuing medical education (CME) or mailing information to clinicians.
- **Clinical information systems:** there is a growing body of evidence that improved clinical information, to both providers and patients, improves the quality of care. Health care providers can evaluate and improve care given to both individuals and populations. Examples of clinical information systems are patient registries and reminder systems.

The goal of these interventions is to improve patient outcomes by 1) providing information to patients who can more effectively and collaboratively participate in their own treatment and 2) developing a coordinated, trained provider team.

Multiple, coordinated interventions are more effective than single, fragmented efforts. For example, many organizations have tried to initiate the use of diabetes documentation flow sheets. The objectives of these flow sheets are to 1) remind providers of the types of screening and monitoring tests and examinations that are needed and 2) provide an efficient format for documentation.

If a health care organization mails flow sheets to physicians and asks them to use the sheets for their diabetic patients, the intervention will probably fail. However, if the health care organization wins the support of a physician opinion leader, who agrees to 1) help develop a plan for team training and coordination and 2) present the plan to other physicians, then the intervention is more likely to succeed. The plan may call for an office nurse to perform a preliminary foot exam, review the flow sheet, and inform the physician which tests should be ordered. The opinion leader would also point out that the physicians' schedules remain efficient, while patient care quality is improved in a way that can be easily documented.

Summary Table One

Overview of Studies

Abstract Number	First Author & Year	Interventions	Patients	Setting	Measures	Page Number
1.	Aqurs-Collins TD, 1997	Patient education: nutrition and exercise	64 African Americans age >55 with NIDDM	Hospital in Washington, DC	Weight, physical activity, intake of fat, dietary knowledge, HbA1c	1-12
2.	Aubert RE, 1998	Nurse case management	100 diabetics meeting inclusion criteria	Two large clinics serving an HMO in Jacksonville, Florida	HbA1c, blood glucose, weight, cholesterol, blood pressure, health status score	1-13
3.	Carlson A, 1991	Medical education and organizational development	566 diabetic outpatients	Primary health care centers in Sweden	Height recorded, HbA1c, eye exams, glucose self-monitoring	1-14
4.	Corkery E, 1997	Patient education: use of a bicultural community health worker	64 Hispanic diabetics age >20	Nurse-managed diabetes clinic in a hospital in East Harlem, NY City	Program completion, knowledge levels, self-care practices, HbA1c	1-15
5.	DCCT Research Group, 1995	Intensive glucose control compared to conventional treatment	1,441 insulin-dependent diabetics aged 13-39	29 centers in the US and Canada	Adherence to treatment regimens, HbA1c values, and complications	1-16
6.	Feder G, 1995	Medical education and prompting system	National health service diabetics age >16	24 primary care practices in London, England	Fundoscopy, blood glucose, weight, blood pressure, smoking, foot exam, HbA1c	1-17
7.	Fox CH, 1998	CQI program: developed consensus guidelines, audited charts, fed back results, improvement plan, re-audited	African American, indigent diabetics	Family Practice Residency Program, Deaconess Family Medicine Center, Buffalo, New York	Foot exam, HbA1c, kidney assessment, diet, exercise, foot care, flu & pneumovax immunization, eye exam	1-18
8.	Friedman NM, 1998	Physician guideline education and profiling; patient education, improved access to care, and reminder system	Health plan enrollees ages 31 to 64	Lovelace Health Care System (HMO), Albuquerque, New Mexico	HbA1c, eye exams, access to education	1-19
9.	Glasgow RE, 1992	Patient education: diet, exercise, and blood glucose monitoring	102 NIDDM patients responsible for self-care, age >60	Outpatient settings, Eugene, Oregon	Weight, HbA1c, quality of life, self-care behaviors	1-20
10.	Glasgow RE, 1997	Variety of dietary patient education methods including computer touch screen and videotapes	206 diabetics from primary care internal medicine practices	Internal medicine offices, Eugene, Oregon	Food habits, calories per day, fat intake, body mass index, cholesterol, and HbA1c	1-22

Abstract Number	First Author & Year	Interventions	Patients	Setting	Measures	Page Number
11.	Greenfield S, 1998	Patient education on how to interact with their physician	73 diabetics meeting inclusion criteria from two outpatient clinics	University general medicine and diabetes outpatient clinics, Los Angeles, California	HbA1c, quality of life measures, and number of questions patients asked physicians	1-24
12.	Greenfield S, 1985	Patient training on medical information seeking	200 patients with peptic ulcers	Outpatient clinic, Wadsworth/Veterans Administration Hospital, Los Angeles, California	Length of visits and types of interactions in visits	1-25
13.	Gruesser M, 1993	Training physicians and office staff to provide diabetes patient education	Subjects were 139 physicians and their office staff; measurement was based on records from 139 diabetic patients	Physician offices in Hamburg, Germany	Physician ratings of training course contents and materials; patient data: weight, HbA1c, medication use, and self-monitoring.	1-26
14.	Ho M, 1997	Comparison of clinic specifically staffed to provide care to diabetics to a general medicine clinic	112 male diabetics	West Los Angeles VA Medical Center outpatient clinics	Cardiac system assessment, glucose self-monitoring, blood pressure, foot exam, eye exam, HbA1c	1-27
15.	Hurwitz B, 1993	Patient reminder system	181 diabetic outpatients	Physician offices in Islington, England	Office visits, eye exams, lab tests, and continuity of care	1-28
16.	Jaber LA, 1996	Pharmacist case management	45 African American diabetics	Outpatient clinic, Wayne State University, Detroit, Michigan	Fasting plasma glucose and glycosylated hemoglobin	1-29
17.	Koperski M, 1992	Establishing a "diabetic day" in a general practice	111 diabetic patients	Seven physician general practice in London, England	Weight, HbA1c, blood glucose, eye exam, blood pressure	1-30
18.	Levetan CS, 1995	Use of an inpatient diabetes care team	104 inpatients with a principal diagnosis of diabetes	Beth Israel Medical Center, NY City	Average length of stay	1-31
19.	Litzelman DK, 1993	Patient and provider foot care education and reminders	395 outpatients with NIDDM	General medicine practice, Regenstrief Institute for Health Care, Indianapolis, Indiana	Patient self-care, amputations and other foot-related physical findings	1-32
20.	Malone JM, 1989	Patient foot care education	203 diabetic patients with a history of foot problems	Podiatry and vascular surgery clinics at the Tucson VA Medical Center	Amputations, ulcerations, and infections	1-34
21.	McCulloch DK, 1998	Computerized diabetic registry, guidelines, patient education, practice re-design, and use of a diabetes care team	15,000 diabetics enrolled in an HMO	Group Health Cooperative of Puget Sound, a staff model HMO in Seattle, Washington	Provider satisfaction, eye exams, foot exams, HbA1c	1-35

Abstract Number	First Author & Year	Interventions	Patients	Setting	Measures	Page Number
22.	McDowell I, 1989	Patient and physician reminders	8,296 outpatients	Family Medicine Center, Ottawa Civic Hospital, Canada	Blood pressure checks	1-36
23.	Meneghini LE, 1998	Electronic case management system for patients	184 diabetics	Diabetes center, University of Miami, Florida	System use, diabetic crises, clinic visits	1-38
24.	O'Connor PJ, 1998	Study of utilization and outcomes of diabetics having/not having a regular provider of care	Adult diabetics enrolled in an HMO	HealthPartners, an HMO in Minneapolis, Minnesota	Diet, self-monitored glucose, HbA1c tests, foot exams, eye exams, cholesterol checks, HbA1c levels	1-39
25.	Peters AL, 1995	Nurse case management, diabetes team, protocols, electronic reminder system	754 diabetics in a capitated plan	An IPA affiliated with the Cedars Sinai Medical Center in Los Angeles, California; serves 22 HMOs	HbA1c and hospital admission rates	1-40
26.	Rith-Najarjian SJ, 1992	Identify patients at high risk for foot problems	358 diabetic Native Americans	An Indian Health Service primary care clinic at Red Lake, Minnesota	Ulcerations and amputations	1-42
27.	Ronnemaa T, 1997	Foot care and patient education provided by podiatrists	733 diabetics	Outpatient clinics in Turku, Finland	Patient foot care knowledge and self care	1-43
28.	Smith SA, 1998	Use of the diabetes electronic management system (DEMS)	82 diabetic outpatients	Outpatient diabetes clinic, Mayo Clinic, Rochester, Minnesota	Blood pressure, foot exams, eye exams, lab tests, diet, smoking cessation counseling	1-44
29.	Smith DM, 1986	Patient education and reminders	859 diabetics on antidiabetic agents	General medicine practice, Regenstrief Institute for Health Care, Indianapolis, Indiana	Kept appointments, prescription refills, number of contacts	1-46
30.	Vinacor F, 1987	Physician and patient education	532 diabetics meeting inclusion criteria	General medicine practice, Regenstrief Institute for Health Care, Indianapolis, Indiana	Glycemic control, weight, blood pressure	1-48
31.	Weinberger M, 1995	Telephone calls by nurses to patients for education and appointment reminders	275 diabetics meeting inclusion criteria	Durham Department of Veterans Affairs Medical Center, North Carolina	HbA1c, blood glucose, quality of life (SF-36), self-reported symptoms	1-50
32.	Wing RR, 1996	Behavioral therapy compared to other diet programs	163 diabetic outpatients	University of Minnesota and University of Pittsburgh	Weight, dietary patterns, knowledge, physical activity	1-52

Summary Table Two

Interventions by Category

Abstract Number	First Author & Year	Self Management Support	Delivery System Change	Decision Support	Information Systems	Page Number
1.	Agurs-Collins TD, 1997	Nutrition and exercise education				1-12
2.	Aubert RE, 1998	12 hr. diabetes education program	Nurse case management	Patient management algorithms	Follow-up calls to patients	1-13
3.	Carlson A, 1991		Reorganized care process	CME for physicians		1-14
4.	Corkery E, 1997	Use of a bicultural community health worker				1-15
5.	DCCT Research Group, 1995		Intensive glucose control			1-16
6.	Feder G, 1995			Physician education on practice guidelines	Physician prompting system	1-17
7.	Fox CH, 1998			Developed internal guideline; audit and feedback system		1-18
8.	Friedman NM, 1998	Patient education	Improved patient access to care	Physician education on practice guidelines	Patient reminder system, patient profile screens	1-19
9.	Glasgow RE, 1992	Patient education: diet, exercise, and blood glucose monitoring				1-20
10.	Glasgow RE, 1997	Variety of dietary patient education methods including computer touch screen and videotapes				1-22
11.	Greenfield S, 1998	Patient education on how to interact with their physicians				1-24
12.	Greenfield S, 1985	Patient training on medical information seeking				1-25
13.	Gruesser M, 1993	Training physicians and office staff to provide diabetes patient education				1-26

Abstract Number	First Author & Year	Support	Delivery System Change	Decision Support	Clinical Information Systems	Page Number
14.	Ho M, 1997		Comparison of 1) a clinic specifically staffed to provide care to diabetics to 2) a general medicine clinic			1-27
15.	Hurwitz B, 1993				Patient reminder system	1-28
16.	Jaber LA, 1996		Pharmacist case management			1-29
17.	Koperski M, 1992		Establishing a "diabetic day" in a general practice			1-30
18.	Levetan CS, 1995		Use of an inpatient diabetes care team			1-31
19.	Litzelman DK, 1993	Patient foot care education		Provider foot care education	Patient reminder system	1-32
20.	Malone JM, 1989	Patient foot care education				1-34
21.	McCulloch DK, 1989	Patient education	Practice re-design, use of a diabetes care team	Physician guideline education	Computerized diabetic registry	1-35
22.	McDowell I, 1989				Patient and physician reminders	1-36
23.	Meneghini LE, 1998	Electronic case management system for patients				1-38
24.	O' Connor PJ, 1998		Continuity of diabetes care			1-39
25.	Peters AL, 1995		Nurse case management, use of a diabetes team	Diabetes care protocols for case managers	Electronic reminder system	1-40
26.	Rith-Najarian SJ, 1992				Risk stratification system for foot care	1-42
27.	Ronnema T, 1997	Foot care education	Foot care and patient education provided by podiatrists			1-43
28	Smith SA, 1998				Diabetes electronic management system (DEMS)	1-44
29.	Smith DM, 1986	Patient education			Patient reminders	1-46

Abstract Number	First Author & Year	Self Management Support	Delivery System Change	Decision Support	Clinical Information Systems	Page Number
30.	Vinacor F, 1987	Patient self-management education		CME; protocols	Physician reminders	1-48
31.	Weinberger M, 1995	Patient education	Using nurses for patient education		Patient reminders	1-50
32.	Wing RR, 1996	Behavioral therapy and diet programs				1-52

Abstract Number: 1

Agurs-Collins TD, Kumanyika SK, Ten Have TR, Adams-Campbell LL. A randomized controlled trial of weight reduction and exercise for diabetes management in older African American subjects. *Diabetes Care* 1997;20:1503-11.

Objective: To evaluate a weight loss and exercise program designed to help improve diabetes management in older African-Americans.

Design: Randomized trial.

Setting: The study was held at an urban hospital in an African-American community in Washington DC

Patients: African-American men and women aged 55 years or older with a diagnosis of non-insulin-dependent diabetes mellitus (NIDDM) by medical history were eligible for the study if they were $\geq 120\%$ of metropolitan weight standards, had HbA1c levels $>8\%$, were ambulatory, and had no medical contraindications to program participation.

Sixty-four patients were randomized, 58 (91%) completed the 3-month visit and 55 (88%) completed the 6-month visit. The age range was 55-79 years (mean 62.4 ± 5.9 years for intervention group and 61.0 ± 5.7 years for usual care group). Most participants were women, unemployed, nonsmokers, and had completed high school.

Interventions: The intervention involved 12 weekly group sessions with 60 minutes of nutrition education followed by 30 minutes of exercise. Each participant also had one individual diet counseling session. After the initial 12 weeks, six biweekly group sessions were held. These sessions were 90 minutes in length and involved more sharing and problem solving than diabetic instruction. Both interventionists were African-American; one was a registered dietician and the other an exercise physiologist.

The control (usual care) group attended one class related to methods of glycemic control and received two mailings of nutrition information at 3 and 6 months.

Main outcome measures and results: Significant net differences in the intervention versus usual care were observed for weight (-2.0 kg, $p=0.006$), physical activity, and dietary intake of fat, saturated fat, and cholesterol, and dietary knowledge at 3 months ($p<0.05$) and for weight at 6 months (-2.4 kg, $p=0.006$) and mean HbA1c values at 3 and 6 months (respectively, -1.6 and -2.4% both $p<0.01$). After the adjustment for changes in weight and activity, the intervention participants were approximately twice as likely to have a one unit decrease in HbA1c value as those in usual care. Blood pressure increases in usual care participants resulted in net differences (intervention minus control) at 3 and 6 months of -3.3 ($p=0.09$) and -4.0 ($p=0.05$) mmHg diastolic, respectively and -8.4 ($p=0.06$) and -5.9 ($p>0.10$) mmHg systolic, respectively. Blood lipid profiles improved more in intervention than usual care participants, but not significantly.

Conclusions: The intervention program was effective in improving glycemic and blood pressure control. The decrease in HbA1c values was generally independent of the relatively modest changes in dietary intake, weight, and activity which may reflect indirect program effects on other aspects of self care.

Abstract Number: 2

Aubert RE, Herman WH, Waters J, Moore W, Sutton D, Peterson BS, Bailey CM, Koplan JP. Nurse case management to improve glycemic control in diabetic patients in a health maintenance organization. *Annals of Internal Medicine* 1998;129:605-12.

Objective: To compare diabetes control in patients receiving nurse case management and patients receiving usual care.

Design: Randomized controlled trial.

Setting: This study took place in Jacksonville, Florida at two large clinics in the largest health maintenance organization (HMO) in the city. The HMO, Jacksonville Health Care Group, has 43 physicians in eight clinics and more than 75,000 plan members.

Patients: Of the 545 patients listed on the diabetes register, 138 were randomized and 100 of these provided 12-month follow up data. Patients were ineligible for the study if they had a recent HbA1c < 7.0%, had uncontrolled hypertension (>180/110), had unstable angina, had experienced a myocardial infarction in the past 3 months, had two or more seizures, had alcoholism or drug abuse documented, had late stage complications of diabetes or other chronic conditions, were pregnant or planning to become pregnant in the next twelve months, or were unable to perform self management.

The baseline demographic characteristics of the study participants were similar for most characteristics, but the intervention group had fewer ethnic minorities, more smokers, and more insulin-treated patients.

Interventions: The nurse case manager (NCM), a registered nurse and certified diabetes educator, was trained to follow a set of detailed management algorithms under the direction of a family medicine physician and an endocrinologist who were responsible for all diabetes management decisions. Each participant had a 45-minute initial visit and a 2-week follow-up visit to review the patient's blood glucose log. These patients were also referred to a 5-week 12-hour diabetes education program that included individual counseling by a dietician and an exercise therapist. Patients on insulin received weekly follow-up calls.

Patients in the usual care group were given blood glucose meters and strips and were encouraged to discuss enrollment in the 5-week diabetes education course with their physician. All care and follow-up was performed by their primary care physician.

Main outcome measures and results:

Mean Change Scores of Outcome Variables by Treatment Group

Variable	NCM	Usual Care	Difference (95%CI)	p value
HbA1c	-1.70	-0.6	-1.1 (-1.62 to 0.58)	<0.001
Mean FBG	-48.30	-14.5	-33.8 (-56.12 to 11.48)	0.003
Weight	-0.21	-0.4	-0.19 (-1.6 to 2.0)	>0.2
Serum cholesterol	-11.90	-7.2	-4.7 (-21.54 to 12.14)	>0.2
Systolic BP	1.90	6.1	-4.2 (-9.8 to 1.41)	>0.2
Diastolic BP	-0.80	-0.4	-0.19 (-1.6 to 2.0)	>0.2
Health status score	0.47	0.2	0.27 (-0.03 to 0.57)	0.02

Conclusions: This study shows that a nurse-implemented diabetes management program, directed by a primary care physician and an endocrinologist and implemented in a group model HMO setting, can help patients achieve near normal glycemic control.

Abstract Number: 3

Carlson A, Rosenqvist U. Diabetes care organization, process, and patient outcomes: effects of a diabetes control program. *The Diabetes Educator* 1991;17:42-8.

Objective: This study was conducted to evaluate the Diabetes and Education Training Unit's (DETU) effect on the organization and process of diabetic care and on patient's health and well-being.

Design: Randomized controlled trial.

Setting: Primary health care centers in Sweden.

Patients: Patients who had visited the primary health care centers in the 12 months prior to evaluation made up the sample. Care was evaluated at 34 centers with a total of 4,492 patients. Five hundred and sixty-six of these patients were randomly selected to participate in completing a questionnaire and blood test.

Interventions: The DETU developed an implementation strategy that combined continuing medical education (CME) and organizational development (OD) measures to improve diabetes management in primary care.

Diabetes care was evaluated at primary health care centers that either had been exposed to the combined CME-OD program for 18 months (17 centers—intervention) or were about to enter the program (17 centers—control). Specific data were collected from each patient's case record along with the questionnaire and HbA1c measurement from the randomly selected sample.

Main outcome measures and results: Significant differences were found between the two groups of centers (intervention vs. control) in the following areas: patient's height noted in case notes (73%, 50% $<$ 0.01), HbA1c value measured (27%, 8%, $<$ 0.001), and eye examination performed during the previous year (40%, 28%, $<$ 0.01). In addition, patients from the intervention group of health centers reported significantly more self-monitoring of blood glucose than the control group (37% and 23%, respectively). There were no differences found between the two groups regarding access to care or its continuity, patient education, or dietary knowledge. The two groups of patients also had a similar degree of metabolic control, with mean HbA1c values 8.2 ± 1.8 (intervention) and 7.8 ± 1.6 (control).

Conclusions: Findings showed that patients from the intervention centers received a higher quality of service and monitored their blood glucose levels more often than did patients from the control centers. However, they did not demonstrate significantly better metabolic control. One explanation for the weak correlation between the organization of care and quality of service and the patient's degree of metabolic control, as assessed by HbA1c values, may be that the evaluation was made too soon after the intervention.

Abstract Number: 4

Corkery E, Palmer C, Foley ME, Schechter CB, Frisher L, Roman S. Effect of a bicultural community health worker on completion of diabetes education in a Hispanic population. *Diabetes Care* 1997;20:254-7.

Objective: To determine the effect of a bicultural community health worker (CHW) on completion of diabetes education in an inner-city Hispanic patient population and to evaluate the impact of completion of the education program on patient knowledge, self-care behaviors, and glycemic control.

Design: Randomized trial.

Setting: The study took place in a nurse-managed diabetes management clinic (DMC) at a tertiary care teaching hospital in New York City serving the community of East Harlem. East Harlem is composed mainly of Hispanic-American and African-American residents and is characterized by high unemployment and low formal educational attainment levels.

Patients: Eligible patients were Hispanic-Americans who were newly referred to the DMC for patient education and were >20 years old. A total of 64 patients were enrolled in the study, with a mean age of 52.8 ± 11.7 years. Seventy-four percent were women and 75% identified Puerto Rico as their country of origin. Twenty-six percent spoke fluent English, 25% spoke only Spanish and the remainder spoke primarily Spanish.

Interventions: During the study period, the CHW, a bicultural, bilingual Hispanic-American of Puerto Rican heritage who lived in East Harlem, acted as a liaison between the patients, their families, and health providers for the CHW intervention group. The CHW attended clinic sessions with assigned patients and served as a Spanish interpreter, reinforced self-care instructions, reminded patients of upcoming appointments, and rescheduled missed appointments.

For the control group, encounters took place only between the nurse and the patients, and in some cases, the family member.

Main outcome measures and results: Of the 64 patients enrolled, 40 (63%) completed the program. Of the patients having the CHW intervention, 80% completed the education program, compared with 47% of controls ($p=0.01$). For the program completers, knowledge levels significantly improved, with the mean knowledge pretest score being 74.4% and the mean post-test score, 95.4% ($p<0.001$). Selected self-care practices, such as following a meal plan, carrying fast-acting sugar, and performing daily foot care, also significantly improved ($p=0.013$, $p<0.001$, and $p<0.001$, respectively). Glycohemoglobin levels improved from a baseline of 11.7% to 9.9% at program completion ($p=0.004$) and 9.5% at the post program follow-up ($p<0.001$).

The effect of the CHW assignment on program completion, controlling for financial status and language spoken, was also significant ($p=0.007$). The effect of the CHW on knowledge, self care behavior, or glycohemoglobin outcome variables was not statistically significant.

Conclusions: These findings suggest that intervention with a bicultural CHW improved rates of completion of a diabetes education program in an inner-city Hispanic patient population irrespective of literacy or educational levels attained.

Abstract Number: 5

Diabetes Control and Complications Trial Research Group. Implementation of treatment protocols in the diabetes control and complications trial. *Diabetes Care* 1995;18:361-76.

Objective: To describe the methodologies utilized to implement intensive and conventional therapies utilized in the study.

Design: The Diabetes Control and Complications Trial (DCCT) that this discussion is based upon was a randomized, controlled clinical trial that showed that intensive insulin therapy positively impacted the long-term complications of insulin-dependent diabetes mellitus.

Setting: University-based, multi-centered (29 centers in the U.S. and Canada) study.

Patients: 1,441 individuals with insulin-dependent diabetes mellitus between the ages of 13-39 years.

Interventions: Individuals were randomly assigned to either intensive or conventional therapy. All individuals were assigned to a treatment team consisting of a nurse, a physician, and a dietician. And in most centers regular meetings with a mental health professional (i.e., social worker, psychologists, psychiatrist) was incorporated into the treatment plan.

Conventional treatment group—The primary goal for the conventional treatment group was to prevent symptoms due to hypoglycemia or hyperglycemia, to prevent ketonuria and to maintain normal growth and development. They received conventional diabetes education, nutrition counseling, and advice on insulin administration. Each center instructed their patients based on locally developed programs and methods. These patients received up to two injections of insulin (any mixture) and were seen every three months by their team.

Intensive treatment—The primary goal of this group was to achieve and maintain glycemic control as close to nondiabetic range while minimizing severe hypoglycemia. They received a more comprehensive program including flexible adjustment of insulin dose, frequent monitoring of glucose levels and diet, and behavior change. Insulin was given either as a continuous subcutaneous insulin infusion or with multiple daily injections (i.e., at least 3 shots). At enrollment, patients were hospitalized for 2-4 days and taught the use of the insulin pump or how to give daily injections, to measure and record blood glucose levels, and to use monitoring data to adjust insulin regimens. These patients were seen weekly until they were comfortable with their regimen, and then monthly.

Main outcome measures and results:

Conventional Treatment Group

- Glycemia—median HbA1c was 9.0% at feasibility phase and remained between 8.9 and 9.0% throughout the study except for one year when it dipped to 8.7%.
- Hypoglycemia and diabetic ketoacidosis (DKA) episodes—19 episodes of severe hypoglycemia per 100 patient-years—DKA occurred between 1-5% of patients per year.

Intensive Treatment Group

- Glycemia—Median HbA1c was lowest during feasibility phase (6.7 and 6.5) and remained between 7.0 and 7.1% during the study except for one year when it was 7.2%.
- Hypoglycemia and diabetic ketoacidosis episodes—62 episodes of severe hypoglycemia per 100 patient-years—DKA occurred in approximately 2% of patients per year.

Conclusions: The DCCT study proved that intensive insulin therapy both statistically and clinically reduced end organ damage. This article highlights the required intensive medical, nursing, dietary, and psycho-social interventions that must occur in parallel with intensive therapy.

Abstract Number: 6

Feder G, Griffiths C, Highton C, Eldridge S, Spence M, Southgate L. Do clinical guidelines introduced with practice-based education improve care of asthmatic and diabetic patients? A randomized controlled trial in general practices in east London. *British Medical Journal* 1995;311:1473-8.

Objective: To determine whether locally developed guidelines on asthma and diabetes disseminated through practice-based education improve quality of care in non-teaching inner-city general practice.

Design: Randomized controlled trial.

Setting: Non-training general medicine practice clinics in east London, England.

Patients: Of 49 non-training general practices in the area, 24 accepted the invitation to participate in this study. The majority of the practices were single practitioner offices (15), with only two having 3 or more partners.

Interventions: The educational intervention consisted of three lunchtime sessions—approved for the postgraduate education allowance—to which all relevant members of the practice were invited. The first session introduced the allocated guidelines and each practitioner was given a prompt stamp or booklet for reviewing asthmatic or diabetic patients. These prompts reflected the content of an annual review consultation for patients with asthma or diabetes as recommended in the guidelines. The second session reviewed the practice’s organizational decisions and focused on the clinical content of the guidelines. The third session took place about six months later and focused on audit data from notes of patients.

The content and delivery of each session was standardized among the four educators, who worked in pairs. Every practice received guidelines for only one condition, asthma or diabetes, and acted as a control for the other condition. The practices were stratified on the basis of practice size, employment of a nurse, deprivation score, number of patients, and existence of asthma and diabetes clinics. The asthma group and diabetes group were similar with respect to stratifying variables.

Size of disease register is a measure of case finding by practices. Changes in the size of disease register were calculated as the ratio of the size after the introduction of the guidelines to the size before.

Main outcomes measures and results: Recording of key variables in patient records varied greatly. Analysis of covariance showed that diabetes practices significantly improved their recording of all variables (see table). In both groups, significant improvements over baseline were found in the recording of three asthma variables. The use of structured prompts was associated with improved recording of 4 of 7 diabetes variables and all of the asthma variables. Sizes of the disease registers were unchanged.

Average Percentage* of Patients with Diabetes Variable Recorded

Variable	Baseline		After One Year		Difference in Proportion (95% CI)
	<i>Asthma Guidelines</i>	<i>Diabetes Guidelines</i>	<i>Asthma Guidelines</i>	<i>Diabetes Guidelines</i>	
Funduscopy		20.5	20	38.1	17.6 (6.9 to 33.9)
Blood glucose		56.8	57.8	75.2	20.6 (6.4 to 33.9)
Weight	37.5	40.4	40	68.1	26.5 (7.7 to 45.4)
Blood pressure	66.1	69.0	58.3	79.5	18.1 (2.8 to 33.4)
Smoking habit	23.2	34.8	31.7	62.4	25.5 (8.7 to 42.3)
Feet examination	28.3	31.4	27.2	51.8	24.7 (7.1 to 42.3)
HbA1c recorded	20.6	24.8	30	48.1	13.8 (1.2 to 26.3)

*Weighted by number of patients sampled in practice.

Conclusions: This study shows that local guidelines disseminated with practice-based education can improve the management of diabetic patients and possibly asthmatic patients in inner city non-training practices. The use of simple prompts may enhance this improvement.

Abstract Number: 7

Fox CH, Mahoney MC. Improving diabetes preventive care in a family practice residency program: a case study in continuous quality improvement. *Family Medicine* 1998;30:441-5.

Objective: This article reviews key results of a continuous quality improvement (CQI) project instituted in a family medicine clinic focusing on non-insulin-dependent diabetes mellitus.

Design: This program utilized a CQI process using 10 key steps.

1. Brainstorming and baseline chart audit—The program used a brainstorming and consensus approach to develop explicit guidelines and then performed a chart audit to determine baseline rates of compliance with these guidelines.
2. Validating criteria—Next, the scientific literature was reviewed to assure that selected guidelines were valid. Key references were the US Preventive Services Task Force guidelines, the Centers for Disease and Control and Prevention guidelines for care of the type II diabetic patient, and performance measures in the Health Plan Employer Data and Information Set (HEDIS).
3. Chart audits—30 records were randomly selected and reviewed quarterly during the first year and every 4 months during the second year.
4. Feedback of results
5. Reexamination of criteria—Changed HbA1c from looking at actual values to determining if it was performed every six months—added foot exam, microalbumin measurement, flu shot and pneumococcal vaccination to the guidelines.
6. Revalidation of modified criteria
7. Re-audit of charts
8. Feedback of results
9. Planning for further improvement
10. Implementation of continuing cycle of process evaluation

Setting: Deaconess Family Medical Center, New York and its family practice residency program.

Patients: Diabetic patients of the clinic, mostly indigent and mostly African-American

Interventions: Implementation of a CQI process focusing on non-insulin-dependent diabetes mellitus and use of a diabetes chart stamp that prompted specific interventions.

Main outcome measures and results: Initial guidelines included 1) diet counseling within the last six months; 2) exercise counseling within the last six months; 3) foot care counseling within the last year; 4) referral to an ophthalmologist within the last year; 5) HbA1c <10% in the last 6 months; and 6) measurement of kidney function in the last year. After the first year, improvement was noted in all criteria. Statistically significant improvement was noted in all but the measurement of kidney function. The degree of improvement was maintained through year two.

The additional guidelines added at the end of year one (i.e., flu shot annually, pneumovax at least once, microalbuminuria, and foot exam) also showed improvement. Statistically significant improvement was noted only for pneumovax.

Conclusions: This is a description of the use of the CQI methodology in a clinic setting to improve diabetes care. This method could be utilized by physicians in solo practice to large group practices. However, the time commitment required of a physician in solo practice could be significant if he or she does not utilize support staff effectively.

Abstract Number: 8

Friedman NM, Gleeson JM, Kent MJ, et al. Management of diabetes mellitus in the Lovelace Health Systems' Episodes of Care program. *Effective Clinical Practice* 1998;1:5-11.

Objective: To implement the Lovelace Diabetes Episodes of Care program in a managed care setting.

Design: Observation study.

Setting: Lovelace Health Care Systems in Albuquerque, New Mexico—an integrated health care delivery system with a staff model and network delivery system.

Patients: Lovelace Health Plan members with type II diabetes.

Interventions: The Lovelace Episode of Care program is a multispeciality diabetes care program. Each team involves an endocrinologist, a primary care provider, a diabetes educator, a registered dietician, a pharmacist, a quality consultant, a case manager, an administrator, and patients. Interventions within the program are divided into physician interventions and patient interventions.

Physician interventions include practice guidelines, medical profile screens, and provider support reports. Guidelines include the diagnosis and initial therapy of type II diabetes mellitus, non-insulin management of type II diabetes mellitus, insulin management of type II diabetes mellitus, diabetic nephropathy screening and follow-up, angiotensin-converting enzyme inhibitor therapy for proteinuria, diabetic retinopathy screening and follow-up, diabetic neuropathy screening, and impotence therapy in diabetic men. The medical profile screens are computerized medical records including treatment summary, diabetes guidelines, and diabetic foot examination criteria. The diabetes provider support report is a quarterly report summarizing a provider's performance in ordering and giving critical tests, examinations, and education on a periodic basis.

Patient interventions include diabetes education, improved access to care, with focused diabetes clinic visits, "Diabetes Days" and reminder systems. Patients are encouraged to participate in comprehensive diabetes education composed of nine education sections. Focused diabetes clinic visits include diet counseling, insulin administration and oral agent use, exercise and education, testing and evaluation of glycemic control, complications screening, insulin reactions and hypoglycemia, assessment of attitudes and barriers to care, and medical care plan. "Diabetes Days" were designed to remove barriers to care by offering a comprehensive 2.5 hour program that includes individual patient visits with physicians, blood tests, dilated eye examinations, diabetes education classes, and group sessions on type II diabetes mellitus. Reminder letters are sent to all patients who have not had an eye exam in the last year.

Main outcome measures and results: Main outcomes include glycohemoglobin values, dilated eye examination rates, and access to education. The glycohemoglobin values in the Health Plan Employer Data & Information Set (HEDIS) sample decreased from 12.2 in 1994 to 10.4 in 1996. Dilated eye examination rates for the HEDIS population improved from 47.3% in 1994 to 53.2% in 1996. In addition, the proportion of the HEDIS population seen by the diabetes educators increased from 52% in 1993 to 78% in 1995.

Conclusions: The Lovelace Diabetes Episode of Care program is a multi-speciality diabetes care program that has shown small but consistent improvement in glycohemoglobin values, routine eye exams, and access to education via a diabetic educator. For the level of effort, the gains are small for HbA1c and eye exams. In addition, they do not link their improvements to pertinent outcomes (i.e., prevention of end organ damage). So the value of the program is difficult to determine.

Abstract Number: 9

Glasgow RE, Toobert DJ, Hampson SE, Brown JE, Lewinsohn PM, Donnelly J. Improving self-care among older patients with type II diabetes: The “Sixty Something” Study. *Patient Education and Counseling* 1992;19:61-74.

Objective: The objective of this study is to describe and evaluate a program to improve diabetes self-care developed specifically for persons with type II diabetes who are over 60 years of age.

Design: Randomized trial.

Setting: The setting of this study is described as “well-known, accessible, pleasant facilities” that were thought to be convenient for the participants. No other descriptors of the physical location were mentioned.

Patients: 102 patients with an average age of 67 years were randomized into the study. There were more females (63.5%—immediate intervention, 62%—delayed intervention). About one quarter of the patients were treated with insulin, another half were on oral medication for diabetes. Eighty-eight percent had other chronic diseases, most commonly arthritis and hypertension (both affecting 44% of subjects).

Eligibility criteria for the program included being 60 years of age or older, being primarily responsible for one’s own self-care, meeting the Welborn et al. clinical criteria for type II diabetes, and not having major complications which would interfere with self-care.

Interventions: The “Sixty Something...” program focused on dietary and exercise health care behaviors, and also included regular blood glucose monitoring. The program was led by an interdisciplinary team including psychologists, a registered dietician, certified exercise leaders, and other unspecified educators. Group meetings of six to twelve participants were held and the emphasis was on developing individualized plans to overcome barriers to adherence, primarily through problem-solving methods.

Groups met weekly for 8 weeks with all participants working on similar goals, followed by two meetings held at 2-week intervals during which participants chose the specific self-care area on which they wished to focus. Twice weekly group exercise (walking) sessions led by a trained exercise leader were held during the middle 8 weeks of the program. Measures were collected at baseline (pre-test), after 3 months (post-test), and at 6 months post-treatment for the delayed intervention group (follow-up).

Main outcomes measures and results:

Measure	Pre-Test Mean and (SD)	Post-Test Mean and (SD)	Follow-Up Mean and (SD)
Weight	188.0 (34.2) 184.5 (34.4)	182.2 (33.9) ^{ab} 185.9 (34.6) ^b	186.1(32.6) ^a 181.0 (34.7) ^a
HbA1c	6.8 (1.6) 7.4 (1.8)	6.3 (1.5) ^a 7.0 (1.5)	6.7 (1.7) 6.4 ^a (1.4)
Diabetes Quality of Life	37.9 (8.8) 36.8 (8.0)	38.2 (7.4) 36.3 (8.0)	38.1 (9.2) 37.2 (7.5)

Bold face type indicates intermediate intervention group

^a Significant improvement ($p < 0.05$) from pretest

^b Significant difference between treatment group

Results on Targeted Self-Care Behaviors

Measure	Pre-Test Mean and (SD)	Post-Test Mean and (SD)	Follow-Up Mean and (SD)
Mean Calories/Day			
Block/NCI	(927.0) 2079.3 (1300.5)	(702.0) 2083.3 (907.7)	(721.7)^a 1745.3 (777.5)
3-Day Food Record	1631.6 (494.6) 1636.1 (412.5)	1468.2 (474.0)^{a,b} 1686.0 (426.7) ^b	1511.6 (432.7) 1413.5 (355.7)
Mean Fat Calories (%)			
Block/NCI*	39.5 (8.9) 41.4 (8.5)	35.9 (7.6)^{a,b} 41.7 (8.0) ^b	37.0 (8.3) 36.4 (7.5) ^a
3-Day Food Record	33.2 (7.2) 34.5 (8.5)	29.0 (6.7)^{a,b} 33.6 (6.0) ^b	29.6 (8.5)^a 29.2 (6.1) ^a
Mean Fiber (g)/Day			
Block/NCI*	19.3 (11.2) 20.8 (14.9)	21.0 (9.3) 19.6 (9.0)	(7.8) 20.1 (9.3)
3-Day Food Record	20.9 (8.8) 19.9 (6.8)	21.7 (10.0) 21.0 (7.1)	20.4 (8.1) 22.0 (7.6)
Number of Days Exercised	4.4 (2.4) 3.7 (2.3)	4.5 (2.0) 3.7 (1.8)	4.4 (2.1) 4.6 (1.9) ^a
Energy Exp. by Weight	3099.6 (762.2) 2900.0 (573.1)	2997.8 (673.5) 2909.7 (557.6)	4227.8 (895.5)^a 2880.1 (615.3)
Activity (min.)/Day	36.3 (5.2) 34.6 (2.1)	36.2 (3.2)^{a,b} 34.5 (2.2)	50.8 (4.7)^a 35.8 (4.6)

Bold face type indicates intermediate intervention group

* Block/NCI refers to the diet history portion of the Health Habits and History Questionnaire from the National Cancer Institute

^a Significant improvement (p<0.05) from pretest

^b Significant difference between treatment group

Conclusions: The “Sixty Something...” program was generally effective in producing behavior change on the measures of dietary intake and glucose testing behavior targeted for intervention. There were not significant increases in dietary fiber intake associated with treatment. Three possibilities for this are noted: 1) the subjects were already closer to the recommended levels of fiber intake at baseline; 2) fiber is a less familiar concept and therefore harder to change; 3) the fiber intervention came at the end of the program when it may have been difficult to make additional dietary changes.

Lack of significant changes in physical activity could have resulted from the fact that the subjects were already fairly active at baseline and further increases would have been unrealistic. It may also be that increasing the activity level among seniors is difficult due to physical barriers (such as arthritis, back pain, etc.) that commonly affect them.

The intervention produced weight losses that were maintained at the 6-month follow-up. However, corresponding glycemic control effects were not significant, which may be due to the complexity and multidetermined nature of glycemic control.

Abstract Number: 10

Glasgow RE, La Chance P-A, Toobert DJ, Brown JE, Hampson SE, Riddle MC. Long term effects and costs of brief behavioral dietary intervention for patients with diabetes delivered from the medical office. *Patient Education and Counseling* 1997;32:175-84.

Objective: The objective was to evaluate results and costs of a personalized, medical office-based intervention focused on behavioral issues related to dietary self-management.

Design: Randomized controlled trial.

Setting: This intervention was evaluated in the office of two primary care internists, part of a large medical group.

Patients: Patients were recruited via letter from physicians and follow-up phone calls from study staff. Two hundred and six patients were randomized within the physician practice. Demographic variables were similar with respect to age (intervention mean 61.7 years, control mean 63.1 years) and gender (63% female in the intervention group and 60% female in the control group). Most of the patients in both groups had type II diabetes, were on insulin, had high cholesterol levels and a variety of medical problems, and had lived with diabetes for over 10 years.

Intervention: All study participants completed a 4-day food record, a background questionnaire, and a clinical assessment including laboratory studies. The control patients received their regular care with reassessments at 3 and 12 months and a touch screen computer assessment.

The intervention participants completed an additional 5-10 minute computer touch screen assessment that focused on dietary barriers. These patients also had a patient-centered goal setting and problem solving session and received dietary self-help materials. Patients with higher self-efficacy levels (based on self rating of ability to achieve goals) received a take-home video that contained strategies to address the most frequent types of barriers experienced. Patients with lower self efficacy levels returned to clinic for a 30-minute interactive video with the same information. This intervention sequence was repeated 3 months later. At 6 months these patients received a phone call and at 9 months they received a book, *The Human Side of Diabetes*.

The cost assessment was based on the incremental costs of the intervention above the costs of the usual care visit.

Main outcome measures and results:

12-Month Outcome Results

Area/Measure	Condition	Baseline	Follow-Up	Significance
Dietary Behavior	Overall	MANCOVA	F(3140)=3.16	p=0.008
Food Habits		2.26 2.20	2.06 2.17	p=0.007*
4-day Food Record				
Kcals per Day		1740 1761	1547 1659	p=0.050
% Fat Cals		33.8 32.9	30.5 32.0	p=0.023
% Sat Fat Cals		11.2 10.8	9.7 10.7	p=0.003
Physiologic Outcomes	Overall	MANCOVA	F(3150)=2.27	p=0.04
BMI		30.4 30.2	30.5 30.4	NS
Serum cholesterol		217 223	208 226	p=0.002
HbA1c		7.9 7.9	7.8 7.8	NS

Bold face print indicates intervention group results

*Significance comparing treatment and control follow up scores adjusted for baseline scores

Costs for the delivery of the intervention as implemented in this study totaled \$14,755 or \$137 per participant. The marginal costs per unit improvement in the outcomes was \$62 per reduction of each percent in dietary fat, \$105 per each percent reduction in saturated fat, and \$8 per each mg/dl reduction in serum cholesterol.

Conclusions: Long-term impacts on both dietary behaviors and serum cholesterol levels at one year follow-up were seen in this study. There was no overall improvement in weight and HbA1c in the intervention group relative to the usual care group. Several factors may have obscured the relationship between behavior change, weight and glycemic control. These include the presence of 22% type I diabetics, use of insulin by the majority of subjects, the arrival of metformin in the US during the study period, inclusion of many patients who were not overweight and many with good glycemic control at entry, and the wide range of duration of diabetes.

The intervention was relatively low-cost and cost-effective for producing improvements in dietary behavior and in serum cholesterol.

Abstract Number: 11

Greenfield S, Kaplan S, Ware J, Yano E, Frank H. Patients' participation in medical care: effects on blood sugar control and quality of life in diabetes. *Journal of General Internal Medicine* 1998;3:448-57.

Objective: The purpose of this paper is to describe an intervention developed to increase the involvement of diabetic patients in medical decision making.

Design: Randomized controlled trial.

Setting: The study was conducted in two university hospital outpatient clinics. One clinic was devoted exclusively to diabetes treatment and the second was a general medicine clinic.

Patients: Seventy-three patients were randomized into the experimental or control group at the beginning of the study. These patients came from a pool of all the diabetic patients in the two clinics, of which 98 met the criteria. Patients were excluded if they were over 75 years old, blind, non-English speaking, on an insulin pump, or had any disease that would reduce the effectiveness of their diabetes management.

Interventions: The intervention was conducted during the waiting time immediately preceding the patient's visit. During the intervention session, the patient was helped to identify relevant medical issues likely to arise at that visit. The focus was on treatment issues that could be affected by life-style changes. Negotiation skills were also reviewed and patients were encouraged to ask focused questions of their physician. The patients then rehearsed simple techniques for overcoming obstacles to interaction with the physician, such as embarrassment, forgetfulness and intimidation.

The patients in the control group also visited a research assistant immediately prior to a scheduled visit. During these sessions, standard educational materials were reviewed and problems with adherence to treatment regimens were discussed according to guidelines recommended by the diabetes patient educators.

Conversations during baseline and two post-intervention patient-physician visits for each patient were recorded on audiotape and coded using a validated coding scheme.

Main outcome measures and results: The post intervention glycosylated hemoglobin mean of the experimental group differed significantly from that of the control group, which did not change from baseline.

Effects of Intervention on Glycosylated Hemoglobin (%)

	Experimental Group	Control Group	Mean Difference (95% CI)
Before Intervention	10.59	10.26	0.33 (-0.74, 1.40)
After Intervention	9.06 ^a	10.61	-1.55 ^b (-0.49, -2.61)

^a p<0.01 for experimental group mean before and after intervention

^b p<0.01 for experimental group mean vs. control group mean after intervention

Experimental group patients asked an average of 1.04 ± 3.86 questions per minute at the follow-up visit compared with 0.30 ± 0.25 for controls. This difference was not significant due to large standard deviation observed in the experimental group. The total numbers of controlling behaviors (including questions, interruptions, and directions) were significantly greater among experimental group patients following the intervention than the controls (means 2.72 ± 0.82 and 0.55 ± 0.53 , respectively). Sixteen percent of the total conversation of experimental group patients was characterized as controlling compared with 5% for controls.

Mean differences in the health related quality of life were noted on three of four of the indices related to functional limitations. There was no statistically significant difference between control and experimental groups before or after the intervention in patient satisfaction or in knowledge of disease.

Conclusions: The authors conclude that the intervention is feasible and that it changes patient behavior, improves blood sugar control, and decreases functional limitations.

Abstract Number: 12

Greenfield S, Kaplan S, Ware J. Expanding patient involvement in care: effects on patient outcomes. *Annals of Internal Medicine* 1985;102:520-8.

Objective: Assess the impact of increased patient involvement in care on outcomes and patient satisfaction.

Design: Randomized controlled trial.

Setting: The Center for Ulcer Research and Education, an outpatient clinic at the Wadsworth Veterans Administration Hospital in Los Angeles, California between September 1980 and October 1981. The clinic held weekly meetings with a staff of eight physicians.

Patients: Approximately 200 patients with peptic ulcer disease were seen at the clinic. Patients were eligible for the study if they had a visit with a clinic physician within the previous 6 months, had no record of psychological problems, could read English, and were under the age of 75 years. Only 87 patients were eligible and only 51 made clinic visits during the enrollment period. Five refused to participate and 1 was hospitalized during the study. The remaining 45 composed the study group. This group was 91% male, mean age of 55 years, mean years of education was 13, 47% were employed, and the median yearly income was \$13,000 dollars.

Interventions: The intervention for the experimental group was designed to instruct patients about the logic of the medical care process and to improve their information-seeking skills. The intervention included a review of the patient's record, a review of a treatment algorithm for chronic ulcer disease, and a behavior-change strategy designed to increase patient involvement in the physician-patient interaction.

The control group received an educational session of similar length that covered information about causes of ulcer disease, its complications, and treatments. Also they reviewed a diagram of the gastrointestinal tract.

Main outcome measures and results: Effects on physician-patient interaction—There was no difference in length of visits between treatment and control groups. There were differences in interaction during the visits. For example, there was a statistically significant 30% increase in patient conversation in the experimental group. In addition, patients in the intervention group were significantly more likely to attempt to direct the flow of communication and the physician's behavior during the visit. Last, patients in the intervention group elicited significantly more factual statements from the physician.

Effects on patient's functional ability—Patients in the experimental group noted significantly fewer physical and role limitations.

Conclusions: This study, performed in 1980-1981 gives evidence that patients prefer an active involvement in their care. This involvement results in altered patterns of patient-physician interactions. In addition, it results in the patient reporting fewer limitations in activity or roles. It is important to note that to move a patient from a more passive to a more active role required a 20 minute training session just prior to the physician visit. In addition, there is no long term follow-up to determine if the 20-minute intervention had any long lasting impact.

Abstract Number: 13

Gruesser M, Bott U, Ellermann P, Kronsbein P, Joergens V. Evaluation of a structured treatment and teaching program for non-insulin-treated type II diabetic outpatients in Germany after the nationwide introduction of reimbursement policy for physicians. *Diabetes Care* 1993;16:1268-74.

Objective: To evaluate the practicability and efficacy of a structured treatment teaching program for non-insulin-treated type II diabetic patients in routine primary health care.

Design: Before-after descriptive study.

Setting: This study took place in Hamburg, Germany in the offices of physicians who had participated in a special diabetes management training course.

Patients: The study subjects were 139 physicians and their staff along with a random sample of 179 patient charts from 17 of the offices.

Interventions: The training course for office-based physicians followed guidelines developed by the German Diabetes Association Committee for Patient Education and Postgraduate Training. The doctors and staff were informed about the objectives, content and organization of the program and role-playing techniques were used. In addition, the office staff received training in basic methods of adult education. The physicians received remuneration for enrolling their patients in the patient education program if this training program was completed.

The patient education program is composed of 4 sessions per week and the bulk of patient teaching is conducted by the physician's office staff. The curriculum covers 9 areas of patient education: basic information, metabolic self-monitoring, causes of elevated blood glucose levels, oral hyperglycemic agents, diet, foot care, physical activity, sick day rules, and late complications.

A standardized interview was conducted with 127 (91%) of the 139 physicians who had participated in the training course. The interviews were conducted approximately 12 months after training course completion.

Specific data were collected from the charts of the 17 randomly selected offices, representing 179 patients. The mean patient age was 67 ± 9.6 years; 65% were female with a 7.4 ± 6.3 year history of diabetes.

Main outcome measures and results: The scientific and educational content of the training course was rated positively by the interviewed physicians: 122 (96%) rated the content as good and useful; 2 (1.6%) reported that they learned nothing new and 3 (2.4%) rated the content as poor or useless. One hundred nineteen physicians (94%) rated the teaching material as very good or good with no suggestions for improvement, while 8 (6%) suggested changes or additional materials.

The data collected on the 179 patients from the 17 randomly selected offices demonstrated the efficacy of the program at the treatment level. The data, collected 5.1 months on average after the intervention, showed reduction of body weight (mean 2.8 kg, <0.0001) and HbA1c levels (from 8.11 ± 1.68 to $7.47 \pm 1.64\%$, <0.0001). The individual prescribed volume of oral antidiabetic agents was 50% lower after patient attendance in the program (decrease from 1.41 ± 1.42 to 0.76 ± 1.11 tablets/patient/day, <0.0001). The proportion of patients treated with oral antidiabetic drugs decreased from 63% to 42% (<0.0001). The number of patients who performed ≥ 1 urine test for glycosuria per week rose from 5 patients before the program to 158 after the program.

Conclusions: After the introduction of nationwide remuneration of outpatient education for type II diabetic patients by office-based physicians, a relevant improvement was observed in the quality of care.

Abstract Number: 14

Ho M, Yip I, Marger M, et al. Is the quality of diabetes care better in a diabetes clinic or in a general medicine clinic? *Diabetes Care* 1997;20:472-5.

Objective: To compare the quality of ambulatory diabetes care in the diabetes clinic versus care provided in the general medicine clinic of a university-affiliated Veterans Administration (VA) medical center.

Design: Retrospective medical record review.

Setting: The West Los Angeles VA Medical Center which serves over 35,000 patients annually. Two ambulatory clinics serve diabetic patients: the general medicine clinic (GMC) is staffed by faculty internists, medical fellows, medical residents, and nurse practitioners, while the diabetes clinic (DC) is staffed by faculty diabetologists, endocrine fellows, medical residents, a diabetic nurse educator, a podiatrist, and an optometrist.

Patients: Male diabetes patients with a mean age of 61 years in the DC and 65 years in the GMC. Patients had been diagnosed with diabetes for 12-13 years on average with over half on insulin therapy. No clinically important differences were found between patients seen at either clinic. A total of 112 cases were randomly selected, half of which came from each clinic.

Interventions: None. This study compared two clinics with different staffing mixes, referral systems, and staff training.

Main outcome measures and results:

Criteria	GMC (n=56) Compliance	DC (n=56) Compliance	Significant Difference
Cardiac Systems Inquiry	46%	29%	*
Self-Monitored Blood Glucose Record	52%	77%	*
Blood Pressure Measurement Each Visit	98%	96%	
Foot Exam Each Visit	48%	86%	*
Eye Exam Annually	71%	89%	*
Hemoglobin A1c Annually	84%	100%	*

*p≤0.05

Conclusions: If primary care physicians are to provide high quality care for diabetics, they must: 1) have current education on monitoring and treatment; 2) provide referrals to relevant specialists such as podiatrists, eye care professionals, and diabetes educators; and 3) improve their clinics' patient management systems.

Abstract Number: 15

Hurwitz B, Goodman C, Yudkin J. Prompting the clinical care of non-insulin dependent (type II) diabetes patients in an inner city area: one model of community care. *British Medical Journal* 1993; 306: 624-30.

Objective: To evaluate the effectiveness and acceptability of centrally organized prompting for coordinating community care of non-insulin dependent diabetic patients.

Design: Randomized controlled trial.

Setting: This study took place in two hospital outpatient clinics, 38 general practices, and 11 optometrists' offices in Islington, England

Patients: Out of 570 diabetic patients registered with the hospital clinics, 181 patients were randomized into the study. The study aimed to include mobile non-insulin dependent diabetic patients under age 80, who had attended the district general hospital diabetic clinics in the previous two years. Women of childbearing age and patients with one or more significant complications of diabetes were excluded.

Interventions: Eighty-nine patients were allocated into the intervention group and 92 patients served as controls. The hub of the prompting system was a database which sent requests to patients asking them to provide blood and urine samples for random plasma glucose, glycated hemoglobin, and albumin estimations. These samples were taken by a practical nurse at a health center or hospital convenient for the patient. The results were sent to the patients with a request to take them to their general practitioner within 10 days. This prompting occurred every six months, with the total study period being 2 years and 6 months.

Main outcome measures and results:

Process outcomes: Fourteen control patients failed to receive a single review during the study period, compared with 3 patients in the prompted group ($\chi^2=6.1$, $df=1$, $p=0.013$). Follow-up for retinal screening was better in prompted patients than in controls, with 2 prompted patients defaulting vs. 12 controls ($\chi^2=6.9$, $df=1$, $p=0.008$). Annual rate of test for albuminuria, plasma glucose estimations, and glycated hemoglobin estimations were more frequent in prompted patients (3.0 vs. 2.3, $p=0.03$; 3.1 vs. 2.5, $p=0.003$; and 2.4 vs. 0.9, $p<0.001$, respectively). Continuity of care was also better in the prompted group with 3.2 reviews by each doctor vs. 2.2 in the controls ($p<0.001$).

Medical outcomes: No significant differences were seen between groups in random plasma glucose concentrations, glycated hemoglobin values, hospital admissions for diabetes, or number of deaths.

Conclusions: Semi-annual prompting reminders to non-insulin dependent diabetic patients for care by inner city general practitioners and optometrists is a cost-effective method for improving monitoring and continuity of care.

Abstract Number: 16

Jaber LA, Halapy H, Fernet M, Tummalapalli S, Diwakaran H. Evaluation of a pharmaceutical care model on diabetes management. *The Annals of Pharmacotherapy* 1996;30:238-43.

Objective: To assess the effectiveness of a pharmaceutical care model on the management of non-insulin dependent diabetes mellitus (NIDDM) in urban African-American patients.

Design: Randomized trial.

Setting: The study was carried out in a university-affiliated internal medicine outpatient clinic.

Patients: Forty-five patients were recruited and randomized from a review of 891 medical charts for urban African-American patients with NIDDM. The intervention group contained 17 patients, majority female with an average age of 59 ± 12 years. The control group contained 22 patients, also majority female, with an average age of 65 ± 12 years.

The criteria for exclusion included insulin dependence, renal dysfunction, hepatic disorder, significant cardiac complications within 6 months, mental incompetence, or a history of noncompliance with regular clinic visits.

Interventions: For the intervention group, all diabetes related management aspects were solely provided by a pharmacist and included diabetes-specific pharmacotherapeutic evaluation and dosage adjustments, diabetes education, training on management of hypo- and hyperglycemia, medication counseling, diet and exercise instruction, and training for self-monitoring of blood glucose. These patients came to the clinic every 2-4 weeks throughout the 4 month duration of the study.

Patients in the control group reported to the clinic only for the initial assessment and for the final exit visit, which is in accord with the customary medical care standards for this clinic.

Main outcomes measures and results: Primary therapeutic outcome measures included fasting plasma glucose (FPG) and glycated hemoglobin (GHb) concentrations.

Glycemic Control Parameters at Baseline and End of Study

Variable		Control	Intervention
FPG (mmol/L)	Baseline	12.7 ± 4.7	11.1 ± 4.0
	Final	11.0 ± 3.9	$8.5 \pm 2.3^{a,b}$
	Change	1.8 ± 3.9	2.6 ± 3.4
GHb (%)	Baseline	12.2 ± 3.5	11.5 ± 2.9
	Final	12.1 ± 3.7	$9.2 \pm 2.1^{a,b}$
	Change	0.1 ± 3.0	2.2 ± 2.6^b

^a Significantly different within a group ($p < 0.05$)

^b Significantly different between groups ($p < 0.05$)

Results of secondary outcome endpoints are as follows: A trend toward a statistically significant ($p=0.07$) decline in the final systolic blood pressure and diastolic blood pressure values compared with baseline was observed in the intervention group. No significant changes were seen in body weight, serum lipid measurements or renal function parameters with the exception of final serum creatinine decrease (88 ± 18 vs. 97 ± 18 mmol/L, $p=0.005$) and a tendency toward an increase in final LDL (3.54 ± 0.28 vs. 3.23 ± 1.32 mmol/L, $p=0.023$) concentrations compared with baseline in the control group. All of the secondary endpoints values were within normal ranges, with less than 2% change occurring during the study.

Quality of life analyses revealed no significant differences.

Conclusions: Glycemic control as evidenced by FPG and GHb measurements significantly improved in those patients receiving pharmaceutical care interventions. Patients with the poorest control experienced the greatest reduction in hyperglycemia. Optimizing the oral hypoglycemic therapeutic regimens and enhancing patient understanding of the disease were most likely responsible for the observed reduction in hyperglycemia.

Abstract Number: 17

Koperski M. How effective is systematic care of diabetic patients? A study in one general practice. *British Journal of General Practice* 1992;42:508-11.

Objective: To evaluate the effect of introducing systematic care into a general practice on the recording of six process measures and glycosylated hemoglobin levels.

Design: Retrospective before-after study.

Setting: This study was conducted in a seven-partner general practice located in a health center in central London, England.

Patients: Sixty-four of 111 diabetic patients in this practice entered the study over a period of 20 months. The study sample consisted of those diabetic patients who were diagnosed and registered with the practice at least two years before attending the “diabetic day”, remained registered for two years after entry, and attended the diabetic day at least once.

Patients were excluded from the study if they were homebound, left the practice prior to study completion, died prior to study completion, carried diabetes diagnosis for less than two years, remained under the care of a specialist, or refused to enter the study.

Interventions: The “diabetic day” takes place on one day each month and the practice as a whole focuses on seeing patients with diabetes. The patients see a physician and nurse at the visit and a dietician and chiroprapist also see the patients regularly. A detailed history, health education, and assessment of patient’s urine testing technique are conducted during the nursing visit. Funduscopy and estimation of glycosylated hemoglobin levels are also performed.

Main outcome measures and results: The general practice records were analyzed retrospectively over a period of four years—two years before to two years after attending the “diabetic day”.

Percentage of Patients Attending the “Diabetic Day” for Whom Process Measures Were Recorded

Process Measures Recorded	Percentage of Patients Attending the “Diabetic Day” (n=64)			
	2 Years Before	1 Year Before	1 Year After	2 Years After
Weight	35.9	46.9	100	90.6
Glycosylated Hemoglobin Level	12.5	26.6	100	84.4
Blood Glucose Level	46.9	70.3	100	93.8
Funduscopy	4.7	3.1	89.1	51.6 ^a
Visual Acuity	6.3	1.6	98.4	60.9 ^b
Blood pressure	46.9	57.8	100	92.2

^a 76.6% if patients referred to ophthalmologist or for retinal photography are included.

^b 85.9% if patients referred to ophthalmologist or for retinal photography are included.

Mean glycosylated hemoglobin levels fell from 10.52% in the year before attending the diabetic day to 9.71% in the second year after entry ($p < 0.01$, 95% CI 0.19 to 1.39). (Glycosylated hemoglobin levels were unavailable for 56 out of 64 patients two years prior to attendance, so this comparison was not made.)

Conclusions: The introduction of systematic care for diabetic patients led to an improvement in recorded process measures and reduction in patients’ glycosylated hemoglobin levels in a general practice which had made previous efforts to improve diabetic care and was already well staffed, organized, and motivated.

Abstract Number: 18

Levetan CS, Salas JR, Wilets IF, Zumoff B. Impact of endocrine and diabetes team consultation on hospital length of stay for patients with diabetes. *The American Journal of Medicine* 1995;99:22-8.

Objective: To determine whether consultation by an individual endocrinologist or by a multidisciplinary diabetes team can impact the length of hospital stay of patients with diabetes.

Design: Retrospective cohort.

Setting: Beth Israel Medical Center.

Patients: Consecutive patients discharged from the medical center with principal diagnoses of diabetes prior to the initiation of the diabetes-team care served as sequential historical controls. After the establishment of the diabetes team all consultations to the endocrine service for patients admitted with a principal diagnosis of diabetes were evaluated.

Forty-three patients were seen by an individual endocrine consultant, 27 were managed by an internist alone, and 34 were seen in consultation by the diabetes team. There were no statistically significant differences among groups with respect to age, duration of diabetes, admitting diagnosis, glucose levels, or concomitant acute or chronic illness.

Interventions: The diabetes team, made up of an endocrinologist, diabetes nurse educator, and registered dietician, operated as an inpatient endocrine consultation team. All team members met daily and gave recommendations to the primary care physicians based on the team's evaluation of each patient. Educational services were also provided, but no medical orders were written by team members and all decisions regarding discharge were made by the primary care physician.

Main outcome measures and results: Average length of stay of diabetes team patients was 3.6 ± 1.7 days, 56% shorter than the value (8.2 ± 6.2 days) of patients in the no-consultation group (<0.0001), and 35% shorter than the value, 5.5 ± 3.4 days, of patients who received a traditional individual endocrine consultation (<0.05). The length of stay correlated with the time from admission to consultation. The slope of the regression equation (1.09) indicates that each 1-day delay in consultation resulted in a 1-day increase in length of stay.

Conclusions: Length of stay was shortest in patients who received diabetes team consultation. The authors believe that the intensive education provided by the diabetes team empowered patients and their families to play an active role in their own diabetes care and may have had a dramatic impact on their acute medical status. It is likely that physicians were more confident to discharge their patients sooner knowing that patients and their families were taught the basic diabetes care skills.

A limitation of this study is that it was not a randomized trial. This would have enabled patients receiving consultation to have their initial evaluation at the same point in their hospital stay and eliminated the possibility of factors influencing the length of stay that may have varied between the two study periods.

Abstract Number: 19

Litzelman DK, Slemenda CW, Langefeld CD, et al. Reduction of lower extremity clinical abnormalities in patients with non-insulin dependent diabetes mellitus—a randomized, controlled trial. *Annals of Internal Medicine* 1993;119:36-41.

Objective: To reduce the prevalence of risk factors for lower extremity amputations in patients with non-insulin dependent diabetes.

Design: Blinded, randomized control trial. Two clinical teams were randomly assigned as treatment teams and two teams were assigned as control teams.

Setting: The Regenstrief Health Center in Indianapolis, Indiana. This is a teaching facility with four primary care teams. Each team has its own nursing and clerical staff. Each is staffed by one or two faculty internists and two to four house staff.

Patients: There were 728 eligible patients of which 244 refused to participate and 89 enrolled in the study but failed to keep their appointments for initial assessment. 395 patients enrolled in the study and completed the initial assessment. The only statistically significant difference in patient characteristics was hemoglobin A1c at enrollment. The intervention group had a mean HbA1c of 10.5 and the control group had a mean level of 10.0. Otherwise the intervention group and control group were similar in percentage of patients that were black (75% vs. 77%), the percentage of patients that were female (82% vs. 80%), mean age (60.9 vs. 59.9), annual income < \$10,000 (77% vs. 77%), body mass index (34 vs. 33.4), percentage taking insulin (52% vs. 47%), and the number taking oral hypoglycemic agents (43% vs. 46%).

The inclusion criteria included patients who had been seen at least twice in one year by the same provider, an age greater than 40, a diagnosis of diabetes after 30 years of age, a diagnosis of diabetes based on National Diabetes Data Group criteria or the presence of disease requiring medication for the control of hyperglycemia, an intention to obtain care at the general medicine practice for the next 2 years, and a body weight that was either ideal or heavier than ideal.

Exclusion criteria included pregnancy, major psychiatric illness including dementia, terminal illness likely to cause death within one year, renal failure, previous bilateral amputations above or below the knee, or an inability to provide self-care.

Interventions: During the 12 month intervention, patients in the intervention group were exposed to multiple interventions. These included:

- Nurse-led patient education—covering appropriate foot-care behaviors and footwear using a commercially available slide and audio presentation and pamphlet;
- Behavior contracts— negotiated with each patient covering desired foot-care behaviors;
- Telephone follow-up—two weeks after the educational session and contract development to reinforce the contracted behaviors; and,
- Post card reminders—sent at 1 month and 3 months post-contact to remind patients of agreed upon behaviors.

System interventions include colorful medical record folders with special foot decals on the folder to identify intervention patients and an informational flow sheet provided to physicians that shows patient-specific risk factors and foot-care guidelines for assessment, diagnostic work-up, treatment, and referral recommendations. The decals prompted physicians to ask patients to remove footwear, perform foot examinations, and provide foot-care education.

Main outcome measures and results: Number of serious foot lesions at study end, self reports of appropriate self-foot care, and likelihood of physicians to exam feet for ulcers, pulses, and abnormal dermatologic conditions and to refer patients to podiatry clinic.

At the end of the study, intervention patients had a statistically significant reduction in number of foot lesions and dry or cracked skin. It approached significance for ingrown nails, and fungal nail infections. Also, intervention patients reported a significant improvement in self foot-care behavior for foot washing, not soaking feet, inspecting feet, inspecting shoes, drying between toes, and filing calluses.

Physicians at the end of the study were more likely to have asked patients to take off their shoes and socks, to examine the feet, and to provide foot-care education.

Conclusions: With the exception of the development of the behavioral contract and its follow-up, these represent fairly simple interventions to institute within a clinic system. It would be useful to know the actual impact of each component. However, the study was not designed to make this determination. In addition, the study did not have adequate duration or sample size to determine the impact of these interventions on the ultimate outcome, reduction in amputations.

Abstract Number: 20

Malone JM, Synder M, Anderson G, et al. Prevention of amputation diabetic education. American Journal of Surgery 1989;158:520-4.

Objective: To prevent lower extremity amputation using a simple education program.

Design: Randomized control trial. Patients were randomly divided into two groups. The intervention group (103 patients with 203 limbs) received a one-hour education class on diabetic foot care. The control group (100 patients, 193 limbs) did not receive this class. All patients received routine clinical management and received routine diabetic teaching with respect to diet, weight, exercise, and medication.

Setting: Podiatry and vascular surgery clinic at the Tucson Veterans Administration Medical Center.

Patients: Diabetic patients with foot infection, ulceration, or prior amputation who were referred to either the podiatry or vascular surgery clinic from February 1, 1984 to December 31, 1985 were included. Patients were excluded if they required wound debridement, formal incision and drainage of foot infections, amputation, or vascular reconstruction, until after definitive surgical treatment.

Two hundred twenty-seven patients were randomized into two groups based upon the odd or even last digit of their social security number. Despite pre-randomization screening to rule out patients needing definitive surgical treatment, 24 patients did not fit study criteria and were dropped from the study.

Interventions: The diabetic foot care class was taught by one of the authors on a weekly or bimonthly basis. The class included slides depicting infected diabetic feet and amputated diabetic limbs. The class also featured a simple set of patient instructions for the care of the diabetic foot. Once the course was successfully completed, no further short-term or long-term education, except routine diabetic teaching, was attempted.

For Group 1 (intervention), maximum time for patients to be seen by the clinic was 26 months, with a mean of 13.2 months. For Group 2 (control), maximum time in the clinic was 26 months, with a mean of 9.2 months.

Main outcome measures and results: Thirteen in Group 1 and eight in Group 2 either died or were lost to follow-up. This left 90 patients and 177 limbs in Group 1 and 92 patients and 177 limbs in Group 2. The primary outcome was amputation rates. Secondary outcomes were infections and ulcers.

Outcome	Group 1 (n=177)	Group 2 (n=177)	p value
Amputation	7	21	<0.025
Ulcerations	8	26	<0.005
Infections	2	2	NS

Conclusions: The only significant distinguishing intervention between groups was the addition of the one hour diabetic foot education intervention. However, the authors rightfully point out that equivalent diabetic education, vascular surgery, and podiatric care were available to all patients. Thus, while this is a simple intervention, it is instituted in a multi-speciality care setting. In addition, the study did not attempt to stratify the results to look at differences in diabetic management, the impact of diabetic education, or the impact of the vascular and podiatry clinics. While this is an interesting intervention with good results, it would be difficult to assess the impact of this intervention in other practice settings.

Abstract Number: 21

McCulloch DK, Price MJ, Hindmarsh M, Wagner EH. A population-based approach to diabetes management in a primary care setting: early results and lessons learned. *Effective Clinical Practice* 1998;1:12-22.

Objective: To determine the effects of a multifaceted program of support on the ability of primary care teams to deliver population-based diabetes care.

Design: Population-based intervention.

Setting: Group Health Cooperative of Puget Sound, a staff-model health maintenance organization (HMO) in which more than 200 primary care providers treat approximately 15,000 diabetic patients.

Patients: Diabetic patients treated by this staff-model HMO.

Interventions: Interventions included a continually updated on-line registry of diabetic patients, evidence-based guidelines on retinal screening, foot care, screening for microalbuminuria, and glycemic management, improved support for patient self-management, practices redesigned to encourage group visits for diabetic patients in the primary care setting, and decentralization of expertise through a diabetes expert care team (a diabetologist and nurse certified diabetes educator) seeing patients jointly with the primary care teams.

Main outcome measures and results: Main outcome measures included:

- Provider satisfaction—from 1992 to 1996 rankings by providers for key diabetes care resources improved (e.g., rankings of excellent or very good for access to retinal care increased from 66% to 86%);
- Retinal eye exams—(annual retinal exam)—increased from 46% in 1993 to almost 66% in 1996;
- Documented foot exams—in one year after implementation of a computer system to track foot exams, the rate increased from approximately 20% to 50%; and,
- Testing for hemoglobin A1c—at least one test per year) increased in a two-year period from 77% in 1994 to 80% in 1996.

Conclusions: As opposed to a research design, this paper describes the evolution of a delivery system designed to provide care for patients with diabetes mellitus. The article describes the data elements captured on the diabetes registry, the organization of the chronic care clinic, the role of the diabetes expert team including nursing involvement and the impact of the diabetes expert team on clinics that requested their services compared to clinics that did not request their services. In addition, it shows trends in compliance with key process measures.

Abstract Number: 22

McDowell I, Newell C, Rosser W. A randomized trial of computerized reminders for blood pressure screening in primary care. *Medical Care* 1989;27:297-305.

Objective: To evaluate three mechanisms to improve the number of patients having a blood pressure measurement within a one-year period.

Design: Six group practices were divided into two groups: two practices and their patients were control practices and four practices and their patients were intervention practices. The patients in the intervention practices were randomly allocated (by family unit) to a physician reminder group, a patient letter reminder group, a nurse-initiated telephone reminder group and a control group.

Setting: The Family Medicine Center at the Ottawa Civic Hospital, a teaching unit of the university medical school composed of six practices, each with a staff physician, a nurse, and between three and five family-medicine residents. This program has utilized a computerized system which records diagnoses, prescriptions, treatment, and billing information.

Patients: The eligible patient population included all clinic patients (8,296 with 2,554 in the control practices and 5,744 in the intervention practices) who were at least 18 years of age and had not had a blood pressure measurement recorded in the previous year. The mean age of the patients was 44.5 years and 56.5% were female.

Interventions:

- Letter reminder—patients due for a blood pressure check were sent a letter during their assigned reminder week. This letter encouraged them to have their blood pressure checked. Letters to the same address were sent at one time. A follow-up letter was sent within 21 days to those that did not respond.
- Telephone reminder—patients assigned to this group received a telephone call from a nurse during an assigned reminder week. The computer generated the list of patients and their telephone number. The nurses made up to five attempts during the day to contact each family. The nurse recorded the number and duration of the calls and the patient’s stated intentions.
- Physician reminder—For these patients, a physician reminder was printed with the encounter form when the patient made an appointment and was seen. Until a blood pressure measurement was recorded, the computer continued to generate a reminder at each visit.
- NOTE: Patients in the letter and telephone reminder group were assigned a week to be contacted.

Main outcome measures and results: Blood pressure measurement taken and recorded.

Required Blood Pressure Readings Taken During the Trial by Intervention Group

	Number Allocated	Required BP Check	BP Checked
Randomized Control	1,371	996	210 (21.1%)
Physician Reminder	1,432	1,059	325 (30.7%)
Letter Reminder	1,508	1,094	391 (35.7%)
Telephone Reminder	1,433	1,042	251 (24.1%)
Control Practices	2,554	1,925	359 (18.6%)
Total	8,298	6,116	1,536 (25.1%)

Conclusions: This study does show an incremental improvement from randomized control to telephone reminder, physician reminder to letter reminder. The difference between the control group and intervention group were significant. The difference between the three interventions was also significant. Also, the difference between the physician intervention and the randomized control was significant.

It is interesting to note that of the 8,298 patients only 2,182 (26%) had a blood pressure recorded in the previous year on a routine visit. Also, after the impact of all interventions were taken into account, only another 18.5% (1,536) of the original 8,298 patients had a blood pressure check. This low rate may be explained by the difficulty in contacting patients. Fourteen percent of the letters were returned as undeliverable. Fifty-six percent required a second letter, and practice staff contacted only 66% of patients they attempted to call. Also, it might be that patients visit this clinic infrequently. This point is highlighted by the fact that only 52% of the patients in the physician-reminder group visited the practice during the trial year. Of note, the greatest impact was in patients aged 65 years and older. In this group, 25.2% received a blood pressure check in the randomized group, 39.8% in the telephone reminder group, 42.7% in the physician reminder group, and 45.2% in the letter group.

Abstract Number: 23

Meneghini LE, Albisser AM, Goldberg RB, Mintz DH. An electronic case manager for diabetes control. *Diabetes Care* 1998;21:591-6.

Objective: To evaluate the usage and safety of an electronic case manager (ECM) system designed to facilitate the task of glycemic control.

Design: Open case series.

Setting: This study was conducted in an academic diabetes center.

Patients: One hundred eighty-four patients were entered into the study program over a 12-month period. Entrance criteria were unrestricted with respect to sex, age, socioeconomic class, geographic location, type of diabetes, method of treatment, type of medication (over 94% were insulin users), or method of self glucose measurement.

Interventions: The ECM is based on a personal computer (PC) platform with two interfaces, one for the health care professional and one for the patient. The health care professional interface permits an on-screen review of patient-entered blood glucose measurements, life-style events (changes in diet, exercise, stress, etc.), and other indexes (intercurrent illness, fever, vomiting, etc.) The health care professional can then activate a virtual recorder and leave voice messages for the patient regarding specific instructions. All reports are standardized and interactions by the health care professional are documented in the electronic medical chart.

The patient may use any available touch-tone telephone as a terminal through which to enter each glucose measurement, crisis event, life-style factor, and self-administered medication in response to verbal instructions given by the ECM.

Main outcome measures and results: The main outcome measures dealt with the system's utilization statistics, the fiscal and administrative aspects of the implementation, and ongoing use. A subgroup of active users, for which HbA1c data were available was retrospectively evaluated in terms of change over time.

Annual System Usage for ECM

Period	1 year
Registered Users	184
Active Users	107 (58%)
Nonusers	77 (42%)
Telephone Calls to System	45,882
Total Calls Reporting Hyperglycemia ^a	589
Total Calls Reporting Hypoglycemia ^b	1,087

^a hyperglycemia >400mg/dl (22mmol/l)

^b hypoglycemia <50mg/dl (2.8mmol/l)

Specific usage on average was 58 ± 34 calls per patient per month. Out of a maximum of 31 days, patients accessed the ECM on 29 ± 9 days per month. The average rate of crises (hyper- and hypoglycemia) was 2.1 ± 3.6 per patient per month. Among the crises, the mean rate of hypoglycemia was 1.4 ± 2.5 events per patient per month.

Prevalence of diabetes-related crises decreased approximately threefold ($p < 0.05$) with a concomitant statistically significant decrease in HbA1c of 0.8% at 6 months ($n=45$, $p=0.024$) and 0.9% at 12 months ($n=30$, $p=0.044$). Clinic visits in managing complex diabetes were reduced approximately twofold ($p < 0.0001$).

Conclusions: Patients with diabetes who accessed the ECM system received timely and reliable medical intervention. This reduced the incidence of diabetic crises and the need for frequent clinic visits.

Abstract Number: 24

O'Connor PJ, Desai J, Rush WA, et al. Is having a regular provider of diabetes care related to intensity of care and glycemic control? *Journal of Family Practice* 1998;47:290-7.

Objective: To determine if utilization of a regular health care provider by diabetics was positively related to intensity of care as measured by the use of preventive services or glycemic control.

Design: Mail survey of randomly selected adult patients with diabetes mellitus linked to information from the administrative and laboratory data files.

Setting: HealthPartners, a large HMO (700,000 members) in Minneapolis/St. Paul in collaboration with the Minnesota Department of Health.

Patients: A random sample of 1,828 adult (at least 19 years of age) patients with diabetes.

Patients were defined as having diabetes mellitus if they had been continuously enrolled in calendar year 1994, had two or more clinic visits that resulted in a primary or secondary diagnosis of diabetes, or filled at least one prescription for a diabetes-specific drug.

Interventions: Patients were surveyed via mail with a follow-up telephone call. Initial response rate was 85.6%. Once individuals were excluded for incomplete data, the final sample size was 1,387 (75.9%). The survey was 16 pages with 61 items. Data collected included demographics, disease characteristics, comorbidity, duration of disease, diabetes treatment, preventive care, diabetes monitoring, and self-care practices.

In addition, claims and laboratory data including number of primary care visits, visits with endocrinologists, dilated retinal examinations, and HbA1c test results were collected, linked to the patient survey, and once linked, had the identifiers removed.

Main outcome measures and results: The survey revealed that 1243 patients had a regular physician (RP) and 144 did not have a regular physician (NRP). The two groups were similar in age, mean age at diagnosis, sex, and educational level. The RP group had a statistically significant longer duration of diabetes, was more likely to be married, and was more likely to take insulin.

The RP group was more likely to have had a routine visit for a check-up, blood cholesterol checked, and a flu shot within the last year. There was no difference between the groups for blood pressure check or dental check within the last year or a pneumonia immunization ever. In addition, the RP group was more likely to have two or more visits for diabetes and more likely to have two or more HbA1c measures in the last year. The RP group was more likely to follow a special diet and to check finger stick blood sugars 2 or 3 times per week.

Conclusions: It is interesting that the authors note that "there are important psychological factors... that contribute to a patient's lack of a regular health care provider." Yet they apparently made no attempt beyond routine comparisons (e.g., age, race, education level) to identify these characteristics. In addition, a subset of the RP population was seen in HMO-owned clinics. The authors had access to HbA1c levels for these individuals. There was no statistical difference between the two groups. In addition, within this group, a subset had at least two HbA1c levels performed. There was no difference in the change seen between readings. Since we know that control of the glucose level is a key factor in reducing diabetic complications and since reducing or preventing diabetic complications is a major goal in diabetic care, it is difficult to conclude from this study that having a primary care provider does any more than increase access to care for this population. Last, there is no analysis by inclusion criteria. That is to say that the authors did not look at the number of patients in the RP group versus the NRP group who were included because they filled a prescription as opposed to patients who had two visits. It is possible that patients who were included only because they filled a prescription are more resistant to establishing a relationship with a primary care provider.

Abstract Number: 25

Peters AL, Davidson MB, Ossorio RC. Management of patients with diabetes by nurses with support of subspecialists. HMO Practice 1995;9:8-13.

Objective: To develop a program for managing diabetic patients within a health maintenance organization (HMO) system that focuses on preventing hospitalization as well as preventing the development of diabetic complications.

Design/Intervention: The “Comprehensive Diabetes Care Service” (CDCS) is a system in which diabetes nurse specialists, supervised by physicians, provide diabetes care following established protocols for the management of diabetes and lipids.

The physician-supervisors are diabetologists who manage 4 diabetes nurse specialists. The diabetes nurse specialists are registered nurses who have received intensive training in diabetes management and are certified diabetes educators. The established patient ratio is 250 patients per nurse specialist and 1,000 patients per diabetologist.

There are 32 protocols which cover the management of patients treated with diet, sulfonylurea agents, insulin, and other topics (e.g., treatment for lipid disorders, gestational diabetes, impaired glucose). In addition, there are protocols established for the management of complications of diabetes.

The diabetologist sees the patient initially, and annually with the nurse specialist. The nurse specialist sees the patients quarterly and follows a defined format each visit. Patients are referred to a dietician, an ophthalmologist, and diabetic educator upon entry into the system. If the retinal exam is normal, the nurse follows up annually with retinal photographs. Podiatrists are utilized as needed based on protocol.

A computer system was developed to track patient appointments, generate lab reminders, maintain an ongoing clinical and laboratory database on each patient, and adjust insulin doses. For example, every two months a lab reminder is generated for patients to get a glycated hemoglobin and a fasting plasma glucose. Also, if a patient has a change in a lipid medication, the computer generates a reminder to perform a lipid profile in one month.

Setting: In Los Angeles, at Cedars Sinai Medical Center, a physician group (IPA) developed a capitated contract with 12 HMOs in 1986. Since then, it has grown to 22 HMOs serving 65,000 members.

Patients: In 1987, the capitated population-at-risk was approximately 8,000. At that time, there were 236 diabetics followed by the CDCS. In 1994, the capitated population-at-risk was 65,000 with 754 diabetics followed by the CDCS.

Main outcome measures and results: As an example of their success, they looked at changes in glycosylated hemoglobin levels over time.

	Percent + Standard Error			
Year	0	1	2	3
All*	12.5+0.4	9.5+0.2	9.4+0.4	9.1+0.4
Compliant*	12.3+0.5	8.6+0.2	8.2+0.2	8.1+0.3
Noncompliant+	12.9+0.5	11.8+0.4	11.6+0.6	10.7+0.6

*p<0.01
+=NS

In addition, they estimated the number of hospitalizations that were prevented. Over a four year period, the authors estimate that the CDCS prevented 244 hospitalizations, saving an estimated \$588,741 dollars.

Conclusions: The article describes a new model for diabetes care within the managed care setting. The methodology described utilizes diabetes nurse specialists following detailed protocols to provide outpatient diabetes care. The supervision is provided by diabetologists.

The authors use glycated hemoglobin levels as an indicator of their success. They show good improvement in the control of glycated hemoglobin over time. As in any practice, they have greater success with compliant patients. Due to the nature of this report, they do not provide a control group to compare their success to “standard care.”

The authors also look at cost savings produced by reduction in hospitalization. They indicate that the CDCS program is cost effective. However, they do not describe their mechanism for determining the number of hospitalizations prevented. As such, it is difficult to assess the true impact of this program on cost.

Abstract Number: 26

Rith-Najarian SJ, Stolusky T, Gohdes, DM. Identifying diabetic patients at high risk for lower-extremity amputation in a primary care setting. *Diabetes Care* 1992;15:1386-9.

Objective: To evaluate prospectively a risk categorization scheme for lower-extremity problems that incorporates the Semmes-Weinstein 5.07 monofilament and a simple exam to stratify patients who were followed in a primary care setting into risk groups for plantar ulceration and lower extremity amputation.

Design: Prospective cohort.

Setting: The study was conducted at Red Lake, Minnesota where primary care is provided to 4,500 Indian Reservation residents by the Indian Health Service.

Patients: Three hundred fifty-eight individuals with diabetes in the community were given screening exams. Slightly more than half of the subjects were women (56%). Average age of the group was 55.0 ± 12.3 with average duration of diabetes 12.3 ± 6.7 years.

Interventions: From July 1988 to February 1991, individuals on the diabetes registry had a foot exam at least annually and were assigned to one of four categories based on the presence of a foot deformity, history of lower extremity event (ulceration or amputation) and the ability to perceive the 5.07-U monofilament. Patients were considered sensate if they correctly identified the time at which the monofilament was applied to all areas on both feet.

Main outcomes measures and results:

Risk Categorization and Number of Lower Extremity Events

Risk Category	Sensate to 5.07 Monofilament	Deformity Present	Past Lower Extremity Event	Number in Category	Plantar Ulceration (n)	Amputation (n)
0	+	+/-	-	266	4	0
1	-	-	-	30	7	0
2	-	+	-	16	6	1
3	+/-	+/-	+	46	24	13

(+) criteria present

(-) criteria absent

Eighty-eight percent of patients on the diabetes register were screened and 13% of those fell into the highest risk category. All amputations occurred in high-risk patients, whereas ulceration rates increased progressively by category ($p < 0.0001$ for trend).

Insensitivity occurred in 19% of the patients screened. Among this group, the odds ratio of subsequent ulceration was 9.9 (95% CI 4.8-21.0) and amputation was 17 (95% CI 4.5-95.0) compared with those who retained sensation.

Conclusions: These data suggest that the risk categorization described may have a role in identifying patients at risk for lower extremity events who are followed in a primary care setting.

Abstract Number: 27

Ronnemaa T, Hamalainen H, Toikka T, Liukkonen I. Evaluation of the impact of podiatrist care in the primary prevention of foot problems in diabetic subjects. *Diabetes Care* 1997;20:1833-7.

Objective: To evaluate the impact of podiatrist care in preventing primary foot problems in diabetic patients.

Design: Randomized controlled trial. Patients that passed the screens were randomized to a podiatric care group (n=267) that received free care that included education and primary prevention measures, or a control group (n=263) that received written instructions only from their routine care provider.

Setting: Routine care was provided in public outpatient health care system clinics in Turku, Finland. Podiatrists in Finland are not included in the staff of these clinics. Podiatrists practice in the private setting.

Patients: Seven hundred thirty-three patients in the age range of 10-79 (mean age 46.9 years) years who were living in the town of Turku or its vicinity were identified using the drug reimbursement register. One hundred ten patients had visited the podiatrist in the previous year and were excluded. In addition, 93 had obvious need for foot care (e.g., previous amputation, present ulcer or infection) and were referred to a podiatrist. The remainder were randomly allocated into the podiatry group (n=267) or to the control group (n=263). The randomization was performed separately for men and women and for individuals under and over 20 years of age.

Interventions: The intervention group received foot care education and primary preventive care from one of three podiatrists.

The education was given individually and took into account the patient's age, occupation, earlier foot care habits, etc. Topics included proper footwear, daily hygiene, cutting of toe nails, use of emollient cream, avoidance of high-risk situations (e.g., walking barefoot), and guidance for foot gymnastics.

Preventive measures included gentle debridement of calluses, preparation of individual insoles, promotion of the use of emollient creams, treatment of ingrown toenails, and foot gymnastics.

Main outcome measures and results: The main outcomes include knowledge of diabetic foot care, self-care, and or foot problems.

Knowledge of diabetic foot care increased in both groups from baseline to follow-up. The knowledge increase was significantly greater in the intervention group ($p=0.004$). Self-care also increased in both groups. Again, the improvement in the podiatrist group was significantly greater ($p<0.001$). There was significant reduction in the development of callosities in noncalcaneal regions in the intervention group ($p=0.009$) as compared to the control group. There was no significant difference between intervention and control groups in the formation of callosities in calcaneal region, corns, ingrown toenails, inability to spread toes, or inability to flex toes. Of note, the use of special insoles increased significantly in the intervention group from baseline to follow-up ($p<0.001$).

Conclusions: This article shows that initial intervention by a podiatrist results in improvement in knowledge and self foot care scores. It does not have a long enough follow-up period to determine if intervention by a podiatrist early on will lead to reduction in major foot problems. Of note, results from this study may not be transferrable to the Medicare population, as the study population took into account patients aged 10-79 years. In addition, it appears that patients received free care from the podiatrist and free medications (i.e., patients were identified from the National Drug Imbursement Registry).

Abstract Number: 28

Smith SA, Murphy ME, Huschka TR, Dinneen SF, Gorman CA, Zimmerman BR, Rizza RA, Naessens JM. Impact of a diabetes electronic management system on the care of patients seen in a subspecialty diabetes clinic. *Diabetes Care* 1998;21:972-6.

Objective: The objective of this study was to compare the compliance with diabetes care performance indicators by diabetes specialists using a diabetes electronic management system (DEMS) and by those using the traditional paper medical record.

Design: Retrospective cohort.

Setting: Medical records were selected from a diabetes clinic staffed by 19 board-certified endocrinologists and one nurse practitioner.

Patients: The study sample included established patients with diabetes seeking continuing care from the group practice described above. To be eligible for the study, patients must have had a diagnosis of diabetes for a minimum of one year and have had a diabetes clinic visit coded for in the 12-24 months prior to the study. Out of 238 eligible patients, 82 were selected at random for medical record review.

Of the 82 patients, 17% had type I diabetes and 65% were taking insulin. The 39 patients whose providers used the DEMS did not differ significantly from the 43 patients whose providers used the paper record only with regard to age (mean for both groups ≥ 60 years), sex (majority male for both groups), type of diabetes, and the type or frequency of diabetic medications.

Interventions: A DEMS was gradually introduced into this subspecialty practice and its value was assessed by a 3-month retrospective review of medical records. The DEMS allows entry of clinical information as the provider is in the room with the patient. An electronic interface with laboratory data systems allows the automatic entry of diabetes-specific core laboratory data. When information has been entered into the DEMS before the provider sees the patient (such as vital signs, current medications, etc.), the provider reviews the information and makes additions or corrections based on his or her interview with the patient. All other information is entered by the provider during the course of the encounter. At the end of the clinical encounter, the DEMS generates a report for the paper medical record and the patient.

Providers using the paper medical record followed their traditional process of documentation.

Main outcome measures and results:

Performance Indicators: DEMS vs. Paper Medical Record Only

	DEMS	Paper Record Only	p value
Number	39	43	
Blood Pressures/Pt/Yr	3.6 \pm 1.6	2.7 \pm 1.6	0.0035
Diastolic BP	80.6 \pm 9.6	93.6 \pm 25.0	0.043
Systolic BP	138.3 \pm 16.9	140.9 \pm 19.6	NS
Foot Exams/Pt/Yr	2.9 \pm 1.1	1.8 \pm 1.4	<0.001
Dilated Eye Exams in Last Year	64.1	65.1	NS
Documentation of SMBG	100	100	NS
Measurement of Urinary Microalbumin	30.8	27.9	NS
Four Glycated Hemoglobins per Year	76.9	51.2	0.016
Most Recent Glycated Hemoglobin	9.7 \pm 1.7	10.2 \pm 1.9	NS
Lipid Profile in Last Year	71.8	65.1	NS
Tobacco Status and Advice to Quit	97.4	95.4	NS
Diet Documentation	100	95.4	NS
Diet Education	66.7	55.8	NS
Diabetes Self-Mgt Education	94.9	90.7	NS
Mean Weighted Criterion Score	66.3 \pm 12.9	55.4 \pm 16.5	0.0025

Data are means \pm SD or %

Conclusions: Performance and documentation of the process of care for patients with diabetes in a subspecialty clinic are greater with the use of a DEMS than with the traditional paper record. Two major limitations of the study are cited. First, providers were not randomized as to use of the DEMS. Thus the differences observed may not relate solely to the use of the electronic versus the paper record. Second, observed differences in documentation may not be reflective of actual differences in practice, but merely reflective of improved documentation through the use of the DEMS.

Abstract Number: 29

Smith DM, Norton JA, Weinberger M, McDonald CJ, Katz BP. Increasing prescribed office visits: a controlled trial in patients with diabetes mellitus. *Medical Care* 1986;24:189-99.

Objective: The short term goal for this study was to determine the effectiveness of the intervention on increasing patient-provider contacts among patients of different risk levels.

Design: Randomized controlled trial.

Setting: The study took place at the Regenstrief Health Center, the outpatient facility for Wishard Memorial Hospital, located in Indianapolis, Indiana. The clinic is attended by house staff and full-time faculty of the Indiana University School of Medicine Department of Internal Medicine.

Patients: Of 1,887 patients on antidiabetic agents at the clinic, 859 were enrolled for the study during a 7-month period. The enrolled patients met the following criteria: (1) insulin or oral hypoglycemic agents prescribed or continued, (2) receiving all care at the facility and not institutionalized, (3) age over 15 years, (4) visiting the clinic within the last year, and (5) having a return appointment scheduled.

The 859 patients were stratified by risk of hospitalization (low=232, medium=278, and high=349 patients) and then randomized into treatment and control groups. Patients in the treatment and control groups were similar in age (control mean 59.0 ± 13.2 , treatment mean 59.3 ± 12.5), sex and race, with the majority in both groups being black and female. Also, the majority of patients were on insulin alone (70.7% control, 76.5% treatment).

Interventions: Patients in the treatment group were mailed packets with information on how to use the clinic, providers names and phone numbers, after-hours phone numbers, a list of early warning signs, and a booklet on managing diabetes. One week prior to a scheduled return visit, each patient was sent a reminder postcard. If the patient failed to show, then a sequence of letters, phone calls, and ultimately home visits was initiated until the patient kept his or her scheduled appointment. The initial packet of materials was sent every six months to the patients in the treatment group.

The control patients received their usual care. Information packets were available in the clinic but required a specific request by the physician or patient. Patients were reminded to reschedule missed appointments four months after a failed visit.

Main outcome measures and results:

Effects of Intervention on Patient-Provider Contacts

	Control	Intervention	Change	p
Number of Patients	430	429		
Follow-up Time (Days)	340 ± 80	341 ± 89		NS
Kept Appointments	3.61 ± 2.46	4.13 ± 2.88	+0.52	0.0062
Rx Refills	0.94	1.00	+0.06	NS
Walk-in Visits	0.63	0.72	+0.09	NS
Total Contacts	5.18 ± 3.60	5.84 ± 4.06	+0.66	0.0105
Visit Failures	1.16	1.13	-0.03	NS

When patient contacts were assessed by risk groups, the number of kept scheduled visits increased with increasing level of risk. Also, a significant reduction in visit failures was observed in the high-risk level. In the high-risk level, mean visit failure was 1.51 in the control group and 1.31 in the intervention group. The intervention did not significantly affect other contacts or the lower risk groups.

Conclusions: This study demonstrates that a multifaceted intervention applied systematically and repetitively increased kept scheduled visits and that the effect was consistent over a period of approximately one year. The effect of the intervention was observed in the groups at higher risk for hospitalization. These same groups would be at a higher risk for developing significant early warning signs. This supports the postulate that some of the increased visits by the intervention group appear to be due to increased compliance with this general prescription. Finally, the interventions did reduce failures in the highest risk group. Thus some of the increased visits by the intervention group appear to be due to increased compliance with specifically prescribed visits.

The persistent failure rate of 21.5% in the intervention group is still not acceptable. With a population of largely elderly and indigent patients, the costs of ambulatory care and transportation may be significant barriers.

Abstract Number: 30

Vinicor F, Cohen SJ, Mazzuca SA, Moorman N, Wheeler M, Kuebler T, Swanson S, Ours P, Fineberg E, Gordon EE, Duckworth W, Norton JA, Fineberg NS, Clarck CM. DIABEDS: a randomized trial of the effects of physician and/or patient education on diabetes patient outcomes. *Journal of Chronic Disease* 1987;40:345-56.

Objective: To examine the effects of intensive patient and/or physician diabetes education on patient health outcomes.

Design: Randomized controlled trial.

Setting: This study was conducted in a general medicine clinic at Wishard Memorial Hospital, Indiana University Medical Center.

Patients: Diabetic patients were identified through the Regenstrief Medical Record System. Inclusion criteria were 1) health care provided by a resident; 2) fasting plasma glucose >129 on two occasions or >149 on one occasion, 2-hr postprandial plasma glucose >249, or random plasma glucose >299; 3) ability to perform at least two of the following: draw up and administer insulin, influence food selection, test urine for ketones and glucose; and 4) absence of major psychiatric illness or terminal medical condition. Out of 994 patients contacted over 29 months, 532 completed the baseline evaluation.

The average age and duration of diabetes in the patients were 57 and 8.9 years, respectively. The majority of the patients were black females with limited formal education.

In addition to the patient participants, 45 resident physicians participated in the physician education portion of the study.

Interventions: The study participants were assigned to one of four study groups: Group 1—control—residents and their patients received diabetic education that was routinely available in the clinic. Group 2—patient education—patients received a systematic education program focusing on target behaviors for diabetes self management. Diet and activity instruction took place over an 8-week period and included a home visit by a dietician. Group 3—physician education—resident physicians received a six-component course of instruction with problem-oriented protocols, a seminar, conferences with diabetes specialists, retrospective practice audits, a telephone hotline to diabetes specialists, and protocol-based physician reminders. Group 4—physician and patient education—where both physicians and patients entered the education programs described in Groups 2 and 3 above.

Main outcome measures and results: Patient education resulted in improvements in glycemic indices, body weight, and blood pressure. Patients not receiving education experienced an average 2.7 mg/dl decrease in fasting plasma glucose and an average 0.35% increase in hemoglobin A1c levels. In contrast, fasting plasma glucose and glycosylated hemoglobin values decreased in subjects receiving patient education by an average of 27.5 mg/dl and 0.43%, respectively ($p < 0.05$ for both variables).

Similar results were noted for physician education. Fasting plasma glucose for patients of residents who received no physician education decreased by an average of 4.1 vs. 26.1 mg/dl for patients of residents who participated in the Diabetes Research and Training Center (DRTC) training program ($p = 0.05$). Similarly, physician education resulted in a decrease in glycosylated hemoglobin of 0.39% vs. 0.31% increase in control patients ($p < 0.05$).

When both patients and their physicians participated in the education initiatives (Group 4), patient outcomes were significantly improved. Fasting plasma glucose values decreased by 39 mg/dl vs. an increase of 7.7 mg/dl in control patients ($p < 0.01$). Glycosylated hemoglobin values revealed a similar trend, with a 0.92% reduction in Group 4 patients vs. a 0.56% increase in patients receiving routine care ($p < 0.01$). Post-intervention 2-hour postprandial blood glucose, body weight, and diastolic blood pressure were also significantly improved by the combination of physician and patient education: adjusted means were 329.7 vs. 290.5 mg/dl ($p < 0.05$); control vs. patient plus physician education); 189.3 vs. 183.9 lb ($p < 0.01$); 85.5 vs. 81.5 mm Hg ($p < 0.005$), respectively.

Conclusions: This study indicates that patient or physician education alone resulted in improvements in short-term patient health outcomes. When both resident physicians and their patients received structured training in diabetes management, the greatest improvements in glycemic control and weight were observed.

Despite intensive patient and physician education programs, ideal therapeutic goals were not achieved. Resident knowledge deficiency was an unlikely explanation for this outcome as physician knowledge at baseline appeared adequate for the provision of optimal care. Similarly, major deficiencies in patient knowledge about diabetes were not present, suggesting that their knowledge level was also adequate.

It is possible that while physicians and patients attained positive attitudes and appropriate skills during the early phases of DIABEDS, such improvements were not sustained during the duration of the study. Similarly, more attention to the clinical support systems in which physicians practice might have resulted in achievement of treatment goals.

Abstract Number: 31

Weinberger M, Kirkman MS, Samsa GP, 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. *Journal of General Internal Medicine* 1995;10:59-66.

Objective: To test the hypothesis that a nurse-driven telephone intervention between primary care visits will improve glycemic control, health-related quality of life, and diabetes-related signs and symptoms.

Design: Randomized controlled trial.

Setting: The General Medical Clinic (GMC) of the Durham Department of Veterans Affairs Medical Center. The clinic covers approximately 3,000 patients and is covered by internal medicine specialists with or without the assistance of internal medicine house staff. Approximately 20% of GMC patients have diabetes mellitus.

Patients: 593 patients were identified via computer audit. After application of inclusion and exclusion criteria, 307 patients were eligible for the study. 275 patients (90%) gave initial consent and were enrolled. Patients were randomly assigned to the treatment group in a 3:1 ratio.

Patients were eligible if they had non-insulin-dependent diabetes mellitus (NIDDM), were on oral hypoglycemic agent or insulin, had access to a telephone, received primary care from GMC, and kept scheduled GMC appointments during a six-month enrollment period in 1991.

Exclusion criteria included the following: being incompetent for interview, residing in a nursing home, having severely impaired vision, hearing, or speech, receiving home health care, or being terminally ill.

Patients in the treatment group had an average age of 63.2 years, 57.7% were white, and 100% were male. In addition, average duration of diabetes was 10.3 years, with a mean ideal body weight of 130.6% and a mean glycohemoglobin of 10.7.

Patients in the control group had an average age of 63.9 years, 60% were white, and 98% were male. In addition, average duration of diabetes was 11.5 years, with a mean ideal body weight of 130.6%, and a mean glycohemoglobin of 10.7.

Interventions: Nurses attempted to telephone intervention patients monthly in order to:

- Educate patients by reviewing medication regimens and significant signs and symptoms of hypoglycemia and hyperglycemia;
- Facilitate compliance by reviewing medication regimens and reinforcing the importance of compliance, identifying barriers to compliance, and initiating actions to facilitate compliance;
- Monitor patients' health status, focusing on detection of significant hypoglycemic and hyperglycemic symptoms;
- Facilitate resolution of identified problem by alerting patient's GMC physician to problems; and,
- Facilitate access to primary care by reviewing all upcoming scheduled outpatient appointments, assessing potential barriers to clinic attendance, and providing increased telephone availability during regular clinic hours.

The control group received usual care.

Main outcome measures and results: The main outcome measures were glycemic control measured by glycosylated hemoglobin and fasting blood sugar, health-related quality of life measured by the SF-36, and diabetes symptoms measured by patient self report. At one year, between-group differences were significantly better for the intervention group for fasting blood sugar (174.1 mg/dl vs. 193/1 mg/dl, $p=0.011$) and glycosylated hemoglobin (10.5% vs. 11.1%, $p=0.046$). There were no significant differences in quality of life score or self reported diabetes-related symptoms.

Conclusions: This study shows that nurse telephone intervention has a small, positive impact on glycemic control in patients with highly elevated glycosylated hemoglobin levels. There was no concomitant improvement in quality of life as measured by the SF-36 and by self-reported symptoms. The lack of improvement in self reported symptoms is probably due to the relative lack of glycemic control even in the treatment group. In addition, it is difficult to assess the relationship between quality of life as measured by the SF-36 and physiologic markers such as glycated hemoglobin levels.

Abstract Number: 32

Wing RR, Jeffery RW, Burton LR, Thorson C, Nissinoff KS, Baxter JE. Food provision vs. structured meal plans in the behavioral treatment of obesity. *International Journal of Obesity* 1996;20:56-62.

Objective: The objective of this study was to examine the contribution of the following three components to the benefits observed with food provision: (1) the specific meal plans indicating what foods should be eaten at each meal; (2) the food itself; or (3) the fact that food was provided free.

Design: Randomized controlled study.

Setting: Half of the study participants were from Minneapolis-St. Paul, Minnesota and the other half were from Pittsburgh, Pennsylvania. No other information about the specific location of the intervention was given.

Patients: One hundred sixty-three women were recruited for the study from newspaper advertisements. Subjects averaged 41.3 ± 7.4 years, with a body weight of 86.4 ± 5.9 kg.

Eligibility requirements included age between 15 and 55 years, being overweight by 30-70 lbs, not pregnant or planning to become pregnant, and free of restrictions from a diet or exercise program.

Interventions: Subjects were randomly assigned to one of four conditions: (1) Standard Behavioral Treatment (SBT)—26 weekly sessions led by therapists with training in nutrition and/or behavior modification. Participants were given instructions to stay below their calorie and fat goals and were taught basic principles of healthy eating. An exercise program was prescribed and behavioral strategies were presented at each of the weekly sessions. (2) Menu—same as SBT but with the addition of written meal plans indicating exactly what types of foods and portion sizes they should consume. They were also given a weekly grocery list to use for preparation of the prescribed meals. (3) Buy food—same as SBT and menu groups, however, this group received a box of food containing all the items in the meal plans. The participants were required to pay \$25.00 per week for the food. (4) Free food—same as SBT and menu groups, however, this group received a box of food containing all the items in the meal plans at no cost.

Main outcome measures and results: Ninety-one percent of the subjects completed assessments at the end of six months. Seven dependent measures were evaluated in this study:

1. Weight: Weight losses in the SBT group (8.0 ± 6.2 kg) were significantly smaller than those in the other three groups (Menu— 12.0 ± 7.2 kg, Buy food— 11.7 ± 5.4 kg and Free food— 11.4 ± 6.5 kg), with analysis of covariance $F(3,143)=30.4$, $p<0.03$. The contrast between SBT and all other groups was highly significant, $F(1,140)=8.97$, $p<0.003$, but other contrasts were not.
2. Barriers to adherence: Groups that were given meal plans, with or without food, reported greater decreases in perceived difficulties associated with estimating portion sizes, finding time to plan meals and controlling eating when not hungry.
3. Dietary intake: Subjects in the SBT group reported consuming 1,055 kcal/day compared with a mean for the other three groups of 990 kcal/day, $F(1154)=5.57$, $p<0.02$. No significant differences were seen between the other three groups.
4. Food stored in home: The reported number of fruits and vegetables, low-fat meats, medium-fat meats, breads and cereals and low-calorie frozen entrees all increased significantly more in the groups with menus and food than in the SBT group.
5. Eating patterns: Both the menus and food provision led to more regular eating patterns. The number of times/week subjects reported eating breakfast and lunch increased more and the number of times/week subjects reported eating snacks decreased more in all groups except SBT.
6. Knowledge: Increases in knowledge about dieting and in the accuracy of estimating calories were observed in all groups, but there were no significant differences between treatment conditions.
7. Physical activity: There were no significant differences in self-reported exercise based on the activity questionnaire or on the self-monitoring diaries.

One year follow-up data were obtained for 146 subjects. The a priori contrasts showed that the SBT group produced significantly poorer long-term weight losses than the remaining three treatment groups ($p < 0.002$), which did not differ from each other.

Conclusions: Subjects in the standard behavioral weight control program lost 8.0 kg over 26 weeks. The groups with the additional benefit of meal plans and grocery lists significantly improved this outcome to an average weight loss of 12 kg. Moreover, meal plans and grocery lists produced weight losses that were equivalent to those achieved by providing the subject with specified foods. Thus, the element of the food provision intervention that appears responsible for its success is the provision of meal plans and grocery lists.

The data suggest two mechanisms by which the meal plans may improve weight loss: by structuring the eating behavior of the subject and by changing the food in the home environment.