Evaluating Concordance to American Diabetes Association Standards of Care for Type 2 Diabetes Through Group Visits in an Uninsured or Inadequately Insured Patient Population

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OBJECTIVE — To evaluate the effectiveness of a managed care approach to health care delivery, group visits, in the management of uninsured or inadequately insured patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS — A total of 120 patients with uncontrolled type 2 diabetes were randomly assigned to receive their care in group visits or usual care for 6 months. After 6 months, concordance with 10 process-of-care indicators recommended by the American Diabetes Association (ADA) standards of care was evaluated through chart abstraction. The 10 items evaluated were up-to-date HbA_{1c} levels and lipid profiles, urine for microalbumin, appropriate use of ACE inhibitor or angiotensin receptor blockers, use of lipid-lowering agents where indicated, daily aspirin use, annual foot examinations, annual referrals for retinal examinations, and immunizations against streptococcal pneumonia and influenza.

RESULTS — Patients who received care in group visits showed statistically significant improvement in concordance with these 10 process-of-care indicators ($P < 0.001$). Of the patients, 76% who received care in group visits had at least 9 of these 10 items up to date, as compared with 23% of control patients; 86% of patients in group visits had at least 8 of the 10 indicators compared with 47% of control patients.

CONCLUSIONS — Group visits proved more effective in promoting concordance with ADA standards of care than usual care in the treatment of uninsured or inadequately insured patients with type 2 diabetes.

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During this time of more tightly controlled resources, all health care organizations are challenged to deliver efficient and effective care to their patients with type 2 diabetes, consistent with American Diabetes Association (ADA) standards of care (1). The group visit model, developed in managed care settings to address issues of treatment effectiveness and efficiency, offers promise. Previous studies have shown group visits to be at least as effective as usual care but less costly. Beck et al. (2) developed and implemented a group visit intervention for geriatric patients with a history of high health services utilization patterns. A physician and nurse conducted these group visits, which lasted 2 h monthly, for a duration of 1 year (12 sessions). Although there were no significant improvements in self-reported health and functional status for the intervention group, there were significant decreases in emergency care visits, specialty care visits, and hospital admissions, as well as higher administration rates of influenza and pneumonia vaccinations, completion of advance directives, and improved satisfaction with care.

Trento et al. (3) demonstrated that providing health care in groups of patients with type 2 diabetes resulted in improved metabolic control compared with usual care. Group patients showed significantly increased knowledge of type 2 diabetes and quality of life. Except for race, the patients who participated in this Italian study were similar demographically to the patients in the study reported here, with similar employment, education, and insurance.

Another study targeting patients with type 2 diabetes aged 16–75 years, with either a recent HbA_{1c} level >8.5% or no HbA_{1c} measurement in the previous year, evaluated a slightly different model of group visits (4). In this model, a team led by a diabetes nurse educator, with input from a dietitian, behaviorist, and pharmacist and supported by two diabetologists, conducted monthly 2-h group visits in 6-month cycles focused on diabetes. Patients continued to receive their routine care from their primary care providers in

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Abbreviations: ADA, American Diabetes Association; APCC, Adult Primary Care Center; CHCC, Cooperative Health Care Clinics.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

the managed care organization. Although the physician coinvestigators met periodically with the diabetes nurse educators to review the patients' progress and a physician was readily available to the group if needed, the physicians were not active participants in these group visit sessions. The investigators reported improvement in diabetes control, self-efficacy, and patient satisfaction, with decreased use of health services. It should be noted, however, that an intent-to-treat analysis was not performed, except for the health services use analyses.

While the group visit model of health care delivery has proven effective in managed care patient populations, there have been no studies to date in disadvantaged populations. The present study was conducted to evaluate group visits as a modality of care for uninsured and inadequately insured patients with uncontrolled type 2 diabetes.

Objectives and outcomes

We hypothesized that delivering care in a group setting would improve our ability to follow ADA clinical practice recommendations for management of type 2 diabetes. These recommendations included up-to-date HbA_{1c} and lipid levels, urine for microalbumin, use of ACE inhibitor or angiotensin receptor blockers when indicated, use of lipid-lowering agents when indicated, daily use of aspirin, annual foot examinations, annual referrals for retinal examinations, and immunizations against streptococcal pneumonia and influenza. Additionally, we compared medical outcomes as measured by actual HbA_{1c} levels and lipid profiles.

RESEARCH DESIGN AND METHODS

Study population

This study took place at the Adult Primary Care Center (APCC) at the Medical University of South Carolina (MUSC), a clinic that serves ~6,000 uninsured or inadequately insured patients in the Charleston, South Carolina, area. Diabetes is the second most common diagnosis for which patients are seen at this clinic. The equivalent of four full-time academic internal medicine faculty physicians who supervise residents, nurse practitioners, physician assistants, and students serve this largely minority patient population.

Eligible patients aged ≥18 years with a diagnosis of type 2 diabetes and HbA_{1c} >8.5% (a pool of >2,000 patients) were identified through a query of the electronic medical record used at the APCC. Exclusion criteria included primary diagnosis of substance abuse or dependence, current pregnancy, dementia, or inability to speak English. Identified patients were invited to participate through telephone or on-site solicitation. This was accomplished with a standardized script that was presented to the patients by one of three consistent interviewers. Modest patient compensation (for transportation and time) for all patients (intervention and control) was provided whenever the patients came in for baseline, 3-month, and 6-month study data collection.

Randomization and blinding

A total of 120 patients providing written informed consent were randomly assigned to the intervention group (group visits) or the control group (usual care). A program developed by the University of Texas System Cancer Center (Randlst), which allows stratification and blocking, was used for randomization (http://odin.mdacc.tmc.edu/anonftp/). We used block randomization with a block size of four to ensure balance in numbers of patients randomized to the two interventions. Assignment notification was accomplished through the patients' opening of sealed envelopes upon giving written consent and having baseline data collected. Once the patients received their assignments, they advised the study administrator, who recorded the assignments in a log. The intervention patients were then able to schedule themselves into the group visit schedule that was most convenient for them. Clinic personnel were blinded to the patients' assignments throughout the study, unless the patients volunteered that information at visits other than group visits.

Procedure

At baseline and within a 2-week period at 3 and 6 months postrandomization, all study patients came to the same laboratory for measurement of HbA_{1c} and lipid profiles (total cholesterol, HDL, LDL, and triglycerides). These study test results were in addition to those obtained for the clinical care and were paid for by the study. Study participants were reimbursed for time and transportation to the laboratory for the specimen collections, as previously described. Laboratory results obtained for study purposes were not entered into the medical record until after study completion, to avoid influence on patterns of care.

Upon conclusion of the study, record abstraction was performed on the charts of all patients enrolled. Medical records were abstracted to determine process-of-care indicators, including pneumonia and influenza vaccination rates, frequency of HbA_{1c} and lipid profile measurements, screening for microalbumin, lipid treatment, appropriate use of ACE inhibitors, annual foot examinations, referrals for retinal examinations, and use of aspirin. The record abstraction was performed using a standardized template. Accuracy of abstraction was confirmed by independent review of 10% of the records by the outcomes manager for the clinic, who was blinded to patient assignment.

Intervention

Group visits were co-led by a primary care internal medicine physician and diabetes nurse educator. These visits were modeled after the approach of the Cooperative Health Care Clinics (CHCC) developed by Beck et al. (2). Before starting the study, and after having reviewed the pertinent literature and the orientation manual for the CHCC, the physician and nurse who were to conduct the group visits were trained at the CHCC in Denver, Colorado. They met with the Coordinator for the CHCC who trains all CHCC providers, and they observed several group visits in session. This mirrored the training that providers in the CHCC receive.

After the provider training had been completed and baseline data had been obtained from the patients, those randomized to the intervention condition were scheduled into three groups, consisting of 19 or 20 patients each, that met monthly for 6 months. The visits were held in the same building but on a different floor from the clinic itself and were intended to be the main source of medical care. If patients needed care between the scheduled group visits, or if specific medical needs could not be accommodated in the group visit, they could schedule a one-on-one visit with an APCC provider. Each group visit session was scheduled for 2 h; each session consisted of 15 min of warm-up and socialization; 30 min of presentation of a health-related topic (facilitated by the physician or another team member with

special expertise); a 15-min break, during which time the nurse and physician circulated, attending to individual needs, immunizations, appointment scheduling, and other issues; 15 min of questions and answers; 15 min of planning the next session; and 30 min of one-on-one consultations with the physician. Key preventive measures, e.g., pneumonia and influenza vaccinations as well as foot examinations, could be performed during the group visits. Content of the group visits was guided by the group members themselves, although the educational topics covered included the core curriculum topics used by Sadur et al. (4), such as nutrition, exercise, foot care, medications, complications, and the emotional aspects of diabetes. Upon conclusion of the group portion of the visit, patients had the opportunity to see the physician individually if desired.

Control

Patients randomized to the control condition continued to receive care at the clinic as usual. Usual care at the APCC consists of seeing a medical professional (faculty or resident physician; medical assistant, physician assistant, or nurse practitioner student; physician assistant; or nurse practitioner), who would attempt to see the patients at least quarterly, as recommended by the ADA. Due to the volume of patients at the APCC, patients do not usually have the opportunity to see the same provider at each visit nor do they consistently have quarterly visits due to insufficient numbers of providers, staff, and available appointments. The staff at the APCC attempts to follow the ADA standards of care for patients with type 2 diabetes with quarterly visits and laboratory assessments of HbA_{1c} levels. In addition to the personnel noted above, referrals are available for the patients with type 2 diabetes to see a diabetes educator or a dietitian.

RESULTS — A total of 242 patients were contacted by phone or on site during a 4-week period in May and June 2001 to reach the enrollment goal of 120 patients. Using the procedures specified above, 59 patients were randomly assigned to group visits and 61 patients were assigned to usual care. The demographics of the patients are shown in Table 1. Ten patients in usual care and seven patients in group visits withdrew from the study. One of the seven patients who withdrew from the study moved out of the area after randomization but before the first group visit. This patient's data were not used in the final data analysis.

Table 1—*Baseline demographics*

Variables	Group visit	Usual care
n	59	61
Age (years)	52.64	55.23
Sex (male)	12	14
Race		
African American	46	47
Caucasian	14	12
Other	0	1
Marital status		
Single	23	22
Married	25	16
Divorced	3	8
Separated	1	9
Widowed	7	6
Education years completed	10.81	10.44
Insurance		
Commercial	4	3
Medicaid	16	17
Medicaid A&B	8	12
Medicare/Medicaid	12	10
Medicare alone	1	1
No insurance	18	18
Work		
Full/part time	17	11
Retired/unemployed	42	50

Data are *n*.

HbA_{1c} levels and lipid profiles were analyzed at baseline and at 3 and 6 months postrandomization (Table 2). Record abstraction was performed at study completion for process-of-care indicators. For each single outcome, Student's *t* test for continuous outcomes and nonparametric Wilcoxon's rank test for ordinal outcomes were used to compare the differences between the group visit and the control conditions. At each domain of the outcomes, the global statistical test was performed again to see whether there was any overall difference between group visit and control conditions. Using the intention-to-treat model, all patients were included in the final analysis, except for the one control patient who moved out of the area postrandomization but before the first group visit. The HbA_{1c} levels and lipid profiles of patients who withdrew or were withdrawn from the study were held at their baseline values, and their chart reviews were performed in the same manner as for the patients remaining in the study.

We used SAS procedures based on generalized estimating equations or random effect models to take clustering into account, adjusting for covariates and treatment effects. Using the SAS procedures, we adjusted for clustering and used linear regression for HbA_{1c} analyses (with transformations as needed). In all analyses, we included the stratifying variables (race and sex) used in randomization in the analysis as covariates. These differences at baseline in covariates between groups were assessed by nonparametric (continuous or ordinal variables) or χ^2 tests. For analyses of HbA_{1c} levels, patients with missing values were assumed to have no change from baseline. For binary variables, patients with missing values were given the worst score.

Baseline analyses showed that all variables were well balanced between the group visit and control groups (Table 2). The mean HbA_{1c} levels at baseline were similar for intervention patients (10.3%) and control patients (10.6%) (range 6.6–16.7%). At mid-study and study completion, both patient groups showed improvement (although not statistically significant) in diabetes control compared with baseline; however, at completion of

Table 2—*HbA_{1c} and lipid profile data*

	Usual care (control) (n = 61)			Group visits (intervention) (n = 59)		
	Baseline	3 months	6 months	Baseline	3 months	6 months
HbA_{1a} (%)	10.263	9.576	9.714	10.556	9.873	9.513
Cholesterol (mg/dl)	204.569	199.431	196.961	205.769	197.250	195.635
Triglycerides (mg/dl)	179.765	181.667	174.294	205.365	164.827	182.904
HDL (mg/dl)	47.255	47.608	47.529	46.346	49.019	50.885
LDL (mg/dl)	121.714	117.646	116.149	123.333	109.940	107.617

Data are means.

the study, the intervention patients' HbA_{1c} levels were continuing to decrease and the control patients' levels were beginning to increase.

Lipid profiles measured at baseline showed no significant differences between the patient groups. The mean total cholesterol level was 205.8 mg/dl in the intervention patient group and 204.6 mg/dl in the control group ($P = 0.8965$). Triglycerides, LDL levels, and HDL levels also showed no statistically significant differences at baseline between the two groups. At conclusion of the study, all lipid profile components were improving in the intervention and control patients. Although the slopes of the curves were steeper in intervention patients, they were not statistically significant.

We combined outcome measures from all three visits into a mixed model and tested whether outcome changes from baseline were different between the treatment and control groups. For each of the five outcomes (HbA_{1c}, cholesterol, triglycerides, HDL, and LDL), we first fit a mixed model that included covariates, treatment group indicator, the number of months from baseline to the current visit, and the interaction between treatment group and month. The dependent variable was the change of the outcome measure from baseline. We used an unstructured correlation matrix for the repeated outcome measures in the mixed model. SAS procedure PROC MIXED was used in the computation. After checking for no significant treatment × month interactions for all five models, we refit each model without the treatment × month interaction term. Although treatment effect from each model was not significant for all five outcomes (*P* values 0.095–0.590), the coefficients (i.e., the slopes) for the treatment were negative for models of HbA_{1c}, cholesterol, triglycerides, and LDL, and the coefficient for treatment was positive for model of HDL. This implies that, after adjusting for baseline measures, patients in the treatment group had more improved outcomes (although not significantly) in all five measures (HbA_{1c}, cholesterol, triglycerides, HDL, and LDL) than those in the control group.

For the 10 process-of-care indicators (up-to-date HbA_{1c} levels and lipid profiles; urine for microalbumin; use of ACE inhibitor or angiotensin receptor blocker, especially in the face of microalbuminuria; use of lipid-lowering agents for LDL levels >100 mg/dl; daily use of aspirin; annual foot examinations; annual referrals for retinal examinations; and immunizations against streptococcal pneumonia and influenza), there was a significant advantage in the intervention group, which is described as follows. The mean total number of criteria met was 8.75 ± 0.17 in the intervention group and 7.22 ± 0.24 in the control group ($P < 0.001$ from Student's *t* test). Using the Wilcoxon's test to compare the number of compliance items, we saw that patients who received care in group visits showed a statistically significant advantage in concordance with these 10 processes of care ($P < 0.001$). This difference remained highly significant (all $P < 0.001$), no matter how we dichotomized the data. A total of 16 of the 59 patients in group visits (27%) had all 10 of the process-of-care indicators performed, as compared with only 5 of 60 control patients (8%). Further analysis showed that 45 group patients (76%) compared with 14 control patients (23%) had at least 9 of the 10 indicators ($P < 0.001$) and 51 group patients (86%) compared with 28 control patients (47%) had at least 8 of the 10 indicators addressed ($P < 0.001$). These process-of-care indicators were measured only at completion of the study. Because these were isolated measurements, a mixed effect general linear modeling could not be used for comparison. Of note, the median of the items in the treatment group was nine, compared with seven in the control group.

Although conceptualized as an effectiveness study, we also captured data on outpatient, inpatient, and emergency room costs and use. Because of the skewed distributions, all tests were performed using the Wilcoxon's rank test, which is suitable for such data. In the 6-month study period, overall costs were significantly higher ($P = 0.0003$) for the group visit patients ($2,886 per patient) compared with the control patients ($1,490 per patient). Both outpatient costs ($1,444 for intervention patients versus $1,099 for control subjects) and inpatient costs ($1,410 for intervention patients versus $365 for control subjects) were statistically significant ($P = 0.008$ and 0.049, respectively), but emergency department costs were not ($32 for intervention patients vs. $26 for control subjects) ($P = 0.396$). Group visit patients made an average of 6.4 visits compared with 5.1 visits for control patients. There were 4 patients in usual care that had hospital admissions (4 total episodes) and 12 patients in group visits who had hospital admissions (15 total episodes). Only 8 patients in usual care and 12 patients in group visits had emergency department visits.

CONCLUSIONS — In our study, we were able to show statistically significant differences between the intervention and control patients in the adherence to ADA standards of care (1). Group visits, longer in duration than the typical primary care encounter, offer the provider more time to address process-of-care indicators. Seeing patients on a monthly basis provides more frequent contact with the physician, which gives the patients more opportunities to ask questions and the provider more opportunities to address process-of-care indicators in a systematic fashion. Additionally, when providers care for patients in groups, they are able to deliver consistent messages to multiple patients at once, rather than giving the same message multiple times.

Despite the improvement in delivery of the process-of-care indicators, there were no significant differences seen in diabetes or lipid control. This is likely due to the small sample size as well as the short duration of the pilot. A previously conducted Italian study with patients of similar self-reported educational levels showed that the differences in HbA_{1c} levels between the control and intervention groups began to show strong associations at 12 months and statistical significance at 24 months (3). In our study, the intervention patients did show a greater improvement (albeit not statistically significant) in HbA_{1c} levels as well as total, LDL, and HDL cholesterol levels over the 6 months than those in usual care. With a larger study that is longer in duration, we would expect to see improved quality of care translate into improved physiologic markers. The fact that our patients have significant financial limitations and may not be able to obtain medications as prescribed could have contributed to the lack of significant change in medical outcomes. Interestingly, all patients were asked via survey whether they were having difficulty paying for their diabetes treatment and supplies. By the final data collection point, the group visit patients indicated that they were having a problem

less often than did the control patients ($P = 0.04$). Many of the patients may have been too proud to admit to financial difficulties in obtaining medications, however. Therefore, perhaps evaluation of refill histories (with patient consent) would have alerted the team to the possibility of such a problem and the need for intervention.

The fact that costs for patients in group visits were higher than those in usual care differs from previous studies. These cost findings should be interpreted with caution. Three lines of reasoning are important here. First, the samples are relatively small for economic analyses, and there is a high degree of variability (SDs were often larger than means). Inpatient costs are the main driver of the $1,396 difference between average intervention and control patients' costs. In the intervention group, the top five patients' costs accounted for 81.3% of that group's inpatient costs, thus demonstrating how a small number of patients can influence the overall results. The second point to consider is that the group visits themselves may have served to "activate" the participants. Additional outpatient visits may have been appropriate to "catch up" on care that had previously been neglected and for which the patients now understood the need for and were now motivated to schedule. Additionally, appointments could be easily scheduled at the time of group visits. Last, it is possible that there might be a time lag for decreased costs that might not show up in the first 6 months of group visits, because patients are getting "caught up" in their care. Furthermore, the benefits of improved self-care might not be evident in the first 6 months. Others have found that increased access to primary care has actually increased other service use (5).

In conclusion, this study of group visits in disadvantaged patients with type 2 diabetes showed statistically significant improvements in process-of-care indicators. Despite this, there were no significant improvements noted in medical outcomes, although there were positive trends. Further evaluation with a larger study of longer duration is needed to determine whether this model of health care delivery will result in improved physiologic markers. Although patient satisfaction trended toward being higher among patients who participated in groups than in the control population, the results were not statistically significant. Because the physician and nurse were held constant across the groups throughout the study, no provider satisfaction surveys were performed. This could be performed with a larger study in which more providers participate.

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