Effectiveness of diabetes resource nurse case management and physician profiling in a fee-for-service setting: a cluster randomized trial

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Nurses with advanced training—diabetes resource nurses (DRNs)—can improve care for people with diabetes in capitated payment settings. Their effectiveness in fee-for-service settings has not been investigated. We conducted a 12-month practice-randomized trial involving 22 practices in a fee-for-service metropolitan network with 92 primary care physicians caring for 1891 Medicare patients ≥ 65 years with diabetes mellitus. Each practice was randomized to one of three intervention groups: physician feedback on process measures using Medicare claims data; Medicare claims feedback plus feedback on clinical measures from medical record (MR) abstraction; or both types of feedback plus a practice-based DRN. The primary endpoint investigated was hemoglobin A_{1c} level. Other measures were low-density lipoprotein (LDL) cholesterol level, blood pressure, annual hemoglobin A_{1c} testing, annual LDL screening, annual eye exam, annual foot exam, and annual renal assessment. Data were collected from medical chart abstraction and Medicare claims. The number of patients with hemoglobin A_{1c} $< 9\%$ increased by 4 (0.9%) in the Claims group; 9 (2.1%) in the Claims + MR group (comparison with Claims: $P = 0.97$); and 16 (3.8%) in the DRN group (comparison with Claims: $P = 0.31$). Results were similar for the other clinical outcomes, with no differences significant at $P = 0.10$. For process of care measures, decreases were seen in all groups, with no significant differences in change scores. Quality improvement strategies must be evaluated in the appropriate setting. Initiatives that have been effective in capitated systems may not be effective in fee-for-service environments.

In 2002 approximately 18 million people in the USA had diabetes mellitus (1), and the costs associated with this disease approach \$100 billion per year (2). The bulk of this cost is due to complications, particularly cardiovascular, eye, kidney, and lower-extremity disease, that can be prevented or delayed by control of lipids, glycemia, and blood pressure and by early detection and treatment of diabetic retinopathy, nephropathy, and foot disease (3–9). However, studies show that less than half the people with diabetes achieve the American Diabetes Association (ADA) recommended levels for hemoglobin A_{1c}, blood pressure, and low-density lipoprotein (LDL) cholesterol; receive tests to monitor these indicators; or receive screening for diabetic retinopathy and nephropathy as frequently as the ADA recommends (3, 10–17).

Multiple interventions to improve diabetes care and control have been tested in diverse care settings (18–23), with varied success (23). In 1998, Aubert et al reported improving glycemic control in a health maintenance organization setting through nurse case management (22). Other studies show similar success in an independent practice association (24), a Veterans Affairs (VA) general medical clinic (25), an inner-city hospital diabetes clinic (26), and a Kaiser Permanente medical center (27). Systematic reviews suggest that nurse case management leads to improvements in patient outcomes and processes of care for diabetes patients (23, 28). However, a recent study conducted in VA medical centers found that nurse case management did not improve key physiologic outcomes for patients with type 2 diabetes—a difference the authors suggest may be due to the type of patient targeted, organizational factors, and program structure (29).

We report the results of a practice-randomized trial testing the effectiveness of a diabetes resource nurse (DRN) in improving diabetes care for Medicare patients in a multisite, fee-for-service primary care setting. Based on the results of a pilot study conducted between 1999 and 2001 (19), we expected the intervention group with access to the DRN to show improvements in process measures and patient outcomes.

The DRN intervention group also received patient-specific feedback related to clinical Diabetes Quality Improvement Project (DQIP) measures taken from chart review. To further assess the advantage of using a DRN over this approach to improving diabetes care, we included an intervention group of physician practices that received patient-specific feedback in addition to usual claims-based feedback. We hypothesized that this group

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Funding was provided by the American Diabetes Association, Pfizer, Inc., and the Baylor Health Care System.

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would show intermediate performance when compared with the other groups.

METHODS

We randomized 22 practices to one of three strategies for improving diabetes care: feedback from Medicare claims data (Claims group); feedback from Medicare claims data and patient-specific DQIP measures determined from medical record (MR) abstraction (Claims + MR group); or feedback from Medicare claims and patient-specific DQIP measures plus access to a DRN (DRN group). DRNs were registered nurses with 3 to 5 years of experience as certified diabetes educators who performed initial patient assessments, developed plans of care, administered screening tools, and monitored clinical outcomes. DRN care protocols for glycemic, lipid, and hypertension control were developed by members of the research team leading the DRN intervention and approved by a quality committee with representatives from all practices that participated in the trial. We collected medical record data for each diabetes patient over the 1-year baseline period. Follow-up data were collected for this same cohort over the 1-year follow-up period.

Setting

HealthTexas Provider Network (HTPN) is the employed physician component of the Baylor Health Care System, an integrated health care delivery system in Dallas–Fort Worth, Texas. HTPN physicians operate in a fee-for-service setting; risk-based contracts are prohibited by group policy.

Sample selection

Sample size. Using estimates of patient numbers, correlation, and variance based on Medicare claims data from HTPN practices, we estimated prior to recruitment that 21 practices (7 per arm) would provide 80% power to detect a 0.76-percentage-point difference in hemoglobin A_{1c} improvement between arms.

Practices. We considered the 32 HTPN family medicine and internal medicine practices. Practices that had been part of Baylor Health Care System for <1 year (n = 2), had <10 diabetes patients with Medicare coverage (n = 4), had previous exposure to the interventions we planned to test (n = 2), were in the process of closing (n = 1), or included residency programs (n = 1) were excluded. Within participating practices, physicians specializing in internal medicine or family practice, employed by the practice during the full baseline period, and with at least 1 diabetes patient meeting study criteria were included, giving a final cohort of 22 practices and 92 physicians (Figure).

Figure. Flow diagram showing the randomization of practices to the study arms in the randomized controlled trial testing the effectiveness of a diabetes resource nurse in improving diabetes care for Medicare patients in a fee-for-service primary care setting. HTPN indicates HealthTexas Provider Network (the Baylor Health Care System–affiliated physician network in Dallas–Fort Worth, Texas); Claims study arm, feedback on diabetes processes of care provided, based on Medicare claims data; Claims + MR study arm, feedback on diabetes processes of care provided plus patient outcomes based on Medicare claims data and medical record abstraction; Claims + MR + DRN study arm, feedback on diabetes processes of care provided plus patient outcomes based on Medicare claims data and medical record abstraction, plus access to a practice-based diabetes resource nurse.

Patients. With the Texas Medical Foundation, we defined the study cohort of Medicare diabetes patients, using an algorithm developed by Hebert and colleagues (30) and used by the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) in defining the national diabetes cohort for the Sixth Scope of Work (31). Patients aged ≥65 years on January 1, 2000, with a physician visit related to diabetes in 2000 and Medicare insurance coverage were identified from HTPN billing data. Length of Part B enrollment, vital status, and length of state residency were determined from Texas Medicare enrollment files.

Patients who received care from more than one HTPN physician were assigned, for feedback and analysis, to the physician with whom they had the most primary care visits during the study period. Patients who did not fulfill National Diabetes Quality Improvement Alliance criteria for diagnosis of diabetes mellitus were excluded, as were patients whose charts were not available for abstraction. To ensure that all enrolled patients had 12 months of follow-up, we excluded patients who died before the end of the follow-up period.

Data collection

Baseline measures were abstracted for January 1, 2000, through December 31, 2000. Follow-up data for these same patients were collected from January 1, 2001, to December 31, 2001.

The primary data source was a retrospective medical record analysis conducted by nurse abstractors using the DQIP abstraction tool. To account for the possibility that in this fee-for-service setting, patients might seek care from providers outside the network or from specialists (e.g., ophthalmologists for eye exams) that would not be reflected in HTPN records, we collected available indicators from Medicare claims data. All indicators can be determined from medical record abstraction, but only hemoglobin A_{1c} testing, lipid screening, and dilated eye exam are recorded in Medicare claims data. All individuals involved in data collection were blinded to patients' study arm assignments.

Randomization

Practices were stratified by number of diabetes patients seen during the baseline period (7–49, 50–109, and ≥110 patients) to ensure even distribution of patients across arms. Since several practices shared a single location, we performed stratification on these practices to ensure that they fell into different study arms. Since all practices in the multipractice location were in the two larger strata, this resulted in five strata total. Within each stratum, practices were sampled and randomized in triplets to ensure even distribution. Since only four sites fell into the larger multisite strata, these were force randomized so that only one fell into the Claims group.

Variables

Primary outcome measures. The primary endpoint was hemoglobin A_{1c} level, classified as <9% or ≥9% based on the National Diabetes Quality Improvement Alliance guidelines (32). Other clinical endpoints were LDL level and diastolic and systolic blood pressures. These were collected as continuous measures from medical record abstraction and classified in two ways, based on the ADA and National Diabetes Quality Improvement Alliance guidelines for adequate control (32, 33). For LDL, the respective cutoff points were 100 mg/dL and 130 mg/dL; for blood pressure, 130/80 mm Hg and 140/90 mm Hg.

Secondary outcome measures. As secondary outcomes we analyzed the levels of hemoglobin A_{1c}, LDL, and diastolic and systolic blood pressures as continuous measures. We also collected process measures data. From medical record review, we

collected data on annual hemoglobin A_{1c} assessment, annual lipid assessment, annual blood pressure measurement, annual eye exam, annual foot exam, and annual renal assessment. From Medicare claims, we collected data on annual hemoglobin A_{1c} assessment, 6-month hemoglobin A_{1c} assessment, annual eye exam, and annual lipid assessment.

If multiple clinical measures were found in either the baseline or follow-up period for a given patient, the most recent measure in that period was used.

Additional variables. Age, sex, and race data were collected from Medicare claims files. Race was classified as white, black, or other, as data from the Centers for Medicare and Medicaid Services are unreliable beyond this level (34). Socioeconomic status (SES) was determined by an algorithm using patient ZIP code and the Claritas ZQ score (35). The ZQ score (Claritas, Inc, San Diego, CA), is derived from census data, calculated from household income, level of education, occupation scores, and home values aggregated by ZIP code; this score ranges from 1 (lowest SES) to 100 (highest SES). These variables were compared between groups, and significant differences were accounted for in the final analysis.

Statistical analysis

Because patients were randomized by clusters (practices), we used techniques appropriate for clustered data. Analysis of variance demonstrated nontrivial within-cluster variance in all outcomes at both physician and practice level, as well as substantial within-practice variance for patient characteristics. All analyses accounted for the correlation of measurements within practices or, for outcome measures, physicians and practices (36, 37).

We summarized patient and physician characteristics overall and for each study arm. We tested the effectiveness of the randomization by comparing patient and physician characteristics across arms using practice-adjusted chi-square and *t* tests (37).

In addition, because of the potential for floor effects related to good performance on baseline hemoglobin A_{1c} levels, we assessed differences in baseline measures across arms for clinical outcomes. Where differences were found, we adjusted for baseline measures.

Primary analyses. To assess the effectiveness of the two interventions, we calculated a change score for each primary and secondary outcome, subtracting the follow-up value from the baseline value for each patient. Patients missing either value were excluded. To test for differences in change scores between study arms, we used a three-stage hierarchical model (36–38) for each outcome to estimate the effect of the interventions on the change in endpoint from baseline to follow-up. Change scores for the dichotomous measures were scored as –1, 0, or 1, with a positive value indicating increased guideline adherence or increased incidence of that process. We used ordered logistic models to test the hypothesis that patients in the intervention groups were more likely to meet guidelines or to receive these processes of care.

Secondary analyses. We performed a secondary analysis using all observations, including patients missing baseline or

follow-up clinical measures. We estimated a repeated measures model for each outcome and tested the interaction between measurement period (pre- or postintervention) and intervention group assignment. These were linear four-level hierarchical models with observations nested within patients, clustered within physicians, who were clustered within practices. For process measures there were no missing data; any process not documented in the record was scored as negative.

An additional secondary analysis repeated the primary and secondary analyses above including patients who did not survive the follow-up period. We also compared 12-month mortality across the three arms. Finally, to assess the potential impact of floor effects, we repeated the primary analysis using only those patients with baseline hemoglobin A_{1c} levels ≥7%.

Software. All statistical analyses were performed using SAS 8.2 (SAS Institute, Cary, NC), Stata 9 (Stata Corporation, College Station, TX), and HLM6 (Scientific Software International, Lincolnwood, IL).

Approval and funding

Our study was approved by the Baylor University Medical Center institutional review board for human protection. External funding was provided by the American Diabetes Association and Pfizer, Inc. Neither organization was involved in study design, data collection, data analysis, or interpretation of data or asked to approve the final version of the manuscript.

RESULTS

Study sample

In the baseline period, 2155 diabetes patients were identified. Of these, 130 were excluded for unconfirmed diabetes diagnosis; 15 were excluded for missing charts in the baseline period; and 119 died before the end of the follow-up period, leaving 1891 patients (Figure). Age, sex, ethnicity, and SES measure did not differ significantly across study arms (Table 1). A total of 92 internal medicine and family practice HTPN physicians served as primary care physicians for these patients (Table 2). There was no imbalance in age, sex, or specialty (family practice vs internal medicine) across the study arms.

Of the 1891 included patients, charts could not be found for 3 in the follow-up period. Table 3 shows baseline and follow-up results for patient outcome and process measures for the remaining 1888 patients. A number of outcome measures were missing: 5.0% of patients were missing blood pressure readings; 13.2%, hemoglobin A_{1c} values; and 31.9%, LDL readings. There were no differences in baseline clinical measures or

Table 1. Characteristics of 1891 Medicare diabetes patients aged ≥65 years participating in the randomized controlled trial testing the effectiveness of a diabetes resource nurse (DRN) in improving diabetes care in a metropolitan, fee-for-service, primary care setting (HealthTexas Provider Network, Dallas–Fort Worth, Texas, 2000–2001)

Characteristic	Study arm			Total (n = 1891)
	Claims (n = 565)	Claims + MR (n = 758)	Claims + MR + DRN (n = 568)	
Mean age (years)	73.1	72.6	73.2	72.9
Female	290 (51.3%)	380 (50.1%)	279 (49.1%)	949 (50.2%)
Ethnicity				
White	492 (87.1%)	676 (89.2%)	521 (91.7%)	1689 (89.3%)
Black	53 (9.4%)	64 (8.4%)	33 (5.8%)	150 (7.9%)
Other	20 (3.5%)	17 (2.2%)	13 (2.3%)	50 (2.6%)
UTD	0 (0%)	1 (0.1%)	1 (0.2%)	2 (0.1%)
SES*	50.8	55.8	53.0	53.5

*ZQ score for patient ZIP code. The ZQ score (Claritas, Inc, San Diego, CA), derived from census data, is calculated from household income, educational attainment, occupation scores, and home values aggregated by ZIP code. It ranges from 1 (lowest socioeconomic status [SES]) to 100 (highest possible SES).

MR indicates medical record; UTD, unable to determine.

Table 2. Attributes of 92 family practice and internal medicine physicians participating in the randomized controlled trial testing the effectiveness of a diabetes resource nurse (DRN) in improving diabetes care for Medicare patients aged ≥65, in a metropolitan, fee-for-service, primary care setting (HealthTexas Provider Network, Dallas–Fort Worth, Texas, 2000–2001)

Characteristic	Study arm			Total (n = 92)
	Claims (n = 25)	Claims + MR (n = 44)	Claims + MR + DRN (n = 23)	
Mean age (years)	39.8	44.1	38.6	41.6
Female	4/22 (18.2%)	9/42 (21.4%)	6/23 (26.1%)	19/87 (21.8%)
UTD	3/25 (12%)	2/44 (4.5%)	0 (0%)	5/92 (5.4%)
Family practice (vs internal medicine)	8 (32.0%)	8 (18.2%)	8 (34.8%)	24 (26.1%)

MR indicates medical record; UTD, unable to determine.

in the data missing across study arms. There were no missing values for process measures, as patients were assumed to have failed the criteria if no record was found in the medical record or Medicare data.

Effectiveness

The primary analysis using multilevel ordered logistic regression models found little difference in the change in the guideline adherence for the clinical measures across the three study arms (Table 4). For the patients with hemoglobin A_{1c} measures in both the baseline and follow-up periods in the Claims group, the mean (standard deviation [SD]) change score was 0.01 (0.34), indicating that of these 425 patients, the total number with hemoglobin A_{1c} <9% increased by only 4 (0.9%). The corresponding increase in patients meeting this guideline was

Table 3. Comparison of patient outcome and process measures between the three study arms in the randomized controlled trial testing the effectiveness of a diabetes resource nurse (DRN) in improving diabetes care for Medicare patients aged ≥ 65 in a metropolitan, fee-for-service, primary care setting (HealthTexas Provider Network, Dallas–Fort Worth, Texas, 2000–2001)*

Patient outcome and process measures	Claims		Claims + MR		Claims + MR + DRN	
Primary outcomes	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
	N (%)		N (%)		N (%)	
Hemoglobin A _{1c} <9%	461 (90.7%)	422 (91.3%)	630 (90.9%)	584 (93.4%)	481 (91.4%)	444 (95.1%)
LDL level <100 mg/dL	158 (44.1%)	149 (41.7%)	244 (45.2%)	257 (51.3%)	198 (47.6%)	196 (49.0%)
LDL level <130 mg/dL	281 (78.5%)	287 (80.4%)	423 (78.3%)	418 (83.4%)	339 (81.5%)	323 (80.8%)
Blood pressure <130/80 mm Hg	110 (19.6%)	128 (25.0%)	136 (18.1%)	147 (21.4%)	99 (17.6%)	116 (22.4%)
Blood pressure <140/90 mm Hg	273 (48.6%)	283 (55.3%)	329 (43.9%)	336 (49.0%)	242 (43.1%)	266 (51.3%)
Secondary outcomes						
<i>Continuous measures</i>	Mean (SD)		Mean (SD)		Mean (SD)	
Hemoglobin A _{1c} level (%)	7.2 (1.5)	7.2 (1.4)	7.2 (1.4)	7.0 (1.2)	7.1 (1.4)	7.0 (1.3)
LDL level (mg/dL)	106.9 (32.9)	106.6 (31.7)	104.6 (32.6)	101.3 (30.7)	104.3 (33.9)	104.1 (31.6)
Diastolic blood pressure (mm Hg)	76.0 (9.9)	74.7 (10.4)	77.7 (9.5)	76.5 (9.7)	77.1 (9.8)	75.6 (10.7)
Systolic blood pressure (mm Hg)	139.5 (18.5)	137.0 (17.9)	139.7 (18.6)	138.4 (18.3)	140.2 (18.0)	138.1 (18.1)
<i>Medical record</i>	N (%)		N (%)		N (%)	
Annual hemoglobin A _{1c} assessment	508 (89.9%)	462 (81.9%)	693 (91.4%)	625 (82.5%)	526 (92.6%)	467 (82.5%)
Annual lipid assessment	380 (67.3%)	380 (67.4%)	567 (74.8%)	521 (68.7%)	441 (77.6%)	432 (76.3%)
Annual blood pressure assessment	562 (99.5%)	512 (90.8%)	751 (99.1%)	686 (90.5%)	561 (98.8%)	519 (91.7%)
Annual eye exam	61 (10.8%)	58 (10.3%)	127 (16.8%)	114 (15.0%)	119 (21.0%)	119 (21.0%)
Annual foot exam	229 (40.5%)	167 (29.6%)	409 (54.0%)	363 (47.9%)	270 (47.5%)	261 (46.1%)
Renal documentation	168 (29.7%)	193 (34.2%)	304 (40.1%)	357 (47.1%)	234 (41.2%)	279 (49.3%)
<i>Medicare claims</i>	N (%)		N (%)		N (%)	
Annual hemoglobin A _{1c} assessment	512 (90.6%)	420 (74.5%)	680 (89.7%)	559 (73.7%)	533 (93.8%)	439 (77.6%)
Annual eye exam	350 (61.9%)	296 (52.5%)	497 (65.6%)	448 (59.1%)	353 (62.1%)	317 (56.0%)
Annual lipid assessment	398 (70.4%)	347 (61.5%)	582 (76.8%)	467 (61.6%)	448 (78.9%)	403 (71.2%)
Semiannual hemoglobin A _{1c} assessment	394 (69.7%)	328 (58.2%)	540 (71.2%)	458 (60.4%)	434 (76.4%)	371 (65.5%)

*Outcome and process measures taken from the American Diabetes Association and the National Diabetes Quality Improvement Alliance. The baseline period was from January 1, 2000, to December 31, 2000. The follow-up period was from January 1, 2001, to December 31, 2001.

MR indicates medical record; SD, standard deviation; LDL, low-density lipoprotein.

9 (2.1%) in the Claims + MR group (comparison with Claims group: $P = 0.97$); and 16 (3.8%) in the DRN group (comparison with Claims group: $P = 0.31$). Results were similar for the other three clinical outcomes, with no comparisons involving the DRN group significant at the $P = 0.10$ level.

Change scores for the continuous measures of effectiveness were similar. Hemoglobin A_{1c} dropped a mean (SD) of 0.05 (1.28) percentage points in the Claims group; 0.16 (1.44) percentage points in the Claims + MR group (comparison with Claims group: $P = 0.26$); and 0.14 (1.24) percentage points in the DRN group (comparison with Claims group: $P = 0.31$). Results were similar for the other three clinical outcomes, again with no comparisons involving the DRN group significant at the $P = 0.10$ level.

Processes of care

Decreases were similar for the 10 process measures across all three study arms (Table 4). Patients in the Claims arm had an annual hemoglobin A_{1c} assessment mean (SD) change score

of -0.08 (0.45) percentage points, indicating that patients in the study had their hemoglobin A_{1c} measured more often in the 12 months before the intervention than in the 12 months after the intervention. Change scores for the other groups had means (SD) of -0.09 (0.44) percentage points and -0.10 (0.45) percentage points; these did not differ significantly from the Claims group. Results were similar for all process measures, with the exception of renal documentation, which occurred more often in the follow-up period than the baseline period, though there were no statistically significant differences between the intervention and Claims arms.

Secondary analyses

Analyses including patients missing pre- or postintervention values gave similar results (not shown). P values for the interaction between intervention arm and study period were above 0.15 for all four primary outcomes. Including patients who did not survive the follow-up period did not alter these results, and there were no differences in 12-month survival

Table 4. Comparison of change scores (individual follow-up minus baseline values) for patient outcome and process measures between the three study arms in the randomized controlled trial testing the effectiveness of a diabetes resource nurse (DRN) in improving diabetes care for Medicare patients aged ≥ 65 in a metropolitan, fee-for-service, primary care setting (HealthTexas Provider Network, Dallas–Fort Worth, Texas, 2000–2001)

Patient outcome and process measures	Claims			Claims + MR			P value*	Claims + MR + DRN			P value†
	n	Change score, mean (SD)		n	Change score, mean (SD)			n	Change score, mean (SD)		
Primary outcomes											
Hemoglobin A _{1c} <9%	425	0.01	(0.34)	584	0.02	(0.32)	0.966	437	0.04	(0.32)	0.307
LDL level <100 mg/dL	268	−0.01	(0.52)	406	0.07	(0.50)	0.069	320	0.02	(0.52)	0.551
LDL level <130 mg/dL	268	0.00	(0.40)	406	0.05	(0.44)	0.208	320	−0.01	(0.45)	0.663
Blood pressure <130/80 mm Hg	510	0.05	(0.47)	680	0.03	(0.50)	0.600	512	0.04	(0.45)	0.927
Blood pressure <140/90 mm Hg	510	0.06	(0.61)	680	0.05	(0.60)	0.666	512	0.07	(0.59)	0.903
Secondary outcomes											
Continuous measures											
Hemoglobin A _{1c} level (%)	425	0.05	(1.28)	584	0.16	(1.44)	0.255	437	0.14	(1.24)	0.308
LDL level (mg/dL)	268	0.22	(28.15)	406	3.88	(28.54)	0.097	320	−1.20	(30.37)	0.807
Diastolic blood pressure (mm Hg)	510	1.21	(10.51)	680	1.04	(10.32)	0.608	512	1.26	(11.73)	0.867
Systolic blood pressure (mm Hg)	510	2.35	(20.11)	680	1.08	(20.99)	0.195	512	1.80	(19.97)	0.702
Medical record											
Annual hemoglobin A _{1c} assessment	564	−0.08	(0.45)	758	−0.09	(0.44)	0.845	566	−0.10	(0.45)	0.413
Annual lipid assessment	564	0.00	(0.55)	758	−0.06	(0.52)	0.487	566	−0.01	(0.53)	0.996
Annual blood pressure assessment	564	−0.09	(0.29)	758	−0.09	(0.30)	0.909	566	−0.07	(0.30)	0.451
Annual eye exam	564	−0.01	(0.37)	758	−0.02	(0.46)	0.658	566	0.00	(0.52)	0.936
Annual foot exam	564	−0.11	(0.56)	758	−0.06	(0.67)	0.473	566	−0.01	(0.59)	0.447
Renal documentation	564	0.04	(0.48)	758	0.07	(0.49)	0.537	566	0.08	(0.46)	0.332
Medicare claims											
Annual hemoglobin A _{1c} assessment	564	−0.16	(0.51)	758	−0.16	(0.51)	0.986	566	−0.17	(0.47)	0.860
Annual eye exam	564	−0.09	(0.54)	758	−0.06	(0.59)	0.498	566	−0.06	(0.54)	0.382
Annual lipid assessment	564	−0.09	(0.55)	758	−0.15	(0.57)	0.110	566	−0.08	(0.53)	0.988
Semiannual hemoglobin A _{1c} assessment	564	−0.12	(0.62)	758	−0.11	(0.62)	0.881	566	−0.11	(0.56)	0.685

*Claims vs Claims + MR.

†Claims vs Claims + MR + DRN.

MR indicates medical record; SD, standard deviation; LDL, low-density lipoprotein.

across arms ($P > 0.5$). Analysis using only those patients with baseline hemoglobin A_{1c} values $\geq 7\%$ ($n = 811$) also showed no significant differences across arms ($P > 0.1$).

DISCUSSION AND CONCLUSIONS

This practice-randomized trial found no difference in clinical outcomes or processes of care between patients treated at practices with a DRN and those treated at practices without such a nurse.

Certain limitations and potential sources of bias should be considered when interpreting the results of this study. All of the participating practices belonged to the same network of fee-for-service practices in the Dallas–Fort Worth area, which may reduce the generalizability of the results. On the other hand, enrolling practices subject to the same administrative and environmental pressures reduced the chance of unobserved bias due to imbalance in these factors. Furthermore, our cohort defi-

nition, similar to that used in other studies utilizing Medicare claims data (31, 39), should ensure that our sample of Medicare beneficiaries with diabetes is representative of Medicare beneficiaries in Dallas–Fort Worth, Texas, who receive primary care in fee-for-service settings, increasing the generalizability of our results.

As with any negative result, it is possible a true effect was overlooked through lack of statistical power. However, our original sample size assumptions turned out to be conservative, and post hoc simulations based on parameter estimates from the actual trial found $>90\%$ power to detect a true difference in hemoglobin A_{1c} improvement of 0.3 percentage points between the DRN group and the other study groups. Given that Aubert et al (22) observed a 1.1-percentage-point change in their nurse-managed group over 12 months, power of this magnitude should have enabled us to detect any effect the DRN had on care.

Another limitation was the lack of blinding. It was neither feasible nor meaningful to conceal the DRNs' efforts from physicians serving the same patients, and it was impossible to prevent the DRNs' existence from being known to other practices in the network. Both medical record and Medicare claims data were, however, collected by individuals blinded to patients' study arm assignments. Given the minimal change in clinical measures for all study arms, contamination seems unlikely.

Another possible reason no improvement was seen is that this population began with better-than-average care (40), and so-called "floor" effects made further improvement difficult. However, while only 9% of patients had baseline levels worse than the National Diabetes Quality Improvement Alliance marker for poor glycemic control (hemoglobin A_{1c} ≥9%), only 53% met the ADA criterion for good control (hemoglobin A_{1c} <7%), suggesting that there was substantial opportunity for improvement. Moreover, the secondary analysis of the primary endpoint using only those patients with baseline measurements not meeting this criterion, while perhaps underpowered, found intervention effects similar to those of the main analysis, both in moderate magnitude and statistical nonsignificance.

As this was an effectiveness rather than an efficacy trial of diabetes quality improvement interventions, all analyses were done on an intention-to-treat basis. It is worth noting that the DRNs reported throughout the study that despite endorsement of this trial and the related DRN protocols by the HTPN Quality Committee, physicians were reluctant to delegate responsibility to them, suggesting that some recognized barriers to quality improvement initiatives, such as physician insistence on practice autonomy (41), may have been at work. Nevertheless, the influence of such factors does not negate our finding that the DRN intervention was ineffective in this typical fee-for-service setting. It is also worth noting that this was not the first experience HTPN physicians had with intermediate-care providers, one of the larger practice sites having previously participated in the asthma care portion of the RAND Improving Chronic Illness Care Evaluation (42).

Finally, as with any complex intervention targeting long-term clinical care, it is possible that the 1-year intervention period was inadequate. However, trials of DRN care in other settings have found clinically significant effects within 1 year (22, 25). Moreover, we extended the trial to 18 months to assess whether the 12-month study had inadequate follow-up for the intervention. Analysis of this extended follow-up data gave results similar to those reported here, showing no benefit in providing either DQIP measures feedback to physicians or having a practice-based DRN.

While it is important to note all the above limitations, it should be kept in mind that this was an effectiveness study—not an efficacy study. Using the gold standard for determining the effectiveness of an intervention to improve care, a randomized controlled trial, we tested the real-world implementation of the DRN model in a fee-for-service setting. Previous trials have found that DRNs can improve diabetes patients' care and clinical outcomes in capitated settings (22) or VA medical clinics (25). We found the same intervention had no effect when

compared with either usual physician feedback on claims data or usual feedback supplemented with DQIP indicators abstracted from medical record review in a fee-for-service setting.

Some work examining the environments created by different physician payment systems has been undertaken. A survey of physicians in Saskatchewan conducted in 1992 asked respondents to identify which of four payment systems (fee-for-service, salary, capitation, or sessional) they thought best met each of 12 objectives, two of which were clinical autonomy and clinical teamwork. Results showed that the fee-for-service method was felt to be superior in providing or ensuring clinical autonomy, while capitation and salary were both felt to be superior in providing or ensuring clinical teamwork (43). Future research may better elucidate how differences in remuneration schemes impact the effectiveness of quality improvement initiatives such as the DRN model tested in this study. Our experience with the intervention clinics suggests a few possible obstacles to effective use of the DRNs in a typical fee-for-service setting. Other considerations include the possibility that DRNs were less able to impact patient care than in a capitated setting and that patients in a fee-for-service setting differ in ways we have not measured, such as education or SES, from those in capitated services or VA clinics.

We found that an administrative intervention known to improve diabetes care in capitated and VA settings was ineffective in a fee-for-service setting. This finding shows that quality improvement strategies must be evaluated in the appropriate setting before widespread implementation. This may be particularly applicable when transferring initiatives to or from countries that use publicly funded capitated care models. In our own environment, based on the results presented here, we decided against extending the DRN model beyond the trial, and currently no DRNs are employed within HTPN.

Acknowledgments

We thank Ashley Collinsworth and Briget da Graca, MS, for background research and writing and editorial assistance; Cheryl Skinner, RN, for her work as information systems project manager; Shirley Falls, MS, for her work as project manager; and Covance and Texas Medical Foundation for providing the Medicare data.

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