

# Renal Assessment Practices and the Effect of Nurse Case Management of Health Maintenance Organization Patients With Diabetes

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**OBJECTIVE** — To examine baseline renal screening practices and the effect of nurse case management of patients with diabetes in a group model health maintenance organization (HMO).

**RESEARCH DESIGN AND METHODS** — We performed both 1-year retrospective and 1-year prospective studies of renal assessment practices and ACE inhibitor usage in a cohort of 133 diabetic patients enrolled in a randomized controlled trial of a diabetes nurse case management program in a group model HMO. In accordance with American Diabetes Association recommendations, urine dipstick and quantitative protein and microalbuminuria testing rates were calculated.

**RESULTS** — At baseline, 77% of patients were screened for proteinuria with dipsticks or had quantitative urine testing. Of patients with negative dipstick findings, 30% had appropriate quantitative protein or microalbumin follow-up at baseline. Baseline ACE inhibitor usage was associated with decreased follow-up testing (relative risk = 0.47). Nurse case management was associated with increased quantitative protein or microalbumin testing and increased follow-up testing (relative risk = 1.65 and 1.60, respectively).

**CONCLUSIONS** — We found a higher degree of adherence to recommendations for renal testing than has been reported previously. Nurse case management intervention further increased renal screening rates. The inverse association between ACE inhibitor usage and microalbumin testing highlights a potentially ambiguous area of current clinical pathways.

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Approximately 20–30% of patients with type 1 or type 2 diabetes develop evidence of nephropathy (1,2). In 1995, diabetic nephropathy was the leading cause of end-stage renal disease (ESRD) in the U.S., accounting for 40% of new cases (3). Estimated direct medical payments for

ESRD by public and private sources totaled \$13.06 billion in 1995 (3). Recent studies have demonstrated that the onset and course of diabetic nephropathy can be significantly ameliorated by improving glycemic control, managing blood pressure, and using ACE inhibitors, which exert a beneficial impact

on diabetic nephropathy independent of their effect on blood pressure (4–16). The interventions are most effective if they are initiated early in the course of nephropathy.

In response to this evidence, since 1992 the American Diabetes Association (ADA) has encouraged routine screening and early detection and treatment of the renal complications associated with diabetes. In 1996, the ADA published a consensus statement for the diagnosis and management of nephropathy in patients with diabetes (17). The ADA recommends 1) annual urinalysis to detect proteinuria for all type 2 patients and for type 1 patients beginning 5 years after the onset of disease or at puberty and 2) follow-up microalbuminuria screening for patients with negative urine dipstick protein (18). The ADA recommends ACE inhibitor therapy for 1) all hypertensive diabetic patients with microalbuminuria or overt nephropathy, 2) normotensive type 1 diabetic patients with microalbuminuria, and 3) normotensive type 2 diabetic patients with albuminuria (18).

Unfortunately, adherence to these clinical recommendations has been less than optimal. Previous studies have documented screening rates for urine protein ranging from 10 to 48% (19–23). Less is known about microalbuminuria screening practices or the appropriate use of ACE inhibitors.

Improving compliance with recommended diabetes standards of care requires better knowledge of existing practice patterns and simple, minimally intrusive quality improvement initiatives (24–26). The use of nonphysician personnel who use an organized approach to guideline implementation may provide an opportunity to improve renal assessment practices and treatment (27). In a 12-month prospective randomized controlled trial, we examined baseline renal assessment practices among diabetic patients enrolled in a group model health maintenance organization (HMO) and the effect of nurse case management (NCM), designed primarily to improve glycemic management, on renal screening rates.

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**Abbreviations:** ADA, American Diabetes Association; ESRD, end-stage renal disease; HMO, health maintenance organization; JHCG, Jacksonville Health Care Group; NCM, nurse case management; RR, relative risk.

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

**Table 1—Baseline demographics of the 133 study participants**

Age (years)	53.8 ± 10.1
Duration of diabetes (years)	8.8 ± 8.2
Sex	
Male	54 (40.6)
Female	79 (59.4)
Diabetes	
Type 1	14 (10.5)
Type 2	117 (88.0)
Other	2 (1.5)
Race/ethnicity	
White	101 (75.9)
Black	27 (20.3)
Asian	2 (1.5)
Other	3 (2.3)
Medication	
Insulin	49 (36.8)
Sulfonylurea	82 (61.7)
Metformin	27 (20.3)
ACE inhibitor	52 (39.1)
Hypertensive	79 (59.4)
On ACE inhibitor*	48 (60.8)

Data are means ± SD or n (%). \*Among hypertensive patients.

## RESEARCH DESIGN AND METHODS

### Subjects and methods

The primary study was a 12-month prospective randomized controlled trial of nurse case management intervention for diabetes care in a group model HMO. The goals of the NCM program were to improve glycemic control and adherence to ADA-recommended standards of care. Participants in the trial were recruited from two of the largest clinics within the Jacksonville Health Care Group (JHCG), the largest provider of primary care services for the Prudential HealthCare (PHC) HMO of Jacksonville, Florida. The JHCG is a group of 43 primary care physicians who provide care in 8 clinics to more than 75,000 members enrolled in PHC.

Potential participants were identified through a database used to support quality improvement activities. Members in the plan who had diabetes were included in the database if they had a visit to the doctor for diabetes (*International Classification of Diseases, Ninth Revision* [ICD-9] code 250.0 to 250.9), had a hospital claim processed for diabetes, were seen by the utilization management nurse, or had a referral to the ophthalmologist for a diabetic retinal exam. In addition, a list of potential members with diabetes was identified using pharmacy data.

Adult members with diabetes who were potential study participants received a recruitment call and were invited to schedule an appointment with a research assistant to discuss participation. A total of 14 calls were made at different times and on different days before a member was coded as unavailable. After the subject gave consent and completed our eligibility assessment, baseline information was obtained. Patients were ineligible if they had any one of the following: a recent HbA<sub>1c</sub> <7.0%, currently pregnant or planning a pregnancy in the next 12 months, uncontrolled hypertension (>180/110 mmHg), unstable angina (class 4), myocardial infarction in the past 3 months, two or more episodes of seizures, inability to perform self-management, alcoholism or drug abuse documented in the chart, late-stage diabetes complications, or other chronic conditions.

Patients were randomized in blocks to NCM or usual care based on a 1:1 allocation ratio and block size of three. Each block contained six patients, three in each arm of the study. This randomization scheme ensured that the desired allocation ratio of one NCM patient to one usual care patient was maintained after sequential enrollment of every sixth patient.

Of the 545 members in the diabetes registry, we were able to gather eligibility and recruitment information for 480. Eligibility status was established for 92% of those. Of the 208 members who met eligibility criteria for randomization, 34% did not appear for their scheduled appointments and were not randomized, and 66% were randomized to NCM or usual care. Of the 138 members randomized into the study, 100 (72%) provided 12-month follow-up data.

A cross-sectional chart review was conducted of diabetic patients participating in the trial. Of the 138 study participant charts, five charts were not located because the study participant had moved or had died. The remaining 133 charts were reviewed for both documentation of urinalysis/dipstick results and use of an ACE inhibitor for a period of 12 months before and after randomization. The renal assessment data were merged with an extensive demographic and clinical database generated from the randomized controlled trial.

### Outcomes

Renal assessment practices were determined during a 1-year baseline and a 1-year intervention period. Screening was considered to have occurred if at least one test was done

during the year. Rates were determined for urine dipstick screening, quantitative urine protein testing, and quantitative microalbuminuria testing. To determine compliance with ADA urine microalbumin screening recommendations, we defined a group eligible for follow-up quantitative protein and microalbumin testing as 1) patients with a urine dipstick negative for protein and without evidence of a urinary tract infection during baseline (negative blood, leukocytes, and protein) and 2) patients without a baseline urine dipstick but with a baseline quantitative protein or microalbumin test. Microalbuminuria was determined using quantitative nephelometry (SmithKline Beecham Laboratories, Tampa, FL).

### Treatment

Patients were randomized into usual care or NCM. The NCM program was conducted by a registered nurse/certified diabetes educator trained to follow a set of detailed diabetes management algorithms under the direction of a board-certified family medicine physician and an endocrinologist. The algorithms were developed by a multidisciplinary team that represented endocrinology, family medicine, nursing, pharmacy, health services research, and epidemiology.

In addition to the glycemic control algorithms, renal assessment algorithms were developed in accordance with published ADA recommendations. In summary, the algorithms were designed to identify patients with proteinuria, conduct follow-up microalbumin screening of patients with negative urine protein tests, and confirm positive microalbuminuria results with additional testing.

At the initial visit and annually, the nurse case manager was instructed to order a clean catch, random urine sample for dipstick protein, blood, and leukocytes. Based on the results of the random urine sample dipstick, the nurse case manager ordered appropriate follow-up testing and notified the primary care provider. The nurse case manager sent physicians a follow-up letter with literature citations suggesting ACE inhibitor therapy for their eligible patients.

### Statistical analysis

Logistic regression was used to determine the relationship between clinical and demographic variables and baseline screening rates. The Cochran-Mantel-Haenszel  $\chi^2$  test and logistic regression were used to determine the effect of NCM on screening rates. Patients lost to follow-up during the

**Table 2—Baseline renal assessment rates of the 133 study participants**

Dipstick test	95 (71.4)
Quantitative protein/microalbumin test	29 (21.8)
Quantitative protein/microalbumin or dipstick test	102 (76.7)
Eligible for follow-up	90 (67.7)
Quantitative protein/microalbumin test*	27 (30.0)

Data are n (%). \*Among patients eligible for follow-up.

intervention period were not included in the analysis of the effect of NCM on renal screening rates. All statistical analyses were performed using SAS version 6.12 (28).

## RESULTS

### Baseline renal assessment practices

A total of 133 patients were included in the analysis (Table 1). The majority of patients were white (76%) and female (59%); 88% had type 2 diabetes, 37% were being treated with insulin, and 59% had hypertension. A prescription for an ACE inhibitor was noted in the medical record of 39% of the population.

During the baseline period, some form of renal assessment, either a dipstick or quantitative protein/microalbumin test, was performed in 77% of patients (Table 2). At baseline, 90 patients were determined to be eligible for follow-up quantitative protein or microalbumin testing. Testing was performed in 30% of that group.

At baseline, patients who were prescribed ACE inhibitors were less likely to be screened (Fig. 1). Patients on ACE inhibitors had urine dipstick testing and quantitative protein/microalbumin testing less frequently than patients not on ACE inhibitors, but the difference was not statistically significant. Patients eligible for follow-up quantitative protein or microalbumin testing and on ACE inhibitors were significantly less likely to have follow-up testing than patients not on ACE inhibitors (relative risk [RR] = 0.47,  $P = 0.046$ ).

### Nurse case management

Baseline screening rates among patients randomized to NCM were not significantly different from those in usual care (Table 3). In the intervention time frame, however, NCM was associated with increased renal assessment (Fig. 2). Patients with diabetes under the care of the nurse case manager were significantly more likely to have quantitative protein or microalbumin testing (RR = 1.65,  $P = 0.033$ ). Among the 58 patients

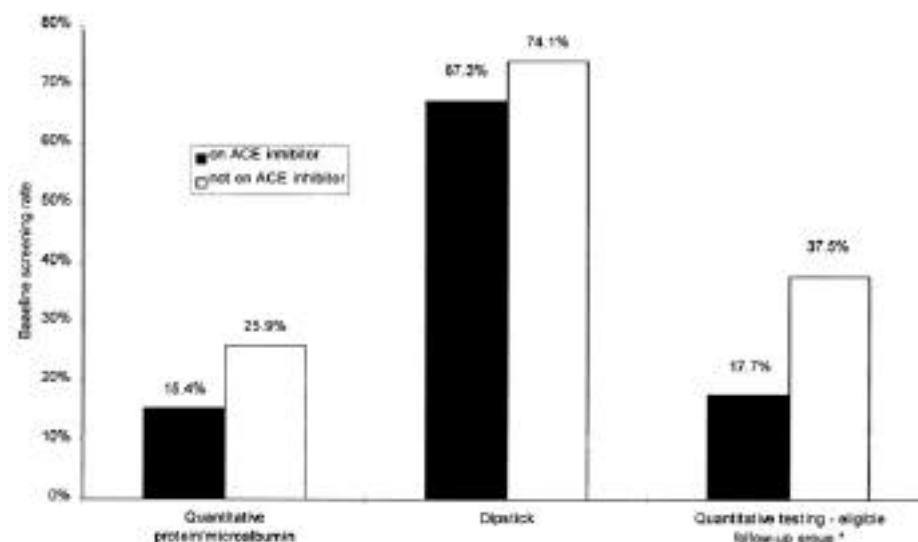
eligible for quantitative protein or microalbumin follow-up, NCM was significantly associated with increased quantitative protein/microalbumin testing (RR = 1.60,  $P = 0.02$ ).

**CONCLUSIONS**—Renal assessment practices have been described in both fee-for-service and managed care settings. In a survey of 1,434 primary care physicians, respondents reported poor adherence (<50% across all specialties and age groups) to annual urinary protein screens for patients with both type 1 and type 2 diabetes (19). In a cross-sectional chart review of prevention practices in 378 patients with type 2 diabetes in a large urban HMO, annual urine dipstick testing was the least frequently noted prevention practice, occurring in 32% of all patients (21). In another chart audit of 353 diabetic patients enrolled in an HMO, 48% of patients had a documented urine dipstick for protein during the course of 1 year (22). In our study, urine dipstick and quantitative urine testing were performed in 71 and 24%, respectively, of patients at baseline.

Few studies have examined follow-up testing for microalbuminuria. In a retrospective chart review of 157 diabetic patients followed for 27 months at primary care clinics, only 5% of diabetic patients received a 24-h urine measurement, the only method of assessing microalbuminuria at the institution (20). When charts of diabetic patients enrolled in five Arizona Medicare managed care plans were audited, tests for microalbuminuria were performed in 31% of patients (23). Neither study examined the relationship between microalbumin testing and the absence of gross proteinuria. In our analysis, 24% of all patients received a quantitative protein or microalbumin test.

Adherence to recommendations for the use of ACE inhibitors in diabetic patients with proteinuria or hypertension has not been well studied in clinical practice. In the previously mentioned chart audit of Arizona Medicare managed care plans, 23% of diabetic patients with hypertension were on ACE inhibitors. About one-third of the diabetic patients with gross proteinuria or microalbuminuria were also on ACE inhibitor therapy (23). In our analysis, 39% of the study participants were on ACE inhibitor therapy; it was the treatment of choice for 61% of the participants with hypertension.

Several demographic and clinical variables seem to influence testing rates—patient socioeconomic status and race may have an impact on medical care (29–32), and physician perception of type 1 diabetes as more serious than type 2 may lead



**Figure 1—Assessment rates by use of ACE inhibitors during baseline.** \*Statistically significant difference  $P < 0.05$ .

**Table 3—Baseline renal assessment rates by case and control status**

	NCM	Usual care	P value
<i>n</i>	51	50	
Dipstick test	35 (68.6)	35 (70.0)	0.881
Quantitative protein/microalbumin test	13 (25.6)	9 (18.0)	0.362
Quantitative protein/microalbumin or dipstick test	38 (74.5)	38 (76.0)	0.862
Eligible for follow-up	36 (70.6)	32 (64.0)	—
Quantitative protein/microalbumin test*	12 (33.3)	9 (28.1)	0.643

Data are *n*, *n* (%), or *P*. \*Among patients eligible for follow-up.

to increased testing (19). This study, however, found no association between a patient's screening status and their age, sex, race, or education level and no correlation between screening rates and a variety of clinical variables, including type of diabetes, duration of disease, number of diabetes outpatient visits, and use of insulin or oral agents. Our results are consistent with the findings of Martin et al. (21). They found no differences in diabetic prevention practices or complication rates by race or ethnicity in a large urban HMO. The access to primary care provided by insurance coverage may offset the impact of certain demographic variables.

Our analysis did reveal an inverse association between quantitative protein/microalbumin testing and ACE inhibitor use. This finding highlights a potentially ambiguous area of current clinical recommendations and practice. The ADA renal assessment recommendations do not provide guidance for renal screening in patients already on ACE inhibitors. Physicians may believe there is no benefit to renal assessment after controlling blood pressure or initiating ACE inhibitor therapy (21).

The sample of patients participating in this study have documented rates of renal assessment higher than reported in previous studies. These higher rates may be partially explained by the quality improvement initiatives of the JHCG. The JHCG primary care physicians participate in an annual diabetes care seminar and undergo regular peer review of their adherence to published diabetes care standards. The peer review scores are used in the annual evaluation and retention process.

Our definition of an eligible follow-up group for microalbumin testing may be deemed overly restrictive given the questionable value of confirming negative gross proteinuria with a urine dipstick before microalbuminuria testing. Some clinicians advocate dispensing with dipsticks for

gross proteinuria and using microalbumin and quantitative protein measurements as the only step in diabetic renal assessment. We present calculations of quantitative protein and microalbumin testing across both the entire study population and a negative proteinuria subset to address the two conflicting views. By either definition, there is still an opportunity for improved diabetic nephropathy testing and increased awareness of screening recommendations.

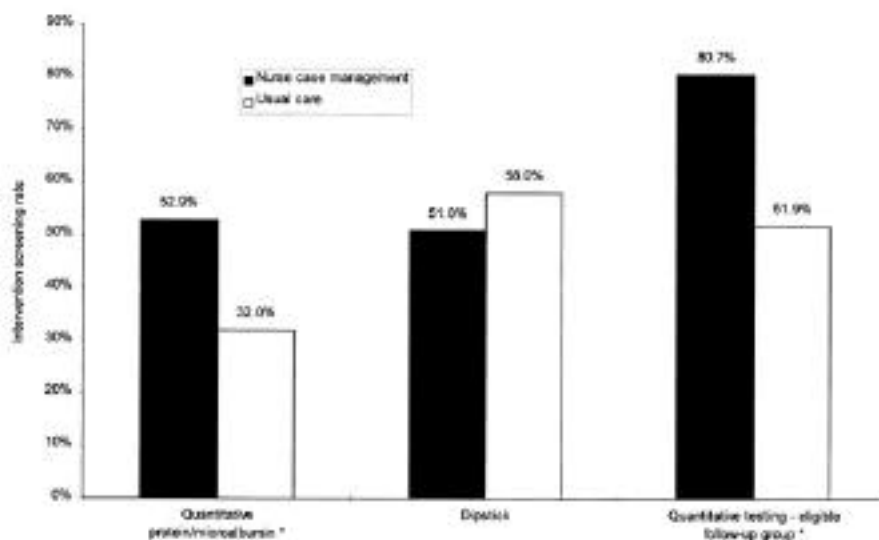
The NCM program expanded on the strengths of current preventive practices and increased compliance with clinical standards of care. The most profound change was in quantitative urine testing for protein and microalbumin. Quantitative urine testing enables the detection of diabetic nephropathy at a subclinical phase and thus offers the greatest opportunity for ESRD prevention. Since only four additional patients were placed on ACE inhibitors during the intervention phase, we were unable to determine the effect of NCM on ACE inhibitor use. It is conceivable that institut-

ing NCM over a longer time frame could lead to improved rates of ACE inhibitor therapy among eligible patients.

Although the NCM algorithm was designed to increase random urine dipstick rates, that effect was not observed. Initial difficulty occurred in implementing the renal screening protocols; since 24-h urine collections are not done as frequently as random urine tests, there was initial confusion among technical staff, resulting in incorrect urine specimen collection containers being given to patients. In general, patient cooperation was good, but the logistics of the 24-h collection was a challenge for patients with limited vision and dexterity. Despite this, the intent of the program—to increase renal assessment—was achieved.

An initiative such as NCM that identifies and treats nephropathy early can reduce morbidity and yield significant economic savings. The Collaborative Study Group calculated the direct and indirect savings associated with ACE inhibitor therapy and blood pressure control compared with blood pressure control alone for diabetic patients with clinical nephropathy (33). Their economic simulation revealed direct and indirect cost savings of \$32,550 and \$84,390, respectively, per patient with type 1 diabetes over a lifetime, compared with placebo. Treatment of people with type 2 diabetes with ACE inhibitors would yield a direct and indirect cost savings of \$9,900 and \$45,730, respectively, per patient over a lifetime, compared with placebo.

Although improved glycemic control was the major outcome in this study, com-



**Figure 2—Assessment rates by case and control status during intervention.** \*Statistically significant difference  $P < 0.05$ .

prehensive diabetes management can also be improved with NCM. The existence of an organized system of health care delivery and a centralized database that included enrollment, inpatient and outpatient encounters, and pharmacy data facilitated the implementation of the NCM intervention. Furthermore, the successful implementation of the program was largely due to the participation of a local physician advocate. The medical director of the physician group was responsible for initiating the study, was part of the clinical management team, and was respected by his peers. In addition, the endocrinologist who participated on the clinical team was also respected in the local community of physicians and commonly received referrals from the medical group. We believe their clinical support for the NCM intervention created high comfort and confidence levels regarding patient safety and program value.

The nurse case manager in this study, an RN with 14 years of clinical experience, was a certified diabetes educator. She managed a case load of 71 patients for this study. In circumstances where an intervention program is conducted without an investigative component, we estimate that the nurse could manage as many as 300 patients. This is consistent with other studies that estimate a nurse case load of 250 patients (26).

The clinical and economic factors in favor of diabetic renal assessment and ACE inhibitor treatment are compelling. Diabetes practice recommendations are an avenue toward improvement of the quality of care and more prudent spending of limited health care dollars. The challenge of modern medicine is to integrate these advances in scientific understanding into everyday practice, which requires better measurement of clinical phenomena and the design of easily implemented interventions.

The implementation of evidence-based protocols in a primary care setting can be challenging. With dedicated staff and appropriate clinical support and information systems, however, a physician-directed nurse management intervention program can produce better outcomes for people with diabetes. In such an environment of information and cooperation, a more organized approach to managing chronic conditions such as diabetes can improve the quality of medical care.

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