A Nurse-coordinated Model of Care *versus* Usual Care for Stage 3/4 Chronic Kidney Disease in the Community: A Randomized Controlled Trial

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Summary

Background and objectives It is unclear how to optimally care for chronic kidney disease (CKD). This study compares a new coordinated model to usual care for CKD.

Design, setting, participants, & measurements A randomized trial in nephrology clinics and the community included 474 patients with median estimated GFR (eGFR) 42 ml/min per 1.73 m^2 identified by laboratory-based case finding compared care coordinated by a general practitioner (controls) with care by a nurse-coordinated team including a nephrologist (intervention) for a median (interquartile range [IQR]) of 742 days. 32% were diabetic, 60% had cardiovascular disease, and proteinuria was minimal. Guided by protocols, the intervention team targeted risk factors for adverse kidney and cardiovascular outcomes. Serial eGFR and clinical events were tracked.

Results The average decline in eGFR over 20 months was −1.9 ml/min per 1.73 m^2. eGFR declined by ≥4 ml/min per 1.73 m^2 within 20 months in 28 (17%) intervention patients *versus* 23 (13.9%) control patients. Control of BP, LDL, and diabetes were comparable across groups. In the intervention group there was a trend to greater use of renin-angiotensin blockers and more use of statins in those with initial LDL >2.5 mmol/L. Treatment was rarely required for anemia, acidosis, or disordered mineral metabolism. Clinical events occurred in 5.2% per year.

Conclusions Patients with stage 3/4 CKD identified through community laboratories largely had nonprogressive kidney disease but had cardiovascular risk. Over a median of 24 months, the nurse-coordinated team did not affect rate of GFR decline or control of most risk factors compared with usual care.

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Introduction

Chronic kidney disease (CKD) is associated with end-stage kidney disease as well as cardiovascular events and premature death (1–6). Interventions such as BP control, renin-angiotensin-aldosterone (RAAS) blockade (7,8), and treatment of dyslipidemia (9) have been shown to modify disease outcomes in CKD, but studies suggest a need for improved care in CKD (10–12). The optimal approach to CKD care is unclear. In the United Kingdom, an emphasis is on electronic records to detect CKD at the primary care level linked to guidelines selecting patients for referral to specialized kidney care teams (13). Other systems, particularly in Canada, suggest a role for specialized multidisciplinary clinics in CKD care (14–16). Similarly, there have been suggestions to involve pharmacists in CKD care (17), and an ongoing trial compares nurse practitioners with physicians in management of patients with CKD (18). Finally, disease-management strategies have been proposed, especially in the United States and in the context of managed care (19,20), but there remains great variability in delivery of CKD care including at the interface between nephrology and primary care in the United States (21).

Key elements in managing chronic disease include an organized approach using evidence-based therapies, supporting self management, examination of trends to determine whether patients meet treatment targets, and communication among providers. We hypothesized that by incorporating these elements, a model of CKD care involving a nurse as a primary caregiver, but supported by medical protocols and a nephrologist, might be superior to usual care. To test the effectiveness of such an intervention, we conducted a pilot randomized controlled trial.

Materials and Methods

We conducted a randomized, unblinded, pilot clinical trial in five urban centers in Canada. Patients with elevated serum creatinine levels were identified by

community laboratories, and their family physicians were then asked to consider referring the patient to the study. This approach was used to minimize recruitment of patients already under the care of a nephrologist, and in fact only 4% of those recruited were already receiving nephrology care. Eligible patients were aged 40 to 75 yrs and had documented CKD with an estimated GFR (eGFR) between 25 and 60 ml/min per 1.73 m^2. Patients were excluded if they had any of the following: likely to die within 6 months; recently unstable/advanced cardiovascular disease; current treatment for malignancy; receiving immunotherapy for kidney disease; on dialysis or with an organ transplant either currently or likely within 6 months; already enrolled in a disease management program for kidney or cardiovascular disease or another interventional clinical trial; or resident of a location too distant to attend study visits.

All of the patients received the usual care, and half were randomized to additional nurse-coordinated care focused on risk factor modification. The nurse followed medical protocols and worked in close collaboration with a nephrologist. Randomization was masked and stratified by site and clinical status (diabetes, nondiabetic with proteinuria, or nondiabetic without proteinuria). All of the participants provided informed consent, and the study was approved by ethics review boards at each site. The aims of this pilot trial were to assess recruitment and the application of the intervention as well as achievement of surrogate endpoint targets. These targets included: BP <130/80 mmHg; use of RAAS blockers; minimization of proteinuria; LDL <2.5 mmol/L; use of anti-platelet agents in those with a history of ischemic disease or diabetes; Hba_{1c} of ≤7.0% in diabetics; serum bicarbonate >22 mmol/L; serum phosphate <1.8 mmol/L; hemoglobin >105 g/L; and iron saturation >0.2. The change in kidney function was tracked by serum creatinine every 4 months. Major clinical kidney and cardiovascular adverse events were predefined, and their occurrence was judged by a blinded assessment team.

Study Visits and Measurements

After randomization, all of the trial participants were seen every 4 months. For intervention-group patients, the visits included clinical care. For controls, the visits only assessed outcomes. At each visit, any adverse clinical outcomes were noted. Current drugs and all health care resources used since the prior visit were recorded. Serum was sent to a central laboratory for measurement of creatinine. eGFR was calculated using the Modification of Diet in Renal Disease formula for standardized creatinine levels (22). Central laboratory values were not available to guide care. At baseline and annually, all of the participants had height, weight, and BP recorded. Blood and urine samples were sent to local laboratories for complete blood count, chemistry, Hba_{1c}, lipid profile, ferritin, iron saturation, and parathyroid hormone. Serum creatinine levels were measured locally in intervention-group patients only. Local laboratory results were made available to each patient's family doctor. Additional laboratory data were obtained at any point during the trial if requested by each patient's own health care provider. At several points during the trial, the nurses and nephrologists completed logs of trial-related activities.

Care Provided to Each Trial Group

All of the patients received whatever usual care that their health care providers felt indicated. Usual care meant care delivered by a family doctor providing assessments and treatments for their patients as they saw fit. The family doctors could consult specialists or involve allied health personnel if necessary. Intervention group participants had additional clinical care delivered by the study nurse and nephrologist guided by protocols aimed at achieving the targets noted above but focused on the needs of the individual. Such care was coordinated with the usual care being provided by the family doctors. Most intervention-group patients were seen for additional interim study visits to address identified clinical issues. Protocols allowed for both pharmacologic and nonpharmacologic interventions. There was emphasis on patient self-management and working collaboratively. Details of the nature of the care provided have been described (23).

Study staff only intervened in the clinical care of controls if they became aware of a serious or life-threatening clinical problem not already being managed. Recommendations for management did not accompany laboratory data sent to physicians caring for controls.

Outcome Measures

The main focus of this pilot study was on achievement of treatment targets for surrogate outcomes, but "quality of life" as measured by the KDQOL-SF (24), the WHOQOL-BREF (25), and the HUI Mark 3 (26) together with resource utilization were also recorded. The effect on quality of life and the cost utility of the intervention are reported elsewhere. Satisfaction with care in the experimental group only was measured using the Client Satisfaction Questionnaire 8 (27).

Sample Size Estimation

One goal of this study was to determine whether 500 patients could be recruited across five sites within 12 to 18 months. This sample size was also chosen to achieve specific confidence interval (CI) widths around possible estimates of clinical endpoint event rates (*e.g.* estimate 4%, 95% CI, 2.5% to 6.1%).

Analysis

The characteristics of the study groups are presented as proportions, median (interquartile range [IQR]), or means (SD) as appropriate. Comparison of proportions was by χ^2. The means were compared by *t* tests, and the medians were compared by a median test. Generalized estimating equations were used to compare groups at baseline and over time in terms of the proportion meeting treatment targets. The groups were compared over time adjusting for baseline BP using a general linear model for repeated measures. Similar methods were used to compare groups in terms of LDL, cholesterol, and eGFR over time. All of the analyses were completed using SAS (version 9.1.3) or SPSS (version 15).

Results

The trial ran from May 2005 to June 2008. Figure 1 shows the distribution of trial participants. Median (IQR) follow-up time was 742 days (614 to 854 days) for the 474 participants.

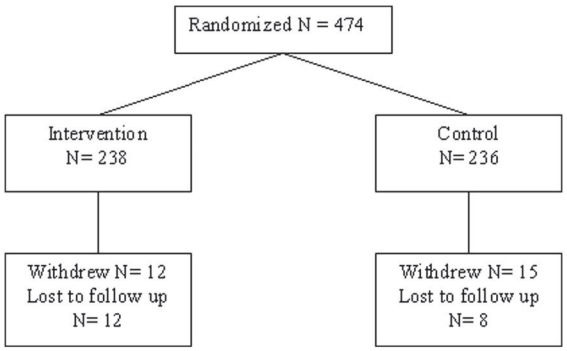

Figure 1. | Disposition of trial participants.

Twenty (4.2%) were lost to follow-up, and 27 (5.7%) withdrew, of which five (1%) withdrew after they developed cancer or another serious health condition. Table 1 shows baseline characteristics of trial participants. The participants were largely Caucasian seniors living independently, and a little over half were female. Baseline eGFR centered around 42 ml/min per 1.73 m^2. Proteinuria was minimal with only 19 patients in total (six intervention and 13 control) having proteinuria of >1 g/d. Almost one-third had diabetes mellitus, and 59.7% had a history of cardiovascular disease. There were few current smokers. Baseline BP tended to be higher in the control group. Delivering care to the intervention group took an average of 12 minutes of nephrologist time and 187 minutes of nursing time per working day.

Rate of Change of Kidney Function

310 patients had at least 20 months of follow-up with eGFR estimates every 4 months. In a general linear model for repeated measures adjusted for baseline eGFR, mean

Table 1. Baseline characteristics of the trial population

	Median (IQR)		*P* Values for the Difference
	Experimental Intervention (n = 238)	Standard Care Control (n = 236)	
Age (years)	67 (62, 72)	67 (61, 72)	0.85
Baseline serum creatinine (μmol/L)	127 (112, 145)	128 (114, 143)	0.85
Baseline eGFR (ml/min per 1.73 m^2)	42 (40, 46)	42 (37, 46)	0.78
Weight (kg)	83 (72, 96)	82 (72, 91)	0.33
Systolic BP	128 (116, 140)	132 (120, 144)	0.001
Diastolic BP	74 (66, 80)	74 (68, 81)	0.96
Proteinuria (g/day)	0.11 (0.07, 0.2)	0.12 (0.08, 0.22)	0.06
LDL cholesterol (mmol/L)	2.6 (2.1, 3.3)	2.7 (2.1, 3.5)	0.07
Hba_{1c} among diabetics (%)	6.9 (6.4, 7.9)	7.1 (6.3, 7.6)	0.58
Hemoglobin (g/L)	136 (125, 144)	134 (126, 144)	0.33
	Number (%)	Number (%)	
Female	131 (55)	132 (56)	0.85
Caucasian	223 (94)	224 (95)	0.28
Retired	144 (61)	158 (67)	0.15
Working	58 (24)	55 (23)	0.42
Post-secondary school education	96 (40)	100 (42)	0.90
Married/living as married	167 (70)	154 (65)	0.37
Living in own home, no hired assistance	224 (94)	219 (93)	0.77
Current smoker	18 (8)	18 (8)	1.0
Systolic BP >130 mmHg	84 (36)	120 (51)	0.001
Systolic BP >140 mmHg	61 (26)	81 (35)	0.05
Diastolic BP >80 mmHg	40 (17)	60 (26)	0.03
Diastolic BP >90 mmHg	10 (4)	11 (5)	0.98
Diabetes mellitus	73 (31)	76 (33)	0.65
Angina	19 (8)	28 (12)	0.21
History of myocardial infarction	39 (17)	33 (14)	0.55
History of PTCA	26 (11)	20 (9)	0.46
History of CABG	25 (11)	19 (8)	0.45
History of heart failure	13 (6)	9 (4)	0.53
History of cardiac arrhythmia	32 (14)	32 (14)	1.0
History of cerebrovascular event	10 (4)	15 (7)	0.40
History of hypertension	182 (78)	178 (77)	0.87
History of chronic lung disease	46 (20)	49 (21)	0.78
History of cancer	34 (15)	40 (17)	0.50
Taking an ACE inhibitor or ARB	165 (70)	156 (66)	0.51
Taking a statin	118 (25)	103 (22)	0.23

PTCA, percutaneous transluminal coronary angioplast; CABG, coronary artery bypass graft; ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor blocker. Continuous variables are presented as medians (intraquartile range). Binary variables are presented as numbers (percentages).

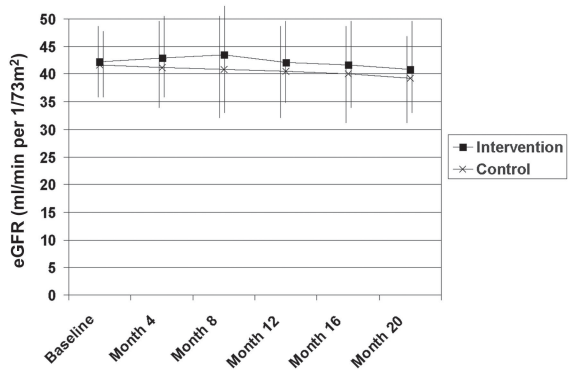

Figure 2. | Mean ± SD estimated GFR from baseline to 20-month follow-up by trial group.

eGFR was slightly higher in the intervention group (P = 0.009, difference in marginal mean 1.4 ml/min per 1.73 m^2 [95% CI, 0.36 to 2.5]). Much of the difference related to an increase in eGFR in the intervention group at months 4 and 8, with both groups showing a similar rate of decline after that (Figure 2). This pattern could not be explained by differences in use of nonsteroidal anti-inflammatory drugs (9.1% of intervention and 6.4% of controls) or diuretics (25.4% of intervention *versus* 24.1% of controls) at 4 months. eGFR declined by ≥4 ml/min per 1.73 m^2 from baseline to 20 months in 28 (17%) of the intervention group *versus* 23 (13.9%) of controls (P = 0.43). Overall the average decline in eGFR over 20 months was −1.9 ml/min per 1.73 m^2 (95% CI, −1.2 to −2.6).

Achievement of Clinical and Treatment Targets (Table 2)

BP Management. BP was lower in the intervention group at baseline, but the proportion meeting treatment targets did not significantly change over time in either group. At baseline, the mean number of anti-hypertensive medications taken was similar in the control and intervention groups (mean, 2.2 *versus* 2.3). Adjusting for baseline number of anti-hypertensive drugs in a Poisson regression, the number of such drugs prescribed was only higher by an average of 0.1 drugs ($P < 0.01$) throughout 24 months of follow-up in the intervention group.

Use of RAAS Blockade. At baseline, 165 patients (70%) in the intervention group and 156 (66%) in the control group used RAAS blockade. This proportion was higher in diabetics (64 [88%] *versus* 70 [91%]). At 24 months 78% of intervention patients *versus* 66% of controls were on RAAS blockers (P = 0.06 for group comparison over time).

Lipid Management. Among all patients, the proportion meeting LDL targets at baseline was nonsignificantly higher in the intervention group, whereas the proportion meeting targets rose comparably over time in each study group. Among those with baseline LDL >2.5 mmol/L, a similar proportion in each group were already treated with a lipid-lowering agent (intervention 39% *versus* controls

Table 2. Achievement of clinical and treatment targets comparing trial groups over time

	Time	Experimental Intervention Number (%)	Standard Care Control Number (%)	P
BP ≤130/80	Baseline	139/236 (59)	101/235 (43)	0.03[a]
	12 months	134/218 (61.5)	100/218 (45.9)	0.47[b]
	24 months	81/128 (63.2)	64/136 (47)	0.76[c]
LDL <2.5 mmol/L	Baseline	99/230 (43)	81/220 (36.8)	0.41[a]
	12 months	97/206 (47.1)	99/214 (46.3)	<0.001[b]
	24 months	78/122 (63.9)	76/128 (59.4)	0.74[c]
On RAAS blocker	Baseline	165/236 (70)	156/235 (66)	0.49[a]
	12 months	165/219 (75)	146/220 (66)	0.92[b]
	24 months	102/130 (78)	92/140 (66)	0.06[c]
Hba_{1c} ≤7.0% in diabetics	Baseline	38/68 (55.9)	36/74 (48.6)	0.58[a]
	12 months	50/70 (71.4)	52/77 (67.5)	<0.001[b]
	24 months	40/49 (81.6)	43/52 (82.7)	0.76[c]
Hemoglobin ≥105 g/L	Baseline	229/235 (97.4)	232/234 (99.1)	0.81[a]
	12 months	208/214 (97.2)	203/214 (94.8)	0.07[b]
	24 months	125/128 (97.7)	130/136 (95.6)	0.64[c]
Iron saturation ≥0.2	Baseline	169/225 (75.1)	160/226 (70.8)	0.28[a]
	12 months	154/210 (73.3)	155/210 (73.8)	0.24[b]
	24 months	95/128 (74.2)	95/124 (76.6)	0.31[c]
Serum phosphate <1.8 mmol/L	Baseline	235/235 (100)	233/233 (100)	NA
	12 months	211/211 (100)	218/218 (100)	NA
	24 months	125/126 (99.2)	126/127 (99.2)	NA
Bicarbonate ≥22 mmol/L	Baseline	225/234 (96.1)	230/234 (98.3)	0.18[a]
	12 months	209/215 (97.2)	212/214 (99.1)	0.68[b]
	24 months	124/127 (97.6)	124/127 (97.6)	0.37[c]

All of the P values are from generalized estimating equations. NA, statistical analysis is not applicable as target was almost uniformly met. RAAS, renin-angiotensin-aldosterone.
[a]Comparison at baseline.
[b]Comparison over time within group.
[c]Comparison between groups over time adjusted for baseline.

35%), whereas at each time point after baseline, this subgroup was more likely to be taking lipid-lowering therapy if they were in the intervention group (at month 12, 66% *versus* 42%, $P = 0.0003$, and at month 24, 84% *versus* 51%, $P = 0.0003$). Among those with baseline LDL >2.5 mmol/L, there was a nonsignificant trend to greater involvement of a dietitian by 12 months in the intervention group (21% *versus* 13% in controls, $P = 0.09$). Nearly all patients taking lipid-lowering therapy at baseline in each group remained on such therapy at later time points (at month 12, 97% of intervention *versus* 98% of controls, and at month 24, 99% *versus* 92%).

Management of Iron and Anemia. The vast majority of patients in each group met hemoglobin targets, and there was no significant difference in this proportion over time or between groups. Erythropoiesis-stimulating agents were used in between one and five patients in each group at any time. The proportion meeting targets for iron saturation was comparable over time and between groups. Among people with baseline iron saturation <0.2, oral iron supplements were more likely to be prescribed in the intervention group by 12 months (35% *versus* 14% for controls, $P = 0.005$).

Management of Diabetes. The proportion of diabetics meeting Hba_{1c} target increased over time but comparably across study groups. A similar proportion of diabetics in each trial group reported a visit to a dietitian (23% intervention *versus* 25% control, $P = 0.8$) or a nurse educator (16% *versus* 18%, $P = 0.75$) within 12 months of enrollment.

Management of Mineral Metabolism. Almost all of the trial participants met serum phosphate targets throughout the study. During the trial, phosphate binders were taken by 2% to 5% of patients, and vitamin D was taken by 10 to 15% at any given time with no difference between groups.

Management of Acidosis. Serum bicarbonate was at target in the vast majority of patients at all time points and did not differ over time or across groups.

Use of Anti-platelet Therapy. Among those with diabetes or cardiovascular disease, for whom anti-platelet therapy might be indicated (28), this therapy was prescribed to 95 (80%) in the intervention group and 88 (77%) of controls at 12-month follow-up ($P = 0.54$). The same pattern was seen at other time points.

Smoking Cessation. Less than 8% of trial participants reported being current smokers at trial entry. There was no apparent difference in the quit rates between intervention and control groups.

Satisfaction with Care

Intervention-group patients were extremely satisfied with their care. With a maximum possible score of 32, the median (IQR) score was constant at 31 (29,30) at 8, 16, and 24 months.

Clinical Endpoints

As shown in Table 3, there were 48 clinical endpoints, half in each trial group. In the intervention group, one person had an amputation followed by cardiac death, another doubled serum creatinine and required dialysis, whereas a third had acute coronary syndrome and was hospitalized for heart failure before suffering a noncardiac death. Among controls, one person had two legs amputated, two people were hospitalized twice for heart failure, whereas another had three such events. Overall the annual incidence of clinical endpoints was 5.2% (95% CI, 3.8% to 6.7%).

Table 3. Distribution of clinical endpoints by study group

	Experimental Intervention ($n = 238$)	Standard Care Control ($n = 236$)
Cardiovascular death	2 (0.8)	2 (0.8)
Other death	5 (2.1)	0 (0.0)
Myocardial infarction	5 (2.1)	4 (1.7)
Acute coronary syndrome	1 (0.4)	2 (0.8)
Congestive heart failure	5 (2.1)	8 (3.4)
Stroke	1 (0.4)	1 (0.4)
Amputation above ankle	2 (0.8)	2 (0.8)
Dialysis	2 (0.8)	1 (0.4)
Doubled serum creatinine	1 (0.4)	4 (1.7)
Total cases with ≥1 event	19 (8.0)	19 (8.0)
Total events	24	24
Event rate per year (%)	5.3	5.2

The proportions are presented as numbers (percentages).

Discussion

This trial was designed to test a nurse-coordinated model of care in people with CKD identified from the community. The vast majority of the care time was provided by the nurses. The care model had a similar effect on control of cardiovascular risk factors as care by family doctors. Some drugs were used more frequently in eligible patients. There was a trend to greater use of RAAS blockers in the intervention group over time, and intervention-group patients with high LDL or low iron saturation were more likely to receive treatment than similar controls.

The recruitment mechanism was intended to enroll a group of people with CKD that would be more representative of those in the general community rather than the referred populations already receiving care from nephrology teams. Although reduction of proteinuria was a treatment target, very few patients with significant proteinuria were entered in the trial. The slowly progressive nature of the kidney disease in these patients identified from the community using laboratory-based case findings supports the argument that the majority of stage 3 patients who have nonproteinuric CKD do not need care by a nephrologist (31). The observed rate of loss of kidney function was close to that documented in studies of community dwelling adults aged greater than 50 years (29). Chan *et al.* (32) recently reported a similar trial in patients with type 2 diabetes and nephropathy who had a higher risk of progression of kidney disease. Although care process was improved, the study was not powerful enough to determine whether there would be differences in kidney outcomes. Significant anemia, hyperphosphatemia, and hyperparathyroidism were not common in our trial, largely because of the relatively preserved level of kidney function.

Even though this study population had a low rate of kidney disease progression, they had a significant risk for

adverse cardiovascular events (5.2% per annum) despite the relatively well-controlled traditional cardiovascular risk-factor profile of the population at trial entry. The results of this trial did not show any difference in clinical cardio-renal endpoints between trial groups, but this pilot study was not powered for this outcome. At about 5% per annum, the rate of cardiovascular events seen was comparable with that in other populations with CKD (5). The preponderance of cardiovascular events over kidney events is similar to that seen in unselected populations with CKD (5). Indeed, the relative likelihood of reaching end-stage kidney disease only approaches that of cardiovascular events in selected populations with more advanced stages of kidney failure under the care of nephrology teams (2).

As documented elsewhere, the intervention teams applied the model of chronic disease care as designed (23). Intervention group participants expressed a high degree of satisfaction with the care received, whereas this was not measured in the controls. The nature of the interventions actually used lie within the scope of practice of most generalist physicians and advanced practice nurses or nurse practitioners. As such, any effort to apply this model of chronic disease care to populations with CKD similar to that seen in this trial population should probably be focused at the level of the primary health care team (30). Indeed, a very similar intervention based in primary care was recently reported as having positive effects on other chronic diseases (33). Specialized nephrology teams do not appear necessary to apply the interventions used in this trial, and such teams might be better to concentrate on care of those with more advanced and progressive kidney disease.

The trial has a number of limitations. First, it targeted CKD patients not referred to nephrologists and thus more likely to have nonprogressive kidney disease. Second, the recruitment process may have led to bias in that the family physicians may have selected their "best" patients to refer to the trial, knowing that their prior and ongoing care for these patients would be under scrutiny. BP control was better than often seen in populations with hypertension and CKD (12). Average LDL levels were also not that high, and diabetic control was excellent. The proportion of current smokers was low. Consequently, there was less room for the intervention to make an effect in comparison with usual care (3). Third, a bias caused by contamination in the control group may be a further factor reducing the difference between groups in the use of therapies and achievement of surrogate endpoints (such as LDL targets). For ethical reasons, the results of the annual laboratory tests done for outcome assessment were shared with the physicians caring for controls. This may have triggered some interventions, such as the increased use of statins, which might not have occurred if these physicians would not have ordered the laboratory tests in the first place.

Three conclusions can be reached: (*1*) CKD patients identified through community laboratories usually have nonprogressive kidney disease and do not necessarily require specialized nephrology care; (*2*) these patients have a substantial risk of cardiovascular events despite good management of traditional risk factors; and (*3*) in this particular trial, despite its limitations, the nurse-coordinated model of care had similar effects on control of risk factors as usual care provided by a family doctor and was associated with greater use of some drugs in eligible patients. Given the limitations, the model should be further assessed.

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Disclosures

None.

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