Chronic Care Clinics: A Randomized Controlled Trial of a New Model of Primary Care for Frail Older Adults

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OBJECTIVE: To determine whether a new model of primary care, Chronic Care Clinics, can improve outcomes of common geriatric syndromes (urinary incontinence, falls, depressive symptoms, high risk medications, functional impairment) in frail older adults.

DESIGN: Randomized controlled trial with 24 months of follow-up. Physician practices were randomized either to the Chronic Care Clinics intervention or to usual care.

SETTING: Nine primary care physician practices that comprise an ambulatory clinic in a large staff-model HMO in western Washington State.

PARTICIPANTS: Those patients aged 65 and older in each practice with the highest risk for being hospitalized or experiencing functional decline.

INTERVENTION: Intervention practices (5 physicians, 96 patients) held half-day Chronic Care Clinics every 3 to 4 months. These clinics included an extended visit with the physician and nurse dedicated to planning chronic disease management; a pharmacist visit that emphasized reduction of polypharmacy and high-risk medications; and a patient self-management/support group. Control practices (4 physicians, 73 patients) received usual care.

MEASUREMENTS: Changes in self-reported urinary incontinence, frequency of falls, depressive symptoms, physical function, and satisfaction were analyzed using an intention-to-treat analysis adjusted for baseline differences, covariates, and practice-level variation. Prescriptions for high-risk medications and cost/utilization data obtained from administrative data were similarly analyzed.

RESULTS: After 24 months, no significant improvements in frequency of incontinence, proportion with falls, depression scores, physical function scores, or prescriptions for high risk medications were demonstrated. Costs of medical care including frequency of hospitalization, hospital days, emergency and ambulatory visits, and total costs of care were not significantly different between intervention and control groups. A higher proportion of intervention patients rated the overall quality of their medical care as excellent compared with control patients (40.0% vs 25.3%, $P = .10$).

CONCLUSIONS: Although intervention patients expressed high levels of satisfaction with Chronic Care Clinics, improved outcomes for selected geriatric syndromes were not demonstrated. These findings suggest the need for developing greater system-wide support for managing geriatric syndromes in primary care and illustrate the challenges of conducting practice improvement research in a rapidly changing delivery system. J Am Geriatr Soc 47:775–783, 1999.

Key words: chronic care clinics; primary care; geriatric syndromes; disease management; health care organization

Innovative primary care delivery approaches are needed to improve care delivered to the growing number of frail older adults.[1–3] Primary care practices tend to be oriented and organized to respond to the acute and urgent needs of their patients rather than structured to provide a comprehensive approach to chronic disease management. Geriatric syndromes in particular are frequently underrecognized and, consequently, underaddressed within the acute care orientation of traditional primary care.[4,5] However, these syndromes, including urinary incontinence, depressive symptoms, falls, and the use of high-risk medications have substantial effects on health and function and may contribute to higher utilization, lower satisfaction, and lower quality of life for older patients.[6–12]

for editorial comment, see p. 908

Focus groups of primary care physicians who care for older patients reveal that knowledge alone may not be the critical barrier to improved management of these conditions.[13–15] Rather, these physicians have pointed to structural limitations of their delivery system, specifically inflexible schedules and not having adequate ancillary support staff to address the multifaceted nature of geriatric care. These insights suggest that restructuring the delivery of primary care,

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combined with the provision of additional ancillary support, may hold more promise for improving management and outcomes of geriatric syndromes. Evidence from the practice improvement literature supports the importance of the use of explicit plans and protocols, systematic attention to the behavioral change needs of patients, ready access to necessary expertise, supportive information systems, and a reorganization or redesign of the structure of care delivery to better meet the needs of patients with chronic illness.[16] This latter intervention, practice redesign, has been conducted in Britain for more than 2 decades in the form of mini-clinics to address particular conditions such as asthma and diabetes.[17,18] These mini-clinics entail dedicating blocks of practice time to similar patients who share a particular chronic condition. Mini-clinics facilitate a structured approach to the condition while also providing an economy of scale advantage for martialing scarce resources and clinical expertise. The evidence that patients benefit from the mini-clinic approach is largely observational. However, a recent randomized trial of group visits has empirically demonstrated the merits of practice redesign in meeting the comprehensive care needs of older health plan enrollees.[19]

This current trial was an attempt to reorganize the delivery of primary care services to better meet the needs of older persons with chronic illness using an approach similar to the mini-clinics that we have termed Chronic Care Clinics (CCCs). Chronic Care Clinics attempt to redesign the structure and content of the delivery of primary care through the addition of scheduled visits devoted to chronic disease management for cohorts of frail older patients. Geriatric syndromes were selected for the focus of this study because they are often underaddressed despite their potential for improvement. The primary objective of this trial was to conduct a randomized controlled trial to test whether this new model of primary care, Chronic Care Clinics, could improve outcomes for common geriatric syndromes in a population of frail older adults.

METHODS

General

This intervention targeted a population of frail older adults who receive their health care from Group Health Cooperative of Puget Sound, a large Health Maintenance Organization located in western Washington State with approximately 450,000 enrollees, of which approximately 50,000 are aged 65 and over. The particular syndromes that served as the focus for the intervention include urinary incontinence, depressive symptoms, falls, the use of high-risk medications and functional decline. The study received approval from the Human Subjects Review Committees at both the University of Washington and Group Health Cooperative of Puget Sound.

Study Subjects

For the purpose of this trial, frail older adults were those enrollees at high risk for hospitalization and functional decline. A computer-based predictive index, developed and validated previously,[20] was used to identify potential subjects who were at high risk for hospitalization and functional decline in the subsequent 4 years. Automated data regarding age, gender, presence in system-wide disease registries for diabetes and heart disease, history of hospitalization or more than six outpatient visits in the prior 12 months, and the Chronic Disease Score (a pharmacy-based comorbidity index)[21] comprised the individual predictive variables used to identify frail potential participants. These Risk Scores were computed for all patients 65 years of age and older. For each practice, the 36 patients with the highest Risk Scores were selected and physicians were then asked, using their unique knowledge of their patients and clinical judgment, to remove those patients who were too ill to participate or who had moderate to severe dementia. Additional exclusion criteria included residence in a nursing home, terminal illness, and those who had disenrolled. The remaining patients were invited to participate in the trial through a letter signed by their physician. Two additional attempts, a second invitation letter and a phone call, were made to follow-up on persons who did not respond to the initial letter. A total of 169 participants within the nine practices were eligible, provided informed consent to be randomized, and completed a baseline health status questionnaire. An average of 19 patients (range 13 to 23) were randomized per practice.

Elements of the Intervention

This study was a randomized, controlled trial of Chronic Care Clinics that attempted to reorganize the delivery of primary care services to better meet the needs of older persons with chronic illness. Frail older patients in each intervention physician practice were divided into cohorts of six to eight patients who were invited to participate in scheduled half-day visits with their primary care team every 3 to 4 months. The specific components of these quarterly clinics included: (1) An extended (30 minutes) visit to the patient's physician and team nurse dedicated to developing a shared treatment plan that emphasized the reduction of disability; (2) A session with the pharmacist (15 minutes), held in the primary care examination room, that addressed polypharmacy and medications associated with functional decline; (3) A patient self-management group session (45 minutes), led by a team nurse or social worker, that emphasized self-management skills and group problem-solving for chronic health problems (individual groups were encouraged to select the topics, some of which included physical activity, nutrition, and advanced care planning); and (4) The provision of health status assessment information to the practice team at the time of the CCC visits. This assessment included the systematic collection of information regarding each participant's health status, chronic conditions (including geriatric syndromes), and current medications. In summary, the CCC has several elements and can be conceptualized as a package rather than as a discrete intervention.

In addition to a reorganized structure of the delivery of primary care, physicians and team nurses also received training in population-based medicine and management strategies designed to enhance their management of selected geriatric syndromes. Team nurses received individual on-the-job coaching from study staff. As suggested by existing evidence,[22] multiple simultaneous approaches were employed. Specifically, study staff provided intervention physicians with: (1) Brief (one-page) evidence-based treatment strategies for the selected geriatric syndromes; (2) Health status assessment information that included information on functional status as well as the geriatric syndromes of interest for each patient attending the CCC; (3) Key points from the management strategies highlighted on a care-planning worksheet for

syndromes identified through health status assessment; and (4) A one-time case-based care conference guided by a geriatrician from the research team was held in place of the weekly staff meeting for intervention physicians and team nurses. The conference emphasized the formulation of a treatment plan that incorporated geriatric care priorities.

Study Setting

All clinics in the Seattle region of Group Health Cooperative agreed to participate in either this trial or a similar trial that involved patients with diabetes. Clinics were allowed to select their target condition of focus: frail older adults or persons with diabetes. Only one of six clinics chose to focus on frail older adults. This clinic was a primary care facility that consisted of nine physician practices serving an older population. The physicians were board certified in Family Practice and did not have formal training or certification in geriatric medicine.

Study Design

The unit of randomization was the physician practice. The nine practices of the aforementioned clinic were randomized using simple randomization to receive either the CCC intervention or continue with usual care. The intervention group comprised five physician practices for a total of 96 study participants. The control group comprised four physician practices and 73 participants. The follow-up period was 24 months.

Data Collection and Measurement

Demographic, comorbidity, utilization, and cost information were obtained from Group Health Cooperative's administrative sources. Intervention and control patients were asked to fill out a health status assessment survey at baseline and at 12 and 24 months. In order to improve response rates, potential study subjects who did not respond to the initial mailed baseline health status survey were given the option of completing a shortened version to reduce the burden of data collection on these frail older patients. However, at baseline, the shortened version of the health status survey inadvertently did not include the questions pertaining to urinary incontinence or depressive symptoms that were part of the longer baseline version. These questions on incontinence and depression were, however, included on all subsequent surveys at 12 and 24 months. At 24 months, proxy respondents were asked to complete an abbreviated functional status questionnaire containing the 10 items of the physical function scale of the SF-36[23] for subjects too ill to complete the survey on their own.

Functional status was ascertained using the MOS SF-36. Self-rated health was assessed using the standard excellent, very good, good, fair or poor scale. Urinary incontinence was measured using a standardized screening instrument[24] on an ordinal scale from 1 to 6 where 1 = daily incontinence and 6 = never incontinent. Depressive symptoms were determined using the CES-D.[25] Falls were assessed using a standardized questionnaire.[26] Patient satisfaction was determined using questions based on standardized instruments.[27]

High-risk medications were defined as those medications for which there is empirical evidence regarding the potential to threaten functional status in older adults. The main adverse effects targeted were confusion, sedation, mental status changes, and predisposition to inducing orthostatic hypotension. The list of high-risk medications was developed from the existing literature,[10,28] discussions with national experts, and knowledge of the pharmacologic effects in older patients (e.g., longer half-life). Steps were taken to ensure that the list was consistent with Group Health Cooperative's Formulary recommendations with regard to medications to avoid in older patients. The complete list of classes of medications determined to be high-risk is provided in the Appendix. By referring to these medications as high-risk we did not mean to imply that there would be no acceptable indication for these medications. Rather, we attempted to account for the cumulative effect of risk incurred by repeated prescribing of medications that are associated with a significant risk for adverse outcomes in older adults.

Prescribed medications for intervention and control patients were assessed using Group Health Cooperative's pharmacy database. A baseline window of 1 year before the initiation of the study was compared with follow-up windows of months 1 to 12 and 12 to 24. The unit of comparison was the number of 30-day equivalent initial prescription and/or refills of high-risk medications. Prescriptions within the same drug class (e.g., diazepam and alprazolam) were analyzed as one medication class (benzodiazepines).

At the conclusion of the 24-month trial, intervention physicians were interviewed by a social scientist trained in qualitative research methodology. These interviews were semi-structured and focused primarily on the physicians' impressions of how the CCC intervention enhanced or detracted from their ability to provide comprehensive primary care to their frail older patients.

Chart Abstraction

In order to gain greater insight into the process of care[29] associated with the Chronic Care Clinics, chart abstraction was conducted at 12 months for all intervention and control patients. The focus was on examining the physicians' documentation of their efforts around improving the selected geriatric syndromes. A priori process of care measures for each of the geriatric syndromes were developed with decision rules for acceptable documentation. The chart abstraction was performed by one member of the study team along with an additional reviewer blinded to knowledge of the study group and study hypothesis. The overall level of agreement between the two reviewers was acceptable based on published ranges (kappas for geriatric syndrome process measures .75-.85).[30,31]

Statistical Analysis

A modified intention-to-treat analysis was employed. Patients with follow-up data were included in the follow-up analysis irrespective of level of exposure to the intervention. Because physician practices were randomized rather than individual patients, we used techniques that account for potential within-practice correlation that results from randomizing practices. For continuous variables, we used mixed model analysis of covariance and regression analysis,[32,33] and for binary variables we used Generalized Estimating Equations (GEE).[34] To obtain more valid P values in the GEE analysis, we based P values on the t distribution (degrees of freedom derived from number of practices) rather than on the normal distribution.[33]

For all process and outcome measures, analyses of follow-up data were run twice, once controlling only for the

baseline value of the outcome and once adjusting for baseline and the following baseline covariates: age, age-squared, gender, age by gender, Chronic Disease Score, chronic disease score-squared, and self-reported health status. In the results we present follow-up means and percentages adjusted only for the baseline value of the outcome measure. The *P* value from the fully adjusted analysis (baseline value and baseline covariates) is also provided. The particular geriatric syndromes were analyzed both with restriction to those individuals who reported the syndrome at baseline and again without any such restriction. As the two approaches did not reveal different results, only the latter is presented because of its greater clarity for presentation.

Because patients who experienced greater exposure to the CCC intervention may have had different outcomes than those with less exposure, we used regression analysis to perform a dose-response analysis limited to the intervention patients. In this analysis, we explored whether there were any significant trends for selected outcomes versus the number of chronic care clinics attended. These regression analyses were run with and without adjustment for the same covariates described above for the main analyses.

Recognizing that the cost and utilization outcomes were highly positively skewed, we ran the analyses using raw data as well as using data that had been log-transformed or rank-transformed (a nonparametric analysis). We also performed a two-part analysis looking first at the percentage of participants with any utilization and then at the mean levels of utilization among those participants identified in the first part. Because the *P* values were consistent irrespective of the approach employed, we report only means and *P* values for nontransformed data.

Implementation of the CCC

The intervention was initially implemented with the efforts of a study nurse who helped structure the visits, scheduled the health professionals who participated in the CCCs (e.g., pharmacist, social worker), and conducted self-management sessions with groups of patients. Early in the intervention, the study nurse helped with flow of the clinic, keeping the health providers moving from one patient room to another. Study staff provided teams with the health assessment information and attempted to reinforce the clinical priorities by summarizing the critical information on a care priority worksheet. However, the study staff did not provide direct patient care. As the study progressed, study staff gradually withdrew administrative and clinical support, eventually turning over all or nearly all functions to the existing clinical staff. A procedural handbook was provided to describe the scheduling and patient notification protocols.

Disruption Within The Delivery System

Less than 1 year after the initiation of the trial, the delivery system under study experienced an unprecedented level of change. This included offering a voluntary severance package to its physicians in an attempt to increase panel size and reduce costs. Two randomized physicians accepted this offer. In one case, the physician's practice (an intervention practice) was transferred intact to a different physician. This physician was not previously involved with the intervention and received training identical to that of the remaining intervention physicians. In the other physician practice (a control practice), the corresponding patients were not transferred to a particular physician but were offered the same physician choice as new enrollees (these patients were kept in the study). This disruption in personnel, however, was not limited to physicians. Team nurses were reassigned with new responsibilities, many of which did not involve direct interaction with patients. To preserve the integrity of the randomized trial, we strove to maintain patients and practices in their original randomized groups to the closest extent possible. All of the original physician practices (n = 9) and patients (n = 169) were included in the analysis, consistent with an intent-to-treat analysis.

RESULTS

Figure 1 summarizes the recruitment and retention efforts. Sixty-nine of the 324 (21%) patients originally selected by the computerized model as potentially being frail were excluded either by study eligibility criteria or because their physicians considered them poor candidates for the intervention. Of the remaining 255 potential subjects contacted, 169 (66%) consented to participate in the randomized trial, 84 (33%) refused to participate, and two (1%) could not be contacted. To be randomized, all participants had to complete a baseline survey. Most completed the full, long-form, self-administered version. To increase participation rates, some (23% of the intervention group and 32% of the control group) completed an abbreviated version (short form). Patients who were able to complete the long form had higher average chronic disease scores (7.6 vs 7.0, $P = .09$) but lower rates of hospitalization in the previous year (39.1% vs 54.0%, $P = .06$). The overall follow-up rate at 24 months for this frail study population was 89%, (84% for control practice patients, 93% for intervention practice patients).

Table 1 illustrates that the intervention and control patients were similar with regard to demographic factors and health status at baseline. However, control patients had, on average, higher Chronic Disease Scores than intervention patients (7.7 vs 7.3, respectively; $P = .06$). Previous studies have indicated that a score of 7 or higher is associated with poor health status, high utilization, and significantly elevated risk of subsequent mortality.[21] Risk Scores, derived from administrative data to identify patients at high risk for hospitalization and functional decline, did not differ significantly between groups.

At baseline, the prevalence of the selected geriatric syndromes did not differ between groups (Table 2) with the exception that control participants had higher mean rates of fills of high-risk medications (3.92 vs 1.99, $P = .04$). The high prevalence of these syndromes, the advanced degree of functional impairment (as evidenced by SF-36 scores), and the high Chronic Disease Scores noted above combine to reflect the high degree of frailty in the patients selected. The cumulative death rate of 16% over a 24-month period (15 deaths in the intervention group (16%) and 12 deaths in the control group (17%)) further characterizes the extent of the impaired health status of the participants.

At 12 and 24 months, we found no significant differences in outcomes of the selected geriatric syndromes with the exception of urinary incontinence (Table 2). At 12 months, control participants were experiencing significantly more frequent urinary incontinence than intervention participants (3.32 vs 3.95, respectively; $P = .04$), but by 24 months, this difference was no longer present. We found no significant differences between control and intervention groups at either

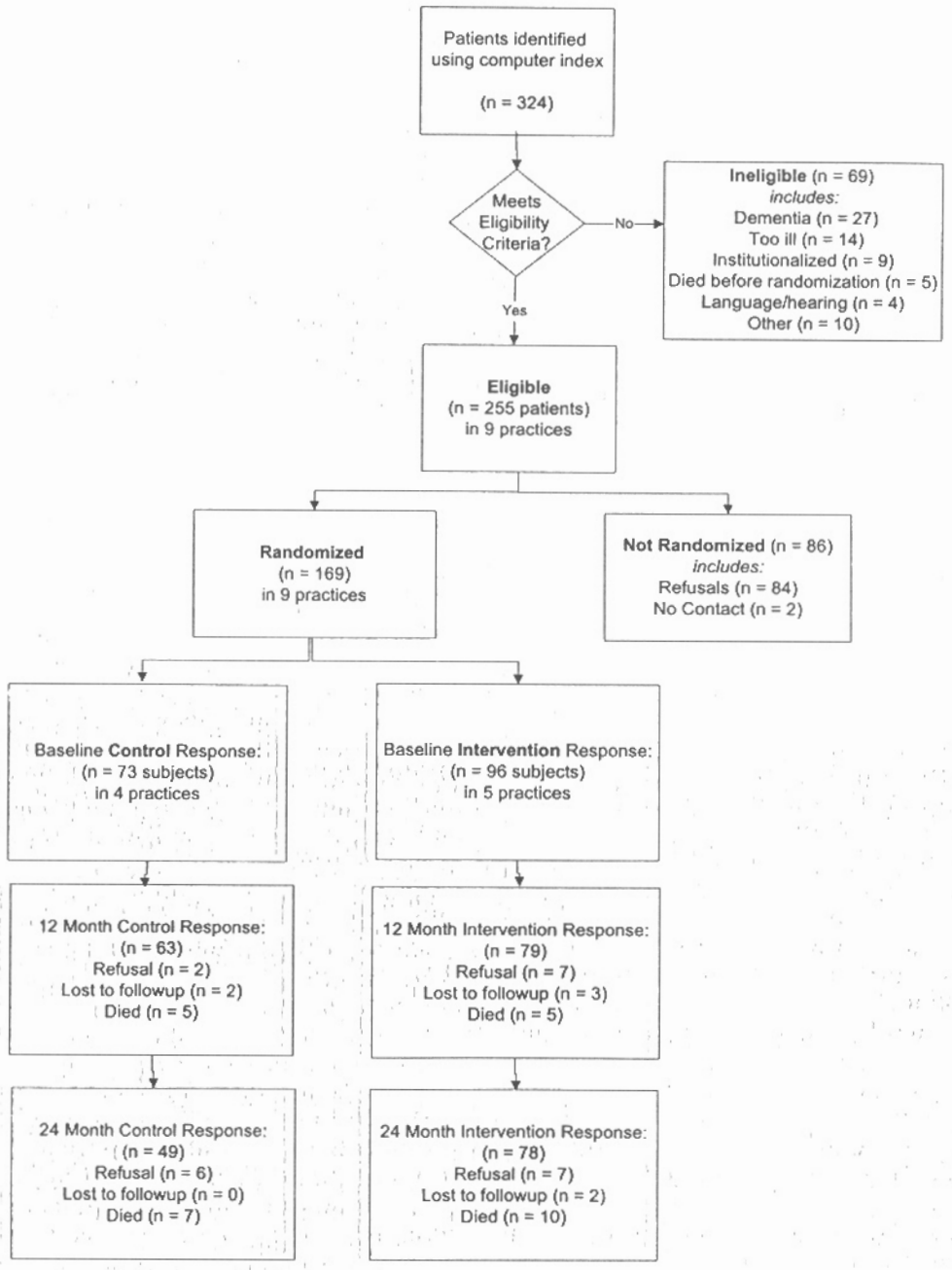

Figure 1. Summary of recruitment and retention.

12 or 24 months on depressive symptoms as measured using the CES-D, the proportion of patients who reported falling in the past year; functional status as measured using the SF-36, or the rate of use of high risk medications.

To further characterize the effects of the intervention, we assessed process measures from chart data at 12 months and survey data at 12 and 24 months. Intervention patients with urinary incontinence were not significantly more likely to receive behavioral instruction (e.g., Kegel's exercises, scheduled voiding trials) (17% intervention vs 4% control, $P = .19$) and were less likely to receive pharmacologic intervention (e.g., oxybutinin, hyoscyamine) (3% intervention vs 18% control, $P = .04$). Intervention patients were more likely to report that their physicians discussed their urinary problems (22% intervention vs 6% control, $P = .06$). Intervention patients with depressive symptoms were not significantly more likely to have discussed symptom criteria for the diagnosis of depression with their physician (10% intervention vs 14% control, $P = .74$) and were not more likely to have an antidepressant medication prescribed (39% intervention vs 44% control, $P = .74$). Among patients who reported falling, we found no significant differences in the percent who had a documented gait examination (24% intervention vs 5% control, $P = .19$), although intervention participants were more likely to have their home evaluated for safety during a home visit within the year (46% intervention vs 25% control, $P = .07$).

Participant and control patients were asked to rate their satisfaction with their primary care (Table 3). These results have been adjusted to reflect baseline differences in satisfaction. There were no significant differences in satisfaction at 12

Table 1. Demographic and Health Status Comparison of Control and Intervention Groups at Baseline*

Measure	Control n = 73	Intervention n = 96	*P* Value
Mean age (years)	77.4	77.3	.70
Female (%)	49.3	47.9	.81
Education (% ≥12 yrs)	66.7	77.1	.10
Non-white (%)	4.1	2.8	.54
Married (%)	58.3	55.2	.63
Income (% <$15,000)	14.0	15.8	.75
Diabetes (%)	48.6	53.2	.62
Hospitalized in prior year (%)	39.7	46.7	.15
Mean CDS	7.7	7.3	.06
Mean risk score	0.53	0.55	.35

*Simple means or percentages presented. *P* values account for within-practice correlation (mixed model *t* test for continuous outcomes, chi-squared from GEE for percentages).

months. After 24 months, 40.4% of intervention patients rated their care coordination as excellent although this was not significantly different when compared with the 24.3% of control patients ($P = .13$). Similarly, 40% of intervention patients rated their overall medical care as excellent compared with 25.3% of controls ($P = .10$).

In order to account for the possibility that higher levels of exposure to the CCC intervention (i.e., participating in more clinics) might be associated with improved outcomes, (i.e., a dose-response effect), we analyzed key outcomes according to the number of CCCs attended using regression analysis. No differences in SF-36 health status outcomes or numbers of prescriptions for high-risk medications were demonstrated. However, greater CCC attendance was associated with higher levels of patient satisfaction with their overall quality of care (test for trend $P = .03$

Table 4 compares annualized costs and utilization rates between intervention and control groups. At baseline, there was one significant difference: intervention patients were more likely to be hospitalized. During the 24-month follow-up period, there were no significant differences on any of the utilization variables (primary care visits, emergency visits, hospitalizations, mean hospital days) or cost variables (pharmacy costs, total costs) between the two study groups.

Four of the five intervention physicians participated in the semistructured qualitative interviews (one physician was unavailable). Overall, these physicians expressed a high level of support for the CCCs and believed that they were able to better meet the needs of their frail older patients through this approach.

DISCUSSION

We were not able to demonstrate improved management of selected geriatric syndromes after 24 months of the CCC intervention. Neither patient self-reported information nor chart review revealed consistent improvements in the process or outcomes of care for geriatric syndromes attributable to this redesign of primary care. Further, the intervention had no apparent effect on cost and utilization. Overall, however, intervention participants expressed high levels of satisfaction suggesting that these patients valued some aspects of this more comprehensive approach to their primary care.

Among the methodologic limitations of this intervention, three in particular require additional emphasis. This intervention targeted frail older adults at a single clinic site with nine physician practices that may or may not have been representative of primary care practice in general. It is not known whether the results of this intervention would have been more promising had the CCCs been based at different clinic sites. That only one of the seven clinics from the larger trial selected frail older patients as their content area of focus (versus diabetes care) makes a rather important statement in its own right with regard to physician confidence and interest in improving care to this population. Second, this tradeoff of autonomy and buy-in on the part of clinic leadership (i.e., allowing clinics to choose the clinical area of focus) for mandatory participation in this trial placed definite constraints on sample size and, consequently, limited study power. Study power was determined by the leadership of the clinics. We estimate, for example, that we had 80% power to detect a 27% effect on the SF-36 Physical Function Scale or on the satisfaction measures evaluated. Process of care measures revealed trends suggestive of improvement in the intervention group, but these were not statistically significant. Thus, our inability to demonstrate statistically significant effects with this intervention could, in part, have been attributed to limited study power. Finally, low levels of participation in CCCs may have undermined further our ability to show improvement in geriatric syndromes. Only 53% of intervention patients participated in two or more clinics, and 29% of intervention patients did not attend any of the offered specialized clinics. We further investigated the potential effect of this low penetration of the intervention using a dose-response approach and were unable to find an association between levels of exposure to the intervention and improved health status outcomes.

We had hypothesized that redesigning ambulatory care for this frail population would afford a critical step toward encouraging physicians to approach and manage their frail patients differently. Evidence supports the need for a comprehensive approach to the care of individuals with chronic disease that includes: the use of explicit plans and protocols; systematic attention to the behavioral change needs of patients; ready access to necessary expertise; supportive information systems; and a reorganization or redesign of the structure of practice.[16] Directed largely by the qualitative studies of physicians who care for older patients, our study focused primarily on this latter component, practice redesign. We believe strongly, however, that clinic redesign alone cannot be successful as a sole intervention. Rather, comprehensive system change,[1,2] including the integration of data information systems that support physicians' practice and facilitate monitoring of pertinent clinical parameters, institutionally endorsed clinical practice guidelines, available collaborative expertise in geriatrics, and coordination across sites of geriatric care are essential to the improved management of older patients. At Group Health Cooperative, many of these components have been developed and accepted for selected individual chronic conditions (e.g., diabetes, heart disease, depression) but are far less developed for the comprehensive care of frail older patients. We believe that the lack of these supporting elements was an important factor in our inability to demonstrate the intended impact of practice redesign.

Table 2. Comparison of Main Outcomes Between Control and Intervention Groups at Baseline, 12, and 24 Months

Outcome	Control	Intervention	*P* Value*	Adjusted P Value†
Baseline‡				
SF-36 Physical Function	43.8	47.7	.72	
CES-D Depression	15.9	11.4	.18	
Incontinence¶	3.71	3.54	.72	
Falls past 12 months (%)	48.6	44.2	.56	
High risk medication fills	3.92	1.99	.04	
12 months#				
SF-36 Physical Function	44.5	43.9	.73	.64
CES-D Depression	14.5	16.0	.12	NA**
Incontinence¶	3.32	3.95	.11	.04
Falls in past 12 months (%)	37.9	43.5	.37	.27
High risk medication fills	3.26	2.94	.67	.57
24 Months#				
SF-36 Physical Function	37.5	37.5	.99	.97
CES-D Depression	12.4	14.8	.11	.19
Incontinence¶	3.19	3.79	.22	.33
Falls past 12 months (%)	35.6	43.5	.35	.63
High-risk medication fills	2.54	1.86	.17	.20

*P-value compares control and intervention means and percentages, adjusted for baseline value of the outcome obtained from mixed model analysis of covariance for means and GEE for percentages.

†P value compares control and intervention means or percentages, adjusted for baseline value of the outcome in addition to other baseline covariates using GEE.

‡Simple means and percentages presented at baseline.

¶Incontinence frequency measured on an ordinal scale of 1–6 where 1 = daily incontinence and 6 = never incontinent.

#Means and percentages are adjusted for baseline differences in the outcome using mixed model analysis of covariance and GEE, respectively.

**Could not be estimated because of problems with data convergence in mixed model. Total samples by outcome and time period—SF 36 Physical Function: 169 at baseline, 151 at month 12, and 154 at month 24; for CES-D Depression: 124, 108, and 90; for Incontinence: 118, 103 and 82; for Falls: 167, 140, and 126; for High-risk medication fills: 169, 169 and 169, respectively.

Table 3. Comparison of Satisfaction Between Control and Intervention Groups at Baseline, 12, and 24 Months

	% Excellent			
	Control	Intervention	*P* Value*	Adjusted *P* Value†
Baseline‡				
Medical team coordination	32	49	.06	
Overall medical care rating	33	50	.03	
12 Months¶				
Medical team coordination	32.4	35.1	.67	.67
Overall medical care rating	37.3	34.8	.66	.88
24 Months¶				
Medical team coordination	24.3	40.4	.17	.13
Overall medical care rating	25.3	40	.13	.10

**P* value compares control and intervention percentages, *adjusted for baseline value of the outcome obtained from GEE.*

†*P* value compares control and intervention percentages, adjusted for baseline value of the outcome in addition to baseline covariates using GEE.

‡Simple percentages are presented at baseline.

¶Percentages are adjusted for baseline difference in the outcome using mixed model analysis of covariance,

Total samples by outcome and time period—Medical team coordination: 157 at baseline, 129 at 12 months and 104 at 24 months; Overall medical care rating 166, 133, and 112, respectively.

Beck and colleagues recently reported a randomized controlled trial of redesign using a different configuration whereby older patients see their physician in a large group format.[19] In addition to high levels of satisfaction among patients and their physicians, this intervention was able to demonstrate higher rates of implementation of selected preventive interventions and lower rates of utilization of emergency services and repeat hospitalizations. Improvement in health status measures, however, was not demonstrated. The goals for the group visit intervention differed as this approach did not specifically target the management of geriatric conditions. The patients followed in this trial were, on average, younger and with less functional impairment than in the trial reported herein. Doubt has been raised as to whether the group visit format would be appropriate for older patients with complex conditions or functional impairment.[2] Overall, their approach provided distinct advantages in meeting the needs of older patients, particularly with regard to patient education, socialization, and support in self-management of chronic conditions.

Table 4. Comparison of Cost and Utilization Between Control and Intervention Groups at Baseline and at 24-Month Follow-up

Utilization or Cost Measure	Control	Intervention	*P* Value*	Adjusted P Value†
Baseline‡				
Primary Care (Visits/Year)	9.9	8.9	0.72	
Pharmacy Cost ($/Year)	952	850	0.99	
Emergency Visits (Mean/Year)	0.36	0.17	0.07	
>1 Hospitalization/Year (%)	63.0	79.2	0.03	
Hosp. Admits (Mean/Year)	0.70	0.76	0.70	
Hosp. Days if Admitted (Mean)	4.8	3.7	0.25	
Total Costs ($/Year)	10,587	10566	0.72	
24-Month Follow-up¶				
Primary Care (Visits/Year)	8.2	8.5	0.71	0.82
Pharmacy Cost ($/Year)	1071	1073	0.99	0.83
Emergency Visits (Mean/Year)	0.27	0.23	0.67	0.73
>1 Hospitalization (%)	34.3	36.5	0.77	0.72
Hosp. Admits (Mean/Year)	0.59	0.58	0.94	0.91
Hosp. Days if Admitted (Mean)	5.4	6.4	0.64	0.57
Total Costs ($/Year)	10,116	9535	0.72	0.73

*At baseline, *P* value is based on mixed model *t* test (for means) and chi-squared test for GEE (for %). At 24-month follow-up, *P* value is adjusted for baseline value of the outcome using mixed model analysis of covariance (for means) and GEE (for %).

†*P* value compares control and intervention means or percentages adjusted for baseline value of the outcome in addition to other baseline covariates using mixed model analysis of covariance (for means) and GEE (for %).

‡Simple mean and percentages are presented for baseline.

¶Means and percentages for 24-month follow-up are adjusted for baseline difference in the outcome using mixed model analysis of covariance (for means) and GEE (for %). Total samples by outcome and time period = 169.

The opportunity to study practice redesign has provided valuable insight into why improving ambulatory care to frail patients is so challenging. The majority of the intervention physicians commented anecdotally early in the study that although the additional time to care for these complex patients was welcomed, they were often uncertain as to how to make the transition from unstructured acute care to organized chronic disease management. Chart review at the midpoint of the trial confirmed their uncertainty. At 12 months, all charts were reviewed to examine physicians' initial attempts at managing the chronic problems outlined on the care worksheets. It was apparent that there was a strong tendency for acute symptoms, minor lab abnormalities, and ongoing joint symptoms to distract physicians from the management of incontinence, falls, and depressive symptoms. Kottke and colleagues address this challenge in the "Dual Task Theory" of primary care that prioritizes urgency over severity and encourages physicians to be responders rather than initiators.[35] In the face of uncertainty, physicians may have tended to revert back to the areas of medicine for which their level of comfort is relatively high. The intervention might have been improved by establishing the clinical content of care of frail older adults before the initiation of the intervention as well more individualized geriatric care modeling for primary care physicians such as the addition of collaborative visits with a geriatrician.

Similar to their physicians, older patients may share (or have been conditioned to embrace) this same priority of urgency over severity. We may have underestimated the need to prepare the intervention patients for the shift from the emphasis on responding to problems to the detection and management of less obvious geriatric syndromes. The physicians' difficulty in making the transition to a focus on chronic disease planning and management may also have been influenced by their patients' perceptions and agendas for how to best use this additional time allotted with their physician and nurse.[36,37] Although considerable effort was made to facilitate clinic attendance, not all intervention patients attended the series of clinics, and some (29%) did not attend any. The low level of attendance of these specialized clinics in a group of patients selected for their propensity toward high utilization of healthcare services[20] may reflect a similar orientation toward acute problems among study patients. Further, we did not evaluate patient adherence to the chronic disease management plan formulated during the CCCs. Patient involvement in the treatment plan for geriatric syndromes has been identified as a key factor for adherence.[5,38,39]

The frail older adults who participated in this trial had multiple medical and social problems that needed to be addressed simultaneously. Although attempts were made to help intervention physicians establish treatment priorities, it is highly possible that these multiple problems competed with one another[40] and potentially diluted any overall effect. Different intervention physicians may have emphasized different syndromes. Empirical evidence[37] has suggested that the rates of treatment for geriatric syndromes vary considerably by the number and combination of the individual syndromes present. Whether the results of this trial would have differed had the intervention been structured around a single geriatric syndrome (e.g., falls or incontinence)[41] is not known but remains of interest.

The initiation of this trial coincided with major changes in the delivery system under study, and virtually no practice was unaffected. The redesign of primary care is challenging enough, let alone without the continuity and support of clinical and administrative staff. Magnan and colleagues recently summarized the challenges of incorporating practice improvement efforts in a rapidly changing delivery system.

These challenges included a prolonged implementation phase, personnel changes, and external and internal environmental changes that left little energy for pursuing innovative approaches.[42] Similar disruption undoubtedly influenced our ability to demonstrate improvement in the selected geriatric syndromes through the CCC intervention. Additionally, the continued chaos and uncertainty with regard to clinic staffing delayed the transition of CCC responsibilities from the study staff to the clinic staff and delayed the physician practices' sense of "ownership" of the intervention.

In conclusion, although the intervention patients and their physicians expressed high levels of satisfaction for the Chronic Care Clinics, improved outcomes for selected geriatric syndromes were not demonstrated. Few trials designed to improve the delivery of primary care have led to improvement in patient health outcomes.[41] Our findings suggest that improving management for chronic conditions such as geriatric syndromes requires a much larger framework of system-wide support in addition to clinic redesign. The level of disruption experienced in this trial has served to reinforce further the critical need for primary care interventions that are designed to improve the management of chronic illness for older adults.

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APPENDIX

Medication Classes Considered "High Risk" for the Purposes of This Study

- Sedative hypnotics
- Muscle relaxants
- Narcotics
- Meprobamate
- Barbiturates
- Selected antihistamines
- (diphenhydramine, hydroxyzine, meclizine)
- Selected tricyclic antidepressants
- (amitriptyline, doxepin)
- Selected antipsychotics
- (haloperidol prochlorperazine, thioridazine).