

# Chronic Care Clinics for Diabetes in Primary Care

## A system-wide randomized trial

EDWARD H. WAGNER, MD, MPH  
LOUIS C. GROTHAUS, MS  
NIRMALA SANDHU, MPH  
MARY SUE GALVIN, RN, MN

MARY MCGREGOR, RN, MN  
KAREN ARTZ, RN, MS  
ERIC A. COLEMAN, MD, MPH

**OBJECTIVE** — To evaluate the impact of primary care group visits (chronic care clinics) on the process and outcome of care for diabetic patients.

**RESEARCH DESIGN AND METHODS** — We evaluated the intervention in primary care practices randomized to intervention and control groups in a large-staff model health maintenance organization (HMO). Patients included diabetic patients  $\geq 30$  years of age in each participating primary care practice, selected at random from an automated diabetes registry. Primary care practices were randomized within clinics to either a chronic care clinic (intervention) group or a usual care (control) group. The intervention group conducted periodic one-half day chronic care clinics for groups of  $\sim 8$  diabetic patients in their respective doctor's practice. Chronic care clinics consisted of standardized assessments; visits with the primary care physician, nurse, and clinical pharmacist; and a group education/peer support meeting. We collected self-report questionnaires from patients and data from administrative systems. The questionnaires were mailed, and telephoned interviews were conducted for nonrespondents, at baseline and at 12 and 24 months; we queried the process of care received, the satisfaction with care, and the health status of each patient. Serum cholesterol and HbA<sub>1c</sub> levels and health care use and cost data was collected from HMO administrative systems.

**RESULTS** — In an intention-to-treat analysis at 24 months, the intervention group had received significantly more recommended preventive procedures and helpful patient education. Of five primary health status indicators examined, two (SF-36 general health and bed disability days) were significantly better in the intervention group. Compared with control patients, intervention patients had slightly more primary care visits, but significantly fewer specialty and emergency room visits. Among intervention participants, we found consistently positive associations between the number of chronic care clinics attended and a number of outcomes, including patient satisfaction and HbA<sub>1c</sub> levels.

**CONCLUSIONS** — Periodic primary care sessions organized to meet the complex needs of diabetic patients improved the process of diabetes care and were associated with better outcomes.

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It is difficult to fulfill the complex needs of patients with diabetes in brief problem-focused office visits (1). This may account for the fact that in some studies, specialized diabetes clinics achieve better outcomes than usual generalist care (2–4). Such specialized diabetes clinics reorganize care by bringing together the

personnel and resources required to meet the needs of diabetic patients.

In the U.K., an increased use of hospital-based diabetes clinics raised concerns among general practitioners and spurred efforts to improve the management of diabetes in primary care (5,6). Chronic disease “mini-clinics” were one response (7,8). The creation of mini-clinics was an attempt to incorporate some of the organizational features of the hospital specialty clinic into primary care by inviting a group of patients with a given condition to participate in specially designed visits at regular intervals with the primary care team. Although one observational study showed no positive effect of diabetes mini-clinics (9), others have found benefits such as better glyce-mic control (10,11), reduced hospitaliza-tion (12), and better follow-up of patients (13). To examine the impact of chronic care clinics (mini-clinics) on the process and outcomes of diabetes care, we conducted a randomized trial in a U.S. health maintenance organization (HMO).

## RESEARCH DESIGN AND METHODS

### Study setting, selection, and randomization of practices

The intervention took place in the Seattle region of Group Health Cooperative (GHC) of Puget Sound, a staff and network model HMO serving  $\sim 500,000$  individuals in Western Washington. The study region included 57 primary care practices that served  $\sim 100,000$  enrollees. Before the study, GHC had initiated major diabetes clinical improvement efforts (14,15) that made system-wide enhancements available to all practices. These efforts included guidelines for retinal screening, foot care, microalbuminuria testing, and glyce-mic control; a computerized diabetes registry; a diabetologist and nurse educator who, on request, saw patients collaboratively with primary care teams in their respective practices; and standardized patient education materials.

From the W.A. MacColl Institute for Healthcare Innovation, Center for Health Studies, Group Health Cooperative of Puget Sound, Seattle, Washington.

Address correspondence and reprint requests to Edward H. Wagner, M.D., M.P.H., Center for Health Studies, Group Health Cooperative, 1730 Minor Ave., Suite 1290, Seattle, WA 98101. E-mail: wagner.e@ghc.org.

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**Abbreviations:** GHC, Group Health Cooperative; HMO, health maintenance organization.

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

These interventions improved the process of diabetes care throughout GHC during the study period (15).

Each clinic (containing 5–20 practices) was given the choice of intervening with diabetic patients or frail older adults. A primary care practice generally includes one full-time or two part-time physicians. The clinics that selected geriatrics were randomized separately, and the results of their trial have been reported elsewhere (16). Because of the strong leadership endorsement of the trial, only two practices with at least 20 diabetic patients in the clinics targeting diabetes chose not to participate. All consenting primary care practices were randomized within clinics to either a chronic care clinic (intervention) group ( $n = 14$ ) or a usual care (control) group ( $n = 21$ ). Most of the physicians in the practices involved were family physicians.

Shortly after the initiation of the trial, the HMO, because of financial pressure, underwent two major changes that affected the intervention and the trial. First, primary care practitioners were offered early retirement, and this impacted 6 of the 14 intervention group practices. Three intervention practices were eliminated, and their patients were unable to participate in chronic care clinics. Three practices remained intact, but underwent a change in physician. Second, primary care nurse staffing was substantially reduced, limiting nurse involvement in chronic care clinics.

### Patient selection and recruitment

From an automated diabetes registry (15), we identified all diabetic patients  $\geq 30$  years of age in each participating practice and randomly selected 36 patients if there were  $>36$  patients in the practice. Those receiving insulin or oral hypoglycemic therapy were preferentially selected. Physician(s) were asked to exclude patients who were terminally ill, demented or psychotic, or otherwise not able to participate in the study. Those patients not excluded by their physicians were contacted by the research staff via mail and asked to return a signed consent form and a baseline questionnaire.

Of the 1,209 diabetic patients initially identified, 163 (13.5%) were excluded by their physicians. An additional 45 patients (3.7%) were found to be ineligible, mostly because of communication problems and HMO disenrollment. Of the

1,001 eligible patients, 707 (70.1%) completed and returned baseline data and consent forms. The rates of nonparticipation did not differ significantly between intervention group. Most practices had 20 or more patients in the trial.

### Intervention

Each intervention practice divided their participating patients into groups of 6–10 and invited them to attend chronic care clinics together at intervals of 3–6 months. Approximately 35% of invited patients never attended a single clinic session. Most patients refused at the outset, often citing a reluctance to participate in groups and/or a concern about the length of the visit. Among patients attending at least one chronic care clinic, two-thirds participated in three or more (up to six) clinics over the 2-year follow-up period.

Each chronic care clinic consisted of an assessment; individual visits with the primary care physician, nurse, and clinical pharmacist; and a group educational/peer support session. Self-management support was provided through one-on-one counseling with the practice nurse and a group session. The 1-h group sessions conducted by the practice nurse or another relevant health professional covered various self-management issues and encouraged group involvement and interaction. Each clinic was preceded by a brief planning session involving a Masters-trained research nurse and the practice nurse in which registry information was reviewed and plans were established for the individual patients and for the group. Individual patient data and plans were summarized on a worksheet that indicated those assessments and management issues to be addressed.

### Data collection

We collected data from self-report questionnaires and administrative data systems. The patient questionnaires were administered at baseline and at 12 and 24 months. On all three survey occasions, questionnaires were sent by mail, and then nonrespondents were interviewed by telephone. Nearly one-half (46%) of trial participants completed a shorter baseline telephone interview, which limited the number of measures for which we could control for their baseline values. Follow-up mailed and telephone surveys contained the same full set of questions. Proxy responses were obtained at 24

months for 13 patients (11 control patients).

The survey instruments included questions about the receipt of recommended preventive maneuvers (e.g., foot examination or influenza immunization) and patient education. They also included several well-established measures of health status: subdomains of the SF-36 (general health, physical function, physical role function, emotional role function, social function, and pain; each scored on a 0–100 scale) (17), bed and restricted-activity days (18), and the Center for Epidemiologic Studies Depression scale (19).

Patient satisfaction measures included medical care satisfaction (satisfaction with overall care, care coordination, and coordination of services) (20) and diabetes care satisfaction. The five diabetes care satisfaction items required respondents to rate their doctor and nurse on a five-point scale from very satisfied to very dissatisfied with respect to: 1) their help in developing a diabetes treatment plan, 2) their appreciation of the patient's efforts to maintain the diabetes treatment plan, 3) their concerns about successes and failures with the plan, 4) their availability to discuss patient concerns between clinic visits; and 5) their role in helping the patient manage their diabetes better. For both scales, interitem correlations exceeded 0.50, and Cronbach's coefficient  $\alpha$ 's, using the mean of the item responses as the scale score, ranged from 0.90 to 0.94.

Administrative data systems served as the source of information for clinical measures and comorbidity (the chronic disease score) (21). The chronic disease score is a weighted sum of drugs taken for chronic illness (22). The laboratory assessments were taken from clinical data and were not assessed independently for study purposes. Health care uses and costs were also obtained from GHC administrative data systems. The time required of the clinical study personnel is not included in the total health care costs. GHC data systems, the cost methods, and the chronic disease score have been used extensively for research.

### Data analysis

Because of the number of potential health outcome measures evaluated, we a priori selected three subscales of the SF-36, i.e., general health, physical function, and physical role function, and the presence

**Table 1—Baseline characteristics of intervention and control patients\***

|                              | Intervention patients | Control patients | P    |
|------------------------------|-----------------------|------------------|------|
| n                            | 278                   | 429              | —    |
| Age (mean)                   | 61.2                  | 60.4             | 0.76 |
| Sex (female)                 | 44.0                  | 49.2             | 0.45 |
| Education (>12 years)        | 88.5                  | 89.5             | 0.64 |
| Non-Caucasian                | 26.9                  | 33.7             | 0.38 |
| Income (>\$15,000)           | 8.0                   | 8.2              | 0.95 |
| Chronic disease score (mean) | 5.4                   | 5.3              | 0.9  |
| HbA <sub>1c</sub> (mean)     | 7.5                   | 7.4              | 0.69 |
| Treatment                    |                       |                  |      |
| Insulin                      | 23.4                  | 28.2             | 0.88 |
| Oral agents                  | 50.4                  | 50.6             | —    |
| Both                         | 7.2                   | 6.3              | —    |
| None                         | 19.1                  | 14.9             | —    |

Data are % unless otherwise indicated. \*Unadjusted means or percentages.

of bed disability and restricted-activity days as our primary health status outcomes. The intention of the primary analysis was to include all practices and patients in the analysis regardless of whether the practice disbanded or whether the intervention patients ever attended a diabetes clinic. Because the physician practice is the unit of randomization, all analyses were performed using either mixed model analysis of variance or mixed model regression analysis to account for the within-practice correlations resulting from the randomization of physician practices (23–25).

At baseline, we report simple means or proportions with *P*-values from an un-

adjusted mixed model analysis to compare the control and intervention groups. At follow-up, we report means and proportions that have been adjusted for the baseline value of the outcome, if available, plus age, sex, self-reported health status, and chronic disease score using mixed model regression analysis. *P*-values are also adjusted for these same covariates. Analyses of cost and use variables were performed on untransformed as well as on log- and rank-transformed versions to account for their highly skewed distributions. There were no major differences in results, but the log results are presented. We also performed mixed model regression analyses to test for a linear trend in

outcomes by the number of clinics attended among those in the intervention group (dose-response analysis). We present only 24-month results, because the chronic care clinics were slow to develop and because the 12-month findings were intermediate between baseline and 24 months.

**RESULTS**— Completed follow-up responses were obtained from 87% of surviving intervention patients and 79% of surviving control patients. There were no significant differences between respondents and nonrespondents in age, sex, educational achievement, marital status, or baseline health status.

Table 1 shows that there were no significant demographic, treatment, or health status differences between groups. Compared with the GHC population as a whole, the study patients were much more likely to be non-Caucasian (African-American or Asian-American). An average chronic disease score of >5 indicates that the typical patient had other chronic diseases besides diabetes.

Table 2 shows that intervention patients were significantly more likely at 24 months to report having received preventive procedures and having a microalbuminuria test recorded in the diabetes registry. They also had somewhat higher rates of foot exams, retinal exams, and medication reviews, but these differences were not statistically significant. When

**Table 2—Process of care and satisfaction of intervention and control patients at baseline and at 24 months\***

|  | Baseline              |                  |       | 24 months             |                  |        |
|--|-----------------------|------------------|-------|-----------------------|------------------|--------|
|  | Intervention patients | Control patients | P     | Intervention patients | Control patients | P      |
| Clinical prevention                                |                       |                  |       |                       |                  |        |
| Prevention procedures (mean frequency)†            | 3.1                   | 2.9              | 0.24  | 3.4                   | 3.0              | 0.02   |
| Medication review (% every visit)                  | 61.2                  | 57.1             | 0.19  | 68.8                  | 60.5             | 0.13   |
| Retinal eye exam (% in last year)                  | 60.6                  | 62.2             | 0.72  | 67.9                  | 63.5             | 0.27   |
| Foot examination (% in last year)‡                 | —                     | —                | —     | 87.7                  | 80.8             | 0.07   |
| Microalbumin test (% in last year)‡                | —                     | —                | —     | 59.2                  | 44.7             | 0.04   |
| Use and helpfulness of patient education*          |                       |                  |       |                       |                  |        |
| Written materials (% used and found helpful)       | 70.8                  | 64.0             | 0.19  | 83.6                  | 73.9             | 0.03   |
| Classes (% used and found helpful)                 | 39.6                  | 27.3             | 0.008 | 62.5                  | 24.1             | 0.0001 |
| Face-to-face counseling (% used and found helpful) | 65.7                  | 58.6             | 0.16  | 76.6                  | 59.1             | 0.0001 |
| Satisfaction                                       |                       |                  |       |                       |                  |        |
| Medical care satisfaction (mean % excellent)       | 30.8                  | 33.5             | 0.46  | 35.3                  | 35.3             | 0.96   |
| Diabetes care satisfaction (mean % very satisfied) | 50.9                  | 57.4             | 0.19  | 61.3                  | 53.7             | 0.10   |

\*Unadjusted means or percentages reported at baseline. At 24 months, means/percentages are adjusted for chronic disease score, self-reported health, age, sex, and baseline value of outcome if available. †Mean reported frequency (never [1]–every visit [5]) of the following procedures: discussed urinary problems, foot care, dietary counseling, and exercise counseling; ‡registry data unavailable during baseline year.

Table 3—Outcomes of care of intervention and control patients at baseline and 24 months\*

|                                 | Baseline              |                  |       | 24 Months             |                  |       |
|---------------------------------|-----------------------|------------------|-------|-----------------------|------------------|-------|
|                                 | Intervention patients | Control patients | P     | Intervention patients | Control patients | P     |
| <b>Health Status</b>            |                       |                  |       |                       |                  |       |
| General health (mean)           | 45.7                  | 44.5             | 0.53  | 46.8                  | 44.0             | 0.03  |
| Physical function (mean)        | 67.0                  | 68.3             | 0.7   | 59.3                  | 58.5             | 0.69  |
| Physical role limitation (mean) | 55.0                  | 55.8             | 0.86  | 56.4                  | 57.1             | 0.82  |
| Bed disability days (% ≥1)      | 34.2                  | 34.9             | 0.85  | 31.5                  | 39.4             | 0.02  |
| Restricted activity days (% ≥1) | 45.1                  | 40.6             | 0.25  | 40.7                  | 42.9             | 0.59  |
| CES-D (mean)                    | 10.9                  | 11.6             | 0.46  | 11.3                  | 11.2             | 0.87  |
| <b>Clinical</b>                 |                       |                  |       |                       |                  |       |
| HbA <sub>1c</sub> (mean %)      | 7.5                   | 7.4              | 0.69  | 7.9                   | 7.9              | 0.99  |
| Total cholesterol (mean mg/dl)  | 215.1                 | 217.5            | 0.60  | 202.8                 | 204.6            | 0.58  |
| <b>Costs and use</b>            |                       |                  |       |                       |                  |       |
| Primary care visits (mean/year) | 5.6                   | 5.7              | 0.83  | 6.4                   | 5.5              | 0.05  |
| ER visits (mean/year)           | 0.15                  | 0.1              | 0.67  | 0.1                   | 0.2              | 0.04  |
| Specialty visits (mean/year)    | 4.1                   | 4.1              | 0.97  | 2.8                   | 3.7              | 0.007 |
| Hospital admission (% admitted) | 32.7                  | 32.9             | 0.97  | 16.9                  | 21.0             | 0.10  |
| Total costs (median \$)         | 2,540.0               | 2,670.0          | 0.60† | 2,122.0               | 2,208.0          | 0.79† |

\*Unadjusted means or percentages reported at baseline. At 24 months, means/percentages are adjusted for chronic disease score, self-reported health, age, sex, and baseline value of outcome if available (physical function, bed and restricted-activity days, HbA<sub>1c</sub> and cholesterol, use, and costs). †P based on comparison of log costs. CES-D, Center for Epidemiological Studies Depression scale.

compared with control patients, intervention patients reported higher rates of participation in patient education, and they rated the helpfulness of all forms of diabetes education significantly more highly (Table 2). These differences were especially large with respect to one-on-one and group education, important elements of the chronic care clinics.

There were no significant differences between groups on either satisfaction measure at 24 months, although intervention patients reported nonsignificantly higher levels of satisfaction on the diabetes care satisfaction scale ( $P = 0.1$ ).

There were no significant differences in physical function or depression measures at follow-up, but intervention patients reported their general health to be significantly better than that of control patients (Table 3). The percent of control patients reporting days confined in bed were significantly higher than that of intervention patients, but there was little difference for restricted-activity days. The mean HbA<sub>1c</sub> levels were equally higher in the two groups at the end of the follow-up

period, and cholesterol levels were equally lower.

Chronic care clinic patients visited primary care nearly one time more per year, and this difference approached statistical significance. This increase was offset by significant reductions in specialty and emergency room visits. Intervention patients were less likely to be hospitalized during the second year of follow-up, but this difference was not significant. Total health care costs did not differ between the groups.

We next addressed the hypothesis that 24-month process and outcome measures within the intervention group would be positively correlated to chronic care clinic attendance. Table 4 shows the characteristics of patients attending different numbers of chronic care clinics and the impact within the intervention group of clinic attendance on selected process and outcome measures. There were no significant trends in clinic attendance by age, sex, or chronic disease score. The number of clinics attended was positively and significantly associated with receiv-

ing preventive procedures, having medications reviewed, and perceiving the helpfulness of one-on-one patient education. Unlike the overall 24-month results, both satisfaction measures increased significantly with the number of clinics attended. Clinic attendance was also significantly associated with reduced bed disability days and HbA<sub>1c</sub> levels and somewhat better cholesterol levels. Within the intervention group, chronic care clinic attendance did not increase the number of primary care visits.

**CONCLUSIONS**— Analyses of effective models of care for diabetes and other chronic diseases suggest that the design of practice plays an important role in their success (26). The design of the practice refers to the delegation of roles within the practice team, the involvement of other disciplines, the organization of visits and follow-up, and the integration of psychoeducational interventions. Efforts to redesign primary care to improve outcomes in diabetes have varied widely in approach. The interventions include increased involvement of nonphysician providers (usually nurses or nurse practitioners) (27,28), or changing the design of visits or the handling of follow-up (29). An early approach was the establishment of a periodic mini-clinic in primary care.

We chose to test the effectiveness of chronic care clinics (mini-clinics) with relatively unselected primary care practices and diabetic patients in an HMO, as opposed to limiting the intervention to volunteer practices and highly motivated patients, in an attempt to assess its practicality and effectiveness as a system change strategy. Because potential study patients were selected at random, not by virtue of their interest in participating, we had to make compromises in the completeness of the baseline data to assure high rates of participation. Nonetheless, we were able to enroll 70% of randomly selected diabetic patients and to complete data collection with >80% of them.

A more serious threat to the validity of the findings is the fact that the study was conducted at a time of considerable instability in the HMO. As a result, nearly one-half of the intervention patients never attended a chronic care clinic, and the average number of clinics among those who did attend at least one chronic care clinic was three, not the planned six, over the 2-year period. Nonetheless, the inten-

**Table 4—Process and outcomes of care at 24 months in the intervention group by the number of chronic care clinics attended\***

|  | Number of chronic care clinics |       |       |        |
|--|--------------------------------|-------|-------|--------|
|  | 0                              | 1–2   | 3–6   | P      |
| n  | 136                            | 52    | 90    | —      |
| Age (years)  | 60.3                           | 61.7  | 62.1  | 0.21   |
| Sex (% female)                                     | 55.2                           | 50.1  | 60.3  | 0.44   |
| Chronic Disease Score                              | 5.2                            | 5.9   | 5.4   | 0.93   |
| Process  |                                |       |       |        |
| Prevention procedures (mean frequency)             | 3.2                            | 3.2   | 3.6   | 0.001  |
| Medication review (% every visit)                  | 63.0                           | 69.1  | 76.7  | 0.010  |
| One-on-one counseling (% used and found helpful)   | 63.7                           | 78.7  | 89.4  | 0.0001 |
| Outcomes   |                                |       |       |        |
| Medical care satisfaction (mean % excellent)       | 27.0                           | 29.5  | 45.3  | 0.0003 |
| Diabetes care satisfaction (mean % very satisfied) | 54.4                           | 58.8  | 69.7  | 0.007  |
| General health                                     | 47.2                           | 44.3  | 46.7  | 0.54   |
| Bed disability days (% ≥1)                         | 36.7                           | 28.5  | 26.3  | 0.04   |
| Restricted activity days (% ≥1)                    | 44.1                           | 40.9  | 39.3  | 0.33   |
| HbA <sub>1c</sub> (mean %)                         | 8.1                            | 7.8   | 7.7   | 0.04   |
| Cholesterol (mean mg/dl)                           | 206.8                          | 197.7 | 195.5 | 0.13   |
| Primary care visits per year                       | 6.3                            | 5.6   | 6.9   | 0.33   |

\*Means/percentages are adjusted for chronic disease score, self-reported health, age, sex, and baseline value of outcome if available.

tion-to-treat analysis findings suggest that participation in chronic care clinics resulted in improved processes of care and somewhat better health. All measures of the process of diabetes care were better in the intervention group than in the control group, and many reached statistical significance. Two self-reported health status measures of the five primary measures were significantly better in the intervention group at 24 months, and the remaining three primary measures displayed no trend. These benefits accrued with no increase in health care use; the intervention group patients experienced one additional primary care visit, but one fewer specialty care visit and less emergency room visits than control patients.

The positivity of the primary analysis received confirmation from the dose-response analysis. With the exception of the SF-36 general health measure, all measures showing differences between groups became more positive as the number of diabetes clinic visits increased. In addition, two important outcomes that were not significantly different by group in the intent-to-treat analysis (HbA<sub>1c</sub> levels and the two care satisfaction scales) improved significantly as the number of attended clinic visits increased. Although it is entirely possible that the outcomes influenced the number of clinics at-

tended, e.g., more satisfied or better controlled patients might be more likely to continue attending clinics, our impression is that the number of clinics attended after the first visit depended more on the ability of a practice to schedule clinics than on the behavior of the patient.

Whereas chronic care clinics relied on existing clinic personnel to deliver services, study nurses played an important role that must be considered when estimating the full cost of the intervention. For the first year of the intervention, a study nurse handled most of the chronic care clinic organizational tasks, i.e., scheduling time, space, and patients; organizing patient assessments and treatment planning; and planning the group session. Our initial plan was to have the study staff gradually turn most of these responsibilities over to practice staff, but the system upheaval forced us to rely on the study nurse until well into the second year of the intervention. Ultimately, several practices took on these responsibilities. We suspect that the impact of mini-clinics on clinical and health outcomes would have been much greater if practice nurses had sufficient time and training to provide clinical case management as described in the work of Aubert and colleagues (27,30). This may explain the

modest effects of chronic care clinics on HbA<sub>1c</sub> and other health status indicators.

In a different set of randomized practices within the same GHC region, we also tested the mini-clinic concept for frail older patients with a myriad of problems (16). Other than somewhat greater patient satisfaction, we observed no differences in the process or outcomes of care in the geriatric group. However, the system-wide supports for geriatric care, such as guidelines or registries, were substantially less well developed than that for diabetes care. The limited impact of the chronic care clinics on the health status of frail seniors (16) and on the glycemic control of patients with diabetes may have been the result of the small amount of change in the content of the physician-patient interaction and clinical approaches.

This study provides evidence that relatively unselected primary care practices can be reorganized to provide better care for patients with chronic illnesses in a system with other enhancements, such as registries and guidelines. A related model, the cooperative health care clinic (31), has been shown to improve outcomes in diabetic patients (32). The diabetes cooperative health care clinics differed from the chronic care clinics in that they were led by a diabetes nurse educator, they did not involve the primary care team, and they conducted most of their assessment, education, and other activities in a group setting (32). Bringing groups of chronically ill patients into special primary care sessions designed to meet their clinical, educational, and psychosocial needs appears to be a feasible and effective way of improving their care.

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