

Health Systems, Patients Factors, and Quality of Care for Diabetes

A synthesis of findings from the TRIAD Study

THE TRIAD STUDY GROUP*

Health care systems have played a central role in the public health response to the growing problem of diabetes (1–2) and its complications. During the 1990s, managed care organizations (MCOs) began seeking system-level approaches to improve diabetes outcomes and control costs in covered populations. Although previous clinical trials (3–6) had demonstrated that several clinical interventions could reduce complication rates and possibly control costs, these findings were not being systematically applied (7,8).

Performance-reporting initiatives, such as the National Committee on Quality Assurance's Diabetes Quality Improvement Program (9), led MCOs to develop disease management programs that used diabetes registries, internal performance monitoring and feedback, physician and patient reminder systems, case management, and provider incentives to improve quality (10,11). Simultaneously, MCOs introduced cost-containment strategies, including utilization review, preauthorization requirements, cost-related incentives, and patient cost-sharing (12).

MCO structures ranged from decades-old not-for-profit group/staff model HMOs to contractual arrangements between traditional indemnity insurers and newly formed provider groups or individual providers. Provider groups ranged from relatively integrated multi-specialty group practices to loosely affiliated physician networks or independent practice associations (IPAs). This heterogeneity persists today; however, neither structural variation nor disease management strategies have been carefully stud-

ied for their associations with diabetes care quality or patient outcomes.

In 1998, the Centers for Disease Control and Prevention and the National Institute of Diabetes and Digestive and Kidney Diseases launched a multicenter, prospective observational study, the Translating Research into Action for Diabetes (TRIAD) Study (13). The TRIAD Study Group includes investigators from six translational research centers that partnered with ten health plans. These plans contracted with 68 provider groups to deliver primary and specialty care to more than 180,000 diabetic enrollees in 1998. From this population, TRIAD assembled one of the largest cohorts of diabetic patients ever studied, collecting and linking data from patients, providers, provider groups, and health plans.

TRIAD assessed associations between system-level structures and strategies and the quality of diabetes care and patient outcomes using Donabedian's paradigm (14) (Fig. 1). TRIAD also studied patient-level characteristics that may influence outcomes, either directly by affecting patients' abilities to self-manage diabetes or indirectly by affecting interactions with health care systems (Fig. 2). In Fig. 2, we synthesize published TRIAD studies that addressed the influences of either system-level or patient-level characteristics on processes or outcomes for diabetic patients.

RESEARCH DESIGN AND METHODS

The original TRIAD cohort consisted of a geographically, racially, and socioeconomically diverse group of U.S. adult (aged 18 and above)

diabetic patients. They were selected, using a standardized algorithm, (13) from diabetic patients who, in 1999, had been enrolled in one of the ten participating health plans for at least 18 months. The cohort was surveyed three times by computerized telephone or mailed survey in 2000–2001, 2002–2003, and 2005 (Fig. 3). The numbers of participants (and response rates adjusted for inability to contact and mortality) were 11,927 (69%), 8,781 (83%), and 5,751 (75%), respectively. The majority of the participants' medical records were obtained and reviewed at the first two surveys. The cohort was linked to the U.S. Census Bureau's Census 2000 block groups to obtain measures of neighborhood socioeconomic status (SES) and annually to the Centers for Disease Control and Prevention's National Death Index to obtain mortality.

For the first survey, each participating health plan's medical director and a representative from 63 of the 68 provider groups were interviewed. For the second, participants' primary care physicians were surveyed by mail for physician demographics, knowledge, and attitudes toward MCO structure and strategies ($n = 1,248$ physician respondents, 54% response rate). TRIAD survey instruments are available at <http://www.triadstudy.org>.

In 2005, TRIAD findings led study researchers to develop a Cardiovascular Disease (CVD) Risk Survey focused on patient-level determinants of risk factor control for blood pressure, A1C, and LDL cholesterol in seven of the original ten TRIAD plans. Using telephone or mail, researchers surveyed patients who were either in "good control" of all three risk factors (i.e., A1C <8%, LDL cholesterol <130 mg/dl, and systolic blood pressure [SBP] <140 mmHg) or in "poor control" of at least two risk factors (i.e., values at or above these cut points). Data were collected on patients' perceptions of risks, self-efficacy, communication with their providers, access to care, cost barriers, self-reported adherence to a regimen of prescribed medications, and reasons for nonadherence.

In 2006, TRIAD investigators

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*A complete list of the TRIAD Study Group members is available in the online appendix at <http://care.diabetesjournals.org/cgi/content/full/dc09-1802/DC1>.

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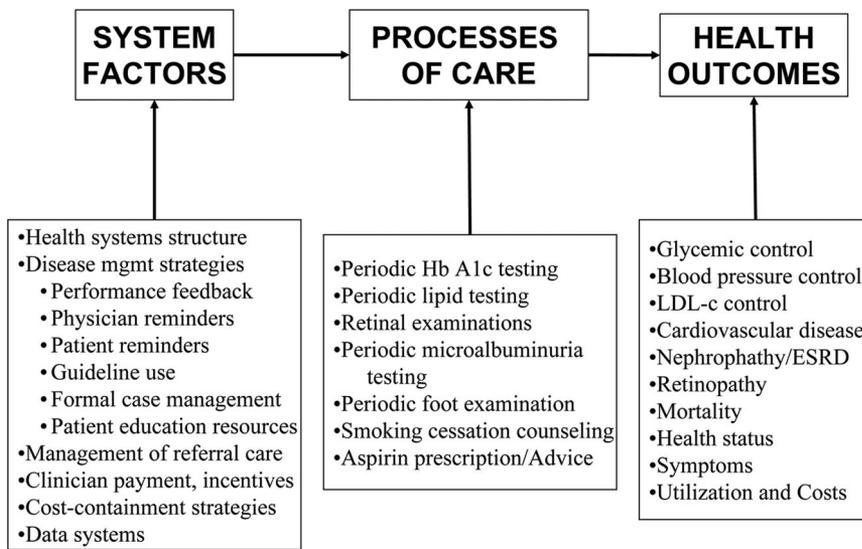


Figure 1—TRIAD conceptual model for relationships of system-level factors, processes, and outcomes of care. LDL-c, LDL cholesterol. ESRD, end-stage renal disease.

launched several theme studies involving 1–4 health plans that evaluated natural experiments such as plan-specific disease management interventions, changing health insurance benefits, and the effects of Medicare Part D. Other theme studies explored determinants of medication adherence and health disparities.

All TRIAD findings reported herein are based on the results from multivariable hierarchical models that account for the nesting of patients within provider groups and provider groups within health plans. System-level characteristics and strategies were incorporated as second-level fixed effects in patient-level regres-

sions. Reported associations are statistically significant ($P < 0.05$) unless otherwise stated.

STUDY FINDINGS

Managed care structure

Four of TRIAD’s ten health plans self-identified as for-profit organizations and six as not-for-profit. Physician groups self-identified as either group/network models ($n = 25$), IPAs ($n = 25$), or group/staff models ($n = 18$). Process measures of care quality were quite high across all plans (15), but among for-profit plans, patients in group/network model arrangements were at least 10% more likely to receive six of seven recommended “processes of care” than were patients in IPA arrangements (16). The profit status of health plans was not significantly associated with process scores.

Disease management strategies

From the medical directors’ survey, intensity scores were produced that measured the extent to which plans and provider groups used six disease management strategies: 1) performance feedback to physicians, 2) physician reminders, 3) use

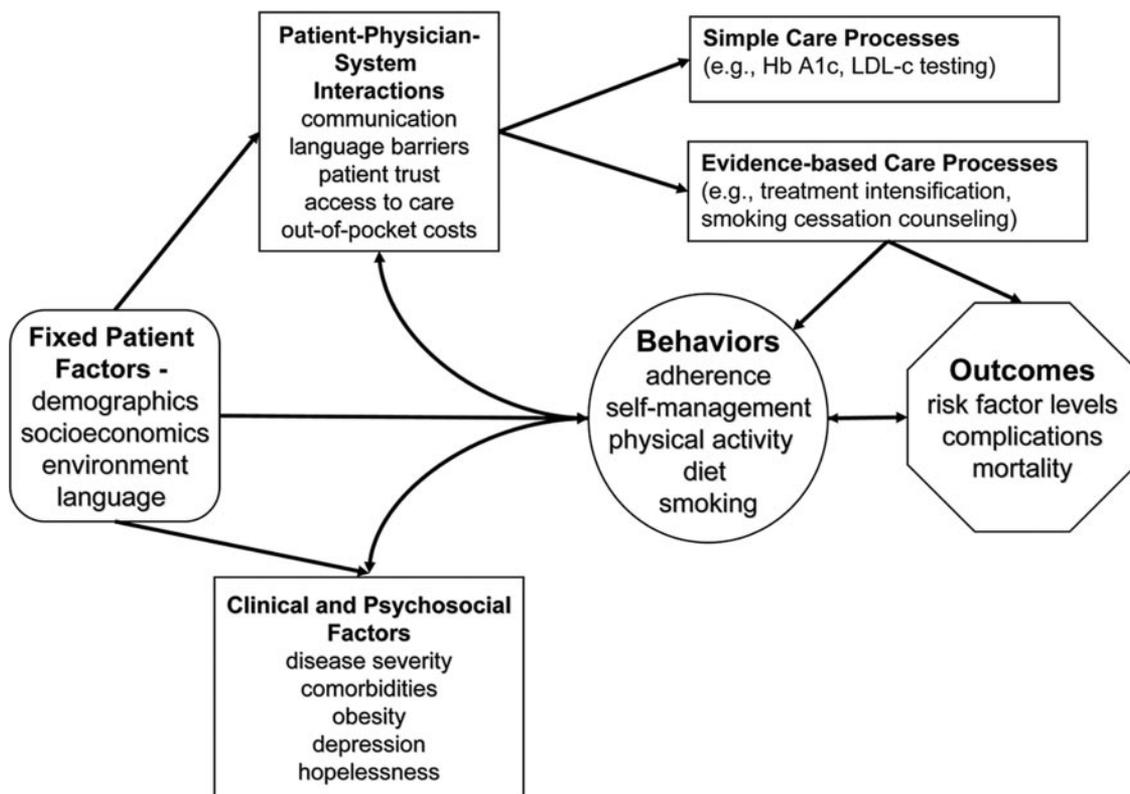


Figure 2—TRIAD conceptual model for relationships of patient factors and patient-system interactions with processes and outcomes of care. LDL-c, LDL cholesterol.

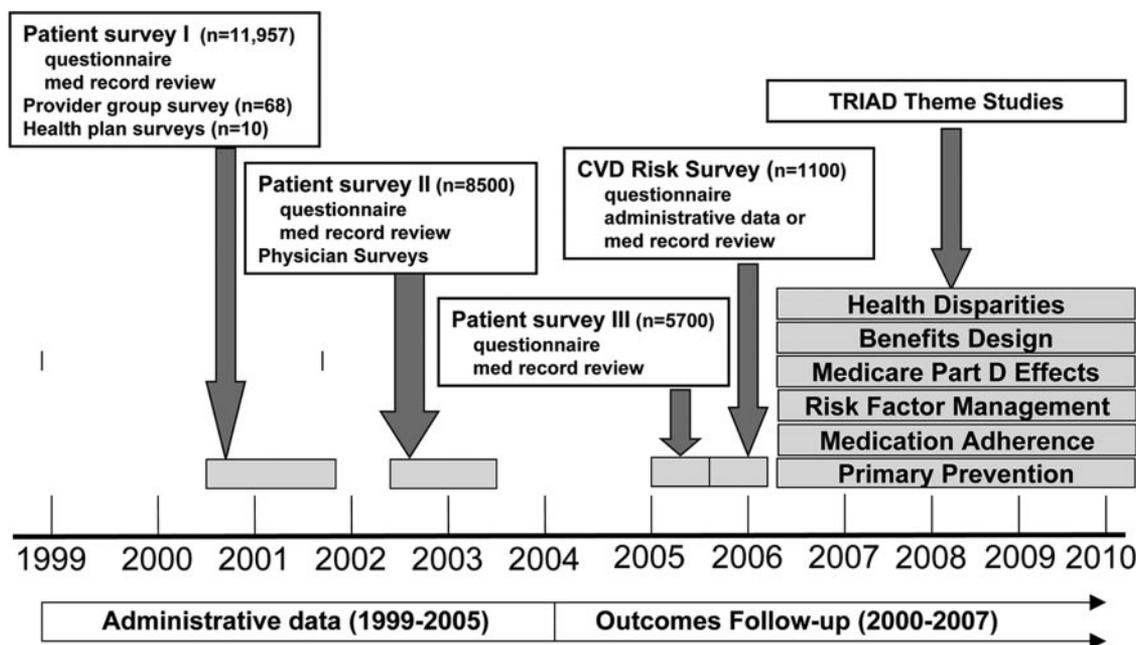


Figure 3—TRIAD timeline and component studies.

of clinical guidelines, 4) patient reminders, 5) formal care/case management by nonphysician providers, and 6) health education resources (17). The latter four were highly correlated and were combined into a structured care management score. Researchers assessed associations of these intensity scores with care processes, cardio-metabolic risk factor control, and risk factor management (17,18).

Greater intensity of performance feedback, physician reminders, and structured care management were each strongly associated with better care processes (17). For five to six of the eight processes listed in Fig. 1, provider groups at the 3rd versus the 1st tertile of each intensity score had a 5–15 percentage point better compliance with recommended process measures. In contrast, no intensity score was related to better A1C, LDL cholesterol, or blood pressure control or to the intensity of pharmacotherapy for these risk factors.

Process of care rankings of provider groups were entirely unrelated to the groups' rankings for patient A1C or blood pressure control and only weakly associated with rankings by patient LDL cholesterol levels (18). Thus, simple process of care indicators should not be interpreted as meaningful proxies for the quality of clinical care or the health status of patients.

Quality of care at TRIAD plans was compared with that of five geographically matched Veterans' Administration (VA)

health care centers in 2000 (15). The VA centers performed significantly better on all seven process measures. Importantly, VA center patients also had higher control rates for A1C and LDL cholesterol (A1C <8.5%: 83 vs. 65%; LDL cholesterol <100 mg/dl: 86 vs. 72%). Blood pressure control and patient satisfaction measures did not differ significantly.

Physician reimbursement and incentives

At the initial survey, provider group medical directors reported that physician reimbursement ranged from 100% salary to 100% fee-for-service. Performance-related incentive pay linked to either quality of care, utilization, or both also varied widely. Patients of providers reimbursed predominantly through salary were more satisfied, had significantly higher eye and foot examination rates, significantly more frequent tests for albuminuria, and better glycemic control (19). Incentive pay related to quality was associated with better performance on several care processes and with greater patient satisfaction. However, the relatively small number of provider groups made it difficult to distinguish the impact of reimbursement and incentive strategies from other aspects of the medical groups. Thus, when analyses were adjusted for group type (medical group vs. IPA), these differences diminished and most were no longer significant. Findings were similar when reimbursement information was

obtained directly from the TRIAD physician survey (20).

Cost-containment strategies

Among TRIAD health plans, various processes of care did not differ by the presence or intensity of utilization-based physician incentives or referral management strategies (e.g., prior authorization, gate-keeping, physician profiling) (21). Furthermore, participants in plans using referral management did not report lower specialist visit rates or greater difficulty getting specialty referrals. Thus, physician incentives based on controlling costs did not appear to adversely affect diabetes care (22,23).

In contrast, strategies that increased patient costs were associated with adverse consequences. Participants having full coverage for selected services were more likely than those without coverage to have had a retinal examination (78.4 vs. 69.8%) or to have attended a diabetes education session within the past year (28.8 vs. 18.8%) and, among insulin users, to practice daily self-monitoring of blood glucose (SMBG) (74.8 vs. 58.6%) (24). Patients with partial coverage (e.g., copayments, coinsurance) had similar rates of retinal examinations and health education class attendance to those with full coverage, but lower rates of SMBG (68.0 vs. 74.8%). Among the third-survey respondents (2005), 14% reported using less medicine than recommended because of costs. Compared with having

monthly out-of-pocket costs of less than \$50, costs of \$150 or more were associated with greater medication underuse (24 vs. 7%) (25). At the second survey, patients reporting that out-of-pocket costs were a barrier to self-management were significantly less likely to be in good control of all three cardiometabolic risk factors (26).

Implementation of Medicare Part D's prescription drug coverage in 2006 introduced a new coverage gap for many older TRIAD patients. Commonly referred to as the "doughnut hole," this gap began after the first \$2,250 of prescription costs. In two TRIAD plans, ~25% of diabetic Medicare enrollees entered the gap during 2006 (27). This proportion was lower than had been projected, possibly because both plans effectively encouraged greater use of generic medications. Nevertheless, compared with patients without coverage gaps, patients with only Part D reported cost-related medication non-adherence and had lower observed adherence for antidiabetic, antihypertensive, and lipid-lowering medications (28,29).

Other system interventions

TRIAD theme studies evaluated several health system interventions (30–34). One group-model plan used electronic health record dates to link prescription fills with recent measures of A1C, LDL cholesterol, and SBP. Of patients not in control for each risk factor, only 20–23% had evidence of poor medication adherence; from 30 to 47% were adherent to prescribed medications but had not received treatment intensification in response to elevated risk factor levels (30). These findings emphasize the potential utility of electronic clinical data for monitoring and improving evidence-based processes of care, such as treatment intensification (35,36), which has been shown to improve patient outcomes (37).

One TRIAD plan evaluated a nurse care management program that sought to enroll all diabetic patients with poor A1C control, microalbuminuria, or recent hospital or emergency department visits (32). Despite a large staff deployment, only 22% of the eligible patients were enrolled during 2004, in part because many non-targeted patients were enrolled and also because many patients were retained longer than the planned 6 months (median 8 months). Compared with matched eligible but unenrolled patients, enrollees had 0.3–0.5% greater improvement in A1C levels 12 months later, and slightly

better LDL cholesterol and blood pressure levels. During follow-up, both groups improved substantially on all three measures, suggesting that usual primary care may have sufficed for many.

Another plan changed from requiring appointments to providing open-access visits (32). After adjustment for differences in baseline rates, the six clinics with open access had lower rates of A1C and microalbuminuria testing and poorer blood pressure control than six clinics that required appointments.

The TRIAD CVD Risk Survey (38) found that missing medications was associated with poor risk factor control. Reasons for missing medications included transportation difficulties to pharmacies and pharmacies not having prescribed medications. In a follow-up study in one TRIAD plan, adherence to antidiabetic, antihypertensive, and lipid-lowering medications was higher among diabetic patients who refilled prescriptions by mail rather than in person (33).

Although TRIAD did not find associations of disease management strategies with better risk factor control in 2000, TRIAD health plans did observe marked improvements in control from 2001 to 2006. In one plan (34), an extensive chronic care model–based diabetes disease management program was implemented. Clinically important improvements in A1C and LDL cholesterol control, smaller but significant improvements in SBP, and improvements in all services classified as a process of care were observed.

PATIENT FACTORS— The lack of association of system-level factors with patient outcomes led TRIAD researchers toward a conceptual model (Fig. 2) that emphasizes patient-level factors as determinants of outcomes.

Sociodemographic characteristics

Notable differences in intermediate and longer term outcomes and smaller differences in processes of care were observed across patient subgroups. Younger diabetic patients were consistently less likely to receive recommended care processes; more likely to have missed a recommended process for an entire 3-year period (a "persistent lapse") (39); and less likely to have good concurrent control of A1C, LDL cholesterol, and SBP at the second examination (26) and 6 years later in one TRIAD plan (40). Moreover, their treatment was less likely to be intensified for poorly controlled blood pressure and

LDL cholesterol, and only slightly more likely for poorly controlled A1C.

Sex differences were relatively small (41–43), but for patients with known CVD, women were less likely than men to be using aspirin (33.2 vs. 39.0%) or lipid-lowering agents (52 vs. 58%) (41) and less likely to be in control for blood pressure and LDL cholesterol (44). In patients without CVD, women were less likely to have had a recent lipid profile (54 vs. 58%) or to have been advised to use aspirin (27 vs. 33%). In the 2005 single plan study (43), women remained significantly less likely than men to be in control for both LDL cholesterol (47 vs. 55%) and blood pressure (52 vs. 60%).

Race/ethnicity was not consistently related to differences in care processes (44,45), but important, consistent differences in control of all three intermediate outcomes were observed (26,38,44). African Americans had the poorest blood pressure control: 45% had blood pressure <140/90 mmHg versus 56% of whites. Mean LDL cholesterol levels were significantly greater for African American patients than white patients (118 vs. 111 mg/dl). All three minority populations had slightly but significantly higher A1C levels than whites (44). African Americans were more frequently in poor control of at least two risk factors at the second survey (2002) (26) and again in the 2005 CVD Risk Survey (38). Their poorer control occurred despite comparable or more intensive treatment (see below).

Neither household income nor education was strongly associated with processes of care, but they were associated with intermediate outcomes and also with mortality. Of process measures, only rates of dilated eye exams differed, being lower among poor or less educated respondents (75% in each group) compared with more educated patients or those making over \$75,000 annually (80 and 85%, respectively) (44). Persistent lapses in care processes were only slightly less frequent in people with higher household incomes and did not differ by education (39). Higher incomes and greater education were independently related to being in control for all three risk factors simultaneously. Poor control was more common in participants who expressed concerns about cost as a barrier to medical care (26).

TRIAD examined the independent effects of neighborhood SES to determine whether the social and spatial separation of poorer neighborhoods with fewer re-

sources and greater stress may contribute to disparities. After adjustments for individual income, education, and objective measures of neighborhood SES, participants reporting greater neighborhood problems were more likely to smoke, less likely to participate in regular physical activity, and had worse self-reported mental and physical health scores (46). Objective and subjective measures of neighborhood problems were independently associated with poorer blood pressure control.

Health behaviors

Many associations of health-related behaviors with outcomes were found, but they were modest in strength and explained little of the sociodemographic differences in outcomes. Fully 50% of patients 25–44 years of age with less than a high school education were current smokers compared with 7% of college-educated people age 65 and above (47,48). Smoking prevalence did not differ by race/ethnicity, but was higher among Spanish-speaking Latino patients. Current smoking was a strong and independent predictor of poor risk factor control (26), but adjustment for smoking did not reduce associations of younger age or lower educational level (SES) with control.

Daily walking for at least 20 min was less frequent in patients older than 65 years of age than in younger patients (64 vs. 70%); in women less frequent than in men (65 vs. 70%); and in whites or African Americans less frequent than in Asian/Pacific Islanders or Latino patients (49). Less education was also associated with a lower likelihood of regular physical activity (48). As with smoking, regular activity was an independent predictor of being in good control but did not explain age or SES differences in control (26).

Among insulin users, Latinos reported lower rates than whites of SMBG (62 vs. 77%) (48). SMBG did not vary by SES. African Americans and Latinos reported spending about 5% more time than whites on several diabetes self-care behaviors including foot care, shopping for and cooking diabetic meals, and exercising to manage diabetes (50). Patients of lower SES reported spending more time than higher SES patients on self-care, but less time using health-related websites or participating in support groups (50).

Lower income patients were more likely to underuse prescribed medications due to costs (15 vs. 5%) (25). After adjustment for income, Latinos' cost-related un-

deruse of medications was slightly greater than that of other groups (14 vs. 7–11%) (25).

Clinical and psychosocial factors

Depression, measured by the Patient Health Questionnaire 8 (PHQ-8) (51), was more prevalent, more often untreated, and more strongly associated with poor risk factor control in African American patients (adjusted odds ratio [OR] 2.28 [95% CI: 1.09–4.74]) than in whites (adjusted OR 1.04 [0.63–1.72]) (38).

More than 50% of TRIAD participants were obese (BMI >30 kg/m²) at baseline. Obesity was more frequent in women than men (61 vs. 51%) and in African American participants and was associated with lower likelihood of regular walking (49). Obesity was also associated with a lower likelihood of being in control for all three cardio-metabolic risk factors but explained little of the poorer risk factor control in African Americans (26).

Physicians managed medications differently by patient race/ethnicity. African Americans, Latinos, and Asians/Pacific Islanders received similar or more intense pharmacotherapy than whites for hypertension and lipid management (44) and were more likely to receive intensification for poor blood pressure control than whites (52). By contrast, all nonwhite groups were less likely than whites to be intensified for poorly controlled A1C (52).

PATIENT-SYSTEM INTERACTIONS

Communication

Patient assessments of providers' ability to listen, explain, respect, and spend time with the patient were unrelated to risk factor control (26), did not explain educational disparities in health behaviors (smoking, physical activity, diabetes-related health seeking activity) (48), and did not lessen the negative impact of cost-sharing on use of SMBG, health education classes, or annual retinal examinations (24). However, patients reporting greater trust in their physicians were more likely to be in good control of all three CVD risk factors (26). However, differences in trust did not explain racial/ethnic control differences. In one TRIAD plan, reported receipt of advice on physical activity or dietary changes was not associated with differences in these behaviors among

women with gestational diabetes mellitus (53).

Most Spanish-speaking TRIAD patients lived in south Texas. Nearly 90% reported having a bilingual physician. In this context, SMBG rates were similar and dilated eye exam rates (84 vs. 81%) and foot self-care rates (76 vs. 70%) were higher for Spanish-speaking versus English-speaking Latino patients (48). Nevertheless, mean A1C levels were somewhat higher for Spanish-speaking versus English-speaking Latinos (9.1 vs. 8.8%).

Intensity of disease management (in 2000) did not appear to affect racial/ethnic disparities in risk factor control, flu vaccination rates, or intensity of medication management for elevated risk factors either positively or negatively (54). Similarly, educational disparities in smoking, physical activity, and various health-seeking behaviors were unrelated to the intensity of disease management (47).

STUDY LIMITATIONS — Most TRIAD analyses were cross-sectional, which leaves open a possibility that system-level interventions such as disease management may have affected patient outcomes if observed for a longer period. However, our study focused on intermediate outcomes that change more rapidly and on well-established programs described in medical director interviews. System-level interventions have evolved markedly since 2000; the lack of association of programs with outcomes in 2000 may not generalize to the current context. As noted, the relatively small number of health plans and, to a lesser extent, of provider groups in the TRIAD sample made it difficult to study more than one system-level characteristic at a time. TRIAD patients were drawn from a diverse set of plan types, which should enhance generalizability. However, all plans participated voluntarily and all scored relatively high in performance (15). A broader range of plans may have enhanced our ability to detect associations of system factors with quality and possibly with risk factor levels. Whether our findings for physician incentives, performance feedback, and physician reminders generalize to non-managed care settings cannot be examined in TRIAD, but we see no reason why patient-level associations we observed should differ.

SYNTHESIS AND IMPLICATIONS — TRIAD found that more integrated health systems—

those implementing more intensive disease management strategies and using financial incentives related to quality—achieved higher levels of diabetes care processes. However, these strategies were not associated with better intermediate outcomes. A similar “disconnect” between improved processes and unaffected outcomes has been reported elsewhere (55,56). Process measures are more directly under the control of providers than outcomes. A logical conclusion is that systems should specifically focus on improving processes of care, but only on processes shown to be linked to improved outcomes (e.g., use of statins, ACE inhibitors, aspirin, and treatment intensification for poor risk factor control) (35–37).

The proposition that well-planned system-level interventions can ultimately improve patient outcomes found some support in TRIAD in the superior intermediate outcomes of the VA, a highly integrated system with excellent clinical data and strong quality improvement programs, and in the recent outcome improvements reported by at least one TRIAD plan (34).

Strategies of shifting health care costs to patients through co-payments or coverage gaps reduced the use of both preventive services and recommended medications—especially for lower-income patients. Cost-shifting among patients with chronic illnesses does not save money and is associated with higher rates of hospitalization and death (57). It is ironic that a health plan's cost-shifting strategies may undermine the large investments it makes in disease management. One TRIAD plan is currently evaluating a benefits program for diabetic patients that eliminates all copayments for evidence-based diabetes medications (58).

TRIAD has found numerous associations of patient-level sociodemographic, psychosocial, and behavioral factors with both self-care and intermediate outcomes that suggest that the next generation of system-level interventions could be better tailored to meet the needs of diabetic subpopulations. Younger patients, who are the most likely to benefit from better risk factor control, (59) were the least likely to be benefiting from system-level programs, having poorer care processes, risk factor control, and self-care behaviors. Fewer physician encounters, busier work or family schedules, or less motivation while still asymptomatic in this rapidly

growing segment of the diabetes population may explain these disparities.

Modest disparities in risk factor management and control were noted between males and females, whereas African Americans and patients of lower SES had much poorer control for CVD risk factors. They also had higher rates of obesity, cigarette smoking, undiagnosed and untreated depression, greater sensitivity to out-of-pocket costs, lower trust in physicians, and adverse neighborhood environments. If future system-level interventions can address these differences, they will have a greater chance of reducing disparities and a greater net effect on quality improvement. In fact, “one size fits all” interventions may exacerbate disparities within populations, thereby limiting the potential for quality and outcome improvement (60).

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