More than 23 million people in the United States have diabetes, and projections show that this number will increase to 48.3 million by 2050. Many of these patients will seek care in primary care clinics that are currently ill-equipped to address the rising demand.

Large studies such as the Diabetes Control and Complications Trial (DCCT), the U.K. Prospective Diabetes Study, and multiple studies on cardiovascular risk reduction have shown that improved glycemic, blood pressure, and cholesterol control can substantially reduce the risk of complications from diabetes. The American Diabetes Association has developed evidence-based process and outcome recommendations to meet these metabolic and cardiovascular goals. However, these guidelines have not been routinely met.

Primary care practices are the main source of health care for most diabetic patients, but providers in these clinics face significant challenges in meeting the medical and psychosocial needs of this population. Long intervals between patient visits and limited time with patients can result in clinical inertia (the lack of timely treatment and intensification of therapy). The medical, educational, and psychosocial needs of diabetic patients are often complex and cannot always be adequately addressed in infrequent short visits with a single provider.

These difficulties were illustrated in a study of an electronic system that reminded clinicians of needed diabetes care during each visit. Even a well-designed system change was unable to substantially improve diabetes care. The processes had been previously agreed on by the providers, but even with this customized care plan in a motivated group, the physicians carried out only about one-third of the electronic reminders. They cited time constraints and other competing patient problems as barriers.

With the rising prevalence of diabetes, overcoming these issues will become even more challenging.

IN BRIEF

Most diabetic patients are managed by primary care physicians, but clinical inertia and limited time with patients hamper efforts to meet treatment goals. Successfully caring for the medical and psychosocial needs of the expanding diabetic population seen in primary care will require new strategies. This article reviews interdisciplinary efforts by primary care physicians, advanced practice nurses, and clinical pharmacists that can achieve improvements in clinical processes and outcomes at reasonable costs.

Additional resources will be needed to meet the rising demand and to overcome barriers that primary care physicians face in the current health care system. Nurses and clinical pharmacists are increasingly joining with physicians in care teams to more successfully care for diabetic patients.

A recent Institute of Medicine report calls for expanding the role of nurses into areas such as care coordination and basic primary care delivery. Indeed, evidence from many studies shows that nurse practitioners can provide care for simple acute illnesses and routine chronic disease management with outcomes similar to primary care physicians. A large, well-known trial of community clinical pharmacists working collaboratively with primary care physicians to care for diabetic patients has shown improvements in clinical outcomes at reasonable cost. Nurse or pharmacist case management consisting of patient education, patient and family counseling, and close monitoring of health outcomes in conjunction with a physician has also been shown to improve outcomes for chronic illness, especially for diabetic patients. Notably, nurse case management was an integral part of intensive therapy in the DCCT. Team-based care has the potential to meet the complex needs of many diabetic patients.
A variety of quality improvement interventions, including the addition of mid-level providers, have been studied to improve diabetes care in the primary care setting. In general, these involve redistributing responsibilities to nurse or pharmacist providers, implementing new electronic tools, or facilitating communication and data exchange among patients and providers.

Table 1 describes programs that may fit well into primary care practices. Most are implemented within multifaceted programs involving more than one strategy. Although the results of studies have been varied, those involving team-based care and case management seem to be the most efficacious. Because each clinic has its own culture and patient needs, the suitability and results of each intervention will vary by location.

As described in Table 2, a number of systematic reviews and meta-analyses have summarized the research on nurse- and pharmacist-involved diabetes care to date. The interventions commonly included were patient education, case management, and medication management. Most of the programs showed promising results with significant improvements in glycemic control. The four meta-analyses each demonstrated pooled effects on A1C favoring nurse or pharmacist involvement. Also, several review articles reported improvements in blood pressure and cholesterol measurements, although the results were often inconsistent between studies. A breadth of evidence supports the use of strategies that allow pharmacists and nurses to join with physicians to expand the capacity to care for diabetic patients.

Many models exemplify team and process structures that can support nurses or pharmacists in partnership with primary care physicians. To successfully manage diabetes, patients may need more contact with the care team than a single primary care physician can provide. Additional visits and care coordination by other providers is one solution that has been studied. The following section highlights two successful models that have been implemented and rigorously evaluated.

Case Studies

A pharmacist-led disease management program

Rothman et al. established a clinical pharmacist team within a primary care clinic that provided patient education, case management, and medication management to diabetic patients. This randomized trial was conducted from February 2001 to April 2003 at an academic general internal medicine practice staffed by attending faculty and residents. Participating patients, recruited by primary care provider referral (n = 217), were adults with type 2 diabetes who had an A1C result > 8.0%.

Patients were randomized to an intervention group or a control group. Those assigned to the control condition received a single management session from a clinical pharmacist followed by usual care from their primary care provider. The intervention group received a variety of services coordinated by three clinical pharmacists and a case manager within the general internal medicine practice. After receiving training in outpatient diabetes management (two became certified diabetes educators), they executed the program, which was supplemental to the patients’ usual primary care visits.

Pharmacists had contact with the patients every 2–4 weeks by phone or in person. Individualized counseling and education and medication management were provided according to evidence-based algorithms. The algorithms were developed with input from clinic physicians and approved by the clinic’s leadership. Primary care providers were notified of the results of these sessions. Additionally, the care coordinator contacted patients regularly to remind them about appointments, identify barriers to care, and address treatment adherence.

Primary care providers could choose whether they wanted to receive medication adjustment recommendations from the pharmacists or be notified after the changes had been made. Proactive management of clinical parameters was facilitated by regular review of an electronic patient database. Patients whose blood pressure was uncontrolled, for example, were identified and targeted for further medication intensification.

After 12 months of follow-up, multiple key indicators improved significantly. Control patients’ mean A1C improved by 1.6% compared to 2.5% among intervention patients (difference 0.8%; 95% CI 0.0–1.7). Both systolic and diastolic blood pressure improved more among intervention than control patients. From baseline to 12 months of follow-up, control patients had an increase of 2 mmHg in systolic blood pressure, whereas intervention patients had a decrease of 7 mmHg (difference 9 mmHg; 95% CI 3–11). Diastolic blood pressure increased 1 mmHg in control patients compared to a decrease of 4 mmHg in the intervention group (difference 5 mmHg; 95% CI 1–9). Aspirin use for cardiovascular risk reduction was also significantly higher among intervention patients. Total cholesterol improved more in the intervention group, but the difference was modest and did not reach statistical significance.
### Table 1. Summary of Quality Improvement Strategies

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case management</td>
<td>Coordination, monitoring, and support of patient medical needs, often by a nurse or pharmacist (i.e., nurse assigned to high-risk diabetic patients to coordinate specialist care and assist patients with diet and medication management)</td>
</tr>
<tr>
<td>Medication therapy management</td>
<td>Prescription and adjustment of medications by an advanced practice nurse or clinical pharmacist, often using algorithms; conducted by phone and in person and in collaboration with care physician or independently</td>
</tr>
<tr>
<td>Clinician education</td>
<td>Medical education directed at clinicians about the latest guidelines, medications, and treatment techniques</td>
</tr>
<tr>
<td>Community health workers</td>
<td>Lay people, often from an underserved patient population, who provide culturally appropriate nonclinical support and links to community resources</td>
</tr>
<tr>
<td>Telemedicine</td>
<td>A system to facilitate remote clinician consultation and collaboration</td>
</tr>
<tr>
<td>Audit and feedback</td>
<td>Summary of provider or group performance on clinical or process indicators delivered to clinicians to increase awareness of performance (i.e., monthly reports delivered to providers about the percentage of their diabetic patients who are at their A1C goal)</td>
</tr>
<tr>
<td>Patient reminder systems</td>
<td>Messages to patients such as phone calls, letters, or e-mails to provide reminders about appointments or important aspects of self-management</td>
</tr>
<tr>
<td>Patient education</td>
<td>Interventions to promote patient understanding of disease, treatment, self-management, or prevention strategies; often delivered through group sessions or one-on-one visits with a diabetes educator or by printed materials</td>
</tr>
<tr>
<td>Electronic patient registries</td>
<td>Electronic medical records that allow tracking of provider or clinic diabetes population clinical measures; facilitate proactive management of patients who have not reached their goals (i.e., generates a report of all patients who have not had a diabetic eye exam and then sends targeted referral letters)</td>
</tr>
<tr>
<td>Continuous quality improvement</td>
<td>Techniques for examining and measuring clinical processes, designing interventions, testing their impacts, and then assessing the need for further improvement (i.e., identifying barriers to effective pneumonia vaccination in a clinic’s diabetic patients and implementing solutions while assessing changes in frequency of the vaccination)</td>
</tr>
<tr>
<td>Team changes</td>
<td>Restructuring provider teams to maximize efficacy of each person’s role in providing patient care (i.e., nurse practitioner rather than physician seeing diabetic patients for routine follow-up)</td>
</tr>
<tr>
<td>Clinician reminders</td>
<td>Messages directed at practitioners during clinical practice that prompt actions based on patient needs or physiological parameters (i.e., electronic medical record messages reminding clinicians to order yearly lipid profiles when they are due)</td>
</tr>
<tr>
<td>Facilitated relay of clinical data to providers</td>
<td>A system for capturing data directly from patients and transmitting them to providers (i.e., an Internet-based patient portal or other home device for transmitting daily blood glucose measurements)</td>
</tr>
<tr>
<td>Promotion of self-management</td>
<td>Strategies that enhance patients’ ability to manage their condition; these include devices for self-monitoring (i.e., home blood pressure cuff), provision of results to patients (i.e., sending patients their lab results), or follow-up phone calls from the provider with recommendations</td>
</tr>
<tr>
<td>Financial incentives, regulation, and policy</td>
<td>Strategies that reinforce certain behaviors such as financial incentives to providers or patients or changes in regulation, policy, licensure, or accreditation</td>
</tr>
</tbody>
</table>

Adapted from refs. 32 and 54.
Labor and cost analyses of the program showed that the additional personnel resources came at a moderately increased expense. Patient care–related activities such as visits, phone calls, or medical chart reviews occurred more often for the intervention group (mean 4 vs. 1.1 times per month) and more time was spent (38.6 vs. 10.7 minutes per month) (P < 0.001 for both). Among intervention patients, 46% of this time

### Table 2. Summary of Recent Review Articles and Meta-Analyses on Nurses or Pharmacists Caring for Diabetic Patients in Collaboration With Physicians*

<table>
<thead>
<tr>
<th>Review</th>
<th>Overview</th>
</tr>
</thead>
</table>
| Davidson, 2007* | **Review type:** Narrative  
**Providers:** Nurses and pharmacists  
**Summary:** Of those studied, few methods for improving diabetes care have been consistently effective in reducing A1C levels across studies. A notable exception is case management by nurses or pharmacists who have the authority to make independent treatment decisions. |
| Chisholm-Burns et al., 2010* | **Review type:** Systematic review and meta-analysis; 298 studies  
**Providers:** Pharmacists  
**Summary:** Included studies of medication therapy management, patient education, drug utilization review, and chronic disease management. Favorable results were found in therapeutic and safety outcomes. The meta-analysis combined studies of direct clinical pharmacist patient care. It demonstrated significant improvements in A1C, LDL cholesterol, blood pressure, and adverse drug events. Medication adherence, patient knowledge, and quality of life were also improved. In a meta-analysis of six studies with 550 patients, the mean A1C difference between the pharmacist intervention group and the comparison group was –1.8% (95% CI –2.7 to –0.9). |
| Loveman et al., 2003* | **Review type:** Cochrane systematic review; six studies, 1,382 patients  
**Providers:** Nurses  
**Summary:** Examined the effects of specialist nurse practitioner diabetes care. A significant impact on A1C was observed in four of six trials. Two of the trials were conducted in pediatric populations. In studies reporting the duration of the intervention, the benefits were not sustained at 12 months or beyond the termination of the interventions. |
| Machado et al., 2007* | **Review type:** Systematic review of 36 studies, meta-analysis of 16 studies, 2,247 patients  
**Providers:** Pharmacists  
**Summary:** Diabetes education (69%) and medication therapy management (61%) were the most common interventions studied. Also examined were recommendations to physicians, physical exams, and adherence support. Sixty-nine percent of systematically reviewed studies showed clinically and statistically significant A1C reductions in the intervention groups. In the meta-analysis, A1C levels in the pharmacists intervention group fell 1.0% (± 0.28%, P < 0.001), while levels in the control group fell 0.28% (± 0.29%, P = 0.335). Pharmacist interventions reduced A1C values over control group care by 0.62 (± 0.29%, P = 0.03). |
| Saxena et al., 2007* | **Review type:** Systematic review; seven studies with A1C measured  
**Providers:** Nurses, dietitians, and “link workers”  
**Summary:** Two models were studied in underserved populations: a case management model and a link worker model. In the first model, nurses and dietitians, sometimes under the supervision of a diabetologist, followed algorithms to deliver education and medical care. Clinically and statistically significant A1C declines were seen in three of four studies. The link worker model employed trained lay people from the minority ethnic communities who provided culturally appropriate guidance to educate patients and improve health care access. Link worker studies did not demonstrate significant A1C reductions. |

*continued on p. 64*
was spent for in-person contact, 42% for telephone management, and 11% for medical chart review, appointment setting, and other activities.

The costs associated with the program were modest compared to most modern medical interventions. The labor and indirect costs for the intervention group were $47.21 per patient per month versus $10.23 for the control group. The marginal costs of implementing the program were $36.97 per patient per month. Possible cost savings resulting from potential reductions in emergency department or hospital utilization were not assessed.

This model could function with clinical pharmacists or nurses within a single clinic or, to spread the cost burden, as an adjunct program that supports patients from multiple practices. A pharmacist-led disease management program that increases opportunities for patient education, case management, and medication management can efficiently improve diabetes outcomes at a reasonable cost.

An advanced practice nurse–physician team model

By creating structured care processes, primary care physicians and nurse practitioners working in teams can improve both diabetes patient care and clinical outcomes. Litaker et al.29 studied clinical processes, outcomes, and costs in a randomized, controlled trial from October 1996 to January 1998. Nurse practitioner–primary care physician (NP-MD) teams managed patients with both hypertension and diabetes. One hundred and fifty-seven patients with mild to moderate hypertension and diabetes managed without insulin were identified by providers or responded to advertisements at this academic institution. Participants were randomized to an intervention group managed by the NP-MD team or a control group managed as usual by their primary

### Table 2. Summary of Recent Review Articles and Meta-Analyses on Nurses or Pharmacists Caring for Diabetic Patients in Collaboration With Physicians* , continued from p. 63

<table>
<thead>
<tr>
<th>Study</th>
<th>Review type</th>
<th>Providers</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shojania et al., 200632</td>
<td>Meta-regression, 66 studies</td>
<td>Nurses and pharmacists</td>
<td>Quality improvement strategies studied were classified as case management, team changes, electronic patient registry, clinician education, clinician reminders, facilitated relay of clinical information to clinicians, patient education, promotion of self-management, patient reminder systems, and continuous quality improvement. Interventions reduced A1C values by a mean of 0.42% (95% CI 0.29–0.54) during a median of 13 months of follow-up. After statistical adjustment, only two of the 11 strategies were associated with reductions in A1C values of at least 0.50%: team changes (0.67%, 95% CI 0.43–0.91, n = 26 trials) and case management (0.52%, 95% CI 0.31–0.73, n = 26 trials). Trials in which pharmacists or nurses could make independent treatment decisions had greater combined A1C reduction (0.80% [95% CI 0.51–1.10] compared to 0.32% [95% CI 0.14–0.49], P = 0.002 for the comparison).</td>
</tr>
<tr>
<td>Welch et al., 201033</td>
<td>Meta-analysis of 29 studies, 9,397 patients</td>
<td>Nurses</td>
<td>Included interventions of nurse diabetes case management. Mean A1C in the intervention groups was reduced by 0.89% (95% CI 0.63–1.15), a statistically significant improvement over controls. Nurse-led team case management was found to be superior to that delivered by a single clinician, usually a nurse. Higher baseline A1C (&gt; 8.0%) predicted a larger effect size than lower A1C (&lt; 8.0%). The ability of the case manager to change medications independently did not significantly improve the outcome, contrary to the reviews by Shojania32 and Wubben.37</td>
</tr>
<tr>
<td>Wubben et al., 200837</td>
<td>Systematic review of 21 studies</td>
<td>Pharmacists</td>
<td>All studies involved adding visits with a clinical pharmacist to usual primary care for adult diabetic patients. The differences between intervention and control groups in change of A1C ranged from an increase of 0.2% to a decrease of 2.1%. Strategies in which pharmacists could independently prescribe medications had a larger effect size.</td>
</tr>
</tbody>
</table>

*Most studies took place in outpatient settings. The primary studies are limited by heterogeneous methodology, interventions, and settings.
trending back toward baseline levels, indicating that the team care may need to be continued throughout patients’ chronic illness to sustain the benefits.

The researchers predicted that the personnel costs for 12 months would be reduced by shifting the locus of care from physicians to nurse practitioners. However, the cost per patient for 1 year was higher in the team care than in the usual care group ($134.68 vs. $93.70, \( P < 0.001 \)). A retrospective chart review revealed that, because of the additional care of the nurse practitioner, team care patients had a significantly greater average amount of time spent during 12 months for management of hypertension or diabetes (180 vs. 85 minutes, \( P < 0.001 \)). This increased time likely offset the lower labor cost of the nurses relative to the physicians.

Notably, patient satisfaction was significantly higher in the intervention group. Although this program accrued additional expenses over usual care, it did demonstrate that advanced practice nurses working in collaboration with primary care physicians to deliver algorithm-based diabetes care can improve A1C and patient satisfaction levels, as well as other important prevention and clinical outcomes.

**Discussion**

To achieve broad acceptance, programs such as these may need to offset expenses through savings generated by reduced health care utilization. This will require new payment models that reward cost-effective practice in primary care. Numerous studies have now demonstrated that improving diabetes control can reduce complications and likely reduce costs. Reduction in the risk of complications can lower the health care system or societal expense associated with diabetes. For example, in one evaluation of diabetes costs at a health maintenance organization that implemented enhanced diabetes management, patients whose baseline AIC was > 10% and improved by > 1% generated a mean savings of $820 in health care costs for each year during a 4-year period. In a separate pharmacist-run diabetes management program, average AIC fell from 9.5% at baseline to 7.8% after 1 year, with a total cost avoidance from this benefit calculated to be $59,040.

Primary care providers who are eager to adopt models of team care may therefore be able to justify the added costs if the savings can be captured within a single larger organization. Financial models such as the Accountable Care Organization and Patient-Centered Medical Home models that could reward care coordination, quality improvement, and more cost-effective services are under study by both the Centers for Medicare and Medicaid Services and private insurers. Intensified care, possibly through coordination with nurses and clinical pharmacists, is not only efficacious, but may also prove to be cost-effective for meeting the rising demand for diabetes care.

Multiple training opportunities exist for nurses and clinical pharmacists who wish to specialize in caring for diabetic patients. Primary care practices may wish to specifically seek candidates with specialized training when implementing team-based diabetes programs. Clinical pharmacists have typically received doctorate of pharmacy degrees and then elected to complete post-graduate residency training programs, which open more opportunities to care for patients directly. To further specialize, clinical pharmacists can opt to complete a second post-graduate residency year (PGY2) in their preferred area. PGY2 residencies are available in multiple practice
areas, including ambulatory care, cardiology, internal medicine, and pharmacotherapy. Pharmacists can also attain certification in various areas of expertise. The Board of Pharmacy Specialties offers certifications in both pharmacotherapy and ambulatory care pharmacy that provide skills for outpatient diabetes management. Pharmacists and advanced practice nurses have also been eligible for board certification in advanced diabetes management, although this certification is currently under review.

Specifically for certifications in diabetes, multiple disciplines including pharmacists and registered nurses can become certified diabetes educators (CDEs) through the National Certification Board for Diabetes Educators. This training provides specialized knowledge in diabetes self-management education and training (DSME/T), which is a core component of the diabetes comprehensive care plan. It facilitates the knowledge, skill, and ability necessary for self-care by supporting informed decision-making, problem-solving, and collaboration with the care team. To become a CDE, candidates must have experience in their respective discipline, as well as 1,000 hours of DSME/T experience.

Pharmacists and advanced practice nurses have also been eligible for board certification in advanced diabetes management, although this certification is currently under review.

Conclusions

The field of primary care faces substantial challenges in transforming itself to meet the rising tide of diabetes and other chronic illnesses. Team care that used the unique training of pharmacists and nurses in medication management and individualized case management in coordination with the medical expertise of primary care physicians will be a powerful tool to address these needs.

As the nurse and clinical pharmacist workforces broaden their scopes, the Chronic Care Model and Patient-Centered Medical Home concept can come closer to achieving more comprehensive chronic disease management in primary care. Both systems are designed around multidisciplinary care teams, and both address barriers at the system, community, patient, and provider levels. Additionally, models have been put forth that detail how such systems might be adapted for team approaches to diabetes care.

These innovative systems will lay the groundwork for making team approaches to diabetes care more feasible in community practices and health systems. As our patients demand that we shift from treating mostly acute illnesses to managing chronic diseases, teams of providers working collaboratively at the top of their skill sets can best meet patients’ complex needs.

REFERENCES


Valley Health System. Kathleen Wolff, MSN, APRN, BC-FNP, is a diabetes nurse practitioner at the Vanderbilt University Medical Center Eskind Diabetes Clinic. Russell Rothman, MD, MPP, is an associate professor of internal medicine and pediatrics; chief of the Internal Medicine and Pediatrics section; and director of the Vanderbilt Program in Effective Health Communication at the Vanderbilt University Medical Center.