Development and Evolution of a Primary Care–Based Diabetes Disease Management Program

Robb Malone, PharmD, CDE, CPP; Betsy Bryant Shilliday, PharmD, CDE, CPP; Timothy J. Ives, PharmD, MPH; and Michael Pignone, MD, MPH

High-quality diabetes care can reduce diabetes-related complications and improve quality of life. Evidence from randomized trials, including the U.K. Prospective Diabetes Study and the Diabetes Control and Complications Trial, have shown that tight glucose control can decrease microvascular complications.[1,2] The Steno 2 trial demonstrated that a multifactorial approach that includes behavioral modification and intensive therapy targeting hyperglycemia, hypertension, and dyslipidemia is effective in reducing progression of microvascular complications among high-risk patients with type 2 diabetes and microalbuminuria.[3] Other evidence supports the use of aspirin and statins in middle-aged and older patients with diabetes to prevent heart disease.[4]

Translating this evidence into practice has proven to be difficult. National data suggest that a large proportion of patients with diabetes continue to receive suboptimal care and have suboptimal outcomes. Only 7% of adults with diabetes in National Health and Nutrition Examination Survey from 1999 to 2000 attained a hemoglobin A_{1c} (A1C) < 7%, blood pressure < 130/80 mmHg, and total cholesterol < 200 mg/dl.[5] Attempts to deliver excellent care face a wide variety of barriers at the patient, provider, and system level. For example, competing demands exist for providers' time: patients often have needs they feel are more pressing and demand their providers' attention, whereas providers feel other pressure ranging from time constraints to health maintenance needs.

One potential strategy for overcoming the barriers to high-quality care is to implement structured care programs in clinical settings. Effective structured care programs, sometimes referred to as disease management programs, create an "organized system of care that is tailored to multiple problems of chronic illness," versus the traditional model of care that is designed to address acute illness.[6] A recent meta-analysis to assess the impact of these programs on glycemic control in type 2 diabetes found that they were effective, with the greatest efficacy occurring in programs that expanded the role of nonphysician providers to make interventions, particularly medication adjustment.[7]

In this article, we describe the development of a primary care–based structured diabetes care program in our academic internal medicine practice. We feel our experience may be helpful to others who are attempting to improve the care of their patients with diabetes.

Our program (now known as the University of North Carolina [UNC] Enhanced Care Diabetes Program) was developed and implemented within the UNC Chapel Hill general internal medicine practice. This practice serves a wide socioeconomic range of patients and is staffed by 70 medical residents and > 20 attending faculty, all of whom practice on a part-time basis varying from 1 to 7 half-days per week. In the following sections, we will describe the evolution of the structure, processes, and outcomes of the program, along with some practical lessons learned.

The timeline for our program's development is shown in Table 1. Before our program's existence, the clinic cared for diabetes in an ad hoc manner, with each provider doing his or her best to implement excellent care. The practice used a hybrid information system: an electronic medical record for laboratory results and paper charts for other information. There was no registry of individuals with diabetes, nor did the clinic have ancillary staff for patient education or self-management training.

Beginning in 1998, we have proceeded through three phases of development. The initial phase involved the development, pilot testing, and revision of the program of structured care. In phase 2, we tested the efficacy of the revised program in a randomized trial. After demonstrating the program's efficacy, phase 3 translated the program throughout the entire practice of > 1,500 patients with diabetes.

Funding for our program during the developmental years was tenuous. Initial funding came from within the health care system. This funding cycle lasted for 1 year. The remainder of funding for the pilot came from the UNC Hospital Department of Pharmacy, UNC Physicians and Associates, and North Carolina Medicaid, Carolina Access. The randomized trial was funded by the Robert Wood Johnson Clinical Scholars Program, UNC Division of General Internal Medicine, and numerous small grants from within the institution. The program is now funded by the UNC Division of General Internal Medicine, UNC Healthcare, UNC School of Pharmacy, and clinical revenue.

Phase 1. Developing and Pilot-Testing the Program

Ground work for the first phase of the

Table 1. Diabetes Program Timeline

	Development	Phase 1: Pilot	Phase 2: RCT	Phase 3: Clinic-Wide Adoption
Timeline	1997 to June 1999	July 1999 to June 2001	July 2001 to April 2003	2003 to present
Medical Staff, Extenders	None	2 pharmacists	3 pharmacists	1.3 pharmacists 1 nurse practitioner 1 dietitian
Nonmedical Staff	None	None	1 research assistant	3 care assistants
Funding	UNC Physicians and Associates	UNC Physicians and Associates, Medicaid, Carolina Access, UNC Department of Pharmacy	Robert Wood Johnson, UNC Division of General Internal Medicine, small grants from within the institution	Clinical revenue, UNC Healthcare, UNC Division of General Internal Medicine, UNC School of Pharmacy
Patient Enrollment	0	300	600	1,500
Method of Intervention	None	Pharmacist clinic and telephone follow-up. No automated laboratory, vitals, or appointment data; All data for intervention collected through chart.	Pharmacist and research assistant clinic and telephone follow-up. Provision of toll-free patient phone line for questions and glucose reporting. Limited automated laboratory, vitals, and appointment data; most data for intervention collected through chart review.	Individual, templated visits with extenders. In clinic, PCP visit follow-up care assistants. Telephone-based intervention by extenders and care assistants. Provision of toll-free patient phone line for questions and glucose reporting. Advanced automated laboratory, vitals, and appointment data; minimal amount of data for intervention collected through chart review.
Type of Intervention	None	Patient-centered education, medication adherence, physician-directed medical intervention through extender recommendation	Patient-centered education using techniques to minimize the impact of low literacy, assist with goal setting, and enhance medication adherence. Extender medication titration and physician-directed therapy initiation through extender recommendation.	Patient-centered education using techniques to minimize the impact of low literacy, assist with goal setting and behavior change, and enhance medication adherence. Extender medication titration and initiation through algorithm.
Extender Algorithms	None	Limited; metformin and insulin titration	Expanded; metformin, insulin, sulfonylurea, statin, and antihypertensive titration	Expanded; metformin, insulin, sulfonylurea, statin, antihypertensive, and antidepressant initiation and titration; refills of chronic medications; prescription of durable medical equipment; vaccination ordering; and laboratory monitoring

program began in 1998. Representatives from UNC School of Medicine and the UNC Hospital Department of Pharmacy performed a medical record review that showed that 1,172 uninsured or Medicaid patients with diabetes accrued $17 million in charges over an 8-month period. A large proportion of these patients were cared for in our practice. At that time, it was estimated that 1,600 of the 11,000 patients in the UNC Internal Medicine practice had a diagnosis of diabetes. Approximately 66% of these patients were covered by Medicaid or Medicare or were uninsured. This information led to funding of a pilot program to improve care as a means of reducing morbidity and costs.

In the pilot phase, two clinical pharmacists with advanced training were hired to develop and implement an intervention. They worked with interested attending physicians and health services researchers to develop the pilot program. Before initiation of the program, a brief root cause analysis was performed (Table 2). A root cause analysis is a problem-solving approach aimed at identifying and intervening in the underlying cause of a problem or situation versus addressing obvious, intermediate symptoms of a problem.

Based on this analysis, the program was initially structured as follows: the pharmacist provided increased frequency of clinical intervention by clinic-based and telephone contact, streamlining patient access to expert care, increasing intensity of intervention through frequent provider consultation and feedback, focusing on treatment decisions based on best evidence, frequently disseminating program outcomes and summaries of data collected, and targeting patients at highest risk for poor outcomes.

A Microsoft Access database was created for the pilot (now referred as the Comprehensive Interactive Patient Health Evaluation Registry [CIPHER]). The system functioned as a registry, data repository, and reminder system. Two pharmacists provided supplementary care during patients' visits with their primary care provider (PCP) and via telephone. These encounters focused on individualized education and interventions that were adapted to patients' needs, barriers, and literacy level. Problem-solving exercises, goal setting, and medical intervention were key components of these encounters. There were no individual appointments with the pharmacists.

Table 2. Root Cause Analysis

Root Causes	Actions
• Continuity of care is poor because providers have limited clinical time.	• Make clinical pharmacists available to patients daily.
• Patients often miss follow-up . appointments.	• Call patients to remind them of appointments.
• Transportation barriers can hinder care.	• Increase phone management.
• Physicians lack time and skill to provide proper diabetes education.	• Pharmacists provide individualized education.
• Patients have low education and literacy.	• Design interventions that do not rely on literacy.
• Physicians contribute to clinical inertia by failing to escalate therapy.	• Evidence-based approach to therapy; led to development of algorithms.
• Tracking of patient outcomes is poor.	• Designed computer system to allow better tracking of patients.

Care was proactive; pharmacists sought patients and recruited them from daily clinic schedules, engaged physicians, and placed calls to patients after their visits based on clinical judgment. No formal plan outlining follow-up care was in place at that time. Because most patients live 30–60 miles away, phone calls were a primary focus of care to overcome this barrier (Figure 1). Initially no algorithms existed, and therapeutic interventions were made only through pharmacist recommendations and subsequent PCP approval. During the pilot, algorithms for diabetes medication titration were developed for glycemic control. These algorithms were based on a combination of guidelines, best evidence, and group consensus. Initial algorithms included insulin and metformin, allowing pharmacists to titrate these agents.

To evaluate the pilot program, 137 patients with an A1C > 8.0% were enrolled between 1999 and 2000. The

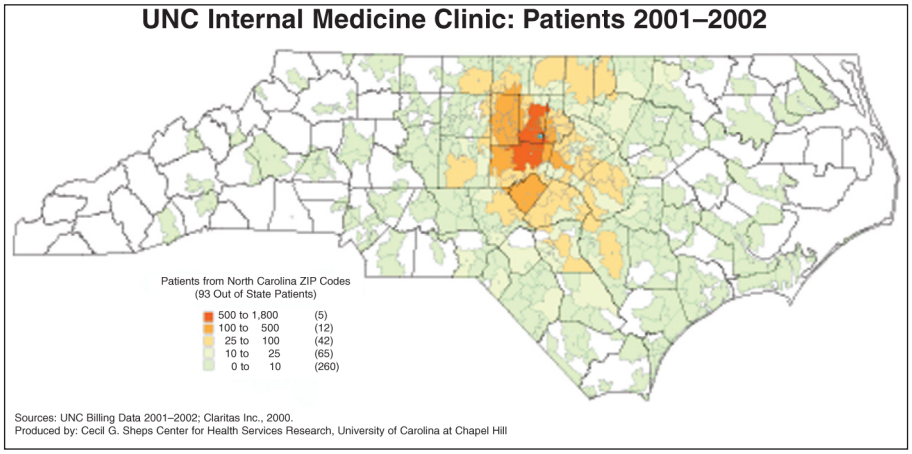

Figure 1. State-wide Patient Distribution

mean A1C at program enrollment was 10.8%. At 6 months follow-up, the mean reduction in A1C was 1.9% (95% CI 1.5–2.3, $P < 0.0001$).[8] The intervention was successful in improving glycemic control, the area for which the pharmacists could make medication changes, but not for blood pressure control, for which no algorithm existed. After review and discussion with division faculty, consensus was that the program should be expanded to include a larger scope of practice for the pharmacists, including new algorithms for blood pressure control, lipid control, and initiation of aspirin therapy.

Phase 2. Randomized Controlled Trial

The second phase of our program began in February 2001, when we began enrollment in a randomized, controlled trial to assess the efficacy of our expanded disease management program. The database system continued to function mainly as a registry, data repository, and reminder system. The program pharmacists continued to focus on frequent intervention, both clinic and telephone based, for patients at highest risk.

The most significant changes beyond our algorithms was formalization of flow or follow-up and the addition of a trained, non–health care provider staff member to provide education and facilitate therapeutic intervention. Algorithms for laboratory monitoring, diabetes durable medical equipment, and refills were added. We also added an algorithm to initiate aspirin therapy. These algorithms allowed clinical pharmacists to be more aggressive and addressed what we felt were weaknesses of our previous intervention.

We compared our disease management program to standard care received by a physician. A total of 194 patients were enrolled in the trial, and at 12 months the intervention group had significantly greater lowering of systolic blood pressure (−9 mmHg; 95% CI −16 to −3) and A1C level (−0.8%; −1.7 to 0%). Large increases in aspirin therapy (58% control vs. 91% intervention, $P < 0.0001$) and improvements in diabetes-related knowledge and satisfaction were also noted.[8] Improvements in glycemic control were similar to those noted in the pilot phase. We attribute improvements in blood pressure control to more intensive care with aggressive use of evidence-based algorithms. On average, intervention patients were evaluated 4 times per month versus 1.1 per month for control subjects. Fifty-four percent of intervention patient encounters were via telephone, 26% were in clinic visits, and the other 20% consisted of mailings and medical history reviews.[9]

Phase 3. Consensus Development and Clinic-wide Adoption

After the success of the randomized controlled trial, we focused on the challenge of transforming the program from a research-based endeavor into a clinical entity. The results of the trial were presented to the faculty and staff of the practice, and a decision was made to implement the program as the standard of care for all patients with diabetes in our practice.

To expand the program, several key changes were required, including increased staffing, further expansion of algorithms, improved information systems, risk stratification, implementation of automated data transfer, planned follow-up, and quality reporting. Our patient population grew from almost 600 patients to 1,500 patients. All patients within our practice who were identified with diabetes were automatically enrolled in our program. Algorithms were revised and expanded once more, with the addition of algorithms for vaccination administration and statin initiation.

Staffing changes included shifting research assistants to clinic-based educators and care navigators, which we referred to as "care assistants." These changes were made to derive clinical revenue from individual visits with our pharmacist practitioners, create efficiencies by pairing appropriately trained staff to perform key interventions, and improve our ability to care for a larger number of patients. Care assistants are entry-level medical assistants trained by the clinical pharmacist practitioners to address issues related to health behaviors and health education, such as using verbal versus written forms of communication and teach-back techniques during education sessions. Care assistants intervened with patients in the clinic who were seeing their PCP and via telephone. Care assistants performed basic education, identified and attempted to resolve barriers, made routine referrals, and downloaded glucose meter readings for the clinicians to interpret. The program continued to be staffed by 1.3 full-time equivalent clinical pharmacist practitioners and 3 care assistants.

We also made significant strides in improving our information system. After negotiation with a range of key stakeholders throughout our institution, we began to receive data transfers daily from our electronic medical record into the Access database. This data included vital signs, appointment information, and recent laboratory results. These data, in combination with information maintained in our database, were used to develop detailed printed information sheets that were used on a daily basis to direct care, facilitate communication with the PCP, and give program providers information to use at the point of care.

The database was used to proactively identify patients who had scheduled appointments or who were not receiving appropriate follow-up care. To improve efficiency, we also stratified patients based on risk and developed follow-up plans based on this information (Table 3).

We now meet once monthly to review program data and outcomes. Data maintained within the Access database are used to create run charts. This multidisciplinary meeting focuses on revising or developing new interventions to obtain predetermined goals. Current efforts revolve around improving adherence to annual dilated retinal exams, pneumococcal vaccinations, and

Table 3. Stepped-Care Approach

Intervention	Low Risk	Moderate Risk	High Risk
Goal for certified diabetes educator visits	Per provider or patient request	Quarterly	Bimonthly
Care assistant with PCP	Per provider or patient request	Every other PCP visit	Every PCP visit
Nutrition classes	Per provider or patient request	As needed	Yearly and as needed
Phone follow-up	As needed	Bimonthly to monthly	Monthly to biweekly
Toll-free help line	As needed	As needed	As needed

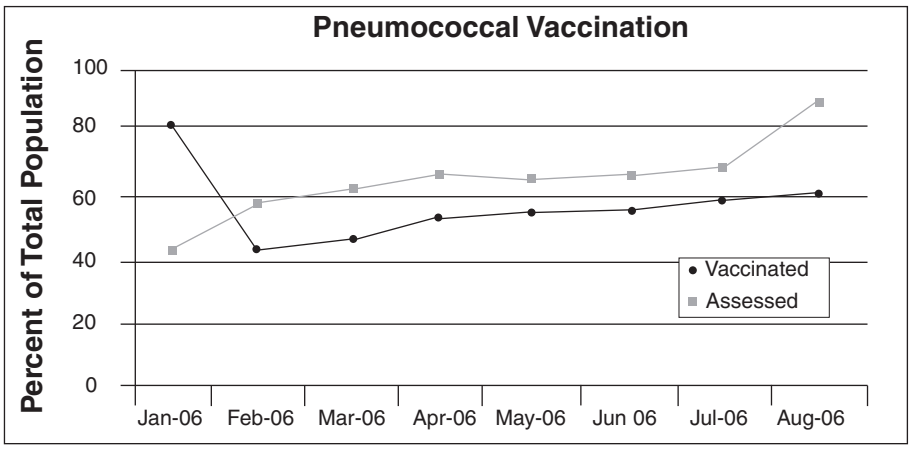

Figure 2. Example of a run chart from current intervention.

depression screening (Figure 2). Recent interventions include assessment of both ophthalmalogical and vaccination status of all patients, automated referral for dilated retinal exams, and nurse-driven administration of pneumococcal vaccination.

Conclusions

Structured care programs in clinical settings can overcome barriers to high quality care. We feel the primary care–based structured care program in our academic internal medicine practice is a model experience that can be replicated in other practices.

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Robb Malone, PharmD, CDE, CPP, is the assistant medical director of General Internal Medicine, an assistant professor of medicine, and an assistant clinical professor of pharmacy; Betsy Bryant Shilliday, PharmD, CDE, CPP, is an assistant professor of medicine and an assistant clinical professor of pharmacy; and Timothy J. Ives, PharmD, MPH, is an associate professor of pharmacy and a clinical associate professor of medicine in the University of North Carolina Department of Medicine, Division of General Internal Medicine and Clinical Epidemiology in Chapel Hill. Michael Pignone, MD, MPH, is an associate professor of medicine and associate chief of the Division of General Internal Medicine at the same institution. He is also an associate editor of Clinical Diabetes.