

This supplement was sponsored by the Primary Care Metabolic Group and the Primary Care Education Consortium and is supported by funding from Novo Nordisk Inc. It was edited and peer reviewed by *The Journal of Family Practice*.

Copyright © 2011
Quadrant HealthCom Inc.



SUPPLEMENT TO
THE JOURNAL OF
**FAMILY
PRACTICE**

VOL 60, NO 11 | NOVEMBER 2011 | www.jfponline.com



Health care models for treatment and management of diabetes

S3 >> Introduction

S6 >> **Traditional or centralized models of diabetes care:** The multidisciplinary diabetes team approach

S12 >> **Nontraditional or noncentralized models of diabetes care:** Medication therapy management services

S19 >> **Nontraditional or noncentralized models of diabetes care:** Boutique medicine

S26 >> **Nontraditional or noncentralized models of diabetes care:** Models in which other HCPs take on a leading role in managing patients' diabetes

FACULTY AND AFFILIATIONS

INTRODUCTION

Kellie Rodriguez, RN, MSN, CDE

Diabetes Research Institute
Miami, Florida

Bresta Miranda-Palma, MD

Diabetes Research Institute
Division of Diabetes, Endocrinology and Metabolism
University of Miami Leonard M. Miller School of Medicine
Miami, Florida

TRADITIONAL OR CENTRALIZED MODELS OF DIABETES CARE: THE MULTIDISCIPLINARY DIABETES TEAM APPROACH

Christina R. Bratcher, MD, FACE

DCOA-Physician Associates, PA
Diabetes America, Inc. Health Center at Plano
Plano, Texas

Elizabeth Bello, RD, LD, CDE

Diabetes America, Inc.
Houston, Texas

NONTRADITIONAL OR NONCENTRALIZED MODELS OF DIABETES CARE: MEDICATION THERAPY MANAGEMENT SERVICES

Sweta Chawla, PharmD, MS, CDE

Assistant Professor of Pharmacy Practice
Arnold & Marie Schwartz College of Pharmacy
Long Island University
Kings Pharmacy
Brooklyn, New York

NONTRADITIONAL OR NONCENTRALIZED MODELS OF DIABETES CARE: BOUTIQUE MEDICINE

Jeffrey P. Schyberg, MD, PC

Savannah, Georgia

NONTRADITIONAL OR NONCENTRALIZED MODELS OF DIABETES CARE: MODELS IN WHICH OTHER HCPS TAKE ON A LEADING ROLE IN MANAGING PATIENTS' DIABETES

K.C. Arnold, ANP, BC-ADM

The Diabetes Center, PLLC
Ocean Springs, Mississippi

FACULTY DISCLOSURES

Kellie Rodriguez, RN, MSN, CDE, serves on the Board of Directors (2011-2014) for the National Certification Board for Diabetes Educators (NCBDE).

Bresta Miranda-Palma, MD, has no conflicts of interest to disclose.

Christina R. Bratcher, MD, FACE, practices at a DiabetesAmerica center.

Elizabeth Bello, RD, LD, CDE, is an employee of Diabetes America.

Sweta Chawla, PharmD, MS, CDE, has no conflicts of interest to disclose.

Jeffrey P. Schyberg, MD, PC, has no conflicts of interest to disclose.

K.C. Arnold, ANP, BC-ADM, has served on speaker bureaus for Eli Lilly, Medtronic, sanofi-aventis, and Novo Nordisk Inc.

LEARNING OBJECTIVES

After reading this supplement, clinicians should:

- Be better able to describe models for the treatment and management of patients with diabetes that are alternative to conventional management in the primary care physician's office
- Have a better understanding of the advantages and limitations of the:
 - Centralized multidisciplinary team approach
 - Medication therapy management services provided by pharmacists
 - Boutique medicine model
 - Nurse practitioner-led approach
- Be better informed to stimulate the development of his or her own opinions regarding the ideal strategy to providing the best care for patients with diabetes

SPONSORSHIP AND SUPPORT

This program is sponsored by the Primary Care Metabolic Group and the Primary Care Education Consortium (PCEC) and is supported by funding from Novo Nordisk Inc.

Introduction

Kellie Rodriguez, RN, MSN, CDE, and Bresta Miranda-Palma, MD

Diabetes mellitus is a chronic lifelong disease whose management requires ongoing collaboration among a team of health care providers and the patient. Although primary care physicians (PCPs) provide the majority of diabetes care, they are unable to meet the ongoing and growing demands of diabetes management by themselves, needing instead to be a part of an amplified care system. The health care system is beginning to evolve from its historic orientation toward acute illnesses, but acute care remains the dominant paradigm. Management of complex chronic illnesses is given insufficient attention, with inadequate time for physician-patient interactions, and with diabetes often treated alongside other chronic conditions. It is unrealistic to expect chronic diseases, such as diabetes, to be managed in a health care system designed for acute conditions.

The growing incidence of diabetes has been a driving force behind this supplement, which explores a variety of health care models that are evolving to manage chronic illness in the United States (US). With an estimated 25.8 million US adults and children (8.3% of the population) diagnosed with diabetes and 79 million people with pre-diabetes,¹ establishment of effective diabetes care approaches is a major health care priority. Many Americans are uninsured or underinsured,¹ placing them at potentially devastating economic risk. Consideration of race or ethnicity is also essential in establishing effective health care approaches in the US, ensuring care addresses the unique cultural needs of American Indians and Alaska Natives (with diabetes prevalence rates varying by region, from 5.5% among Alaska Native adults to 33.5% among American Indian adults in southern Arizona), non-Hispanic blacks (12.6%), Hispanics (11.8%), Asian Americans (8.4%), and non-Hispanic whites (7.1%).²

The burden of diabetes is personal, societal, and economic. The ability of the health care system to meet treatment goals of the American Diabetes Association³ and the

American Association of Clinical Endocrinologists⁴ is grossly inadequate. Approximately 40% of people with diabetes are not achieving glycated hemoglobin targets⁵ and only an astonishingly low 12.2% of treated patients meet the combined targets for glycated hemoglobin, blood pressure, and cholesterol.⁶ The prevalence of macrovascular and microvascular complications that arise due to suboptimal glycemic control is unacceptable. Heart disease mortality and risk of stroke are both 2–4 times higher in people with diabetes than in the general population. Diabetes is the leading cause of blindness among adults, is a principal cause of kidney failure, and accounts for 60% of nontraumatic lower-limb amputations. The societal and economic impact of diabetes and its complications are no less staggering, with \$174 billion in estimated total costs as of 2007 (\$116 billion in direct medical costs, and \$58 billion in indirect costs, such as disability, work loss, and premature mortality). Factoring in the additional costs of undiagnosed diabetes, pre-diabetes, and gestational diabetes brings the total cost of diabetes in the US in 2007 to \$218 billion.²

Given the extent of the problem and the cultural and socioeconomic diversity of people living with diabetes, it is clear that there is no one correct diabetes care model that will address these factors. However, core elements have been defined that should be considered in all. The Chronic Care Model (CCM) developed by Ed Wagner is the most widely recognized approach for improving diabetes care at the levels of the community, organization, practice, and patient.⁷ While disease management programs vary in design and implementation, almost all emphasize 1 or more of the 6 core elements of the CCM as a framework for promoting high-quality chronic disease care and improving outcomes.⁸ The CCM rests on the premise that the combination of an informed, active patient, working with providers who have resources and expertise, leads to productive interactions and improved outcomes.⁹ There is substantial evidence that chronic disease management strategies “achieve better disease control, higher patient satisfaction, and better adherence to guidelines by redesigning delivery systems to meet the needs of chronically ill patients.”¹⁰

While the PCP, acting as an individual, can implement each of the 6 elements of the CCM, it is important to

Kellie Rodriguez, RN, MSN, CDE, serves on the Board of Directors (2011-2014) for the National Certification Board for Diabetes Educators (NCBDE). Bresta Miranda-Palma, MD, has no conflicts of interest to disclose.

see the elements as components of a comprehensive and coordinated approach to care. Research suggests that the more aspects of the CCM you use, the more likely you are to achieve better process and patient outcomes.¹¹ The 6 core elements are:

The community: partnerships with community programs to support patients' needs.

Health system design: creation of a culture, organization, and mechanisms that promote safe, high-quality care.

Self-management support: recognizing the central role of the patient in managing his or her own care.

Delivery system design: focus on teamwork; proactive vs reactive health care management; follow-up beyond the office visit; case management for more complex patients; recognition of cultural variations.

Decision support: use of evidence-based treatment, with clinician access to ongoing education.

Clinical information systems: data available to monitor progress at the individual patient level and the service level.

In this supplement, several models for the treatment and management of diabetes patients are discussed as alternatives to conventional management in the PCP's office. Christina R. Bratcher, MD, FACE, and Elizabeth Bello, RD, LD, CDE, describe a centralized multidisciplinary team approach that integrates the skills of practitioners from different disciplines, all practicing under one roof: generalist and specialist physicians, registered nurses and nurse practitioners, physician assistants, certified diabetes educators, dietitians, and, possibly, pharmacists. Patients receive all of their diabetes care in an integrated fashion and in a single stop: medical care, individualized diabetes education, nutrition, exercise and lifestyle coaching, and counseling and monitoring of drug effects. Integration of care is facilitated by the use of electronic medical records. Evidence suggests that this approach results in improved patient outcomes and reduced overall costs. However, the main issue of concern with the model is the negotiation of coverage, which leaves the patient responsible for some noncovered services. The expenses could be substantial and the patient might have to decide which services to receive.

Sweta Chawla, PharmD, MS, CDE, describes a nontraditional model of diabetes care delivered by pharmacists, called medication therapy management (MTM). Pharmacists are playing an increasing role in diabetes management and their rapid growth as a sector of qualified health professionals makes them an important asset that should complement primary diabetes care. The pharmacist can help improve outcomes by preventing medication-related morbidity and mortality and providing patient education. However, it is of

concern that a physician referral is not needed for MTM services and that the pharmacist can take over patient care and even override the physician's recommendations, as suggested in the case presented by Dr. Chawla. The role of pharmacist-delivered MTM in the overall scheme of diabetes management is clear: it can help optimize diabetes drug therapy, reducing risks and possibly also improving patient compliance via educational interventions. However, pharmacist-delivered MTM should definitely be part of an integrated and coordinated multidisciplinary team, whether centralized or not.

The boutique medicine model, developed in the 1990s, has provided physicians hampered by the constraints of managed care with an alternative approach to increasing the amount of time spent with each patient and improving their quality of care. In this model, the practice enrolls fewer patients and each patient pays a monthly or annual fee to have improved access to services. In return, the patient receives extended visits with a comprehensive plan of care that includes not only medical assessment, but also individualized education and close follow-up. In the practice described by Jeffrey P. Schyberg, MD, the physician has time to undertake multiple aspects of diabetes care, including extensive diabetes education. This approach might deny patients the opportunity to utilize valuable available resources and skills from other health care providers that are important for the integral management of diabetes. The business model is attractive; however, the services are not available to most patients. Boutique medicine has raised mixed reactions, but is currently considered part of physicians' free market opportunities by the American Medical Association.

In the final section, K.C. Arnold, NP, CDE (ANP, BC-ADM), describes a nontraditional/noncentralized model of diabetes care led by other health care providers—in this case, nurse practitioners (NPs). Advanced-practice nurses are increasingly delivering primary care to fill gaps left by the physician shortage. The American Nurses Credentialing Center has partnered with organizations, including the American Association of Diabetes Educators and the American Diabetes Association, to establish credentialing that allows NPs to fill more specialized diabetes management roles. These roles can be accomplished within physician-led practices, but also in independently run clinics, with or without physician involvement, depending on state laws. The article presents evidence that NP-provided primary care can be comparable to physician care for multiple health outcomes, and it emphasizes the nurturing nature of the patient-provider relationship within this model. The limitations for the NP-led practice described in this article seem to be similar to the ones encountered by traditional physician-

led models, with cost and reimbursement issues and a high patient volume requiring follow-up visits to be spaced every 3 months. Nurse-led practices have the additional challenges of legal restrictions and physician resistance.

Another model, which is not discussed in this supplement but shares elements of the CCM, is the Patient-Centered Medical Home (PCMH). This model has been gaining attention and popularity in recent times.¹² The PCMH has been proposed as an enhanced model of primary care,¹³ with the following key components: care coordination, quality and safety, whole person orientation, personal physician, physician leadership, enhanced access, and payment. Within this model, each patient has a personal physician or provider who leads a team to ensure that care is coordinated across different specialties and providers, and health care team meetings take place at regular intervals. Aspects of care for which in-depth medical training is not required may be delegated to nonphysician members of the health care team.¹² Randomized trials have not yet been conducted, but PCMH pilot initiatives across the US have reported encouraging results, which support this model as a useful strategy for improving the quality and costs of diabetes care.¹²

No single model of care has been fully able to overcome the limitations that patients and health care providers encounter in trying to achieve quality diabetes care. The authors of the articles in this supplement have tried to provide the reader with a glimpse of their specific practices, with a candid view of the advantages and disadvantages inherent to their own models. With consideration given to the 6 core components of the Chronic Care Model, we hope that the

reader will find elements in these models to stimulate the development of his or her own opinions regarding provision of optimal care for our patients with diabetes. ■

REFERENCES

1. Schoen C, Collins SR, Kriss JL, Doty MM. How Many Are Underinsured? Trends Among U.S. Adults, 2003 and 2007. *Health Affairs* Web Exclusive, June 10, 2008:w298-w309.
2. Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2011.
3. American Diabetes Association. Standards of Medical Care in Diabetes—2011. *Diabetes Care*. 2011;34(suppl 1):S11-S61.
4. Rodbard HW, Blonde L, Braithwaite SS, Brett EM, Cobin RH, Handelsman Y, et al; AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Management of Diabetes Mellitus. *Endocrine Practice*. 2007;13(suppl 1):1-68.
5. Hoerger TJ, Segal JE, Gregg EW, Saaddine JB. Is glycemic control improving in U.S. adults? *Diabetes Care*. 2008;31(1):81-86.
6. Gakidou E, Mallinger L, Abbott-Klafter J, Guerrero R, Villalpando S, Ridaura RL, et al. Management of diabetes and associated cardiovascular risk factors in seven countries: a comparison of data from national health examination surveys. Comprehensive management of blood glucose, arterial hypertension and hypercholesterolemia among adults with diabetes. *Bull World Health Organ*. 2011;89:172-183.
7. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. *Health Aff (Millwood)*. 2001 Nov-Dec;20(6):64-78.
8. Wagner E. System changes and interventions: delivery system design. Improving Chronic Illness Care. Institute for Health Care Improvement National Forum, Orlando, FL; 2001.
9. Siminerio L, Zgibor J, Solano FX Jr. Implementing the Chronic Care Model for improvements in diabetes practice and outcomes in primary care: the University of Pittsburgh Medical Center experience. *Clinical Diabetes*. 2004;22(2):54-58.
10. Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? *Eff Clin Pract*. 1998;1(1):2-4.
11. Renders CM, Valk GD, Griffin SJ, Wagner E, van Eijk JT, Assendelft WJ. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. *Cochrane Database Syst Rev*. 2000; Issue 4. Art. No: CD001481.
12. Bojdziewski T, Gabbay RA. Patient-centered medical home and diabetes. *Diabetes Care*. 2011;34(4):1047-1053.
13. Berenson RA, Hammons T, Gans DN, et al. A house is not a home: keeping patients at the center of practice redesign. *Health Affairs*. 2008;27(5):1219-1230.

Traditional or centralized models of diabetes care: The multidisciplinary diabetes team approach

Christina R. Bratcher, MD, FACE, and Elizabeth Bello, RD, LD, CDE

TAKE-HOME POINTS

- Specialized diabetes care (SDC) centers utilize a multidisciplinary diabetes team to provide patients with highly individualized care
- Patients at SDC centers receive their integrated diabetes care in one place—the “one-stop” approach
- The components of the SDC center model are:
 - Medical care
 - Individualized diabetes education
 - Nutrition
 - Exercise and lifestyle coaching
 - Counseling
 - Monitoring of drug effects
- This model results in improved patient outcomes and reduced overall costs

Christina R. Bratcher, MD, FACE, practices at a DiabetesAmerica center. Elizabeth Bello, RD, LD, CDE, is an employee of DiabetesAmerica.

Introduction

Although patients with diabetes may be well managed by primary care physicians, the application of a team approach to the delivery of care enables a range of health care providers to integrate their skills to facilitate improved patient management and outcomes. Centralized diabetes care clinics bring together the expertise of primary care physicians, endocrinologists, registered nurses, nurse practitioners (NPs), physician assistants (PAs), certified diabetes educators (CDEs), dietitians, and/or pharmacists into a multidisciplinary diabetes team (MDT) that operates under a single roof to provide integrated care.

This approach contributes to comprehensive patient management and improved disease outcomes.¹⁻⁴ Specialized diabetes care (SDC) centers rely on an MDT structure to provide patients with individualized disease management. The centralized model encourages ongoing communication and interaction between the patient and multiple members of the care team. These SDC centers are typically statewide or regional.

A centralized model of diabetes care

Overview and organizational structure

SDC centers offer medical services for patients with diabetes, based on 4 cornerstones of disease management: medical care; personalized education; nutrition counseling; and lifestyle and exercise coaching. The centralized model involves patients in the management of their diabetes, with the goal of promoting wellness and preventing complications. Specifically, physicians, nurses, and dietitians work with patients to develop personalized treatment plans to prevent and detect diabetes-related complications. At Diabetes America centers, team members include physicians, NPs, PAs, and CDEs. Some SDC centers do not employ pharmacists, while other centralized diabetes clinics have a pharmacist on staff.

Within the MDT structure, the physician, NP, or PA is primarily in charge of monitoring patient health and making pharmacologic decisions; he or she is aware of the full range of available therapeutic options for diabetes management, as well as clinical practice guidelines and emerging evidence. Physicians, in conjunction with the MDT, also provide expert knowledge regarding new management technologies, such as insulin pumps and glucose sensors. Lastly, physicians provide expertise and patient management in other aspects of care, including hypertension and lipid management, and the treatment of diabetes-related complications. NPs and PAs work closely with physicians to coordinate personalized patient treatment plans; these professionals also provide integral support and education to patients who are newly diagnosed with diabetes and/or who are making the transition to

insulin therapy (when patients face new lifestyle considerations, including daily glucose monitoring and insulin shots).

In addition to encouraging effective self-management and patient autonomy, SDC patients are provided with comprehensive, ongoing patient education delivered by CDEs. The role of the CDE is to promote positive health behaviors across all areas of diabetes self-management.⁵ The curriculum employed in our centers is consistent with the recommendations of the American Association of Diabetes Educators (AADE) and the American Diabetes Association (ADA). Patients learn about diabetes pathophysiology and management, circulatory health, medical nutrition therapy, and eye health in individual sessions, group classes, or seminars. The timing and sequence of training and education is predicated on patients' needs and schedules. Additionally, CDEs are responsible for specific diabetes management tasks; for example, they can discuss treatment issues, medication titration, or dose adjustments, based on patient feedback. A patient's need for education is evaluated during the clinical part of the visit. For example, when a physician initiates insulin treatment, the CDE would provide all necessary information and training to allow the patient to successfully self-administer insulin.

Dietitians help patients develop personalized nutrition plans, including meal and weight management plans, with the goal of developing targeted lifestyle change programs based on personal preferences. A recent review has confirmed that medical nutrition therapy delivered by registered dietitians is effective and essential in the management of diabetes.⁶ Diabetes America centers offer nutrition education in individual and classroom sessions, and encourage patients, as well as their families and caregivers, to attend. These sessions cover issues such as carbohydrate counting, reading and understanding nutrition labels, healthy portion sizes, meal planning, and weight management. Fitness and nutrition experts educate patients on the basics of healthy lifestyle, and offer tools to help patients reach their goals. In addition, patients are counseled on sick-day management, coping mechanisms for stress, and skin and foot care. The coaching approach is essential to ease patients' adjustment into lifestyle changes essential for optimal diabetes management.

Lastly, with an increasing number of diabetes treatment options available, pharmacists are starting to play a larger role in MDTs. Traditionally, pharmacists have helped to oversee drug therapy prescribed by physicians. However, some pharmacists are now taking on additional responsibilities, including initiating or changing patient medications, ordering laboratory tests to monitor drug effects, and counseling patients to assess medication knowledge.⁷ Pharmacist involvement seems to be beneficial: a systematic review of

21 studies involving pharmacists in diabetes management revealed a significant decrease (0.5% or greater) in glycated hemoglobin (A1C) levels among patients, compared with standard care, in more than half of the studies (13 out of 21) evaluated.⁸ In addition, overall A1C improvements were greater in interventions in which pharmacists were involved with direct medical management.

Coordination of care

A major strength of MDT centers is that all elements of care coordination are brought together at 1 location. SDC patients typically visit a clinic a minimum of 5 times per year. At each routine visit, patients see a physician, receive counseling from a CDE or dietitian, and are given routine laboratory tests, with results available in real time from point-of-care testing; this permits immediate action and discussion to monitor and advance the treatment plan. In addition to routine testing, we also perform metabolic lab work and fundus eye scans on-site. Physicians, dietitians, and nurses collaborate with patients to create individualized, comprehensive care plans, which are then supported by other staff. In addition, patients can be referred to on-site educational groups or seminars, or individual education as necessary. Our lifestyle instruction and exercise coaching includes around-the-clock access to online education and a forum through which patients can submit questions to providers at any time (to be answered during business hours), as well as a hotline that can be called during or after office hours. The after-hours hotline is managed by CDEs, who are able to triage to other members of the provider team or to emergency care, if needed.

Patient management

During an initial clinic visit, intake is conducted at the general registration office. The registration period includes an evaluation of current diabetes management, an assessment of additional management needs, and on-site lab work. A series of lab tests are performed during the initial intake, the majority of which produce same-day results (in as little as 2–8 minutes for some tests). Patients may also require ancillary testing or care, such as retinal testing or a flu vaccine; these needs would be identified either over the phone or during the initial clinic intake visit. Next, the patient sees a physician, who conducts a thorough medical exam, may identify further necessary ancillary tests, and discusses diabetes management options. Following the physician visit, the patient meets with a CDE for basic education on coping skills, or training on medication administration, which may include basic information or more advanced diabetes topics within the wide scope of diabetes education, depending on the patient's needs.

All of the linked care occurs at a single visit. The 3 components comprising visits to SDC centers are: intake and screening; a physician examination, including evaluation of needs for disease management; and diabetes education (depending on need). Typically, the patient's first visit will be used to obtain a comprehensive history and to conduct a thorough evaluation and initial education and care plan, and will usually last about 2 hours. Subsequent visits follow the same model and typically last 1 hour, depending on the patient's needs. Patient records are managed using electronic medical records, which allow the clinic to easily track each patient's progress, clinical indications for screening and intervention, and individual and aggregate outcomes. While patients generally receive medical evaluation and care from a physician at their first visit, NPs and PAs in our offices also act as primary providers in our model in order to provide patients with greater flexibility.

The approach to patient care should be highly individualized, which unfortunately sometimes leads to difficulties with payers when it comes to negotiating coverage for the most appropriate medications. Practitioners at SDC centers typically do not follow formulaic algorithms; rather, they approach each patient individually, taking into consideration his or her medical history and current health status to make treatment decisions. Staff time can often be spent contacting payers and completing paperwork to ensure that patients get the care they need. The extra time required for paperwork issues is to be expected when implementing individualized patient care. This tiered medication support and management is a system not frequently available from primary care physicians in private practice.

Business model and profitability

The business model should be adaptable to support changing staffing needs in an SDC network with multiple centers. It is important to provide timely, quality care to patients, but equally important is engaging patients in ongoing care, maintaining a proper rate of patient flow at each clinic every day. Often the model employs a staffing process to match appropriate team members to the number of patients seen at a center, meaning that staff may rotate to different centers depending on need.

For diabetes education services to be covered for reimbursement, the Centers for Medicare and Medicaid Services requires accreditation for all diabetes self-management education and training (DSME/T) programs by the ADA, the AADE, or Indian Health Services. Programs must meet quality standards of the accrediting organization.⁹

Some federally qualified or academic-based diabetes centers are supported entirely by grant and other public

resources, and require grant renewals to become sustainable; other centers have a grant-funded component, and a private-funding component. Unlike diabetes clinics that have a nonprofit component, the SDC that we are associated with (Diabetes America) is completely privately funded and receives no grants to cover clinic or care expenses. We are unable to comment with certainty on whether Diabetes America is unique in its funding. Because of our business model, it is fiscally sound to maintain a mix of patients supported by both private and government payers. Self-payers are accepted, but make up only a small percentage of our patient population.

Costs to patients will vary based on the individual patient's insurance plan. Many employers, and in turn many patients, are unaware of the placement of diabetes care and education within their comprehensive insurance plan. Some plans cover only the physician visit; all other services are applied towards the patient's deductible. In some cases, patients may incur substantial costs until the deductible has been reached. In recent years, we have seen deductibles increase for all segments of our population, which can be a financial strain for patients. Patients now scrutinize further which medications or diagnostic testing services they will take or reject based on what their insurance will cover. Patients also face the challenge of having to learn how to calculate their co-payment responsibility in advance.

From our knowledge, many employers are evaluating their diabetes care plans and are beginning to recognize education and preventive services as vital parts of diabetes management that should be covered as part of comprehensive care. As a result, we are working with more employers to design and implement full-service plans that include education and supplies (such as blood glucose testing devices and strips) intended to minimize costs over the long term.

Comparisons of multidisciplinary diabetes team care to standard care

A growing body of research supports the benefits of using an MDT for diabetes care. Specifically, available evidence suggests that a physician-led team encompassing nursing staff, diabetes educators, and dietitians to provide intensive diabetes care may significantly improve patient adherence and glycemic control, as well as the quality of care provided.

A randomized, controlled trial evaluated an MDT approach for the management of diabetes and other chronic conditions at a family health network serving more than 1000 patients in Ottawa, Canada.¹⁰ Patients were randomized to receive MDT care or usual physician care. The study measured quality of chronic disease management care based on predetermined performance measures (guideline recommendations) for diabetes, coronary artery disease,

chronic heart failure, and chronic obstructive pulmonary disease (primary outcome measure). The study also evaluated quality of preventive care (adherence to the Canadian Task Force on Preventive Health Care recommendations for 6 preventive indicator maneuvers, such as influenza vaccination, eye examination, and hearing examination). The performance measures for diabetes management recommended an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) when appropriate; measuring A1C twice yearly; and giving foot and eye examinations within the past 2 years. After an average of 1.25 years of follow-up, there was significant improvement in the primary outcome measure, with the network's chronic disease management quality of care improving by 9.2% with MDT care compared with traditional care ($P<.001$). In addition, the secondary outcome measure of quality of preventive care had also improved, by 16.5%, with MDT care compared with traditional care ($P<.001$).¹⁰ There were no significant improvements in other secondary outcome measures (eg, glycemic control, hypertension, quality of life, and functional status), but, according to the authors, the clinical team did not concentrate on the 2 specific clinical outcomes (glycemic control and hypertension); instead, they had a more general focus of improving the management of the chronic diseases of individuals in their care. Furthermore, the study may not have had enough power to detect a significant difference in these outcomes. With regard to the lack of improvement in quality of life and functional status measures, inclusion of complex older patients who may be at increased risk of irreversible functional decline might have been a limitation of the study.¹⁰

Two primary care clinics in Israel compared MDT outcomes to standard care in patients with poor glucose control (A1C levels $\geq 10\%$); the patients were studied for 6 months.¹¹ One clinic was randomly chosen to provide patients with standard medical care, delivered by physicians and nurses (control group), while another clinic provided patients with an MDT approach that included care from a diabetes specialist, a dietician, and a diabetes nurse educator. At the 6-month follow-up, patients at the intervention clinic had significantly lowered mean A1C levels (-1.8% , $P=.00001$) and plasma glucose readings (-1.5 mmol/L [~ 27 mg/dL], $P=.003$), with no significant changes seen in either measure at the control clinic.¹¹ Patients in the intervention group also had twice the response rate to treatment (defined as a $\geq 0.5\%$ decrease in A1C at 6-month follow-up) vs the control group (71% vs 35%, respectively). Additionally, patients in the intervention group had a higher rate of follow-up (attendance at 6-month visit) than patients in the control group (82% vs 35%, respectively).

Another study evaluated (over 1 year) a community-based family medicine residency program that implemented MDT care for 105 patients with type 2 diabetes and compared pre- and post-intervention outcomes.¹² Successful disease management was defined as having A1C $<7\%$, low-density lipoprotein (LDL) cholesterol <100 mg/dL, and blood pressure $<130/80$ mm Hg. At 1 year following program implementation, patients improved in all metabolic and process measures. Additionally, 17.1% of patients achieved successful disease management, defined as meeting all 3 criteria, as compared with 5.7% prior to the intervention.¹² The patients who did not meet all 3 criteria, however, would still benefit from care coordination and targeted intervention to help them manage the disease and achieve goals.

Individual and group diabetes management education approaches are also integral parts of centralized care, and are associated with proven patient benefits. A meta-analysis that included data from 31 randomized, controlled trials evaluating self-management education showed that, at immediate follow-up after the last educator-patient contact, patients who had received self-management education decreased their A1C levels by 0.76% more than patients who did not receive self-management education (95% confidence interval, 0.34–1.18).¹³ Patient outcomes further improved as more time was spent with educators.

Another meta-analysis of 11 studies showed that group-based education for diabetes was related to A1C decreases of 1.4% after 4–6 months of follow-up; these decreases endured at 1 year (0.8%) and 2 years (1.0%) of follow-up ($P<.00001$ for all 3 time points).¹⁴ Patients who received group-based education also had reduced body weight (1.6 kg; $P=.02$) and improved diabetes knowledge ($P<.00001$) at 12–14 months of follow-up, and reduced systolic blood pressure (5 mm Hg; $P=.01$) at 4–6 months of follow-up. Lastly, about 1 in 5 patients who received group-based education were able to decrease their doses of diabetes-related medications at 12–14 months ($P<.00001$).¹⁴

Outcomes data from a subset of patients from the Diabetes America clinics showed that after 4 visits, the average patient A1C value was 7.0%. Overall, 59% of patients had A1C values $<7.0\%$ and only 9% had A1C values $>9.0\%$. Additionally, 62% of patients had LDL cholesterol values <100 mg/dL, and only 14% had values >130 mg/dL. A total of 64% of patients sustained systolic blood pressure levels <130 mm Hg, and only 14% had values >140 mm Hg. Lastly, 62% of patients sustained diastolic blood pressure levels <80 mm Hg, and only 5% had values >90 mm Hg.¹⁵ All of these outcomes surpass recommended guidelines from the National Committee for Quality Assurance (NCQA) Diabetes Physician Recognition Program (DPRP).¹⁶

Cost-effectiveness analyses from a 3-year study of Diabetes America clinics were performed by Aetna, a health insurance provider. Outcomes and costs were monitored for 4 large, public-sector employers who provided their employees with incentives (co-payment waivers) to use an SDC center (in this case, Diabetes America clinics).¹⁷ Costs were then compared between patients who did and did not use Diabetes America clinics. For the first 2 years of the study, outcomes were similar, but in the third year the SDC patients had average monthly medical costs that were \$226 less per member.¹⁷ These cost savings appeared to be due to fewer emergency room visits and shorter hospital stays. Although prescription costs for the clinic patients were on average \$40 more per month than for patients not accessing care at these sites, the higher cost was offset by lower medical costs in the long run. Additionally, patients at the Diabetes America centers were more compliant with disease maintenance requirements (such as regular eye exams and blood screenings).

Reasons for success and key challenges

By bringing comprehensive, patient-centered care together in single locations, SDC centers can offer both quality and convenience to patients. The “one-stop” approach is a major benefit for patients who would not otherwise have time to attend separate appointments to have required laboratory work and diagnostic tests, and to see physicians, nutritionists, and CDEs. Furthermore, these health centers accept most insurance plans, with only 1 insurance co-payment for all services rendered, which can provide substantial patient cost-savings compared with noncentralized providers. Many of these clinics are patient-friendly and may provide amenities such as ample parking, free coffee, wireless Internet access, and comfortable waiting rooms.

Financial constraints, which can limit the size of the MDT, are an ongoing challenge of providing care within a centralized model. Patients are taught self-care principles that encourage them to become involved in their own disease management. To achieve goals, team members must have good interpersonal skills, as well as a clear understanding of specific and shared responsibilities. To ensure success, management needs to be proactive in clarifying these responsibilities. Lastly, training provided to the team must be tailored to the clinical environment and community needs (eg, training on cultural sensitivity).

Conclusions

The SDC center model provides highly individualized, quality care to patients. The model is exemplified in the choice not to rely on generalized algorithms for treatment decisions; instead, clinical decision-making takes into account multiple

factors about an individual patient. Each provider (physician, NP, or PA) sees a limited number (approximately 15–18) of patients per day, giving providers sufficient time to discuss with them the complexities of diabetes management, as well as the opportunity to individualize therapies. Patient involvement in treatment decisions is solicited, which is especially important when working with patients from diverse ethnic and cultural backgrounds on topics such as individualized approaches to diet. In addition, compared with individual primary care providers, we are early adopters of newer medications and advocate with insurers for full patient coverage. We believe that all of these steps help to ensure successful diabetes management for our patients.

Education is the cornerstone to diabetes care¹⁸; our patients are empowered by the education they receive, and often give positive feedback about the educational aspect of our care centers. Providers at SDC center clinics (physicians, NPs, and PAs) offer diabetes care and education options in a “menu” format for patients, and steer them toward the appropriate treatments, diagnostic tests, and education based on their individual needs. In our centers we take the time to explain to patients the pros and cons of various treatment options, how medications work, and our goals for their overall treatment plan. With an increased understanding of the pathophysiology of diabetes and the mechanisms through which their therapies work, patients can have more say in, and ownership of, their treatment decisions. Because of time constraints, integrative discussions can be difficult for many primary care physicians to accommodate. However, having patient care and education provided at the same clinic helps unite treatment decisions and education goals, enabling patients to increase both their understanding of diabetes management and their own self-efficacy and ability to follow their treatment plan.

It is important for payers and employers to continue to evaluate their goals for diabetes care and ensure that the proper administrative policies are put in place to support diabetes care in a comprehensive manner. Patients respond to incentives to improve care if they can be implemented. With the chronic nature of diabetes and insidious onset of diabetes complications, patient barriers to care must be identified and addressed to continually engage the patient in good diabetes care. We encourage increased collaboration between employers, providers, patients, and payers so that all incentives can be aligned. In particular, it is important that all parties involved understand the nature of, and need for, ongoing diabetes education.

Lastly, SDC centers may provide early intervention to prevent the worsening of diabetes-related conditions and comorbidities that will cost patients and payers more in the

long term. Going forward with chronic disease management in the United States, it will be increasingly important to focus on both long- and short-term outcomes if we wish to see both positive and cost-effective results. ■

REFERENCES

- Codispoti C, Douglas MR, McCallister T, Zuniga A. The use of a multidisciplinary team care approach to improve glycemic control and quality of life by the prevention of complications among diabetic patients. *J Okla State Med Assoc*. 2004;97(5):201-204.
- McGill M, Felton AM. New global recommendations: a multidisciplinary approach to improving outcomes in diabetes; Global Partnership for Effective Diabetes Management. *Prim Care Diabetes*. 2007 Feb;1(1):49-55. Epub 2006 Dec 19.
- Aschner P, LaSalle J, McGill M. The team approach to diabetes management: partnering with patients; Global Partnership for Effective Diabetes Management. *Int J Clin Pract Suppl*. 2007;(157):22-30.
- Antoline C, Kramer A, Roth M. Implementation and methodology of a multidisciplinary disease-state-management program for comprehensive diabetes care. *The Permanente Journal*. 2011;15(1):43-48.
- AADE Guidelines for the Practice of Diabetes Self-Management Education and Training (DSME/T). American Association of Diabetes Educators. 2009. Revised 2010.
- Franz MJ, Powers MA, Leontos C, et al. The evidence for medical nutrition therapy for type 1 and type 2 diabetes in adults. *J Am Diet Assoc*. 2010;110(12):1852-1889.
- Sisson E, Kuhn C. Pharmacist roles in the management of patients with type 2 diabetes. *J Am Pharm Assoc (2003)*. 2009;49(suppl 1):S41-S45.
- Wubben DP, Vivian EM. Effects of pharmacist outpatient interventions on adults with diabetes mellitus: a systematic review. *Pharmacotherapy*. 2008;28(4):421-436.
- US Department of Health and Human Services, Centers for Medicare and Medicaid Services. CMS Manual System: Pub 100-02 Medicare Benefit Policy. August 2009. <http://www.cms.gov/transmittals/downloads/R109BP.pdf>. Accessed April 26, 2011.
- Hogg W, Lemelin J, Dahrouge S, et al. Randomized controlled trial of anticipatory and preventive multidisciplinary team care: for complex patients in a community-based primary care setting. *Can Fam Physician*. 2009;55(12):e76-e85.
- Maislos M, Weisman D. Multidisciplinary approach to patients with poorly controlled type 2 diabetes mellitus: a prospective, randomized study. *Acta Diabetol*. 2004;41(2):44-48.
- Yu GC, Beresford R. Implementation of a chronic illness model for diabetes care in a family medicine residency program. *J Gen Intern Med*. 2010;25(suppl 4):S615-S619.
- Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care*. 2002;25(7):1159-1171.
- Deakin TA, McShane CE, Cade JE, Williams R. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2005;(2):CD003417.
- Diabetes America. Information for Health Professionals. <http://www.diabetesamerica.com/healthprofessionals.cfm>. Accessed April 26, 2011.
- National Committee for Quality Assurance. Diabetes Recognition Program. 2011. <http://www.ncqa.org/tabid/1023/Default.aspx>. Accessed May 5, 2011.
- Davis A. Everything's bigger in Texas: Study shows Texas employers post significant diabetes savings using specialty provider. *Employee Benefit News*. 2010 Apr 1:30-31. <http://digital.benefitnews.com/benefitnews/20100401?pg=3#pg30>. Accessed April 28, 2011.
- Gagliardino JJ, Etchegoyen G. A model educational program for people with type 2 diabetes: a cooperative Latin American implementation study (PEDNID-LA). *Diabetes Care*. 2001;24:1001-1007.

Nontraditional or noncentralized models of diabetes care: Medication therapy management services

Sweta Chawla, PharmD, MS, CDE

TAKE-HOME POINTS

- Medication therapy management (MTM) services were introduced in the mid-2000s as part of Medicare Part D—the prescription drug benefit
- Key goals of MTM services are to:
 - Counsel patients to improve understanding of their medications
 - Improve medication adherence
 - Detect adverse drug reactions and patterns of improper drug use
- MTM services are becoming well established in pharmacy practice
- Pharmacists can help improve outcomes by:
 - Following patient progress between physician visits
 - Utilizing their clinical expertise to monitor and manage diabetes medication plans
 - Educating patients on disease, lifestyle, and adherence issues
- Although referral by a physician/health care professional (HCP) is not required for MTM provided by a pharmacist, the physician/HCP needs to be contacted for anything that requires a change in management

Sweta Chawla, PharmD, MS, CDE, has no conflicts of interest to disclose.

Introduction

Patients with type 2 diabetes mellitus (T2DM) have a large unmet medical need for appropriate treatment and continuity of care. Treatment of T2DM requires a complex, stepped approach combining behavioral modifications and multiple medications, as well as close monitoring of the effects of these interventions. In addition, these patients often require treatment for diabetes-related complications and comorbid medical conditions. Problems may arise from the complex medication regimens that T2DM patients often require. The primary care physician (PCP) has been the traditional provider or coordinator of care for T2DM. However, recent trends have imposed limits on access to the full scope of primary care needed by the growing number of patients affected by this and other chronic illnesses. The pool of PCPs is shrinking, physicians lack the time needed for complex patient interactions, and planners are discussing the shifting of primary care responsibilities to other types of health care professionals (HCPs), such as nurse practitioners, physician assistants, and pharmacists.¹⁻⁴

The pharmacist's role in managing chronic diseases

Pharmacists are a professional group with sufficient education and skills to take a leading role in the primary care of patients with T2DM and other patients with complex needs. Pharmacists are the third-largest group of health professionals in the United States (US).² The emphasis of professional pharmacy practice has been shifting from a product-oriented, medication-dispensing role, to a patient-centered role, in which the pharmacist provides cognitive services and patient management. Provision of time-consuming primary care for T2DM is made more feasible not only by this growing supply of practicing pharmacists—expected to reach 300,000 by 2020—but also by 2 trends that should increase the availability of their time: the automation of pharmacy practice and the growth of certified pharmacy technicians to a number about equal to that of pharmacists.⁴

The “pharmaceutical care” philosophy was first articulated 2 decades ago as a call for pharmacists to assume a wider scope of professional responsibility in improving the outcomes of drug therapy, preventing medication-related morbidity and mortality, and improving patients' quality of life.⁵ Falling within this paradigm are diabetes self-management education or training (DSME/DSMT), disease management, and collaborative drug therapy management (CDTM), all of which are models that have been applied to pharmacy care in recent decades.^{6,7} DSME/DSMT programs aim to educate patients on all aspects of diabetes control, including nutrition and exercise, blood glucose control, medication management, and prevention of complications. DSME is taught in an individual or classroom format by certified

diabetes educator (CDE) nurses, dietitians, pharmacists, or other professionals. The CDE credential, administered by the National Certification Board of Diabetes Educators, is the national credential for health professionals who provide diabetes patient education and counseling.⁸

Disease management programs, widely adopted in the 1990s, may be delivered by physicians, pharmacists, or other HCPs or teams. These programs are disease-specific and focus on conditions that require a considerable degree of patient self-management. They provide a wider range of services than just patient education, and may include drug and nondrug therapy. However, they do not usually encompass the needs of patients with multiple chronic illnesses. Some pharmacists are now specializing in management of specific diseases, such as diabetes, and the Board Certified-Advanced Diabetes Management (BC-ADM) credential has been introduced for pharmacists, nurses, and dietitians.⁹ This credential was originally introduced in 2000, but is currently being reviewed by the American Association of Diabetes Educators. The BC-ADM certifies expertise in patient evaluation and clinical management, as well as patient education. However, because the responsibilities for disease management are often shared among members of a team, pharmacists who provide disease management services may have difficulty obtaining compensation for their contribution.⁷

CDTM programs consist of partnerships between physicians and pharmacists in which the pharmacist can start, modify, or continue drug therapy for a specific patient according to a written protocol. Protocols may be specific to a single patient or may cover all patients treated by a physician for a specified condition. For example, in a low-risk patient with T2DM, a protocol might specify that the pharmacist can adjust a patient's insulin dose as long as the glycated hemoglobin (A1C) or blood glucose remains below a certain threshold, but the physician should be contacted if a threshold is exceeded. CDTM programs also may allow pharmacists to take responsibility for ordering tests and providing patient education. Individual state laws have established CDTM legislation, and the activity of pharmacists within CDTM programs is regulated at the state level. The programs are currently available in all but 3 states: Alabama, Oklahoma, and Maine. In most jurisdictions, CDTM agreements are easily established between physicians and regular retail pharmacists, or pharmacists working in a clinic setting.^{6,10,11} In New York, CDTM was recently assessed for pharmacists practicing in teaching hospitals only.

Medication therapy management (MTM) programs are a further evolution in pharmaceutical patient care. MTM was introduced as part of Medicare legislation in the mid-2000s as a means for pharmacists and other qualified HCPs

to improve the care of selected Medicare beneficiaries with multiple chronic illnesses who require multiple medications. MTM services may help address the need to prevent medication-related morbidity and mortality in patients with T2DM and comorbid conditions. Pharmacists can provide continuity of care by following patient progress between physician visits; by utilizing their clinical expertise to monitor and manage diabetes medication plans; and by educating patients on disease, lifestyle, and adherence issues. This level of service can be provided adequately by pharmacists, pharmacist CDEs, and pharmacists with the BC-ADM credential. In addition, many local, state, and national pharmacy organizations and pharmacy schools are providing targeted training for pharmacists wishing to deliver MTM services.¹²⁻¹⁴

Overview of MTM services

The US Medicare Modernization Act of 2003 established MTM services as part of Medicare Part D—the prescription drug benefit. The Act requires Medicare insurers to provide MTM services to a defined group of beneficiaries expected to benefit from enhanced medication management. Key goals of MTM services are to counsel patients to improve understanding of their medications, to improve medication adherence, and to detect adverse drug reactions and patterns of improper drug use.¹⁵ For the first time, the Act created a mechanism for insurers to compensate pharmacists directly for providing these services. To encourage competition and innovation, the exact nature of MTM services and the criteria for patients to qualify were initially left undefined. Basic program requirements and eligibility criteria have since evolved, although the programs are far from standardized. A consortium of 11 national pharmacy organizations developed a consensus definition of MTM programs that identified pharmacists as the key service providers.¹⁶ The eligibility criteria for beneficiaries of MTM programs are described in **TABLE 1**.¹⁷ Benefit plans can offer MTM services to patients with any chronic disease or may limit them to selected diseases. Diabetes is the most frequently targeted disease and is covered by virtually all MTM services (**FIGURE**).¹⁷

Pharmacy organizations next developed a guideline that specified 5 core activities of MTM services to be provided in pharmacies (**TABLE 2**).¹⁸ According to this guideline (hereafter referred to as the “Core Elements of MTM”), patients who qualify for MTM services must receive an annual comprehensive medication therapy review, with additional reviews and ongoing pharmacist monitoring as necessary.^{17,18} Over-the-counter medications, herbal therapies, and dietary supplements should be included in the medication review. Though face-to-face interaction is preferred, and should be required, services may be provided by telephone and may

TABLE 1 Patient eligibility criteria for MTM programs¹⁷

Multiple chronic diseases
Programs must offer MTM services to patients who have at least 2 or 3 chronic diseases (at the plan's discretion) and must target at least 4 of the following: <ul style="list-style-type: none"> • Diabetes • Hypertension • Heart failure • Dyslipidemia • Respiratory diseases (such as asthma or COPD) • Bone disease/arthritis • Mental disorders (such as depression, schizophrenia, bipolar disorder).
Multiple covered drugs
Plans vary in the number of drugs patients must be prescribed to qualify, with thresholds ranging from 2 to 8.
Cost threshold
Patients must be expected to incur at least \$3000 in annual Part D drug costs.

COPD, chronic obstructive pulmonary disease; MTM, medication therapy management.

be either by appointment or on a walk-in basis.¹⁸ According to the guideline, patients should be provided with a printed or written document, such as a summary of recommendations or an action plan, to take with them. Services may be provided regardless of whether the pharmacist is dispensing medications to the patient. Physician referrals are also not required for pharmacists to offer MTM services to qualifying patients.¹⁸ However, although referral by a physician/HCP is not required for MTM provided by a pharmacist, the physician/HCP does need to be contacted for anything that requires a change in management (eg, changes to treatment). In my practice, I typically write a summary letter to the patient's physician/HCP; this includes my assessment of the session and any recommendations. Patients are also encouraged to share their personal medication record and action plan with their HCPs. MTM enrollment requirements were revised in 2010 and now require payers to identify target beneficiaries for automatic enrollment.¹⁷

MTM services in pharmacy practice

MTM services are becoming well established in pharmacy practice. According to an annual survey conducted by the American Pharmacists Association, 72% of pharmacist respondents were offering MTM services in 2009, and about one-third of the rest planned to offer the services soon.¹⁹ About 84% of payer respondents (mostly health maintenance

organizations, managed care insurers, and prescription benefit management plans) were offering MTM services. Contracted pharmacists provided about two-thirds of MTM care, with in-house pharmacists and contracted MTM organizations providing substantial amounts of services, and nurses and physicians providing a small proportion.¹⁹⁻²⁰ MTM services are not restricted to Medicare patients, but are increasingly being offered by managed care organizations and fee-for-service plans.^{12,21} Some payers support pharmacist-provided MTM services as part of a broader multidisciplinary disease management program.²⁰

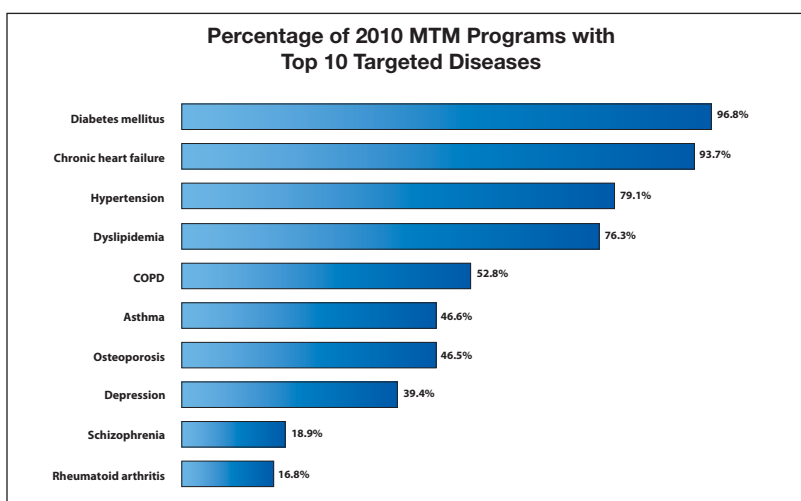
Community pharmacists wishing to offer MTM services have several potential business models. Although they can contract directly with Medicare Part D insurers, it can be difficult and time-consuming to develop these individual contracts. Many insurers are not yet equipped to deal efficiently with pharmacists wishing to initiate this type of arrangement, and insurers are only slowly making the shift toward regarding pharmacists as providers.

A second option is to contract with an MTM intermediary company that links payers with pharmacists. These companies can be approached via their Web sites.¹² Their services make it unnecessary for pharmacists to contract with different payers, find patients, or establish new billing systems. The American Society of Consultant Pharmacists offers a program through its Web site (<http://www.ascp.org>). Known as the MTM Provider Partners Program, it is a pathway for its members to enter the MTM world.

A third option is for pharmacists to provide patients with MTM services and then bill payers—so-called blind billing. Bills for patients covered by Medicare can be submitted using the CMS-1500 form available from the Web site of the Centers for Medicare and Medicaid Services, <http://www.cms.gov>. Assistance with billing codes is available from the Pharmacist Services Technical Advisory Coalition, <http://www.pstac.org>. It should be noted that although submission of these claims to various payers is becoming more standardized, there is no guarantee of payment with blind billing. Pharmacists may be reluctant to provide complex, time-consuming MTM services in the absence of such a guarantee. Providing MTM directly to patients in a fee-for-service manner is another option being explored in a few pharmacies.

Inconsistent documentation requirements and reimbursement policies among payers are barriers to community pharmacists' adoption of MTMs.²⁰ Other barriers to adoption of MTMs, or to their most effective use, include a lack of pharmacists' time, staffing issues, difficulty forming collaborative relationships with physicians, poor patient mobility and low health literacy, a lack of medical information, and difficulty motivating patients to engage in the programs.^{15,20-23} It can be

FIGURE The top 10 diseases targeted by MTM programs in 2010 and the percentage of MTM programs that targeted these diseases¹⁷



COPD, chronic obstructive pulmonary disease; MTM, medication therapy management.

Reproduced with permission from Centers for Medicare and Medicaid Services. 2010 Medicare Part D Medication Therapy Management (MTM) Programs. https://www.cms.gov/PrescriptionDrugCovContra/Downloads/MTMFactSheet_2010_06-2010_final.pdf. Published June 8, 2010. Accessed February 1, 2011.

challenging to persuade patients of the value of a commitment to time-consuming MTM care, but once they have tried it, many become enthusiastic participants. As the following case study illustrates, use of the various components of the MTM model can help give patients with diabetes and multiple other illnesses a sense of ownership and control.

CASE STUDY ► Patient with T2DM and multiple comorbidities

A 49-year-old African American woman, who qualifies for Medicare because of disability, first enrolled in our pharmacy's advertised diabetes education classes 3 years ago, out of concern over her long history of uncontrolled diabetes. At that time, her body mass index (BMI) was 35 kg/m² and her A1C was 10%. In addition to T2DM, she had asthma, gastroesophageal reflux disease (GERD), hypertension, hyperlipidemia, gout, seasonal allergies, and a prior myocardial infarction.

I have worked closely with this patient over the succeeding 3 years, providing weekly diabetes education and counseling. At first she was using NPH insulin twice a day and adjusting the doses on her own, without the close involvement of her endocrinologist. As long-acting insulin analogs (ie, insulin glargine and insulin detemir) have relatively flat and more predictable time-action profiles that last up to 24 hours,²⁴ I persuaded her to switch to a basal-bolus regimen with insulin detemir and insulin aspart. Insulin detemir is also associated with less weight gain and fewer hypoglycemic episodes

than NPH insulin,²⁵⁻²⁷ which was especially important given this patient's obesity and fear of hypoglycemia. It is, however, important to note that changes in medication should also be reviewed with the patient's treating physician. In addition, I spent a year working closely with the patient on carbohydrate counting.

Pharmacists can also explore different insulin delivery methods with patients. Many patients find insulin pens more convenient, more discreet, and easier to use than a vial and syringe.^{28,29} Insulin pumps can also be a useful option for certain patients.³⁰ Recently, this patient began using an insulin pump, which was recommended to help her achieve better blood glucose control, despite her erratic meal patterns. The results are generally good, although she still has glucose spikes due to metabolic issues and inconsistent eating patterns, and her BMI has increased slightly (36.1 kg/m²). However, her current A1C is 7.1%.

This patient's complicated medical history and large number of medications (TABLE 3) suggested the need for a

TABLE 2 Core elements of an MTM service model¹⁸

Medication therapy review
Systematic review of the patient's medications to assess and prioritize problems and create a plan to resolve them.
Personal medical record
Comprehensive record of the patient's prescription and nonprescription medications, herbal agents, and nutritional supplements. The record is kept and updated by the patient, brought to appointments in different settings, and used by the patient in medication self-management.
Medication-related action plan
List of actions for the patient to use in self-management. The plan is developed collaboratively by the patient and pharmacist and used to track progress toward achieving specific goals.
Intervention and/or referral
The pharmacist intervenes or refers the patient to another health professional to address medication-related problems.
Documentation and follow-up
The pharmacist documents all MTM services and interventions—ideally, electronically. Follow-up or a referral to a different care setting is scheduled based on the patient's needs.

MTM, medication therapy management.

TABLE 3 Case study: Health problems and medications at the time of medication therapy review

Health problems	Medications	Recommendations
Type 2 diabetes	<ul style="list-style-type: none"> • Insulin detemir 40 U qAM and 60 U qhs; then titrate appropriately if necessary • Insulin aspart according to advanced carbohydrate counting technique 	<ul style="list-style-type: none"> • Titrate basal insulin as necessary. • Continue self-monitoring of blood glucose 3 or more times a day. • Patient's blood glucose still spikes even with continued carbohydrate counting for each meal. Stress the importance of eating 3 meals a day. • Patient should be educated on signs of hypoglycemia because her beta-blocker may enhance the hypoglycemic effect of insulin.
Hyperlipidemia	<ul style="list-style-type: none"> • Statin (temporarily discontinued to investigate muscle cramps) • Prescription omega-3 fatty acids (noncompliant because of large capsule size) 	<ul style="list-style-type: none"> • Consider ruling out other causes of muscle symptoms and of creatine kinase elevation. Evaluate possible statin drug-drug interaction with other medications that patient is currently using. Restart appropriate statin therapy after evaluation is completed. • Start fenofibric acid delayed-release to reduce hypertriglyceridemia if triglyceride levels are still elevated on statin therapy. • Switch to smaller, over-the-counter omega-3 capsules.
Hypertension (poorly controlled)	<ul style="list-style-type: none"> • Angiotensin II receptor antagonist • Beta-blocker 	<ul style="list-style-type: none"> • Maintain current angiotensin II receptor antagonist. • Consider switching from twice-daily to once-daily formulation of beta-blocker to increase adherence. • Stress importance of exercise and of following the low-salt DASH diet. • Consider adding a third medication if blood pressure is not in control after the above interventions.
Cardiovascular disease	<ul style="list-style-type: none"> • Low-dose aspirin 	<ul style="list-style-type: none"> • Consider evaluating patient for the diagnosis of congestive heart failure.
Gout	—	<ul style="list-style-type: none"> • Measure uric acid levels. • Start allopurinol 100 mg once daily if uric acid level is high, and check uric acid levels periodically for dose adjustments. • Advise avoidance of purine-rich foods such as organ meat.
GERD	<ul style="list-style-type: none"> • Proton pump inhibitor 	<ul style="list-style-type: none"> • Maintain current therapy. • Advise avoidance of foods that exacerbate or induce GERD.
Obesity	—	<ul style="list-style-type: none"> • Consider cortisol testing as patient shows signs of Cushing's syndrome. • Advise on exercise and dietary changes to promote weight loss.
Seasonal allergies	<ul style="list-style-type: none"> • H₁-receptor blocker 	<ul style="list-style-type: none"> • Maintain current therapy as necessary during allergy season.

DASH, Dietary Approaches to Stop Hypertension; GERD, gastroesophageal reflux disease.

comprehensive medication review, as described in the Core Elements of MTM.¹⁸ The result of the review was a letter to her physician, with a number of recommendations about her medications, lifestyle changes, and symptoms to investigate. Among the problems discovered were muscle pain and creatine kinase elevation as a possible side effect of her statin therapy; poorly controlled hypertension; poor compliance with some of her medications; the possibility of an interaction between her insulin and beta-blocker; symptoms of congestive heart failure; and signs of possible Cushing's syndrome. Among the recommended actions were withdrawal of the statin until muscle symptoms could be investigated and modifications of some of her medications to a more easily tolerated form or dosage schedule. Diet, exercise, and

weight loss were recommended to ameliorate many of her health problems. Her physician was also advised that she should avoid foods that would exacerbate her GERD and gout and that she should follow the low-salt DASH (Dietary Approaches to Stop Hypertension) diet to help manage her hypertension. It is important to note that, while the pharmacist may make recommendations for symptoms to be investigated, it is the physician who should be making the diagnosis, and pharmacists and physicians should be collaborating as part of a treatment team.

This patient's fear of hypoglycemia has presented an ongoing challenge in her diabetes education. She often would load up on carbohydrates before leaving work to avoid becoming hypoglycemic on the train ride home. She is

extremely insulin resistant, and it has required a major effort to help her feel comfortable with taking enough insulin. She has been very conscientious in documenting the results of her glucose self-monitoring, but has received little education from her physician about what to do with the information. Carbohydrate counting has been difficult for her and continues to be a major focus of our weekly sessions.

The close attention that this patient receives from her pharmacist contrasts with the usual care received by many patients with diabetes. It is not uncommon for patients to tell me that, when they were first diagnosed with T2DM, they were given a prescription and, at best, sent to a dietitian for nutritional counseling. Newly diagnosed patients are advised to monitor their blood glucose; because I see patients once a week, it is easy to help them understand the immediate interactions between diet, exercise, insulin sensitivity, specific medications and doses, and glucose levels.

The medication-related action plan (MAP), one of the Core Elements of MTM,¹⁸ is a useful tool to help patients take control of their progress in managing their diabetes. We use it as a medical action plan, involving far more than just medications. These plans are completed at every visit, collaboratively with the patient, and reviewed as follow-up at the next visit. The form contains a space for each planned activity and a space to document progress toward that activity or its completion. Activities might include changing the time of day a medication is taken, going for a lab test, asking the physician to explain cholesterol levels, or observing the emotional states that might lead to binge eating. Holding patients accountable for the activities in the MAP helps them to achieve their self-management goals.

Clinical and economic outcomes of MTM

As MTM programs are too diverse to be studied as a group, most outcome studies conducted to date provide data only on specific MTM programs and provide little information about MTMs overall.¹⁵ Furthermore, few, if any, studies have examined the effects of MTMs specifically in diabetes. However, numerous publications suggest that pharmacist-provided care can improve clinical outcomes. According to 2 systematic reviews of studies conducted in patients with diabetes, A1C was highly sensitive to a variety of interventions by pharmacists, such as diabetes education and medication management.^{31,32} In a Veterans Affairs Health Care System, pharmacists' use of a preplanned insulin initiation and titration protocol resulted in the successful implementation of an insulin initiation clinic through CDTM and improved patients' glycemic control compared with when the patients were receiving only oral antihyperglycemic agents.³³ Two often-cited programs, the Asheville Project³⁴ and the Dia-

betes Ten City Challenge,³⁵ demonstrated that pharmacist-provided MTM-like care for T2DM resulted in health care cost savings, as well as improved clinical outcomes. However, these results are not directly applicable to MTM services because they were conducted in relatively healthy employee populations. Many studies have examined the overall effects of MTMs on health care costs, but results have been inconsistent, in part because of variation in which costs were included in the analyses.²⁰ It seems inevitable that as the MTM model matures, data will demonstrate the clinical and economic value of pharmacists providing primary care for patients with T2DM and other complex medical conditions.

Conclusions

Pharmacists can help optimize diabetes drug therapy by improving tolerability, reducing risks, and increasing patients' likelihood of attaining treatment goals. Pharmacist-led diabetes education can go beyond medication and glycemic control to promote overall wellness and a healthy lifestyle. With their involvement in MTM, pharmacists can apply their expertise in drug therapy to a patient population with complex and challenging needs. ■

REFERENCES

1. Biola H, Green LA, Phillips RL, et al. The U.S. primary care physician workforce: minimal growth 1980–1999. *Am Fam Physician*. 2003;68(8):1483.
2. Council on Credentialing in Pharmacy. Scope of contemporary pharmacy practice: roles, responsibilities, and functions of pharmacists and pharmacy technicians. *J Am Pharm Assoc* (2003). 2010;50(2):e35–e69.
3. Drab S. Translating clinical guidelines into clinical practice. Role of the pharmacist in type 2 diabetes management. *J Am Pharm Assoc* (2003). 2009;49(6):e152–e162.
4. Posey LM, Tanzi MG. Diabetes care: Model for the future of primary care. *J Am Pharm Assoc* (2003). 2010;50(5):623–626.
5. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm*. 1990;47(3):533–543.
6. Malloy MJ, DeBellis R. Collaborative drug therapy management, medication treatment management, and Medicare Part D: What do they have in common? *Harvard Health Policy Review*. 2006;7(1):186–188.
7. McGivney MS, Meyer SM, Duncan-Hewitt W, Hall DL, Goode JV, Smith RB. Medication therapy management: its relationship to patient counseling, disease management, and pharmaceutical care. *J Am Pharm Assoc* (2003). 2007;47(5):620–628.
8. Funnell MM, Brown TL, Childs BP, et al. National standards for diabetes self-management education. *Diabetes Care*. 2011;34(suppl 1):S89–S96.
9. Daly A, Kulkarni K, Boucher J. The new credential: advanced diabetes management. *J Am Diet Assoc*. 2001;101(8):940–943.
10. Alliance for Pharmaceutical Care. Collaborative Drug Therapy Management: A Coordinated Approach to Patient Care. http://www.ashp.org/s_ashp/docs/files/about/CDTM.doc. Accessed February 3, 2011.
11. Roberts S, Gainsbrugh R. Medication therapy management and collaborative drug therapy management [letter]. *J Managed Care Pharm*. 2010;16(1):67–68.
12. Martin CM, McSpadden CS. Dispelling the myths about medication therapy management services. *Consult Pharm*. 2008;23(11):866–872, 875.
13. American Pharmacists Association. Delivering Medication Therapy Management Services in the Community. <http://www.pharmacist.com/ctp/mtm>. Published March 1, 2009. Accessed February 1, 2011.
14. American Society of Consultant Pharmacists. Delivering Medication Therapy Management Services in The Community—Updated for 2010. <https://www.ascp.com/articles/professional-development/delivering-medication-therapy-management-services-community-update>. Accessed February 1, 2011.
15. Pellegrino AN, Martin MT, Tilton JJ, Touchette DR. Medication therapy management services: definitions and outcomes. *Drugs*. 2009;69(4):393–406.
16. Bluml BM. Definition of medication therapy management: development of profession-wide consensus. *J Am Pharm Assoc* (2003). 2005;45(5):566–572.
17. Centers for Medicare and Medicaid Services. 2010 Medicare Part D Medication

- Therapy Management Programs. https://www.cms.gov/PrescriptionDrugCovContra/Downloads/MTMFactSheet_2010_06_2010_final.pdf. Published June 8, 2010. Accessed February 1, 2011.
18. American Pharmacists Association; National Association of Chain Drug Stores Foundation. Medication therapy management in pharmacy practice: core elements of an MTM service model (version 2.0). *J Am Pharm Assoc* (2003). 2008;48(3):341-353.
 19. American Pharmacists Association. Medication Therapy Management Digest. Perspectives on 2009: A Year of Changing Opportunities. <http://www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=22674>. Published March 2010. Accessed February 1, 2011.
 20. Abt Associates. Exploratory Research on Medication Therapy Management. Final report. <http://www.cms.hhs.gov/Reports/downloads/blackwell.pdf>. Published July 8, 2008. Accessed February 1, 2011.
 21. Buffington DE. Future of medication therapy management services in delivering patient-centered care. *Am J Health Syst Pharm*. 2007;64(15 suppl 10):S10-S12; quiz S21-S23.
 22. Law AV, Okamoto MP, Brock K. Ready, willing, and able to provide MTM services?: A survey of community pharmacists in the USA. *Res Social Adm Pharm*. 2009;5(4):376-381.
 23. Lounsbury JL, Green CG, Bennett MS, Pedersen CA. Evaluation of pharmacists' barriers to the implementation of medication therapy management services. *J Am Pharm Assoc* (2003). 2009;49(1):51-58.
 24. Freeman JS. Insulin analog therapy: improving the match with physiologic insulin secretion. *J Am Osteopath Assoc*. 2009;109(1):26-36.
 25. Davies MJ, Derezinski T, Pedersen CB, Clauson P. Reduced weight gain with insulin detemir compared to NPH insulin is not explained by a reduction in hypoglycemia. *Diabetes Technol Ther*. 2008;10(4):273-277.
 26. Fajardo Montanana C, Hernandez Herrero C, Rivas Fernandez M. Less weight gain and hypoglycaemia with once-daily insulin detemir than NPH insulin in intensification of insulin therapy in overweight Type 2 diabetes patients: the PREDICTIVE BMI clinical trial. *Diabet Med*. 2008;25(8):916-923.
 27. Mandosi E, Fallarino M, Rossetti M, Gatti A, Morano S. Waist circumference reduction after insulin detemir therapy in type 2 diabetes patients previously treated with NPH. *Diabetes Res Clin Pract*. 2009;84(2):e18-e20.
 28. Korytkowski M, Bell D, Jacobsen C, Suwannasari R. A multicenter, randomized, open-label, comparative, two-period crossover trial of preference, efficacy, and safety profiles of a prefilled, disposable pen and conventional vial/syringe for insulin injection in patients with type 1 or 2 diabetes mellitus. *Clin Ther*. 2003;25(11):2836-2848.
 29. Molife C, Lee LJ, Shi L, Sawhney M, Lenox SM. Assessment of patient-reported outcomes of insulin pen devices versus conventional vial and syringe. *Diabetes Technol Ther*. 2009;11(8):529-538.
 30. Jankovec Z, Cechurova D, Krcma M, Lacigova S, Zourek M, Rusavy Z. The influence of insulin pump treatment on metabolic syndrome parameters in type 2 diabetes mellitus. *Wien Klin Wochenschr*. 2009;121(13-14):459-463.
 31. Machado M, Bajcar J, Guzzo GC, Einarson TR. Sensitivity of patient outcomes to pharmacist interventions. Part I: systematic review and meta analysis in diabetes management. *Ann Pharmacother*. 2007;41(10):1569-1582.
 32. Wubben DP, Vivian EM. Effects of pharmacist outpatient interventions on adults with diabetes mellitus: a systematic review. *Pharmacotherapy*. 2008;28(4):421-436.
 33. Rochester CD, Leon N, Dombrowski R, Haines ST. Collaborative drug therapy management for initiating and adjusting insulin therapy in patients with type 2 diabetes mellitus. *Am J Health Syst Pharm*. 2010;67(1):42-48.
 34. Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc (Wash)*. 2003;43(2):173-184.
 35. Fera T, Bluml BM, Ellis WM. Diabetes Ten City Challenge: Final economic and clinical results. *J Am Pharm Assoc* (2003). 2009;49(3):383-391.

Nontraditional or noncentralized models of diabetes care: Boutique medicine

Jeffrey P. Schyberg, MD, PC

TAKE-HOME POINTS

- Boutique medicine (also referred to as concierge health care, concierge medicine, or retainer medicine) was developed in the mid-1990s in Seattle, Washington
- In this model, patients pay an annual or monthly fee to have improved access to health care services
- All boutique medical practices are limited to 600 patients
- Boutique medicine allows primary care physicians to spend considerably more time with diabetes patients to develop a comprehensive plan of care that includes:
 - Medical assessment
 - Individualized education
 - Close follow-up
- Boutique medicine has raised mixed reactions
 - Services are not available to most patients

Jeffrey P. Schyberg, MD, PC, has no conflicts of interest to disclose.

Introduction

The International Diabetes Federation estimates that 285 million people worldwide have diabetes. This number is expected to rise to 438 million within 20 years.¹ With the increasing population of patients with diabetes and pre-diabetes, treatment of this condition is shifting from secondary specialist centers to the primary care setting. Continuity of care with the same doctor and nurse team may be particularly important for diabetes patients,² and this may be easier to provide in the primary care setting. Indeed, examination of randomized trials of diabetes care in the hospital vs general practice (in the United Kingdom and Australia) showed that structured primary care settings—ie, those involving central recall and prompting of physicians and doctors—provided comparable or even better levels of care than the hospital outpatient clinic setting.³ However, unstructured care in the community was associated with poorer follow-up, worse glycemic control, and greater mortality than hospital care.³ A sustainable and successful shift of diabetes care to the primary setting therefore requires that primary care physicians (PCPs) effectively provide aspects of diabetes care traditionally supplied by specialists. In particular, given the increasing complexity of diabetes care,⁴ appropriate treatment guidance, including the early and appropriate use of insulin in type 2 diabetes mellitus (T2DM), will increasingly become the responsibility of PCPs.

Traditional managed care frequently necessitates that physicians have a limited time frame in which to conduct appointments and carry out preventive visits. Delivering competent care within these time constraints is a continuing source of frustration among PCPs; this is further hindered by the pressures of increasing patient numbers, rising financial costs, and less physician reimbursement. As a result of these limitations, more physicians are turning to alternative medical approaches in order to increase the amount of time that they spend with their patients, with the ultimate aim of improving their patients' quality of care. This review describes the delivery of primary care using boutique medicine and how this might impact the patient with diabetes.

Boutique medicine

Boutique medicine (also referred to as concierge health care, concierge medicine, or retainer medicine) is a type of medical practice in which physicians see a smaller number of patients, allowing patients to get more individualized treatment and personalized care, and thereby avoid the restraints of managed care. Boutique medicine was originally developed in Seattle, Washington, in the mid-1990s.⁵ The basic premise is that patients pay an annual or monthly fee in return for a health care system with improved access and services.⁶ Following its original conception, the boutique medical practice organization, MDVIP, was founded in 2000. MDVIP comprises a national network of PCPs

who practice “proactive, preventive and personalized health-care with the aim of putting the patient first.”⁷

From a personal perspective, I have been practicing boutique medical care for approximately 2 years as part of a nationwide boutique medical organization. I was motivated by a desire to engage in better preventive care and to spend more time with patients so that they can better understand their condition. In terms of organization, we are significantly smaller than the traditional primary care practice. Our practice comprises one office manager, one nurse, and one PCP. We currently have 540 patients, with an ongoing waiting list for new patients and, as with all boutique medical practices, we are limited to 600 patients. Approximately half of our patients are eligible for Medicare. A number of our patients are in their 30s, but most are between 50 and 65 years of age.

In our practice, patients make an annual payment of \$1500, which can be paid quarterly, every 6 months, or annually, and we continue to accept all types of insurance and participate with Medicare. This payment entitles our patients to a range of services including longer appointment times and better access to care. Because of our smaller patient numbers, appointments are scheduled for a minimum of 30 minutes and can be up to an hour long, depending on the needs of the patient. This compares with the usual 5- to 10-minute appointment times typical of our previous practice. We also offer our patients same-day appointments and aim to coordinate specialty care in a timely fashion so that patients are not subjected to unnecessary waiting times.

Although evidence-based guidelines do not recommend routine physical examination and testing in asymptomatic adults,⁸⁻¹⁰ the boutique medicine model offers an annual preventive visit. In our traditional practice, these were scheduled for 30 minutes, and for many patients did not happen at all; however, with boutique medicine this visit can last up to 2 hours and includes investigations such as blood analysis, urinalysis, and vision and hearing tests. Glycated hemoglobin (A1C) levels are also tested at each visit. The following section describes how boutique medicine might impact the patient with diabetes, with a brief overview of strategies that may be effectively applied in the boutique practice setting.

Boutique medicine and the diabetes patient

For patients with diabetes, the benefits of early and intensive glycemic control with respect to preventing or delaying the onset and progression of microvascular and neuropathic complications are well established.¹¹⁻¹³ Diabetes management targeted at glycemic control is therefore fundamental to the long-term health of patients with diabetes. This is reflected in guidelines from the American Diabetes Association (ADA) and the American College of Endocrinology

(ACE)/American Association of Clinical Endocrinologists (AACE), which recommend target A1C levels of <7.0% and ≤6.5%, respectively.^{14,15}

Despite the proven importance of achieving good glycemic control, more than 40% of adults diagnosed with T2DM are not achieving glycemic goals.^{16,17} One possible reason for this is the delay in initiating insulin treatment that can occur with the stepwise approach to therapy.¹⁸⁻²⁰ In other cases, psychological resistance on the part of both health care providers and patients can delay insulin therapy.^{21,22} This potential for resistance was examined as part of the Diabetes Attitudes, Wishes, and Needs (DAWN) study, a trial conducted in 3170 patients with T2DM.^{21,22} Findings from this study showed that many patients see insulin initiation as a personal failure, while health care providers often delayed insulin until considered “absolutely necessary.”^{21,22} On a more promising note, findings from DAWN showed that the quality of collaboration between the patient and health care provider was the strongest predictor of patient-reported outcomes, with access to, and relationship with, a provider being most strongly associated with a patient’s well-being and perceived diabetes control. Patients who had a higher level of interaction with their health care provider were also more likely to adhere to their treatment regimen.^{22,23}

From the perspective of the physician, patient nonadherence and physician failure to initiate or intensify treatments appropriately are clearly significant challenges in achieving glycemic control. Boutique medicine allows PCPs to spend significantly more time with diabetes patients, and as a result they may be able to optimize the quality of collaboration with their patients. Accordingly, patients may have a better understanding of their condition and show better adherence to therapies. Longer and more frequent patient appointments may also facilitate a diabetes treatment plan that is aligned with the individual patient’s needs as part of a collaborative therapeutic alliance between the patient and health care provider.

Insulin treatment

The issues surrounding insulin treatment, as well as possible advantages of boutique medicine for patients requiring insulin, are discussed in detail in the sidebar on page S21. Increased physician availability, increased monitoring of the patient, and good collaboration between physician and patient in the boutique medicine model appear to play an important role in obtaining good outcomes in patients requiring insulin treatment.

Diabetes and ongoing self-management education

Any diabetes management plan needs to recognize diabetes

Insulin, Primary Care, and Boutique Medicine

Although insulin is considered the most effective pharmacologic agent for achieving glucose control, it is often underused and considered a last resort.²¹⁻²³ Insulin analogs have been developed with the aim of more closely replicating physiologic insulin profiles than do human insulins, and insulin analogs are now recommended as preferred insulin therapies by AACE/ACE guidelines.²⁷ The availability of these analogs should make insulin treatment simpler and more convenient from the patient's and the PCP's perspective. To date, 2 long-acting basal insulin analogs are available, insulin detemir and insulin glargine, along with 3 rapid-acting insulin analogs, insulin lispro, insulin aspart, and insulin glulisine.²⁸⁻³² Fixed-ratio insulin analog premixes (derived from rapid-acting analogs) are also available (TABLE).

In our boutique practice, the physician performs the role of a certified diabetes educator, in that he or she provides information about treatments, side effects, and lifestyle changes. Insulin device technology continues to improve, and ideally physicians should not only discuss the different treatment options available to patients but also provide advice on the correct use of these devices. Insulin pens offer advantages of being discreet, portable, and accurate, and their ease of use makes them attractive to both patients and health care providers (TABLE).^{33,34} Comparative clinical trial data have demonstrated that patients not only prefer pen devices over syringe/vial delivery,^{33,35} but also experience an improvement in quality of life compared with the traditional syringe/vial delivery method.³⁶⁻³⁸ Despite these advantages, uptake of insulin pens continues to be slower in the US than in Europe.³⁹

Patients in our practice who require insulin treatment have been able to achieve excellent glycemic control. This is possibly due to the increased availability of the physician, increased frequency of patient monitoring, and the good collaboration between physician and patient.

The current consensus recommendations of the ADA and the European Association for the Study of Diabetes are to initiate therapy with lifestyle interventions and metformin with the aim of achieving a treatment goal of A1C <7.0%.⁴⁰ For patients failing to meet targets despite these interventions, the next step should include insulin or a sulfonylurea. In selected patients (eg, in those who have hazardous jobs, for whom hypoglycemia could be particularly detrimental), the addition of thiazolidinediones (TZDs) or glucagon-like peptide-1 (GLP-1) agonists may be considered.⁴⁰ The AACE/ACE has also issued a consensus statement providing therapeutic pathways for T2DM patients with A1C in 3 ranges: 6.5%–7.5%, 7.6%–9.0%, and >9.0%. In this algorithm, there is progression from monotherapy, to dual therapy, to triple therapy, to insulin therapy with or without additional agents.²⁷ For example, to achieve a goal A1C of 6.5% in patients in the 6.5%–7.5% range, dipeptidyl-peptidase-4 (DPP-4) inhibitors, or α -glucosidase inhibitors (AGIs), are recommended as second-line monotherapy (with metformin being recommended as first-line treatment); for dual therapy, metformin with one of the following agents is recommended: GLP-1 agonist, DPP-4 inhibitor, or an insulin secretagogue (eg, glinide, sulfonylurea), in the order specified.²⁷

Physicians and patients are often reluctant to start with basal-bolus insulin therapy. The consensus statement algorithm to guide effective use of insulin suggests targeting the fasting component first with a basal intermediate- or long-acting insulin (FIGURE).⁴⁰ Empowering patients with self-titration goals may be particularly helpful for achieving and maintaining glycemic goals with once-daily basal insulin analogs. Ideally, this self-management approach should be complemented by an ongoing collaboration with the physician.

Indeed, perhaps one of the biggest challenges in primary care is finding sufficient time to effectively initiate or intensify insulin treatment, and boutique medicine may be especially advantageous in this setting. The structure of boutique medicine allows for detailed discussions on treatment options and frequent monitoring of insulin treatment side effects. Within the boutique medicine setting, patients can fax, call, or stop by with their blood glucose level results so that adjustments to insulin therapy can be made on a regular basis, and patients can follow up with any queries relating to their self-directed adjustments.

self-management education (DSME) and ongoing diabetes support as integral components of care.¹⁴ Patient education is a powerful tool in helping patients take control of their condition and achieve glycemic goals. Boutique medicine is well placed to support effective implementation of DSME. Patients' concerns regarding their condition and its management can often be resolved through a clear understanding of an individual patient's attitudes and knowledge. Indeed,

common misconceptions and fears regarding insulin treatments—such as concerns regarding the risk of hypoglycemia, weight gain, impact on lifestyle, and apprehension related to injections/needles—can be allayed through comprehensive discussions with patients to provide them with the knowledge to make informed choices about their therapy options.

An additional key strategy that the boutique medicine PCP can implement is to ensure that the patient has access to

TABLE Available insulin analogs and their associated delivery devices²⁸⁻³²

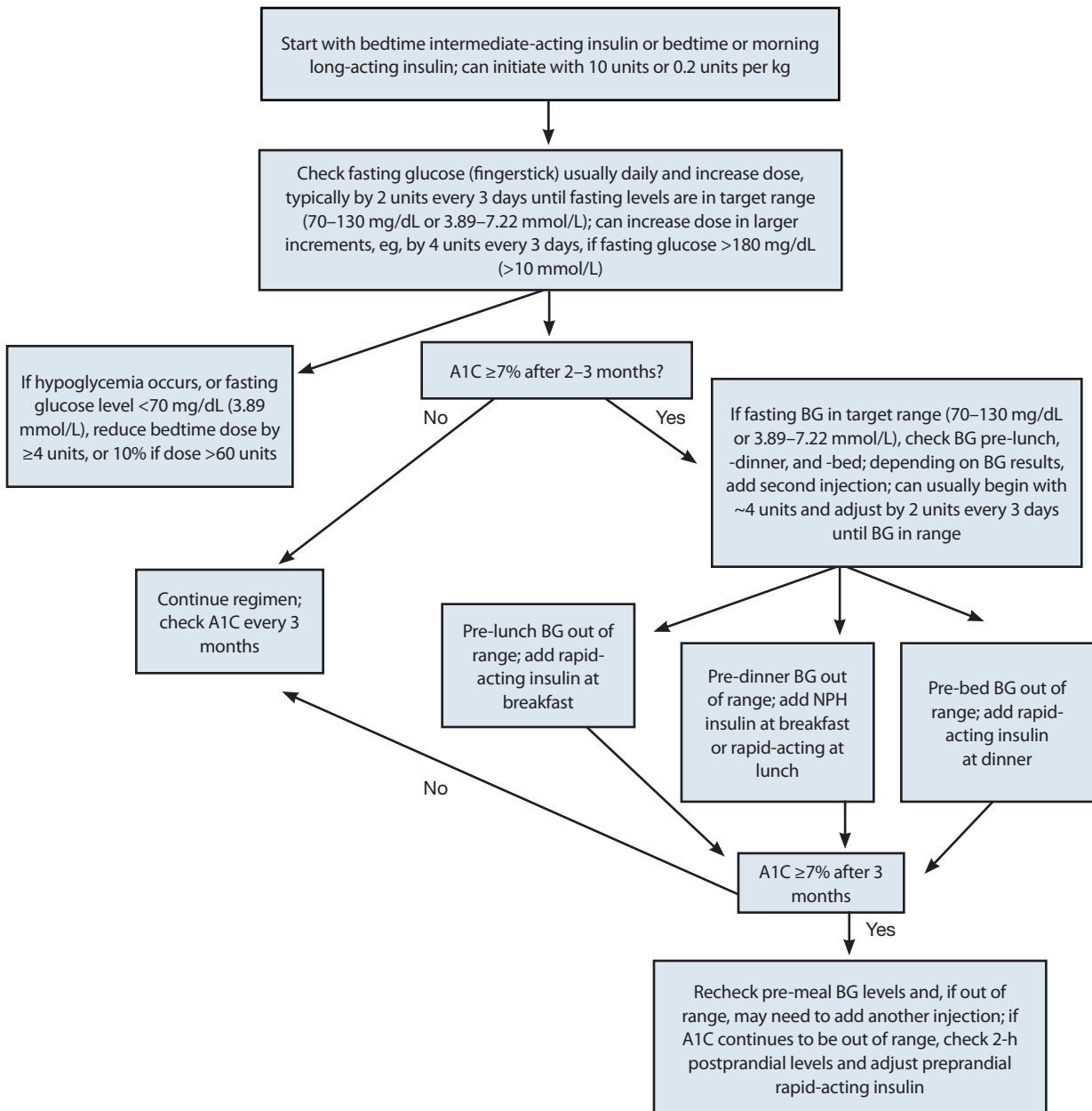
Insulin analog	Type	Manufacturer	Delivery device
Insulin detemir (Levemir)	Long-acting	Novo Nordisk	Next Generation FlexPen NovoPen 3 NovoPen 3 Demi NovoPen Junior InnoLet pen
Insulin glargine (Lantus)	Long-acting	sanofi-aventis	SoloSTAR pen OptiClik pen ClikSTAR pen (Canada and Europe)
Insulin lispro (Humalog)	Rapid-acting	Eli Lilly & Co.	Humalog KwikPen HumaPen MEMOIR HumaPen LUXURA HD
Insulin aspart (NovoLog)	Rapid-acting	Novo Nordisk	NovoLog FlexPen NovoLog in a Pump NovoPen Junior NovoPen 3
Insulin glulisine (Apidra)	Rapid-acting	sanofi-aventis	SoloSTAR Apidra in a Pump OptiClik pen ClikSTAR pen (Canada and Europe)

continued care. The boutique medicine approach means that patients can be proactive about their results and outcomes, which helps them feel more confident and in better control of their condition. This is supported by the overall improvements in A1C levels that we have observed in our current practice compared with our previous standard-of-care practice. The case study that follows illustrates the benefits of personalized care in the treatment of diabetes within the boutique medicine setting.

CASE STUDY ▶ A 71-year-old male presented with T2DM, diagnosed approximately 20 years ago, along with other comorbidities, including dyslipidemia and obesity. The patient had been feeling unwell and complaining of polyuria, polydipsia, and significant nocturia. At examination, he weighed 107 kg (236 lb), with a body mass index of 38 kg/m² and blood pressure 118/74 mm Hg. Current medications included metformin 1000 mg twice daily, glipizide 10 mg twice daily, allopurinol 100 mg daily, ezetimibe and simvastatin 10/40 daily, quinapril 40 mg daily, indapamide 2.5 mg daily, fenofibrate 130 mg daily, and aspirin 81 mg daily. Although the patient had received previous counseling on

the importance of weight loss and had initially lost some weight, he was no longer following a standard diabetic diet. He was also reluctant to self-monitor his blood glucose following elevated levels of more than 200 mg/dL. Initial laboratory tests revealed an A1C level of 10.5% and blood glucose of 192 mg/dL. The patient also showed elevated microalbuminuria and evidence of peripheral neuropathy.

The boutique medicine approach meant that we were able to schedule a 90-minute office visit with the patient and his wife. This allowed detailed discussion of appropriate treatments and monitoring, as well as the importance of a healthy lifestyle. Following review of different treatment options, it was agreed to initiate treatment with a long-acting insulin and to use a rapid-acting insulin at mealtimes. Considerable time was devoted to teaching the correct use of insulin pens via a demonstration pen and practice injections. Detailed discussion also allayed patient concerns about insulin therapy, including signs and symptoms of hypoglycemia and available options for managing such events. The importance of regular blood glucose testing was also discussed, and it was agreed

FIGURE Consensus algorithm for initiation and adjustment of insulin regimens⁴⁰

A1C, glycated hemoglobin; BG, blood glucose; NPH, neutral protamine Hagedorn. Nathan DM, et al. Adapted with permission from Nathan DM, et al. Medical management of hyperglycemia in type 2 diabetes: A consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care*. 2009;32(1):193-203. © 2009 American Diabetes Association and Springer.

that the patient should carry out 4 fingerstick tests per day. Goals were set for fasting blood glucose levels and 2-hour postprandial blood glucose; the patient also was given correction insulin for use with his rapid-acting insulin. He was instructed to telephone or visit the practice in approximately 2–3 days to report on his insulin use and blood glucose levels.

Significant time was allocated to the importance of diet and exercise, with the patient's wife particularly involved in issues of meal planning and portion control. Literature was provided relating to the 2000-calorie ADA diet plan and carbohydrate counting, as well as information regarding eating out at restaurants. A formal exercise prescription was given,

with a suggested daily walk of 45–60 minutes. The benefits of exercise on the patient's blood glucose level were also explained, including the impact on insulin dosage. Formal goals were set regarding weight loss over a 3-, 6-, and 12-month period. Once the patient felt comfortable with all aspects of his care, the long-term consequences of uncontrolled diabetes were discussed in detail.

Shortly after his visit, the patient phoned to report his morning blood glucose level; his long-acting insulin dose was then adjusted accordingly in order to obtain blood glucose levels less than 120 mg/dL. Our general rule is to add 3 units of basal insulin every 3 days until the average blood glucose is less than 120 mg/dL; however, the treatment plan is also adjusted according to individual circumstances. In this case, adjustments were made every 3–4 days, following which his blood glucose levels were reduced. The patient was very animated about his improved glucose control and this motivated him to read about the importance of diet and exercise—he is now following a proper meal plan and walking on a regular basis.

The longer duration of patient appointments with boutique medicine was important to provide reassurance about the importance of the selected therapeutic regimen, as well as education and clinical teaching. Boutique medicine was also crucial for continued communication with the patient to maintain outcomes. The patient in this case study continues to call with or fax his blood glucose levels, which have been remarkably lowered.

The future of boutique medicine

Reactions to the use of boutique medicine have been mixed. Physicians and public health advocates who are skeptical about boutique medicine claim that selective patient care will exaggerate class distinctions by reducing resources available to the uninsured and underinsured, while accentuating the shift of best care to the privileged few.²⁴ Boutique practices are limited in the number of patients that they can enroll in order to ensure that they are able to deliver the promised level of care, and this, in turn, has the potential to increase the patient load in managed practices. Ethical concerns have also been voiced regarding a two-tiered system of medicine based on willingness and ability to pay.²⁵ In response to this, the American Medical Association has established guidelines for boutique medicine and highlighted that “Retainer contracts...to patients who pay additional fees distinct from the cost of medical care, are consistent with pluralism in the delivery and financing of health care.”²⁶ Moreover, the benefits for those involved in boutique medicine suggest an optimistic future for this health care approach. A reduced patient load for physicians often translates into longer and same-day appointments, exten-

sive preventive visits, better coordination with specialists, and more follow-up, as well as greater emphasis on wellness care.

Conclusions

With the pressures of increased patient numbers and diminishing financial support in standard primary practice, boutique medicine is an alternative health care approach that continues to grow in popularity. For patients with diabetes, PCPs should be able to forge a collaborative relationship with the aim of ensuring that patients are aware of their condition and of the treatment options available to them. In particular, boutique medicine PCPs can spend significantly more time with patients with diabetes discussing treatment options, side effects of medications, and the importance of self-management. Enhanced preventive services in the boutique medicine setting may also allow appropriate provision of support and counseling in order to forestall the progression and complications associated with T2DM. ■

REFERENCES

1. International Diabetes Federation. Diabetes facts. <http://www.idf.org/>. Accessed March 11, 2011.
2. Dearinger AT, Wilson JE, Griffith CH, Scutchfield FD. The effect of physician continuity on diabetic outcomes in a resident continuity clinic. *J Gen Intern Med.* 2008;23(7):937-941.
3. Griffin S. Diabetes care in general practice: meta-analysis of randomised control trials. *BMJ.* 1998;317(7155):390-396.
4. Grant RW, Pirraglia PA, Meigs JB, Singer DE. Trends in complexity of diabetes care in the United States from 1991 to 2000. *Arch Intern Med.* 2004;164(10):1134-1139.
5. Rutter C. A brief history of concierge medicine. <http://www.aapp.org/a-brief-history-of-concierge-medicine/>. Accessed March 11, 2011.
6. American Academy of Private Physicians. <http://www.aapp.org/>. Accessed March 11, 2011.
7. MDVIP. <http://www.mdvip.com/patient/default.aspx>. Accessed March 11, 2011.
8. Canadian Task Force on the Periodic Health Examination. The periodic health examination. *CMAJ.* 1979;121:1193-1254.
9. US Preventive Services Task Force. Guide to Clinical Preventive Services: Report of the Preventive Services Task Force. 2nd ed. Baltimore, MD: Williams & Wilkins; 1996.
10. Prochazka AV, Lundahl K, Pearson W, Oboler SK, Anderson RJ. Support of evidence-based guidelines for the annual physical examination. *Arch Intern Med.* 2005;165:1347-1352.
11. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med.* 1993;329(14):977-986.
12. UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). *Lancet.* 1998;352(9131):854-865.
13. Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospective 6-year study. *Diabetes Res Clin Pract.* 1995;28(2):103-117.
14. American Diabetes Association. Standards of medical care in diabetes—2011. *Diabetes Care.* 2011;34(suppl 1):S11-S61.
15. Rodbard HW, Blonde L, Braithwaite SS, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the management of diabetes mellitus. *Endocr Pract.* 2007;13(suppl 1):1-68.
16. Ford ES, Li C, Little RR, Mokdad AH. Trends in A1C concentrations among U.S. adults with diagnosed diabetes from 1999 to 2004. *Diabetes Care.* 2008;31(1):102-104.
17. Hoerger TJ, Segel JE, Gregg EW, Saaddine JB. Is glycemic control improving in U.S. adults? *Diabetes Care.* 2008;31(1):81-86.
18. Brown JB, Nichols GA. Slow response to loss of glycemic control in type 2 diabetes mellitus. *Am J Manag Care.* 2003;9(3):213-217.
19. Brown JB, Nichols GA, Perry A. The burden of treatment failure in type 2 diabetes. *Diabetes Care.* 2004;27(7):1535-1540.

20. Nichols GA, Koo YH, Shah SN. Delay of insulin addition to oral combination therapy despite inadequate glycemic control: delay of insulin therapy. *J Gen Intern Med.* 2007;22(4):453-458.
21. Peyrot M, Rubin RR, Lauritzen T, et al. Patient and provider perceptions of care for diabetes: results of the cross-national DAWN Study. *Diabetologia.* 2006;49(2):279-288.
22. Peyrot M, Rubin RR, Lauritzen T, et al. Resistance to insulin therapy among patients and providers: results of the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) study. *Diabetes Care.* 2005;28(11):2673-2679.
23. Rubin RR, Peyrot M, Siminerio LM. Health care and patient-reported outcomes: results of the cross-national Diabetes Attitudes, Wishes and Needs (DAWN) study. *Diabetes Care.* 2006;29(6):1249-1255.
24. Reinhardt UE. "Boutique medicine" in the US. Doctors are more interested in having high incomes than providing better health care. *BMJ.* 2002;324(7349):1335.
25. Carroll J. Concierge care by any name raises ethical concerns. *Manag Care.* 2003;12(11):48-51.
26. American Medical Association. Retainer Practices. <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8055.shtml>. Accessed March 11, 2011.
27. Rodbard HW, Jellinger PS, Davidson JA, et al. Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology consensus panel on type 2 diabetes mellitus: an algorithm for glycemic control. *Endocr Pract.* 2009;15(6):540-559.
28. Levemir (insulin detemir). Prescribing information. Princeton, NJ: Novo Nordisk Inc.
29. Lantus (insulin glargine). Prescribing information. Bridgewater, NJ: sanofi-aventis U.S. LLC.
30. Humalog (insulin lispro). Prescribing information. Indianapolis, IN: Eli Lilly and Company.
31. NovoLog (insulin aspart). Prescribing information. Princeton, NJ: Novo Nordisk Inc.
32. Apidra (insulin glulisine). Prescribing information. Bridgewater, NJ: sanofi-aventis U.S. LLC.
33. Korytkowski M, Bell D, Jacobsen C, Suwannasari R. A multicenter, randomized, open-label, comparative, two-period crossover trial of preference, efficacy, and safety profiles of a prefilled, disposable pen and conventional vial/syringe for insulin injection in patients with type 1 or 2 diabetes mellitus. *Clin Ther.* 2003;25(11):2836-2848.
34. Rex J, Jensen KH, Lawton SA. A review of 20 years' experience with the NovoPen family of insulin injection devices. *Clin Drug Investig.* 2006;26(7):367-401.
35. Summers KH, Szeinbach SL, Lenox SM. Preference for insulin delivery systems among current insulin users and nonusers. *Clin Ther.* 2004;26(9):1498-1505.
36. Graff MR, McClanahan MA. Assessment by patients with diabetes mellitus of two insulin pen delivery systems versus a vial and syringe. *Clin Ther.* 1998;20(3):486-496.
37. Hornquist JO, Wikby A, Andersson PO, Dufva AM. Insulin-pen treatment, quality of life and metabolic control: retrospective intra-group evaluations. *Diabetes Res Clin Pract.* 1990;10(3):221-230.
38. Lee IT, Liu HC, Liau YJ, Lee WJ, Huang CN, Sheu WH. Improvement in health-related quality of life, independent of fasting glucose concentration, via insulin pen device in diabetic patients. *J Eval Clin Pract.* 2009;15(4):699-703.
39. Marcus A. Diabetes care—insulin delivery in a changing world. *Medscape J Med.* 2008;10(5):120.
40. Nathan DM, Buse JB, Davidson MB, et al. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care.* 2009;32(1):193-203.

Nontraditional or noncentralized models of diabetes care: Models in which other HCPs take on a leading role in managing patients' diabetes

K.C. Arnold, ANP, BC-ADM

TAKE-HOME POINTS

- Nurse practitioners (NPs) are advanced-practice nurses who have increased responsibility, such as prescribing authority
- In the NP-led model, the NP is the primary care provider for clinic patients and takes on an autonomous role in patient management
 - In some states, NP-led clinics are required to have a supervising or collaborating physician
- There is evidence that NP-led and physician-led primary care is comparable for multiple health outcomes
- The NP-led model emphasizes the strong interaction between health care provider and patient
- Challenges of NP-led care include physician resistance, legal restrictions, inaccessibility and cost of malpractice insurance, and limited payouts from insurance companies

K.C. Arnold, ANP, BC-ADM, has served on speaker bureaus for Eli Lilly, Medtronic, sanofi-aventis, and Novo Nordisk Inc.

Introduction

Based on patient and health care industry needs, the role of nurse practitioners (NPs) in patient care and disease management has expanded over the past 50 years. This professional category was developed in response to a physician shortage in the mid-1960s, with the first NPs certified in 1965.^{1,2} NPs first worked within pediatric settings and were gradually given increased authority over illness diagnosis and management.² As early as 1971, United States (US) federal policy began to include recommendations for shared responsibility between physicians and nurses in primary care settings.² The American Academy of Nurse Practitioners was formed in 1985, and in 1993 released its first set of standards.^{2,3}

The US is facing a potential shortage of primary care and general practice physicians. In particular, more practitioners are needed to address chronic conditions, which often require longer clinic visits and ongoing follow-up.⁴ It is also anticipated that the recently enacted Patient Protection and Affordable Care Act (PPACA) will improve health care access for many Americans and further increase demand for health care services.⁵ According to the Association of American Medical Colleges (AAMC), by 2015 the primary care pool will lack more than 20,000 needed physicians.⁶ This shortage can, in part, be addressed by the use of NP-led services.⁴ In fact, \$30 million in PPACA funding has been dedicated to training at least 600 new NPs, and an additional \$15 million has been allotted to establish 10 new nurse-managed health clinics, which will also assist in the training of NPs.⁶

These developments are not surprising, as the past 20 years have seen a substantial increase in the number of advanced practice nurses (APNs) and NPs, as well as an increased number of specialization areas available for these health care professionals. During the health care reform negotiations conducted in the 1990s, a need was identified for increased health care service providers; during that time, academic programs for NPs flourished.² At the same time, the US diabetes epidemic was identified as a major public health concern. In response, in 2000, the American Nurses Credentialing Center partnered with other leading experts (such as the American Association of Diabetes Educators and the American Diabetes Association) to create the Board Certified-Advanced Diabetes Management (BC-ADM) credential, a new certification for diabetes educators.¹ This specialization allows NPs and APNs to fill more specialized disease management roles.

This article discusses the evolving role of the NP within the context of NP-led diabetes clinics. Specifically, it describes my experience in opening and operating The Diabetes Center (TDC), in Ocean Springs, Mississippi. The decision to open the clinic stemmed from necessity rather than ambi-

tion, but our success has been substantial. It is hoped that this experience may provide some guidance to NPs who are considering opening their own NP-led clinics.

The nurse practitioner-led model

Overview

APNs are registered nurses (RNs) with extended education and expertise. The exact definition of, and qualifications for, APNs vary by state, but in general APNs perform more advanced roles than RNs in areas such as patient diagnosis and disease management. NPs are advanced APNs who hold a master's degree and have increased responsibility, such as prescribing authority.^{1,7} Different states have their own educational and certification requirements for APNs and NPs.⁸ Additionally, several states restrict the authority of NPs to prescribe controlled substances. A summary of prescribing regulations for NPs in the US, as well as a link to online state-by-state information, can be found in **TABLE 1**.⁹

Regardless of setting, the NP in a diabetes clinic plays an integral role in providing education for patients with newly diagnosed diabetes, as well as support during transitional periods (eg, medication changes). NPs are involved in patient education and safety, treatment decision-making, medication titration or adjustment, self-care promotion, development of individualized care strategies, acquisition of physical skills, and the provision of psychological support.¹⁰ In the most immediate sense, NPs who specialize in diabetes help patients adapt to self-care requirements; this is particularly the case for patients who are learning to integrate daily glucose monitoring and/or insulin injections into their lifestyle (for an example of how a patient transitioning to insulin therapy might be managed at TDC, see **CASE STUDY**). The services provided by NPs are essential for patients who find themselves needing to learn

multiple, new practical skills, and to assume the responsibilities associated with managing a lifelong disease.

CASE STUDY ▶ A 62-year-old female weighing 73 kg (161 lb), with a body mass index of 29.7 kg/m², and glycosylated hemoglobin (A1C) of 9.2% is a new patient. She is currently on metformin 1000 mg twice daily and pioglitazone 15 mg once daily. Because of her poor A1C control despite dual oral medications, we decided to start her on basal insulin, using a long-acting insulin analog.

As a first step, the patient was asked about insurance coverage; some payer formularies only approve insulin glargine, while others only allow for insulin detemir. In this patient's case, we decided to move forward using insulin glargine. She was started on 10 units administered each night before bedtime, and was instructed to send TDC her weekly blood glucose readings (fasting and postprandial) over our secure email access system.

The patient was asked to inject insulin for a 2-week trial period; after this point, it would be determined if other treatment decisions would be necessary. Based on her reported fasting plasma glucose readings, each week her insulin dose could subsequently be adjusted by as many as 2–4 units per day.

The NP wrote this patient's insulin prescription. Then, another nurse instructed the patient on how to administer injections, perform blood glucose testing, and download glucometer results. At this time, the patient was offered access to the clinic's educational classes, such as a 1.5-hour session providing an overview of diabetes (offered twice monthly), or a carbohydrate-counting class. Before leaving the clinic that day, her appointments were made for these classes, and she was asked to set up a follow-up appointment in 2 weeks.

TABLE 1 Summary of prescribing regulations for nurse practitioners in the United States

General principles applicable in all US states and the District of Columbia⁹

- It is assumed that every prescription will include the standard information expected from all authorized prescribers, such as the prescriber's name, title, license/specialty, ID/Rx number as applicable, practice address, and phone number; the patient's name; the date of the prescription; and the name of the drug, strength, dosage, route, specific directions, quantity, number of refills, and instructions regarding generic substitution.
 - For a state-by-state summary of specified elements of a written prescription beyond the standard requirements, see Byrne (2010),⁹ available at <http://www.medscape.com/viewarticle/440315>.
- The co-signature of a collaborating physician is not required in any state on any prescription that an NP is authorized to write.

Controlled substances⁹

- Several states restrict the authority of NPs to prescribe controlled substances. For a state-by-state summary, see Byrne (2010),⁹ available at <http://www.medscape.com/viewarticle/440315>.
- In states that allow NPs to prescribe controlled substances, any prescription written for a controlled substance will include the NP prescriber's federal US Drug Enforcement Administration number, denoting the NP's independent or plenary authority to prescribe in accordance with state scope of practice.

Following insulin initiation, we would expect to see this patient's fasting glucose levels decrease within several weeks. We would also monitor her submitted postprandial glucose levels. At the 2-week follow-up, the NP would review her progress and assess which meals were most affected by her new treatment. For example, if she presented with high glucose levels before lunch, a premeal injection of prandial insulin would be added at this time of day.

After this, unless new issues or concerns arose, the patient would not need to return to the clinic for 3 months. At our NP-led diabetes center, it is our philosophy that it is best for patients, and for the NPs, to make swift and sure transitions to new medications. Because our patient volume is high, we cannot schedule frequent visits for insulin adjustments. However, we would continue to closely monitor this patient's blood glucose readings via email, fax, or downloading of glucometer data, and would advise her to come to the clinic when medically necessary.

Prior to August 2005, I worked at a satellite diabetes care clinic with 2 endocrinologists and a second NP. When the clinic closed, in the wake of Hurricane Katrina, I opened an NP-led diabetes center to address the gap in services left by this closure. As the state of Mississippi requires a collaborating physician, TDC recruited medical providers to work with me. In our experience, it is extremely important to have multiple providers as collaborators; that way, if a physician's situation changes, and he or she can no longer act as the collaborator, the clinic can continue to deliver seamless care to patients. TDC first recruited an internal medicine nephrologist, and within 2 weeks, 3 more physicians agreed to collaborate. Approximately 2 years after opening the clinic, TDC established a collaborative relationship with a local endocrinologist.

Organizational structure

In general, patients receive the same level of care in an NP-led clinic as in a physician-based model.^{11,12} At the outset, there is an understanding that patients will entrust the NP with most of their day-to-day management, as no physicians are on-site. This means that NPs are involved in every level of clinic management, including governance, which gives NPs the chance to take on leadership roles.¹³ Laws regarding physician involvement vary by state; in some cases, NP-led clinics are required to have a supervising or collaborating physician, who may be involved in a range of clinic activities, such as consultation on treatment decisions, systematic chart reviews, and/or direct, on-the-job performance evaluation. In some states, however, no physician involvement is necessary.⁸ A key difference between NP-led and traditional clinic settings is the level of expected patient involvement in

his or her care. Compared with more traditional models, NP-led clinics are more focused on actively recruiting patients to take a proactive role in the planning, implementation, and evaluation of their diabetes management plan, and on coordinating care strategies between patients and all members of the care team.¹⁴

Coordination of care

Coordination of care requires intentional communication and collaboration between the patient and all participants (eg, diabetes educators, physicians, NPs) to maximize health care utilization for improved outcomes.¹⁵ Coordination of care has several aspects: consistent, organized care; a strong referral network; and ongoing patient contact. An initial patient visit at the NP-led diabetes center includes a comprehensive physical examination and medical history, a review of recent blood glucose data (using data from a glucometer or a continuous glucose monitoring [CGM] device), assessment of patient educational needs, and appropriate recommendations or other referrals, as needed. Once patients are established, they are asked to send blood glucose readings to us every week, which they can do via an online portal. Patients are asked at their initial visit to sign an agreement to use this online service for patient-provider communications. However, patients who do not have regular Internet access, or who prefer not to use online communication, are given the option to fax or mail in their blood glucose readings. Each reading is recorded in the patient record, which is regularly reviewed. As part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, funded by the 2009 federal stimulus bill, the clinic can receive financial incentives for using electronic health records for Medicare and Medicaid patients. In order to be eligible for these incentives, clinics must demonstrate "meaningful use" of the electronic health records system in ways that can be quantified and qualified for evaluation.¹⁶

Patient management

When opening TDC, the necessary staff requirements were assessed, based on expected patient load. The center serves an area with a 75-mile radius, and is located in a suburban area. The practice was started with a nurse and me; within a year, a receptionist and a medical assistant were hired. The clinic coordinates supplies, writes prescriptions, manages third-party authorizations, provides education, and makes referrals for kidney complications and for retinal, neuropathic, and routine wound care. TDC also provides full management of common diabetes-related comorbidities (eg, lipid levels, blood pressure). Approximately 60% of our diabetes patients have type 2 diabetes mellitus. Although patients are trained on the

use of insulin pumps and other aspects of day-to-day diabetes management, outside providers are also recruited for more in-depth education. Also, the clinic does not have the capacity to perform chronic wound management or hyperbaric medicine on a patient with a recurring foot ulcer. However, we have formed relationships with local, trusted providers to whom we can make referrals for additional care.

Just as with physician-led care, NPs consider unique patient issues and comorbidities when assessing management options for diabetes or intercurrent illnesses. During the initial intake, we collect information on each patient's lifestyle habits, as well as potential support, and barriers that may affect treatment success. We provide education on diet and food choices, exercise, and obesity. Due to the strong interaction, we are uniquely positioned to build a sustainable, long-term relationship with patients.

Providing quality care in an NP-led clinic requires hard work and a willingness to commit time. As a solo provider, I am on call 24 hours a day, 7 days a week. I also visit patients when they are hospitalized. The center is open 4.5 days a week and has roughly 20 patient openings a day, although new patients are allotted 2 time slots for their first visit, which allows appropriate time for an intake. Research indicates that patients who have a better patient-provider collaboration, including feeling satisfied with the duration of appointments and feeling heard and understood by providers, experience decreased diabetes-related stress and improved overall well-being and treatment adherence.¹⁷ At our clinic, average appointments are 30 minutes for a follow-up, and 60 minutes for a new patient, whereas research indicates that appointments with primary care physicians last on average 15–22 minutes, sometimes with as few as 5 minutes of physician talk time.^{18–20}

Business model and profitability

Our NP-led diabetes center has been open for 5 years and currently has a staff of 5. As with many businesses, the largest cost is overhead, which includes employee costs and office rental. A key business management task is to ensure that these costs are kept within a reasonable percentage of the overall income.

While there are few billable procedures in diabetes care, some insurers will reimburse for point-of-care testing performed in-office; this includes checking A1C levels and drawing blood for laboratory testing. Under the NP-led clinic business model, we can bill for patient management using evaluation and management (E&M) codes. Our team also administers and bills for retrospective CGM, which provides detailed information on patient glucose patterns over the past 72 hours. The CGM device must be inserted and removed by a

health care professional during office visits. CGM results must be interpreted by the NP to be eligible for reimbursement, but not necessarily during a patient visit. Personal CGM devices are not currently reimbursable through Medicare or Medicaid. Some private insurance plans cover both professional and personal-use CGM devices; however, policies may vary widely between payers, so it is recommended that patients and providers verify coverage prior to initiating use of CGM.²¹

We also do not bill for education performed in the clinic; however, this service is provided as a free option. We invite educators to come in and present information to patients. For example, insulin pump device representatives may come in to provide information on how to properly use specific products. In addition, whenever possible, we establish relationships with outside agencies able to provide specialized classes (eg, on carbohydrate counting). If patients request or require additional education, clinic staff can coordinate their attendance at American Diabetes Association training sessions, held at the local hospital.

Critical to profitability for any clinic, but especially challenging for NP-led clinics, is to be “in network” with as many insurers as possible. Very soon after opening our doors, we applied to the following networks—Medicare, Medicaid, TRICARE (US government military insurance), as well as all local private insurers—to become a third-party NP provider. This involved substantial background research, paperwork, and some direct negotiations. To date, a few physician-owned hospital programs have not accepted our applications, but in general our efforts have resulted in TDC being included as an in-network option for about 95% of our community members. This is a great success, and has reduced the number of patients required to pay out of pocket or out of network to a small minority.

Evaluation and comparisons of NP-led care to standards of care

NP-led health care has been evaluated for nearly as long as it has been practiced. In general, findings indicate parity of care between physician- and NP-led clinics. In 1974, results from the Burlington Trial were published. Conducted in Ontario, Canada, the Burlington Trial was a landmark randomized controlled trial (RCT) evaluating health outcomes of patients receiving care primarily from NPs, as compared with patients receiving care primarily from physicians.²⁰ No differences were found in mortality, patient satisfaction, quality of care, and patient physical, social, and emotional function. However, due to reimbursement restrictions, NP-led care was not cost-effective at that time.^{22,23}

Since the completion of the Burlington Trial, a growing body of evidence supports NP-led health care as a practical

alternative to physician-led care. A large-scale RCT completed between 1995 and 1997 assigned more than 1300 patients to either NP- or physician-led care.¹¹ After the initial visit, patients in both groups reported similar satisfaction with their care. After 6 months, patient interviews revealed no significant differences between the 2 groups in terms of diabetes, asthma, or psychological outcomes. Although more time may be required to fully evaluate long-term patient satisfaction and disease progression, patients who had received care at an NP-led clinic had lower diastolic blood pressure than patients who had received care at a physician-led clinic (82 mm Hg and 85 mm Hg, respectively; $P=.04$). The mean satisfaction score (on a scale of 5, where 5 = excellent) for NP-led clinics was 4.1, compared with a mean score of 4.2 for physician-led clinics ($P=.05$). At 1-year follow-up, no between-group differences were found in health care utilization; furthermore, the utilization of emergency services had decreased and utilization of primary care had increased for both groups.¹¹

At the clinic level, strategies to evaluate clinic operations and outcomes should be built into any new business plan. However, when running a clinic, it is sometimes necessary to be creative when identifying comparison data to hold up against your outcomes. In our case, the Mississippi State Department of Health does not track A1C control or other markers of diabetes management among state residents.²⁴ For a comparator, we selected a nearby state with a similar diabetes rate, Texas. Diabetes prevalence in Texas is only slightly lower than in Mississippi (9.8% and 10.9% age-adjusted prevalence in 2009, respectively).^{25,26} Additionally, age-adjusted diabetes incidence in the 2 states is similar, with Texas again having a lower rate than Mississippi (10.6% [in 2009] vs 11.3% [in 2007], respectively).^{27,28} Texas reports diabetes statistics gathered through the Healthcare Effectiveness Data and Information Set (HEDIS). HEDIS does not report average A1C levels for patients with diabetes, but does report the percentage of patients with A1C >9.0%. **TABLE 2** shows 2009 data from TDC for this value, as well as blood pressure and low-density-lipoprotein cholesterol targets, compared with 2009 diabetes outcomes for Texas and the US overall.²⁹ While not purporting to provide a scientific evaluation, these numbers do indicate that our patients benefit from the care they receive in this NP-led diabetes center.

Reasons for success and key challenges

Existing literature indicates that certain elements unique to NP-led care may result in improved patient

outcomes—for example, improved self-care and increased diabetes knowledge.¹⁰ A review of 22 trials on NP-led diabetes care also found that patients improved their glycemic control.¹⁰ Nine studies (8 RCTs and 1 quasi-experimental trial [using a one-group pretest-posttest design]) that incorporated aspects of NP-led care (ie, increased patient education, frequent contact with specialists, self-managed care) found improved A1C values for the intervention groups compared with standard care or baseline values. In addition, 1 RCT in which patients received increased diabetes education and 1 RCT in which patients had continual contact with diabetes specialists on a weekly basis both resulted in shorter lengths of hospital stay for patients in the intervention groups.¹⁰ These findings are supported by recent research: a retrospective, observational study evaluating an NP-led glucose management service (GMS) team found that, after 6 months of providing GMS to patients with high A1C levels following a hospitalization, patients had slightly lower A1C values (average glucose = 158.35 mg/dL) compared with patients who did not receive GMS care (average glucose = 161.80 mg/dL).³⁰ In addition, fewer patients in the GMS group vs the non-GMS group were rehospitalized within 3 months (29.6% vs 36.5%, respectively). The improved A1C findings were of particular interest considering that patients were originally referred to GMS care because of poor glucose control. These results did not reach statistical significance, however; this was probably due to the small sample size ($n=27$ and $n=85$ for patients who did and did not receive GMS care, respectively).³⁰

Successes such as these may be, at least in part, due to the individual attention that patients receive in a nurse-led environment. The Diabetes Attitudes, Wishes, and Needs (DAWN) study, an international, cross-sectional survey of both patients and providers, found that nurses spent more time with patients, provided more support and education to patients and their families, and were more likely to encourage patient involvement in treatment than physicians.³⁰ Furthermore, nurses who were also diabetes specialists were more likely to talk to patients about self-management and medica-

TABLE 2 Key diabetes control parameters of patients at The Diabetes Center, in Texas, and in the United States overall, 2009

Parameter	Patients (%)		
	The Diabetes Center	Texas ^a	United States ^a
A1C >9%	24.0%	56.0%	28.4%
Blood pressure <130/80 mm Hg	51.4%	28.7%	33.4%
LDL cholesterol <100 mg/dL	53.7%	30.5%	45.5%

A1C, glycated hemoglobin; LDL, low-density lipoprotein.

^aHealthcare Effectiveness Data and Information Set (HEDIS) data for Texas and the United States overall.²⁹

Resources available to advanced practice nurses and nurse practitioners who are interested in starting a nurse-led diabetes clinic

- *Advance for NPs & PAs*, online: <http://nurse-practitioners-and-physician-assistants.advanceweb.com>.
- Buppert C. *Nurse Practitioner's Business Practice and Legal Guide*. 4th ed. Sudbury, MA: Jones and Bartlett Publishers; 2011.
- National Nursing Centers Consortium (NNCC). This organization's mission is: "To advance nurse-led health care through policy, consultation, programs and applied research to reduce health disparities and meet people's primary care and wellness needs." They also have a nationwide listing of 125 NP-led care centers: <http://www.nncc.us/site/>.
- NP Central, in Kent, WA. This website has a list of NP-related professional and peer-reviewed journals: <http://www.npcentral.net/journals/>.
- Nurse Entrepreneur Network provides business solutions for nurse entrepreneurs, available online: <http://www.nurse-entrepreneur-network.com>. The Web site offers a free "nursepreneur tip of the week" email; past tips are archived.
- Nurse Practitioner Business Owner, online: <http://www.nursepractitionerbusinessowner.com>.
- *Practice Management: A Business Guide for Nurse Practitioners*, online magazine: <http://www.nppracticemgt.com>.
- Zaumeyer CR. *How to Start an Independent Practice: The Nurse Practitioner's Guide to Success*. Philadelphia, PA: FA Davis Company; 2003.

tions, and were more willing to take on extra responsibilities compared with nonspecialist nurses.^{17,31,32}

As with any health care service, however, running and managing an NP-led clinic is not without its challenges. It is not uncommon for NPs to encounter barriers to care, including physician resistance, legal restrictions, and inaccessibility and cost of malpractice insurance, as well as limited payouts from insurance companies.³³ Prior to any new undertaking, it is important to research state-level laws regarding NP-led clinics. Additionally, although NPs have prescribing authority in all 50 states, rules regarding what information must be included on a prescription written by an NP vary from state to state (for a summary of these regulations, see Byrne [2010],⁹ available at <http://www.medscape.com/viewarticle/440315>). Other useful resources related to NP prescribing laws may be found through the National Council of State Boards of Nursing (www.ncsbn.org) and the National Association of Boards of Pharmacy (www.napb.net).

Two major challenges that we have encountered include difficulties with payers and referrals. While TDC has successfully applied for in-network status with many payers, the process of becoming approved was sometimes a struggle, and some payers still refuse to cover services at an NP-led clinic. This is a barrier that affects patients directly, and one that can only be remedied with inclusive legislative changes. Whether patients require referrals to attend clinic is another important, upfront consideration. While patients seen at endocrine clinics are often required to have referrals, at TDC, patients do not need to present with a referral unless a particular insurance company requires one for coverage. Our current policy is that patients must provide a physician's referral only in cases where it is required by their insurer (eg, TRICARE Prime military benefits).

Conclusions

In October 2011, the Robert Wood Johnson Foundation Initiative on the Future of Nursing at the Institute of Medicine released *The Future of Nursing: Leading Change, Advancing Health*, a 700-page consensus statement with action-oriented recommendations for the nursing profession.⁵ This report emphasized the role nurses can play in bridging access to care to meet anticipated increased demand for health care services. In line with NP-led clinics, key messages of the report supported nurses practicing to the full extent of their ability, and, importantly, noted that nurses should be considered equal partners with physicians in offering health care during this period of systematic reform.⁵ Backed by evidence of outcomes as being equal, and at times superior, to those of physician-led clinics, NP-led clinics are a necessary tool for improving access to care and overall population health.

Clinics that run on the NP-led model will differ depending on both community needs and the staff and resources available. However, we know that a supportive, patient-centered approach that encourages participation, education, and empowerment is likely to increase patients' engagement in their diabetes management and lead to improved outcomes.^{34,35} At TDC, we consider the patient experience to be the core of our practice; specifically, we have shifted the clinical focus from what the provider can do for patients, to what patients can do for their own diabetes management. Successful diabetes management depends on the daily activities and choices made by the patient; I see myself essentially as a coach, helping patients reach their own diabetes care goals.

At the core of the NP-led model is the understanding that the NP is the primary care provider for clinic patients and will take on an autonomous role in patient management, including the prescribing of medications. If additional medical

guidance is needed, clinic staff members have access to the collaborating physician. However, compared with traditional practice, NPs are able to devote more time to individual patients and are trained to coordinate the provision of direct care, with opportunities for additional education. In my practice, technology also plays an integral role. The downloading of data and integration of weekly glucose readings into patient care allows us to track patients at an intensive level.

At the 5-year mark, our clinic is expanding. Having outgrown the single center, we are preparing to expand by buying a second office nearby and hiring a new NP to staff it. I encourage other NPs, particularly those with full prescriptive authority, to take the initiative if they see the need, and open more patient-centered NP-led diabetes clinics. ■

REFERENCES

- Valentine V, Kulkarni K, Hinnen D. Evolving roles: from diabetes educators to advanced diabetes managers. *Diabetes Educ*. 2003;29(4):598-602.
- Sherwood GD, Brown M, Fay V, Wardell D. Defining nurse practitioner scope of practice: Expanding primary care services. *Internet J Advanced Nursing Practice*. 1997;1(2).
- American Academy of Nurse Practitioners. About AANP. <http://www.aanp.org/AANPCMS2/AboutAANP>. Accessed March 20, 2011.
- Cooper RA. Weighing the evidence for expanding physician supply. *Ann Intern Med*. 2004;141(9):705-714.
- IOM (Institute of Medicine). *The Future of Nursing: Leading Change, Advancing Health*. Washington, DC: The National Academies Press; 2011.
- US Department of Health and Human Services. Fact Sheet: Creating Jobs and Increasing the Number of Primary Care Providers. 2010. <http://www.healthreform.gov/newsroom/primarycareworkforce.html>. Accessed March 22, 2011.
- American Academy of Nurse Practitioners. Position statement on nurse practitioner curriculum. 2010. <http://www.aanp.org/AANPCMS2/AboutAANP/NPCurriculum.htm>. Accessed March 22, 2011.
- Buppert C. *Nurse Practitioner's Business Practice and Legal Guide*. Gaithersburg, MD: Aspen Publishers; 1999.
- Byrne W. US Nurse Practitioner Prescribing Law: A State-by-State Summary. Updated: November 2, 2010. <http://www.medscape.com/viewarticle/440315>. Accessed April 26, 2011.
- Carey N, Courtenay M. A review of the activity and effects of nurse-led care in diabetes. *J Clin Nurs*. 2007;16(11C):296-304.
- Mundinger MO, Kane RL, Lenz ER, et al. Primary care outcomes in patients treated by nurse practitioners or physicians: a randomized trial. *JAMA*. 2000;283(1):59-68.
- Lenz ER, Mundinger MO, Kane RL, Hopkins SC, Lin SX. Primary care outcomes in patients treated by nurse practitioners or physicians: two-year follow-up. *Med Care Res Rev*. 2004;61(3):332-351.
- Ontario leads the way. NP-led clinics. *Can Nurse*. 2010;106(9):30-35.
- Ontario Ministry of Health and Long Term Care. Nurse practitioner-led clinic guide sheets: No. 7 Business plan and operational plan. 2010. http://www.health.gov.on.ca/transformation/np_clinics/guides/np_guide_7.pdf. Accessed March 22, 2011.
- McDonald KM, Sundaram V, Bravata DM, et al. Care Coordination. Vol 7 of: Shojania KG, McDonald KM, Wachter RM, Owens DK, eds. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies*. Technical Review 9 (Prepared by the Stanford University-UCSF Evidence-based Practice Center under contract 290-02-0017). AHRQ Publication No. 04(07)-0051-7. Rockville, MD: Agency for Healthcare Research and Quality; June 2007.
- US Department of Health and Human Services. Centers for Medicare & Medicaid Services. Official Web Site for the Medicare and Medicaid Electronic Health Records (EHR) Incentive Programs. <https://www.cms.gov/ehrincentiveprograms/>. Accessed April 27, 2011.
- Rubin RR, Peyrot M, Siminerio LM. Healthcare and patient-reported outcomes: results of the cross-national Diabetes Attitudes, Wishes and Needs (DAWN) study. *Diabetes Care*. 2006;29(6):1249-1255.
- Tai-Seale M, McGuire TG, Zhang W. Time allocation in primary care office visits. *Health Serv Res*. 2007;42(5):1871-1894.
- Geraghty EM, Franks P, Kravitz RL. Primary care visit length, quality, and satisfaction for standardized patients with depression. *J Gen Intern Med*. 2007;22(12):1641-1647.
- Bensing JM, Roter DL, Hulsman RL. Communication patterns of primary care physicians in the United States and the Netherlands. *J Gen Intern Med*. 2003;18(5):335-342.
- Harrell RM, Orzcek EA. Coding guidelines for continuous glucose monitoring. *Endocr Pract*. 2010;16(2):151-154.
- Sackett DL. A landmark randomized healthcare trial: the Burlington Trial of the nurse practitioner. *J Clin Epidemiol*. 2009;62(6):567-570.
- Sackett DL, Spitzer WO, Gent M, Roberts RS. The Burlington randomized trial of the nurse practitioner: health outcomes of patients. *Ann Intern Med*. 1974;80(2):137-142.
- Mississippi State Department of Health. Reportable Disease Statistics. http://msdh.ms.gov/msdhsite/_static/29,0,261.html. Accessed March 24, 2011.
- US Centers for Disease Control and Prevention. Texas—Percentage of Adults with Diagnosed Diabetes, 1994-2009. <http://apps.nccd.cdc.gov/DDTSTRS/Index.aspx?stateId=48&state=Texas&cat=prevalence&Data=data&view=TO&trend=prevalence&id=1>. Accessed March 25, 2011.
- US Centers for Disease Control and Prevention. Mississippi—Percentage of Adults with Diagnosed Diabetes, 1994-2009. <http://apps.nccd.cdc.gov/DDTSTRS/Index.aspx?stateId=28&state=Mississippi&cat=prevalence&Data=data&view=TO&trend=prevalence&id=1>. Accessed March 25, 2011.
- US Centers for Disease Control and Prevention. Texas—Rate of New Cases of Diagnosed Diabetes per 1000 Adults, 1996-2009. <http://apps.nccd.cdc.gov/DDTSTRS/Index.aspx?stateId=48&state=Texas&cat=prevalence&Data=data&view=TO&trend=prevalence&id=1&ext=incidence>. Accessed March 25, 2011.
- US Centers for Disease Control and Prevention. Mississippi—Rate of New Cases of Diagnosed Diabetes per 1000 Adults, 1996-2009. <http://apps.nccd.cdc.gov/DDTSTRS/Index.aspx?stateId=28&state=Mississippi&cat=prevalence&Data=data&view=TO&trend=prevalence&id=1&ext=incidence>. Accessed March 25, 2011.
- State of Texas Office of Public Insurance Counsel and the Department of State Health Services Center for Health Statistics. Guide to Texas HMO quality: 2009. <http://www.dshs.state.tx.us/thcic/publications/HMOs/HMORports.shtm>. Accessed March 24, 2011.
- Comi RJ, Jacoby J, Basta D, Wood M, Butterly J. Improving glucose management by redesigning the care of diabetes inpatients using a nurse practitioner service. *Clin Diabetes*. 2009;27(2):78-81.
- Siminerio LM, Funnell MM, Peyrot M, Rubin RR. US nurses' perceptions of their role in diabetes care: results of the cross-national Diabetes Attitudes Wishes and Needs (DAWN) study. *Diabetes Educ*. 2007;33(1):152-162.
- Siminerio LM. Overcoming barriers to better health outcomes in patients with diabetes: Improving and balancing patient education and pharmacotherapy initiation. *US Endocrinology*. 2008;4(2):42-44.
- US Congress, Office of Technology Assessment. Nurse Practitioners, Physician Assistants, and Certified Nurse-Midwives: A Policy Analysis (Health Technology Case Study 37). OTA-HCS-37. Washington, DC: US Government Printing Office; December 1986.
- van Dam HA, van der Horst F, van den Borne B, Ryckman R, Crebolder H. Provider-patient interaction in diabetes care: effects on patient self-care and outcomes. A systematic review. *Patient Educ Couns*. 2003;51(1):17-28.
- Pagels AA, Wang M, Wengstrom Y. The impact of a nurse-led clinic on self-care ability, disease-specific knowledge, and home dialysis modality. *Nephrol Nurs J*. 2008;35(3):242-248.