Clinical Pharmacists in Outpatient Diabetes Care: Essential Members of the Multidisciplinary Team

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The American Diabetes Association (ADA), in its annual Standards of Medical Care in Diabetes, advocates a team-based approach to diabetes care, incorporating the involvement of health care professionals from various backgrounds who have expertise and interest in diabetes.[1] It is widely accepted that this physician-led team may include nurses, certified diabetes educators, and advanced practice providers such as physician assistants and nurse practitioners.

Since 2003,[2] ADA has included pharmacists in the list of potential diabetes care team members. There is an increasing number of pharmacists involved in the direct care of patients with diabetes in the outpatient environment, as evidenced by the emerging body of literature on the subject.[3–5] This article describes one such practice site.

Background

The University of North Carolina (UNC) Hospitals' endocrine clinic has long provided specialized care to patients with diabetes, including the clinical services of approximately nine attending physicians, four endocrine fellow physicians, one physician assistant, two diabetes educators (both of whom are also registered dietitians), two registered nurses, four certified medical/nursing assistants, and a large clinical trials group. In early 2009, the clinic created a position for a clinical pharmacist to be added to this extensive care team. Since then, the position has grown to include two clinical pharmacists (each of whom sees patients on a part-time basis), as well as pharmacy residents and students who rotate through the site.

At the time the clinical pharmacist position was created, there was limited understanding on the part of the physicians, mid-level providers, clinic staff, and patients regarding the role of a clinical pharmacist. Much time was initially spent educating providers and staff about the educational background, post-graduate training, and certifications that allow pharmacists to operate in their unique role. This introductory period also included significant amounts of face time between the physicians and mid-level providers and the clinical pharmacist, allowing the providers to become more comfortable with the pharmacist's level of competence and clinical knowledge. The introductory time also allowed for development of clinical protocols that could be used to guide the clinical pharmacist in practice as a mid-level provider. Figure 1 provides an example.

North Carolina legislation

A unique aspect of this practice is the clinical pharmacist's ability to practice as a mid-level practitioner. In 2001, the North Carolina Boards of Medicine and Pharmacy adopted legislation allowing pharmacists with certain levels of education, training, and experience to apply for clinical pharmacist practitioner (CPP) status. A CPP is defined as "a licensed pharmacist who is approved to provide drug therapy management, . . . under the supervision of a licensed physician, . . . which may include ordering, changing, substituting therapies or ordering tests."[6] At the UNC Hospitals' endocrine clinic, the CPPs' primary role is to serve as providers of interim care, with the goal of helping patients to reach therapeutic goals sooner than what would otherwise be attained with the usual quarterly visit schedule.

It should be noted that, although the CPP legislation in North Carolina affords a level of independence and prescriptive authority, this type of collaborative drug therapy management legislation is not vital to pharmacist presence and success in the outpatient management of patients with diabetes. In states that do not allow pharmacist provision of collaborative drug therapy management services, many pharmacists are successfully providing services similar to the ones described here.

Health system–specific provider privileges

CPPs at UNC undergo a credentialing process through the School of Medicine that is similar to the other allied health professionals within the institution. This provides CPPs with a health system provider identification number, which allows for creation of CPP-specific visit scheduling templates and laboratory ordering privileges. Similarly, CPPs docu-

CLINICAL PHARMACIST PRACTITIONER PROTOCOL

Supervising physician: John Smith, MD

Clinical Pharmacist Practitioner: Jane Doe, PharmD

The following protocol summarizes medication and laboratory prescribing privileges granted to Jane Doe, PharmD, by John Smith, MD, for patients of the UNC Hospitals Endocrine Specialty Clinic.

Patients seen at the UNC Hospitals Endocrine Specialty Clinic by John Smith, MD, or another attending physician may be referred to the Clinical Pharmacist Practitioner for drug therapy management of medical conditions including the following, with medication therapy as outlined below.

Diagnosis	**ICD-9 code**
Diabetes	250.0-250.8
Hyperlipidemia	272.0, 272.1, 272.4
Hypertension	401.1, 401.9
Hypothyroidism	243, 244.0, 244.1, 244.8, 244.9
Osteoporosis	733.00
Thyroid hormone overproduction	242.8
Tobacco use disorder	305.1

Medication Therapy
Medications authorized by John Smith, MD, for written or telephone prescription order by Jane Doe, PharmD, include the following. Medications listed below are grouped by therapeutic category.

Insulins	HMG-CoA reductase inhibitors
Sulfonylureas	Fibric acid derivatives
Thiazolidinediones	Bile acid sequestrants
Biguanides	Niacin
Alpha-glucosidase inhibitors	Omega-3 fatty acids
Meglitinides	
Dipeptidyl peptidase IV (DPP-IV) inhibitors	Levothyroxine
Amylin mimetics	Liothyronine
Incretin mimetics	Thyroid, dessicated
Tricyclic antidepressants (neuropathy therapy)	Antithyroid agents (methimazole, propylthiourac
Gabapentin (neuropathy therapy)	
Duloxetine (neuropathy therapy)	Bisphosphonates
	Calcitonin
Diuretics	Calcitriol
Beta blockers	Raloxifene
Alpha blockers	Parathyroid hormone analog (teriparatide)
ACE inhibitors/angiotensin receptor blockers	
(ARBs)	Nicotine replacement therapy
Calcium channel blockers	Partial nicotine agonist (varenicline)
Alpha 2 adrenergic agonists	Bupropion (as smoking cessation aid)
Vasodilators	

Medication dosage forms include oral, transdermal, inhaled, intranasal, and subcutaneous therapies. Dose and schedule will be determined according to standard medical, pharmacy, and drug information references (e.g., *Lexi Comp Drug Information Handbook*) as well as primary literature sources, including consensus guidelines such as those of the American Diabetes Association. The *Lexi Comp Drug Information Handbook* is updated monthly via electronic device by the Clinical Pharmacist Practitioner and will be maintained on site during clinic times.

Laboratory Tests and Monitoring
Laboratory tests that may be ordered by Jane Doe, PharmD, include the following. Laboratory evaluation will be used as a means of appropriately dosing and monitoring efficacy and safety of medication therapy.

Laboratory Test	Medication Therapy
Blood glucose	Diabetes medications
Hemoglobin A1C	Diabetes medications
Liver enzymes	Thiazolidinediones, hyperlipidemia medications
Serum electrolytes/creatinine	Diabetes medications, diuretics, ACE inhibitors/ARBs
Complete blood count	Biguanides, antithyroid agents
B_{12}	Biguanides
Folate	Biguanides
Urine microalbumin/creatinine	Diabetes medications, ACE inhibitors/ARBs
Urinalysis	Diabetes, hypertension medications
Lipid panel	Hyperlipidemia medications
Creatine phosphokinase	Hyperlipidemia medications
Apolipoprotein B	Hyperlipidemia medications
Thyroid stimulating hormone	Thyroid medications
Free or total triiodothyronine (T3)	Thyroid medications
Free or total thyroxine (T4)	Tthyroid medications
Alkaline phosphatase	Osteoporosis medications
Serum/urine calcium	Osteoporosis medications
Serum phosphorus	Osteoporosis medications
Uric acid	Osteoporosis medications
Urine/serum N- or C-telopeptide	Osteoporosis medications
Serum osteocalcin	Osteoporosis medications
Serum PINP/PICP	Osteoporosis medications
Bone mineral density (DXA)	Osteoporosis medications

Emergency Plan
Medical emergencies will be handled following UNC Hospitals Endocrine Specialty Clinic procedures for such situations. In the event of a cardiopulmonary arrest, cardiopulmonary resuscitation will be initiated while office staff calls 911.

Consultation and Supervision
Physician consultation will be sought by the Clinical Pharmacist Practitioner for all of the following situations as well as any other deemed appropriate.

- Any situation that extends beyond the intent of the protocols, scope of practice, or experience level of the Clinical Pharmacist Practitioner
- A patient's condition fails to respond to the management plan in an appropriate time frame
- Any uncommon, unfamiliar, or unstable patient condition is encountered
- Any condition that does not fit the commonly accepted diagnostic pattern for a disease/condition
- All emergency situations (after initial stabilizing care has been started)

Notation of the physician consultation, including the physician's name, will be made in the clinic visit note included in the patient's medical record.

Countersignature
The supervising physician (or referring attending physician) will countersign all clinic notes made by the Clinical Pharmacist Practitioner within 7 days of the visit.

Patient Notification
Patients will be notified of their referral to the Clinical Pharmacist Practitioner at the time of scheduling the appointment. The practice agreement will be explained to the patient at the beginning of the first visit with the Clinical Pharmacist Practitioner.

Termination Provision
The practice agreement will be terminated if either the Clinical Pharmacist Practitioner or the supervising physician resigns from the agreement.

Approved: _____ _____
Supervising Physician Date

_____ _____
Clinical Pharmacist Practitioner Date

Figure 1. General CPP protocol.

ment care provided in the electronic medical record in the same manner as other allied health providers; this includes clinic notes, documentation of patient phone calls, and patient mailed/e-mailed correspondence. In accordance with the CPP legislation, all clinic notes are co-signed by an attending physician.

Pharmacist Responsibilities

Clinical pharmacists' diabetes-related responsibilities at the UNC Hospitals' endocrine clinic can be divided into two primary categories: clinical care and assistance with quality improvement initiatives. Within the realm of clinical care, there are multiple aspects of the pharmacist services that are noteworthy, including interim therapy visits, patient education, adherence monitoring, health barriers assessment, and prevention screening.

Clinical care

Interim therapy visits

Interim therapy visits with a clinical pharmacist include an opportunity to review patients' blood glucose readings (via meter download and/or logbook review) and interview patients regarding their practices related to diabetes therapies, blood glucose monitoring, diet, and exercise. The clinical pharmacists use this information to identify areas in which therapy modifications would be appropriate. As the CPP legislation allows, the pharmacists are able to provide prescriptions reflecting therapy modifications, order laboratory tests where appropriate, and determine the need for follow-up. In this practice, patients are often seen by a clinical pharmacist on multiple occasions between visits with their medical provider.

Patient education

As a part of any diabetes program, a focus on patient education is key. The clinical pharmacists spend time during each visit assessing patients' specific educational needs and tailoring the therapeutic approach to patients' concerns and abilities. Additionally, outside of scheduled visits, the clinical pharmacists are regularly asked to provide education to patients who are newly starting injectable therapies or blood glucose monitoring.

Adherence monitoring and counseling

Clinical pharmacists include in each visit an assessment of patient adherence, not only to medication therapies, but also to blood glucose monitoring and lifestyle recommendations. Adherence is assessed using a combination of available resources, including patient interview and review of prescription-filling practices. Clinical pharmacists advise patients regarding ways to improve adherence via such tools as simplified therapy dosing schedules, minimization of unnecessary therapies, and the use of pill boxes.

Health barriers assessment

Clinical pharmacist visits are intentionally arranged to be longer than visits with medical providers. All clinical pharmacist visits are 40 minutes in duration regardless of whether the patient has been seen by the clinical pharmacist previously. The longer visit duration allows time for a more thorough assessment of patients' knowledge of their diabetes and self-management skills. In the complex subset of patients who present to this practice, psychosocial or health literacy issues are often identified as barriers to appropriate self-care, and addressing such barriers can be more challenging in the context of shorter visit times.

Commonly, barriers are related to simple miscommunications, compounded by specific patients' inability to navigate the health care system or advocate for themselves within the complexities of the system. Frequently, these barriers result in patients not obtaining therapies or testing supplies, with examples including:

- A non-preferred test strip or therapy is prescribed, resulting in increased cost to the patient (often cost-prohibitive)
- Suboptimal billing of testing supplies or therapies to a patient's insurance provider(s), resulting in increased cost to the patient
- Suboptimal therapy selection or dosing regimen to minimize adverse effects

Prevention screening and maintenance

As is well established in the realm of diabetes management, attention to preventive measures is of utmost importance. Therefore, clinical pharmacist visits also include a focus on prevention, including making medication therapy modifications to assist patients in achieving blood pressure and lipid goals, as well as laboratory monitoring associated with these medication adjustments. Additionally, the clinical pharmacists work to ensure that foot exams, eye exams, and vaccinations are up to date and also help to ensure appropriate use of daily aspirin therapy. Finally, the clinical pharmacists provide smoking cessation counseling and medication therapy management for smoking cessation.

Quality improvement

In addition to the clinical care provided to specific patients at the UNC Hospitals' endocrine clinic, the clinical pharmacists work closely with providers, clinic managers, and nursing staff on various quality improvement initiatives. Examples include:

- Tracking of quality parameters related to the National Committee on Quality Assurance Diabetes Physician Recognition Program

and making adjustments to clinic workflow to maintain compliance with these parameters
- Tracking provider status with respect to parameters outlined to achieve Meaningful Use certification, with ongoing modification to clinic processes to improve adherence to these parameters
- Feedback regarding a local registry database used for population management of patients with diabetes

Lessons Learned

Each year, the clinical pharmacists in this practice conduct an average of 600 patient visits and are involved in ~400 additional patient interactions, including patient correspondence via phone and mail. While engaging in these activities for the past few years, the pharmacists have learned several lessons, a discussion of which may benefit other practices or pharmacists seeking to implement similar services.

1. Pharmacist patient volume may be low. This does not seem to be related to a lack of patients who might benefit from pharmacist services nor to a lack of confidence on the part of the medical providers in the abilities of the clinical pharmacists. Rather, it seems related to the multitude of issues that must be addressed during a clinic visit; providers simply neglect to refer patients to the pharmacists.

   One potential solution is to develop an automatic referral process, through which the clinical pharmacist and supervising physician(s) identify parameters that would deem patients to be appropriate candidates for pharmacist services. In our practice, the two parameters that trigger an automatic referral are an A1C level > 9% and a return visit needed sooner than the usual quarterly visit. Nursing and administrative staff members are trained to identify these parameters, removing some of the burden from the medical providers. As is appropriate, the medical providers have the ability to cancel the automatic referral easily if they see fit.
2. Medical providers often identify with and trust a specific clinical pharmacist rather than clinical pharmacist services as a whole. This can make it challenging to expand clinical pharmacist services to include multiple pharmacists.
3. Patient no-shows or short cancellation times are difficult to manage. Pre-visit phone call reminders may help somewhat with this. Also helpful is a short information page to be provided to patients at the time of scheduling an appointment with a clinical pharmacist. The information sheet may outline what patients should expect during a visit with a clinical pharmacist and what they should bring to the visit. However, despite these efforts, no-shows and short cancellation times are particularly challenging issues to address in the setting of outpatient diabetes management.

Summary

It is widely accepted that a team-based approach to outpatient diabetes care is key to managing this complex disease. As the population of patients with diabetes continues to grow, clinical pharmacists can serve as vital and complementary members of the specialized, multidisciplinary team.

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