

Implementing Evidence-Based Guidelines: The Role of Ambulatory Care Pharmacists

Emily Hawes, Gretchen Tong

Pharmacists strive to align patients' medication regimens with evidence-based guidelines through medication therapy management and through the utilization of protocols based on best practices for chronic disease management. Ambulatory care pharmacists also assist in implementing guidelines through developing evidence-based algorithms and processes, educating providers and staff, and participating in population management.

Pharmacists in a variety of practice settings, including those practicing in ambulatory care settings, utilize both clinical guidelines and process guidelines in their professional activities.

Ambulatory Care Pharmacists

According to the American Society of Health-System Pharmacists, ambulatory care pharmacy practice involves the "provision of integrated, accessible health care services by pharmacists who are accountable for addressing medication needs, developing sustained partnerships with patients, and practicing in the context of family and community. This is accomplished through direct patient care and medication management for ambulatory patients, long-term relationships, coordination of care, patient advocacy, wellness and health promotion, triage and referral, and patient education and self-management."

Starting in the 1960s, the pharmacy profession began shifting from a perspective that was primarily product-based to a more patient-centered approach, with an emphasis on reducing morbidity and mortality associated with medications [1]. In fact, a 1990 report of the Office of Inspector General for the US Department of Health & Human Services found that clinical pharmacy services in the ambulatory care setting add value "including not only improvements in clinical outcomes and enhanced patient compliance, but also reductions in health care utilization costs associated with adverse drug reactions" [2]. Over the past 10 years, the role of clinic-based pharmacists has continued to evolve. Even postgraduate residency training has been specifically developed for preparing pharmacists to practice in the ambulatory care setting [1]. Ambulatory care pharmacists incorporated into care teams are needed "to close the gaps between best practice and usual care" [3].

Clinical Guidelines

Clinical guidelines, which are often created by experts in the field, are used as a foundation for establishing best practices and are routinely the basis for accrediting body standards. For example, the performance measures for the National Committee for Quality Assurance's Diabetes Recognition Program are primarily based on recommendations from the American Diabetes Association [4]. Supporting evidence-based guidelines can help practices reach the Institute for Healthcare Improvement's Triple Aim of improving population health, enhancing patient experience, and reducing cost of care [5]. Clinic-based pharmacists are well suited to promote the Triple Aim through implementation of guidelines.

Clinic-Based Patient Care

Pharmacists embedded in clinics assist in the implementation of evidence-based guidelines through direct patient care activities for management of diseases such as asthma, chronic obstructive pulmonary disease (COPD), chronic heart failure, diabetes, hypertension, osteoporosis, and atrial fibrillation. Given that medication management plays a key role in chronic disease management, clinical pharmacists can reduce medication-related problems such as nonadherence, inappropriate use, and suboptimal therapy [1]. The 1996 Asheville Project, which contracted with pharmacists to provide diabetes care, has been widely publicized because it showed significant improvements in clinical and economic outcomes [6]. In addition to caring for individual patients, pharmacists can conduct group visits for patients with chronic disease, which has been shown to enhance patient experience and improve population health. Pharmacists also directly optimize preventive care by counseling on appropriate immunizations, recommending aspirin if indicated, assisting in tobacco cessation, and counseling on cancer screening.

In North Carolina, a pharmacist with advanced train-

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ing can serve as a clinical pharmacist practitioner (CPP), a designation by the North Carolina boards of medicine and pharmacy that confers approval to provide collaborative drug therapy management—including billing, prescribing medication, and ordering laboratory tests—under the direction of a licensed physician. Each CPP practices by following a protocol developed with and approved by a supervising physician for the drug therapy management of agreed upon conditions [7]. Figure 1 (online version only) displays a sample CPP protocol [8]. These protocols and component algorithms are predominantly based on evidence-based guidelines for the conditions they cover.

FIGURE 1.
Sample Clinical Pharmacist Practitioner Protocol

This figure is available in its entirety in the online edition of the NCMJ.

One way that pharmacists improve adherence is by ensuring patients are receiving evidence-based therapies, ordering recommended monitoring parameters, and providing thorough patient education about the benefits and anticipated side effects of each drug. For example, starting colchicine for gout flare prophylaxis when initiating allopurinol, monitoring uric acid levels, and providing patient education about the potential for flares when initiating and dose-adjusting allopurinol, as well as the goal of attaining a target uric acid level, can promote patient understanding, thus enhancing adherence and optimal use of urate-lowering therapy to ultimately improve long-term gout control. Ambulatory care pharmacists are optimally positioned to utilize guidelines by providing direct comprehensive medication management, which has demonstrated improved clinical and economic outcomes [1].

Network-Based Patient Care

Pharmacists also participate in the care of individual patients and help align patients' medication use with clinical guidelines outside of embedded settings. For example, the Community Care of North Carolina (CCNC) program brings together regional networks of professionals who address patients' health care needs and provide coordinated care through the patient-centered medical home model [9]. Pharmacists have been integral members of CCNC networks' interdisciplinary teams since 2007, and they assist in the management of complex patient populations. The CCNC program has grown to include more than 50 pharmacists, 1,500 North Carolina practices, and 1.2 million patients [10]. In order to provide coverage for this large patient population, many CCNC pharmacists function wholly or partially in centralized placement models. From a central location, a pharmacist may interact with patients and providers from multiple health care practices.

In addition to involvement in education, coordination, and implementation of pharmacy benefit changes, CCNC pharmacists participate in medication management services. Pharmacists perform comprehensive medication reviews following the completion of medication reconciliation by care managers for both chronic care and transitional care patient populations and upon request from network providers. Pharmacists utilize clinical information obtained from a variety of sources—including the primary care provider, specialists, the hospital discharge summary, prescription claims, pharmacies, and the patient—to identify medication discrepancies between settings, close gaps in care, and find opportunities to optimize a patient's medication regimen in alignment with evidence-based therapeutic guidelines. Working towards a "well-coordinated, goal-oriented, continually reinforced drug use plan" [10], CCNC pharmacists communicate medication issues and recommendations to the patient's primary care provider and other members of the health care team. Approximately one-third of discrepancies identified through an early initial sample of CCNC's transitional care program were the types of discrepancies usually associated with medication reconciliation. Discrepancies included failure to initiate a discharge medication post-hospitalization (22.8%) and medication discontinuations by the patient without confirmation to stop (15.4%) [11]. These discrepancies may result in a patient's medication regimen being out of alignment with evidence-based care. Through communication with prescribers or care managers, or through patient education, pharmacists may clarify intended regimens and resolve discrepancies in medication use. Specifically, pharmacists may make recommendations for the addition of indicated therapy based on patient-specific factors, such as the addition of an ACE inhibitor, ARB, or beta-blocker therapy when indicated but not present in the medication regimen of heart failure patients. They may also suggest modifications in medication regimens in order to meet standards of care, such as recommending a change from metoprolol tartrate to metoprolol succinate in heart failure patients, or by suggesting dose titrations to meet therapeutic goals. In these ways, pharmacists assist in meeting guidelines in patient care through review of individual patient cases, even through remote mechanisms working with multiple practices.

Population Management

Pharmacists also implement evidence-based guidelines through population management in embedded or regional network settings. Pharmacists embedded in clinics often provide chronic disease management specific to the clinic in which they practice. In managing these patient populations, protocols are developed based on published guidelines to aid providers in making sound clinical decisions. For example, use of decision support tools during warfarin therapy has been shown to increase the amount of time patients are in the therapeutic range and subsequently to reduce bleed-

ing and thrombosis [12-14]. Figure 2 (online version only) includes a sample warfarin algorithm developed by pharmacists [15].

FIGURE 2.
Warfarin Algorithm With Goal International Normalized Ratio of 2-3

This figure is available in its entirety in the online edition of the NCMJ.

Note. INR, international normalized ratio; RTC, return to clinic.

Evidence-based guidelines also serve as a foundation for many of the informatics functionalities in electronic medical records; pharmacists may be involved in the development of such tools or may utilize them in improving clinical practice. For example, care alerts may remind providers of recommended activities (such as labs, medications, vaccines, and screening tools) during a specific patient visit. Likewise, electronic medical records can often generate daily gap reports that provide a list of patients scheduled for a clinic visit that day who lack documentation of particular guideline-recommended therapies based on their medical histories, such as foot exams for patients with diabetes. Panel management allows providers and pharmacists to identify patients who need a targeted intervention; for example, practices could identify all patients who have a COPD diagnosis but lack documentation of having the pneumococcal vaccine. This would allow a practice to send outreach letters educating these patients on the importance of the vaccine.

Furthermore, pharmacists can provide in-service training and teaching sessions for clinic staff, providers, and multidisciplinary learners to educate them on standards of care, which reinforce the importance of complying with protocols and guidelines. Ambulatory care pharmacists can contribute to the practice's quality improvement efforts by monitoring outcomes of interventions in targeted patient populations and by participating in or even leading sequential plan-do-study-act cycles to improve overall adoption of standards.

CCNC's informatics systems allow for population management at the level of an individual primary care practice or at the level of a network of practices. CCNC pharmacists may utilize population-level reports for a specific practice or for their entire network to identify opportunities for clinical services or targeted quality improvement projects. For example, using a combination of medical claims data and prescription claims, patients who are not meeting treatment thresholds, such as patients with diabetes and a hemoglobin A_{1c} greater than 9%, can be identified. Claims can also be used to identify patients without recommended therapy components, such as patients with diabetes who have been prescribed a hypertension medication but have not filled a prescription for an ACE inhibitor or ARB medication.

CCNC care alerts were developed to identify gaps

between published guidelines and patient medication use [16]. Pharmacists may use this data to target development of educational sessions with practices, to discuss the management of individual patients with providers, or even to identify patients for direct pharmacist intervention (through education or adherence support in chronic disease management). Through a variety of mechanisms of provider education and patient engagement, pharmacists aim to more closely align medication use with standards of care.

Process Guidelines

In addition to utilizing clinical guidelines, pharmacists rely on process guidelines for implementing best practices. Health care reform is placing an emphasis on reducing preventable hospital readmissions, and pharmacists are often embedded in the multidisciplinary teams caring for patients after discharge. Practices may choose to adopt the principles of the Institute for Healthcare Improvement's State Action on Avoidable Rehospitalizations (STAAR) guide, such as implementing the recommended clinic visit components, when developing an evidence-based care transitions program [17]. In addition, the patient-centered medical home model was developed to address the need to improve the quality and consistency of health care services provided in primary care. Pharmacists can help to establish and sustain these core principles—such as improved access, accountability, continuity, coordination, and comprehensiveness—in the medical home through patient care as well as clinic leadership [18].

Guidelines have been created to improve population health, enhance the patient experience, and reduce the cost of care. Ambulatory care pharmacists rely on clinical and process guidelines when implementing best practices through direct and indirect patient care. **NCMJ**

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References

1. Helling DK, Johnson SG. Defining and advancing ambulatory care pharmacy practice: it is time to lengthen our stride. *Am J Health Syst Pharm.* 2014;71(16):1348-1356.
2. Kusserow RP; Office of Inspector General. The Clinical Role of the Community Pharmacist. Report OEI-89-89160. Washington, DC: US Dept of Health & Human Services; 1990. <http://oig.hhs.gov/oei/reports/oei-01-89-89160.pdf>. Accessed May 26, 2015.
3. Adams K, Corrigan JM, eds; Committee on Identifying Priority Areas for Quality Improvement. Priority Areas for National Action: Transforming Health Care Quality. Washington, DC: National Academies Press; 2003.

4. National Committee for Quality Assurance. Changes to diabetes recognition program. <http://www.ncqa.org/Programs/Recognition/ChangestoDRP.aspx>. Accessed May 26, 2015.
5. Institute for Healthcare Improvement. IHI Triple Aim Initiative. www.ihiofferings.org/Initiatives/TripleAIM/Pages/default.aspx. Accessed May 26, 2015.
6. 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.* 2003;43(2):173-184.
7. North Carolina Board of Pharmacy. Clinical pharmacist practitioners. North Carolina Board of Pharmacy website. http://www.ncbop.org/pharmacists_cpp.htm. Accessed May 26, 2015.
8. North Carolina Board of Pharmacy. Clinical pharmacist practitioner protocol. North Carolina Board of Pharmacy website. <http://www.ncbop.org/PDF/SampleCPPprotocolCMisitaMay2013.pdf>. Accessed May 26, 2015.
9. Steiner BD, Denham AC, Ashkin E, Newton WP, Wroth T, Dobson LA Jr. Community Care of North Carolina: improving care through community health networks. *Ann Fam Med.* 2008;6(4):361-367.
10. Welcome to the Pharmacy Home Project. The Pharmacy Home Project website. <http://www.pharmacyhomeproject.com>. Accessed May 10, 2015.
11. Trygstad T. A series of well-coordinated dismounts. *N C Med J.* 2012;73(1):35-36.
12. Ansell J, Hirsh J, Hylek E, Jacobson A, Crowther M, Palareti G; American College of Chest Physicians. Pharmacology and management of the vitamin K antagonists: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). *Chest.* 2008;133(6 Suppl):160S-198S.
13. Oake N, Jennings A, Forster AJ, Fergusson D, Doucette S, van Walraven C. Anticoagulation intensity and outcomes among patients prescribed oral anticoagulant therapy: a systematic review and meta-analysis. *CMAJ.* 2008;179(3):235-244.
14. Holbrook A, Schulman S, Witt DM, et al; American College of Chest Physicians. Evidence-based management of anticoagulant therapy: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest.* 2012;141(2 Suppl):e152S-e184S.
15. UNC Center for Excellence in Chronic Illness. UNC General Internal Medicine Anticoagulation Algorithm. http://medicine.med.unc.edu/education/internal-medicine-residency-program/files/pdf/4.1.2.15.1Coag_2-3prot.pdf. Accessed July 8, 2015.
16. Pharmacy Home: Medication reconciliation improves safety, quality. Community Care of North Carolina Website. <http://www.communitycarenc.com/informatics-center/pharmacy-home/>. Accessed May 10, 2015.
17. Schall M, Coleman E, Rutherford P, Taylor J. How-to Guide: Improving Transitions from the Hospital to the Clinical Office Practice to Reduce Avoidable Rehospitalizations. Cambridge, MA: Institute for Healthcare Improvement; 2013.
18. Rosenthal TC. The medical home: growing evidence to support a new approach to primary care. *J Am Board Fam Med.* 2008;21(5):427-440.

FIGURE 1.
Sample Clinical Pharmacist Practitioner Protocol

CLINICAL PHARMACIST PRACTITIONER PROTOCOL

Supervising physician: Thomas O’Connell, MD

Clinical Pharmacist Practitioner: Caron Misita, PharmD, BCPS

The following protocol summarizes medication and laboratory prescribing privileges granted to Caron Misita, PharmD, BCPS by Thomas O’Connell, MD for patients of the UNC Hospitals Highgate Specialty Center in Durham, NC.

Patients seen at the UNC Hospitals Highgate Specialty Center and evaluated by Thomas O’Connell, MD, or another physician, may be referred to the Clinical Pharmacist Practitioner for drug therapy management of the following medical conditions.

<u>Diagnosis</u>	<u>ICD-9 code</u>
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

The following medication classes are authorized by Thomas O’Connell, MD for written, electronic or telephone prescription order by Caron Misita, PharmD, BCPS. 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
SGLT2 inhibitors	Antithyroid agents (methimazole, PTU)
Tricyclic antidepressants (neuropathy therapy)	
Gabapentin (neuropathy therapy)	Bisphosphonates
Duloxetine (neuropathy therapy)	Calcitonin
	Calcitriol
Diuretics	Raloxifene
Beta Blockers	Parathyroid Hormone Analog (teriparatide)
Alpha Blockers	
ACE Inhibitors/Angiotensin Receptor Blockers	Nicotine Replacement Therapy
Calcium Channel Blockers	Partial Nicotine Agonist (varenicline)
Alpha 2 Adrenergic Agonist	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.

Substitution of chemically dissimilar products is not permitted without written physician authorization.

Laboratory Tests and Monitoring

The following laboratory tests are authorized by Thomas O’Connell, MD for ordering by Caron Misita, PharmD, BCPS. Laboratory evaluation will be used as a means of appropriately dosing and monitoring efficacy and safety of medication therapy.

<u>Laboratory Test</u>	<u>Medication Therapy</u>
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
B12	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)	thyroid 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 Highgate Specialty Center 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 which 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.

Quality Control, Review and Countersignature

The Clinical Pharmacist Practitioner and supervising physician will meet weekly in a face-to-face conference for the purpose of quality control and review. The supervising physician (or referring attending physician) will countersign all clinic notes made by the Clinical Pharmacist Practitioner within seven 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

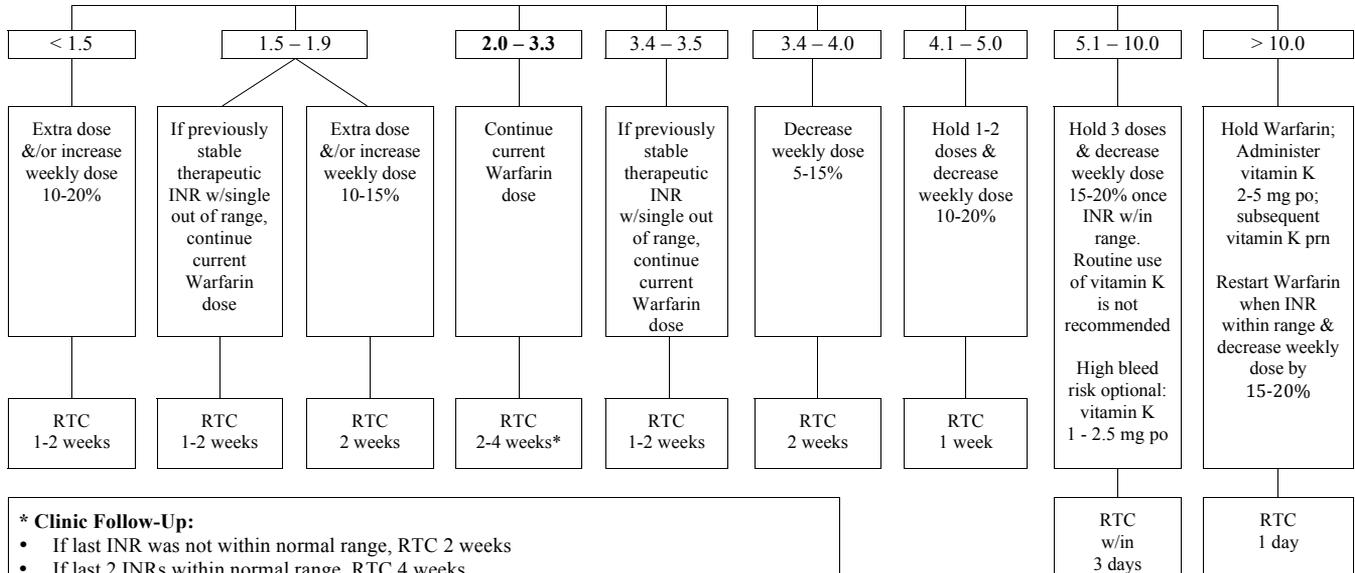
Date

Clinical Pharmacist Practitioner

Date

FIGURE 2.
Warfarin Algorithm With Goal International Normalized Ratio of 2-3

UNC General Internal Medicine Anticoagulation Algorithm
Goal INR 2 - 3



*** Clinic Follow-Up:**

- If last INR was not within normal range, RTC 2 weeks
- If last 2 INRs within normal range, RTC 4 weeks
- If consistently stable INR on the same dose for ≥ 6 months, consider extended follow-up

Major bleed:

- Hold Warfarin and admit patient to hospital
- Rapid reversal of anticoagulation with four-factor prothrombin complex concentrate rather than plasma
- Additionally use vitamin K 5-10 mg administered by slow IV injection
- Recheck INR q 6 hrs; repeat Vit K q 12 hrs prn

Signature: _____
 Internal Medicine Clinic Director