

# ACCP WHITE PAPER

## Tenets for Developing Quality Measures for Ambulatory Clinical Pharmacy Services

American College of Clinical Pharmacy

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During the past several years, the emphasis on quality in health care has been evolving. Alongside this evolution of change has been the advancement of clinical pharmacy services in ambulatory care settings. Although they share importance, both health care quality and ambulatory clinical pharmacy services have progressed and moved in their own directions. Nevertheless, in today's evolving health care landscape, collaboration among providers, including pharmacists, must occur to enhance quality. Pharmacy services must improve quality to be a sustainable health care service. This White Paper provides a rationale and structure that unite health care quality and ambulatory clinical pharmacy services. By applying national principles of quality measurement, this paper proposes five tenets to consider when developing measures for clinical pharmacy services in the ambulatory care setting: comprehensive, accountable, scientifically sound, feasible, and usable. Definitions of each tenet are presented. This paper uses exemplary literature on ambulatory clinical pharmacy services including diabetes mellitus, dyslipidemia, chronic lung disease, hypertension, anticoagulation, and heart failure to provide a context for the tenets and a discussion of their use. This paper also describes issues pertaining to health care quality and related costs using similar exemplary literature. Finally, a discussion is presented on both the opportunities and the challenges of measuring quality for ambulatory clinical pharmacy services. Issues related to the tenets, including shared accountability for health care quality, availability of comprehensive data to assess quality outcomes, feasibility of collecting and reporting quality, and the need for additional rigorous scientific evaluation of ambulatory clinical pharmacy services, are described.

**Key Words:** ambulatory care, pharmacy practice, clinical pharmacy services, quality measures.

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In 1990, Hepler and Strand introduced the concept of pharmaceutical care, transforming the profession of pharmacy practice from a product-dispensing entity to a patient care-centered model that optimizes drug therapy outcomes and

improves medication safety.<sup>1</sup> The pharmacy profession has embraced this evolution and implemented the model across a variety of care settings, including ambulatory care. Recently, change has become an overall theme of the

health care industry. The need for change has been driven by the widespread recognition that health care delivery in the United States is costly, inefficient, and error-prone. Almost one-third of adverse events leading to hospitalization are attributed to medications.<sup>2</sup> These medication-related misadventures have a staggering effect on health care costs, with reported estimates of more than \$177 billion.<sup>3</sup>

Given these statistics, the payers for health care services (e.g., employers and the federal government) are demanding action from health care organizations and providers to reduce errors and improve quality of care. This has led to the development of public reports, such as "To Err Is Human," on the quality of health care providers and to the creation of Web sites such as the federal government's Hospital Compare site as well as the Joint Commission's QualityCheck program. In addition, the federal government has announced plans to create a Physician Compare Web site by 2011.<sup>4</sup>

During the past 25 years, many studies have documented that the inclusion of a pharmacist on a health care delivery team leads to improved patient outcomes.<sup>5-31</sup> This evidence helped support legislation for pharmaceutical care. Both the Medicare Modernization Act of 2003 and the Patient Protection and Affordable Care Act of 2009 include several provisions for pharmaceutical care or medication therapy management (MTM). The Patient Protection and Affordable Care Act explicitly and implicitly describes roles for pharmacists to improve patient outcomes and includes opportunities for payment for pharmacy services.<sup>32</sup> However, payment may be tied to the quality of care provided.<sup>33</sup>

Payers have also begun to provide financial incentives/rewards for providers that achieve the highest levels of quality. Generally known as pay for performance (P4P), this financial incentive is becoming a high-stakes reality under the new

Centers for Medicare & Medicaid Services (CMS) value-based purchasing plan. Under P4P, top-performing hospitals will receive financial bonuses for higher-level quality, and low-performing hospitals will be financially penalized.<sup>34</sup> Although CMS has no current plans to implement P4P for pharmacies and pharmaceutical care programs such as MTM, it has begun the public reporting of quality measures for Part D drug plans. As the scrutiny of drug plans increases, plan administrators are likely to begin requiring the participation of their network pharmacies in quality measurement programs and to begin reporting pharmacy-based performance data to the public.<sup>35</sup>

Organizations such as the National Committee for Quality Assurance and the Pharmacy Quality Alliance have developed measures for evaluating quality of care, but these measures may not be applicable across the spectrum of ambulatory pharmacy services (Table 1). The National Committee for Quality Assurance is a not-for-profit organization dedicated to improving health care quality through a process of measurement, analysis, improvement, and repetition.<sup>36</sup> The National Committee for Quality Assurance develops and maintains these measures within HEDIS (Healthcare Effectiveness Data and Information Set), a tool used by more than 90% of America's managed care organizations to measure performance on important dimensions of care and service.<sup>37</sup> The measures of the National Committee for Quality Assurance encompass a broad range of medical services and related patient outcomes across 71 measures and 8 domains. Several of the measures include items such as asthma medication use, diabetes care, hypertension control, and tobacco cessation.<sup>38</sup> Arguably, these measures apply to pharmaceutical care, and they could be used to assess the quality of care provided by ambulatory clinical pharmacists. However, the measures were not necessarily designed with the pharmacist/pharmacy as a care provider; rather, they focus on other medical providers (e.g., physicians) and other health care facilities (e.g., hospitals and clinics).

The Pharmacy Quality Alliance was formed in 2006 with the mission to "improve the quality of medication use across health care settings through a collaborative process in which key stakeholders agree on a strategy for measuring and reporting performance information related to medications."<sup>39</sup> The Pharmacy Quality Alliance partnered with the National Committee for

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Table 1. Organizational Contributions Toward the Development of a New Health Care Model

Organization	Description	Contribution Toward the Development of a New Health Care Model
Joint Commission of Pharmacy Practitioners (JCPP)	Forum for officers of organizations to share information, perspectives, and concerns about vital issues facing the profession. Participating organizations: Academy of Managed Care Pharmacy Accreditation Council for Pharmacy Education American Association of Colleges of Pharmacy American College of Apothecaries American College of Clinical Pharmacy American Pharmacists Association American Society of Consultant Pharmacists American Society of Health-System Pharmacists National Alliance of State Pharmacy Associations National Association of Chain Drug Stores National Community Pharmacists Association	Development and dissemination of the vision statement: “Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes.”
National Committee for Quality Assurance (NCQA)	Dedicated to improving health care quality through a process of measurement, analysis, improvement, and repetition Develops and maintains the measures within the Healthcare Effectiveness Data and Information Set (HEDIS) HEDIS measures are used by more than 90% of America’s managed care organizations to measure performance on important dimensions of care and service Measures encompass a broad range of medical services and related patient outcomes 71 measures and 8 domains Examples include asthma medication use, diabetes care, hypertension control, and tobacco cessation	Provided impetus for increased focus on quality of care and health outcomes. Supported the Pharmacy Quality Alliance in the development of pharmacy-specific measures.
Pharmacy Quality Alliance (PQA)	Composed of more than 50 organizations from pharmacy, patient, employer, and health plan communities; state governments; and federal governments Partnered with NCQA to assist in developing initial pharmacy measures Promotes improvement in the quality of medication use across health care settings through a collaborative process in which key stakeholders agree on a strategy for measuring and reporting performance information related to medications	Developed, tested, and promoted quality measures focused on medication adherence, medication safety, and appropriate medication use. Measures were developed primarily to assess the quality of community pharmacies and drug plans using the prescription claims data commonly available to these entities. Measures do not include medical and laboratory data.
Agency for Healthcare Research and Quality (AHRQ)	Primary federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care. Supports health services research that will improve the quality of health care and promote evidence-based decision-making. Compiles data on medication errors	Caused payers and government to demand that providers and health care organizations improve quality and reduce errors. Interest in quality improvement and error reduction created interest in developing new models of care

Quality Assurance to assist in developing their initial pharmacy quality measures. The Pharmacy Quality Alliance developed, tested, and promoted these quality measures, which focus on medication adherence, medication safety, and appropriate medication use (Table 2).<sup>40</sup> The measures were developed primarily to assess the quality of community pharmacies and drug plans

using the prescription claims data that are commonly available to these entities. However, medical and laboratory data are not part of these measures; thus, the measures are limited in their ability to evaluate the overall quality of pharmaceutical care for patients in ambulatory care settings.

These descriptions of the quality landscape

Table 1. (Continued)

Organization	Description	Contribution Toward the Development of a New Health Care Model
Patient-Centered Primary Care Collaborative (PCPCC)	Coalition of health care stakeholders including employers, consumer groups, patient quality organizations, health plans, hospitals, and clinicians Collaboration on topics to develop and advance the patient-centered medical home (PCMH) model for the delivery of health care services	Developed a resource guide titled “Integrating Comprehensive Medication Management to Optimize Patient Outcomes.” Assembled by the Medication Management Task Force under the Center for Public Payer Implementation. Believes that maximizing appropriate medication use is critical to the PCMH model. Provides a framework for integrating comprehensive medication management into the PCMH model and reinforces the need for payment reform for medication management

identify both opportunities and challenges for the pharmacy profession when the development of quality measures for clinical pharmacy services (CPS) is considered. Payers in the government and private sector are pushing for better quality of care, creating an opportunity for pharmacists to provide pharmaceutical care that enhances overall quality. The challenges arise in not having measures of clinical pharmacist services that fully capture the pharmacist's contributions to health quality, which is combined with a lack of financial incentives that directly support the role of pharmacists in improving the quality of care.

The goal of this paper is to provide a synopsis of the current state of quality measures for ambulatory CPS and to illustrate the challenges surrounding the progress in developing them. In this paper, a quality measure for ambulatory CPS is defined as a measurement tool (or set of measurement tools) to encompass the act (or acts) of providing quality pharmaceutical care to patients in ambulatory care environments. Ambulatory care encompasses all health-related services in which patients “walk in” to seek care. Walk-in care includes visits to emergency departments, urgent care clinics, and, most commonly, primary care clinics and community pharmacies.<sup>41</sup>

This paper will begin by describing the various ambulatory care settings and models of care delivery in which the pharmacist has a role in improving the quality of patient care. Then, the authors will propose five fundamental tenets for quality measure development. These tenets will

be highlighted through selected papers from the scientific literature that document the pharmacist's role in improving patient care quality. The paper will conclude with a discussion of both the challenges of and opportunities for developing “pharmacist-centric” measures of quality.

#### Evolving Models of Care Delivery and the Effect on Quality Measurement

Conventional health care has focused on acute issues—the patient would visit the physician with a specific problem requiring immediate treatment. However, the increasing incidence of chronic disease has made the conventional model of sick care, rather than preventive care, an inefficient and substandard approach to health care delivery. Neither patients nor providers have been satisfied with the current systems of care to address chronic illness. Providers feel productivity pressures to rush through visits, and patients feel as if their concerns have not been acknowledged.<sup>42</sup> The increasing prevalence of chronic disease and costs of care have prompted a reevaluation of the health care delivery paradigm, and acute care delivery systems are transitioning into chronic disease management. These newer models for chronic disease care delivery include group-based medical care, patient-centered medical homes (PCMHs), and distance or electronic health care.

In group-based care, pharmacists can optimize medication therapy and educate patients. Pharmacists involved in group-based care have

Table 2. Pharmacy Quality Alliance Performance Measures

Measure Type	Measure Description
Proportion of days covered	The percentage of patients who were dispensed a drug within the targeted drug class who met the PDC threshold of 80%. This category contained seven measures within targeted drug classes: ACEI/ARBs, $\beta$ -blockers, calcium channel blockers, statins, biguanides, sulfonyleureas, and thiazolidinediones. A combined diabetes measure also was calculated
Gap in therapy	The percentage of prevalent users of a medication within the targeted drug class who had a significant gap (> 30 days) in medication therapy. This category contained seven measures with targeted drug classes: ACEI/ARBs, $\beta$ -blockers, calcium channel blockers, statins, biguanides, sulfonyleureas, and thiazolidinediones. A combined diabetes measure also was calculated
Diabetes medication dosing	The percentage of patients who were dispensed a dose higher than the FDA-indicated maximal dose for the following three therapeutic categories of oral antihyperglycemic agents: biguanides, sulfonyleureas, and thiazolidinediones, as well as a combination score of the three
Suboptimal treatment diabetes	Percentage of patients receiving a medication for diabetes and hypertension who are not receiving an ACE or ARB medication
Suboptimal treatment asthma - short-acting $\beta$ -agonist	Percentage of patients with persistent asthma who were dispensed more than 5 canisters of a short-acting $\beta$ 2-agonist inhaler within a 90-day period
Suboptimal treatment asthma - absence of controller therapy	Percentage of patients with persistent asthma who were dispensed more than 5 canisters of a short-acting $\beta$ 2-agonist inhaler within a 90-day period and did not receive controller therapy
Potentially inappropriate medication, at least one high-risk medication in elderly individuals 65 and older	Percentage of patients 65 years and older who have received one or more high-risk medications
Potentially inappropriate medication, two or more high-risk medications in elderly individuals 65 and older	Percentage of patients 65 years and older who have received two or more high-risk medications

ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; FDA = U.S. Food and Drug Administration; PDC = proportion of days covered.

demonstrated effective management of anticoagulation, improved diabetes measures, and reduced emergency department visits.<sup>7, 14, 19</sup> The PCMH model is an “approach to providing comprehensive primary care for children, youth and adults.” In a paper discussing PCMHs, Sipkoff pointed out that pharmacists in this role can both improve outcomes and reduce costs to health plans and that pharmacists are essential to medical homes.<sup>43</sup> Group care and PCMHs pose a challenge to the development of quality measures, as it is difficult to determine whether one individual or the entire team is responsible for outcome improvement. Telemedicine, which uses telecommunications technology to bring the provider to the patient, has developed as a means of increasing access to health care. A variety of methods may be used, including telephonic care, e-mail, and video-teleconferencing consultations.<sup>44</sup> Pharmacists have used Web-based technologies to improve blood pressure control.<sup>18</sup> Pharmacists have also used telemedicine to provide patient counseling to rural patients and

improve adherence to newly prescribed medications.<sup>45, 46</sup> Distance-based care also compels practitioners to collaborate for optimal patient outcomes. These evolving models of care and the emphasis on collaborative, team-based approaches for care delivery present challenges for quality measurement.

### Collaborative Care and the Effect on Quality Measurement

The Institute of Medicine report titled “Crossing the Quality Chasm: A New Health System for the 21st Century” identified the need for interdisciplinary programs and cooperation among clinicians.<sup>47</sup> Collaborative teamwork with shared responsibility benefits patients by improving the quality of their care. Inter-professional collaborative practice-based interventions, such as interdisciplinary rounds, have been documented to positively change health care quality.<sup>31</sup> Pharmacists have been collaborating with physicians in this way for

many years.<sup>24</sup> Collaborative drug therapy management (CDTM) has been used as an interdisciplinary approach to enhance patient outcomes and quality.<sup>5</sup> In CDTM, pharmacists act not as physician substitutes or extenders, but as physician enhancers, applying their specific drug therapy knowledge, skills, and abilities to complement other types of care provided by physicians and other collaborating professionals.<sup>5</sup> These clinical services can occur in various settings along the patient care continuum, such as in community pharmacies, ambulatory care clinics, and the hospital.

Pharmacist collaboration in the outpatient setting has been documented since the early 1970s when McKenney and colleagues collaborated with physicians to improve blood pressure control.<sup>24</sup> As collaborative health care teams evolved, pharmacists were integrated into ambulatory care clinics. As this paper will discuss in greater detail, pharmacists currently have active roles in improving chronic disease states such as asthma, hypertension, anticoagulation, and dyslipidemia through team-based health care. Similar to the evolving models of care, these collaborative roles for pharmacists present additional challenges to the development and measurement of health care quality.

### Five Tenets of Quality Measurement in Ambulatory Pharmacy

Quality measures developed by the National Committee for Quality Assurance and the Pharmacy Quality Alliance serve as a foundation but may not be the most appropriate measures by which to evaluate the quality of pharmaceutical care in all practice settings. Considering the principles of quality measurement from the Institute of Medicine and the National Committee for Quality Assurance and building on the Pharmacy Quality Alliance measures, the authors propose five tenets to consider when developing quality measures for CPS in the ambulatory care setting.

#### 1. Comprehensive

The analytic framework for quality measures in health care has been well developed and is based on the Donabedian components of structure, process, and outcomes.<sup>48</sup> The structural gaps in CPS mainly stem from a lack of information sharing and disjointed continuity of care. The adoption of an electronic medical record is an example of a structure-based measure. *Process*

refers to the set of activities that occur between patients and providers, encompassing the services and products provided to patients and the manner in which the services are provided. The quality measures developed by the Pharmacy Quality Alliance to measure community pharmacy quality exemplify process-based measures.<sup>35</sup> Such measures include the percentage of patients who are dispensed a drug for diabetes and hypertension but who are not taking an ACEI (angiotensin-converting enzyme inhibitor) or ARB (angiotensin receptor blocker) and the percentage of patients with persistent asthma and suboptimal asthma control on asthma controller therapy.<sup>40</sup> *Outcome* measures pertain to the consequences of medical care from an economic, clinical, or humanistic perspective. These outcomes include decreases in or goal attainment of low-density lipoprotein cholesterol (LDL-C) or blood pressure, but they may also include patient satisfaction and cost savings. Researchers of CPS often report a combination of process and outcome measures. A comprehensive quality measure set should include measures of structure, process, and outcomes whenever possible.

#### 2. Accountable

Outcome-based measures appear to be a stronger indicator of the quality of CPS, but they present additional challenges. These measures may not always be solely the result of the activity of the clinical pharmacist but may reflect contributions from other health care professionals as well. In the evolution of the PCMH model and team-based care, a variety of health care providers may affect a patient's medical outcome. Each member of the health care team must be accountable for the improvement in patient quality. A decrease in a patient's blood pressure could be the result of a physician's diagnosis and prescribing of an initial antihypertensive medication, the dietitian's education to the patient about a low-sodium diet, the nurse's education to the patient about hypertension goals and home-based monitoring of blood pressure, and the pharmacist's education to the patient about his/her medication and adherence to therapy as well as the pharmacist's titration of the medication and adjustment of the therapy in collaboration with the physician.<sup>49</sup> Determining the effect of each practitioner on an outcome such as blood pressure is problematic. Development of quality measures for CPS must

account for team-based care and the relative contribution of all health care professionals. Although a team or organization may be held accountable for the outcomes of medical care, it may be most appropriate to hold individual practitioners accountable for their components of the process of care.

### 3. Feasible

Feasibility is based on the ways in which data can be obtained within the normal flow of clinical care and the extent to which an implementation plan can be achieved. Generating data for a homogeneous set of quality measures that can be applied to many practice settings will require the sharing of medical, laboratory, and prescription data between health systems and pharmacies. To assess feasibility, those who generate the data necessary for quality measurement must ensure that it is current, available across the health care continuum, and mindful of the burden of measurement on pharmacists and other health care providers who may need to collect it. Ideally, all clinical pharmacy quality measures would ensure their feasibility for use by minimizing additional data collection on the part of the service providers.

### 4. Scientifically sound

Quality measures should produce reliable and valid results when implemented. Reliability occurs through consistently producing the same results when repeating analyses with the same data. Validity indicates that a measure reflects what it is intended to measure. The basis for developing clinical pharmacy quality measures should be derived from scientific evidence supporting the roles and responsibilities of pharmacists. In addition, these measures should be developed to be both reliable and valid.

### 5. Usable

The development and implementation of quality measures in clinical pharmacy will only be accepted if they are usable. Usability reflects the extent to which intended audiences (e.g., clinicians, patients, payers) can understand the measure's results and can use them in decision-making. Clinicians should be able to use the quality measures to guide their quality improvement efforts, and payers may use the measures to guide their payment or contracting decisions. Ultimately, we can also hope that the

quality measures will enhance patients' engagement in care by providing information that is relevant to their decisions. Therefore, quality measure development may add value to patient care by being patient centered. Patients who understand the measures and the importance of them can then play an active role in positively changing the quality of their care. Interpretation of differences in quality performance should be understandable from both statistical and practical perspectives and should pertain to clinical importance.

### Using Evidence to Guide Quality Measure Development—Example Papers of CPS

The importance of CPS in the outpatient setting is supported by a vast array of published literature. Because an in-depth evaluation of all literature supporting outpatient CPS would have been cumbersome, we chose example studies supporting CPS among five disease states (Table 3). Studies were selected on the basis of study methodology, robust outcomes, common disease states or generalized patient populations, niches for ambulatory CPS, and diversity of outpatient settings. These studies may guide the development of quality measures for ambulatory CPS, and a description is provided of their application to the five tenets.

#### The Asheville Project

The Asheville Project was a multisite, community-based MTM program that focused on improving outcomes in patients with the chronic disease states of diabetes, asthma, hypertension, and dyslipidemia. The clinical and economic outcomes of this project were evaluated using a quasi-experimental, longitudinal, pre-post study design. The study took place at 12 community pharmacies in Asheville, North Carolina, during a 5- to 6-year period. The results of those evaluations are described in the following paragraphs.

#### Diabetes

Patients with diabetes received education from a certified diabetes educator, followed by regular, long-term follow-up (up to 7 years) by pharmacists using scheduled consultations, clinical assessment, goal setting, monitoring, and CDTM. Clinical and economic outcomes were evaluated for almost 200 patients. Hemoglobin A1c (A1c) and the percentage of patients with an

Table 3. Summary of Example Studies of Clinical Pharmacy Services

Design	Setting	Disease(s)	Intervention
Quasi-experimental, longitudinal, pre-post study <sup>8</sup>	Community pharmacy	Asthma	Asthma education followed by pharmacist follow-up for monitoring and drug CDTM
Quasi-experimental, longitudinal, pre-post study and CDTM <sup>9</sup>	Community pharmacy, hospital clinic	HTN, dyslipidemia	CV risk reduction education followed by pharmacist follow-up for monitoring
Interim observational analysis <sup>17</sup>	Community pharmacy	Diabetes	Scheduled consultations, clinical goal setting, validated patient self-management tool, health status monitoring, CDTM
Prospective, cluster randomized, controlled clinical trial <sup>49</sup>	Community-based family medicine residency programs	HTN	CDTM
Quasi-experimental, longitudinal, pre-post study <sup>15</sup>	Community pharmacy	Diabetes	Diabetes education followed by pharmacist follow-up for monitoring and drug CDTM
Randomized, controlled trial <sup>26</sup>	University-affiliated, inner-city, ambulatory care practice	Heart failure	Pharmacist provided multilevel intervention

A1c goal of less than 7% improved from baseline at all follow-ups; however, this improvement was statistically significant in follow-up years 1–3. During study years 4–7, there was insufficient power to detect a difference in A1c.<sup>15</sup>

#### *Asthma*

Two hundred seven adult patients with asthma received education from a certified asthma

educator, followed by regular long-term follow-ups by pharmacists using scheduled consultation, monitoring, and CDTM. Significant improvement was noted in forced expiratory volume in 1 second (FEV<sub>1</sub>), in asthma severity classification, and in the proportion of patients with an asthma action plan. Annual percentages of emergency department visits and hospitalizations decreased.<sup>8</sup>

Table 3. (Continued)

Main Outcome Measure(s)	Main Results
FEV <sub>1</sub> asthma severity	After 1 year or longer: Mean FEV <sub>1</sub> : 81→90% predicted (p<0.00001)
Symptom frequency	After 1 year or longer: Severe or moderate persistent: 82→49% Mild persistent or mild intermittent: 18→51% (p<0.001)
Asthma action plan in place	Awakening frequently at night: 28→12% (p=0.01) ≥ 2 attacks per week: 35→16% (p<0.01)
ED visits	63→99% (p<0.0001)
Hospitalizations	16.9/100→1.9/100 patients/year 5.1/100→1.9/100 patients/year
SBP	-11 mm Hg (p<0.0001)
DBP	-4.8 mm Hg (p<0.0001)
LDL	↓ 18.9 mg/dL (p<0.0001)
CV event rates	↓ 53% (OR 0.4691 [95% CI, 0.328–0.671])
A1c	-0.4% (p<0.001)
LDL-C	-3 mg/dL (p<0.001)
SBP	-2.6 mm Hg (p<0.001)
DBP	-2 mm Hg (p<0.001)
Flu vaccines	36.3%→61.5%
Foot examinations	38%→68%
Eye examinations	60%→70% (p<0.001)
Guideline adherence	Control ↑ 8.1% Intervention ↑ 55.4% (NS)
SBP/DBP	Control ↓ 6.8/4.5 mm Hg Intervention ↓ 20.7/9.7 mm Hg (SBP comparison, p<0.05)
BP goal rates	↑ 34% (P<0.001)
A1c	Years 1–3: -0.5 to 0.8 (p<0.001)
A1c < 7%	Years 1–3: ↑ 18.2% to 24.3% (p<0.05)
Adherence	Intervention better than UMC Difference: 10.9% (95% CI, 5.0% to 16.7%)
Major exacerbations	Intervention better than UMC ↓ 18% (IRR 0.82 [95% CI, 0.72–0.93])
Improvement in HRQoL	No significant difference
Patient satisfaction	Intervention better than UMC (p<0.05)

### Hypertension and Dyslipidemia

Five hundred sixty-five patients received cardiovascular or cerebrovascular (collectively abbreviated as CV) risk reduction education from professional educators, followed by regular, long-term follow-up with pharmacists using scheduled consultations, monitoring, and CDTM. Significant decreases were noted in systolic blood pressure, diastolic blood pressure, LDL, total

cholesterol, and triglycerides. The percentage of patients at goal blood pressure and LDL increased. A 53% decrease in the risk of a CV event and a 54% decrease in CV-related emergency department visits were noted (Table 3).<sup>9</sup>

The Asheville Project can serve as a basis on which to develop quality measures for pharmacists in the community setting who are providing MTM services and practicing under the CDTM model. The results of this study provide insight into potential quality outcomes, including changes in FEV<sub>1</sub>, the percentage of patients with an asthma action plan, and the percentage of patients at goal blood pressure, A1c, or lipids. Using the five tenets as a framework, the Asheville Project measured the effect of pharmacist education on patients' asthma using the change in FEV<sub>1</sub> as an outcome measure and the percentage of patients with an asthma action plan as a process measure in accordance with the comprehensive tenet. However, these quality outcomes present challenges in feasibility because the data needed for FEV<sub>1</sub> measurement must be accessible and measured routinely by pharmacists or another health care provider. Furthermore, it is unclear how to ascertain the pharmacist's accountability or the portion of his or her contribution to the quality outcomes. Finally, although the merits of the study design and methodology may have limitations, it appears that most of the outcomes are usable.

### The Ten City Challenge

The Ten City Challenge is an ongoing multisite project being carried out in community pharmacies, ambulatory care clinics, and on-site workplace locations in 10 distinct geographic regions. The Ten City Challenge was based on the success of the Asheville Project. Community-based pharmacists provide patient care services through scheduled consultations, clinical goal setting, a validated patient self-management program tool, and health status monitoring within a collaborative care management model. After 1 year, significant improvements were noted in A1c, LDL, systolic blood pressure, and diastolic blood pressure. After 10 months, notable improvements were observed in the percentage of patients receiving eye examinations, foot examinations, and influenza immunizations. In addition, 97.5% of enrolled patients reported being very satisfied or satisfied with the diabetes care provided by the

Table 3. (Continued)

Design	Setting	Disease(s)	Intervention
Retrospective chart review <sup>27</sup>	Anticoagulation clinic	Various indications requiring warfarin use	Anticoagulation clinic comparing three models: UMC, RN, and RPH service

AC = anticoagulation; A1c = hemoglobin A1c; CDTM = collaborative drug therapy management; CI = confidence interval; CV = cardiovascular; DBP = diastolic blood pressure; ED = emergency department; FEV1 = forced expiratory volume in 1 second; HDL-C = high-density lipoprotein cholesterol; HRQoL = health-related quality of life; HTN = hypertension; INR = international normalized ratio; IRR = incidence rate ratio; LDL-C = low-density lipoprotein cholesterol; NS = nonsignificant; OR = odds ratio; RN = nurse managed; RPH = (registered) pharmacist managed; RR = relative risk; SBP = systolic blood pressure; TC = total cholesterol; TE = thromboembolic event; TG = triglycerides; UMC = usual medical care.

pharmacists in the Ten City Challenge. The percentage of patients who had individual self-management goals for nutrition, exercise, and weight increased as well (Table 3).<sup>17</sup>

Applying the five tenets to the results of The Ten City Challenge appears to show an improvement in addressing some of the challenges associated with the Asheville Project. Specifically, by expanding the intervention across 10 sites, the generalizability of the Ten City Challenge improves on the scientifically sound tenet as well as the feasible and usable tenets. In addition, the Ten City Challenge assessed other process measures as part of the comprehensive tenet. Similar to the Asheville study, ascertaining the pharmacist's accountability relative to other health care providers is unclear.

#### Anticoagulation

Pharmacists have a well-documented history of success in providing anticoagulation services. A recent study by Rudd and Dier evaluated pharmacist-managed anticoagulation services compared with both nurse-managed care and usual medical care (UMC).<sup>27</sup> This retrospective analysis was completed within an eight-county health care system in New York. Patients' time in range and the percentage of international normalized ratio (INR) values in range both were

statistically and clinically significantly better for patients in the pharmacist-managed group than for those who were managed by nurses or usual care. Hospitalization rates and emergency department visits were also lower in the pharmacist-managed group than in those managed by nurses or usual care (see Table 3). Other studies have also measured the clinical and economic outcomes of pharmacist-managed anticoagulation care.<sup>12, 29, 48</sup> These studies have shown increased rates of bleeding events as much as 20 times greater in usual care groups than in groups provided care by pharmacists.<sup>29</sup> In addition, both the Chiquette and Chamberlain studies observed higher hospitalization rates and emergency department visits in usual care groups than in pharmacist groups.<sup>11, 12</sup>

These anticoagulation studies provide a basis on which to develop quality measures for pharmacists in ambulatory settings. This service is unique, given the impact of safety in measuring the outcomes of care. Some of these measures include time spent within therapeutic INR range, time spent either above or below range, major and/or minor bleeding events, and thromboembolic events. The pharmacist's role in anticoagulation provides another opportunity to apply the five tenets recommended for quality measures. An extensive body of literature exists,

Table 3. (Continued)

Main Outcome Measure(s)	Main Results
% INR time within range	UMC: 57.4 RN: 71.8 RPH: 83.6 (p<0.05)
% INR values within range	UMC: 49.4 RN: 67.3 RPH: 74.9 (p<0.05)
Hospitalizations	RPH: Reduced by 56% vs. RN rates (p<0.01) RPH: Reduced by 61% vs. UMC rates (p<0.01)
Warfarin-related hospitalizations	UMC: 13.9/100 patient-years RN: 12.3/100 patient-years RPH: 5.4/100 patient-years (p<0.05)
Warfarin-related ED visits	UMC: 3 RN: 11 RPH: 4 (p<0.01)

many publications of which are scientifically sound when UMC is compared with expanded medical care with a pharmacist. These studies, over time, have consistently shown comprehensive and accountable outcomes. In addition, although the outcomes related to time within or outside the INR range are usable, challenges exist to make these outcomes feasible. Collecting, reporting, and sharing of laboratory values (e.g., INRs) across health care facilities remain difficult, particularly with the advent of point-of-care testing devices, which do not always transfer results to electronic health records or databases for widespread sharing of laboratory information.

### Hypertension

Many studies in hypertension have shown that pharmacists are able to manage hypertension, in collaboration with physician colleagues.<sup>6, 10, 50</sup> Carter and colleagues conducted a prospective, cluster, randomized, controlled trial of 402 patients with uncontrolled hypertension in six community-based family medicine clinics during a 3-year period.<sup>10</sup> The objective of the study was to determine the effectiveness of a physician and pharmacist collaborative model in a community-based medical setting to improve blood pressure control. At 6 months, blood pressure control rates were significantly improved, and mean guideline adherence scores were increased (Table 3). Physicians accepted more than 96% of

pharmacists' recommendations.

The study by Carter et al supports the blood pressure quality measures suggested by the Asheville Project. Other potential measures extractable from this study include guideline adherence and acceptance of pharmacists' recommendations. This study was scientifically rigorous and showed that a pharmacist could be the most appropriate person on the health care team to manage hypertension, and it supported the tenets of comprehensive, accountable, usable, and scientifically sound. As mentioned with the previous studies, feasibility can be challenging because blood pressure measurements must be shared across health care settings.

### Heart Failure

Murray and colleagues conducted a randomized, controlled trial to determine the effects of pharmacist intervention versus UMC on improving heart failure medication adherence and health care outcomes.<sup>26</sup> Significant improvements were noted in adherence (percentage of doses taken), mean exacerbation rates requiring an emergency department visit or hospitalization, and patient satisfaction. Increases were observed in health-related quality of life, but they were statistically nonsignificant (Table 3).

This study focuses on medication adherence as a process-based outcome linked to clinical outcomes of fewer hospitalizations and emergency department visits. Challenges exist regarding medication adherence as a process outcome and the linking of process outcomes to both structure and clinical outcomes as part of the comprehensive tenet. The Pharmacy Quality Alliance focused on medication adherence when developing its initial quality measures because of the assumed role of the pharmacist (accountability) in improving adherence and the feasibility of pharmacists' access to medication refill information. However, given the various methods to assess medication adherence and the problems with interpreting medication refill data, the scientifically sound tenet presents challenges for medication adherence as a quality measure.

These studies are a small sample of the literature documenting the process and outcome measurements used by pharmacists to affect patient care in several disease states. An extensive body of literature documents the role of the pharmacist in improving patient care. These studies have established a foundation for

developing quality measures. Further rigorously designed trials will be needed as quality measurements are developed and implemented. Many of the studies discussed in this section include an assessment of the costs of the intervention and an evaluation of cost avoidance. When developing quality measures for ambulatory CPS, a consideration of cost savings/cost avoidance or other financial impacts should be included.

### Economics of Quality Measurement

As discussed, quality assessment can encompass various outcomes including disease-specific outcomes (e.g., A1c in diabetes or LDL-C in hypercholesterolemia) as well as economic and humanistic outcomes. In general, the literature reveals that improved outcomes lead to better long-term cost control; however, the link between improved processes of care and total costs of care is not always clear. This section will highlight the cost-related end points from several of the studies described previously as well as those from many additional studies that have examined the economic impact of ambulatory CPS.

Numerous studies evaluating costs use clinical end points such as hospitalization, but they also describe other clinical outcomes (e.g., LDL-C) that are often used for quality measurement. For example, the Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers (IMPROVE) study by Ellis and colleagues found a benefit of ambulatory CPS on lipid parameters as the primary study outcome.<sup>16</sup> However, the evaluation of costs associated with this program used other outcomes such as hospitalization rates, clinic visits, number of prescriptions, and laboratories. The authors reported a nonsignificant difference in the mean cost of ambulatory CPS versus a comparator, despite improvements in lipid parameters.<sup>16</sup> Several concerns with conclusions exist regarding cost when outcomes typically used for quality measurement are the focus of a study. The study by Ellis et al highlights several questions regarding the relationship between the study's "quality-related outcomes" and the associated costs. For instance, why did the CPS improve LDL but not save money? Is there a predisposition for ambulatory CPS to increase medication costs in the short term, only to decrease other medical costs in the long term?

Would ambulatory clinical pharmacists in a study aimed to improve a quality measure (e.g., lipid parameters) be more likely to prescribe more expensive or multiple medications? Although these questions are difficult to answer, the overall data from both the clinical outcomes and the costs suggest that a pharmacy quality measure pertaining to LDL is worth developing.

An older analysis by Chiquette and colleagues suggests a cost benefit from anticoagulation CPS based on hospitalization rates and emergency department visit data.<sup>12</sup> However, the CPS provided focused on a quality measure, prothrombin time (PT)/INR, and the cost-related end points were extrapolated. Issues with these conclusions are similar to those with the IMPROVE trial, but the association of consistently maintaining therapeutic PT/INR levels and the benefit to hospitalization rates is an accepted construct.<sup>12</sup> Therefore, this study has validity as a cost-related quality measure study. One concern with the interpretation of these data is that emergency department visits that were not attributable to anticoagulation were not adjusted for in the final cost reporting. Although studies such as this provide information on the cost-related end points of ambulatory CPS, more consistent reporting methods should be developed for future analyses.

Perhaps the best economic impact data exist in a single disease state with fewer non-cost-related quality measures, asthma. In the Asheville Study, Bunting and Cranor reported direct and indirect cost savings with measures that included quality measures (e.g., FEV<sub>1</sub>) and directly associated cost-related end points (e.g., asthma-related emergency department/hospital events).<sup>8</sup> This study exemplifies a reasonable analysis of high-quality and cost-related impact in a single disease state.

Although the study by Bunting and Cranor may have reported the best individual disease state cost-related quality measure data, a study by Munroe and colleagues evaluated several disease states in a very different manner—cost-related end points without quality measures. The authors prospectively analyzed the four most common disease states (diabetes, asthma, hypercholesterolemia, and hypertension) treated by ambulatory CPS, concentrating on cost in the absence of reported quality measures. As previously theorized, the cost per prescription significantly increased across all disease states with ambulatory CPS. However, patient cost savings were shown across all cost analyses for

total monthly medical cost savings from a conservative estimate of \$143.95 per patient per month to \$293.39 when accounting for age, comorbid conditions, and disease severity.<sup>50</sup> [40] These data indicate a moderate cost benefit of ambulatory CPS across the major four disease states, with a marginal increase in prescription costs regardless of impact on quality measures. However, there are deficiencies to evaluating cost-related end points without quality measures. For example, other than cost-related end points, is there a negative impact on quality measures (e.g., LDL-C or A1c) in these individuals?

Unique methods of assessing cost can also be used to quantify ambulatory CPS. For example, Okamoto and Nakahiro published a prospective analysis comparing the effect of a pharmacist-managed hypertension clinic with a physician-managed general medical clinic on blood pressure. Using preferred cost measures, the authors developed a cost-effectiveness ratio reporting total costs per millimeter of mercury of blood pressure decreased.<sup>51</sup> Although the general acceptability is limited, this analysis directly linked a quality measure with a cost-related end point. In essence, Okamoto and Nakahiro's analysis quantifies quality. Consistent quantification of quality in this manner over time will greatly aid in defining the economic impact of ambulatory CPS.

Although the positive clinical impact of ambulatory CPS on quality measures and patient surrogate outcomes is unquestioned, the economic impact of ambulatory CPS is not well defined. Measures most commonly used to assess pharmacist intervention do not carry a specific attributable cost, and most disease states associated with ambulatory CPS use surrogate measures for disease progression. The best economic measures across any disease state appear to be prescription claims/costs, office visits, emergency department visits, and hospitalizations. An ideal method of evaluating overall ambulatory CPS would combine cost-related end points with directly associated quality measures that encompass the five tenets. Further investigation and consistent reporting (similar to that of Munroe and colleagues) or unique economic analyses, such as database economic modeling or cost-effectiveness ratios in individual disease states, will improve our understanding of the economic impact of ambulatory CPS.

### Challenges of and Opportunities for Developing Clinical Pharmacy Quality Measures

The five tenets, combined with additional relevant economic data, should be used to guide the development of quality measures for ambulatory CPS. Selected studies were highlighted to illuminate the five tenets and discuss a role for related cost data. Nevertheless, both challenges and opportunities remain as the Pharmacy Quality Alliance and other entities continue their work related to pharmacist-centric quality measures. Selected studies have uncovered several issues to developing quality measures: (1) accountability for pharmacists' contributions to health care quality; (2) comprehensiveness of available data across many health care settings; (3) feasibility of pharmacists to collect and report on the quality of their care; and (4) prudent consideration of scientifically sound data to support ambulatory CPS and associated cost savings and/or cost-effectiveness data. Each of these issues will be discussed in further detail.

Several studies describe collaborative care roles and responsibilities of pharmacists as members of the health care team. In addition, the evolving models of chronic care delivery and PCMHs support team-based health care. These care teams present challenging questions to consider when developing quality care measures: "Who is responsible for health care delivery?," "Who is responsible for health care outcomes and quality?," "What proportion of health care outcomes and quality can be assigned to any single member of the health care team?." These questions of accountability must be answered to determine how a pharmacist's contribution to the collaborative care team is to be measured.

An overlap of patient care responsibilities and shared accountability for the resulting outcomes is created by team-based care, but it is reasonable to consider that certain responsibilities and outcomes are led by the clinical pharmacist. These activities are exclusively or primarily performed by a pharmacist. Some of these activities may include the creation of a personal medication record/plan for a patient or the provision of medication education. The quality outcome measures from these activities may include patient satisfaction or an understanding of patients' medication regimens as well as medication adherence. Pharmacists have also played a unique role in medication dosage titration/optimization through prescriptive

protocols for many classes of drugs including anticoagulants, insulin, and antihyperlipidemics.<sup>7, 9, 12, 16, 17, 19</sup> Therefore, additional quality outcome measures may include the appropriateness of a medication regimen,

guideline-concordant medication regimens, or dosage goal attainment. In generating clinical pharmacy quality measures, developers should consider these examples and others when the pharmacist assumes primary responsibility with

Table 4. Summary of Economic Studies of CPS

Design	Setting	Disease	Measure(s)	Cost Data
Quasi-experimental, longitudinal, pre-post study <sup>9</sup>	Community pharmacy, hospital clinic	HTN, dyslipidemia	BP, lipid parameters, CV event rates	Mean cost per CV event in the study period was \$9931 compared with \$14,343 during the historical period. During the study period, CV medication use increased almost 3-fold, but CV-related medical costs decreased by 46.5%. CV-related medical costs decreased from 30.6% of total health care costs to 19%
Quasi-experimental, longitudinal, pre-post study	Community pharmacy	Asthma	FEV <sub>1</sub> , asthma severity, symptom frequency, presence of an asthma action plan, asthma-related ED/hospital events, and changes in asthma-related costs	Direct cost savings averaged \$725/patient/year. Indirect cost savings estimated to be \$1230/patient/year. Indirect costs because of missed/nonproductive workdays decreased from 10.8 days/year to 2.6 days/year
Randomized, comparative trial	Physician office, pharmacist-run clinic	HTN	BP	Average provider visit costs per patient were higher in the uncontrolled than the physician-pharmacist co-management group (\$195 vs. \$160) because of the lower number of visits. However, no statistically significant differences were noted in drug costs
Retrospective chart review	Anticoagulation clinic	Various indications requiring warfarin use	PT, INR	CPS saved \$162,058 per 100 patients per year
Quasi-experimental, longitudinal pre-post cohort study	Community pharmacy	Diabetes	A1c, lipid parameters	Total mean direct medical costs decreased by \$1,200 to \$1,872 per patient per year compared with baseline. Estimated productivity improved ≠ \$18,000/year based on employer sick day assessment.
Prospective, multisite, randomized, controlled trial	VA Medical Center Clinic	Dyslipidemia	Lipid parameters	Nonsignificant difference in mean cost of CPS vs. comparator

minimal input from other health care providers.

The development of quality measures should also account for the comprehensiveness of the measures. An important challenge is to assimilate the abundance of health care data

created by advances in information technology. Data from electronic health records, medical and pharmacy insurance claims, and pharmaceutical care information, as well as laboratory/procedure results, do not necessarily equate to improved quality of patient care.<sup>52</sup> Data are often incomplete and incorrect when observed through separate silos of care. Data aggregation across health care settings is often time-consuming, difficult, and costly. Comprehensive quality measures of ambulatory CPS must overcome these challenges and ensure data sharing among health care entities for the compilation of all patients' health information. A quality measure pertaining to asthma cannot be comprehensive if data on asthma medications, lung function tests, asthma action plans, and emergency department visits are not compiled across health care settings. As mentioned in the Economics of Quality Measurement section, PCMHs offer a promising model for capturing a cost benefit from ambulatory CPS. This model would also help bridge the information sharing gap, thereby bringing comprehensiveness to future quality measurements that include a pharmacist's contribution.

Another consideration for quality measures is feasibility. Although advances in collaborative practice agreements and MTM have occurred, pharmacists still lack recognition as health care providers from many payers of health care services. Traditional reimbursement for prescription drugs has included a "dispensing fee" as payment for the clinical assessment by the pharmacist. This model for funding encourages prescription quantity as a primary method of increasing revenue to pharmacies/pharmacists, with little incentive to increase interventional health care outcomes. As a result, the feasibility of pharmacists to collect, report, and respond to data about their health care quality outcomes is challenging. If health care payers value better health care quality from pharmacists, the model for funding must change. Incentives for quality improvement and equitable reimbursement for time spent delivering quality pharmaceutical care should be implemented. This payment structure would improve the feasibility of the pharmacist to collect, report, and implement changes to improve quality. Models for capturing payment for dispensing pharmacists' interventions are increasing among third-party payers and Medicare Part D, but this effort should be extended to all areas of CPS<sup>53</sup> (Table 4). Reimbursement for pharmacists who practice in

Table 4. (Continued)

Comment
Cost data are unrelated to the measures recorded. Cost measures were average health plan expenditures for CV-related medical costs.
Direct cost measures were medical prescription claims. Indirect cost measures were self-reported missed workdays and hours of lost productivity because of asthma, measured by patient questionnaire.
Cost data are unrelated to measures recorded. Cost measures were drug costs, provider visit cost, and pharmacist appointments.
Cost data is presumed related to measures recorded. Cost measures were hospitalizations and ED visits. However, almost \$30,000 of the \$162,000 savings was due to a 70% reduction in ED visits that were unrelated to anticoagulation. Results did not differentiate between inpatient and outpatient.
Cost data are unrelated to measures recorded. CPS are evaluated by cost. Measures are reported for improvement based on CPS. Contributions to direct medical costs are physician office visit, hospitalizations, ED visits, laboratories, prescription claims.
Cost data are unrelated to measures recorded. Cost measures were hospitalizations, clinic visits, medication costs, and laboratories.

Table 4. (Continued)

Design	Setting	Disease	Measure(s)	Cost Data
Interim observational analysis of de-identified aggregate data	Community pharmacy, ambulatory care clinic, on-site workplace locations	Diabetes	A1c; lipid parameters; BP; BMI; influenza vaccinations; foot and eye examinations; number of patients with nutrition, exercise, and weight goals; patient satisfaction	Out-of-pocket patient savings \$300 per patient per year
Prospective study	Ambulatory clinic	HTN, dyslipidemia	BP, lipid parameters	The decrease in total health care costs per person was \$3768. Cost reduction was greater than the cost for MTM services by 12 to 1.
Ambulatory care pharmacist interviews	Ambulatory care	Various	Physician visits, prescriptions, ED visits, hospital admissions, LTC facility admissions, deaths	According to a cost-of-illness model, the provision of pharmaceutical care in all ambulatory care pharmacy settings would reduce the occurrence of negative therapeutic outcomes by 53%–63% and avoid \$45.6 billion in direct health care costs.
Longitudinal pre-post cohort study	Ambulatory clinic	Diabetes	A1c, fasting BG, BMI, lipid parameters, BP	Costs decreased post-CPS at 6 and 12 months (–\$84 and –\$216, respectively), although not statistically significant. These total direct medical costs decreased despite increases in medications and medication costs.
Prospective	Community pharmacy	HTN, diabetes hypercholesterolemia, asthma	Prescription costs, total medical utilization costs	Cost/prescription significantly higher in intervention vs. control group for all targeted disease states. Differences in total monthly prescription costs significant only for asthma, with higher monthly costs in the group receiving intervention. Substantial savings were shown across all cost analyses for total monthly medical costs. Savings ranged from a conservative estimate of \$143.95 per patient per month to \$293.39 when accounting for possible influence of age, comorbid conditions, and disease severity.

Table 4. (Continued)

Comment
Cost data are unrelated to the measures recorded. Cost savings determined from waived co-payments. The program asks employers to waive co-payments for antidiabetic and related medications as an incentive for patients to enroll and stay in the program. <i>The more measures evaluated, the higher the potential for cost savings.</i>
Cost data is unrelated to measures recorded. Cost measures were actual payment amounts obtained from facility, medical, and prescription claims submitted through insurance.
Cost of illness was estimated for two different situations. Health care resource utilization and associated costs caused by negative therapeutic outcomes were estimated in the absence of pharmaceutical care and in its presence. Costs avoided because of pharmaceutical care were calculated by subtracting the total cost of each outcome with pharmaceutical care from the cost without pharmaceutical care.
Cost data are unrelated to measures recorded. Cost measures were direct medical and prescription costs together with ED and hospital visits.
Total medical utilization costs were calculated from insurance claims and included total claim amount, physician visits, laboratories, procedures, inpatient admissions, ED visits, and prescription medications. Best <i>purely</i> economic data for a multitude of disease states

collaborative and team-based care programs must be elucidated to further drive health care quality. For example, when a given health care entity receives a quality-based bonus, these payments should be distributed among all members of the team.<sup>52</sup>

Finally, the pharmacy profession must continue to perform rigorous evaluations of CPS and bolster the scientific data supporting these services. The development and testing of pharmacy quality measures can and should be performed in a scientific manner to further evaluate the impact of CPS on health care outcomes, quality, and costs. The Pharmacy Quality Alliance has provided seed grants to health care researchers and organizations to test some of their measures using rigorous scientific designs. Additional funding from payers and federal agencies like the Agency for Health Care Research and Quality and the National Institutes of Health should be available to continue scientific evaluations of pharmaceutical health care quality.

## Conclusion

This paper has summarized some of the evidence base for quality measurement in ambulatory practice settings, but gaps and inconsistencies remain. The best practices showcased in this paper are not the “standard of care” for pharmacy practice across the health care system. Nevertheless, the need for comprehensive, collaborative care coordinated across the health care spectrum has been recognized, and the value of pharmaceutical care in CDTM has been established across numerous ambulatory care settings. The pharmacist’s role in preventing, detecting, and resolving drug therapy problems is vitally needed, and it has been shown to have a positive effect on helping patients achieve optimal clinical outcomes. Payment systems have been developed, but they require further refinement to address equity in payment for ambulatory CPS. The remaining challenges and opportunities dwell in the ability to measure the quality-of-care contributions from pharmacists. The paper discussed five tenets for developing quality measures for ambulatory CPS. Application of these tenets should ultimately reward quality and coordinated, team-based care rather than isolated and episodic treatment within professional silos.

Table 4. (Continued)

Design	Setting	Disease	Measure(s)	Cost Data
Randomized, controlled trial	University-affiliated, inner-city, ambulatory care practice	Heart failure	Adherence, exacerbations, quality of life patient satisfaction	Cost of pharmacist intervention was \$205/patient. Mean difference in overall cost of health care (-\$3165 [95% CI, -\$7800 to \$1138]) in the intervention group did not reach statistical significance. Return-on-investment was 2-fold better than previously reported averages.
Prospective, randomized, comparative study	Pharmacist-managed hypertension clinic vs. physician-managed general medical clinics	HTN	BP, patient satisfaction	Total costs for each group werenot different, but cost-effectiveness ratios were lower in the pharmacist intervention DBP
Review article	Ambulatory clinic, community pharmacy	N/A	Various	Median benefit-cost ratio (study-dependent)
Retrospective chart review	Anticoagulation clinic comparing three models: UMC, nurse-managed (RN) care, and pharmacist-managed (RPH) service	Various indications requiring warfarin use	% INR time/values within range, hospitalizations/ED visits, cost avoidance	Pharmacist total cost avoidance \$151,461 vs. RN and \$101,090 vs. UMC

AC = anticoagulation; A1c = hemoglobin A1c; BG = blood glucose; BMI = body mass index; BP = blood pressure; CDTM = collaborative drug therapy management; CI = confidence interval; CPS = clinical pharmacy services; CV = cardiovascular; DBP = diastolic blood pressure; ED = emergency department; FEV<sub>1</sub> = forced expiratory volume in 1 second; HDL-C = high-density lipoprotein cholesterol; HRQoL = health-related quality of life; HTN = hypertension; INR = international normalized ratio; IRR = incidence rate ratio; LDL-C = low-density lipoprotein cholesterol; LTC = long-term care; MTM = medication therapy management; N/A = not applicable; OR = odds ratio; RR = relative risk; SBP = systolic blood pressure; TC = total cholesterol; TE = thromboembolic event; TG = triglycerides; UMC = usual medical care.

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Table 4. (Continued)

Comment
Cost data are <i>RELATED</i> to the measures recorded. Cost data are separated into (1) cost of pharmacist intervention and (2) patient cost. Pharmacist intervention cost included fixed (pharmacist training, material development, programming, and equipment) and variable (intervention time, physician consultation time, written materials). Time spent was measured by random observation. Patient cost measures included direct medical and prescription costs for inpatient and outpatient visits.
Cost data are <i>RELATED</i> to the measures recorded. Cost measures were drug cost, health care costs (clinic visits, ED visits, hospitalizations), group (\$27 vs. \$193/mm Hg SBP and \$48 vs. \$151/mm Hg and total costs per patient. Cost-effectiveness ratios were calculated using total costs per millimeter of mercury of blood pressure decreased.
Benefit-cost ratio calculated by = 2.89:1 dividing reported total costs of CPS by reported gross economic benefit derived from the service for the same period. Included Chiquette E et al
Cost data are presumed to be related to the measures recorded. Cost measures were hospitalizations and ED visits. Similar in concept with improved methodology to earlier study by Chiquette E, et al

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