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ORIGINAL RESEARCH

Expanding Access to Patient Care in Community Pharmacies for Minor Illnesses in Washington State

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Introduction: As the shortage of primary care providers widens nationwide, access to care utilizing non-physician providers is one strategy to ensure equitable access to care. This study aimed to compare community pharmacist-provided care for minor ailments to care provided at three traditional sites of care: primary care, urgent care, and emergency department, to determine if care provided by pharmacists improved access with comparable quality and reduced financial strain on the healthcare system.

Methods: Pharmacy data was provided from 46 pharmacies and 175 pharmacists who participated across five pharmacy corporations over a 3-year period (2016–2019). Data for non-pharmacy sites of care was provided by a large health plan, matching episodes of care for conditions seen in the community pharmacy. Cost-of-care analysis was conducted using superiority study design and revisit data analysis was conducted using noninferiority study design.

Results: Median cost-of-care across traditional sites of care was $277.78 higher than care provided at the pharmacies, showing superiority. Noninferiority was demonstrated for revisit care when the initial visit was conducted by a pharmacist compared to traditional sites.

Discussion: The authors conclude community pharmacist-provided care for minor ailments improved cost-effective access for patients with comparable quality and reduced financial strains on the healthcare system.

Keywords: patient access, community pharmacy, minor ailments, cost of care

Introduction

As the need for healthcare in the United States grows beyond capacity, it is imperative we find new healthcare delivery models to ensure equitable access to efficient healthcare options. We are currently facing a scarcity of healthcare providers, and in 2012 it was projected that by the year 2025 we will face a shortage of primary care physicians (PCP), reaching up to 52,000.[1] Despite the roles of nurse practitioners and physician assistants expanding, it is estimated nearly 1 million office visits per year needed by patients will go unmet due to lack of provider availability.[1] Patients living in low-income neighborhoods with less access to retail clinics or urgent care centers, who are facing long wait times for primary care (PC) appointments, or who work during hours when PC office hours exist often end up in the emergency department (ED) for medical treatment.[2] For reference, in the United States a PCP visit is an outpatient visit with a provider for services, such as chronic medical conditions, annual wellness visits, and same-day appointments for urgent needs that are manageable by a general provider in an outpatient setting during normal daytime business hours. Urgent Care visits are open extended hours (evenings and weekends) and are the site of care for conditions that cannot wait until a PCP visit can be scheduled or that may need services more advanced than provided by a PCP, such as X-ray or casting broken bones but are not considered life threatening. An ED visit is for emergency care needs that may be life threatening, require emergency surgery, or require advanced imaging for conditions such as stroke or heart attack. According to the National Association of Community Health Centers, Inc., more than one-third of all ED visits

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are avoidable and could be treated in an ambulatory setting with a savings of more than $18 billion dollars annually.[3] ED treatment of urinary tract infections (UTIs) alone accounts for approximately $4 billion per year in healthcare costs.[4]

It has been suggested that diversification of roles within the healthcare delivery system, along with workforce development efforts, can be capitalized upon to increase population health in a more efficient way.[5,6] Activities such as motivational interviewing and helping patients set goals for lifestyle modifications have been shown to greatly increase population health.[5] In addition, non-physician healthcare professionals can help fill the demand-capacity gap by utilizing technology and standing orders to provide patient care.[6]

Throughout the years, pharmacists' roles have evolved from solely medication dispensing functions to providing medication therapy management and other healthcare services designed to improve patient outcomes. Pharmacists have been integrated into health system care teams to help improve patient outcomes and forge innovative health delivery models through interprofessional collaborations in the community setting.[7] Key elements of pharmacy education prepare pharmacists to be medication experts, solve therapeutic problems, provide patient-centered care, advance population health, collaborate interprofessionally, and advocate for patients at the highest level.[8] The potential for pharmacists' clinical expertise to improve patient outcomes has been well studied in a range of scenarios, from examination of pharmacist-recommended clinical interventions implemented by a provider to direct pharmacist-provided care in managing acute and chronic disease states.[7]

In Rear Admiral Scott Giberson's Report to the US Surgeon General in 2011 titled "Improving Patient and Health System Outcomes through Advanced Pharmacy Practice", he outlines 55 peer-reviewed articles showing improved clinical outcomes for patients when pharmacists were involved in patient care delivery.[7] One systematic review of 12 randomized controlled trials including 2,060 patients showed pharmacist-directed or pharmacist-collaborative care was correlated with a significant decrease in all-cause hospitalizations (11 studies, 2026 patients) and heart failure hospitalizations (11 studies, 1977 patients).[9]

In the community pharmacy setting, both in the US and around the world, pharmacists have utilized Collaborative Practice Agreements (CPAs) and other prescriptive authority avenues to provide patients with access to affordable and expeditious screenings, treatment initiation, and medication management for many minor or acute ailments and chronic health conditions. Approximately 90% of all Americans live within 5 miles of a community pharmacy, with those residing in metropolitan areas living less than 2 miles from a pharmacy.[10] Proximity, walk-in patient access and extended hours make pharmacists the most accessible healthcare professionals in many geographic areas.

Point of Care (POC) testing and the ability for pharmacies to obtain a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver opened the door for pharmacists to enhance patient care access by providing screenings and prompt treatment initiation within the same pharmacy visit. Various CLIA-waived tests utilized in the outpatient and community pharmacy settings include those for Group A Streptococcus, influenza, Hepatitis C, HIV, hemoglobin A1c, cholesterol, and Helicobacter Pylori.[11,12] As of 2020, more than 15,600, or approximately 28% of US pharmacies, held CLIA-waiver certificates.[13]

Not all conditions appropriate for pharmacist-initiated treatment require testing. There are a number of minor ailments that can be effectively treated in a community pharmacy setting based on patient reported symptoms and examination. Uncomplicated UTIs are among these minor ailments. Since 2010, pharmacists around the world have provided patient care related to uncomplicated UTIs, with positive perceptions reported by patients and pharmacists.[14] Infectious disease guidelines do not require urine testing for uncomplicated UTI treatment, though pharmacists might consider criteria for referral prior to treatment initiation, such as patients who report flank pain, fever, chills, pregnancy, and others.[15] Treatment guidelines provide a framework for assessment and treatment with antimicrobial therapy or referral for complications when appropriate.[12] Many patients have reported seeking care at a pharmacy sooner than they would have with a general practitioner due to increased patient access to a community pharmacy.[12] Pharmacists have demonstrated improved antimicrobial stewardship for UTIs in ED and long-term care settings. Additionally, pharmacists are engaged in work to improve outpatient stewardship programs, which is promising for the future of antimicrobial stewardship of pharmacist-initiated interventions in the outpatient setting.[16–19]

Although some conditions appropriate in a community pharmacy setting do not require the use of CLIA-waived POC tests, like uncomplicated UTIs, others can utilize POC technology to assist in determining if and when medication therapy should be initiated. A literature review found positive evidence demonstrating pharmacist involvement in POC testing and, when

appropriate, initiation of therapy to be successful in improving patient access to safe and effective care for influenza, Group A Streptococcus, Helicobacter pylori (H. pylori), Hepatitis C, and human immunodeficiency viruses (HIV).[20]

As new patient-centered care delivery models are implemented in the community pharmacy setting, we should seek to ensure these care models meet patient needs and are sustainable. Correspondingly, the goals of this study were to conduct a cost-of-care and quality-of-care analysis by comparing pharmacist-provided care for selected conditions to care provided at three traditional sites of care: PCP, urgent care, and ED. The cost-of-care analysis includes median and mean costs from all sites of care for initial care and any revisit care needed for the same episode-of-care. The quality analysis compared patient revisit data as a measure to ascertain if the care provided by community pharmacists reduced the access burden on the traditional healthcare system. In addition, data was collected on the feasibility of offering services in a community pharmacy setting, which included training, supplies needed, space requirements, documentation, workflow, and compliance with prescriptive authority regulations. Data for traditional sites were collected from a large health plan in Washington state and compared to data collected from participating community pharmacies in Washington state over a 3-year period. Community pharmacies utilized in the study include drugstores, groceries, multidepartments, and big boxes. Washington state was selected for the study due to pharmacist delegated prescriptive authority through collaborative drug therapy agreements having been in place since 1979, with no limitation on patient eligibility, disease state, or medication prescribed. Many pharmacists included in the study were experienced in providing patient care services such as for immunizations and POC testing. In addition, pharmacists in Washington state are recognized as medical providers with billing authority, although at the time of this study the authority was new and not implemented in any of the study pharmacy locations.

Materials and Methods

Community Pharmacy Patient Visit Data

Data collected during monthly pharmacy site visits were used for pharmacy sites of care. Individuals under age 18 were excluded from the study. Cost per condition were set within each pharmacy company, of which it became the out-of-pocket cost for a patient to receive the service at that location. Participating study pharmacies did not bill patient insurance. The research team had no influence or decision-making authority as to the price each pharmacy organization set as their price for patient care services. Pharmacy mean and median cost per condition were both calculated; however, mean was utilized in the analysis due to cost data distribution having little variability.

Revisit data from pharmacy claims was collected through 30-day follow-up telephonic calls conducted by researchers. Data were reliant on patient-reported information, which could impact the accuracy of the data. Patient-reported data collected regarding revisits included when the revisit occurred, site of care for the revisit, and if symptoms resolved after the revisit. Utilizing the patient-reported site of care for a revisit, median cost from the traditional site of care data was utilized, in addition to the original pharmacy cost, to complete the total cost of care for those patient encounters. Difference in proportion of revisits between traditional sites of care and pharmacies was compared as a measure of quality with a noninferiority test using an equivalence margin of 20%.[21] Confidence intervals on the difference in the proportion of revisits were established with Wilson intervals.[22] Noninferiority testing was performed using a $1–2\alpha$ confidence interval with an α level of 0.05.[23]

Traditional Sites of Care Patient Visit Data

Health plan episodes claim lines data were used to obtain cost and visit data for traditional sites of care. Primary diagnosis codes were categorized into the conditions considered in this study. Claims for individuals under age 18 were removed from consideration. For cost comparison, only the cost of anchor claims and computed total cost by episode, condition, and provider site of care were considered. An anchor claim was categorized as being the first claim for the condition for that patient in a previous 30-day window of time. Episode costs included that of the anchor claim and any revisit claims within 30-days post-anchor claim organized by the condition and traditional provider site of care. Cost distributions were right-skewed, and thus median costs were used in place of mean costs to reflect cost expectations for a typical episode. Bootstrapping was employed to construct 95% confidence intervals on the median cost. Differences between the median episode cost from each traditional site of care setting and the fixed pharmacy cost along with 95% bootstrap confidence intervals were computed by subtracting a fixed pharmacy cost.

Data for traditional sites of care claims were available only up to monthly resolution, limiting the accuracy to which revisits could be identified. We defined a member revisit as a subsequent episode, as determined through increasing episode number that met the condition of having a claim date either in the same month or 1 month later. We summarized the follow-up visits by constructing a table of episode counts as well as computing the proportion of episodes that were follow-ups by traditional site of care and condition.

The cost-of-care analysis was conducted using superiority study design, comparing community pharmacies to traditional sites of care. The revisit data analysis was conducted using noninferiority study design, comparing the pharmacy setting to traditional sites of care.

There were several steps undertaken in the design of the project, in addition to data analysis methods. These included training programs in partnership with the Washington State Pharmacy Association (WSPA), entering into agreements with community pharmacy organizations to participate in the research project, and to develop a Physician Advisory Committee (PAC) to ensure standards of care are met and to incorporate the PACs feedback into live training sessions.

The WSPA has an online refresher training certificate program titled "Clinical Community Pharmacist", which was made accessible to pharmacists participating in this study. The certificate program focuses on ailments and conditions often seen in a community pharmacy setting. This includes both continuation of care for previously diagnosed conditions, as well as the assessment and initiation of treatment for certain ailments. Conditions included in the research project can be found in Supplemental Box 1.

The research team approached several community pharmacy leaders to recruit sites for participation in the study. A mix of community pharmacies was desired as well as representation from varied regions in Washington state. Five large pharmacy organizations participated in the study with pharmacies located in southwest Washington, the Seattle/Puget Sound area, and the Spokane/Eastern Washington area. Pharmacies included two grocery chains, one drugstore chain, one multidepartment chain, and one warehouse club company. Overall, a total of 46 pharmacies participated and 175 pharmacists were trained.

Live training was created to facilitate participating pharmacists' application of the online certificate modules through patient case discussions aimed at increasing confidence in the clinical decision-making process. The operational portion of the training included patient study consent and federally mandated health privacy forms, documentation requirements for data collection, and partner-specific operational components of implementing a new patient-care service. The clinical portion of the training was dedicated to patient case discussions related to each condition. Activities ranged in complexity and each activity emphasized the decision-making process to determine if a patient met criteria for pharmacist intervention or if referral to a different care provider was appropriate.

Pharmacists were required to complete the online training modules prior to attending the live session. Live training sessions conducted by the researchers were held either onsite at the pharmacy partner location in a large meeting room or on campus at the researcher's university, depending on geographic location and space availability (grant funds supported training module costs, however, each pharmacy organization remained responsible for pharmacist wages). While there is no legal requirement in Washington state for pharmacists to receive additional training to provide these services, researchers required the training to participate in the study to minimize gaps in knowledge based on the length of time since completing pharmacy education and utilization of the knowledge and/or skill set in practice prior to the study.

Researchers shared best practices for documentation, record storage, and patient care workflow; however, implementation of patient care service was customized by each organization. Prescriptive authority Collaborative Drug Therapy Agreements (CDTAs) were the responsibility of each pharmacy organization, and the agreements were signed between each pharmacist and a delegating prescriber, as required in Washington state. Some variability in CDTAs exist, as the delegating prescriber customizes the agreement to meet their standard of care and referral criteria. Each pharmacy organization included policies and procedures to ensure a patient's primary care provider, if they had one, was notified of the care provided by the pharmacist. Having CDTAs in place was a requirement for each organization to participate in the study as, without CDTAs, the pharmacists would not have the authority to prescribe treatment, when needed, based on their assessment of the patient and would have been required to refer all patients needing prescription treatment to a traditional site of care. Study recruitment began during the initial patient intake process at each pharmacy location. Consent into the study was not required for patients to receive care from the pharmacist, as determined by the IRB review.

Researchers visited pharmacies every 4 weeks over a period of 3 years to collect data, as documentation was in paper format. Data collected included patient demographics, insurance status, health history, and condition-specific information including treatments recommended and/or prescribed (Supplemental Exhibit 1). During each data collection visit, pharmacists were able to ask questions of the researchers to improve patient recruitment or patient care. For patients who consented to participate in the study, a 30-day follow-up phone call was conducted by researchers to assess the clinical outcome of the patient, either positively or negatively, and if additional care was sought (and where) for the condition (Supplemental Exhibit 2). Initial visit and 30-day follow-up data were stored utilizing REDCap electronic data tools hosted at the primary investigator's university.[24,25]

This human subject research project was reviewed and approved by the primary investigator's university Institutional Review Board (IRB) which complies with the Declaration of Helsinki.

Results

Data provided by 4 of the 5 pharmacy companies show 977 patients utilized the service during the 3-year study period ending December 2018, while 506 patients across all 5 pharmacy companies consented to participate in the study (one company chose not to provide aggregate service use data for patients not consented to the study). Of the 506 patients consenting to the study, 10 met referral criteria and were not treated by a pharmacist, resulting in 496 patients being included in comparison data. Patient demographics of pharmacies and traditional sites of care were collected for comparison (Supplemental Exhibit 3).

The total number of patients included from health plan data for comparison for all conditions was 84,555: with hormonal contraception, asthma, UTI, allergies, and headache being the top five (Table 1). For each of the ten conditions

Table 1 Initial and Revisit Care by Condition, Initial Site of Care, and Revisit Site of Care

Condition	Initial Site of Care	Number Receiving Initial Care	Cost of Initial Care per Patient	N (%) Revisit Care	Revisit Site of Care	N (%) Revisit Site of Care
Hormonal Contraception	Emergency Room	3	$53.66	2 (66.67%)	Emergency Room	1 (50.0%)
					Primary Care	1 (50.0%)
	Primary Care	21,806	$112.26	1485 (6.81%)	Primary Care	1485 (100%)
	Urgent Care	11	$154.44	1 (9.09%)	Urgent Care	1 (100%)
	Pharmacy	179	$24.00	0 (0%)		
Asthma	Emergency Room	1271	$1472.95	626 (49.25%)	Emergency Room	173 (27.6%)
					Primary Care	432 (69.0%)
					Urgent Care	21 (3.4%)
	Primary Care	17,033	$149.94	2890 (13.97%)	Emergency Room	290 (10.03%)
					Primary Care	2524 (87.34%)
					Urgent Care	76 (2.63%)
	Urgent Care	933	$189.97	185 (19.83%)	Emergency Room	18 (9.73%)
					Primary Care	119 (64.32%)
					Urgent Care	48 (25.95%)
	Pharmacy	26	$23.00	0 (0%)		

(*Continued*)

Table 1 (Continued).

Condition	Initial Site of Care	Number Receiving Initial Care	Cost of Initial Care per Patient	N (%) Revisit Care	Revisit Site of Care	N (%) Revisit Site of Care
Urinary Tract Infection	Emergency Room	1636	$962.70	362 (22.13%)	Emergency Room	106 (29.28%)
					Primary Care	240 (66.30%)
					Urgent Care	16 (4.42%)
	Primary Care	14,971	$121.21	1411 (9.42%)	Emergency Room	97 (6.87%)
					Primary Care	1270 (90.01%)
					Urgent Care	44 (3.12%)
	Urgent Care	1762	$151.23	168 (9.53%)	Emergency Room	12 (7.14%)
					Primary Care	77 (45.83%)
					Urgent Care	79 (47.02%)
	Pharmacy	151	$30.00	6* (3.97%)	Emergency Room	0 (0%)
					Primary Care	3 (50%)
					Urgent Care	3 (50%)
Allergic Rhinitis	Emergency Room	58	$634.11	13 (22.41%)	Emergency Room	8 (61.5%)
					Primary Care	4 (30.8%)
					Urgent Care	1 (7.7%)
	Primary Care	17,683	$95.77	6463 (36.55%)	Emergency Room	2 (0.03%)
					Primary Care	6454 (99.86%)
					Urgent Care	7 (0.11%)
	Urgent Care	401	$150.61	23 (5.74%)	Primary Care	14 (60.9%)
					Urgent Care	9 (39.1%)
	Pharmacy	14	$19.00	0 (0%)		
Headache	Emergency Room	5412	$629.65	1338 (24.72%)	Emergency Room	517 (38.64%)
					Primary Care	737 (55.08%)
					Urgent Care	84 (6.28%)
	Primary Care	11,149	$148.48	1812 (16.25%)	Emergency Room	371 (20.47%)
					Primary Care	1413 (77.98%)
					Urgent Care	28 (1.55%)
	Urgent Care	611	$167.70	124 (20.29%)	Emergency Room	50 (40.32%)
					Primary Care	54 (43.55%)
					Urgent Care	20 (16.13%)
	Pharmacy	11	$23.75	0 (0%)		

(*Continued*)

Table 1 (Continued).

Condition	Initial Site of Care	Number Receiving Initial Care	Cost of Initial Care per Patient	N (%) Revisit Care	Revisit Site of Care	N (%) Revisit Site of Care
Shingles	Emergency Room	209	$548.04	86 (41.45%)	Emergency Room	25 (29.07%)
					Primary Care	57 (66.28%)
					Urgent Care	4 (4.65%)
	Primary Care	3586	$140.52	281 (7.84%)	Emergency Room	17 (6.05%)
					Primary Care	261 (92.88%)
					Urgent Care	3 (10.7%)
	Urgent Care	463	$154.44	56 (12.1%)	Emergency Room	2 (3.57%)
					Primary Care	45 (80.36%)
					Urgent Care	9 (16.07%)
	Pharmacy	7	$30.00	1 (14.29%)	Urgent Care	1
Vaginal Yeast Infection	Emergency Room	41	$922.59	13 (31.71%)	Emergency Room	8 (61.54%)
					Primary Care	4 (30.77%)
					Urgent Care	1 (7.69%)
	Primary Care	2534	$119.44	193 (7.61%)	Emergency Room	1 (0.52%)
					Primary Care	192 (99.48%)
	Urgent Care	121	$153.24	11 (9.09%)	Primary Care	1 (9.09%)
					Urgent Care	10 (90.91%)
	Pharmacy	22	$30.00	1 (4.55%)	Urgent Care	1
Human, Canine, Feline Bite	Emergency Room	416	$621.22	177 (42.55%)	Emergency Room	148 (83.62%)
					Primary Care	27 (15.25%)
					Urgent Care	2 (1.13%)
	Primary Care	444	$162.80	60 (13.51%)	Emergency Room	19 (31.67%)
					Primary Care	39 (65.0%)
					Urgent Care	2 (3.33%)
	Urgent Care	99	$190.00	11 (11.11%)	Emergency Room	4 (36.36%)
					Primary Care	1 (9.09%)
					Urgent Care	6 (54.55%)
	Pharmacy	7	$28.00	1 (14.29%)	Emergency	1

(*Continued*)

Table 1 (Continued).

Condition	Initial Site of Care	Number Receiving Initial Care	Cost of Initial Care per Patient	N (%) Revisit Care	Revisit Site of Care	N (%) Revisit Site of Care
Burn	Emergency Room	15	$133.86	2 (13.33%)	Emergency Room	1 (50.0%)
					Primary Care	1 (50.0%)
	Primary Care	200	$140.52	17 (8.5%)	Primary Care	17 (100%)
	Urgent Care	25	$154.44	1 (4%)	Primary Care	1 (100%)
	Pharmacy	15	$29.00	0 (0%)		
Swimmer's Ear	Emergency Room	5	$397.31	2 (40.0%)	Emergency Room	2 (100%)
	Primary Care	85	$140.74	13 (15.29%)	Primary Care	12 (92.31%)
					Urgent Care	1 (7.69%)
	Urgent Care	14	$150.84	1 (7.14%)	Urgent Care	1 (100%)
	Pharmacy	15	$30.00	3[†] (20%)	Emergency Room	1
					Primary Care	2
Anaphylaxis	Primary Care	13	$109.75	2 (15.38%)	Primary Care	2 (100%)
	Pharmacy	2	$23.00	0 (0%)		

listed, cost-of-care was significantly lower when provided by a community pharmacist than in the comparator traditional sites of care. The median overall cost of care for all conditions across all traditional sites of care combined was $277.78 higher than care provided at the community pharmacies (Figure 1). The largest differences in cost of care between traditional sites and community pharmacy, in order of largest to smallest, are EDs, urgent care, and primary care

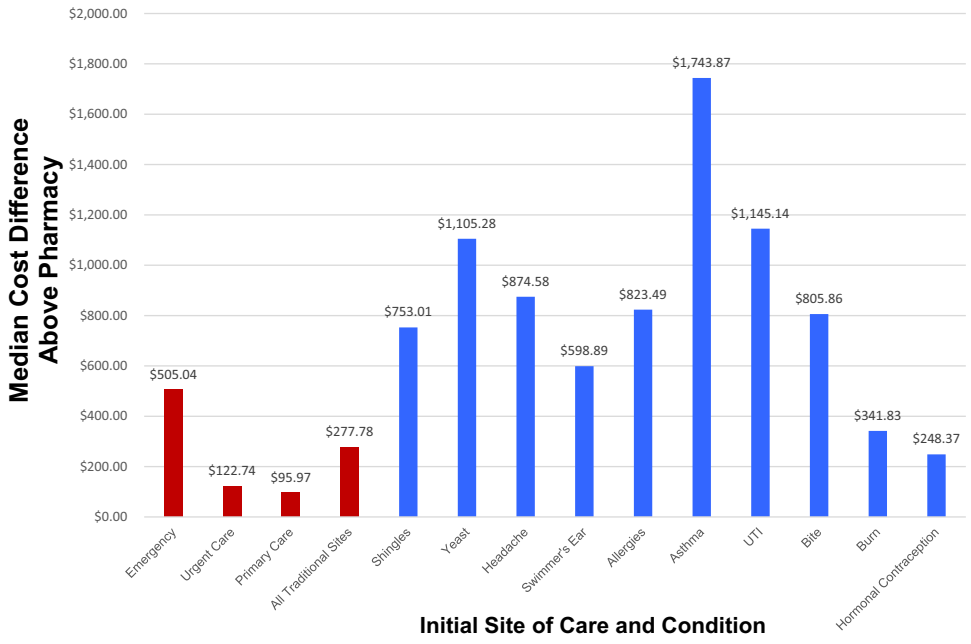

Figure 1 Traditional Site of Care Median Cost Difference Above Pharmacy by Initial Site of Care and Condition.

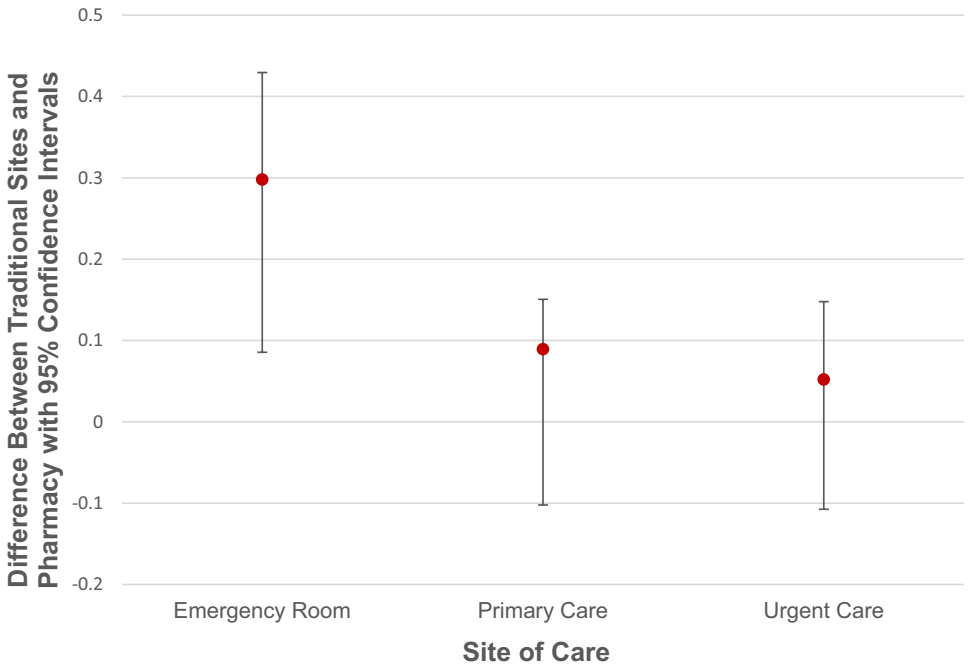

Figure 2 Traditional Sites versus Pharmacy Revisit Noninferiority Analysis.

providers at $505.04, $122.74, and $95.97 respectively (Figure 1). Further breakdown of the median cost of care difference by condition shows asthma, UTI, and yeast infection as the three conditions with the highest median difference of cost (Figure 1).

Patient revisit data was collected to compare the number of patients with an initial visit at a community pharmacy needing to seek additional care to those seen initially at a traditional site of care. The number of patients needing a revisit by condition and the site of care for the revisit can be found in Table 1. The traditional site of care difference in proportion of revisits with 95% CI by condition can be found in Figure 2, which shows noninferiority was found comparing community pharmacy to ED, primary care, and urgent care using a 20% margin (lower CI above −0.2). Further breakdown by conditions within the traditional sites of care show noninferiority in all 11 conditions comparing pharmacy to ED and in 8 of 11 conditions compared to urgent care and primary care (Supplemental Exhibit 4). The total cost of care, including revisits by condition and initial site of care, can be found in Table 2.

Table 2 Total Cost of Care (Initial and Revisit) by Condition and Initial Site of Care

Condition	Initial Site of Care	Total Cost of Care
Hormonal Contraception	**All Traditional Sites**	**$2,616,827.84**
	Emergency Room	$326.90
	Primary Care	$2,614,647.66
	Urgent Care	$1,853.28
	Pharmacy	**$716**

(*Continued*)

Table 2 (Continued).

Condition	Initial Site of Care	Total Cost of Care
Asthma	**All Traditional Sites**	**$3,263,644.50**
	Emergency Room	$2,195,703.25
	Primary Care	$837,224.72
	Urgent Care	$230,716.53
	Pharmacy	**$598**
Urinary Tract Infection	**All Traditional Sites**	**$4,076,441.11**
	Emergency Room	$1,708,533.48
	Primary Care	$2,068,607.63
	Urgent Care	$299,300.00
	Pharmacy	**$5,347.32**
Allergic Rhinitis	**All Traditional Sites**	**$2,419,398.81**
	Emergency Room	$42,384.95
	Primary Care	$2,313,922.98
	Urgent Care	$63,090.88
	Pharmacy	**$266**
Headache	**All Traditional Sites**	**$6,105,398.51**
	Emergency Room	$3,856,704.04
	Primary Care	$2,103,375.89
	Urgent Care	$145,318.58
	Pharmacy	**$261.25**
Shingles	**All Traditional Sites**	**$767,544.36**
	Emergency Room	$136,868.76
	Primary Care	$550,360.44
	Urgent Care	$80,315.16
	Pharmacy	**$364.44**
Vaginal Yeast Infection	**All Traditional Sites**	**$392,547.82**
	Emergency Room	$45,837.91
	Primary Care	$326,516.03
	Urgent Care	$20,193.88
	Pharmacy	**$813.24**

(*Continued*)

Table 2 (Continued).

Condition	Initial Site of Care	Total Cost of Care
Human, Canine, Feline Bite	**All Traditional Sites**	**$468,556.94**
	Emergency Room	$355,143.68
	Primary Care	$90,815.58
	Urgent Care	$22,597.68
	Pharmacy	**$817.22**
Burn	**All Traditional Sites**	**$36,776.64**
	Emergency Room	$2,282.28
	Primary Care	$30,492.84
	Urgent Care	$4,001.52
	Pharmacy	**$435.00**
Swimmer's Ear	**All Traditional Sites**	**$18,846.39**
	Emergency Room	$2,781.17
	Primary Care	$13,802.62
	Urgent Care	$2,262.60
	Pharmacy	**$1128.79**
Anaphylaxis	**All Traditional Sites**	**$1,646.25**
	Primary Care	$1,646.25
	Pharmacy	**$46**
All Conditions	**All Traditional Sites**	**$20,167,629.17**
All Conditions	**Pharmacy**	**$10,793.26**

Discussion

This study quantitatively analyzed the cost-of-care difference between community pharmacies and traditional sites of care for several common conditions and assessed the impact on the healthcare system through revisit data. Data assessing the overall cost-of-care showed a statistically lower mean for patient care interventions provided by a pharmacist in a community pharmacy setting compared to the median cost from EDs, urgent care centers, and primary care. In addition, noninferiority was demonstrated related to the need to revisit care when the initial visit was conducted by a pharmacist compared to traditional sites of care. A sampling of patient comments documented during the 30-day follow up call were positive (Supplemental Exhibit 5). This, in addition to the number of patients who sought care at a community pharmacy, shows feasibility through patient demand as well as the ability to integrate the services into patient care workflows.

Patients in the study paid for services received at the community pharmacy out of pocket. If the 496 patients who received care at the pharmacy had sought care at traditional sites, using the aggregate median cost difference for all three traditional sites of care of $277.78, the additional cost to the healthcare system would have been approximately $138,000. In comparison, using the same aggregate median cost difference of $277.78, if the 84,555 patients who had sought care initially at a traditional site of care had been seen at a community pharmacy, the cost savings would be approximately $23,500,000. The potential cost savings to the healthcare system are staggering. As demonstrated, expanded opportunities for patients to receive clinical care in accessible, community-based settings may enhance sustainability of the healthcare system and, in turn, lower costs for patients and public health programs. As can be seen in the demographic

data (Supplemental Exhibit 3), more women utilized community pharmacies than men, with hormonal contraception and UTI being the two most common conditions. While the overall median cost difference for hormonal contraception was the lowest of the services evaluated, the median cost difference for UTIs was the second highest. The majority of patients seen for a UTI at a traditional site of care in the study utilized the primary care setting; however, a 2015 report by the Washington Health Alliance listed UTIs as the fourth top condition both commercially-insured and Medicaid patients had unnecessarily sought care for at an ED in the five-county Puget Sound region.[26] This study found costs of ED care for a UTI to be more than $1000 higher than care provided by a community pharmacist. By anticipating these needs alone, UTI-associated interventions initiated by community pharmacists could reduce healthcare spending significantly.

The pharmacists included in the study all completed the WSPA Clinical Community Pharmacist Certificate Program, however the certificate is not a requirement for providing the services in Washington state. The confidence gained through the certificate program, as well as the 8-hr live training session, may have increased willingness to offer services to patients seeking care. The same certificate program and live training have been included in the required curriculum in the college of pharmacy where the primary investigator has been employed since 2015.[27] Recommendations made by the PAC (Supplemental Exhibit 6) were implemented in the live training, and recommendations related to the WSPA training were forwarded to them for consideration. As primary care physician shortage looms, and patient access to care is negatively impacted, pharmacy education programs around the country may have an opportunity to help address the gap in care by providing robust education for advanced patient care services and clinical decision making.

Community pharmacies offering patient care services might consider including methods to communicate with the PCP, allowing for a more complete patient health record and to decrease fragmentation of care. Ideally, community pharmacists would have access to electronic health records and input the care directly. For now, most community pharmacists fax or call a patient's PCP. This information may or may not be included in the patient's medical record at all, or in a way that is easily retrievable. One unexpected example of pharmacist and PCP collaboration was a patient informing the community pharmacist they were referred to the pharmacy to be seen for a UTI, as the PCP office stated the patient would be seen sooner than if making an appointment with them. While this is not currently commonplace, this level of trust and collaboration between the clinic and pharmacy is something to strive for in advancing collaborative, patient-centered care.

Conclusion

Overall, this research showed both feasibility and significant patient and public health cost savings when care was provided by a community pharmacist as compared to providers at traditional sites of care. Research findings support nationwide replication of this model of pharmacist-provided patient care resulting in increased access to healthcare for patients, particularly in rural and underserved areas. Enhanced patient outcomes along a continuum of care that is professional and longitudinal, not transactional, are efficient and improved access to timely healthcare.

The findings support the benefit to patients and public health programs of removing barriers to clinical care opportunities for patients in effective community-based settings, such as pharmacies. Due to systematic restrictions, patients in some states would not be able to access the care delivered in this research model. One important barrier, outside the scope of this project, is the lack of patient access to coverage for health interventions in emerging, community-based clinical care settings. Out-of-pocket costs may exacerbate barriers to patient access, especially for vulnerable populations, who may stand to benefit the most from enhanced access to care options.

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CICERO INSTITUTE

Toward Pharmacist Full Practice Authority

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Background and Problem

More than 30 percent of Americans don't have a primary healthcare provider, and those who do often face long wait times to get an appointment with a physician experiencing burnout.[1-2] The dire situation leaves patients the choice to either forgo care altogether or make do with higher-cost urgent care and emergency room visits. While the physician and primary care provider shortage compounds, the United States healthcare system is sidelining 330,000 doctorate-trained (PharmD) pharmacists who are qualified to provide many medical services.[3]

Pharmacists are poised to solve primary care shortages, diagnose and manage chronic diseases and minor ailments, decrease unnecessary emergency room visits, and deliver preventative health outcomes. Beyond the practical application of skills, pharmacists are consistently ranked by patients as trusted licensed healthcare providers for honesty and high ethical standards.[4]

Nearly 90 percent of Americans live within five miles of a community pharmacy, with urban Americans in a two-mile radius of pharmacy services.[5] The weekend hours and evening accessibility make pharmacists one of the most accessible healthcare providers. This is especially true in rural and underserved urban communities, where the local pharmacy often serves as a central pillar of healthcare. Giving pharmacists the ability to deploy the full scope of their training and experience is a safe and effective way to alleviate the pressure of doctor shortages.

Pharmacist Education and Training as Healthcare Providers

Pharmacist education and training standards are consistent across all states requiring prospective pharmacists to graduate from a Doctor of Pharmacy (PharmD) program accredited by the Accreditation Council for Pharmaceutical Education (ACPE) and pass the North American Pharmacist Licensure Examination (NAPLEX) to demonstrate clinical competence.[6] The US Department of Education recognizes ACPE as the national agency for the accreditation of professional degree programs and education standards in pharmacy.[7] Pharmacists receive four years of post-graduate education that includes 1,740 hours of clinical patient care training in all practice settings. All of that is commonly preceded by the four years it typically takes to earn a bachelor's degree. Comparatively, advanced practice registered nurses (APRN) who have been ascended to full practice authority in more than 35 states, complete a doctorate-level education with 750 hours of clinical patient training.[8]

The decades of ACPE standards surrounding diagnosis and prescribing were concisely articulated in the PPCP issued by the Joint Commission of Pharmacy Practitioners (JCPP).[9] The ACPE 2016 Standards adopted the PPCP establishing consistency in pharmacist education across all practice settings on differential diagnosis and prescribing consists of five steps:

1. Collecting subjective and objective patient information
2. Assessing the information collected and analyzing the clinical effects of the patient's therapy
3. Developing an individualized patient-centered plan that is evidence-based and cost-effective
4. Implementing and documenting the care plan
5. Patient follow-up to monitor and evaluate the effectiveness of the care plan[10]

The forthcoming ACPE 2025 Standards continue the curriculum trend towards codification of independent practice for patient screening, the performance of tests and assessments, diagnosis, drug administration, evidence-based clinical decision-making, therapeutic treatment planning, and prescribing.[11]

The intersection between ACPE accreditation standards, the Pharmacists' Patient Care Process (PPCP), and impeding state laws on pharmacists full practice authority is nicely summarized by Adams and Weaver: "For pharmacists to fully engage in the Pharmacists' Patient Care Process, state laws must enable full participation. Unleashing pharmacists to fully engage in the process can improve patient care delivery and reduce total healthcare costs."[12]

Accreditation Council for Pharmacy Education (ACPE) – Standards 2025

Required Elements of the Didactic Doctor of Pharmacy Curriculum
Clinical Laboratory Data • Application of clinical laboratory data to disease state management, including screening, diagnosis, progression, and treatment evaluation.
Medication Prescribing, Preparation, Distribution, Dispensing, and Administration • Prescribing, preparing, distributing, dispensing, and administering medications including, but not limited to: injectable medications, identification and prevention of medication errors and interactions, maintaining and using patient profile systems, prescription processing technology and/or equipment including oversight of support personnel, and ensuring patient safety. Educating about appropriate medication use and administration for various disease states including substance use disorder. All students must receive training in immunizations.
Patient Assessment • Evaluation of patient function and dysfunction through the performance of tests and assessments leading to objective (e.g., physical assessment, health screening, and lab data interpretation) and subjective (patient interview) data important to the diagnosis and provision of care.
Pharmacotherapy • Evidence-based clinical decision making, therapeutic treatment planning (including diagnosing and prescribing), and medication therapy management strategy development for patients with specific diseases and conditions that complicate care and/or put patients at high risk for adverse events. Emphasis on patient safety, clinical efficacy, pharmacogenomic and pharmacoeconomic considerations, and treatment of patients across the lifespan.
Self-Care Pharmacotherapy • Therapeutic needs assessment, including the need for triage to other health professionals, drug product recommendation/selection, diagnosis, prescribing, and counseling of patients on non-prescription drug products, non-pharmacologic treatments, and health and wellness strategies, including nutraceuticals.

Empower Pharmacists to Diagnose and Prescribe

Joffe and Singer articulate a compelling history of the decades of jurisdictional success of independent pharmacist diagnosis and prescribing in the United Kingdom, New Zealand, Australia, Canada, and the United States where peer-reviewed literature ensconces a robust body of evidence of patient acceptance, patient demand, and patient safety profile.[13] Opposition to scope of practice reform relying on emotional anecdotes will be hard-pressed to find evidence-based literature showing inferiority or legitimate patient safety outcomes of pharmacist diagnosis and prescribing care.

Tsyuki and colleagues have published multiple randomized controlled trials [RxEeach, RxACT, RxACTION, RxING] with statistically significant results demonstrating pharmacist care to be superior to usual physician care when independently prescribing and managing for cardiovascular disease (CVD)—hypertension, hyperlipidemia, tobacco cessation, and diabetes mellitus.[14-17] Dixon and colleagues published in the Journal of American Medical Association (JAMA), that the cost-effectiveness of implementing a pharmacist-prescribing intervention to improve blood pressure control in the United States at 50 percent intervention uptake was associated with $1.137 trillion in cost savings and would save an estimated 30.2 million life years over 30 years.[18]

Akers and colleagues demonstrate that pharmacists treating minor ailments at a community pharmacy lowers the median cost of care by $277.78 when compared to urgent care and emergency room visits, showing superiority to traditional care sites.[19] Sammon and colleagues research from the Henry Ford Vattikuti Urology Institute demonstrates patients avoiding the emergency room for urinary tract infections (UTI) alone would save up to $4 billion dollars annually.[20] Beahm and colleagues shows pharmacist prescribing and management of uncomplicated UTI is effective, safe, and patient satisfaction is high.[21] The economic impact on UTIs is one example of the more than thirty minor ailment conditions pharmacists are trained to treat.[22]

Solution to Overregulating Clinical Services: Implement Standard of Care

Why can't patients skip the doctor's office altogether and simply rely on their pharmacist as the primary destination for minor healthcare? The answer is overregulation. For decades, physician protectionism masquerading as patient safety concerns has misled federal and state policymakers on scope of practice, creating a tangled web of pharmacy regulations preventing business innovation and patient choice.[23] Some state legislatures and Boards of Pharmacy have relegated the role of doctorate-trained pharmacists to medication dispensaries, despite the profession having a history of taking care of patients dating back to 2100 B.C.[24] Upon graduation, most pharmacists entering the healthcare marketplace are entering into a practice of regulatory captivity.

Few professionals experience heavy-handed government micromanagement and overregulation the way pharmacists do, evidenced by the hundreds of pages of pharmacy practice regulations.[25-26] Surprisingly, this regulatory burden does not stem from political

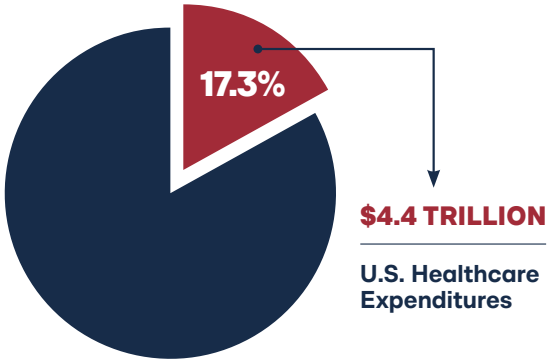
ideology. Texas and California each have more than 850 pages of enforceable statutes and rules governing the pharmacy practice.[27-28] To the surprise of no free-market economist, the continued growth in regulation of the drug supply chain and pharmacy practice correlates to market consolidation and resource competition. Look no further than the total market share for pharmacies, wholesalers, and pharmacy benefit managers for examples.

Regulatory strings prevent pharmacists from practicing at the top of their education, training, and experience. It is long past due for the profession of pharmacy to move to a standard of care regulatory model and for states to pursue pharmacist full practice authority.

A benchmark analysis of Idaho's healthcare regulations between 1996 and 2017 found significantly more pharmacy regulations compared with nursing and medical professions.[29] Notably, pharmacy regulations contained substantially more restrictive words, with 97.5 percent and 105.8 percent higher word counts than nursing and medical regulations, respectively. Furthermore, the analysis showed pharmacy regulations were amended more frequently, underscoring a continuous need to ask governmental permission to adopt advances in educational practices, technological innovations, and evolving professional standards. The difference in Idaho's pharmacy regulatory burden demonstrated a divergence in how other professions were regulated, showing medicine and nursing were traditionally regulated through standard of care. The states with scope of practice and provider reimbursement law that prioritize and reflect physicians as the "quarterback" of the healthcare team—and the only provider who is authorized to independently practice—are part of the problem of overregulating pharmacists.[30] This is a stark difference from states that prioritize implementation of a standard of care and independent full practice authority for providers delivering patient care.

REGULATORY STRINGS PREVENT PHARMACISTS FROM PRACTICING AT THE TOP OF THEIR EDUCATION, TRAINING, AND EXPERIENCE.

In 2022, U.S. healthcare expenditures reached $4.4 trillion, accounting for 17.3 percent of the gross domestic product (GDP), with per capita spending averaging $13,493.[31] State budget officers continue to grasp at policy solutions to contain Medicaid costs, a phenomenon described as Medicaid Pac-Man, eating up precious finite dollars that could otherwise be invested in education, public safety, or infrastructure.[32] Many states do not formally recognize pharmacists as reimbursable providers, and those that do often limit the recognition to narrow scope of practice allowances.[33] In fairness to the insurance payor marketplace, why would they build a provider reimbursement system for services that are legally prohibited? Better yet, how



2022 Gross Domestic Product (GDP)

can businesses and researchers test new—legally prohibited—pharmacist services and their impact on society? Simply put, overregulation of pharmacists' scope of practice and professional autonomy leaves untapped healthcare expertise and cost-containment resources to waste across the entire healthcare system. Transitioning to standard of care and pharmacist full practice authority are potential solutions.

The paramount benefit of standard of care is that standards do not come from top-down government elitist and "expert" regulators, but rather from bottom-up external market forces. . . . New scope of practice allowances, novel patient services, and technological advancements do not require government permission but are inherently authorized by a healthcare professional if acting according to the community standard of care.

Defining Standard of Care

The term "standard of care" in the medical context refers to a healthcare provider acting as a reasonable and prudent provider with similar qualifications in similar circumstances and settings. Standard of care is the regulatory benchmark to measure the actions of healthcare providers and ensure they are performing their duties to prevent patient harm. If a physician, pharmacist, physician assistant, or nurse fails to meet the standard of care for their practice, the licensing board and even the courts will find the provider negligent and guilty of unprofessional conduct or malpractice for failing to meet an adequate community standard of care. The concept of standard of care in medicine and nursing was formalized in the 1980s and has continually refined over time as courts adjudicate cases.[34] Since the 1980s, specialty accrediting organizations and medical practice associations have refined medical standards. New medical research and greater involvement by third-party payers like insurance companies also sped up these refinements to the standard of care.

The paramount benefit of standard of care is that standards do not come from top-down government elitist and "expert" regulators, but rather from bottom-up external market forces. A standard of care regulatory approach also follows another economic principle, perhaps best described as "permissionless innovation."[35] Providers may

perform any act not directly prohibited by federal or state law by default.[36] New scope of practice allowances, novel patient services, and technological advancements do not require government permission but are inherently authorized for a healthcare professional if acting according to the community standard of care.

Standard of care is different from the traditional Board of Pharmacy bright-line regulation approach of a clearly defined and objective legal standard that leaves little room for varying interpretation. Board of Pharmacy regulation has historically produced predictable and consistent results in its application by relying on specific, measurable factors that can decisively resolve legal issues.

Some government executives, particularly pharmacy inspectors, prefer it because it is easy to create a compliance "gotcha" checklist. However, bright-line regulation is a rigid application that often leads to unfair or inappropriate outcomes because it is hard to account for the complexities of individual cases. How does that impact innovation and patient choice? The profession is now entrenched across the states in a "Mother May I" form of practice, needing permission and updates to statutes and rules to perform any new patient care service or use any new technology. The best possible outcome cannot occur under the Boards of Pharmacy bright-line process to regulate licensees to the lowest common denominator. The sheer amount of regulation on the books would be impossible to surmount.

Eid and colleagues compared the total word count in statute and rule for immunization clinical services across all states for the professions of pharmacy, medicine, and nursing. Pharmacy was found to be 283 percent higher (57,425 words) than medicine (14,997 words) and 1,333 percent higher than nursing (4,006 words).[37] The research highlighted the words "vaccine" and "immunization" were not even found in most states for the medicine and nursing profession, due to standard of care.

In 2017, **Idaho was the first state to transition pharmacy regulation to standard of care** (Figure 1).[38] The decision created a cascading impact on the Board of Pharmacy. The Board reduced the regulatory volume from 125 pages to 25 pages of regulation in the last five years. More importantly, the transition included a 47.9 percent cut in the regulations governing professional practice standards and a 68.4 percent cut in the regulations governing technology. In other words, pharmacists are now authorized to innovate and given a broader scope of practice by default so long as they act within their education, training, and experience.

The Idaho Board of Pharmacy offers two questions to help licensees successfully navigate this change in approach from prescriptive, bright-line regulations to professional judgment:

1. If someone asks why I made this decision, can I justify it as being consistent with good patient care and with law?
2. Would this decision withstand a test of reasonableness (i.e., would another prudent pharmacist make the same decision in this situation)?[39]

FIGURE 1. STATE SOLUTION: IMPLEMENT STANDARD OF CARE[40-43]

State	Standard of Care Model Language
Alaska	**Alaska 12 AAC 52.205. General Standard of Pharmacy Practice** (a) To determine whether a specific act is within the scope of pharmacy practice in or into the state, or whether an act can be delegated to other individuals under a licensee's supervision, the licensee must independently determine whether the act is (1) expressly prohibited by (a) this chapter; or (b) any applicable state or federal laws; (2) consistent with the licensee's education, training, and experience; and (3) within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee with similar education, training, and experience. (a) The pharmacist-in-charge shall make necessary changes or improvements to ensure patient safety and employee wellness in a pharmacy, as part of a continuous quality improvement program for pharmacy services **12 AAC 52.920. Disciplinary Guidelines** (15) acts or omissions within the practice of pharmacy that fail to meet the standard of care;
Idaho	**54-1705. Practice of Pharmacy – General Approach** To evaluate whether a specific act is within the practice of pharmacy in or into Idaho, or whether an act can be delegated to other individuals under his supervision, a licensee or registrant of the board of pharmacy shall independently determine whether: (1) The act is expressly prohibited by: (a) This chapter; (b) The uniform controlled substances act; (c) The rules of the board of pharmacy; or (d) Any other applicable state or federal laws or regulations; (2) The act is consistent with the individual's education, training, and experience; and (3) Performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent individual with similar education, training, and experience. **IDAPA 24.36.01.104. Unprofessional Conduct** 16. Standard of Care. Acts or omissions within the practice of pharmacy which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting.

Iowa*	**155A-2B Practice of Pharmacy General Principles** To evaluate whether an act by a licensee or registrant under this chapter violates the appropriate standard of care, a licensee or registrant of the board must consider all of the following: 1. Whether performance of the act is expressly prohibited by a provision of this chapter. 2. Whether performance of the act is expressly prohibited by a rule adopted by the board. 3. Whether performance of the act is consistent with the education, training, and experience of a licensee or registrant. 4. Whether performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training, and experience. **155A.12 Grounds for Discipline** 11. Engaged in conduct outside the accepted standard of care that would be provided in a similar setting by a reasonable and prudent applicant or licensee.

**Note: Iowa language lacks the authority to delegate under a standard of care framework.*

In 2018, the National Association of Boards of Pharmacy (NABP) created a task force to develop pharmacy regulations based on standard of care.[44] The task force report included the following recommendations to the profession and boards of pharmacy:

- **Review the state practice act** and eliminate any unnecessary regulations to recognize evolving pharmacy practice.
- **Consider standard of care** as a regulatory alternative for clinical care services.
- **Develop a standard of care** definition to include in the NABP Model Act.

In 2022, the American Pharmacist Association House of Delegates adopted the *Standard of Care Regulatory Model for State Pharmacy Practice Acts* model policy, requesting state boards of pharmacy and legislative bodies to regulate pharmacy practice using a standard of care regulatory model similar to other health professions' regulatory models.[45] This change allowed pharmacists to practice at the level consistent with their individual education, training, experience, and practice setting. The NABP recommendations and American Pharmacists Association (APhA) model policy combat the bureaucratic inertia and overregulation from Boards of Pharmacy, with an overdue call to action to pivot to standard of care, deregulate, and get out of the way of pharmacists to provide a higher level of care. Notably, the NABP Model Pharmacy Act has since been updated to include a definition of standard of care defined as, "the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances."[46]

In 2023, the Alaska Board of Pharmacy transitioned to a standard of care model through negotiated administrative rulemaking. The change has already spurred a spring-cleaning of administrative rules, including expanding pharmacist scope of practice and continuation of therapy, and more recently becoming the fourth state to remove the Multistate Pharmacy Jurisprudence Examination (MPJE) as a prerequisite of pharmacist licensure.[47] In 2024, the Iowa General Assembly passed and Governor Kim Reynolds signed HF 555 adopting a standard of care regulatory approach for pharmacy practice. Coupled with a zero-based regulation executive order, the Iowa Board of Pharmacy is poised to remove 13 chapters, 141 rules, and 36,000 words from the books.[48-49]

A New Model For States

Adams and colleagues delineate a five-step guide for state policymakers and pharmacy advocates to achieve a standard of care regulatory model based on the experience and lessons learned in Idaho (Figure 2).[50] Of note, by transitioning to standard of care, both Alaska and Iowa integrated elasticity for pharmacist scope of practice over time, as well as ensconced the appropriate accountability mechanisms (Figure 1). As Iowa progresses toward pharmacist full practice authority, a future update to their standard of care statute should include extending the framework to delegation of services to pharmacy technicians and unlicensed personnel. Step one to freeing pharmacists from decades of regulatory capture is adopting explicit standard of care language.

FIGURE 2. FIVE-STEP GUIDE TO ACHIEVING STANDARD OF CARE[51]

1. Adopt a broad definition of "practice of pharmacy"
2. Allow elasticity for scope of practice advancement over time
3. Decide which limited instances still necessitate prescriptive regulation
4. Eliminate all remaining unnecessary regulations
5. Strengthen accountability mechanisms and oversight

Defining Full Practice Authority

Adopting a standard of care regulatory model allows the pharmacy profession to rethink how to define traditional norms regarding pharmacist scope of practice. Ross and colleagues eloquently made a call to action for the profession to stop referring to new pharmacy practice services as "expanded, enhanced, or expanded scope of practice," and outlined a pathway towards full scope that includes performance of prescribing, deprescribing, drug administration, prescription adaptation, laboratory test, and disease management.[52-53] At the core of achieving full practice authority is the underpinning of independent authority and evidence-based practice unhindered by outdated legislation and regulatory restrictions.

> *"Full-scope pharmacist services include all proactive and comprehensive interventions that prevent or manage illness and are within an individual's competency to perform independently."*
>
> —Dr. Ross Tsyuki
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Before creating a new defining standard, the pharmacy profession should consider learning from the jurisdictional challenges and historical success of advanced practice registered nurses' (APRNs) pursuit of full practice authority. The American Nurses Association (ANA) states, that full practice authority is generally defined as an APRN's ability to utilize knowledge, skills, and judgment to practice to the full extent of his or her education and training. Notably, this definition is inherently standard of care and does not create a specific list of permitted authorities.[55] The American Association of Nurse Practitioners (AANP) defines full practice authority as the authorization of nurse practitioners (NPs) to evaluate patients, diagnose, order and interpret diagnostic tests and initiate and manage treatments—including prescribing medications—under the exclusive licensure authority of the state board of nursing.[56]

In the establishment of independent full practice authority, state boards of nursing: (1) implemented standard of care; (2) agreed on a scope of nursing practice decision-making framework; and (3) adopted broad definitions to the practice of nursing and practice of advanced practice registered nurses.[57] In addition, any state with limitations to independent authority functionality or requiring physician oversight through restrictive collaborative practice agreements or supervision ratios are deemed reduced practice or restrictive practice states.[58] Rather than reinventing a new regulatory method or implementing a prescriptive bright-line approach as pharmacy, the profession of nursing mirrored the successes of physicians and the broad definition of the practice of medicine to allow new innovation and practice at the top of each clinicians education, training, and experience.

Toward Collaborative Practice, Not Collaborative Practice Agreements

Previous pharmacy research variations in state advancement on scope of practice can be best described on a continuum of innovation, indicating not all changes in state scope of practice laws are good for patient care, and that some advancements are simply poor concessions that should outrightly be opposed.[59] In 1979 for example, Washington state became the first state to permit pharmacists to enter population-based collaborative drug therapy agreements to initiate therapy. With decades of peer-reviewed literature and patient safety outcomes supporting the Washington state approach, more than 35 states followed by passing restrictive patient-specific collaborative practice laws.[60] More often than not these laws are unusable and impractical in community pharmacy settings. In 2021, Adams and Weaver noted that to fully engage in the Pharmacists' Patient Care Process, states must allow an aggressive continuum toward pharmacists' authorization to (1) order and interpret laboratory tests; (2) prescribe medications; (3) adapt medications; (4) administer medications; and (5) effectively delegate tasks to support staff.[61]

The failed timeline of implementing population-based collaborative practice across the states, medical boards threatening litigation in states where authority has existed for decades, and the lessons learned from APRNs, physician assistants, psychologists, and optometrists on scope advancements indicate that moving forward states should only pursue independent practice models.[62] State and national medical associations openly use existing collaborative practice laws as a fulcrum to oppose full practice authority for every healthcare professional.[63]

Dependence on collaborative practice agreements is dependent on a delegated authority. A legal authority founded on delegation can be undelegated at any time. Rescinding authority pulls the rug out from under from patients and innovation in practice. While collaborative practice agreements may have been the starting point for the past four decades, a new prescription calls for pharmacists to abandon efforts to appease medical opposition with poor concessions that impede patient access to pharmacist services. As such, this research aims to prescribe a continuum of full practice authority for the states, indicating critical regulatory barriers to remove, and pivot toward full practice authority.

A NEW PRESCRIPTION CALLS FOR PHARMACISTS TO ABANDON EFFORTS TO APPEASE MEDICAL OPPOSITION WITH POOR CONCESSIONS THAT IMPEDE PATIENT ACCESS TO PHARMACIST SERVICES

Pharmacist Full Practice Authority: Diagnosis and Prescribing

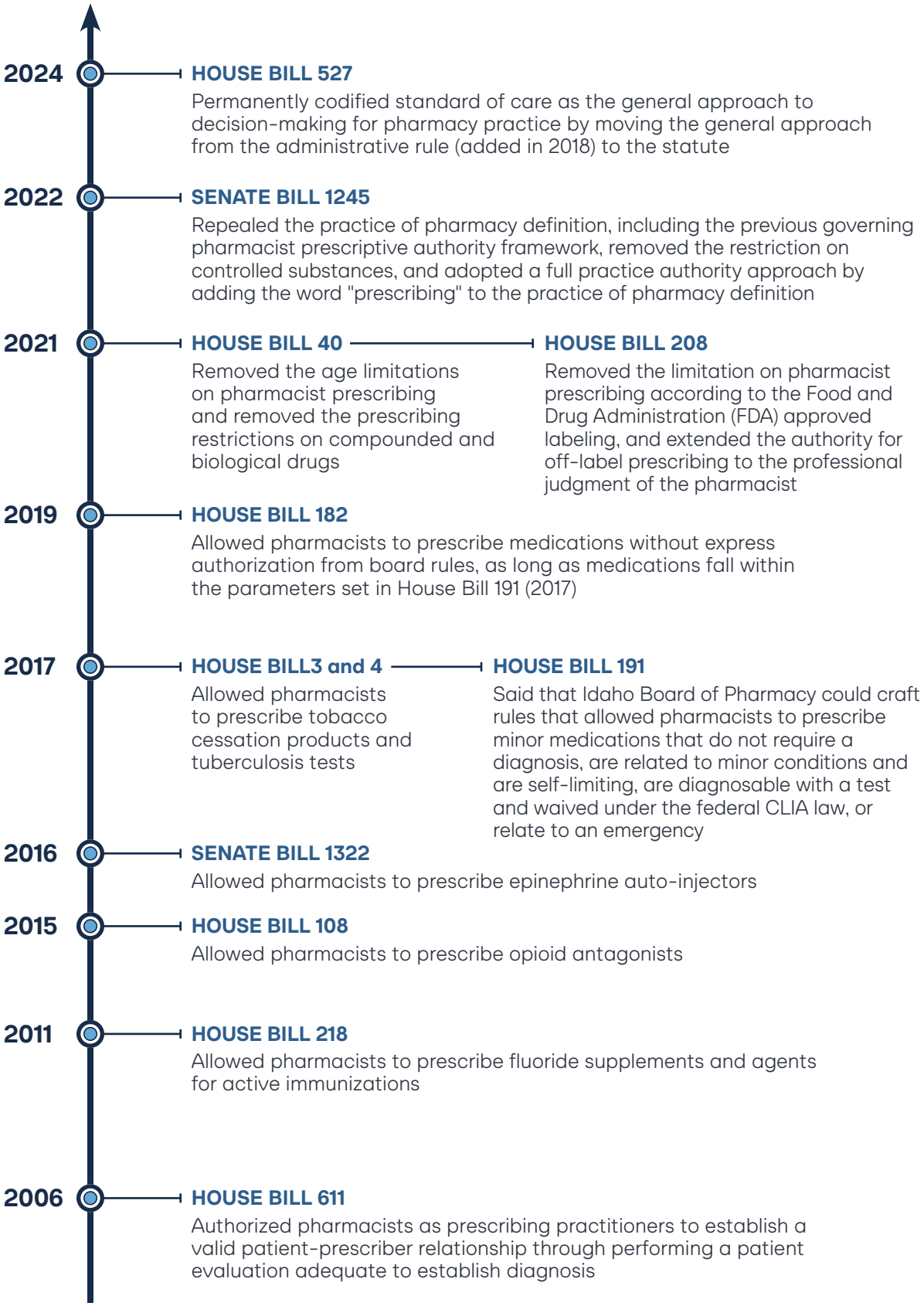
The pathway for states achieving independent authority to diagnose and prescribe has historically been that of one-off legislative authority for a specific drug or disease state category.[64] As states have successfully implemented limited independent prescribing categories for common drug categories such as immunizations, smoking cessation, naloxone, epinephrine, tuberculin purified protein derivative, and hormonal contraceptives, among others—states have experimented with broad governance models such as: (1) medical-veto model sharing authority between boards of pharmacy and boards of medicine; (2) interdisciplinary committee of appointed healthcare providers; (3) board of pharmacy formulary list; and (4) standard of care diagnosis and prescribing model.[65] The literature detailing uptake, patient outcomes, and experiences from Florida (1985) and New Mexico (1993)—and more recent models implemented in Colorado (2017), Oregon (2017), and Idaho (2017)—indicate that a pharmacist-determined diagnosis and prescribing model based on standard of care is the gold standard for states to pursue.[66-71]

Perhaps this is best demonstrated by states that experimented with a model but within a short timeframe upgraded to standard of care. Montana, California, North Carolina, and New Mexico initially pursued advanced practice pharmacist (APP) designations, but research demonstrates these APP designations have low pharmacist uptake and unnecessary barriers to entry such as limited collaborative practice agreement scope and additional licensure thresholds.[72]

Montana has since abandoned the APP designation of "pharmacist clinician" and California updated the authority for APP pharmacists from collaborative practice authority to independent authority. In 2021 and 2023 respectively, Colorado SB 21-094 and Montana SB 112 upgraded to a pharmacist-determined standard of care for diagnosis and prescribing.[73-74] Previous research from Broughel and colleagues well documents the pathway Idaho paved from 2011 until 2019 in implementing a pharmacist-determined diagnosis and prescribing model through numerous legislative and regulatory board efforts (Figure 3).[75] In 2024 Tennessee SB 869 followed the Idaho 2017 approach, accomplishing a strong starting framework list of one-off drug categories pharmacists may prescribe under a standard of care framework.[76]

The momentum in Tennessee accomplishes many of the independent prescribing advancements of California, Oregon, Vermont, Virginia, and Utah without the restrictive mandatory protocol criteria adopted by the Board of Pharmacy through regulations. The starting point for states pursuing independent diagnosis and prescribing should begin with the basis of **Idaho, Colorado, and Montana**.

FIGURE 3. REFORMING THE PRACTICE OF PHARMACY: OBSERVATIONS FROM IDAHO[77]



The core elements of the original Idaho (2017 & 2019) legislation and companion legislation in Colorado (2021) and Montana (2023) have been enshrined in the following model policy for pharmacist prescribing authority:[78]

> ***Section 1. Short Title***
>
> *This Act shall be known and may be cited as the Pharmacist Prescribing Authority Act.*
>
> ***Section 2. Purpose***
>
> *The purpose of this Act is to authorize pharmacists to practice the full extent of their education and training to prescribe medications to patients.*
>
> ***Section 3. Practice of Pharmacy***
>
> *Practice of Pharmacy means:*
> *The prescribing of drugs, drug categories, and devices that are limited to conditions that:*
> *(i) Do not require a new diagnosis;*
> *(ii) Are minor and generally self-limiting;*
> *(iii) Have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal Clinical Laboratory Improvement Amendments of 1988; or*
> *(iv) In the professional judgment of the pharmacist, are patient emergencies.*

Idaho, Colorado, and Montana were the first states to explicitly permit broad authority for a pharmacist to independently diagnose (1) minor or generally self-limiting (minor ailments); and (2) conditions guided by the results of a laboratory test. A robust body of evidence of patient acceptance, patient demand, and patient safety profile for minor ailments and chronic diseases in Canada, the United Kingdom, New Zealand, and Australia supported these actions.[79] States have a longer history of pharmacists performing diagnoses based on the results of laboratory tests for influenza and group B streptococcus, as well as human immunodeficiency virus (HIV) pre-exposure prophylaxis (PEP) and HIV postexposure prophylaxis (PrEP), being the most common.[80]

In July 2022, pharmacist independent authority to diagnose patients based on laboratory testing was catapulted on the national scale when the Food and Drug Administration (FDA) revised its emergency use authorization for Paxlovid, allowing pharmacists in all states to prescribe the drug for patients who test positive for COVID-19.[81] While the FDA approach was over-regulated and inconsistent with the standard of care permissions they created for other health professionals, the change spurred action across multiple states to introduce legislation to make the allowance permanent. Tennessee SB 869 (2024) is a recent example, now permitting a pharmacist to independently prescribe antivirals for influenza and COVID-19 that are waived under the federal clinical laboratory improvement amendments of 1988.[82]

With Zalupski and colleagues recently reporting that 51 percent (29,011) of U.S. pharmacies hold a Clinical Laboratory Improvement Amendments (CLIA) waiver, authorizing the performance of diagnostic laboratory testing—pharmacist diagnosis in primary care settings

is gaining momentum.[83] Many state pharmacy scope of practice restrictions preempted in 2020 during COVID-19 by the Secretary of Health and Human Services (HHS) declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) are set to expire at the end of 2024, creating urgency for permanent patient access solutions.[84]

> *"If waiving these regulations was deemed necessary to improve public health and welfare during the declared emergency, there is a rebuttable presumption that the regulations are unnecessary or counterproductive outside of the declared emergency."*
>
> —Idaho Governor, Brad Little[85]

Since the initial HB 191 (2017) diagnostic and prescribing authority framework, the Idaho Legislature has taken multiple definitive steps to move Idaho pharmacy law to better reflect the independent authority found within the practice of medicine and the practice of advanced practice registered nurses (APRNs). In 2021, Idaho HB 40 removed all remaining age limitations and removed the prescribing restrictions on compounded and biological drugs.[86] In the same year, Idaho HB 208 removed the restriction of only prescribing according to federal Food and Drug Administration (FDA) labeling, again extending the professional judgment to pharmacists.[87] In 2022, Idaho SB 1245 repealed the practice of pharmacy definition, including the previous governing prescriptive authority framework, and replaced the definition with one word: prescribing (Figure 4).[88] In 2024, Idaho HB 527 spurred updates to the definition of pharmaceutical care services to more explicitly authorize independent diagnosis, amending language from "performing or obtaining necessary assessments of the patient's health status" to new language stating, "diagnosing the patient's health status or condition."[89] The changes dovetail nicely with governing statute authority that has been in place since 2006 that includes pharmacists as a "prescriber" and requires a valid prescription to include "a documented patient evaluation adequate to establish diagnoses."[90]

FIGURE 4. IDAHO COMPARISON OF HEALTHCARE BOARDS: DIAGNOSIS AND PRESCRIBING[91-96]

State: Idaho	Diagnosis and Prescribing Authority
Board of Medicine	**54-1803. Definitions** (1) "Practice of medicine" means: (a) The investigation, **diagnosis, treatment, correction, or prevention of or prescription** for any human disease, ailment, injury, infirmity, deformity or other condition, physical or mental, by any means or instrumentality that involves the application of principles or techniques of medical science;
Board of Nursing	**54-1402. Definitions** (1) "Advanced practice registered nurse" means a registered nurse licensed in this state who has gained additional specialized knowledge, skills and experience through a program of study recognized or defined by the board. An advanced practice registered nurse is authorized to perform advanced nursing practice, which may include the **prescribing, administering and dispensing of therapeutic pharmacologic agents**, as defined by board rules. An advanced practice registered nurse shall perform only those acts as provided by the board and for which the individual is educationally prepared. Advanced practice registered nurses shall include the following four (4) roles: certified nurse-midwife; clinical nurse specialist; certified nurse practitioner; and certified registered nurse anesthetist as defined in board rule. An advanced practice registered nurse collaborates with other health professionals in providing **health care**. **24.34.01.002. Definitions** **12. Diagnosis.** Means identification of actual or potential health problems and the need for intervention based on analysis of data collected. **Diagnosis** depends upon the synthesis of information obtained through interview, physical exam, diagnostic tests or other investigations.
Board of Pharmacy	**54-1705. Definitions** (46) "Practice of pharmacy" means the safe interpretation, evaluation, compounding, administration, and dispensing of prescription drug orders, patient counseling, collaborative pharmacy practice, provision of pharmaceutical care services, proper storage of drugs and devices, and **prescribing of drugs and devices** as may be further defined in this chapter. **54-1733. Validity of Prescription Drug Orders** A prescription drug order for a legend drug is valid only if it is issued by a prescriber for a legitimate medical purpose arising from a prescriber-patient relationship that **includes a documented patient evaluation adequate to establish diagnoses**, if applicable, and identify underlying conditions and/or contraindications to the treatment. A valid prescriber-patient relationship may be established through virtual care technologies, provided that the applicable Idaho community standard of care must be satisfied. **24.36.01.010. Definitions and Abbreviations** 19. Pharmaceutical Care Services. A broad range of services for patients performed independently or in collaboration with other **health care** professionals. Pharmaceutical care services are not limited to, but may include one (1) or more of the following: a. **Diagnosing the patient's health status or condition**;

Bridging Clinical Services Gap: Full Practice Authority and Standard of Care

Implementing full practice authority under a standard of care regulatory framework means rejecting the state experimentation with three to fifteen page mandatory protocols for each independent prescribing drug category. These protocols and patient algorithms are static in time and not clinically dynamic with changes in guidelines, requiring state rulemaking for updates. Before standard of care, it stands to reason state Boards of Pharmacy would consider building all the patient inclusion and clinical guidelines into the rule. Adopting a standard of care framework equips the legislature and Board of Pharmacy with the necessary accountability tools to create a balance between patient access and patient safety (Figure 5). Legislators and pharmacy stakeholders who have accomplished independent prescribing through one-off drug category protocols and broad governance models should celebrate the foundational success, but embrace the change to the pharmacist-determined diagnosis and prescribing model based on standard of care (Figure 6). There is a wide margin of error from legislative bill introduction to a governor's signature to the final board rule that determines whether a new practice authority will be operationally usable by business, let alone optimal. States should generally solely rely on the statute authority framework and reject all board rulemaking, deferring to standard of care.

FIGURE 5. STANDARD OF CARE – BALANCING SCOPE EXPANSION AND PATIENT SAFETY

FIGURE 6. TOWARDS PHARMACIST FULL PRACTICE AUTHORITY

Adopt Broad Standard of Care Framework	
Diagnosis and Prescribing **Model Language:** **Preferred** – Amend the practice of pharmacy definition to include: "diagnosis, prescribing" **Alternative** – Amend the practice of pharmacy definition to include: The prescribing of drugs, drug categories, or devices, that are limited to conditions that: 1) Do not require a new diagnosis; 2) Are minor and generally self-limiting; 3) Have a test that is used to guide diagnosis or clinical decision- making and are waived under the federal clinical laboratory improvement amendments of 1988; or 4) In the professional judgment of the pharmacist, are patient emergencies **Alternative** – Amend the practice of pharmacy definition or pharmaceutical care services definition to include: "diagnosing the patient's health status or condition." or "performing or obtaining necessary assessments of the patient's health status" to new language stating,	**State laws and/or regulations should be silent on the following topics deferring to standard of care:** • Do not limit authority to post-diagnostic categories • Do not connect practice authority to collaborative practice agreements or standing orders • Do not require specific patient assessment and diagnosis criteria such as mandatory clinical guidelines, protocols, or static documents • Do not require a new advanced practice designation or prescribing certificate/license • Do not specify liability insurance requirements or thresholds • Do not require mandatory continuing education requirements for each drug category • Do not require new training requirements for each drug category • Do not create patient age limitations • Do not limit prescribing to only FDA approved indication and allow for off-label considerations • Do not mandate primary care provider notification requirements • Do not require specific referral criteria, allowing professional judgment when to referring patients to an appropriate venue of care

Order, Interpret, and Administer Laboratory Testing and Imaging **Model Language:** **Preferred** – Amend the practice of pharmacy definition to include: "ordering, interpreting, or administration of laboratory tests" and "ordering and interpreting imaging" **Alternative** – Amend the "medication therapy management" or "pharmaceutical care services" definition to include ordering, interpreting, and administering laboratory tests	**State laws and/or regulations should be silent on the following topics deferring to standard of care:** • Do not create a list of specific authorized tests • Do not limit testing to only CLIA-waived tests • Do not require a physician medical director as a prerequisite to perform testing or imaging • Do not limit testing or imaging to limited or specific patient settings "institutional or hospital only" • Do not require additional continuing education or specific education/training requirements for laboratory testing or imaging • Do not require additional mandatory liability insurance requirements or thresholds • Do not create restrictions that prevent pharmacist delegation of simple testing, such as CLIA-waived tests to qualified healthcare professionals, such as pharmacy technicians or medical assistants • Do not limit testing or imaging to only occurring in the licensed pharmacy space/location
Drug and Device Administration **Model Language:** **Preferred** – Amend the practice of pharmacy definition to include: "ordering and administration of drugs and devices" **Alternative** – Amend the "medication therapy management" or "pharmaceutical care services" definition to include ordering and administration of drugs and devices	**State laws and/or regulations should be silent on the following topics deferring to standard of care:** • Do not connect authority to only protocols, standing orders, or collaborative practice agreements • Do not create venue restrictions limiting where a pharmacist may administer, such as only institutional, hospital, or within the licensed pharmacy space • Do not create a list or limited categories of drugs or devices a pharmacy may administer • Do not limit the administration of controlled substance drugs for treatment of substance use disorder • Do not require mandatory liability insurance, continuing education, or specific education/training requirements • Do not prevent pharmacist delegation of drug administration to qualified healthcare professionals, such as pharmacy technicians or medical assistants

Prescription Adaptation

Model Language:

Preferred – Amend the practice of pharmacy definition to include: "performing prescription adaptation"

Alternative – Amend the "medication therapy management" or "pharmaceutical care services" definition to include prescription adaptation

State laws and/or regulations should be silent on the following topics deferring to standard of care:

- Do not codify restrictions preventing a pharmacist from using their professional judgment and adapting any prescription from 30-day fills to 90-days, six months, or one-year fills.
- Do not require an initial 30-day prescription fill, prior to allowing a pharmacist to perform prescription adaptation
- Do not codify restrictions on medication synchronization only being performed by "short-filling" one of the refills, in lieu of allowing "extended filling" of the initial quantity (e.g. more than 30 day supply) to coordinate medication synchronization.
- Allow a pharmacist to change the quantity of medication prescribed if:
    - The prescribed quantity or package size is not commercially available;
    - The change in quantity is related to a change in dosage form, strength, or therapeutic interchange;
    - The change is intended to dispense up to the total amount authorized by the prescriber including refills; or
    - The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program.

Continuation of Therapy	State laws and/or regulations should be silent on the following topics deferring to standard of care:
Model Language: Section 1. Continuation of Therapy: Patient Refills A. A prescription drug order may be refilled when permitted by state and federal law and as specifically authorized by the prescriber. B. A pharmacist using their professional judgment may refill a prescription for a non-controlled drug to ensure continuity of care.	• Do not codify onerous language mandating specific provider notification/outreach or pharmacist documentation requirements contributing to alert fatigue, burnout, or patient delays • Do not codify drug category specific restrictions such as only "chronic medications" or "excluding psychotropic medications" • Do not limit the ability for a pharmacist to perform continuation of therapy only during a "Governor declared emergency" or "patient emergency" arbitrarily creating a one-size-fits all qualifying event to continued access to drug therapy • Do not create "only once (or twice) every six months" patient restrictions to continue therapy • Do not codify a "only 72 hours" or "smallest commercially available package" or "up to 30-day supply" maximum quantity to continue therapy • Do not place a one-year or two-year timeframe limitation on a prescription being valid from the date of issuance, preventing a legal barrier to continuation of therapy

Conclusion

Pharmacist full practice authority is a proven safe and evidence-based solution to solving the primary care shortage crisis. Pharmacists are highly trusted, doctorate-trained healthcare providers able to diagnose and manage chronic diseases and minor ailments, decrease unnecessary emergency room visits, and deliver preventative health outcomes.

Governors should direct executive agency Boards of Pharmacy to prioritize regulatory rewrites to unravel the overregulation of pharmacy clinical services and transition to a standard of care model, maintaining strong back-end accountability mechanisms while championing business innovation and patient choice.

Legislators and policymakers should update their state "practice of pharmacy" definitions, following the success of Idaho, Colorado, and Montana, rejecting the anecdotal physician protectionism masquerading as patient safety concerns and embracing independent pharmacist diagnosis and prescribing based on the community standard of care. Legislative and regulatory strings prevent pharmacists from practicing at the top of their education, training, and experience. It is long past due for the pharmacy profession to move to a standard of care regulatory model and for states to pursue pharmacist full practice authority.

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Cost-Effectiveness of Pharmacist Prescribing for Managing Hypertension in the United States

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Abstract

IMPORTANCE Pharmacist-led interventions can significantly improve blood pressure (BP) control. The long-term cost-effectiveness of pharmacist-prescribing interventions implemented on a large scale in the US remains unclear.

OBJECTIVE To estimate the cost-effectiveness of implementing a pharmacist-prescribing intervention to improve BP control in the US.

DESIGN, SETTING, AND PARTICIPANTS This economic evaluation included a 5-state Markov model based on the pharmacist-prescribing intervention used in The Alberta Clinical Trial in Optimizing Hypertension (or RxACTION) (2009 to 2013). In the trial, control group patients received an active intervention, including a BP wallet card, education, and usual care. Data were analyzed from January to June 2023.

MAIN OUTCOMES AND MEASURES Cardiovascular (CV) events, end-stage kidney disease events, life years, quality-adjusted life years (QALYs), lifetime costs, and lifetime incremental cost-effectiveness ratio (ICER). CV risk was calculated using Framingham risk equations. Costs were based on the reimbursement rate for level 1 encounters, medication costs from published literature, and event costs from national surveys and pricing data sets. Quality of life was determined using a published catalog of EQ-5D utility values. One-way sensitivity analyses were used to assess alternative reimbursement values, a reduced time horizon of 5 years, alternative assumptions for BP reduction, and the assumption of no benefit to the intervention after 10 years. The model was expanded to the US population to estimate population-level cost and health impacts.

RESULTS Assumed demographics were mean (SD) age, 64 (12.5) years, 121 (49%) male, and a mean (SD) baseline BP of 150/84 (13.9/11.5) mm Hg. Over a 30-year time horizon, the pharmacist-prescribing intervention yielded 2100 fewer cases of CV disease and 8 fewer cases of kidney disease per 10 000 patients. The intervention was also associated with 0.34 (2.5th-97.5th percentiles, 0.23-0.45) additional life years and 0.62 (2.5th-97.5th percentiles, 0.53-0.73) additional QALYs. The cost savings were $10 162 (2.5th-97.5th percentiles, $6636-$13 581) per person due to fewer CV events with the pharmacist-prescribing intervention, even after the cost of the visits and medication adjustments. The intervention continued to produce benefits in more conservative analyses despite increased costs as the ICER ranged from $2093 to $24 076. At the population level, a 50% intervention uptake was associated with a $1.137 trillion in cost savings and would save an estimated 30.2 million life years over 30 years.

CONCLUSION AND RELEVANCE These findings suggest that a pharmacist-prescribing intervention to improve BP control may provide high economic value. The necessary tools and resources are

(continued)

Key Points

Question What would be the cost-effectiveness of implementing a pharmacist-prescribing intervention to improve blood pressure control in the United States?

Findings In this simulated cost-effectiveness analysis of a 5-state Markov model, 50% uptake of a pharmacist-prescribing intervention to improve blood pressure control was associated with a $1.137 trillion in cost savings and could save an estimated 30.2 million life years over 30 years.

Meaning These findings suggest that pharmacist-prescribing interventions to improve blood pressure control would provide high economic value compared with usual care.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Abstract (continued)

readily available to implement pharmacist-prescribing interventions across the US; however, reimbursement limitations remain a barrier.

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Introduction

Hypertension (HTN) is the leading preventable cause of death and disability throughout the world.[1] More than 100 million people in the US have HTN, a significant risk factor for the development of cardiovascular disease (CVD) and kidney disease.[2] Health care costs associated with HTN in the US alone exceeded $130 billion between 2003 and 2014.[3] Despite affordable medications and lifestyle interventions proven to reduce blood pressure (BP), BP control rates in the US are declining.[4] Currently, only 1 in 4 adults with HTN has their BP under control (ie, less than 130/80 mm Hg).[2]

In 2020, the US Surgeon General issued a Call to Action to Control Hypertension,[5] which "seeks to avert the negative health effects of HTN across the US by identifying interventions that can be implemented, adapted, and expanded across diverse settings." The goals include making HTN a national priority; ensuring the places where people live, learn, work, and play support HTN control; and optimizing patient care for HTN. One of the primary strategies promotes standardized treatment approaches and guideline-recommended care with an emphasis on team-based care.[5]

Pharmacists are well placed in the community to screen and manage HTN because they see patients up to 10 times more frequently than physicians.[6] Numerous randomized clinical trials[7-10] of pharmacist-led case-finding and prescribing interventions have improved HTN outcomes. Given this evidence and the compelling need for new solutions to reduce the clinical and economic burden of uncontrolled HTN, we conducted a cost-effectiveness analysis of implementing pharmacist prescribing for HTN management in the US.

Methods

This economic evaluation followed the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) reporting guideline. Per the Common Rule, institutional review and informed consent were not required because this research did not involve human participants.

A pharmacoeconomic model was developed in Microsoft Excel to assess the potential impact of pharmacist prescribing for HTN compared with usual care (status quo) on long-term costs and health outcomes in the US. The implementation of the model for a Canadian population has been previously described in greater detail[11]; this structure was used and updated to reflect the US population and health care system. Briefly, the model was structured as a 5-state Markov model, with patients entering the model with uncontrolled HTN and no additional history of cardiovascular (CV) or kidney disease. Over time, patients were at risk of developing CV and/or kidney disease and subsequent death (**Figure 1**). All patients were at risk for all-cause mortality based on general population life tables, with an increased risk of mortality in individuals following a CV event. The conceptual model assumed that the pharmacist-prescribing intervention would reduce BP, with a resultant decreased risk of CV and kidney disease; the costs of implementing pharmacist-prescribing HTN management were thus compared with long-term cost offsets as well as health and mortality benefits resulting from this BP reduction.

The base case scenario was a third-party payer perspective, with a 30-year time horizon, 1-year model cycles, and costs and quality-adjusted life years (QALYs) discounted at 3% per annum.[12] Results are reported at both the individual level and scaled up to the US population based on the number of individuals with uncontrolled HTN.

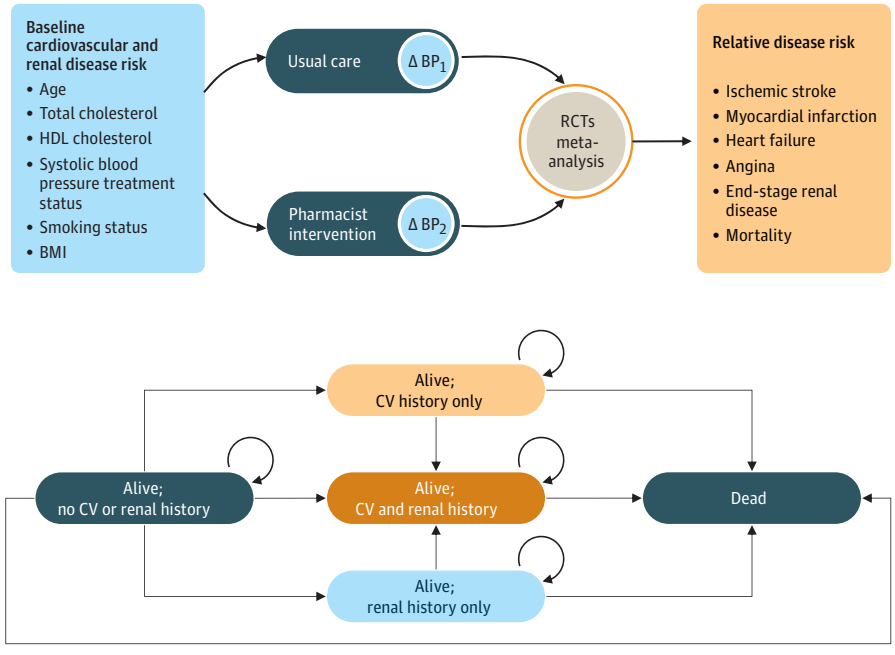
Clinical Model Structure

The Alberta Clinical Trial in Optimizing Hypertension (R_xACTION) was conducted in Alberta, Canada from 2009 to 2013.[10] This analysis was conducted in 2023 and used a model base case based on the mean 6-month reduction in systolic BP (SBP) (−18.3 mm Hg) observed with the pharmacist intervention in the R_xACTION study, which involved pharmacist assessment and counseling of BP, antihypertensive medication review, and prescribing antihypertensives in a face-to-face encounter. Pharmacist follow-up occurred every 4 weeks until BP was at goal for 2 consecutive visits followed by 12-week intervals for the remainder of the 24-week study duration. In the model, it was assumed that this would correspond to 6 visits in the first year and quarterly visits thereafter. For the comparator group, we assumed that BP would remain at baseline levels. We did not use the control group from the R_xACTION trial because it was an active intervention. Baseline clinical and demographic characteristics were based on the trial population (eTable 1 in Supplement 1).

The risk of CVD over time for the control arm was calculated based on Framingham risk equations for myocardial infarction (MI), stroke, heart failure (HF), and angina given baseline BP levels.[13-15] The association between SBP reduction in the intervention group and reduced risk of CVD was estimated using results from the Blood Pressure Lowering Treatment Trialists' Collaboration.[16] A regression analysis was conducted based on the reported values for SBP and risk reduction of major CV events, and the resulting slope was used to estimate the impact of a 1-unit reduction on the relative risk. The resulting estimated association was a 0.026 (SE, 0.004) decrease in relative risk of CVD per each mm Hg decrease in SBP.

The impact of BP on kidney disease was characterized by the risk of end-stage kidney disease (ESKD), which was based on a reported association between BP categories and ESKD incidence observed in a US historical cohort study and a 25-year follow-up study.[17,18] Rates per 100 000 person-years were reported by category (normal, pre-HTN, stage 1 HTN, and stage 2 HTN), and converted to annual probabilities. For the modeled population at baseline, the mean BP corresponded to stage 1 HTN, which corresponded to an ESKD rate of 19.5 per 100 000 person-years, or an annual risk of 0.000194 per person. This annual risk was retained for the control arm. For the treatment arm, regression analysis of risk by BP category was conducted to estimate a risk

Figure 1. Model Structure



Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure; CV, cardiovascular; HDL, high-density lipoprotein; RCT, randomized controlled trial.

reduction of 0.77 associated with observed BP reduction, which was applied to result in an annual ESKD probability of 0.000150 for the pharmacist-prescribing intervention group. Mortality was based on US life tables, with a hazard ratio of 1.71 applied to account for the increased risk of mortality in a population with CVD.[19]

Costs

In the base case of the model, all pharmacist assessments were assumed to incur a cost of $23.10, reflecting the 2019 reimbursement rate for Current Procedural Terminology (CPT) 99211 (level 1 patient encounters).[20] Visits were assumed to be monthly for the first 3 months (assumed time until HTN became controlled), followed by quarterly, with 6 pharmacist visits in the first year and 4 annually after that. Given that the clinical model included pharmacist prescribing of medications, we assumed that patients receiving the intervention would incur an incremental medication cost of $32.78/mo, based on the mean monthly medication cost for individuals with HTN in the US. This was chosen conservatively to maximize the cost of the pharmacist intervention; the true incremental medication cost is likely lower given that some usual care patients receive physician-prescribed HTN medications, and pharmacist-prescribing interventions often result in discontinuation of less appropriate or effective medications.[10,21] Annual background all-cause health care costs for all individuals were based on age-specific values reported by the Agency for Healthcare Research and Quality.[22]

For individuals experiencing health events, the cost of the event was stratified into the first-year postevent and subsequent years. Costs for CV events (ie, stroke, heart failure, angina, and MI) were based on reported values from a US microsimulation model of HTN screening strategies, which used Medical Expenditure Panel Survey data. The cost for ESKD was based on US Renal Data System data (eTable 2 in Supplement 1).[23] All costs were inflated to 2021 US dollar based on the US Consumer Price Index-Medical Care.[24]

Health-Related Quality of Life

Health state utilities were taken from a published catalog of EQ-5D utility values in the US. Baseline utilities were 0.867 for patients without ESKD or CVD and age-adjusted using a utility decrement of 0.00029 per year after age 70 years.[25] The utility values included in the model were 0.694 for stroke, 0.725 for MI, 0.636 for HF, 0.709 for angina, and 0.708 for ESKD. Disease-specific utilities were assumed to be chronic and continued to apply years after the event.

Sensitivity Analyses

One-way sensitivity analyses were used to examine the impact of variation in key inputs, including (1) increased costs per pharmacist visit, reflecting reimbursement values aligned with a greater likelihood of dissemination and sustainability—$100 for an initial visit and $50 per follow-up; (2) reduced time horizon to 5 years; (3) alternative assumptions regarding SBP decrease, ranging from −5 to −27 mm Hg; (4) examining each type of health benefit (ie, reductions in stroke, MI, angina, HF, and ESKD) in isolation; (5) assuming that the HTN benefit is only sustained for 10 years, after which point there is no benefit to the intervention; and (6) a conservative scenario in which the BP decrease is assumed to be −10 mm Hg, losing 50% of benefit at 5 years, and 100% of benefit at 10 years. The range of BP values explored in sensitivity analysis reflects existing literature on the effect of pharmacist interventions on BP. A meta-analysis[7] reported that pharmacist interventions decreased mean SBP by an additional −7.6 mm Hg compared with usual care, but the types of pharmacist interventions in the included studies were heterogeneous and did not include prescriptive authority. Alternatively, the cluster-randomized trial of a pharmacist-prescribing intervention in black barbershops reported a mean reduction in SBP of −27 mm Hg in the intervention group; thus our use of −18.3 mm Hg from the R_xACTION is reasonable.

In addition to the 1-way sensitivity analyses, a 1000-iteration probabilistic sensitivity analysis was conducted to reflect the impact of stochastic parameter uncertainty on results. This included

probabilistic variability of cost, clinical, and health-related quality of life parameters, including the SBP reduction and the relationship between SBP and clinical event risk.

Epidemiologic Analyses

Base case cost-effectiveness results were expanded to the US population to estimate cumulative cost and health impacts over 30 years. Individual-level results output by the model were multiplied year-over-year by the estimated number of incidents and prevalent patients with uncontrolled HTN assumed to be accessing the intervention. This time horizon was chosen to capture the lifetime of the model cohort. The prevalence of uncontrolled HTN was estimated to be 92.1 million[26]; it was assumed that 50% of eligible individuals would access the intervention. Over a 30-year time horizon, incident cases of HTN were added each year based on a US cohort study.[27] It was assumed that the 50% rate of intervention use would persist among incident cases. Clinical and cost outcomes were assessed over the time horizon.

Results

Briefly, the R_xACTION trial enrolled 248 participants (mean [SD] age, 64 [12.5] years; 121 [49%] male; 41 [15%] currently smoked; and 109 [48%] had diabetes). The mean (SD) baseline BP was 150/84 (13.9/11.5) mm Hg with a mean (SD) of 1.7 (1.2) antihypertensives per participant. The pharmacist intervention achieved a significant reduction in SBP at 6 months compared with the active control group (−18.3 mm Hg vs −11.8 mm Hg, respectively; $P < .001$).

In the base case analysis over a 30-year time horizon, the pharmacist intervention was associated with 2100 fewer cases of CVD and 8 fewer cases of kidney disease per 10 000 patients. Per patient, the intervention was associated with 0.34 additional life years (discounted) and 0.62 additional QALYs (discounted) (**Table 1**). The intervention also resulted in overall cost savings of $10 162 per person, as the cost reduction associated with fewer CV events more than offset the cost

Table 1. Base Case, Quality-Adjusted Life Years, and Costs[a]

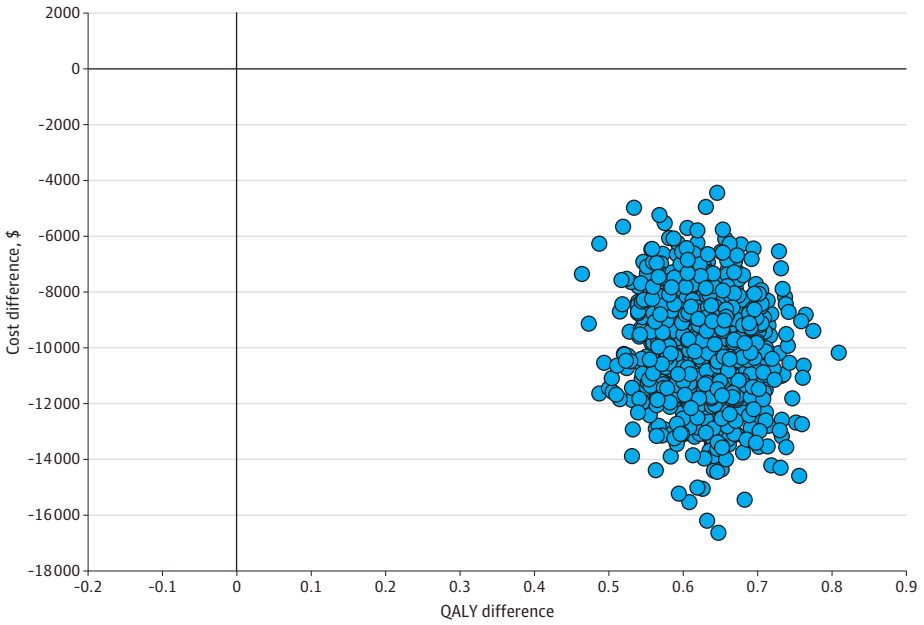
Characteristic	Usual care	Pharmacist intervention	Difference
Base case			
Cardiovascular events	0.61	0.40	−0.21
End-stage kidney disease events	0.0038	0.0030	−0.0008
Life years			
Discounted	14.6 (14.3 to 14.9)	15.0 (14.8 to 15.2)	0.34 (0.23 to 0.45)
Undiscounted	19.7	20.3	0.63
Quality-adjusted life years			
Discounted	11.8 (11.6 to 12.0)	12.4 (12.3 to 12.6)	0.62 (0.53 to 0.73)
Undiscounted	15.7	16.7	1.03
Costs			
Discounted	$189 648 ($151 188 to $237 055)	$179 485 ($140 586 to $225 972)	−$10 162 (−$13 581 to −$6636)
Undiscounted	$276 218	$262 593	−$13 625
Category-specific costs (discounted)			
Intervention costs	$0	$7318	$7318
Background medical costs	$97 481	$99 751	$2270
Total cardiovascular disease	$45 506	$28 242	−$17 264
Stroke	$10 652	$6595	−$4057
Myocardial infarction	$17 905	$11 152	−$6753
Angina	$5631	$3493	−$2138
Heart failure	$11 319	$7003	−$4317
Chronic kidney disease	$46 661	$44 174	−$2487

[a] Results presented are deterministic. Where available for key base-case outcomes, 2.5th to 97.5th percentiles from the probabilistic sensitivity analysis are included.

of pharmacist visits and medication adjustments (Table 1). When comparing health care costs only (ie, excluding the costs of the intervention itself) mean costs were $189 648 in the control group and $172 167 in the intervention group, for a savings of $17 481. As the pharmacist-prescribing intervention was associated with both better health outcomes and lower costs, it was found to be dominant (discounted and undiscounted). Results were robust in the probabilistic sensitivity analysis, because 100% of probabilistic iterations were in the economically dominant quadrant of the cost-utility plane (**Figure 2**).

In 1-way sensitivity analyses, results remained dominant when pharmacist costs were increased from the CPT level 1 reimbursement rate of $23.10 to $100 for an initial visit and $50 per follow-up visit, indicating that further incentivizing the pharmacist intervention would not jeopardize the resulting value of the service and would offset the pharmacist labor costs (**Table 2**). The intervention also continued to dominate usual care when benefits were only accrued for 10 years, at which point the intervention was assumed to be equivalent to usual care. Although in this scenario, cost savings were reduced to $5744 and QALY benefits were reduced to 0.08 per patient. This was further reduced to cost savings of $521 in a scenario where the SBP reduction was reduced to −10 mm Hg,

Figure 2. Probabilistic Sensitivity Analysis of Pharmacist Intervention



Abbreviation: QALY, quality-adjusted life year.

Table 2. Incremental Cost-Effectiveness Ratio and One-Way Sensitivity Analyses[a]

One-way sensitivity analyses	ICER, $
Increased cost per pharmacist visit ($100 first followed by $50)	Intervention dominates
5-y Time horizon	16 987
Systolic blood pressure reduction: 7.6 mm HG	2093
Systolic blood pressure reduction: 27 mm HG	Intervention dominates
Only stroke benefits included	14 572
Only myocardial infarction benefits included	6548
Only angina benefits included	21 995
Only heart failure benefits included	14 895
Only kidney benefits included	24 076
Attenuating benefits to 10 y	Intervention dominates
Systolic blood pressure reduction: 10 mm HG, attenuating benefits to 10 y with 50% efficacy reduction after 5 y	Intervention dominates

Abbreviation: ICER, incremental cost-effectiveness ratio.

[a] Results presented are deterministic. Where available for key base-case outcomes, 2.5th to 97.5th percentiles from the probabilistic sensitivity analysis are included.

with 50% efficacy loss at 5 years and 100% efficacy at 10 years. However, economic dominance was still retained. In a series of more conservative analyses (ie, reduced effectiveness of a less-intensive intervention, considering each respective health outcome in isolation), the intervention continued to result in health benefits, but with an increase in costs; incremental cost-effectiveness ratios ranged from $2093 to $24 076, well within standard thresholds for cost-effectiveness (Table 2). Reducing the time horizon to 5 years yielded an incremental cost-effectiveness ratio of $16 987.

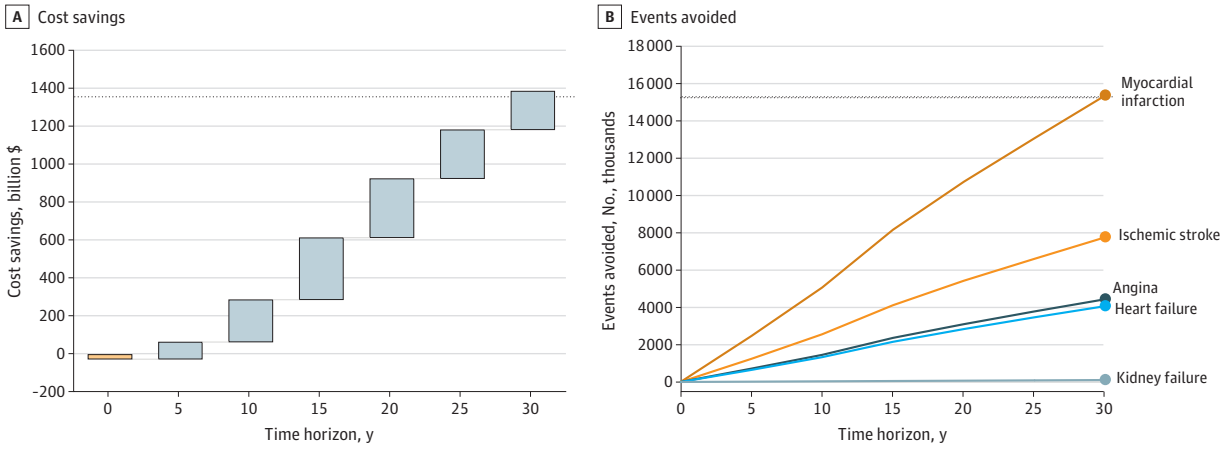
In a more comprehensive 1-way assessment of the association between incremental costs and QALYs across a range of SBP values, the pharmacist intervention was associated with increased QALYs and was associated with reduced costs for SBP reduction of −9 mm Hg or greater (eFigure 1 in Supplement 1). For a hypothetical SBP reduction between −5 and −9 mm Hg, although costs were greater for the pharmacist intervention, incremental cost-effectiveness ratios remained at cost-effective levels, ranging from $500 to $16 000. When the model with base case settings was expanded to the population level, it was estimated that with a 50% access rate, the pharmacist intervention would lead to $1.137 trillion in cost savings and save 30.2 million life years over 30 years (**Figure 3**).

Discussion

Pharmacist interventions significantly improve BP control,[7] but the economic impact of widespread adoption of such interventions has been unclear. Our study demonstrates that a pharmacist prescribing intervention would save $10 162 per person over a 30-year time horizon with and at the population level, a cumulative savings of $1.13 trillion dollars. These savings were largely attributable to a reduction in CV events due to improved BP control with the intervention. These findings mirror those from a similar analysis evaluating the implementation of this model in Canada.[11] The cost savings in that study were less at $6364 per person, translating to a population benefit of 15.7 billion over 30 years, likely due to the lower overall health care costs in Canada compared with the US.

There is a critical need for innovative approaches, such as pharmacist-led interventions, to improve BP control. Between 2010 and 2019, there was a 23.1% increase in HTN-related mortality in the US.[28] In 2019, the rate of HTN-related death among Black individuals aged 35 to 64 years was 96.3 events per 100 000—the highest of any race or ethnicity. Importantly, pharmacist-led interventions have been shown to significantly improve BP control among Black individuals and individuals of racial and ethnic minoritized groups.[8,29-31] There is also a sense of urgency for broader implementation of pharmacist interventions to improve BP control given the worsening shortage of primary care clinicians, which could reach between 17 800 and 48 000 by the year 2034.[32] Given

Figure 3. Cumulative Cost Savings and Health Outcomes Averted With Estimated Population Use of the Pharmacist Intervention



that 95% of individuals in the US live within 5 miles of a pharmacy, pharmacists are a possible solution to improve care access.[33]

Widespread implementation of pharmacist-prescribing interventions targeting uncontrolled HTN is feasible but will require continued advancement in pharmacist scope of practice legislation and eligibility for reimbursement through the Centers for Medicare & Medicaid Services. Today, 49 states and the District of Columbia have legislative provisions allowing pharmacist prescriptive authority through collaborative practice agreements, standing orders, or statewide protocols.[34] Such collaborative models often occur between pharmacists and physicians and permit prescriptive authority to pharmacists to initiate, adjust, or discontinue medications for specific medical conditions per an agreed-upon protocol or current clinical practice guidelines.[35] This approach is also evidence-based as it has been used in randomized trials demonstrating the effectiveness of physician-pharmacist collaborative models for HTN.[8,30] Expansion of prescriptive authority for pharmacists could increase access for those with limited or no source of primary care, which disproportionately affects males, underrepresented minorities, the uninsured, and those living in the southern US.[36]

While pharmacists may participate in collaborative models, pharmacists are infrequently recognized by payers because they are not recognized clinicians under the Social Security Act. Pharmacists can bill for services incident to those provided by a physician or advanced practice clinician; however, this is limited to Level 1, which is only $23.10 for 5 minutes of clinical services and insufficient for the level of service provided.[37] Our analysis showed that a pharmacist-prescribing intervention would remain cost-effective if pharmacists received a hypothetical reimbursement of $100 for the initial visit and $50 for each follow-up. While some states have recently passed clinician status legislation, much work remains to ensure pharmacists are adequately compensated for the clinical services they provide.

Limitations

This study had limitations. The cost savings assume a 50% uptake of the intervention, and the savings magnitude depends on uptake. However, if pharmacists are appropriately incentivized through adequate reimbursement for providing the service, this level of uptake is likely an underestimate. Another assumption is that BP control did not change in the comparator group, and a proportion of patients in the comparator group may have improved BP control with usual care. Further, the proportion of patients with uncontrolled HTN continues to rise and has only worsened because of the COVID-19 pandemic. These findings cannot be generalized to other populations with HTN (eg, pregnancy), and we were unable to determine how alternative delivery methods (eg, telehealth) would impact the cost-effectiveness of this model.

Conclusions

This economic analysis suggests that pharmacist-prescribing interventions are cost-effective, result in significant estimated savings for the health care system, and are economically dominant. Assuming a 50% adoption rate, pharmacist-prescribing interventions would save an estimated $10 162 per person over a 30-year time horizon with cumulative population-level savings of more than a trillion dollars. The necessary tools (eg, collaborative practice, treatment algorithms) and resources (eg, patient access to community pharmacies) are readily available to implement pharmacist-prescribing interventions across the US; however, reimbursement limitations remain a barrier.

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SUPPLEMENT 1.

eTable 1. Assumed Patient Characteristics for Pharmacist Hypertension Intervention, Based on Observed Population in Tsuyuki et al[10] Clinical Trial

eTable 2. Model US Cost Inputs

eFigure 1. Association Between Cumulative Cost Savings and QALY Benefit Across a Range of Hypothetical SBP Reductions Associated With the Pharmacist Intervention

SUPPLEMENT 2.

Data Sharing Statement

Preventing Chronic Disease

PREVENTING CHRONIC DISEASE
PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY

Pharmacy Contributions to Improved Population Health: Expanding the Public Health Roundtable

GUEST EDITORIAL — Volume 17 — September 24, 2020

This article is part of the Public Health and Pharmacy: Collaborative Approaches to Improve Population Health collection.

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Success in health care is increasingly being measured by improvements in population health outcomes in response to interventions rather than by services delivered (1). In this new landscape, cross-sectoral collaboration is paramount (2), and the profession of pharmacy is an often-overlooked partner (3). Our vision is that pharmacists and the profession of pharmacy be included as an integral part of the roundtable of health care and public health. This special collection of articles in *Preventing Chronic Disease* highlights the contributions of pharmacy to the field of public health and expands the vision of how pharmacy can improve population health.

The collection brings together some of the cutting-edge work at the interface of pharmacy and public health that was submitted in response to a call for papers in 2019. The Centers for Disease Control and Prevention (CDC) has long recognized pharmacy's role in addressing chronic diseases (4). The 16 articles included in this collection document a small portion of the innovative work being done by pharmacists to improve population health. We first review the articles to summarize research approaches and contributions. We then describe gaps in research that need to be filled to strengthen the evidence base for the unique role of pharmacy in improving population health. The collection serves as a call to researchers and professionals in pharmacy and public health to evaluate and publish their work in hopes of expanding on what is already known and being done.

Top

Collaboration of Pharmacy With Other Health Care Agencies

Collaboration between pharmacy and other health care professionals and agencies to implement strategies to improve health outcomes is well represented in this collection (5–8). Articles by Rodis et al (5) and Ross et al (6) highlight the impact of pharmacists providing collaborative medication therapy management services to patients in federally qualified health centers. In another description of a collaborative model for medication therapy management implemented by the Pharmacy Society of Wisconsin, the Wisconsin Division of Public Health, and a nonprofit insurer, Thompson et al showed improvements in self-reported use of self-management tools, reductions in medication adherence barriers, and high levels of satisfaction with the pharmacist in controlling hypertension (7). Collaboration between the New Mexico Department of Health and community pharmacies demonstrated the ability of community pharmacists to safely administer latent tuberculosis treatment, with a satisfactory completion rate of 75.0% (8). The program was implemented in collaboration

with the local public health department, thus saving time for their health care providers. Strand et al reported on the many ways in which community pharmacy has responded to the coronavirus disease 2019 (COVID-19) pandemic, with recommendations for deepening formal collaboration with local public health agencies (9). Sun et al reported on pharmacy students training high school students about opioid misuse (10), showing the opportunity for collaboration with public schools. The integration of pharmacy with clinical medicine has been recommended by CDC (4) and the American College of Cardiology (11), and these publications demonstrate that integration with other health care agencies and the community lead to improved health outcomes.

Many Americans do not receive the services recommended by the US Preventive Services Task Force (USPSTF) (12). Although community and clinical pharmacists could be key players in delivering these services (13), barriers to pharmacies receiving reimbursement for the delivery of some of these services compromises the full incorporation of the delivery of USPSTF services into many community pharmacy settings (14). Several articles in this collection speak to this problem. In 2018, only 51.1% of US adolescents aged 13 to 17 were fully covered by the human papillomavirus (HPV) vaccine series (15), so the need for health care providers other than physicians to administer HPV vaccines in various settings is great. Yet as Ryan et al found, both pharmacists and community members identified more barriers than facilitators to providing and receiving the HPV vaccine in the pharmacy setting (16). Work is needed to determine best practices for removing barriers that prevent community pharmacists from delivering vaccines, especially as we anticipate a vaccine against severe acute respiratory coronavirus 2 (SARS-CoV-2). Freeland and Ventricelli made a call to pharmacists to promote the hepatitis B vaccine more aggressively among at-risk patients in settings heavily affected by the opioid epidemic (17). Clearly, the need exists to elevate both the self-efficacy of pharmacists in delivering all vaccines and the awareness among the general public about the appropriateness of pharmacists administering vaccines, to expand beyond vaccines that are currently most frequently administered — influenza, pneumococcal, and herpes zoster (shingles) vaccines.

Diabetes and its determinants are epidemic in the United States, and prevention and management are of vital importance (18). To that end, Roszak and Ferreri conducted key informant interviews among pharmacy executives to identify barriers to and opportunities for implementing the National Diabetes Prevention Program (DPP) in community pharmacies (19). They concluded that realizing this opportunity will require reimbursement for pharmacists' efforts, minimal disruption of routine workflow, and understanding among patients that pharmacists can provide this program effectively. Demonstrating that implementation of the DPP in community pharmacies is possible, Ross et al reported on the ability to nearly triple the number of pharmacies delivering the National Diabetes Prevention Program by following a systematic process and including stakeholders every step of the way (20). Pharmacies are present in most communities around the country, and patients have more interaction with their pharmacist than with any other health care providers (21–23), so pharmacists are well positioned to deliver preventive services. Delivery of USPSTF-recommended and other preventive health services should be expanded in community pharmacies to broaden the base of preventive service delivery across the population, but barriers remain to scaling up the delivery of these services by pharmacists. Widespread implementation of such services, with rigorous evaluation, is needed.

Top

Pharmacy Contributions to Improving Population Health

Since the seminal work of the Asheville Project demonstrated the effect of clinical pharmacists on improving outcomes in diabetes, hypertension, and hyperlipidemia in 2003 (24,25), pharmacist participation in care coordination to manage chronic conditions has been consistently demonstrated. Cowart et al described how a physician–pharmacist team brought a cohort of patients with diabetes to the hemoglobin A_{1c} goal of less than 7.0% in 99 fewer days than the usual medical care of physician alone (26). Clearly, a pharmacist brings added value to the care team.

In this era of health care workforce shortages across the country, pharmacists fill this gap by serving as critical members of team-based care. Two articles in this collection examined the question What happens when access to pharmacies is limited? Using claims data, Pathak et al showed that medication adherence among people with diabetes and hypertension using telepharmacy support was not inferior to medication adherence achieved in face-to-face support (27). Telepharmacy support creates opportunities to expand services to remote areas that lack an onsite pharmacist. Working in Washington State, Graves et al showed that the likelihood of access to a Medicaid-contracted pharmacy decreased significantly as rurality increased (28). To ensure medication access and adherence among low-income Americans who live in rural areas, rural pharmacies need to increase enrollment in Medicaid service provision.

Multisector collaboration is needed to address the epidemic of chronic diseases in the United States. Most chronic diseases depend on the use of long-term medications and high levels of adherence for successful management. As medication experts, the pharmacist is a natural member of the chronic disease management team. Studying US states and census regions, Yang et al found that prescription- and payment-related promoters of adherence to blood pressure medication varied by geography and across the largest patient market segments (medication prescriber, insurance payer type, and age) (29). Blood pressure control rates nationwide are inadequate and could be improved by uptake of promoter strategies such as fixed-dose combinations, mail order refills, being under the management of a designated primary care provider, and having commercial insurance. Many of these promoter strategies can be manipulated by pharmacists. More consistent use of these promoter strategies could increase adherence to blood pressure medication, but more consistent use requires incorporating pharmacists into collaborations that include prescription benefit manager programs, payers, and health care providers.

Evidence of pharmacists evolving beyond their traditional roles is apparent throughout CDC. Through numerous cooperative agreements, CDC's National Center for Chronic Disease Prevention and Health Promotion instructs state health department grantees to engage pharmacists as health care extenders and in team-based care approaches (30). CDC recognizes pharmacists can help to achieve public health outcomes not only in chronic diseases but also in HIV testing, antimicrobial stewardship programs, immunizations, and many others. The role of pharmacists has come a long way, from dispensing, to providing clinical care, to now administering vaccinations, screening for diseases, and health coaching. They are, indeed, critical members of the public health roundtable.

Top

More Research Needed

Several important areas of research at the interface of pharmacy and public health were not covered in this collection. We now turn our attention to research areas that merit further evaluation and reporting.

Social determinants of health such as poverty, unequal access to health care and education, and racism are drivers of health inequities and, thus, are central to the public health mission to achieve health for all. Healthy People 2020 calls for approaches that address these social factors to help improve health equity for populations who are disproportionately affected by chronic conditions and other causes of death and disability (31). The pharmacy profession is sensitive to the social determinants of health: it prioritizes customizing patient care, a concern for cultural competency (32), and attention to health literacy (33), and it fosters each of these concepts through curricula and workforce development. For example, results from the Project IMPACT study show that pharmacists have improved health outcomes for diverse populations disproportionately affected by diabetes (34).

However, achieving health equity will require that social determinants of health be considered not only in how one treats an individual patient but also in the delivery of pharmacist-provided services more broadly, such as determining who receives care and how it is received. In a systematic review of 157 studies on public health services delivered by community pharmacists, none discussed health inequities (13). Qato et al showed that residents of predominantly low-income racial/ethnic minority communities on the south side of Chicago could not use their nearest pharmacy because of cost issues and had to travel further from home to overcome these issues (35); however, more research is needed on how social determinants can be integrated into delivery of care and the outcomes associated with their integration.

Another area of future research is training pharmacists to increase their public health skills to improve population health beyond traditional pharmacy functions. The number of doctor of pharmacy/master of public health (PharmD/MPH) dual degree programs is increasing (36), but enrollment in these programs is not high. Although pharmacy education accreditation standards related to public health competencies exist (37), many schools of pharmacy do not prioritize public health competencies in their curricula. Postgraduate training in public health competencies is another way of conceptualizing public health education for pharmacists. One such example is a 3-hour continuing education training program for pharmacists to implement screening of opioid misuse in community pharmacies (38). The researchers showed improvement in the attitudes and perceptions among pharmacists about opioid-related patient behaviors and the clinical value of screening for opioid misuse. It would be helpful to know what further public health education pharmacists need, and which types of training directly lead to improved population health.

Being located in the community and having the most frequent interaction with patients, compared with all other health professionals (21,22), pharmacists could collaborate with public health to identify and implement systems for disease surveillance and monitoring health outcomes (39). Such systems represent another research gap in this collection, but not entirely. Matus et al used GIS mapping to track opioid use in wastewater, stating, "These maps can in turn provide an evidentiary basis for deployment of pharmacy-centered public health responses" (40). A search of the literature provides further examples. A unique system in Maine used public records from law enforcement to inform medical providers of potential misuse and diversion of narcotic medication (41). Another example of surveillance by community pharmacies is Walgreens' use of Esri location analytics to track retail prescription data for antiviral medications used to treat influenza (42). The volume of antiviral medications dispensed serves as a proxy for the temporal and geographic spread of the influenza season in real time. Linked to the local epidemiology division of the public health department, the data generated by sales records of antiviral medication could lead to early mitigation of influenza outbreaks. However, this linkage would require formal integration of pharmacy and public health informatics systems, something that still needs to be improved.

In a systematic review of 522 studies on the contributions of pharmacy to the 10 essential services of public health, the 2 services least represented were community health needs assessments and diagnosing health problems in the community (43). Community health needs assessments are a key element of the Affordable Care Act and have increased engagement of hospitals in the communities they serve. However, little published evidence exists of pharmacies collaborating with hospitals and public health agencies to conduct these needs assessments. Although some might argue that such work is outside the areas of training for pharmacists, the community location of pharmacists and their accessibility to populations gives pharmacists a unique opportunity to participate in community health needs assessments. None of the articles in this *Preventing Chronic Disease* collection reported on this area of research. Furthermore, a PubMed search identified 26 studies on community health needs assessments, but none of these studies included pharmacy. We see this gap as an opportunity to expand the viewpoint of community health needs assessments and increase access to community members to better inform needs assessments.

We recognize a need for clear criteria by which to evaluate pharmacist contributions to intervention studies (44). Several aspects of interventions should be evaluated (45), such as whether the intervention was implemented as intended as well as its effectiveness and cost-effectiveness. Many studies have shown the effectiveness of pharmacy services as measured by patient outcomes or cost-effectiveness (46), but process evaluations are scarce, especially for services that demonstrate collaboration between public health agencies and pharmacists. Process evaluations involve critical appraisal of whether the intended activities are taking place, who is performing the activities, who is affected by the activities, and whether sufficient resources have been allocated to accomplish the purpose of the intervention (44,45). Evaluations should be performed in such a way that they determine the unique attributes and distinct value provided by collaborations that include pharmacy partners as compared with collaborations that include other disciplines. Additionally, the plan for evaluation should begin while the program is being designed (45). Many readers of *Preventing Chronic Disease* are familiar with such models as RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) (47), and this model has been used to evaluate the population impact of projects implemented in community pharmacies (48). Such evaluation tools, considered best practices in public health, need to be more frequently implemented in pharmacy interventions (49).

It is evident from the small sample of studies articulating the contributions of pharmacists or pharmacies in addressing the health of the population that much work is yet to be done. The pharmacy profession has made advances and contributions, but gaps in service exist and the role of pharmacists in public health needs to be broadened. This recognition leads us to a call to action by both pharmacy and the public health professions to expand their collaboration to improve population health and mitigate health inequities.

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Call to Action

The health care system, including pharmacy and public health, have opportunities to improve population health through greater collaboration (13). To realize this opportunity, partnerships need to be strengthened, current barriers need to be removed, and pharmacists need to be more fully integrated into community health needs assessments, disease surveillance, and monitoring of health outcomes. Furthermore, the profession of pharmacy needs to become more proactive in pursuing opportunities to make these contributions, evaluate them, and then publicly report on them.

Leaders in public health and pharmacy should develop more partnerships that serve to mutually benefit each sector's goals and leverage their strengths. Readers of this collection will find many examples of public health partnering with pharmacists to deliver their programs at the federal, state, and local levels. Pharmacists are uniquely positioned to enhance the quality, reach, and sustainability of preventive services. As pharmacists are asked to implement more preventive services, public health partners have opportunities to apply their expertise to support them, thus establishing mutually beneficial collaborations. For example, public health partners can help pharmacists evaluate their process and outcomes to strengthen the way they capture and communicate success stories, especially to nonpharmacist audiences. Public health partners should be more proactive in ensuring that pharmacy representatives are a part of statewide health planning efforts. Public health and pharmacy leaders can also advocate for policies that reduce the current obstacles to pharmacists delivering preventive and health promotion services.

Barriers need to be considered, with interventions designed to overcome those barriers. Currently, privileges granted to pharmacists in most states do not ascend to the level of their training. An article in this collection by Hamilton et al raises awareness of this issue by describing barriers in Louisiana (50). All states need to grant pharmacists privileges to practice at a level commensurate with their training and education and require third-party payers to reimburse pharmacists for their services. These steps are necessary to fill shortages in the primary care workforce and enable pharmacists to contribute more substantially to improved population health.

The public health infrastructure needs to use pharmacists better in community health needs assessments, disease surveillance, and monitoring of health outcomes. This infrastructure improvement will require transformation in what data pharmacists have access to and contribute to. Community pharmacies now exist in a patient-information vacuum. We need to break down the barriers that isolate community pharmacy from the wider public health and health care systems and to include pharmacy in health information exchanges and surveillance systems.

In addition, the pharmacy profession must aggressively pursue the opportunities available to it. Collaborations with local health care entities in community-based health interventions could be expanded. Pharmacists will need to envision themselves as participants in the wider community and seek ways to collaborate with other health care professions. More collaboration could be achieved in part by pharmacists stepping out of their comfort zone and welcoming people from various disciplines into their professional organizations and meetings. The pursuit of new opportunities will also require expanded training in public health. Although the PharmD degree affords a high level of training in patient care and medication management, it has competency gaps in public health skills such as informatics, program design and evaluation, and policy development. Finally, pharmacists needs to advocate more proactively for their role in the public health arena and to raise awareness of their contributions by publishing more often in journals read by a wider audience than just pharmacy researchers.

We hope that this collection of articles in *Preventing Chronic Disease* will spur others involved in improving population health through pharmacy applications to share their work and expand their research in this arena. Dissemination of information on the contribution of the pharmacy profession to public health is essential to creating awareness among other health professionals and the public about the integral role of pharmacy in public health. Such awareness is crucial to addressing health disparities, given that in most underserved communities, pharmacies are the initial point of contact with the health infrastructure. To this end, we advocate for more integrated involvement of pharmacists in public health and the dissemination of information on their contributions to the health of the people.

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Original Investigation | Pharmacy and Clinical Pharmacology

Pharmacist-Driven Transitions of Care Practice Model for Prescribing Oral Antimicrobials at Hospital Discharge

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Abstract

IMPORTANCE Although prescribers face numerous patient-centered challenges during transitions of care (TOC) at hospital discharge, prolonged duration of antimicrobial therapy for common infections remains problematic, and resources are needed for antimicrobial stewardship throughout this period.

OBJECTIVE To evaluate a pharmacist-driven intervention designed to improve selection and duration of oral antimicrobial therapy prescribed at hospital discharge for common infections.

DESIGN, SETTING, AND PARTICIPANTS This quality improvement study used a nonrandomized stepped-wedge design with 3 study phases from September 1, 2018, to August 31, 2019. Seventeen distinct medicine, surgery, and specialty units from a health system in Southeast Michigan participated, including 1 academic tertiary hospital and 4 community hospitals. Hospitalized adults who had urinary, respiratory, skin and/or soft tissue, and intra-abdominal infections and were prescribed antimicrobials at discharge were included in the analysis. Data were analyzed from February 18, 2020, to February 28, 2022.

INTERVENTIONS Clinical pharmacists engaged in a new standard of care for antimicrobial stewardship practices during TOC by identifying patients to be discharged with a prescription for oral antimicrobials and collaborating with primary teams to prescribe optimal therapy. Academic and community hospitals used both antimicrobial stewardship and clinical pharmacists in a multidisciplinary rounding model to discuss, document, and facilitate order entry of the antimicrobial prescription at discharge.

MAIN OUTCOMES AND MEASURES The primary end point was frequency of optimized antimicrobial prescription at discharge. Health system guidelines developed from national guidelines and best practices for short-course therapies were used to evaluate optimal therapy.

RESULTS A total of 800 patients prescribed oral antimicrobials at hospital discharge were included in the analysis (441 women [55.1%]; mean [SD] age, 66.8 [17.3] years): 400 in the preintervention period and 400 in the postintervention period. The most common diagnoses were pneumonia (264 [33.0%]), upper respiratory tract infection and/or acute exacerbation of chronic obstructive pulmonary disease (214 [26.8%]), and urinary tract infection (203 [25.4%]). Patients in the postintervention group were more likely to have an optimal antimicrobial prescription (time-adjusted generalized estimating equation odds ratio, 5.63 [95% CI, 3.69-8.60]). The absolute increase in optimal prescribing in the postintervention group was consistent in both academic (37.4% [95% CI, 27.5%-46.7%]) and community (43.2% [95% CI, 32.4%-52.8%]) TOC models. There were no differences in clinical resolution or mortality. Fewer severe antimicrobial-related adverse effects

(continued)

Key Points

Question Are antimicrobial stewardship interventions during transitions of care associated with improved prescribing of antimicrobials at hospital discharge?

Findings In this quality improvement study of 800 patients, a pharmacist-driven intervention targeting antimicrobial prescribing at discharge was associated with higher frequency of optimal antimicrobial regimens compared with before the intervention. Patients in the postintervention group had similar rates of mortality, readmission, and clinical resolution and fewer severe antimicrobial-related adverse effects compared with the preintervention group.

Meaning These findings suggest that hospitals can leverage resources toward antimicrobial stewardship during transitions of care to optimize antimicrobial therapy.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Abstract (continued)

(time-adjusted generalized estimating equation odds ratio, 0.40 [95% CI, 0.18-0.88]) were identified in the postintervention (13 [3.2%]) compared with the preintervention (36 [9.0%]) groups.

CONCLUSIONS AND RELEVANCE The findings of this quality improvement study suggest that targeted antimicrobial stewardship interventions during TOC were associated with increased optimal, guideline-concordant antimicrobial prescriptions at discharge.

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Introduction

In the US, 1 in 5 hospitalized adults is prescribed an antimicrobial at the time of discharge, accounting for millions of antimicrobial-days each year.[1] Although prescribers face numerous patient-centered challenges during transitions of care (TOC), resources are sorely needed for antimicrobial stewardship throughout this period.[2] In a statewide collaborative effort, the Michigan Hospital Medicine Safety Consortium classified the appropriateness of more than 20 000 antimicrobials prescribed at discharge, and nearly half were considered overuse.[3] The most common antimicrobial class prescribed at discharge, the fluoroquinolone, has a number of box warnings and safety concerns, yet as few as 25% of these orders are considered appropriate.[1,4,5] Prolonged duration of antimicrobial therapy is consistently the major contributor to inappropriate prescribing during TOC, and a mean of 40% of each patients' total duration of therapy is administered post discharge.[1,3,6] The review of antimicrobial prescribing during TOC represents a crucial moment in a patient's clinical course to ensure safe, effective, and guideline-concordant therapy.

Few antimicrobial stewardship interventions have been targeted in the collaborative discharge planning process.[7-9] Traditional inpatient antimicrobial stewardship initiatives such as audit and feedback may not impact prescribing practices at discharge.[10,11] The Centers for Disease Control and Prevention core elements of outpatient antibiotic stewardship[12] identify transition from acute care to other health care settings as an opportunity to improve the quality of prescribing. Physicians, pharmacists, nurses, and case managers at the front lines of patient care have the tools to collaborate and optimize antimicrobial therapy at discharge.[9] The purpose of this study was to (1) implement a pharmacist-led, multidisciplinary review of discharge planning for oral antimicrobial therapy; (2) quantify inappropriate antimicrobial prescribing at the time of discharge; and (3) evaluate the association of the intervention with optimized antimicrobial therapy, infection-related readmissions, and antimicrobial-associated harms.

Methods

Study Setting and Design

This quality improvement study used a nonrandomized stepped-wedge design to evaluate an antimicrobial stewardship intervention for adults discharged from the hospital with antimicrobial prescriptions for select uncomplicated infections. From September 1, 2018, to August 31, 2019, 5 hospitals within the Henry Ford Health System in southeastern Michigan participated in this study, including Henry Ford Hospital (a 877-bed academic medical center in Detroit), Henry Ford Allegiance Hospital (a 475-bed community hospital in Jackson), Henry Ford Wyandotte Hospital (a 401-bed community hospital in Wyandotte), Henry Ford Macomb Hospital (a 361-bed community hospital in Clinton Township), and Henry Ford West Bloomfield Hospital (a 191-bed community hospital in West Bloomfield). Each hospital had at least a partial full-time equivalent for an antimicrobial stewardship pharmacist (0.8-1.0 full-time equivalent) and physician (0.2-0.8 full-time equivalent), and clinical pharmacists were integrated within medical teams. The intervention was implemented across all

sites in a nonrandomized order. This intervention was selected for feasibility of implementing a new standard of care at TOC with the available resources in the health system. The stepped-wedge design also allowed control for regression to the mean, maturation effects, and confounding due to secular trends in a health system–wide intervention that implemented the TOC initiative for 3 phases (**Table 1**) that were selected in order of institutional readiness.[13] The study was approved by the health system's ethics committee as a quality improvement initiative, and a waiver of informed consent was granted by the institutional review board. This study followed the Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) reporting guideline.

Intervention

The objective of the intervention was to facilitate optimal antimicrobial discharge prescriptions by leveraging the existing pharmacy practice model for TOC with local antimicrobial use and duration guidelines through collaboration with the primary team. The antimicrobial stewardship intervention at TOC was implemented in 3 phases in 17 distinct units (service teams) across the 5 hospitals. Order of intervention rollout was prioritized based on patient volume, availability of resources, and pharmacist training. Group 1 consisted of units at an academic hospital; group 2, both academic and community hospital units; and group 3, community hospital units (Table 1). The TOC model enabled clinical and antimicrobial stewardship pharmacists to identify patients approaching discharge with active antimicrobial orders, to create and communicate collaborative plans related to antimicrobial selection and duration of therapy, and to enter the antimicrobial prescription with a stop date to be signed by the primary clinician at discharge. Local physician champions were identified on each service team to promote intervention uptake.[14]

Clinical pharmacists involved with the intervention were trained in mandatory competency sessions to optimally manage workflow and the operational components for antimicrobial order entry. Before discharge, the pharmacist reviewed an inpatient team census in the electronic health record that included all active antimicrobials at the start of each shift. Patients were reviewed to identify those with qualifying diagnoses of infectious diseases who may be eligible to complete the antimicrobial course with oral therapy after discharge. In the academic center setting, clinical pharmacists assessed discharge readiness with a notification in the electronic team census in addition to daily discussions on collaborative rounds with nurses, physicians, nurse practitioners, physician assistants, and case managers. To identify patients with anticipated discharge in community hospital settings, antimicrobial stewardship pharmacists were alerted in different ways depending on reporting structures specific to each institution. These methods included electronic team census notifications, direct communication from nursing and case management, and/or discussions during collaborative team rounds. Cost inquiries for oral antimicrobials were requested on a case-by-case basis via electronic order to the outpatient pharmacist to address financial

Table 1. Description of Service Teams in Study Groups and Timeline of Nonrandomized, Stepped-Wedge Design and Interventions

Study group	Quarter 1: August to October 2018 (n = 125)	Quarter 2: November 2018 to February 2019 (n = 300)	Quarter 3: March to May 2019 (n = 225)	Quarter 4: June to August 2019 (n = 150)
Group 1 (n = 250): academic hospital service teams including internal medicine, pulmonology, family medicine, and infectious diseases	Preintervention	Intervention in place	Intervention in place	Intervention in place
Group 2 (n = 275): academic and community hospital service teams including nephrology, cardiology, family medicine, and internal medicine	Preintervention	Preintervention	Intervention in place	Intervention in place
Group 3 (n = 275): community service teams including hospitalist and internal medicine	Preintervention	Preintervention	Preintervention	Intervention in place

barriers.[15] Documentation in the electronic medical record was completed by the clinical pharmacist to describe the agent, indication, dose, and duration of therapy for patients during the study period. The discharging prescriber received recommendations for the protocolized antimicrobial regimen during TOC on collaborative rounds or via telephone. After the antimicrobial plan was discussed, the orders for discharge were entered or modified (if needed) in the electronic discharge queue by the pharmacist to be cosigned by the prescriber. Protocol adherence was monitored by assessing documentation in the medical record of intervention completion, and progress was communicated to clinical pharmacists and physician champions each month via internal posters, meetings, and email. To increase intervention uptake, physician champions introduced practice model changes during departmental meetings, signed a letter in support of the intervention, and shared their photographs on a poster for monitoring protocol adherence.

Study Population

Adults admitted to general medical and/or surgical wards who were discharged with oral antimicrobial therapy were eligible for inclusion. Patients who were pregnant, discharged with parenteral antimicrobials, or diagnosed with cystic fibrosis, endovascular infections, central nervous system infections, osteomyelitis, or febrile neutropenia were excluded. Diagnoses of interest included common infections with evidence-based guideline recommendations for antimicrobial courses (eMethods in the Supplement): infections of the urinary tract, respiratory tract, skin and/or skin-structure sites, and intra-abdominal sites with adequate source control (eFigure 1 in the Supplement).[16] Study participants were identified among those patients discharged with a prescription for oral antimicrobials from the data repository of the electronic medical record. Cases were sorted and selected using a random number generator (Excel, version 15.0 [Microsoft Corporation]) and screened until 25 patients in each group every month were included. Electronic medical records were manually reviewed to ascertain data and then entered in REDCap (Research Electronic Data Capture). Patient race and ethnicity data were collected using the demographic populated fields in the electronic medical record and reported to identify possible differences between groups.

Patient Data and End Point Definitions

The primary end point was frequency of discharge with an optimized antimicrobial regimen, determined by review of medical records, prescriptions, and discharge. Health system guidelines were used to assess appropriateness of antimicrobial selection, dose, and duration. Definitions for optimal antimicrobial therapy were modified in alignment with those proposed by Spivak et al[17] (eMethods in the Supplement). Hospital length of stay and antimicrobial duration of therapy were assessed as resource use outcomes. Safety end points included antimicrobial-related adverse effects (ADEs), 30-day unplanned office and/or emergency department visits, 30-day readmissions, and 30- and 90-day mortality. Antimicrobial-related ADEs were categorized as mild to moderate or as severe. Severe ADEs that were assessed to 90 days included *Clostridiodies difficile* infection and isolation (from any clinical culture) of a new multidrug-resistant organism,[18] whereas anaphylaxis and/or angioedema, kidney failure, acute hepatic failure, torsades de pointes, seizure, and serious hematologic toxic effects were measured to 30 days. Mild to moderate ADEs such as diarrhea; QTc prolongation; rash; mild elevations in levels of aminotransferases, bilirubin, and/or creatinine; and others outlined by Tamma et al[19] were assessed to 30 days. When available, outside electronic health records were ascertained for events that were presumed to not occur if not documented. Clinical resolution was assessed only in patients with available follow-up data, defined as resolution of signs and symptoms such that no further antimicrobial therapy was required after completion of planned therapy for the same indication, to 30 days.[20]

Statistical Analysis

Data were analyzed from February 18, 2020, to February 28, 2022. SPSS, version 26.0 (IBM Corp), and SAS, version 9.4 (SAS Institute Inc), were used for calculations. Sample size was estimated by presuming a 20% relative reduction of nonoptimized antimicrobial therapy at discharge from 60% to 48% (historic data indicate 54%-63% of patients receiving antimicrobials receive excessive durations[4]). Very roughly approximating the generalized estimating equation (GEE) logistic regression sample size by that for a χ^2 comparison of proportions, 357 patients in each study arm were needed for a 2-sided $\alpha = .05$ with 90% power. The Mann-Whitney test was used for nonparametric data and an unpaired 2-tailed *t* test was used for parametric data. We used the χ^2 and Fisher exact tests for categorical variables, as appropriate. Two-sided $P < .05$ and 95% CIs were used to describe statistical significance. To account for correlation in data from patients treated at the same location, the primary inferential analyses used GEE logistic regression (SAS procedure PROC_GENMOD) and analysis of covariance models, with service team location at discharge used to define clusters. To adjust for potential temporal trend, time in months since the beginning of the study period was used as a covariate in primary analyses. Multivariable, time-adjusted GEE logistic regression was used to identify independent associations with an optimized antimicrobial regimen at discharge. Candidate variables for the multivariable model included age, sex, study month, and select covariates with predetermined clinical suspicion for optimal prescribing. The final model used covariates with $P < .10$ in time-adjusted GEE analysis.

Results

Of 1440 patients screened, 800 were included across the 3 study phases: 400 in the preintervention period and 400 in the postintervention period (Table 1 and eFigure 2 in the Supplement). The most common reasons for exclusion were at least 1 of the following: complicated or severe infection (n = 423), solid organ transplant or neutropenia (n = 102), transfer to or from an outside hospital or hospice (n = 96), and discharge with intravenous antimicrobial therapy (n = 47) (eFigure 2 and eMethods in the Supplement). A total of 441 included patients (55.1%) were women and 359 (44.9%) were men. The mean (SD) age was 66.8 (17.3) years; mean (SD) body mass index (calculated as weight in kilograms divided by height in meters squared), 29.9 (9.1). The median length of stay was 3 (IQR, 2-5) days. Most patients (427 [53.4%]) were admitted to the academic medical center and discharged home (673 [84.1%]). During the study period, more than 1500 interventions were documented, and overall protocol adherence throughout the health system was 63%. Service teams included medicine, surgery, hospitalist, pulmonology, infectious disease, family medicine, cardiology, and nephrology. The most common diagnoses were pneumonia (264 [33.0%]), upper respiratory tract infection and/or acute exacerbation of chronic obstructive pulmonary disease (214 [26.8%]), urinary tract infection (203 [25.4%]), and skin or soft tissue infection (125 [15.6%]). The median Charlson Comorbidity Index score was 2 (IQR, 1-3); there were no significant differences in comorbid conditions, severity of illness on presentation, or risk factors for multidrug-resistant organisms between groups (**Table 2** and eTable 1 in the Supplement).

The primary end point, optimal antimicrobial prescription at discharge, was associated with intervention implementation (144 of 400 [36.0%] vs 326 of 400 [81.5%]; $P < .001$) (**Table 3**) and remained consistently associated with improved prescribing across all study phases (eTable 2 in the Supplement). The absolute increase in optimal prescribing in the postintervention group was consistent in both academic (37.4% [95% CI, 27.5%-46.7%]) and community (43.2% [95% CI, 32.4%-52.8%]) hospital models. Patients in the postintervention group were more likely to have an optimal antimicrobial prescription (time-adjusted GEE odds ratio [OR], 5.63 [95% CI, 3.69-8.60]). Reductions in prolonged durations of therapy (177 of 400 [44.2%] vs 37 of 400 [9.2%]; mean difference, −35.0% [95% CI, −40.2% to −29.2%]), non–guideline-concordant antimicrobial selection (81 of 400 [20.2%] vs 24 of 400 [6.0%]; mean difference, −14.3% [95% CI, −18.8% to −9.6%]), and treatment of asymptomatic bacteriuria (37 of 400 [9.2%] vs 10 of 400 [2.5%]; mean difference,

−6.8% [95% CI, −10.0% to −3.4%]) were the largest contributing components of improved optimized discharge prescription (Table 3). The intervention was associated with decreased total antimicrobial duration (time-adjusted absolute difference, −1.1 [95% CI, −1.7 to −0.6] antibiotic days) (eTable 3 in the Supplement). Duration of antimicrobial therapy for respiratory tract infection was reduced (time-adjusted absolute difference, −1.8 [95% CI, −2.3 to −1.2] antibiotic-days) in the postintervention period, whereas there was no difference for urinary tract infection or skin and/or soft tissue infections. There were no differences in unadjusted analyses for clinical resolution, readmission at 30 days, or mortality (**Table 4**). The intervention was associated with fewer ADEs, mostly owing to reductions in more severe ADEs such as a new multidrug-resistant organism and *C difficile* infection (Table 4) by day 90 (severe ADEs, 36 [9.0%] vs 13 [3.2%]; time-adjusted GEE OR, 0.40 [95% CI, 0.18-0.88]).

After controlling for service team, study month, and other confounders (**Table 5**), the TOC intervention remained independently associated with the primary outcome, with patients in the postintervention period having nearly 4 times greater odds of being prescribed an optimal antimicrobial regimen at discharge (time-adjusted GEE OR, 3.77 [95% CI, 2.32-6.15]). Length of stay (time-adjusted GEE OR, 0.89 [95% CI, 0.83-0.96]), indications for urinary tract infection (time-adjusted GEE OR, 0.59 [95% CI, 0.44-0.79]), and care at a community hospital (time-adjusted GEE

Table 2. Patient Demographic and Clinical Characteristics

Characteristic	Patient group[a]		Time-adjusted GEE *P* value
	Preintervention (n = 400)	Postintervention (n = 400)	
Age, mean (SD), y	69.0 (17.1)	64.5 (17.2)	.67
Sex			
Women	221 (55.3)	220 (55.0)	.60
Men	179 (44.7)	180 (45.0)	
Race and ethnicity			
Black	113 (28.3)	200 (50.0)	.04
White	259 (64.7)	161 (40.3)	
Other or unknown[b]	28 (7.0)	39 (9.7)	
Charlson Comorbidity Index score, median (IQR)	2 (1-3)	2 (1-3)	.96
≥2 SIRS criteria on day 3	22 (5.5)	18 (4.5)	.54
Length of stay, mean (SD), d	3.6 (2.2)	3.3 (2.2)	.70
Any MDRO risk factor	216 (54.0)	210 (52.5)	.12
Admitted in last 90 d	130 (32.5)	117 (29.3)	.99
Antimicrobial therapy in last 90 d	144 (36.0)	154 (38.5)	.65
Prior MDRO colonization	22 (5.5)	27 (6.7)	.48
Immunocompromised	7 (1.7)	15 (3.7)	.04
Nonambulatory status	32 (8.0)	19 (4.7)	.51
Pneumonia	144 (36.0)	120 (30.0)	.24
Community-acquired without risk factors for MDRO	108 (27.0)	92 (23.0)	.03
Community-acquired with risk factors for MDRO	33 (8.3)	24 (6.0)	.45
Hospital-associated	3 (0.7)	4 (1.0)	.60
Acute exacerbation of COPD or upper respiratory tract infection	101 (25.3)	113 (28.3)	.49
Urinary tract infection	115 (28.7)	88 (22.0)	.23
Pyelonephritis	25 (6.3)	23 (5.7)	.91
Complicated urinary tract infection	46 (11.5)	39 (9.7)	.91
Cystitis	44 (11.0)	26 (6.5)	.14
Skin and/or soft tissue infection	53 (13.3)	72 (18.0)	.90
Purulent	20 (5.0)	39 (9.7)	.17
Nonpurulent	33 (8.3)	33 (8.3)	.15
Intra-abdominal infection	4 (1.0)	12 (3.0)	.69

Abbreviations: COPD, chronic obstructive pulmonary disease; GEE, generalized estimating equation; MDRO, multidrug-resistant organism; SIRS, systemic inflammatory response syndrome.

[a] Unless otherwise indicated, data are expressed as number (%) of patients. Percentages have been rounded and may not total 100.

[b] Includes race or ethnicity reported as Asian, Pacific Islander, unknown, other, and decline.

OR, 0.49 [95% CI, 0.38-0.64]) were associated with a lower likelihood of receiving an optimal regimen at discharge.

Discussion

In this quality improvement study, the implementation of a pharmacist-led discharge stewardship intervention was associated with improved antimicrobial prescribing in this health system–wide TOC intervention. This outcome was further associated with a reduction in antimicrobial-associated harms, which are common after inappropriate, suboptimal, and/or unnecessary antimicrobial prescribing at hospital discharge.[17,21] Clinicians face multiple, complex decisions during TOC such as patient placement, costs, education, follow-up, new medications, etc. Pharmacists are crucial team

Table 3. Patients Receiving Optimal Prescription at Discharge

Prescription component	Patient group, No./total No. (%)		Absolute difference, % (95% CI)	Time-adjusted GEE OR (95% CI)
	Preintervention	Postintervention		
Overall	144/400 (36.0)	326/400 (81.5)	45.5 (39.2 to51.3)	5.63 (3.69 to 8.60)
Group 1	14/25 (56.0)	185/225 (82.2)	26.2 (7.0 to 45.8)	1.09 (0.59 to 2.01)
Group 2	59/150 (39.3)	103/125 (82.4)	43.1 (32.2 to 52.7)	3.93 (1.72 to 8.99)
Group 3	71/225 (31.6)	38/50 (76.0)	44.4 (30.0 to 56.5)	5.53 (1.59 to 19.23)
Community hospitals	86/275 (31.3)	73/98 (74.5)	43.2 (32.4 to 52.8)	4.28 (2.10 to 8.69)
Academic hospital	58/125 (46.4)	253/302 (83.8)	37.4 (27.5 to 46.7)	3.27 (1.87 to 5.72)
Components of nonoptimal prescribing throughout antimicrobial therapy course				
Prolonged duration[a]	177/400 (44.2)	37/400 (9.2)	−35.0 (−40.2 to −29.2)	0.17 (0.11 to 0.26)
Treatment for asymptomatic bacteriuria[a]	37/400 (9.2)	10/400 (2.5)	−6.8 (−10.0 to −3.4)	0.31 (0.11 to 0.86)
Nonbacterial upper respiratory tract infection[a]	7/400 (1.7)	1/400 (0.3)	−1.5 (−3.0 to 0)	0.15 (0.03 to 0.86)
Non-guideline-concordant selection[b]	81/400 (20.2)	24/400 (6.0)	−14.3 (−18.8 to −9.6)	0.28 (0.10 to 0.78)
Suboptimal dose[c]	23/400 (5.7)	4/400 (1.0)	−4.8 (−7.3 to −2.2)	0.11 (0.03 to 0.43)
Organism resistant to antimicrobial agent[b]	8/400 (2.0)	2/400 (0.5)	−1.5 (−3.2 to 0.2)	0.37 (0.07 to 2.09)
Duration too short[c]	6/400 (1.5)	6/400 (1.5)	0 (−1.8 to 1.8)	0.63 (0.10 to 4.11)

Abbreviations: GEE, generalized estimating equation; OR, odds ratio.

[a] Indicates unnecessary subcategory for nonoptimal therapy (eMethods in the Supplement), including antimicrobial days beyond indicated duration of therapy, asymptomatic bacteriuria and other noninfectious syndromes, viral respiratory tract infection without bacterial coinfection, and redundant antimicrobial coverage.

[b] Indicates inappropriate subcategory for nonoptimal therapy (eMethods in the Supplement), including antimicrobial days for an established bacterial infection in which the pathogen is resistant to therapy and antimicrobial selection that is not concordant with institutional guidelines.

[c] Indicates suboptimal subcategory for nonoptimal therapy (eMethods in the Supplement), including use of an excessively broad-spectrum antimicrobial when a preferred or first-line agent is not contraindicated, dose is too high or too low for kidney function, and duration of therapy is shorter than indicated.

Table 4. Patient Outcomes

Outcome	Patient group, No. (%)		Absolute difference, % (95% CI)	Time-adjusted GEE OR (95% CI)
	Preintervention (n = 400)	Postintervention (n = 400)		
30-d Mortality	3 (0.7)	6 (1.5)	0.8 (−0.9 to 2.4)	0.80 (0.09 to 7.18)
90-d Mortality	12 (3.0)	11 (2.7)	−0.2 (−2.7 to 2.2)	0.78 (0.36 to 1.71)
30-d Readmission	77 (19.3)	81 (20.3)	1.0 (−4.5 to 6.5)	0.77 (0.60 to 0.98)
Infection related	33 (8.3)	21 (5.3)	−3.0 (−6.5 to 0.5)	0.48 (0.28 to 0.81)
30-d Unplanned office or emergency department visit	105 (26.3)	109 (27.3)	1.0 (−5.1 to 7.1)	0.59 (0.37 to 0.94)
No clinical resolution[a]	50 (16.5)	34 (12.4)	−4.1 (−9.8 to 1.6)	0.91 (0.63 to 1.30)
Any adverse drug event	78 (19.5)	53 (13.3)	−6.3 (−11.4 to −1.0)	1.09 (0.57 to 2.06)
Severe adverse drug event	36 (9.0)	13 (3.2)	−5.7 (−9.1 to −2.4)	0.40 (0.18 to 0.88)
Clostridioides difficile infection	7 (1.7)	2 (0.5)	−1.2 (−2.8 to 0.4)	0.64 (0.11 to 3.64)
MDRO at 90 d	28 (7.0)	10 (2.5)	−4.5 (−7.6 to −1.6)	0.32 (0.15 to 0.71)

Abbreviations: GEE, generalized estimating equation; MDRO, multidrug-resistant organism; OR, odds ratio.

[a] Includes 303 patients in the preintervention group and 275 in the postintervention group.

members in leading the supportive antimicrobial reviews (eg, determining antimicrobial days), multidisciplinary discussions, addressing medication access barriers, and facilitating antimicrobial orders into discharge queues for cosigning by the prescriber.

The Centers for Disease Control and Prevention has highlighted the importance of antimicrobial stewardship in the TOC setting in the 2019 core elements of hospital antibiotic stewardship as an opportunity to improve prescribing at hospital discharge.[22,23] In a multicenter cohort study assessing antimicrobial orders for respiratory and urinary infections from 21 825 discharged patients, Vaughn et al[3] classified 49% of prescriptions as overuse. These findings were largely owing to excessive durations of therapy and were similar to those in our preintervention group prescribing frequency of prolonged antimicrobial duration at discharge (44.3%). Similar results were observed in a multicenter, cross-sectional study[24] assessing antimicrobial appropriateness in hospitalized adults. Using objective antimicrobial quality assessment algorithms, more than 75% of antimicrobial courses for community-acquired pneumonia and urinary tract infection were considered unsupported generally because of long duration and incorrect selection of antimicrobial therapy and use for treatment of asymptomatic bacteriuria.[24]

Rigorous education and implementation planning largely contribute to the success of an intervention. Investment from all key partners from medicine, pharmacy, and nursing groups promotes ownership, responsibility, and accountability. Six months of upfront effort was invested from the investigator team to develop the design, feedback structure, training, and education required to implement the intervention across 5 hospitals. Using routine monitoring of protocol adherence, we were able to provide transparency of challenges and successes related to intervention progress via meetings, monthly electronic updates, benchmarking, and positive feedback cases. The additional dedicated time to new interventions in the pharmacist workload varied for each site depending on the population, communication model, and total volume of patients cared for on each shift. A mean of 1 to 3 patients were discharged with a prescription for oral antimicrobials each day from any given service team. In addition to audit and feedback, the pharmacy and antimicrobial stewardship personnel's active role in executing the intervention via electronic medication entry into the discharge queue was crucial in antimicrobial optimization (eTable 4 in the Supplement). Sustained growth and success of the model was maintained in both academic and community service

Table 5. Assessment of Covariates and Optimized Discharge Prescription in Univariate and Multivariable Models

Covariate	Optimized discharge prescription[a]		OR (95% CI)[b]	*P* value	Time-adjusted GEE OR (95% CI)[c]	GEE *P* value[c]
	Yes	No				
Overall	470/800 (58.7)	330/800 (41.3)	NA	NA	NA	NA
Postintervention period	326/400 (81.5)	74/400 (18.5)	6.63 (4.45 to 9.86)	<.001	3.77 (2.32 to 6.15)	<.001
Age, mean (SD), y	64.7 (17.6)	69.7 (16.5)	0.83 (0.76 to 0.90)	<.001	0.93 (0.82 to 1.04)	.18
Women	262/441 (59.4)	179/441 (40.6)	0.94 (0.70 to 1.27)	.71	Not tested	NA
Length of stay, median (IQR), d	3 (2-4)	4 (2-5)	0.86 (0.80 to 0.92)	<.001	0.89 (0.83 to 0.96)	.001
Study month	NA	NA	1.25 (1.19 to 1.31)	<.001	1.11 (1.04 to 1.19)	.003
Charlson Comorbidity Index score, median (IQR)	2 (1-3)	2 (1-4)	0.95 (0.88 to 1.03)	.22	Not tested	NA
≥1 MDRO risk factor	251/426 (58.9)	175/426 (41.1)	1.11 (0.83 to 1.50)	.48	Not tested	NA
Community hospital	159/373 (42.6)	214/373 (57.4)	0.23 (0.17 to 0.32)	<.001	0.49 (0.38 to 0.64)	<.001
Urinary source	96/203 (47.3)	107/203 (52.7)	0.58 (0.41 to 0.81)	.002	0.59 (0.44 to 0.79)	<.001
≥2 SIRS criteria on day 3	21/40 (52.5)	19/40 (47.5)	0.79 (0.40 to 1.54)	.49	Not tested	NA
Empirical intravenous antimicrobial	370/650 (56.9)	280/650 (43.1)	0.69 (0.47 to 1.02)	.06	0.76 (0.54 to 1.06)	.11
Dementia	33/71 (46.5)	38/71 (53.5)	0.66 (0.40 to 1.11)	.12	Not tested	NA
Absence of microbiologic or diagnostic data	95/143 (66.4)	48/143 (33.6)	1.19 (0.80 to 1.78)	.39	Not tested	NA

Abbreviations: GEE, generalized estimating equation; MDRO, multidrug-resistant organism; NA, not applicable; OR, odds ratio; SIRS, systemic inflammatory response syndrome.

[a] Unless otherwise indicated, data are expressed as number/total number (%) of patients.

[b] Calculated using standard logistic regression. Covariates with an OR greater than 1.00 are associated with an optimized discharge prescription.

[c] Calculated using multivariable logistic regression. Covariates with an OR greater than 1.00 are associated with an optimized discharge prescription.

teams across each quarter during active intervention (eFigure 3 in the Supplement). Replication of similar TOC models may require a foundation of pharmacy leadership, engagement, and clinical expertise, which are resources that are not available to all health care facilities. Zampino et al[8] observed similar improvement in overall appropriateness of antimicrobial therapy during TOC at an academic hospital after audit and feedback by an antimicrobial stewardship pharmacist for discharge prescriptions from medicine/surgical wards. An interesting finding from our study was that patients discharged from community centers had lower odds of being prescribed an optimal antimicrobial regimen at discharge. These lower odds could be owing to availability of staff in community settings or associated with the study design by having fewer patients in the intervention arm in community hospitals (Table 1).

The synergistic relationships between prescriber and pharmacist in antimicrobial stewardship programs facilitate better care and services.[25] Medication reconciliation, preauthorization of therapies, and facilitating appropriate diagnostic testing are a few of many examples in which these collaborations have proven beneficial.[11] Specifically, during TOC, Chavada et al[26] found large discrepancies between guideline recommendations and the actual antimicrobial discharge prescription. With regard to antimicrobial choice, dose, frequency, and duration, patients who had received an intervention by the antimicrobial stewardship team were more likely to have appropriate therapy.[26] Yogo et al[9] used audit and feedback on discharge prescriptions to transition patients with respiratory, skin, urinary, and gastrointestinal tract infections to an optimized antimicrobial selection and duration. Staff pharmacists were trained to conduct this review in real time for patients being discharged from the hospital; duration of therapy after hospital discharge was reduced by a day and prescribing preferences shifted away from fluoroquinolones.[9] However, appropriateness of the discharge prescription and other clinical end points were unchanged, and among 918 patients prescribed an oral antimicrobial at discharge during the study period, a prescriber was contacted only about 10% of the time.[9] Our ability to capture more patients in the protocol was likely an important component for improving patient safety.

The intervention was not directly associated with clinical resolution, although we observed an association with reduced severe antimicrobial-related ADEs. Interestingly, no difference in readmissions was observed in the unadjusted analysis; however, after controlling for service team and study month, patients in the postintervention period had a lower risk of 30-day readmission and infection-related readmission. Readmission is a highly confounded outcome, and results should be interpreted with caution. In a large prospective national study, several thousand patients were assigned to receive a variety of interventions related to TOC, which reduced readmissions.[27] This finding was driven by hospital-based TOC interventions that included but were not limited to medication reconciliation, identification of high-risk patients, and promotion of trust in the hospital. The hospital-based actions were not specific to patients prescribed antimicrobials, although this population should be a high-risk group given the number of comorbid conditions and readmissions associated with infections. In our study, most antimicrobial optimization from the intervention was related to selecting shorter durations and more targeted therapy, which coincides with the ADE frequency before and after the intervention. Each excess antimicrobial day has been associated with 5% greater odds of developing an ADE.[21] We also found that fewer than 1% (n = 5) of patients had readmissions potentially related to ADEs. Similarly, Vaughn et al[3] concluded that antimicrobial overuse after discharge was not associated with readmissions, mortality, or patient-reported ADEs; however, incidence of new multidrug-resistant organisms was not assessed.

Limitations

There are inherent limitations in the nonrandomized design of this study, including biases due to maturation and Hawthorne effect and regression to the mean. Using a nonrandomized stepped-wedge design with multiple observation periods and points of intervention, we were able to better mitigate biases. Notably, the frequency of protocol adherence (63%, defined by the presence of medical record documentation of antimicrobial plan and guideline recommendation by discharge)

was surpassed by the frequency of optimal discharge-antimicrobial prescribing (81.5%) in the postintervention group. This occurrence is likely attributable to maturation and the Hawthorne effect given that clinicians became aware of the intervention. We also found differences in diagnoses and race between the preintervention and postintervention groups, likely due to the stepped-wedge intervention rollout order, subsequently leading to imbalances in the numbers of patients from community hospitals. In addition, the process of collaborative rounds for service teams in academic centers was modified to include antimicrobial TOC discussions. Communication models differed between hospitals for paging, telephone calls, and rounding on service teams. There were no other major concurrent health system–wide interventions related to antimicrobial stewardship and/or TOC during the study periods.

Conclusions

The findings of this quality improvement study suggest that leveraging resources to provide additional review and intervention on antimicrobial discharge therapies may lead to improvements in the quality and safety of antimicrobial prescriptions. Using pharmacists to reinforce institutional protocols, we were able to successfully target and modify the following areas of antimicrobial optimization: minimization of unnecessary antimicrobial days from prolonged durations and patients without infections; avoidance of therapies that are excessively broad, not concordant with local guidance, or targeted toward pathogens that are not susceptible to the antimicrobial; and transitioning from intravenous agents to accessible and affordable oral options as soon as possible. Health care systems seeking to improve quality of prescribing and safety for patients with common infections should consider adopting antimicrobial stewardship interventions at TOC.

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SUPPLEMENT.

eMethods. Definitions
eFigure 1. Institutional Guidelines for Antimicrobial Selection and Duration of Therapies at the Time of Intervention Implementation
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Pharmacist-delivered Patient Care Services
Evidence Examples

The pharmacist's role in delivering patient care services continues to evolve, with the body of evidence supporting pharmacists' impact growing daily. The American Pharmacists Association (APhA) convened a group of scientific experts and charged them with identifying examples of the best evidence of pharmacists' impact on patient medication–related and other health outcomes. In 2013, the first expert panel[1] limited the search of the medical literature to a 10-year period, from 2000 to 2010. Focusing on medication therapy management (MTM) outcomes, the panel extracted key examples from the literature and created summary statements supported by the research data. The 2014[2], 2015[3], and 2016[4] panels continued to evaluate newly published studies but with an expanded focus on pharmacists' patient care services, including MTM.

The articles below, organized topically, reflect some of the key examples identified by the expert panel. Each example includes a concise statement of key findings, title of the manuscript, and source from which the full manuscript can be obtained.

APhA recognizes the need for an ongoing effort to collect and summarize the best examples of pharmacist-provided patient care services, including MTM. Working closely with APhA's Science Officer, experts will continue to survey the literature for pharmacist-delivered patient-care outcome publications routinely. As the evidence expands, this compendium of pharmacist provision-of-care publications will grow. Have comments, inquiries, suggestions, and/or potential corrections? E-mail APhA's Science Officer, Patrick Clay, at PClay@aphanet.org.

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[1] Members of the 2013 Expert Panel are listed in Appendix A and publications reviewed are indicated by a superscript 1 at the end of the publication summary.
[2] Members of the 2014 Expert Panel are listed in Appendix B and publications reviewed are indicated by a superscript 2 at the end of the publication summary.
[3] Members of the 2015 Expert Panel are listed in Appendix C and publications reviewed are indicated by a superscript 3 at the end of the publication summary.
[4]Members of the 2016 Expert Panel are listed in Appendix D and publications reviewed are indicated by a superscript 4 at the end of the publication summary.

Section 1: Patients with Multiple Chronic Diseases

- This retrospective study evaluated the impact of telephonic medication therapy management (MTM) provided by pharmacists on total health care costs, inpatient visits, emergency department visits, and total days' supply of medication and medication adherence for patients with diabetes, hypertension, dyslipidemia, depression, and asthma. Pharmacists working within an employer group provided MTM at least 3 times over a 1-year period to patients. Researchers compared these patients (n = 2,250) to matching cases that did not receive services under this MTM model (n = 2,250). The researchers discovered those receiving MTM had a decrease in inpatient visits of 18.6% while those who did not participate saw an increase of 24%. Those participating also had statistically significantly lower admission rates, lower rates of ER visits, fewer physician outpatient visits, and higher medication adherence. This study looked at a real-world approach to delivering pharmacist services and appeared to provide economic and clinical benefit in this employer-based setting.[2]

  Moore JM, et al. Impact of a Patient-Centered Pharmacy Program and Intervention in a High-Risk Group. J Man Care Pharm 2013;19:228-36.

- This study described the economic impact of redesigning the healthcare system to help primary care patients achieve their drug therapy treatment goals. Using a team-based healthcare approach in which the pharmacists provided comprehensive medication therapy management (MTM) for patients with chronic medical conditions and coordinated patient-specific goals of therapy, researchers looked longitudinally at the cost to deliver care, drugs, and other care delivery quality benchmarks to see which differed between clinics using this model vs. those that did not. A few of the key findings in the intervention group (n = 823) were: (1) slowed growth in expenditures from 15% (in the 38 clinics not implementing this service) to 4% (11% less) in the 4 clinics where the service was implemented; (2) more than twice as many patients realized success (40% vs. 18%) across all 5 outcome measures examined; and (3) over 4,000 drug therapy problems were resolved in patients with high blood pressure, diabetes, and high cholesterol. This positive outcome study should not be over-interpreted. However, this report seems to give strong support to build care-based, pharmacist-involved systems in team based models.[2]

  Isetts BJ, et al. Managing drug-related morbidity and mortality in a patient-centered medical home. Med Care. 2012: 50;997-1001. DOI: 10.1097/MLR.0b013e31826ecf9a

- Researchers compared two levels of medication therapy management (MTM) activities to each other and standard of care in elderly patients with complicated medical problems. These patients had at least 3 chronic conditions and were on at least 6 medications. Patients were randomly assigned to receive basic MTM (n = 211), enhanced MTM (n = 218) or no MTM (n = 208). The difference between basic and enhanced was that the basic MTM group did not have access to clinical information from medical providers. The MTM model consisted of pharmacists completing comprehensive medication reviews and medication related problem assessment, and sending recommendations to the patients' physicians. Both MTM interventions reduced medication-related problems. There were no measurable differences in adverse drug events and

health care visits over time between the MTM groups and the no MTM group. Physicians responded to approximately half of pharmacist recommendations. When they responded, they accepted the recommendation or altered therapy 94% of the time in the basic MTM and 87% of the time in enhanced MTM groups, suggesting the original therapy was not optimal. Importantly, rejection of recommendations occurred with less than 10% of all recommendations. The researchers encourage development of patient centered models that engage the patient and pharmacist at the point of prescribing rather than afterwards.[2]

Touchette DR, et al. Safety-focused medication therapy management: A randomized controlled trial. JAPhA 2012;52:603-12. DOI: 10.1331/JAPhA.2012.12036

- In a systematic review of 298 published studies, pharmacist-provided MTM services resulted in significantly improved outcomes in disease management, cost savings, or quality of life measures.[1]

Chisholm-Burns MA, Kim Lee J, Spivey CA, et al. US pharmacists' effect as team members on patient care: systematic review and meta-analysis. Med Care 2010;48(10):923–33.

- An analysis of 10 years of results demonstrated the benefit of pharmacist-delivered MTM to more than 9,000 patients. Pharmacists resolved nearly 40,000 drug-related problems with a calculated savings to the health care plan of $750,000. This translated to $1.29 in benefit for every $1 invested in MTM, an excellent rate of return.[1]

Ramalho de Oliveira D, Brummel AR, Miller DB. Medication therapy management: 10 years of experience in a large integrated health care system. J Manag Care Pharm. 2010;16(3):185–95.

- A 1-year study of a pharmacist-directed MTM in a managed care system demonstrated that for every $1 spent on MTM, $12 was saved. Of importance is that these savings occurred along with significant improvements in cholesterol and blood pressure control. Expansion of similarly structured, targeted, pharmacist-provided MTM to all Minnesota's Medicare recipients projects a savings of $7.8 million.[1]

Isetts BJ, Schondelmeyer SW, Artz MB, et al. Clinical and economic outcomes of medication therapy management services: the Minnesota experience. J Am Pharm Assoc. 2008;48(2):203–11.

- In a study involving more than 2,500 medically complicated patients, a collaborative pharmacist–physician MTM program demonstrated a significant increase in those patients who were able to achieve their therapy goals.[1]

Isetts BJ, Brown LM, Schondelmeyer SW, Lenarz LA. Quality assessment of a collaborative approach for decreasing drug-related morbidity and achieving therapeutic goals. Arch Int Med. 2003;163(15):1813–20.

- Following completion of a major systematic review of medication therapy management (MTM) literature performed for AHRQ, the same authors published a description citing the positive findings of pharmacist-provided clinical services. Notably, medication appropriateness, adherence (measured either by doses taken or achieving a threshold percent adherence level that is disease appropriate), and reduced medication dosing (reduced number of doses per day) were all significantly improved via MTM intervention from the studies included in final analysis. There were positive economic measures identified including reduced health plan expenditures, a reduced risk for hospitalization in persons with diabetes or heart failure and reduced costs for diabetes-related hospitalizations. The findings also illustrate the critical need for consistency in MTM interventional study design (prospective methodologies) and in reported outcomes (such as adherence changes and 1-year outcomes) even with the acknowledged broad diversity in 'usual care'. Future studies should include outcomes such as impact on hospitalizations; consistently report on clinical intermediate outcomes and adverse drug effects; report patient-centered outcomes; distinctly define the role (actions) of the pharmacist and clearly defend why information on morbidity and mortality is not present (if applicable). The authors call for researchers and program evaluators to "specify and design MTM interventions based on existing definitions, taxonomies, and service models."[3]

  Viswanathan M, Kahwati LC, Golin CE, Blalock SJ, Coker-Schwimmer E, Posey R, Lohr KN. Medication therapy management interventions in outpatient settings: a systematic review and meta-analysis. J Amer Med Assoc Intern Med 2014;Online:E1-12. DOI: 10.1001/jamainternmed.2014.5841

Section 2: Chronic Conditions

Cardiovascular Disease

- Over a 6-month period, pharmacists provided a variety of medication therapy management (MTM) services to patients with heart disease as a 'no-cost-to-patient' part of an employer's health plan. Researchers compared clinical and economic outcomes for those who received MTM (n=63) with a matched group of patients who did not receive MTM (non-MTM, n=62). Economically, the MTM group's total direct healthcare expenditures were significantly lower ($359/patient) and revealed a return-on-investment of 1.67. Clinically, those who received MTM had higher rates of meeting their blood pressure and body mass index goals. The specific scope of MTM service provided was adapted according to individual patient needs and it showed that in less than one year, pharmacists had a positive financial and clinical impact on patients with cardiovascular disease.[2]

  Wittayanukorn S, et al. Evaluation of medication therapy management services for patients with cardiovascular disease in a self-insured employer health plan. J Manag Care Pharm 2013;19(5):385-95.

- A study demonstrated that pharmacists providing MTM for more than 5,500 older adult veterans with congestive heart failure reduced hospitalizations by 45% compared with those veterans who received only physician-based care.[1]

  Roughead EE, Barratt JD, Ramsay E, et al. The effectiveness of collaborative medicine reviews in delaying time to next hospitalization for patients with heart failure in the practice setting: results of a cohort study. Circ Heart Fail. 2009;2(5):424–8.

- A group of 56 community pharmacies in Alberta, Canada were evaluated to determine if pharmacist-provided medication therapy management delivered to patients who were at high-risk for a major cardiovascular event would be able to lower patient risk in just 3 months. Compared to the group that did not receive the pharmacist's intervention, statistically significant greater reductions in bad cholesterol (LDL-c) and uncontrolled high blood pressure were achieved as well as greater improvements in persons with diabetes and smoking cessation. Overall, patients receiving medication therapy management from the pharmacists experienced a 21% reduction in estimated cardiovascular risk, again confirming the valuable benefit of having community pharmacists provide care to patients with multiple medical conditions.[4]

  Tsuyuki RT, Hammarneh YN, Jones CA, Hemmelgarn BR. Effectiveness of community pharmacist prescribing and care on cardiovascular risk reduction: randomized controlled RxEACH trial. J Amer Coll Cardiol 2016;16:2846-54. DOI: 10.1016/jack.2016.03.52

High Blood Pressure (Hypertension)

- Patients with diabetes who had uncontrolled high blood pressure and received MTM from a community pharmacy supplementing their physicians' care were nearly 13 times more likely to achieve their health care goals compared with those who did not take part in the program.[1]

  Planas LG, Crosby KM, Mitchell KD, Farmer KC. Evaluation of a hypertension medication therapy management program in patients with diabetes. J Am Pharm Assoc. 2009;49(2):164–70.

- A study of a pharmacist–physician collaborative approach to managing high blood pressure demonstrated that within a year and a half, nearly *twice as many patients had control of their blood pressure* when pharmacists helped the patients manage their medications, compared with those not assisted by pharmacists.[1]

  Wentzlaff DM, Carter BL, Ardery G, et al. Sustained blood pressure control following discontinuation of a pharmacist intervention. J Clin Hypertens. 2011;13(6):431–7.

- Over the course of a year, a clinical trial demonstrated a statistically significant improvement in blood pressure control and maintenance through community pharmacy–based MTM services.[1]

Weber CA, Ernst ME, Sezate GS, Zheng S, Carter BL. Pharmacist-physician comanagement of hypertension and reduction in 24-hour ambulatory blood pressures. Arch Int Med. 2010;170(18):1634–9.

- A systematic review of 39 randomized, controlled hypertension trials with 14,225 outpatients was performed to investigate the effect of pharmacist care on blood pressure control, whether delivered alone or through collaborative practice agreements with other health care professionals. In these studies, pharmacists' interventions consisted of patient education (lifestyle, medication adherence), feedback to health care professionals, and medication adjustments. There were clinically meaningful decreases in systolic and diastolic blood pressures. Reflecting highly diverse patient groups and pharmacist interventions types, this broad literature evaluation suggests that the best outcomes result from: (1) interventions occurring more than once a month, (2) led by pharmacists, or (3) conducted in the community pharmacy setting. One important issue left to be determined is if the specific intervention should be predefined by a narrow protocol or flexibility provided to the pharmacist.[2]

Santschi V, et al. Improving blood pressure control through pharmacist interventions: a meta-analysis of randomized controlled trials. J Amer Heart Assoc 2014;3e000718. DOI:10.1161/JAHA.113.000718

- Patients using home blood pressure (BP) telemonitoring with pharmacist case management in 8 clinics (n=228) were compared to patients receiving usual care in 8 different primary care clinics (n=222) over an 18-month period. Working with physicians in a collaborative practice model, pharmacists assessed and adjusted antihypertensive drug therapy, and emphasized importance of lifestyle modifications and medication adherence. At both 6 and 12 months, BP control was greater in the pharmacist group than the usual care group by nearly a 2-fold difference. Also, a difference in BP control remained between groups 6 months after the program ended (72% vs. 57%). Using a very rigorous scientific approach – including randomization - this study demonstrated the positive initial, intermediate, and enduring impact of pharmacist case management using home BP telemonitoring across many different physician practice sites.[2]

Margolis KL, et al. Effect of home blood pressure telemonitoring and pharmacist management on blood pressure control: a cluster randomized clinical trial. J Amer Med Assoc 2013;310:46-56. DOI: 10.1001/jama.2013.6549

- A large (625 patients), multi-site (32 clinics), prospective (up to 24 months), cluster-randomized trial of a collaboration between a physician and pharmacist to improve short and long term blood pressure control demonstrated important positive outcomes. The patients that were assigned to the pharmacists' group were more likely to have a meaningful reduction in blood pressure at 9 months and this reduction continued 13-months after the patients' formal meetings (intervention) with the pharmacists stopped. Of importance, this trial showed this impact was possible in a population that was majority minority, had either diabetes or chronic kidney disease, and nearly all over 55 and 60% female. In addition to the clinical findings, the project, a comparative effectiveness design enabled evaluation of consistency in interventions provided by the pharmacists as well as incorporated provider attitudes on these services and should be emulated to the extent possible in future studies.[3]

Carter BL, Coffey CS, Ardery G, Uribe L, Ecklund D, James P, Egan B, Vander Weg M, Chrischilles E, Vaughn T. Cluster-randomized trial of a physician/pharmacist collaborative model to improve blood pressure control. Circ Cardiovasc Qual Outcomes 2015.8:235043. DOI: 10.1161/CIRCOUTCOMES.114.001283.

- Though entirely conducted outside the US healthcare system, this research note was notable for several key aspects that are instructive to US-based healthcare providers and systems considering evaluating the role of pharmacists on healthcare teams. This planned, secondary analysis, with data drawn from a randomized, controlled clinical trial, specifically assessed for changes made to antihypertensive regimens by pharmacists in patients with diabetes. Diabetes (average age 60) patients (n=200) cared for by a healthcare team including a pharmacist were more likely to have their antihypertensive medications changed with the change most often consisting of a blood pressure medicine added that brought the elderly patients more in-line with US-based hypertension and diabetes guidelines. In those healthcare teams with pharmacists, patients who had change made to their regimen were statistically more likely to have improvement in blood pressure control compared to those with changes on the teams that increased adherence was observed in the patients receiving care from the healthcare team including a pharmacist whereas a decrease was seen in the other teams.[3]

Omran D, Majumdat SR, Johnson JA, Tsuyuki RT, Lewanczuk RZ, Guirguis LM, Makowsky M, Simpson SH. Pharmacists on primary care teams: effect on antihypertensive medication management in patients with type 2 diabetes. J Amer Pharm Assoc 2015;55:e301-4. DOI: 10.1331/JAPHA/2015.14225.

High Cholesterol

- More than 200 Florida Medicare Part D enrollees took part in a study evaluating pharmacist-provided MTM focused on cholesterol management. After 1 year, over *two-thirds had reached their goal* for cholesterol levels compared with just half of those not receiving MTM. Even more powerful was the finding that this group used *less* medicine and *reduced* their *out-of-pocket expenses*. If all 3 million of Florida's Medicare Part D enrollees participated in focused, pharmacist-provided MTM, using 2012 population figures, the *projected out-of-pocket savings* for these seniors is nearly *$12 million.*[1]

Fox D, Ried LD, Klein GE, Myers W, Foli K. A medication therapy management program's impact on low-density lipoprotein cholesterol goal attainment in Medicare Part D patients with diabetes. J Am Pharm Assoc. 2009;49(2):192–9.

Diabetes

- A 1-year pharmacist-led program evaluated outcomes among patients with diabetes who received medication therapy management (MTM). The results compare those receiving MTM (n = 121) with those who did not (non-MTM, n = 103). The MTM group achieved greater diabetes

control than the non-MTM group using the 5-component optimal diabetes care measures (glucose levels, cholesterol, blood pressure, tobacco use, and daily aspirin use). Greater diabetes control and better cholesterol results were especially seen in those MTM group patients who participated in five or more MTM visits in a year – reinforcing the importance of retention in care models. Notably, one year after the program's discontinuation, the diabetic patients who received MTM regressed to baseline, thereby highlighting the benefits of sustaining a MTM program with regular pharmacist follow-up. This study's main limitations were self-referral of a motivated population and a retrospective source of data for the non-MTM group data.[2]

Brummel AR, et al. Optimal diabetes care outcomes following face-to-face medication therapy management services. Popul Health Manag 2013;16:28-34. doi:10.1089/pop.2012.0023

- African Americans make up 51% of the 23 million Americans battling diabetes. This one group (11.7 million African-Americans with diabetes) accounts for $90 billion in annual health care costs, or $7,600 per African American. In a year-long study of a pharmacist-provided MTM program for persons with diabetes, more than half (56.3%) of the African Americans with diabetes significantly improved their diabetes control. This control made them less likely to develop costly complications like dialysis, amputations, and transplants. If MTM were applied to all African Americans with diabetes, reducing their health care costs by even $1 per patient would save $6.6 BILLION annually.[1]

Jameson JP, Baty PJ. Pharmacist collaborative management of poorly controlled diabetes mellitus: a randomized controlled trial. Am J Manag Care. 2010;16(4):250–5.

- Patients participating in a pharmacist MTM diabetic program for 1 year had significant improvement in their *blood pressure, cholesterol, and diabetes*. In addition, because pharmacists also taught the patients how to care for themselves, significantly more had their annual eye examinations and diabetic foot checks and received influenza vaccinations, resulting in significant cost savings.[1]

Fera T, Bluml BM, Ellis WM. Diabetes Ten City Challenge: final economic and clinical results. J Am Pharm Assoc. 2009;49(3):383–91.

- In a 2009 pilot study, 50 type 2 patients with diabetes patients receiving pharmacist-directed MTM made significant and sustained improvement in blood glucose, weight loss, and blood pressure. While these patients spent an additional $300 on medications over this period, they actually reduced their total health care costs from the previous year by approximately $2,500 per patient or $125,000 overall.[1]

Monte SV, Slazak EM, Albanese NP, Adelman M, Rao G, Paladino JA. Clinical and economic impact of a diabetes clinical pharmacy service provided in a university and primary care–based collaboration model. J Am Pharm Assoc. 2009;49(2):200–8.

- An accountable care organization (ACO) evaluation of 23 pharmacists (representing 44 distinct clinics and 30 pharmacies in the upper Midwest) providing medication therapy management services (MTM) to high-risk patients with diabetes (over 20,000) demonstrated positive impact on various clinical measures (glucose control, LDL-cholesterol, blood pressure, smoking cessation and appropriate use of aspirin) while also generating a 12:1 return on investment (ROI). The pharmacist-specific role was to complete a systematic review of medication therapy to identify (over 100,000 identified) and resolve drug therapy problems through communication either in the clinic (via electronic medical record communication, telephonic or face to face with patient), notations in medical record or by directly modifying therapy through collaborative drug therapy management agreements. Included are what was identified as best practices lessons learned from the experience ranging from structure, to outcomes, and the changes required along the way to optimize the service. Authors noted no single delivery approach will likely be successful. Further, it revealed indirect contact (telephone or video conferencing) could be effective as one site only conducted 40% of interactions face-to-face yet still generated similar resuts.[3]

  Brummel A, Lustig A, Westrich K, Evans MA, Plank GS, Penso J, Dubois RW. Best practices: improving patient outcomes and costs in an ACO through comprehensive medication therapy management. J Manag Care Pharm 2014;20:1152-8.

Chronic Kidney Disease

- A 2-year study involving 104 patients with *severe kidney disease and on dialysis* demonstrated that pharmacist-provided MTM resulted in significantly fewer and shorter hospitalizations and reduced medication use compared with dialysis patients not receiving pharmacists' care.[1]

  Pai AB, Boyd A, Depczynski J, Chavez IM, Khan N, Manley H. Reduced drug use and hospitalization rates in patients undergoing hemodialysis who received pharmaceutical care: a 2-year, randomized, controlled study. Pharmacotherapy. 2009;29(12):1433–40.

- Minorities are disproportionately afflicted with chronic kidney disease requiring dialysis, and because fewer transplants are available, they must remain on dialysis for longer periods than nonminorities. Minority dialysis patients receiving pharmacist-provided MTM reported having a better quality of life, improved diet, more physical activity, and a better time with their families compared with those who did not receive MTM.[1]

  - ***Pai AB, Boyd A, Chavez A, Manley HJ. Health-related quality of life is maintained in hemodialysis patients receiving pharmaceutical care: a 2-year randomized, controlled study. Hemodial Int. 2009;13(1):72–9.***

Section 3: Special Populations

Older Adults

- Pharmacist-provided MTM to older adult patients in long-term care facilities saved more than $1.3 million dollars.[1]

> ***Trygstad TK, Christensen DB, Wegner SE, Sullivan R, Garmise JM. Analysis of the North Carolina long-term care polypharmacy initiative: a multiple-cohort approach using propensity-score matching for both evaluation and targeting. Clin Ther. 2009;31(9):2018–37.***

Mental Health

- Pharmacists impacted patient safety in patients prescribed psychotropic agents with known sub-optimal safety monitoring who were exclusively followed by their primary care providers. This benefit was seen after the pharmacist performed population level medication reviews that were limited to having EHR access only. Over a 1-year project period, pharmacists' reviews and subsequent accepted recommendations resulted in an 18% improvement in patients being up-to-date in psychotropic medication safety monitoring as well as a 20% reduction in risk for drug interaction-based adverse events. Notably, the provider survey regarding the service was overall positive, with some feedback that it would be helpful if pharmacists would take a more active role in ordering and completing laboratory monitoring or personally seeing the patients.[4]

> ***Gallimore CE, Sokhal D, Zeidler-Schrieter E, Margolis AR. Pharmacist medication reviews to improve safety monitoring in primary care patients. Families, Systems & Health 2016;34;104-13. DOI: 10.1037/fsh0000185***

Multiple Sclerosis

- By participating in a pharmacist-managed MTM program, Medicare patients with multiple sclerosis took their medications more regularly and correctly, providing for much more cost-effective management of their disease.[1]

> ***Stockl KM, Shin JS, Gong S, Harada AS, Solow BK, Lew HC. Improving patient self-management of multiple sclerosis through a disease therapy management program. Am J Manag Care. 2010;16(2):139–44.***

Palliative Care

- Palliative care represents an area where patients routinely receive multiple medications from numerous providers and where pharmacists are uniquely poised to intervene. Over a 1-year period, pharmacists were able to improve or stabilize pain in patients after a single visit and

demonstrated statistically significant improvement by visit 2 (82% vs. 19%). Further, addressing the primary adverse events in this population (constipation, nausea and vomiting) trended towards resolution in over 88% of patients by the third visit. This study highlighted the important role of pharmacists in managing medications for palliative care patients, and described a clear path for recognizing and credentialing pharmacists.[4]

Ma JD, Tran V, Chan C, Mitchell WM, Atayee RS. Retrospective analysis of pharmacist interventions in an ambulatory palliative care practice. J Oncol Pharm Pract 2016;22:757-65. DOI: 10.1177/1078155212607089

Section 4: Health Policy

- In Health Affairs, noted experts from Yale, University of California at San Francisco, Brigham Women's Hospital, and the University of Connecticut reviewed the available scientific evidence and called for the inclusion of pharmacists as the provider of medication therapy management.[1]

  Smith M, Bates DW, Bodenheimer T, Cleary PD. Why pharmacists belong in the medical home. Health Aff. 2010;29(5):906–13.

- The Journal of the American Medical Association has called for enhanced collaboration between pharmacists and physicians, particularly for older adults, who are at very high risk for poor medical outcomes.[1]

  Steinman MA, Hanlon JT. Managing medications in clinically complex elders: "There's got to be a happy medium." JAMA. 2010;304(14):1592–601.

- In this study, pharmacy researchers have addressed a critical need of governmental and regulatory agencies like Centers for Medicare and Medicaid Services (CMS) to establish relative value units (RVU) for pharmacists working in collaboration with physicians to improve patients' outcomes, Using data from the CAPTION study (demonstrated significant improvement in blood pressure control in a multi-state, collaborative practice model over 5 years), components of pharmacists' work was evaluated, taking into account patient complexity, visit intensity, judgment, training and resources needed to complete the encounter. Pharmacists completed an average 6.2 encounters/patient for a total of 3.44 hours/patient, with nearly 8-times as many encounters taking place via telephone compared to face-to-face. This translated to averages of 33 minutes and 28 minutes per initial and follow-up encounters, respectively. Collectively, including pre- and post- visit time, pharmacists spent 4.99 hours/patient/9-months collaborating with their physician partners to increase blood pressure goal achievement in 43% as compared to no increase in goal achievement in the non-pharmacist group.[4]

  Isetts BJ, Buffington DE, Carter BL, Smith M, Polgreen LA, James PA. Evaluation of pharmacists' work in a physician-pharmacist collaborative model for the management of hypertension. Pharmacother 2016;36:374-84. DOI: 10.1002/phar.1727

Section 5: Miscellaneous Areas

Patient Readmission / Transitions of Care

- Transitions of care after discharge from hospitals were examined for 19,659 elderly patients discharged from two hospitals. The standard for these hospitals was for these patients to receive a telephone call from the hospital call center within 24 hours of discharge. Over a 2-year period, a pharmacist-led a care transition program for 692 patients that consisted of bedside medication delivery by pharmacist prior to discharge and two follow-up phone calls from a pharmacist was implemented. Examining the average 30-day readmission rates between the hospital call center and pharmacist led group, there was a 2-fold reduction in the pharmacist led program. A marked contrast in readmission rates occurred in those over 65 years of age where there was a 6-fold difference favoring the pharmacist-led program. Having the pharmacist make the initial and follow-up contacts, as well as provide the medications prior to hospital discharge, lowered 30-day readmission rates.[2]

  Kirkham HS, et al. The effect of a collaborative pharmacist-hospital care transition program on the likelihood of 30-day readmission. Amer J Health-Syst Pharm 2014;71:739-45. DOI: 10.2146/ajhp130457

- This nationwide, randomized study evaluated if pharmacists providing telephonic medication therapy management (MTM) influenced 30- and 60-day re-hospitalization rates among 895 elderly home health patients. In this study, the MTM service consisted of a minimum of 2 phone calls by the pharmacist over a 30-day period. Despite the study's early termination for budgetary issues, those considered at lower risk for re-admission receiving MTM (n= 232) had a 6-fold reduced risk for re-hospitalization at 30-days and a 3-fold risk reduction at 60-days. There was no statistical difference in either the overall groups or in those at high risk for re-hospitalization, suggesting this MTM model design may be best suited for lower risk patients.[2]

  Zillich AJ, et al. A randomized, controlled pragmatic trial of telephonic medication therapy management to reduce hospitalization in home health patients. Health Serv Res 2014; 49:1537-54. DOI: 10.1111/1475-6773.12176

- Pharmacist-provided telephone-based medication assessment and reconciliation services in persons (n = 243) recently discharged from the hospital significantly decreased readmissions at 7 and 14 days compared to those not receiving services via this MTM model (n = 251). The rate of reduction translated to one readmission prevented for every 25 patients undergoing MTM services. This retrospective analysis balanced patient type, diagnoses, and complexity and included a minimal (single episode) engagement by pharmacists. Researchers projected a savings to the health system of $1.5 million annually. Pharmacists identified medication discrepancies in 80% of patients with many having multiple discrepancies. The benefit was not achieved in those with congestive heart failure (CHF), which raises a question of whether CHF patients benefit from a single intervention.[2]

Kilcup M, et al. Post-discharge pharmacist medication reconciliation: impact on readmission rates and financial savings. J Amer Pharm Assoc 2013;53:78-83. DOI:10.1331/JAPhA.2013.11250

- Addressing the critical healthcare needs in transitions of care, a prospective study looking at community pharmacists providing MTM to recently discharged patients with serious cardiopulmonary conditions was conducted. In partnership with 2 regional hospitals, 7 community pharmacists provided 72-hour, 2 week and 30-day follow-up transitions of care sessions performing medication therapy management services tailored for post-discharge patients. Pharmacists reconciled medications, identified drug therapy problems, recommended changes to therapy, and provided self-management education. The population (90 patients) were overwhelmingly elderly (>60 years old) and averaged 6 medical conditions, 10 medications, and had been hospitalized over 4 days. For over 50% of patients, this was at least their second admission in 1-year. A significant decrease in hospital re-admission rates was realized by the pharmacist intervention group (7%) as compared to those who did not have the pharmacist-provided MTM interventions (20%), a clinically as well as statistically significant difference. Physicians accepted pharmacist therapy modification recommendations in 46% of instances and patients implemented the pharmacist recommendations 72% of the time – both likely key factors in program success.[3]

Luder HR, Frede Sm, Kirby JA, Epplen K, Cavanaugh T, Martin-Boone JE, Conrad WF, Kuhlmann D, Heaton PC. TransitionRx: impact of community pharmacy post-discharge medication therapy management on hospital readmission rate. J Amer Pharm Assoc 2015;55:246-54. DOI: 10.1331/JAPhA.2015.14060

- The IPITCH study was an examination of the impact a face-to-face meeting and follow up phone calls by pharmacists would have on hospital readmissions, emergency department visits, medication errors, and adverse drug events for patients recently discharged from the hospital. Over a 6-month period, the researchers found fewer of those patients being provided pharmacists' care had to be readmitted or go to the ER. This was seen across all disease states with the biggest impact on those patients with a cardiovascular condition. This prospective evaluation demonstrates the value of having pharmacists engage with patients at the point of discharge as well as via telephone once the patient is back home.[4]

Phatak A, Prusi R, Ward B, Hansen LO, Williams MV, Vetter E, Chapman N, Postelnick M. Impact of pharmacist intervention in the transitional care of high-risk patients through medication reconciliation, medication education and post-discharge call backs (IPITCH study). J Hospital Medicine 2016;11:39-44. DOI: 10.1002/jhm.2493.

- Recognizing an opportunity to improve care transitions for all persons, pharmacists in the Pharm2Pharm program provided medication management services to geriatric patients transitioning from hospital to home who were identified as high-risk for medication problems. The project design was for the hospital pharmacists to provide patient-selected community pharmacists the medical and medication information. The community pharmacists would then follow up via telephone (primarily) with the patient (a pharmacist 'hand-off') over a one year

period. Over the 2-year study period, with over 2,000 enrolled patients, the program demonstrated a 36.5% reduction in medication-related hospital re-admissions in the hospitals participating in the program compared to hospitals not participating. The authors provided an estimate of over $6.6 million saved annually by this program with an estimated return on investment of 2.6:1.[4]

Pellegrin KL, Krenk L, Oakes SJ, Ciarleglio A, Lynn J, McInnis T, Bairos AW, Gomez L, McCrary MB, Hanlon AL, Miyamura J. Reductions in medication-related hospitalizations in older adults with medication management by hospital and community pharmacists: a quasi-experimental study. J Amer Geriatr Soc 2017;65:212-9. DOI: 10.1111/jgs.14518

Patient Safety/Medication Errors

- In 2006, Congress directed CMS to work with the Institute of Medicine to reduce medication errors, with a special emphasis on Medicare Part D enrollees. Pharmacist-provided MTM reduced medication costs an average of $840 per patient in year 1 and $1,061 per patient in year 2. In terms of preventing unnecessary hospital admission, patients receiving MTM were *admitted to the hospital 60% less often* with a diagnosis of bleeding ulcers (a $5,000 charge per admission) than those patients not receiving MTM. Every year nearly 500,000 patients are admitted to hospitals in the United States for upper GI bleeds due to peptic ulcers. If pharmacist-directed MTM targeting those with peptic ulcers were delivered across the United States, the health care system could save *$995 million annually*.[1]

Pindolia VK, Stebelsky L, Romain TM, Luoma L, Nowak SN, Gillanders F. Mitigation of medication mishaps via medication therapy management. Ann Pharmacother. 2009;43(4):611–20.

Smoking Cessation

- Allowing pharmacist MTM in a VA (change medications and formally educate patients) produced significant improvements in control of cholesterol, blood pressure, and diabetes and more patients successfully stopping smoking.[1]

Taveira TH, Friedmann PD, Cohen LB, et al. Pharmacist-led group medical appointment model in type 2 diabetes. Diabetes Educ. 2010;36(1):109–17.

- A study of military veterans found that a smoking cessation program provided by pharmacists was 2.5 times more successful than customary VA care.[1]

Dent LA, Harris KJ, Noonan CW. Randomized trial assessing the effectiveness of a pharmacist-delivered program for smoking cessation. Ann Pharmacother. 2009;43(2):194–201.

Appendix A

2013 APhA Evidence for Pharmacist Services Expert Panel

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Appendix B

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Appendix C

2015 APhA Evidence for Pharmacists Services Expert Panel

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Appendix D

2016 APhA Evidence for Pharmacists Services Expert Panel

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QUERI

Pharmacist-led Chronic Disease Management: A Systematic Review of Effectiveness and Harms Compared to Usual Care

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VA HEALTH CARE Defining EXCELLENCE in the 21st Century

PREFACE

The VA Evidence-based Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted healthcare topics of particular importance to clinicians, managers, and policymakers as they work to improve the health and healthcare of Veterans. QUERI provides funding for four ESP Centers, and each Center has an active University affiliation. Center Directors are recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Centers. The ESP is governed by a Steering Committee comprised of participants from VHA Policy, Program, and Operations Offices, VISN leadership, field-based investigators, and others as designated appropriate by QUERI/HSR&D.

The ESP Centers generate evidence syntheses on important clinical practice topics. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The ESP disseminates these reports throughout VA and in the published literature; some evidence syntheses have informed the clinical guidelines of large professional organizations.

The ESP Coordinating Center (ESP CC), located in Portland, Oregon, was created in 2009 to expand the capacity of QUERI/HSR&D and is charged with oversight of national ESP program operations, program development and evaluation, and dissemination efforts. The ESP CC establishes standard operating procedures for the production of evidence synthesis reports; facilitates a national topic nomination, prioritization, and selection process; manages the research portfolio of each Center; facilitates editorial review processes; ensures methodological consistency and quality of products; produces “rapid response evidence briefs” at the request of VHA senior leadership; collaborates with HSR&D Center for Information Dissemination and Education Resources (CIDER) to develop a national dissemination strategy for all ESP products; and interfaces with stakeholders to effectively engage the program.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP CC Program Manager, at Nicole.Floyd@va.gov.

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This report is based on research conducted by the Evidence-based Synthesis Program (ESP) Center located at the **Minneapolis VA Medical Center, Minneapolis, MN**, funded by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Quality Enhancement Research Initiative. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (*eg*, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

EXECUTIVE SUMMARY

INTRODUCTION

Increased involvement of clinical pharmacists in patient care may offer increased access to health care and improved patient outcomes. Defined by Hepler and Strand in 1989, pharmaceutical care involves pharmacist collaboration with health team members to optimize therapeutic outcomes by identifying, solving, and preventing actual and potential drug therapy problems. Since 1995, the Department of Veterans Affairs has allowed Clinical Pharmacy Specialists (CPS) an expanded scope of practice with independent prescribing privileges. In this capacity, CPS have been detailed to perform "pharmaceutical care" or comprehensive medication management along with chronic disease state management services, in addition to less complex services such as patient medication counseling or responding to drug information questions. In the VA primary care setting, CPS are likely to be responsible for therapeutic outcomes for a multitude of conditions for any patient referred to CPS or proactively identified by CPS as a high-risk patient.

The purpose of this review is to determine the effectiveness and harms of pharmacist-led chronic disease management for community-dwelling adults. Chronic disease management aims to control symptoms and slow or stop disease progression. Chronic disease management is typically a multi-component intervention that includes medication therapy review, patient medication education, medication monitoring, immunizations, disease self-care and support, and/or prescribing authority.

This topic was nominated by Heather Ourth, PharmD, VACO Pharmacy Benefits Management Program Manager, on behalf of the National Clinical Pharmacy Research Group, chartered by the VACO Clinical Pharmacy Practice Office of VACO Pharmacy Benefits Management (PBM). We address the following key question developed with input from the topic nominator and a technical expert panel (TEP).

Key Question: What are the effectiveness and harms of pharmacist-led chronic disease management compared to usual care?

Population: Adults (age 18 or older)
Interventions: Chronic disease management; pharmacist takes responsibility for some component of the management or prevention of one or more chronic diseases (*eg*, chronic obstructive pulmonary disease [COPD], congestive heart failure [CHF], diabetes, hypertension, cancer, chronic kidney disease [CKD], pain, depression) (*ie*, pharmacist-led care)
Comparator: Usual care without the services provided by the pharmacists to the intervention group
Outcomes:

- *Clinical Outcomes (including intermediate clinical measures):* disease-specific clinical events (*ie,* severe hypoglycemia or hypotension requiring additional interventions), depression, mortality, health related quality of life, patient satisfaction, disease specific intermediate goal attainment such as glycated hemoglobin [HbA1c], blood pressure, and lipid levels
- *Resource Use*: office visits, urgent care or emergency room visits, hospitalizations, access to care, and costs

• *Medications:* appropriate medications and dosages, drug interactions, (non)adherence, other
Timing: No minimum follow-up required
Setting: Interventions that take place within the United States and are provided to outpatients by pharmacists based in healthcare facilities

METHODS

Data Sources and Searches

We searched MEDLINE (Ovid), CINAHL, the Cochrane Library, and the International Pharmaceutical Abstracts (IPA) database for articles published from 1995 through June 2015. We obtained additional articles by hand-searching the reference lists of systematic reviews and included studies and we also received reference suggestions from peer reviewers.

Study Selection

Abstracts from MEDLINE were independently reviewed in duplicate by investigators and research associates. All other abstracts were reviewed by a single co-investigator or research associate. We included studies of any design that reported on the effectiveness or harms of pharmacist-led chronic disease management in adult outpatients with, or at risk for, a chronic disease. We excluded studies that did not test an intervention that was pharmacist-led (*ie*, where the pharmacist was responsible for a component of patient care), studies without a comparator, studies that did not take place in a healthcare facility in the US (*eg,* studies set in retail pharmacies), and studies of anticoagulation clinics because pharmacist management is considered standard care.

Full-text reports of studies identified as potentially eligible based on abstract review were obtained for further review. Each article was independently reviewed by 2 investigators or research associates.

Data Abstraction and Risk of Bias Assessment

Study characteristics (target population, inclusion/exclusion criteria, intervention goal, follow-up duration, primary outcomes, pharmacist type, setting, and intervention and comparator descriptions) and outcomes (primary and secondary outcomes reported in the studies and broadly categorized as clinical, resource use, and medications) were extracted into evidence tables by one investigator or research associate and verified by another. We assessed the risk of bias based on the following criteria: allocation of subjects to comparison groups, allocation concealment, risk of bias from confounding (for non-randomized studies), blinding, completeness of outcome reports including losses to follow-up, and selective outcome reporting – a modification of the Cochrane approach to determining risk of bias.

Data Synthesis and Analysis

We organized evidence tables by disease state of the study population. We described and qualitatively summarized the characteristics and findings of included studies. Outcomes data were pooled where possible. However, pooled analyses were not appropriate for many outcomes due to heterogeneity of interventions and outcome reporting.

We rated the overall strength of the body of evidence across chronic disease conditions for disease-specific clinical events, patient satisfaction, target goal attainment, urgent care/emergency department visits and hospitalizations, and medication adherence using the method reported by Owens et al.

RESULTS

Results of Literature Search

We reviewed 1,342 abstracts, 504 from MEDLINE and the remaining from additional databases. We excluded 1,151 abstracts and reviewed the full text of 191 articles. During full-text review we excluded 134 articles leaving 57 eligible for inclusion. Hand-searching reference lists of pertinent trials and systematic reviews and peer reviewer suggestions identified an additional 13 references.

We included 70 papers representing 62 studies with 64 unique study populations (k) in cardiovascular diseases (k=6), chronic kidney disease (k=4), chronic obstructive pulmonary disease (k=1), depression (k=4), diabetes mellitus (k=24), dyslipidemia (k=7), hypertension (k=15), and polypharmacy/high risk (k=3). An overview of study characteristics is presented in Executive Summary Table 1.

Summary of Results

Overall findings: (Executive Summary Tables 1-3)

- Most studied interventions included pharmacist-led medication monitoring, medication therapy review, prescribing authority, and/or disease self-care and support.
- Interventions were typically delivered by pharmacists in-person and over multiple times. However, interventions varied in composition, delivery mode, and intensity, making it difficult to draw conclusions about important intervention characteristics.
- Studies were generally short-term and designed to assess intermediate outcomes such as blood pressure, cholesterol, and/or glucose goal attainment in patients with diabetes, hypertension, or cardiovascular disease rather than other clinical or resource use outcomes.
- Many of the outcomes reported in this review were not primary study endpoints supported by rigorous research methods or statistical inferences. Findings based on analyses of outcomes other than the study-defined primary outcomes should be interpreted with caution.
- Most trials reporting disease-specific clinical events found pharmacist-led care and usual care to be similar. However, only 3 of the included studies were designed to assess clinical events, outcomes were sporadically and inconsistently reported, and there were few events (low strength of evidence). Eight studies reported mortality with all finding similar mortality in the pharmacist-led care and control groups.
- Compared to usual care, pharmacist-led care was associated with similar incidences or rates of office, urgent care or emergency department visits, and hospitalizations (moderate strength of evidence) and medication adherence (low strength of evidence).

- There was insufficient evidence to evaluate the effect of pharmacist-led care on patient satisfaction. There was limited reporting of quality of life outcomes.
- No studies reported typical measures of access to care (*eg,* wait time for appointment or percentage of appointments within a specified window of a desired appointment time). Four studies reported either patient satisfaction with reaching someone in an emergency or availability of advice about health condition (both significantly higher in the intervention group) or patient perceptions of communication with the care team and problems getting care (intervention and control groups similar).
- There was limited reporting of harms or other drug-related problems (defined for this review as inappropriate medication or dosage and drug interactions). Studies that reported harms often did not provide data for the control group participants.
- Reported cost outcomes included total costs, medication costs, cost savings per patient, and program costs, but few studies found significant differences between intervention and control groups.
- Patients in the pharmacist-led care groups generally received a greater number or dose of medications although it was difficult to evaluate whether increased number or dose of medications was an indicator of better care quality.
- Compared to usual care, pharmacist-led care improved study-selected glycemic, blood pressure, and lipid goal attainment (moderate strength of evidence).

Executive Summary Table 1. Summary of Included Studies

Characteristic	(Risk of) Cardio-vascular Disease	Chronic Kidney Disease	Chronic Obstructive Pulmonary Disease	Depression	Diabetes Mellitus	Dyslipidemia	Hypertension	Polypharmacy/ High Risk	Total
Total									
Studies	6	4	1	4	24	7	15	3	**64[a]**
Total Patients	3,403	2,920	98	926	17,716	1,834	6,278	1,282	**34,457**
Design									
RCT	4	2	1	3	12	2	13	3	**40**
Other	2	2	0	1	12	5	2	0	**24**
Setting									
VA	1	2	1	0	4	4	4	1	**17**
Non-VA	5	2	0	4	20	3	11	2	**47**
Intervention									
Medication Monitoring	6	4	1	3	22	6	14	2	**58**
Medication Therapy Review	2	2	0	3	13	3	10	2	**35**
Patient Medication Education	2	0	0	3	9	3	4	2	**23**
Prescribing Authority	3	2	0	3	12	5	7	1	**33**
Disease Self-care and Support	4	2	1	4	22	3	14	2	**52**
Immunizations	0	0	0	0	2	0	0	0	**2**
Delivery Mode									
Remote	1	0	0	1	2	2	1	0	**7**
In-Person	4	3	0	0	14	4	8	2	**35**
Mixed	1	1	1	3	8	1	6	1	**22**
Intervention Frequency									
One-time	2	0	0	0	4	1	0	0	**7**
Multiple	4	4	1	4	20	6	15	3	**57**
Risk of Bias									
Low	1	1	0	1	5	0	2	1	**11**
Medium	3	3	1	2	15	3	12	2	**41**
High	2	0	0	1	4	4	1	0	**12**

RCT = randomized controlled trial; VA = Veterans Affairs

[a] 2 studies reported separate results for 2 different disease conditions

Executive Summary Table 2. Number of Studies Reporting Each Outcome (and Study-Defined Primary Outcome)[a]

Condition (number of included studies)	Clinical						Resource Use					Medication					
	Clinical Events	Depression	All-Cause Mortality	Health-Related Quality of Life	Patient Satisfaction	Goal Attainment	Office Visits	Urgent Care/Emergency Room Visits	Hospitalizations	Access to Care[b]	Costs	Inappropriate Dosage/ Prescription	Ineffectiveness	Drug Interactions	(Non)-adherence	Number/Dose of Appropriate Medications	Other
Cardiovascular Diseases (k=6)	2		2 (1)	1	1	3 (2)	2	3 (1)	5 (1)		2	1			3 (1)	3	
Chronic Kidney Disease (k=4)	2		2	1	1	3 (1)			1		3	1			1	4	
Chronic Obstructive Pulmonary Disease (k=1)				1	1		1 (1)	1 (1)	1 (1)			1		1		1	
Depression (k=4)		2 (2)		3	4 (1)		3 (1)	2		2	1				3 (2)	3 (1)	
Diabetes (k=24)	4		3	3	3	16 (10)	6	8 (1)	8 (1)	1	3	1			4	15	4
Dyslipidemia (k=7)						7 (3)	4	1			2				1	6	
Hypertension (k=15)	6		1	7 (2)	7 (1)	13 (8)	9	3	4	1	4 (1)	2		1	11 (1)	13	
Polypharmacy/ High-risk (k=3)	1			2 (2)	2 (1)	2 (1)	1	1 (1)	2 (1)		2	1 (1)	1	1	2 (2)	3	
TOTAL (64 unique study populations)[c]	**15**	**2 (2)**	**8 (1)**	**18 (4)**	**19 (3)**	**44 (25)**	**26 (2)**	**19 (4)**	**21 (4)**	**4**	**17 (1)**	**7 (1)**	**1**	**3**	**25 (6)**	**48 (1)**	**4**

[a] some studies didn't have one of our outcomes as their primary outcome and some had more than one primary outcome; table entries are number of studies reporting that outcome as their primary outcome

[b] access to care assessed as patient satisfaction (reaching someone in an emergency, availability of advice) or patient perceptions (communication with the care team and problems getting care)

[c] 2 studies reported separate results for 2 different disease conditions

Executive Summary Table 3. Strength of Evidence[a]

Outcome	Strength of Evidence	Direction	Number of RCTs (N)	Summary
Disease-specific clinical events[b]	Low	Similar	12 (3,355)	Most trials found similar outcomes between pharmacist-led care and usual care. Outcomes were sporadically and inconsistently reported and there were few events. Overall risk of bias was moderate.
Patient satisfaction	Insufficient	Mixed	16 (12,793)	Results were inconsistent for measures of patient satisfaction between pharmacist-led care and usual care. There was variation in how patient satisfaction was reported (scale score or proportions), some measures may not be validated, and some trials used a single item from a multi-item scale. Overall risk of bias was moderate. Given these limitations, conclusions regarding the strength of evidence for patient satisfaction cannot be determined.
Urgent care/ER and hospitalizations	Moderate	Similar	Urgent care/ER 16 (7,166) Hospitalizations 12 (7,455)	Incidence or rates of urgent care/ER visits or hospitalizations were similar between pharmacist-led care and usual care. Overall risk of bias was moderate.
Non-adherence to medications	Low	Similar	17 (5,933)	In most trials medication non-adherence was similar between pharmacist-led care and usual care. Overall risk of bias was moderate. Pooled results from 7 (n=1479) demonstrated a substantial relative reduction but findings were imprecise, not significant, and had substantial heterogeneity (RR 0.58 [95% CI 0.33, 1.01]; I^2 = 82%).
Goal attainment	Moderate	Improved in pharmacist-led care groups	19 (5,816)	Pharmacist-led care improved the proportion of patients achieving guideline- recommended laboratory or physiologic treatment goals versus usual care, 51% vs 34% (RR 1.56 [95% CI 1.37, 1.78]; I^2 = 48%). Results were precise and fairly consistent. Cluster RCTs, CCTs, and cohort studies not included in the pooled analysis generally reported improved goal attainment in the pharmacist-led care group. Overall risk of bias was moderate.

[a] Strength of evidence determined for specific outcomes across all chronic disease conditions
[b] *ie,* severe hypoglycemia or hypotension requiring additional interventions

Condition-specific Findings

Cardiovascular Disease or Risk Factors (4 RCTs, 2 Cohort Studies)

- Pharmacist-led care
  - resulted in mortality and rates of disease-specific clinical events that were similar to usual care; only one study reported a clinical event as a primary outcome,
  - was associated with mixed results for maintenance or attainment of HbA1c and blood pressure goals compared to usual care,
  - resulted in hospitalization rates that were similar to usual care; there were mixed results for office visits, urgent care visits, and costs; only one study reported resource use as a primary outcome, and
  - was associated with mixed results for medication use and adherence as compared to usual care.
- No studies reported on access to care, or drug interactions or other drug-related problems.

Chronic Kidney Disease (2 RCTs, 2 Cohort Studies)

- Pharmacist-led care
  - improved kidney disease-related quality of life at one year but not 2 years among patients at a university-affiliated dialysis center but resulted in similar quality of life for Veterans with CKD in primary care.
  - lowered medication use in the intervention group in the dialysis study,
  - increased use of anti-hypertensive medications in the VA study with intervention and control groups similar on blood pressure goal attainment,
  - resulted in similar all-cause mortality between groups in both studies, and
  - to manage anemia due to CKD was associated with a lower weekly dose of EPO (k=1), more medication adjustments if hemoglobin levels were low (but not high) (k=1), cost savings (k=2), and better attainment of target hemoglobin (k=2) and iron saturation values (k=1) versus usual care; intervention and control sites reported similar rates of adverse events (k=1).
- No studies reported on office or emergency department visits, access to care, or drug interactions or other drug-related problems.

Chronic Obstructive Pulmonary Disease (1 RCT)

- Multifaceted pharmacist-led care from 8 VA Medical centers
  - resulted in health-related quality of life, number of new medications, number of emergency department visits, and a rate of hospitalization that were similar to usual care,
  - decreased office visits, and
  - resulted in mixed findings for patient satisfaction (*ie,* significant differences on some subscales).
- Effects on drug-related problems were reported only for the intervention group.
- All-cause mortality, disease-specific clinical events, access to care, and costs were not reported.

Depression (3 RCTs, 1 non-RCT)

- Pharmacist-led care
  - was similar to usual care for depressive symptoms and health-related quality of life,
  - was similar to usual care for medication adherence (2 RCTs reporting); self-reported use of antidepressant medications and changes in antidepressant medications were more frequent in the pharmacist-led care groups,
  - resulted in numbers/rates of primary care or urgent care visits that were similar to usual care, and
  - increased patient satisfaction with availability of advice.
- All-cause mortality, hospitalizations, costs, inappropriate prescriptions, drug interactions and other drug-related problems and harms were not compared.

Diabetes (12 RCTs, 2 CCTs, 10 Cohort Studies)

- Pharmacist-led care
  - resulted in all-cause mortality, disease-specific clinical events, and health-related quality of life that was similar to usual care, although few studies reported these outcomes,
  - improved rates of goal attainment for HbA1c, blood pressure, and lipids; the 3 studies in VA settings reported increased attainment of HbA1c and blood pressure goals in patients receiving pharmacist-led care,
  - resulted in significantly higher numbers and/or doses of medications, and
  - resulted in resource use (office visits, urgent care or emergency department visits, and hospitalizations) that was similar to usual care.
- One study reported access to care favoring the intervention group; no studies reported drug interactions or other drug-related problems.

Dyslipidemia (2 RCTs, 2 CCTs, 3 Cohort Studies)

- Pharmacist-led care
  - improved goal attainment (typically LDL < 100 mg/dL) compared to usual care although pooled results from 2 RCTs showed groups were similar,
  - was associated with increased medication use; one study reported adherence in the intervention group but not the usual care group, and
  - led to mixed results for office visits and similar results for urgent care or emergency department visits and costs as usual care.
- No studies reported other clinical outcomes (*ie,* mortality, disease-specific clinical events, health-related quality of life, and patient satisfaction), hospitalizations, access to care, inappropriate prescriptions, or drug interactions or other drug-related problems.

Hypertension (13 RCTs, 1 CCT, 1 Case-Control Study)

- Pharmacist-led care
  - resulted in similar health-related quality of life as usual care; patient satisfaction results were mixed and few studies reported other clinical outcomes,
  - increased medication use but adherence was similar to usual care,

  - led to mixed results for resource use outcomes including office visits and costs; few studies reported urgent care or emergency room visits, and
  - resulted in patient perceptions similar to usual care for "had problems getting needed care."
- No studies reported drug interactions or other drug-related problems; one study reported inappropriate medications for the intervention group but not the control group.

Polypharmacy/High Risk for Drug-related Problems (3 RCTs)

- Pharmacist-led care
  - resulted in health-related quality of life; patient satisfaction, and rates/numbers of disease-specific clinical events that were similar to usual care; goal attainment was improved,
  - resulted in similar medication use as usual care; results were mixed for medication adherence; significance of other medication findings could not be determined, and
  - increased the number of office visits compared to usual care but decreased use of urgent care facilities; results were mixed for hospitalizations and costs.
- No studies reported all-cause mortality or access to care.

DISCUSSION

Summary of Findings and Strength of Evidence

We rated strength of evidence for disease-specific clinical events (low strength of evidence that pharmacist-led care and usual care were similar), patient satisfaction (insufficient evidence), urgent care/emergency department visits and hospitalizations (moderate strength of evidence that pharmacist-led care and usual care were similar), non-adherence to medications (low strength of evidence that pharmacist-led care and usual care were similar), and goal attainment (moderate strength of evidence that pharmacist-led care increased the proportion of patients achieving glycemic, blood pressure, and cholesterol goals compared to usual care). While we did not formally assess strength of evidence on other outcomes we did find that pharmacist-led care was also similar to usual care for depression, health-related quality of life, all-cause mortality, and cost outcomes. However, due to differences in costs reported across studies (program costs, medication costs, visit costs), it is difficult to reach a conclusion about costs. Very few studies reported drug-related problems (inappropriate medication or dosage, drug interactions). Patients in the pharmacist-led care groups generally received a greater number or dose of medications although it was difficult to evaluate whether increased number or dose of medications was an indicator of better care quality.

Applicability

The chronic disease conditions addressed in the included studies (cardiovascular disease, chronic kidney disease, COPD, depression, diabetes mellitus, and hypertension) are common among Veterans. Seventeen studies were conducted in VA facilities. The model of pharmacist-led care reported in these studies varied but likely is similar to ongoing programs in VA.

Limitations/Research Gaps/Future Research

Many of the outcomes reported in this review were not the study-defined primary endpoints and therefore were not supported by rigorous research methods or statistical inferences. Among studies included in our review, sample sizes were too small and follow-up periods too short to detect differences in mortality. There was limited reporting of other clinical events, health-related quality of life, and patient satisfaction. When assessed, authors used varied methods for determining health-related quality of life and patient satisfaction. Scale scores were often not validated, of unknown clinical importance, or included selected findings from subscales. Interventions varied in composition, delivery mode, and intensity as did the usual care comparator, making it difficult to draw conclusions about important intervention characteristics.

One hypothetical benefit of pharmacist-led care for chronic diseases is increased access to care for patients. None of the included studies reported typical measures of access and only 4 studies (2 in patients with depression and one each in patients with hypertension or diabetes) reported patient satisfaction or patient perception measures related to access (*eg,* satisfaction with ability to reach someone in an emergency or satisfaction with availability of advice). Intervention-based increases in the number of scheduled visits or telephone calls may not represent improved access. Further research is needed with conventional measures of access.

A consistent definition of an office visits outcome is needed to distinguish regularly scheduled office visits, study-related office visits, and unplanned office visits. In many cases it was unclear whether the visit was with a pharmacist or primary care provider. Also, a consistently reported cost outcome that includes all of the important economic factors involved in pharmacist-led care would facilitate comparisons across studies and provide more accurate cost-effectiveness estimates.

There was limited reporting of important drug-related problems, in particular drug interactions and inappropriate medications and/or dosages. Some studies did report on adherence with mixed, inconclusive results. Despite existing definitions of polypharmacy, an isolated measure of the number of medications is not an indicator of quality of care as there are situations where adding medications and/or increasing dosages may be helpful. Similarly, de-prescribing medications that emerging evidence suggests are not beneficial and may provide harm may also be helpful. Further research is needed to define and describe these interventions and their association with patient outcomes and value.

Finally, the demonstrated improvement in laboratory and physiologic goal attainment due to pharmacist-led care is potentially encouraging. Intervention group pharmacists successfully achieved the intended study objectives. The target goals were based, in part, on recommendations from selected existing clinical practice guidelines and performance measures. The results indicate that future pharmacist-led programs are likely to achieve intended goals. However, there is conflicting evidence that target goals for glycemic, blood pressure, or cholesterol control have long-term beneficial effects on patient outcomes including clinical events, satisfaction, access, hospitalizations, and costs. Therefore, future research needs to carefully assess whether the magnitude of effect on selected intermediate laboratory and physiologic goals translate to improved patient outcomes including clinical events, satisfaction, access, hospitalizations, and costs. Few studies reported differences in potential harms. Thus the available evidence does not answer the question about whether the benefits of pharmacy-led

interventions justify potential harms and costs. Ideally, future studies will be designed to fully and accurately address final patient outcomes and cost effectiveness.

Conclusions

Evidence is limited on the effectiveness and harms of pharmacist-led chronic disease management compared to usual care for clinical outcomes (*ie,* clinical events, all-cause mortality, patient satisfaction, quality of life, and resource utilization). Moderate-strength evidence indicates that pharmacist-led chronic disease management increases goal attainment for HbA1c, blood pressure, and cholesterol levels. Moderate- or low-strength evidence also indicates that pharmacist-led chronic disease management and usual care were similar for urgent care visits or hospitalizations, clinical events, and adherence to medications. Evidence was insufficient for patient satisfaction. There was little reporting of access to care and drug-related problems. These results suggest that future programs are likely to achieve intended laboratory and physiologic goals. However, to accurately assess health care value, future research studies and implementation projects that utilize intermediate laboratory and physiologic goals as measures of effectiveness need to be certain that these goals are clearly linked to improved patient outcomes including clinical events, satisfaction, access, hospitalizations, costs, medication adherence, and drug-related problems without undue harms and costs.

ABBREVIATIONS TABLE

BP	Blood pressure
CCT	Controlled clinical trial (non-randomized)
CPS	Clinical Pharmacy Specialist
HbA1c	Hemoglobin A1c
HTN	Hypertension
HDL, HDL-C	High density lipoprotein cholesterol
LDL, LDL-C	Low density lipoprotein cholesterol
MTM	Medication Therapy Management
PharmD	Doctor of Pharmacy
RCT	Randomized controlled clinical trial
RR	Risk ratio
VA	Veterans Affairs

May 21, 2014 | Insights & Analysis

Exploring Pharmacists' Role in a Changing Healthcare Environment

Summary

More and more, pharmacists are forging expanded roles in healthcare delivery to ensure optimal drug therapy and improve patient outcomes.

Pharmacists' focused training in drug therapy positions them well for unique contributions to the management of patient health, especially within evolving payment and delivery models that explicitly focus on quality and efficiency.

A new analysis by Avalere Health set out to investigate the ways that pharmacist services are improving care, and how these services are aligned with the changing healthcare environment. With support from several pharmacist associations and organizations*, Avalere conducted a structured assessment of current evidence on the effects of five key pharmacist services and modalities: medication management; medication reconciliation; preventive services (screening and immunization); education and behavioral counseling; and collaborative care models. The analysis uncovered several key findings:

The body of literature continues to validate that pharmacist-provided **medication management** can improve health outcomes, both across a number of settings and high-spend therapeutic areas such as diabetes, cardiovascular disease, and hypertension. Because they manage the entirety of care for a patient, accountable care organizations (ACOs) may look to integrate pharmacist-provided medication management to improve medication adherence and clinical outcomes, while potentially reducing costs.

Pharmacist-provided **medication reconciliation** can help reduce medication discrepancies and

may be an important component of improving transitions of care moving forward. Additionally, some studies suggest that through this focus on medication, pharmacists can reduce healthcare utilization and costs.

Beyond the management of medications, pharmacists have been shown to improve vaccination rates. Payers and policymakers should explore ways to leverage pharmacists' accessibility in the community to provide **preventive care services** (immunization and screening), especially within alternative payment and delivery models such as ACOs and patient-centered medical homes (PCMHs).

Pharmacist-provided **educational and behavioral counseling** can contribute to better outcomes in chronically ill patients, and also can support broader health and wellness in the population.

Formal **collaborative care models** between pharmacists and physicians establish clear channels for pharmacists to deliver the services above with positive clinical effects. Moving forward, collaborative care models that include a pharmacist can help alleviate some of the demand for physician-provided care, and also can facilitate access to primary care services, especially those related to medication management.

As new payment and delivery models such as ACOs and PCMHs proliferate, new roles exist for pharmacists to contribute to the improvement of quality and the reduction of costs and other healthcare services. Further research evaluating pharmacist services will help define the optimal role for pharmacists as the healthcare landscape evolves.

Find the complete white paper attached.

For more information on this research, please contact Morgan Hanger at mhanger@avalere.com. For more information on how Avalere can help support your provider group, please contact Fauzea Hussein at fhussein@avalere.com.

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The Expanding Role of Pharmacists in a Transformed Health Care System

Executive Summary

Pharmacists practice in a variety of health care settings. Although they are most often associated with dispensing medications in retail pharmacies, their role is evolving to include providing direct care to patients as members of integrated health care provider teams.[1]

The critical role that medication management plays in treating chronic diseases suggests that the integration of pharmacists into chronic-care delivery teams has the potential to improve health outcomes. Studies of pharmacists providing medication therapy management (MTM) services to improve therapeutic outcomes indicate that such services can improve outcomes and reduce costs. Pharmacists typically provide those services in interdisciplinary teams through collaborative practice agreements (CPAs). Such agreements with other health care providers allow a licensed provider to refer patients to a pharmacist and delegate the delivery of clinical services under supervision. Several key challenges and barriers, however, prevent the full integration of pharmacists into health care delivery teams: restrictive laws and regulations governing CPAs, lack of provider recognition in federal and state law governing compensation of pharmacists who provide direct patient-care services, and limitations on pharmacists' ability to access health information systems.

States seeking to integrate pharmacists more fully into the health care delivery system can examine state laws and regulations governing the profession to address the challenges to pharmacists practicing to the full scope of their professional training.

Introduction

The health care system is undergoing a significant transformation in both the finance and delivery of health care services. States, in particular, are examining their health care systems to define policies that create efficient models of care focused on improved quality and health outcomes as well as reduced costs. Integrating pharmacists, who represent the third-largest health profession, into such systems is important for achieving intended goals.[2] Pharmacists have the professional expertise to address key challenges facing the health care system, including the prevalence of people who have multiple chronic conditions and the increased use of more complex medications to manage those diseases.

Pharmacists' Clinical Training and Expertise

Pharmacists undergo rigorous education focused on the composition, interaction, and use of medications. Pre-pharmacy students must complete at least two years of college to be eligible to enter pharmacy school, though most obtain a bachelor's degree. To apply to most graduate pharmacy programs, pre-pharmacy students are required to take the Pharmacy College Admissions Test, which measures general and pharmacy-specific academic knowledge.[3]

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[1] According to the U.S. Bureau of Labor Statistics, in 2012, 43 percent of pharmacists were employed in pharmacies and drug stores, 23 percent in hospitals (state, local, and private), 8 percent in grocery stores, and 10 percent in other retail locations (see http://www.bls.gov/ooh/healthcare/pharmacists.htm#tab-3). This paper does not address questions related to compounding pharmacies that create and mix drugs customized to specific patient needs based on a prescription written by a physician or compounding pharmacies that distribute a high volume of compounded drugs without prescription.

[2] American Association of Colleges of Pharmacy, http://www.aacp.org/ABOUT/Pages/default.aspx.

[3] Pharmacy College Admission Test, "About the PCAT: Information," http://www.pcatweb.info/About-the-PCAT.php (accessed November 20, 2013).

The level of education required to practice as a pharmacist has risen significantly over the past few decades, shifting from a bachelor of science (B.S.) degree to a doctor of pharmacy (PharmD) degree. Since 2004, the Accreditation Council on Pharmacy Education has required that students attending schools of pharmacy obtain a PharmD. Despite the escalating educational requirements, most pharmacists practicing today have a B.S. degree.[4]

All accredited colleges of pharmacy include the following core competencies in their curriculum: biomedicine; pharmaceutical sciences; social, behavioral, and administrative sciences; and clinical sciences.[5] Specific coursework varies based on the institution and can include toxicology, pathophysiology, pharmaceutical chemistry, pharmacology, *disease treatments,* and laboratory training.[6] PharmD programs also incorporate clinical training in their curricula through externships, which provide students practical experience in pharmacy settings under the supervision of licensed pharmacists.[7]

To become licensed, every state requires prospective pharmacists to pass the North American Pharmacist Licensure Examination upon completion of a PharmD program. Most states also require a separate exam (typically the Multistate Pharmacy Jurisprudence Examination) to test the pharmacy jurisprudence knowledge defined within the individual state's statutes and regulations.[8] Once licensed, pharmacists can voluntarily obtain certification in a specialty practice area by demonstrating field experience and passing an examination administered by one of several credentialing boards. For example, the Board of Pharmaceutical Specialties certifies pharmacists in six specialties: nutrition support pharmacy, nuclear pharmacy, pharmacotherapy, oncology pharmacy, psychiatric pharmacy, and ambulatory care.[9]

The U.S. Bureau of Labor Statistics indicates that about 286,000 pharmacists were employed in 2012 and projects that number to increase by 14 percent, to more than 325,000, by 2022. Currently, about 60 percent of pharmacists are employed in retail establishments—health and personal care stores, grocery stores, general merchandise stores, and department stores.[10] Undergraduate students continue to demonstrate strong interest in the profession, and enrollment rates in pharmacy programs have risen for 13 consecutive years.[11]

Current Scope of Practice

Pharmacists' scope of practice consists of a legal component set by state laws and board regulations and guidelines set by employers or administrators for specific practice settings. In the early 1990s, an examination of pharmacists' scope of practice identified four primary domains in which pharmacists were permitted to provide care: ensuring appropriate

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[4] The percentage of pharmacists practicing with a B.S. degree has decreased from 74 percent in 2000 to 66 percent in 2009. Midwest Pharmacy Workforce Research Consortium, "Final Report of the 2009 National Pharmacist Workforce Survey," http://www.aacp.org/resources/research/pharmacyworkforcecenter/Documents/2009 National Pharmacist Workforce Survey - FINAL REPORT.pdf (accessed November 1, 2013).

[5] Melissa S. Medina et al., "Center for the Advancement of Pharmacy Education 2013 Educational Outcomes," *American Journal of Pharmaceutical Education* 77 no. 8 (October 2013): 162, doi:10.5688/ajpe778162; and National Association of Boards of Pharmacy, "PCOA Programs," http://www.nabp.net/programs/assessment/pcoa (accessed October 7, 2013).

[6] "Pharmacist: Educational Requirements and Career Summary," Education Portal, http://education-portal.com/articles/Pharmacist_Educational_Requirements_and_Career_Summary.html (accessed September 15, 2014).

[7] Ibid.

[8] "Programs FAQ," National Association of Boards of Pharmacy, http://www.nabp.net/programs/examination/naplex/faqs#3 (accessed November 1, 2013).

[9] "Board of Pharmacy Specialties: Certification: Certification in the Real World," Board of Pharmacy Specialties, http://bpsweb.org/certification/real.cfm (accessed November 20, 2013).

[10] U.S. Department of Labor, Bureau of Labor Statistics, *Occupational Outlook Handbook, 2014–15 Edition*, "Pharmacists," http://www.bls.gov/ooh/healthcare/pharmacists.htm (accessed September 18, 2014).

[11] "Academic Pharmacy's Vital Statistics," American Association of Colleges of Pharmacy, http://www.aacp.org/about/Pages/Vitalstats.aspx (accessed November 2, 2013).

medication therapy and outcomes, dispensing medications and devices, engaging in health promotion and disease prevention, and engaging in health systems management.[12]

In 2004, the Joint Commission of Pharmacy Practitioners began a strategic effort to standardize pharmacists' delivery of care and suggest alternatives for service reimbursement.[13] That effort focused on creating more consistency in pharmacists' delivery of care and promoting quality outcomes for patients, regardless of the type of service provided or the care setting. The Joint Commission expects to agree on a standardized process in 2015.

Alternative Approach Through Advanced Practice Designations

California, **Montana**, **New Mexico**, and **North Carolina** have created the advanced practice pharmacy (APP) designation to expand pharmacists' scope of practice through CPAs. That designation allows pharmacists to provide direct patient care, including primary care. The characteristics of an APP, however, including educational requirements, provider status, service offerings, prescribing authority, and compensation, vary across those states.[14]

For example, in California, a pharmacist seeking recognition as an APP is required to meet two of the following three criteria: certification in a relevant area of practice, a postgraduate residency program, or one year of experience providing clinical services to patients under a CPA or protocol with another practitioner.[15] A California law passed on October 1, 2013, authorizes APP pharmacists to perform a series of expanded functions:[16]

- Prescribing nicotine-replacement products that support tobacco cessation if the pharmacist has completed related training and follows specified procedures;
- Initiating and administering immunizations for people three years of age and older;
- Initiating and furnishing hormonal contraception; and
- Ordering and interpreting tests to monitor drug safety.

The law also grants pharmacists provider status but does not expressly authorize Medicaid reimbursement for professional APP services.[17]

New Mexico's Pharmacist Prescriptive Authority Act, enacted in 1993, recognized pharmacists as midlevel practitioners who can manage primary care patients independently in written collaboration with a physician. Under that designation, pharmacists are allowed to prescribe and dispense medications in accordance with state law.

In North Carolina, the Clinical Pharmacist Practitioner (CPP) Act became effective July 1, 2000. CPPs must meet specific qualifications and receive approval by

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[12] Nicole Paolini Albanese and Michael J. Rouse, *Scope of Contemporary Pharmacy Practice: Roles, Responsibilities, and Functions of Pharmacists and Pharmacy Technicians* (Washington, DC: Council on Credentialing in Pharmacy, February 2009), http://pharmacycredentialing.org/Contemporary_Pharmacy_Practice.pdf (accessed November 3, 2013).

[13] Joint Commission of Pharmacy Practitioners, "Future Vision of Pharmacy Practice," 2004, http://www.aacp.org/resources/education/cape/Documents/Other%20Pharmacy%20Association%20Related%20Documents/JCPP%20Vision%20for%20Pharmacy%20Practice%202004%20and%202008.pdf (accessed February 1, 2014).

[14] Scott Giberson, Sherri Yoder, and Michael Lee, *Improving Patient and Health Systems Outcomes Through Advanced Pharmacy Practice: A Report to the US Surgeon General (Office of the Chief Pharmacist, US Public Health Service),* http://www.usphs.gov/corpslinks/pharmacy/documents/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf (accessed September 15, 2014).

[15] California Senate Committee on Business, Professions, and Economic Development, *Pharmacy Practice: Hearing on S.B. 493,* April 22, 2013, http://www.leginfo.ca.gov/pub/13-14/bill/sen/sb_0451-0500/sb_493_cfa_20130418_144405_sen_comm.html (accessed September 15, 2014).

[16] Ibid.

[17] Ibid.

both the medical and pharmacy boards.[18] The law authorizes the CPP to implement predetermined drug therapies as outlined by a drug therapy management agreement. Those therapies include diagnosis and product selection by the patient's physician; modification of prescribed drug dosages, dosage forms, and dosage schedules by the CPP; and the CPP being allowed to order laboratory tests. A drug therapy management agreement is specific to an individual patient, physician, pharmacist, and disease.[19]

Despite formal laws recognizing APPs, the inability to bill and receive adequate reimbursement for their services continue to create barriers to wider adoption of APPs throughout the health care delivery system.

The Evolving Role of Pharmacists: Integration into Chronic Care Delivery Teams

Health care experts increasingly agree that including pharmacists on chronic care delivery teams can improve care and reduce the costs of treating chronic illnesses.[20] The prevalence of adults who have multiple chronic diseases, such as heart disease, stroke, cancer, arthritis, hepatitis, and asthma, is increasing in the United States, and almost half of U.S. adults—approximately 117 million people—have at least one chronic disease.[21] Most people living with more than one chronic disease take multiple medications to manage their conditions and related co-morbidities but commonly receive uncoordinated and fragmented care with little follow-up.[22] From 1999 to 2008, the percentage of Americans who used two or more prescription drugs increased from 25 percent to 31 percent, and the number of patients using five or more drugs increased from 6 percent to 11 percent.[23] In fact, the average number of prescriptions per capita provided to Americans has increased, from 10.1 in 1999 to 12.6 in 2009.[24] As the number of medications rises, many patients have trouble adhering to medication regimens.[25] The rate of unfilled prescriptions and prescriptions that patients fill but fail to pick up also has trended upwards.[26] The consequences of low or nonadherence to medication therapy can be serious, including medical complications, increased health care costs, and even death.[27]

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[18] An Act Authorizing the North Carolina Medical Board and the Board of Pharmacy to Adopt Rules to Approve Clinical Pharmacist Practitioners to Practice Drug Therapy Management Pursuant to a Drug Therapy Management Agreement, General Assembly of North Carolina, Session Law 1999–290, http://www.ncleg.net/EnactedLegislation/SessionLaws/HTML/1999-2000/SL1999-290.html (accessed September 15, 2014).

[19] "Pharmacy Laws of North Carolina," North Carolina Board of Pharmacy, http://www.ncbop.org/LawsRules/Statutes.pdf (accessed September 15, 2014).

[20] Scott Giberson, *Improving Patient and Health Systems Outcomes.*

[21] Brian W. Ward, Jeannine S. Schiller, and Richard A. Goodman, "Multiple Chronic Conditions Among US Adults: A 2012 Update," *Preventing Chronic Disease* 11 (April 17, 2014), doi:10.5888/pcd11.130389.

[22] U.S. Department of Health and Human Services, "The Challenge of Managing Multiple Chronic Conditions" http://www.hhs.gov/ash/initiatives/mcc/article.html (accessed January 8, 2014); U.S. Department of Health and Human Services, "Multiple Chronic Conditions: A Strategic Framework" (December 2010), http://www.hhs.gov/ash/initiatives/mcc/mcc_framework.pdf (accessed January 8, 2014); and Mary E. Tinetti, Sidney T. Bogardus, and Joseph V. Agostini, "Potential Pitfalls of Disease-Specific Guidelines for Patients with Multiple Conditions," *The New England Journal of Medicine* 351 no. 27 (December 30, 2004): 2870–74.

[23] Qiuping Gu et al. NCHS Data Brief, *Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007–2008,* U.S. Centers for Disease Control and Prevention, September 2010, http://www.cdc.gov/nchs/data/databriefs/db42.htm (accessed September 12, 2014).

[24] Kaiser Family Foundation, "Prescription Drug Trends" (May 2010), http://kaiserfamilyfoundation.files.wordpress.com/2013/01/3057-08.pdf (accessed September 15, 2014).

[25] Murray Aitken and Silvia Valkova, *Avoidable Costs in U.S. Healthcare: The $200 Billion Opportunity from Using Medicines More Responsibly* (Parsippany, NJ: IMS Institute for Health Informatics, June 2013), http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Institute/RUOM-2013/IHII_Responsible_Use_Medicines_2013.pdf (accessed September 15, 2014).

[26] Ibid.

[27] Patrick J. McDonnell and Michael R. Jacobs, "Hospital Admissions Resulting from Preventable Adverse Drug Reactions," *Annals of Pharmacotherapy* 36 no. 9 (September 1, 2002): 1331–36, doi:10.1345/aph.1A333; Gordon D. Schiff et al., "Decompensated Heart Failure: Symptoms, Patterns of Onset, and Contributing Factors," *The American Journal of Medicine* 114 no. 8 (June 1, 2003): 625–30, doi:10.1016/S0002-9343(03)00132-3; B.L. Senst et al., "Practical Approach to Determining Costs and Frequency of Adverse Drug Events in a Health Care Network," *American Journal of Health-System Pharmacy* 58 no. 12 (June 1, 2001): 1126–32, http://www.ajhp.org/content/58/12/1126 (accessed December 17, 2014); and P.T. Rodgers and D.M. Ruffin, "Medication Nonadherence: Part II—A Pilot Study in Patients with Congestive Heart Failure," *Managed Care Interface* 11 no. 9 (September 1998): 67–69, 75, http://europepmc.org/abstract/med/10187590 (accessed December 17, 2014).

More intensive patient care that pharmacists can provide includes MTM, health improvement and wellness counseling, disease-prevention services, and primary care.[28] MTM services are intended to improve therapeutic outcomes from medications for individual patients and include the following components:

- Performing or obtaining necessary assessments of the patient's health status;
- Formulating a medication treatment plan;
- Selecting, initiating, modifying, or administering medication therapy;
- Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
- Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
- Documenting the care delivered and communicating essential information to the patient's other primary care providers;
- Providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;
- Providing information, support services, and resources designed to enhance the patient's adherence to therapeutic regimens; and
- Coordinating and integrating services for MTM within the broader health care management services provided to the patient.[29]

A retrospective analysis of an MTM program in North Carolina suggests that MTM services can improve outcomes and reduce costs, but little additional outcome data are available to analyze MTM services.[30] In addition, the wide variation in MTM programs makes it difficult to generalize results of individual programs.[31] A meta-analysis conducted in 2010 reviewed 298 evaluations of pharmacists' provision of some level of direct intervention, such as MTM services, disease state management, or education.[32] The analysis demonstrated that pharmacists lowered risks associated with various health problems, such as low-density lipoprotein cholesterol, blood pressure, and adverse drug events.[33] In addition, a literature review of pharmacists participating in multidisciplinary teams shows that more intensive and direct care of chronically ill patients by pharmacists reduces preventable adverse drug events and prescribing errors and reduces costs.[34]

Pharmacists play an evolving role as medication-use experts on teams of health care providers.[35] That role can include initiating and modifying drug therapies or performing lab tests when the collaborating health provider agrees that those services are necessary and that the pharmacist is capable of safely providing

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[28] V.J. Willey et al., "Pharmacist Interventions Within a Community Physician Based Medical Home Practice: Diabetes Clinical Outcomes," *Value in Health* 14 no. 3 (May 2011): A51, http://www.valueinhealthjournal.com/article/S1098-3015(11)00429-3/fulltext (accessed December 17, 2014); Elizabeth McGann, "Pharmacists as Direct-Care Providers: An Expert Interview with Vincent J. Willey, PharmD," Medscape, http://www.medscape.com/viewarticle/756349 (accessed September 15, 2014); and Jessica Cherian et al., "Evolving Role of Pharmacists in Care Coordination: A National Survey," *Therapeutic Innovation & Regulatory Science* 48 no. 2 (March 2014): 266–71, http://search.proquest.com/docview/1511639062 (accessed December 17, 2014).

[29] Benjamin M. Bluml, "Definition of Medication Therapy Management: Development of Professionwide Consensus," *Journal of the American Pharmacists Association* 45 no. 5 (October 2005): 566–72, www.ncbi.nlm.nih.gov/pubmed/16295641 (accessed December 17, 2014).

[30] Gretchen F. Jenkins, "Retrospective Analysis of Community Pharmacists' Recommendations in the North Carolina Medicaid Medication Therapy Management Program," *Journal of the American Pharmacists Association* 50 no. 3 (May 1, 2010): 347, doi:10.1331/JAPhA.2010.09021.

[31] Annette N. Pellegrino et al., "Medication Therapy Management Services," *Drugs* 69 no. 4 (March 1, 2009): 393–406, doi:10.2165/00003495-200969040-00001.

[32] Marie A. Chisholm-Burns et al., "US Pharmacists' Effect as Team Members on Patient Care: Systematic Review and Meta-Analyses," *Medical Care* 48 no. 10 (October 2010): 923–33, doi:10.1097/MLR.0b013e3181e57962.

[33] Ibid.

[34] Thomas De Rijdt, Ludo Willems, and Steven Simoens, *Economic Effects of Clinical Pharmacy Interventions: A Literature Review,* American Society of Health-Systems Pharmacists (June 15, 2008), http://www.ashp.org/s_ashp/docs/files/advocacy/policy_alert/AJHP_Economic_Effects_6_15_08.pdf (accessed October 2, 2013).

[35] Barbara Farrell et al., "Working in Interprofessional Primary Health Care Teams: What Do Pharmacists Do?" *Research in Social and Administrative Pharmacy* 9 no. 3 (May 2013): 288–301, doi:10.1016/j.sapharm.2012.05.005.

them.[36] One way to formalize an interdisciplinary role for pharmacists is through a CPA, which allows for a delegation of specified clinical services to pharmacists. Collaborative drug therapy management agreements, provided under CPAs, include written guidelines or protocols that authorize pharmacists to initiate, modify, or continue drug therapy for a specific patient.[37]

State-Specific Models of Team-based Care Using Pharmacists

As support for integrating pharmacist-delivered services across the care continuum grows, states, payers, and health care systems are exploring different team-based models of care using targeted medication therapy management (MTM) pharmacy services for chronically ill patients or patients who are unlikely to take their medications as directed. Three examples in **Minnesota**, **Mississippi**, and **Ohio** are highlighted here.

Minnesota: MTM Through Medicaid and State Employee Plans

In 2005, Minnesota began coverage of pharmacist MTM services for patients in its Medicaid and state employee health programs.[38] MTM services were initially limited to patients receiving four or more prescriptions to treat two or more chronic medical conditions or patients who had received prior authorization because a drug therapy problem was identified and deemed likely to result in significant nondrug costs.[39]

A 2007 evaluation of the first year of MTM services reviewed the work of 34 pharmacists with 259 patients.[40] Results indicate that pharmacists identified and resolved 587 drug therapy problems that included unnecessary drug treatment, the need for additional drug treatment, remediation for doses that were too high or too low, and noncompliance.[41] Patients who have diabetes and were receiving MTM services were more likely to achieve performance standards for diabetes treatment (36 percent achieved the standard compared with only 6 percent statewide). The state also produced modest annual savings. Since 2007, the Medicaid program has expanded coverage to include home- and interactive video–delivered MTM. It has also expanded to include patients taking three or more medications to treat or prevent one or more chronic conditions. In 2010, Minnesota's Ryan White program began reimbursing pharmacists for MTM services using the same general structure as the Medicaid program.

To build on the success of the program and capture further savings, the state in 2013 expanded this effort for diabetic patients within the State Employee Group Insurance Plan in collaboration with the University of Minnesota College of Pharmacy. The program provides reimbursement for MTM services intended to improve outcomes.[42] As an incentive for patients to participate, all MTM services as well as diabetes medications and supplies are made available to the patient without a copayment. Finally, patients who successfully completed the program receive a $250 deposit to their health reimbursement account.

Mississippi: The Delta Pharmacy Patient Care Management Project

In 1998, Mississippi was the first state to receive Medicaid waiver approval to reimburse pharmacists for patient care.[43] The resulting program was a

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[36] Krystalyn Weaver, "Collaborative Practice Agreements Vary Among the States," American Pharmacists Association, http://www.pharmacist.com/collaborative-practice-agreements-vary-among-states (accessed September 15, 2014).
[37] Ibid.
[38] Brian Isetts, *Evaluating Effectiveness of the Minnesota Medication Therapy Management Care Program. Final Report*, December 14, 2007.
[39] Ibid.
[40] Ibid.
[41] Ibid.
[42] Diana Yap, "MTM in Minnesota: Plan Pays Pharmacists for Performance," American Pharmacists Association, http://www.pharmacist.com/mtm-minnesota-plan-pays-pharmacists-performance (accessed October 5, 2013).
[43] Lisa Daigle and David Chen, "Pharmacist Provider Status in 11 State Health Programs," American Society of Health-Systems Pharmacists, September 2008, http://www.ashp.org/DocLibrary/Advocacy/ProviderStatusPrograms.aspx (accessed September 12, 2014); and "Delta Pharmacy Patient Care Management," Delta Health Alliance, http://www.deltahealthalliance.org/project/delta-pharmacy-patient-care-management (accessed September 29, 2013).

collaborative effort between the University of Mississippi School of Pharmacy and community pharmacists. The program provided MTM services in rural areas across the state. Populations that the project served had high rates of poverty and chronic illness (particularly diabetes) and access to few health care providers.

During the first year of the program, the community pharmacists were given training, an MTM toolkit, and assistance with outreach to nonpharmacy providers. The College of Pharmacy also installed health information technology (IT) systems at community pharmacies and worked with large providers to link patient records with the pharmacies' health IT systems.

An evaluation of the program after the third year found that it had provided cost-effective health benefits to participants. The program identified more than 1,000 drug therapy problems.

Ohio: MTM Services for Medicaid-Eligible Patients

In 2012, CareSource, a Medicaid managed care plan, began a comprehensive MTM program for eligible Medicaid enrollees. CareSource, in turn, contracted with OutcomesMTM, a company that designs, delivers, and administers MTM programs.[44] All plan members were eligible for face-to-face MTM services from specially trained local pharmacists. The efforts are intended to improve health outcomes and reduce costs. Through the program, participating local pharmacists received alerts and information regarding patterns of medication use and evidence-based guidance for working with patients and physicians to close therapy gaps.

In the first year of the MTM program, pharmacists provided 106,239 MTM services, and CareSource reported a $4.40-to-$1 return on investment (ROI) for total health care expenditures.[45]

Challenges and Barriers to Maximizing the Effectiveness of Pharmacists Within the Health Care System

Several challenges and barriers prevent the full integration of pharmacists into health care delivery systems. Those challenges fall into three broad categories:[46]

- Laws and regulations governing CPAs;
- Provider recognition in state laws and regulations that enable compensation for pharmacists' direct patient care services; and
- Access to health IT systems.

Variation in State Laws Governing Collaborative Practice Agreements

Although 48 states grant pharmacists the ability to practice collaboratively in some capacity with other health care providers, administrative barriers and lack of flexibility limit pharmacists from practicing to the top of their professional training and education.[47] For example, state laws and regulations governing CPAs place limitations on practice settings, authority to initiate or modify drug therapy, and the number of patients permitted within a CPA. Some states impose extra requirements for education and training before pharmacists can be eligible to participate in a CPA, while still other states require pharmacy and medical board approval for each CPA.[48]

In most states, pharmacists can modify prescriptions

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[44] OutcomesMTM, "About Us," http://www.outcomesmtm.com/about-us.aspx (accessed September 15, 2014).
[45] Jessica Frank and Jim Gartner, "MTM Services for Managed Medicaid: Results, ROI, and Lessons Learned from One Large MCO" (paper presented at the PBMI Drug Benefit Conference, Las Vegas, Nevada, February 4, 2014).
[46] Lucinda L. Maine, Katherine K. Knapp, and Douglas J. Scheckelhoff, "Pharmacists and Technicians Can Enhance Patient Care Even More Once National Policies, Practices, and Priorities Are Aligned," *Health Affairs* 32 no. 11 (November 1, 2013): 1956–62, doi:10.1377/hlthaff.2013.0529; and US Surgeon General, *Letter to Scott Giberson [Internet]*. Rockville (MD): Office of the Surgeon General; December 14, 2011, http://www.usphs.gov/corpslinks/pharmacy/documents/2011SupportLetterFromUSSG.pdf (accessed September 15, 2014).
[47] Krystalyn Weaver, "Policy 101: Collaborative Practice Empowers Pharmacists to Practice as Providers," American Pharmacists Association, October 1, 2014, http://www.pharmacist.com/policy-101-collaborative-practice-empowers-pharmacists-practice-providers (accessed October 8, 2014).
[48] Interview with the National Alliance for State Pharmacy Associations, National Governors Association, February 6, 2014.

under a collaborative agreement that allows pharmacists to address drug-related side effects and improve therapeutic outcomes for patients.[49] Thirty-eight states allow pharmacists to initiate new therapy under a collaborative agreement (see Table 1), but in cases where pharmacists can initiate or modify prescriptions; the extent of the authority is highly variable. For example, some states impose restrictions on which drugs pharmacists can prescribe. In other instances, pharmacists are not permitted to prescribe or modify drug therapy to treat certain diseases. In most states, however, the authorizing physicians with whom a pharmacist works under a CPA may determine those details. Some provider groups argue that the ability to initiate new drug therapy can jeopardize patient safety, although no research is available to support that assertion.[50]

Another challenge comes from the administrative processes required under state laws for pharmacists' participation in CPAs. For example, some states require a separate CPA for each patient a pharmacist and prescriber treat, which limits the ability of physicians and pharmacists to create more efficient agreements at the practice level.[51] In addition, a number of states require that decisions about the structure and contents of CPAs be set in statute or included in CPA rules that the state board of medicine or the state board of pharmacy create. In states with the most restrictive laws, both the pharmacy and medical boards must approve all CPAs.[52]

To assess the appropriateness of current CPA standards, states can evaluate existing board approval processes as well as practice settings and drug therapy restrictions to determine whether unnecessary barriers exist for pharmacists and other providers to engage in collaborative arrangements. In addition, states that allow pharmacists to engage in CPAs can analyze existing data sources or administer surveys to measure provider participation in CPA arrangements.

Table 1. Summary of State Variations in CPA Agreements[53]

CPA Requirements	Total States with Language in Statute
Ability to modify drug therapy	45
Ability to initiate new drub therapy	38

Recognition of Professional Services and Related Payment Issues

The formal recognition of pharmacists as providers in state laws and regulations is a key step toward ensuring that adequate payment is available to support the services they provide. Product-based reimbursement (for example, payment for drug products and the act of dispensing the drug products) drive current payment policies for pharmacy services rather than the direct-care services that pharmacists provide patients. In a 2007 survey, 45 percent of community (retail) pharmacists who reported providing direct care to patients received no compensation for those services.[54] Medicare and Medicaid compensation policies also limit pharmacists' ability to practice, particularly within integrated care teams. For example, under Medicare Part B, pharmacists are not included

[49] National Center for Chronic Disease Prevention and Health Promotion, *A Program Guide for Public Health: Partnership with Pharmacists in the Prevention and Control of Chronic Diseases*, Centers for Disease Control and Prevention, August 2012, http://www.cdc.gov/dhdsp/programs/nhdsp_program/docs/pharmacist_guide.pdf (accessed December 17, 2014); and Raymond Hammond et al., "ACCP Position Statement: Collaborative Drug Therapy Management by Pharmacists," American College of Clinical Pharmacy, 2001, http://www.accp.com/docs/positions/positionstatements/pos2309.pdf (accessed September 8, 2014).

[50] "Pharmacists (Position Paper)," American Academy of Family Physicians, http://www.aafp.org/about/policies/all/pharmacists.html (accessed September 11, 2014).

[51] Scott Giberson, *Improving Patient and Health Systems Outcomes;* and Raymond Hammond, "ACCP Position Statement."

[52] Raymond Hammond, "ACCP Position Statement."

[53] Krystalyn Weaver, "Policy 101." https://www.pharmacist.com/policy-101-collaborative-practice-empowers-pharmacists-practice-providers.

[54] Jody L. Lounsbery et al., "Evaluation of Pharmacists' Barriers to the Implementation of Medication Therapy Management Services," *Journal of the American Pharmacists Association* 49 no. 1 (January 1, 2009): 51–58, doi:10.1331/JAPhA.2009.017158.

in the statutory definition of *providers* and, therefore, cannot directly bill for patient care services.[55] Many state and private health plans align their payment policies with Medicare policies and, as a result, do not allow pharmacists to bill directly for patient care services. Moreover, pharmacists' inability to bill Medicare and others for direct patient care services prevents pharmacists from serving as providers within accountable care organizations (ACOs) and other emerging models of team-based health care built on Medicare systems that charge on a fee-for-service basis.[56]

In contrast, Medicare Part D does reimburse for MTM services when provided under contract with the sponsor of a prescription drug plan. MTM services under Medicare Part D, however, are defined narrowly to include medication review but not services such as chronic disease management, care coordination, or other followup care.[57]

Payment for pharmacy services within state Medicaid or employee programs varies state to state. Within the 15 states that provide Medicaid compensation for direct patient care by pharmacists (see Table 2), the most commonly reimbursed services include smoking cessation, counseling, and other types of preventative services.[58] As of February 2014, nine states provide Medicaid compensation for MTM services: **Colorado**, **Iowa**, **Minnesota**, **Mississippi**, **Missouri**, **New Mexico**, **Oregon**, **Texas**, and **Wisconsin** (see Table 2 below and Table 4 on page 12).[59] Although the **Ohio** Medicaid program does not directly reimburse MTM services, Ohio's largest Medicaid managed care organization, CareSource, covers MTM for all of its members (for more information, see state-specific models on page 6). In addition, **Kentucky**, **Maryland**, **Minnesota**, **North Dakota**, and **Virginia** provide compensation for MTM services under their state employee health programs.[60]

Table 2. Summary of Pharmacist State Payment Variation[61]

Compensation	Total States with Language in Statute
Medicaid payment for professional services	15
Medicaid MTM benefit	9
State employee MTM benefit	5

Access to Health IT Systems

Finally, pharmacists' adoption, integration, and use of health IT improves their efficiency in daily tasks and increases their access to important information such as patients' complete drug records.[62] The rise of health IT in team-based models of delivering integrated care to patients has the potential to improve patient safety and outcomes and lower costs; however, pharmacists have difficulty accessing health IT systems.[63] Two national workgroups focused on health IT suggest the adoption of health IT between pharmacists and other provider groups

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[55] Lisa Daigle, "Pharmacist Provider Status in 11 State Health Programs."
[56] Social Security Administration, *Title XVIII—Health Insurance for the Aged and Disabled,* "Compilation of the Social Security Laws," http://www.ssa.gov/OP_Home/ssact/title18/1800.htm (accessed December 9, 2013); and interview with Stacie Maass, American Pharmacists Association, National Governors Association, January 24, 2014.
[57] Interview with Stacie Maass.
[58] Interview with the National Alliance for State Pharmacy Associations, National Governors Association, February 6, 2014.
[59] Ibid.
[60] Ibid.
[61] Interview with the National Alliance of State Pharmacy Associations, National Governors Association, February 7, 2014; and Krystalyn Weaver, "NASPA Finds State-Level Provider Status Is Widespread, but Not Necessarily Linked to Payment," American Pharmacists Association, February 1, 2014, http://www.pharmacist.com/naspa-finds-state-level-provider-status-widespread-not-necessarily-linked-payment (accessed June 2, 2014).
[62] Jacob Holler, "The Role of Information Technology in Advancing Pharmacy Practice Models to Improve Patient Safety," Pharmacy Times Blog, entry posted January 14, 2013, http://www.pharmacytimes.com/publications/health-system-edition/2013/January2013/The-Role-of-Information-Technology-in-Advancing-Pharmacy-Practice-Models-to-Improve-Patient-Safety (accessed January 8, 2014).
[63] Jeff Hull, Anthony J. Schueth, and William Hein, "Health Information Technology: Supporting Pharmacy Trends in 2014," Pharmacy Times Blog, entry posted December 16, 2013, http://www.pharmacytimes.com/publications/Directions-in-Pharmacy/2013/December2013/Health-Information-Technology-Supporting-Pharmacy-Trends-in-2014 (accessed January 26, 2014).

could improve pharmacists' ability to monitor patient adherence, identify drug interactions, modify medication regimens, and provide care coordination.[64]

The Health Information Technology for Economic and Clinical Health Act of 2009 provided incentives to promote widespread adoption in the meaningful use of health IT across provider groups.[65] As a result, formal groups have formed at the state and regional levels to coordinate and expand health IT across organizations and health care systems. In many instances, however, those groups have not fully incorporated pharmacists into their efforts, often because state laws do not recognize pharmacists as providers.[66]

To promote increased access to health IT, states are exploring a number of options, including health information exchanges (HIEs).[67] Pharmacist participation and access to HIEs, however, has been limited. To address operational and readiness challenges, states could increase pharmacist participation in cross-state collaboration with the Medicaid agency, professional boards, health IT vendors, and health systems as well as ensuring full integration of pharmacists into health IT strategies.[68] Finally, as providers increase their adoption of health IT systems in response to federal initiatives, states could adjust their Medicaid reimbursements to provide incentives for the increased adoption and

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[64] Pharmacy E-Health Information Technology Collaborative, "The Roadmap for Pharmacy Health Information Technology Integration in US Health Care," http://www.pharmacyhit.org/pdfs/11-392_RoadMapFinal_singlepages.pdf (accessed September 8, 2014); and Health Information Technology Workgroup, "Improving Transitions of Care with Health Information Technology: Position Paper," National Transitions of Care Coalition, December 10, 2010, http://www.ntocc.org/Portals/0/PDF/Resources/HITPaper.pdf (accessed September 8, 2014).

[65] Internal Revenue Service, "The American Recovery and Reinvestment Act of 2009: Information Center," http://www.irs.gov/uac/The-American-Recovery-and-Reinvestment-Act-of-2009:-Information-Center (accessed July 11, 2014).

[66] Pharmacy E-Health Information Technology Collaborative, "The Roadmap for Pharmacy Health Information Technology."

[67] HIEs have been implemented across states as a platform for facilitating interoperability across data systems and provide the infrastructure for information exchange. Lynn Dierker, "The State Connection: State-Level Efforts in Health Information Exchanges," *Journal of AHIMA* 79 no. 5 (May 2008): 40–43, http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_038086.hcsp?dDocName=bok1_038086 (accessed December 17, 2014); and State-Level Health Information Exchange Consensus Project, http://www.ahimafoundation.org/PolicyResearch/SLHIE.aspx (accessed September 15, 2014).

[68] Lynn Dierker, "The State Connection"; Nikki Highsmith and Julia Berenson, "Driving Value in Medicaid Primary Care: The Role of Shared Support Networks for Physician Practices," Commonwealth Fund, 2011, http://hsc.unm.edu/community/toolkit/docs1/1484_Highsmith_driving_value_Medicaid_primary_care.pdf (December 17, 2014); and Pharmacy E-Health Information Technology Collaborative, "The Roadmap for Pharmacy Health Information Technology."

[69] Ibid.

integration of health IT across all providers, including pharmacists.[69]

Conclusion

The integration of pharmacists into team-based models of care could potentially lead to improved health outcomes. To realize that prospect, states should consider engaging in coordinated efforts to address the greatest challenges pharmacists face: restrictions in CPAs, recognition of pharmacists as health care providers to ensure compensation for direct patient care services, and access to health IT systems. Examining state-specific challenges and promising practices from other states will allow states to develop policies that permit pharmacists to practice within the full scope of their professional training across the health care continuum.

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Table 3. Summary of State Policy Considerations

Challenges	Policy Considerations	State Example
Collaborative practice provisions	• Enact broad collaborative practice provisions that allow for specific provider functions to be determined at the provider level rather than set in state statute or through regulation. • Evaluate practice setting and drug therapy restrictions to determine whether pharmacists and providers face disincentives that unnecessarily discourage collaborative arrangements. • Examine whether CPAs unnecessarily dictate disease or patient specificity.	**Virginia**: In 2013, Virginia's House Bill 1501 amended the collaborative practice provisions to allow pharmacists to enter into an agreement with multiple providers within a single practice.[70] Previously, a pharmacist could enter into an agreement only with a provider of medicine, osteopathy, or podiatry and their designated alternate practitioners.
Provider recognition and compensation for pharmacist-delivered care services	• Recognize pharmacists as providers within the state insurance code, Medicaid, Medicaid managed care, HIEs, and state employee plans, and encourage private insurers to do the same. • Include authorizing language that recognizes pharmacist-delivered services under a certified patient-centered medical home model, ACO, or equivalent. • Conduct stakeholder meetings with private organizations, health systems, and provider groups to assess existing payment methodologies and incentive structures. • Examine Medicaid policies, Medicaid managed care contracts, and state employee policies around payment for pharmacists' services to ensure that beneficiaries have access to pharmacy services	**Nebraska**: As proposed, Legislative Bill 858 would allow insurance companies to recognize pharmacists as health care providers who have the authority to provide health care services that include MTM services, chronic disease management services, comprehensive medication review, and other professional services.[71] **New Jersey**: As proposed, Senate Bill 2568 would require coverage of MTM in Medicaid and NJ FamilyCare.[72]
Access to health IT systems	• Work with state HIEs to ensure that pharmacists have the ability to access health IT and electronic patient records within collaborative and team-based models of care. • Encourage the adoption of interoperable health IT systems across care settings.	**Minnesota**: By January 1, 2015, all hospitals and health care providers, including pharmacists in Minnesota, must have an interoperable electronic health records (EHR) system within their hospital system or clinical practice setting.[73]

[70] LIS: Virginia's Legislative Information System, 2013 session, HB 1501 Pharmacy; Collaborative Agreements, http://lis.virginia.gov/131/sum/HB1501.HTM (accessed February 10, 2014).

[71] Nebraska Legislature, LB 858: Provide Requirements Relating to Pharmacists and Health Care Services in Health Insurance, http://www.legislature.ne.gov/bills/view_bill.php?DocumentID=21926 (accessed February 8, 2014).

[72] An Act Concerning Medicaid and NJ FamilyCare and Supplementing Title 30 of the Revised Statutes, 215th New Jersey Legislature, http://www.njleg.state.nj.us/2012/Bills/S3000/2568_I1.HTM accessed (September 15, 2014).

[73] Minnesota Department of Health, Division of Health Policy, Office of Health Information Technology, "Guidance for Understanding the Minnesota 2015 Interoperable EHR Mandate," http://www.health.state.mn.us/e-health/hitimp/2015mandateguidance.pdf (accessed January 22, 2014).

Table 4. Summary of State Scope of Practice Rules Governing Pharmacists

State	Medicaid Compensation		CPAs		
	Professional Services	MTM or Another Comprehensive Service	Allowed (Some Restrictions)	Allowed but Restrictive	Not Allowed
Alabama					X
Alaska	X		X		
Arizona			X		
Arkansas			X		
California			X		
Colorado	X	X	X		
Connecticut			X		
Delaware					X
Florida				X[74]	
Georgia			X		
Hawaii			X		
Idaho			X		
Illinois			X		
Indiana	X		X		
Iowa	X	X	X		
Kansas			X		
Kentucky			X		
Louisiana			X		
Maine			X		
Maryland			X		
Massachusetts			X		
Michigan			X		
Minnesota	X	X	X		
Mississippi	X	X	X		
Missouri	X	X	X		
Montana	X		X		
Nebraska	X		X		
Nevada			X		
New Hampshire				X[75]	
New Jersey			X		
New Mexico	X	X	X		
New York				X[76]	
North Carolina			X		

[74] Cannot initiate or modify.
[75] Limited to institutional settings.
[76] Limited to teaching hospitals.

State	Medicaid Compensation		CPAs		
	Professional Services	MTM or Another Comprehensive Service	Allowed (Some Restrictions)	Allowed but Restrictive	Not Allowed
North Dakota	X			X[77]	
Ohio				X[78]	
Oklahoma				X[79]	
Oregon	X	X	X		
Pennsylvania				X[80]	
Rhode Island			X		
South Carolina			X		
South Dakota			X		
Tennessee			X		
Texas	X	X		X[81]	
Utah	X		X		
Vermont			X		
Virginia			X		
Washington			X		
West Virginia			X		
Wisconsin	X	X	X		
Wyoming			X		
TOTALS	**15**	**9**	**40**	**8**	**2**

Notes

- The National Governors Association worked in collaboration with and cited information from state boards of pharmacy, the National Alliance of State Pharmacy Associations, and the American Pharmacist Association. Information for the summary of state scope of practice rules was updated as of October 2014.
- Data represented in the chart does not include the District of Columbia or U.S. territories.
- Professional services provided by a pharmacist, although not exhaustive, includes MTM, smoking cessation, counseling, and administration of immunizations.
- Medicaid recognition and payment vary depending on the state and are determined based on which pharmacist-administered services are classified as covered services.
- The CPA requirement categories were primarily determined based on analysis of state regulatory classifications and trends.
- The column Allowed but Restrictive primarily includes restrictions relating to practice setting, board approval, and additional educational requirements.
- For more information, visit http://www.naspa.us and http://www.pharmacist.com.

[77] Limited to institutional settings.
[78] Agreement needed for each disease state.
[79] Limited to vaccines and injectable medications.
[80] Limited to institutional settings.
[81] Limited to institutional settings.

Improving Patient and Health System Outcomes through Advanced Pharmacy Practice

A Report to the U.S. Surgeon General 2011

Office of the Chief Pharmacist

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RELEVENT ACRONYMS

AACP	American Association of Colleges of Pharmacy
AAFP	American Academy of Family Physicians
AAMC	Association of American Medical Colleges
ACA	Affordable Care Act
ACPE	Accreditation Council for Pharmacy Education
ADE	Adverse Drug Event
APhA	American Pharmacists Association
ASHP	American Society of Health-System Pharmacists
BOP	Federal Bureau of Prisons
BPS	Board of Pharmacy Specialties
CCP	Chronic Care Professional
CDTM	Collaborative Drug Therapy Management
CGP	Certified Geriatric Pharmacist
CMS	Centers for Medicare & Medicaid Services
CPA	Collaborative Practice Agreement
CPHIMS	Certified Professional in Healthcare Information and Management Systems
CPP	Clinical Pharmacist Practitioner
CPS	Clinical Pharmacy Specialist
DMAA	Disease Management Association of America
DOD	U.S. Department of Defense
HCFA	Health Care Financing Administration
HRSA	Health Resources and Services Administration
I/T/U	IHS, Tribal, and Urban
ICP	Infection Control Professional
IHS	Indian Health Service
IOM	Institute of Medicine
MedPAC	Medicare Payment Advisory Commission
MTM	Medication Therapy Management
MTMP	Medication Therapy Management Program
NAPLEX	North American Pharmacist Licensure Examination
NCCPC	North Carolina Center for Pharmaceutical Care
NCPS	National Clinical Pharmacy Specialist
NCPSC	National Clinical Pharmacy Specialist Committee
NP	Nurse Practitioner
NPP	Non-Physician Practitioners
OSG	U.S. Office of the Surgeon General
PA	Physician Assistant
PCMH	Patient-Centered Medical Home
PCP	Primary Care Provider
PDP	Prescription Drug Plan
PSPC	Patient Safety and Clinical Pharmacy Services Collaborative
VA	U.S. Department of Veterans Affairs

EXECUTIVE SUMMARY

The 2011 Report to the U.S. Surgeon General is an update of a previously submitted Report in 2009 to then Acting Surgeon General, RADM Steven Galson. The 2011 Report provides health leadership with evidence-based discussion about improving patient and health system outcomes through an additional paradigm of health care delivery for expanded implementation in the United States. The 2011 Report provides rationale and compelling discussion to support health reform through pharmacists delivering expanded patient care services. In collaboration with other providers, this is an existing, accepted, and additional model of improved health care delivery that meets growing health care demands in the United States.

Health care delivery (including preventive or supportive care) in the United States is challenged by demands of access, safety, quality, and cost. These challenges are amplified by provider workforce shortages and dramatic increases in primary and chronic care visits. Projections suggest worsening of this situation. New or additional paradigms of care must be implemented to reduce these burdens. Current health care demands provide an opportunity for health leadership to recognize and adopt additional and successful health care deliver models.

Health reform has stimulated exploration of innovative care and payment reform models that can improve access to care, provide quality care, contain costs, and afford safe use of medications and other pertinent medication-related issues. The federal sector has already implemented and embraced such a health care delivery model through physician-pharmacist collaboration. This collaboration, through extensive performance data, has demonstrated that patient care services delivered by pharmacists can improve patient outcomes, promote patient involvement, increase cost-efficiency, and reduce demands affecting the health care system.

For over forty years, federal pharmacists have collaboratively managed disease through medication use, and other cognitive and clinical pharmacy services.[1] Although these models are accepted in the non-federal sector, utilization is often impeded due to policy, legislation, and compensation barriers that will be discussed in this Report.

The Report is framed around four focus points that clearly articulate and present evidence-based data that objectively illustrate improved health care delivery through the use of pharmacist-delivered patient care. A substantial amount of published literature from peer-reviewed journals has been collected and analyzed to support the discussion.

Focus Point 1 discusses how pharmacists are already integrated into primary care as health care providers. Pharmacists unquestionably deliver patient care services in a variety of practice settings through collaborative practice with physicians or as part of a health care team. Definitions of primary care assist us to enumerate these integrated roles, and the long history of successful delivery demonstrates a level of interprofessional collaboration and support. After an initial diagnosis is made, pharmacists deliver many patient care services - and function as health care providers - in a variety of practice settings through collaborative practice

agreements (CPAs), to manage disease in patients (where medications are the primary mode of treatment). Pharmacists can:

- Perform patient assessment (subjective and objective data including physical assessment);
- Have prescriptive authority (initiate, adjust, or discontinue treatment) to manage disease through medication use and deliver collaborative drug therapy or medication management;
- Order, interpret and monitor laboratory tests;
- Formulate clinical assessments and develop therapeutic plans;
- Provide care coordination and other health services for wellness and prevention of disease;
- Develop partnerships with patients for ongoing (follow-up) care

The American Academy of Family Physicians, the Institute of Medicine, and the Care Continuum Alliance all describe the many facets of primary care. Once a diagnosis is made by the primary care provider, pharmacists do manage disease and provide patient care. Pharmacists that perform in these roles function as health care providers. Pharmacists are uniquely positioned (through their accessibility, expertise and experience) to play a much larger patient care role in the U.S. health care delivery system to meet these demands and improve the health of the nation. However, **pharmacists may be the only health professionals (who manage disease through medications and provide other patient care services) who are not recognized in national health policy as health care providers or practitioners.** Legislation, policy, and compensation mechanisms thus limit optimal patient outcomes and reduce the positive impact on the patient and the health care system.

Focus Points 2 & 3 discuss how to sustain these value-added patient care services delivered by pharmacists. For pharmacists to continue to improve patient and health system outcomes as well as sustain various roles in the delivery of care, they must be recognized as health care providers by statute via legislation and policy, and be compensated through additional mechanisms commensurate with the level of services provided (and with other practitioners providing comparable services). Pharmacists with approved privileges, who currently perform in expanded clinical roles to manage disease and deliver other patient care functions, are not recognized by the Social Security Act[2] or Centers for Medicare & Medicaid Services (CMS) as health care providers or Non-Physician Practitioners (NPPs). The Social Security Act appropriately recognizes a number of other health care professionals as health care "providers or practitioners," including physician assistants, nurse practitioners, certified nurse midwives, clinical social workers, clinical psychologists, and registered dieticians/nutrition professionals. These health professionals have multiple and varied areas of expertise and provide some facets of primary care, yet all deliver patient care services. Pharmacists provide expertise and health care delivery in a number of ways from primary prevention, to counseling and adherence programs, to comprehensive medication and chronic disease management - and are not yet recognized in this important piece of legislation. This omission is despite evidence that medications are involved in 80 percent of all treatments (and impact every aspect of a patient's life), and drug-related morbidity and mortality cost this country almost $200 billion annually.[3] Failure to recognize expanded roles of pharmacists limits the potential for patients and our health care system to benefit from access to additional quality primary care services. Exclusion

of pharmacists as health care providers also eliminates any subsequent service-sustaining compensation. Pharmacists are increasingly requested by many health systems, providers, and primary care teams to improve outcomes and delivery of care. However, in terms of pharmacist services, as the complexity or level of clinical service increases, the revenue generation potential is reduced. This is in stark contrast to the clinical services provided by other health professionals. In both the public and private sectors, health systems are fiscally challenged to sustain any clinical service without the ability to generate revenue.

Focus Point 4 discusses and **collates the numerous articles, systematic reviews and meta-analyses of positive patient and health system outcomes that have been published** in peer-reviewed journals that validate this model as evidence-based**.** According to a recent comprehensive systematic review of 298 research studies, integrating pharmacists into direct patient care results in favorable outcomes across health care settings and disease states.[4] Pharmacists with larger roles in patient care improve outcomes, increase access to care (especially for medically underserved and vulnerable populations), shift time for physicians to focus on more critically ill patients in need of physician-based care, improve patient and provider satisfaction, assure patient safety, enhance cost-effectiveness, and clearly advance and improve health care delivery.

An opportunity exists for health leadership and policy makers to support and implement additional, existing and evidence-based models of cost-effective pharmacist-delivered patient care as the following demands within our health system escalate:

- **Chronic Care.** Chronic diseases are the leading causes of death and disability in the United States. Chronic diseases currently affect 45% of the population (133 million Americans), account for 81% of all hospital admissions, 91% of all prescriptions filled, 76% of physician visits, and continues to grow at dramatic rates.[5] Additionally, of all Medicare spending, 99% goes to beneficiaries with chronic disease.[6]
- **Access to care.** Medically underserved patients seeking a health care home and the growth of primary care visits are two components that lead to insufficient time for focused or comprehensive disease or medication management and other related health care issues.
- **Provider workforce**. The primary care workforce may not be able to meet the demands of increased access to care. Physician shortages and maldistribution of health care providers impact how we address this issue. The proportion of newly graduated U.S. medical students who choose primary care as a career has declined by 50% since 1997.[7] Currently, it is estimated that over 56 million Americans lack adequate access (not coverage) to primary health care because of shortages of primary care physicians in their communities.[8] As millions of new beneficiaries enter the health care system, the situation will most likely worsen.

Currently, the Affordable Care Act seeks to guarantee more health care choices and enhance the quality of health care for all Americans, while making health care affordable.[9] Innovative practice models need to be considered, especially with the current shortage of primary care providers and limited resources, in order to address these challenges. In medically underserved

and vulnerable populations and the federal health care settings, pharmacists have successfully functioned in interprofessional practice settings (e.g., IHS, VA, and DOD). Allowing pharmacists to function in these advanced models across more practice settings expands the health care infrastructure to meet demands for increased patient care services.

Pharmacists are remarkably underutilized in the U.S. health care delivery system given their level of education, training, and access to the community. Maximizing the roles and scope of pharmacists to deliver a variety of patient-centered primary care and public health, in collaboration with physicians, is a proven and existing paradigm of care that can be efficiently implemented.

During the April 11, 2011 launch of the Partnerships for Patients Initiative, Donald Berwick, CMS Administrator, stated, "America is facing a critical choice in health care. Either cut care or improve care. I don't like to cut care, so the only right thing to do is improve care."[10] The link between the impact of medications on the health system and the expertise of the pharmacist, coupled with the exponential growth in cost of care, draws a logical parallel to this model as a keystone of care. **One of the most evidence-based decisions to improve the health system is to maximize the expertise and scope of pharmacists, and minimize expansion barriers of an already existing and successful health care delivery model.**

Objectives

- Obtain advocacy from the U.S. Surgeon General to acknowledge pharmacists that manage disease through medication use and deliver patient care services, as an accepted and successful model of health care delivery in the United States, based on evidence-based outcomes, performance-based data and the benefits to patients and other health system consumers (physicians, administrators, payers, etc.).
- Obtain advocacy from the U.S. Surgeon General to recognize pharmacists, who manage disease and deliver many patient care services, as health care providers. One such action is advocate to amend the Social Security Act to include pharmacists among health care professionals classified as "health care providers."
- Obtain advocacy from the U.S. Surgeon General to have pharmacists recognized by CMS as Non-Physician Practitioners in CMS documents, policies, and compensation tables commensurate with other providers, based on the level of care provided.
- Advance beyond *discussion* (and numerous demonstration projects) of the expanded roles of pharmacist-delivered patient care and move toward health system implementation.

INTRODUCTION

The 2011 Report to the U.S. Surgeon General is an update of a previously submitted Report in 2009 to then Acting Surgeon General, RADM Steven Galson. The 2011 Report provides health leadership with evidence-based discussion about improving patient and health system outcomes through an additional paradigm of health care delivery for expanded implementation in the United States. The 2011 revision, herein referred to as the "Report," provides a compelling discussion to support health reform through pharmacists that manage disease through medication use and deliver patient care services, in collaboration with other providers, as an accepted and additional model of health care delivery. Timing of this discussion is vital as health reform has stimulated exploration of innovative care and payment reform models that improve access to care, provide quality care, contain costs, and afford safe use of medications and other pertinent medication-related issues.

The Report discusses current and future demands on the health care system, including the challenge of aligning health care coverage with access to care, the increasing burden of chronic care needs, and primary care provider shortages. Current health care demands provide an opportunity to recognize successful and existing models of health care delivery. Within federal health care, utilizing pharmacists on the primary care team to prevent and manage disease, and provide patient care services has been one of the most evidence-based, proven, and time-tested strategies to mitigate similar demands. Federal pharmacy practice, over the past 40 years, has included expanded scopes within comprehensive disease management, health promotion, disease prevention, and other cognitive clinical services such as medication management.

Expanding the role of pharmacists is supported by evidence-based outcomes and existing innovative models. The benefits translate into improved consumer outcomes that support many tenets of health reform - enhanced access and quality of care, cost-effectiveness and patient safety. The Report is framed around four focus points that clearly articulate and present objective data that support the need for innovative practice models that include pharmacists as essential health care providers.

Based on current practice models, perceptions of pharmacists' roles, specifically as a health professional exclusively associated with drug product and delivery, should now include many additional patient care, primary care, and public health services. It is essential to note that pharmacists currently provide multiple levels of direct and indirect patient care services in a variety of practice settings. Management of disease through medication use - inclusive of Collaborative Drug Therapy Management (CDTM), Comprehensive Medication Management (CMM) or Medication Therapy Management (MTM), health promotion, patient safety, disease prevention, care coordination, follow-up care and other primary patient care services - are performed by pharmacists in a similar manner as other health care providers. The rationale for this practice model is the fact that once a diagnosis is made, patient care services rely on pharmacologic interventions as the major form of therapy. Data clearly suggest that

medications are currently the cornerstone of chronic disease therapy, yet our health care system continues to fragment care and 'reward' reactive health care delivery models.

Pharmacists' formal education appropriately prepares them to successfully perform clinical services related to the prevention and control of disease through medications. Pharmacists are also well-positioned (through accessibility, expertise and experience) to play a much larger primary care role in the U.S. health care system to meet these demands and improve health care delivery (and the health) of the nation.

Pharmacists' current scope of practice positions them to provide these services through Collaborative Practice Agreements (CPAs) with physicians or within any coordinated patient care models - such as the Patient-Centered Medical Home (PCMH).

Pharmacists have functioned for decades to deliver expanded patient care services in many federal settings. More recently, non-federal pharmacists and health systems have also embraced expanded patient care roles through CDTM, medication management and other public health initiatives such as immunizations, emergency/disaster care, point-of-care testing, smoking cessation programs, etc. In 2002, the Medicare Payment Advisory Commission (MedPAC) stated that there was mounting evidence that clinical pharmacist involvement in managing drug treatment may reduce costs and improve the quality of care. The MedPAC voted unanimously that the Secretary of the Department of Health and Human Services should assess models for Collaborative Drug Therapy Management (CDTM) services in outpatient settings.[11] Progress has been made; however, eleven years later, the profession continues to perform requested clinical duties without appropriate service-sustaining recognition or compensation.

While longevity of the physician-pharmacist collaborative practice model serves as an indicator of success, further support from key stakeholders is needed. For system-wide improvement, mitigation of the barriers begins with the basic acknowledgement and support of these existing and successful models at the highest levels of health leadership. **A prime example of support to improve health care delivery would be recognition and definition of "Pharmacists; Pharmacist-Delivered Patient Care Services" in the Social Security Act under Title 18, Part E, Section 1861.** To continue to advance these value-added services, pharmacists must be recognized for their ability to provide these services. This includes statute through legislation, policy established by the administration, and commensurate compensation mechanisms similar to other billable practitioners that provide comparable services.

The role of federal and the U.S. Public Health Service (PHS) pharmacy is, and always has been, unique. There is a common acceptance and support structure within the federal system that recognizes pharmacists as essential members of the health care team that can provide specific patient care services, in addition to expertly managing disease through optimal medication use.

Leveraging this unique and effective interprofessional practice environment, it is a PHS Pharmacy responsibility to recommend paradigms of care that will maximize use of our

profession to improve the health of the nation. These models are not new in the federal sector, yet our non-federal colleagues and now even some federal partners, are challenged to sustain these pharmacist-delivered patient care services due to restrictive policy, legislation and compensation mechanisms. These persistent barriers arise during a time of heightened demand for access to care, cost-effective prevention and quality care. Coincidentally, it is also a time in which our health system needs innovation.

Pharmacists within the PHS, the Department of Veterans Affairs (VA), and the Department of Defense (DOD) have been and continue to be innovative in establishing successful models of pharmacist-delivered patient care. With support from physicians and other stakeholders, they continue to demonstrate positive outcomes. These models can be expanded to meet some of the demands on the current and future U.S. health care system. This Report will provide detailed discussion of advanced pharmacy practice through four focus points that offer objective findings to garner wider advocacy and acceptance for further implementation. As stated by the Patient-Centered Primary Care Collaborative, "Only with appropriate and optimal medication use will we see real quality of care improve and health care costs decrease…"[3]

APPENDICES

- Appendix A: National Clinical Pharmacy Specialist (NCPS) Program - In 1997, the Indian Health Service (IHS) established a national credentialing system for IHS, Tribal, and Urban (I/T/U) pharmacists in an effort to assure advanced pharmacy practitioners in the IHS display a uniform level of competency.
- Appendix B: Outcomes Repository Spreadsheet - Evidence-based outcomes that support collaborative primary care. Both federal and non-federal sectors have numerous articles, systematic reviews and meta-analyses of positive patient outcomes that have been published in peer-reviewed journals. Format: Citation, Outcomes, Results/Conclusions.
- Appendix C: U.S. Collaborative Practice Map - Forty-four (44) of fifty (50) states[12] address or mention some form of collaborative practice and/or protocols between physicians and pharmacists.
- Appendix D: Physician Survey - Substantial PHS interprofessional and physician support currently exists for pharmacists practicing in advanced clinical and primary care roles.

OBJECTIVES

- Obtain advocacy from the U.S. Surgeon General to acknowledge pharmacists that manage disease through medication use and deliver patient care services, as an accepted and successful model of health care delivery in the United States, based on evidence-based outcomes, performance-based data and the benefits to patients and other health system consumers (physicians, administrators, payers, etc.).
- Obtain advocacy from the U.S. Surgeon General to recognize pharmacists, who manage disease and deliver many patient care services, as health care providers. One such action is advocate to amend the Social Security Act to include pharmacists among health care professionals classified as "health care providers."
- Obtain advocacy from the U.S. Surgeon General to have pharmacists recognized by CMS as Non-Physician Practitioners in CMS documents, policies, and compensation tables commensurate with other providers, based on the level of care provided.
- Advance beyond *discussion* (and numerous demonstration projects) of the expanded roles of pharmacist-delivered patient care and move toward health system implementation.

DISCUSSION

Focus Point 1: Pharmacists Integrated as Health Care Providers

Once a diagnosis is made, many pharmacists manage disease and deliver patient care services (inclusive of preventive and supportive care) as health care providers in the United States. Definitions of primary care characterize and affirm these integrated direct and indirect patient care roles. Successful delivery of these services demonstrates existing interprofessional collaboration and support.

Definitions of Primary Care

Current pharmacy practice is considerably more diverse than what has been previously reported in terms of scope of practice and practice setting. Traditional roles of the pharmacist tied solely to medication product and delivery have been greatly expanded. Pharmacists evaluate and counsel patients, provide health maintenance information, administer immunizations (as one of many public health functions), reduce drug misadventures through clinical interventions, respond to disaster needs, assume regulatory roles in drug delivery to assure safety, assess patients who access the health system through community pharmacies, and perform point-of-care testing. In more advanced practice settings, pharmacists are involved with provision of more expanded direct patient care through comprehensive disease management, CDTM, medication management, health promotion/disease prevention, care coordination and follow-up patient care. Many of these services are similar in scope and complexity to other primary care services delivered in our health care system.

Following diagnosis, maximizing the expertise of the pharmacist is both logical and critical considering that the majority of patient care - and demand on the health care system - involves the treatment or maintenance of the diagnosed condition through use of medications. Medications are involved in 80 percent of all treatments and impact every aspect of a patient's life.[3] An inordinate amount of time and resources are spent within the health system delivering disease management and monitoring of disease through selected therapy. Even through collaborative practice, pharmacists with a formal education that focus on therapeutics and management of disease through medication use are widely underutilized. **Once a diagnosis is made**, it is undeniable that physicians, physician assistants, nurse practitioners *and* pharmacists assume direct patient care roles. Definitions of primary care help clarify and confirm the provision of similar patient care services by pharmacists.

The American Academy of Family Physicians (AAFP) defines primary care as "health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis, and treatment of acute and chronic illnesses in a variety of health care settings."[13] The definition also states the provision of primary care is often given by a physician in collaboration with other health care professionals in an atmosphere where consultation and referrals are utilized. Primary care also promotes patient involvement and cost-efficiency. The primary care provider is often the patient's first point of contact when seeking medical care, and is the

service that then takes responsibility for each patient's comprehensive continuing health care. Structurally, primary care "teams" often include physicians and non-physician health care professionals. AAFP lists nurse practitioners, physician assistants, and "some other health care providers," under the umbrella of non-physician primary care providers or Non-Physician Practitioners (NPPs), but it does not specifically include pharmacists. Yet pharmacists are continually requested and utilized in provision of patient care services and patient-centered health care homes. AAFP does state that these non-physician providers work in collaborative teams with the primary care physician toward the ultimate goal of optimal patient health.[13]

Pharmacists in advanced practice models with physician-driven privileges have been successful in many of these roles as defined by the AAFP.

The Institute of Medicine (IOM) defines primary care as "integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs," but it does not specifically state what type of clinicians provide this care. It goes on to discuss that services include developing a sustained partnership with patients, and practicing in the context of family and community.[14] More concisely, primary care can be described as consisting of four basic attributes: access, longitudinality, comprehensiveness of care, and care coordination.[15] It further explains primary care has been shown to provide benefits such as greater access, better quality of care, greater focus on prevention, early management of health issues, and reduction of unnecessary specialist care, which can be a strategy to achieve cost-effectiveness.

Pharmacists collaborate as part of this primary care team to achieve the aforementioned benefits and coordinate with primary care providers to minimize unnecessary care and utilize each team member to their utmost ability.[15] Pharmacists in many settings provide additional access to direct patient care, care coordination, comprehensive care through disease management (where medications are the primary method of treatment), and improved quality of care.

The Care Continuum Alliance - formerly the Disease Management Association of America (DMAA) - defines primary care through disease management as "a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant."[16] Disease management also includes prevention of exacerbations and complications, with the ultimate goal of improving the overall health of the patient. Components of disease management include identifying eligible patients, following evidence-based guidelines, utilizing collaborative practice models, encouraging patient self-management of chronic conditions, assessing, evaluating, and managing outcomes, and promoting continual feedback with stakeholders. Stakeholders include the patient, physician, health plan, and other care providers. The Care Continuum Alliance definitively recommends the following to prevent the complications of multiple uncoordinated providers: "all the diseases a patient has are managed by a single disease management program." For the purpose of this Report, the PHS Pharmacy program implies a definition of disease management that is

consistent with primary care models and clinical management of disease (inclusive of medication use and management) with less focus on individual case management services.

According to all cited definitions from the AAFP, IOM, and the Care Continuum Alliance, and similar to other health care providers, many of these patient care services are delivered by pharmacists. Pharmacists have been collaboratively managing disease and providing patient care in this manner. However, pharmacists are the only health professionals providing this level of care who are not recognized in national health policy as health care providers.

The federal sector has supported physician-pharmacist collaboration and demonstrated that these direct patient care services delivered by pharmacists can improve patient outcomes as well as promote patient involvement and cost-efficiency. For over forty years, pharmacists have practiced primary care through disease management and other cognitive and clinical services.[1] In the federal sector, this is not a new model of health delivery. These models are accepted in the non-federal sector; however uptake and growth are slowed due to inherent policy, legislation and compensation barriers discussed later in the Report.

Pharmacist Roles

In some settings, through CPAs, the pharmacist serves as the clinical chronic disease manager (inclusive of customary privileges of similar health care providers) and can refer back to the physician at scheduled intervals for review. This can take place whether the pharmacist is part of a primary care team or as an individual provider of care in collaboration with the physician. Pharmacist-delivered patient care is based upon an effective, sustained relationship between patients, physicians, and other health care practitioners. This integrated team approach also inherently allows for pharmacists to function within the patient-centered medical home (PCMH) or any other patient-centered health care home model.

Currently, pharmacists deliver patient care services in a variety of practice settings through CPAs to manage disease whereby they:

- Perform patient assessment (subjective and objective data including physical assessment);
- Have prescriptive authority (initiate, adjust, or discontinue treatment) to manage disease through medication use and deliver collaborative drug therapy or medication management;
- Order, interpret, and monitor laboratory tests;
- Formulate clinical assessments and develop therapeutic plans;
- Provide care coordination and other health services for wellness and prevention of disease;
- Develop partnerships with patients for ongoing (follow-up) care.

Delivery of comprehensive care requires collaboration and communication of all health care providers. This emphasizes the importance of patient education, follow-up, and individual patient ownership. Although appropriately initiated by a physician as the diagnostician, referral to a collaborating pharmacist to deliver patient care services for provision of ongoing or chronic

care, prevention of exacerbation, and improvement of clinical outcomes is accepted practice in many clinical settings. In this collaborative practice, communication is ongoing between the physician (or another primary care provider) and the pharmacist - functioning as a health care provider that can manage disease through medication use.

The federal infrastructure has provided pharmacy practice a progressive environment, producing some of the oldest documented examples of successful interprofessional practice through expanded roles in direct patient care, disease management, and public health. Pharmacists in the IHS, VA, and the DOD have long been recognized as leaders in innovative pharmacy practice. Their enduring history of physician-supported collaborative pharmacy practice models clearly validates and confirms these models' provision of positive patient-focused quality care. Pioneers like Dr. Allen Brands (Chief Pharmacist for IHS from 1955-1981 and Chief Professional Officer of the U.S. Public Health Service from 1967-1981) recognized the need for expanded pharmacy services as early as the 1960s. During that time frame, the pharmacist's role began to shift from a distributive function of medications to a more clinical role. From the 1960s forward, the IHS led a national effort toward improving patient-pharmacist interaction and education.[17] By 1974, over 90 percent of the IHS sites had one or more pharmacist-run disease management programs in place.[18]

This IHS patient-centered and collaborative approach facilitated the evolution and development of the IHS Pharmacy Standards of Practice, which were developed in the mid-80s, formalized and published in 1989, and continue to this day.[1,19] The IHS Standards of Practice were in use before Hepler and Strand's 1990 article on Pharmaceutical Care that popularized many of these clinical concepts.[20] These six Standards of Practice include:

1. Assure Appropriateness of Drug Therapy
2. Verification of Understanding
3. Assure Availability, Preparation and Control of Medications
4. Provide Drug Information and Staff Education
5. Provide Health Promotion and Disease Prevention
6. Manage Therapy/Care for Selected Patients in Whom Drugs are the Principal Method of Treatment (inclusive of disease management)

The first five standards of practice - basic IHS pharmacy services - already includes non-compensated clinical and cognitive services; for example, completion of all treatment plan elements of current visit (dose, interactions, adverse events, lab values, etc.), current status of health maintenance and wellness parameters, and appropriateness of follow-up for current health problems. Utilizing the full medical record (or electronic health record), pharmacists integrate care coordination and provide comprehensive services. These services optimize therapeutic outcomes and fit well within the core concepts of Medication Therapy Management (MTM) under Medicare Part D discussed later. The sixth standard of practice was developed to encompass expanded patient care services delivered by pharmacists - and truly represents an advanced practice commensurate with many services from other non-physician practitioners.

The evolution of pharmacists' clinical roles in federal pharmacy programs was made possible by certain practice setting variables including full access to medical records, interprofessional support and in most cases, the principle focus on health outcomes. Historically, there was less focus on revenue generation capacity of the practicing pharmacist in these roles. The focus was (and is) improved health care delivery and outcomes. However, because of the demand for services, acceptance of pharmacists in prescriptive roles by physicians, willingness of the entire system to work collaboratively with pharmacists in these innovative roles, and positive patient outcomes, programs were continued. It is not surprising that expanded clinical practice roles occurred first in federal agencies like the IHS, VA, and the DOD due to these and other variables that supported innovation. In fact, in the 1970s, the IHS had already developed and implemented what the IOM proposed in its consensus report from 2009 regarding national directives to deliver interdisciplinary health care.[14] Additional examples of clinical pharmacy practice in the VA date back to 1995 and can be discussed in similar contexts.[21] Through the 1980s and 1990s, IHS pharmacists continued to provide American Indians and Alaska Natives, primarily located in rural and underserved communities, with advanced pharmacy practices that improved patient care and increased access to vital primary care services, disease management, and prevention services. Implementing a similar paradigm of health care delivery utilizing pharmacists may lessen the impending challenges of health reform - such as access to care, particularly with medically underserved and vulnerable populations.

Interprofessional Collaboration and Support

Substantial interprofessional support (from physicians, other NPPs, and administrators) exists for pharmacists practicing as providers in expanded clinical roles. George Halvorson, chairman and **CEO of Kaiser Foundation** Health Plan, Inc. and author of *Health Care Reform Now!: A Prescription for Change*, gave the keynote address at the 2009 Healthcare Information and Management Systems Society (HIMSS) Annual Conference and Exhibition. While speaking on the subject of much needed health reform, Halvorson declared that **"clinical pharmacists are the most underutilized members of the health care team."[22]** Expanded pharmacist-delivered patient care can be an essential component of any collaborative care model. The various services are easily integrated into CPAs that further define pharmacists' clinical privileges and patient care services. These services can be delivered via the PCMH model, disease management, CDTM, or any other type of patient care service.

Health reform calls for an integrated workforce that utilizes the skill sets of health care professionals across disciplines.[22,23] **Turf issues are age-old barriers to interprofessional practice that do not support any type of successful health reform. However, in many practice settings, the 'turf' issue is more a myth that needs to be dispelled than an actual barrier.** Collaborative practice currently exists internal and external to the federal pharmacy sector. In addition to the federal practice setting, **CPAs between physicians and pharmacists are directly authorized by 44 state pharmacy boards.[12]**

Appendix C displays a map of states that legislatively support collaborative practice between pharmacists and physicians. It is important to note, however, that because nuances exist between the terms "CDTM" and "CPA", interpretations can vary. CDTM tends to define the process by which a pharmacist may adjust therapy and manage medication use. CDTM and CDTM agreements are specific to medication use and management. However, CPAs may allow additional flexibility for both the physician and pharmacist to provide more comprehensive primary care and patient services, such as care coordination, disease management, disease prevention, and follow-up care. This added flexibility helps physicians to better meet the diverse and wide-ranging needs of individual patients and practice settings.

As discussed, 44 states allow for some form of collaborative practice, which means that the individual state pharmacy laws allow pharmacists to “initiate, modify, and/or discontinue drug therapy pursuant to a collaborative practice agreement or protocol”.[12] While this definition is very close to the pharmacy associations’ consensual term “CDTM”,[24] some states specifically address CDTM in their state practice acts and others do not. As a matter of fact, a few states address collaborative privileges to pharmacists under their medical acts. Another example of such inconsistency is when one state allows collaborative practice, but it is “limited” by restricting drug therapy management to a setting (e.g., hospitals only) or a drug class (e.g., oral contraceptives only in Maine). In May 2011, the governors of New York signed legislation to expand CDTM to teaching hospitals, moving the Empire state from a “Pending” status with the National Association of Boards of Pharmacy to “Yes” with regards to CDTM. This legislation increased the number of collaborative practice states to 44 in 2011 even though CDTM was already approved at non-teaching hospitals in New York.[12] These statistics, however, don’t truly represent the extent of CDTM since the remaining six states do not address collaborative practice but documentation in pharmacy journals shows that it exists. This ambiguity has pros and cons. Without specific regulations or guidance, state pharmacy boards can have more flexibility to regulate CDTM, prohibit the practice completely, or allow collaboration de facto if no one objects.

In 2008, a pioneering effort was undertaken by the National Clinical Pharmacy Specialist (NCPS) Program within the U.S. Public Health Service to illuminate physician-pharmacist collaboration through a respondent-driven survey and help dispel some of the myths of non-support. The NCPS Program, which now extends beyond the IHS and into the Bureau of Prisons (BOP), has been successful with physicians, medical staffs, and other stakeholder collaborations for 13 years. The program ensures consistency and quality of primary care for patients treated and managed by NCPS pharmacists. Within most literature reviews, the customary approach is to have pharmacists attest to the support they have received from physician. However, attestation and data collected from physician-only perspectives is much less common. To overcome this data gap, the NCPS Program developed a respondent-driven survey to seek the input of IHS physicians on the clinical and administrative impact of pharmacists delivering primary care services including disease management. **Physician-respondent support of this paradigm of health care delivery was decisive**:

- Demographics
  - 117 Physicians representing 13 states and 33 IHS and Tribal facilities responded.
  - 100% of the data collected came from physicians in facilities that have pharmacists practicing under collaborative practice agreements (CPAs).
  - 87.2% of the providers surveyed have worked or are currently working with a pharmacist who was recognized as a NCPS. As discussed, the NCPS Program helps to assure a standardized scope that includes specific prescriptive authority, laboratory authority and some physical assessment privileges.
- Results
  - **96% of physicians who responded reported some benefits, including improved disease management outcomes, increased return on investment, allowing the physician to shift their workload to more critical patients, increased patient access to care and more.**
  - 76.8% of physicians surveyed "agreed" or "strongly agreed" that from their experiences, the services provided by pharmacists provide adequate evidence to recognize them as billable non-physician practitioners.
  - 85.2% of physicians surveyed "agreed" or "strongly agreed" that NCPS certified pharmacists have adequate knowledge/training to provide clinical services.
  - 71.6% of physicians felt that clinical services such as disease management provided by pharmacists are necessary to optimize patient care.
  - 88% of physicians felt this collaborative practice with pharmacists in their facilities has improved overall primary patient care.

A more comprehensive summary of findings can be found in Appendix D. Given these results, **it is the perspective of physician respondents within this survey that the positive outcomes of pharmacists delivering primary care services - with appropriate privileges from the physician or medical staff - are undeniable.** Federal and PHS Pharmacy have been aware of this support for many years. Collecting data from physicians directly involved in this model of health care delivery should help dispel some of the misperceptions of collaboration and demonstrate the substantial amount of positive patient and health system outcomes.

Collaboration between the pharmacist and physician also provides the patient with higher quality, safer, and more comprehensive health care via the team approach. Pharmacists are uniquely qualified to provide additional patient care services through these collaborative and synergistic efforts that compliment physician services. Advanced pharmacy practice models benefit many consumers, including other primary care providers, patients, and administrators. The models also provide benefit to third-party payers in the form of preventive care, quality care, patient safety and cost-containment. Other countries are also working toward integrating the pharmacist into the primary care setting. In Canada, the IMPACT study has placed pharmacists at primary care sites in Ontario, Canada with promising results.[25] In the United Kingdom, "Pharmacy in England: building on strengths – delivering the future," proposes a model that involves the pharmacist in the community setting, as well as schools, care homes, prisons, health centers, and general practice settings.[26] In the United States, specifically in federal pharmacy, this integration has been in place for decades.

In 1997, conclusions reached by the MedPAC stated that "in general, physicians support the concept of collaborative drug management,"[11] suggesting that ongoing involvement would need to be clearly defined. During this discussion, the American College of Clinical Pharmacy (ACCP) offered that in these relationships, the physician would diagnose the patient and decide upon initial treatment. The physician would then authorize the pharmacist to select, monitor, modify and discontinue medications as necessary.[11] In the federal pharmacy sector, both concepts were already applied in practice. As seen over the last decade, support was evident in the non-federal sector, yet less than optimal. More recently, however, an editorial in the AJHP noted that a number of medical society groups have concluded having pharmacists working directly with them is critical. Examples cited included the Society of Critical Care Medicine, the Infectious Diseases Society of America, and the National Association of Epilepsy Centers.[27]

From an academic perspective, the American Association of Colleges of Pharmacy (AACP) annually convenes an Argus Commission comprised of the five immediate past AACP presidents. The 2009-2010 Commission examined the pharmacist's contribution to primary health care delivery in the context of national health care reform. The Commission's President subsequently invited representatives from education associations of various disciplines recognized as primary health care providers. This included providers and representatives from:

- American Dental Education Association
- Association of American Medical Colleges
- Physician Assistant Education Association
- Emory University School of Medicine
- American Association of Colleges of Nursing
- School of Medicine and Health Sciences, The George Washington University
- Association of Schools of Public Health
- Association of American Colleges of Osteopathic Medicine

Two distinct findings resulted: 1) All participants agreed that medication use factors were important elements of quality primary care, including patient education, monitoring, and safety considerations, and 2) All of the disciplines represented embraced interprofessional education (IPE) and practice, and specifically recognized the importance of IPE in addressing deficiencies in the chronic care patient management model.[28]

More recently, an editorial was released from the Chair of the American Medical Association Board of Trustees, Dr. Ardis Dee Hoven. The editorial discussed 'Doctor-pharmacist teamwork' that can apply to many settings. It recognized that collaborative drug therapy management can be a positive and powerful way to enhance patient care and reduce costs. It also noted that successful collaborations already exist.[29] This was a positive step in the right direction with our largest and most renowned medical society. This discussion continues and has involved the pharmacy profession's largest organization, the American Pharmacists Association (APhA).

Focus Point 2: Recognition as Health Care Providers

Pharmacists that deliver patient care services, including management of disease through medication use, should be recognized as health care providers and practitioners as defined in the Social Security Act and other health legislation and policy.

Advanced Pharmacy Practice Models

In some states, pharmacists are recognized for their expanded services, in policy and privileging, through CPAs, or other collaborative practice arrangements - and in rare cases, through licensure as clinicians. **Although separate licensure for pharmacists in these roles is not necessarily needed, current recognition by some states reflects a precedent that primary care services (post-diagnosis) are successfully delivered within the current scope of pharmacy practice through CPAs**. With this level of state recognition, pharmacist-delivered patient care has the potential to be sustained through commensurate compensation and support. For example, some progressive state Medicaid programs (New Mexico, Arizona, South Dakota, and Minnesota) have recognized the benefits of these pharmacist services and already compensate pharmacists for health care services more commensurate with other non-physician practitioners via fee-for-service or more frequently as a flat-rate fee. Even in practice environments without fiscal barriers, this type of recognition and scope, reflective of pharmacist-delivered direct patient care, allows for advanced practice models to flourish and obtain greater support from colleagues and administrators.

Discussion of the IHS pharmacy practice model offers an appropriate example. In response to years (1970-1995) of IHS medical staff support of advanced pharmacy practice, **former IHS Director Michael Trujillo, MD, MS, MPH released a Special General Memorandum (SGM 96-2) in 1996. This groundbreaking document recognized Clinical Pharmacy Specialists (CPSs) as primary care providers with prescribing authority.**[30] In 1997, representatives from the IHS pharmacy program and leaders from the Health Care Financing Administration (HCFA), renamed Centers for Medicare & Medicaid Services (CMS) in 2001, discussed the recognition of pharmacists as primary care providers.[31] There was little disagreement about the expanded scopes and levels of service provided. However, a recommendation was made by CMS to develop a uniform and national credentialing program that would assure consistency and quality of care for patients treated or managed by pharmacists in the IHS. The IHS promptly responded to the recommendation made by CMS with the development of the NCPS in 1997.[31]

Through CPAs, many IHS pharmacists deliver direct patient care through disease management including, but not limited to, anticoagulation, dyslipidemia, congestive heart failure, coronary artery disease, diabetes, asthma, hypertension, end-stage renal disease, pain management, and tobacco cessation.[31] They are uniquely qualified as experts in drug therapy and currently function with expanded scopes in many settings where they perform physical assessment, have prescriptive and laboratory authority, formulate clinical assessments, develop therapeutic plans, provide patient education, care coordination, and follow-up care, manage both acute and chronic disease, and provide many other cognitive clinical services.

These patient care services are delivered by pharmacists once an initial diagnosis is made, which is similar to those services provided by other primary care providers and non-physician practitioners. Over the last 13 years, 278 IHS pharmacists have been certified by the NCPS Program. Currently, there are 179 actively practicing NPCS pharmacists that are increasing access to care and improving quality of care in over 41 sites and 16 states. To become privileged at a particular site within the IHS, a local medical staff and physician must observe and attest that the pharmacist is a competent health care provider. This assures oversight and is a physician-driven and local privileging mechanism. A CPA is developed between the medical staff and the NCPS pharmacist. The CPA identifies the scope of medical conditions the NCPS pharmacist is privileged to manage once the diagnosis is made. Pharmacists, as demonstrated later in this Report, have been able to improve consumer outcomes including clinical, administrative (i.e., increase physician time for more critical care and increased patient access to care), and cost-effectiveness. **Thus, pharmacists in these clinics perform direct patient care services and document the findings similar to any other health care provider, but with recognition and revenue generation capacity only in a limited number of states.** Administrative barriers increase the potential that patients will not be able to access primary care services. For example, access to health care delivery for a medically underserved population may be directly impacted. In some practice settings, pharmacist-delivered care may be the only care available - aside from waiting lists for appointments with overburdened primary care staff.

The Health Resources and Services Administration (HRSA) also strongly supports the role of the pharmacist and the provision of pharmacy services to patients with multiple chronic conditions through an interprofessional team. In 2008, the Senate Appropriations Committee Report "encourages HRSA to establish a pharmacy collaborative to identify and implement best practices, which may improve patient care by establishing the pharmacist as an integral part of a patient-centered, interprofessional health care team."[32] HRSA began its work by studying the leading practices in patient safety, clinical pharmacy services and health outcomes identified in organizations found to be "early adapters" across the nation.[33] In addition to many of the high performing sites in the safety net setting, HRSA also utilized and compiled the decades of experience and leading practices established by the IHS advanced pharmacy practice models. These IHS models can assist health systems, clinics, and communities learn, replicate, test, and adopt these practices to improve health outcomes and reduce adverse drug events. In October 2007, HRSA planned and implemented the Patient Safety and Clinical Pharmacy Services Collaborative (PSPC), where teams of health care providers, including HRSA supported entities and their partners from communities across the nation, are working to transform the delivery of patient care. Using a patient-centered approach, the teams integrated evidence-based clinical pharmacy services into the care and management of high-risk, high-cost, complex patients. Currently, the most successful teams involve clinicians from multiple disciplines, together with their organizations' leaders, understanding, growing, and tracking the impacts of clinical pharmacy services. This integrated interprofessional approach is revising traditional health care team roles and both maximizes and leverages the expertise of the entire team so the patient receives the best quality care. Based on data collected from PSPC teams, 54 percent of patients once identified as "out of control" or not optimally medically managed, are now

"under control" across a range of chronic conditions using standardized measures. Also, adverse drug events (ADEs) or actual events that cause patient harm have fallen by an average of 49 percent for this high-risk patient population. In its third year, the PSPC has expanded to 127 community-based teams in 43 states.[33] Teams continue the rapid spread of leading practices found to improve patient safety and health outcomes most effectively in a health home model. Year three will work to expand and spread to larger patient populations that need this transformation delivery system.

Outside the federal sector, there are some progressive models that have developed, as noted in New Mexico and North Carolina. In both states, pharmacists practicing in advanced clinical scopes are recognized more broadly through policy, legislation, and even licensure. Additionally, both states have identified an advanced scope of practice through CPAs and compensate similarly for a primary care visit. New Mexico's Pharmacist Clinician (PhC) program has developed an appropriate compensation mechanism through its state Medicaid process. This will be discussed in more detail within Focus Point 3.

In North Carolina, the Clinical Pharmacist Practitioner Act became effective July 1, 2000 and opened the door for collaborative practice opportunities. This successful implementation of legislation acknowledged the importance of pharmacists and collaborative practice. The state of North Carolina has offered credentials to pharmacists who wish to become a Clinical Pharmacist Practitioner (CPP). In this model, if the pharmacist meets certain qualifications, he or she is approved by the Medical and Pharmacy Boards of North Carolina as a CPP, and is assigned a provider identification number.[34] Required credentials, in addition to a North Carolina pharmacist license and agreement with supervising physician, include one of the following: 1) certification (either from the Board of Pharmacy Specialties, or is a Certified Geriatric Pharmacist) or an American Society of Health-System Pharmacists (ASHP) Residency including two years of clinical experience, or 2) a Doctor of Pharmacy (PharmD) degree with three years of experience, plus completion of one North Carolina Center for Pharmaceutical Care (NCCPC) or Accreditation Council for Pharmacy Education (ACPE)-approved Certificate Programs, or 3) a Bachelor of Science (BS) degree with five years of experience, plus completion of two certificate programs from NCCPC or ACPE.[34,35] North Carolina's example of certification qualifications offers needed flexibility within the profession. This is important because many different paths arrive at the same place - clinical competence. This flexibility is also seen in the New Mexico PhC program. Once credentialed, a North Carolina CPP is able to order, change, or substitute therapies, and order laboratory tests, while under the purview of a CPA with a licensed physician.[36] CPAs are kept "broad and generalized" to allow choice of therapy based on individual patients, and also include a plan for a weekly "quality control" meeting between the CPP and supervising physician. In these meetings, the physician reviews the pharmacist's orders.[35]

Pharmacy Education and Training

Because pharmacy practice has already shifted to allow more clinical services, the nation's colleges and schools of pharmacy have followed suit with appropriate education and training to support these roles. The entry-level degree, which has been elevated from a BS in Pharmacy to a Doctor of Pharmacy, requires additional years of training. This has increased over the years from four years of training to five, and now to a minimum of six years. The core curriculum includes pathophysiology, pharmacology, therapeutics, clinical problem solving, laboratory monitoring, and physical assessment skills for many diseases. Student pharmacists are required to complete hospital rounds with medical students and physicians. The latest curricular guidelines from the Accreditation Council for Pharmacy Education (ACPE) also mandate early pharmacy practice experience training/shadowing in a physician's office and clinical hospital setting in order to expose student pharmacists to a collaborative practice environment and give them insight into the responsibilities and decision-making skills that physicians perform daily.[37] Most universities that have both medical and pharmacy colleges have built interprofessional practice into the curriculum and teach both professions' students together to provide patient care. Pharmacists' years of education and level of training is aligned with that of dentists and surpasses, in many examples, the amount of education and training required of other non-physician practitioners.

All pharmacy school graduates are required to take the North American Pharmacist Licensure Examination (NAPLEX), a national, comprehensive, and standardized board exam. Having a standardized licensing exam ensures that all pharmacy graduates are held to high and uniform expectations.

Post-graduate training is encouraged throughout the profession, including first and second year residencies, fellowships, Master, and Doctoral-level training. Residencies are one to two years in length and are accredited by the American Society of Health-System Pharmacists (ASHP). Pharmacy residency programs, both in hospitals and in the community, serve to focus a new pharmacist's skills for specialization in the management of a specific or multiple disease states. Residency training is hands-on, multi-disciplinary, and clinically comprehensive. The VA has a robust residency program with approximately 159 sites. The IHS offers 18 progressive practice residency sites and is currently graduating approximately twenty-two resident pharmacists a year. The Bureau of Prisons currently has one residency site.

Clinical specialty certifications are widely available for pharmacists. Pharmacists may become board certified by the Board of Pharmacy Specialties (BPS) as a pharmacotherapy specialist (BCPS), nuclear pharmacist (BCNP), nutrition support pharmacist (BCNSP), oncology pharmacist (BCOP), psychiatric pharmacist (BCPP), or ambulatory care pharmacist (BCACP). BPS regulates applicant eligibility and content of the examination.[38] Although BPS designations are granted to individuals who pass the examination, this board certification is not required of pharmacists. These designations are not analogous to the board specialty examinations that physicians are required to pass for specialty licensure.

Another specialty certification available to pharmacists is the Certified Geriatric Pharmacist (CGP), established by the American Society of Consultant Pharmacists.[31] Additional certifications that pharmacists may pursue include Certified Diabetes Educator (CDE), Board Certified Advanced Diabetes Management (BC-ADM), Infection Control Professional (ICP), a Certified Professional in Healthcare Quality (CPHQ), a Certified Professional in Healthcare Information and Management Systems (CPHIMS) and a Chronic Care Professional (CCP).[39]

This Report, while supportive of the BPS and other credentials, recognizes that certain types of credentials beyond the NAPLEX should not limit the professional scope of pharmacy. The Report also communicates (as discussed under the New Mexico and North Carolina models) that with the exception of the NAPLEX, flexibility of advanced practice pharmacist qualifications is necessary to ensure competence. The BPS and other credentialing programs require satisfactory completion of a thorough exam; they do not require direct observation of competence by medical personnel. Direct observation of competence however, can be required within a collaborative practice agreement (CPA) in order to gain local medical privileges. **Each practice environment should consider what combination of credentials, training, and experience is most appropriate, yet remain flexible to allow for all qualified and competent pharmacists the opportunity to improve outcomes.** Current training and education after six years of focused study on therapeutics and related topics, the subsequent NAPLEX exam, and competency-based experience have proven to be both adequate and successful, and are supported through decades of collaborative physician-pharmacist practice.

Pharmacists undergo a very similar level of education compared to other non-physician practitioners. In all pharmacy school curricula, a pharmacist will need a minimum of six years to complete the didactic education portion, not including a residency. Physician Assistants' (PA) educational programs consist of either a five-year combination bachelor's/master's degree, or a full-time two-year professional program after the completion of a bachelor's degree with appropriate prerequisites.[40] Nurse Practitioners (NP) must first become a registered nurse (through a bachelor's, associate's, or diploma program), which can be accomplished in under four years, and then complete a master's program to obtain practitioner certification, including a two-year course of full-time study.[41] Both PAs and NPs are trained to perform physical examination, diagnose medical conditions, and in most states, prescribe medications to treat their patients. Both of these professional types also focus on patient education and disease prevention.[40,41] In both cases, these highly skilled, recognized, and appropriately compensated health care providers have the same amount and similar type of education as pharmacists.

Compared to PAs and NPs, the educational preparation of pharmacists emphasizes patient assessment and therapeutic monitoring, which establishes pharmacists' expertise in the comprehensive management of disease through medication use. The emphasis on drug therapy in the pharmacy curriculum is inextricably linked to providing quality care subsequent to a diagnosis. Pharmacy school curricula also include diagnostic and physical assessment coursework as well. As discussed in Focus Point 1, once a diagnosis is made, especially in the case of chronic disease, most of patient care (up to 80 percent) is geared to management of disease through drug therapy. Considering these patient care needs, the pharmacist is uniquely

qualified to compliment the diagnosticians, such as physicians, to provide comprehensive care. Other NPPs similarly take on roles that provide value related to their expertise. It is also a good example of how health reform implementation can maximize the skill sets of health care professionals across disciplines.[23] The amount of education or training a pharmacist completes should not be challenged in this discussion. Rather, the most pressing challenge is to facilitate consumer understanding of the proven advantage of having pharmacists involved in the delivery of health care - including provision of quality primary care to meet health system demand. Those consumers include legislators, administrators, health leadership, insurers, and other third party payers.

The federal sector is not the only system that supports pharmacists in advanced practices. Although New Mexico and North Carolina were mentioned as having specific programs with advanced practices, forty-four (44) states (as of May 2011) across the United States support collaborative drug therapy management (CDTM) in their Board of Pharmacy policy or by-laws.[12,42] This is encouraging as it demonstrates that pharmacists are supported by their state boards and that performing these expanded clinical duties (respective of each state policy) is within their legal scope of practice. These collaborative practices range from immunizations, to medication therapy management, to disease management with privileges including prescriptive and laboratory authority.

As another example, "health care providers" are generally seen as having prescriptive authority. Much like pharmacists in the IHS and VA, a growing number of states (such as New Mexico, North Carolina, and Massachusetts) already allow for prescriptive authority to pharmacists through collaborative practice. In February 2011, the Drug Enforcement Administration (DEA) granted prescriber numbers to pharmacists in Massachusetts (1 of 7 states).[43] This important recognition of pharmacists as mid-level practitioners allows pharmacists working under CDTM agreements to prescribe controlled substances.

The existing roles of pharmacists and their current delivery of patient care in multiple settings based on health system demands necessitates further evolution of legislation and policy. **Recognition of pharmacists' provision of additional levels of patient care through legislation and policy will promote the support needed (increased private sector response and adequate compensation mechanisms) to fully sustain these value-added services that are proven to improve patient outcomes and health care delivery.**

In the Affordable Care Act (ACA), there are several references to pharmacists as "part of a health team" (Section 3502), and "pharmacist-delivered and pharmacist-provided services" (Section 3503). In addition, Section 3503 authorizes Medication Management Services in Treatment of Chronic Disease to be provided by licensed pharmacists as a collaborative, multidisciplinary, interprofessional approach.[23] **Recognizing "Pharmacists (Pharmacist-Delivered Patient Care Services)" in the Social Security Act as health care providers is the appropriate evolution of legislation that will expand the utility and eligibility of pharmacists to better address the nation's health care demands, and improve patient and health system outcomes.**

Focus Point 3: Compensation Mechanisms

Current compensation mechanisms for pharmacists in advanced practice roles need to expand and reflect the level of patient care services provided. The lack of compensation mechanisms is a current barrier for optimal health system outcomes, and the expansion and sustainability of pharmacist involvement.

Essential for Sustainability

Snella, et al. suggests that compensation, rather than reimbursement, is the proper term to apply to the payment of pharmacists who are recognized as health care providers. Compensation refers to "payment for a service that reflects both reimbursement for the cost of an item or service and the value added by the provider."[44] Pharmacists functioning as health care providers perform cognitive patient care services that add value to the patient's care. The current reimbursement model indicates that pharmacists should only be paid for a drug product or device, with little or no payment for the cognitive and value-added portion of the service.

At the 2008 World Health Care Congress, health stakeholders recognized that aligning reimbursement with the quality of care is expected to drastically improve the health care system as a whole.[45] This suggests a performance-based compensation. Focus Point 4 illustrates hundreds of evidence-based outcomes within many different advanced pharmacy practice models. These models demonstrate that after rigorous collection and analysis of data within the appropriate practice environment, including expanded pharmacist privileges, outcomes improve. Pharmacists who demonstrate positive patient and health system outcomes, and perform a level of care with similar impact to Nurse Practitioners, Physician Assistants, or Physicians need to be equally compensated. Improved parity in compensation for pharmacists providing similar levels of care through disease management or other patient care services is imperative if these valuable and sought-after resources are to continue.

In both the public and private sectors, health systems are challenged to sustain any clinical service without the ability to generate revenue from the service provided. Although pharmacists do play a larger patient care role in many federal settings, sustainability is threatened by the lack of commensurate compensation.

As an example, federal funding for the IHS falls below the mainstream health plan annually. Because of this continual resource disparity gap, fiscal appropriation for the IHS now necessitates revenue generation from Medicaid, Medicare, and other third party payers. Consequently, many progressive practice settings are fast approaching a crossroads and must decide whether to continue value-added services that have been provided without compensation and potential revenue generation, or discontinue them, further escalating problems with access, quality, and cost-effectiveness. The IHS continues to demonstrate successful advanced pharmacy practice models in many states. However, states where pharmacists can generate additional revenue through Medicaid programs greatly assist in

sustaining these services. These states either recognize pharmacists as health care providers for clinical services to Medicaid recipients (New Mexico and North Carolina) or provide additional compensation for cognitive pharmacist services (Arizona, Minnesota, South Dakota). **However, the level and consistency of compensation vary greatly. These variations may be significant enough to create a disparity of health care services offered to certain state populations with a need for a health care home or with other health inequities.**

HRSA funded a study to collect clinical pharmacy services outcomes data from one of its networks of HRSA-supported health centers. The study was conducted by an impartial, objective, non-pharmacy, research corporation: Mathematica Policy Research, Inc. Mathematica noted that, "The current financing environment creates a major challenge to sustainability of these services."[46] Clinical pharmacy services could feasibly assist both patients (through clinical outcomes) and providers (by reducing time constraints). However, Mathematica suggested that reconsideration of payment policies are needed to recognize these pharmacy services as a legitimate approach to care.[46] These conclusions suggest that clinical pharmacy could play a more substantial role in the delivery of care if supported by appropriate compensation mechanisms.

In March 2011, the Patient-Centered Primary Care Collaborative (PCPCC) released *Better to Best: Value-Driving Elements of the Patient Centered Medical Home and Accountable Care Organizations.* This consensus report presents four themes or "value-driving elements" that either require urgent overhaul (enhanced access, care coordination) or are essential tools (health information technology, payment reform) to optimize value in health care.[47] Regarding payment reform, the report reviews the leading proposed models:

- Fee-for-service + management fee + performance model
- Episode of care (case rate model)
- Risk-adjusted comprehensive payment and bonus
- Accountable care organization

Pharmacists with physician-approved patient care privileges, performing in expanded clinical roles of disease management, and other patient care functions could seamlessly be a value-added piece to any of these models. **One advantage of the decades of evidence-based performance is that our work is currently built around demonstrating positive outcomes that subsequently decrease overall health care costs.** The pharmacy profession has frequently been called upon to "prove" its capacity in demonstrating outcomes. This Report collates some (but not all) of the success. Thus, pharmacists could be compensated appropriately within any one of these models based on the level of service provided.

The most significant and influential payer for these services is the CMS. Many additional third party payers follow the CMS compensation structures and guidance. Pharmacists are not currently recognized by CMS as health care providers, potentially impeding some private and federal sector patients from receiving optimal quality patient care services. As a point of comparison, the Social Security Act appropriately recognizes a number of other health care

professionals as “providers or practitioners,” including physician assistants, nurse practitioners, certified nurse midwives, clinical social workers, clinical psychologists, and registered dieticians or nutrition professionals. Recognition of pharmacists as health care providers in the Social Security Act under Title 18, Part E, Section 1861 is a critical addition of language needed to sustain these services to meet the growing demands of access to care as well as serving vulnerable and rural populations. CMS payment policies and definitions can then parallel pharmacists’ current and critical role to improve health care delivery.

Legislation History

In May 2001, Senator Tim Johnson (D-SD) introduced the Medicare Pharmacist Services Coverage Act of 2001 into the Senate. The bill proposed changes to the Social Security Act to provide for coverage of pharmacist services under Part B of the Medicare program. Senator Johnson expressed that the Act will “reform Medicare by recognizing qualified pharmacists as health care providers within the Medicare program and make available to beneficiaries important drug therapy management services that these valuable health professionals can and do provide. These services, which are coordinated in direct collaboration with physicians and other health care professionals as authorized by State law, help patients make the best possible use of their medications.”[48] This legislative motion demonstrated recognition, at the lawmaking level, of the value of pharmacists as health care providers. The bill was referred to the Committee on Finance, only to be cleared from the books at the end of the session.[49]

In August 2001, the Medicare Pharmacist Services Coverage Act of 2001 was introduced into the House of Representatives. After being referred to the Subcommittee on Health, it remained there until cleared from the books at the end of the session.[50]

In 2004, the Medicare Clinical Pharmacist Practitioner Services Coverage Act of 2004 was introduced to propose changes to the Social Security Act to provide for coverage of clinical pharmacist practitioner services under Part B of the Medicare Program. This was the first time that legislation appropriately addressed a change to the Social Security Act that would add the definition of Clinical Pharmacist Practitioner to the list of non-physician practitioners already being reimbursed for their services through Medicare. A month later, the bill was referred to the House Subcommittee on Health, and no further action was taken.[51]

In 2008, the Medicare Clinical Pharmacist Practitioner Services Coverage Act of 2008 was introduced to propose changes to the Social Security Act to provide for coverage of clinical pharmacist practitioner services under Part B of the Medicare Program.[52] The bill was referred to the House Subcommittee on Health, and no further action was taken. Again, this bill demonstrated that expanding compensation through Medicare Part B for the cognitive pharmacy services these clinicians provide is the next logical step.

In 2010, the Medicare Clinical Pharmacist Practitioner Services Coverage Act of 2010 was introduced to propose changes to the Social Security Act to provide for coverage of clinical pharmacist practitioner services under Part B of the Medicare Program. This bill was assigned to

the Subcommittee on Health on May 27, 2010, but no further action was taken.[53] It was cleared from the books with the convening of the 111th Congress in December 2010.

As of July 2011, there have been three pharmacy-related bills that have been introduced into the 112th Congress, 1st Session.

- H.R. 891 – The Medication Management Therapy Benefits Act of 2011 proposes to amend Part D of title XVIII of the Social Security Act to promote medication therapy management under the Medicare part D prescription drug program.[54]

- S. 48 – The Pharmacist Student Loan Repayment Eligibility Act of 2011 proposes to amend the Public Health Service Act to provide for the participation of pharmacists in National Health Services Corps programs, and for other purposes.[55]

- S.274 – The Medication Therapy Management Empowerment Act of 2011 proposes to amend title XVIII of the Social Security Act to expand access to medication therapy management services under the Medicare prescription drug program.[56]

Multiple attempts to change national legislation through bills have been proposed in the last 10 years. It appears state-specific bills may contain nomenclature that is limited in such a way that documentation, support, or explanations are insufficient to justify the change. **Attempts have been made to consult the most experienced, evidence-based and innovative federal pharmacy systems (that have advanced the profession for the last half-century); however process barriers have prevented further discussion. This Report collates many of these data points for the first time and can be utilized by health leadership to advance this discussion.**

On a state level, New Mexico Medicaid pioneered a pharmacist-directed compensation mechanism that has experienced success for a number of years. In the mid-1990s, pharmacists worked with the State of New Mexico Board of Pharmacy and Medical Examiners to develop an advanced practice license designated as a Pharmacist Clinician (Ph.C).[57] New Mexico legislation has recognized Ph.Cs, along with Physician's Assistants and Nurse Practitioners, as mid-level providers with prescriptive authority. As a licensed New Mexico provider, the Pharmacist Clinician can apply to become a Medicaid provider, and is therefore eligible for Medicaid reimbursement.[58] This program offers an appropriate level of compensation for eligible pharmacists providing an advanced level of care. This state recognition demonstrates that pharmacists can be recognized successfully with regards to receiving an appropriate level of compensation, and with experience and local privileging (including some level of physician supervision). Although the delineation of scope is through separate licensure in the state of New Mexico, it is not necessarily needed as new models of credentialing and privileging are considered. With additional competency training and assessment by physician supervisors, a pharmacist can be privileged through a CPA and still remains within the current scope of state licensure.

Another example of a state-level attempt took place in Minnesota. In 2001, Minnesota Medicaid policy recognized "Physician Extenders" as primary care providers, making anyone falling into their classification system eligible for reimbursement. The clause listed examples of Physician Extenders and did not specifically name pharmacists. Details of the definition were questioned. State officials, although supportive of the perspective, were unable to determine whether this list was all-inclusive or merely listing examples of "Physician Extenders" based on the level of care provided was sufficient. If the latter, pharmacists providing and documenting a similar level of care could be considered physician extenders. A final determination was not made at that time. Since then, Minnesota has been innovative in their advancement of payment mechanisms for pharmacists providing clinical patient care.

One key point to consider with these programs and any others that may develop from the concepts of this Report is that not all pharmacists will be eligible for this level of compensation. **Pharmacist's eligibility for higher levels of compensation commensurate with other primary care providers should be based upon the level of service provided.**

Medication Therapy Management (MTM) under Medicare Part D

Currently, pharmacists are eligible to receive some compensation for Medication Therapy Management (MTM) through Medicare Part D. CMS designed these programs (MTMP) to ensure optimal therapeutic outcomes for targeted beneficiaries through improved medication use and reduce the risk of adverse events.[59] MTM programs are administered by Prescription Drug Plans (PDPs) and are required to be developed in cooperation with licensed and practicing pharmacists and physicians. However, numerous policy constraints limit patient participation in these programs even with the 2010 CMS enhancements.

- Medicare Part D restricts patient eligibility: Currently, only senior age, disabled, and low-income patients are eligible for prescription benefits and MTM services via Part D. However, disease management and all other patient care services occur at any age within our U.S. health system as both a preventive measure for progression or exacerbation of chronic disease, and as a treatment measure.
- Patients must be a Medicare Part D participant: For those patients meeting the Medicare Part D eligibility criteria, monthly premiums payable directly by participants are required. In the current IHS system for example, where 100% of health care expenses for eligible patients are covered, the patient-perceived benefit of paying monthly premiums possibly reduces participation in MTM services.
- Eligibility for MTM services varies among the PDPs: Patients who suffer from co-morbid chronic diseases like diabetes, hypertension, dyslipidemia, must take multiple Medicare Part D-covered prescription medications, and must incur at least $3,000 in Medicare Part D drug expenses annually in order to qualify for MTM services.[59] CMS allows the PDP to define certain eligibility parameters: number of medications a patient must be taking, number of chronic conditions the patient must have, and specific diseases covered. The PDP also defines whether all drugs are covered, only disease-specific drugs are included, or only specific drug classes are included. Because of specific targeting

criteria, patients who may need MTM services but do not meet the plan's criteria will not be able to participate. MTM compensates pharmacists for a subset of cognitive services they can provide in only some of our sickest patients.

- Enrollment has been historically low: In 2006, approximately 10% of Medicare Part D-enrolled participants met the criteria for MTM services. More recent program years show a slight increases to 12%.[60]
- MTM under Part D does not incentivize the health system to focus on prevention: The growing incidence of various complex disease states such as cardiovascular diseases, heart failure and hypertension are affecting patients at earlier stages of their lives.[61] These younger patients require pharmacists to spend significant amounts of time and resources managing their health care needs, but without a compensatory mechanism for the pharmacist's cognitive services. This delay of care seems to go against current medical practice and withholds value-added, preventive, cost-effective, and patient-centered services until the customer has progressed to a more critical state of health.
- Part D Sponsors can determine which discipline of provider to deliver their MTM services: Although pharmacists are specifically named by CMS for MTM delivery, and currently provide 99.9% of services, other qualified providers such as nurses, physicians, and other Non-Physician Practitioners represent health care alternatives for utilization in MTM programs.[59]

This Report recognizes ongoing and expanded Medicare Part D reimbursement for MTM services is critical for the advancement of the pharmacy profession in multiple settings. Many MTM advocates are aware that expansion of eligible beneficiaries, as well as potential increases in levels of compensation, will need to take place in order to make MTM more applicable in a wider variety of pharmacy practice settings. **This Report supports expanded MTM programs and other pragmatic solutions to the barriers of eligibility requirements.**

From PHS's ongoing pharmacy experiences, MTM Part D is utilized when patients fit the restrictive criteria and pharmacists have the time to complete additional paperwork needed to obtain limited reimbursement. The medication therapy management model improves outcomes; however, eligibility restrictions neither foster cost-effective or efficient care nor promote comprehensive health, disease management, nor prevention of progression of disease or primary prevention. Although rates and frequency of compensation for MTM services are well defined in most Medicare Part D plans, they may not be adequate to support or sustain provision of these services. Also, MTM service opportunities are offered only periodically and appear primarily targeted toward expanded patient medication profile reviews and/or physician intervention, including identification of drug-related problems, generic conversion potential, and medication adherence. While patient medication reviews clearly reduce and avoid medication-related adverse effects, it is only one component in the potential array of patient care provided by pharmacists. Furthermore, the rate of compensation offered by most Part D sponsors does not equate to the degree and complexity of care delivered in pharmacist-delivered patient care visits. As described above, the breadth of knowledge and skill required by any physician, NPP, or pharmacist to deliver primary care is not reflected with current MTM Part D compensatory rates. While periodic, limited cognitive compensation is openly offered

through MTM, there remains apprehension within the PHS Pharmacy program to contract with PDPs offering MTM Programs due to questionable cost-effectiveness and resources to implement on a national basis. In the private sector, MTM has improved the utilization of clinical pharmacists; however growth is slow, in part because of patient restrictions and inadequate compensation.

Restrictions, eligibility constraints, and fiscal considerations limit the feasibility of MTM Part D becoming a central (or substantial) source of compensation or revenue for services for any health professional. Upon literature review, no studies of other NPPs (eligible for MTM compensation) have been found to utilize MTM as their primary source (or even an adequate source) of compensation. Yet, at this time, it is basically the sole mechanism for compensating pharmacists for cognitive and/or primary care services.

Even the largest of industry giants can identify a potential barrier in the utility of MTM. Walgreen's Chief Executive, Greg Wesson, wished to have his "army of coaches" take on a greater role for President Barack Obama as the White House and Congress came together to expand health insurance coverage to the nation's uninsured. Wesson says his "company's efforts go beyond just filling prescriptions" as part of a solution he calls medication therapy management, where "helping patients stick to taking their medications and making better and more cost-effective choices...could help save billions of dollars in medical care costs." But Wesson also says that "to make MTM work, pharmacies would need to be paid more, and the payments would need to include the time to provide patient consultations, plus wellness advice and other tips." [62]

As noted, pharmacists practice in many different settings. The provision and core concepts of MTM, under Medicare Part D, are not intended to parallel the comprehensiveness of a primary care practice or visit to a health care provider. In a 2011 published study by Kucukarslan et al., evidence suggests MTM services are capable of providing measurable improvements in two areas: patients who are newly diagnosed with a chronic condition and patients who have not yet achieved their therapeutic goal.[63] However, pharmacy practice settings best suited for MTM services with regard to the Medicare Part D model often lack access to a full patient health record, adequate staffing and guidance, and the prescriptive or laboratory privileges usually needed for comprehensive pharmacist-delivered patient care. MTM services in all practice settings need to continue in order to improve health system and patient outcomes; however, changes in eligibility, compensation mechanisms, and barriers to implementation need ongoing advancement and support.

Focus Point 4: Evidence-Based Alignment with Health Reform

Through the delivery of patient care services, pharmacists improve outcomes, increase access to services for medically underserved and vulnerable populations, improve patient safety, shift time for physicians to focus on diagnosis and more critically ill patients, improve patient and provider satisfaction, enhance cost-effectiveness, and demonstrably improve the overall quality of health care through evidence-based practice.

Quality of Care and Patient Outcomes

Pharmacists involved in the delivery of patient care services with appropriate privileges across many practice settings have been successful at improving patient outcomes. The implementation of more expanded pharmacy practice models demonstrates improved performance measures through evidence-based outcomes. Hundreds of peer-reviewed publications and sustained interprofessional support indicate that this successful practice is both evidence-based and accepted as an additional model of health care delivery with improved access to patient care services. As presented below through large database reviews, pharmacist-delivered patient care services clearly have a positive impact on disease outcomes (prevention and management), quality care, access to care, cost-containment, patient safety, and overall health system efficiency.

- Diabetes: Machado et al. reviewed and identified 302 articles, including 108 pharmacists' interventions encompassing 2,247 patients in 16 studies. They found a significant reduction in hemoglobin A1C levels in diabetic patients in the pharmacist intervention group.[64]
- Hypertension: Machado et al. performed a literature-based meta-analysis that involved 203 articles, 2,246 patients in 13 studies. They found pharmacists' interventions significantly reduced systolic blood pressure.[65]
- Dyslipidemia: Machado et al. found 48 studies, of which 23 met inclusion criteria, that demonstrated a significant reduction in both total and LDL cholesterol in the pharmacist intervention group.[66]
- Congestive heart failure: Two systematic reviews of the literature concluded that pharmacists can improve patient care and reduce the rate of hospitalization, particularly in heart failure patients.[67,68]
- Cost-containment and health system efficiency: A Cochrane database review of 25 studies involving more than 40 pharmacists and 16,000 patients found expanded pharmacist services led to a decrease in the number of non-scheduled health services, as well as a decrease in specialty visits and the number and cost of drugs.[69]
- Quality care and patient safety: University of Arizona researchers conducted a comprehensive systematic review with focused meta-analysis to explore the effects of pharmacist-provided direct care on therapeutics, safety, and humanistic outcomes. A total of 298 studies were included and the researchers found favorable therapeutic and safety outcomes. Additionally, they conducted a meta-analysis study of specific quality care

indicators (HgA1c, LDL, blood pressure, etc.) and the results were significantly in favor of pharmacist-delivered care over comparative services.[4]

Because the quantity, depth, and variety of these clinical studies are far too numerous to detail in this Report, a partial summary of published outcomes has been provided in Appendix B. Nearly 60 studies have been cited from various peer-reviewed publications. In some cases, as denoted above, a published study may be a meta-analysis of many additional studies yielding a substantial amount of documented outcomes. These published outcomes are collected from various practice settings to include community, hospital, and federal facilities, and demonstrate improved outcomes (patient, administrative, economic, etc.) among pharmacist-managed clinics and programs.[25,70-104]

Although discussion in this Report focuses on improving health care delivery through utilization of the pharmacist, a pivotal piece to successful implementation also hinges on continued efforts to leverage health information technology (HIT). HIT has long been recognized as a key means for supporting improvements in health care quality, safety, and efficiency. With the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, many health care collaborations were formed to support and advance HIT to the fullest extent. According to the Patient-Centered Primary Care Collaborative (PCPCC), health IT "can provide critical information about the patient to the entire care coordination team across all stages of care, support physician-patient communication, enable more timely and accurate performance measurement and improvement, and improve accessibility of the physician practice to the patient."[105]

The pharmacy profession has traditionally been an early adopter of HIT and recognizes the benefits of HIT to optimizing patient care and outcomes-based measurement. In 2010, nine national pharmacist associations formed the Pharmacy e-Health Information Technology Collaborative (e-HIT Collaborative) to focus on and ensure the technology needs of the pharmacy profession advance with the federally-incentivized progression of HIT infrastructure in the United States. The goal of this collaborative was to define a common vision for HIT to improve patient care quality and outcomes through the integration of pharmacists' patient care services into the national electronic health records (EHR) infrastructure. The focus of the e-HIT Collaborative is to "assure the meaningful use (MU) of standardized EHR to support safe, efficient, and effective medication use, continuity of care, and provide access to the patient-care services of pharmacists with other members of the interdisciplinary patient care team. The e-HIT Collaborative assures the pharmacist's role of providing patient-care services is integrated into the National health IT interoperable framework."[106] The e-HIT Collaborative is pursuing EHR standards that support the delivery, documentation, quality measures, and billing for pharmacist-provided patient care services across all care settings. Thus, the pharmacy profession has already realized the clinical utility of electronic health data and has positioned itself well ahead of the curve for standardized outcomes-related data collection and enhanced electronic data accessibility for delivering quality patient care services.

Disease Prevention and Management

Disease prevention, or preventing progression of chronic disease, directly alleviates the disproportionate amount of chronic care needs and demands on the health system. Approximately 125 million Americans (45 percent of the U.S. population) had one or more chronic conditions in 2000 and 61 million (21 percent of the U.S. population) had multiple chronic conditions. It is estimated the population of people with chronic conditions will increase steadily, and that by 2020, 164 million people (almost 50 percent of the U.S. population) will have a chronic condition and 81 million (24 percent) of them will have two or more conditions.[107,108] Inpatient admissions for ambulatory care sensitive conditions and hospitalizations with preventable complications increased with the number of chronic conditions. As an example, Medicare beneficiaries with four or more chronic conditions were 99 times more likely than a beneficiary without any chronic conditions to have an admission for an ambulatory care sensitive condition (95% confidence interval, 86-113). Per capita Medicare expenditures increased with the number of types of chronic conditions from $211 among beneficiaries without a chronic condition to $13,973 among beneficiaries with four or more types of chronic conditions.[109] The number of people with chronic conditions is projected to increase steadily for the next 30 years. While current health care financing and delivery systems are designed primarily to treat acute conditions, 78 percent of health spending in the United States is devoted to people with chronic conditions.[110]

Chronic diseases are the leading causes of death and disability in the United States. Chronic diseases currently affect 45 percent of the population (133 million Americans), account for 81 percent of all hospital admissions, 91 percent of all prescriptions filled, 76 percent of physician visits, and continues to grow at dramatic rates.[111] These numbers are daunting. Quality medical care for people with chronic conditions requires a new orientation toward prevention of multiple chronic disease conditions, and provision of ongoing care and care management to maintain their health status and functioning.

It has been stated that specific focus should be applied to people with multiple chronic conditions.[107,108] However, a single chronic condition (for example, hypertension) causes many other potential co-morbidities and negative health outcomes. Any chronic condition, even without co-morbidities would benefit from prevention of disease progression. This must be realized in discussion and applied to legislation involving health care delivery paradigms in order to provide the highest quality and most cost-effective care (both short and long term). This perspective must also be evident in legislation to minimize any restrictions placed on eligibility for these types of services whether they are delivered by pharmacists or not. As a reminder, in some MTM Part D cases, the pharmacist is not eligible to practice MTM unless the patient has more than one chronic disease. The health system would not restrict primary care delivered by a physician or other care provider simply because a patient has only one chronic disease. Why would it do so in the case of pharmacist-delivered services? Why would it do so in a system that is attempting to prevent further progression of disease or development of new co-morbid conditions? Pharmacists are uniquely qualified to work within this scope, with

extensive formal education on therapy and management of chronic disease (single or multiple) through the safe use of pharmacologic interventions.

The Diabetes Ten City Challenge (DTCC) was a multi-site community pharmacy health management program for patients with diabetes. It was an employer-funded, collaborative health management program using community-based pharmacist coaching, evidenced-based diabetes care guidelines, and self-management strategies. DTCC successfully implemented the program and demonstrated positive clinical and economic outcomes for 573 patients who participated in the program for at least one year, compared with baseline data. However, in addition to the clinical and economic benefits, many preventive measures showed substantial improvement demonstrating the value of pharmacists in preventive care. Between the initial visit and the end of the evaluation period, influenza vaccination rate more than doubled from 32 percent to 65 percent, eye examination rate increased from 57 percent to 81 percent, and foot examination rate increased from 34 percent to 74 percent.[70]

The Asheville Project is yet another widely-known example of successful pharmacist-delivered patient care in the non-federal sector. It began in 1995 as a result of a strategic planning committee held by state pharmacy leaders. The idea was to sponsor a pharmaceutical care demonstration project in the state of North Carolina. The Asheville project utilized advanced practice pharmacists, in coordination with the Diabetes Education Center and physicians to provide Disease State Management (DSM) services to people with diabetes.[112] The outcomes were extremely positive in terms of both fiscal and clinical outcomes. The Asheville Project demonstrated that patients, providers, and managers believed aligned incentives and community-based resources (i.e., pharmacists) providing health care services to patients offer a practical, patient-empowering, and cost-effective solution to escalating health care costs.[113]

More recently, a collaborative project in Connecticut (Connecticut Medicaid Program; the Connecticut Pharmacists Association; and the University of Connecticut School of Pharmacy) tested a pharmacist practice model in patients with chronic conditions and complex medication regimes. Although small sample limitation and generalizability were addressed, the study demonstrated that pharmacists are crucial for optimizing patient outcomes with regards to disease management. There were 369 face-to-face encounters, and pharmacists identified 917 drug therapy problems. Pharmacists resolved 78 percent of these problems without the patient having to be referred back to their primary care provider. Additionally, 82 percent of prescribers made changes in their patients' therapies based on the pharmacists' recommendations.[114]

With a projected shortage of general primary care practitioners and a growing mass of eligible consumers, the Report strongly encourages health leadership to consider pharmacists as providers that can assist to reduce the burden of chronic disease on the health care system, especially in cases where further progression of disease or development of co-morbid conditions can be prevented.

Cost-Effectiveness and Cost-Containment

In addition to pharmacists' ability to improve clinical outcomes for patients through disease management or other advanced clinical roles, pharmacists have contained or reduced health care costs, whether associated with reduced adverse clinical events (hospitalizations, emergency room visits, etc.),[115,116] reduced outpatient visits, cost savings to a health care institution or health insurance plan,[93,95,112,116-123] direct cost savings to the patient,[124,125] or less missed/non-productive workdays.[112,115] Bond and Raehl have shown on a macro-level that advanced patient care services delivered by pharmacists reduce drug-related morbidity and mortality, and lower the overall cost of care.[126]

Utilizing pharmacists as drug therapy experts will maximize resources, contain or reduce costs and improve care. Significant reductions in drug misadventures could be potentiated by allowing pharmacists greater clinical intervention and comprehensive medication management authorities. By selecting and monitoring therapeutic and patient care regimens through focused disease management, pharmacists can improve the overall quality of the health care system.

Pharmacists have been shown to produce annual health care savings of:

- $3.5 billion in hospital costs by coordinating medications from multiple providers.[127]
- More than $1,600 in direct health care costs per patient at a pharmacist-run anticoagulation clinic, compared with usual medical costs.[93]
- $1,200 to $1,872 per patient in direct health care costs for patients with diabetes enrolled in the Asheville Project for up to five years.[112]
- $918 per patient in direct health care costs for patients with diabetes enrolled in the Patient Self-Management Program for Diabetes for one year.[113]
- $1,230 per patient in indirect costs for those with asthma and direct cost savings of $725 average per patient.[115]
- $1,123 per patient on medication claims and $472 per patient on medical, hospital, and emergency department expenses at five primary care sites in Connecticut.[114] (The pharmacists in this study provided comprehensive evaluation of multiple medical conditions.)

The Asheville Project, in which more than 50 percent of patients in the study improved clinically, also demonstrated notable administrative and fiscal benefits:

- Patient and physician satisfaction increased and health care costs were reduced.
- Direct medical costs decreased by $1,200 per patient per year and an estimated annual increase in productivity of $18,000 due to reduction of sick time were reported.[115] Even after paying the pharmacists to provide these services, net costs were lower.[112]

Schumock et al.[123,128] and Perez et al.[129] conducted multiple ACCP-funded studies across two decades that evaluated the economic value of clinical pharmacy services. Collective research supported significant economic savings in a broad range of clinical categories among multiple care settings (See Table 1: Benefit to Cost Ratio). The categories included disease management, general pharmacotherapeutic monitoring, pharmacokinetic monitoring, targeted drug programs, patient education program, and cognitive service. The table below represents economic value of clinical pharmacy services in the form of benefit to cost ratio (financial benefit/dollar invested to provide the service) for the periods shown. The benefit to cost ratio was calculated by dividing the reported gross economic benefits derived from the service, by reported total costs to provide the clinical pharmacy service described for the same time period.

Table 1: Benefit to Cost Ratio

Benefit to Cost Ratio	**1988-1995**	**1996-2000**	**2001-2005**
Lowest	$1.08 : $1	$1.70 : $1	$1.02 : $1
Highest	$75.84 : $1	$17.01 : $1	$34.61 : $1
Median	$4.09 : $1	$4.68 : $1	$4.81 : $1
Mean	$16.70 : $1	$5.54 : $1	$7.98 : $1

Even at the ratios' lowest level, clinical pharmacy services benefit is still higher than the cost. The average benefit gained in each of the time periods shown was between 5.5 and 16.7 times greater than cost. **Consequently, for each dollar invested in the clinical pharmacy service over the period from 1988 to 2005 (nearly two decades), the overall average benefit gained was $10.07 per $1 of allocated funds.**

One final way to measure the cost-efficiencies of pharmacist-delivered patient care is to consider the calculated return on investment (ROI). This ROI reflects the value of the service based on the cost of delivering the service. The data collected from medication management services demonstrated an ROI of as high as 12:1 and an average of 3:1 to 5:1. This value is based on the ability of medication management services to reduce hospital admissions, reduce the use of unnecessary or inappropriate medications, and reduce emergency room admissions and overall physician visits.[130 131]

Thus, effective patient care services related to medication management can lower total health care costs. Although initial medication costs may rise due to improved medication adherence, it has been shown that hospital and emergency room visits are reduced.[3] Given the significance of this calculation and the challenging economic environment, the ROI of medication management services can be seen as a legitimate cost-containment and cost-effective strategy for health plans, employers and other third party payers.

Primary Care Workforce

In recent years, many reports have identified an imminent shortage of primary care physicians.[132-135] As health reform presses forward, trends in health care workforce capacity may become the critical issue. Solutions are minimal, yet current data shows the number of graduating physicians entering primary care is decreasing, due in part to high patient loads and declining revenue when compared to specialists, among other reasons.[135-137] The "backbone of the American medical system" is threatened by this severe shortage of primary care physicians, which could lead to fragmented health care.[135]

Providing affordable and accessible insurance to all Americans does not solve the problem of access *to services* of those insured. Those gaining insurance benefits as a result of health reform are part of the medically disenfranchised population in the United States. According to "Access Denied," most people living in these disenfranchised areas have health insurance.[134] It has been said that "having insurance coverage without a source of care is like having currency without a marketplace."[132] A recent and comprehensive report from the Association of American Medical Colleges (AAMC) Center for Workforce Studies enumerated roughly 26 reference documents and articles that all speak to current and future physician shortages. Some of the studies projected a physician shortage anywhere from 85,000 to 200,000 by 2020,[138] and a 38 percent increase in demand for general internists is projected by the year 2020.[136] These are not predictions. These projections indicate if current physician utilization and work patterns continue, a physician shortage is imminent – if it is not already here. The report also hypothesized non-static models that demonstrate:

- Growth in future demand could double if visit rates by age continue to increase at the same pace they have in recent years;
- Universal health care coverage could add 4% to demand for physicians; this would increase the projected physician shortfall by 25% to nearly 155,000 physicians; and
- If the relationship between economic growth and physician demand holds true – a demand for physicians will occur that is likely beyond what supply could meet.
  If younger physicians continue working fewer hours than their predecessors, which seems probable, then any and all shortages will be amplified.

Even a modest increase in physician productivity could alleviate some of the projected gap, but productivity improvements in health care have been hard to achieve as care has become more complex. An increase in health care coverage would introduce millions of patients into an already stressed system, further increasing the number of medically disenfranchised. At least 12 states have already reported current or projected physician shortages (AZ, CA, FL, GA, KY, MA, MI, MS, NC, TX, OR, and WI).[133] The current supply of physicians would simply be unable to provide primary care to the increased population of insured individuals.

This Report supports maximizing the utility of the current health care workforce. There is an identifiable and projected need whereby pharmacists, through advanced pharmacy practice models, can contribute.[139] Current health systems utilize other non-physician providers.

Physicians work alongside PAs, NPs, and other health professionals who increase the productivity of physicians both by assisting with patient care and providing patient care (i.e., providing comprehensive assessment for a primary care visit) under the direction of a physician. The AAMC report cites "of particular importance are clinicians who can provide some of the services usually provided by physicians."[140] These Non-Physician Practitioners listed include PAs, NPs and "others." To parallel current pharmacy practice, this Report clearly articulates that pharmacists can function as health care providers and provide direct patient care services. Increasing the capacity of pharmacists to provide these services (through recommendations in this Report) will provide one existing solution to address some of the growing shortages and demand for primary care services.

The AAMC report also considers two scenarios to assist with the demand for primary care services in which NPs and PAs: 1) increase their growth beyond baseline or 2) provide more primary care services. While these two scenarios project future demand under what may be attractive policy goals, current infrastructure might be insufficient to produce the virtual doubling of PA and NP supply that these hypothetical scenarios would require. The report suggests that PA and NP numbers will not be sufficient to eliminate the physician shortage likely to come. Nonetheless, it appears evident that an increased role in the provision of care is just one part of the solution to the projected shortage. The AAMC report proposes to reduce physician demand based on an increased role for PAs and NPs in primary care. However, PAs are increasingly moving into non-primary care specialties. Thus, trends in PA and NP specialty choice may also require as close a watch as those for physicians.[133] Adding pharmacists into the models of this particular report will substantially boost access and distribution of providers that provide primary care services. Much like current roles in the Indian Health Service, PAs, NPs and pharmacists play a larger role in rural and medically underserved areas as well as offering services to those without a medical home. The health system will better utilize pharmacists across the United States if they are given similar patient care roles that leverage their expertise in focused or comprehensive disease management. This provides more opportunity to improve patient and health system outcomes.

There are other benefits of involving a pharmacist in primary care settings. In the UK, a database has estimated there are about 57 million primary care physician consultations per year. About 51.4 million out of those are for minor ailments alone, which also could be handled by a pharmacist.[141] A similar model has been in place in the IHS from the early 1970s with the initial Pharmacy Practitioner Program. Much of this model dissipated as a result of growth in the dispensary role of the pharmacist as well as the lack of appropriate compensation. The detrimental combination of the number of patients that need primary/chronic care, high use of medications, provider shortages, and shortened appointments, does not provide adequate time to focus on comprehensive disease management or other important health issues. These factors create a strained practice environment with the potential for multiple liability issues and sub-optimal outcomes.

Pharmacists have demonstrated their competence as health care providers in the delivery of patient care services. Additionally, it has also been said the presence of pharmacists embedded within the community allows pharmacists to play the role of "gatekeeper" to the health care system.[142] This supports the notion that pharmacists also provide primary care through care coordination. As previously discussed, pharmacists are equipped to provide complementary clinical services to supplement physician care with expertise in managing disease outcomes through medication use. Healthy People 2020 states "as one approaches health equity, health disparities become smaller." [143] As public health professionals, through interprofessional practice, pharmacists can directly affect health determinants in each of the levels provided by the Healthy People 2020 Action Model.

Access to Care

A report from the National Association of Community Health Centers states 56 million Americans are medically disenfranchised: they do not have a health care home.[93,132,134] One of the most common problems of our health system is that even if patients have health care coverage, it may not translate equally as access to care. Thus, increasing access to quality care for those Americans necessitates discussion on how to alleviate additional burden on the health system and providers. Another report states "hospitalization rates and expenditures are higher in areas with fewer primary care physicians and limited access to primary care."[144] Rural areas attract fewer doctors, and thus become overburdened more easily.

A significant contribution to health reform by the pharmacy profession may be to increase access to patient care services, in collaboration with other primary care providers, particularly to the underserved or medically disenfranchised populations.

Pharmacists are the most accessible health care professionals in the United States and have always been one of the most trusted professions.[145] **A 2000 estimate of pharmacy patronage showed that the equivalent of the entire U.S. population (approximately 275 million people at the time of publication) visited pharmacies each week.[146] This statistic alone is remarkable and suggests, as a profession, pharmacists are underutilized in addressing the health care needs of the nation.** As noted, physicians are currently overburdened, and the problem is only going to worsen as the first of the baby-boomer generation turns 65 in 2011. The U.S. population as a whole is aging; it is projected by 2030, one in five Americans will be over the age of 65.[136] [147] Older Americans require more health care, including office visits, hospital visits, and prescriptions.

Physicians in the NCPS survey in Focus Point 1 (Interprofessional Collaboration and Support) affirm that pharmacists offer increased access to care for underserved populations where other primary care providers are in limited number or distribution. Pharmacists can decrease physicians' routine or "chronic" workloads, potentially increasing the amount of time physicians can spend with their more complex patients providing increased revenues per physician-unit time. Generally the physician initially diagnoses the patient, sends them for disease management with the pharmacist for continued regular follow-up, laboratory monitoring, and

some level of prescriptive authority, but the physician remains as the driver behind the system. The pharmacist provides primary care collaboratively, managing the patient for optimal disease outcomes through medication use and preventing disease progression or exacerbation. Pharmacists that deliver direct patient care services can reduce physician time spent on these patients by eliminating multiple follow-up visits with the physician and increases focused disease management by the pharmacist: creating a "win-win" (non-zero sum gain) situation.

The U.S. health care system is transforming to include increased health coverage, where access to primary care and access to quality care will become paramount for the projected millions of new beneficiaries. **With increased demand for services, it will be essential to consider all populations, including racial and ethnic minorities, medically underserved, and vulnerable populations with additional health disparities.** Primary care health services are now a focus of a larger health care strategy in which a great need for these services will evolve. De Maeseneer et al. argued primary care contributes to public health by improving access; however they added that primary care also contributes to social cohesion and empowerment of people so that they become less vulnerable.[148] This only occurs when quality of care and health care delivery is optimized. **Coverage without access, coupled with accessibility without quality, could develop into a perilous public health situation. Pharmacists may be in the best position of any health professional to effectively meet the demands and address the changing needs of the health care system**.

Pharmacists are the most accessible cadre of health professionals in the United States and are remarkably underutilized in our health care system. The pharmacy profession is uniquely situated to expand to help meet our health care system's changing needs. Pharmacists have the appropriate education, training, scope, and support (as providers of patient care complimentary to existing providers) to deliver quality care. Pharmacists already perform as health care providers in the PHS and federal pharmacy settings, and some non-federal health systems as well. These pharmacists are trained to handle this type of role and can rapidly expand to meet some of the demand for access to care across the nation – especially if appropriate policy structures are in place. The cost to the system to implement this change is minimal as it is more a change in policy and perception than it is a change in fiscal resources. **The American Pharmacists Association (APhA) states that "by expanding the use of pharmacists' expertise in the treatment of chronic diseases, monetary savings and patient care improvements can help solve many challenges facing the U.S. health care system."[149]**

Dramatic changes are needed to fix our health care system: expanding coverage and access to all; reforming compensation to promote value; supporting clinicians' efforts to reengineer care; and engaging patients in making better choices and managing their health conditions. The burden of health care in the United States will likely broaden to create an even greater need through increasing workload and plans of more universal insurance coverage. Truly better quality of care - care that is more effective, safe, and efficient - is imperative for aiding our nation's economic recovery and making good on our commitment to cover the uninsured.[150]

CONCLUSION

Multiple bills and committee briefings have been submitted to Congress from leading pharmacy and non-pharmacy organizations that would fully support, utilize, and advance the pharmacy profession by maximizing pharmacists' value within current health delivery structures.[31, 11,48,111,151-153] Implementation of these pharmacy practice models require strong and urgent consideration as partial solutions to the demand for health care in the United States. **Existing pharmacy practice models can rapidly relieve some of the projected burden of access to quality care, reduce health disparities, and improve overall health care delivery.** Pharmacists are integral to the provision of and access to quality patient care. Maximizing the expertise of the pharmacist, pharmacy profession, and each pharmacy practice is critical to advance our nation's health.

Physicians, administrators and patients *that have worked within this paradigm* of collaborative patient care delivered by pharmacists have supported and continue to support this model. **What has occurred over time within this paradigm is somewhat analogous to "common law."** In common law, decisions are based on past precedent in lieu of specific policy or statute. Federal pharmacy systems have developed a "common pharmacy practice" across decades of implementation where it has become common and accepted for pharmacists to function as health care providers and deliver direct patient care services in collaboration with physicians based on positive outcomes. **Although this collaborative practice is implemented as a pragmatic solution to meet some of the health care demands and improve delivery of care, it is not clearly discussed at the highest levels of health leadership or correctly articulated in current pharmacy legislation or compensation structures.** This Report includes objectives that would acknowledge and advance this "common pharmacy practice" in the form of advocacy, policy, and legislation.

The Partnership to Fight Chronic Disease (PFCD) briefed the Senate Finance Committee (SFC) regarding the SFC's health reform paper, *Transforming the Health Care Delivery System: Proposals to Improve Patient Care and Reduce Health Care Costs*. In the letter dated May 15, 2009, the PFCD stated, "**Without changes in Medicare payments and delivery models that emphasize chronic disease prevention and control, we will fail in our efforts to control Medicare costs and improve the health of our population."** Also in the letter, **the PFCD recognized and exemplified pharmacists as one of "our nation's primary health care providers**."[111]

Throughout the Report, a rational and logical justification has been made for pharmacists to help bridge some of the gaps and needs of our primary care and health care systems. It has been exhaustively demonstrated through evidence-based data that pharmacists within these models of care improve outcomes and contain costs. Organizations, academia, industry, community, hospital, and federal pharmacy can and will continue to demonstrate the positive outcomes of its pharmacists. Pharmacists have evolved as providers of care because it is the right thing to do for patient care and the nation's health.

It is essential that additional fiscal and policy support exist for this paradigm shift to allow pharmacists to continue to sustain these expanded services and improve outcomes. **It is time to enact legislation to recognize and compensate pharmacists - reflecting a change in the pharmacy practice that has *already* occurred**. These changes will rapidly answer a need to improve the cost-effectiveness, quality, and access to primary care and further advance the health of the nation.

Given the practice environment and innovative care models of federal pharmacy, the non-federal sector has historically looked to federal pharmacy to assist in advancing the profession. Federal pharmacy has pioneered many facets of service delivery utilizing pharmacists to the maximum extent of their licensure and education. During this era of health reform, it is once again necessary for PHS and federal pharmacy to advance these successful and existing health care delivery models past exploration and into implementation. **PHS Pharmacy is poised and capable to assist the nation toward the overall goal of improved health care delivery.**

Those in decision-making positions (in the face of decades of proven performance, interprofessional support and evidence-based outcomes) may need to consider expanded implementation of the full spectrum of pharmacist-delivered patient care services with appropriate policy and compensatory mechanisms - or clearly state the barriers of this paradigm change - that has demonstrated improved health care delivery.

During the April 11, 2011 launch of the Partnerships for Patients Initiative, Donald Berwick, CMS Administrator, stated, “America is facing a critical choice in health care. Either cut care or improve care. I don’t like to cut care, so the only right thing to do is improve care.”[10] One of the most logical, evidence-based decisions that can be made to improve care is to maximize the expertise and scope of pharmacists, and minimize expansion barriers of an already existing and successful health care delivery model.

If the objectives of this paper are actualized, the U.S. Public Health Service, in partnership with federal pharmacy leadership and the Office of the U.S. Surgeon General, will directly support health care delivery improvement and advance the health of the nation with a new paradigm for care.

APPENDICES

A. National Clinical Pharmacy Specialist (NCPS) Program
B. Outcomes Repository Spreadsheet
C. U.S. Collaborative Practice Map
D. Physician Survey

Appendix A: National Clinical Pharmacy Specialist (NCPS) Program

Issue

For decades, Indian Health Service (IHS) pharmacists have practiced in a variety of expanded and advanced clinical roles to provide patient care. IHS pharmacy is widely known (in the federal sector, private sector and academia) for its innovative pharmacy practice, which includes privileges in disease management. In many IHS facilities, it is common for patients to have pharmacists providing focused medical care through clinic visits very similar to that of other primary care providers. With this advanced level of clinical care provided by pharmacists (through expanded scopes of practice agreements approved by local facilities), it is important to establish best practices, promote uniformity among credentials and competencies, and explore appropriate reimbursement for services. As of December 2008, this uniformity extends beyond the IHS into the Bureau of Prisons (BOP) as a Memorandum of Understanding was signed between the IHS and the BOP to expand the NCPS Program into the BOP.

Purpose

The IHS established a national credentialing system for IHS, Tribal, and Urban (I/T/U) pharmacists in an effort to promote enhanced patient outcomes and address the following:

- Promote uniform clinical competency among I/T/U and BOP pharmacists;
- Define and recognize advanced scopes of practice for I/T/U and BOP pharmacists;
- Establish critical elements for developing collaborative practice agreements (CPAs);
- Develop a review process to approve CPAs and clinical pharmacy specialists by a national group of subject matter experts to help ensure uniformity of scope and competency both locally and nationally;
- Review credentials, protocols, training, education and experience of I/T/U and BOP pharmacists, and grant NCPS certification to recognize a pharmacist's local privileges that meet the specified national standards for credentialing;
- Establish these elements to help promote universal recognition of NCPS pharmacists as billable providers.

Background

The October 18, 1996 memorandum from the IHS Director established IHS pharmacists as primary care providers (PCPs) and allows for privileges to include prescriptive authority. In response to a growing interest in clinical practice nationwide, and meetings with key stakeholders such as the Health Care Financing Administration (HCFA), the NCPS Program and NCPS Committee (NCPSC) were established by the Chief Pharmacy Officer in 1997 and 1998 to provide a mechanism to assure all Clinical Pharmacy Specialists in the IHS display a uniform level of competency. The provision of advanced pharmacy care follows the IHS Pharmacy Standards of Practice as outlined in Chapter 7 of the Indian Health Manual. With this official charge and history of advanced clinical care spanning over 30 years, the scope of NCPS care includes all criteria and responsibilities covered in the IHS Standards of Practice, as well as focused management of disease states for selected patients in whom medications are the principle method of treatment. Patient care may include a patient interview, chart review,

ordering and interpretation of laboratory tests, physical assessment, prescriptive authority, formulation of clinical assessments, and development of therapeutic plans, patient education, and patient follow-up. Treatment and management are performed through a collaborative practice agreement (CPA) that has been approved by the local medical staff. If the pharmacist is a credentialed NCPS, the CPA has also been approved by the NCPSC. NCPS certification is intended to uniformly recognize an advanced scope of practice locally aimed at managing one or more diseases and/or optimizing specific pharmacologic therapy. Pharmacists may practice disease management at a facility after completing local requirements, however NCPS certification will only be granted after submission of an appropriate application and fulfillment of all national requirements. In order to promote uniform competency and consistency in the credentialing process, it is now also strongly recommended that all facilities adopt, at a minimum, the NCPS standards for local credentialing of pharmacists in advanced scopes of practice.

Activity

After 13 years, the program has reviewed the credentials and certified 279 I/T/U pharmacists from 18 states (approximately 20 percent of IHS pharmacists); directly increased the access to and quality of primary care through collaborative practice and disease management.

Appendix B: Outcomes Repository Spreadsheet

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Improved Clinical Outcomes		
Barbanel D. Eldridge S, et al. (2003). Can a self-management program delivered by a community pharmacist improve asthma control? A randomized trial. *Thorax* 58(10):851-4. (YES)	A randomized controlled study was undertaken to determine whether a community pharmacist could improve asthma control using self-management advice for individuals recruited during attendance at a community pharmacy. Methods: Twenty four adults attending a community pharmacy in Tower Hamlets, east London for routine asthma medication were randomized into two groups: the intervention group received self-management advice from the pharmacist with weekly telephone follow-up for three months and the control group received no input from the pharmacist. Participants self-completed the North of England asthma symptom scale at baseline and three months later.	Results: Symptom scores improved in the intervention group and marginally worsened in the control group to 20.3 (4.2) and 28.1 (3.5), respectively. Conclusions: A self-management program delivered by a community pharmacist can improve asthma control in individuals recruited at a community pharmacy. Further studies should attempt to confirm these findings using larger samples and a wider range of outcome measures.
Beney J, Bero LA, Bond C. Expanding the roles of outpatient pharmacists: effects on health services utilization, costs, and patient outcomes. *Cochrane Database Syst Rev* 2000(3):CD000336	Cochrane Review of articles discussing pharmacists with expanded roles	Twenty-five studies included >40 pharmacists and 16,000 patients. Scheduled service utilization was slightly increased, and hospital admissions and ER admissions were decreased. Pharmacist services decreased the use of non-scheduled health services, the number of specialty physician visits, or the number and costs of drugs, compared to control patients (six studies). Improvements in targeted patient condition were reported in 10 of 13 studies that measured patient outcomes, but patients' quality of life did not seem to change. All studies demonstrated that pharmacist interventions produced the intended effects on physicians' prescribing practices.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Bluml BM, McKenney JM, Cziraky MJ. (2000). Pharmaceutical care services and results in project ImPACT: hyperlipidemia. *J Am Pharm Assoc* 40(2):157-65. (YES)	Objective: To demonstrate that pharmacists, working collaboratively with patients and physicians and having immediate access to objective point-of-care patient data, promote patient persistence and compliance with prescribed dyslipidemic therapy that enables patients to achieve their National Cholesterol Education Program (NCEP) goals. Participants: 26 community-based ambulatory care pharmacies: independent, chain-professional, chain-grocery store, home health/home infusion, clinic, health maintenance organization/managed care. Outcome measures: Rates of patient persistence and compliance with medication therapy and achievement of target therapeutic goals.	Over an average period of 24.6 months and in 397 patients, observed rates for persistence and compliance with medication therapy were 93.6% and 90.1% respectively, and 62.5% of patients had reached and were maintained at their NCEP lipid goal at the end of the project. Conclusion: Working collaboratively with patients, physicians, and other health care providers, pharmacists who have ready access to objective clinical data, and who have the necessary knowledge, skills and resources, can provide an advanced level of care that results in successful management of dyslipidemia.
Bogden PE, Koontz LM, et al. The physician and pharmacist team. An effective approach to cholesterol reduction. *J Gen Intern Med* 1997;12(3):158-64.	Objective: To assess the effect of a program that encourages teamwork between physicians and pharmacists on attempts to lower total cholesterol levels and to meet recommended goals proposed by the National Cholesterol Education Program (NCEP). Design: Single-blind, randomized, controlled trial lasting six months. Setting: An ambulatory primary care center. Patients: A sample of 94 patients with total cholesterol levels of 240 mg/dL or higher. Intervention: Equal numbers of patients were randomly assigned to a control arm in which standard medical care was received, and an intervention arm which implemented close interaction between physicians and pharmacists.	Results: The rate of success in achieving NCEP goals in the intervention arm was double the rate in the control arm (43% vs 21%, $P < .05$). Total cholesterol levels in the intervention arm declined 44 +/- 47 mg/dL versus 13 +/- 51 mg/dL in the control arm ($p < .01$). An effect of intervention was absent in patients without coronary heart disease and with fewer than two risk factors. Conclusions: Attempts to lower total cholesterol levels and achieve NCEP goals are likely to be more successful when combined with programs that include teamwork between physicians and pharmacists. Some programs, however, may be more successful for high-risk patients, for whom it is often easier to provide more aggressive therapies. Although altering adverse lipid profiles in lower-risk patients may be difficult, achieving optimal cholesterol levels could have an important impact on preventing movement to higher risk strata.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Bozovich M, Rubino CM, Edmunds J. Effect of a Clinical Pharmacist-Managed Lipid Clinic on Achieving National Cholesterol Education Program Low-Density Lipoprotein Goals. *Pharmacotherapy* 2000;20(11):1375-1383. (YES)	Patients in each arm were followed for a minimum of six months. A protocol for therapy changes in clinic patients was developed by the clinical pharmacist and approved by the cardiologist.	At the end of six months, 69% of patients in the pharmacist-managed clinic achieved their LDL goal, compared with 50% of controls. Compliance with laboratory tests and drug regimens also improved in clinic patients. Compliance with lipid panels went from 8% two months before to 89% two months after the start of the study. At the end of six months, compliance with laboratory work and refills was 80%. Thus the clinical pharmacist-managed clinic was highly successful in achieving NCEP goals for secondary prevention.
Carson, J. J. Pharmacist-coordinated program to improve use of pharmacotherapy for reducing risk of coronary artery disease in low-income adults. *Am J Health Syst Pharm* 1999;56(22):2319-24. (YES)	Patients were categorized as secondary prevention, or high-risk primary prevention of cardiovascular disease. Intervention: The pharmacist made pharmacotherapy recommendations based on guidelines. Patients' use of aspirin, lipid-lowering therapy, and HRT was noted before program entry. Use of these pharmacotherapeutic modalities was then tracked through subsequent visits. In addition, the patient's baseline serum lipid values were recorded and tracked.	Results: In secondary-prevention group, mean LDL fell by 26% ($p < 0.0001$), and 24 (73%) of the patients had a reduction in LDL concentration. Mean total cholesterol concentration among secondary-prevention patients decreased by 11% ($p = 0.007$), and the mean HDL concentration increased by 19% ($p < 0.0001$). The percentage of secondary-prevention patients achieving their NCEP LDL goal of <100 mg/dL increased from 6% to 27% ($p < 0.04$). In the primary-prevention group, the mean LDL concentration fell by 27% ($p < 0.0001$), and 29 (71%) of the patients had a reduction in LDL concentration after entry into the program. The mean total cholesterol concentration fell by 15% ($p = 0.0002$), and the mean HDL concentration increased by 12% ($p = 0.009$). The percentage of patients achieving their NCEP-recommended LDL goal of <130 mg/dL increased from 20% to 51% ($p = 0.006$). Conclusion: A program in which a pharmacist estimated patients' risks for coronary artery disease and recommended pharmacotherapeutic interventions improved the use of these pharmacotherapeutic modalities by low-income adults.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Carter BL, Barnette DJ, et al. (1997). Evaluation of hypertensive patients after care provided by community pharmacists in a rural setting. *Pharmacotherapy 1997;*17(6):1274-85. (YES)	Blood pressure control, quality of life, quality of care, and satisfaction of patients who were monitored by specially trained community pharmacists in a group medical practice was evaluated. After participating in an intensive skill development program, pharmacists performed in an interdisciplinary team in a rural clinic. The primary objective was assessed by evaluating outcome variables at six months compared with baseline in 25 patients randomly assigned to a study group. A control group of 26 patients was also evaluated to determine if outcome variables remained constant from baseline to six months.	Results: Systolic blood pressure was reduced in the study group (151 mmHg baseline, 140 mmHg at 6 mo., $p < 0.001$) and diastolic blood pressure was significantly lower at 2, 4, and 5 months compared with baseline. Ratings from a blinded peer review panel indicated significant improvement in the appropriateness of the blood pressure regimen, going from 8.7 +/- 4.7 to 10.9 +/- 4.5 in the study group, but they did not change in the control group. Several quality of life scores improved significantly in the study group after six months. There were no significant changes in the control group. Patient satisfaction scores were consistently higher in the study group at the end of the study. Results indicate that when community pharmacists in a clinic setting are trained and included as members of the primary care team, significant improvements in blood pressure control, quality of life, and patient satisfaction can be achieved.
Coast-Senior EA, Kroner BA, Kelley CL, et al. Management of patients with type 2 diabetes by pharmacists in primary care clinics. *Ann Pharmacother* 1998 Jun;32(6):636-41.	The objective of this study was to determine the impact of clinical pharmacists involved in direct patient care on the glycemic control of patients with type 2 diabetes mellitus in two primary care clinics in a university-affiliated Veterans Affairs Medical Center. The pharmacists provided diabetes education, medication counseling, monitoring, and insulin initiation and/or adjustments. All initial patient interactions with the pharmacists were face-to-face. Thereafter, patient-pharmacist interactions were either face-to-face or telephone contacts. Study subjects were patients with type 2 diabetes who were referred to the pharmacists by their primary care providers for better glycemic control. Primary outcome variables were changes from baseline in glycosylated hemoglobin,	Twenty-three veterans aged 65-94 years completed the study. Fifteen (65%) patients were initiated on insulin by the pharmacists eight (35%) were already using insulin. Patients were followed for a mean-SD of 27-10 weeks. Glycosylated hemoglobin, fasting blood glucose concentrations, and random blood glucose concentrations significantly decreased from baseline by 2.2% ($p = 0.00004$), 65 mg/dL ($p < 0.01$), and 82 mg/dL ($p = 0.00001$) respectively. Symptomatic hypoglycemic episodes occurred in 35% of patients. None of these episodes required physician intervention. Conclusion: This study demonstrated that pharmacists working as members of interdisciplinary primary care teams can positively impact glycemic control in patients with type 2 diabetes requiring insulin.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
	fasting blood glucose, and random blood glucose measurements. Secondary outcomes were the number and severity of symptomatic episodes of hypoglycemia, and the number of emergency room visits or hospitalizations related to diabetes.	
Dolovich L, Pottie K, et al. Integrating family medicine and pharmacy to advance primary care therapeutics. *Clin Pharmacol Ther* 2008;83(6):913-7. (YES)	Pharmacists placed in seven family practice sites in Ontario, Canada. Physicians reviewed advice provided by the pharmacists and determined a management approach.	Pharmacists evaluated 969 patients over a 24 month period. Pharmacists identified an average of 4.4 drug related problems per patient (3974 total). Pharmacists identified adverse drug reactions in 241 patients.
Ellis SL, Carter BL, Malone DC, et al. Clinical and economic impact of ambulatory care clinical pharmacists in management of dyslipidemia in older adults: the IMPROVE study. Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers. *Pharmacotherapy* 2000 Dec;20(12):1508-16.	This study examined the impact of ambulatory care clinical pharmacist interventions on clinical and economic outcomes of 208 patients with dyslipidemia and 229 controls treated at nine Veterans Affairs medical centers. This was a randomized, controlled trial involving patients at high risk of drug-related problems, though only those with dyslipidemia are reported here. In addition to usual medical care, clinical pharmacists were responsible for providing pharmaceutical care for patients in the intervention group. The control group did not receive pharmaceutical care. Seventy-two percent of the intervention group and 70% of controls required secondary prevention according to the National Cholesterol Education Program guidelines.	Significantly more patients in the intervention group had an improved fasting lipid profile compared with controls. The absolute change in total cholesterol (17.7 vs 7.4 mg/dl, p = 0.028) and low-density lipoprotein (23.4 vs 12.8 mg/dl, p=0.042) was greater in the intervention than in the control group. There were no differences in patients achieving target lipid values or in overall costs despite increased visits to pharmacists. Ambulatory care clinical pharmacists can significantly improve dyslipidemia in a practice setting designed to manage many medical and drug-related problems.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Erhun WO, Agbani EO, et al. Positive benefits of a pharmacist-managed hypertension clinic in Nigeria. *Public Health* 2005;119(9):792-8. (YES)	Design: One-year prospective, randomized cohort study of the outpatients of a state comprehensive health centre in South-western Nigeria. Free primary health services including free drugs were provided for all patients. Methods: 51 Nigerian patients with uncomplicated hypertension aged 45 years or more were included. Participating pharmacists counseled on current medication, personalized goals of lifestyle modification stressing weight loss and/or increased activity, increased patient awareness by providing relevant education about hypertension and associated/related diseases, adjusted drug therapy to optimize effectiveness and minimize adverse events, utilized treatment schedules that enhanced patients' adherence to therapy, and monitored treatment outcomes between enrollment and return visits. Patient satisfaction and the number of treatment failures within six months post enrollment were compared with retrospective data from an earlier study involving physician-managed patients under a similar setting.	Results: Uncontrolled BP reduced from 92% to 36.2% by 10.15+/-5.02 days after enrollment. Treatment failures were observed at 5.9% of the total return visits (n=184) within six months. Conclusion: Pharmacist-managed hypertension clinics can improve BP control, reduce treatment failure and increase patient satisfaction.
Gattis WA, Hasselblad V, et al. Reduction in heart failure events by the addition of a clinical pharmacist to the heart failure management team: results of the Pharmacist in Heart Failure Assessment Recommendation and Monitoring (PHARM) Study. *Arch Intern Med* 1999;159(16): 1939-45. (YES)	181 patients with heart failure and left ventricular dysfunction (ejection fraction <45) undergoing evaluation in clinic were randomized to an intervention or a control group. Patients in the intervention group received clinical pharmacist evaluation, which included medication evaluation, therapeutic recommendations to the attending physician, patient education, and follow-up telemonitoring. The control group received usual care. The primary end point was combined all-cause mortality and heart failure clinical events.	Results: Median follow-up was six months. All-cause mortality and heart failure events were significantly lower in the intervention group compared with the control group (4 vs 16; P = 0.005). In addition, patients in the intervention group received higher angiotensin-converting enzyme (ACE) inhibitor doses as reflected by the median fraction of target reached (25th and 75th percentiles), 1.0 (0.5 and 1) and 0.5 (0.1875 and 1) in the intervention and control groups, respectively (P < 0.001). The use of other vasodilators in ACE inhibitor-intolerant patients was higher in the intervention group (75% vs 26%; P = 0.02). Conclusions: Outcomes in heart failure can be improved with a clinical pharmacist as a member of the

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
		multidisciplinary heart failure team. This observation may be due to higher doses of ACE inhibitors and/or closer follow-up.
Goode JV, Swiger K, et al. Regional osteoporosis screening, referral, and monitoring program in community pharmacies: findings from Project ImPACT: Osteoporosis. *J Am Pharm Assoc* (2003) 2004;44(2):152-60. (YES)	Design: Single-cohort observational study in a 29-store pharmacy chain in Richmond, VA. Participants were 532 consumers with one or more known risk factors for osteoporosis in the chain's customer service area. Intervention: During the initial phase (health promotion and disease prevention) of the project, pharmacy-based osteoporosis screening with referral and follow-up was provided to consumers who responded to the chain's screening promotions. The second phase – provision of collaborative community health management services focused on osteoporosis monitoring and management – is ongoing and includes patients who are at risk for or diagnosed with osteoporosis and are covered by a regional payer. Outcome measures: Results of screenings; responses of patients and physicians to notifications; and long-term results during collaborative care.	Results: 305 patients were available for follow-up interviews three to six months later. The stratification for risk of fracture was 37%, high risk; 33%, moderate risk; and 30%, low risk. A total of 78% of patients indicated they had no prior knowledge of their risk for future fracture. In the moderate- and high-risk categories, 37% of patients scheduled and completed a physician visit, 19% had a diagnostic scan, and 24% of those patients were initiated on osteoporosis therapy subsequent to the screening. Participating pharmacies received payment for both the osteoporosis screening and the collaborative health management services. Conclusion: Pharmacists can play a useful role in the identification, education, and referral of patients at risk for osteoporosis through pharmacy-based BMD screening. Patients are willing to pay for pharmacy-based osteoporosis screening services. Third-party payers are willing to compensate pharmacists for collaborative community health management services.
Hanlon JT, Weinberger M, Samsa GP, et al. A randomized, controlled trial of a clinical pharmacist intervention to improve inappropriate prescribing in elderly outpatients with polypharmacy. *Am J Med* 1996 Apr;100(4):428-37.	The purpose was to evaluate the effect of sustained clinical pharmacist interventions involving elderly outpatients with polypharmacy and their primary physicians. Methods: Randomized, controlled trial of 208 patients aged 65 years or older with polypharmacy (> or = 5 chronic medications) from a general medicine clinic of a Veterans Affairs Medical Center. A clinical pharmacist met with intervention group patients during all scheduled visits to evaluate their drug regimens and make recommendations to them and their physicians. Outcome	Results: Inappropriate prescribing scores declined significantly more in the intervention group than in the control group by three months and was sustained at 12 months. Fewer intervention than control patients experienced adverse drug events. Measures for most other outcomes remained unchanged in both groups. Physicians were receptive to the intervention and enacted changes recommended by the clinical pharmacist more frequently than they enacted changes independently for control patients (55.1% versus 19.8%; $P < 0.001$). Conclusion: A clinical pharmacist providing pharmaceutical care for

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
	measures were prescribing appropriateness, health-related quality of life, adverse drug events, medication compliance and knowledge, number of medications, patient satisfaction, and physician receptivity.	elderly primary care patients can reduce inappropriate prescribing and possibly adverse drug effects without adversely affecting health-related quality of life.
Jaber LA, Halapy H, et al. Evaluation of a pharmaceutical care model on diabetes management. *Ann Pharmacother* 1996;30(3):238-43. (YES)	Patients were randomized to either a pharmacist intervention (diabetes education, medication counseling, instructions on dietary regulation, exercise, and home blood glucose monitoring, and evaluation and adjustment of their hypoglycemic regimen) or control group (standard medical care provided by their physicians) and followed over a 4-month period. Primary outcome measures: fasting plasma glucose and HbA1c. Secondary outcomes: blood pressure, serum creatinine, creatinine clearance, microalbumin to creatinine ratio, total cholesterol, triglycerides, HDL, and LDL.	In the 39 patients who completed the study, significant improvement in glycated hemoglobin and fasting plasma glucose was achieved in the intervention group. No change in glycemia was observed in the control subjects. Statistically significant differences in the final glycated hemoglobin and fasting plasma glucose concentrations were noted between groups. Conclusion: This study demonstrates the effectiveness of pharmaceutical care in the reduction of hyperglycemia associated with non-insulin-dependent diabetes mellitus (NIDDM) in a group of urban African-American patients.
Jackson SL, Peterson GM, et al. Improving the outcomes of anticoagulation: an evaluation of home follow-up of warfarin initiation. *J Intern Med* 2004;256(2): 137-44. (YES)	A number of studies have reported the risk of bleeding associated with warfarin is highest early in the course of therapy. This study examined the effect of a program focused on the transition of newly anticoagulated patients from hospital to the community. Design: Open-label randomized controlled trial. Setting: Home-based follow-up of patients discharged from acute care hospital in southern Tasmania, Australia. Subjects: 128 patients initiated on warfarin in hospital and subsequently discharged to general practitioner (GP) care were enrolled in the study. Sixty were randomized to home monitoring (HM) and 68 received usual care (UC). Interventions: HM patients received a home-visit by the project pharmacist and point-of-care international normalized ratio (INR) testing	Results: At discharge, 42% of the HM group and 45% of the UC group had a therapeutic INR. At day eight, 67% of the HM patients had a therapeutic INR, compared with 42% of UC patients ($P < 0.002$). In addition, 26% of UC patients had a high INR, compared with only 4% of HM patients. Bleeding events were assessed three months after discharge and occurred in 15% of HM patients, compared with 36% of the UC group ($P < 0.01$). Conclusion: This program improved the initiation of warfarin therapy and resulted in a significant decrease in hemorrhagic complications in the first three months of therapy.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
	on alternate days on four occasions, with the initial visit two days after discharge. The UC group was solely managed by the GP and only received a visit eight days after discharge to determine anticoagulant control.	
Kaboli PJ, Hoth AB, et al. Clinical pharmacists and inpatient medical care: a systematic review. *Arch Intern Med* 2006;166(9):955-64. (YES)	Purpose: to evaluate published literature on the effects of interventions by clinical pharmacists on processes and outcomes of care in hospitalized adults. Methods: Peer-reviewed, English-language articles were identified from January 1, 1985 through April 30, 2005. Three independent assessors evaluated 343 citations. Inpatient pharmacist interventions selected if they included control group and objective patient-specific health outcomes; type of intervention, study design, and outcomes such as adverse drug events, medication appropriateness, and resource use were abstracted.	Results: Thirty-six studies met inclusion criteria, including 10 evaluating pharmacists' participation on rounds, 11 medication reconciliation studies, and 15 on drug-specific pharmacist services. Adverse drug events, adverse drug reactions, or medication errors were reduced in 7 of 12 trials that included these outcomes. Medication adherence, knowledge, and appropriateness improved in 7 of 11 studies, while there was shortened hospital length of stay in nine of 17 trials. No intervention led to worse clinical outcomes and only one reported higher health care use. Improvements in both inpatient and outpatient outcome measurements were observed. Conclusions: The addition of clinical pharmacist services in the care of inpatients generally resulted in improved care, with no evidence of harm. Interacting with the health care team on patient rounds, interviewing patients, reconciling medications, and providing patient discharge counseling and follow-up all resulted in improved outcomes. Future studies should include multiple sites, larger sample sizes, reproducible interventions, and identification of patient-specific factors that lead to improved outcomes.

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Koshman SL, Charrois TL, et al. Pharmacist care of patients with heart failure: a systematic review of randomized trials. *Arch Intern Med* 2008;168(7):687-94. (YES)	To clarify the role of pharmacists in the care of patients with heart failure (HF), a systematic review was performed evaluating the effect of pharmacist care on patient outcomes in HF. Methods: A search was conducted on PubMed, MEDLINE, EMBASE, International Pharmaceutical Abstracts, Web of Science, Scopus, Dissertation Abstracts, CINAHL, Pascal, and Cochrane Central Register of Controlled Trials for controlled studies from database inception to August 2007. Randomized controlled trials that evaluated the impact of pharmacist care activities on patients with HF (in both Inpatient and outpatient settings) were included. Summary odds ratios (ORs) with 95% confidence intervals (CIs) were calculated using a random-effects model for rates of all-cause hospitalization, HF hospitalization, and mortality.	Results: A total of 12 randomized controlled trials (2060 patients) were identified. Extent of pharmacist involvement varied among studies, and each study intervention was categorized as pharmacist-directed care or pharmacist collaborative care using a priori definitions and feedback from primary study authors. Pharmacist care was associated with significant reductions in the rate of all-cause hospitalizations (11 studies [2026 patients]) and HF hospitalizations (11 studies [1977 patients]), and a non-significant reduction in mortality (12 studies [2060 patients]). Pharmacist collaborative care led to greater reductions in the rate of HF hospitalizations than pharmacist-directed care. Conclusions: Pharmacist care in the treatment of patients with HF greatly reduces the risk of all-cause and HF hospitalizations. Since hospitalizations associated with HF are a major public health problem, the incorporation of pharmacists into HF care teams should be strongly considered.
Leal S, Herrier RN, Glover JJ, Felix A. Improving quality of care in diabetes through a comprehensive pharmacist-based disease management program. *Diabetes Care* 2004;27(12):2983-84. (YES)	Pharmacist worked under a collaborative practice agreement as the PCP for a diabetic population; collaboration also included HTN and lipid management in 199 patients	Significant decreases in HbA1c, LDL, total cholesterol, triglycerides, SBP, DBP, and blood glucose; "pts managed by pharmacist were more likely to have attained treatment goals and had recommended examinations, medications, and tests"
Lee J, McPherson ML. Outcomes of recommendations by hospice pharmacists. *Am J Health Syst Pharm* 2006;63(22): 2235-9. (YES)	Purpose: The value of pharmaceutical care recommendations made by consultant pharmacists and the outcomes of these recommendations were studied. Methods: The study was conducted at three hospice programs, and the investigators were	Ninety-eight interventions were collected and evaluated. Eighty-seven of the 98 interventions were classified as clinical interventions with specific therapeutic goals established. Of these 87 interventions, 73 (84%) were accepted by the prescriber and 56

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	consultant pharmacists who shared the responsibility of providing drug therapy recommendations to the three programs. A literature search was conducted to determine if any tools had been developed to evaluate recommendations made by pharmacists in clinical practice settings. One tool was identified and adapted for use in a hospice clinical setting. Drug-related problems (DRPs) (n = 98), clinical interventions (n = 87), and outcomes data were collected by two hospice consultant pharmacists and evaluated by a panel of experts using the assessment tool.	(77%) out of the 73 helped achieve the therapeutic goals. An additional six (8%) interventions partially achieved the therapeutic goals. Over 75% of all of the pharmacists' recommendations achieved their intended therapeutic effect, which resulted in better management of the patients' physical symptoms. None of the accepted recommendations resulted in the patient coming to harm or having an adverse effect. Overall agreement between raters for severity and value was moderately high, 60-70% and 63-80%, respectively. Kappa scores were low. Conclusion: Hospice-based clinical pharmacists influenced patient outcomes positively by identifying DRPs and recommending appropriate drug therapy.
Lipton HL, Bero LA, et al. The impact of clinical pharmacists' consultations on physicians' geriatric drug prescribing. A randomized controlled trial. *Med Care* 1992;30(7):646-58. (YES)	The impact of clinical pharmacists' consultations on geriatric drug prescribing was studied in a prospective randomized controlled trial of patients 65 years of age and over discharged on three or more medications for chronic conditions from a 450-bed community hospital. The pharmacists provided consultation to experimental patients and their physicians at hospital discharge and at periodic intervals for three months post discharge. Using a standardized tool, a physician-pharmacist panel, blinded to study group assignment of patients, evaluated the appropriateness of prescribing for a random sample of 236 patients.	88% had at least one or more clinically significant drug problems, and 22% had at least one potentially serious and life-threatening problem. Drug-therapy problems were divided into six categories: 1) inappropriate choice of therapy; 2) dosage; 3) schedule; 4) drug-drug interactions; 5) therapeutic duplication; and 6) allergy. Experimental patients were less likely to have one or more prescribing problems in any of the categories (P = 0.05) or in the appropriateness (P = 0.02) or dosage (P = 0.05) categories. A summary score, measuring the appropriateness of the patient's total drug regimen, indicated that experimental patients' regimens were more appropriate than those of controls (P = 0.01). Results of this trial reveal that clinical pharmacists can improve the appropriateness of geriatric drug prescribing in outpatient settings.
Machado M, Bajcar J, Guzzo GC, Einarson TR. Sensitivity of patient outcomes to	Meta-analysis of pharmacist intervention in diabetes management	Diabetes education and medication management were the most frequently utilized interventions. Significant reduction in HbA1c in pharmacist intervention

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pharmacist interventions. Part I: systematic review and meta-analysis in diabetes management. *Ann Pharmacother* 2007;41:1569-82. (YES)		
Machado M, Bajcar J, Guzzo GC, Einarson TR. Sensitivity of patient outcomes to pharmacist interventions. Part II: systematic review and meta-analysis in hypertension management. Ann Pharmacother 2007;41:1770-81. (YES)	Meta-analysis of pharmacist intervention in hypertension management	Hypertension education and medication management were the most frequently utilized interventions. Significant reduction in systolic blood pressure (BP) in pharmacist intervention
McKenney JM, Slining JM, Henderson HR, et al. The effect of clinical pharmacy services on patients with essential hypertension. *Circulation* 1973 Nov;48(5):1104-11.	Compared clinical pharmacy services provided to 25 study patients vs. 25 control patients with regard to essential hypertension.	Results: Significant improvement in number of study patients whose blood pressure (BP) was kept within the normal range during the study period. Conclusion: Pharmacy clinical services are beneficial and pharmacists should become more involved in the long term care given to hypertensive patients.
Radley AS, Hall J, et al. Evaluation of anticoagulant control in a pharmacist operated anti-coagulant clinic. *J Clin Pathol* 1995;48(6):545-7. (YES)	Compared pharmacist-run anticoagulation to rotation medical senior staff-run clinic. Switched from medical staff to senior staff in April 1992 – retrospective study of the four months before and four months after the switch	No clear difference between pharmacist-run and medical staff-run clinics in the 382 patients who were analyzed. Patients with an INR result "out" of control limits were more likely to be returned "in" to control at their next visit by the pharmacists than by the physicians.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Reeder TA, Mutnick A. Pharmacist- versus physician-obtained medication histories. *Am J Health Syst Pharm* 2008;65(9):857-60. (YES)	Physician-obtained medication histories were compared to those obtained by a pharmacist. Methods: Patients whose medication histories were obtained were included in the evaluation if they were at least 18 years old and admitted to an internal medicine service at the University of Virginia Medical Center. Data were collected in two phases. The first 20 patients identified for inclusion were asked to provide an accurate medication history to pilot test the medication history form used by the pharmacist and received no pharmacist follow-up or interventions. In the second phase, patients were asked to provide an accurate medication history, and a pharmacist intervened when discrepancies in the pharmacist-obtained medication history were identified.	Results: A total of 55 patients were included in the study. The pharmacists identified 614 medications for these patients, compared with 556 identified by the physicians ($p < or = 0.001$). The pharmacist documented significantly more medication doses and dosage schedules than did physicians (614 versus 446 and 614 versus 404, respectively) ($p < or = 0.001$ for both comparisons). The pharmacist identified 353 discrepancies, including 58 medications not initially identified from the physician-obtained histories. The pharmacist intervened for 161 discrepancies, correcting 142 after contacting the respective physician; 19 medication discrepancies could not be justified by the physician. Conclusion: A total of 353 discrepancies were identified when medication histories obtained by physicians were compared with those obtained by a pharmacist during the study. During the intervention phase, the majority of discrepancies identified were either corrected by the pharmacist after contacting the respective physician or justified by the physician.
Rosen CE, Copp WM, Holmes S. Effectiveness of a specially trained pharmacist in a rural community mental health center. *Public Health Rep* 1978:93(5);464-7. (YES)	Compared pharmacist-provided care with psychiatrist-provided care to mental health patients in eight clinics over a three year period.	Patients in the pharmacist group reported being significantly healthier since coming to the clinic than did other patients; also reported needing significantly less additional help than did the other patients.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Rothman R, Malone R, et al. Pharmacist-led, primary care-based disease management improves hemoglobin A1c in high-risk patients with diabetes. *Am J Med Qual* 2003;18(2):51-8. (YES)	Primary care-based diabetes disease management program for patients with type 2 diabetes and poor glucose control. Pharmacists offered support to patients with diabetes through direct teaching about diabetes, frequent phone follow-up, medication algorithms, and use of a database that tracked patient outcomes and actively identified opportunities to improve care.	After an average of six months of intervention, the mean reduction in HbA1c was 1.9 percentage points in the 138 patients who completed the study. In conclusion, a pharmacist-based diabetes care program integrated into primary care practice significantly reduced HbA1c among patients with diabetes and poor glucose control.
Sadik A, Yousif M, et al. Pharmaceutical care of patients with heart failure. *Br J Clin Pharmacol* 2005;60(2):183-93. (YES)	Objective: Investigate the impact of a pharmacist-led pharmaceutical care program, involving optimization of drug treatment and intensive education and self-monitoring of patients with heart failure (HF) within the United Arab Emirates (UAE), on a range of clinical and humanistic outcome measures. Methods: Randomized, controlled, longitudinal, prospective clinical trial of HF patients. Intervention patients received a structured pharmaceutical care service while control patients received traditional services. Patient follow-up took place when patients attended scheduled outpatient clinics (every three months). A total of 104 patients in each group completed the trial (12 months). The patients were generally suffering from mild to moderate HF (NYHA Class 1, 29.5%; Class 2, 50.5%; Class 3, 16%; and Class 4, 4%).	Results: Intervention patients showed significant improvements in a range of summary outcome measures including exercise tolerance, forced vital capacity, health-related quality of life, as measured by the Minnesota living with heart failure questionnaire. The number of individual patients who reported adherence to prescribed medications was higher in the intervention group (85 vs. 35), as was adherence to lifestyle advice (75 vs. 29) at the final assessment (12 months). There was a tendency to have a higher incidence of casualty department visits by intervention patients, but a lower rate of hospitalization. Conclusion: The research provides clear evidence that the delivery of pharmaceutical care to patients with HF can lead to significant clinical and humanistic benefits.

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Scott DM, Boyd ST, et al. Outcomes of pharmacist-managed diabetes care services in a community health center. *Am J Health Syst Pharm* 2006;63(21): 2116-22. (YES)	Purpose: Outcomes of pharmacist-managed diabetes care in a community health center were studied. Methods: Eligible patients over age 18 years with diagnosis of type 2 diabetes mellitus, randomly assigned by the clinical pharmacist and nurse to intervention (n = 76) or control group (n = 73). Patients in the intervention group were enrolled in a pharmacist-managed diabetes care program. Patients in the control group received the standard diabetes care. The primary endpoint was reduction in HbA1c; secondary outcome measures included weight loss, an improved body mass index, decreased blood pressure, and an improved lipid panel. Quality-of-life measures (health level, satisfaction, impact, worry about disease, and worry about social and vocational issues) were also assessed.	Results: Mean HbA1c levels fell significantly from baseline to nine months in both groups. A difference of 1.0 was reported between the groups' HbA1c levels. Satisfaction level improved from 63.7 to 77.4 in the intervention group, which was significant when compared with the control group, whose satisfaction score improved from 57.0 to 63.4 ($p < 0.05$). Conclusion: Patients with type 2 diabetes mellitus who received pharmacist-managed diabetes care demonstrated improved HbA1c, systolic blood pressure, and low-density-lipoprotein cholesterol levels and quality-of-life measures and met treatment goals more often than patients receiving standard care.
Sookaneknun P, Richards RM, et al. Pharmacist involvement in primary care improves hypertensive patient clinical outcomes. *Ann Pharmacother* 2004;38(12):2023-8. (YES)	Objective: To evaluate the effect of pharmacist involvement in treatment with hypertensive patients in primary care settings. Methods: The treatment objective was to stabilize the blood pressure (BP) of hypertensive patients in accordance with the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure guidelines. Patients were randomly assigned to a pharmacist-involved group (treatment) or a group with no pharmacist involvement (control). Pre- and post-test BPs, tablet counts, lifestyle modifications, and pharmacists' recommendations were recorded. The 6-month study was carried out in Mahasarakham University pharmacy and two primary care units. Patients were monitored monthly by reviewing their medications and supported by providing pharmaceutical care and counseling.	Results: From a total of 235 patients, the treatment group (n = 118) had a significant reduction in both systolic (S) and diastolic (D) BP compared with the 117 patients of the control group. The 158 patients (76 treatment, 82 control) with BPs > or = 140/90 mmHg at the beginning of the study showed significant BP reductions. The proportion of 158 patients whose BP became stabilized was higher in the treatment group. The treatment group showed significantly better adherence and exercise control at the end of the study. Physicians accepted 42.72% of medication modifications and 5.34% of the suggestions for additional investigations. Conclusion: Hypertensive patients who received pharmacist input achieved a significantly greater benefit in BP reduction, BP control, and improvement in adherence rate and lifestyle modification.

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Weinberger M, Murray MD, et al. Effectiveness of pharmacist care for patients with reactive airways disease: a randomized controlled trial. *JAMA* 2002;288(13):1594-602. (YES)	Design: Randomized controlled trial at 36 community drugstores in Indianapolis, Indiana, including 898 participants with asthma or active chronic obstructive pulmonary disease (COPD) over 12 months. Interventions: The pharmaceutical care program provided pharmacists with recent patient-specific clinical data (peak expiratory flow rates [PEFRs], emergency department [ED] visits, hospitalizations, and medication compliance), training, customized patient educational materials, and resources to facilitate program implementation. The PEFR monitoring control group received a peak flow meter, instructions about its use, and monthly calls to elicit PEFRs. However, PEFR data were not provided to the pharmacist. Patients in the usual care group received neither peak flow meters nor instructions in their use; during monthly telephone interviews, PEFR rates were not elicited. Outcome measures: Peak expiratory flow rates, breathing-related ED or hospital visits, health-related quality of life (HRQOL), medication compliance, and patient satisfaction.	Results: At 12 months, patients receiving pharmaceutical care had significantly higher peak flow rates than the usual care group but not higher than PEFR monitoring controls. No significant between-group differences in medication compliance or HRQOL. Asthma patients receiving pharmaceutical care had significantly more breathing-related ED or hospital visits than the usual care group. Patients receiving pharmaceutical care were more satisfied with their pharmacist than the usual care group and the PEFR monitoring group, and were more satisfied with their health care than the usual care group at six months only. Despite ample opportunities to implement the program, pharmacists accessed patient-specific data only about half of the time and documented actions about half of the time that records were accessed. Conclusion: This pharmaceutical care program increased patients' PEFRs compared with usual care but provided little benefit compared with peak flow monitoring alone. Pharmaceutical care increased patient satisfaction but also increased the amount of breathing-related medical care sought.
Yamada C, Johnson JA, et al. Long-term impact of a community pharmacist intervention on cholesterol levels in patients at high risk for cardiovascular events: extended follow-up of the second study of cardiovascular risk intervention by pharmacists (SCRIP-plus).	Objective: Determine the effect of a community pharmacist intervention in patients at high risk for coronary heart disease on LDL levels one year after completion of the Second Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP- plus). Methods: Patients who completed the original study were invited to make a single return visit to their community pharmacy so the pharmacist could measure their fasting LDL level using a point-of-care device. The primary outcome was change in LDL level from the 6-month (final) visit to the extended follow-up evaluation.	Results: Data were collected for 162 patients. The mean +/- SD LDL level at completion of the original study was 107.9 +/- 33.6 mg/dl. Sixty-one (38%) patients were at the target LDL level (< 96.7 mg/dl). Conclusion: The LDL reduction was maintained one year after completion of the extended follow-up. Since most patients were still not at the target LDL level, this finding suggests that continuing intervention is necessary to help patients reach this target.

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Pharmacotherapy 2005;25(1):110-5. (YES)		
Improved Clinical Outcomes AND Cost Reduction		
Bond CA, Monson R. Sustained improvement in drug documentation, compliance, and disease control. A four-year analysis of an ambulatory care model. *Arch Intern Med* 1984 Jun;144(6):1159-62.	The effectiveness of an intervention program involving a clinical pharmacist and nurse clinician in improving drug documentation in medical records, patient compliance, and disease control was analyzed. Medical records and prescription files were reviewed for patients in a rheumatology and renal clinic. Compliance was estimated by examining prescription refill patterns. Reviews were performed before intervention (control group), nine months after intervention (study group 1), and four years and nine months after the intervention program began (study group 2).	A six-month retrospective analysis at each review point demonstrated a significant improvement in drug documentation, compliance, and disease control (BP) for both study groups. Cost reductions associated with the intervention program suggest that this program is cost-effective.
Bunting BA, Cranor CW. (2006). The Asheville Project: long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. *J Am Pharm Assoc* (2003) 2006;46(2):133-47. (YES)	Intervention: regular long-term follow-up of 207 adult patients with asthma by pharmacists (reimbursed for medication therapy management [MTM] by health plans) using scheduled consultations, monitoring and recommendations to physicians. Outcomes included changes in forced expiratory volume in one second (FEV1), asthma severity, symptom frequency, the degree to which asthma affected people's lives, presence of an asthma action plan, asthma-related emergency department/hospital events, and changes in asthma-related costs over time.	All objective and subjective measures of asthma control improved and were sustained for as long as five years. FEV1 and severity classification improved significantly. Spending on asthma medications increased; however, asthma-related medical claims decreased and total asthma related costs were significantly lower than the projections based on the study population's historical trends. Direct costs savings averaged $725/pt/yr and indirect cost savings were estimated to be $1230/pt/yr. Indirect costs due to missed/non-productive workdays decreased from 10.8 days/year to 2.6 days/yr. Patients were six times less likely to have an ED/hospitalization event after program interventions. Conclusion: patients with asthma who received education and long-term medication therapy management services achieved and maintained significant improvements, and had significantly decreased overall asthma-related costs despite increased medication costs that resulted from increased

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		use.
Bunting BA, Smith BH, et al. The Asheville Project: clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia. *J Am Pharm Assoc* (2003) 2008;48(1):23-31. (YES)	Objective: Assess clinical and economic outcomes of a community-based, long-term medication therapy management (MTM) program for hypertension (HTN)/dyslipidemia over a 6-year period. Interventions: Cardiovascular or cerebrovascular (CV) risk reduction education; regular, long-term follow-up by pharmacists (reimbursed by health plans) using scheduled consultations, monitoring, and recommendations to physicians. Main outcome measures were clinical and economic parameters.	Data from 620 patients in the financial cohort and 565 patients in the clinical cohort were analyzed. Several indicators of CV health improved over the study – mean SBP, mean DBP, percentage of patients at BP goal, lowered mean LDL, percentage of pts at LDL cholesterol goal, lowered mean total cholesterol and mean serum triglycerides. The CV event rate declined by almost one-half during the study period. Mean cost per CV event was $9,931 vs. $14,343. CV medication use increased three-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%. A 53% decrease in risk of a CV event and greater than 50% decrease in risk of a CV-related ED/hospital visit were also observed. Conclusions: Patients with HTN and/or dyslipidemia receiving education and long-term MTM services achieved significant clinical improvements that were sustained for as long as six years; a significant increase in the use of CV medications, and a decrease in CV events and related medical costs.
Chiquette E, Amato MG, Bussey HI. Comparison of an anticoagulation clinic with usual medical care: anticoagulation control, patient outcomes, and health care costs. *Arch Intern Med* 1998 Aug 10-24;158(15):1641-7.	The objective was to compare newly anticoagulated patients who were treated with usual medical care (general medicine physicians) with those treated by a clinical pharmacist at an anticoagulation clinic (AC) for patient characteristics, anticoagulation control, bleeding and thromboembolic events, and differences in costs for hospitalizations and emergency department visits.	Results: When compared to usual medical care (UMC), patients treated at the anticoagulation clinic (AC) had fewer international normalized ratios greater than 5.0, spent more time in range, spent less time at an international normalized ratio greater than 5, and had fewer international normalized ratios less than 2.0. The AC group had lower rates of significant bleeding, major to fatal bleeding, and thromboembolic events. The AC group also demonstrated a trend toward a lower mortality rate. Significantly lower annual rates of warfarin-related hospitalizations and emergency department visits reduced annual health care costs by $13,2086 per 100

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		patients. Additionally, a lower rate of warfarin-unrelated emergency department visits produced an additional annual savings in health care costs of $2,972 per 100 patients. Conclusion: A clinical pharmacist-run AC improved anticoagulation control, reduced bleeding and thromboembolic event rates, and saved $162,058 per 100 patients annually in reduced hospitalizations and emergency department visits.
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):173-84. (YES)	Changes in glycosylated hemoglobin (A1c) and serum lipid concentrations, changes in diabetes-related and total medical use, costs over time.	Mean A1c decreased at all follow-ups, more than 50% of patients demonstrated improvements at each follow-up, number of patients with optimal A1c increased at each follow-up, and >50% improved in lipid levels. Costs shifted from inpatient and outpatient services from physicians to prescriptions, mean direct medical costs decreased by $1,200 to $1,872 per patient per year, and sick days decreased for one employer group, with increases in productivity estimated at $18,000 annually.
Cranor CW, Christensen DB. The Asheville Project: short-term outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc* 2003;43(2):149-59. (YES)	Assessment of short-term clinical, economic, and humanistic outcomes of pharmaceutical care services (PCS) for 85 patients with diabetes in community pharmacies. Pharmacists provided education, self-monitored blood glucose (SMBG) meter training, clinical assessment, patient monitoring, follow-up, and referral over seven to nine months. Outcomes: Change from baseline in the two employer groups in glycosylated hemoglobin (A1c) values, serum lipid concentrations, health-related quality of life (HRQOL), satisfaction with pharmacy services, and health care utilization and costs.	Results: A1c concentrations were significantly reduced. Significant dollars 52 per patient per month increase in diabetes costs, with PCS fees and diabetes prescriptions accounting for most of the increase. Patients experienced a non-significant but economically important 29% decrease in non-diabetes costs and a 16% decrease in all-diagnosis costs. Conclusion: A clear temporal relationship was found between PCS and improved A1c, improved patient satisfaction with pharmacy services, and decreased all-diagnosis costs. Findings from this study demonstrate pharmacists provided effective cognitive services and refute the idea that pharmacists must be certified diabetes educators to help patients with diabetes improve clinical outcomes.

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Dole EJ, Murawski MM, et al. Provision of pain management by a pharmacist with prescribing authority. *Am J Health Syst Pharm* 2007;64(1):85-9. (YES)	Purpose: The clinical and financial outcomes of a pain clinic managed by a pharmacist with prescribing authority are described. Summary: Pharmacist clinicians in a for-profit, integrated health system recently received permission to bill for their services in certain ambulatory clinics. A pharmacist clinician, who had an individual DEA number and whose services are billable under New Mexico law, was chosen to assume the medication management responsibilities in a clinic where 90% of the patient population is treated for chronic non-cancer-related pain. No additional personnel were needed, and no additional space was required, eliminating overhead for the space and utilities needed for operating a clinic. The revenue generated was tracked by a medical billing system, and clinical outcomes were tracked using the clinic's database for patients' individual visual analogue scale (VAS) pain scores.	With the ability to bill for the pharmacist clinician's services, a new model for justification of clinical pharmacy services was developed for the ambulatory care clinics. Between June 2004 and June 2005, an average of 18 patients was seen by the pharmacist clinician each day. The clinic generated $107,550 of actual revenue and saved the health plan over $450,000. There was a consistent decrease in mean VAS pain scores with continued visits. Conclusion: Patients with chronic non-cancer-related pain were managed effectively by a pharmacist with prescribing authority and refill authorization in a pain management clinic. The favorable clinical outcomes, revenue generated, and cost savings achieved justified the pharmacist clinician's services in this health system.
Farris KB, Kumbera P, et al. Outcomes-based pharmacist reimbursement: reimbursing pharmacists for cognitive services part 1. *J Manag Care Pharm* 2002;8(5):383-93. (YES)	Methods: A cross-sectional descriptive study was completed using the claims submitted by pharmacists to summarize findings from the first year of operations of this outcomes-based pharmacist reimbursement program (OBPR). The program involved collaboration between pharmacy benefit managers (PBMs) and community pharmacists to improve medication use. Pharmacists were reimbursed for (1) converting therapeutic regimens to generic drugs or preferred formulary medications when a prescriber contact is required; (2) conducting patient education and follow-up after initiation of new medications, changes in drug therapy, or following an over-the-counter (OTC) consultation; and (3) resolving drug-therapy problems. An efficient, no-cost	Results: Data analysis for the first year of operation, July 1, 2000, through June 30, 2001, showed 11,326 enrollees obtained 124,768 prescriptions. The majority of individuals (n = 8335, 74%) received some intervention service. The majority (90%) of intervention services were patient education and follow-up on new prescriptions or changes in prescriptions. More than 200 individuals had drug-related problems. Conclusion: This unique system of outcomes-based pharmacist reimbursement permits community pharmacists to document and bill for cognitive services. It has demonstrated that PBMs and community pharmacists can work together to improve drug therapy, and it may reduce health care costs.

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	billing system was created. The main outcome measures were descriptive statistics of prescriptions, intervention claims, and pharmacist participation in the program. Frequency distributions and descriptive statistics were used to summarize the first year of claims.	
Garrett DG, Bluml BM. Patient self-management program for diabetes: first-year clinical, humanistic, and economic outcomes. *J Am Pharm Assoc* (2003) 2005;45(2):130-7. (YES)	Objective: Assess the outcomes for the first year following the initiation of a multisite community pharmacy care services (PCS) program for 256 patients with diabetes. Interventions: Community pharmacist patient care services using scheduled consultations, clinical goal setting, monitoring, and collaborative drug therapy management with physicians and referrals to diabetes educators. Outcomes: Changes in HbA1c; LDL; BP; flu vaccinations; foot screens; eye exams; patient goals for nutrition, exercise, and weight; patient satisfaction; and changes in medical and medication utilization and costs.	Results: Over the initial year of the program, participants' mean A1C decreased from 7.9% at initial visit to 7.1%, mean LDL-C decreased from 113.4 mg/dL to 104.5 mg/dL, and mean systolic blood pressured decreased from 136.2 mmHg to 131.4 mmHg. During this time, influenza vaccination rate increased from 52% to 77%, the eye examination rate increased from 46% to 82%, and the foot examination rate increased from 38% to 80%. Patient satisfaction with overall diabetes care improved from 57% of responses in the highest range at baseline to 87% at this level after 6 months, and 95.7% of patients reported being very satisfied or satisfied with the diabetes care provided by their pharmacists. Total mean health care costs per patient were $918 lower than projections for the initial year of enrollment. Conclusion: Patients who participated in the program had significant improvement in clinical indicators of diabetes management, higher rates of self-management goal setting and achievement, and increased satisfaction with diabetes care, and employers experienced a decline in mean projected total direct medical costs.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Jameson J, VanNoord G, et al. The impact of a pharmacotherapy consultation on the cost and outcome of medical therapy. *J Fam Pract* 1995;41(5):469-72. (YES)	This prospective, randomized trial investigated whether a single consultation by a clinical pharmacist with high-risk patients and their primary physicians would result in improved prescribing outcomes. Patients at risk for medication-related problems were identified and randomized to receive a pharmacotherapy consultation (consult group) or usual medical care (control group). Outcomes, including the number of drugs, number of doses per day, cost of medications, and patient reports of adverse effects, were recorded at baseline and at six months following the intervention.	Results: Fifty-six subjects were evaluable: 29 in the control group, and 27 in the consult group. Six months after the consultation, the number of drugs, the number of doses, and the 6-month drug costs all decreased in the consult group and increased in the control group; the net difference was 1.1 drugs (P = 0.004), 2.15 doses per day (P = 0.007), $586 per year (P = 0.008). The side effects score improved by 1.8 points more in the consult group compared with the control group (P = not significant). Similarly, the prescribing convenience score in the consult group improved by 1.4 points more than that of the control group (P = not significant). Conclusions: This study demonstrated several important benefits of integration of a clinical pharmacist into a primary care setting, including improvement in cost and simplification of the medication regimen with no reduction in quality of care.
Johnston AM, Doane K, Phipps K, Bell A. Outcomes of pharmacists' cognitive services in the long-term care setting. *Cons Pharm* 1996;11(1):41-50. (YES)	Outcome measures: Number and type of interventions, change in drug therapy, change in medication cost, change in patient health.	Pharmacists made 3,464 interventions. Response rate for interventions requesting a response was 85.7%, with a 68% acceptance rate. Accepted recommendations resulted in a total cost savings of $15,111.38 for the 1-month period. Accepted recommendations resulted in favorable health outcomes 99.5% of the time.
McLean W, Gillis J, et al. The BC Community Pharmacy Asthma Study: A study of clinical, economic and holistic outcomes influenced by an asthma care protocol provided by specially trained community pharmacists in British	Objectives: The study incorporated a care protocol with asthma education on medications, triggers, self-monitoring and an asthma plan, with pharmacists taking responsibility for outcomes, assessment of a patient's readiness to change and tailoring education to that readiness, compliance monitoring and physician consultation to achieve asthma prescribing guidelines. Methods: Thirty-three pharmacists in British Columbia, specially	Results: Compared with patients in the UC group, the results of those in the EC group were as follows: symptom scores decreased by 50%; peak flow readings increased by 11%; days off work or school were reduced by approximately 0.6 days/month; use of inhaled beta-agonists was reduced by 50%; overall quality of life improved by 19%, and the specific domains of activity limitations, symptoms and emotional function also improved; initial knowledge scores doubled;

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Columbia. *Can Respir J* 2003;10(4):195-202. (YES)	trained and certified in asthma care, agreed to participate in a study in which experienced pharmacists would have asthma patients allocated to enhanced (pharmaceutical) care (EC) or usual care (UC). Pharmacists less experienced were clustered by geography and had their pharmacies randomized to two levels of care; each pharmacy then had patients randomized to EC versus control, UC versus control or EC versus UC depending on their pharmacy randomization. 631 patients provided consent, of which 225 in EC or UC were analyzed for all outcomes. Patients were followed for one year.	emergency room visits decreased by 75%; and medical visits decreased by 75%. A patient satisfaction survey revealed the population was extremely pleased with their pharmacy services. Cost analysis reinforces the EC model, which is more cost-effective than UC in terms of most direct and indirect costs in asthma patients. Conclusion: Specially trained community pharmacists in Canada, using a pharmaceutical care-based protocol, can produce impressive improvements in clinical, economic and humanistic outcome measures in asthma patients. The health care system needs to produce incentives for such care.
Simpson SH, Johnson JA, Tsuyuki RT. Economic impact of community pharmacist intervention in cholesterol risk management: an evaluation of the study of cardiovascular risk intervention by pharmacists. *Pharmacoth* 2001 May;21(5):627-35.	The Study of Cardiovascular Risk Intervention by Pharmacists, a randomized, controlled trial in over 50 community pharmacies in Alberta and Saskatchewan, Canada, demonstrated a pharmacist intervention program improved cholesterol risk management in patients at high risk for cardiovascular disease. In a sub study, costs and consequences were analyzed to describe the economic impact of the program. Two perspectives were taken: a government-funded health care system and a pharmacy manager. Costs were reported in 1999 Canadian dollars.	Incremental costs to a government payer and community pharmacy manager were $6.40/patient and $21.76/patient, respectively, during the 4-month follow-up period. The community pharmacy manager had an initial investment of $683.50. The change in Framingham risk function for the intervention group from baseline also was reported. The 10-year risk of cardiovascular disease decreased from 17.3% to 16.4% ($p < 0.0001$) during the four months. The intervention program in this study led to a significant reduction in cardiovascular risk in the intervention group during the 4-month follow-up period. The incremental cost to provide the program appeared minimal from both government and pharmacy manager perspectives. It is hoped that these results could support negotiations for reimbursement of clinical pharmacy services with payers.
Sturgess, IK, McElnay JC, et al. Community pharmacy based provision of pharmaceutical care to older patients. *Pharm*	Methods: A randomized, controlled, longitudinal, clinical trial with repeated measures was performed over an 18-month period, involving community pharmacies (five interventions and five controls) in Northern Ireland. Elderly,	Results: A significantly higher proportion of intervention patients were compliant at the end of the 18-month study and experienced fewer problems with medication compared to control patients ($P < 0.05$). There was little impact on quality of life and health care

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
World Sci 2003;25(5):218-26. (YES)	ambulatory patients (> or = 65 years), taking four or more prescribed medications were eligible for participation. Patients attending an intervention pharmacy received education on medical conditions, implementation of compliance strategies, rationalizing of drug regimens and appropriate monitoring; patients attending control sites received normal services. A battery of clinical, humanistic and economic outcomes was assessed.	utilization. Conclusions: Pharmaceutical care provision to community-dwelling patients resulted in an improvement in medication compliance and evidence of cost-savings. Future pharmaceutical care studies may benefit from a more focused selective approach to data collection and outcomes measurement.
Cost Reduction		
Bootman JL, Harrison DL, et al. The health care cost of drug-related morbidity and mortality in nursing facilities. *Arch Intern Med* 1997;157(18):2089-96. (YES)	Objective: to assess the impact of pharmacist-conducted, federally mandated, monthly, retrospective review of nursing facility residents' drug regimens in reducing the cost of drug-related morbidity and mortality. Methods: Using decision analysis techniques, a probability pathway model was developed to estimate the cost of drug-related problems within nursing facilities. An expert panel consisting of consultant pharmacists and physicians with practice experience in nursing facilities and geriatric care was surveyed to determine conditional probabilities of therapeutic outcomes attributable to drug therapy. Health care utilization and associated costs derived from negative therapeutic outcomes were estimated.	Results: Baseline estimates indicate the cost of drug-related morbidity and mortality with the services of consultant pharmacists was $4 billion compared with $7.6 billion without the services of consultant pharmacists. Conclusions With the current federally mandated drug regimen review, it is estimated that consultant pharmacists help to reduce health care resources attributed to drug-related problems in nursing facilities by $3.6 billion.
Brooks JM, McDonough RP, Doucette W. Pharmacist reimbursement for pharmaceutical care services: Why insurers may flinch. *Drug Benefit Trends* June 2000;45-62. (YES)	Researchers developed complex economic model to evaluate whether pharmaceutical care is cost-effective.	Researchers concluded that enrolling high-risk patients into pharmaceutical care programs can be of value to insurers if the savings incurred is more than the program expense. Based on the model, authors conclude that reimbursing pharmacists to provide pharmaceutical care is optimal if a relatively inexpensive patient screening method is available that enables insurers to limit visits to those patients who offer cost savings to the insurer.

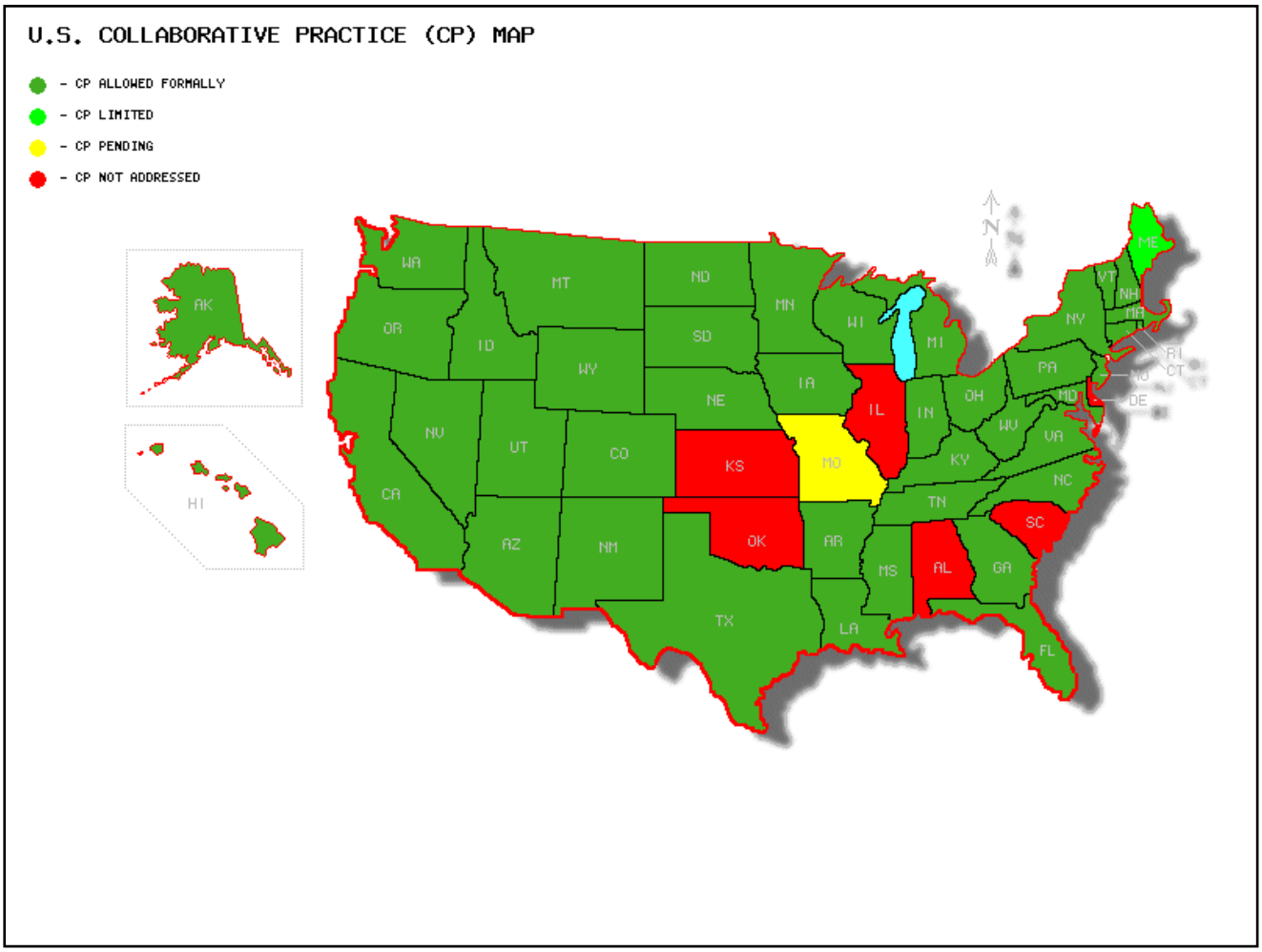
CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Christensen DB, Neil N, et al. Frequency and characteristics of cognitive services provided in response to a financial incentive. *J Am Pharm Assoc* 2000;40(5):609-17. (YES)	To determine the effects of a financial incentive on the number and types of cognitive services (CS) provided by community pharmacies to Medicaid recipients in the State of Washington. CS were reported using a problem-intervention-result coding system over a 20-month period.	Results: Study pharmacists documented an average of 1.59 CS interventions per 100 prescriptions over a 20-month period, significantly more than controls, who documented an average of 0.67 interventions ($P < 0.05$) per 100 prescriptions. One-half (48.4%) of all CS were for patient-related problems, 32.6% were for drug-related problems, 17.6% were for prescription-related problems, and 1.4% were for other problems that did not involve drug therapy. A change in drug therapy occurred as a result of 28% of all CS documented in this demonstration. Changes were rarely (2.4%) due to generic or therapeutic substitution and almost always (90%) followed communication with the prescriber. The average self-reported time to perform CS was 7.5 minutes; 75% of interventions were < or = 6 minutes. Considerable differences existed between study and control groups in the types of problems identified, intervention activities performed, and results of interventions. Conclusion: A financial incentive was associated with significantly more, and different types of, CS performed by pharmacists.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Christensen D, Trygstad T, et al. A pharmacy management intervention for optimizing drug therapy for nursing home patients. *Am J Geriatr Pharmacother* 2004;2(4):248-56. (YES)	The goals of this study were to determine: (1) the frequency with which recommendations were made by pharmacists in response to targeted profile alerts aimed at high-risk patients, (2) the frequency and type of drug therapy changes, and (3) the impact on drug-related quality and costs. Objective was to reduce polypharmacy in Medicaid recipients.	Prescription profiles were generated from Medicaid claims data and sent to consultant pharmacists for 9,208 patients in 253 nursing homes. Pharmacists returned 7548 (82%) of all profiles sent to them. After excluding 1,204 patients (13%) who were discharged or deceased, 6,344 patients (69%) remained for analysis. Baseline mean was 9.52 prescriptions per month, with mean drug cost of $502.96 to North Carolina Medicaid program. Pharmacists offered a mean of 1.58 recommendations to prescribers. After physician consultation, > or = 1 recommendation was implemented for 72% of patients with a change recommendation, 68% of whom experienced a switch to a lower-cost drug. After intervention, mean reduction in drug cost was $30.33 per patient per month. Cost savings from one month alone covered the compensation paid to pharmacists for consultation efforts. Conclusion: This supplemental program of medication reviews for targeted nursing home patients resulted in a reduction of polypharmacy and was beneficial based solely on drug cost savings.
McMullin, ST, Hennenfent JA, et al. A prospective, randomized trial to assess the cost impact of pharmacist-initiated interventions. *Arch Intern Med* 1999;159(19):2306-9. (YES)	Objective: To assess the impact of pharmacist-initiated interventions on cost savings. Methods: Six pharmacists at a large university hospital recorded patient-specific recommendations for 30 days. All quality-of-care interventions were completed by the pharmacists, but those strictly aimed at reducing costs were stratified by drug class and randomized to an intervention or control group. Pharmacists contacted physicians with cost-saving recommendations in the intervention group, while control group patients were simply observed. Outcome measure: Drug costs after randomization.	Results: Most (79%) of the 1,226 interventions recorded were aimed at improving quality of care. The remaining 21% provided equivalent quality of care, but at less expense. These cost-saving interventions typically involved streamlining therapy to less expensive agents, discontinuing an unnecessary medication, or modifying the route of administration. The group randomized to receive a pharmacist's intervention had drug costs that were 41% lower than those in the control group (mean, $73.75 vs. $43.40; P < 0.001). Interventions involving anti-infective agents had the greatest cost savings (mean, $104.08 vs. $58.45; P < 0.001). For the institution, this extrapolates to an annual savings of approximately $394,000 (95% confidence interval, $46,000-$742,000). As expected, these interventions had no

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
		impact on length of hospital stay, in-hospital mortality, 30-day readmissions, or the need to re-administer the targeted medication or restart IV therapy. Conclusion: While interventions solely aimed at reducing costs represent a small portion of a pharmacist's activities, they can result in significant savings for an institution.
Schumock GT, Meek PD, Ploetz PA. Economic evaluations of clinical pharmacy services – 1988-1995. The Publications Committee of the American College of Clinical Pharmacy. *Pharmacotherapy* 1996 Nov-Dec;16(6):1188-208.	Literature review of 104 articles identified as economic assessments of clinical pharmacy services. The articles fell into four main categories: disease state management (4%), general pharmacotherapeutic monitoring (36%), pharmacokinetic monitoring services (13%), and targeted drug programs (47%).	The majority (89%) of the studies reviewed described positive financial benefits for the variety of clinical pharmacy services evaluated, and studies that were well-conducted were most likely to demonstrate positive results.
Walker S, Willey CW. Impact on drug costs and utilization of a clinical pharmacist in a multisite primary care medical group. *J Manag Care Pharm* 2004;10(4):345-54. (YES)	Objectives: To measure the cost and utilization outcomes of a pharmacist intervention in a primary care medical group operating under a financial risk contract with a health plan. Methods: A prestudy-poststudy design using national drug utilization for the comparison was employed to assess the impact of physician-prescriber education using information derived from prescriber-specific drug cost and utilization analyses. Drug costs were measured as net medical group costs per enrolled member per year (PMPY), the product of the average cost per prescription, and the number of prescriptions PMPY, over two year period.	Drug costs per patient per year increased 1.7% versus national increase of 31.2%. Prescriptions per patient per year increased 4% versus unchanged national rate. Cost per prescription decreased 2.1% versus national increase of 31.2%. Results due to increase in use of generics. Conclusion: A targeted educational program for physician-prescribers conducted by a clinical pharmacist working for a primary care medical group can reduce the expenditures for outpatient drug therapy by lowering the average cost per pharmacy claim.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Carmichael JM, Alvarez A, Chaput R, DiMaggio J, Magallon H, Mambourg S. (2004). Establishment and outcomes of a model primary care pharmacy service system. *Am J Health-Syst Pharm* 2004 Mar 1;61(5):472-82. (YES)	A primary care pharmacy practice model was established at a government health care facility in March 1996. The original objective was to establish a primary pharmacy practice model that would demonstrate improved patient outcomes and maximize the pharmacist's contributions to drug therapy.	Many outcomes studies have been performed on the pharmacist-initiated and managed clinics, leading to improved patient care and conveying the quality conscious and cost-effective role pharmacists can play as independent practitioners in this environment. A system using pharmacists as independent practitioners to promote primary care has achieved high-quality and cost-effective patient care.

Appendix C: U.S. Collaborative Practice Map



Appendix C displays a map of the United States. Color-blocked states depict where regulatory authority for pharmacists and physicians to collaborate exist. As of May 2011, 44 states have specific regulatory authority for pharmacist-physician collaboration, six states do not (AL, DE, IL, KS, OK, SC and DC), and one is pending legislation (Missouri). Maine is color-blocked but has limited application, (emergency contraception only).

The authors used the 2011 Survey of Pharmacy Law available from the National Association of Boards of Pharmacy as a source for this map. Under Section 28 - Miscellaneous State Pharmacy Laws, the answer to “May Pharmacists Initiate, Modify, and/or Discontinue Drug Therapy Pursuant to a Collaborative Practice Agreement or Protocol?” was utilized in determining Collaborative Practice status.

Appendix D: Physician Survey

Objective: The Indian Health Service (IHS) National Clinical Pharmacy Specialist (NCPS) Program sought to obtain information from IHS physicians on their attitudes and perceptions 1) toward pharmacists that deliver patient care services, and 2) on the effectiveness of this model of health care delivery (in terms of patient outcome and health care system improvement). The goal of the survey was to collect data regarding physicians' perceptions in terms of effectiveness and impact of health care delivery working with NCPS pharmacists. This is the first physician-only survey completed regarding IHS clinical pharmacy specialists distributed IHS-wide and provides a unique look at physician attitudes within a mature (experienced) collaborative practice setting between physicians and pharmacists.

Methods: An internet-based survey tool was developed and distributed by the NCPS Program to sites that have IHS physicians who work with NCPS pharmacists practicing through collaborative practice agreements (CPAs). The survey was distributed to approximately 356 IHS physicians from IHS (n=20) and Tribal (n=13) facilities, spanning 13 states across nine of the 12 IHS geographic Areas. The respondent-driven sampling survey was disseminated by email.

Results: A total of 118 (33%) of 356 physicians responded. Physician demographics included diverse practice environments such as referral medical centers, small hospitals and ambulatory health clinics. Physicians reported CPAs were utilized to work with NCPS pharmacists. The majority of disease states managed by pharmacists included anticoagulation, dyslipidemia and tobacco cessation. However, many other conditions such as heart failure, pain management, asthma, chronic kidney disease, diabetes, infectious disease (HIV, tuberculosis, etc.) and alcohol abstinence clinics were also reported. Pharmacist-delivered patient care services included (but were not limited) to prescriptive, laboratory and assessment privileges. Many CPAs also include care coordination, patient follow-up and disease prevention/health promotion services. Overall, respondent physicians reported seeing positive patient and health system outcomes from these patient care services (96%). More specifically, respondents indicated that collaborative practice with pharmacists in their facilities helped them to improve overall primary care (88%). Additionally, they reported reductions in complications of therapy (77%). Respondents reported that pharmacist-based primary care clinics increase patient access to care and improved disease outcomes (75%). A decreased physician workload was noted by physicians (82%), which allowed them to shift the focus of care to more critically-ill patients. Physicians agreed that these pharmacists have adequate knowledge and training to provide clinical services to patients (85%) and that these services are necessary to optimize patient care (72%). Respondents felt that the scope of diseases managed by NCPS pharmacists was adequate (80%), while some even reported the scope was too narrow (11%).

Physicians also agreed or strongly agreed that services provided by pharmacists provide adequate evidence to recognize them as billable non-physician practitioners (76%). Several physicians commented that because of these pharmacist-delivered patient care services, they are able to expand the ability to provide primary care in underserved settings. Other comments included:

- “In the IHS, I depend on pharmacists to aid in providing the best quality of care for my patients.”
- “Pharmacy-based health care providers have been an integral part of the IHS during my tenure with the agency and have almost uniformly improved/elevated health status for Native Americans. These services should be recognized by CMS.”
- “In an extremely underserved setting, our clinical pharmacists provide excellent care to patients who would otherwise receive no care at all or less frequent and therefore lower quality care.”
- “Clinical pharmacists have greatly expanded the ability of our department to provide care in a very underserved setting.”
- “Our department [Family Medicine] feels that we could improve patient care/access/education/compliance by having more pharmacist clinicians in our clinics.”

Conclusion: An overwhelming majority of IHS physician respondents, who work with NCPS pharmacists delivering primary care services, believe this collaborative approach improves health outcomes, health care delivery, and access to care. To sustain and scale up these valued services to the patient and health care system, more formal recognition as health care providers and appropriate compensation mechanisms are essential.

[The survey tool is displayed as four pages; original format is electronic. The survey consists of Section 1-Purpose of Survey and NCPS Program Background, Section 2-NCPS Provider Survey (12 questions), Section 3-Demographics, and Section 4-Feedback.]

1. NCPS Program Background

This survey seeks the input of IHS, Tribal, and Urban (I/T/U) providers opinion on the clinical and administrative impact of pharmacists working in disease management roles. We will be collecting and analyzing this data to help justify our position and garner support for future (and expanded) compensation mechanisms for pharmacists providing primary care.

Background:

The Indian Health Service (IHS) established a national certification process for IHS, Tribal, and Urban (I/T/U) and Bureau of Prison (BOP) pharmacists, the National Clinical Pharmacy Specialist(NCPS) Program. The NCPS has a national committee composed of practicing pharmacists and physicians from IHS and BOP. The NCPS program was established in response to meetings with the Center for Medicaid and Medicare Services (CMS, formerly HCFA) to ultimately promote enhanced patient outcomes, increase access to care and improve quality of care through the following:

- Define advanced scopes of practice for I/T/U and BOP pharmacists;
- Establish critical elements for developing collaborative practice agreements (CPA) within a physician-driven privileging system;
- Develop a review process to approve CPAs and clinical pharmacy specialists by a national group of subject matter experts to help ensure uniformity of scope and competence;
- Promote uniform clinical competency among I/T/U and BOP pharmacists;
- Review credentials, protocols, training, education and experience of I/T/U and BOP pharmacists and grant NCPS certification to recognize a pharmacist's local privileges that meet the specified national standards for certification;
- Establish the above elements to help promote universal recognition of NCPS pharmacists as billable providers.

2. NCPS Provider Survey

*** 1. In your facility, do you have pharmacists practicing under collaborative practice agreements/protocols?**

- ◯ YES
- ◯ NO

*** 2. Have you ever (or currently) worked with a pharmacist who was NCPS certified?**

- ◯ YES
- ◯ NO

If yes, describe your experience:

3. If yes, what disease areas? Check all that apply

- ☐ Anticoagulation
- ☐ Asthma
- ☐ Chronic Kidney Disease
- ☐ Heart Failure
- ☐ Lipid Management
- ☐ Pain Management
- ☐ Tobacco Cessation

Other (please specify)

4. What benefits in the clinical services that pharmacists provide have you seen in your facility? (Check all that apply)

- ☐ Decreased physician workload
- ☐ Allows physicians to shift workload to more critical patients
- ☐ Increased patient access to care
- ☐ Reduction in complications of therapy (e.g. interactions, duplicate drugs, drug allergies, appropriate dosing, hospitalizations)
- ☐ Improved disease management outcomes
- ☐ Increased return on investment

Other (please specify)

5. Mark the answer that best agrees with your opinion.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Do you feel that NCPS certified pharmacists have adequate knowledge/training to provide clinical services for patients?	◯	◯	◯	◯	◯

6. Mark the answer that best agrees with your opinion.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Do you feel that clinical services, such as disease management, provided by pharmacists are necessary to optimize patient care?	◯	◯	◯	◯	◯

7. Mark the answer that best agrees with your opinion.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Do you feel that the collaborative practice has helped you to improve overall primary patient care?	◯	◯	◯	◯	◯

8. Mark the answer that best agrees with your opinion.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Have you seen improvements in medication adherence in patients who are seen by clinical pharmacists?	◯	◯	◯	◯	◯

9. The NCPS Committee sets specific criteria that applicants and collaborative practice agreements must meet. Do you feel the standards and protocols set by the NCPS program to establish national uniformity for clinical pharmacy are adequate?

◯ YES

◯ NO

◯ Not familiar with standards

10. How do you feel about the scope of diseases that are managed by NCPS pharmacists?

◯ Adequate

◯ Too broad

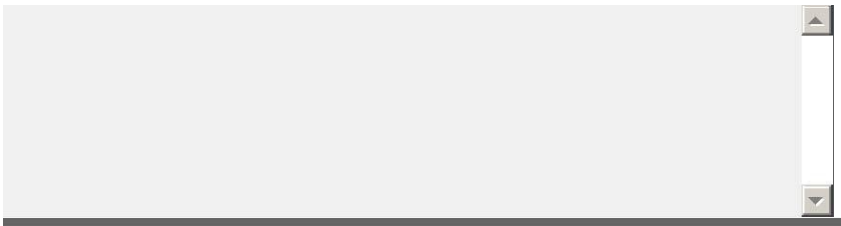
◯ Too narrow

11. Mark the answer that best agrees with your opinion.

NCPS pharmacists provide a level of primary care which includes some prescriptive authority, laboratory monitoring and physical assessment.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
From your experience, do you feel these services provide adequate evidence to recognize them as billable non-physician practitioners?	◯	◯	◯	◯	◯

. Are there any additional comments?



3. Demographics

Please let us know where you practice.

Company:

City/Town:

State:

4. Feedback

Thank you for completing this survey and for your support of the NCPS Program.

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