ALASKA'S PHARMACISTS

IMPROVING THE HEALTH OF COMMUNITIES

AKPhA
ALASKA PHARMACY ASSOCIATION

Pharmacists are essential members of the healthcare team and evidence clearly shows the growing need for pharmacist-provided patient care services. To guarantee equitable access to this vital care, both public and private health plans must cover pharmacists' patient care services.

Learn More!

QUALIFIED

HIGHLY QUALIFIED HEALTHCARE PROVIDERS

EDUCATION
6-8 years of education including pharmacotherapy, disease management, and clinical decision-making

CLINICAL TRAINING
At least 1,740 hours of clinical practice experience focused on high-quality patient care in a variety of healthcare settings

ADDITIONAL TRAINING
Many complete post-graduate residencies, fellowships, and/or board certifications in various specialty areas

All current pharmacy school graduates earn the PharmD degree, a doctorate degree reflecting the advanced pharmacotherapy knowledge and comprehensive patient care training essential for providing high quality pharmacist services, a requirement that has been in place **since 2004**.

ACCESSIBLE

MOST ACCESSIBLE HEALTHCARE PROFESSIONAL

520 Pharmacists in Alaska [1]

860 Pharmacy Technicians in Alaska [1]

89% Americans live within 5 miles of a community pharmacy. [2]

Number of pharmacies is **15% higher** than number of provider's offices in communities where more than 30% of households live in poverty. [3]

PUBLIC HEALTH IMPACT

VITAL TO IMPROVING PUBLIC HEALTH

Approximately 50% of all adults in the U.S. have one or more chronic disease conditions. [4]

Chronic conditions account for over 85% of total U.S. health care costs. [4]

$4 Saved for every $1 spent on pharmacist service. [5]

COVERAGE OF SERVICES

Pharmacists' clinical services are **rarely** covered under the medical benefit by **health plans**. This creates **barriers** to patients using their health insurance to receive care from pharmacists.

$9.64 return on investment for every $1 when pharmacists are paid for providing various patient care services.[6]

All health plans, public and private, **must** cover the services pharmacists provide to ensure patient access.

TEST & TREAT

Pharmacy-based point-of-care testing and treatment services provide prevention and early detection for minor health conditions.

30 States now authorize pharmacists to directly order and administer CLIA-waived tests.

States now authorize pharmacists to directly prescribe treatment pursuant to a CLIA-waived test. **13**

Common Pharmacy-Based CLIA-Waived Tests*

COVID-19	Flu	UTI	HIV
Strep	RSV	STI	& more

*Abbreviation details available on references page.

IMMUNIZATIONS

Alaska pharmacists are independently prescribing vaccines.

Pharmacies offer **TWICE** the operating hours for giving immunizations vs. provider's offices[7]

2023-24 Flu Season

Pharmacies gave **37.6 Million** flu shots

vs

25.5 Million given at provider's offices[8]

27 States now authorize pharmacists to **directly prescribe** and administer vaccines to patients.

OPIOID USE DISORDER

81,000 Americans died from an opioid overdose in 2023.[9]

222 average deaths per day[9]

13 States authorize pharmacists to prescribe medications for opioid use disorder.

Naloxone access laws that grant pharmacists direct authority to prescribe are associated with significant reductions in fatal overdoses.

HIV PREVENTION

Pharmacists have been identified by the White House as key professionals in achieving one of the CDC's goals of ending the HIV Epidemic in the U.S. by preventing HIV infection.

States authorize pharmacists to directly prescribe HIV pre-exposure prophylaxis (PrEP) medications. **16**

19 States authorize pharmacists to directly prescribe HIV post-exposure prophylaxis (PEP) medications.

This information was developed through a collaboration between NASPA and APhA, with generous support from the Community Pharmacy Foundation.

Access our references at tinyurl.com/2024factsheet
Or scan this QR code

REIMBURSING U.S. PHARMACISTS TO TEST AND TREAT COMMON ILLNESSES

Prepared for:
State of Alaska
7/10/2024

Can speed up treatment, increase convenience, improve access to care and decrease costs for Alaska and its residents

HEALTHCARE WORKERS ARE IN SHORT SUPPLY

The national shortage of U.S. healthcare workers **(more than 3.2 million by 2026** [2] **)** leaves many individuals without timely access to diagnosis and treatment services for low acuity respiratory symptoms.

Pharmacist test and treat services can help free up specialized medical technologists across the health system for priority testing and treatment of life-threatening illness.

"HEALTHCARE DESERTS" COMPOUND THE PROBLEM

Nearly **75 million people**, or almost one-third of the population, reside in one of the **7,475** Primary Care Health Professional Shortage Areas (HPSAs) across the U.S.[1] HPSAs can be both rural and urban, and have limited access to basic medical services.

IN ALASKA THERE ARE

287.7 THOUSAND
people living in
333
Healthcare Primary Care Professional Shortage Areas (HPSAs)[1]

112.9 THOUSAND
Medicare enrollees, or
15.0%
of the population[3]

44 THOUSAND
Estimated **Medicare enrollees** experiencing challenges to access care in HPSAs*

PHARMACISTS ARE FILLING THE VOID, ESPECIALLY IN RURAL AND UNDERSERVED COMMUNITIES

89%
of Americans live within **5 miles** of a pharmacy[4]

62
Alaska pharmacies with CLIA-waivers to perform diagnostic tests[5]

Since 2020, pharmacists have delivered over
42 MILLION
respiratory illness tests, establishing a **nationwide network for rapid testing**[6]

PHARMACY TEST AND TREAT SERVICES CAN REDUCE HEALTHCARE COST

UPPER RESPIRATORY TRACT INFECTIONS	PATIENT OUT-OF-POCKET (COST SHARING)	HEALTH SYSTEM PAYMENT
Average visit cost - Emergency Department	$523 [7]	$1,535 [7]
Pharmacy test and treat (assumes 20% co-pay)	$28.70	$143.50 [8, 9]

If 1% of Medicare enrollees in Alaska visited a pharmacy instead of an emergency department,
$1 MILLION
in **health care system savings** could be achieved**
reducing patient out-of-pocket costs***
95%

Estimates shown are for illustrative purposes only. There is no guarantee of the potential savings indicated.

*% of state population living in HPSA (287,657 people in HPSA[1]/733,406 census population[10]) x 112,886 Medicare enrollees[3].
Assumes distribution across HPSAs consistent with general population.

**(ED Health System Payment ($1,535-$523[7]) - Pharmacy test and treat ($143.50-$28.70[8])) x (112,886 Medicare enrollees[3] x .01)

***$523 out-of-pocket cost for ED visit[7] vs.$28.70 out-of-pocket cost for pharmacy test and treat[8]

06/2024

TEST AND TREAT AT THE LOCAL PHARMACY CAN REDUCE COST AND OFFER HIGH-QUALITY, CONVENIENT CARE

REDUCED COST

Pharmacy test and treat services have the potential to reduce health system costs as well as out-of-pocket expenses for patients. These services, if reimbursed at current cash pay prices, would be **similar to costs for low acuity urgent care or primary care** office visits.

Patients who do not have access to a primary care doctor will have the opportunity to be quickly diagnosed and treated, so their respiratory **symptoms do not progress into a more serious and costly health care condition** such as bronchitis or pneumonia. [11-13]

Patients and insurers will receive the full clinical benefit of money spent on COVID-19 and influenza **treatments which are only effective if started within 2-5 days of symptom onset**. [14-16] Studies have shown that treatment within 48 hours for the Flu can shorten the duration, severity and cost of the illness. [17]

Individuals who live in medical provider shortage areas will have an **alternative to using the ER for respiratory infections** which are common and generally uncomplicated if diagnosed and treated early. [18]

HIGH QUALITY CARE

Pharmacist education includes the **extensive study of diseases, their diagnosis, and corresponding treatments**. [19]

All states **mandate that pharmacists maintain their clinical expertise** through continuing education credits, and many states require pharmacists providing test and treat services to complete additional training. [19, 20]

CONVENIENCE

Pharmacies are often located near homes, along bus lines or within locations people already frequent daily, like grocery and convenience stores. Reimbursing pharmacists to test and treat will **empower patients to seek care** at drug stores nearby, making convenience even greater.

Pharmacists can **speed up diagnosis and treatment** of common illnesses by offering both services in a single location. Immediate treatment can help patients get well sooner, allowing them to **return to work or school more quickly**.

Pharmacies have **flexible hours** beyond just the traditional workday, with many open on weekends or even 24/7. They can provide test and treat services during hours other care may not be available, **especially in parts of the country that lack other flexible options** (e.g. urgent care, after hours clinics).

LEGISLATIVE ACTION IS NEEDED

Respiratory testing access with pharmacists nationwide is at risk

Without action, pharmacies will lose their incentive to maintain their testing infrastructure, causing a **significant loss in availability of test and treat services needed during respiratory illness seasons** when preventing the spread of infection is most important for seniors. Ultimately, patient outcomes may suffer. [21, 22]

Across the U.S., more than 7,000 pharmacies have closed since 2019. Experts say they can leave behind communities that have come to depend on them as trusted sources of care and advice - both of which can be hard to find in many urban and rural areas. [23]

Reimbursement of pharmacy test and treat services can help offset losses from reduced dispensing reimbursement and DIR (direct and indirect remuneration) reform. [24]

H.R. 1770 / S. 2477 EQUITABLE COMMUNITY ACCESS TO PHARMACIST SERVICES ACT

Authorizes pharmacists to **receive reimbursement for low-acuity respiratory illness** services for seniors and others receiving Medicare [25]

- Does not provide Medicare reimbursement for all services such as medication, chronic disease management, health and wellness screening, and education
- Does not recognize pharmacists as health care providers for all Medicare patients
- **Does not supersede state scope of practice laws** [26]

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SB 147

PHARMACIST PROVIDED PATIENT CARE SERVICES / STANDARD OF CARE

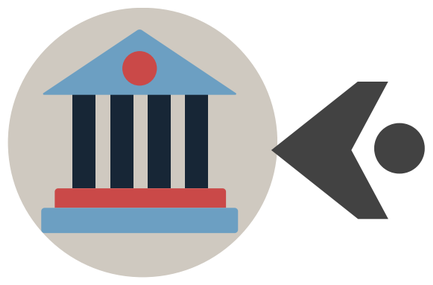
The goal of this bill is to increase access to pharmacist-provided patient care services, allowing healthcare practitioners in Alaska to practice at the top of their education, training, and experience.

INCREASED ACCESS TO TIMELY CARE FOR ALASKANS

Pharmacists are uniquely positioned to help manage chronic diseases and minor ailments, decrease unnecessary emergency department visits, and deliver preventative health outcomes.

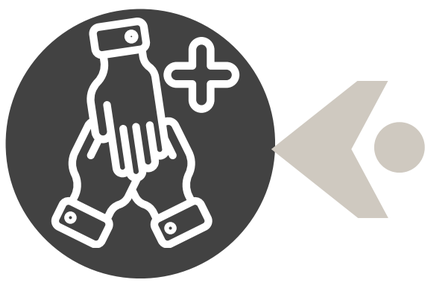
ALIGNMENT WITH THE STANDARD OF CARE

The Alaska Board of Pharmacy already regulates pharmacists under the standard of care, this bill aligns the statute with this model.



ESTABLISHED FEDERALLY

Expanded pharmacist services have been established federally. MAT Act allows pharmacists to prescribe for opioid use disorder. Nearly 100 years of evidence based practice at federal healthcare settings show improved patient outcomes.



INTERDISCIPLINARY COLLABORATION

The bill encourages interdisciplinary collaboration & patient referral to higher levels of care as needed.

DOCTOR OF PHARMACY EDUCATION

Pharmacists complete a standardized Doctor of Pharmacy (PharmD) degree nationwide, accredited by Accreditation Council Pharmacy Education, with 1,740 hours of clinical training.

State Boards of Pharmacy help ensure safe care through participation in accreditation reviews.

Communities trust their pharmacists. With pharmacists permitted to practice at the top of their education, training, and experience, a pharmacist can better triage a patient for referral to more acute care when needed.

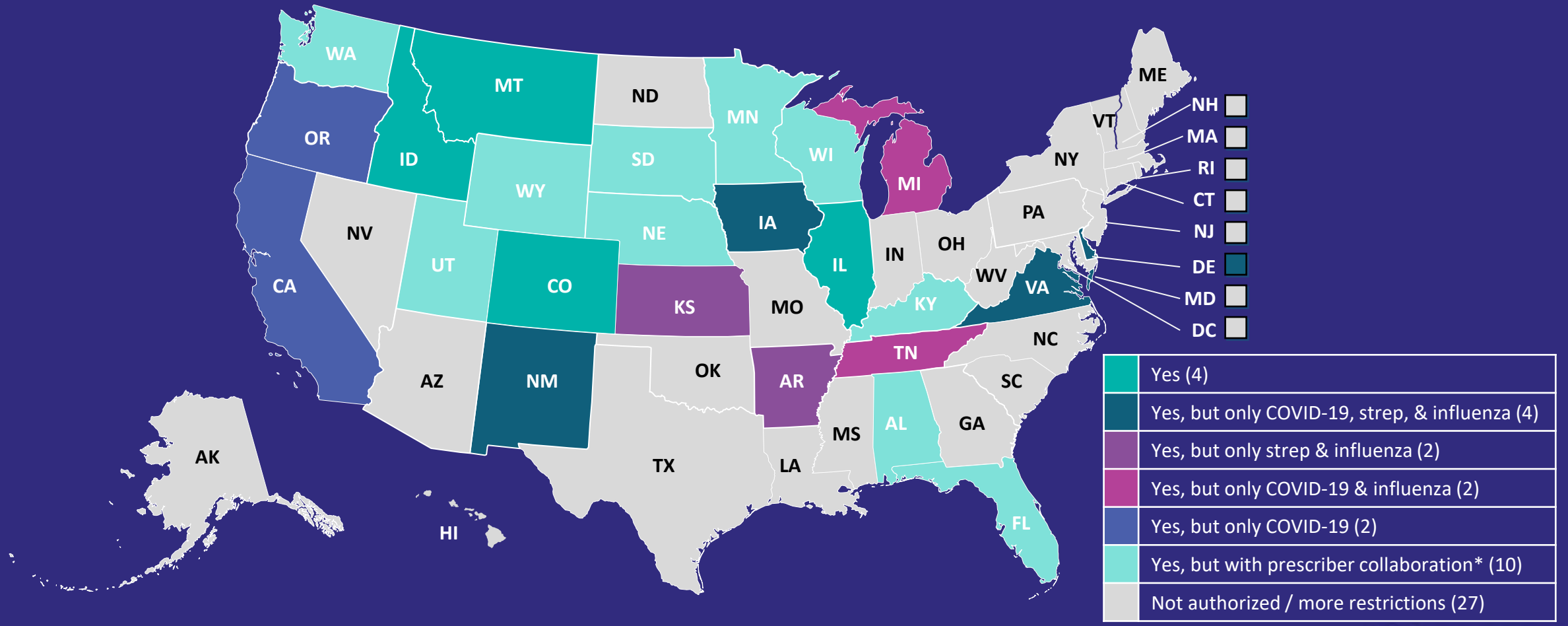
Alaskans Strongly Support Expanded Pharmacist Care. A recent national poll, including Alaska-specific data, reveals that Alaskans overwhelmingly support expanded roles for pharmacists in testing, treatment, and prevention of common and chronic conditions at thier local community pharmacies.

Alaska's healthcare system in general has limited hospital beds, emergency department space, and other services in general. Utilizing every provider at the top of their education, training, and experience can increase access to timely and appropriate care

SUPPORTED BY THE ALASKA BOARD OF PHARMACY & THE ALASKA PHARMACY ASSOCIATION

Updated November 2024

Can pharmacists test and treat for COVID–19, influenza, respiratory syncytial virus, or streptococcal pharyngitis via prescriptive authority, statewide protocol, or other means?*



*Limited to collaborative practice agreements or prescriber protocols that allow multiple patients and do not require past prescriber-patient relationship

American Pharmacists Association
For Every Pharmacist. For All of Pharmacy.

Press Releases

Published on Tuesday, December 10, 2024

HHS extends federal authority consistent with APhA request for pharmacy personnel to independently administer vaccines and test to treat services through 2029

WASHINGTON, DC — The American Pharmacists Association (APhA) released the following statement regarding the U.S. Department of Health and Human Services (HHS) response to APhA's request to issue a **twelfth amendment** to the declaration under the federal Public Readiness and Emergency Preparedness (PREP) Act for medical countermeasures.

"Today's necessary actions by HHS will continue to **save lives and lower health care costs**, particularly in rural and underserved areas where the local pharmacy may be the only health care provider for miles," said Michael D. Hogue, PharmD, FAPhA, FNAP, FFIP, executive vice president and CEO of APhA. "As a vital part of our nation's health care infrastructure, pharmacy teams serve as the front line of defense against infectious disease. APhA applauds HHS for extending these federal authorities until **legislation** is passed by the U.S. Congress to make them permanent."

Key changes finalized in the amendment include:

- **Extends PREP Act coverage and authority for COVID-19 and seasonal influenza vaccines and COVID-19 tests.** PREP Act immunity from liability is extended through December 31, 2029, to pharmacists to order and administer and pharmacy interns and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (three and over), and COVID-19 tests.

Since 2020, licensed pharmacists in all 50 states have been able to utilize federal PREP Act authority to provide vaccination, and testing and treatment services, specifically to children ages 3 to 18 years, where they previously had not been permitted in certain states. Several states have taken action (**see map**) to make these federal PREP Act authorities permanent.

###

DEA Drug Schedules **from Senator Giessel's office**

Schedule I

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Some examples of Schedule I drugs are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote.

Schedule II

Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are: combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin

Schedule III

Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. Some examples of Schedule III drugs are: products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone

Schedule IV

Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol

Schedule V

Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin

ClinicoEconomics and Outcomes Research

Dovepress

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Open Access Full Text Article

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

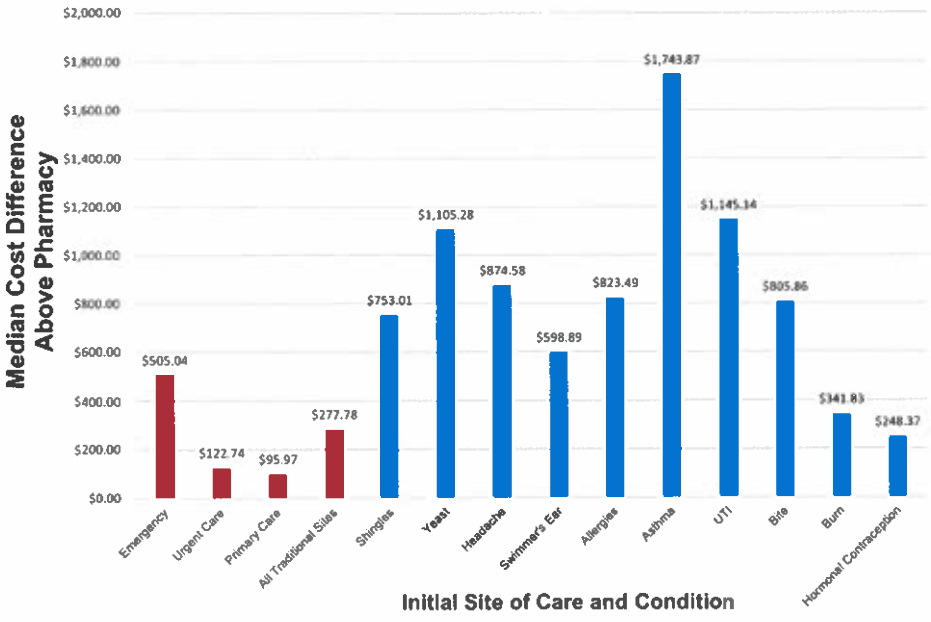

Figure 1 Traditional Site of Care Median Cost Difference Above Pharmacy by Initial Site of Care and Condition.

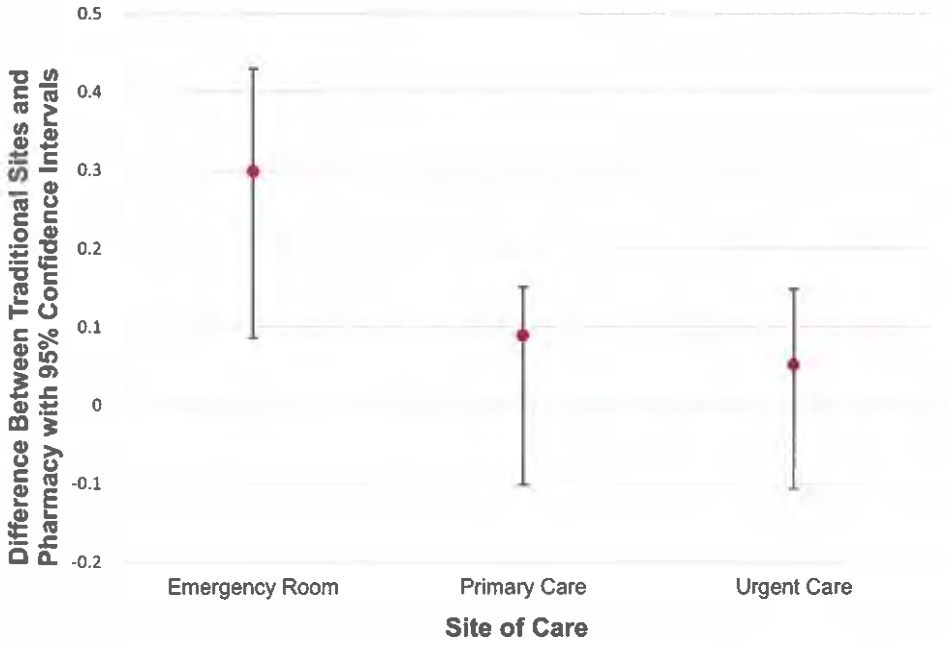

Figure 2 Traditional Sites versus Pharmacy Revisit Noninferiority Analysis.

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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Disclosure

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