PREVENTING CHRONIC DISEASE
PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY

Public Health and Pharmacy:
Collaborative Approaches to Improve Population Health

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About the Journal

Preventing Chronic Disease (PCD) is a peer-reviewed public health journal sponsored by the Centers for Disease Control and Prevention and authored by experts worldwide. PCD was established in 2004 by the National Center for Chronic Disease Prevention and Health Promotion with a mission to promote dialogue among researchers, practitioners, and policy makers worldwide on the integration and application of research findings and practical experience to improve population health.

PCD's vision is to serve as an influential journal in the dissemination of proven and promising public health findings, innovations, and practices with editorial content respected for its integrity and relevance to chronic disease prevention.

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Table of Contents

11. **The Mississippi Delta Health Collaborative Medication Therapy Management Model: Public Health and Pharmacy Working Together to Improve Population Health in the Mississippi Delta**
Ross LA, Bloodworth LS, Brown MA, Malinowski SS, Crane R, Sutton V, et al. The Mississippi Delta Health Collaborative Medication Therapy Management Model: Public Health and Pharmacy Working Together to Improve Population Health in the Mississippi Delta. Prev Chronic Dis 2020;17:200063.

12. **Using an Advanced Practice Pharmacist in a Team-Based Care Model to Decrease Time to Hemoglobin A1c Goal Among Patients With Type 2 Diabetes, Florida, 2017–2019**
Cowart K, Updike W, Emechebe N, Zgibor J. Using an Advanced Practice Pharmacist in a Team-Based Care Model to Decrease Time to Hemoglobin A1c Goal Among Patients With Type 2 Diabetes, Florida, 2017–2019. Prev Chronic Dis 2020;17:190377.

13. **Telepharmacy and Quality of Medication Use in Rural Areas, 2013–2019**
Pathak S, Haynes M, Qato DM, Urick BY. Telepharmacy and Quality of Medication Use in Rural Areas, 2013–2019. Prev Chronic Dis 2020;17:200012.

14. **Rural–Urban Disparities in Access to Medicaid-Contracted Pharmacies in Washington State, 2017**
Graves JM, Abshire DA, Undeberg M, Forman L, Amiri S. Rural–Urban Disparities in Access to Medicaid-Contracted Pharmacies in Washington State, 2017. Prev Chronic Dis 2020;17:200066.

15. **State and Regional Variation in Prescription- and Payment-Related Promoters of Adherence to Blood Pressure Medication**
Yang PK, Ritchey MD, Tsipas S, Loustalot F, Wozniak GD. State and Regional Variation in Prescription- and Payment-Related Promoters of Adherence to Blood Pressure Medication. Prev Chronic Dis 2020;17:190440.

16. **Mapping Community Opioid Exposure Through Wastewater-Based Epidemiology as a Means to Engage Pharmacies in Harm Reduction Effort**
Duvallet C, Hayes BD, Erickson TB, Chai PR, Matus M. Mapping Community Opioid Exposure Through Wastewater-Based Epidemiology as a Means to Engage Pharmacies in Harm Reduction Efforts. Prev Chronic Dis 2020;17:200053.

17. **Louisiana State Policies Prove Problematic for Pharmacist–Physician Collaboration**
Hamilton AL, Darr M. Louisiana State Policies Prove Problematic for Pharmacist–Physician Collaboration. Prev Chronic Dis 2020;17:200051.

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COMMENTARY

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

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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 14 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.

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.

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.

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 phar-

macies 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.

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 RESEARCH

Pharmacists in Federally Qualified Health Centers: Models of Care to Improve Chronic Disease

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PEER REVIEWED

Summary

What is already known on this topic?

Evidence shows that pharmacist-provided medication management can improve chronic disease outcomes; however, pharmacists are not consistently considered integral members of health care teams.

What is added by this report?

It provides an example of how collaboration among state public health, clinical, and academic partners can catalyze expansion of models of care that include pharmacists and that inclusion of pharmacists on care teams has the potential to improve chronic disease outcomes.

What are the implications for public health practice?

Findings can provide guidance to public health, clinical, and academic partners in their efforts to expand care models that include pharmacists, to help improve chronic disease outcomes.

Abstract

Introduction

Pharmacists are underused in the care of chronic disease. The primary objectives of this project were to 1) describe the factors that influence initiation of and sustainability for pharmacist-provided medication therapy management (MTM) in federally qualified health centers (FQHCs), with secondary objectives to report the number of patients receiving MTM by a pharmacist who achieve 2) hemoglobin A1c (HbA_{1c}) control (≤9%) and 3) blood pressure control (<140/90 mm Hg).

Methods

We evaluated MTM provided by pharmacists in 10 FQHCs in Ohio through qualitative thematic analysis of semi-structured interviews with pharmacists and FQHC leadership and aggregate reporting of clinical markers.

Results

Facilitators of MTM included relationship building with clinicians, staff, and patients; regular verbal or electronic communication with care team members; and alignment with quality goals. Common MTM model elements included MTM provided distinct from dispensing medications, clinician referrals, and electronic health record access. Financial compensation strategies were inadequate and varied; they included 340B revenue, incident-to billing, grants, and shared positions with academic institutions. Of 1,692 enrolled patients, 60% (n = 693 of 1,153) achieved HbA_{1c} ≤9%, and 79% (n = 758 of 959) achieved blood pressure <140/90 mm Hg.

Conclusion

Through this statewide collaborative, access for patients in FQHCs to MTM by pharmacists increased. The factors we identified that facilitate MTM practice models can be used to enhance the models to achieve clinical goals. Collaboration among clinic staff and community partners can improve models of care and improve chronic disease outcomes.

Introduction

Although well positioned to fill gaps in health care, pharmacists have long been underused (1,2). This is especially relevant in chronic disease management despite evidence that demonstrates pharmacists' success in improving outcomes through collaborative care and medication therapy management (MTM) (1–6). MTM involves a multifaceted approach of reviewing medications, identifying and remedying medication-related problems, providing dis-

ease state management and self-management education, addressing medication adherence issues, and considering preventive health strategies to optimize medication-related health (3,4,7,8). An MTM service includes a comprehensive medication review to ensure that the patient's medication-related needs have been met and all of their medications are appropriate, effective, safe, and convenient. At the end of the visit, a care plan is developed and shared with the patient and the primary care provider to resolve and prevent any drug therapy problems by eliminating unnecessary medications, initiating appropriate medications, adjusting dosage regimens, addressing adverse reactions, and increasing the patient's willingness and ability to adhere to the medication regimen (9,10). Through MTM, pharmacists play an important role in addressing health care disparities in underserved areas (11–14). Developments including passage of the Patient Protection and Affordable Care Act (15), subsequent expansion of Medicaid, and the establishment of federally qualified health centers (FQHCs) have created more opportunities for pharmacists to provide care in community-based settings. Integration of MTM remains limited in many community-based settings due to lack of reimbursement, medical provider buy-in, time, and resources (16,17). Additionally, evidence is sparse with regard to outcomes in FQHCs and factors that facilitate initiation, continuation, and sustainability of care provided by pharmacists in FQHCs (17,18).

The Ohio Department of Health (ODH), Ohio Pharmacists Association (OPA), and Ohio Association of Community Health Centers (OACHC) collaborated with colleges of pharmacy in Ohio on a 5-year, 2-phase project to address these gaps and opportunities. This project involved developing a statewide learning community and advisory board, tracking aggregate outcomes for patients receiving care from pharmacists, and qualitatively evaluating processes surrounding pharmacist-provided MTM. The primary objectives of this project were to 1) describe factors that influence initiation of and sustainability for pharmacist-provided MTM in FQHCs, and 2) report the number of patients receiving MTM by a pharmacist who achieved hemoglobin A1c (HbA_{1c}) control (≤9%) and blood pressure control (<140/90 mm Hg).

Methods

This was a multi-site, prospective project approved by the institutional review boards of The Ohio State University and the Ohio Department of Health. A multidisciplinary consortium was created to oversee the project. The consortium set a mission to expand team-based care involving pharmacists to prevent chronic disease; disseminate outcomes to support successful models of care; and collaborate across private, public, and academic entities to promote statewide advancement in patient access to pharmacist care. Members of the consortium included representatives from the ODH, the OPA, the OACHC, all 7 colleges of pharmacy in Ohio, the state's Medicare quality improvement organization, and pharmacists providing care to patients in FQHCs. The consortium met quarterly to guide project activities, review goals and plans for disseminating outcomes, and share updates and best practices among the FQHC pharmacists related to practice models and care strategies. The project used qualitative research methods and descriptive statistics to report on objectives.

The first project phase (Phase 1) was initiated in March 2014 and concluded in December 2016 and involved 3 FQHCs with well-established models for pharmacists to provide MTM to patients. The processes for recruitment, quantitative data reporting, and analysis for this first phase were published previously (19). Patients were recruited at each FQHC from reports created with each site's electronic health record (EHR). Patients were included if they were aged 18 to 75 years; had a diagnosis of hypertension, diabetes, or both, with diagnosis occurring at least 1 year prior; were seen for a medical visit(s) at least once in the last year; and had a most recent HbA_{1c} >9% and/or a most recent systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg. We assessed how well patients had control of their diabetes (good control, HbA_{1c} <7% to poor control, HbA_{1c} >9%) and whether patients had controlled (<140/90 mm Hg) or uncontrolled (≥140/90 mm Hg) hypertension. Visit lengths and structures varied with the pharmacist providers based on individual patient needs and clinic structures among the 10 FQHCs involved in the project. Follow-up data were gathered from EHRs in each FQHC site and reported centrally to the Ohio Department of Health for analysis. These metrics were based on Uniform Data System clinical measures defined by the Health Resources and Services Administration (HRSA) and required for reporting by FQHCs (20). Patients were excluded if they were pregnant, diagnosed with end stage renal disease, or had received a pharmacist visit at the site within 1 year before enrollment.

The second phase (Phase 2) of this project was initiated in January 2016. Investigators recruited 2 additional cohorts of pharmacists. These next 2 cohorts (4 FQHCs in the first and 3 in the final) included pharmacists with new or emerging opportunities to establish pharmacist-provided MTM in FQHCs. First and second phase sites (10 sites in total) provided MTM according to their individual clinic policies, procedures, and workflow. Inclusion and exclusion criteria as well as quantitative data reporting and analysis were the same for the first and second phases of the project (19). All 10 sites continued to enroll patients from their start date through December 31, 2017; data reporting concluded on June 30, 2018.

To understand facilitators and barriers to implementing MTM in an FQHC setting, semi-structured interviews were conducted with

both clinical pharmacists and nonpharmacist clinic leaders (eg, medical directors, chief executives) recruited from FQHCs taking part in this project. The 3 sites from Phase 1 and 5 of the 7 sites from Phase 2 participated in the qualitative interviews; however, due to site staff turnover and resulting incomplete information, qualitative data from one Phase 2 site was eliminated from thematic analysis, leaving 7 total sites involved in the qualitative analysis. Comparable qualitative data were not collected from sites in the final cohort, because these sites were still in the process of initiating MTM services and could not contribute comparable data.

A single investigator identified a clinical pharmacist to be interviewed at each FQHC. Clinical pharmacists then identified nonpharmacist clinic leaders in their affiliated FQHC to be interviewed in an effort to gather more than one perspective at each FQHC and capture the nuances and complexity of MTM implementation at each site.

Interview protocols were developed by 3 investigators with input from ODH epidemiology and evaluation staff. A set of interview protocols was developed for each clinical pharmacist to capture perspectives close to the beginning of each project phase and 6 to 12 months later. A separate protocol, drawn from a subset of questions from the clinical pharmacy protocol, was developed to capture the perspectives of nonpharmacist clinic leaders. Protocols aimed to gather information about each site's approach to implementing MTM: rationale for implementing the service; financial supports used; patient identification and referral processes; staffing; elements of the MTM model of care; and key facilitators, barriers, and lessons learned, as well as the future sustainability of MTM at each site and advice for others contemplating MTM implementation.

Two investigators conducted telephone interviews with clinical pharmacists at each of the 3 Phase 1 sites between July and August 2015 and again in January 2016. Nonpharmacist clinic leaders from these sites were interviewed in January and February 2016. A similar series of interviews was conducted with 4 Phase 2 sites by the same 2 investigators in July 2016 and again in July or August 2017. All interviewees consented to have their interviews recorded and were provided with their interview summary to review for completeness and accuracy. Corrections or additions supplied by interviewees were incorporated into the final summaries.

After finalizing all interview summaries (n = 20 interviews, n = 14 unique interviewees) across cohorts, 2 investigators conducted an inductive, cross-case thematic analysis (19) using the qualitative data analysis software NVivo11 (QSR International). Informed by analysis techniques described in Patton (21) and Charmaz (22) and to identify emergent themes, 2 investigators identified and discussed broad common themes and broke those themes down further to more nuanced themes. Throughout this process, investigators resolved any differences that arose via consensus. The themes were further vetted for cohesiveness and validity by 2 additional investigators with training and experience in clinical pharmacy and MTM. Significance throughout qualitative analysis was defined by the study team as at least 4 of the 7 sites reporting an element or theme. Quotations or excerpts from interview summaries and recordings were de-identified to protect the confidentiality of the interviewees and the FQHCs.

Results

Seven pharmacists (2 male, 5 female) and 7 nonpharmacist clinic leaders (2 male, 5 female) from 7 FQHC sites were interviewed. Information gathered during these interviews was categorized into 3 key areas related to MTM models of care in FQHCs: common elements (Table 1), strategies for financial compensation (Table 2), and facilitators to initiation, continuation, and expansion (Table 3).

Elements of clinic structure, workflow, and patient care processes common to all sites providing MTM in FQHCs were pharmacists providing MTM services billed through Medicare Part D–integrated platforms (eg, Mirixa [Outcomes Incorporated], OutcomesMTM [Cardinal Health]), at least partial pharmacist access to EHRs, a care team minimally inclusive of a medical provider and a pharmacist, and referral of patients to pharmacists by a medical provider. With regard to clinic operations, a notable commonality described among all MTM models was patient visits with pharmacists separate from dispensing functions (Table 1).

Strategies for financial compensation for MTM also demonstrated commonalities with all sites engaging in billing through MTM platforms and every FQHC reporting involvement in a 340B drug pricing program. Other strategies for financial compensation were mixed and included clinic or pharmacy grants, collaboration or shared funding with a college of pharmacy, and billing with evaluation and management medical codes either as incident-to or through shared medical visits (Table 2).

Facilitators were organized based on whether they were related to MTM initiation or continuation and expansion (Table 3). In addition to the top facilitators described in Table 3, the need for sustainable compensation for pharmacists providing MTM emerged as another significant theme among pharmacists and nonpharmacist leaders. The lack of adequate levels and modalities of reimbursement for care was described as a major barrier to initiation and expansion of MTM. Interviews across all sites mentioned the importance of recognition of pharmacists as providers and the need for appropriate financial compensation for care provided by pharmacists. For example, one clinic leader shared:

> Recognizing pharmacists as providers at the federal level would help with reimbursement for services. If the provider status of pharmacists is ever approved, they will be able to obtain adequate reimbursement for Medicaid and Medicare, can bill under the pharmacists' name, and will be properly paid for their time and effort. Depending on the degree to which this actually happens and how many insurance providers will accept the change in status, [pharmacists] could add more clinical positions and not rely solely on medication dispensing. If this were approved, [pharmacies] would hire more pharmacists, serve many more patients, and could provide clinical services at locations where they don't have a dispensing component.

Other themes emerged but did not reach significance, including workflow and clinical infrastructure considerations and staff education. More specifically, a few sites mentioned the importance of clinicians directly referring patients to pharmacists, availability of private rooms for pharmacist and patient meetings, clinicians' prior experience collaborating with pharmacists on patient care, and pharmacists with past experience providing comprehensive MTM as being important facilitators of MTM initiation. Educating nonclinicians and other clinic staff on MTM (what it entails, benefits of) was mentioned by a few sites as important to obtaining buy-in and support for MTM, along with educating patients and clinicians to improve understanding and participation.

Between March 2014 and December 2017, 1,692 patients were enrolled in this study at the 10 FQHCs in all phases of the project; 1,153 of these patients were enrolled with uncontrolled diabetes, and 959 of these patients were enrolled with uncontrolled hypertension. At final data collection ending on June 30, 2018, approximately 60% (n = 693) of patients with uncontrolled diabetes achieved an HbA_{1c} ≤9%, 20.6% (n = 238) between 8% and 9%, 20.2% (n = 233) between 7% and <8%, and 19.3% (n = 222) <7% (Figure 1). Of those with hypertension, 79% (n = 758) achieved a blood pressure that was in range at <140/90 mm Hg (Figure 2).

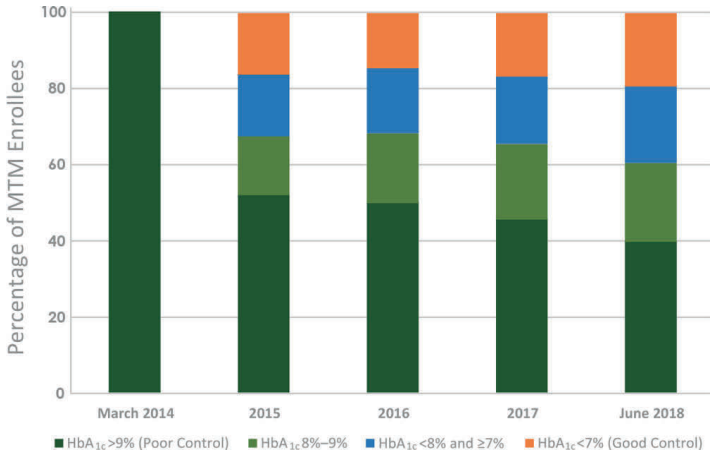

Figure 1. Aggregate achievement of HbA_{1c} goals of patients enrolled in medication therapy management (MTM) services at 10 Ohio federally qualified health centers from March 2014 through June 2018. Abbreviation: HbA_{1c}, hemoglobin A1c.

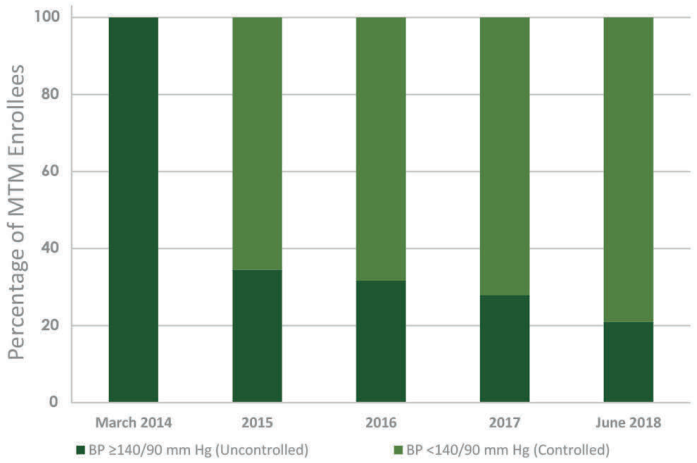

Figure 2. Aggregate achievement of blood pressure (BP) goals of patients enrolled in medication therapy management services at 10 Ohio federally qualified health centers from March 2014 through June 2018.

Discussion

Semi-structured interviews with pharmacists and FQHC leadership identified common elements of MTM workflow among sites and key facilitators to initiation, continuation, and expansion of these services. Patients with previously uncontrolled diabetes and blood pressure displayed aggregate achievement of HbA_{1c} and blood pressure goals following visits with pharmacists.

The degree of clinical goal achievement in this project was comparable to results reported by the Patient Safety and Clinical Phar-

macy Services Collaborative (PSPC), a national initiative designed by HRSA in 2008 to enhance medication use in safety-net organizations, including FQHCs. In 2012, PSPC reported achievement of goals, with 35% of PSPC sites attaining desired HbA_{1c} levels and 43% of PSPC sites reporting meeting hypertension goals. In the Ohio project, 60.1% of patients achieved HbA_{1c} goals and 79.0% reported achievement of hypertension targets (23). The Change Package initiative with PSPC provided implementation steps and best practice tips from FQHCs with established pharmacy services. The Change Package recommendations align with themes that emerged in the Ohio MTM analysis. Similar facilitators between the 2 included identifying physician champions, providing EHR access for pharmacists, sharing outcomes from pharmacy services with clinic leadership and clinicians, educating clinicians on benefits of clinical pharmacy services, and pharmacists engaging in regular communication with clinicians and care team members (18).

Investigations have demonstrated strategies to build successful pharmacist-provided MTM in community-based settings, such as FQHCs. Pestka et al (17) proposed a stepwise process for community pharmacies to integrate MTM into practice sites. With the focus on traditional community pharmacies, their findings were aimed mainly at the internal pharmacy staff and considerations for changes within the pharmacies. In our qualitative analysis of pharmacists in FQHCs, it is notable that many of the key facilitators to initiation involved stakeholders external to the pharmacists and pharmacy staff, such as clinicians, patients, and clinic leadership. Snyder et al (16) evaluated 3 community-based models of care including an independent pharmacy, a chain pharmacy, and an FQHC practice model. Barriers to MTM in these settings included reimbursement as well as lack of provider buy-in, time, resources, and collaborative practice agreements (CPAs). Facilitators included team-based care and collaboration with academic partners. Jorgensen et al (24) conducted telephone interviews with pharmacists, physicians, and nurse practitioners from 23 health care teams that had integrated a new pharmacist role and identified 7 key themes describing the barriers and facilitators the teams experienced during pharmacist integration. The themes identified in their study aligned and reinforced results described in this project, including the importance of relationship-building, experience of providers working with pharmacists, and the need for adequate resources and funding. Finally, Fischer et al (25) conducted a mixed-methods cohort study in one FQHC with a pharmacy to examine the implementation and impact of a broad program involving MTM. Interviews identified enabling factors to success that align with our results, including data access, leadership support, staffing, and 340B funding.

Our findings correlate well with other pharmacist service–specific literature, which confirms and expands the evidence base for pharmacist-provided care in FQHCs. However, no previous study involved the breadth and number of FQHCs and interview participants as the Ohio project. Additionally, no previous study described a state-specific learning community. The state-focused collaboration involving the OPA, all 7 colleges within the state, the ODH, and OACHC facilitated a learning and practice advancement consortium with shared payor opportunities as well as pharmacy practice act considerations.

Strategies for financial compensation varied among the sites involved in this statewide project. Sites identified that improvement in compensation opportunities for pharmacists as providers of care is needed and may be necessary for continued expansion of pharmacy services in FQHCs. Murawski et al (26) evaluated practice characteristics and reimbursement for pharmacists in certified collaborative clinical practice in New Mexico and North Carolina and found, as we did, that despite integration and acceptance of pharmacists providing care by patients and clinicians, reimbursement challenges continued to limit expansion of the model.

Limitations

Individual pharmacists and FQHCs developed the workflow models that fit with their infrastructure, resources, and patient populations. Thus, these individual processes of care may have influenced results by introducing unknown confounders because quantitative data was not analyzed at the individual FQHC site or patient level. Patient experience with the pharmacist-provided care was not evaluated in this study and is an opportunity for future evaluation. Transcripts from interviews conducted with first phase, experienced sites as well as second phase, emerging sites were compiled and analyzed as one group of data. Data from pharmacist and nonpharmacist interviewees were also analyzed in aggregate and included 7 of the 10 pharmacy sites. An additional confounder was that a few questions were developed and added mid-study, based on information volunteered by some early interviewees. Themes that arose from responses to those questions were less likely to reach thematic significance. For example, expansive CPA legislation involving pharmacists and physicians were passed in Ohio in 2016 while this project was in process. A consistent theme or commonality in CPAs may have arisen if all interviewees had been asked to discuss CPAs during all interview phases.

Conclusion

Statewide collaboration among state public health, FQHCs, pharmacists, and colleges can catalyze expansion of pharmacist models of care and improve chronic disease outcomes. Through this

statewide collaborative, patients cared for in FQHCs had access to pharmacist-provided MTM services for diabetes and/or blood pressure management. Although this statewide public health collaboration model with pharmacy is transferable to other states, key elements to patient care models and facilitators to success that were identified can be applied at the clinic site level to build successful MTM models of care in FQHCs. Pharmacists and other health care providers and policy makers must continue to strive for sustainable financial compensation to improve patient access to pharmacist-provided MTM.

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Tables

Table 1. Common Elements to Medication Therapy Management Models of Care in 7 Ohio Federally Qualified Health Centers (FQHCs), March 2014–June 2018

Element	7 FQHCs	4–6 FQHCs
Clinic and pharmacy structure		
MTM services provided onsite at FQHC	●	
Pharmacy has at least partial clinical access to EHR	●	
Collaborative Practice Agreement used		●
On-site pharmacy		●
FQHC owns pharmacy		●
Care team members		
Medical provider (MD, NP, PA)	●	
Pharmacist	●	
Pharmacy resident(s)		●
Pharmacy student(s)		●
Patient identification		
Medical provider referral	●	
Referral through EHR		●
EHR data mining		●
Eligibility criteria		
Uncontrolled chronic condition[a]	●	
Multiple medications (ie, polypharmacy)		●
Visit structure and content		
Separate visit with a pharmacist[b]	●	
MTM platform documentation and billing[c]	●	
Communication (verbal or via EHR) with clinician	●	
Medication assistance (ie, cost)		●

Abbreviations: EHR, electronic health record; MD, doctor of medicine; MTM, medication therapy management; NP, nurse practitioner; PA, physician assistant.
[a] Inclusion criteria required patients to have either uncontrolled hypertension (blood pressure >140/90 mm Hg) or uncontrolled type 2 diabetes (hemoglobin A_{1c} >9%).
[b] Two sites also conducted joint visits with a medical provider.
[c] Mirixa (Mirixa Corporation, Reston, Virginia) and/or OutcomesMTM (Cardinal Health, Dublin, Ohio).

Table 2. Medication Therapy Management (MTM) Financial Compensation Strategies Implemented in 7 Ohio Federally Qualified Health Centers, March 2014–June 2018

Site	OutcomesMTM and/or Mirixa Electronic MTM Platforms	Participation in 340B Drug Pricing Program	Medical Billing[a]	Portion of Pharmacist Salary Supported by a University	Clinic Budget or Grants	Pharmacy Budget or Grants
1	•	•[b]	•[c,d]	•	•	
2	•	•[b]	•		•	
3	•	•[e]		•		
4	•	•[c]			•	
5	•	•[b]				
6	•	•[c]	•		•	
7	•	•[c]		•	•	•

[a] Billing through Evaluation and Management codes 99211–99215.
[b] Funds go to clinic, used to expand clinical pharmacy services, including MTM.
[c] Funds go to clinic, not allocated to any specific services.
[d] Billing through lower-level, incident-to code 99211.
[e] Funds go to clinic, used to support patient care generally. No information available about allocation of funds to MTM or other clinical pharmacy services.

Table 3. Facilitators to Initiation, Continuation, and Expansion of Medication Therapy Management Models of Care in 7 Ohio Federally Qualified Health Centers, March 2014–June 2018

Theme (No. of Sites Contributing to Theme)	Selected Representative Statements
Facilitators to Initiation	
Identify or cultivate a champion in administration, quality improvement committee, or C-suite (n = 7)	The administrative team and the board of directors were all supportive of MTM from the beginning. The CEO is a registered nurse with a strong clinical background and understood the need for MTM.
	The CMO has a history of working with clinical pharmacists for most of her career. One of the primary preceptors (a physician) had a BS in pharmacy as an undergraduate. The CEO of the clinic is also supportive of pharmacy being an integral part of the clinic. The support is embedded within the culture. The clinic is extremely supportive of pharmacy.
Engage clinician champions (n = 7)	The associate medical director indicated relying on pharmacists to help provide education and follow-up support to her patients. This carries over into new clinician orientation where she talks about how helpful support from pharmacists has been to her and her patients and encourages them to take advantage of on-site MTM services.
	The clinical pharmacist reports that open communication with clinicians and finding clinician champions early on who are supportive of a pharmacist's role on the care team are important. Champions can be used as a sounding board and can relay to other clinicians how pharmacists can complement their work with patients.
	At first the clinical pharmacist worked exclusively with one NP who had some previous experience working with a pharmacist. This NP became a champion and served as a model for other clinicians. The NP would identify 10 to 20 of his patients with the greatest needs who had upcoming appointments and ask the clinical pharmacist to work with them. Through this collaboration, they were able to capture data to show the benefit of MTM.
Ensure pharmacists have support to conduct MTM outside of medication dispensing (n = 7)	The CMO remarked that it is often difficult for a dispensing pharmacist to have time to conduct MTM. Having a clinical pharmacist and resident, and sometimes students, who can conduct or help with MTM has been key.
	The clinical pharmacists work alongside the medical providers and not in the dispensary.
Align the potential benefits of MTM with FQHC quality care goals (patient experience, health outcomes, clinical quality measures) (n = 7)	From the start of MTM, administrators were excited about MTM because of the potential it held for improving patient outcomes
	Reimbursement was not as important to administrators as improving quality of patient care and, along with that, quality measures.
	MTM improves the quality of patient care . . . and helps them achieve their goals as a patient-centered medical home.
Educate clinicians on how pharmacists can contribute to the care team (n = 4)	In the beginning, to help foster buy-in among clinicians, the clinical pharmacist held monthly 1-hour meetings to present the project and to describe how the pharmacist planned to communicate with the clinicians about patient care.
	Before implementation of MTM, the clinical pharmacist attended medical staff meetings. She introduced the program in advance so that everyone was clear about what it offered and worked to establish relationships with clinicians in advance.
	The CEO noted that initially some clinicians and staff had a tough time grasping the idea of having a pharmacist on the care team, so the clinical pharmacist started out providing some basic information to clinicians such as what MTM is and how to use pharmacy services.
Facilitators to continuation and expansion	
Collect data on patient outcomes/quality of care; share with clinicians and management (n = 7)	Collecting, tracking, and sharing outcome data with clinicians and management were very important. The clinical pharmacist had a plan from the beginning as to how they were going to use the data to increase buy-in and support for MTM. They track 3 types of data: physician perspectives, patient perspectives, and patient outcomes, for example, hemoglobin A1C, blood pressure, and LDL cholesterol. Without this evidence they would not have support continued for their efforts.
	The CEO noted that once a practice is able to document positive patient outcomes and share those outcomes with clinicians, they see the value of it. The clinical pharmacist produces a quarterly newsletter that includes a patient story. The CEO finds this has been an effective communication strategy for clinicians and staff.
Show how clinical pharmacy services benefit the care team (n = 7)	The associate medical director noted that having pharmacists on the care team really enhances the team: "[The pharmacist's efforts] could serve as a text-book example of what team-based care looks like in a PCMH."
	The CEO remarked that physicians support MTM because the program allows them to do their job. They do not have extensive time to speak with patients about medication adherence or to provide the lengthy conversations needed to help patients who are confused, elderly, cannot read, or just cannot understand. Clinicians know if they hand these

Abbreviations: 340B, 340B drug pricing program; BS, bachelor of science; C-suite, top senior staff within an FQHC; CEO, chief executive officer; CMO, chief medical officer; EHR, electronic health record; FQHC, federally qualified health center; LDL, low-density lipoprotein; MCOs, Medicaid-managed care organizations; MTM, medication therapy management; NP, nurse practitioner; PCMH, patient-centered medical home.

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Table 3. Facilitators to Initiation, Continuation, and Expansion of Medication Therapy Management Models of Care in 7 Ohio Federally Qualified Health Centers, March 2014–June 2018

Theme (No. of Sites Contributing to Theme)	Selected Representative Statements
	patients off to the pharmacist that it makes their day go more smoothly.
Seek and illuminate the financial benefits of MTM to the clinic (n = 7)	The executive director and chief financial officer have always been supportive of pharmacy services, but as reimbursement is starting to be tied to it (eg, quality of care, reduced hospital readmissions), there is a greater focus on this type of service.
	They also plan to continue having conversations with third-party payers (eg, MCOs) around direct reimbursement for MTM.
	Clinic management and physicians see the benefit of investing 340B revenue into clinical pharmacy services because it improves patient outcomes.
	There was no expectation from the FQHC that MTM should generate revenue to support the clinical pharmacist's salary. But as the project developed, he began to plan for ways to make MTM sustainable post grant. He wanted to be able to show the project's worth, and also to avoid having the position be a cost burden.
Communicate regularly with clinicians (in person or via EHR) (n = 6)	The clinic workstation is shared by all of the clinicians, and the clinical pharmacist finds this helps facilitate collaboration across staff and clinicians.
	All pharmacists are also invited to attend the monthly clinician meeting. In the past, these meetings were only for physicians and nurse practitioners. The pharmacists requested to be invited to attend those meetings as well. This allows pharmacists a chance to interact with clinicians outside of the clinic and the opportunity to hear what they are hearing from administration.
	Now that the clinical pharmacist has access to the health center's EHR, they can document visit notes and recommendations directly into the EHR as they meet with patients.
Show how MTM contributes to meeting clinic goals (n = 6)	The associate medical director finds that providing MTM makes it easier for the clinic to reach its quality goals and make improvements in quality measures, for example hemoglobin A1c levels for diabetes.
	Focusing on quality measures was already a priority at this organization, so the MTM team worked to incorporate improvement in these measures as a priority.
	External factors such as quality measures certainly influence clinicians' and administration's willingness to take on MTM. The clinical pharmacist expects they will have the data they need to demonstrate these improvements to providers and administration.
Build relationships with clinicians (n = 5)	Where the clinical pharmacist sees the greatest need for clinical pharmacy is in support of midlevel clinicians (eg, nurse practitioners and physician assistants) and is working on building relationships with these clinicians.
	Getting buy-in can be a challenge but is critical. The clinical pharmacist suggests that pharmacists work alongside physicians as much as possible, spend time at the nurses' station, stay in communication, and get to know the medical assistants. Other care team members don't necessarily know what pharmacists can do, so they need to be there to show them what they can do. It is important to build these relationships and know that this might take time.
	There is still more work to be done, however, to build support for MTM among clinicians. Some clinicians still don't trust the service, or they just get caught in their old routines and don't think about how the pharmacist can help them. The clinical pharmacist thinks that continuing to build relationships with each clinician, by helping answer their patient's questions, will help her build buy-in for working with a larger number of patients in a more in-depth manner.

Abbreviations: 340B, 340B drug pricing program; BS, bachelor of science; C-suite, top senior staff within an FQHC; CEO, chief executive officer; CMO, chief medical officer; EHR, electronic health record; FQHC, federally qualified health center; LDL, low-density lipoprotein; MCOs, Medicaid-managed care organizations; MTM, medication therapy management; NP, nurse practitioner; PCMH, patient-centered medical home.

PREVENTING CHRONIC DISEASE
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PUBLIC HEALTH PRACTICE BRIEF

Continuous Stakeholder Engagement: Expanding the Role of Pharmacists in Prevention of Type 2 Diabetes Through the National Diabetes Prevention Program

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PEER REVIEWED

Summary

What is already known on this topic?

Pharmacists are well positioned and can be highly effective in providing preventive health services to patients in their communities; however, they remain underutilized as public health service providers.

What is added by this report?

We strategically leveraged partnerships with pharmacy stakeholders to develop resources and promotional materials tailored to the needs and values of pharmacists. Our efforts can help expand type 2 diabetes prevention services through the pharmacy workforce.

What are the implications for public health practice?

A systematic process of continuous stakeholder engagement can be replicated as an approach to involve pharmacists and other health professionals in similar public health prevention efforts.

Abstract

The pharmacy sector is a key partner in the National Diabetes Prevention Program (National DPP), as pharmacists frequently care for patients at high risk for type 2 diabetes. The Centers for Disease Control and Prevention aimed to increase pharmacist involvement in the program by leveraging partnerships with national pharmacy stakeholders. Continuous stakeholder engagement helped us to better understand the pharmacy sector and its needs. With stakeholders, we developed a guide and promotional campaign. By following a systematic process and including key stakeholders at every step of development, we successfully engaged these valuable partners in national type 2 diabetes prevention efforts. More pharmacy sites (n = 87) are now offering the National DPP lifestyle change program compared to before release of the guide (n = 27).

Background

One in 3 US adults has prediabetes, which can lead to type 2 diabetes, heart disease, and stroke (1). To help prevent or delay type 2 diabetes, the Centers for Disease Control and Prevention (CDC) established the National Diabetes Prevention Program (National DPP) in 2010. The National DPP is a partnership of public and private organizations building a nationwide delivery system for an evidence-based lifestyle change program for adults at high risk for type 2 diabetes. The program follows a CDC-approved curriculum and is delivered by trained lifestyle coaches in person or virtually. The goal is to help participants engage in healthy behaviors and achieve 5% to 7% weight loss (2). Evidence shows that participants in the National DPP lifestyle change program can cut their risk of developing type 2 diabetes by 58% and 71% for people aged 60 years or older (3). The National DPP lifestyle change program is offered in various settings, such as hospitals and clinics, community organizations, and worksites.

Pharmacists are the third largest group of health care professionals in the United States, after physicians and nurses, and are often on the front lines of care for medically underserved patients who are at risk for type 2 diabetes. Despite the extensive training of pharmacists and their service expansion beyond traditional medication dispensing, they remain underused as public health service providers (4). Ninety-two percent of US residents live within 1.6

miles of a pharmacy, and patients see their pharmacist more frequently than their primary care physician (5,6). Pharmacies are well positioned to provide preventive health services because of their convenient locations and extended hours of operation, which allow them to reach patients who might otherwise have limited access to care (5). They often provide services that align with National DPP activities, including patient education, screening and identifying patients at high risk for chronic disease, initiating referrals, and providing chronic disease and weight management services (5,7,8).

Intervention Approach

CDC manages quality assurance of the National DPP, awarding CDC recognition to organizations that deliver the lifestyle change program and meet national quality standards (9). In 2016, CDC identified 7 pharmacies already offering the lifestyle change program and invested in efforts to determine how the pharmacy workforce (pharmacists, technicians, residents, community health workers, and students) could expand and sustain the National DPP. This CDC multiyear effort was to scale the National DPP in more pharmacies by collaborating with national pharmacy stakeholders and leveraging these partnerships to better understand the pharmacy landscape, develop a tailored resource for pharmacists, and disseminate pharmacy-specific information about the National DPP to the pharmacy workforce (Figure).

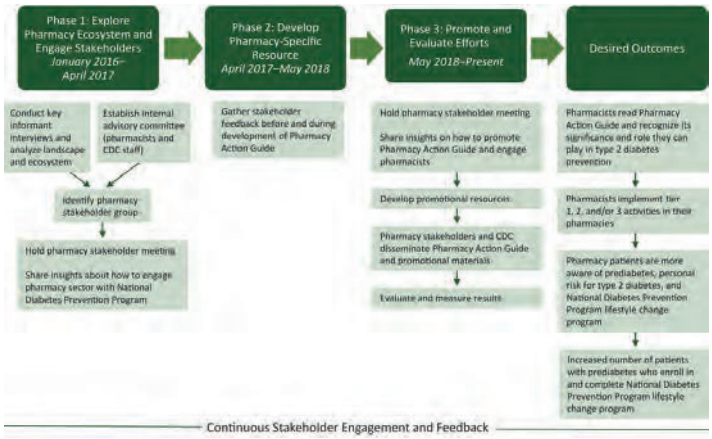

Figure. Model for pharmacist engagement in the National Diabetes Prevention Program.

Phase 1: explore and engage

We began by establishing relationships with the 7 pharmacies already implementing the National DPP lifestyle change program and exploring their motives for involvement. These pharmacies serve diverse patient populations across the United States. Five serve rural populations, and 4 focus on patients who have a low income or who are medically underserved. Five are independent pharmacies; 1 is a school of pharmacy; and 1 is a retail chain grocery pharmacy. We learned through key informant interviews that several of these pharmacies attributed success in implementing the National DPP to alignment of the program with wellness services the pharmacies already offered, sufficient financial and staffing support, and strong preexisting relationships in their communities. Our pharmacy ecosystem and landscape analysis indicated the following facts:

- Pharmacists are increasingly working as providers, expanding their portfolio of patient care services.
- More independent pharmacies than other pharmacy types exist in areas with a high prevalence of diabetes, although their limited resource capacity makes scalability a challenge.
- National pharmacy associations are strong advocates for enabling pharmacists to offer more services and can serve as influencers in pharmacist decision making.

Based on results of the analysis and recommendations from an internal advisory committee, we established a national pharmacy stakeholder group of pharmacy associations, pharmacies implementing or interested in the National DPP lifestyle change program, and public health and pharmacy representatives from government and advocacy groups. We involved this group in decisions and strategies to engage the pharmacy sector in National DPP activities.

In March 2017, we convened a meeting of pharmacy stakeholders (Box). Representatives of 10 national pharmacy organizations attended to discuss pharmacy roles in the National DPP, marketing and communication strategies, and resources needed for engagement. Stakeholders shared insights on the validity of the landscape analysis, determined how the National DPP could fit within the pharmacy sector, and stressed the need for resources, including concrete, practical information on how pharmacies could become involved in type 2 diabetes prevention efforts. They shared ideas for content for a guidance document, including how pharmacies can incorporate the program into their workflows.

Box. Organizations Represented at Pharmacy Stakeholder Meetings, 2017–2018

Pharmacies and Pharmacy Associations

American Association of Colleges of Pharmacy
American Pharmacists Association
American Society of Health-System Pharmacists
CVS Health — 2nd meeting only, May 24, 2018

Georgia Community Pharmacy Enhanced Services Network
National Alliance of State Pharmacy Associations
National Association of Chain Drug Stores
National Community Pharmacists Association

Pharmacies Delivering the National Diabetes Prevention Program Lifestyle Change Program

Duquesne University Center for Pharmacy Care
Jefferson Community Health and Life
Kroger, Kentucky (Louisville Division)

Federal Government: Public Health and Pharmacist Representatives

Center for Medicare and Medicaid Innovation, Centers for Medicare & Medicaid Services — 2nd meeting only, May 24, 2018
Centers for Disease Control and Prevention
United States Department of Veterans Affairs — 2nd meeting only, May 24, 2018
United States Public Health Service — 2nd meeting only, May 24, 2018

Public Health Advocacy

American Diabetes Association — 2nd meeting only, May 24, 2018

Phase 2: develop and test

In Phase 2, we collaborated with pharmacy stakeholders to develop and test a resource tailored to the needs of pharmacists that would prompt their involvement in the National DPP. Stakeholders provided instrumental insights for the development of the Rx for the National Diabetes Prevention Program: Action Guide for Community Pharmacists (Pharmacy Action Guide), released in May 2018. At the March 2017 meeting, stakeholders conveyed that, as a result of limited time and resources, not all pharmacies would be able to deliver the lifestyle change program, but they could support the National DPP in other ways. Therefore, the guide highlighted the following 3 tiers of pharmacy involvement:

- Tier 1: Promote awareness of prediabetes and the National DPP. This is a simple, low-cost step to get involved with type 2 diabetes prevention efforts. The guide outlines existing promotional materials and campaigns that pharmacies can use to raise awareness of prediabetes and the National DPP.
- Tier 2: Screen, test, and refer. By using a CDC-approved risk assessment or blood glucose test, pharmacies can help determine whether patients are at high risk of developing type 2 diabetes or currently have prediabetes. Pharmacy staff can then refer eligible patients to the CDC-recognized lifestyle change program.
- Tier 3: Offer the lifestyle change program. The guide describes how pharmacies can become CDC-recognized providers of the National DPP lifestyle change program.

Based on stakeholder feedback on the capacity of pharmacists versus other pharmacy staff members (residents, students, technicians) to implement the 3 tiers, the guide outlines how members of the pharmacy workforce can become involved in expanding the reach of the National DPP. Stakeholders from a university and retail grocery pharmacy shared case studies describing how they operationalized tiers 2 and 3 in their pharmacy settings, respectively (10).

Furthermore, stakeholders provided feedback on multiple iterations of the guide. Some also shared copies of the draft guide with pharmacists in their networks, who provided additional feedback that we incorporated. This iterative process of incorporating revisions from our target audience resulted in a comprehensive resource, providing user-friendly, motivational information specific to the needs of the pharmacy sector.

Phase 3: promote and evaluate

The purpose of Phase 3 was to strengthen partnerships within the pharmacy sector, create a campaign to promote the Pharmacy Action Guide, increase pharmacist awareness and uptake of National DPP activities, and evaluate efforts. We developed the promotion campaign on the basis of what we learned about the pharmacy landscape through our partners. Furthermore, we leveraged our partnerships to disseminate the guide and accompanying promotional materials.

After release of the Pharmacy Action Guide, we facilitated a second stakeholder meeting in May 2018. Attendees shared ideas about motivating pharmacists to read and adopt the guide, supplemental resources for pharmacist decision making about adopting the 3 tiers, and strategic communication channels. Stakeholders also discussed potential barriers and facilitators to success in pharmacist engagement that we incorporated into a promotion framework.

We tailored promotional messages to align with pharmacists' values. Stakeholders noted that many pharmacists are motivated by a sense of commitment to community health but need a business case to ensure National DPP efforts are feasible and sustainable. Based on these insights, we chose 2 key messages as a focus for the first phase of the promotion campaign.

- Engagement in National DPP activities provides an opportunity to diversify pharmacy services and revenue in an increasingly competitive market.

- Offering National DPP-related services is a way to help the community by improving patient outcomes, while reinforcing perceptions of pharmacists as trusted sources for preventive care.

We used testimonials from pharmacy program advocates to show pharmacists that their peers were implementing activities successfully. Given that pharmacy associations are key influencers for the pharmacy audience, they are critical partners to establish pharmacist buy-in. Pharmacy association stakeholders disseminated key messages to their members with links to the guide and additional resources. They reached pharmacists at multiple touchpoints through a multichannel marketing and outreach strategy that combined traditional (direct mail, event marketing) and digital media (email, web, social media, video marketing).

We gained momentum by strategically targeting segments of the pharmacy community most likely to adopt type 2 diabetes prevention activities. We started with independent and grocery retail pharmacists, because many successful early implementers of the program belonged to these 2 groups. Their values and locations were also well-suited to offer type 2 diabetes prevention services in communities at high risk.

We are evaluating our promotion efforts to measure pharmacy uptake of National DPP activities and will use results to prioritize strategies for future promotion. Early results are encouraging. In June 2019, we provided marketing toolkits to 12 pharmacy associations. Of those, 7 have disseminated promotional materials to their members, resulting in more than 2,100 video views and 4,200 downloads of the Pharmacy Action Guide as of October 2019. In addition, significant growth occurred in the number of pharmacies seeking CDC recognition to offer the National DPP lifestyle change program. In October 2019, 87 pharmacy organizations had CDC recognition, many in underserved areas, compared with 27 before release of the guide.

Implications for Public Health Practice

Although we attempted to create accessible resources relevant to the entire pharmacy workforce, limitations existed for what we could accomplish in a national engagement campaign. Differences exist state-to-state regarding pharmacist scope of practice (eg, blood glucose testing), and each pharmacy has its own unique facilitators and barriers to engage in type 2 diabetes prevention activities. Although CDC might not be able to address the myriad needs of the entire pharmacy workforce related to National DPP adoption, we are more in tune and better positioned to support our partners as they expand the reach of our efforts.

Our successes in collaborating with pharmacists in the National DPP demonstrate how partnerships between public health and the pharmacy sector can expand and sustain prevention efforts. Pharmacists are accessible, credible, and dedicated health professionals who can play a key role in preventing type 2 diabetes and other chronic diseases while addressing health inequities in their communities. Our project sought to establish reciprocal support and feedback between the public health and pharmacy sectors. Through continual stakeholder engagement and inclusion of members of the pharmacy community at every step, we collaboratively built a relevant and successful program that optimized pharmacist involvement in national type 2 diabetes prevention efforts. This systematic process of stakeholder engagement and iteration can be replicated as a model for engaging pharmacists and other health professionals in similar public health prevention efforts. Information on how pharmacists can become involved in the National DPP is available at https://www.cdc.gov/diabetes/prevention/pharmacists.html.

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PROGRAM EVALUATION BRIEF

Hypertension-Focused Medication Therapy Management: A Collaborative Pilot Program Uniting Pharmacists, Public Health, and Health Insurers in Wisconsin

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PEER REVIEWED

Summary

What is already known on this topic?

Pharmacy-delivered medication therapy management can improve health outcomes. However, evidence across studies varies because of the inconsistency in operationalization of service delivery and population heterogeneity.

What is added by this report?

We evaluated a collaborative medication therapy management pilot program for people with hypertension in Wisconsin. We demonstrated improvements in self-reported use of blood pressure self-management tools and barriers to medication adherence.

What are the implications for public health practice?

Sustainable reimbursement mechanisms were established for select pharmacies delivering medication therapy management to members of a private health plan. Other public health entities might consider replicating our collaborative pilot model to secure reimbursement for pharmacist-delivered services.

Abstract

Heart disease and stroke are leading causes of death and disability in the United States, and high blood pressure is a major risk factor for both. Community pharmacists are readily positioned to improve cardiovascular health through services such as medication therapy management and self-management education. In 2018, the Pharmacy Society of Wisconsin, the Wisconsin Division of Public Health, and NeuGen, a not-for-profit health insurer, piloted a pharmacist-led medication therapy management program for people with hypertension in partnership with 8 community pharmacies. We evaluated changes in use of blood pressure self-management tools and barriers to antihypertensive medication adherence before and after medication therapy management services. Participant satisfaction was also assessed for the 59 participants at the end of the program. We observed improvements in self-reported use of self-management tools, reductions in medication adherence barriers, and high satisfaction with pharmacist care. This collaborative pilot resulted in sustainable reimbursement for participating pharmacies delivering medication therapy management services to eligible NeuGen members.

Introduction

Heart disease and stroke are leading causes of death and disability in the United States, and high blood pressure is a major risk factor for both (1). The Centers for Disease Control and Prevention recommends pharmacist-delivered medication therapy management (MTM) services to improve cardiovascular health for those with hypertension (2). MTM is an umbrella term for medication services that include, but are not limited to, comprehensive medication review/assessment (CMR/A), the creation of medication-related action plans, pharmacist referral or intervention, and documentation and follow-up (3). Evidence suggests that pharmacist-led interventions with elements of MTM delivered in a community pharmacy setting are effective in helping patients with hypertension lower their blood pressure and even achieve control. A 2014 systematic review and meta-analysis of randomized controlled trials associated community pharmacist-led interventions with significant reductions in systolic and diastolic blood pressure

compared with usual care (4). Interventions included pharmacological components (eg, identifying adverse drug effects and prescribing issues), nonpharmacological components (eg, providing education on healthy lifestyle changes), or both. Early evidence also suggests that when pharmacists are engaged in education about self-measured blood pressure monitoring, patients with hypertension achieve better blood pressure outcomes (5–7).

In 2017, the Association of State and Territorial Health Officials (ASTHO) announced a year-long learning collaborative with the state public health agency focused on improving population-level blood pressure control. (8) The ASTHO learning collaborative required that state public health agencies partner with private health insurers to improve cardiovascular outcomes in an innovative manner. The collaborative's design allowed Wisconsin's grant recipients to contribute to evidence surrounding pharmacist-delivered MTM and its impact on cardiovascular health.

Purpose and Objectives

From December 2017 through September 2018, the Wisconsin Department of Health Services' Division of Public Health partnered with the Pharmacy Society of Wisconsin and NeuGen (https://www.neugenhealth.com/), a not-for-profit health insurer, to implement and evaluate a pharmacist-led MTM pilot program for people with hypertension as part of the ASTHO learning collaborative. The pilot program's design was informed by the Pharmacists' Patient Care Process (PPCP) model and by evidence supporting pharmacist-led interventions in community pharmacy settings. PPCP is a framework created by the Joint Commission of Pharmacy Practitioners to guide pharmacist collaborative and patient-centered care to improve health and medication outcomes (9). In addition to a CMR/A, our pilot also included pharmacist-led education about self-measured blood pressure. Our evaluation assessed changes resulting from pharmacist-delivered MTM services in participant knowledge and health beliefs about hypertension, use of blood pressure self-management tools (logs and monitors), and medication adherence barriers.

Partnerships and established MTM program infrastructure. The Pharmacy Society of Wisconsin supports more than 4,000 pharmacists, technicians, and pharmacy students in Wisconsin. In 2008, the society launched the Wisconsin Pharmacy Quality Collaborative (WPQC) to align incentives for pharmacies and health insurers. WPQC currently comprises 187 pharmacies and 340 pharmacists accredited and certified by the Society. WPQC pharmacists complete training and receive certification to resolve drug therapy problems, improve adherence, and engage people in their care through MTM service delivery. All WPQC-accredited pharmacies have a private area for MTM service delivery.

The Wisconsin Department of Health Services Forward Health program (Medicaid) covers MTM in the form of CMR/A services when provided to eligible members by WPQC pharmacists. In this context, CMR/A involves a WPQC pharmacist evaluating a patient's health status and medications to identify and resolve medication-related issues. If the pharmacist and patient identify concerns, they work with the primary care provider to resolve them. Partnerships with the Wisconsin Department of Health Services and with federal and private grants over the last decade have aided the promotion and expansion of the WPQC program and MTM service delivery.

NeuGen insures more than 105,000 people in Wisconsin. NeuGen and the Pharmacy Society of Wisconsin connected their efforts through mutual relationships with the Wisconsin Department of Health Services' Division of Public Health. The pilot program described and evaluated here benefitted from existing relationships and MTM program infrastructure to improve chronic disease outcomes.

Intervention Approach

Pharmacy selection and participant eligibility. NeuGen facilitated pharmacy selection for the pilot program by identifying clusters of members with hypertension who filled prescriptions at WPQC pharmacies. We defined member eligibility as any adult (aged ≥18 y) NeuGen health plan member with diagnosed hypertension who filled an antihypertensive medication prescription at a WPQC pharmacy during the 12 months before April 2018. By using claims data, NeuGen identified eligible members and associated prescription fills with corresponding WPQC pharmacies. Partners ranked WPQC pharmacies by the total associated, eligible member count. The Pharmacy Society of Wisconsin used this list to recruit 8 WPQC pharmacies: 4 pharmacies in Kenosha County, 3 in Sauk County, and 1 in Langlade County. Kenosha is an urban county in the southeast corner of Wisconsin. Sauk and Langlade are rural counties in the south-central and northern parts of the state, respectively.

Participating pharmacies represented 145 NeuGen health plan members. Pharmacists and staff at these locations participated in an orientation webinar that introduced program design and implementation. Pharmacists were also asked to view e-learning modules on self-measurement of blood pressure and accurate blood pressure management (10,11). The Pharmacy Society of Wisconsin provided hypertension-specific clinical toolkits and adherence training and tools to work with patients to identify solutions to self-reported adherence barriers. NeuGen incentivized participat-

ing pharmacies by providing reimbursement for MTM service delivery, a tablet computer to facilitate survey completion, and a stipend for marketing and data collection.

Recruitment. NeuGen contacted 145 eligible members via mail, informing them of the program, that their pharmacy was participating, and offering them a $25 gift card incentive to a local gas station/convenience store for completion of 2 in-person visits with the pharmacist. Interested members were asked to contact their pharmacy to learn more. Pharmacy staff members made follow-up telephone calls to nonrespondents 2 to 4 weeks after the mailing. Of 145 eligible NeuGen members, 42% (N = 61) agreed to participate.

MTM service delivery and participant survey. Pharmacists successfully delivered 2 in-person MTM visits to 59 participants from May through September 2018. The time between participant visits varied from approximately 4 to 6 weeks. At the beginning of each visit, pharmacists administered a participant survey that documented self-reported barriers to antihypertensive medication adherence and use of blood pressure self-measurement/monitoring tools. The survey was followed by the completion of a CMR/A service. Throughout the service, pharmacists provided verbal education about healthy lifestyle changes, educated participants on blood pressure self-measurement and monitoring, and used motivational interviewing techniques to address adherence barriers. Classifying adherence barriers into 5 domains (system, understanding, motivation, recall, and financial) aided pharmacists in generating adherence solutions. Pharmacists also provided the following tools to patients: personal medication list, medication action plan, self-measurement of blood pressure education form, and a log for recording home blood pressure readings. Following both visits, participants completed an online exit survey on satisfaction. To ensure HIPAA (Health Insurance Portability and Accountability Act) compliance, pharmacists submitted anonymous survey data directly to NeuGen via SurveyMonkey (www.surveymonkey.com/). If needed, pharmacists communicated with participants' primary care providers to optimize medication therapy following both visits. Pharmacists gave each participant a blood pressure monitor paid for by NeuGen and the Department of Health Services.

Evaluation Methods

We conducted McNemar tests of correlated proportions on paired survey data collected from May through September 2018 to evaluate changes in participant-reported use of self-management tools. We also quantified changes in proportions of participants who reported experiencing barriers to antihypertensive medication adherence before and after MTM service delivery. Finally, we assessed overall participant satisfaction with pharmacist-provided care. We conducted quantitative analyses in SAS version 9.4 (SAS Institute Inc) and Microsoft Excel version 14.0 (Microsoft Corp). The Pharmacy Society of Wisconsin adapted pharmacist satisfaction questions from Ried et al (12) and medication adherence tools from the Brief Medication Questionnaire (13) (Box). We did not conduct prospective power calculations because of the rapid planning and execution of the pilot required by the ASTHO learning collaborative's timeline.

Box. Questions in Pharmacist Satisfaction Survey

How would you rate the overall care you received from your pharmacists? [Answer options were very poor, poor, fair, good, or very good.]

Do you use any of the following to help you manage your blood pressure? [Answer options were yes or no.]

- A monitor to check my blood pressure at home
- A log to keep track of my blood pressure readings
- A log to track the days I take my blood pressure medication

How much difficulty do you have in the following areas with your blood pressure medication? [Answer options were none, a little, some, or a lot.]

- Remembering my medication dosage(s)
- Remembering if I took my medication
- Paying for my medication
- Refilling my medication
- Unwanted side effects from my medication
- Reading my medication bottles
- Other concerns or problems with my medications

Results

From May through September 2018, 28 women and 33 men participated in the pilot program. Ages ranged from 35 to 76, with a mean age of 60. Fifty-nine participants completed both visits.

Self-reported use of self-management tools. We observed improvements in self-reported use of self-management tools (Table). Following program participation, patients were more likely to report use of a log to track blood pressure readings (χ^2 [1, N = 59] = 35.1, $P < .001$). Participants were also more likely to report use of a log to track antihypertensive medication use (χ^2 [1, N = 59] = 8.1, $P = .045$). Participants were also more likely to report use of self-measuring blood pressure monitors (χ^2 [1, N = 59] = 39.0, $P < .001$).

Adherence barriers. The number of patients experiencing adherence barriers decreased across all categories after the second visit (Table). Participants most frequently reported remembering dosage and remembering to take medications as barriers to antihypertensive medication adherence. The proportion of participants who reported experiencing any level of difficulty remembering their medication dosage decreased by 50% following MTM service delivery. The proportion of participants who experienced difficulty remembering to take their antihypertensive medications decreased by 60%. Participation in the adherence barrier questions was not powered for statistical comparison of pre/post results.

Satisfaction and participant engagement in self-management. Following MTM delivery, 58 participants rated the pharmacist's overall care and ability as very good. Most (58) also agreed or strongly agreed with the statement that, as a result of their participation in the program, they were going to take a more active role in managing their blood pressure.

Implications for Public Health

We created, implemented, and evaluated an MTM pilot program in Wisconsin that showed early indications of the positive impact pharmacists can have on blood pressure self-management. We observed reductions in self-reported barriers to adherence to antihypertensive medication therapy and increased use of self-management tools. Moreover, participants reported high satisfaction with their pharmacist's care overall. NeuGen indicated that member engagement for this collaborative pilot was considerably higher than for pilot interventions they implemented alone. When patient, pharmacist, and payer incentives are aligned, sustainable programs with demonstrable benefits are created. Collaborative programs between pharmacists, public health, and health insurers contextualize and localize existing evidence that MTM services improve cardiovascular-related health outcomes.

Our study had several limitations. The number of pharmacies and participants was modest and limited our ability to conduct more rigorous analyses of clinical outcomes, particularly on blood pressure readings. Additionally, our participants were drawn from a nonrandom cluster sample of NeuGen members and likely shared similar social, educational, economic, and cultural backgrounds. Pharmacist selection was also based on nonrandom clustering of NeuGen members with hypertension, and aided by Pharmacy Society of Wisconsin recruitment. Finally, the short time frame of the ASTHO learning collaborative did not allow exploration of longitudinal outcomes. Despite these limitations, our pilot program galvanized and matured interagency relationships to improve population health in Wisconsin. In 2019, NeuGen extended its collaboration with the Pharmacy Society of Wisconsin and the Wisconsin Department of Health Services Division of Public Health by launching another MTM program for members with comorbid chronic conditions (hypertension, prediabetes, diabetes, and hyperlipidemia). NeuGen continues to reimburse WPQC pharmacists for MTM service delivery and to provide technology support, blood pressure monitors, and gift card incentives to qualifying members.

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Table

Table. Participant (N = 59) Characteristics Related to Antihypertensive Medication Therapy and Blood Pressure Management Practices, Before and After Implementation of Medication Therapy Management Services, Wisconsin, May–September 2018[a]

Characteristic	Before	After
Experienced adherence barrier[b]		
Remembering dosage	10	5
Remembering to take medications	10	4
Reading medication bottles	8	2
Medication side effects	8	2
Responded yes to use of blood pressure management techniques		
Monitor blood pressure at home	14	53
Keep a blood pressure reading log	14	45
Keep a blood pressure medication log	3	14

[a] Values are number of participants.
[b] Only categories with at least 1 participant reporting are shown. Includes reports of any level of difficulty (Box).

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ORIGINAL RESEARCH

Addressing Latent Tuberculosis Infection Treatment Through a Collaborative Care Model With Community Pharmacies and a Health Department

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PEER REVIEWED

Summary

What is already known on this topic?
It is estimated that 13 million people in the United States have latent tuberculosis infection (LTBI). This large number of potential LTBI cases poses a challenge for successful tuberculosis control and elimination.

What is added by this report?
We examined a novel, collaborative care model using community pharmacies as additional access points for LTBI treatment for patients using combination weekly therapy with isoniazid and rifapentine and directly observed therapy for 12 weeks.

What are the implications for public health practice?
High completion rates and safe administration of LTBI treatment can be achieved in the community pharmacy setting.

Abstract

Introduction
The objective of this study was to evaluate a novel collaborative care model using community pharmacies as additional access points for latent tuberculosis infection (LTBI) treatment for patients using combination weekly therapy with isoniazid and rifapentine (3HP) plus directly observed therapy for 12 weeks.

Methods
This prospective pilot study included adult patients diagnosed with LTBI. Patients were eligible for study participation if they spoke English or Spanish and were followed by the New Mexico Department of Health (NM DOH). Patients were excluded if they were pregnant, receiving concomitant HIV antiretroviral therapy, or had contraindications to 3HP due to allergy or drug interactions. Community pharmacy sites included chain, independent, and hospital outpatient pharmacies in Albuquerque and Santa Fe, New Mexico.

Results
A total of 40 patients initiated treatment with 3HP and were included. Most were female (55%) and had a mean age of 46 years (standard deviation, 12.6 y). A total of 75.0% of patients completed LTBI treatment with 3HP in a community pharmacy site. Individuals of Hispanic ethnicity were more likely to complete treatment (76.7% vs 40.0%, $P = .04$). Most patients (60%; n = 24) reported experiencing an adverse drug event (ADE) with 3HP therapy. Patients who completed treatment were less likely to experience an ADE than patients who discontinued treatment (50.0% vs 90.0%, $P = .03$). Pharmacists performed 398 LTBI treatment visits (40 initial visits, 358 follow-up visits), saving the NM DOH approximately 143 hours in patient contact time.

Conclusion
High completion rates and safe administration of LTBI treatment can be achieved in the community pharmacy setting.

Introduction

Tuberculosis (TB) is a curable disease, yet it is the tenth leading cause of death worldwide, ranking above HIV (1). TB disease resulted in an estimated 1.3 million deaths worldwide in 2017 (1). The World Health Organization has outlined a framework for TB elimination in low-incidence countries such as the United States

(2). Included in the TB elimination strategy is the identification and treatment of latent tuberculosis infection (LTBI) to prevent progression to and transmission of active disease (2). Treatment of LTBI decreases illness and death associated with active TB disease (3) and is associated with less medication toxicity and cost compared with active TB disease treatment (4–6). It is estimated that 13 million people have LTBI in the United States (7). This large number of potential LTBI cases poses a serious public health challenge for successful TB control and elimination. Using community pharmacies is a possible strategy to expand access for testing and treatment.

In 2011, because of nursing resource limitations at the New Mexico Department of Health (NM DOH), tuberculin skin testing was made available in New Mexico community pharmacies (8). As of 2016, more than 200 New Mexico pharmacists had been trained to provide this public health service, which provides testing access for patients in small city locations and has been widely used by patients across the state (8,9). In 2017, the NM DOH TB program wanted to expand access to patients by also providing LTBI treatment in the community pharmacy setting.

In 2012 the NM DOH transitioned from LTBI treatment with isoniazid monotherapy to weekly combination therapy with isoniazid plus rifapentine (3HP). This short 12-week combination regimen is associated with higher completion rates and lower rates of hepatotoxicity (10,11). However, the 3HP regimen is still associated with medication toxicity, drug–drug interactions, and nonadherence. Providing this once-weekly regimen in a community pharmacy setting is one potential option to address these issues.

Completion rates for LTBI vary considerably in the literature, ranging from 35%–90%, with higher completion rates generally reported with shorter treatment regimens (10,12–17). Predictors for noncompletion include unstable housing, tobacco use, alcohol use, adverse drug events (ADEs), older age, patient location, poverty, and non-Hispanic ethnicity (14,18–21).

Data evaluating the use of pharmacists in the treatment of LTBI are limited (22–25). However, the available studies have reported high completion rates when a pharmacist was included in treatment management. Tavitian et al reported high completion rates (93%) associated with a pharmacist-managed clinic for treatment of LTBI with isoniazid monotherapy in health care workers (22). Carter et al also reported high LTBI completion rates (94%) with a pharmacist-run clinic using monotherapy with either rifampin or isoniazid for refugee patients (25). To our knowledge, administration of LTBI treatment in the community pharmacy setting has never been evaluated.

The primary objective of this study was to evaluate a novel and collaborative care model using community pharmacy sites to support increased patient access to LTBI treatment using combination weekly therapy with isoniazid 900 mg plus rifapentine 900 mg for 12 weeks. Secondary objectives were evaluation of treatment completion rates and ADEs.

Methods

The University of New Mexico Health Sciences Research Protection Office institutional review board approved the study protocol. This prospective pilot study included adult patients ≥18 years of age who were diagnosed with LTBI by a physician at the NM DOH. Patients were eligible for study participation if they spoke English or Spanish and were followed by the NM DOH offices in Albuquerque or Santa Fe, New Mexico. Patients also had to be able to take LTBI treatment with weekly combination therapy with 900 mg of rifapentine and 900 mg of isoniazid for 12 weeks. Patients were excluded if they were pregnant, receiving concomitant HIV antiretroviral therapy, or had contraindications to 3HP due to allergy or drug interaction. Eligible patients with newly diagnosed LTBI who were seen at the Santa Fe or Albuquerque departments of health from February 2017 through April 2018 were given the choice to receive usual care through the NM DOH or participate in the study, receiving 3HP with directly observed therapy (DOT) at a participating community pharmacy of their choice.

Before consent, patients were provided with a list of 9 possible pharmacy locations (3 pharmacies in Santa Fe and 6 pharmacies in Albuquerque) and their hours of operation. Study investigators identified and contacted 10 pharmacies as potential pilot sites based on geographical distribution and site diversity. Nine pharmacies agreed to participate. Community pharmacy sites included chain, independent, and hospital outpatient pharmacies, in Albuquerque and Santa Fe, New Mexico (NM). The pharmacies were geographically distributed throughout the cities to provide a variety of pharmacy locations for study participants. Patients were allowed to choose only 1 pharmacy location and could not switch locations after consent. No study incentive was offered to patients. Medications were provided to patients at no charge regardless of study participation. Women of childbearing age were counseled to use a barrier birth control method before enrollment and with rifapentine initiation. Study investigators consented patients for study participation at the NM DOH clinics. Baseline laboratory tests (liver function tests, complete blood counts, comprehensive metabolic panel, and HIV with opt-out option) were drawn at the NM DOH before 3HP initiation. Patient demographics, comorbidities, and additional TB risk factors (1) were collected to characterize the patient population being served.

Before implementation, participating pharmacies (range, 1–3 pharmacists per pharmacy) attended (either in person or via videoconferencing) a 2-hour accredited continuing education training on LTBI treatment held at the University of New Mexico. NM DOH nursing personnel at the participating department of health locations were also included in the training program. The NM DOH TB program medical director, the NM DOH TB program manager/TB nurse consultant, and an infectious diseases pharmacist provided the training for community pharmacies. The infectious diseases pharmacist trained additional pharmacists who joined the project at a later date, using the same training materials.

After consenting a patient for study participation, the patient's prescriptions for rifapentine 900 mg (4 tablets) and isoniazid 900 mg (3 tablets), to be taken weekly with DOT, were faxed to the participating pharmacy with 11 refills (12 doses total of 3HP). The TB physician could adjust the dose for weight. The TB physician could also order pyridoxine (vitamin B6) if appropriate.

The participating pharmacies were responsible for acquiring and storing the LTBI medications according to the state law and pharmacy policy. The cost of the medication varied for each site (~$25–30/week). Grant funds provided pharmacies adequate compensation to cover the cost of the medication and pharmacist time. In addition, telephonic interpreter services, also provided through grant funding, were available for Spanish-speaking patients at all pharmacy locations.

Participating pharmacies followed the NM DOH nursing protocol for LTBI treatment with DOT. Patients picked up their weekly doses at the community pharmacy. At each visit the pharmacist would 1) complete a drug–drug interaction evaluation, 2) screen the patient for 3HP treatment toxicity, 3) screen the patient for symptoms of active TB disease, 4) provide the LTBI treatment medication, and 5) watch the patient take the medication (DOT). Screening questions were adopted from the DOH LTBI treatment protocol. If a patient developed signs and symptoms suggestive of liver or hematologic toxicity, the pharmacist contacted the DOH TB program nurse manager and instructed the patient to hold the medications. Potentially serious ADEs were reported to the NM DOH TB Program and reviewed by the TB physician. Reportable potential ADEs were jaundice, persistent nausea or vomiting, abdominal pain, easy bruising or bleeding, and changes in urine or stool color. Medications could be resumed or discontinued after evaluation by the NM DOH TB program's medical director. Patients could discontinue treatment at the community pharmacy and complete treatment through the NM DOH if closer follow-up was required by the TB physician. Treatment was considered complete if patients received 12 doses. To be consistent with DOH completion rate reporting calculations, patients who did not start therapy were not included in the data analysis.

Continuous variables were described by using measures of central tendency (mean, standard deviation [SD]), and binary and categorical variables were described by using the number of nonmissing and missing observations and the frequency and percentage of responses. Patients receiving treatment were categorized into 2 groups: 1) those receiving the complete 12 doses of treatment and 2) those receiving partial treatment. Statistical differences between the 2 groups were determined using the Student's *t* test for continuous variables (pooled method for equal variances, Satterthwaite method for unequal variances) and Fisher exact test for binary and categorical variables. All tests were 2-sided and used a significance level of $P < .05$. SAS statistical software version 9.4 (SAS Institute, Inc) was used to perform analyses.

Results

Of the 41 patients who consented to participate in the study during the evaluation period, 40 initiated treatment and were included in the data analysis (Figure). Thirty patients received LTBI treatment at an Albuquerque community pharmacy, and 10 patients received LTBI treatment at a Santa Fe community pharmacy. Most patients were female (55%; n = 22), Hispanic white (37.5%; n = 15), and had an average age of 46 years (SD, 12.6 y) (Table 1).

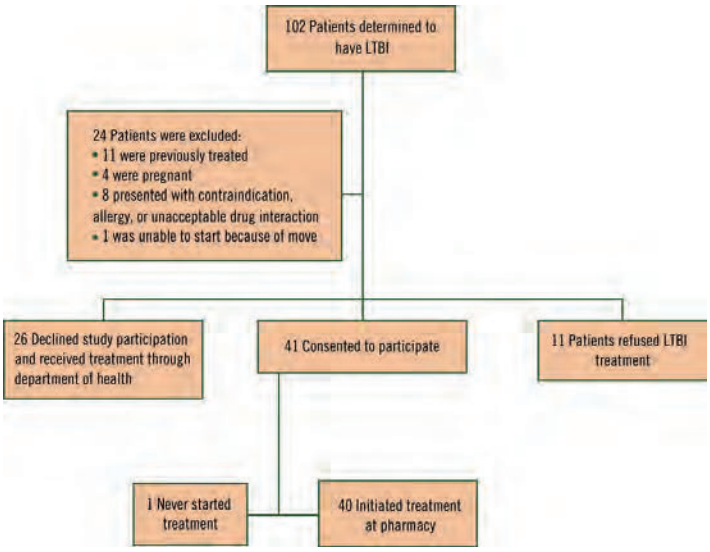

Figure. Flow diagram for patient enrollment, study on using a collaborative care model to treat LTBI, New Mexico, 2017–2018. Abbreviation: LTBI, latent tuberculosis infection.

Of 40 patients who initiated treatment, 75% (n = 30) completed LTBI treatment with 3HP at 1 of the participating community pharmacy sites. Seven patients discontinued 3HP because of po-

tential ADEs, and 3 patients were lost to follow-up. A higher percentage of patients who completed treatment were of Hispanic ethnicity compared with patients who discontinued treatment (76.7% vs 40.0%, $P = .04$) (Table 1). Other demographic characteristics, including age, sex, and substance use (ie, tobacco or alcohol) did not differ between patients who completed or discontinued LTBI treatment. Most patients (60%; n = 24) reported experiencing an ADE with 3HP therapy (Table 2). The most common ADEs reported were dark urine (27.5%; n = 11), excessive fatigue (22.5%; n = 9), and nausea/vomiting (22.5%; n = 9). Differences between the groups were significant with regard to ADEs. Fewer patients who completed treatment experienced any ADE compared with patients who discontinued treatment (50% vs 90%, $P = .03$). ADEs that patients who completed treatment experienced less often than those who discontinued treatment were excessive fatigue (13.3% vs 50.0%, $P = .03$) and nausea/vomiting (13.3% vs 50.0%, $P = .03$). Potentially serious ADEs were reported to the NM DOH TB Program and reviewed by the TB physician. In 7 cases (17.1%) it was determined that the patient should discontinue 3HP treatment. Of the 7 patients who discontinued 3HP therapy at a community pharmacy site, 1 was able to complete LTBI therapy with another LTBI regimen through the NM DOH, bringing the overall completion rate to 77.5%. No cases of active tuberculosis or death were reported during the study period. The average number of doses received by patients who discontinued therapy at a community pharmacy was 3.8 (SD, 2.3).

Pharmacists performed 398 LTBI treatment visits (40 initial visits, 358 follow-up visits) during the evaluation period. Pharmacists recorded the estimated time for initial and follow-up visits for 26 patients. The average time for an initial visit was 25 (SD, 10.1) minutes. The average time for follow up visits was 22 (SD, 9.7) minutes. The initiative saved the NM DOH more than 8,876 minutes (148 hours) in patient visit time. Most patients (62.5%; n = 25) lived 5 miles or less from the pharmacy where they received 3HP treatment (Table 3).

Discussion

This is the first study to evaluate the feasibility of providing LTBI treatment with DOT in a community pharmacy setting as a strategy to improve patient access in collaboration with a state health department. We demonstrated that 3HP can be safely administered in a community pharmacy collaborative care setting and result in high rates of LTBI treatment completion (75% in community pharmacy setting; 77.5% overall). Our LTBI completion rate was similar to rates reported by the NM DOH. In 2017, the NM DOH reported that 374 patients in NM were determined to have LTBI at a DOH clinic location (26); 167 patients initiated treatment, 107 (64.1%) completed LTBI treatment (New Mexico Department of Health Tuberculosis Prevention Program, 2017, unpublished data). High rates of completion in the community pharmacy setting are likely a result of a variety of accessible pharmacy locations, extended operating hours, and no requirement for scheduled appointments.

In our cohort we found that Hispanic patients were more likely to complete LTBI treatment compared with non-Hispanics. This finding is consistent with those of prior studies (14,19–21,28,29), but its cause is unclear. However, perception of disease risk has been previously reported as a predictor for LTBI treatment completion (30), which this study did not assess. These patients may have had an increased perception of risk if they or their family members were born in TB-endemic areas.

We reported high rates of potential ADEs (n = 24; 60%). ADEs, including nausea/vomiting and fatigue, were associated with noncompletion of LTBI treatment in this study. This finding is also consistent with prior studies (18,21). Most potential medication side effects reported with 3HP were not serious and may have been due to other causes. Most patients were managed through the pharmacy with direct communication and collaboration with the DOH. This resulted in treatment completion in 17 of the 24 patients (71%) that experienced a potential ADE. Pharmacists were able to ensure pyridoxine (vitamin B6) supplementation when appropriate and discuss options to address nausea. Addressing potential ADEs in a community pharmacy setting is an opportunity to increase completion rates before losing patients to follow-up.

WHO describes the importance of accessible and free TB services in their elimination framework (2). Community pharmacies may be able to offer an additional accessible setting to provide LTBI treatment. To achieve TB elimination, it is important to increase access to treatment in ways that are convenient for patients while also relieving a portion of the burden from the DOH. A total of 41 of the 67 patients who received treatment chose to participate in this study and receive treatment at a community pharmacy site, highlighting patient interest in this treatment setting. With an increase in available community pharmacy sites, it is likely that more patients will have the opportunity to complete treatment.

Data from this pilot project provide important information about LTBI treatment administered in the community pharmacy setting. However, our study has limitations. First, results cannot be generalized outside of New Mexico. This was a pilot study with a small sample in 2 large city settings in New Mexico, which is largely rural and has health care professional shortages and patient socioeconomic barriers. In addition, only a small subset of the total number of pharmacies in the state participated in the study. To minimize this limitation, we included pharmacies that were geographically distributed, including both independent and chain

pharmacies. We would not expect the study results to differ significantly if all New Mexico pharmacies offering this public health service had participated. In addition, we only evaluated LTBI treatment with 3HP plus DOT. Another consideration is that this project was supported by a grant, which covered the cost of 3HP medication provided in the community pharmacy. If this public health service is to be sustainably offered to patients at no charge, a mechanism will need to be identified to address the cost of providing this service in the community pharmacy setting. Finally, the success of this program can be attributed to the collaboration with the DOH, in which training and expert consultation was provided.

LTBI treatment with 3HP plus DOT can be safely administered in a community pharmacy collaborative care setting and offers opportunity for improved access to care for patients. High rates of completion in a community pharmacy setting are likely a result of increased access to care through neighborhood pharmacy locations, extended operating hours, and no requirement for scheduled appointments. The largest barrier to LTBI treatment completion was ADEs. Pharmacists can help identify and manage potential ADEs in the community pharmacy setting, which may minimize loss to follow-up.

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Tables

Table 1. Treatment Completion Rates of Participants (N = 40), by Demographic Characteristics, Study on Using a Collaborative Care Model to Treat LTBI, New Mexico, 2017–2018

Demographic Characteristic	Value[a]	Completed Treatment[b] (n = 30)	Discontinued Treatment (n = 10)	*P* Value[b]
Male sex	18 (45.0)	15 (50)	3 (30)	.46
Mean age, y (SD)	46.0 (12.6)	45.6 (14.0)	47.2 (7.5)	.73
Mean BMI, kg/m^2 (SD)	28.6 (6.1)	28.0 (5.6)	30.2 (7.5)	.37
Hispanic ethnicity				
Yes	27 (67.5)	23 (76.7)	4 (40)	.04
No	12 (30.0)	7 (23.3)	5 (50)	
Unknown	1 (2.5)	0	1 (10)	
Race/ethnicity				
Hispanic white	15 (37.5)	12 (40.0)	3 (30)	.008
Hispanic other	12 (30.0)	11 (36.7)	1 (10)	
Non-Hispanic white	7 (17.5)	6 (20.0)	1 (10)	
Non-Hispanic black	2 (5.0)	1 (3.3)	1 (10)	
Non-Hispanic Asian	3 (7.5)	0	3 (30)	
Unknown	1 (2.5)	0	1 (10)	
Birth country				
United States	10 (25.0)	7 (23.3)	3 (30)	.70
Non-US	29 (72.5)	22 (73.3)	7 (70)	
Unknown	1 (2.5)	1 (3.3)	0	
Substance use				
Alcohol	10 (25.0)	7 (23.3)	3 (30)	.69
Tobacco	14 (35.0)	12 (40.0)	2 (20)	.45
Comorbidities[b]				
Diabetes	7 (17.5)	6 (20.0)	1 (10)	.66
Asthma	2 (5.0)	2 (6.7)	0	>.99
End-stage renal disease	4 (10.0)	4 (13.3)	0	.56

Abbreviations: BMI, body mass index; LTBI, latent tuberculosis infection; SD, standard deviation.
[a] Values are no. (%) unless otherwise indicated.
[b] Determined using *t* test for mean differences and Fisher exact test for frequency differences.

Table 2. **Reported Adverse Drug Events of Patients (N = 40), by Patient Treatment Completion Status, Study on Using a Collaborative Care Model to Treat LTBI, New Mexico, 2017–2018**

Type of ADE	No. (%)	Completed Treatment[a] (n = 30)	Discontinued Treatment (n = 10)	*P* Value[a]
		No. (%)		
Any	24 (60.0)	15 (50.0)	9 (90)	.03
Dark urine	11 (27.5)	8 (26.7)	3 (30)	>.99
Nausea/vomiting	9 (22.5)	4 (13.3)	5 (50)	.03
Excessive fatigue	9 (22.5)	4 (13.3)	5 (50)	.03
Appetite loss	6 (15.0)	3 (10.0)	3 (30)	.15
Abdominal discomfort	6 (15.0)	3 (10.0)	3 (30)	.15
Flu-like symptoms	5 (12.5)	2 (6.7)	3 (30)	.09
Urine output change	3 (7.5)	1 (3.3)	2 (20)	.15
Stool color change	3 (7.5)	1 (3.3)	2 (20)	.15
Rash/itching	2 (5.0)	0	2 (20)	.06
Numbness or tingling	2 (5.0)	2 (6.7)	0	>.99
Fever >3 days	1 (2.5)	1 (3.3)	0	>.99
Jaundice	0	0	0	>.99
Bleeding/bruising	0	0	0	>.99
Other	13 (32.5)	10 (33.3)	3 (30)	>.99
Number of ADEs				
0	16 (40.0)	15 (50.0)	1 (10)	.03
1	8 (20.0)	6 (20.0)	2 (20)	
2	7 (17.5)	4 (13.3)	3 (30)	
3	1 (2.5)	1 (3.3)	0	
4	1 (2.5)	0	1 (10)	
5	3 (7.5)	2 (6.7)	1 (10)	
6	2 (5.0)	2 (6.7)	0	
7	2 (5.0)	0	2 (20)	

Abbreviations: ADE, adverse drug event; LTBI, latent tuberculosis infection.
[a] Determined using *t* test for mean differences and Fisher exact test for frequency differences.

Table 3. Characteristics of Patient (N = 40) Pharmacy Visits, by Patient Treatment Completion Status, Study on Using a Collaborative Care Model to Treat LTBI, New Mexico, 2017–2018

Pharmacy Visit Characteristic	Value	Completed Treatment[a] (n = 30)	Discontinued Treatment (n = 10)	*P* Value[a]
Mean distance, mi (SD)	5.2 (3.1)	5.4 (3.4)	4.8 (1.8)	.53
Distance to pharmacy, mi				
≤5	25 (62.5)	18 (60.0)	7 (70)	.79
>5	14 (35.0)	11 (36.7)	3 (30)	
Unknown	1 (2.5)	1 (3.3)	0	
Days between positive test and treatment start				
0–60	16 (40.0)	10 (33.3)	6 (60)	.55
61–120	14 (35.0)	11 (36.7)	3 (30)	
121–180	3 (7.5)	3 (10.0)	0	
>180	4 (10.0)	4 (13.3)	0	
Unknown	3 (7.5)	2 (6.7)	1 (10)	
	25.0 (10.1)	25.3 (9.3)	24.4 (12.1)	.84
Follow up visit time, min (SD) (n = 25)	22.0 (9.7)	23.75 (10.1)	18.9 (8.6)	.24

Abbreviations: ADE, adverse drug event; LTBI, latent tuberculosis infection; SD, standard deviation.
[a] Determined using *t* test for mean differences and Fisher exact test for frequency differences. Values are no. (%) unless otherwise indicated.

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COMMENTARY

Community Pharmacists' Contributions to Disease Management During the COVID-19 Pandemic

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PEER REVIEWED

Summary

What is already known on this topic?

More than 90% of people in the United States live within 5 miles of a community pharmacy. Pharmacists deliver important public health services such as vaccinations, point-of-care testing, and chronic and acute disease prevention and management. These services are and will continue to be critical in the coronavirus disease 2019 (COVID-19) pandemic.

What is added by this report?

The COVID-19 pandemic has demonstrated needed roles for the community pharmacist in an emergency, including continuity of provision of medications, providing preventive services, and ensuring health equity. Along with medication management, pharmacists provide infectious disease mitigation, point-of-care testing, and vaccinations.

What are the implications for public health practice?

Community pharmacists are essential contributors to public health and play a key role as the United States continues to combat COVID-19, especially among populations with health disparities.

Abstract

Community pharmacists assist patients to manage disease and prevent complications. Despite the enormous challenge the coronavirus disease 2019 (COVID-19) pandemic has dealt to the health care system, community pharmacists have maintained the delivery of critical health services to communities, including those most at risk for COVID-19. Community pharmacists are in a key position to deliver priority pandemic responses including point-of-care testing for chronic disease management, vaccinations, and COVID-19 testing.

Background

The coronavirus disease 2019 (COVID-19) pandemic has challenged community pharmacists to perform under difficult circumstances. The pandemic has also highlighted the key public health functions community pharmacists play in medication therapy, chronic disease management, self-care recommendations, vaccinations, point-of-care screening and testing services, and adherence support (1–4). Although the role of pharmacists in chronic disease prevention and management is well established, the COVID-19 pandemic has accentuated the critical contributions community pharmacists make during an infectious disease outbreak.

This commentary describes the current and future roles of community pharmacists in the United States in optimizing their broad access to medically and socially vulnerable populations before and during a pandemic. We show that community pharmacists are highly accessible both temporally and geographically, which puts them in a position to serve at-risk populations. The ongoing role of community pharmacists in preventing and managing common diseases during a pandemic is also addressed. Finally, we describe the key roles pharmacists play in priority pandemic responses, including point-of-care testing for chronic disease management, testing for COVID-19, and administering and advocating for vaccinations.

Community Pharmacists in the United States

Community pharmacies are located in most communities in the United States, and more than 90% of the US population live within 5 miles of one (5). Furthermore, patients visit their community pharmacist 12 times more frequently than their primary care provider (6). As medication experts, community pharmacists fill a key role in providing care for patients with chronic diseases (Table 1), with particular contributions made among economically and geographically underserved populations (8). When many health care organizations restricted patient access to noncritical services in the

early stages of the COVID-19 pandemic, patients with chronic diseases struggled to receive routine care. Through the thoughtful implementation of social distancing guidelines, most pharmacies remained open and were in a position to support patients (9). These critical services included medication dispensing for chronic and acute conditions, vaccinations, recommendations for over-the-counter medications, and medication management (10).

The COVID-19 pandemic has resulted in an excessive burden of mortality among at-risk populations, a burden exacerbated by preexisting racial and socioeconomic inequities in health care access and use (11–14). The proportion of COVID-19 deaths among Black and American Indian/Alaska Native people is in excess of their weighted population distributions compared with other racial/ethnic groups (Table 2). Hypertension, diabetes, and respiratory diseases are disproportionately prevalent among communities of color (16), resulting in exponentially higher mortality among minority populations than among White populations (17). COVID-19 has brought into full view the need to address health inequities experienced by some segments of the US population (18).

Community pharmacies have opportunities to redress racial and ethnic disparities in health care delivery because of their accessibility (8). Pharmacies are located close to at-risk populations, such as in rural areas or areas with higher concentrations of people of lower socioeconomic status (19). During the pandemic, pharmacists have been able to leverage their social capital with their patients in those areas, and safely maintain patient access to essential medications through curbside pickup, larger refill quantities, and home delivery (20,21). Through close partnerships with pharmacy associations, corporate and individual ownership networks, and providers, pharmacists prepared for and have met the need for surges of chronic disease medication prescriptions and for potentially beneficial COVID-19 therapies (22). These actions have shown that community pharmacies are key players in addressing the pandemic and in ensuring health equity among patients.

Others at disproportionate risk of COVID-19 are people aged 60 or older, health care workers, and medically vulnerable patients with underlying chronic diseases (23). When these people develop severe COVID-19, they are hospitalized more frequently and die at higher rates (24,25). This is particularly true of patients with diabetes, cardiovascular disease, hypertension, chronic obstructive pulmonary disease, chronic kidney disease, and possibly pregnant women (23,26). Community pharmacists play a significant role in caring for patients with these conditions because these patients are frequently on chronic medications. Therefore, community pharmacists are in a position to educate patients about the importance of protecting themselves from exposure to COVID-19.

Concerns about health equity have been raised as the COVID-19 pandemic continues to change the landscape of public health and health care delivery (13,27). All aspects of health care need to be reevaluated with regard to how they may contribute to reducing inequality and increasing health equity. The role that community pharmacists play in providing care for at-risk populations must be included in this evaluation.

Community Pharmacists' Response During COVID-19 Pandemic

Community pharmacies have continued to deliver critical services to their patients during the COVID-19 pandemic (10). In support of these efforts, the Centers for Disease Control and Prevention provided substantial guidance for pharmacists to ensure the safety of their workforce and their patients while simultaneously ensuring uninterrupted patient care (20). Two key roles played by community pharmacists are point-of-care testing and vaccinations.

Point-of-Care Testing

In the absence of proven treatment medications or vaccines to prevent transmission, the priority actions to protect the public against COVID-19 and to mitigate future waves of infection are to test, trace, and quarantine people who are infected or exposed. These roles are assumed by local public health services; however, community pharmacists can play a significant role in COVID-19 testing (28). More than 10,000 pharmacies already perform Clinical Laboratory Improvement Amendments (CLIA)-waived tests to detect influenza and streptococcal pharyngitis and to monitor chronic diseases through a wide range of CLIA-waived point-of-care testing, such as finger stick glucose, Hb_{A1c}, lipid panel, and more. These tests provide pharmacists with objective data in real time to educate patients about results, lifestyle recommendations, and referral to care. Therefore many pharmacies are authorized and prepared to incorporate COVID-19 testing into their workflow.

The COVID-19 pandemic has changed the landscape of primary care. Many patients have consulted health care providers via telehealth or cancelled their preventive care appointments (29), and these practices may continue for some time. Globally, COVID-19 has substantially affected services for noncommunicable diseases (30), which may leave a gap in chronic disease management, with people missing needed laboratory tests such as blood glucose, Hb_{A1c}, or lipid screening (7). This screening gap is an area that awaits evaluation as the consequences of the COVID-19 pandemic become clearer. Because people who postpone screening will continue to receive their medications from their pharmacies, community pharmacists will have the opportunity to encourage pa-

tients to receive these screenings to ensure effective chronic disease management.

In addition to point-of-care testing for chronic disease management, pharmacists will also play a key role in COVID-19 testing (31). Pharmacists across the country have been called on to coordinate the administration of COVID-19 tests (32–34). In the future, providing ongoing COVID-19 surveillance to communities by allowing walk-in testing at community pharmacies might be more sustainable and convenient than the large-scale public screening being done as of the summer of 2020. By the fall of 2020, many pharmacies will be offering 1 or more of the following COVID-19 diagnostic services: selling home testing kits, collecting specimens to send to partner laboratories for testing and reporting, collecting specimens for on-site symptomatic testing and reporting, and collecting specimens for point-of-care antibody surveillance (31,35,36). The US Department of Health and Human Services has authorized all pharmacists to provide these COVID-19 testing services, overriding state law where it exists (37). The Centers for Medicare and Medicaid Services (CMS) is reimbursing pharmacies for this COVID-19 testing, overcoming a major hurdle to pharmacy-based clinical and diagnostic services during the pandemic (38).

Vaccinations

Community pharmacists play a key role in advocating for and administering adult vaccines (39) (Table 1). Pharmacists must work to provide essential vaccinations to everyone entrusted to their care, especially children and at-risk populations who have fallen behind because of medical office closures (40). Additionally, community pharmacists will be key players in wide-scale administration of vaccines once a safe vaccine for the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is available. This will make vaccines widely available in convenient locations and in familiar settings. Now is the time for community pharmacy organizations to prepare for this critical public health role. Additionally, the community pharmacist's role in providing accurate health information about COVID-19 and the safety and appropriateness of vaccines will continue (41).

Implications for Public Health

In addition to ensuring uninterrupted delivery of routine pharmacy services, pharmacists are able to respond quickly to fill public health roles during a pandemic. Pharmacists have other opportunities to contribute even further to delivering upstream preventive health care measures while mitigating social and structural determinants of health in underserved and marginalized communities. Pharmacy-based community clinics, led by public health pharmacists and primary care providers, may become a common feature in community pharmacies. Pharmacist-provided vaccinations, specimen collection, and point-of-care testing will establish rapid and convenient diagnosis and surveillance of both acute and chronic diseases. Because a pharmacy is likely to be located in or near acute or chronic disease hotspots, and have real-time communication links to public health and primary care authorities, pharmacists can help public health leaders detect and prepare for surges of known and novel diseases. However, this will require deeper integration of pharmacy with the public health infrastructure than currently exists, a clear opportunity for future growth.

The United States has been hit particularly hard by the COVID-19 pandemic, revealing significant and widespread vulnerabilities and structural health disparities that challenge its health care system. The slow and uneven responses to COVID-19 indicate a public health infrastructure that lacks the resources and the authority to tackle such challenges. One reason is the lack of sustained resources to build strong public health infrastructures at the state, county, and city levels across the country (42). Furthermore, although progress has been made, the interfacing of public health in the United States with other sectors of the health care system, including community pharmacy, need to be strengthened to better prepare for quick response to a public health crisis (43). Twelve leading pharmacy organizations have signed the Pharmacy Organization's Joint Policy Recommendations to Combat the COVID-19 Pandemic to delineate key roles pharmacists play in the response (31). Among the recommendations are authority to test, treat, and vaccinate patients; easing operational barriers to address workforce issues; addressing drug shortages; reimbursement for services provided; and removal of barriers to reimbursement. These all represent growth opportunities for collaboration between public health and pharmacy.

During this pandemic, and in past pandemics, the importance of community pharmacies and pharmacists in public health and the health of their patients has been evident (10). It is imperative that systematic evaluation and dissemination of pharmacists' contributions be undertaken to determine areas where community pharmacy can best be incorporated into the way public health is operationalized and carried out in the United States. The COVID-19 pandemic has created the opportunity to strengthen the US public health system to make it even more inclusive, accessible, and effective.

The COVID-19 pandemic has challenged health care systems all over the world. During this pandemic, the community pharmacist has provided critical health services to communities, including those most at risk for COVID-19. As the role of the community pharmacist during the COVID-19 pandemic continues to evolve,

pharmacy's impact on improving patient and population health outcomes should be evaluated. The COVID-19 pandemic will likely reveal new roles that community pharmacists can play during a pandemic and beyond.

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Tables

Table 1. Pharmacist Interventions and Anticipated Outcomes in Contributing to Population Health[a]

Intervention	Anticipated Outcomes
Prevention	
Medication monitoring	• Provide appropriate preventive medications • Address medication access issues in the face of pandemic restrictions
Patient education	• Educate patients about preventing coronavirus disease 2019 (COVID-19) infection and symptoms of the disease • Provide education on over-the-counter medications • Increase patient self-efficacy and reduce adverse outcomes from medications
Vaccinations	• Reduce novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission when a vaccine becomes available • Prevent outbreaks of vaccine-preventable diseases
Point-of-care testing	Increase access to COVID-19 testing and reduce transmission by early detection and quarantine of detected individuals
Management	
Medication monitoring	Increase treatment success
Patient education	• Educate patients about COVID-19 disease • Increase patient self-efficacy and reduce adverse outcomes from medications
Medication therapy review	Optimize patient medication adherence and quality of life
Disease self-care and support	• Ensure access when medical facilities are not accepting patients • Empower patients, increase pharmacist role in multidisciplinary team, and improve population health
Point-of-care testing	Provide real-time point of care screening results for chronic disease management

[a] Based on Greer N, Bolduc J, Geurkink E, Rector T, Olson K, Koeller E, et al. Pharmacist-led chronic disease management: a systematic review of effectiveness and harms compared with usual care (7).

Table 2. Comparison of Proportion of US Deaths From Coronavirus Disease 2019 (COVID-19) and Weighted Population Distribution by Race/Ethnicity[a]

Race/Ethnicity	Percentage of US Population	Percentage of COVID-19 Deaths	States With Known Racial Disparity in Outcomes
Asian	10.7	5.0	Nevada
Black	17.2	23.0	Alabama, District of Columbia, Georgia, Illinois, Kansas, Louisiana, Maryland, Michigan, Mississippi, Missouri, New York, South Carolina, Texas, Wisconsin
Hispanic or Latino	16.6	27.7	None
American Indian/Alaska Native	0.3	0.7	Arkansas, New Mexico, Oklahoma
Non-Hispanic White	42.3	53.4	Florida, Indiana, Kentucky, Massachusetts, Minnesota, New Hampshire, New Jersey, Ohio, Oregon, Pennsylvania, Rhode Island, Tennessee, Washington

[a] Table modified from Centers for Disease Control and Prevention, Weekly updates by select demographic and geographic characteristics, June 24, 2020, Table 2a (15).

PREVENTING CHRONIC DISEASE
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RESEARCH BRIEF

Rx for Addiction and Medication Safety (RAMS-PEER): Evaluation of an Education and Peer Program on Opioid Misuse

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PEER REVIEWED

Summary

What is already known on this topic?

Rhode Island adolescents had among the highest estimated prevalence rates of illicit drug use from 2015 to 2016.

What is added by this report?

The Rx (prescription) for Addiction and Medication Safety program was developed to deliver opioid misuse education for Rhode Island public high schools to reverse the trend of illicit drug use. Results found student knowledge of opioid misuse and use disorder improved following a pharmacy-implemented intervention. However, spillover benefits were not observed, indicating that consistent program delivery may be needed.

What are the implications for public health practice?

Our study provides evidence of an effective adolescent opioid misuse awareness program and, perhaps, a foundation for a statewide opioid misuse educational program within Rhode Island public schools.

Abstract

The Rx (prescription) for Addiction and Medication Safety (RAMS) program was developed during the 2017 through 2018 academic year to educate students from 6 selected Rhode Island public high schools about opioid misuse, overdose, and recovery. During 2016, 3 schools participated in the RAMS program and returned for RAMS-PEER in 2017; 3 schools were newly recruited in 2016. Tenth graders returned from schools that participated during RAMS in 2016, and all ninth graders were new. Our study's aim was to evaluate the overall effect and spillover benefit of the RAMS-PEER intervention from tenth to ninth graders by surveying students both before and after the education program. Survey questions were modified from the 2015 Youth Risk Behavior Survey and the 2015 Ontario Study Survey. Student responses were matched for preintervention and postintervention analysis using a unique identifier. We observed an improvement in knowledge of opioid misuse; however, we found no evidence of a significant spillover benefit.

Introduction

The United States is facing an unprecedented crisis of drug overdose. More than 70,200 people died from an overdose during 2017 alone. From the 70,200 deaths, 47,600 (68%) were overdoses from all opioids, and 17,029 (24%) were overdoses from prescription opioids (1). In Rhode Island, the opioid overdose death rate was 26.9 per 100,000 population and ranked tenth in the United States in 2017. RI adolescents were especially at high risk of substance misuse. Based on the 2015–2016 National Survey on Drug Use and Health, RI had one of the highest estimated percentages of adolescents (aged 12 to 17 y) who used illicit drugs, 12.5% (95% confidence interval [CI], 10.18%–15.19%), compared with the national average of 8.3% (95% CI, 7.98%–8.71%) (2).

To prevent opioid misuse and overdose among youth, we implemented the Rx for Addiction and Medication Safety (RAMS) program. Developed by the University of Rhode Island (URI) College of Pharmacy, RAMS was an opioid misuse prevention education program delivered by trained pharmacy students for freshmen students at 8 public high schools in Rhode Island during the 2016 through 2017 academic year. Of students surveyed, 33 (7%) significantly improved their identification of opioid misuse, 19% improved knowledge of opioid withdrawal symptoms, 14% improved knowledge of the need for treatment referral, and 28% improved knowledge of naloxone administration (3). The PEER program was developed as a 1-hour, online, supplemental curriculum for RAMS. We implemented the RAMS-PEER program during

the subsequent 2017 through 2018 academic year to boost learning effects and evaluate potential spillover benefit of peer education. Three of 8 schools from the previous academic year returned to the program, and 3 new public high schools began participation. We delivered the booster course only to tenth-grade students from the returning schools who had participated in the RAMS program during the previous year. The full 3-hour RAMS curriculum was then delivered to ninth graders in all 6 schools.

Purpose and Objectives

Our study aimed to evaluate the overall effect and possible spillover benefit of the RAMS-PEER intervention among high school students, specifically, to determine if tenth graders participating in the prior year shared their knowledge with incoming ninth graders (4–6). Leveraging spillover mechanisms to sustainably scale up and deliver the RAMS intervention is necessary, given the often resource-constrained setting of public-school systems. Recent evidence points to stronger influences of peer-to-peer education for risk reduction, as compared with provider-to-peer, and we anticipated this resonance might be stronger among adolescent peers (5,7). We conclude with a discussion of next steps to evaluate spillover of the RAMS-PEER intervention.

Intervention Approach

RAMS is a 3-hour, on-site, school-based curriculum, providing 3 to 4 interactive educational sessions. Sessions include medication safety, signs, symptoms, and risk factors for opioid misuse and withdrawal; opioid overdose identification and response; and local treatment and recovery resources. Implementation of RAMS has been described previously (3). The RAMS-PEER program is a booster curriculum for RAMS and designed as an online supplement. Seven, 5-minute videos were created for RAMS-PEER to highlight RAMS education, and the curriculum includes facilitator guides for instructors' in-class discussions. All RAMS-PEER materials were available on the RAMS-PEER website (www.ramspeer.com) during the program's implementation. Returning tenth graders who had received the RAMS curriculum in the first year were instructed to view videos either in school or in their spare time. A discussion led by high-school faculty was mandatory after each booster video. Once completed, URI pharmacy students delivered the primary RAMS program to ninth graders at both new and returning schools.

Evaluation Methods

We conducted a pre-post comparison study to measure an initial RAMS-PEER intervention on student knowledge, perceptions, risk, and protective behaviors related to opioid misuse. Our study population included students entering the ninth and tenth grades during the 2017 through 2018 academic year. Students voluntarily participated in 2 confidential surveys answering questions by using SurveyMonkey (SVMK, Inc). Before program delivery (preintervention), ninth graders completed a 20-minute survey that included risk and protective factors for substance misuse; past 30 days nonmedical use of opioids, alcohol use, and use of other substances; students' perception of risk or harm from prescription drugs and prescription drug overdose; awareness of resources and treatment of substance misuse; proper disposal and storage of prescription medications; and how to obtain and administer naloxone. These items were modified from the 2015 Youth Risk Behavior Survey from the Centers for Disease Control and Prevention and the 2015 Ontario Study Survey from the Canadian Centre for Addiction and Mental Health and identical to surveys administered in the RAMS first-year program (3,8,9). The survey also collected student demographic information, such as age, race/ethnicity, and sex, as well as home environment, social media use, self-reported mental health, academic assessment, and substance use. The same survey was administrated again 1 to 2 months after the RAMS-PEER curriculum was completed among the ninth and tenth graders (postintervention). In this analysis, the intervention was a booster for tenth graders from returning schools and a full curriculum for ninth graders from all 6 schools. All postsurveys were administered after all students received the full intervention. Each student response was matched for preintervention and postintervention analysis using a unique identifier.

Descriptive statistics, including means and proportions, were used to report participant demographics and other characteristics. We used the χ^2 test to conduct cross-sectional and paired comparisons between outcomes at the 6 schools at preintervention and postintervention. Because the matched sample had missing values (n = 129, 40%), a multiple imputation approach was used with discriminant function for categorical variables to impute missing values. We used the fully conditional specification method to impute the missing data. Multiple imputation was performed on combined preintervention and postintervention data to generate 30 data sets with complete information, assuming a multivariate normal distribution and that missing data depended only on observed covariates (10,11). CIs for imputation results were based on standard errors using Rubin's estimator of variance (12). To assess if ninth grade students in returning schools had an associated improvement in knowledge due to the educational program (RAMS) and the booster (PEER), as compared with ninth grade students in new schools who received only RAMS, we fit a logistic model with binary versions of each outcome (responses to knowledge questions were identified as either correct or incorrect; 5-level confidence questions were dichotomized into 2 groups (eg, none of your closest friends use pain relief pills versus at least some). In the

models for matched precomparisons and postcomparisons, each student served as their own control; therefore, time-invariant confounding was subtracted by individual level differencing, and secular trends were less of a concern, short of a follow-up period. We also included the confounders of age, sex, race, grade, access to pain relief, and mental health (significance set at $P < .20$) in the logistic model evaluating the association of school type on outcomes. Statistical analysis was completed using SAS Version 9.4 (SAS Institute, Inc), and all tests were 2-sided at $P < .05$ significance.

To evaluate the possible spillover and peer education benefit from tenth to ninth graders in returning schools, we calculated the adjusted odds ratios (aORs) of correct responses or improvement in knowledge among ninth graders in returning schools versus ninth graders in new schools. Improvement in knowledge was defined as having correct answers in both the presurvey and the postsurvey, or having incorrect answers in presurvey and correct answers in the postsurvey.

Results

Of ninth grade students in 2017 through 2018, 1,030 participated in the preintervention survey, and 439 participated in the postintervention survey. We matched 321 students with both preintervention and postintervention surveys for the year. Most ninth graders from the 6 high schools were aged 14 or 15 years (n = 1,013, 98.3%), 823 were white (79.9%), and 908 (88.2%) earned nearly all A and B grades. Of the 1,030 students, 715 (69.4%) reported good mental health status, with no feelings of worthlessness (n = 594, 57.7%) or hopelessness (n = 622, 60.4%). Additionally, 707 students found it difficult or did not know how to obtain pain relief medication (68.6%) or medication to treat attention deficit hyperactivity disorder without prescription (n = 759, 73.7%) (Table 1).

After the RAMS-PEER program, during the 2017 through 2018 academic year, ninth grade student knowledge of opioid misuse improved. The percentage of correct answers increased significantly from preintervention to postintervention for questions on knowledge of opioid misuse (from 76.2% correct to 84.4% correct), and perceptions of people who use drugs (from 27.4% correct to 33.9% correct) (Table 2).

Improvement was observed among matched ninth graders (n = 321) regarding their knowledge that accepting a prescription medication from a friend was drug misuse. For Question 93, $P = .01$ (Table 2). After receiving the intervention, among the matched students, we observed an 8% increase in knowledge of identifying addiction as a chronic brain disorder (aOR, 1.08; 95% CI, 0.64–1.83), a 26% increase in understanding of reasons people use drugs (aOR, 1.26; 95% CI, 0.79–1.98), and a 78% increase in knowledge that nonmedical use is using a prescription medication without a prescription (aOR, 1.78; 95% CI, 0.87–3.6) (Table 2). Knowledge improvement, however, was not significantly higher among ninth graders in the returning schools versus ninth graders in the new schools.

Implications for Public Health

In our assessment of an opioid misuse education program among ninth- and tenth-grade students in Rhode Island, we found that ninth-grade students had improved knowledge of opioid misuse and improved perceptions of people who use drugs after the education program during the 2017 through 2018 academic year, demonstrating effectiveness of the program. We also found a positive, although nonsignificant, spillover effect among ninth graders from the 3 returning schools. Although a more robust assessment of the spillover mechanism is needed, these findings indicate that an educational awareness and prevention program needs consistent delivery to provide beneficial outcomes.

Our study has several limitations. Although each school administration approved survey implementation, the Rhode Island Department of Education halted it for several months before revoking the approval midstudy. Approval was again obtained after the department's expanded review of the identical survey; however, critical time lost during the study negatively affected data collection and limited evaluation of spillover effects. We received 1,030 preintervention survey respondents from ninth graders; however, only 415 students completed the postsurvey, and we were only able to match 321 pre- and postrespondents. The preintervention survey had approximately 30% missing answers and the postintervention survey had approximately 20% missing. A low response rate to the postsurvey and missing outcomes limited our ability to detect improvements in knowledge. Another limitation was our use of a fully conditional specification, a semiparametric method that is flexibly suitable for this study. One known theoretical limitation of this study is its high sensitivity to imputing values, and this might have affected our results (13). To avoid this drawback we imputed variables following the order that they appeared in the survey, which was appropriate and matched the monotone pattern of missing data. Additionally, selection bias might have been introduced by student self-reports of earning A or B grades. Students who received good grades might have been more likely to respond to the survey than students who received lower grades.

Future studies could use a randomized design, which might provide a more accurate evaluation of spillover effects of the RAMS-PEER intervention and offer additional insights into the

intervention coverage levels needed to change and sustain norms around opioid misuse among adolescents.

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Tables

Table 1. RAMS-PEER Intervention Surveys and Matched Respondent Demographic Characteristics Among Ninth Grade Students, Rhode Island, 2017

Characteristic	RAMS-PEER 2017 Presurvey, N = 1030, n (%)[a]	RAMS-PEER 2017 Matched Presurvey and Postsurvey, N = 321, n (%)[a]
Sex		
Female	493 (47.9)	190 (59.2)
Male	518 (50.3)	128 (39.9)
Other	19 (1.8)	3 (0.9)
Age, y		
14	551 (53.5)	127 (39.6)
15	462 (44.9)	188 (58.6)
16	11 (1.1)	5 (1.6)
17	6 (0.6)	1 (0.3)
Race		
White	823 (79.9)	271 (84.4)
Other	207 (20.1)	50 (15.6)
Grades		
B or better	908 (88.2)	299 (93.2)
Less than B	122 (11.8)	22 (6.9)
Daily social media use, h		
<2	349 (33.9)	109 (34.0)
2–4	481 (46.7)	148 (46.1)
>5	199 (19.3)	64 (19.9)
Missing	1 (0.1)	0
How easy or difficult would it be for you to get pain relief pills without going to a doctor?		
Easy	269 (26.1)	88 (27.4)
Difficult	400 (38.8)	142 (44.2)
I don't know	307 (29.8)	78 (24.3)
Missing	54 (5.2)	13 (4.0)
How easy or difficult would it be for you to ADHD medications without going to a doctor?		
Easy	205 (19.9)	74 (23.1)
Difficult	419 (40.7)	146 (45.5)
I don't know	340 (33.0)	86 (26.8)
Missing	66 (6.4)	15 (4.7)
Self-reported emotional health		
Good	715 (69.4)	219 (68.2)
Poor	63 (6.1)	19 (5.9)
Missing	252 (24.5)	83 (25.9)

Abbreviations: ADHD, attention deficit hyperactivity disorder; RAMS, Rx for Addiction and Medication Safety.
[a] Values of polytomous variables might not sum to 100% due to rounding.

(continued on next page)

(continued)

Table 1. RAMS-PEER Intervention Surveys and Matched Respondent Demographic Characteristics Among Ninth Grade Students, Rhode Island, 2017

Characteristic	RAMS-PEER 2017 Presurvey, N = 1030, n (%)[a]	RAMS-PEER 2017 Matched Presurvey and Postsurvey, N = 321, n (%)[a]
Self-reported hopeless feeling		
Little or no	594 (57.7)	169 (52.7)
Some time or more	178 (17.3)	67 (20.9)
Missing	258 (25.1)	85 (26.5)
Self-reported worthless feeling		
Little or no	622 (60.4)	186 (57.9)
Some time or more	150 (14.6)	50 (15.6)
Missing	258 (25.1)	85 (26.5)

Abbreviations: ADHD, attention deficit hyperactivity disorder; RAMS, Rx for Addiction and Medication Safety.
[a] Values of polytomous variables might not sum to 100% due to rounding.

Table 2. Improved Knowledge Comparison Among Ninth Grade Students From Returning Schools Versus New Schools, Rhode Island, Academic Year 2017–2018

Questions (Q) and Dichotomized Answers	2017 Presurvey N =1,030, n (%)	2017 Postsurvey N = 415, n (%)	*P* Value[a]	Matched 2017 Presurvey N = 321, n (%)	Matched 2017 Postsurvey N = 321, n (%)	*P* Value	Adjusted Odds Ratios (95% Confidence Interval)
Q93 Addiction is a chronic brain disease or disorder.[b]							
Correct	591 (79.3)	284 (83.5)	.10	191 (82.0)	232 (86.6)	.15	1.08 (0.63–1.83)
Q93 Drug misuse is accepting prescription medication from a friend.[b]							
Correct	568 (76.2)	287 (84.4)	.01	181 (77.7)	230 (85.8)	.01	0.72 (0.44–1.18)
Q93 Drug misuse is use of a prescription medication is exceeding the recommended dose.[b]							
Correct	653 (87.7)	305 (89.7)	.33	208 (89.3)	245 (91.4)	.41	0.85 (0.48–1.51)
Q93 Nonmedical use is using a prescription medication without a prescription.[b]							
Correct	634 (85.1)	299 (87.9)	.21	209 (89.7)	240 (89.6)	.95	1.77 (0.86–3.63)
Q100 Drug users are responsible for their addiction.[c]							
Correct	202 (27.4)	114 (33.9)	.03	67 (29.0)	91 (34.2)	.21	0.93 (0.60–1.44)
Q100 Drug users can stop using drugs whenever they want to.[c]							
Correct	557 (75.5)	272 (81.0)	.05	182 (78.8)	22 (83.1)	.22	1.13 (0.70–1.82)
Q100 People use drugs to avoid dealing with their own inadequacies.[c]							
Correct	128 (17.3)	80 (23.8)	.01	40 (17.3)	53 (19.9)	.45	1.26 (0.79–1.98)
Q100 Drug users have weak characters[c]							
Correct	442 (59.9)	213 (63.4)	.28	147 (63.6)	17 (63.9)	.95	0.97 (0.65–1.43)
Q76 Feel so depressed (sad) that nothing could cheer you up?[d]							
None	489 (63.3)	204 (58.1)	.09	138 (58.5)	16 (58.8)	.93	1.16 (0.75–1.81)
A little, sometime, most time, or all the time	283 (36.7)	147 (41.9)	NA	98 (41.5)	11 (41.2)	NA	NA
Q78 In the last 4 weeks, did you feel that you were under any stress, strain, or pressure?[d]							
Not at all	101 (13.1)	47 (13.4)	.89	20 (8.5)	34 (12.3)	.16	1.96 (0.83–4.61)
A little, some, a lot, or more than I could take	671 (86.9)	304 (86.6)	NA	216 (91.5)	24 (87.7)	NA	NA
Q83 How many of your CLOSEST friends use pain relief pills such as Percocet, Tylenol #3, Vicodin, Oxycodone?[e]							
None	540 (70.8)	242 (69.3)	.628	160 (68.1)	19 (69.2)	.78	0.92 (0.64–1.39)
Some, most, all, or don't know	223 (29.2)	107 (30.7)	NA	75 (31.9)	85 (30.8)	NA	NA
Q97 My parent(s) showed me affection.[f]							
Always or frequently	640 (86.7)	284 (84.5)	.34	201 (87.0)	22 (85.7)	.67	1.38 (0.76–2.52)
Sometimes or rarely	98 (13.3)	52 (15.5)	NA	30 (13.0)	38 (14.3)	NA	NA

[a] *P* value was calculated by using χ^2 test.
[b] 285 Missing values in 2017 presurvey, 75 in 2017 postsurvey, 88 in matched presurvey, and 53 in matched postsurvey.
[c] 292 Missing values in 2017 presurvey, 79 in 2017 postsurvey, 90 in matched presurvey, and 55 in matched postsurvey.
[d] 258 Missing values in 2017 presurvey, 64 in 2017 postsurvey, 85 in matched presurvey, and 44 in matched postsurvey.
[e] 267 Missing values in 2017 presurvey, 66 in 2017 postsurvey, 86 in matched presurvey, and 45 in matched postsurvey.
[f] 292 Missing values in 2017 presurvey, 79 in 2017 postsurvey, 90 in matched presurvey, and 55 in matched postsurvey.

PREVENTING CHRONIC DISEASE
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RESEARCH BRIEF

Exploring Opportunities to Leverage Pharmacists in Rural Areas to Promote Administration of Human Papillomavirus Vaccine

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Summary

What is already known on this topic?

Parents are willing to use pharmacies as an alternative to clinics for their children's vaccination services, including the human papillomavirus (HPV) vaccine. However, the willingness of pharmacists to administer or promote this vaccine, especially in rural areas, is not well understood.

What is added by this report?

Rural pharmacists have the potential to be effective collaborators for HPV vaccine administration and promotion, but barriers, such as lack of education and capacity, exist.

What are the implications for public health practice?

Barriers to using pharmacists as providers of HPV vaccine could be overcome through partnerships with stakeholders who are already promoting the administration of HPV vaccine, and these barriers should be the focus of future research.

Abstract

Rural pharmacists have been identified as potential partners, along with health care providers, schools, and public health agencies, in administering and promoting the human papillomavirus (HPV) vaccine. We sought to understand the role of pharmacists in this work. We interviewed 11 pharmacists working at independently owned pharmacies in Iowa to explore their perspectives on HPV vaccine administration and promotion. Most pharmacists agreed that HPV vaccination was within their professional scope. They identified factors that facilitate vaccine administration (eg, accessibility of pharmacies). They also reported personal barriers (eg, lack of information, concerns about safety) and organizational barriers (eg, time and staff capacity). Future work should focus on alleviating barriers and building on strengths to improve vaccination rates and ultimately prevent HPV-related cancers.

Objective

Nationally, 51.1% of adolescents are up-to-date with the human papillomavirus (HPV) vaccine series (1). Rural populations are less likely to be vaccinated (2) and have higher rates of HPV-associated cancers (3). To increase HPV vaccination rates in rural areas, collaborations for vaccine administration and promotion should be explored. Pharmacists are potential partners, especially since 22 states, including Iowa, passed legislation permitting pharmacists to administer the HPV vaccine to adolescents (4). Previous research demonstrated high levels of acceptance in the United States of vaccinations administered by pharmacists (5,6). The objective of this study was to describe rural pharmacists' role in administering and promoting the HPV vaccine in counties in Iowa with low rates of HPV vaccine uptake.

Methods

As part of a larger study assessing HPV vaccination barriers and facilitators in rural counties with low HPV vaccination rates, we interviewed pharmacists at independently owned pharmacies in Iowa. We first identified 7 rural counties that had 1) HPV vaccination completion rates lower than the state average (27%), and 2) a percentage-point discrepancy larger than the average discrepancy in Iowa (31 percentage points) between completion rates for HPV vaccination and completion rates for other adolescent vaccinations (7). We used National Center for Health Statistics definitions of rurality and Iowa's Immunization Registry for data on vaccination completion rates. We identified independently owned pharmacies (n = 14) through internet searches and conducted interviews in May and June 2018. We designed our interview guide by

using questions and concepts adapted from previous projects (8,9) and included the following topics: the role of rural, independent pharmacists in HPV vaccine promotion and uptake; willingness to educate parents, refer patients, and administer the HPV vaccine; priority of HPV vaccine promotion; and vaccination barriers and facilitators in the pharmacy and the community (8,9). This project was determined not to be human subjects research by the University of Iowa Institutional Review Board. We attempted to contact 14 pharmacists by telephone up to 4 times to complete an interview and ultimately completed 11 interviews (average duration, 9.5 min). All interviews were audiorecorded and transcribed verbatim by a third-party service.

After an initial examination of transcripts, the research team created a codebook. Two researchers independently (E.A., W.B-B.) used it to code the same transcript, with additional codes to capture all relevant information. They met with a third researcher (G.R.) to resolve coding discrepancies and finalize the codebook. At this point, they determined that data saturation had been reached and remaining transcripts were divided for final coding. After all transcripts were coded, the research team met to discuss themes and subthemes that emerged from the codes.

Results

Of the 11 pharmacists interviewed, 3 reported offering no vaccines and only 1 reported offering the HPV vaccine (Table 1). We identified 4 themes: pharmacists' role in HPV vaccine administration and promotion, personal barriers to vaccine administration, organizational barriers to vaccine administration, and facilitators for vaccine administration (Table 2). Pharmacists reported that HPV vaccination should be a priority for adolescent health but that it was not a priority in their workplaces. Most indicated that recommending HPV vaccination was within their role. Many pharmacists were willing to educate and refer patients, but fewer reported willingness to administer the vaccine.

We identified 4 subthemes for personal barriers to HPV vaccine administration: sensitivity of subject, lack of information, concerns about safety, and misinformation. Pharmacists reported insufficient knowledge to recommend, refer, or educate parents about the vaccine. Although no pharmacists cited religious or moral objections, some reported that discussion of the vaccine could have a political, and therefore contentious, aspect.

Organizational barriers to HPV vaccination administration were time and staff capacity, liability, and competition with local health care providers. Although some pharmacists reported that they were not certified to administer the vaccine, others had not created protocols for administering the vaccine. Lack of space, such as consultation rooms big enough for both a parent and an adolescent, was also described as a barrier. Barriers cited less frequently were related to liability in administering the vaccine, low numbers of adolescents coming to the pharmacy, and the potential to be seen as competitive with local health care providers.

Pharmacists also identified 2 factors that could facilitate administration and promotion of the vaccine: accessibility of community pharmacies and an increase in advertising through social media. Many recognized the better accessibility and convenient hours of pharmacies, compared with clinics, for busy parents. Other potential facilitators were more training to increase knowledge about the vaccine and how to administer it and collaborating with health care providers, schools, or public health agencies.

Discussion

Our aim was to better understand the role of independent pharmacists in administering and promoting the HPV vaccine in rural Iowa. Overall, we found that although barriers exist to HPV vaccine administration and promotion, most pharmacists interviewed were willing to overcome them with support and training. Similar to our study, recent studies also identified time, staff constraints, and lack of integration with clinics as barriers to HPV vaccine administration and promotion (10,11). Also similar to other studies, our study indicated that participants identified convenience and accessibility as facilitators for vaccine administration and promotion (12).

However, many pharmacists expressed a need for more information and training on the vaccine and how to administer it. More information and training could overcome barriers they identified. Given their interaction with adolescents and parents, pharmacists could not only provide HPV vaccinations but also act as a vaccine champion by educating parents, distributing information, and providing referrals to local health care providers. Finally, although a few expressed concerns about being viewed as competition for clinics, others saw opportunities for valuable partnerships with clinics to establish referral systems or combine promotion or advertising activities.

A limitation of our study is the small sample of 7 rural counties. Our results should not be generalized beyond this setting.

Ultimately, our findings offer insight into the potential to work with pharmacists to increase HPV vaccine uptake in rural areas. This work should focus on simultaneously overcoming barriers while using the strengths noted by these pharmacists (ie, accessibility and convenience). Partnerships between pharmacists and state public health agencies or academic institutions could be explored as one pathway toward overcoming barriers (13). Effectively sup-

porting pharmacists in administering and promoting HPV vaccination will translate to increased HPV vaccination rates and prevention of future HPV-related cancers.

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Tables

Table 1. Demographic Characteristics of Pharmacists (N = 11) Participating in Study on Using Pharmacists in Rural Areas to Promote Administration of Human Papillomavirus (HPV) Vaccination and Vaccinations Offered at Their Pharmacies, Iowa, May–June 2018

Characteristics	No. (%)
Sex	
Male	5 (45.5)
Female	6 (54.5)
Vaccines offered	
None	3 (27.3)
Hepatitis A	1 (9.1)
HPV/Gardasil	1 (9.1)
Influenza	7 (63.6)
Meningitis	1 (9.1)
Pneumococcal	7 (63.6)
Shingles	8 (72.7)
Tetanus, diphtheria, and pertussis	4 (36.4)

Table 2. Summary of Themes and Subthemes and Sample Quotes From Interviews of 11 Pharmacists Participating in Study on Using Pharmacists in Rural Areas to Promote Administration of Human Papillomavirus (HPV) Vaccination, Iowa, May–June 2018

Theme	Subtheme	Sample Quotes[a]
Pharmacists' role in HPV vaccine administration and promotion	—	• "Not all pharmacies may agree or be comfortable" (May 22, F.P., pharmacist A). • "Oh, I'd be interested. I think educating people is a good idea, so there would be interest for sure" (May 2, F.P., pharmacist B). • "I feel like [HPV vaccination] was just not a common thing that's gonna come up in the pharmacy" (June 6, T.A., pharmacist C).
Personal barriers to vaccine administration	Sensitivity of subject	"Because of HPV and how you get HPV, I feel like sometimes it can be a sensitive subject" (May 22, F.P., pharmacist A).
	Lack of information	• "The information continues to change [so] it's always a matter of staying up to date with reading and following . . . resources. On that particular vaccine, I'm probably not as up to date as I should be" (June 6, F.P., pharmacist C). • "I'm not familiar with the costs of it all, the storage, those kind of things" (June 14, T.A., pharmacist D).
	Concerns about safety	"I have a few concerns just with the HPV hype about injury and things that have happened to people after they've gotten [it], like back pain" (June 6, T.A., pharmacist E).
	Misinformation	• "Yes, it's considered a rural area, but I think in general we have good coverage" (June 11, T.A., pharmacist F). • "Medicaid does not allow us to do it for those under 18, even with a prescription" (June 20, T.A., pharmacist G). • "[Adolescents] are supposed to go to the doctor's office" (June 4, T.A., pharmacist H).
Organizational barriers to vaccine administration	Time and staff capacity	"Usually there's only one pharmacist . . . so that interrupts everything to do the vaccination" (June 11, T.A., pharmacist F).
	Liability	"You incur a little bit more liability when you're dealing particularly with an adolescent, because generally they have a greater risk of fainting or having an episode after a vaccination" (June 6, F.P., pharmacist C).
	Competition with local health care providers	"I feel that we probably need to work more closely with the clinics to be more collaborative with the clinics, so that they didn't feel like anybody was stepping on anyone's toes" (June 6, F.P., pharmacist C).
Facilitators for vaccine administration	Accessibility	"As far as in our rural community, customers or patients are very likely to pop in the pharmacy and ask questions. We're very accessible, whereas a practitioner really isn't. So, I think it's just the ease of availability of information for them" (June 4, T.A., pharmacist H).
	Increase in advertising	"If they knew it was available at a pharmacy . . . you know how they've got Facebook and everything, stuff can spread pretty fast" (June 4, T.A., pharmacist H).

[a] Each quote is followed by the date of the interview, the initials of the interviewer, and an identifier for the pharmacist interviewed.

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ESSAY

The Role of the Pharmacist in Preventing Hepatitis B in the Context of the Opioid Crisis

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Across the United States, more than 70,000 people died from drug-related overdoses in 2017, and 47,600 of those reported deaths involved an opioid (1). The largest increase in opioid-related overdoses can be attributed to a rise in the use of synthetic opioids including illicitly manufactured fentanyl, a potent opioid with rapid onset and a short duration of effect (1). Fentanyl is primarily administered by injection, and the shorter duration of effect may lead people who inject drugs to inject more frequently to stave off withdrawal symptoms between doses (2). The use of fentanyl poses an obvious risk of overdose; however, other health risks attributed to increased injection frequency are less often discussed. Increased injection frequency has been associated with a greater likelihood of syringe sharing and, in turn, increased risk of infectious disease exposure (2). The behavior has been linked to increased transmission of HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV), especially when people who inject drugs do not have access to syringe service programs or other harm reduction services. A study by Lambdin and colleagues stated, "Participants reporting perceived illicit fentanyl use were more likely to report high frequency opioid use, high frequency injection and receptive syringe sharing compared with people using heroin and other street drugs but not fentanyl" (2). Because of the rise in fentanyl use, the US health care system must implement more effective strategies for reducing the risks of infectious disease transmission among people who inject drugs and broaden their focus to include HBV and other less frequently discussed infectious disease concerns associated with increased injection frequency.

Hepatitis B is transmitted through infected blood and body fluids, and common routes of transmission include unprotected sexual contact, perinatal transmission, and injection drug use (3). In the United States, up to 2.2 million individuals are chronically infected with HBV (4) and only 25.0% of adults aged 19 years or older report full vaccination coverage (5). Additionally, in 2014, populations considered to be at high risk for HBV infection reported similarly low vaccination coverage (eg, reported vaccination coverage for individuals who traveled to endemic countries [>2% prevalence of HBV infection] was 30.5%, for those who have diabetes mellitus it was 23.5%, and for those with chronic liver conditions it was 29.8%) (5).

State surveillance reports have revealed nationwide increases in acute HBV infection, with the largest increases occurring in the Appalachian region (3). An analysis of the National Notifiable Diseases Surveillance System from 2006 through 2013 assessed the incidence of acute HBV infection in 3 Appalachian states, Kentucky, Tennessee, and West Virginia, noting an increase of 114% among non-Hispanic white people aged 30 to 39 years who also reported injection drug use (3). Maine saw a 729% increase in new acute HBV cases from 2015 through 2017, with 45% of new cases coinfected with HCV (6). According to 2017 surveillance from the Centers for Disease Control and Prevention, the adjusted number of acute infections for HBV was 22,200, and there is limited data on incidence of coinfection for HBV and HCV (7). Increases in hepatitis infections have been associated with the ongoing opioid crisis and attributed to increases in injection frequency (2,3).

In the absence of effective prevention measures, the transmission and spread of viral hepatitis infections among people who inject drugs is likely to continue. Fortunately, 3 single antigen recombinant HBV vaccines (Recombivax HB [Merck], Engerix-B [GlaxoSmithKline Biologicals], and Heplisav-B [Dynavax Technologies Corporation]) and 1 combination vaccine (Twinrix [GlaxoSmithKline Biologicals]) are available and provide appropriate protection from HBV (8). All high-risk individuals are recommended to receive the full HBV vaccine series to ensure a protective antibody response, but even an incomplete series has the potential to produce clinically significant levels of protection (8). For example, the 3-dose series has been reported to produce a protective antibody response in 30% to 55% of healthy adults aged 40 years or

younger following just the first dose, 75% following the second dose, and greater than 90% following the third dose of the series (8).

The HBV vaccines are safe and effective, but inconsistent access to health care services remains a barrier to obtaining the multidose immunization series among many high-risk populations. To improve vaccination coverage among people who inject drugs, new strategies should be employed to ensure the HBV vaccine series is available in a wider range of medical settings. These settings include pharmacies, primary care offices, emergency departments, social service organizations, and correctional facilities. Community pharmacists in particular have the potential to substantially increase the nation's capacity to provide the HBV vaccine to high-risk populations and have already been called upon to play a greater role in addressing the needs of patients with opioid use disorder. Efforts by the profession include increasing pharmacy-based access to naloxone (a medication used to reverse an opioid overdose), increasing provision of sterile syringes, and ensuring medications for opioid use disorder are readily available (9). In the context of the opioid crisis, pharmacists have specifically been identified as having an important role to play in providing immunizations for health concerns associated with opioid use disorder, including HBV (10). The pharmacists' long-standing history of involvement with vaccine storage, preparation, distribution, education, and, in more recent years, as immunization providers themselves, lends support to their ability to provide this public health service (10,11).

Today, pharmacists are recognized by the Centers for Disease Control and Prevention and the Food and Drug Administration as immunization providers (11). Some states have specific restrictions or varying laws; nevertheless, all 50 states, the District of Columbia, and Puerto Rico allow pharmacists to administer vaccinations in some capacity (11). Additionally, all accredited Doctor of Pharmacy programs across the country must provide an avenue for their graduating students to become certified in immunization delivery, thus bolstering the profession of pharmacy's ability to provide greater immunization services with each year of new graduates (12).

Today, it is quite common for patients to receive their influenza, pneumococcal, zoster, or other single-dose vaccines from their local community pharmacy. The general convenience of community pharmacies, their extended hours compared with a traditional physician setting, and the normalization of receiving the "flu shot" from one's local pharmacy have contributed to the successful implementation of immunization services at most community pharmacies (12). Still, this practice setting has struggled to implement models that ensure that pharmacists are able to effectively provide access to a multidose vaccine series (12). The HBV vaccine is listed among those available in less than 50% of pharmacies (12), and, according to the American Pharmacists Association, some states reporting rising acute HBV infection rates also restrict the pharmacist's authority to administer HBV vaccinations (eg, age limitations and prescription requirements) (13). For example, Maine, a state that has seen substantial increases in HBV infections, restricts pharmacist administration of the HBV vaccine to adults aged 18 years or older, and New York does not provide pharmacists with any authority to administer the HBV vaccine to their patients (13). Policy efforts should work to expand the pharmacist's authority for administration of the HBV vaccine to address the gap in adult vaccination coverage across the United States.

The profession of pharmacy can look to existing best practices and successful models to provide vaccines having multiple doses or short follow-up requirements to identify methods for improving HBV vaccine services in the community pharmacy setting (12). These methods may include different reminder options, such as creating an order for follow-up doses when the first dose is administered, providing patient reminders through smartphone applications or text messaging, and aligning future vaccine dosages with medication synchronization models (12). Many pharmacy systems are accustomed to using reminder options such as these to improve adherence to chronic disease medications (12), and these same strategies can be leveraged to improve the community pharmacies' ability to provide the full HBV vaccine series to their patients.

We must acknowledge that the rise of acute HBV infections is also associated with the opioid crisis, and that a portion of these acute infections will result in increased chronic HBV infections (approximately 10%) (14). Collaboration among public health agencies and pharmacy organizations, with particular emphasis on community pharmacies, should focus on designing and implementing new strategies for providing vaccines requiring multiple doses. This is an essential step to effectively mobilize pharmacists to increase the nation's capacity to improve HBV immunization coverage among high-risk populations, including people who inject drugs. Furthermore, implementation of a successful model for providing multidose vaccines has the potential to positively impact population health far beyond opioid use disorder alone. Creating an effective model for providing the HBV vaccine series in the community pharmacy setting would likely translate to other preventable diseases requiring the administration of a multidose vaccine. The urgency to address the needs of people who inject drugs cannot be understated. Community pharmacists play a critical role in our nation's multipronged approach to addressing the opioid crisis and must be mobilized to help prevent further increases in acute HBV infection rates across the country.

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ORIGINAL RESEARCH

Community Pharmacy Engagement in Diabetes Prevention: Key Informant Interviews with Pharmacy Executives

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PEER REVIEWED

Summary

What is already known on this topic?

Effective yet underused strategies exist to prevent or delay the onset of type 2 diabetes. Community pharmacies are accessible destinations for preventive and chronic care management, and some pharmacies offer diabetes prevention services, including diabetes testing and lifestyle-change interventions.

What is added by this report?

This study identified factors that influence whether community pharmacies adopt and implement diabetes testing and National Diabetes Prevention Program (DPP) lifestyle-change interventions.

What are the implications for public health practice?

Community pharmacies can offer diabetes testing and the National DPP lifestyle-change intervention, both of which support public health goals to increase awareness and action for people with prediabetes. Barriers to implementation of diabetes prevention programs should be addressed.

Abstract

Introduction

Even though evidence-based diabetes prevention interventions exist, more than 1 in 3 Americans have prediabetes; the use of pharmacies has been explored as a way to reach and care for this population. The objective of this study was to analyze factors that influence adoption of type 2 diabetes prevention programs by community pharmacies.

Methods

We conducted 21 semistructured interviews in 2018 with decision makers from 11 independent pharmacies in 6 US states and the District of Columbia and from 10 chain pharmacies operating in 1 state, multiple states, and nationwide. We identified participants by using purposive sampling. We used qualitative methods to analyze data and conducted interviews until we reached saturation.

Results

Multiple themes emerged: 1) initiation of services is more likely if initial financial support is received; 2) patient demand for services, actual or perceived, is paramount; 3) diabetes prevention services often fit within the existing operations of a pharmacy and allow maximum use of resources; 4) customer loyalty is a clearly articulated advantage against competition; and 5) engagement in diabetes prevention affirms an expanded role and the value of pharmacies to serve communities.

Conclusion

Pharmacies are well situated to deliver diabetes prevention programs to communities. Although considerable opportunity exists for pharmacies to address diabetes prevention, more could be done to reduce barriers to their use.

Introduction

Diabetes imposes a societal and public health burden. More than 100 million Americans live with diabetes or prediabetes. Developing type 2 diabetes is a gradual but preventable process. In a 2019 study, nearly 1 in 5 adolescents aged 12 to 18 and 1 in 4 young adults aged 19 to 34 were living with prediabetes (1).

For people with prediabetes, reducing body weight and exercising can prevent or delay onset of type 2 diabetes. Studies demonstrated that such modifications resulted in a 30% to 60% reduction in diabetes incidence (2); these studies influenced the creation of the Centers for Disease Control and Prevention's (CDC's) National Diabetes Prevention Program (National DPP). This pro-

gram offers evidence-based, cost effective interventions to prevent diabetes. The National DPP, a lifestyle-change intervention, is offered by programs that meet quality standards through its recognition program (Table 1).

Several commercial and government payers provide coverage for the National DPP lifestyle-change intervention (Table 2). Expanding coverage is important to reach eligible participants and reduce financial burdens. Increases in the number of partnerships and access points are needed to prevent diabetes. Pharmacies are well-positioned to support this effort. CDC has promoted collaboration with pharmacies and pharmacists since its release of a guide supporting such action (3).

The current transformative health care landscape provides an opportunity to look beyond traditional models of care to increase access, reduce costs, and improve health outcomes. Despite mounting evidence on the value of pharmacists as patient care providers (5), legal, policy, and reimbursement frameworks have not kept pace nor adequately recognized pharmacists as providers.

Our study considers community pharmacies as a health care destination for diabetes prevention programs. Few studies have explored how pharmacies can affect diabetes prevention, and no study has considered factors that influence the decision making of pharmacy executives. The objective of our study was to identify factors that enable or hinder pharmacy adoption of diabetes prevention programs.

Methods

We gathered data through semistructured interviews with a purposive sample of key informants that discussed their company's engagement, or lack thereof, in diabetes prevention programs. We conducted interviews from May through August 2018 until we reached saturation of information and themes. To recruit key informants from pharmacies engaged in the National DPP lifestyle-change intervention, we reviewed CDC's publicly available registry of 1,693 participating organizations on March 30, 2018. The registry listed 26 independent and 5 chain pharmacy corporate entities, and we contacted executives at these pharmacies. To identify the appropriate executives, the interviewer (S.E.R.) had access to chain pharmacy executives through personal connections and her employer, and she received a list of independent pharmacy contacts through the National Community Pharmacy Association. We sought a convenience sample of independent pharmacies not engaged in such programs through referrals from state pharmacy associations and pharmacy professors. For chain pharmacies, the interviewer contacted executives by using a list of the top 25 pharmacies by prescription share. This qualitative research study was deemed exempt by the institutional review board at the University of North Carolina, Chapel Hill.

We conducted interviews with 22 key informants, individuals who had the decision-making authority to determine whether their employer could adopt new patient care services. We excluded information from 1 key informant because we realized after the interview was complete that this person did not meet our eligibility criterion of having the appropriate decision-making authority. The 21 participants represented 11 independent and 10 chain pharmacies. We analyzed data from the 21 interviews by using MAXQDA (VERBI GmbH) to write memoranda, develop codes, and identify themes. We used well-documented qualitative data analysis techniques (6,7) which led to 5 equally weighted key themes. A second coder, an undergraduate student, reviewed all transcripts, and an intercoder reliability score of 83.3%, above the 80% benchmark, was reached.

Results

The 11 independent pharmacy executives were affiliated with pharmacies in Illinois, North Carolina, Pennsylvania, Tennessee, Texas, Utah, and the District of Columbia. The 10 chain pharmacy executives represented 3 traditional drug stores, 5 grocery stores with pharmacies, and 2 mass merchants with pharmacies. Half of the chain pharmacy participants worked for companies with a national presence, operating more than 1,000 stores. The other half worked for companies with a regional presence, including primarily companies operating 200 or more stores; one had fewer than 20 stores. Nearly all independent pharmacy participants had been with their company for up to 15 years. Conversely, more than half of chain pharmacy participants had been with their company for 16 years or more, with 4 chain pharmacy participants reporting 26 to 30 years.

More than half of companies interviewed delivered both diabetes testing and the National DPP lifestyle-change intervention. Five key themes emerged as factors that enable or hinder pharmacy adoption of diabetes prevention programs (Table 3).

Theme 1: Financial feasibility

Diabetes prevention programs are more likely to be offered at pharmacies if initial financial support is received. Almost half of participants received a grant from a state or local health department or a state pharmacy association to offset initial costs of implementation. Participants who received grant support said funding was critical to mitigate financial risk while launching or expanding their program. Even though no participants were eligible

to bill through Medicare, the potential to do so positively influenced the pharmacies' willingness to offer the program and served as a catalyst for adoption. Most chain pharmacy participants discussed the value of piloting programs with their employees — an opportunity for cost avoidance through self-insured plans and aggregation of data to demonstrate value to payers.

Most adopters of diabetes prevention programs reported no reimbursement beyond grants. Only grocery store participants reported receiving reimbursement for the National DPP lifestyle-change intervention and had better results with payment coverage of diabetes testing than did other interviewees who conducted diabetes prevention programs at other types of pharmacies. Grocery participants secured employer group contracts for diabetes testing (eg, blood glucose test, hemoglobin A_{1c} test) and covered services for their employees through self-insured plans. They also offset testing costs through manufacturer sponsorship and use of clinic staff (eg, dietitians) for medical billing.

Financial sustainability was an important factor many adopters considered when deciding whether to continue services. Participants shared concerns about the inadequacy of the traditional business model, which is built on reimbursement for medications rather than care delivery. Nearly all former adopters or nonadopters expressed willingness to consider offering diabetes prevention programs if a sustainable, scalable model existed.

Theme 2: Patient participation

Patient participation emerged as a central, unexpected theme. Most participants said buy-in and demand for services were ongoing or anticipated barriers that influenced whether they offered diabetes prevention programs. Their concern for diabetes testing buy-in related to uptake of the service, whereas their concern for the National DPP lifestyle-change intervention centered on enrollment and retention. A recurring concern for patient retention was the 52-week length of National DPP lifestyle-change intervention and related challenges to meet performance measures set by CDC and payers.

Many participants felt that the low level of patient buy-in and demand was fueled by inadequate education and unwillingness to proactively improve one's health. Other perspectives on why participants may not demand the services included not fully understanding the seriousness of prediabetes, finding time in their schedules to participate, and their social determinants of health. Despite barriers related to patient buy-in and demand, many study participants expressed optimism about identifying solutions. A traditional chain pharmacy nonadopter said, "It's just figuring out what is really [going to] resonate with the patient, and how do we get them to engage."

Theme 3: Operational fit

Participants discussed alignment with existing pharmacy operations as an important factor for adoption. Participants characterized alignment across several areas, including legal, policy, and documentation issues; physical space; standardization and time; staffing; and technology. The most cited legal and policy barrier was the lack of recognition of pharmacists as a provider at the federal level, which affects reimbursement for testing. A few participants cited complicated or nonexistent pharmacy Clinical Laboratory Improvement Amendments (CLIA)-waiver authority in some states, preventing them from offering point-of-care tests (eg, hemoglobin A_{1C}). Some discussed complex administrative barriers related to updating pharmacy management systems and executing medical billing.

Participants agreed that clinical and support staff should work to the top of their professional capacity, allowing pharmacists more time for patient care. Most participants carefully considered how and when to use valuable personnel resources, weighing quality, appropriateness, and cost. All grocery store participants employed dietitians, and two-fifths used dietitians as lifestyle coaches for their National DPP lifestyle-change intervention classes. Participants spoke positively about the role of pharmacy interns and residents. Those without access to such personnel noted their value. One independent pharmacy participant said, "We don't currently have a resident. If I did have a resident, absolutely, that [diabetes prevention program] would be one of the things that I would very adamantly have them participating in."

Some participants discussed technology. One grocery participant mentioned their company's proactive effort to develop a "digital and face-to-face option [for the National DPP lifestyle-change intervention], and highly encouraging a combination option. Initial visit in-person and then customize the program based on their needs."

Theme 4: Customer loyalty

Many participants stated the primary advantage of offering diabetes prevention programs is increased customer loyalty. Delivery of such services increased trust and good will. Several participants felt delivering these services contributes to positively changing public opinion of pharmacists as care providers.

Several participants saw a clear advantage to offering diabetes prevention programs when doing so clearly aligned with their company's core values; for nonadopters, making that connection led to a greater consideration of these programs. Grocery store parti-

cipants discussed their proximity to fresh food and wellness as advantages, beyond using dietitians. One participant said, "because we're a pharmacy embedded in a supermarket . . . teaching someone how to read labels, teaching someone how to shop correctly, teaching someone how to carb count. I mean, that's the advantage that we would have."

Theme 5: Expanded access and collaboration

Most participants felt pharmacies can positively address prediabetes. Several participants identified disease prevention as critical for their pharmacies, and some mentioned the value of supporting their communities, helping patients — including at-risk and rural communities — to make more informed choices and expand access to enhanced care services. One independent pharmacy participant said, "Anything we can do to help to bring down the rate of diabetes is a great plus, and personally I'm passionate about diabetes prevention . . . [and] want to see chronic disease come down."

Connection to primary care providers and delivery of team-based care was important, and a few participants mentioned referrals to health departments. One mass merchant participant mentioned a pilot program to conduct diabetes testing for patients and make referrals for enrollment in the National DPP lifestyle-change intervention at local YMCAs. A few participants emphasized the value of team-based care. An independent pharmacy participant said, "The one thing I still hold today is that successful health care for patients doesn't come from one health care professional; it doesn't come from the physician; it doesn't come from the pharmacist; it doesn't come from the nurse. It comes from working as a team." Many participants expressed a strong connection to the communities and people they serve; they had a strong desire to "do the right thing."

Discussion

Key informant interviews with pharmacy executives identified factors that influence whether pharmacies adopt diabetes prevention programs. Our strongest recommendation to increase pharmacy engagement in diabetes prevention programs is to focus on pharmacies most likely to succeed — such as grocery stores with pharmacies in areas with a high prevalence of diabetes. More work is needed to overcome challenges so more pharmacies can alleviate the public health burden of prediabetes. Literature exists that considers potential solutions to overcome these challenges.

Financial feasibility and sustainable reimbursement are critical for adoption of diabetes prevention programs. Although grant funding is helpful initially, long-term sustainability is needed. One national organization has shifted its grant giving to focus on delivery of services that include community pharmacy (8). The importance of grant funding to pharmacy is not specific to diabetes prevention programs but instead to myriad services such as hepatitis C point-of-care testing and prenatal breastfeeding services (9,10). Previous research explored development of business models for care services delivery in pharmacies (11).

A regional division of a national grocery store chain pharmacy attributed its success in offering diabetes prevention programs in its stores to several factors, including experience in processing third-party payments and support from initial grant funding, which allowed for staff training, participant scholarship opportunities, assistance with medical billing, and access to data management programs (12). CDC has funded all state health departments to advance coverage through Medicaid agencies (12). At least 1 national entity has received CDC funds to implement diabetes prevention in pharmacies (12), but the number of similar grants at the state or local level is unknown. Nine states have full or partial coverage of the National DPP lifestyle-change intervention through Medicaid demonstration projects. Managed care organizations participated in projects that focused on implementation and uptake in 2 states (4). Description of these projects did not specify whether pharmacies were involved.

On November 2, 2017, the Centers for Medicare and Medicaid Services issued the 2018 Physician Fee Schedule final rule, which included a policy that introduced a new benefit to cover the National DPP lifestyle-change intervention for eligible Medicare beneficiaries. The final rule was developed on the basis of a YMCA Diabetes Prevention Program, a pilot study supported by the Center for Medicare and Medicaid Innovation that yielded a cost savings of $2,650 per Medicare enrollee (13). Community pharmacies, among others, can apply to become "suppliers," which can yield reimbursement from $195 to $670 per enrolled beneficiary, depending on achievement of performance goal (14). However, Medicare does not cover pharmacist-conducted diabetes testing to determine eligibility for enrollment in the National DPP lifestyle-change intervention, even though half of participants enrolled by 1 supplier are required to obtain a diabetes blood test for enrollment rather than a paper-based assessment. To improve pharmacy participation, Medicare should use their existing authority to allow pharmacies to supply patient care services with reimbursement for diabetes testing, among other care services. Modernization of Medicare regulations to ensure pharmacies and pharmacists are covered to deliver care services is an important policy change consistent with a recent executive order focused on improving Medicare (15).

As of October 2018, CDC showed that fewer than 250,000 people had enrolled in the National DPP lifestyle-change intervention since the program began in 2010. This number represents less than

1% of the nation's population with prediabetes. The problem of scaling diabetes prevention programs to those eligible is a broad public health challenge, not one specific to pharmacy. The National DPP lifestyle-change intervention was piloted at 5 New York City recreation sites that served men from disadvantaged neighborhoods. Extensive recruitment efforts were conducted with the guidance of an advisory panel and incentives for participation, yet recruitment was still challenging (16). One example of successful recruitment took place at an African American church. This church recruited participants by adapting the National DPP lifestyle-change intervention to include faith-based references for those who were eligible to participate (17). In another intervention, health promotion led by barbers in coordination with medication management by pharmacists in barbershops led to reductions in uncontrolled hypertension (18). Pharmacy could use its previous successes in addressing hypertension and other health conditions by offering accessible care services for patients and applying such knowledge to diabetes prevention.

A 2013 study of the YMCA and UnitedHealth Group's National DPP lifestyle-change intervention, in collaboration with CDC, indicated that patient engagement was its greatest challenge (19). The greatest success for enrollment in this study came from community- and employer-based diabetes testing events coupled with onsite counseling and enrollment to leverage "teachable moments" (19). A 2019 review of findings from 6 CDC-funded national organizations demonstrated that encouraging self-referral or word of mouth as a recruitment strategy, providing nonmonetary incentives to participants, and using cultural adaptations to address participants' needs were significantly associated with higher levels of attendance for those participating in the National DPP lifestyle-change intervention (20). Veterans who participated in an intensive, multifaceted online version of the National DPP lifestyle-change intervention were more likely to complete 8 or more sessions than those participating in person (87% online vs 59% in person); however both groups had similar weight loss (21). Among low-income populations, a digital, modified 52-week offering of the National DPP lifestyle-change intervention resulted in weight loss (22). Pharmacies and other health care providers should consider digital delivery of the National DPP lifestyle-change intervention, and payers, including Medicare, should broaden their coverage requirements accordingly.

Operational fit is important for patient care services delivered in pharmacies, not specific to diabetes prevention (23). For instance, vaccination has successfully been integrated into pharmacies, with most pharmacies offering walk-in services, while maximizing staff, physical space, and resources to meet patient needs (24). Researchers attribute the success of pharmacist-delivered vaccination to 5 fundamental factors, including 2 factors that are particularly relevant for this study: a policy/legal platform and a sustainable business model (25). In the United Kingdom, researchers identified barriers similar to those in our study, including the pressure to find time for pharmacy staff to deliver diabetes prevention services, space challenges, and lack of access to medical records (26). An article describing the experience of delivering a diabetes prevention program at a regional division of a national grocery store chain pharmacy highlighted the importance of using the entire pharmacy workforce for program sustainability (12).

The relationship between pharmacists and patients in the loyalty-building path has shown that trust in pharmacists is the most important driver of satisfaction and store loyalty. Experts largely agree that loyalty is made up of both attitudinal (eg, intentional, cognitive) factors and behavioral (eg, purchasing) factors (27).

Regardless of whether customers engage in diabetes prevention, the existence of diabetes prevention programs at pharmacies may increase customer loyalty and appreciation for the pharmacy brand. In a study that defined loyal patients as those who filled all their prescription drugs at a single pharmacy during the first year of diabetes treatment, the loyal patients were more adherent to their medication use regimen than patients who used multiple pharmacies (28). In Canada, participation in pharmacy-based inducement programs (eg, cash, coupons, discounts, gifts, or points as incentives) among new statin users was associated with better medication adherence than among a control group with no inducement programs (29). In a cohort study that used data from a health insurance board in Canada, pharmacy loyalty may have been associated with improved adherence to antipsychotic medication and treatment implementation among people with severe mental illness (30). These studies indicate that not only is the relationship between pharmacists and patients important but also that efforts made by pharmacies to improve customer loyalty can improve health outcomes.

A study describing a diabetes prevention program at a grocery store with a pharmacy credited the success of the program in part to the uniqueness of practice locations, proximity to food, and convenience (12). Furthermore, the study suggested that pharmacists may have greater access to populations that need to increase their awareness of diabetes prevention than other nonpharmacy care providers.

Collaboration among pharmacists and others is critical to improve chronic disease outcomes, and pharmacists should be included in value-driven, collaborative models such as patient-centered medical homes and accountable care organizations. Furthermore, fostering strong relationships between physicians and pharmacists on care teams is well documented as critical to patient care (31). Specific to diabetes prevention, Medicare beneficiary enrollment in a

YMCA National DPP lifestyle-change intervention was improved when a physician made a point-of-care referral rather than retrospective methods (eg, use of electronic medical record systems to identify eligible patients via a registry) (32).

In the United Kingdom study, stakeholders (eg, community pharmacists, general practitioners, and commissioners) viewed pharmacies as a place for prescription services and not necessarily as a place for diabetes management. However, those stakeholders agreed that pharmacies provided patients with increased choices for their primary care services and have potential for greater reach to certain populations given the normalized, nonjudgmental setting of a pharmacy. Additionally, the stakeholders felt that community pharmacies could be locations for individualizing interventions as an alternative to the traditional group in-person format of the National DPP (26). Such findings are consistent with the perception among some people that community pharmacies and retail clinics are more accessible and less stigmatizing than traditional sites for delivery of HIV testing (33).

Our study gave equal weight to the perspectives of adopters, nonadopters, and former adopters, and themes were weighted equally. However, we were unable to identify nonadopters and former adopters among grocery store participants (they were all adopters in our study) and interviewed fewer traditional chain pharmacy and mass merchant participants than participants from other pharmacy types. We attempted to include those who adopted the National DPP lifestyle-change intervention and adopters of other lifestyle change programs, but only 1 adopter in the study delivered a lifestyle-change intervention other than the National DPP, and it was a modified, shortened version based on the National DPP curriculum. The views of the participants may not entirely reflect the views of all decision makers in their company or the final decision makers in their company. However, the included participants represented approximately half of pharmacies in the United States in 2018. Finally, this study did not garner input from patients of the National DPP lifestyle-change intervention, even though a major theme emerged related to patient buy-in. To that end, this study did not closely examine provider referrals or their effect on patient perception of pharmacy services. Further research is warranted in this area.

Addressing the threat of diabetes is a national public health concern. Reducing or eliminating barriers that prevent pharmacies from fully adopting diabetes testing programs and the National DPP lifestyle-change intervention could have a profound effect on patient care. Our study identified factors that influence pharmacy decision-maker adoption of diabetes testing programs and the National DPP lifestyle-change intervention. Pharmacy decision makers have many competing interests in patient care programs. Diabetes testing and the National DPP lifestyle-change intervention are not of interest to all pharmacies; however, our study indicates that several companies are offering such services and want to expand. Pharmacies are a strong asset in public health's efforts to address diabetes prevention nationally; however, given the current legal, regulatory, and financial landscape, some pharmacies may not see the value in participation without removal of these barriers.

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Tables

Table 1. Diabetes Prevention Recognition Program (DPRP) Process, Adapted from Rx for the National Diabetes Prevention Program (DPP) Action Guide for Community Pharmacists[a]

Phase of Process	Steps in Process
Pre-application	• Read and understand the current DPRP standards. • Complete the organizational capacity assessment tool (strongly recommended). • Address any capacity gaps identified by the assessment. • Review other materials about the National DPP and DPRP on the National DPP's website, Implement a Lifestyle Change Program (for Professionals).
Application submitted for recognition	• Complete the online DPRP application form.
Pending recognition	Meet the following requirements: • Submit a completed application. • Use a CDC-approved curriculum. • Offer a 12-month lifestyle-change program that includes a minimum of 16 weekly sessions in months 1 to 6 and 6 monthly sessions in months 7 to 12. Agree to: • Start the first session within 6 months of effective date. • Start at least 1 session every 12 months. • Submit required participant data to DPRP every 6 months.
Preliminary recognition	Meet the following requirements: • Submit required data every 6 months. • Start at least 1 session every 12 months. • Continue to meet the pending recognition requirements. • Submit a full 12 months of data on at least 1 completed group of participants. • Have a minimum of 5 participants who attended at least 3 sessions in months 1 to 6 and whose time from first session to last session was at least 9 months. • Provide evaluated data that show that at least 60% of participants attended at least 9 sessions in months 1 to 6 and at least 60% attended at least 3 sessions in months 7 to 12.
Full recognition	Meet the following requirements: • Submit required data every 6 months. • Start at least 1 session every 12 months. • Continue to meet the requirements for pending and preliminary recognition. • Body weight documentation: Participants must have had their body weight documented during at least 80% of sessions.[b] • Physical activity documentation: Physical activity minutes must have been documented for participants during at least 60% of sessions.[b] • Weight loss at 12 months: Average weight loss across all participants in 1-year–long program must be a minimum of 5% of starting body weight.[b] • Participant eligibility: A minimum of 35% of all participants in 1-year–long program must be eligible on the basis of either a blood glucose test indicating prediabetes or a history of gestational diabetes. The rest must be eligible on the basis of a high score on the CDC Prediabetes Screening Test or the American Diabetes Association Type 2 Diabetes Risk Test.[b,c]

[a] Centers for Disease Control and Prevention (3).
[b] Evaluation for these requirements based on all participants attending at least 3 sessions during months 1 to 6 and whose time from first session to last session is at least 9 months. At least 5 participants per submission who meet this criterion are required for evaluation.
[c] All Medicare Diabetes Prevention Program beneficiaries must have a blood glucose test for eligibility.

Table 2. Payer Coverage of the National Diabetes Prevention Program Lifestyle-Change Program as of 2018[a]

Type of Insurer	Name of Insurer
Commercial insurers	
Many commercial health plans provide some coverage for the National DPP lifestyle change program.	AmeriHealth Anthem Blue Cross Blue Shield Florida Blue Shield California Blue Cross Blue Shield Louisiana Cigna Denver Health Managed Care: Medicaid, Medicare, Public Employees Emblem Health: New York Government Employees Health Association Highmark Humana Kaiser: Colorado Kaiser: Georgia Louisiana Care: Medicaid MVP Health Care Medicare Advantage Priority Health: Michigan United Health Care (national, state, local, private, and public employees)
US government	
The Centers for Medicare and Medicaid Services issued a final rule that allows for coverage of the National DPP lifestyle change program on a pay-for-performance basis.	Medicare (April 2018) Medicaid
State coverage	
The National DPP is a covered benefit for more than 3.4 million public employees/ dependents in 19 states. Demonstration projects ongoing in North Dakota, Pennsylvania, and Utah.	California Colorado Connecticut (Department of Transportation) Delaware Georgia (Kaiser Permanente) Indiana Kentucky Louisiana Maine Maryland (partial payment) Minnesota New Hampshire New York Oregon (educators) Rhode Island Tennessee Texas Vermont Washington

[a] From Albright (4).

Table 3. Major Themes and Findings on Community Pharmacy Engagement in Diabetes Prevention From Key Informant Interviews With Pharmacy Executives, 2018

Theme	Explanation of Theme	Finding	Representative Quote
Financial feasibility	Initiation of services is more likely if initial financial support is received and likely to result in a sustainable business model.	Financial feasibility and sustainable reimbursement models are critical for adoption of diabetes prevention programs, with grant funding a catalyst most commonly used by independent pharmacies and grocery stores with pharmacies.	An independent pharmacy participant said, "[W]e obviously are testing the waters and figuring things out in this beta version. And hopefully we'll have all the kinks ironed out for our second go, which would be when we are Medicare-payment eligible."
Consumer participation	Consumer buy-in and demand for services, actual or perceived; initiation and retention in diabetes prevention services is paramount.	Inadequate consumer participation in diabetes prevention programs is problematic, but pharmacies are committed to solving this issue.	An independent pharmacy participant said, "A lot of people don't want to participate, they don't want to take the time."
Operational fit	Diabetes prevention services fit within the existing operational structure of a pharmacy and allow the pharmacy to maximize its personnel and resources.	Operational fit is important, and appropriate use of nonpharmacists is essential to adoption and success of diabetes prevention programs.	A traditional chain pharmacy participant explained this decision process as follows: "Our workflow is designed to really generate large volumes of scripts [prescriptions] in a very standard and high-quality, safe way. And so, we do offer pharmacy interventions, and we take our pharmacist out of workflow to have conversations with patients, but . . . we're really strategic . . . because there's only so much time that the pharmacist has to have these conversations and conduct these interventions."
Customer loyalty	A clearly articulated advantage against competition, and alignment of values, is key to a pharmacy's adoption of diabetes prevention services.	Customer loyalty is a top advantage gained by pharmacy adopters of diabetes prevention programs, but specific characteristics of grocery stores that made delivery of those programs easier was an advantage not seen in other settings.	An independent pharmacy participant said patients feel valued and, "they can leave having learned about diabetes, and physically how to prevent it. And that, ultimately, promotes customer loyalty, which would then promote pharmacy shopping. It's a domino effect."
Expanded access and collaboration	Demonstrates and affirms expanded role and value of pharmacies to serve communities. Reaching those without health care access also drives initiation of services.	Pharmacies are focused on expanding health care access to at-risk populations and collaborating with health care teams.	One mass merchant participant said, "I think it's a great public service, so raising awareness and helping to serve the patient has been really beneficial. I think it helps to engage our pharmacists in a way that they haven't been engaged previously, and so that professional satisfaction to really have a meaningful clinical conversation with someone who's unaware that they may be prediabetic."

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ORIGINAL RESEARCH

The Mississippi Delta Health Collaborative Medication Therapy Management Model: Public Health and Pharmacy Working Together to Improve Population Health in the Mississippi Delta

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PEER REVIEWED

Summary

What is known on this topic?

The Mississippi Delta has high rates of chronic disease and is known for its poor health outcomes and health disparities. Medication therapy management (MTM) improves the safe and effective use of medications, and ensuring appropriate medication use can improve clinical outcomes related to cardiovascular disease (CVD).

What does this research add to the literature?

Pharmacists met face-to-face in federally qualified health centers with patients who had a diagnosis of diabetes, hypertension, and/or dyslipidemia to provide MTM. Patients experienced mean reductions in systolic and diastolic blood pressure, low-density lipoprotein cholesterol, triglycerides, total cholesterol, and hemoglobin A_{1c}.

What are the implications for public health practice?

MTM is an effective way to improve CVD outcomes in residents of regions like the Mississippi Delta that have high rates of poverty, health disparities, and poor health outcomes.

Abstract

Introduction

The Mississippi Delta has high rates of chronic disease and is known for its poor health outcomes and health disparities. The University of Mississippi School of Pharmacy (UMSOP) and the Mississippi State Department of Health partnered in 2009 through the Mississippi Delta Health Collaborative to reduce health disparities and improve clinical outcomes by expanding the UMSOP's evidence-based medication therapy management (MTM) initiative, focused in Mississippi's 18-county Delta region, to federally qualified health centers (FQHCs) in 4 of those counties.

Methods

Between January 2009 and August 2018, the MTM initiative targeted FQHC patients aged 18 years or older with a diagnosis of diabetes, hypertension, and/or dyslipidemia. Pharmacists initially met face-to-face with patients to review all medications, provide education about chronic diseases, identify and resolve drug therapy problems, and take appropriate actions to help improve the effectiveness of medication therapies. Clinical parameters evaluated were systolic blood pressure (SBP), diastolic blood pressure (DBP), total cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides, and hemoglobin A_{1c} (HbA_{1c}).

Results

The analysis included 335 patients with hypertension (n = 287), dyslipidemia (n = 131), and/or diabetes (n = 331). Significant mean reductions occurred in the following metrics: SBP (7.1 mm

Hg), DBP (6.3 mm Hg), LDL cholesterol (24.9 mg/dL), triglycerides (45.5 mg/dL), total cholesterol (37.7 mg/dL), and HbA_{1c} (1.6% [baseline ≥6%] and 1.9% [baseline ≥9%]).

Conclusion

Despite the cultural and environmental disadvantages present in the Mississippi Delta, the integrated MTM treatment program demonstrated significant health improvements across 3 chronic diseases: hypertension, dyslipidemia, and diabetes. This model demonstrates that a partnership between public health and pharmacy is a successful and innovative approach to care.

Introduction

The 18 counties of the Mississippi Delta are characterized by high levels of poverty, high prevalence of chronic disease, and mortality rates that significantly exceed the national average (1,2). Moreover, regional mortality rates have increased during the past 4 decades, even as national rates have decreased (2). As of 2017, the cardiovascular disease (CVD)-attributed mortality rate was the highest in the nation, and rates have continued to increase (3,4). The difficulties experienced in the Mississippi Delta are further exacerbated by disparities related to sex and race/ethnicity (5).

Medications are an important aspect of the treatment of chronic disease; 5.8 billion prescriptions were filled in the United States in 2018 (6). Medication therapy management (MTM) improves the safe and effective use of medications, including resolving drug therapy problems, promoting adherence, and increasing continuity of care, as well as improving measures of patient and provider satisfaction (7–13). Ensuring appropriate medication use can improve CVD clinical outcomes, reduce mortality rates, and decrease health care costs (14).

To address the detrimental effect of CVD in this region, the University of Mississippi School of Pharmacy (UMSOP) started a community-based research program in 2008 that implemented pharmacist-delivered MTM services. That same year, the Mississippi State Department of Health, with funding from the Centers for Disease Control and Prevention, created the Mississippi Delta Health Collaborative (MDHC) to implement evidence-based strategies in the Mississippi Delta for CVD prevention and management. With this shared goal of improving cardiovascular outcomes for patients in this region, the UMSOP and the Mississippi State Department of Health partnered in 2009 to expand the MTM initiative from community pharmacies into federally qualified health centers (FQHCs) in 4 Mississippi Delta counties where CVD and health disparities were prevalent and MTM services were not readily available.

Methods

The UMSOP implemented a program to integrate pharmacists as members of health care teams at FQHCs and provide MTM services focused on CVD risk reduction in underserved patients in rural Mississippi. MTM services were provided and evaluated in 4 FQHCs in the Mississippi Delta: Aaron E. Henry Community Health Services Center in Batesville (Panola County) and Clarksdale (Coahoma County), G.A. Carmichael Family Health Center in Yazoo City (Yazoo County), and Vicksburg-Warren Family Health Care Clinic (Warren County). Between January 2009 and August 2018, the MTM initiative enrolled FQHC patients aged 18 years or older with a diagnosis of diabetes, hypertension, and/or dyslipidemia. Patients were included in the outcomes analysis if they had at least 1 follow-up visit within 12 months after enrollment. This project was approved by the University of Mississippi institutional review board.

For the clinical outcomes analysis portion of this partnership evaluation, we focused on the most recent 12-month period funding cycle. This period was chosen because it was most representative of the culmination of our partnership efforts and clinical practice guidelines.

Intervention. Participating patients were current FQHC patients referred to the program by practitioners of participating clinics in an attempt to improve outcomes of existing chronic diseases they were being treated for, patients newly diagnosed with 1 of the identified chronic diseases, or patients at risk for CVD. Services provided were developed based on the MTM Core Elements Service Model, which includes medication therapy review, personal medication record, medication-related action plan, intervention or referral, and documentation and follow-up (15). Upon consent and enrollment, clinical pharmacists set appointments to see patients for an initial encounter. Before the face-to-face encounter, the pharmacists reviewed patients' records to determine what measures were needed to help patients achieve their desired health goals.

Initial pharmacist MTM visit. During the 60-minute initial visit, the pharmacist performed any number of the following activities depending on the patient's needs, including but not limited to the following:

- Conducting a comprehensive medication review and a medication reconciliation
- Identifying and resolving potential and actual drug therapy problems
- Assessing clinical parameters, including systolic blood pressure (SBP), diastolic blood pressure (DBP), total cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides, and hemoglobin A_{1c} (HbA_{1c}) to determine needed

changes in therapy or other intervention

- Taking any appropriate actions to help improve the effectiveness of medication therapies, including initiating or modifying medication therapy via collaborative practice agreement or through recommendations to the primary provider
- Developing a medication action plan, which may include changes to medication therapy
- Delivering health education on chronic disease state and self-management practices
- Providing patient with medication adherence tools
- Initiating laboratory monitoring (including noninvasive monitoring, such as self-monitoring blood pressure or blood glucose)
- Communicating medication therapy changes and recommendations with primary provider via electronic health record or other mechanism
- Facilitating any additional referrals (eg, primary care provider, specialist providers, community health worker, social work, podiatry, optometry)

Follow-up pharmacist MTM visit. At the conclusion of the initial visit, the pharmacist scheduled a follow-up visit to help the patient monitor health conditions, review medication therapies, provide any additional education or counseling needed, and take appropriate actions to more effectively manage health conditions. Pertinent activities from the initial visit may occur on the follow-up visit for the pharmacist assessment, intervention, and plan. Following each visit, the pharmacist documented the encounter details in the patient's electronic health record to share and communicate MTM recommendations with members of the clinical team and update patient action plans and medication profiles.

Medically relevant tests. Blood pressure was measured and evaluated at each visit with the pharmacist. If a diagnosis of diabetes was present, HbA_{1c} levels were checked at the initial visit and then every 3 months or as deemed appropriate. A lipid panel was obtained at the initial visit and then every 3 months or as deemed appropriate.

Clinical data were collected throughout MTM implementation. Clinical parameters evaluated were SBP, DBP, LDL cholesterol, triglycerides, total cholesterol, and HbA_{1c}. Clinical data were dependent on clinical diagnoses, specifically hypertension, dyslipidemia, diabetes, or any combination of the 3. Accordingly, HbA_{1c} percentage was collected for patients with a diagnosis of diabetes. LDL cholesterol, triglycerides, and total cholesterol were collected for patients with dyslipidemia. SBP and DBP were collected for all patients; however, only those presenting with elevated levels were included in analyses. Furthermore, there was considerable overlap or comorbidity in patient diagnoses; therefore, totals for the reported number of participants were not mutually exclusive from those of other chronic disease conditions. Because there was no expectation of improvement for patients with clinical measures that were normal at baseline, these patients' data for those variables were not included in the analysis.

For comparative purposes, patient data were analyzed by duration of participation in the MTM initiative. Time zero (T1), the pre-MTM intervention measure, was compared with the post-MTM intervention measure (T2). Hypertensive patients' T2 measures were collected 6 to 12 months into participation in the MTM initiative, and T2 measures for patients with other chronic disease diagnoses were collected 9 to 12 months into program participation. Because hypertensive patients typically experienced rapid improvement after beginning the MTM intervention and had shorter participation duration, we extended their time frame for analysis. Participation duration–based analysis was needed to aggregate participants across the many years of the initiative and to facilitate the rolling admissions process, allowing a pre–post within-factor design. We used *t* tests to assess significance of clinical change. Accordingly, any patients with fewer than 2 clinical assessments at least 6 months apart were excluded from the study. Patients who presented with elevated clinical numbers and were enrolled in the MTM program but who had their blood pressure at goal were also excluded from hypertension analyses. For patients with multiple clinical measures in the T2 point, we used a mean of those measures.

Finally, hypertension was further analyzed by stage, broken into 4 groups according to severity of elevated blood pressures, using the higher stage of SBP or DBP at the time measurement. The Figure displays the cut-off scores used to determine normal versus elevated levels for each clinical measure, as well as a breakdown of hypertension stages used in this analysis.

Clinical Measure	Classification				
			Severely Elevated		
	Normal	Elevated	Stage I	Stage II	Stage III & IV
Systolic blood pressure, mm Hg	≤120	121–139	140–159	160–179	≥180
Diastolic blood pressure, mm Hg	≤80	81–89	90–99	100–109	≥110
	Normal	Elevated	Severely Elevated		
Hemoglobin A_{1c}, %	4–6.9	7–9.9	≥10		
	Normal	Above Normal	Borderline	High	Very high
Low-density lipoprotein, mg/dL	<100	100–129	130–159	160–189	≥190
	Normal	Borderline	High	Very High	
Triglyceride, mg/dL	<150	150–199	200–499	≥500	
Total cholesterol, mg/dL	<200	200–239	≥240	—	

Figure. Classification of disease states, by severity, Mississippi Delta Health Collaborative Medication Therapy Management Model, 2009–2018. Hypertension staging was based on clinical guidelines from the 8th Joint National Committee for the Management of Hypertension in Adults (31). Abbreviation: —, not applicable.

Results

A total of 335 patients met the inclusion criteria for analysis. This represented a 71.3% retention rate (ie, 335 of 470 patients returned for a follow-up visit within 1 year after enrollment and were included in the comparative analysis). This population averaged 2.4 total visits per year. Grouped by diagnosis, 287 patients with hypertension, 131 patients with dyslipidemia, and 331 patients with diabetes were included in the analyses. Patients were 61.2% female and had a mean age of 60 years. The population studied was 95.0% Black, 4.5% White, and 0.5% other race.

MTM participant outcome data (Table 1) include mean baseline or pre-MTM intervention mean scores (T1) and mean post-MTM intervention scores (T2), as well as actual and relative change in each clinical measure. All clinically relevant metrics demonstrated significant improvement ($P < .01$; range, –4.2% for SBP to –18.2% for triglycerides).

Blood pressure outcomes varied considerably across disease severity or hypertension stage (Table 2). Patients with Stage III and IV hypertension (blood pressure at or above 180 systolic and/or 110 diastolic) experienced the greatest level of improvement (16.8% and 12.5%, $P = .002$ and $P = .01$, respectively). Significant results were also experienced by Stage II ($P < .001$) and Stage I participants ($P = .003$).

Discussion

The results of the MDHC MTM efforts strongly support the use of pharmacist-delivered MTM as a part of integrated care in rural Mississippi. MTM care delivery models have a considerable literature base to support its usefulness, although little research has targeted rural, Black populations in the Deep South (9,16–20). This program targeted a largely Black population in one of the most medically underserved areas in the United States. Despite the cultural and environmental disadvantages present in this area, the integrated MTM treatment program demonstrated significant health improvements across chronic diseases, including hypertension, dyslipidemia, and diabetes. The level of impact on clinical metrics in our study is similar to other published findings.

Pharmacists have been involved in the provision of services to ensure optimal medication use for many years. This provision has evolved from Pharmaceutical Care Services or Disease Management Services terminology in the 1990s to the consensus definition of MTM adopted by the pharmacy profession in 2004, and more recently Comprehensive Medication Management (CMM), which emphasizes the team-based approach to care. Because different terms have been used historically and the components and delivery of MTM may vary, such as with Medicare Part D MTM programs, it is important to have an understanding of the robustness of this intervention. The MDHC MTM service model incorporates the MTM core elements and aligns with the Pharmacist Patient Care Process (PPCP) (15,21). In the PPCP, the pharmacist uses a patient-centered approach in collaboration with other providers on the health care team to optimize patient health and medication outcomes. This approach is accomplished by collecting the necessary information, assessing the information collected, and analyzing the clinical effects of the patient's therapy in the context of the patient's overall health goals to identify and prioritize problems. The pharmacist then develops and implements an individualized, evidence-based, patient-centered care plan with other providers via collaborative practice agreement or recommendations.

This initiative used several aspects of MTM that were expected to be a good match for the needs of the Mississippi Delta, including a close working relationship between pharmacists and other care provider team members at participating clinics, following the principles of interprofessional collaborative practice, and incorporating the core elements of MTM into a robust intervention. The benefits of enhancing the team-based approach have been well docu-

mented as the quadruple aim of Interprofessional Collaborative Practice, supporting the value of close collaboration and heightened interprofessional communication on reducing the cost of care while promoting provider wellbeing and improving patient outcomes (14–18,22–26). This MTM model supports the integration of pharmacists in collaborative, team-based care models in clinic settings such as this to achieve this goal.

In our study, significant reductions were demonstrated for lipemic parameters. Serum concentrations of total cholesterol, LDL cholesterol, and triglycerides improved significantly compared with baseline. Eighty-four percent of patients with dyslipidemia also had concomitant diabetes, which is a noteworthy finding because dyslipidemia is a major risk factor for CVD in patients with diabetes (27). For patients with diabetes, significant reductions in HbA_{1c} were demonstrated. Patients with the highest risk for diabetes complications (baseline HbA_{1c} >9%) experienced a 1.9% reduction in HbA_{1c} (for a 17.1% relative reduction). Similarly, SBP and DBP (analyzed separately) were significantly lower after receiving MTM services. The relative reductions observed are clinically meaningful given the various stages of hypertension at baseline. These levels of effect on clinical parameters are consistent with other published figures regarding pharmacist-delivered MTM (9,16,28–30). Improvements such as these, combined with pharmacist coaching and counseling, will likely contribute to a reduction in risk of CVD in this population.

In addition to improved patient outcomes, the design of this program provided for continuity of care with the pharmacist during primary care provider transition periods, which occurred several times in the clinic sites. The pharmacist was consistent and present to address concerns and facilitate the delivery of historical context during these transitional periods. The face-to-face encounters were helpful in patient assessment and in ensuring that patients had a good understanding of the plan. Many of these patients had complex disease states and comorbidities and this team-based approach provided efficiency for patients, while ensuring delivery of comprehensive patient care.

Limitations

This practice-based implementation initiative did not allow for a control group but was structured to evaluate patient outcomes in an actual care model. In this region with this disadvantaged population, challenges are often encountered in providing health care. Patients may be unable to attend clinic visits because of lack of transportation, primary provider transitions, and other financial barriers. Although pharmacists worked with patients to identify issues hindering care and attempted to incorporate social work and other resources, patients were not always successful in overcoming these challenges and continuing care. Pharmacists communicated effectively with collaborating providers through the FQHC electronic health record; however, their systems were not structured to capture the data necessary for the evaluation of services, requiring additional electronic documentation by the pharmacists. Through this grant-supported project, the pharmacist services provided were not billed or compensated. These identified challenges set the stage for future research to explore more options for pharmacist MTM delivery, such as through telehealth, and to explore additional payment options for team-based care.

In addition to the lack of a control group, small sample size was a limitation because it precluded the ability to conduct complex analyses to account for potential confounding factors. The intent was to describe a real-world care model and experience with a focus on the benefits of partnering with a state health department, and as such, the study was not designed as a large, randomized controlled trial. The small sample size also limited interpretation and extrapolation of our findings. Although the outcome variables improved significantly compared with baseline, a causal inference cannot be established, nor can it discount the fact that the results seen might have otherwise occurred naturally over time without the intervention. Despite this model being effective in this particular setting and population, it is uncertain whether the benefits would be seen in other disease states or in a more diverse population.

We were unable to account for the potential variability among the clinics included in the analysis. All clinics were FQHCs in the Mississippi Delta region that serviced a medically underserved sociodemographic. Inherent differences or variabilities were not captured or adjusted for in clinic characteristics during the study period. The intended study population was patients at high risk for cardiovascular complications from diabetes, hypertension, and dyslipidemia, which is typical of pharmacist-provided MTM and CMM services described in the literature and from our previous experiences. Unfortunately, this introduces the possibility of our results being biased toward positive findings, as patients with normal or well-controlled metrics were not included in the design or analyses. Regression toward the mean is expected in this scenario. The main reason for only including high-risk patients was that limited resources necessitated prioritizing patients with high disease burden, and subsequently, high risk for complications.

Another potential limitation was the variability in follow-up visits. Patient acuity and medical necessity largely determined individual follow-up scheduling. A large number of no-shows and reschedulings caused further variability among subjects regarding the number of encounters with MTM pharmacists. The analysis did not account for these varying levels of exposure to the intervention. Key differences may exist in the characteristics and disease severity between patients who had multiple versus few visits with the phar-

macists. Furthermore, relative reductions of measured parameters were used to compare variables. Arguably, quantifying the percentage of patients achieving therapeutic goals or targets would be insightful. However, given our previous experience, relative reductions seemed more meaningful in this medically underserved population.

Lastly, the analysis did not adjust for comorbidities. Although this lack of adjustment may have made the results inherently more conservative, it does not take into account the potential impact of comorbidities across the spectrum of the findings and outcomes. Future studies focusing more on clinical outcomes and implementation science, rather than real-world partnerships, should attempt to incorporate a propensity score analysis for comorbidities or use of a tool such as the Charlson comorbidity index.

Conclusion

Pharmacists are well equipped and positioned as medication experts to contribute in a meaningful way to team-based, collaborative care. The partnership between the UMSOP and the Mississippi State Department of Health provided an opportunity to test and demonstrate the positive impact of this intervention on markers that influence CVD, in one of the most underserved and medically challenged regions of our country. This partnership demonstrates how public health and pharmacy can align to achieve the shared goals of preventing chronic disease and improving population health through implementation of innovative strategies such as the MDHC MTM model.

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Tables

Table 1. Overall MTM Clinical Laboratory Outcomes Within the First Year of Enrollment, Mississippi Delta Health Collaborative, 2009–2018[a]

Clinical Measure	No.	Baseline Mean	Post-MTM Mean	Change	*P* Value[b]	Relative % Change
Systolic blood pressure, mm Hg	287	142.7	135.6	−7.1	<.001	−4.2
Diastolic blood pressure, mm Hg	191	89.9	83.6	−6.3	<.001	−7.0
LDL cholesterol, mg/dL	112	140.9	116.0	−24.9	<.001	−17.6
Triglycerides, mg/dL	70	249.9	204.4	−45.5	.001	−18.2
Total cholesterol, mg/dL	82	245.3	207.6	−37.7	<.001	−15.3
Hemoglobin A_{1c}, % (Baseline ≥6)	331	10.7	9.1	−1.6	<.001	−14.8
Hemoglobin A_{1c}, % (Baseline ≥9)	275	11.2	9.3	−1.9	<.001	−17.1

Abbreviation: LDL, low-density lipoprotein; MTM, medication therapy management.
[a] For all patients. Normal values at baseline were excluded.
[b] *P* values determined by using paired *t* test.

Table 2. Blood Pressure Change Among MTM Patients (N = 298), by Hypertension Stage, Mississippi Delta Health Collaborative, 2009–2018[a]

Baseline	No. of Patients Showing Decrease in BP, No. (%)[b]	Change in BP Between Baseline and Follow-Up					
		BP type	Baseline Mean, mm Hg	Post-MTM Mean, mm Hg	Change, mm Hg	*P* Value[c]	Relative % Reduction
At Risk (n = 137)	93 (68)	Systolic	128.9	129.0	0.1	.92	—
		Diastolic	79.3	77.5	−1.8	.03	2.3
Stage I (n = 100)	77 (77)	Systolic	145.1	139.3	−5.7	.003	3.9
		Diastolic	84.9	80.9	−4.0	<.001	4.7
Stage II (n = 46)	41 (89)	Systolic	160.9	147.5	−13.4	<.001	8.3
		Diastolic	92.2	85.1	−7.1	<.001	7.7
Stage III and IV (n = 14)	14 (100)	Systolic	177.5	147.6	−29.8	.002	16.8
		Diastolic	104.4	91.3	−13.1	.01	12.5

Abbreviations: —, not applicable; BP, blood pressure; MTM, medication therapy management.
[a] Normal values at baseline were excluded. Second laboratory result was 6 to 9 months after first visit.
[b] Decrease in either systolic or diastolic blood pressure.
[c] *P* values determined by using paired *t* test.

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RESEARCH BRIEF

Using an Advanced Practice Pharmacist in a Team-Based Care Model to Decrease Time to Hemoglobin A_{1c} Goal Among Patients With Type 2 Diabetes, Florida, 2017–2019

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PEER REVIEWED

Summary

What is already known on this topic?

Few studies have evaluated the influence of team-based practice models involving an advanced practice pharmacist (APP) on the time needed to reach a hemoglobin A_{1c} goal. APPs function in a way similar to a mid-level provider, adjusting antidiabetic medications and providing diabetes self-management education under a defined scope of practice.

What is added by this report?

As compared with usual medical care, a team-based practice model using an APP led to a shorter median time to reach a hemoglobin A_{1c} goal of less than 7% in patients with type 2 diabetes mellitus.

What are the implications for public health practice?

Team-based care involving an APP might lead to improvements in glycemic control, which have the potential to decrease the burden of diabetes as a chronic disease.

Abstract

Collaborative practice models that use an advanced practice pharmacist (APP) have been shown to improve outcomes for patients with chronic diseases. Few studies have evaluated the effects of team-based practice models involving an APP for time needed to attain glycated hemoglobin A_{1c} (HbA_{1c}) goals in patients with diabetes mellitus (type 2 diabetes). Ours is a retrospective cohort study, involving patients with type 2 diabetes who worked with a pharmacist in an academic family medicine clinic. These patients experienced a shorter time to achieve an HbA_{1c} of less than 7%, as compared with patients who did not work with a pharmacist. Future studies should evaluate the length of time patients can sustain an HbA_{1c} of less than 7% with team-based care involving an APP and the influence of such care on diabetes-related complications.

Objective

Achievement of treatment goals for patients with type 2 diabetes is suboptimal. Only half of the patients with diabetes achieve a glycated hemoglobin A_{1c} (HbA_{1c}) of less than 7% (1), despite the availability of effective antidiabetic therapy and clinical practice guidelines that are updated annually (2). Timely achievement of an HbA_{1c} goal might have a beneficial effect on clinical outcomes, such as development of macrovascular and microvascular complications of type 2 diabetes (3). The aim of our study was to analyze the time to achieve an HbA_{1c} of less than 7% for a pharmacist–physician managed (PPM) cohort, as compared with a usual medical care (UMC) cohort of patients with type 2 diabetes.

Methods

Our retrospective cohort study was conducted between January 2017 and July 2019, at the University of South Florida (USF) Health Morsani Center, Department of Family Medicine. Inclusion criteria were adults, aged 18 to 80 years, having type 2 diabetes for least 12 months, and an HbA_{1c} at 7% or higher at the index visit (the first visit during the study). Inclusion criteria were confirmed by chart review. Demographic and clinical data were collected from existing medical records. Exclusion criteria were confirmed pregnancy (because gestational diabetes typically involves more stringent glucose control) or a documented endocrinology visit during the study (to evaluate influence of the non-

biased, team-based practice model). Our study was certified exempt by the USF Institutional Review Board.

We assigned patients to the PPM cohort if they had at least 1 visit with their primary care physician (PCP) in the past 3 years and at least 1 visit with an advanced practice pharmacist (APP) in the USF Health Department of Family Medicine. Patients were assigned to the UMC cohort if they were managed solely by their PCPs and did not have a clinic visit with an APP during the study. A collaborative drug therapy management agreement gave APPs the authority to initiate, titrate, or discontinue antidiabetic medications; order drug therapy–related laboratory tests; and provide diabetes self-management education. APPs practiced in the same clinic as the PCP and independently saw patients face-to-face following referrals from the PCP. Visits with the APP were scheduled for 30 to 60 minutes, whereas visits with patients in the UMC cohort were 20 to 40 minutes. Visits in the UMC cohort were either routine follow-up visits or sick visits.

Median time (in days) to an HbA_{1c} less than 7% was calculated by using the Kaplan-Meier estimate among each cohort and compared by using a log rank test. To account for the PPM cohort having increased interactions with patients, each cohort was categorized into 3 groups, based on adherence to their visit schedules. Adherence to visit schedules was calculated as a proportion by dividing the total number of actual interactions with a PCP, an APP, or both by the total number of expected interactions for each patient (sum of actual, no-show, and canceled visits). Therefore, if a participant in the PPM cohort had 12 PCP and 8 APP visits during the study without any missed visits, then the patient would have an adherence value of 1 (20 visits / 20 expected interactions = 1). Similarly, if a patient in the UMC cohort had 12 visits with the PCP without any missed visits, then the patient was assigned an adherence value of 1. This approach, rather than the actual number of interactions, accounts for the disparate number of expected interactions inherent with the PPM cohort relative to the UMC cohort. Patients were subsequently categorized as having low, moderate, and high visit adherence according to the distribution of the adherence scores. The entire patient population was stratified by adherence and the study groups (PPM vs UMC) were compared within each stratum. The analysis was also stratified by the median HbA_{1c} value.

Chi-square tests and 2 independent sample *t* tests were used to determine whether a statistically significant difference existed between groups for categorical and continuous variables, respectively, at baseline. Follow-up time was calculated as time in days from first visit to achieving the HbA_{1c} goal or last clinic visit. Statistical significance was defined as $P < .05$. The analysis was conducted using SAS version 9.4 (SAS Institute, Inc).

Results

A total of 257 patients were included (n = 76 in the PPM cohort and n = 181 in the UMC cohort) with a median follow-up time of 357 days (interquartile range, 199–538 days). Groups did not differ substantially at baseline, except for HbA_{1c}, which was significantly higher in the PPM cohort as compared with the UMC cohort ($P < .001$). For characteristics of the study population, mean age was 59.4 (SD = 11.8) years, 63.2% were white, and mean duration of type 2 diabetes was 3.2 (SD = 1.2) years. Mean body mass index was 34.2 kg/m^2 (SD = 7.7). More than half (56.7%) of patients were commercially insured and 41.6% of patients were former or current tobacco smokers (Table 1).

Median time to achieve an HbA_{1c} of less than 7% in the PPM cohort was 470 days, as compared with 569 days in the UMC cohort (median difference of 99 days, $P = .60$) (Table 2). However, when results were stratified by baseline HbA_{1c}, the median time to achieve an HbA_{1c} of less than 7% was 512 and 668 days for the PPM and UMC cohorts, respectively ($P = .11$). Similarly, when results were stratified by adherence to clinic visits, the median time to achieve an HbA_{1c} of less than 7% in the PPM cohort was 441 days based on moderate adherence to clinic visits, and 381 days based on high adherence to clinic visits (Table 2). Among those included in the PPM cohort with low adherence to clinic visits, time to achieve an HbA_{1c} less than 7% was not estimable. That is, 50% of patients in the PPM cohort with low adherence to clinic visits did not achieve an HbA_{1c} less than 7%, based on the time specified in this analysis. Among patients in the UMC cohort, time to achieve an HbA_{1c} less than 7% was 612 days for those with low adherence, 457 days for moderate adherence, and 569 days for high adherence. However, these differences were not statistically significant ($P = .80$).

In the PPM cohort, 50% of patients met an HbA_{1c} goal of less than 7%, as compared with 43.1% in the UMC cohort ($P = .31$). When stratified by adherence to clinic visits, 33.3% of patients in the PPM cohort with low adherence to clinic visits met an HbA_{1c} goal of less than 7%, as compared with 38.7% of patients with low adherence to clinic visits in the UMC cohort. A higher percentage of patients in the PPM cohort with moderate adherence (63.3%) and high adherence (50.0%) to clinic visits met an HbA_{1c} goal of less than 7% compared with patients in the UMC cohort with moderate and high adherence to clinic visits (46.6% and 44.6%, respectively).

Discussion

Patients exposed to an APP in our study (PPM) experienced a shorter median time to achieve an HbA_{1c} of less than 7% than did

those receiving usual care (UMC), although results were not statistically significant. To account for an expected greater number of clinic visits in a team-based care practice model using an APP, results were stratified by adherence to clinic visits. The stratified analysis demonstrated that patients in the PPM cohort with moderate and high adherence to clinic visits had a shorter median time to reach an HbA_{1c} of less than 7% compared with the UMC cohort with the same level of clinic visit adherence. Among patients who had a high level of adherence to clinic visits, the mean and median time to an HbA_{1c} of less than 7% was shorter in the PPM cohort than in the UMC cohort. These results are not surprising, especially in light of additional time spent with the APP for diabetes self-management education. Our findings also highlight the need for new methods to improve adherence and outreach, especially among patients with low to moderate adherence to clinic visits.

Our findings confirm the results in 2 similarly designed studies (4,5). In the first, time to HbA_{1c} goal was 23 days shorter among patients exposed to a collaborative practice model involving an APP, as compared with usual care (4). Among those with a baseline HbA_{1c} more than 8% and exposed to an APP, the time to HbA_{1c} goal was 144 days shorter ($P < .05$), as compared with usual medical care (4). In a second study, time to HbA_{1c} goal was 125 days shorter in patients exposed to an APP, as compared with usual care, although results were not statistically significant (5). However, the clinical significance of these findings is meaningful because a shorter duration of uncontrolled diabetes might decrease the risk of developing microvascular and macrovascular complications (6).

Our study has limitations. First, because the study design is retrospective, information obtained is dependent on existing documentation in the medical record. Second, because patients in the PPM model were also managed by their PCP, attributing positive outcomes to the PPM intervention alone is a challenge. The same limitation might apply to the UMC cohort, as PCPs might often consult with the APP informally for drug selection recommendations for patients who might not have been included in the PPM cohort.

Third, information about use of antidiabetic medication during the study, which might influence HbA_{1c}, was not collected. Finally, patients may have been referred to the APP for poorly controlled diabetes (as indicated by higher baseline HbA_{1c} in the PPM cohort), creating the potential for bias from inclusion in the PPM cohort. Findings indicate that implementation of a team-based practice model involving a pharmacist in an academic family medicine setting might shorten time to achieve the HbA_{1c} goal, although cautious interpretation with respect to level of adherence to clinic visits is needed. Additional research needs to include confirmation of our findings in a larger sample size, evaluation of medication-related treatment intensification, and qualitative barriers to treatment intensification.

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Tables

Table 1. Participants with Type 2 Diabetes by Adherence Group[a], Florida, 2017–2019

Characteristic	All Participants (N = 257)	Adherence in PPM Cohort			Adherence in UMC Cohort			*P* Value
		Low (n = 24)	Moderate (n = 30)	High (n = 22)	Low (n = 62)	Moderate (n = 54)	High (n = 5)	
Age, mean (SD), y	59.4 (11.8)	56.4 (12.0)	62.1 (9.9)	60.2 (12.3)	57.7 (12.9)	57.7 (12.3)	61.9 (10.5)	.13
Race, n (%)[b]								
Non-Hispanic black	69 (27.6)	11 (45.8)	7 (23.3)	9 (40.9)	19 (32.2)	15 (28.8)	8 (12.7)	<.001
Non-Hispanic white	158 (63.2)	13 (54.2)	21 (70.0)	11 (50.0)	34 (57.6)	27 (51.9)	52 (82.5)	
Other	23 (9.2)	0	2 (6.7)	2 (9.1)	6 (10.2)	10 (19.2)	3 (4.8)	
Insurance, n (%)[b]								
Commercial	139 (56.7)	12 (54.5)	12 (42.9)	12 (57.1)	33 (55.0)	34 (65.4)	36 (58.1)	.74
Government[c]	104 (42.4)	10 (45.5)	16 (57.1)	9 (42.9)	27 (45.0)	17 (32.7)	25 (40.3)	
Medicaid	2 (0.8)	0	0	0	0	1 (1.9)	1 (1.6)	
Smoking status, n (%)								
Never smoked	150 (58.4)	13 (54.2)	17 (56.7)	15 (68.2)	34 (54.8)	32 (59.3)	39 (60.0)	.71
Quit smoking	81 (31.5)	6 (25.0)	11 (36.7)	6 (27.3)	19 (30.6)	18 (33.3)	21 (32.3)	
Currently smoke	26 (10.1)	5 (20.8)	2 (6.7)	1 (4.5)	9 (14.5)	4 (7.4)	5 (7.7)	
BMI, mean (SD)	34.2 (7.7)	34.7 (8.1)	36.1 (9.5)	35.9 (8.9)	34.0 (6.3)	34.2 (8.0)	32.9 (7.1)	.49
Duration of diabetes, mean (SD), y[d]	3.2 (1.2)	3.2 (1.4)	3.4 (1.5)	3.1 (1.1)	3.1 (1.2)	3.0 (1.1)	3.2 (1.1)	.76
Baseline HbA_{1c}, mean (SD), %	8.5 (1.6)	9.4 (1.9)	9.2 (1.7)	9.0 (1.8)	8.4 (1.4)	8.1 (1.4)	8.2 (1.4)	<.001
Days to HbA_{1c}, mean (SD)	371 (206)	376 (188)	412 (200)	353 (221)	345 (197)	371 (198)	383 (226)	.77
HbA_{1c} goal met								
No	141 (54.9)	16 (66.7)	11 (36.7)	11 (50.0)	38 (61.3)	29 (53.7)	36 (55.4)	.25
Yes	116 (45.1)	8 (33.3)	19 (63.3)	11 (50.0)	24 (38.7)	25 (46.3)	29 (44.6)	
Clinic visits								
Actual visits, mean (SD)	7.8 (4.9)	9.2 (4.4)	13.7 (5.1)	13.0 (7.3)	5.4 (2.6)	6.5 (3.4)	6.2 (2.5)	<.001
Canceled visits, mean (SD)	3.2 (3.2)	8.3 (5.8)	4.7 (1.9)	1.8 (1.7)	4.2 (2.5)	2.4 (1.3)	0.7 (0.7)	<.001
No-shows, mean (SD)	0.5 (1.0)	1.4 (1.9)	0.7 (1.3)	0.3 (0.6)	0.8 (1.0)	0.4 (0.7)	0.0 (0.2)	<.001
Actual visits: expected visits, mean (SD)[e], %	70.7 (17.3)	50.0 (9.6)	72.5 (4.4)	88.4 (7.3)	52.2 (8.8)	69.8 (4.2)	89.9 (8.2)	<.001

Abbreviations: BMI, body mass index; HbA_{1c}, glycated hemoglobin A_{1c}; PPM, pharmacist–physician managed; SD, standard deviation; UMC, usual medical care.
[a] Adherence calculated as a proportion by dividing the total number of actual interactions with a primary care physician, advanced practice pharmacist, or both by the total number of expected visits for each patient.
[b] Percentages are based on available data from the electronic health record. Not all data were available.
[c] Government represents benefits from Civilian Health and Medical Program of the Department of Veterans Affairs, Medicare, or Medicare Advantage.
[d] Duration defined as number of years since diabetes or prediabetes was diagnosed.
[e] Expected visits are the sum of actual visits, no-shows, and canceled visits.

Table 2. Analysis of Glycated Hemoglobin A_{1c} Goal Achievement Between Pharmacist-Physician Managed Care and Usual Medical Care, Florida, 2017–2019

Goal Achievement	Pharmacist–Physician Managed		Usual Medical Care		*P* Value
	Patients Who Met HbA_{1c} Goal, No./Total	Time to HbA_{1c} Goal, Median (95% CI), d	Patients Who Met HbA_{1c} Goal, No./Total	Time to HbA_{1c} Goal, Median (95% CI), d	
Overall	38/76	470 (372.0–NE)	78/181	569 (437–707)	.60
Cohort classification by baseline HbA_{1c}					.11
Less than median (<8%)	12/20	380 (224.0–NE)	57/104	437 (383.0–638.0)	NA
Greater than or equal to median (≥8%)	26/56	512 (372.0–NE)	21/77	668 (612.0–NE)	NA
Stratification by adherence to visit schedule					.80
Low adherence	8/24	NE	24/62	612 (424.0–NE)	NA
Moderate adherence	19/30	441 (335.0–NE)	25/54	457 (392.0–NE)	NA
High adherence	11/22	381 (263.0–NE)	29/65	569 (383.0–867.0)	NA

Abbreviations: CI, confidence interval; HbA_{1c}, glycated hemoglobin A_{1c}; NA, not applicable; NE, not estimable.

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ORIGINAL RESEARCH

Telepharmacy and Quality of Medication Use in Rural Areas, 2013–2019

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Summary

What is already known on this topic?

Pharmacy closures disrupt medication access and decrease patient adherence to prescription medications. Telepharmacy is a potential solution to this problem; however, research on the relationship between telepharmacy and adherence, as well as other aspects of the quality of medication use, is limited.

What is added by this report?

In rural areas, the quality of medication use at telepharmacies is no worse than at traditional pharmacies.

What are the implications for public health practice?

Our study informs public health officials and policy makers who are considering telepharmacy as an option for pharmacy support services in communities with limited medication access.

Abstract

Introduction

Pharmacy closures in rural areas is an increasingly common problem. Closures disrupt medication access and decrease adherence to prescription medications. Telepharmacy is a potential solution to this problem; however, research on the relationship between telepharmacy and the quality of medication use is scarce. Our study sought to address this gap by comparing the quality of telepharmacies serving rural areas and traditional pharmacies that support them.

Methods

We obtained dispensing data for the first 18 months of operation from 3 telepharmacies and 3 traditional pharmacies located in the upper Midwest. We evaluated adherence for noninsulin diabetes medications, renin-angiotensin system antagonists, and statins, as well as inappropriate use of high-risk medications in older adults and statin use in persons with diabetes. All metrics were calculated using Medicare Part D specifications. We estimated the differences between telepharmacies serving rural areas and traditional pharmacies using generalized linear regression. We adjusted our models for potential sociodemographic and clinical confounders.

Results

A total of 2,832 patients contributed 4,402 observations to the quality measures. After covariate adjustment, we observed no significant differences between telepharmacies and traditional pharmacies for noninsulin diabetes medications, renin-angiotensin system antagonists, statins, and high-risk medications. However, statin use in persons with diabetes was higher in telepharmacies than traditional pharmacies.

Conclusion

We found that the quality of medication use at telepharmacies that serve rural areas was no worse than at traditional pharmacies. For communities considering the adoption of telepharmacy, results indicate that telepharmacies provide a suitable solution for expanding medication access and that using telepharmacy would not negatively affect the quality of medication use.

Introduction

Across the United States, rural populations are decreasing and growing older (1). As a result, local businesses close in many small rural towns, and pharmacies that dispense medications to older adults are at risk of closing (2). In 2018, 16% of rural independent pharmacies had closed during the previous 16 years (3). Community pharmacies dispense 90% of medications in the United States (4), and pharmacy closures create disruptions in

medication access that negatively affect medication adherence (5). Decreasing adherence rates lead to greater disease progression and create a substantial financial burden on the health care system (6).

A potential solution for maintaining medication access in rural communities is telepharmacy, which is the provision of patient care by pharmacists through the use of telecommunication or other technologies (7). In the community setting, telepharmacy most often replaces a physical check of patient adherence by a pharmacist with a remote check by a pharmacist. Filling prescriptions by a pharmacy technician also occurs under remote supervision. Additionally, patient counseling services are delivered by telephone or by video connection, as needed (8).

Although regulatory restrictions on telepharmacy have eased in recent years, as of 2016, less than half of all US states had rules or legislation authorizing telepharmacy practice (9). The safety of telepharmacy services has been explored to some extent (10,11), but the effects of telepharmacy on the quality of medication use is largely unknown. Limiting physical access to a pharmacist might negatively influence the quality of medication use, and this uncertainty has created barriers for the implementation of regulations that make telepharmacy licensure possible (12). The primary objective of our study was to evaluate the relationship between telepharmacy services in rural areas and the quality of medication use.

Methods

Our cross-sectional study used retrospective data from the dispensing records of 3 pairs of telepharmacies and the traditional pharmacies that supported them. Telepharmacies were located in smaller rural communities and served a more rural population than the traditional pharmacies. The participating pharmacies are part of a commercial chain located in the upper Midwest region of the United States. Data were obtained from 15 to 18 months for each telepharmacy–traditional pharmacy pair, starting with the opening date of the telepharmacy. An uptake period of 3 months was allowed for the establishment of operations, and the subsequent 12-month observation period was used for quality measurement. Each telepharmacy–traditional pair had different evaluation periods that were based on the opening date of telepharmacy services at each telepharmacy site. The date ranges for telepharmacy–traditional pharmacy pairs were 1) April 1, 2013, to October 31, 2014; 2) May 1, 2015, to November 30, 2016; and 3) October 2, 2017, to January 11, 2019. The University of North Carolina at Chapel Hill's Institutional Review Board approved the study.

We examined more than 150,000 dispensing records for 10,923 patients, of which, 8,786 patients met our overall population eligibility of adults aged 18 or older. Our primary exposure variable was the use of either telepharmacy or traditional pharmacy for medication management. Patient attribution to telepharmacy or traditional pharmacy was determined separately for each quality measure, according to the site where the patient filled at least 50% of their measure-eligible medications. Outcomes were assessed for 5 quality measures from 2 domains of quality of medication use: medication adherence and inappropriate medication use. Patients were eligible for inclusion in our sample if they met the inclusion criteria for any 1 of the 5 quality measures.

Medication adherence

Medication adherence was evaluated for 3 common classes of medications: 1) noninsulin diabetes medications (NIDMs), 2) renin-angiotensin system antagonists (RASAs), and 3) statins. Each medication class is included in Medicare Part D Star Rating measures and Part D measure specifications (13), developed by the Pharmacy Quality Alliance (14) and endorsed by the National Quality Forum (15). Proportion of days covered (PDC), which is the preferred method to measure adherence (14), was used to assess patient adherence to these drug therapies. The PDC method assesses the percentage of patients covered by prescription claims for the same drug or for another drug in the same therapeutic class within a given period. Measure specifications for NIDM, RASA, and statin adherence require a denominator of patients aged 18 or older with at least 2 fills in the specified medication classes during the measurement year. Patients in the denominator with a PDC at 80% or higher (conventional cut-off) across the classes of medications were considered adherent to a given class of medication. A binary indicator of adherence was created for every patient who met measure specifications in the 12-month post-uptake window of their pharmacy.

Inappropriate medication use

Inappropriate medication use was assessed using measures that are also part of Medicare Star Ratings. These measures were 1) use of high-risk medications (HRM) in the elderly and 2) statin use in persons with diabetes (SUPD). HRM eligibility, by definition, applies only to people aged 65 or older. The HRM measure includes all patients aged 65 or older as eligible for the measure denominator. Eligible patients who received 2 or more prescription fills for the same HRM class during the measurement period were included in the numerator. For the SUPD measure, denominator-eligible patients were aged 40 to 75 years with at least 2 diabetes medication fills during the measurement period. Patients in the denominator who received a statin medication fill during the measurement period were included in the numerator.

Like medication adherence measures, a binary indicator of inappropriate medication use was created for each patient who met the measure specification criteria within the 12-month post-uptake

window of their pharmacy. For the SUPD measure, we found that all denominator-eligible patients in the telepharmacy Pair 1 site met the numerator specifications for this measure, making the lack of variation impossible to accurately assess the differential effect of pharmacy type on the outcome.

Covariates

Covariates of patient age, sex, patient location (rural or urban), payer (Medicaid or other), patient risk indicator (low, moderate and high), and telepharmacy-traditional pair indicators were used to control for variations in observations on the basis of patient demographic and clinical factors. Because dispensing data for the same patient can appear across different points in time for different quality measures, the first fill date for eligible patients within each measure was used to calculate patient age. A Medicaid and non-Medicaid payer indicator was developed as a proxy for patient socioeconomic status. Patients were flagged as Medicaid payers if they had a prescription with Medicaid as the primary or secondary biller. Rural and urban classifications were made by linking county classification of rurality (16) to patient zip codes through a county-zip code crosswalk (17). The original classification scheme by the US Department of Agriculture's Economic Research Service has 6 rural categories and 3 urban categories (16), which were combined into a binary indicator. Most urban patient zip codes were from counties of a population size of 250,000 or less, although rural patients were from a population size of 2,500 to 19,999. A pharmacy pair indicator was used to absorb any additional geographic or practice-related variation not accounted for by other covariates in the study.

Finally, an indicator of relative patient risk was derived by calculating medication counts for eligible patients within each quality measure. The medication count was determined by the count of distinct therapeutic classes of dispensed medications and was used to categorize prescription burden of patients into relative categories of low, moderate, and high risk based on the tercile of the distribution of the medication counts for each quality measure (18). This risk indicator was a proxy for disease severity in the covariate-adjusted models. A sensitivity analysis, using an alternative risk indicator for prescription burden categories of low polypharmacy (0–4), polypharmacy (5–9), and hyperpolypharmacy (≥9) using conventional polypharmacy cut-offs (19), was also performed.

Statistical analysis

All variables were summarized by using counts and percentages for categorical variables and means, standard deviation, and interquartile ranges for continuous variables. Patient population characteristics were compared within telepharmacies and traditional pharmacies by using χ^2 tests of proportions for categorical variables and Student *t* tests for continuous variables.

The effect of observations clustered within pharmacies on estimates was accounted for by using pharmacy as a repeated measure in generalized estimating equations (GEE), an extension of a generalized linear model. Additionally, binomial distributions with logit links were used to model all outcomes. This approach accounted for within-pharmacy heteroscedasticity to produce population-averaged estimates of binary outcomes. Unadjusted GEE models with only the pharmacy indicator and covariate-adjusted models were assessed for all 5 measures. Beta coefficients derived from unadjusted and adjusted models were converted to odds ratios for ease of interpretation. Additionally, least square-means for adjusted models and 95% confidence intervals for all models were estimated. All analyses were conducted using SAS version 9.4 (SAS Institute Inc).

Results

Our final data set consisted of 2,832 patients who met eligibility criteria for at least 1 of our 5 measures. These patients contributed 4,402 observations to quality measures. Tercile-based risk stratification of patients yielded varied medication count cutoffs for each measure. The cut-off between low and moderate risk was 6 for NIDM, 5 for RASA, 5 for statins, 2 for HRM, and 6 for SUPD. The cut-off between moderate and high risk was 10 for NIDM, 9 for RASA, 9 for statins, 6 for HRM, and 10 for SUPD. More than 20% (661/2832 = 23.3%) of patients in our study received services through telepharmacies. Of 2,832 patients, pharmacy Pair 1 contributed 43.4% (n = 1,230), pharmacy Pair 2 contributed 37.0% (n = 1,049) and pharmacy Pair 3 contributed 19.5% (n = 553). The proportion of patients who used telepharmacies was 12.0% (148 of 1,230) in pharmacy Pair 1, 30.4% (319 of 1,049) in pharmacy Pair 2, and 35.1% (194 of 553) in pharmacy Pair 3. We observed no significant differences between telepharmacies and traditional pharmacies in population characteristics, such as patient age, sex, or payer (Table 1). Telepharmacies, however, had a significantly higher proportion (χ^2 statistic, 352.2; $P < .001$) of patients from rural residential areas (84.1%; 556 of 661) than traditional pharmacies (27.8%; 603 of 2,171). Conversely, we observed a significantly higher proportion (χ^2 statistic, 12.8; $P = .002$) of patient risk among those using traditional pharmacies (25.6%; 555 of 2,171) than telepharmacies (21.5%; 142 of 661).

For the adherence measures and SUPD, we found more male than female patients, and a greater proportion of the population was younger than 65. However, for the HRM measure, we found more

female than male patients. Similarly, a higher proportion of patients were from urban residential areas in all measures except SUPD, where the proportion of patients from rural residential areas (50.3%) was almost equal to patients from urban residential areas (50.3%). Prevalence of adherence was 73.2% (188 of 257) for NIDMs, 75.6% (731 of 967) for RASAs, and 73.0% (755 of 1034) for statins. The prevalence of HRM use was 8.3% (164 of 1985), and the use of statins among diabetes patients was 66.0% (105 of 159) (Table 2). Covariate adjustment affected all quality measures (Table 3). After covariate adjustment, we observed no significant difference in adherence between telepharmacies and traditional pharmacies for NIDMs, RASAs, statin medications, or HRM. Predicted margins from adjusted models indicate proportions of adherence and inappropriate use for variables in the models (Table 4). Patients with diabetes who used telepharmacies; however, had a significantly higher likelihood of statin use ($P <$ .001) than those using traditional pharmacies. Except for SUPD (83% vs 75%), the differences in the predicted margins for telepharmacies and traditional pharmacies were not significant. Sensitivity analysis using polypharmacy cut-offs did not meaningfully change the results for any of our quality measures.

Discussion

This is the first study to evaluate differences in the quality of medication use between telepharmacies in rural areas and traditional pharmacies by using a broad set of standardized measures. We found that the quality of telepharmacies, as assessed by medication adherence and appropriateness, was no worse than in the traditional pharmacies that supported them. Substantial demographic and clinical differences, however, were observed in the populations served by the 2 pharmacy types. Telepharmacy patients were more likely to reside in rural areas and had a lower medication count. When accounting for these potential confounders, no significant differences were observed between telepharmacy and traditional pharmacies, except for the SUPD measure, on which telepharmacies scored higher. Additional data are needed to confirm that the lack of significance for the HRM measure was not a result of type 2 error.

Our findings on medication adherence support findings from a previous study (20), which found no difference in adherence rates among patients at an urban telepharmacy and those at a retail chain pharmacy. Unlike that study, our study assessed adherence to medications by using standardized measure specifications and examined additional measures of quality, such as inappropriate use. Moreover, our study used data from multiple pairs of telepharmacies in rural areas and traditional pharmacies, increasing our sample size and allowing us to use stronger evaluation methods for assessing our outcomes.

Coupled with safety data from previous studies (10,11), our study can inform boards of pharmacy about the positive relationship between telepharmacy practice and the quality of medication use. Our study might be useful as boards consider this alternative practice model to support their public mission of expanding medication access and improving population health in underserved communities in rural areas. Additionally, for community pharmacy owners and health care institutions considering new telepharmacy operations, our research suggests that new telepharmacies are likely to perform similarly to existing pharmacies that will support them. Establishment of telepharmacies, therefore, might not necessarily place organizations at an additional risk for performance-related penalties, which have become common among third-party payers in the United States (21).

Our study can also inform public health officials, researchers, and policy makers considering telepharmacy as an alternative to increase medication access in communities with poor access to medications. A common term for these communities is pharmacy deserts, and pharmacy deserts are prevalent in both rural and urban areas (22,23). Urban telepharmacies might have similar relative qualities to rural telepharmacies; however, boards of pharmacy, public health leaders, and policy makers should carefully consider regulations that limit the geographic scope of telepharmacies until a better understanding of the implications on medication access and quality of telepharmacies in urban areas is obtained.

Our study had several limitations, primarily as a result of the use of dispensing records for assessment of outcomes and the small number of pharmacies. Dispensing data provide limited information on sociodemographic and clinical factors that can affect the quality of medication use. We addressed this limitation to the extent possible by creating indicators for patient rurality, Medicaid-status and patient risk. Additionally, dispensing data do not capture the complete spectrum of pharmacies visited by patients. It is unlikely, however, that the use of outside pharmacies varied systematically by pharmacy type, and therefore any bias would be balanced across cohorts.

Differences in community pharmacy practice in rural and urban areas (24) might have influenced our findings of telepharmacy and traditional pharmacy outcomes, but we were unable to disentangle those differences in our study. Finally, because telepharmacy practice can differ across states (9), our findings are only generalizable to similar pharmacies serving similar populations. Additional study is needed to evaluate the relative quality of telepharmacies in urban areas and other demographically diverse settings.

Our study indicates that the quality of medication use at telepharmacies serving rural areas is similar to the quality provided through traditional pharmacies. Our findings can be used to in-

form public health policy makers on the suitability of telepharmacy as one solution for improving medication access and facilitating population health in rural pharmacy deserts. Moreover, our results support telepharmacy deregulation and imply that, for institutions participating in alternative payment models, contracting with telepharmacies to dispense medications should not negatively affect patient health or affect quality. Future studies should consider evaluating differences in medication quality for telepharmacies using other outcomes, such as glycosylated hemoglobin, and in other settings, such as urban telepharmacies.

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Tables

Table 1. Comparison of Overall Patient Characteristics by Pharmacy type to Evaluate Quality of Medication Use, 2013–2019

Characteristics	Traditional, No. (%)[a] (n = 2,171)	Telepharmacy, No. (%)[a] (n = 661)	*P* Value
Patient sex			
Female	1,100 (50.7)	336 (50.8)	.94[b]
Male	1,071 (49.3)	325 (49.2)	
Age group, y			
18–49	182 (8.4)	57 (8.6)	.10[b]
50–64	509 (23.4)	134 (20.3)	
65–74	750 (34.5)	261 (39.5)	
>74	730 (33.6)	209 (31.6)	
Patient location			
Urban	1,568 (72.2)	105 (15.9)	<.001[b]
Rural	603 (27.8)	556 (84.1)	
Patient risk[d]			
High	555 (25.6)	142 (21.5)	.002[b]
Moderate	816 (37.6)	225 (34.0)	
Low	800 (36.8)	294 (44.5)	
Payer			
Medicaid	66 (3.0)	28 (4.2)	.13[b]
Other	2,105 (97.0)	633 (95.8)	
Patient age, mean (SD), y	68.5 (13.1)	68.2 (12.9)	.63[c]
No. of medications, mean (SD)[e]	6.3 (4.5)	5.5 (4.2)	<.001[c]

[a] Percentages may not add to 100 because of rounding.
[b] Derived from χ^2 test.
[c] Derived from Student *t* test.
[d] Tercile-based stratification of the medication counts for measure-eligible patients; varies for each quality measure.
[e] Number of medications calculated as the count of distinct classes of dispensed medications.

Table 2. Description of Patient (N = 2,832) Characteristics by Outcomes for Medication Adherence and Inappropriate Use[a], 2013–2019

Characteristics	Adherence to Noninsulin Diabetes Medications (n = 257)	Adherence to Renin-Angiotensin System Antagonist (n = 967)	Adherence to Statins (n = 1,034)	Use of High-Risk Medications[b] (n = 1,985)	Statin Use In Persons With Diabetes (n = 159)
Patient sex					
Female	125 (48.6)	436 (45.1)	482 (46.6)	1,104 (55.6)	73 (45.9)
Male	132 (51.4)	531 (54.9)	552 (53.4)	881 (44.4)	86 (54.1)
Age, y					
18–49	38 (14.8)	151 (15.6)	108 (10.4)	—	22 (13.8)
50–64	116 (45.1)	365 (37.7)	432 (41.8)	—	73 (45.9)
65–74	50 (19.5)	239 (24.7)	255 (24.7)	1,046 (52.7)	59 (37.1)
>74	53 (20.6)	212 (21.9)	239 (23.1)	939 (47.3)	5 (3.1)
Patient location					
Urban	168 (65.4)	603 (62.4)	698 (67.5)	1,127 (56.8)	79 (49.7)
Rural	89 (34.6)	364 (37.6)	336 (32.5)	858 (43.2)	80 (50.3)
Patient risk[c]					
Low	73 (28.4)	298 (30.8)	305 (29.5)	574 (28.9)	48 (30.2)
Moderate	93 (36.2)	341 (35.3)	378 (36.6)	711 (35.8)	54 (34.0)
High	91 (35.4)	328 (33.9)	351 (33.9)	700 (35.3)	57 (35.8)
Payer					
Other	234 (91.1)	916 (94.7)	977 (94.5)	1,970 (99.2)	144 (90.6)
Medicaid	23 (8.9)	51 (5.3)	57 (5.5)	15 (0.8)	15 (9.4)
Pharmacy type					
Traditional	202 (78.6)	753 (77.9)	852 (82.4)	1,510 (76.1)	114 (71.7)
Telepharmacy	55 (21.4)	214 (22.1)	182 (17.6)	475 (23.9)	45 (28.3)
Pharmacy pairs					
Pair 3	35 (13.6)	169 (17.5)	169 (16.3)	412 (20.8)	38 (23.9)
Pair 2	90 (35.0)	335 (34.6)	307 (29.7)	804 (40.5)	121 (76.1)
Pair 1	132 (51.4)	463 (47.9)	558 (54.0)	769 (38.7)	—
Prevalence[d] of Adherence or Inappropriate Use	188 (73.2)	731 (75.6)	755 (73.0)	164 (8.3)	105 (66.0)
Age, mean (SD) [IQR], y	62.3 (14.1) [53–73]	63.4 (13.7) [54–73]	64.5 (12.8) [55–74]	75.2 (7.9) [69–81]	60.9 (9.6) [54–69]
No. of medications, mean (SD) [IQR][e]	9.3 (4.1) [6–12]	8.2 (4.5) [5–11]	8.3 (4.5) [5–11]	5.6 (4.3) [2–8]	9.4 (4.4) [6–12]

Abbreviations: — , not applicable; IQR, interquartile range.
[a] All values are number (percentage) unless otherwise indicated.
[b] Use of high-risk medications applies only to patients aged 65 or older, as per measure specifications.
[c] Tercile-based stratification of the medication count for measure-eligible patients; varies for each quality measure.
[d] Prevalence defined as all observations that met numerator specifications for each quality measure.
[e] Number of medications calculated as the count of distinct therapeutic classes of dispensed medications.

Table 3. Unadjusted and Covariate-Adjusted Estimates of the Effect of Pharmacy type on Quality of Medication Use

Variables	Quality Measures				
	Adherence to Noninsulin Diabetes Medications	Adherence to Renin-Angiotensin System Antagonist Medications	Adherence to Statins	Use of High-Risk Medications[b] (≥65 y)	Statin Use in Persons with Diabetes[c]
Unadjusted model pharmacy type[a]					
Traditional	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Telepharmacy	0.6 (0.4–0.8) [.001]	1.1 (0.8–1.4) [.60]	1.0 (0.7–1.7) [.84]	0.9 (0.8–1.1) [.20]	0.9 (0.7–1.3) [.80]
Covariate adjusted model pharmacy type[a]					
Traditional	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Telepharmacy	0.8 (0.5–1.3) [.42]	1.0 (0.9–1.2) [.70]	1.3 (0.8–2.1) [.30]	1.3 (1.0–1.8) [.06]	1.7 (1.3–2.0) [<.001]
Patient sex					
Male	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Female	1.4 (0.9–2.1) [.15]	0.7 (0.6–1.0) [.02]	0.9 (0.8–1.1) [.02]	1.1 (0.8–1.5) [.71]	0.3 (0.2–0.5) [<.001]
Age group					
18–49	1 [Reference]	1 [Reference]	1 [Reference]	—	—
50–64	3.2 (1.5–7.2) [.004]	1.8 (1.3–2.5) [.001]	2.1 (1.7–2.4) [<.001]	—	—
65–74	6.9 (2.5–16.5) [<.001]	2.5 (1.8–3.3) [<.001]	2.6 (2.2–3.2) [<.001]	1 [Reference]	—
≥65	—	—	—	—	3.9 (2.2–7.2) [<.001]
<65	—	—	—	—	1 [Reference]
>74	2.3 (1.4–3.7) [<.001]	2.2 (1.6–3.2) [.001]	2.2 (1.6–2.9) [<.001]	0.8 (0.6–1.0) [.03]	—
Patient location					
Urban	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Rural	0.4 (0.3–0.6) [<.001]	1.3 (1.1–1.6) [.005]	0.7 (0.5–0.9) [<.003]	0.9 (0.6–1.2) [.40]	0.7 (0.5–1.1) [.11]
Patient risk[d]					
Low	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Moderate	0.8 (0.4–1.9) [.69]	1.1 (0.7–1.5).80	0.9 (0.6–1.3) [.50]	5.5 (2.9–10.4) [<.001]	1.2 (0.7–2.1) [.49]
High	1.3 (0.5–3.3) [.52]	0.9 (0.7–1.1) [.40]	1.3 (1.0–1.5) [.02]	19.7 (10.6–36.3) [<.001]	2.1 (1.6–2.8) [<.001]
Payer					
Medicaid	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Other	3.9 (2.1–6.9) [<.001]	1.9 (1.1–3.1) [<.02]	2.1 (1.2–3.8) [.01]	1.0 (0.4–2.2) [.94]	0.4 (0.3–0.6) [<.001]
Pharmacy pair					
Pair 3	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Pair 2	3.1 (1.7–5.6) [.001]	1.7 (1.5–1.9) [<.001]	1.3 (1.0–1.7) [.08]	1.1 (1.0–1.3) [.13]	0.8 (0.7–1.0) [.01]
Pair 1	1.6 (0.9–2.9) [.14]	1.3 (1.1–1.4) [<.001]	0.6 (0.5–0.7) [<.001]	1.3 (1.1–1.5) [.01]	—

Abbreviation: — , not applicable.
[a] All values are odds ratio (95% CI) and [*P* value].
[b] Use of high-risk medications applies only to patients aged 65 or older, as per measure specifications.
[c] Age groups combined for model development; no assessment for pharmacy Pair 1.
[d] Tercile-based stratification of the medication count for measure-eligible patients; varies for each quality measure.

Table 4. Predicted Margins From Adjusted Models of Medication Adherence and Inappropriate Use Using Least Square Means[a]

Characteristics	Quality Measures				
	Noninsulin Diabetes Medications Adherence	Renin-Angiotensin System Antagonist Adherence	Statin Adherence	Use of High-Risk Medications[b]	Statin Use in Persons with Diabetes[c]
Patient sex					
Male	0.54 (0.46–0.61)	0.73 (0.65–0.79)	0.68 (0.60–0.75)	0.05 (0.03–0.08)	0.69 (0.65–0.74)
Female	0.61 (0.54–0.86)	0.67 (0.61–0.72)	0.67 (0.58–0.74)	0.05 (0.03–0.08)	0.87 (0.81–0.91)
Age group					
18–49	0.33 (0.21–0.49)	0.57 (0.50–0.63)	0.53 (0.43–0.62)	—	—
50–64	0.62 (0.56–0.68)	0.70 (0.63–0.77)	0.70 (0.61–0.77)	—	—
<65	—	—	—	—	0.66 (0.63–0.69)
65–74	0.78 (0.68–0.85)	0.76 (0.71–0.81)	0.75 (0.67–0.81)	0.05 (0.03–0.09)	—
≥65	—	—	—	—	0.88 (0.82–0.93)
>74	0.54 (0.49–0.58)	0.74 (0.67–0.80)	0.71 (0.63–0.78)	0.04 (0.03–0.07)	—
Patient location					
Urban	0.67 (0.60–0.73)	0.67 (0.58–0.74)	0.72 (0.63–0.79	0.05 (0.03–0.09)	0.82 (0.78–0.85)
Rural	0.47 (0.42–0.52)	0.73 (0.68–0.77)	0.63 (0.54–0.71)	0.04 (0.03–0.08)	0.77 (0.69–0.83)
Patient risk[d]					
Low	0.56 (0.41–0.71)	0.70 (0.65–0.75)	0.67 (0.56–0.76)	0.01 (0.00–0.02)	0.74 (0.67–0.80)
Moderate	0.52 (0.42–0.62)	0.71 (0.62–0.79)	0.64 (0.56–0.72)	0.06 (0.04–0.08)	0.77 (0.72–0.82)
High	0.63 (0.50–0.75)	0.68 (0.61–0.74)	0.72 (0.64–0.78)	0.17 (0.12–0.25)	0.85 (0.78–0.91)
Payer					
Non-Medicaid	0.73 (0.68–0.77)	0.76 (0.75–0.77)	0.75 (0.72–0.78)	0.05 (0.04–0.06)	0.72 (0.70–0.74)
Medicaid	0.41 (0.30–0.52)	0.63 (0.50–0.74)	0.59 (0.43–0.73)	0.05 (0.02–0.12)	0.85 (0.79–0.90)
Pharmacy pair					
Pair 3	0.44 (0.34–0.55)	0.64 (0.58–0.70)	0.70 (0.64–0.75)	0.04 (0.03–0.07)	0.81 (0.75–0.85)
Pair 2	0.71 (0.65–0.76)	0.75 (0.69–0.80)	0.75 (0.65–0.82)	0.05 (0.03–0.08)	0.78 (0.74–0.81)
Pair 1	0.56 (0.48–0.63)	0.69 (0.64–0.74)	0.57 (0.47–0.66)	0.05 (0.03–0.09)	—
Pharmacy type					
Traditional	0.60 (0.52–0.67)	0.69 (0.65–0.73)	0.65 (0.59–0.70)	0.04 (0.03–0.07)	0.75 (0.69–0.80)
Telepharmacy	0.55 (0.47–0.63)	0.70 (0.63–0.77)	0.70 (0.58–0.80)	0.06 (0.03–0.10)	0.83 (0.79–0.87)

Abbreviations: — , not applicable.
[a] All values are predicted margin (95% CI).
[b] Use of high-risk medications applies only to patients aged 65 or older, as per measure specifications.
[c] Age groups combined for model development; no assessment for Pharmacy Pair 1.
[d] Tercile-based stratification of the medication count for measure-eligible patients; varies for each quality measure.

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ORIGINAL RESEARCH

Rural–Urban Disparities in Access to Medicaid-Contracted Pharmacies in Washington State, 2017

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PEER REVIEWED

Summary

What is already known on this topic?

Community retail pharmacies provide prescription services, as well as health promotion and disease management services, such as immunizations, rapid influenza screening, cholesterol testing, blood pressure management, blood glucose monitoring, and substance use treatment.

What is added by this report?

Areas outside urban core centers in Washington State were significantly less likely to have access to a pharmacy contracted with Medicaid insurance. Disparities in access to pharmacy care exist for Medicaid recipients across the rural–urban continuum.

What are the implications for public health practice?

Ensuring that rural residents have access to pharmacies that contract with Medicaid is important for improving access to health care in rural areas. Public health professionals should advocate for policies to ensure such access.

Abstract

Introduction

Community retail pharmacies offer multiple public health services to meet the health care needs of medically underserved rural communities. Many rural residents are enrolled in Medicaid insurance, and it is important that pharmacies contract with Medicaid to meet the health care needs of these people. The objective of this study was to evaluate disparities in access to Medicaid-contracted pharmacies across the rural–urban continuum in Washington State.

Methods

We linked data on licensed community retail pharmacies in Washington State in 2017 to lists of state Medicaid-contracted pharmacies. We classified pharmacies as being located in small rural, large rural, suburban, and urban areas by using rural–urban commuting area (RUCA) codes. We evaluated the likelihood of zip code–level access to at least 1 pharmacy that was contracted with a Medicaid insurance plan across the rural–urban continuum by using descriptive statistics and modified Poisson regression models, adjusted for zip code–level community characteristics.

Results

Of 1,145 pharmacies in our study sample, 8.4% (n = 96) were not contracted with a Medicaid plan. Compared with urban core zip codes, small rural zip codes (adjusted relative risk [ARR] = 0.64; 95% CI, 0.46–0.91) and large rural zip codes (ARR = 0.68; 95% CI, 0.49–0.95) were significantly less likely to have access to a Medicaid-contracted pharmacy. Suburban zip codes did not differ significantly from urban core areas in their access to Medicaid-contracted pharmacies.

Conclusion

In Washington State, the likelihood of access to a Medicaid-contracted pharmacy decreased significantly as rurality increased. Policy efforts should aim to improve access for Medicaid enrollees, especially those outside urban centers.

Introduction

Pharmacists serve an essential role in the provision of community-based services in the United States. Besides traditional services such as dispensing prescription and over-the-counter medications, pharmacists' roles now include extended services such as immunizations, rapid influenza screening, wellness testing, chronic disease screening and management, health education, medication monitoring and reviews, emergency contraception, smoking cessation, substance use treatment, and prevention of hospital readmission (1–4). As a testament to the importance of their role and the

array of services they provide, pharmacists' contributions have been recognized as critical elements in the prevention and management of chronic diseases in the United States (5)

Pharmacists' expanded roles have implications for the provision of health care services in rural areas. Rural stakeholders have identified access to quality health care services as the top rural health priority of the decade, along with many other priorities pertaining to chronic conditions and behavioral risk factors (6) that pharmacists are capable of addressing. However, the closure of rural pharmacies is negatively affecting access to health services in rural areas. From 2003 to 2018, the number of independently owned pharmacies in rural areas of the United States decreased by 16% (7). Among 119 community retail pharmacies that closed from 2006 through 2010, thirty-one were in rural communities that had no other health care provider, and 17% of these were in remote rural areas (8). Pharmacy closures are particularly concerning for the nearly 3 million people who live in rural communities that have a single independently owned pharmacy (9). This decreasing number of rural pharmacies creates pharmacy deserts (10), requiring rural residents to travel farther distances for services that were once nearby and mitigating potential gains in access brought about by the expanded role of pharmacies in delivering rural community health services.

Compared with urban residents, rural residents tend to be older, have lower income, and have less education; are less likely to be employed; and are more likely to have a disability (11–13). Rural residents are also less likely to have private health insurance and, therefore, rely more often on public sources of insurance (12,13). The probability of having Medicaid as a result of the Patient Protection and Affordable Care Act's Medicaid expansion increased more for rural childless adults than for urban childless adults (14), and the effect of expansion on reducing uninsurance was 68% higher in rural areas than in urban areas (15). Medicaid expansion also decreased the percentage of infants born into rural households with no insurance, but this decrease was smaller than the decrease among urban households (16). Pharmacies are not, however, mandated to have a contract with Medicaid prescription insurance. Many pharmacies may not be contracted with Medicaid because of low reimbursement rates, which are contractually established and vary by state (17). Consequently, increasing Medicaid coverage does not unequivocally translate to improved access to pharmacy services.

Because community retail pharmacies may be widely dispersed in areas of low population density, rural residents with Medicaid insurance may have a greater burden than their urban counterparts in accessing timely, affordable medications and other pharmacists' or pharmacy-related services. Lack of access to pharmacy care can affect a patient's ability to adhere to prescribed medical regimens (18–20), in addition to restricting access to public health services provided by pharmacies. These services are particularly needed in rural areas, because the prevalence of many chronic conditions and associated risk factors is higher in rural areas than in urban areas (21–24), and many rural areas have seen a loss of general health services.

Washington State is 1 of 5 states in the Pacific Census division, the census division with the highest percentage (~92%) of the population living in urban areas (25). Given the relatively small proportion of rural-dwelling residents in the Pacific Census division, communities of rural-dwelling residents often garner less attention from policy makers and receive fewer state and federal resources to address the health needs of their populations across wide geographical areas. Community pharmacies that contract with Medicaid are an important health care resource for residents of rural communities in Washington State. The objective of this study was to evaluate disparities in access to Medicaid-contracted pharmacies across the rural–urban continuum in Washington State.

Methods

This cross-sectional study involved merging of pharmacy licensing data and contracted pharmacy lists from Medicaid insurance plans in Washington State. The study was conducted from August 2017 through October 2018 and did not involve human subjects or records; institutional review board approval was not required.

Data sources

Pharmacy data. We obtained business names, addresses, telephone numbers, and, if available, email addresses, for pharmacies from the Washington State Department of Health in August 2017 (N = 6,203) (Figure 1). We excluded from the sample pharmacies with pending, closed, or terminated licenses (55.3%, n = 3,429), pharmacies with a site address outside Washington State (14.6%, n = 904), and duplicate listings (0.1%, n = 6). To focus on the primary point of pharmacy contact for community residents, we excluded the following types of nonretail, noncommunity pharmacies (11.6%, n = 719): specialty clinics (n = 278), general clinics (n = 219), specialty pharmacies (n = 68), long-term care facilities (n = 33), compounding pharmacies (n = 26), jails (n = 21), hospitals (n = 20), urgent care clinics (n = 18), medical supply centers (n = 8), surgery centers (n = 8), imaging clinics (n = 7), pharmaceutical wholesalers (n = 4), dental clinics (n = 5), call centers (n = 2), a blood bank (n = 1), and a mail order pharmacy (n = 1). We did not exclude pharmacies in federally qualified health centers or community health centers. Two study team members reviewed exclusions independently; any discrepancies were individually re-

viewed and evaluated until consensus was achieved. The final sample consisted of 1,145 pharmacies.

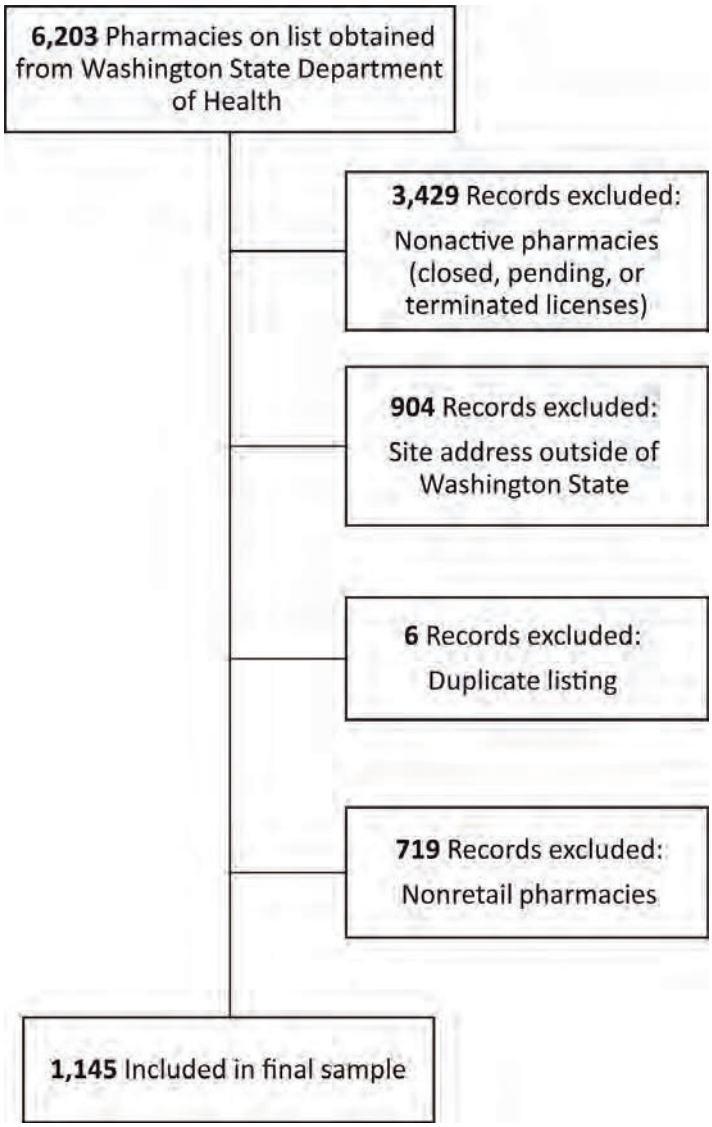

Figure 1. Flowchart of selection of pharmacies for study sample, Washington State, 2017.

In Washington State, 5 insurance carriers administer Medicaid insurance to enrollees. Each pharmacy in Washington State can hold a contract with none, some, or all 5 Medicaid insurance plans; Medicaid enrollees may choose any plan. We obtained the names, addresses, and contact information for pharmacies contracted with each Medicaid insurance plan from each health plan in September, October, and November 2017 through formal requests, direct download, or public record disclosure requests to the Washington Health Care Authority. Using business names, addresses, and telephone numbers, we manually matched data from Medicaid insurance plans to the list of actively licensed pharmacies from the Washington State Department of Health. Lists of insurance plans were sortable by county, city, or pharmacy name to facilitate matching. After matching, 2 study team members reviewed the entire list for accuracy. We then classified pharmacies by zip code. We created a dichotomous indicator for access to a Medicaid-contracted pharmacy (at least 1 pharmacy that was contracted with a Medicaid insurance plan in a zip code).

Rural-Urban Commuting Area (RUCA). We categorized zip codes into degrees of rurality by using the RUCA 3.10 framework classification Scheme 2 developed by a collaboration of the Health Resources and Service Administration's Office of Rural Health Policy, the Department of Agriculture's Economic Research Service, and the Washington, Wyoming, Alaska, Montana, Idaho (WWAMI) Rural Health Research Center (26). This scheme uses the geographic characteristics of population size, population density, and daily commuting patterns to establish 4 tiers of rurality: urban core (RUCA 1.0, 1.1), suburban (RUCA 2.0, 2.1, 3.0 and >100 residents/square mile), large rural (RUCA 4.0, 4.1, 4.2, 5.0, 5.1, 5.2, 6.0, 6.1 and >100 residents/square mile), and small town/rural (RUCA 7.0, 7.1, 7.2, 7.3, 7.4, 8.0, 8.1, 8.2, 8.3, 8.4, 9.0, 9.1, 9.2, 10.0, 10.1, 10.2, 10.3, 10.4, 10.5, 10.6 or not urban core with population density <100 residents/square mile) (26).

Census data. Characteristics of zip codes were derived from zip code–level data extracted from the 2017 American Community Survey 5-year estimates (27). We summarized data on the following community characteristics: total population (median and mean); mean percentage of population that was over age 65, nonwhite, Hispanic, and Medicaid-insured; and mean percentage with income below 200% of federal poverty level.

Statistical analysis

We conducted all analyses in Stata/MP version 15.1 (StataCorp LLC). The primary outcome measure was access to a Medicaid-contracted pharmacy. We summarized zip code–level community characteristics across rurality by using descriptive statistics. We used a nonparametric test for trend (*nptrend*) across ordered groups to test for differences in access to a Medicaid-contracted pharmacy across levels of rurality. We also used χ^2 tests to compare the proportion of zip codes in each level of rurality that had access to a Medicaid-contracted pharmacy.

We used a modified Poisson regression model (28) to examine the associations between rural–urban classification and access to a Medicaid-contracted pharmacy. Multivariable models included covariates relating to the following zip code–level characteristics:

percentage of population over age 65, percentage of nonwhite population, percentage of Hispanic population, percentage of Medicaid-insured population, percentage of population with income below 200% of the federal poverty level, and total population size. We chose covariates a priori on the basis of differences in population characteristics between rural and urban areas that are likely to influence health services access and use (29). We assessed multicollinearity between covariates by using the variance inflation factor, with a factor above 10 indicating moderate to strong collinearity. We used ESRI ArcGIS version 10.5.1 to create a map that illustrates the geographic distribution of pharmacies and their contracting with a Medicaid insurance plan. For all analyses, we set significance at $P < .05$.

Results

Of the 1,145 pharmacies included in the final sample, most (78.3%, n = 896) were in urban areas; the remainder were located in suburban (7.8%, n = 89), large rural (8.1%, n = 93), and small town/rural (5.9%, n = 67) areas. Urban areas had a lower percentage of residents over age 65 and a higher percentage of nonwhite residents compared with other areas (Table 1).

Most pharmacies (91.6%, n = 1,049) were contracted with at least 1 Medicaid insurance plan. There were similar proportions of Medicaid-contracted pharmacies in urban core areas (92.3%, 827 of 896), suburban areas (91.0%, 81 of 89), and large rural areas (92.5%, 86 of 93); a significantly smaller percentage of Medicaid-contracted pharmacies were located in small rural areas (82.1%, 55 of 67) ($\chi^2 = 8.6$; $P = .04$).

Overall, of 706 zip codes, 39.4% (n = 278) had access to at least 1 Medicaid-contracted pharmacy. Medicaid-contracted pharmacies were distributed throughout Washington State; we found larger proportions surrounding cities (Figure 2). The proportion of zip codes with a Medicaid-contracted pharmacy varied across urban (54.1%, 184 of 340), suburban (30.0%, 36 of 120), large rural (27.5%, 19 of 69), and small rural (22.0%, 39 of 177) classifications ($\chi^2 = 61.7$; $P < .001$). The nonparametric test for trend showed a significant decrease in the percentage of zip codes with a Medicaid-contracted pharmacy as rurality increased (Cuzick nonparametric trend test across ordered groups, $z = -7.36$; $P < .001$).

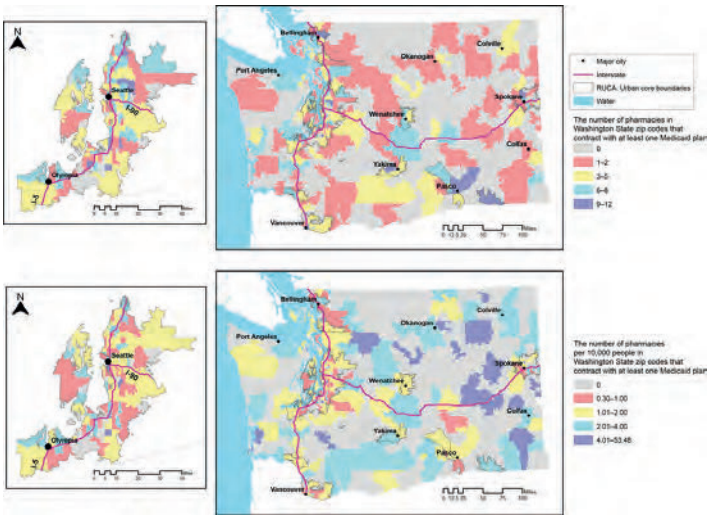

Figure 2. Geographic patterns of Medicaid-contracted pharmacies in Washington State, 2017, showing the number of pharmacies (top) and the number of pharmacies per 10,000 residents (bottom) in Washington State zip codes that contract with at least 1 Medicaid insurance plan. Inserts show the greater Seattle/Olympia area.

Unadjusted regression models showed a significant association between increasing rurality and limited access to a Medicaid-contracted pharmacy (Table 2). The multivariable (adjusted) regression model showed that the likelihood of access to a Medicaid-contracted pharmacy decreased significantly as rurality increased. Compared with urban core zip codes, small rural zip codes had a 36% lower likelihood of access to a Medicaid-contracted pharmacy, after adjusting for zip code characteristics (adjusted relative risk = 0.64; 95% CI, 0.46–0.91; $P = .01$). Large rural zip codes were also significantly less likely than urban core areas to have access to a Medicaid-contracted pharmacy, after adjusting for zip code characteristics (adjusted relative risk = 0.68; 95% CI, 0.49–0.95; $P = .02$). We found no evidence of multicollinearity; the variance inflation factor for all variables in the adjusted model was less than 10.

Discussion

Contemporary pharmacies have evolved today to expand beyond the traditional dispensing of medications and providing of over-the-counter products. Pharmacists continue to provide prescription monitoring and drug information and education; however, pharmacists now also offer a broad array of health care services. In rural areas, particularly in areas that no longer have a local primary care provider or clinic, pharmacies and pharmacists may be the only direct medical provider for rural residents. Pharmacies'

decision to contract with Medicaid can have a large effect on access to affordable medications, coordination of medications, and access to pharmacy services that are crucial for the prevention and management of chronic diseases.

Findings from our study illustrate disparities in access to pharmacy care for Medicaid recipients across the rural–urban continuum. After accounting for zip code–level characteristics, including measures of socioeconomic status and demographic characteristics, small and large rural areas of Washington State were significantly less likely than urban core areas to have access to a pharmacy that was contracted with at least 1 Medicaid insurance plan. This disparity in access could negatively affect prescription adherence and access to critical public health services now offered at pharmacies.

Policy efforts aimed at promoting and reducing barriers to telepharmacy may help to improve access to pharmacy services in medically underserved rural areas (30). Researchers who have developed and tested telepharmacy interventions have reported promising findings on patient self-management of chronic conditions and that rural patients are largely satisfied with interacting with pharmacists remotely (31). Telepharmacy has also been shown to decrease health care use among rural veterans at high risk for adverse drug events and medication reconciliation discrepancies (32). Despite the potential for improving access to care in medically underserved areas, only about half of the states in the United States have passed legislation allowing telepharmacy, and regulations vary by state (33). Addressing issues such as reimbursement, licensing, and data security (33) will be important for expanding pharmacy services in the United States.

In addition to pharmacy closures, that more than 1 in 6 pharmacies in small rural areas are not contracted with a Medicaid insurance plan and that nearly 80% of rural zip codes lack access to a Medicaid-contracted pharmacy, as shown in our study, generates increased concern about limited access to pharmacy services in many rural communities. The implementation of Medicare Part D and associated challenges with reimbursement, payment, and claims management have been implicated in reduced revenues for and closures of independently owned pharmacies, especially pharmacies in rural areas (7,34–36). As a by-product of the challenges created by Medicare Part D expansion, Medicaid patients may face a lack of access to critical services. Policy efforts targeting improved access to pharmacy services may require incentive allocations for Medicaid-contracted pharmacies based on geographic location. Pharmacists in both rural and urban areas have reported that lack of reimbursement is one of the top barriers to expanding the delivery of public health services (37).

Our study has several limitations. Many health plans encourage enrollees to use mail order pharmacies. Medicaid enrollees can receive recurring prescriptions and refills by mail rather than in local pharmacies. Therefore, although the results of our study may be less applicable to prescription services for long-standing chronic conditions, they are relevant for dose and formulary changes, as well as for acute conditions that require timely access to prescriptions. Community retail pharmacies serve an important role beyond ensuring timely access to prescriptions.

We did not determine the kinds of services offered at each pharmacy in our study. Some community retail pharmacies in rural parts of Washington State may provide only traditional services and not ancillary public health services. Additionally, we included pharmacies associated with community health centers in our study; however, we excluded pharmacies in general and specialty clinics because we could not determine whether they limited their services to clinic patients, which such clinics often do. We also could not determine why each pharmacy chose not to contract with a Medicaid insurance plan. Pharmacies are not mandated to contract with Medicaid insurance, and the low reimbursement rates and administrative burden may lead pharmacies to forgo contracting with this insurer. Future research examining these pharmacy-level factors may provide additional insight into the trends observed in our study.

Community retail pharmacies provide vital prescription services to people needing acute and chronic treatment as well as disease management and health promotion services. Our study showed that although 91.6% of pharmacies in our study were contracted with Medicaid, geographic areas located outside urban core centers were significantly less likely to have access to a Medicaid-contracted pharmacy. In small rural areas, nearly 80% of zip codes did not have access to a Medicaid-contracted pharmacy, compared with nearly half of urban core zip codes. This disparity in access to health care at pharmacies can place an undue burden on residents in rural areas. Barriers in accessing traditional and ancillary pharmacy services should be minimized for publicly insured individuals who live in rural and medically underserved areas of Washington State.

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Tables

Table 1. Zip Code Characteristics by Rurality Classification, Washington State, 2017[a]

Characteristic	Urban Core (n = 340)	Suburban (n = 120)	Large Rural (n = 69)	Small Rural (n = 177)	All Zip Codes (N = 706[b])
Percentage aged >65	13.6	19.3	20.1	23.0	17.5
Percentage nonwhite	24.8	11.1	11.7	14.4	18.6
Percentage Hispanic	11.1	9.6	16.6	11.1	11.4
Percentage Medicaid-insured	16.0	16.4	16.8	21.3	17.4
Percentage with income below 200% of the federal poverty level	28.4	30.6	33.9	38.9	31.9
Total population, no.					
Median	24,972	3,950	6,472	1,340	9,785
Mean	25,530	7,510	11,238	2,749	15,359

[a] Data were obtained from the 2017 American Community Survey 5-year estimates and represent the means for zip codes in each rurality classification (27). All values are percentages, unless otherwise indicated.
[b] Census data did not link to zip code data for 8 zip codes (2 urban core, 2 suburban, and 4 rural).

Table 2. Likelihood of Zip Code–Level Access to a Pharmacy Contracted With at Least 1 Medicaid Insurance Plan, Washington State, 2017[a]

Characteristic	Unadjusted Model		Adjusted Model	
	Risk Ratio (95% CI)	*P* Value	Risk Ratio (95% CI)	*P* Value
Rurality classification				
Urban core	1 [Reference]	—	1 [Reference]	—
Suburban	0.55 (0.41–0.74)	<.001	0.76 (0.58–1.01)	.06
Large rural	0.51 (0.34–0.76)	.001	0.68 (0.49–0.95)	.02
Small rural	0.41 (0.30–0.55)	<.001	0.64 (0.46–0.91)	.01
Sociodemographic				
Percentage aged >65	0.98 (0.97–0.98)	<.001	1.00 (0.99–1.01)	.55
Percentage nonwhite	1.01 (1.01–1.02)	<.001	1.00 (0.99–1.00)	.92
Percentage Hispanic	1.00 (0.99–1.00)	.92	0.99 (0.99–1.00)	.18
Percentage Medicaid-insured	0.99 (0.99–1.00)	.10	1.01 (1.00–1.02)	.13
Percentage with income below 200% of the federal poverty level	0.99 (0.99–1.00)	<.001	1.00 (0.99–1.00)	.33
Total population	1.00 (1.00–1.00)	<.001	1.00 (1.00–1.00)	<.001

[a] Adjusted model includes all listed covariates. Variance inflation factor for all variables <10.

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ORIGINAL RESEARCH

State and Regional Variation in Prescription- and Payment-Related Promoters of Adherence to Blood Pressure Medication

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PEER REVIEWED

SUMMARY

What is already known on this topic?

Approximately three-fourths of US adults with hypertension do not have their blood pressure controlled. Medication adherence is important in hypertension management and can be affected by how medications are prescribed and purchased.

What is added by this report?

We found considerable variation in prescription- and payment-related factors that promote medication adherence by geography and across the largest patient market segments comprised of medication prescriber, insurance payer type, and age.

What are the implications for public health practice?

Blood pressure control rates are low and may be affected by uptake of the adherence promotion factors assessed. Increased uptake of these promoters, especially in the regions and populations in most need, could improve hypertension management.

Abstract

Introduction

Medication adherence can improve hypertension management. How blood pressure medications are prescribed and purchased can promote or impede adherence.

Methods

We used comprehensive dispensing data on prescription blood pressure medication from Symphony Health's 2017 Integrated Dataverse to assess how prescription- and payment-related factors that promote medication adherence (ie, fixed-dose combinations, generic formulations, mail order, low-cost or no-copay medications) vary across US states and census regions and across the market segments (grouped by patient age, prescriber type, and payer type) responsible for the greatest number of blood pressure medication fills.

Results

In 2017, 706.5 million prescriptions for blood pressure medication were filled, accounting for $29.0 billion in total spending (17.0% incurred by patients). As a proportion of all fills, factors that promoted adherence varied by state: fixed-dose combinations (from 5.8% in Maine to 17.9% in Mississippi); generic formulations (from 95.2% in New Jersey to 98.4% in Minnesota); mail order (from 4.7% in Rhode Island to 14.5% in Delaware); and lower or no copayment (from 56.6% in Utah to 72.8% in California). Furthermore, mean days' supply per fill (from 43.1 in Arkansas to 63.8 in Maine) and patient spending per therapy year (from $38 in Hawaii to $76 in Georgia) varied. Concentration of adherence factors differed by market segment. Patients aged 18 to 64 with a primary care physician prescriber and Medicaid coverage had the lowest concentration of fixed-dose combination fills, mean days' supply per fill, and patient spending per therapy year. Patients aged 65 years or older with a primary care physician prescriber and commercial insurance had the highest concentration of fixed-dose combinations fills and mail order fills.

Conclusion

Addressing regional and market segment variation in factors promoting blood pressure medication adherence may increase adherence and improve hypertension management.

Introduction

Hypertension is highly prevalent in the United States, affecting almost half of US adults (1). In most cases, hypertension can be effectively managed through lifestyle modification and often with pharmacologic therapy (2,3). However, around three-fourths of US adults with hypertension have blood pressures (BPs) above the thresholds recommended in current guidelines, placing them at increased risk for heart disease and stroke (2).

Medication nonadherence, defined as patients not taking medication as prescribed by their health care provider, is a modifiable barrier to effective management of hypertension and other chronic diseases. Nonadherence increases US health care costs by hundreds of billions of dollars annually (4), often because of the increased risk for cardiovascular events such as myocardial infarction and stroke (4). BP medication nonadherence is highly prevalent and varies by geography and patient demographics (5,6). Multiple prescription- and payment-related factors have been identified that can improve BP medication adherence, thereby increasing the number of patients who achieve a BP goal (7). Prescription-related factors are prescribing fixed-dose combination medications to reduce total pill consumption (8), using mail order prescriptions to address barriers in access to retail pharmacies and to make acquiring prescriptions more convenient for patients (9), and increasing the days' supply per fill to decrease pharmacy visits (10). Payment-related factors to reduce financial barriers are prescribing low-price generic formulations (11), using medications with lower or no patient copayments (12), and minimizing overall out-of-pocket costs for patients (13).

Previous research has described national trends in prescription- and payment-related factors that promote improved BP medication adherence (14). However, we are unaware of any study assessing state and regional variation in these factors, especially by market segment. Therefore, we used data representing most prescription BP medications filled from US retail and mail order pharmacies in 2017 to describe geographic variation in these adherence promotion factors across the largest market segments (ie, combinations of prescriber type and primary insurance payer type), by patient age group, and by US Census region. These findings can inform strategies to improve BP medication adherence and hypertension control.

Methods

We obtained prescription fill data through Symphony Health's 2017 Integrated Dataverse (IDV) (15). The IDV contains data on over 90% of outpatient prescription fills from retail and mail order pharmacies, and combined with market purchasing data, creates national fill and spending estimates. Symphony Health provided data on aggregate number of fills, therapy days, and spending, including total spending and patient spending, for BP medication. These data are presented by 3 patient demographics (age group [18–64 y or ≥65 y], US Census region [northeast, midwest, south, west], and the state the prescription was prescribed in); by 4 prescriber specialties: primary care physicians (PCPs) (includes family practice, internal medicine, and osteopathic medicine], cardiologists, nurse practitioners and physician assistants, and other physician prescribers); 2 pharmacy types (mail order and retail); 2 formulation types (brand and generic); and 4 primary payer types (patient out-of-pocket, commercial insurance, Medicare Part D, and Medicaid). Fills that contained more than one BP-lowering medication per pill (ie, fixed-dosed combinations) were counted by the total number of drugs contained when determining the total number of medications filled and total therapy years (1 therapy year equals 365 days of available medication) of BP medication dispensed.

Descriptions of adherence promotion factors related to prescriptions and payment used in our study are available elsewhere (14). Briefly, prescription-related factors are the percentage of fills that were for fixed-dose combination, the percentage that were fills by mail order, and the mean number of days' supply per fill, defined as the length of time before a prescription would need to be refilled. Payment-related factors are the percentages of fills for generic formulations and fills with lower or no patient copayment ($5.00 or less per fill), and patient spending per years' supply of medication (estimated cost of having medication on hand for 365 days). To account for missing values in patient spending (2.6% of fills), we calculated patient spending-value means stratified by medication class (eg, β-blockers) and payer type and applied them to the respective combinations to impute missing values.

Concentration ratios (CRs) were used as a measure of how concentrated a promotion factor was within each market segment (combination of the 4 prescriber types and 4 payer types) and US Census region compared with that observed nationally among all prescribers and payers combined. First, the 3 market segments accounting for the highest number of fills among adults aged 18 to 64 or 65 or older were identified at the national level. CRs were then calculated by dividing the medication adherence promotion factor value observed for those 3 market segments within each region by the value observed nationally. For example, a CR was calculated for the percentage of fills acquired via mail order (an adherence promoter) among patients aged 18 to 64 in the South Census region who had a primary care prescriber and Medicaid

coverage (market segment) divided by the overall percentage of fills acquired via mail order observed nationally. CRs greater than 1.0 imply an overall higher concentration of that factor within that specific market segment and US Census region compared with what is observed nationally among that age group.

Analyses were conducted in SAS version 9.4 (SAS Institute, Inc). The Human Subjects Review Board of the Centers for Disease Control and Prevention (CDC) deemed use of these de-identified, aggregate data exempt from institutional review board review.

Results

In 2017, 706.5 million BP medication prescriptions were filled, representing approximately $29.0 billion in total spending, including $4.9 billion in patient spending (Table 1). PCPs were the most frequent prescribers (59.7% of all fills) and commercial insurance the most frequent payer (46.0%). Patients aged 18 to 64 accounted for most fills (52.6%) and patient spending (51.0%), although patients aged 65 or older accounted for most total spending (53.9%).

Nationally, 11.9% of all fills were fixed-dose combinations (range, 5.8% [Maine] to 17.9% [Mississippi]), 97.4% were for generic formulations (range, 95.2% [New Jersey] to 98.4% [Massachusetts and Minnesota]), 8.6% were obtained from mail order pharmacies (range, 4.7% [Rhode Island] to 14.5% [Delaware]) and 65.9% had lower or no copayment (range, 56.6% [Utah] to 72.8% [California]) (Table 2). On average, 1 year of therapy for a single BP medication cost patients $50 out of pocket (range, $38 [Hawaii] to $76 [Georgia]), and fills had a mean days' supply of 51.3 days (range, 43.1 [Arkansas] to 63.8 [Maine]). Fixed-dose combination fill rates were highest in the South (median, 13.8% of all fills; range, 10.7% [Florida] to 17.9% [Mississippi]) and were the lowest in the Northeast (median, 9.3% of all fills; range, 5.8% [Maine and Massachusetts] to 13.2% [New Jersey]). Generic formulation fill rates were high throughout the country. Use of mail order pharmacies was lowest in the South (median, 8.0%; range, 5.2% [Mississippi] to 10.2% [Virginia]) and highest in the Northeast (median, 9.8%; range, 4.7% [Rhode Island] to 14.5% [Delaware]). The South had the highest percentage of fills with lower or no copayment (median, 65.3%; range, 61.1% [Texas] to 70.5% [Louisiana]). In contrast, patient out-of-pocket spending per therapy year was highest in the South (median, $51 per therapy year; range, $43 [Florida] to $76 [Georgia]), driven, at least in part, by the South having the lowest median for mean days' supply per fill (median, 49.9 days; range, 43.1 [Arkansas] to 59.6 [Maryland]). The West had the lowest patient out-of-pocket spending per therapy year (median, $47; range, $38 [Hawaii] to $54 [Colorado]), and the Northeast had the highest median for mean days' supply per fill (median, 55.8 days; range, 44.7 [Rhode Island] to 63.8 [Maine]).

More than 50% of all BP medication fills observed nationally were concentrated in the 3 largest market segments (prescriber–payer combinations) for each age group (Table 3). Among adults aged 18 to 64 years, the 3 largest market segments were PCPs and commercial insurance (40.5% of fills), nurse practitioners and physician assistants and commercial insurance (11.8%), and PCPs and Medicaid (8.5%). Among adults aged 65 or older, the 3 largest market segments were PCPs and Medicare (43.0% of fills), PCPs and commercial insurance (14.7%), and cardiologists and Medicare (10.2%).

CRs for the prescription-related (Figure 1) and payment-related (Figure 2) adherence promotion factors varied by prescriber–payer combination and US Census region. Fixed-dose combination fills tended to be more concentrated, regardless of age, among patients with commercial insurance compared with public insurance (Medicare or Medicaid), especially in the South (Figure 1). The lowest CRs for fixed-dose combination fills were observed among patients aged 18 to 64 with PCP prescribers and Medicaid coverage (CR range, 0.51 [West] to 0.86 [South]) and patients aged 65 or older with cardiologist prescribers and Medicare coverage (CR range, 0.41 [Midwest] to 0.58 [South]). Mail order fills were most concentrated among commercially insured patients aged 18 to 64 with PCP prescribers across all regions (CR range, 1.06 [South] to 2.09 [Northeast]) or with NP or PA prescribers in the Midwest (CR, 1.28) and Northeast (CR, 1.62), and, among commercially insured patients aged 65 or older with PCP prescribers, across all regions (CR range, 1.62 [South] to 2.74 [Midwest]). The lowest mail order concentrations were observed among patients aged 18 to 64 with PCP prescribers and Medicaid coverage (CR range, 0.03 [Northeast] to 0.15 [South]) and among patients aged 65 or older with cardiologist prescribers and Medicare coverage (CR range, 0.46 [Northeast] to 0.83 [Midwest]). Most of the variation in the concentration of days' supply per fill was observed among patients aged 18 to 64 with PCP prescribers and Medicaid coverage (CR range, 0.76 [South] to 0.84 [West]).

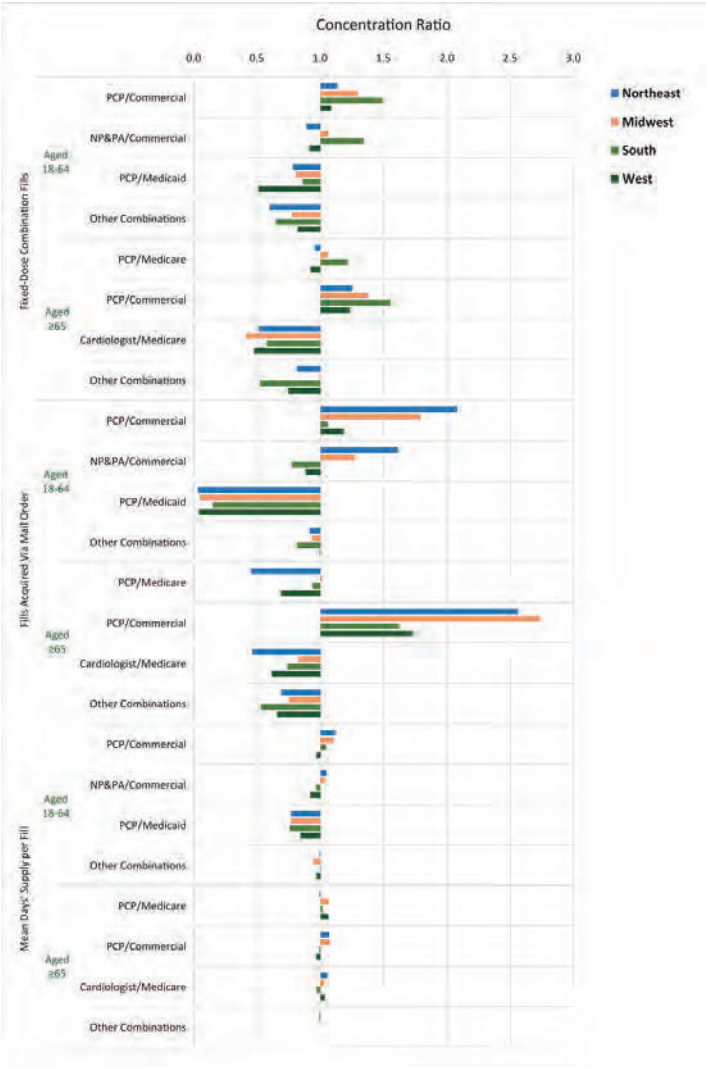

Figure 1. Concentration ratios of adherence promotion factors related to prescriptions among the largest market segments, by US Census region, 2017. Data source: 2017 Symphony Health Integrated Dataverse (15). Abbreviations: NP, nurse practitioner; PA, physician assistant; PCP, primary care physician.

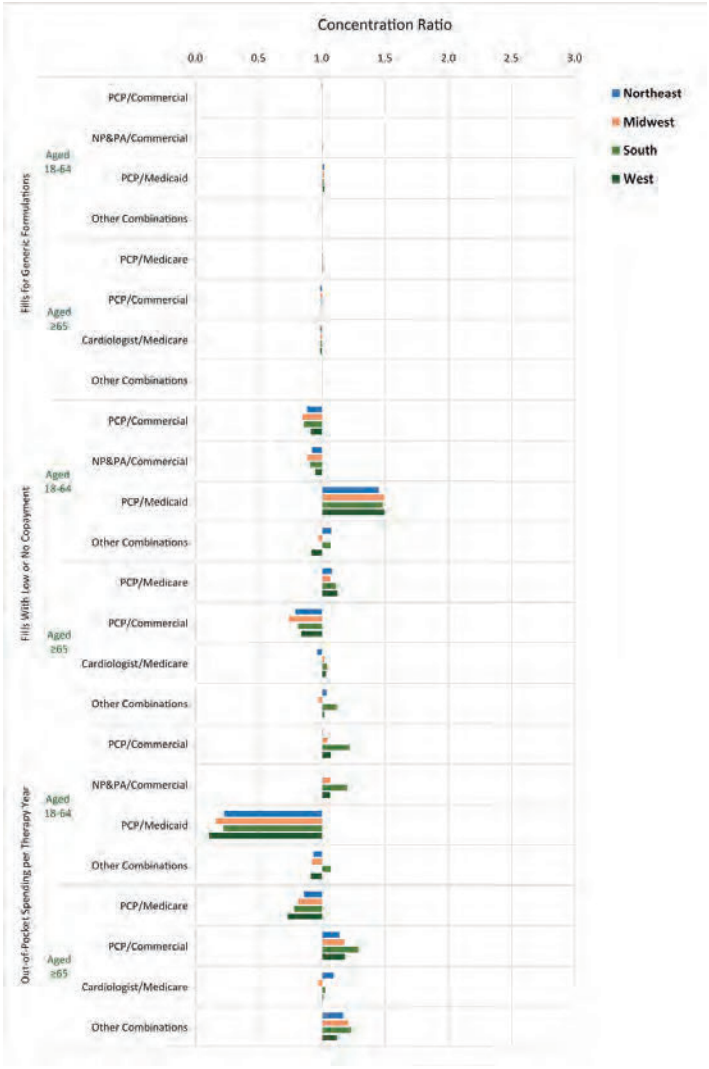

Figure 2. Concentration ratios of adherence promotion factors related to payments among the largest market segments, by US Census region, 2017. Data source: 2017 Symphony Health Integrated Dataverse (15). Abbreviations: NP, nurse practitioner; PA, physician assistant; PCP, primary care physician.

The concentration of fills for generic formulations was similar across all markets and regions for both age groups (Figure 2). The concentration of fills with lower or no copayment among patients aged 18 to 64 was highest among patients with PCP prescribers and Medicaid coverage (CR range, 1.45 [Northeast] to 1.49 [Midwest and West]) and lowest among those with PCP prescribers and commercial coverage (CR range, 0.84 [Midwest] to 0.91 [West]). The group with PCP prescribers and Medicaid coverage also had the lowest concentration of out-of-pocket spending per therapy year (CR range, 0.10 [West] to 0.23 [Northeast]), whereas those

with PCP prescribers and commercial coverage had the highest concentration (CR range, 1.01 [Northeast] to 1.22 [South]). Among patients aged 65 or older, the concentration of fills with lower or no copayment was highest among patients with PCP prescribers and Medicare coverage (CR range, 1.06 [Midwest] to 1.12 [West]) and was lowest among those with PCP prescribers and commercial insurance (CR range, 0.74 [Midwest] to 0.83 [West]). Likewise, patients aged 65 or older with PCP prescribers and Medicare coverage had the lowest concentration of out-of-pocket spending per therapy year (CR range, 0.73 [West] to 0.86 [Northeast]), whereas PCP prescribers and commercial insurance had the highest (CR range, 1.14 [Northeast] to 1.29 [South]).

Discussion

Despite the 706.5 million BP medication prescription fills that occurred in the United States in 2017, BP medication adherence (16) and BP control rates (17) are low and may be affected by the level of uptake of the adherence promotion factors assessed in this study (18). These factors include modifying how medications are prescribed (ie, prescription-related factors) and by reducing patients' out-of-pocket costs to obtain the medication (ie, payment-related factors). We found considerable variation in these factors by geography and across the largest market segments serving younger and older adults. The opportunity to increase the use of these adherence promoters, especially in the regions and populations in most need, could improve hypertension control, decreasing risk for negative cardiovascular events, including myocardial infarction and stroke.

Evidence suggests that adherence may be affected by how medications are prescribed (8–10). For example, most patients with hypertension require more than 1 medication to control their BP (19). Prescribing fixed-dose combinations for patients taking more than one BP medication has been shown to increase patient adherence by reducing the number of prescriptions they need filled and by decreasing the number of pills they need to take each day (8). However, fixed-dose combinations constituted only 12% of all national BP medication fills in 2017. Furthermore, the percentage varied considerably by geography and market segment. This includes low concentrations being observed in the South and West — regions with high rates of nonadherence (20,21) — as well as being particularly low among patients aged 18 to 64 years with PCP prescribers and Medicaid coverage. Enrollees in traditional Medicaid more often have a disability, have low income, and have higher rates of chronic disease than similarly aged people with other insurance types (22), and they traditionally have high rates of nonadherence (23). These high rates can be attributed to multiple factors (24), including limited pharmacy access (25), complex drug regimens, and poor refill consolidation (20). Prescribing fixed-dose combination drugs among this population (8), in addition to using other strategies assessed in this study, including use of mail order pharmacies (9) and increasing the days' supply per fill (10), may help address these barriers. Furthermore, evidence suggests that expanding insurance formulary restrictions or tier status of certain medications, such as generic fixed-dose combinations, within preferred drug lists (26) and covering 90-day prescriptions (27) and use of mail order pharmacies (9) can help reduce barriers to adherence. Therefore, state Medicaid programs seeking to improve their rates of BP medication adherence can consider such options. In addition, outreach to prescribers on potential barriers to adherence that Medicaid patients may be at high risk for, and outcomes of incorporating these promoters in prescribing habits, including avenues for groups to use fixed dose combinations, could support these efforts (28,29).

Improving the affordability of medications by addressing payment-related adherence factors is another opportunity to increase adherence among patients with hypertension (11–13). Minimal variation was observed in generic medication concentrations across markets, suggesting that access to these lower cost therapies is widespread. However, there was notable variation in fills with lower or no copayment and out-of-pocket spending per therapy year, especially by payer type and by region. Lower out-of-pocket spending was more concentrated in public insurance markets, especially Medicaid, while higher copayments and out-of-pocket costs were observed among patients with commercial plans, especially in the South where our analysis identified the highest rates of out-of-pocket spending per therapy year among the commercially insured in this region. Higher costs may impose a barrier to adherence, particularly for low-income patient populations for whom even low costs can be prohibitive (13), especially when these costs are compounded by complex medication regimens potentially needed for multiple comorbidities (30). These cost-related factors may be a reason for the low adherence rates seen in the South (31) and, consequently, may play a role in the region's lower BP control rates and higher rates of cardiovascular disease morbidity and mortality than in other census regions (32).

Interventions to address many of the barriers to adherence assessed in this study might require large-scale, collaborative, and long-term quality improvement efforts at multiple levels, including the individual prescriber level (15,26). Health care systems and medical practices could consider incorporating evidence-based strategies that focus on increasing uptake of adherence promotion factors among their prescribers. For example, Kaiser Permanente Northern California improved hypertension control rates by prioritizing generic and fixed-dosed combination drugs as first-line hypertension therapies in their standardized treatment approach (ie, protocol) while using multidisciplinary care teams (19). In Min-

neapolis–St Paul, Minnesota, BP control rates improved from around 30% to around 70% through collaboration with insurance companies, health care institutions, and government agencies that involved collectively developing and adopting clinical guidelines and shared goals for hypertension treatment (33). Key interventions used in these programs and prescription- and payment-related factors highlighted in our study could be replicated and translated into diverse communities to improve BP control. Furthermore, states can work with insurance underwriters (34) to create environments through health insurance market policies with incentives for adherence-promoting prescriptions, like coverage for mail order fills and low copays. Although these measures may lead to higher costs for insurance companies in the short term, they can ultimately lower costs by preventing hospitalizations for expensive acute events (35).

Our study had potential limitations. First, the indications for why medications are being prescribed and whether patients are actually taking the prescriptions they are filling are unknown. If these factors vary by patient demographics or prescriber–payer combinations, it may affect our comparisons across market segments. Second, the cross-sectional nature of this study and the inability to link prescription fill data at the patient level prevents formally establishing relationships between the promotion factors and adherence rates. However, prior studies have described these relationships (7–13). Third, we estimated fills with unknown copay amounts in proportion to fills where copays were known, possibly redistributing fills to incorrect categories. However, the impact was probably minimal because fills with unknown copays represented less than 3% of fills. Fourth, we might have underestimated patients' average spending per years' supply because our data captured only copayment-related spending and no other patient spending, including drug plan premiums and deductibles. Fifth, misclassification of payment source for some fills may have occurred. For example, fills acquired under Medicare Advantage–associated Part D plans may have been classified as having commercial payment sources and not Medicare Part D, thereby underestimating fills paid for by the latter. Sixth, we are unaware of any study assessing the relationship between the magnitude of the concentration ratios presented in this study and health outcomes. Further analyses are needed to identify meaningful cutpoints that can be applied to these ratios to help identify the market segments in most need of intervention. Finally, IDV data do not account for fills obtained through systems with their own outpatient pharmacies (eg, US Department of Veterans' Affairs, integrated private sector delivery systems, Federally Qualified Health Centers); therefore, regional comparisons may be affected by variation in penetration rates of these systems.

Our study identified considerable variation, by geography and across the largest market segments, in prescription- and payment-related factors that promote adherence to BP medication. Future research on the use of adherence promoters by prescribers and payers may identify additional opportunities for interventions. Continued assessment of these data can help evaluate public and private initiatives aimed at addressing these factors in an effort to improve adherence and optimize hypertension management.

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Tables

Table 1. Prescription Blood Pressure Medication Fills, Total Spending, and Patient Spending Among Adults Aged 18 Years or Older, by Age Group, Prescriber Type, Payer Type, and US Census Region[a], 2017

Variable	Fills					Total Spending					Patient Spending				
		US Census Region					US Census Region					US Census Region			
	US	NE	MW	S	W	US	NE	MW	S	W	US	NE	MW	S	W
Total no.[b]	706.5	162.1	141.4	285.8	117.2	29.0	6.0	7.0	11.6	4.4	4.9	1.0	1.1	2.1	0.7
Percentage of Total															
Age group, y															
18–64	52.6	50.0	52.2	53.7	53.6	46.1	43.8	45.8	48.0	45.0	51.0	45.9	48.9	54.8	49.8
≥65	47.4	50.0	47.8	46.3	46.4	53.9	56.2	54.2	52.0	55.0	49.0	54.1	51.1	45.2	50.2
Prescriber type															
Primary care physician[c]	59.7	59.1	63.2	58.7	58.3	61.2	65.4	58.5	60.8	59.2	60.3	58.3	64.4	59.7	58.7
Nurse practitioner or physician assistant	16.3	14.6	15.3	17.1	18.1	12.8	11.3	11.9	13.6	14.3	14.4	12.5	13.8	15.4	15.4
Cardiologist	11.9	13.8	10.6	12.1	10.8	14.8	18.2	12.4	14.6	14.3	13.8	17.3	11.6	13.5	13.3
Other	12.0	12.6	10.9	12.0	12.9	11.2	12.0	10.3	11.0	12.3	11.5	11.9	10.2	11.5	12.6
Payer type															
Commercial	46.0	45.5	45.4	47.3	44.0	53.8	58.1	53.5	54.2	47.7	54.1	54.0	52.9	55.6	51.7
Medicare	37.6	37.4	38.6	37.5	36.9	37.6	34.4	37.8	37.9	41.1	30.2	32.8	32.3	27.4	31.4
Medicaid	10.9	13.4	11.1	8.0	14.6	5.0	4.9	5.5	3.7	7.6	2.4	3.0	2.4	2.0	2.8
Patient self-pay	5.5	3.8	4.9	7.1	4.5	3.6	2.7	3.2	4.3	3.7	13.4	10.3	12.4	14.9	14.2

Abbreviations: NE, Northeast; MW, Midwest; S, South; US, United States; W, West.
[a] Data source, 2017 Symphony Health Integrated Dataverse (15).
[b] Number of fills is in millions and spending is in billions of US dollars.
[c] Includes family practice, internal medicine, and osteopathic medicine.

Table 2. Adherence Promoter Values for Blood Pressure Medication, Nationally and by State with Medians by US Census Region, 2017

Region	State	Fixed-Dose Combination Fills, %	Mean No. of Days' Supply per Fill	Lower or No Copayment Fills, %	Mail Order Fills, %	Generic Medication Fills,%	Patient Spending, in Millions, US$	Patient Spending per Therapy Year, in Millions, US$	Patient Spending per Therapy Year, in Millions, US$
United States overall		11.9	51.3	65.9	8.6	97.4	4,926.6	99.4	49.6
Northeast	Regional median	9.3	55.8	64.7	9.8	97.5	41.4	0.9	46.8
	Connecticut	10.2	55.7	67.4	8.2	96.1	61.1	1.2	49.5
	Delaware	12.6	61.0	60.9	14.5	96.7	15.4	0.3	47.8
	Massachusetts	5.8	52.2	67.0	9.7	98.4	106.5	2.4	43.5
	Maine	5.8	63.8	61.6	7.4	98.3	21.6	0.5	41.3
	New Hampshire	6.5	55.8	61.8	12.8	97.6	21.5	0.4	48.1
	New Jersey	13.2	56.1	61.6	12.0	95.2	174.9	3.1	56.8
	New York	11.3	49.8	69.2	8.1	96.9	303.4	6.6	46.0
	Pennsylvania	10.5	50.6	64.9	10.0	97.4	232.3	4.9	47.5
	Rhode Island	8.3	44.7	71.1	4.7	98.2	19.1	0.4	44.6
	Vermont	6.3	62.1	64.6	9.9	97.7	8.6	0.2	39.8
Midwest	Regional median	11.4	52.5	64.5	9.4	97.5	80.3	1.8	49.1
	Iowa	11.2	51.5	71.0	7.5	98.0	47.7	1.1	44.4
	Illinois	11.8	53.2	64.7	9.3	97.4	197.1	4.0	49.2
	Indiana	13.6	51.7	61.8	12.4	97.0	122.0	2.4	51.7
	Kansas	11.9	49.8	63.2	8.1	97.1	52.5	1.0	53.7
	Michigan	11.6	56.8	64.4	12.8	97.6	162.2	3.7	43.3
	Minnesota	9.6	60.2	64.3	9.4	98.4	70.7	1.6	44.4
	Missouri	10.8	49.3	65.0	9.5	97.0	110.0	2.2	49.9
	North Dakota	10.0	53.6	58.9	6.5	98.0	13.9	0.3	54.7
	Nebraska	12.6	48.6	64.8	7.6	96.8	33.7	0.6	57.1
	Ohio	12.3	49.6	65.4	12.6	97.4	212.2	4.5	46.8
	South Dakota	10.1	53.3	66.2	8.0	97.7	13.8	0.3	49.1
	Wisconsin	10.0	60.2	62.0	11.2	97.8	89.9	1.9	46.5
South	Regional median	13.8	49.9	65.3	8.0	97.5	93.4	1.9	50.5
	Alabama	16.0	53.6	61.2	6.0	97.5	96.2	1.9	50.1
	Arkansas	14.5	43.1	67.5	5.9	97.6	61.3	1.1	54.3
	District of Columbia	12.4	49.4	70.6	5.5	97.3	9.4	0.2	49.3
	Florida	10.7	54.9	70.0	7.6	97.8	296.1	6.8	43.4
	Georgia	14.5	47.0	64.1	5.9	97.6	243.1	3.2	76.3
	Kentucky	11.9	44.6	69.4	8.7	97.5	87.0	1.9	46.3
	Louisiana	14.0	44.2	70.5	8.0	97.2	96.1	1.9	50.7

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(continued)

Table 2. Adherence Promoter Values for Blood Pressure Medication, Nationally and by State with Medians by US Census Region, 2017

Region	State	Fixed-Dose Combination Fills, %	Mean No. of Days' Supply per Fill	Lower or No Copayment Fills, %	Mail Order Fills, %	Generic Medication Fills,%	Patient Spending, in Millions, US$	Patient Spending per Therapy Year, in Millions, US$	Patient Spending per Therapy Year, in Millions, US$
	Maryland	13.7	59.6	61.3	8.8	97.2	90.6	1.8	49.8
	Mississippi	17.9	43.4	68.1	5.2	97.5	64.4	1.1	56.7
	North Carolina	13.9	50.4	64.9	8.7	97.6	168.0	3.3	50.3
	Oklahoma	12.1	52.5	63.9	6.3	97.0	65.1	1.2	52.8
	South Carolina	15.5	48.7	63.3	8.3	97.5	88.3	1.7	52.3
	Tennessee	13.4	51.1	65.6	8.8	97.1	132.9	2.7	50.0
	Texas	15.1	52.0	61.1	8.1	96.9	431.8	7.3	59.1
	Virginia	13.3	51.1	61.4	10.2	97.4	130.7	2.5	52.5
	West Virginia	11.6	47.3	69.8	8.6	97.6	37.8	0.8	45.2
West	Regional median	10.8	52.7	65.1	8.1	97.9	29.8	0.6	46.6
	Alaska	11.0	59.1	64.3	8.1	95.6	8.0	0.2	51.5
	Arizona	9.2	51.5	65.1	8.0	97.6	81.8	1.6	49.6
	California	9.4	47.9	72.8	5.3	97.8	332.8	7.5	44.3
	Colorado	11.7	53.8	59.5	10.0	97.2	52.9	1.0	53.5
	Hawaii	12.3	60.1	61.5	6.5	98.1	12.4	0.3	38.2
	Idaho	11.0	55.2	64.4	7.3	97.9	21.1	0.5	46.6
	Montana	9.6	52.7	66.7	8.7	98.3	14.0	0.3	45.5
	New Mexico	10.4	50.3	68.0	8.1	98.3	22.1	0.5	45.8
	Nevada	11.5	49.8	66.1	8.7	97.8	35.4	0.7	49.5
	Oregon	8.4	51.5	69.5	7.0	98.1	44.8	1.1	42.5
	Utah	14.6	53.8	56.6	7.8	98.0	29.8	0.6	53.3
	Washington	8.1	50.8	68.8	8.9	97.9	73.7	1.7	42.4
	Wyoming	10.8	54.6	58.5	9.0	97.3	8.8	0.2	58.0

Table 3. Prescription Blood Pressure Medication Fill Market Share by Prescriber Type, Payer Type and Patient Age Group[a], 2017

Payer and Prescriber Combination	18–64 Years		≥65 Years		All Ages
	Market Share, %	Top 3 Rank[b]	Market Share, %	Top 3 Rank[b]	Market Share, %
Commercial insurance					
Primary care physician	40.5	1	14.7	2	28.3
Nurse practitioner or physician assistant	11.8	2	2.6		7.4
Cardiologist	6.4		3.9		5.2
Other	7.8		2.3		5.2
Medicare					
Primary care physician	5.7		43.0	1	23.4
Nurse practitioner or physician assistant	2.1		8.8		5.3
Cardiologist	1.0		10.2	3	5.4
Other	1.6		6.8		4.0
Medicaid					
Primary care physician	8.5	3	2.3		5.6
Nurse practitioner or physician assistant	4.2		0.5		2.5
Cardiologist	1.3		0.5		0.9
Other	2.4		0.4		1.5
Patient self-pay					
Primary care physician	3.8		2.4		3.1
Nurse practitioner or physician assistant	1.7		0.6		1.2
Cardiologist	0.5		0.6		0.5
Other	0.6		0.4		0.6

[a] Data source: 2017 Symphony Health Integrated Dataverse (15).
[b] Used to identify the top 3 prescriber and payer combinations (market segments) for each age group to determine the greatest concentration of blood pressure medication fills.

PREVENTING CHRONIC DISEASE
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GIS SNAPSHOTS

Mapping Community Opioid Exposure Through Wastewater-Based Epidemiology as a Means to Engage Pharmacies in Harm Reduction Efforts

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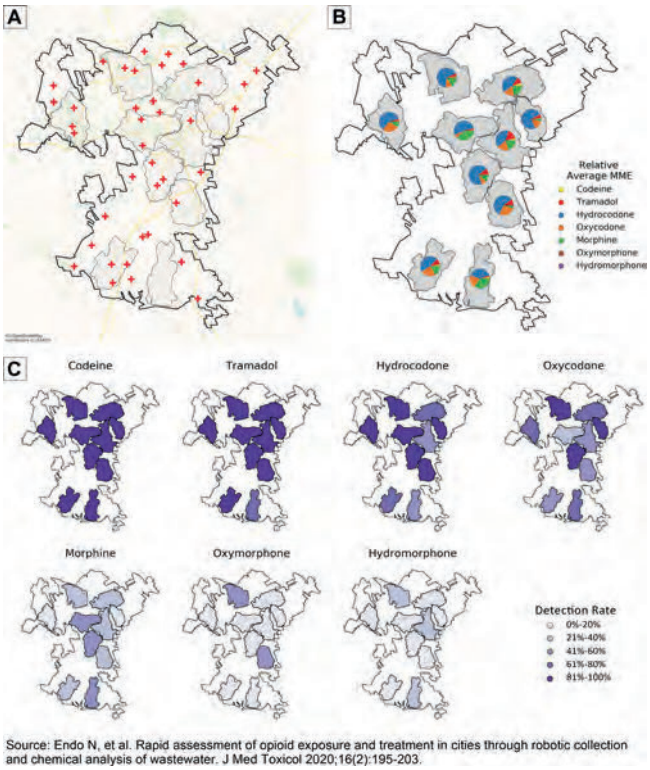

Source: Endo N, et al. Rapid assessment of opioid exposure and treatment in cities through robotic collection and chemical analysis of wastewater. J Med Toxicol 2020;16(2):195-203.

Map. Wastewater-based monitoring of opioid exposure from a pilot study conducted in North Carolina, June–November 2018. Opioid exposure was determined by measuring the concentration of opioid metabolites in sewage using LC-MS/MS. Mapping exposure within cities highlights priority substances and areas for tailoring harm reduction efforts. Map A shows anonymized outline of the municipality, sampling locations, and pharmacies. Map B shows relative average exposure to prescription opioids, highlighting priority substances in each location. Map C shows detection rates for each opioid, showing geographic patterns of opioid use and identifying municipality-wide priorities. All geographical data are anonymized, are for illustrative purposes only, and have no relation to the original location of the study. Abbreviation: LC-MS, liquid chromatography–mass spectrometry; MME, morphine milligram equivalents; MS, mass spectrometry.

Background

The opioid epidemic is an unprecedented public health crisis in the United States. Community pharmacies are important stakeholders in detecting and addressing opioid misuse. Neighborhood pharmacies are the primary distributors of naloxone and are critical access points for individuals who get opioid prescriptions filled (1). They are ideal locations where referral to substance use disorder treatment, initiation of medication assisted therapy, or community outreach can occur (2,3). Despite this, pharmacies are not fully integrated into opioid response; pharmacists have less information than physicians do about the local milieu of nonmedical opioid use (4–6). Mapping opioid exposure in areas surrounding pharmacies can provide important insights to pharmacists about the prevalence and patterns of opioid use and potential misuse. These maps may also enable pharmacies to function as novel, nontraditional sites that link individuals who have opioid use disorder to formal treatment programs (7).

Visualizing opioid exposure in communities can be accomplished using wastewater-based epidemiology (WBE) (8,9). In WBE, the concentrations of metabolites excreted after drug exposure are measured from city sewers, providing naturally de-identified data on opioid exposure within a community. Combined with geographic information systems techniques, maps of community-level opioid exposure and potential hidden populations of opioid use can be generated. These maps can in turn provide an evidentiary basis for deployment of pharmacy-centered public health responses.

Data and Methods

The maps depict anonymized results from a pilot study of wastewater opioid monitoring in a municipality in North Carolina from June through November 2018. All geographies were manually distorted at the request of the municipality to preserve anonymity. The map presented has no relation to the original pilot study location. Pharmacy locations represent the same total number and number in each sampling location as in the original study but are otherwise randomly located (Map A). In the pilot study, discussions with the municipality were based on the original nonanonymized maps.

Wastewater data were collected and processed as described by Endo et al (8). Twenty-four-hour aggregate samples were collected from 10 residential manholes every 2 weeks from June through August and monthly from September through November 2018. Opioid metabolites were measured and quantified using LC-MS/MS (liquid chromatography–mass spectrometry/mass spectrometry) and converted to morphine milligram equivalents (MME) as described previously (8,9). Relative average MME (Map B) was calculated by taking the average of each opioid over the sampling period. Detection rates (Map C) were calculated as the number of non-zero samples divided by total successful samples in each location. Maps were created in Python 3 (Python Software Foundation). Code to reproduce these analyses is available at https://github.com/biobotanalytics/gis-snapshot-opioids-public.

Highlights

Map A provides an overview of the sampling locations and pharmacies within the community. Map B quantifies opioids relative to one another in each sampling location after correcting for potency (ie, by converting to MME) and highlights priority substances in each location so that pharmacists can counsel individuals seeking opioids of potential misuse in their neighborhood. Map C shows detection rates of select opioids, allowing for citywide comparisons. This visualization demonstrates patterns of drug exposure across a community, highlights areas with particularly high or low exposures to different opioids, and indicates which opioids have ubiquitous community-level exposure versus those with geographical specificity.

These maps display 3 points that are immediately actionable by public health officials and pharmacies. First, they highlight key opioids of importance in specific areas within a community. For example, oxycodone exposure varies throughout the city (Maps B and C), which could be a result of differences in community consumption, prescribing practices, or drug availability. Such maps may trigger pharmacies to initiate oxycodone-specific drug "take-back" programs in areas with high exposure to this opioid. Second, WBE maps reflect the pattern of opioid exposure across a city. For example, despite being ubiquitously detected across all sampling locations (Map C), codeine does not contribute much to the overall opioid burden (Map B). This may be in part driven by codeine's low potency relative to the other opioids (codeine has an MME of 0.15; 6.7 mg of codeine is equivalent to 1 mg of morphine) or by technical factors that result in more reliable detection of its metabolite in wastewater. In contrast, hydrocodone contributes to more than half of the total opioid burden in all sampling locations (Map B), so targeting it rather than codeine may be more effective for interventions like drug take-back campaigns. Third, monitoring and mapping community-level wastewater-based opioid exposure over time can indicate when specific opioids enter the community and inform pharmacists in assessing the effectiveness of their opioid-related outreach and harm reduction efforts.

Action

Maps of wastewater-based opioid exposure within cities can be used to target new policies and programs geographically within a community, facilitate partnerships and coordination between stakeholders involved in opioid response efforts, monitor the effect of interventions on community health over time, and tailor educational materials to the substances being consumed in each community. In this pilot study, wastewater-based data were used to initiate more than 30 community conversations about opioid use disorder with neighborhood and civic groups, churches, and the chamber of commerce; modify public educational and outreach materials in local and national media outlets; and inform drug disposal locations for National Prescription Drug Take Back Day, leading to a twofold increase in the prescription medications taken back by community leaders (10).

WBE can also be used to integrate pharmacies into the opioid response. For example, WBE could be used to find pharmacies frequented by opioid "shoppers" (11). Pharmacies with many more prescriptions filled than their community's respective opioid exposure could be flagged as potential "shopping" locations and their opioid prescribing policies subsequently reviewed. Additionally, despite standing orders that authorize most US pharmacies to dispense naloxone, inadequate training and lack of patient education prevents many from doing so (12). Communities with high overdose rates but low wastewater-based naloxone exposure could be promising targets for educational campaigns, supporting pharmacists in those communities to dispense naloxone and educating the public on its availability.

Finally, hidden populations with opioid use disorder who overdose and receive naloxone but do not present to traditional health care centers may present to pharmacies for naloxone refills. These and other vulnerable populations could benefit from pharmacy-centered interventions informed by WBE maps (13). WBE fills important data gaps, providing information on all individuals within a community regardless of their access to health care, and informs pharmacists about opioid use in their local communities. Together, WBE and mapping techniques provide actionable information for public health officials, pharmacies, and other stakeholders involved in opioid response efforts.

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ESSAY

Louisiana State Policies Prove Problematic for Pharmacist–Physician Collaboration

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In a nation that spends more than 17% of its gross domestic product on health care, where health care costs are rising faster than costs in any other industry, one of our roles as public health practitioners is to identify and promote efficient care-delivery models (1). Well-Ahead Louisiana, a chronic disease prevention and health care access initiative of the Louisiana Department of Health, helps health care facilities identify and implement strategies to optimize efficient care. Well-Ahead Louisiana has partnered with pharmacists to increase the use of collaborative drug therapy management (CDTM) agreements, a proven method for improving patient outcomes by maximizing the pharmacist's ability to practice at the top of their license in a team-based setting (2). True collaboration between clinicians and pharmacists, leveraging the unique expertise of both providers, has demonstrated significant improvements in patient outcomes (3,4). However, we encountered legal restrictions that prohibited small, rural pharmacies in Louisiana from establishing such agreements. Rural regions of Louisiana are more likely than nonrural regions to be designated as primary care health provider shortage areas (HPSAs) and could benefit most from the improved provider coordination that CDTM provides. We believe altering these regulations will make CDTMs a viable tool for pharmacists in rural Louisiana.

CDTM agreements, also known as collaborative practice agreements (CPAs), are legal accords between a pharmacist and a provider that allow the pharmacist to assume increased responsibility over patient care functions. First initiated in Washington State in 1979, CDTM agreements permit pharmacists, without the direct approval of a physician, to initiate, modify, or discontinue drug therapy, order and interpret laboratory tests, and advise patients on control of chronic conditions. Currently, 48 states and the District of Columbia have some form of authorized CDTM (5). The efficiencies created by CDTM have increased access to care, facilitated patient care management, and improved chronic disease outcomes, such as blood pressure control and hemoglobin A_{1c} regulation among people with diabetes (2).

In July 2018, Well-Ahead Louisiana launched an initiative to increase use of CDTM to treat heart disease and diabetes in rural areas. Because Louisiana has the fourth-highest diabetes prevalence and fifth-highest heart disease prevalence in the nation, our team targeted 4 geographic regions of the state, primarily rural, where the burden of these diseases was greatest (6). To assess pharmacists' use of and familiarity with CDTM, Well-Ahead Louisiana fielded a SurveyMonkey questionnaire to 55 community pharmacies, 15 of which responded, and also conducted a short telephone interview with similar questions among 7 hospital pharmacies. Of the 22 respondents, only 1 pharmacist reported participating in an active CDTM. Answers ranged from "familiar" to "no experience" with CDTM, and several noted a lack of knowledge of the requirements and benefits of CDTM among pharmacy staff members and leadership. We also contacted the Louisiana Board of Pharmacy and the Louisiana State Board of Medical Examiners, reviewed CDTM policies in other states, and reviewed available online resources in Louisiana. According to Louisiana Board of Pharmacy records, only 75 (<1%) of the 9,087 licensed pharmacists in Louisiana participate in an active CDTM. After the interviews, Well-Ahead selected 2 rural hospital pharmacies and 1 community pharmacy to pursue the establishment of a CDTM agreement based on readiness and location in Well-Ahead Louisiana's priority regions.

Well-Ahead Louisiana has developed Louisiana-specific tools for CDTM and made them available to providers and pharmacists on its website (www.walpen.org/mtm). These tools include provider outreach guides, an overview of Louisiana regulations and requirements, and worksheets to assess readiness and capacity. In providing this technical assistance, Well-Ahead identified several barriers to establishing CDTM agreements:

- Agreements in Louisiana limit pharmacists to treatment of anticoagulation, diabetes, asthma, and dyslipidemia; smoking cessation; and providing vaccinations unless approved by the Louisiana State Board of Medical Examiners, despite evidence demonstrating CDTM benefits for other purposes, such as hormonal contraception, hepatitis C treatment, and HIV treatment (2).
- Louisiana is among 22 states that allows only a physician to collaborate (7), restricting CDTM agreements to a collaboration between a pharmacist and physician only. Of the 48 states that allow CDTM agreements, 23 allow any prescriber to enter into the agreement, and 3 allow any physician or nurse practitioner.
- The collaborating physician must be "physically present daily" to enter into such an agreement (8). Louisiana is 1 of only 3 states with such a proximity requirement; a fourth state requires the physician and pharmacist be located in the same practice (7).
- The paperwork associated with a CDTM is extensive. In contrast to less burdensome requirements in several other states (7), Louisiana requires documentation of demographic characteristics, the condition to be managed, drug substitutions, and the type and extent of drug therapy management for each patient. Detailed follow-up documentation of all physician consultations with the pharmacist and monthly patient status reports must be available in the event of an inspection. Adding to the administrative burden, agreements must be renewed annually and approved by the Louisiana State Board of Medical Examiners (9).

As we delved into the effect of these stipulations, we found that they rendered CDTM agreements impractical for many providers.

One of our partner sites, an independently owned community pharmacy, was interested in collaborating with a nearby rural health clinic. Both providers were eager to use a CDTM agreement as a tool to support their collaborative management of a subset of patients with diabetes. However, as with many rural providers, the clinic was managed by a nurse practitioner under another collaborative practice agreement with a physician who was only occasionally present onsite. Clarification from the Louisiana State Board of Medical Examiners indicated that the physician could not participate in CDTM because the physician was not physically present at the clinic at all times. The nurse practitioner is not considered an eligible provider for a CDTM agreement in Louisiana. Therefore, the agreement could not be pursued.

Another of our partner sites, a rural hospital pharmacy, planned to provide medication therapy management (MTM) services to patients referred by a nearby heart specialty clinic. Both parties were interested in pursuing a CDTM agreement as a tool to strengthen the benefit of the MTM visit. However, patients selected by the heart specialty clinic for MTM were often referred to the hospital pharmacist within 24 hours of seeing the physician and then seen by the pharmacist within 48 hours. This created only a 3-day window for a unique order set to be documented, including patient consent. Both parties preferred to continue using traditional authorization pathways rather than hurriedly submitting the paperwork required for CDTM.

On the basis of our experience with our 3 partner pharmacies, in addition to feedback from the 15 community pharmacies and 7 hospital pharmacies surveyed, we believe several changes to the current CDTM rules could increase use of CDTM and improve patient outcomes in Louisiana. We know of no historical barriers in Louisiana that would prevent consideration of these changes.

- In consultation with specialist stakeholders, consider adding hormonal contraception, hepatitis C, and HIV to the conditions and diseases eligible for CDTM agreements.
- Expand the definition of providers eligible to participate in a CDTM agreement to include nurse practitioners and other advanced-practice nurses. This expansion would increase the number of primary care sites that can participate, particularly in rural areas. Louisiana ranks 30th nationally in the number of primary care physicians per 100,000 residents (10), and more than 84% of the state's land area is designated as a health professional shortage area by the Health Resources and Services Administration (HRSA) (Figure). It is of critical importance to the health of rural residents that providers and pharmacists in these underserved areas have opportunities to maximize their collaboration, thereby expanding treatment options for those residents.

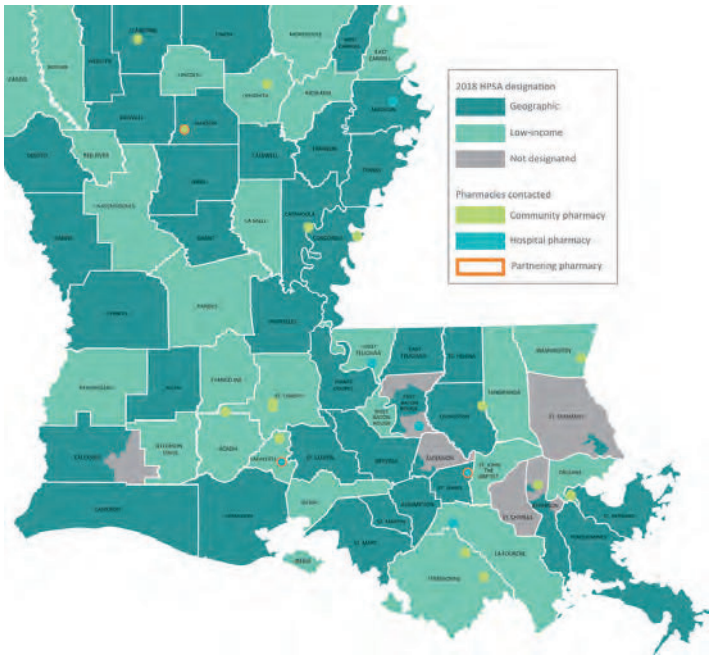

Figure. Location of geographic health professional shortage areas (HPSAs), low-income HPSAs, and 22 pharmacies that participated in a study on pharmacist–physician collaboration through collaborative drug therapy management (CDTM) agreements. A geographic HPSA designation is determined by the Health Resources and Services Administration (HRSA) as the ratio of the number of primary care providers to the number of people in a census tract, and a low-income HPSA designation is determined as the ratio of the number of primary care providers to the number of low-income people in a census tract (11).

- Allow eligible providers to enter into a contract as long as they can be "physically present as needed," rather than at all times. This modification would bring Louisiana in line with most other states offering CDTM, which do not have such strict physical proximity requirements. These states demonstrate that requiring the physical presence of a provider at all times is not necessary for the viability of CDTM.
- If CDTM agreements are to become viable tools for pharmacists, the record-keeping burden must be reduced. Many states allow a CDTM agreement to define the scope of care, outlining what the pharmacist is authorized to do and for which diseases or conditions, rather than requiring the agreement to include the names of covered patients, as Louisiana does (7). This change would provide more flexibility for the collaborating providers to add new patients without having to update the agreement. Further, the CDTM could cover prospective patients, including those referred within a short time frame, such as in the example of the rural hospital described earlier. Removing the annual renewal requirement would also reduce the administrative burden of CDTM.

We believe any or all of these changes would increase the number of pharmacists participating in CDTMs in Louisiana. Pharmacists we have spoken with have demonstrated a strong interest in partnering with their physician counterparts, but the perceived and experienced barriers of CDTM have discouraged them from pursuing such an agreement. CDTMs are a powerful tool that can improve care for patients with chronic disease and empower our medical workforce to provide care at the top of their license. By removing these restrictions, we can maximize the agreements' functionality and allow pharmacists to adopt a stronger role in chronic disease treatment.

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