Community Pharmacy Enhanced Dispensing Model to Improve Medication Access for Rural Patients Living with HIV

Anushka Burde, PharmD, AAHIVP[1]; Shanna O'Connor, PharmD[1]; David Hachey, PharmD, AAHIVP[2]

[1]Department of Pharmacy Practice and Administrative Sciences, Idaho State University;

[2]Department of Family Medicine, Idaho State University

Abstract

Objective: To demonstrate the utility of a community pharmacy-centric workflow for improving access to medications for high-risk, rural persons living with HIV (PLWH) in partnership with a Federally Qualified Health Center (FQHC).

Setting: University-sponsored independent community pharmacy and rural FQHC providing care to PLWH.

Practice Description: Patient-centered Pharmacy Program is a service designed to improve access to HIV medications for PLWH in rural Idaho. The service is delivered in partnership with a 340B-covered entity (FQHC).

Practice innovation: The workflow for the service in the community pharmacy is described in detail, including time assessments and descriptions of tools and forms developed for rollout.

Evaluation: Quality improvement initiatives over three years are described.

Results: This service ensures medication access for rural PLWH and is sustainable for the community pharmacy. Expansion of services is feasible for the future.

Conclusion: This partnership may be one that could be implemented at other rural, independent community pharmacies seeking to have outreach to rural patients with chronic medication needs.

Keywords: Medication Adherence and Persistence; Underserved Communities; HIV/AIDS; Community Pharmacy

Introduction

Persons living with HIV (PLWH) with poor adherence to antiretroviral therapy (ART) are at increased risk for mortality, virologic failure, hospitalizations, opportunistic infections, and drug resistance.[1] Due to the pill burden, side effects, and drug interactions associated with ART and coexisting comorbidities, medication adherence is challenging for many patients. Despite evidence that higher adherence rates are associated with optimal viral suppression, the reported rates of adherence in PLWH in the United States (US) tend to be between 70 and 85%.[1-3] Ensuring high adherence in PLWH presents an important concern not only to individual patients, but to the public at large.

While advanced support services for PLWH exists in urban areas, many such social support services are absent in rural areas of the US. In addition to the inherent challenges of managing complex regimens, PLWH in the rural US typically have decreased access to healthcare and may face added barriers to receiving care or medications in a timely manner.[4-6]

Corresponding author: Anushka Burde, PharmD, AAHIVP
Department of Pharmacy Practice and Administrative Sciences
Idaho State University, Pocatello
921 S 8th Ave, Pocatello, ID 83209, USA
Email: burdanu1@isu.edu
Phone: 208-282-3231; Fax: 208-282-3003

In a study of adherence in patients with solid organ transplant living in the rural US, the adherence rate to complex regimens was 58%, leaving 42% of patients non-adherent; this concept would likely translate to PLWH as well.[7] One component of promoting patient adherence to ART is establishing mechanisms that increase patient access to medications. Community pharmacies have demonstrated success in delivering programs that promote patient adherence to general chronic medications such as appointment-based models and medication synchronization.[8-10] One study showed patients enrolled in such a program had three to six times the likelihood of adherence than patients not enrolled.[9]

One component to promoting patient adherence that is specific to ART is ensuring medication access from an inventory management and financial affordability standpoint. As ART medications can be incredibly expensive, many pharmacies opt not to stock them as they can carry a heavy inventory cost. As patients living in the rural US tend to have lower incomes than their urban counterparts, it is critical to have options for payment in place for patients who cannot afford their medications.[11] Partnerships between clinics and community pharmacies that help overcome some of these barriers and support PLWH in the rural US may be possible.

Objective

The objective of this project is to demonstrate the utility of a community pharmacy-centric workflow for improving access to medications for high-risk, rural PLWH in partnership with a Federally Qualified Health Center (FQHC). The authors present

their work intended with detail sufficient to permit the implementation of this workflow at other community pharmacies and are willing to share any resources described herein.

Setting
HIV care services for PLWH in eastern Idaho began in 1998 when the epidemic focused primarily on managing opportunistic infections and complications from complex antiretroviral regimens. Over the subsequent two decades, with the support from the Health Resources and Services (HRSA) HIV/AIDS Bureau (HAB) and funding through the Ryan White Part C Program (RWPC), the population grew from only a few patients to an active roster of 150 patients engaged and retained in care.

With more PLWH moving to rural Idaho, better testing and diagnosis of HIV, and patients living longer, a stable partnership has been developed between an FQHC and a RWPC-funded Family Medicine Residency training program where PLWH can receive comprehensive HIV primary care and future health care providers are trained in HIV care. The pharmacist at the clinic serves as a drug information source to the providers, identifies potential drug interactions, provides side effect management, and assesses medication adherence. The RWPC program encompasses 16 counties from two health districts in rural Eastern Idaho (approximate equivalent square mileage to the entire state of South Carolina). More than half the patients live greater than 50 miles from the clinic, driving up to three hours to receive care. This is particularly relevant as Idaho has four distinct seasons, meaning many roads are impassable in the winter months.

As the rate of PLWH moving to rural and isolated parts of Idaho increased, clinic staff experienced the recurrent problems of patients not having a pharmacy in close geographic proximity to their home, transportation barriers to accessing their pharmacy, and concerns of anonymity in small communities. Therefore, the idea grew for a partnership between the FQHC and a nearby pharmacy to meet medication-related needs of patients. In 2014, Idaho State University applied for and was awarded a Ryan White Part C Capacity Development Grant (P06HA28068) to create and implement the Patient-Centered Pharmacy Program (PCPP). The project aligned with the National HIV and AIDS Strategy Goals to 'improve access to care and improve health outcomes' and to 'reduce HIV-related health disparities'.[12] Patients were surveyed and interviewed to identify key variables as to why they chose a certain pharmacy, and what characteristics they would find appealing in a pharmacy that partners closely with their medical team.[13] From these interviews, the PCPP was created and marketed at large to the entire HIV patient population within the clinic. PCPP was thus initially focused as an expansion of a pre-existing HIV clinic delivered by the FQHC.

Practice description and initiation
The pharmacy chosen to be the collaborating site was Bengal Pharmacy, LLC, due to geographical proximity, existing business and educational relationships between Idaho State and the FQHC, and a shared commitment to education and rural patient care.

Bengal Pharmacy, LLC, is a University-sponsored non-profit community pharmacy which serves a rural patient population in Idaho. Its mission is to serve as a learning laboratory and to promote education, innovation, and research. The pharmacy is an educational facility and has extensive learner engagement opportunities for technician, pharmacy, and pre-professional students; pharmacy residents; and visiting pharmacists. Bengal Pharmacy staff primarily consists of University and pharmacy-funded pharmacists, pharmacy residents, and student interns; the staff do not have additional training specific to HIV and are therefore representative of a typical pharmacy staff across the rural US. In addition to dispensing for the local, campus-centric population, the pharmacy is a tele-pharmacy and delivers dispensing services in real time to patients living at four distant rural sites across the state of Idaho. The pharmacy operates under a 340B contract of the FQHC, which serves as the 340B covered entity.

Once the planning for PCPP was completed, program launch was coordinated by a pharmacist with 25% time dedicated to the service and the remaining time dedicated to staffing the pharmacy. The cost of this pharmacist was intended to be offset by the increase in revenue generated by the 340B-filled medications via the PCPP program. As the program grew, the role of residents, technicians, and interns was expanded to decrease the time dedicated from a pharmacist.

Practice Innovation
Summary
This is an ongoing service currently delivered in the pharmacy in partnership with the clinic. Steps for the entire process are outlined in detail below, with the intent that this might serve as a tool for other rural independent pharmacies to seek similar partnerships in their drive to promote services for PLWH in rural communities as well as other patients with access-to-care issues surrounding medications. Because rural areas are typically slower to adapt novel services, this description is innovative in that it is the first to describe a tailored approach for high-quality, low-cost medication-access-service for PLWH in rural areas of the US.

Patient identification and enrollment
While PCPP accepts enrollment from any interested patient seen at the clinic, clinic-based case managers, prescribers, or pharmacists identify patients who may benefit from PCPP and proactively recruit patients for the service. Typical characteristics of patients that are perceived to benefit from the service include rurality, comorbid diagnosis of substance abuse or other mental health disorder, adherence issues, and

polypharmacy or concerns with the patient's usual pharmacy (e.g. privacy concerns, access to affordable pricing models). The clinic-based pharmacist assesses patient's interest in enrolling in PCPP and, if the patient consents, enrolls the patient using the PCPP enrollment form (described below). Patients are informed that they are allowed to opt-out of the service at any time and there is no correlation between participation in PCPP and services received at the clinic. Enrollment forms are couriered to the pharmacy for patient enrollment.

Pharmacy workflow

Upon receipt of enrollment forms at the pharmacy, patient profiles are created and patients are identified as PCPP enrollees via pop-up notes in the dispensing software. The pop-up notes include assigned batch date, requests for adherence packaging if applicable, and a reminder for the dispensing team of the need to save labels for delivery records. Depending on the patient situation, the pharmacy either transfers pre-existing prescriptions and/or receives new prescriptions for the patient from the FQHC.

Determination of batch date

Batch date is determined based on quantity of medication the patient has. Patients new to antiretroviral Therapy (ART) are assigned to the closest batch date; an approximate count of medication on hand is determined for patients already on ART in order to identify when medication will be needed and then patients are assigned to the closest batch date from when they will need medication. Three batch dates are available every month (10th, 18th, and 30th); these dates are similar to medication synchronization dates and indicate when the patient's medications will be mailed or available for pick-up at either the clinic or the pharmacy depending on patient preference. Unlike medication synchronization, however, short or extended fills are not completed for ARVs (always dispensed as a month's supply) due to the medications being pre-packed and inventory cost burdens of unused medications. Batch dates are set earlier than the patient is due to run out of medication; this at times means the patient has up to a week of extra medication on hand, which was determined to be preferable to potentially running short on medication.

Inventory management

To keep on-hand inventory costs contained, medications are ordered three days before batch dates. If it is a 340B-eligible prescription, the pharmacy is provided with the medication in accordance with 340B contracts. Excess unopened medication is returned to the vendor weekly. On-hand medication inventory is thus kept to a minimum and inventory turns maximized to maintain a reasonable cost burden related to stocking expensive medications.

Patient tracking

When batch dates are determined, all patients are added to a spreadsheet on a designated pharmacy computer. A description of the spreadsheet and data collected is provided

in Table 1. Within the spreadsheet, the communication documentation field is used for documentation of notes between pharmacy staff members and to track patient communication as needed. The counseling field is used to document completion of monthly patient communication (typically via phone call). Each batch has an assigned staff member responsible for ensuring the monthly workflow is completed. If patients opt out of PCPP, they are moved from the list of active patients to an inactive patient list on the same spreadsheet. Patients are never removed fully from the program; inactive patients are able to re-enroll in the service at any time and both the pharmacy and clinic staff work with patients to ensure access to medications.

First fill

Depending on the patient situation, the first fill with PCPP either occurs immediately (for patients new to ARV or without medication on-hand) or patients are rolled into a batch and receive their first fill when their on-hand medication runs out. Because patients are encouraged to use a single pharmacy, whenever possible all HIV and chronic medications are transferred from other pharmacies for the first fill with PCPP and included in the batch fills. Counseling regarding the service is conducted initially at the clinic and reinforced by pharmacy staff.

Monthly workflow

The monthly workflow for PCPP is outlined in Figure 1. Assigned pharmacy staff begin working on a batch two to five days before the batch date to ensure medication packages are ready. If the batch date falls on a day the pharmacy is closed, the batches are processed on either the preceding or following workday depending on patient medication needs. When questions are resolved and counseling is provided, the staff fills all requested medications as a part of regular workflow. The pharmacy offers a free bubble packing service for medications if requested. Patients who receive mailed packages are permitted to opt-out of signing for packages and required to sign a statement of liability for this decision. Patients who prefer to pick up their medications from the clinic are added to the clinic delivery tracking form and sign for them upon pickup. The tracking forms, when completed, are returned to the pharmacy for completion of records.

Staff onboarding

Selection of appropriate staff support is essential for the success of this service. Interns and technicians (typically also part-time students) are eligible to be trained for service delivery from any year of education--the skill set sought after for ideal candidates is the key factor in determining who should deliver the service. Specific attributes and skills include: ability to work independently, responsibility, communication, detail-oriented, basic computer skills, and teamwork. Training takes roughly six weeks and consists of rotating twice through an entire workflow with other staff then working independently on an assigned batch. All staff work is double-checked by the

supervising pharmacist upon release from shadowing for at least three months and staff are given praise and critiques accordingly; when the pharmacist review results in no errors for two consecutive months, staff work is rolled into the routine 'spot check' for quality described below.

Unique payment support models
Because of the pharmacy's partnership with the FQHC, multiple payment mechanisms in addition to processing private insurance have been created to assist patients who cannot afford their medications or co-pays. Non-ARV medications are processed via 340B pricing mechanisms wherever possible, which typically reduces the co-pay cost to the patient. Most co-pays for ARV medications are zero due to patient enrollment in Idaho's AIDS Drug Assistance Program (ADAP). Non-ADAP-eligible patient's regimens are often able to be covered through manufacturer co-pay coupon cards, which are sought and processed by either the clinic or the pharmacy staff. Additionally, funding has been allocated from the Ryan White grant to help some patients. In these cases, the clinic determines eligibility and has set up an account with the pharmacy so patients can obtain their medications upon approval; the pharmacy then invoices the clinic for charges. Any patients who still have a co-pay are contacted via phone for payment information--if the patients are able to pay for the co-pay, a credit card authorization is requested over the phone for payment. If the patient cannot afford their co-pays, they are referred to the clinic's case management staff for payment resolution. This set-up has significantly reduced gaps in care for eligible patients.

Tools and forms
In addition to the patient tracking form spreadsheet described above, five additional tools have been created to streamline the service. These forms are detailed in Table 1. Copies of the forms are available from the authors upon request in a format that allows for modification to other pharmacy programs. Standardization of the information processing has been incredibly valuable to the service as it has streamlined steps, particularly those that involve medications leaving the physical pharmacy building.

Evaluation
Quality
Initial quality was ensured by a pharmacist double-check of each patient fill history monthly to ensure accurate completion of each batch. This process was maintained for one year and identified two gaps: consistency of filling chronic medications and confirming address every month. Both of these gaps were remedied via targeted training delivered through monthly meetings with intern and technician staff. After the initial year rollout, interns and technicians became proficient at independently administering this program; proficiency was defined by consistently positive feedback from patients and case managers and demonstrated capacity to work with minimal supervision.

Quality is maintained via random pharmacist-conducted checks every month. These checks are conducted for at least 50% of patients per batch and take the pharmacist approximately 30 minutes each week to complete. The random check includes confirming that all chronic and antiretroviral medications were mailed in a timely fashion, all tracking numbers were noted for all mailed packages, and the spreadsheet was updated with counseling acceptance or refusal. Patients who cannot be reached after multiple attempts or who report non-adherence are referred to both the pharmacist and clinic for further management. Suggested non-adherence from failure to pick up medications from either the clinic or the pharmacy also results in a referral.

Identified ongoing quality concerns include inconsistency between service staff, which has been partially addressed using a standard work procedure and the forms described above. At the most recent spot checks, 100% of service staff (technicians and interns) used the same question format and documentation.

Identified barriers to adherence with this service typically revolve around communication. Patients in this particular service's population are difficult to reach and most do not answer phone calls. Patients often change housing situations without informing the clinic or pharmacy; they may be unavailable to receive packages or have incorrect address information on file. Three attempts at contact are made every month and packages are sent to the address on file regardless of successful contact to ensure patient access to medications. Referrals due to potential non-adherence (repeated months with no contact, returned package, or medications not picked up) are steady at two or three patients per month. This rate is deemed acceptable due to the highly complex patient population being served. Ongoing quality checks are in place to note if this number should spike so that changes to workflow or additional patient outreach can be implemented.

Staff time requirements
At launch, the service was delivered entirely by a recently graduated pharmacist with other dispensing duties at the pharmacy. Design and rollout of the project took 4 months at 50% time, or 20 hours per week. After launch, time dedicated to PCPP averaged 40%, or 16 hours per week. This time decreased as duties were shifted to interns and workflows became standardized.

Currently, PCPP is mostly staffed by 2 interns and a certified technician. Each has an assigned batch and has 5 hours during their assigned week to complete PCPP-related duties; the remainder of their time is dedicated to routine staffing. Pharmacist oversight is currently one hour per week and limited to ensuring quality of service.

Of note, Idaho pharmacy laws are progressive and facilitate an expanded role for technicians and interns. The law, in short,

permits delegation of tasks so long as staff are appropriately trained and the pharmacist is confident in their abilities. Pharmacies interested in this service must be cognizant of their state's rules and regulations regarding delegation of tasks.

Discussion

PCPP is a demonstrated successful partnership between a community pharmacy and an FQHC that benefits the clinic, the pharmacy, and patients. It offers enhanced opportunities for additional expansion of services as well as teaching of residents and student pharmacists. Now that the model is developed, it is incredibly affordable to deliver and requires minimal oversight from a pharmacist. In pharmacies with decreased access to interns, these duties could be taken on by a trained technician without extensive alteration of the workflows presented herein.

Practice Implications

The service has been able to maintain the high outcomes expected by the clinic in terms of patient engagement and follow-up (data pending publication). Anecdotal reports from practice suggest PCPP helps engage patients who otherwise would not have access to medications and eases the burden of HIV infection. The impact on dispensing workflow has been minimized by physically separating PCPP-specific duties from usual workflow.

Parallel service lines have developed around PCPP that suggest expansion of this service is reasonable. A program has been launched to provide vaccines for patients that focuses on administration of annual influenza vaccination and completion of hepatitis and pneumococcal series. The pharmacy is building its non-HIV medication synchronization program, with planned rollout of an extended program that involves all telepharmacy sites within the year. Other partnerships focused on different patient populations have been initiated with the FQHC, including a parolee program, Hepatitis C adherence program and suboxone treatment partnership.

Inventory management has been critical to the maintenance of this program and will need continued vigilance, especially with expansion of the service. Because almost all of the medications involved are expensive, a careful balance of stock-on-hand and carrying cost must always be maintained. Pharmacies seeking to implement this or a similar service should use their inventory management resources proactively to ensure inventory costs are as contained as possible.

Future directions and limitations

While the pharmacy, clinic, and patient perspectives of this service are positive and there is belief that this service is beneficial to patients, this data is lacking. Specific problems that are identified are resolved as part of usual practice (e.g. incorrect dose written) and not currently tracked. Patients are likely more adherent than they would be without access to the service, but a comparator group is unavailable due to the nature of the clinic-pharmacy partnership and multi-variate potential impacts on adherence in this particular patient group--this metric may never be collectable.

Future directions for this service include better tracking of specific adherence interventions, resolution of prescription-related problems, and 'caught' medication errors. The program is also planning to collect formal tracking of feedback from stakeholders in order to be able to review more than anecdotal information as the program grows. Other pharmacies considering launching this or a similar service might consider tracking these factors from baseline to better assess the impact of their service and the pharmacy-clinic partnership. Future quality projects include onboarding of additional staff and expansion of the program to additional patients.

Conclusion

The workflow developed at the community pharmacy and partner FQHC is streamlined and appears to promote access to medications for PLWH in rural Idaho. It is the hopes of the authors that the information provided herein can promote development of similar services elsewhere.

References

1. Machtinger EL, Bangsberg DR. "Adherence to HIV Antiretroviral Therapy." HIVInSite. University of California, San Francisco. Published May, 2005. Available from: http://hivinsite.ucsf.edu/InSite?page=kb-03-02-09#S2X. Accessed October 30, 2019.
2. Golin CE, Liu H, Hays RD, et al. A prospective study of predictors of adherence to combination antiretroviral medication. *J Gen Intern Med*. 2002;17(10):756–765.
3. Beer L, Skarbinski J. Adherence to antiretroviral therapy among HIV-infected adults in the United States. *AIDS Educ Prev*. 2014;26(6):521-37.
4. Pellowski JA.Barriers to care for rural people living with HIV: a review of domestic research and health care models. *J Assoc Nurses AIDS Care*. 2013;24(5): 22-37.
5. Sowell RL, Christensen P. HIV infection in rural communities. *Nurs Clin North Am*. 1996;31(1):107-23.
6. Mckinney MM. Variations in rural AIDS epidemiology and service delivery models in the United States. *J Rural Health*. 2002;18(3):455-66.

7. Sankaranarayanan J, Collier D, Furasek A, et al. Rurality and other factors associated with adherence to immunosuppressant medications in community-dwelling solid-organ transplant recipients. *Res Social Adm Pharm*.2012;8:228-239.

8. Pharmacy's appointment based model: a prescription synchronization program that improves adherence. APhA Foundation website. http://www.aphafoundation.org/sites/default/files/ckeditor/files/ABMWhitePaper-FINAL-20130923(3).pdf. Published 2013. Accessed November 8 2018.

9. Holdford DA, Inocencio TJ. Adherence and persistence associated with an appointment-based medication synchronization program. *J Am Pharm Assoc (2003)*. 2013;53(6):576-583. doi: 10.1331/JAPhA.2013.13082.

10. Holdford D, Saxena K. Impact of appointment-based medication synchronization on existing users of chronic medications. *J Manag Care Spec Pharm*. 2015;21(8):662-669.

11. Bishaw A, Posey K. A comparison of rural and urban america: Household income and poverty. US Census website. https://www.census.gov/newsroom/blogs/random-samplings/2016/12/a_comparison_of_rura.html. Published 12-8-16. Accessed November 8, 2018.

12. National HIV/AIDS strategy for the United States. The Office of National AIDS Policy. https://www.hiv.gov/federal-response/national-hiv-aids-strategy/documents-and-shareables. Updated July 2015. Accessed on November 8, 2018.

13. Vickers J, Force R, Hachey D, Holmes J. Pharmacy Experiences and Expectations of an HIV Patient-Centered Pharmacy Service. Abstract presented at NAPCRG on 10/27/2015. Available from http://www.napcrg.org/Conferences/PastMeetingArchives/2015AnnualMeetingArchives/SearchEducationalSessions?language=en-US&m=0&s=hachey&p=0. Accessed November 8, 2018.

Table 1: PCPP Forms

Form name	Purpose	Fields	Additional notes
PCPP enrollment form	Used to obtain patient demographic data and history	Address, allergies, current HIV medications, third party payer, emergency contact information Check-boxes for enrollment in additional free services (enhanced medication education, bubble- packing, and side effect management) Preferred avenue for medication access (pharmacy pick-up, delivery to home/work, clinic pick- up) Signatures for permission to transfer prescriptions from other pharmacies (if applicable) Waiver of in-person receipt of delivered packages	
Patient Tracking Spreadsheet	Track and document ongoing monitoring of active patients and maintain running list of inactive patients	Batch Date Patient Name Date of Birth Communication Medication(s) Delivery Method (USPS/Clinic/Pharmacy) Patient Address USPS Tracking# Counseling (Accept/Decline/Unreachable)	
Clinic delivery tracking form	Organize and track prescriptions delivered to the clinic for patient pickup	Delivery dates, initials of person responsible for delivery, signature from patients upon receipt	Delivered with the batched medications and returned to pharmacy, monthly for verification of medication pickup
Mailing tracking form	Organize and track lists of shipped medications	Corresponding tracking numbers and shipment dates, initials of person responsible for shipping, and cost of delivery	
Medication counseling offer letter	Informs patients of the availability of medication counseling services	Written in patient-friendly language Provides the pharmacy phone number	Included in every mailed medication package
Individual patient paper file	Correlated patient-specific paperwork and documentation	Signed enrollment form, third party payer information, any other patient-specific hard-copy data	Patients that become inactive in the service: Forms are removed from active patient file folder and transferred to the inactive patient folder

Figure 1: PCPP Workflow

Pre-Batch Day Workflow

- Pharmacy staff starts working on batch two-five days before batch date
- Patient contacted and asked which medications are needed for that month, medication counseling offered, resolution of problems (e.g. copay, adherence, adverse effects)
- Refills requested from provider's office if needed
- HIV medications ordered three days before batch day
- Refills and new medications processed based on patient's response/needs
- Medications bubble packed if requested

Batch Day Workflow

- All medications checked out of cash register
- Packages containing requested medications and medication counseling offer letter are created for individual patient
- Packages directly mailed to patient, delivered to the clinic, or ready for pick up from the pharmacy
- Dispensing label sticker used to track packages that leave the pharmacy either via mail or delivery on either the clinic delivery or mailing tracking form
- Mailed packages are sent via US postal service with a tracking number which is added to mailing tracking form
- Packages for clinic delivery are hand-delivered with clinic delivery tracking form