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Implementing a pharmacist-run Lyme disease postexposure prophylaxis clinic augmented by academic detailing within the Veterans Health Administration

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ABSTRACT

Objective: To describe the implementation of a pharmacist-run Lyme disease postexposure prophylaxis (PEP) clinic augmented by academic detailing within a health care system.

Setting: Butler Veterans Affairs Health Care System.

Practice description: A pharmacist-run clinic, referred to as a PharmLD clinic, was established. A patient presenting to the health care system with a chief complaint of a tick bite would be scheduled to the PharmLD clinic for the evaluation of appropriateness of Lyme disease PEP. The pharmacist prescribed a single dose of doxycycline 200 mg and provided education on Lyme disease, provided education only, or referred the patient to their primary care provider (PCP). Academic detailing with PCPs, nurses, and pharmacists was used to improve outcomes in those not seen in the clinic.

Practice innovation: To our knowledge, the evaluation of a pharmacist-run Lyme disease PEP clinic in a health care system alone or in combination with academic detailing has not been previously described in the literature.

Evaluation: Doxycycline PEP prescriptions from April through September 2016 (pre-implementation) were compared with prescriptions from April through September 2018 (postimplementation). A retrospective chart review was performed to evaluate prescribing appropriateness on the basis of Infectious Diseases Society of America guidelines.

Results: The postimplementation group saw a 55.9% improvement in doxycycline prescribing appropriateness. The improvement in appropriateness stemmed largely from the dose and duration prescribed. Eighteen of the 39 prescriptions (46%) came from the PharmLD clinic. During the postimplementation period, 40 patients were seen in the PharmLD clinic. Of these patients, 18 were prescribed doxycycline PEP (45%), 12 received education only (30%), and 10 were referred to their PCP for further evaluation (25%). These PharmLD clinic encounters resulted in the mitigation of 30 PCP visits.

Conclusion: A pharmacist-run Lyme disease PEP clinic, coupled with academic detailing, has increased access to care and improved the quality of care received.

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Background

Lyme disease is the most common tick-borne infection in North America, with the number of cases increasing.¹ In May 2018, the Centers for Disease Control and Prevention (CDC) released a Morbidity and Mortality Weekly Report

highlighting that the number of annual reports of tick-borne bacterial and protozoan diseases has more than doubled in the United States from 2004 to 2016.² In 2015, 95% of Lyme disease cases were reported from 14 states in the upper mid-western and northeastern United States.³ It is theorized that there may be as many as 300,000 people infected with Lyme disease each year, although many go undiagnosed.⁴ In 2017, Pennsylvania, which had 28% of all Lyme disease cases within the United States, ranked first in the number of cases and third in incidence per 100,000 individuals.³ Within Pennsylvania, Butler County had the highest number of Lyme disease cases in 2016 and 2017. Untreated Lyme disease can produce a wide

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Key Points**Background:**

- The incidence of Lyme disease is steadily increasing.
- Doxycycline may be offered as Lyme disease post-exposure prophylaxis (PEP).
- A local medication use evaluation identified a Lyme disease knowledge gap with the opportunity to decrease inappropriate antibiotic prescribing.

Findings:

- A pharmacist-run Lyme disease PEP clinic, coupled with academic detailing, can improve the quality of care received.
- A pharmacist-run Lyme disease PEP clinic can increase patient access.
- Outpatient pharmacists are well-suited to perform antimicrobial stewardship.

range of symptoms, including fever, rash, facial paralysis, arthritis, and other heart and nervous system disorders.^{1,5} The CDC states that reducing the spread of these vector-borne diseases and responding to outbreaks effectively will require additional capacity at the state and local levels.²

For the prevention of Lyme disease after a recognized tick bite, the Infectious Diseases Society of America (IDSA) states that a single 200-mg dose of doxycycline may be offered to adult patients for postexposure prophylaxis (PEP) when all of the following circumstances are met: 1) the attached tick can be reliably identified as an adult or nymphal *Ixodes scapularis* tick that is estimated to have been attached for 36 hours or more on the basis of degree of engorgement of the tick with blood or of certainty regarding the time of exposure to the tick; 2) prophylaxis can be started within 72 hours of the time that the tick was removed; 3) ecologic information indicates that the local rate of infection of these ticks with *Borrelia burgdorferi* is 20% or more; and 4) doxycycline is not contraindicated.¹ With a growing shortage of primary care physicians, pharmacists are highly trained and accessible health care providers who are ideally positioned to take a more direct role in patient care.⁶ Within the U.S. Department of Veterans Affairs (VA), clinical pharmacy specialists (CPSs), serving as advanced practice providers with a scope of practice, are well-suited for this role. The scope of practice, as part of collaborative medication management, allows the pharmacist to function with a high level of autonomy and independent clinical decision-making for activities included in the scope of practice.⁷ CPSs in medication management have been shown to increase patient access as well as improve outcomes.^{8–10} Open access to care, defined as having space in the schedule of a primary care provider (PCP) for a veteran to be seen the same day, is a priority within the VA system.⁸

Given the high local Lyme disease prevalence, a medication use evaluation (MUE) was completed in 2017 for outpatient doxycycline prescriptions from the VA Butler Healthcare System. The MUE identified that Lyme disease was the primary indication for doxycycline use. In addition, the MUE identified a Lyme disease knowledge gap with the opportunity to improve prescribing practices to be more guideline-congruent.

Most antibiotic prescribing occurs in the outpatient setting; however, almost half of that prescribing may be unnecessary, establishing the need for outpatient antimicrobial stewardship.^{11–13} Locally, the MUE data further demonstrated the opportunity for outpatient antimicrobial stewardship interventions. With the increasing prevalence of Lyme disease and media publicity, our facility expected a continued growing strain on the health care system regarding access to PCPs.¹⁴ As a result, VA Butler Healthcare System implemented an evidence-based quality improvement project incorporating a pharmacist-run Lyme disease PEP clinic and academic detailing to improve access to care and the quality of care received.

Objective

To describe the implementation of a pharmacist-run Lyme disease PEP clinic augmented by academic detailing within a health care system.

Setting

VA Butler Healthcare System is a level 3 facility that offers quality health care services at its 2 main campuses in Butler, PA, and at 5 community-based outpatient clinics in Armstrong, Clarion, Lawrence, Mercer, and Butler (Cranberry township) counties. The facility serves more than 25,000 veterans in western Pennsylvania and eastern Ohio with outpatient programs generating more than 205,000 visits per year.

Practice description

In April 2018, VA Butler Healthcare implemented a pharmacist-run Lyme disease PEP clinic (PharmLD clinic), allowing CPSs in the patient-aligned care team (PACT) setting to prescribe doxycycline for PEP. A PACT setting is a health care team-based approach that allows coordinated care among team members that is personalized for each patient.¹⁵ There were 8 PACT CPSs in the ambulatory care setting performing disease state management. Before implementation, the scope of practice of these CPSs included management of diabetes, hypertension, hyperlipidemia, and anticoagulation therapy. The scope of practice for a PACT CPS was modified by the credentialing and privileging committee to allow prescribing of antibiotic PEP. The PharmLD clinic, as part of a quality improvement initiative, was approved by the Medical Executive Committee at VA Butler Healthcare and was included within the CPS scope of practice as an advanced practice prescriber. This quality improvement project was deemed nonresearch, operations-based activity, and received exemption from the institutional review board.

Patients presenting for a primary care appointment or a walk-in visit, who had a chief complaint of a tick bite, were referred by appointment schedulers to the PharmLD clinic. Once in the clinic, the CPS evaluated the appropriateness of doxycycline for PEP on the basis of the inclusion criteria shown in Table 1. If PEP was appropriate, the CPS ordered a single dose of doxycycline 200 mg and provided education on Lyme disease. If PEP was inappropriate, the CPS provided education but no doxycycline prescription. If the patient was displaying symptoms of Lyme disease, or if the CPS was unsure if a patient's clinical status warranted doxycycline prophylaxis, the

Table 1

Inclusion criteria for the PharmLD clinic to dispense doxycycline (must meet all)^a

1. Patient has a <i>Ixodes scapularis</i> tick bite with reported attachment to the skin for ≥ 36 h
2. Patient still has tick attached or has removed it within the last 72 h
3. Patient does not have a contraindication/precaution to doxycycline therapy
a. Pregnancy or breast-feeding
b. Known allergy to doxycycline
4. Patient is not displaying any signs/symptoms of Lyme disease ^b
5. Patient has not participated in this protocol within the last y ^c

Note:

^a Ecologic information indicates that 34% of Pennsylvania's *I. scapularis* ticks are infected with *B. burgdorferi* which satisfies the Infectious Diseases Society of America postexposure prophylaxis criteria component of $\geq 20\%$.²²

^b Patients with symptoms were to be seen by a provider for assessment and diagnosis.

^c Facility preference.

patient's case was discussed with their PCP and seen as a covisit on the same day if necessary. This provision was necessary as a CPS's defined scope of practice does not allow for a diagnosis to be made by the CPS. Patient education was delivered using an educational CDC brochure, "Lyme Disease: What You Need to Know."¹⁶ Areas of education emphasis included recognizing the signs and symptoms of Lyme disease and how to protect against tick bites. A standardized note template was used to document the encounter in the patient's chart within the computerized patient record system (CPRS).

The PharmLD clinic was not intended to reach all patients with a tick bite, as enrollment was not mandatory. Enrollment relied upon the scheduler recognizing a tick bite as the chief complaint and providing the patient with the option to be referred to the PharmLD clinic. Furthermore, patients presenting for any other chief complaint, or for a regularly scheduled appointment, would be seen by their PCP.

Academic detailing was used to improve outcomes in patients with a tick bite not seen in the PharmLD clinic. Academic detailing is a multifaceted educational outreach that is delivered to clinicians by clinicians with the goal of aligning their prescribing behavior with evidence-based practice.¹⁷ Typically, the clinician delivering academic detailing is a clinical pharmacy specialist with specific training. A key hallmark of academic detailing is the synthesis of the current literature and guidelines into easy-to-read information, presented through interactive discussion in a balanced and impactful way. Academic detailing has been shown to reduce inappropriate prescribing in a statistically significant manner.^{17,18} The academic detailer created educational tools and scheduled visits with the health care staff to provide information regarding relevant key messages associated with Lyme disease and proper use of doxycycline for PEP.

A Lyme disease quick reference handout was created that highlighted when to administer PEP, what the appropriate dosing of doxycycline for PEP would be, and when to order serologic testing. This quick reference handout as well as a CDC reference manual, titled "Tickborne Diseases of the United States: A Reference Manual for Health Care Providers,"¹⁹ were used as the academic detailing campaign materials. In addition, key messages, which are evidence-based behavior change recommendations that propose specific actions related to prescribing or other clinical decisions, were developed.

These key messages focused on referring patients to the PharmLD clinic for prophylaxis, ordering serologic testing only when appropriate, prescribing appropriate dosing and durations for PEP, and educating patients on the appropriate response to treatment.

Academic detailing encounters began being performed before implementation of the PharmLD clinic and continued throughout the evaluation period. Multiple clinical disciplines were targeted for academic detailing encounters, including primary care physicians and midlevel prescribers, primary care nurses, and pharmacy staff. Each academic detailing interaction was performed by an academic detailer and was typically one-on-one. The encounter was performed face-to-face or through a computerized video teleconference lasting for 15-30 minutes. The campaign materials were used to emphasize the key messages and were left with the individual at the end of the encounter. In addition, the individuals were provided with the CDC brochure, "Lyme Disease: What You Need to Know,"¹⁶ which was being used in the PharmLD clinic. Throughout the implementation, CPSs provided prospective recommendations through consultation when requested.

Doxycycline is the only antibiotic indicated for Lyme disease PEP.¹ Therefore, a list of all doxycycline prescriptions from the VA Butler Healthcare System was obtained to evaluate the appropriateness of PEP prescribing. Doxycycline prescriptions were included in the analysis if the indication was identified as Lyme disease PEP. Doxycycline scripts for Lyme disease treatment or for treatment of an alternative condition were excluded from the analysis. Prescriptions from April 1, 2016, through September 30, 2016, represented the pre-implementation phase. These prescriptions were initially reviewed as part of the MUE performed in 2017. Prescriptions from April 1, 2018, through September 30, 2018, represented the postimplementation phase. A retrospective chart review was performed to evaluate if doxycycline was being prescribed for Lyme disease PEP, and if so, if it was appropriate. The primary outcome was the overall appropriateness of doxycycline prescriptions for Lyme disease PEP. Because both interventions were part of the outpatient antimicrobial stewardship program, the primary outcome combines both the intervention groups (PharmLD clinic and academic detailing). Appropriateness was determined based on the prescription being IDSA-guideline-congruent for prophylaxis.¹ A chi-square test was used to determine the difference in doxycycline prescribing appropriateness between pre- and post-implementation groups. Statistical significance was defined as a 2-tailed alpha level of less than 0.05.

The following data were collected from the chart review: patient name, patient age, patient race, medication dispensed, quantity of medication dispensed, days' supply of medication, prescribing provider, release date of prescription, prescribing location, Lyme disease testing status, if Lyme disease treatment had been received previously, and if there was a related return visit within 30 or 90 days.

The number of PharmLD clinic encounters and their outcomes were used to evaluate the impact the PharmLD clinic had on access. To capture PharmLD clinic encounters, a list was generated of all PharmLD clinic encounter notes in the CPRS from April 1, 2018, through September 30, 2018. Subsequently, a retrospective chart review was performed to evaluate each encounter and its outcome.

Practice innovation

To our knowledge, the evaluation of a pharmacist-run Lyme disease PEP clinic in a health care system alone or in combination with academic detailing has not been previously described in the literature.

Evaluation

From April 1, 2016, through September 30, 2016, there were a total of 261 doxycycline prescriptions, 64 of which were for Lyme disease (25%). Of those 64, 22 were specifically for PEP (34%) and included in the analysis as the preimplementation group. From April 1, 2018, through September 30, 2018, there were a total of 256 doxycycline prescriptions, 90 of which were for Lyme disease (35%). Of these 90, 39 were specifically for PEP (43%) and included in the analysis as the postimplementation group.

The primary patient population in both groups were white men residing in Butler County, PA (Table 2). Previous Lyme disease treatment was similar between both groups, whereas the postimplementation group had fewer Lyme disease tests

Table 2
Patient demographics of those prescribed doxycycline postexposure prophylaxis

Characteristic	Historical 4/1/16 through 9/31/16 (n = 22)	Intervention 4/1/18 through 9/31/18 (n = 39)
Age, mean (SD) [range], y	57 (18) [23–88]	64.1 (12.5) [32–83]
Sex		
Male	22 (100%)	38 (97%)
Female	0 (0%)	1 (3%)
Race, n (%)		
White	22 (100%)	38 (97%)
Unspecified	0 (0%)	1 (3%)
Region/country of residence, n (%)		
Allegheny	5 (23%)	2 (5%)
Armstrong	2 (9%)	3 (8%)
Beaver	1 (5%)	2 (5%)
Butler	7 (32%)	22 (56%)
Clarion	3 (14%)	5 (13%)
Indiana	1 (5%)	0 (0%)
Lawrence	0 (0%)	3 (8%)
Mercer	0 (0%)	1 (3%)
Venango	2 (9%)	1 (3%)
Unknown	1 (5%)	0 (0%)
Previous antibiotic for Lyme disease prophylaxis or treatment (within 12 mo), n (%)		
Prophylaxis	3 (14%)	6 (15%)
Treatment	0 (0%)	0 (0%)
Lyme disease testing, n (%)		
Prior to prescription (24 mo)	2 (9%)	1 (3%)
At time of prescription	2 (9%)	1 (3%)
Post prescription (12 Mo)	3 (14%)	3 (8%)
Follow-up encounter for potential Lyme disease symptoms, n (%)		
30 d	1 (5%)	1 (3%)
90 d	3 (14%)	3 (8%)

performed and fewer follow-up encounters for potential Lyme disease symptoms.

The postimplementation group saw an improvement of 55.9% (95% CI 31.7–73.1; $P < 0.001$) in doxycycline prescribing appropriateness for Lyme disease PEP. The improvement in appropriateness largely stemmed from the dose and duration of doxycycline prophylaxis prescribed. The average dose prescribed increased by 61 mg between the preimplementation (136 ± 68 mg) and postimplementation groups (197 ± 16 mg), whereas the average duration of therapy decreased by 13.4 doses between the preimplementation (15.1 ± 16.5 doses) and postimplementation groups (1.7 ± 4.3 doses). A further breakdown of doxycycline prescribing appropriateness can be found in Table 3. Eighteen of the 39 doxycycline prescriptions (46%) came from the PharmLD clinic (Figure 1). All prescriptions from the PharmLD clinic were deemed appropriate on the basis of the clinic inclusion criteria shown in Table 1.

During the 6-month postimplementation period, 40 patients were seen in the PharmLD clinic. Of these patients, 18 were prescribed doxycycline prophylaxis (45%), 12 received education only (30%), and 10 were referred to their PCP for further evaluation (25%) (Figure 1). These PharmLD clinic encounters resulted in the avoidance of 30 PCP visits. In addition, CPSS were solicited for curbside consultations for 30 patients who were not seen in the PharmLD clinic, primarily regarding Lyme disease treatment.

Of the 30 patients who had an avoidance of a PCP visit because of the visit to the PharmLD clinic, 1 patient presented for a related PCP visit within 30 days (3.3%). During the PharmLD clinic appointment, this patient did not meet PEP criteria as the tick had been attached for less than 36 hours and had been removed more than 72 hours before the appointment. The patient subsequently developed symptoms 2 days after the PharmLD clinic appointment and received treatment for the suspected Lyme disease. The patient's symptoms continued, which was ultimately diagnosed as hyperthyroidism.

There were 52 encounters for Lyme disease academic detailing that occurred over the specified 6-month postimplementation time frame, reaching a total of 62 attendees: 16 providers, 25 registered nurses, and 21 pharmacists. “Face-to-face” encounter was the primary method used to perform

Table 3
Doxycycline prescriptions for postexposure prophylaxis

Characteristic	Preimplementation 4/1/16 through 9/31/16 (n = 22)	Postimplementation 4/1/18 through 9/31/18 (n = 39)
Dose, mean (SD) [range], mg	136 (68) [50–200]	197 (16) [100–200]
Duration, mean (SD) [range], doses	15.1 (16.5) [1–42]	1.7 (4.3) [1–28]
Doxycycline appropriateness ^a , n (%)		
Yes	8 (36%)	36 (92.3%)
No		
Dose/duration	9 (41%)	1 (2.6%)
Criteria	3 (14%)	2 (5.1%)
Criteria/dose	1 (5%)	0 (0%)
Criteria/dose/duration	1 (5%)	0 (0%)

Note:

^a Appropriateness was determined based on if the prescription was Infectious Diseases Society of America–guideline-congruent for prophylaxis.¹

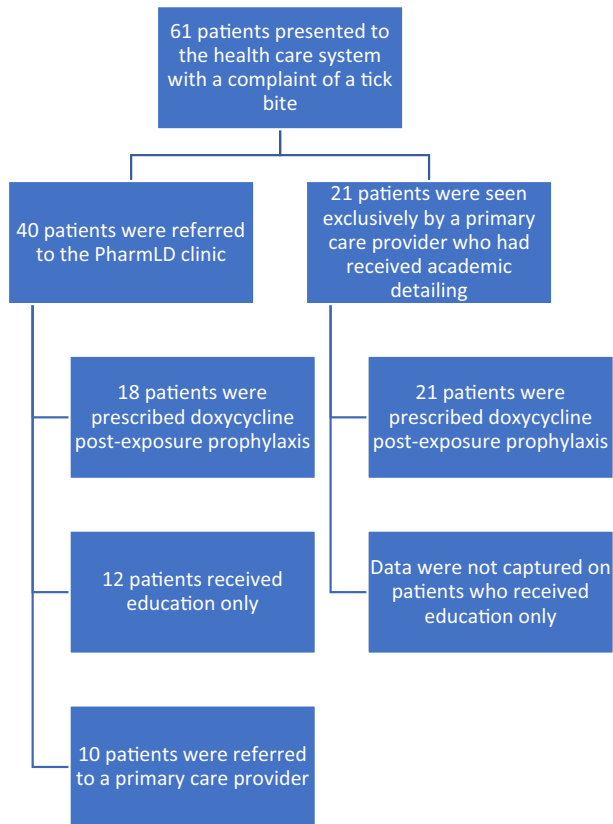


Figure 1. Depicts which intervention the patient received and the result of the encounter.

academic detailing. Academic detailing took up 18.25 hours, excluding preparation work. By the end of the post-implementation period, 84% of the PCPs had received academic detailing. All doxycycline prescriptions came from a provider who had received academic detailing.

Practice implication

Health care systems can use pharmacists as advance practice providers in clinics such as the Lyme disease PEP clinic to improve overall access to care as well as the appropriateness of care received. Academic detailing may have broader implications for outpatient antimicrobial stewardship in improving the appropriateness of antibiotic prescribing.

Discussion

The pharmacist-run Lyme disease PEP clinic, augmented with academic detailing, was associated with statistically significant improvements in doxycycline PEP prescribing appropriateness at the VA Butler Healthcare System. By prescribing doxycycline more appropriately, it is theorized that patients will have improved health outcomes, decreased likelihood of developing multidrug resistance, and decreased risk of adverse effects.

Using the PharmLD clinic and academic detailing has demonstrated a practical and sustainable strategy for VA

Butler Healthcare to expand antimicrobial stewardship in the outpatient setting. PACT CPSs typically do not participate in antimicrobial stewardship and infectious disease management but are well-suited to be involved owing to their alignment within the primary care team. As the primary care team became accustomed to CPSs in this role, further opportunities to promote antimicrobial stewardship and its principles arose. The use of academic detailing was demonstrated to be an efficient strategy that could be employed for future antimicrobial stewardship initiatives.

Our clinic differed in design from a previous pharmacist-initiated PEP study, which used community pharmacists located off-site from the primary care offices.²⁰ An independent pharmacy in Rhode Island, under a collaborative practice agreement, dispensed doxycycline to 8 patients for Lyme disease PEP. The study found a high level of patient satisfaction with no reports of subsequent development of Lyme disease symptoms or major adverse events. Our design of having the pharmacist integrated into the health care team permitted a more direct impact on prescribing practices by allowing interdisciplinary collaboration. When Lyme disease treatment was warranted, the pharmacist could present the case and provide treatment recommendations directly to the PCP. In addition, the pharmacist was easily accessible to health care professionals to answer any Lyme disease-related questions. However, this integration came at the loss of accessibility that a frontline community pharmacist position provides to patients. Community pharmacists are often visible to the public at numerous locations and for extended hours. Only 46% of the doxycycline PEP prescriptions came from the PharmLD clinic, which highlights the opportunity for the PharmLD clinic to enroll more patients. Despite this opportunity to further decrease the number of PCP visits, the data show that academic detailing improved appropriate doxycycline prescribing in those patients not seen in the clinic.

The PharmLD clinic provided a viable option to handle patients seeking Lyme disease PEP and education, ultimately increasing patient access to care. Before the clinic implementation, a patient presenting with a tick bite would put additional strain on the nurse and provider to see more patients than what their schedule allowed. The PharmLD clinic has eliminated the need for the patient to see a nurse and PCP, thus increasing their ability to care for other patients.

In the future, there are multiple ways that the VA Butler Healthcare System could further prevent Lyme disease transmission and decrease unnecessary primary care appointments. These areas of opportunity include educating patients regarding Lyme disease and PEP, treatment appropriateness, and the availability of the pharmacist-run PharmLD clinic. By providing education, it is theorized that we would reach patients who would otherwise be unaware of the opportunity for PEP, while also potentially decreasing the number of visits where PEP was not indicated. By increasing awareness of this clinic, it can be anticipated that care would shift from urgent care and emergency rooms to the primary care setting, ultimately decreasing health care costs. In addition, the PharmLD clinic could expand into the telehealth arena by using virtual video visits to reach more patients.

Although this review has shown positive outcomes at the VA Butler Healthcare System, it does have several limitations. If patients were seen outside of the PharmLD clinic through the conventional route, and doxycycline prophylaxis was not prescribed, this encounter would not have been included in the pre- or postimplementation data collection. In addition, if the patient presented to an alternate institution, such as an urgent care or emergency room, this would not have been captured as a return visit, thus decreasing the accuracy of the 30- and 90-day follow-up data. The small sample size made it challenging to capture follow-up data because of attrition, which can have an impact on the generalizability of these findings.²¹ Furthermore, it was a limitation that data were collected from a single health care system and we used a retrospective chart review, which meant that all data gathered were dependent on accurate documentation.

Conclusion

The implementation of a pharmacist-run Lyme disease PEP clinic, coupled with academic detailing, has increased access to care and improved the quality of care received at the VA Butler Healthcare System.

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