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Posted Date: 21 January 2025

doi: 10.20944/preprints202501.1487.v1

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Article

A Pilot Study Evaluating the Impact of an Algorithm-Driven Protocol on Guideline-Concordant Antibiotic Prescribing in a Rural Primary Care Setting

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Abstract: Approximately 2.8 million cases of bacterial antimicrobial resistance (AMR) infections result in over 35,000 deaths annually in the U.S. AMR is driven largely by inappropriate antibiotic prescribing, especially in clinics serving rural communities or underserved populations. Antibiotic Stewardship Programs (ASPs) improve prescribing practices, but many rural clinics lack fully functional ASPs. This pilot study evaluated the impact of an algorithm-driven protocol on antibiotic prescribing in a rural primary care setting. We conducted a pre-post quasi-experimental study at a Federally Qualified Health Center (FQHC), focusing on upper respiratory infections, urinary tract infections, and sexually transmitted infections. Eligible patients were enrolled in the study during their primary care visits. The primary outcome was the frequency of guideline-concordant treatment, analyzed using descriptive statistics and Chi-square tests. Among 201 patients (101 pre-intervention, 100 post-intervention), the pre-intervention group consisted of 77% females and 47% African Americans, while the post-intervention group consisted of 72% females and 46% African Americans. The intervention was associated with a 12.6% decrease in the number of antibiotic prescriptions discordant with clinical guidelines (37.6% to 25%) from the pre- to post-intervention periods. This corresponded to an odds ratio (OR) of 0.55 (95% CI: 0.30–1.01, $p=0.054$). Although not statistically significant at $\alpha=0.05$, this numerical decrease suggests potential benefits of algorithm-driven protocols in improving antibiotic stewardship in resource-limited settings. Longer study periods may further elucidate these benefits.

Keywords: Antibiotic stewardship program; rural health; underserved population; antibiotics; pharmacy

Introduction

Each year in the United States, approximately 2.8 million cases of bacterial antimicrobial resistance (AMR) infections result in over 35,000 deaths [1]. A significant driver of AMR is the inappropriate prescribing of antibiotics, particularly in outpatient settings, where over 50% of prescriptions are deemed unnecessary or inappropriate [2–4]. This issue is especially pronounced in clinics serving rural or underserved populations [5,6].

Fortunately, antibiotic stewardship programs (ASPs) have been shown to significantly improve antibiotic prescribing practices, as supported by a growing body of evidence in the literature [7–9].

Yet, ASPs are rarely implemented in clinics serving rural or underserved populations. While the Centers for Disease Control and Prevention (CDC) has highlighted the widespread issue of inappropriate antibiotic prescribing in rural and underserved communities—contributing to AMR and cases of *Clostridioides difficile* (*C. diff*) infections—the precise extent of this problem among rural U.S. residents or underserved populations remains unclear [10]. A 2020 cross-sectional multicenter survey of Vizient member hospitals with outpatient settings revealed that only 7% of ambulatory practices had functional ASPs compared to 88% of inpatient member institutions [11]. Of note, in the study, most of the ambulatory practices were located in urban areas. Thus, in areas where social determinants of health limit access to care or availability of resources, such as in rural areas, the number of ambulatory practices with functional ASPs is expected to be significantly lower than reported in the aforementioned study. This gap in knowledge underscores the urgent need to identify strategies to address the misuse and overuse of antibiotics in rural or underserved communities.

Several randomized controlled trials have demonstrated that strategies such as point-of-care testing, communication skills training, clinical decision support, and individualized audit-and-feedback for providers can effectively reduce unnecessary antibiotic use in primary care clinics [12–16]. However, these strategies often require substantial technical resources that may not be available or sustainable in resource-limited settings, such as rural or underserved clinics.

In an effort to better understand rural patients' and clinicians' perspectives regarding the implementation of ASPs, we conducted a survey study. The survey, conducted in a clinic serving rural or underserved populations, revealed that both patients and healthcare providers expressed openness to the implementation of ASPs [17,18]. Furthermore, as part of this endeavor to improve antibiotic prescribing in a resource-limited clinic, we tested whether pharmacist-led medication therapy management integrated with an ASP could result in positive outcomes. In this study, we performed a quasi-experimental, single-center study to evaluate the potential effects of an ASP integrated with pharmacist-led medication therapy services in a low-income clinic [19]. Using an interrupted time series analysis controlled for COVID-19 and seasonal variation, our results showed a 65.22% increase in antibiotic prescriptions per 1,000 patients immediately after the intervention (change in level = 13.284; 95% CI: [2.85, 23.72].; $P < 0.014$). However, over several weeks, the intervention was associated with a 63.69% reduction in antibiotic prescriptions per 1,000 patients (change in slope = -0.173; 95% CI: [-0.30, -0.05].; $P < 0.007$). While we controlled for the effects of COVID-19, there may have been other unobservable factors related to the unprecedented disruptions caused by the pandemic that were not accounted for [19].

Building on findings from our prior studies and acknowledging the resource constraints faced by rural clinics, we hypothesized that a low-tech approach—specifically, a simplified algorithm-driven antibiotic protocol—could effectively improve antibiotic prescribing practices in rural or underserved settings.

Thus, the objective of our pilot study was to evaluate the impact of an algorithm-driven protocol on antibiotic prescribing in a clinic serving rural or underserved communities.

Methods

Study Design

This was a pre-post, quasi-experimental study aimed at evaluating antibiotic prescribing practices in a rural healthcare setting. We developed and implemented an algorithm targeting the most prevalent infectious diseases observed in our Federally Qualified Health Center (FQHC): upper respiratory infections (URIs), urinary tract infections (UTIs), and sexually transmitted infections (STIs). Due to the significant challenges and ethical concerns associated with conducting randomized clinical trials in rural or underserved communities—particularly the ethical dilemmas of withholding potentially beneficial intervention from a control group in resource-limited settings—a pre-post design was chosen for this study to ensure that all eligible participants had access to the intervention. This study was approved by the Florida A&M University Institutional Review Board (IRB).

Data collection for the pre-intervention period was conducted from November 2023 to January 2024, while the post-intervention period occurred from March 2024 to May 2024, coinciding with patient visits. To ensure that individual patients were not re-enrolled during multiple visits, the medical record numbers of all enrolled patients were documented for both the pre- and post-intervention periods. This approach maintained the integrity of the dataset by preventing duplicate entries.

Setting and Prior Intervention

The study was conducted at a major local healthcare clinic designated as a Federally Qualified Health Center (FQHC). These federally funded, nonprofit health centers serve medically underserved populations, providing care on a sliding fee scale based on financial need. In 2023, the clinic served 53,824 patients, accounting for approximately 120,818 medical visits. Of these, 56% were covered by Medicaid, 20% were uninsured, 16% had private insurance, and 7% were enrolled in Medicare.

The clinic collaborates with four community pharmacies, all of which participate in the 340B program, ensuring access to affordable medications. Additionally, these pharmacies offer pharmacist-led home health services accredited by the Accreditation Association for Ambulatory Health Care (AAAHC) and provide telehealth services. At the time of the study, the clinic lacked an established Antibiotic Stewardship Program (ASP).

Intervention

The intervention consisted of educational sessions for all healthcare providers, focusing on antibiotic stewardship and the implications of antibiotic resistance, using guidelines and materials provided by the Centers for Disease Control and Prevention (CDC). A simplified antibiotic prescribing algorithm was developed based on Infectious Diseases Society of America (IDSA) and CDC-recommended strategies for the management of URIs, UTIs, and STIs. This algorithm emphasized appropriate dosing, frequency, and duration and was distributed to all providers to encourage adherence to evidence-based prescribing practices.

Study Population: The study included adult patients at least 18 years old who presented with symptoms consistent with infectious diseases, such as fever, cough, or dyspnea, and were diagnosed by primary care providers with upper respiratory infections (URIs), urinary tract infections (UTIs), or sexually transmitted infections (STIs). Pediatric patients under the age of 18 were excluded from the analysis, although care was provided to these patients during the study period.

Enrollment: Patients who met the inclusion and exclusion criteria were identified during their primary care visits. During these clinic visits, a pharmacy resident informed eligible participants about the study at the time of enrollment and obtained verbal consent. However, patients were not informed whether they belonged to the pre-intervention or post-intervention group. Data were collected for both the pre- and post-intervention periods.

Outcomes: The primary outcome of the study was to evaluate the change in the proportion of patients receiving guideline-concordant antibiotic prescriptions before and after the intervention. For this study, "guideline-concordant treatment" was defined as adherence to IDSA or CDC-recommended dosing strategies, including appropriate therapy duration, dosing frequency, and strength. Non-concordance was characterized by any deviations in these parameters. Diagnoses were further categorized into UTI, URI, and STI groups for analysis.

Data Collection

To assess the impact of the intervention, patient demographics, diagnoses, and prescription details were recorded in an Excel database. For each prescription, we documented the dose (strength), frequency, and duration. To further evaluate prescribing accuracy, prescription concordance was assessed in relation to patients' renal function and documented allergies. Data were collected during

the pre- and post-intervention periods to evaluate changes in antibiotic prescribing patterns and identify potentially inappropriate prescriptions. Of note, in this study, neither the researchers nor the pharmacy resident assessed the accuracy of the diagnoses. Instead, all prescription evaluations were based solely on the diagnoses documented in the electronic health record by the prescribing clinician.

Statistical Analysis:

To assess the impact of the intervention, antibiotic prescriptions for eligible patients during the post-intervention period were compared to those for eligible patients during the pre-intervention period. Descriptive statistics were reported as counts and percentages to summarize patient demographics at the time of their primary care visits. To assess whether the intervention was associated with a significant change in guideline-concordant antibiotic prescribing, a Chi-square test for independence was conducted. This test compared the proportions of guideline-concordant prescriptions between the pre- and post-intervention periods, as these groups were independent. The odds ratio and 95% confidence interval for potentially inappropriate antibiotic prescriptions will be reported comparing pre- and post-intervention periods. A priori, statistical significance was defined as $P < 0.05$ using a two-tailed test. This analysis was conducted with IBM SPSS Statistics version 29.0.2.0 (20).

Results

A total of 201 patients participated in this pilot study, with 101 patients in the pre-intervention group and 100 patients in the post-intervention group. Among the pre-intervention group, 77% of the participants were female, compared to 72% in the post-intervention group. Regarding racial demographics, 47% of the pre-intervention group identified as African American, and 41% identified as White. In the post-intervention group, 46% were African American, and 33% were White. Additional demographic details are presented in Table 1.

Table 1.

Demographics	Pre-Group (N=101)	Post-Group (N=100)
Gender		
Female	77 (76.2%)	72 (71.3%)
Male	24 (23.8%)	28 (27.7%)
Race/Ethnicity		
African American	47 (46.5%)	46 (45.5%)
White	41 (40.5%)	33 (32.7%)
Hawaiian	1 (1.0%)	2 (2.0%)
Hispanic	1 (1.0%)	3 (3.0%)
Alaskan	0 (0.0%)	1 (1.0%)
American Indian	0 (0.0%)	1 (1.0%)
Unknown	11 (11%)	14 (13.9%)
Age		
18-24	18 (17.8%)	23 (23.0%)
25-34	33 (32.7%)	27 (27.0%)
35-44	21 (20.8%)	16 (15.8%)
45-54	13 (12.9%)	18 (18.0%)
55-64	12 (11.9%)	12 (12.0%)
65 and older	4 (4.0%)	3 (3.0%)
Unknown	0 (0.0%)	1 (1.0%)
Insurance		
Private	33 (32.7%)	33 (32.7%)
Medicare	7 (7.0%)	7 (7.0%)

Medicaid	27 (27.0%)	27 (27.0%)
Uninsured	34 (33.7%)	34 (34.0%)
Diagnosis		
Chlamydia	12 (11.9%)	8 (8.0%)
Chlamydia/Trichomonas	1 (1.0%)	0 (0.0%)
Gonorrhea	7 (7.0%)	5 (5.0%)
Gonorrhea/Trichomonas	2 (2.0%)	1 (1.0%)
Trichomonas	17 (16.8%)	13 (13.0%)
Syphilis	3 (3.0%)	2 (2.0%)
Urinary Tract Infection	20 (19.8%)	16 (16.0%)
Pharyngitis	23 (22.8%)	24 (24.0%)
Sinusitis	16 (15.8%)	20 (20.0%)
Gonorrhea/Chlamydia	0 (0.0%)	2 (2.0%)
Gonorrhea/Chlamydia/Syphilis	0 (0.0%)	1 (1.0%)
Urinary Tract Infection/Trichomonas	0 (0.0%)	1 (1.0%)
Pharyngitis/Trichomonas	0 (0.0%)	1 (1.0%)
CAP	0 (0.0%)	2 (2.0%)
Upper Respiratory	0 (0.0%)	4 (4.0%)

Following the intervention, the proportion of patients receiving potentially inaccurate antibiotic prescriptions—defined as deviations from guideline-concordant recommendations—decreased by 12.6%, from 37.6% in the pre-intervention group to 25.0% in the post-intervention group. Chi-square analysis indicated a numerical decrease approaching statistical significance ($\chi^2 = 3.72$, $p = 0.054$). The odds ratio (OR) from pre- to post-intervention periods was 0.55 (95% CI: 0.30–1.01). Table 2 presents all types of errors categorized by the type of infectious disease.

Table 2.

Type of Discrepancy	Pre-intervention (N=101)	Post-intervention (N=100)
All [Irrespective of diagnosis].	38	25
All - Duration	23	10
All - Wrong ABX	17	12
All - Strength	2	1
All - Frequency	2	1
All - ABX not recommended	9	6
UTI (All Patients)	19/20	4/17
UTI Duration	15/20	3/17
UTI Wrong ABX	4/20	2/17
UTI Strength	1/20	0/17
UTI Frequency	2/20	1/17
UTI ABX not recommended	0/20	0/17
URI (All Patients)	16/39	13/49
URI Duration	6/39	4/49
URI Wrong ABX	4/39	2/49
URI Strength	0/39	1/49
URI Frequency	0/39	0/49
URI ABX not recommended	7/39	6/49
STI (All Patients)	4/35	7/42
STI Duration	3/35	3/42
STI Wrong ABX	1/35	4/42
STI Strength	1/35	0/42
STI Frequency	0/35	0/42
STI ABX not recommended	1/35	0/42

Table 2 presents the number of patients with at least one prescription that is discordant with clinical guidelines - before and after intervention. Note: A single patient may have more than one type of prescription discrepancy. ABX: antibiotics.

Discussion/Conclusion

In this pilot study, we observed the potential benefits of implementing an algorithm-driven protocol to improve antibiotic prescribing in clinics with limited resources to fully adopt antimicrobial stewardship programs (ASP). Following the protocol's introduction, there was an improvement in guideline-concordant prescribing practices. Although the reduction in inappropriate prescriptions (12.6%) did not reach statistical significance during the study's short duration, the numerical decrease suggests that such interventions can positively influence prescribing behavior. In a similar study conducted in an urgent care setting, Lee et al. (2022) observed significant improvements after implementing outpatient antimicrobial stewardship guidelines [20]. Their intervention, which included provider education and pocket guides, increased guideline-concordant prescribing from 50% to 70% ($P < 0.001$) and reduced antibiotic duration for UTIs from 7 days to 5 days ($P = 0.007$). These findings align with our hypothesis, suggesting that targeted interventions, even with minimal resources, can enhance antibiotic stewardship. Extending the duration of our study could provide a clearer understanding of the long-term benefits, but the observed results underscore the potential role of algorithm-driven protocols in improving prescribing practices in resource-limited settings.

While prescribing practices for urinary tract infections (UTIs) improved, discrepancies persisted in guideline adherence for upper respiratory infections (URIs) and sexually transmitted infections (STIs). These results suggest that while the intervention was beneficial for certain conditions, targeted, condition-specific strategies may be necessary to align prescribing practices with recommended guidelines across all infectious disease categories. The small sample size and short study duration likely limited our ability to fully observe the intervention's impact.

Implications for Public Health

Our study is significant as it contributes to the growing body of literature on antimicrobial stewardship in rural primary care settings. It also emphasizes the vital role primary care practices play in influencing the rate of AMR through their antibiotic prescribing practices. Yau et al. (2021), in their narrative review, collated evidence of the correlations between prescribing patterns in rural primary care centers and increased AMR. For instance, azithromycin use was associated with nasal carriage of *S. pneumoniae* and *S. aureus* strains resistant to macrolides [21–23]. Similarly, Hare et al. identified a dose–response relationship between azithromycin use and the carriage of macrolide-resistant *S. pneumoniae* and *S. aureus* [22]. Furthermore, Costelloe et al. emphasized this connection, demonstrating that multiple or prolonged antibiotic courses, particularly with amoxicillin and trimethoprim, are linked to higher AMR rates [21,24]. These findings underscore the urgent need for optimized antibiotic stewardship in rural primary care settings to reduce AMR and preserve the efficacy of treatments.

Implementing antibiotic stewardship programs (ASPs) in rural or underserved communities offers a valuable opportunity to reduce the spread of antibiotic-resistant organisms. Our experience provides a practical model for ASP implementation in resource-limited settings, demonstrating that even small-scale interventions can drive meaningful changes. With sustained efforts, we anticipate that this tailored approach will prove both sustainable and impactful in improving antimicrobial use in such settings.

Strengths and Limitations

The strength of our study lies in the use of evidence-based, algorithm-driven strategies tailored to the unique needs of a resource-limited clinic. However, our findings must be interpreted in light

of the study's limitations, including a small sample size and short duration, which may have contributed to the lack of statistically significant differences observed, potentially leading to a type II error. These factors limit the generalizability of our results. Additionally, the inherent limitations of the pre-post study design, such as its inability to account for unmeasured confounding variables or external events that may have influenced outcomes during the study period, further impact the robustness of our findings. However, given the constraints of our setting, the pre-post design was the most practical choice to ensure inclusivity and avoid excluding individuals. Despite these limitations, our study provides meaningful insights for those aiming to implement and adapt ASPs in rural or resource-constrained environments, contributing to the broader understanding of effective strategies to address antimicrobial resistance in these settings.

Future Directions

In this study, we did not assess the appropriateness of antibiotic selection but focused solely on evaluating the concordance of prescribed antibiotics with clinical guidelines based on the documented diagnosis. Future studies will aim to evaluate the effect of the algorithm on the appropriateness of antibiotic selection. As we continue this study, we will further refine our intervention to improve antibiotic prescribing practices. We anticipate that as we extend the study's duration and increase the sample size, we will be able to evaluate the long-term outcomes and the sustainability of the intervention. Additionally, as this current study does not have a control group, future studies should consider conducting a cluster analysis involving multiple rural clinics, with some clinics implementing an educational intervention (with the algorithm) while others serve as controls. Our overarching goal is to enhance the implementation and effectiveness of ASPs in resource-limited clinics.

Conclusion

This pilot study demonstrates the potential of algorithm-driven antibiotic stewardship protocols in rural and underserved settings. While the observed improvement in guideline-concordant prescribing practices was promising, further research with larger sample sizes and longer study periods is necessary to confirm these findings. Our experience underscores the importance of implementing ASPs tailored to the unique needs of resource-limited settings, with the potential to significantly impact antimicrobial resistance on a broader scale.

Author Contributions: A.N.O- Conceptualization, methodology, project administration, writing—original draft preparation, writing—review and editing; A.P-investigation, data curation; S.S- data curation, formal analysis, writing—review and editing, P.E formal analysis, writing review and editing.

Funding: The study was supported by the American Society of Health-System Pharmacist (ASHP) foundation and American Association of Colleges of Pharmacy (AACP) Foundation. Additionally, research reported in this publication was supported by the National Center For Advancing Translational Sciences of the National Institutes of Health under Award Number UM1TR004403. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Institutional Review Board Statement: The Florida Agricultural and Mechanical University Institutional Review Board has approved, and this submission has received Expedited Review based on applicable federal regulations. The initial approval date on July 2, 2019 (reference 052-19) and subsequent approval date on 10 January 2024, reference 105-23.

Acknowledgements: Additionally, we express our appreciation to the staff, pharmacist and health care providers at Community Health Northwest Florida who made the implementation of antibiotic stewardship program possible.

Conflicts of Interest: All authors: No reported conflict

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