

The Impact of Pharmaceutical Care on Infection Control Measures Among Hemodialysis Patients. A Randomized Interventional Study

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Purpose: This study seeks to highlight the impact of clinical pharmacists in protecting hemodialysis patients from catheter-related infections. By ensuring appropriate antimicrobial use, guiding patients on prevention practices, and collaborating with the healthcare team. This study also examines how pharmacists improve safety, treatment adherence, and quality of life.

Patients and Methods: This randomized interventional study was conducted between November 2024–April 2025. Patients were divided into intervention and non-intervention groups. The care bundle comprised culture-guided antibiotic locks (except gentamicin–heparin), in-hospital exit-site dressing with 3M Tegaderm by trained staff, and safety medication checks (e.g. blood-pressure monitoring before the use of erythropoiesis-stimulating agents) were used. The primary endpoint was the incidence of catheter-related bloodstream infections (CRBSIs); secondary endpoints were length of stay, admissions, ICU admissions, catheter replacements, and death. Monthly averages of vitals, drug therapy problems (DTPs), and laboratory parameters were obtained for both groups.

Results: A total of ninety patients included in this study. The patients were randomly assigned to either the intervention or non-intervention group and a total 81 out of 90 patients successfully completed the study. After four visits and six months of implementing infection control measures within the context of pharmaceutical care, the infection rate showed a significant reduction in the intervention group (from 0.64 ± 0.48 to 0.20 ± 0.4 , $p = 0.0001$) compared with the non-intervention group (0.66 ± 0.48 to 0.71 ± 0.45 , $p = 0.9731$). The mean differences increased over time, reaching 0.26 (95% CI of diff.= 0.09 to 0.43) at visit 1, 0.41 (95% CI of diff.= 0.24 to 0.58) at visit 3, and 0.51 (95% CI of diff.= 0.34 to 0.68) at visit 4.

Conclusion: Clinical pharmacist intervention via implementing infection control within the context of a pharmaceutical-care process can improve infection rates among hemodialysis patients.

Keywords: hemodialysis, CRBSI, tunneled catheter, arteriovenous fistula, antibiotic lock, Tegaderm, CKD, ESA, pharmaceutical care

Introduction

Hemodialysis (HD) is a life-sustaining renal replacement therapy, widely used for patients suffering from end-stage renal disease (ESRD). Despite its therapeutic necessity, HD inherently increases patients' vulnerability to infectious complications, particularly bloodstream infections (BSIs), due to repeated vascular access, frequent healthcare exposure, and underlying immune dysfunction. The combination of uremia-induced immunosuppression, frequent invasive procedures, and the use of central venous catheters (CVCs) create a high-risk environment for infection development and progression among HD patients.^{1–3} Catheter-related bloodstream infections (CRBSIs), in particular, represents a significant clinical burden, with elevated morbidity, hospitalization rates, and healthcare costs. The incidence of CRBSIs among dialysis patients ranges between 2 to 7.74 events per 1000 catheter-days, often leading to prolonged antibiotic therapy, vascular access replacement, and—in severe cases—sepsis or endocarditis.^{4,5} The pathogenesis of CRBSIs is largely driven by microbial colonization and biofilm formation on catheter surfaces, especially in cases involving *Staphylococcus aureus* or *Candida* species.

The Centers for Disease Control and Prevention (CDC) have issued comprehensive infection prevention guidelines for outpatient dialysis settings, focusing on evidence-based strategies such as hand hygiene, catheter hub disinfection,

chlorhexidine antiseptics, sterile dressings, antimicrobial ointments, and regular infection surveillance (CDC, 2023; WHO, 2022). However, implementing and maintaining these practices is often hampered by systemic challenges such as limited financial resources, a high patient load, inconsistent staff training, and lack of multidisciplinary collaboration. In this context, the role of clinical pharmacists has become increasingly vital. Pharmaceutical care, as defined by Mikeal et al, encompasses the responsibility of pharmacists to ensure the safe and effective use of medications through direct involvement in patient care. Through structured processes including patient assessment, identification of drug therapy problems (DTPs), development and implementation of care plans, and continuous follow-up, pharmacists contribute significantly to optimizing treatment outcomes and minimizing preventable complications.

Pharmacists are uniquely positioned to support infection control in HD units through the preparation of antibiotic lock therapy (ALT), medication safety checks, patient counseling, and participation in antimicrobial stewardship. Their engagement helps ensure the correct use of prophylactic strategies, timely interventions for suspected infections, and adherence to national and international infection control standards. Therefore, this study aims to evaluate the impact of clinical pharmacists in reducing catheter-related bloodstream infections (CRBSIs) among hemodialysis patients through targeted pharmaceutical care interventions. The study further explored how pharmacist-led practices—such as medication safety monitoring, antibiotic stewardship, patient education, and multidisciplinary collaboration—contribute to enhancing treatment adherence, minimizing drug therapy problems, and improving the overall safety and quality of life of patients undergoing chronic dialysis. Pharmaceutical care is a patient-centered practice, where the pharmacist assumes responsibility for identifying, preventing, and resolving drug therapy problems (DTPs). These problems are defined as any undesirable event or risk involving drug therapy that interferes with desired health outcomes. Broadly categorized into four domains: Indication, Effectiveness, Safety, and Adherence.⁶

According to Cipolle et al (2012), the pharmaceutical care process follows a structured model that consists of five essential steps:⁶

1. Assessing the patient: This includes collecting and evaluating patient-specific clinical and drug information.
2. Identifying DTPs: The pharmacist determines whether the patient's current medication regimen is appropriate, effective, safe, and being adhered to.
3. Developing a care plan: The pharmacist collaborates with the healthcare team to establish a plan that resolves identified DTPs.
4. Implementing the plan: Interventions may include medication changes, patient counseling, dosage adjustments, or follow-up scheduling.
5. Follow-up and monitoring: Continuous evaluation ensures that the patient's goals of therapy are being met and that new DTPs are promptly addressed.

Patients and Methods

Study Design and Setting

This randomized interventional study was conducted at the Hemodialysis Center of Shar Hospital in Sulaymaniyah City, Iraq. It was performed over a six-month period from November 2024 to April 2025. The primary aim was to assess the effect of clinical pharmacist-led pharmaceutical care interventions on reducing catheter-related bloodstream infections (CRBSIs) and addressing drug therapy problems (DTPs) in patients receiving maintenance hemodialysis.

Participants were randomly assigned into two groups: the intervention group, which received structured pharmaceutical care, and the non-intervention group, which received standard care without additional pharmacist involvement. All patients were followed up monthly, starting from baseline, with a total of four scheduled visits throughout the study (V0–V3). Monthly evaluations focused on monitoring infection control practices, recording adverse drug events, reviewing laboratory and clinical parameters, and documenting any DTPs encountered.

The intervention group received a comprehensive care bundle implemented by clinical pharmacists. This included medication reconciliation, assessment of therapy indication, effectiveness, safety evaluations, patient counseling, and

collaboration with nephrologists and nursing staff. Educational sessions also addressed infection prevention measures and reinforced patient adherence to treatment protocols.

At the first follow-up visit (V1), a detailed assessment of drug therapy problems (DTPs) was made for the intervention group. These DTPs were classified into domains such as indication, effectiveness, safety, and adherence. [Figure 1](#) presents the distribution of DTPs identified during this initial visit. The most common issues observed were “incorrect administration”, “more effective drug available” “unsafe drug for the patient”, and “direction not understood”. These baseline findings helped guide the targeted interventions implemented in subsequent visits.

Ethical Consideration

- This study was approved by the Ethical Committee of the College of Pharmacy, University of Sulaimani (Approval Number: PH 140–24).
- The study was conducted in accordance with the principles outlined in the Declaration of Helsinki.
- All participants were enrolled voluntarily, and informed consent was obtained from each subject prior to their inclusion in the study.
- Data sharing statement: No additional data will be publicly shared, as researchers did not obtain ethics approval or participant consent for open data dissemination. However, upon formal request by the journal’s editorial board, data may be shared privately with the editor.

Trial Registration

The study is registered in the ClinicalTrials.gov database under the identifier NCT0696875.

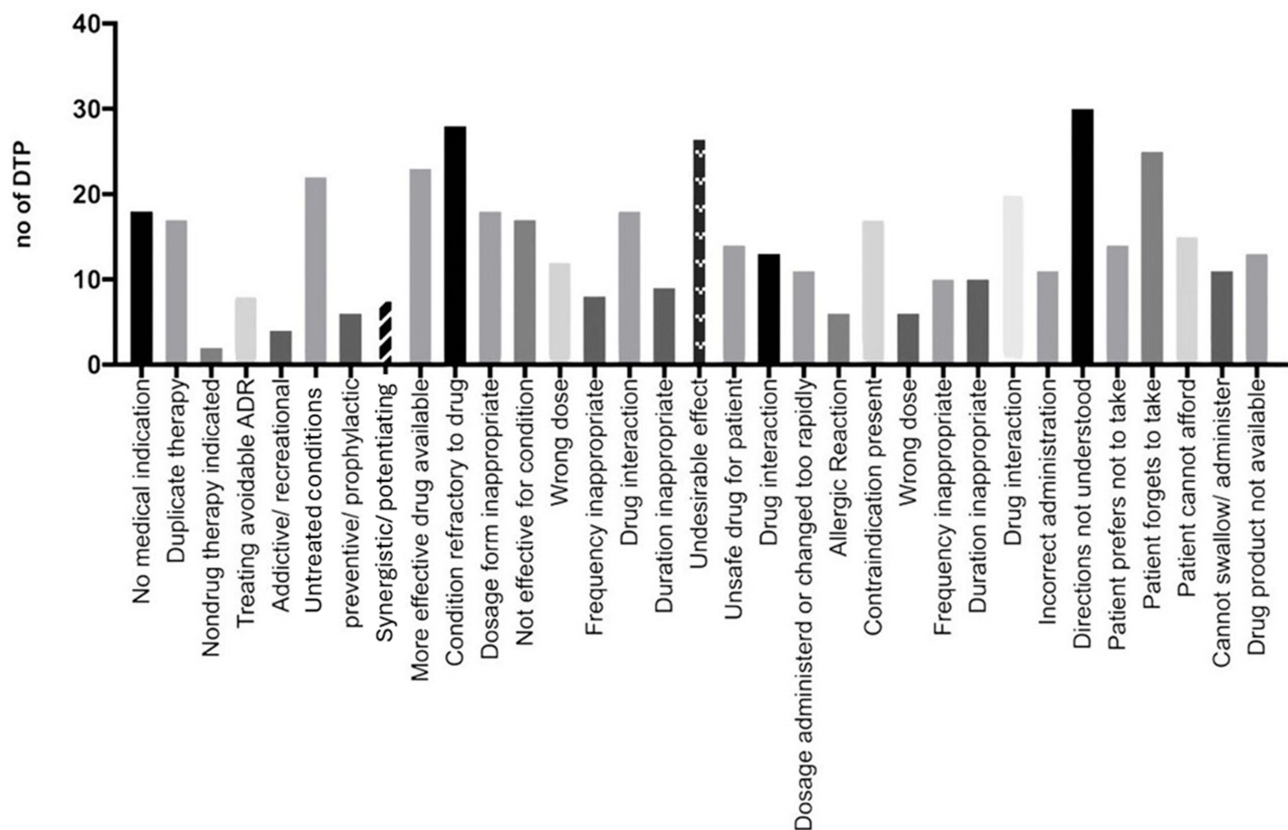


Figure 1 DTPs among intervention group at 1st visit.
Abbreviation: DTPs, drug therapy problems.

Sample Size Calculation

Z-test approximation was used to determine the sample size:

$$n = \frac{2(Z_{1-\alpha/2} + Z_{1-\beta})^2 \sigma^2}{\Delta^2}$$

Where:

- $Z_{1-\alpha/2} = 1.96$
- $Z_{1-\beta} = 0.84$
- $\sigma = \text{SD}$

$\Delta =$ expected mean difference

Plugging in:

$$n = \frac{2(1.96 + 0.84)^2 (1.5)^2}{(1.0)^2} \approx 36 \text{ per group}$$

Then inflate for attrition (~20%):

$$36/0.8 \approx 45 \text{ per group}$$

The sample size was calculated based on the ability to detect a clinically meaningful difference between the intervention and control groups in the primary outcome. Assuming a two-sided significance level (α) of 0.05, a statistical power of 80%, a standard deviation of 1.5, and an expected mean difference of 1.0 unit between groups, a minimum of 36 patients per group was required. To account for an anticipated attrition rate of approximately 20% due to mortality or renal transplantation, the sample size was increased to 45 patients per group. Therefore, a total of 90 patients were enrolled at baseline. A total of 81 patients completed the study, providing adequate statistical power (>80%) to detect moderate effect sizes between groups.

Inclusion Criteria

- Age ≥ 18 years
- ESRD on maintenance hemodialysis
- Central venous catheter in use
- On Hemodialysis ≥ 3 months
- Provided informed consent.

Exclusion Criteria

- AVF/AVG only (no catheter)
- Peritoneal dialysis
- Active infection/sepsis at baseline
- Prior kidney transplantation
- Expected survival <3 months
- Refused consent or lost to follow-up.

Patient Selection

A total of ninety patients diagnosed with end-stage renal disease (ESRD) and undergoing maintenance hemodialysis therapy were enrolled in this study. Among them, eighty- one patients successfully completed the study, while nine patients were lost to follow-up due to either mortality or renal transplantation during the study period.

Participants were randomly assigned into two groups: an intervention group and a control (non- intervention) group, with forty-five patients in each group at baseline. All participants were receiving hemodialysis as a renal replacement

therapy. In the intervention group, patients received structured pharmaceutical care in addition to standard hemodialysis treatment. Clinical evaluation and follow-up were conducted at baseline and continued throughout the study. Key parameters such as vital signs (blood pressure, oxygen saturation [SpO₂], temperature, heart rate [HR], and respiratory rate [RR]) and laboratory tests (including serum levels of sodium, calcium, potassium, iron, phosphate, creatinine, and urea) were assessed at baseline and then monitored every two months. Pharmaceutical care in the intervention group targeted four primary categories of drug therapy problems (DTPs): indication, effectiveness, safety, and adherence. These categories were further subdivided into 33 specific DTP subcategories, which were evaluated and managed monthly by the research pharmacists. The research team was actively involved in the detection, prevention, and resolution of these problems. An overview of these DTP categories and their distribution is presented in Figure 2. In contrast, the non-intervention group (n = 45 at baseline, n = 38 at final follow-up) received conventional medical care without the involvement of clinical pharmacists. Although DTPs were noted in this group, no pharmaceutical intervention was undertaken. Vital signs and laboratory parameters (electrolytes, creatinine, and urea) were also monitored in this group at baseline and then every three months.

Data Collection

At baseline and during each monthly follow-up visit (V1–V4), patient data were systematically abstracted from clinical records and summarized as monthly means. The primary outcome of the study was the rate of catheter-related bloodstream infections (CRBSIs). Secondary outcomes included length of hospital stay, infection led- hospital admissions, intensive care unit (ICU) admissions, frequency of catheter replacements, and mortality. Alongside these clinical

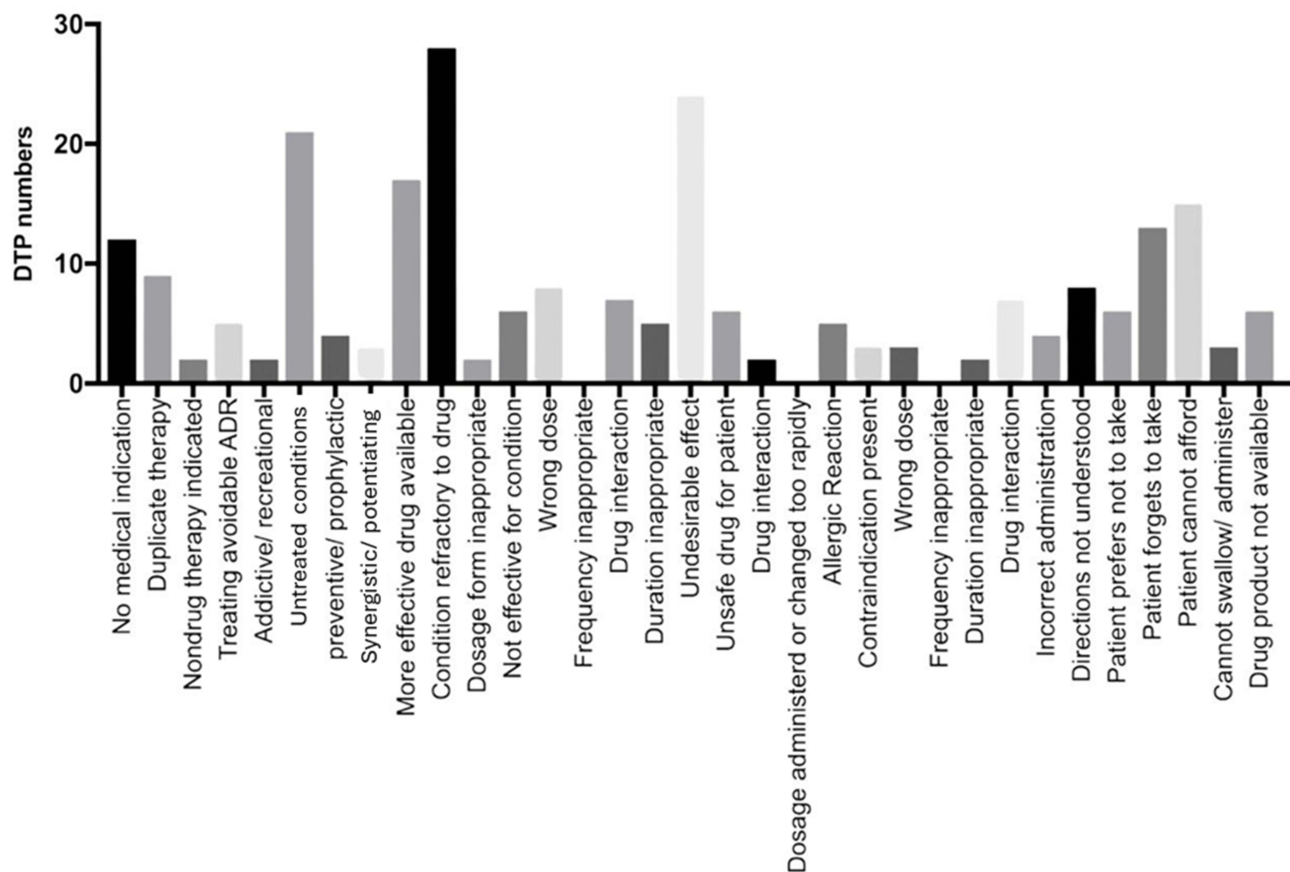


Figure 2 DTPs in the intervention group during 2nd visit.
Abbreviation: DTP, drug therapy problem.

outcomes, vital signs such as peripheral oxygen saturation (SpO₂), blood pressure (BP), and temperature were recorded at every visit to monitor patient stability.

A comprehensive panel of laboratory tests was also performed, including electrolytes (potassium, sodium, chloride), phosphate, serum iron, urea, creatinine, C-reactive protein (CRP), hemoglobin, red blood cells, platelets, white blood cells, and glucose. These biomarkers provided insights into both the metabolic and hematologic status of patients and supported medication adjustments where necessary, particularly in relation to phosphate management, iron optimization, and anemia treatment.

In addition to clinical and laboratory monitoring, drug therapy problems (DTPs) were evaluated monthly across four domains: indication, effectiveness, safety, and adherence. By the third month (V3), the distribution of DTPs in the intervention group showed that effectiveness-related problems—particularly “condition refractory to drug”—remained the most prevalent. Safety concerns, such as undesirable effects, continued to be identified but were actively addressed through dose modifications and therapeutic substitutions. Meanwhile, adherence and administration problems, including incorrect administration and directions not understood, were notably reduced compared to the first month, reflecting the benefits of repeated patient education. However, challenges with drug availability occasionally reappeared, as shown in Figure 3.

Implementation Challenges (Fidelity and Contamination)

Two real-world constraints influenced the fidelity of the intervention and help to explain some of the patterns seen in Figure 3. The first was the transition from the legacy lock policy of gentamicin plus heparin to culture-guided antibiotic lock solutions. Because the switch had to be phased, short periods of mixed practice occurred, which contributed to temporary safety and effectiveness DTPs until the protocol was standardized. The second challenge was that not all patients could be transitioned simultaneously to optimized vascular access and standardized 3M Tegaderm dressings.

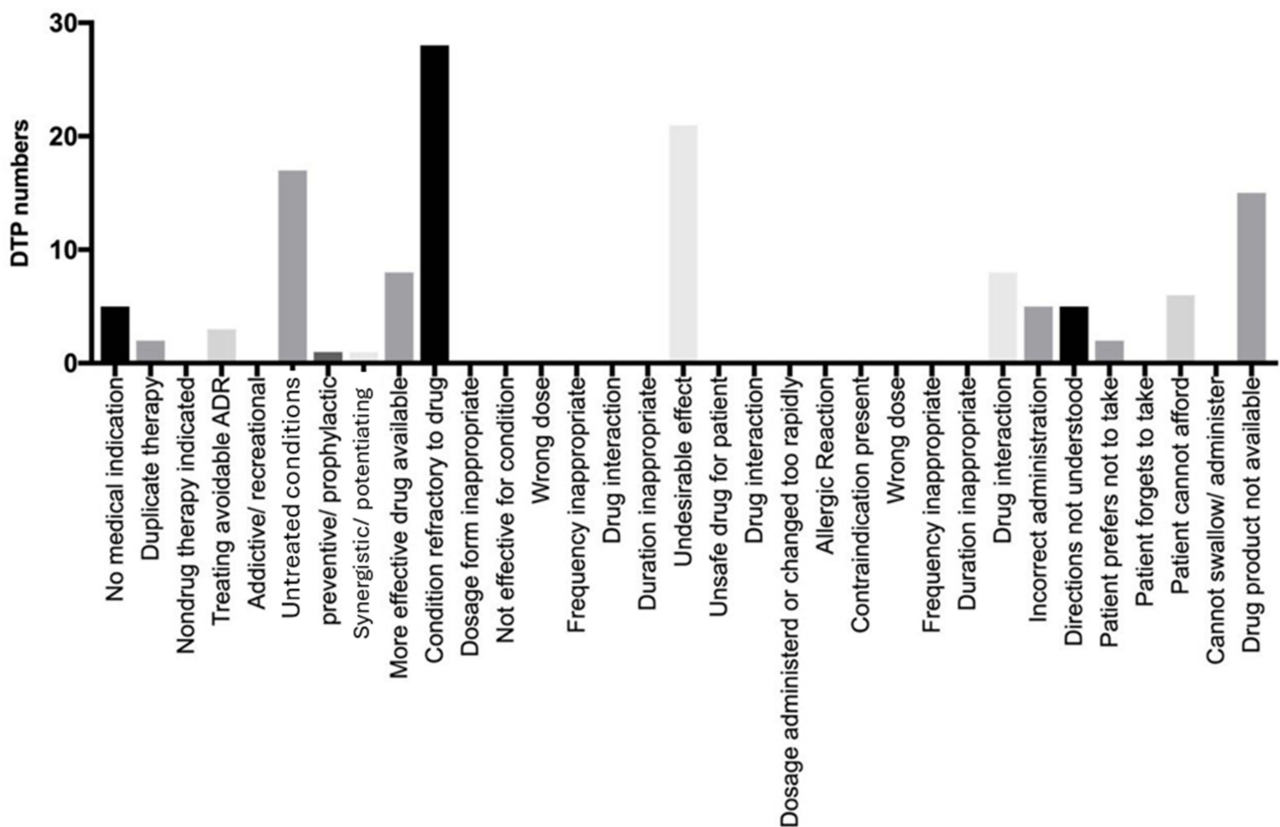


Figure 3 DTPs in the intervention group during 2nd visit.
Abbreviation: DTP, drug therapy problem.

This staggered roll-out created variability in the timing of patient education and supply logistics, explaining the persistence of some adherence-related problems and the sporadic occurrence of drug availability issues.

Allocation

The trial was conducted as a randomized clinical study, with patient assignment to intervention or control arms guided by pragmatic allocation influenced by service capacity consistent with real-world clinical constraints.

Per hospital policy, patients with central venous catheters underwent monthly catheter replacement intended to lower infection risk. Dressings were frequently performed at home, and gentamicin mixed with heparin was used in such cases as a catheter lock despite gram-positive predominance.

Intervention (Care Bundle)

Intervention Summary

1. Catheter Insertion Monitoring

- Clinical pharmacist directly observed all CVC insertions.
- Ensured maximum sterile barrier precautions (sterile gloves, gown, mask, cap, large sterile drape).
- Verified sterility/expiry of all materials.
- Documented breaches and reported for correction.
- Recorded site and date of insertion for surveillance.

2. Aseptic Exit Site Care

- Dressing changes in controlled private setting with full PPE.
- Protocol: skin antiseptics with 2% chlorhexidine in 70% alcohol, followed by povidone-iodine ointment + chlorhexidine-impregnated dressing (Tegaderm 3M).
- Supplying validated (sterility, expiry, single use only); expired/contaminated items replaced immediately.

3. Patient Education & Hygiene Compliance

- Structured education at enrollment and follow-ups.
- Key points: keep site dry/covered, waterproof protection when bathing, avoid manipulation, strict hand hygiene.
- Adherence monitored with hygiene checklist; non-adherence corrected with counseling + materials (pamphlets, visual aids).

4. Drug Therapy Problem (DTP) Identification

- Based on Cipolle's framework: Indication, Effectiveness, Safety, Adherence.
- Pharmacist reviewed complete medication regimen at baseline, 3, and 6 months.
- DTPs discussed with nephrology team; interventions included dose adjustment, substitution, discontinuation, counseling.
- All actions documented in patient file and structured logbook.

5. Infection Surveillance & Management

- Exit sites visually assessed each dialysis session.
- Suspected CRBSI → paired blood cultures (catheter + peripheral).
- Empirical systemic antibiotics + antibiotic lock therapy (ALT) pending cultures.
- Therapy tailored per sensitivity results.

6. Staff Training & Compliance

- Training on hand hygiene, single-use sterile items, and equipment disinfection.
- Unannounced audits conducted; noncompliance retrained.
- Monthly review of audit results with unit supervisor.

7. Documentation & Monitoring

- Structured logbook + digital form recorded: infection signs, interventions, cultures/antibiotics, patient hygiene, staff compliance.
- Real-time monitoring for intervention fidelity.

8. Catheter Evaluation & Replacement

- Routine checks for complications (occlusion, thrombosis, bacteremia).
- Recurrent/unresponsive CRBSIs → catheter removal/replacement (per CDC & KDOQI).
- Decision made jointly by pharmacist, nephrologist, infection control specialist.

Statistical Analysis

The data collection was completed, and the questions of the study were coded. Then data entry and analysis were performed. Data entry was carried out by using an Excel spreadsheet and then the statistical analysis was performed by GraphPad Prism, version 8. Different types of bar charts (component bar charts) and line graphs were used to describe the variables of the study diagrammatically. Ordinary one way ANOVA test and Tukey's multiple comparison test have been used to elucidate the significance of the changes. Any p-value < 0.05 considered to be significant statistically.

Results

Patient Characteristics

A total of 90 patients with end-stage renal disease (ESRD) undergoing maintenance hemodialysis were enrolled in this study, with 45 assigned to the intervention group and 45 to the non- intervention group. By the end of follow-up, 81 patients completed the study, while 9 patients were lost to follow-up due to mortality or renal transplantation. As shown in Table 1, baseline demographic and anthropometric characteristics were comparable between the two groups. The mean age was 55.5 ± 16.83 years in the intervention group and 52 ± 13.6 years in the non- intervention group ($p = 0.893$). Mean body weight was 77.6 ± 21.0 kg for the intervention group versus 74.1 ± 13.1 kg for the non-intervention group ($p = 0.906$). Mean height was 167.75 ± 10.9 cm and 169 ± 9.22 cm, respectively ($p = 0.968$). Gender distribution was also balanced, with 57% males in the intervention group and 62% males in the non-intervention group ($p > 0.999$). None of these differences reached statistical significance, confirming that randomization achieved baseline comparability.

Table 1 Characteristics of Study Population

Parameter	Intervention Group (n = 45)	Non-Intervention Group (n = 45)	P-value
Gender (Male)	57%	62%	>0.999
Age (years)	55.5 ± 16.83	52 ± 13.6	0.893
Weight (kg)	77.6 ± 21.0	74.1 ± 13.1	0.906
Height (cm)	167.75 ± 10.9	169 ± 9.22	0.968

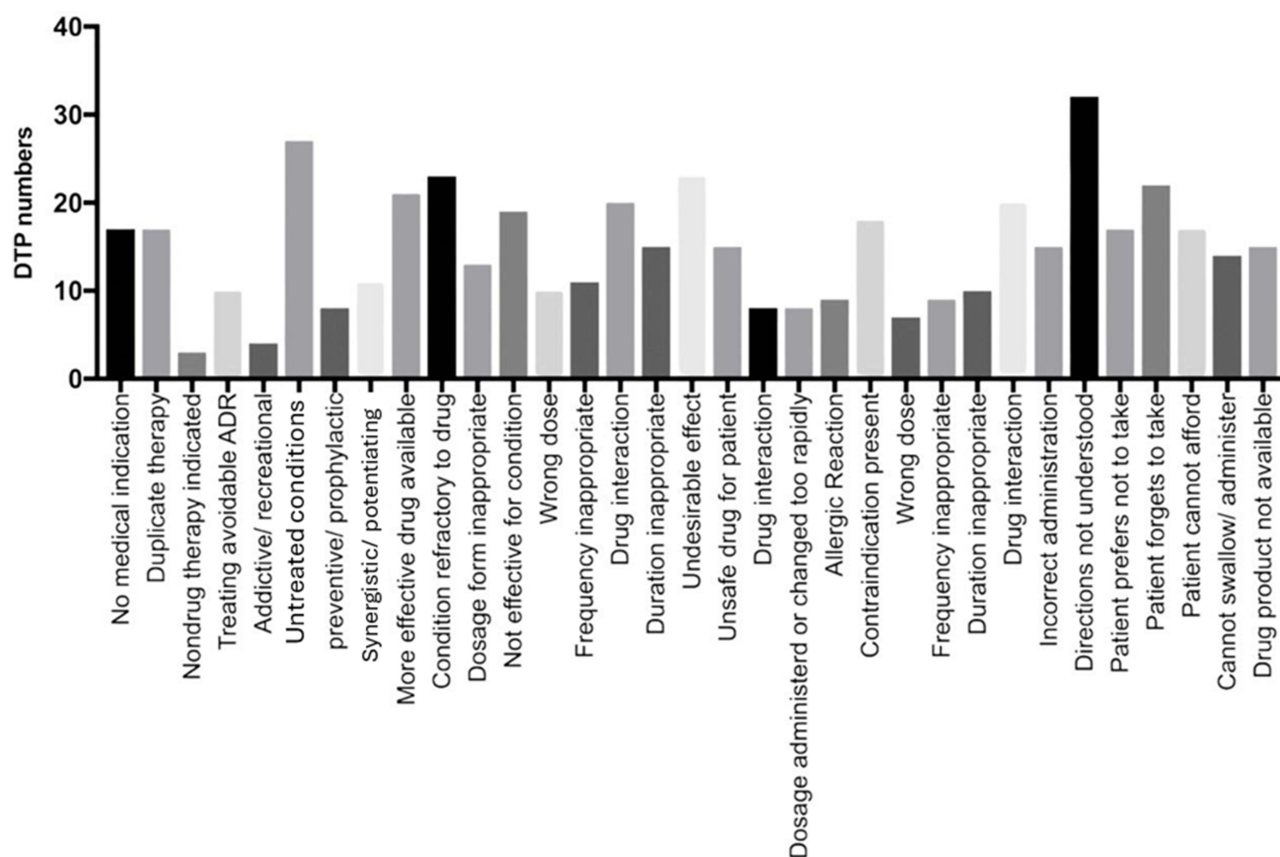


Figure 4 DTPs among non- intervention group during the 1st visit.
Abbreviation: DTP, drug therapy problem.

Drug Therapy Problems (DTPs) at Baseline (First Month)

Drug therapy problems (DTPs) were assessed at baseline (first month) in both groups. In the non- intervention group, the most frequently observed problems were incorrect administration, condition refractory to drug, and patient forgets to take medication, followed by issues related to direction not understood and drug product not available (Figure 4). These findings highlight the prevalence of both adherence-related and effectiveness-related problems in the absence of structured pharmaceutical care. The changes in this pattern throughout the study is summarized in Figures 5 and 6.

Infection Rate

Across the six-month follow-up, the intervention group showed a steady and clinically meaningful decline in CRBSI rate from approximately 0.6 at baseline to about 0.2 by V3, with a significant time trend ($p = 0.0001$) (Figure 7A). In contrast, the non-intervention group remained essentially unchanged over the same period (baseline ≈ 0.65 – 0.7 to ≈ 0.7 at V3), and the within- group change was not significant (ns) (Figure 7B). The diverging trajectories indicate that the pharmacist-led care bundle was associated with a progressive reduction in infection burden that was not observed under usual care.

Blood Culture Findings

Blood cultures were obtained at baseline and during each monthly visit to monitor infection incidence. At baseline, the number of positive blood cultures was relatively low in both groups, with similar distribution between the intervention and non-intervention arms. As shown in Figure 8, By Visit 1, a marked increase in positive cultures was observed, reaching the highest level during the study. The non- intervention group consistently showed higher culture positivity compared to the intervention group at each time point. In contrast, in the intervention group, the number of positive cultures gradually declined after Visit 1, with a steady downward trend through Visits 2 and 3, reflecting the impact of the

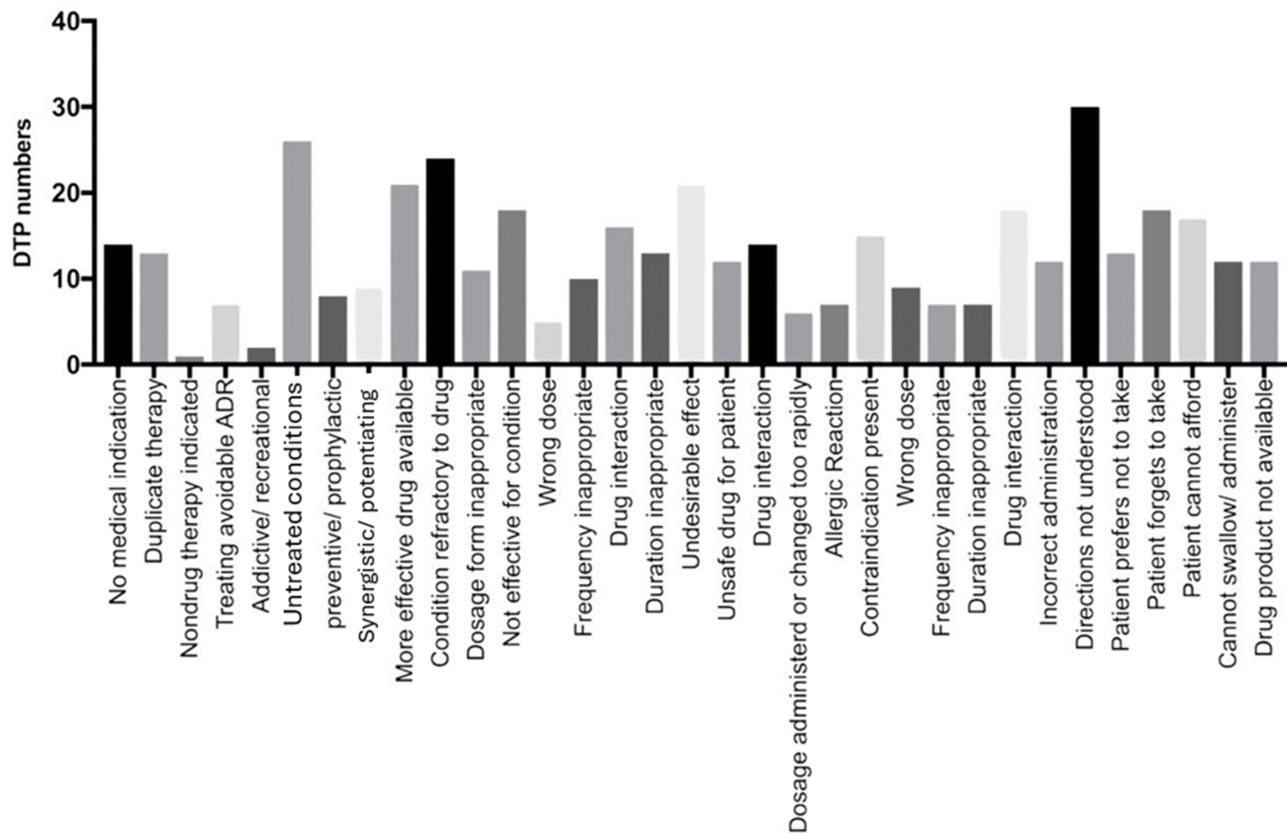


Figure 5 DTPs among non-intervention group during the 2nd visit.

Abbreviation: DTP, drug therapy problem.

pharmaceutical care bundle and infection-control measures. The non-intervention group, however, showed minimal fluctuation, with blood culture positivity remaining relatively stable across Visits 1–3. These findings highlight the effect of pharmacist-led interventions in reducing infection burden over time.

Length of Stay in Hospital

The average length of hospital stays (LOS) demonstrated a marked difference between the two groups over time. At baseline, both groups had relatively high hospitalization rates, with the non-intervention group recording the highest values. From Visit 1 onward, the intervention group showed a sharp and sustained reduction in hospital stay, reaching consistently low levels by Visits 2 and 3. In contrast, the non-intervention group continued to experience longer hospital stays throughout the study, with only modest improvement by Visit 2 followed by an increase again at Visit 3. As illustrated in [Figure 9](#), the difference in LOS between the two groups was statistically significant ($p < 0.0001$), indicating that the pharmacist-led infection control program contributed to a substantial reduction in hospitalization burden among hemodialysis patients.

ICU Admissions

Admissions to the intensive care unit (ICU) differed significantly between the two groups during the study period. At baseline, ICU admission rates were comparable, with both groups reporting around 10–11 cases. By Visit 1, the non-intervention group experienced a rise in ICU admissions, reaching its peak at approximately 12 cases, while the intervention group showed a sharp decline, dropping to just 1 admission. This trend persisted across subsequent visits. By Visit 2, ICU admissions in the intervention group fell to zero, whereas the non-intervention group maintained consistently higher levels

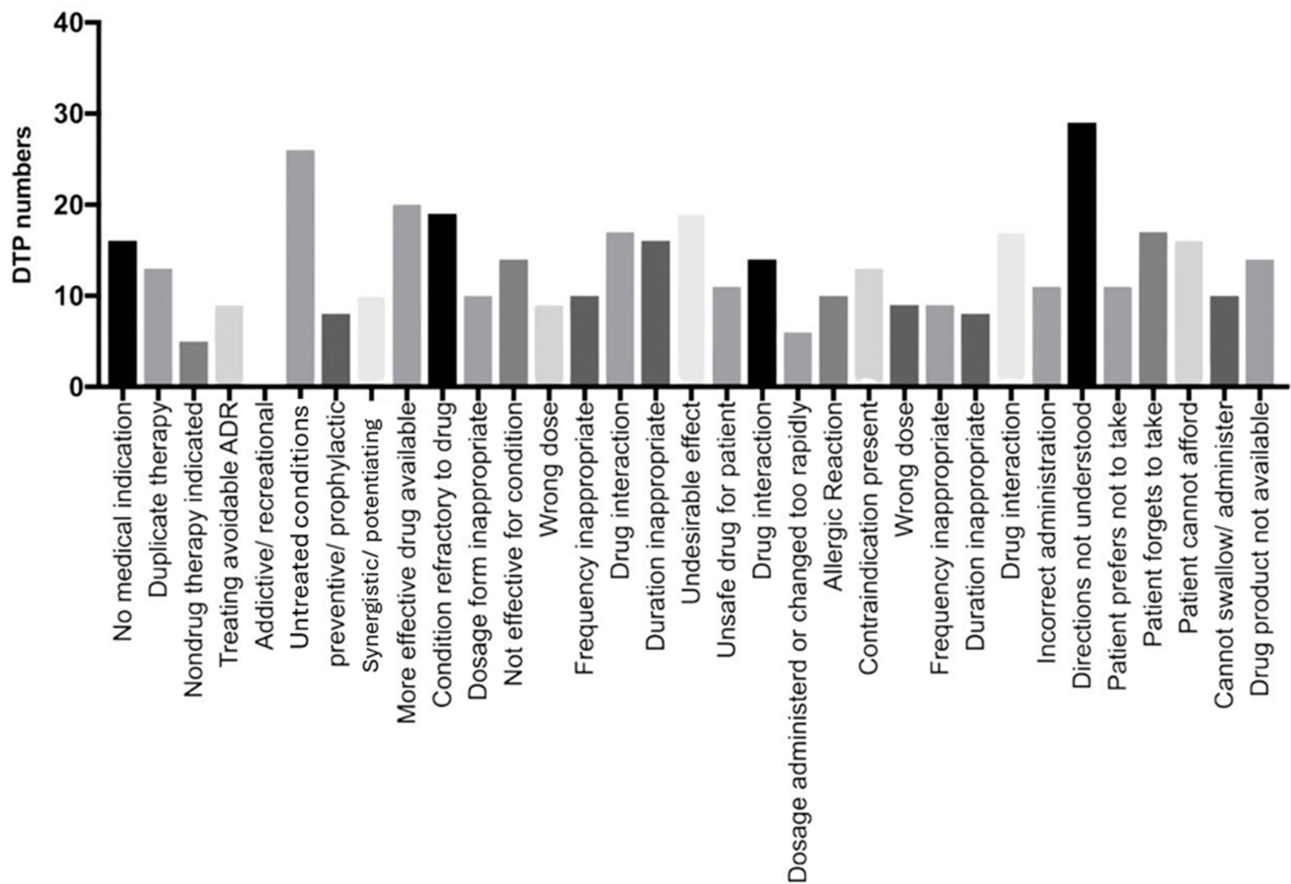


Figure 6 DTPs among non-intervention group during the 2nd visit. **Abbreviation:** DTP, drug therapy problem.

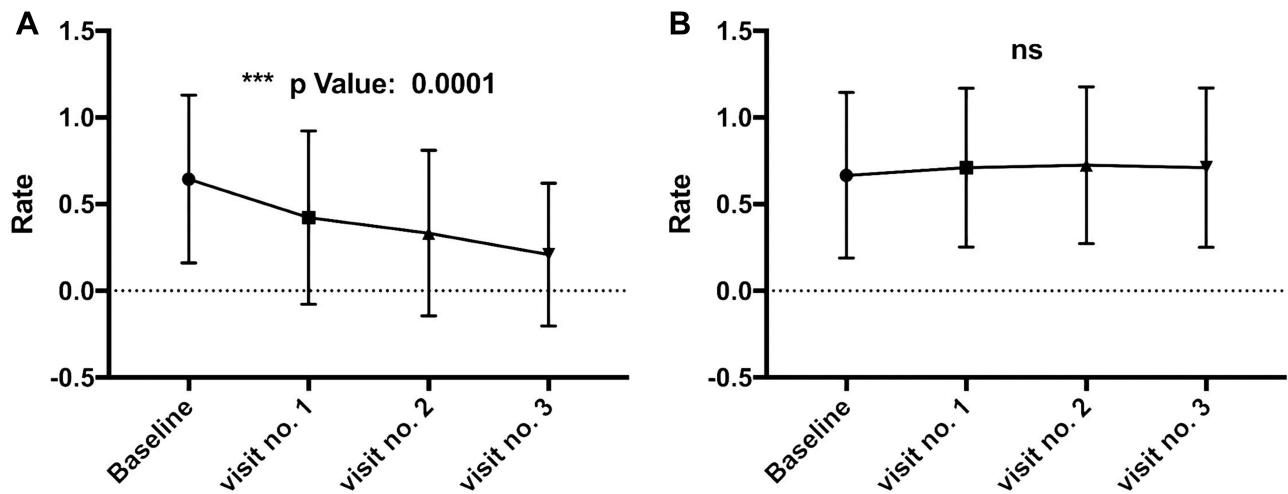


Figure 7 (A) Infection rate in the intervention group at baseline and follow-up visits. The rate decline over time significantly; $***p = 0.0001$, 95% CI (0.1752 to 0.695). **(B)** Infection rate in the non-intervention group at baseline and follow-up visits. No significant change over time (ns), 95% CI (-0.3082 to 0.2204).

(9 admissions). At Visit 3, the intervention group remained very low (2 admissions) compared with the non-intervention group (8 admissions). As shown in Figure 10, these differences were statistically significant ($p < 0.01$), underscoring the effectiveness of pharmacist-led infection control in reducing severe complications requiring ICU care.

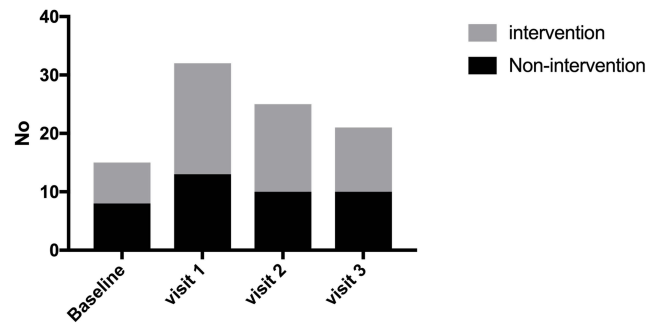


Figure 8 Number of positive blood cultures among intervention and non-intervention groups at baseline and follow-up visits.

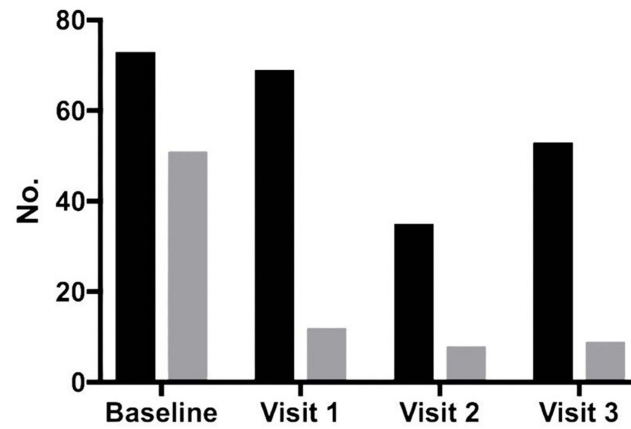


Figure 9 Length of hospital stay among intervention and non-intervention groups across baseline and follow-up visits.

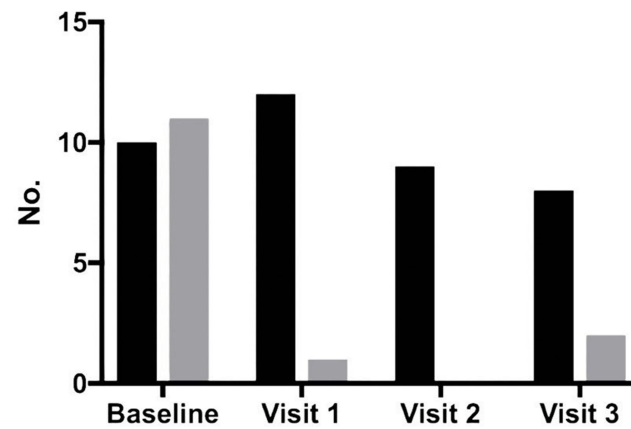


Figure 10 ICU admission among intervention and non-intervention groups at baseline and follow-up visits. $p < 0.01$.

Catheter Changes

The frequency of catheter changes showed a clear difference between groups over the study period. At baseline, both groups reported high numbers, with the non-intervention group recording 23 changes compared with 20 changes in the intervention group. By Visit 1, the intervention group demonstrated a substantial reduction, falling to around 5 changes, while the non-intervention group remained higher at approximately 18 changes. This trend persisted throughout the study. At Visit 2, catheter changes in the intervention group were stable at 5 cases, while the non-intervention group recorded 17 cases. By Visit 3, the intervention group decreased further to just 2 changes, whereas the non-intervention group remained at a comparatively

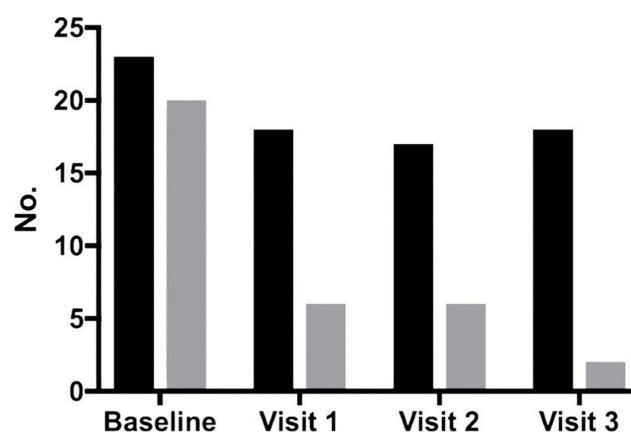


Figure 11 Catheter change among intervention and non-intervention groups at baseline and follow-up visits. $p < 0.05$.

elevated level (18 cases). As shown in [Figure 11](#), this reduction in catheter changes was statistically significant ($p < 0.05$), indicating that pharmacist-led infection-control strategies—including antibiotic lock use, aseptic site care, and adherence counseling—contributed to the preservation of vascular access in the intervention group.

Mortality

A significant difference in mortality was observed between the two groups during the study period. In the non-intervention group, a total of five deaths were recorded, compared with only one death in the intervention group. This marked reduction in mortality highlights the effectiveness of pharmacist-led pharmaceutical care and infection-control measures in improving survival outcomes among hemodialysis patients.

Electrolytes and Iron Indices

In the intervention group, phosphate declined significantly by V3 (from ~ 6.6 to 4.40 ± 1.52 mg/dL, $p < 0.0001$), whereas the non-intervention group showed no significant change over time ($p = 0.0811$). This improvement coincided with pharmacist-led medication review and optimization (eg, phosphate binder selection/titration, dosing with meals, interaction checks), plus targeted counseling, indicating that hyperphosphatemia was correctable with drug review. Serum iron parameters varied but did not change significantly within groups over time ($p = 0.9989$ non-intervention; $p = 0.1665$ intervention), consistent with individualized iron/ESA adjustments.

Table 2. Longitudinal electrolytes and iron indices (mean \pm SD) in non-intervention and intervention groups across visits (V0–V3). Significant decline is observed only for phosphate in the intervention arm ($p < 0.0001$).

Table 2 Longitudinal Electrolytes and Iron Indices Across Visits

Group & Visit	Chloride (Mean \pm SD)	Na (Mean \pm SD)	Phosphorus (Mean \pm SD)	K (Mean \pm SD)	Fe (Mean \pm SD)
Non-intervention (V0)	108 \pm 3.99	137 \pm 16.10	6.08 \pm 1.96	4.88 \pm 0.74	49.30 \pm 27.40
Non-intervention (V1)	109.26 \pm 4.42	139.50 \pm 3.48	7.13 \pm 1.83	4.93 \pm 0.80	48.18 \pm 25.49
Non-intervention (V2)	110.49 \pm 2.19	139.14 \pm 17.36	7.05 \pm 1.77	4.75 \pm 0.80	48.50 \pm 21.80
Non-intervention (V3)	109.61 \pm 2.77	140.50 \pm 2.89	7.03 \pm 1.54	4.64 \pm 0.81	48.40 \pm 19.67
p-value (within group)	0.0996	0.5737	0.0811	0.6428	0.9989
Intervention (V0)	107.98 \pm 4.60	140.98 \pm 3.27	6.59 \pm 1.85	4.47 \pm 0.71	65.09 \pm 1.85

(Continued)

Table 2 (Continued).

Group & Visit	Chloride (Mean± SD)	Na (Mean± SD)	Phosphorus (Mean± SD)	K (Mean± SD)	Fe (Mean± SD)
Intervention (V1)	107.20 ± 5.30	139.75 ± 3.17	6.90 ± 1.78	4.65 ± 0.80	59.90 ± 15.10
Intervention (V2)	107.60 ± 4.22	140.07 ± 2.76	6.25 ± 1.60	4.88 ± 0.73	60.05 ± 13.70
Intervention (V3)	105.68 ± 3.94	135.97 ± 3.45	4.40 ± 1.52	4.65 ± 0.62	58.60 ± 15.03
p-value (within group)	0.9991	0.9380	<0.0001	0.9820	0.1665

Notes: Values are patient-level monthly means (±SD). p-values indicate within-group change across visits V0–V3. Only phosphate in the intervention arm decreased significantly over time.

Discussion

Our study demonstrates that enrolling a pharmacist-led care bundle into routine hemodialysis has a significant impact on catheter-related bloodstream infections (CRBSIs), alongside with other parameters compared with usual care. These findings align with the broader evidence that multifaceted interventions—hand hygiene, hub disinfection, antisepsis, lock optimization, and patient/staff education—are most effective for preventing infectious complications in patients with central venous catheters (CVCs) used for hemodialysis.^{1,2,7}

Interpreting the Infection Outcomes

The reduction in the rate of infection among intervention group is consistent with systematic reviews showing that catheter-care bundles and optimized lock solutions reduce bacteremia and excessive loss.^{1,2,7} Our approach—culture-guided locks, chlorhexidine-based exit-site care, and consistent education—echoes best practices (eg, chlorhexidine for device disinfection) that have previously demonstrated efficacy in dialysis settings.^{7,8} It also compatible with reports that non-heparin adjuncts can reduce catheter dysfunction and infection risk (eg, sodium bicarbonate and ethanol locks), suggesting that lock choice is a modifiable driver of outcomes.^{3,9}

Microbiologically, hemodialysis CRBSIs stem from biofilm-mediated colonization of the catheter lumen/extraluminal space. Preclinical work in a tunneled-catheter pig model underlines the difficulty of eradicating established biofilm and the need for prevention-first strategies.¹⁰ Case reports of uncommon pathogens (eg, *Enterococcus gallinarum*) further emphasize the importance of rigorous culture practices and tailored therapy in this population.¹¹ Our observed reduction in positive blood cultures after Visit 1 in the intervention group is consistent with the biofilm-prevention focus of our bundle.

Clinical Impact Beyond Infection Rates

The intervention was associated with materially better downstream outcomes—shorter hospitalizations and fewer ICU admissions—mirroring prior observations that catheter-associated infections drive substantial morbidity and resource use.^{2,7,12} Pediatric data also show high hospitalization costs for catheter-associated bloodstream infection,¹² underscoring the potential economic implications of the reductions we observed. Fewer catheter changes in the intervention group suggest better catheter survival, an outcome that matters given the morbidity associated with repeated procedures and the recognized hazards of CVCs in complex vascular settings (including interactions with cardiac implantable electronic devices).^{6,13}

Mortality was lower in the intervention arm (1 vs 5 deaths). Although the study was not powered for mortality, this signal is directionally consistent with broader epidemiology showing excess mortality among patients on kidney replacement therapy and the contribution of infection to that burden.^{4,5,7} Observational studies from diverse settings (eg, Northern Tanzania; Fars Province, Iran) document high rates of CVC-related infection and attendant risks, reinforcing the relevance of scalable prevention in both resource-replete and resource-limited environments.^{5,14–16}

Role of the Pharmacist and DTP Resolution

A central feature of our model was systematic identification and resolution of DTPs (indication, effectiveness, safety, adherence). We observed early, frequent problems in administration/adherence and “condition refractory to drug”, which

declined with repeated pharmacist-led education, dose adjustment, and therapeutic substitution. The significant fall in serum phosphate uniquely within the intervention arm (to 4.40 ± 1.52 mg/dL by V3) illustrates how medication review (binder choice/titration, dosing with meals, interaction management) can address biochemical targets that, if uncontrolled, worsen outcomes.^{2,7} These findings echo guidance and prior quality-improvement work showing that pharmacist engagement improves medication safety, aligns therapy with evidence, and supports infection-prevention behaviors in dialysis units.^{2,7,8,17}

Practice Context and Feasibility

Two fidelity challenges—phased replacement of a legacy gentamicin–heparin lock policy and staggered roll-out of access/dressing standardization—reflect real-world constraints that many dialysis centers face. Similar operational barriers are described across the literature: technique variation (eg, differences in restitution connection methods), supply inconsistencies, and the general vulnerability tied to CVC use.^{7,13,17–19} Even within these constraints, our results show that a pharmacist-anchored program can deliver clinically important gains.

Comparison with Existing Strategies and Lock Options

While our bundle relied on culture-guided antibiotic locks and chlorhexidine-based care, emerging data suggest several avenues for further optimization. Sodium bicarbonate locks appear to reduce both thrombosis and bloodstream infection,³ and ethanol locks have shown preventive benefit compared with heparin in meta-analysis.⁹ Strategy papers continue to emphasize individualized access planning, strict hub/exit-site protocols, and stewardship to minimize resistance and toxicity.^{2,7} Future work should directly compare lock regimens head-to-head within pharmacist-led programs, ideally with standardized definitions and cost-effectiveness analysis.

Strengths and Limitations

Strengths include randomized, pragmatic design, comprehensive pharmacist involvement, multiple patient-relevant outcomes, and repeated measures over six months. Limitations include single-center setting, modest sample size, short follow-up for hard outcomes (mortality), and potential contamination during protocol transition. The study did not adjudicate organism-specific outcomes or perform formal cost analyses. As others have noted, generalizability can vary with local access patterns, device handling techniques, and resource availability.^{5,7,16–18} These caveats argue for multi-center trials powered by clinical events and economic endpoints.

Implications and Next Steps

Our findings support integrating clinical pharmacists into hemodialysis infection-prevention programs, particularly where CVCs remain prevalent. Priority elements include: standardized chlorhexidine-based exit-site care, lock regimen stewardship (considering non-heparin options where appropriate), rigorous culture algorithms, recurrent patient/staff education, and continuous DTP audit with targeted interventions.^{1–3,7–9} Future research should evaluate scalability in resource-constrained settings, examine device/technique factors (eg, connection methods),¹⁷ and explore strategies to mitigate unique risks (eg, coexisting cardiac devices).⁶ Given the association between infection control and survival in kidney replacement therapy,^{4,5,7} pharmacist-led bundles may represent a high-value, implementable path to better outcomes.

Conclusion

This study shows that pharmacist-led pharmaceutical care was associated with lower CRBSI rates, shorter hospital stays, and fewer ICU admissions compared to usual care. Systematic identification and resolution of DTPs—through medication review and patient education—also improved adherence and biochemical control (notably phosphate). These results highlight the potential role of clinical pharmacists in multidisciplinary dialysis care and suggest this model is a practical, scalable approach to improving outcomes, including in resource-limited settings.

Abbreviations

ALT, Antibiotic lock therapy; AVF, Arteriovenous fistula; AVG, Arteriovenous graft; BP, Blood pressure; BSI, Bloodstream infection; CDC, Centers for Disease Control and Prevention; CFU, Colony-forming unit; CRBSI, Catheter-

related bloodstream infection; CRP, C-reactive protein; CVC, Central venous catheter; DTP, Drug therapy problem; ESA, Erythropoiesis-stimulating agent; ESRD, End-stage renal disease; HD, Hemodialysis; HR, Heart rate; ICU, Intensive care unit; K, Serum potassium; KDOQI, Kidney Disease Outcomes Quality Initiative; LOS, Length of stay; MRSA, Methicillin-resistant *Staphylococcus aureus*; MSSA, Methicillin-susceptible *Staphylococcus aureus*; Na, Serum sodium; ns, Not significant; RBC, Red blood cell; RR, Respiratory rate; SD, Standard deviation; SpO₂, Peripheral oxygen saturation; Tegaderm, Transparent chlorhexidine-impregnated dressing (3M); V0–V3, Study visits (baseline to month 3); WBC, White blood cell; WHO, World Health Organization.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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