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A Nurse-Led Bundle to Reduce Unplanned Discontinuation of Continuous Renal Replacement Therapy: A Single-Centre Pilot Study

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Abstract

Background. Unplanned discontinuation (UPD) of continuous renal replacement therapy (CRRT) compromises delivered treatment dose and is driven substantially by modifiable operational and educational factors. Before a definitive multicentre trial, the feasibility of delivering a multi-component, nurse-led bundle must be established.

Aim. To evaluate the feasibility, fidelity, and acceptability of an eight-component, nurse-led PDCA bundle to reduce CRRT UPD in a single centre, and to generate parameters for a future definitive trial.

Study Design. Single-arm, single-centre pilot study in a hospital-based haemodialysis centre in Xiamen, China, January–August 2025, with a six-month baseline period. The intervention was an eight-component PDCA bundle addressing nurse credentialing, structured training, device-specific standard operating procedures (SOPs), alarm handling, ultrasound-guided catheter placement, pre-treatment access assessment, anticoagulation standardisation, and blood-sampling/priming workflows. Feasibility outcomes were delivery within the planned timeline, fidelity (proportion of eligible nurses completing credentialing, threshold ≥ 80%), and acceptability (credentialing uptake and self-rated capability). The preliminary signal was the UPD rate. Patient-level baseline characteristics were not systematically collected in the source registry; this is reported explicitly as a scope limitation of the feasibility design.

Results. All eight components were delivered between March and May 2025. Fidelity was 100% (8/8 eligible nurses); theory scores 86–93, operational scores 85–90. The preliminary UPD rate was 8.0% (2/25 sessions; 95% CI 2.2%–25.0%), compared with 17.3% (18/104 sessions) in the baseline period. The wide confidence interval confirms the imprecision anticipated in a pilot. No intervention-attributable adverse events were recorded.

Conclusions. Delivering the eight-component nurse-led bundle was feasible and acceptable in this centre, with complete credentialing fidelity. Patient-level baseline data were not available, which limits interpretation of the preliminary UPD signal and should be addressed in a definitive trial. A multicentre stepped-wedge pilot with prespecified progression criteria, systematic baseline data collection, and statistical process control is the appropriate next step.

Relevance to Clinical Practice. A structured, nurse-led bundle combining credentialing, standardised protocols, and alarm management was feasible to implement and yielded a preliminary signal of reduced CRRT unplanned discontinuation, providing a practical framework for critical care units seeking to optimise CRRT delivery.

What is known about this topic?

Unplanned discontinuation of continuous renal replacement therapy (CRRT) compromises treatment adequacy and increases consumable use.

Nurse-led interventions and structured training programmes have been associated with prolonged circuit lifespan and fewer unplanned interruptions in various settings.

What this paper adds?

This pilot demonstrates that an eight-component nurse-led bundle can be delivered with 100% fidelity and is acceptable to bedside nurses in a haemodialysis centre.

The study provides critical event-rate parameters and highlights the necessity of systematic patient-level baseline data collection for designing future definitive multicentre trials.

Introduction

Continuous renal replacement therapy (CRRT) is the preferred renal replacement modality for haemodynamically unstable critically ill patients, but its effectiveness depends on uninterrupted delivery of the prescribed dose [1]. Unplanned discontinuation (UPD)—premature cessation before the prescribed dose is achieved—compromises treatment adequacy and consumes consumable and nursing resources; circuit clotting leading to failed blood restitution also contributes to iatrogenic blood loss [2].

The reported incidence of UPD varies widely, from 2.46% in a large Chinese tertiary-centre series of 3128 sessions to 27.4%–32.8% in elderly ICU cohorts, with circuit-clotting-related interruption documented in 17%–74% of sessions depending on case mix and anticoagulation practice [2–4]. A meta-analysis of nine studies involving 1165 participants identified red blood cell count, filter lifespan, transmembrane pressure, blood flow velocity, prothrombin activity and activated partial thromboplastin time as factors influencing unplanned interruption [5]. This variability indicates that UPD is at least partly determined by local practice rather than by patient biology alone [3]. Anticoagulation regimen, treatment duration, and net ultrafiltration rate have been identified as independent predictors, and elevated circuit pressure is the leading proximate cause [3, 4]. A 2-hour transmembrane pressure (TMP) threshold above 86 mmHg has been incorporated into a validated early-warning nomogram, reinforcing the principle that circuit-pressure surveillance is a modifiable nursing target [4]. Pre-filter pressure has been proposed as an earlier warning signal than TMP, although the evidence base remains limited [2].

Nurse-led interventions have shown consistent promise. A systematic review of 15 studies concluded that nurse-led CRRT management was associated with prolonged circuit lifespan and reduced unplanned interruptions, although mortality effects were variable and heterogeneity in staffing models and outcome definitions was substantial [1]. In a Chinese centre, a nurse-led homogeneous management strategy reduced the unplanned interruption rate from 16.57% to 9.49% (P = 0.003) [6]. Structured nurse training and competency-based credentialing have been proposed as mechanisms for standardising CRRT practice and reducing avoidable interruptions [7, 8]. The SimHeR randomised controlled trial demonstrated that adding high-fidelity simulation training to a conventional CRRT training programme reduced the rate of unplanned session interruption and the need for nurses to request assistance [9]. Structured alarm-management protocols, summarised in recent evidence syntheses, are a further

operational lever for maintaining treatment continuity [10]. A systematic review of interventions to improve filter life similarly identified staff education, anticoagulation protocols, and circuit surveillance as recurrent targets [5]. The KDIGO acute kidney injury guideline recommends regional citrate anticoagulation over heparin in patients without contraindications, providing a guideline anchor for standardising anticoagulation practice [11].

At our centre, a review of 225 CRRT sessions in 2024 revealed an overall UPD rate of 13.8%, rising from 10.7% in the first half to 17.3% in the second half. Root-cause verification pointed predominantly to educational and standardisation gaps: an incomplete CRRT training plan and the absence of a standardised operating procedure each accounted for 22.4% of verified cause-events. These causes are operationally addressable but had not previously been tested as a coherent, deliverable bundle.

Before committing to a definitive trial, we therefore designed a single-arm pilot study with three questions: (1) Can the eight-component nurse-led bundle be delivered as planned within the intended timeline? (2) Is the bundle acceptable to bedside nurses, as reflected in credentialing uptake and self-rated capability? (3) What preliminary UPD rate and implementation parameters would inform the design of a future multicentre trial? Because this was a non-randomised implementation study using a retrospective registry, we adapted reporting from the CONSORT extension for pilot and feasibility trials [12] where applicable, alongside SQUIRE 2.0 for the improvement components [13].

Methods

Study design and reporting framework

Single-arm, single-centre pilot study with a before–after comparison against a six-month baseline. The study was designed to assess deliverability, fidelity, and acceptability, and to generate preliminary parameter estimates; it was not powered to test effectiveness [12, 14]. We report against the CONSORT extension for pilot and feasibility trials for items applicable to a non-randomised implementation study and explicitly acknowledge deviations from a fully randomised pilot design, including the absence of systematic patient-level baseline data collection.

Setting and participants

The haemodialysis centre of Xiamen Humanity Hospital, a tertiary hospital in Xiamen, China, operating a nurse-led CRRT service for dialysis and hospitalised patients. Nurse participants were all registered nurses expected to perform CRRT independently during the study period. Patient sessions were all adult CRRT sessions recorded in the centre's CBP (continuous blood purification) registry during baseline (July–December 2024) and implementation (March–August 2025). Therapeutic plasma exchange (TPE) and hemoperfusion (HP) sessions were excluded from the UPD denominator because of different circuit configurations and interruption mechanisms [1].

Patient-level baseline characteristics. The CBP registry was designed for operational documentation rather than research and does not systematically capture illness severity scores, baseline coagulation parameters, vasopressor use, or comorbidity indices. Consequently, patient-level baseline characteristics are not available for the present analysis. This is a scope limitation of the feasibility design and is reported transparently rather than imputed. For the nurse-level intervention (credentialing, training, SOPs), baseline characteristics are fully described because the unit of intervention is the centre and the nursing workforce, not the individual patient.

Intervention: the eight-component PDCA bundle

Developed through a Plan–Do–Check–Act cycle. The Plan phase comprised a nine-member multidisciplinary team, weighted theme selection, a Gantt chart, a fishbone diagram, structured cause verification, and Pareto analysis. The Do phase comprised eight components, each mapped to one or more verified causes (Table 1). The Check phase assessed credentialing, preliminary UPD, and self-rated capability. The Act phase standardised effective components into institutional documents. The bundle was anchored in the national blood purification standard operating procedures [15], the KDIGO anticoagulation recommendation [11], and structured alarm-management evidence [10, 16].

Feasibility and implementation outcomes

Delivery was completion of all eight components within March–May 2025. **Fidelity** was the proportion of eligible nurses completing both theoretical and operational credentialing, with a prespecified threshold of ≥ 80%. **Acceptability** was assessed through credentialing completion and change in a nine-item self-rated capability scale. Each item was scored 1–5, giving a total score range of 9–45; the scale covered quality-improvement methods, problem-solving, implementation capability, team cohesion, communication, confidence, initiative, responsibility, and technical skill. It was administered before and after the project as a process measure, not as a patient-level outcome.

Preliminary clinical outcome

UPD was defined a priori as cessation of a CRRT session before completion of the prescribed dose due to persistent pressure-limit alarms (TMP, access, filter, or effluent pressure), TMP > 250 mmHg, filter clotting grade II or higher, refractory hypotension, patient inability to cooperate, or inadequate blood flow despite troubleshooting [3, 4]; filter clotting grading was aligned with the KDIGO framework [11]. Sessions in which the circuit was changed and treatment continued to the prescribed dose were recorded as circuit-replacement events and were **not** counted as UPD. The numerator and denominator were extracted independently by two investigators, with discrepancies resolved by a third. No formal sample size calculation was performed, consistent with pilot design [12, 14].

Analysis

Feasibility outcomes are reported as counts and proportions. The UPD rate is reported with a 95% Wilson confidence interval to make imprecision explicit. A Fisher exact test was performed for descriptive comparison only; the resulting P value is not interpreted as evidence of effectiveness. Patient-level characteristics are not compared because they were not systematically collected. Analyses used SPSS version 26.0.

Ethics

This project was reviewed and approved by the Institutional Quality Improvement and Ethics Committee of Xiamen Humanity Hospital (approval no. HAXM-MEC-20261110-115-01, **approved on 10 11 2026**). The need for individual patient informed consent was waived because (1) the intervention was a system-level educational and procedural standardisation initiative with no deviation from standard clinical care, and (2) all patient data were extracted retrospectively from the registry with identifiers fully removed. Verbal informed consent was obtained from nurse participants for the use of their anonymised credentialing data.

Results

Feasibility of delivery

All eight components were delivered within March–May 2025. No component was abandoned, and no substantive protocol deviation occurred. The most time-consuming component was developing device-specific SOPs for two CRRT platforms, which required reconciliation of manufacturer documentation with local workflow. The alarm-handling protocol required iterative review because alarm nomenclature differed between devices, a barrier also noted in recent alarm-management evidence syntheses [10, 16].

Fidelity and nurse acceptability

Eight nurses were eligible. All eight completed theoretical and operational assessments, giving a **fidelity of 100% (8/8)**, exceeding the 80% threshold. Theory scores ranged from 86 to 93 and operational scores from 85 to 90; all passed and were authorised to practise independently.

On the nine-item self-rated capability scale (total score range 9–45), item-level and total mean scores increased across all nine domains from pre-project to post-project assessment. Because the scale was administered without a control group, these changes are reported as **descriptive signals of acceptability and perceived capability**, not as evidence of a causal training effect. Qualitatively, credentialing was perceived by the nursing team as clarifying expectations and legitimising independent practice; this was captured in team meeting minutes but not subjected to formal qualitative analysis.

Preliminary UPD signal

In the baseline period (second half of 2024), the UPD rate was 17.3% (18/104 sessions). After implementation, the observed rate was **8.0% (2/25 sessions; 95% CI 2.2%–25.0%)**. The point estimate

fell below the prespecified target of 9.4%, but the confidence interval spans a wide range that includes the baseline rate. Fisher's exact test yielded P = 0.33. **This result should be read as a parameter estimate for future trial design, not as a test of effectiveness** [12, 14]. The observed event rate of approximately 8% and the session volume of 25 sessions over the post-implementation window are the parameters a future trial should use for sample-size calculation.

Harms and unintended consequences

No credentialing-related adverse events and no intervention-attributable patient safety events were identified. One implementation-level barrier was documented: anticoagulation standardisation required a change to the electronic prescription form, which introduced a temporary delay in prescription completion during the first two weeks. This was resolved through a brief reminder workflow and did not require abandonment of the component. No unintended increase in circuit-replacement events was observed, although the small sample precludes formal assessment of this balance measure.

Discussion

This pilot addressed feasibility rather than effectiveness. The answer is affirmative on the feasibility dimensions: the eight-component bundle was delivered as planned, nurse credentialing achieved 100% fidelity against an 80% threshold, and the intervention was acceptable as reflected in full participation and improved self-rated capability. The preliminary UPD estimate of 8.0% is compatible with a clinically meaningful reduction, but the confidence interval is too wide to support an effectiveness conclusion. This is precisely the uncertainty a pilot is designed to expose rather than conceal [12, 14].

Comparison with existing evidence

The feasibility findings align with the broader literature. The systematic review of nurse-led CRRT management reported consistent associations with prolonged circuit lifespan and reduced unplanned interruptions, while noting heterogeneity in staffing models and outcome definitions—exactly the parameters a pilot must characterise before a definitive trial [1]. The Chinese homogeneous-management study reported a larger absolute reduction (16.57% to 9.49%) in a substantially larger sample, but it was conducted in a different service model and did not report implementation fidelity [6]. Systematic reviews of filter-life interventions similarly identify staff education, anticoagulation protocols, and circuit surveillance as recurrent targets [5]. Action-research-based quality improvement has also been associated with reduced unplanned discontinuation and prolonged circuit use in a Chinese ICU setting [17]. Our bundle extends this logic by combining training with standardisation (SOPs, alarm guides), access optimisation (ultrasound, pre-treatment assessment), and anticoagulation standardisation. The finding that educational and procedural causes dominated the verified-cause profile supports the argument that UPD is a system performance issue as much as a biological one [3, 7].

The preliminary estimate of 8.0% sits within the lower range reported in Chinese cohorts but is not directly comparable because of case-mix and anticoagulation differences [2–4]. Anticoagulation

regimen has been consistently identified as an independent predictor, and the choice between nafamostat and regional citrate appears to modify filter survival in a centre-specific manner [3, 11, 18]. Mode of CRRT may also influence circuit longevity, with some evidence suggesting CVVHD/CVVHDF may offer longer filter life than CVVH [19], although this was not tested in our pilot. This reinforces that a feasibility signal should not be interpreted as evidence that the bundle eliminates UPD; rather, the bundle targets the **modifiable operational fraction**, and the preliminary estimate is consistent with a plausible effect on that fraction.

Implementation barriers and facilitators

Three practical considerations are directly relevant to replication. **First**, device heterogeneity is a real barrier: SOPs and alarm guides for two CRRT platforms required more time than anticipated and would be more complex in centres with three or more device types [10, 16]. **Second**, electronic prescription modification facilitated anticoagulation standardisation but introduced a transient workflow disruption; future implementations should pair prescription changes with a brief embedded reminder. **Third**, credentialing functioned as both an educational and a governance mechanism, creating a visible standard for independent practice that may have contributed to acceptability beyond the training content itself [7, 8].

Limitations

First, the single-arm, before–after design cannot separate the bundle's effect from secular trends, case-mix changes, or the Hawthorne effect [13]. **Second**, the post-implementation denominator of 25 sessions produced a wide confidence interval; this was anticipated in the pilot design and is the basis for recommending a larger study, not a reason to dismiss the signal [12, 14]. **Third**, patient-level baseline characteristics were not systematically collected; without illness severity, coagulation status, or vasopressor use, the pre- and post-implementation populations cannot be formally compared, and the UPD signal must be interpreted as hypothesis-generating only [20]. This is the most important limitation of the present report and should be addressed in a definitive trial through prospective, standardised baseline data collection. **Fourth**, UPD was ascertained from a routine registry rather than by an independent adjudication committee; despite a priori definitions and double extraction, misclassification remains possible. **Fifth**, the nurse capability scale was self-reported and unblinded, making it susceptible to social desirability and expectation bias. **Sixth**, the study was conducted in a nurse-led haemodialysis centre; generalisability to ICU-based CRRT services with different staffing and case mix is uncertain [1].

Implications for a definitive trial

The pilot generates concrete parameters. The observed post-implementation UPD rate of 8% and a session volume of approximately 4–5 CRRT sessions per month in a single centre imply that a definitive trial would require either substantially longer accrual or, more feasibly, a multicentre design with 8–12 centres. Because the intervention is delivered at the centre level (protocols, credentialing, SOPs), a **stepped-wedge cluster design** is likely more appropriate than individual randomisation [12]. Progression criteria for a future pilot-to-definitive transition should be prespecified and include: (i) ≥ 80% fidelity

across centres; (ii) completion of all components within a 4-month window; (iii) systematic collection of patient-level baseline characteristics in ≥ 90% of sessions; (iv) no evidence of intervention-attributable harm; and (v) a point estimate of UPD reduction compatible with a clinically meaningful effect, without requiring statistical significance at the pilot stage [12, 14]. Statistical process control—specifically a u-chart of monthly UPD rates—should be used alongside conventional before–after comparisons because it is better suited to detecting special-cause variation in low-volume settings and to distinguishing signal from background fluctuation [13].

Conclusion

A nurse-led, eight-component PDCA bundle for reducing CRRT unplanned discontinuation was feasible to deliver and acceptable to bedside nurses in a single haemodialysis centre, with complete credentialing fidelity. The preliminary UPD estimate of 8.0% is imprecise, and the absence of systematic patient-level baseline data further limits interpretation; the estimate should not be read as proof of effectiveness. Nevertheless, the pilot provides the event-rate and implementation parameters needed to design a definitive multicentre trial. The next step should be a stepped-wedge pilot with prespecified progression criteria, mandatory baseline data collection, independent outcome adjudication, and statistical process control monitoring.

Declarations

Author Contribution

Mingming Liao: Conceptualization, Methodology, Project administration, Supervision, Writing – review & editing. Zhihui Chen: Methodology, Data curation, Writing – original draft, Writing – review & editing. Xiaojing Zhang: Investigation, Data curation, Resources. Miaoshui Xu: Formal analysis, Investigation, Validation. Xiaoshan Wang: Formal analysis, Investigation, Visualization. All authors read and approved the final manuscript.

Data Availability

Data availability statement:The data that support the findings of this study are not openly available due to reasons of patient privacy and institutional ethical restrictions. However, de-identified data are available from the corresponding author upon reasonable request.

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Tables

Table 1. The eight-component bundle, targeted causes, and delivery

Developed through a Plan–Do–Check–Act cycle. The Plan phase comprised a nine-member multidisciplinary team, weighted theme selection, a Gantt chart, a fishbone diagram, structured cause verification, and Pareto analysis. The Do phase comprised eight components, each mapped to one or more verified causes (Table 1). The Check phase assessed credentialing, preliminary UPD, and self-rated capability. The Act phase standardised effective components into institutional documents. The bundle was anchored in the national blood purification standard operating procedures, the KDIGO anticoagulation recommendation , and structured alarm-management evidence.

Component	Targeted verified cause	Delivery details	Date
1. Nurse CRRT credentialing	Incomplete training plan	Written policy; theory and operational assessment; authorisation to practise	Mar 2025
2. Structured CRRT training	Incomplete training plan	Theory curriculum, operation drills, clinical preceptorship; assessment criteria	Mar 2025
3. Device-specific SOPs (Fresenius, Prismaflex)	No standardised operating procedure	SOPs and scoring checklists per device	Mar 2025
4. Alarm-handling protocol	No standardised operating procedure	Consolidated manufacturer documentation; common-alarm guide (TMP, access, filter, effluent pressure)	Mar 2025
5. Ultrasound-guided catheter placement	Inadequate catheter position	Policy revision: pre-placement ultrasound measurement of vessel diameter, course, skin-to-vessel distance	Mar 2025
6. Pre-treatment access assessment	Inadequate catheter position	Patency criteria incorporated into CRRT operation assessment	Apr–May 2025
7. Anticoagulation/pre-flush standardisation	Failure to adjust anticoagulation; unfamiliarity with nafamostat	Pre-flush and dose-adjustment requirements added to CRRT prescription form; nafamostat training	Apr 2025
8. Blood-sampling/priming workflows	Improper circuit blood sampling	Pre-treatment sampling score sheet; priming workflow displayed on CRRT carts; training and assessment	May 2025

Table 2. Preliminary UPD signal

In the baseline period (second half of 2024), the UPD rate was 17.3% (18/104 sessions). After implementation, the observed rate was **8.0% (2/25 sessions; 95% CI 2.2%–25.0%)**. The point estimate fell below the prespecified target of 9.4%, but the confidence interval spans a wide range that includes the baseline rate. Fisher's exact test yielded P = 0.33. **This result should be read as a parameter estimate for future trial design, not as a test of effectiveness**. The observed event rate of approximately 8% and the session volume of 25 sessions over the post-implementation window are the parameters a future trial should use for sample-size calculation.

Period	UPD events / CRRT sessions	UPD rate (95% CI)	Interpretation
Baseline (Jul–Dec 2024)	18 / 104	17.3%	Baseline reference
Post-implementation (Mar–Aug 2025)	2 / 25	8.0% (2.2%–25.0%)	Imprecise pilot estimate; no effectiveness claim

Baseline patient-level characteristics are not available and are not presented, consistent with the scope limitation stated in Methods.