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EFFECT OF PHARMACIST-LED ANTIMICROBIAL DOSE OPTIMIZATION IN ADULT INTENSIVE CARE UNITS: A SYSTEMATIC REVIEW WITH EXPLORATORY META-ANALYSIS OF DOSE ADJUSTMENT, THERAPEUTIC DRUG MONITORING, AND PHARMACOKINETIC-GUIDED DOSING

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Abstract

Background: Critical illness alters antimicrobial pharmacokinetics, and under- or over-dosing is common in intensive care units (ICUs). Clinical pharmacists can adjust doses, run therapeutic drug monitoring (TDM) and apply pharmacokinetic (PK) models, but the clinical effect of these activities in adult ICUs is unclear. **Methods:** We searched PubMed (last run 18 November 2026) following PRISMA 2020 for comparative studies of pharmacist-led or pharmacist-delivered antimicrobial dose optimization in adult ICUs. Outcomes were dosing appropriateness or PK/PD target attainment, mortality, length of stay, and vancomycin-associated acute kidney injury (AKI). Risk of bias was judged with ROBINS-I principles, and certainty with GRADE. Pooling was attempted only where at least two studies reported a comparable effect measure. **Results:** Of 108 unique records screened, 5 non-randomized studies were included (Thailand, China, Germany, Palestine, United States); no eligible Saudi or Gulf comparative study was found. Pharmacist-led programmes improved dosing appropriateness (36% to 63.6% of prescriptions in one study) and vancomycin target attainment (55.1% to 70.2%). ICU mortality fell from 29.4% to 18.6% in one Thai pre-post study but did not differ in the other studies reporting it. Mortality could not be pooled. For vancomycin AKI, AUC/Bayesian pharmacist-delivered dosing versus trough-guided dosing gave a pooled odds ratio of 0.72 (95% CI 0.58–0.89; two studies, $I^2 = 0\%$), with one study carrying 96% of the weight. Certainty of evidence was very low for all outcomes. **Conclusions:** Pharmacist-led dose optimization reliably improves process measures, and may reduce vancomycin nephrotoxicity, but its effect on mortality is unproven. Controlled, ICU-specific studies, including studies from Saudi Arabia, are needed.

Keywords: clinical pharmacist; intensive care; antimicrobial dosing; therapeutic drug monitoring; model-informed precision dosing; vancomycin; Saudi Arabia

1. Introduction

Antimicrobial therapy in critically ill adults is complicated by an enlarged volume of distribution, augmented or impaired renal clearance, hypoalbuminaemia, and renal replacement therapy. These changes make standard doses unreliable. In the standard-dosing arm of the multicentre DOLPHIN trial, only 60.9% of ICU patients met the pharmacodynamic target at first sampling (Ewoldt et al., 2022). Missing the target has been linked with treatment failure and resistance, whereas excess exposure adds toxicity, such as nephrotoxicity with vancomycin.

Pharmacists contribute at several points of this pathway: renal and organ-function dose adjustment, TDM interpretation, Bayesian or model-informed precision dosing (MIPD), and prospective audit and feedback within stewardship programmes. A recent multi-country observational study of 28,795 ICU patients, including Saudi centres, found 20% higher odds of in-hospital mortality when pharmacist-delivered comprehensive medication management was absent for at least one ICU day (odds ratio [OR] 1.20; 95% CI 1.03–1.40) (Smith et al., 2026). That study addressed medication management broadly, not antimicrobial dosing in particular.

In Saudi Arabia, critical care pharmacists are established in ICUs: in a national survey, 86.9% of 44 respondents joined multidisciplinary rounds five days a week (Ismail et al., 2023). Local stewardship reports exist, but they mostly describe consumption or prescribing appropriateness (Haseeb et al., 2021; Alnajjar et al., 2026). Internationally, randomized trials of TDM-guided dosing show mixed results: target attainment rose in a small trial of piperacillin and meropenem (De Waele et al., 2014) but not in DOLPHIN, which also found no effect on ICU stay or mortality (Ewoldt et al., 2022). Whether pharmacist-led delivery of dose optimization changes patient outcomes has not been synthesised. Our aim was to review comparative evidence on pharmacist-led antimicrobial dose adjustment, TDM and PK-guided dosing in adult ICUs, to pool effects where the data allow, and to describe the Saudi and regional evidence base.

2. Methods

2.1 Design and registration

This is a systematic review reported according to PRISMA 2020. The protocol was not registered in PROSPERO or elsewhere before the search; this is a limitation (Section 4.2). Because the evidence was expected to be sparse and heterogeneous, a meta-analysis was planned only for outcomes reported by at least two eligible studies with a comparable effect measure.

2.2 Eligibility criteria

Population: adults (≥18 years) treated in an ICU or, for mixed units, a population in which ICU patients were explicitly analysed. *Intervention:* antimicrobial dose adjustment, TDM, or PK/PD- or model-guided dosing led or delivered by a clinical pharmacist or a pharmacist-led stewardship team with an explicit dosing component. *Comparator:* usual care, pre-implementation period, or non-pharmacist (trough-guided or empiric) dosing. *Outcomes:* dosing appropriateness or PK/PD target attainment, mortality, ICU length of stay, and vancomycin-associated AKI. *Designs:* randomized trials, controlled or uncontrolled before–after studies, and cohort studies with a comparison group. Single-arm series, surveys, qualitative studies, protocols, paediatric studies and narrative reviews were excluded.

2.3 Search and selection

PubMed was searched from inception to 18 November 2026 with fifteen query strings combining pharmacist terms (pharmacist, clinical pharmacist, pharmacist-led, pharmacist-driven), setting terms (intensive care, critically ill, ICU), and intervention terms (dose adjustment, dose optimization, therapeutic drug monitoring, pharmacokinetic, AUC-guided, vancomycin, beta-

lactam, aminoglycoside, antimicrobial stewardship; Table S1). Three further queries (two location-based, one on aminoglycoside and beta-lactam TDM) were first written with an unbounded Boolean structure, returned unusable result sets of 324,768, 154,346 and 827 records, and were not screened; the same topics were rerun with explicit [Title/Abstract] field tags (queries 11 and 13–15). Where a query returned more than 15 records, only the first 15 in relevance order were screened. The Consensus platform and other databases (Embase, Scopus, CINAHL) were not searched. Titles and abstracts were screened by a single reviewer; potentially eligible records were assessed in full text where a PubMed Central copy was available and otherwise from the complete abstract.

2.4 Data extraction, risk of bias, and synthesis

For each study we extracted setting, design, sample, intervention, comparator, outcomes and numerical results. Counts that were reported only as percentages were reconstructed from the stated denominators. Risk of bias was judged for non-randomized studies using the ROBINS-I domains as a guide; a full domain-by-domain assessment was not completed. Certainty was rated with GRADE. Effect measures were odds ratios (OR) or risk ratios (RR) with 95% confidence intervals (CI). Where pooling was possible we used the inverse-variance method on the log scale with fixed- and DerSimonian–Laird random-effects models and report Cochran's Q, I^2 and τ^2. Egger's test and funnel plots were not planned because fewer than ten studies were expected. Analyses were run in Python (NumPy, SciPy).

3. Results

3.1 Study selection

The searches returned 112 records; after removing four duplicates, 108 were screened and 89 were excluded at title and abstract level (Figure 1). Nineteen records were assessed in more detail, of which fourteen were excluded: one because the ICU setting could not be verified (Xu et al., 2018); three because a pharmacist was not the lead or the pharmacist role was not described (De Waele et al., 2014; Ewoldt et al., 2022; Schmid et al., 2023); three because stewardship or observational work had no pharmacist dosing component (Haseeb et al., 2021; Alnajjar et al., 2026; Aldardeer et al., 2024); six because they had no comparator group (Althomali et al., 2022; Almaghrabi et al.,

2026; Landry et al., 2025; Schmid et al., 2025; Fulbright et al., 2024; Xu et al., 2021); and one because it compared infusion modes only (Aardema et al., 2020). Five studies were included.

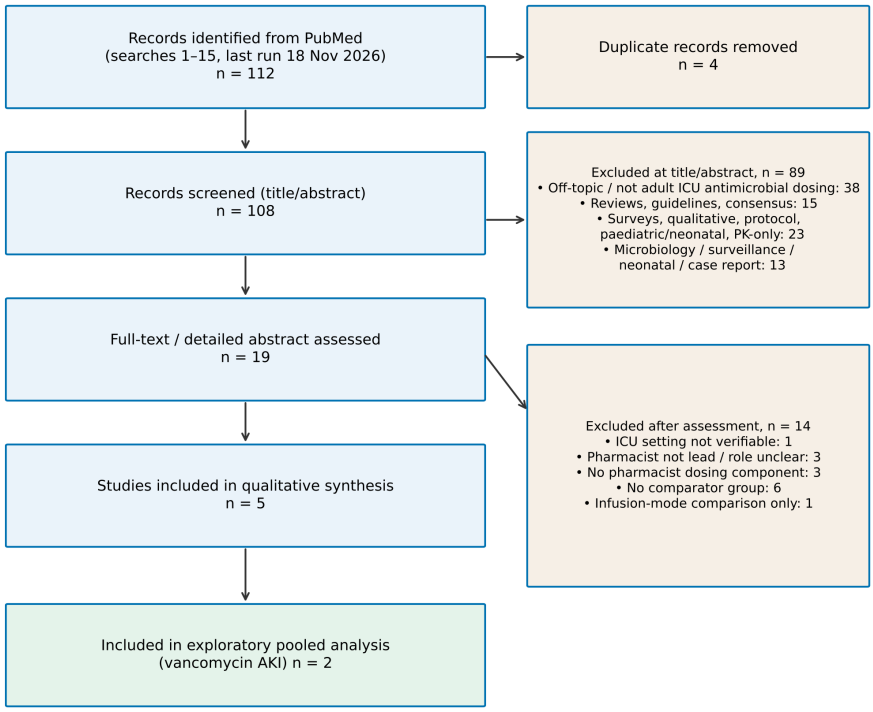


Figure 1. PRISMA 2020 flow diagram of study selection. Records come from PubMed only; counts are of unique records screened by one reviewer.

3.2 Characteristics of included studies

All five included studies were non-randomized: three before–after designs, one propensity-matched cohort, and one retrospective cohort comparing three dosing methods (Table 1). Four were conducted in ICUs or ICU-and-intermediate-care units; Knight et al. (2023) analysed a hospital-wide pharmacy dosing service in which ICU admission was a covariate, so its population is only indirectly relevant. Three studies delivered broad dose and stewardship interventions (Gatechan et al., 2025; Gu et al., 2023; Khdour et al., 2018) and two focused on vancomycin AUC-based dosing (Gundlach et al., 2026; Knight et al., 2023). None was conducted in Saudi Arabia or another Gulf country.

Table 1. Characteristics of the included studies

Study (country)	Design / setting	Sample	Pharmacist intervention	Comparator
Gatechan et al. 2025 (Thailand)	Retrospective before–after; medical ICUs, 2019–2021	269 patients (455 prescriptions) before; 376 (604) after	ID and clinical pharmacists: education plus prospective audit and feedback on dosing and TDM; 40 interventions, 87.5% accepted	Pre-implementation period

Study (country)	Design / setting	Sample	Pharmacist intervention	Comparator
Gu et al. 2023 (China)	Retrospective propensity-matched cohort; ICU, 2017–2019	1,523 screened; 102 matched pairs	Clinical pharmacist stewardship: regimen adjustment, de-escalation, TDM suggestions	Patients without pharmacist intervention
Gundlach et al. 2026 (Germany)	Before–after; ICU and intermediate care	216 retrospective; 57 prospective	Pharmacist-performed Bayesian AUC-guided vancomycin dosing	Trough-guided dosing (historical)
Khdour et al. 2018 (Palestine)	Prospective before–after; ICU; 4 months each period	Not stated in retrieved abstract	Stewardship team audit and feedback; 176 interventions; dose optimization most accepted (87.0%)	Pre-stewardship period
Knight et al. 2023 (USA)	Retrospective cohort; hospital pharmacy dosing consult (ICU as covariate)	3,459 encounters	Pharmacist AUC-guided Bayesian software (n = 659) or AUC nomogram (n = 303)	Pharmacist trough-guided dosing (n = 2,497)

ID, infectious diseases; TDM, therapeutic drug monitoring; AUC, area under the concentration–time curve. All studies are from non-Saudi settings (International).

3.3 Dosing appropriateness and target attainment

Process measures improved in every study that reported them (Table 2; Figure 2A). In the Thai study, the proportion of prescriptions with appropriate dosing and TDM rose from 36% to 63.6%, equivalent to an unadjusted OR of 3.10 (95% CI 2.40–3.99) at prescription level, which overstates precision because prescriptions within patients are not independent (Gatechan et al., 2025). In the German study, vancomycin target attainment rose from 55.1% to 70.2% (p = 0.049) and supratherapeutic exposure fell from 24.5% to 8.8% (p = 0.01) (Gundlach et al., 2026). Physicians accepted most pharmacist dosing recommendations: 87.5% in Thailand and 87.0% for dose optimization in Palestine. In China, antibiotic use density fell from 241.91 to 176.64 defined daily doses per 100 bed-days (p = 0.018) (Gu et al., 2023).

Table 2. Main outcomes reported by the included studies (intervention versus comparator)

Outcome	Study	Comparator	Intervention	Effect (95% CI) / p
Appropriate dosing and TDM	Gatechan 2025	36% (164/455 prescriptions)	63.6% (384/604)	OR 3.10 (2.40–3.99)*
Vancomycin target attainment	Gundlach 2026	55.1%	70.2%	p = 0.049
ICU mortality	Gatechan 2025	29.4% (79/269)	18.6% (70/376)	RR 0.63 (0.48–0.84)*; p = 0.001
30-day mortality	Khdour 2018	26.9%	23.9%	p = 0.1
Mortality, pharmacist exposure	Gu 2023	—	—	No difference (p = 0.288)

Outcome	Study	Comparator	Intervention	Effect (95% CI) / p
30-day hospital mortality	Gatechan 2025	—	—	No significant difference
ICU length of stay	Gatechan 2025	7 days	5 days	p = 0.005
ICU length of stay	Khdour 2018	11 (3–21) days	7 (4–19) days	p < 0.01
Vancomycin AKI	Gundlach 2026	27.8% (60/216)	14.0% (8/57)	p = 0.04; matched OR 0.74 (0.26–1.9)
Vancomycin AKI	Knight 2023	32% (trough)	21% (Bayesian); 22% (nomogram)	aOR 0.72 (0.58–0.89); 0.71 (0.53–0.95)

*Calculated by the authors from reported counts or percentages (counts reconstructed from stated denominators); not adjusted for confounding. AKI, acute kidney injury; aOR, adjusted odds ratio.

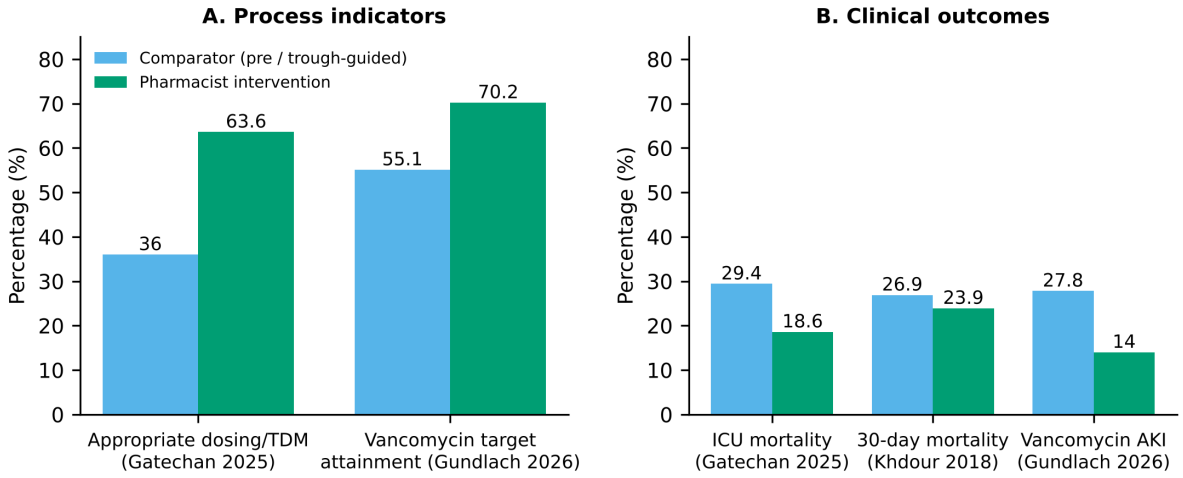


Figure 2. Reported process indicators (A) and clinical outcomes (B) before and after pharmacist-led interventions, as stated in each study. Different studies and definitions are shown side by side for orientation only; the bars are not pooled.

3.4 Mortality and length of stay

Mortality results were inconsistent and could not be pooled. Only the Thai study reported counts that could be reconstructed: ICU mortality fell from 29.4% (79/269) to 18.6% (70/376), an unadjusted RR of 0.63 (95% CI 0.48–0.84). The same study found no difference in 30-day in-hospital mortality, and multivariable analysis showed that mortality was driven by severity of illness (APACHE II), septic shock and continuous renal replacement therapy (Gatechan et al., 2025). The Palestinian study found no change in 30-day mortality (26.9% vs 23.9%; p = 0.1) (Khdour et al., 2018), and the matched Chinese cohort reported no mortality difference associated with pharmacist intervention (Gu et al., 2023). Length of stay was shorter after implementation in two studies (Gatechan et al., 2025; Khdour et al., 2018), but both used before–after designs in which secular trends cannot be excluded.

3.5 Exploratory meta-analysis: vancomycin-associated AKI

Two studies compared pharmacist-delivered AUC/Bayesian vancomycin dosing with trough-guided dosing and reported adjusted or matched odds ratios for AKI. The pooled OR was 0.72 (95% CI 0.58–0.89) under both fixed- and random-effects models ($Q = 0.003$, $df = 1$; $I^2 = 0\%$; $\tau^2 =$

0) (Figure 3). The result is dominated by Knight et al. (2023), which carries 95.6% of the weight; the matched estimate from the ICU-based German study (OR 0.74; 95% CI 0.26–1.90) is compatible with both benefit and harm. Using the unadjusted German counts (8/57 vs 60/216) instead gave OR 0.42 (95% CI 0.19–0.95). An I^2 of 0% with two studies carries little information about true consistency, and the pooled estimate mixes an ICU-specific with a mixed-ward population. We therefore treat it as hypothesis-generating. No funnel plot or Egger's test was possible.

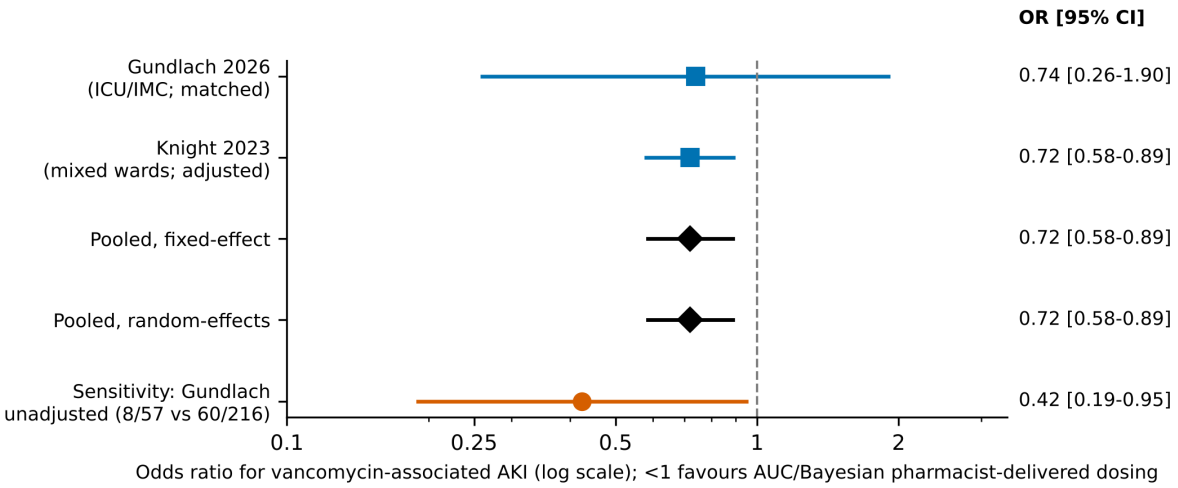


Figure 3. Forest plot of vancomycin-associated acute kidney injury with pharmacist-delivered AUC/Bayesian dosing versus trough-guided dosing. Squares show study estimates, diamonds pooled estimates, and the orange circle a sensitivity analysis not included in the pooled result.

3.6 Risk of bias and certainty of evidence

All five studies were at serious risk of bias, mainly from confounding (Table 3). Before–after designs cannot separate the intervention from secular change in case mix, antimicrobial resistance and clinical practice, and the German prospective arm contained only 57 patients. Certainty was rated very low for every outcome, starting from low for observational designs and downgraded for risk of bias, imprecision, and, for AKI, indirectness.

Table 3. Risk of bias and certainty of evidence (authors' judgement)

Study	Main bias concerns	Overall risk of bias
Gatechan 2025	Historical control; some adjustment for mortality predictors; prescription-level analysis	Serious
Gu 2023	Retrospective; propensity matching handles measured confounders only	Moderate to serious
Gundlach 2026	Historical control; 57 prospective patients; matched analysis imprecise	Serious
Khdour 2018	Four-month windows; no concurrent control; sample size not available to us	Serious to critical
Knight 2023	Retrospective; mixed-ward population; adjusted for creatinine, age and ICU stay	Moderate to serious
Certainty (GRADE)	Dosing appropriateness: very low; mortality: very low; length of stay: very low; vancomycin AKI: very low	—

Judgements follow ROBINS-I domains informally; a formal domain-level assessment was not completed.

3.7 Saudi Arabian and regional evidence

No eligible comparative study from Saudi Arabia or the Gulf region was identified. Seven regional records were reviewed to describe the local context (Table 4). They show established ICU pharmacy practice and stewardship activity but no study that measured the effect of pharmacist-led dose optimization against a comparator. Alnajjar et al. (2026) found no inappropriate dosing among meropenem courses, and their appropriateness gains came from spectrum and duration. Aldardeer et al. (2024) is the closest clinical link: in 224 Saudi ICU patients with sepsis and AKI, later renal dose adjustment of antipseudomonal beta-lactams was associated with lower in-hospital mortality (HR 0.588; 95% CI 0.355–0.974), which argues for careful, not reflexive, early dose reduction.

Table 4. Saudi and regional records reviewed, with two international randomized benchmarks

Study	Setting tag	Design and population	Key finding	Reason not included
Haseeb 2021	Saudi	Quasi-experimental ICU stewardship, 20 beds	Antimicrobial use −25% (742.86 to 555.33 DDD/100 bed-days; p = 0.110)	No dosing or TDM outcome
Alnajjar 2026	Saudi	Retrospective before–after, 113 adult ICU patients	Appropriate meropenem use 23.5% (2020) to 57.9% (2023); no inappropriate dosing found	No pharmacist dosing intervention described
Althomali 2022	Saudi	Descriptive, 165 ICU patients	404 pharmacist interventions; 91.5% accepted	No comparator
Aldardeer 2024	Saudi	Prospective cohort, 224 ICU patients with sepsis and AKI	Late dose adjustment: HR 0.588 for mortality	Not pharmacist-led; observational timing study
Almaghrabi 2026	Saudi	Single-centre QI report, military medical centre	Appropriateness 54% to 89% in high-risk units; 66 dose-adjustment recommendations	Descriptive; no comparator
Ismail 2023	Saudi	Survey of 44 critical care pharmacists	86.9% join rounds five days a week	Survey
Smith 2026	Saudi, Jordan, USA	Observational, 64 ICUs, 28,795 patients	No pharmacist CMM ≥1 day: OR 1.20 (1.03–1.40) for mortality	Exposure is CMM, not dosing
Ewoldt 2022	International	Multicentre RCT, 388 ICU patients	MIPD vs standard: ICU stay IRR 1.16 (0.96–1.41); target attainment at day 3: 59.5% vs 60.4%	Pharmacist role not specified
De Waele 2014	International	RCT, 41 ICU patients	Target attainment at 72 h (100% fT>4×MIC): 58% vs 16%	Pharmacist role not specified

CMM, comprehensive medication management; DDD, defined daily doses; MIPD, model-informed precision dosing; HR, hazard ratio; IRR, incidence rate ratio.

4. Discussion

This review found that pharmacist-led antimicrobial dose optimization in adult ICUs consistently improved process measures, namely dosing appropriateness, TDM quality and vancomycin target attainment, and that clinicians accepted most recommendations. Evidence that these gains reach patient outcomes is thin. ICU mortality fell in one before–after study and did not change in others, and the exploratory pooled estimate suggests lower vancomycin-associated AKI with AUC/Bayesian dosing. Every included study was observational and the certainty of evidence is very low.

The pattern matches the randomized evidence outside pharmacist-specific work. Daily TDM raised target attainment in a small trial (De Waele et al., 2014), whereas the larger DOLPHIN trial found no gain in target attainment, ICU stay or mortality from model-informed dosing (Ewoldt et al., 2022). A plausible reading is that better exposure does not automatically improve survival in a population where severity, source control and timing dominate outcomes; Gatechan et al. (2025) found exactly those factors predicted mortality. Delay between sampling and dose change, restrictive dose-change limits and pharmacokinetic variability over 48 hours were offered as reasons for the null DOLPHIN result, and they apply to pharmacist-led services too.

The vancomycin signal is the most coherent finding. Switching from trough-guided to AUC-guided dosing lowered AKI in the large US cohort, and the German ICU-based study moved in the same direction, although its matched estimate was imprecise. This is consistent with the rationale for AUC-guided monitoring, which is to avoid unnecessary high exposure, but two studies cannot establish it. The Saudi picture, in contrast, is a gap: local ICU studies describe stewardship consumption, appropriateness and intervention counts, and none reports dose-optimization outcomes against a comparator. Aldardeer et al. (2024) suggests that dose timing matters in Saudi ICUs, and Smith et al. (2026), which included Saudi centres, links daily pharmacist medication management with lower mortality. Hospitals that wish to measure the effect of pharmacist dosing services could use prospective audit with predefined indicators (target attainment, AKI, ICU mortality adjusted for severity) and a concurrent control or interrupted time-series design.

4.1 Strengths and limitations

Strengths are a transparent PRISMA process, explicit separation of process from clinical outcomes, calculation of effects from reported counts, and a deliberate review of Saudi and regional evidence. The limitations are substantial. Only PubMed was searched, no protocol was registered, and screening was done by one reviewer, so relevant studies may be missing. For five queries only the first 15 of a larger result set were screened, and three early queries had to be rerun. Some data came from abstracts rather than full texts, and the Palestinian sample size was not available to us. The pooled analysis includes two studies of different populations, with one dominating, and I^2 cannot be interpreted. Several studies delivered multi-component stewardship, so the dose-optimization effect cannot be isolated. Exclusion of two RCTs for unspecified pharmacist roles may understate the relevant trial evidence. Future work should search additional databases, use dual screening, register a protocol, and contact authors for individual-study counts.

5. Conclusion

Pharmacist-led dose adjustment, TDM and PK-guided dosing in adult ICUs improve dosing appropriateness and target attainment, and AUC/Bayesian vancomycin dosing may lower nephrotoxicity. Effects on mortality and length of stay remain unproven because the evidence is

observational and very low certainty. No comparative Saudi study was found. Controlled, ICU-specific evaluations with patient-level outcomes, including from Saudi hospitals, are needed before firm conclusions are drawn.

Declarations

Ethics approval and consent: Not applicable; the review used published data only. **Funding:** [to be completed by the authors]. **Conflicts of interest:** [to be completed by the authors]. **Data availability:** All extracted values are in the tables above; analysis code is available from the corresponding author. **Author contributions:** [CRediT statement to be completed by the authors]. **Registration:** The review was not registered. **AI transparency:** Literature searching, data extraction, calculations and drafting were carried out with the assistance of Claude (Anthropic). The authors must verify every extracted value against the source articles, repeat the search in additional databases, and take responsibility for the final content before submission.

Supplementary Table S1. Search strategy

#	PubMed query (abbreviated)	Records	Screened
1	pharmacist AND intensive care AND antimicrobial AND dosing AND (TDM OR dose optimization OR pharmacokinetic) AND mortality	13	13
2	pharmacist-led AND antimicrobial stewardship AND ICU AND meta-analysis	0	0
3	TDM AND beta-lactam AND critically ill AND randomized controlled trial AND target attainment	6	6
4	clinical pharmacist AND intervention AND ICU AND antibiotic AND dose AND adjustment AND renal function	3	3
5	pharmacist AND vancomycin AND dosing AND ICU AND pharmacokinetic AND AUC-guided	3	3
6	Saudi Arabia AND pharmacist AND antimicrobial stewardship AND ICU	8	8
7	critical care AND pharmacist AND systematic review AND mortality	25	15
8	pharmacist-driven AND antibiotic AND dosing AND protocol AND ICU AND outcomes	2	2
9	pharmacist AND critically ill AND vancomycin AND target attainment AND before AND after AND implementation	1	1
10	clinical pharmacist AND intervention AND critically ill AND antimicrobial dosing AND mortality AND length of stay AND cohort	0	0
11	Saudi Arabia[tiab] AND pharmacist*[tiab] AND (intensive care[tiab] OR critically ill[tiab])	21	15
12	Aldardeer AND renal dose adjustment AND antibiotics AND sepsis AND mortality	1	1
13	Saudi[tiab] AND (vancomycin OR meropenem OR colistin)[tiab] AND (intensive care OR critically ill)[tiab]	84	15

#	PubMed query (abbreviated)	Records	Screened
14	pharmacist*[tiab] AND (aminoglycoside* OR gentamicin OR amikacin OR tobramycin)[tiab] AND (intensive care OR critically ill OR ICU)[tiab]	36	15
15	pharmacist*[tiab] AND (beta-lactam* OR piperacillin OR meropenem)[tiab] AND (TDM OR dose adjustment OR dose optimization)[tiab] AND (intensive care OR critically ill)[tiab]	20	15
	Total records screened (before removing 4 duplicates)		112

tiab, [Title/Abstract]. Three unbounded early queries (not screened) are described in Section 2.3. Searches were run on 18 November 2026.

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