

# Can a pharmacist-led vancomycin monitoring and stewardship service improve safe and coordinated vancomycin care in adults at a provincial hospital in Vietnam?

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|----------------------------------------|----------------------------------------------------------|-----------------------------------------------------------------|
| <b>Submission date</b><br>26/08/2026   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered               |
| <b>Registration date</b><br>26/08/2026 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Protocol                               |
| <b>Last Edited</b><br>26/08/2026       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> Statistical analysis plan              |
|                                        |                                                          | <input type="checkbox"/> Results                                |
|                                        |                                                          | <input type="checkbox"/> Individual participant data            |
|                                        |                                                          | <input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Vancomycin is an antibiotic used to treat serious bacterial infections. Safe and effective use requires careful monitoring because drug exposure that is too high may increase the risk of kidney injury, whereas exposure that is too low may be insufficient for treatment. This study evaluated whether a pharmacist-led vancomycin monitoring and antimicrobial-stewardship service could improve the coordination, reliability and safety of vancomycin care in a provincial hospital in Vietnam.

### Who can participate?

Adults aged 18 years or older who started intravenous vancomycin in one of the participating clinical clusters and were expected to receive treatment for at least 48 hours.

### What does the study involve?

During usual-care periods, vancomycin prescribing, drug-level monitoring, dose adjustment and kidney-function monitoring followed existing hospital practice. Clinical clusters then moved in a prespecified sequence to a pharmacist-led service. The service coordinated review of the treatment indication, vancomycin dose and infusion, kidney function, drug-level sampling, Bayesian estimation of vancomycin exposure, microbiological results, antimicrobial reassessment and source-control planning. The order in which clinical clusters moved to the service was prespecified for operational purposes and was not randomised. Each participant contributed one treatment episode to the study.

### What are the possible benefits and risks of participating?

The service was designed to improve coordination, monitoring and medication safety during vancomycin treatment. The evaluation involved no experimental treatment or additional invasive procedure beyond routine clinical care. The main research-related concern was confidentiality; data used for analysis were de-identified and protected according to institutional requirements.

Where is the study run from?  
Tien Giang General Hospital, Vietnam.

When did the study take place?  
April 2025 to October 2025.

Who is funding the study?  
The study was investigator initiated and self-funded. It received no external research grant or commercial sponsorship.

Who is the main contact?  
Nguyen Thanh Nam, MD, PhD. Email: ntnam@tvu.edu.vn

## Contact information

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## Additional identifiers

## **Institutional scientific-protocol approval**

221/QĐ-BVĐKTG (17/03/2025)

# **Study information**

## **Scientific Title**

A prospective non-randomised stepped-wedge study of a pharmacist-led AUC-guided vancomycin stewardship service versus usual care in adults receiving intravenous vancomycin, evaluating early target AUC24 attainment in a provincial referral hospital in Vietnam

## **Study objectives**

To evaluate whether implementation of a pharmacist-led AUC-guided vancomycin stewardship service is associated with improved early target AUC24 attainment compared with usual care, and to evaluate excessive vancomycin exposure, acute kidney injury, clinical outcomes, implementation and stewardship processes, and direct hospital resource use.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

Approved 21/03/2025, Biomedical Research Ethics Committee (Institutional Review Board), Tien Giang General Hospital (Tien Giang General Hospital, 315 National Road 1A, Long Hung Quarter, Trung An Ward, Dong Thap Province, Trung An, 84118, Viet Nam; +84 273 3872 363; daotaobvdktg@gmail.com), ref: 232/BVĐKTG-HĐĐĐ

## **Primary study design**

Interventional

## **Allocation**

Non-randomized controlled trial

## **Masking**

Open (masking not used)

## **Control**

Active

## **Assignment**

Prospective, pragmatic, single-centre, non-randomised stepped-wedge implementation study with repeated cross-sectional sampling. Six clinical clusters transitioned sequentially from usual care to the pharmacist-led intervention according to a prespecified operational sequence. The crossover sequence was not randomised and no washout period was used.

## **Purpose**

Health services research

## **Study type(s)**

## **Health condition(s) or problem(s) studied**

Antimicrobial stewardship and medication safety in adults receiving intravenous vancomycin for serious suspected or confirmed bacterial infection.

## Interventions

During usual-care periods, intravenous vancomycin prescribing, therapeutic drug monitoring, dose adjustment and renal monitoring followed existing hospital practice.

During intervention periods, a pharmacist-led stewardship service integrated review of indication, body weight, renal function and nephrotoxicity risk; loading and maintenance dose review; infusion-rate review; therapeutic-drug-monitoring planning; Bayesian AUC<sub>24</sub> estimation and dose optimisation; creatinine surveillance and nephrotoxin review; microbiological sampling before the first dose when feasible; antimicrobial time-out after an actionable microbiological result; de-escalation; and coordination of source control.

Six clinical clusters transitioned sequentially from usual care to the intervention according to a prespecified non-randomised operational sequence. Each participant contributed one index treatment episode.

## Intervention Type

Other

## Primary outcome(s)

1. Early target AUC<sub>24</sub> attainment measured using proportion of primary AUC-eligible treatment episodes with a first valid Bayesian AUC<sub>24</sub> estimate of 400–600 mg·h/L, estimated using InsightRX maximum a posteriori Bayesian estimation from reconciled vancomycin dose, infusion and serum-concentration sampling times at within 48 hours of intravenous vancomycin initiation

## Key secondary outcome(s)

1. Excessive vancomycin exposure measured using proportion of primary AUC-eligible treatment episodes with a first valid Bayesian AUC<sub>24</sub> estimate >600 mg·h/L, estimated using InsightRX maximum a posteriori Bayesian estimation from reconciled vancomycin dose, infusion and serum-concentration sampling times at within 48 hours of intravenous vancomycin initiation

2. Acute kidney injury measured using proportion of evaluable treatment episodes meeting the serum-creatinine component of KDIGO criteria at within 7 days of intravenous vancomycin initiation

## Completion date

31/10/2025

## Eligibility

### Key inclusion criteria

1. Adults aged 18 years or older, with no protocol-defined upper age limit
2. Male or female
3. Initiation of intravenous vancomycin in a participating clinical cluster
4. Expected vancomycin treatment duration of at least 48 hours

### Healthy volunteers allowed

No

### Age group

Mixed

**Lower age limit**

18 Years

**Upper age limit**

120 Years

**Sex**

All

**Total final enrolment**

506

**Key exclusion criteria**

1. Oral vancomycin or prophylactic use only
2. More than 24 hours of vancomycin therapy before screening
3. Incomplete baseline data
4. Age below 18 years
5. Withdrawal
6. Other prespecified exclusion reasons defined in the approved study protocol

**Date of first enrolment**

01/04/2025

**Date of final enrolment**

27/10/2025

## **Locations**

**Countries of recruitment**

Viet Nam

**Study participating centre**

**Tien Giang General Hospital**

Tien Giang General Hospital, 315 National Road 1A, Long Hung Quarter, Trung An Ward, Dong Thap Province

Trung An

Viet Nam

84118

## **Sponsor information**

**Organisation**

Tien Giang General Hospital

**ROR**

<https://ror.org/056sq4g25>

## **Funder(s)**

**Funder type**

**Funder Name**

Investigator initiated and funded

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

De-identified participant-level data, the data dictionary and statistical analysis code may be made available from the corresponding author on reasonable request, subject to institutional, ethics and data-protection approval. The data will not be made publicly available because they originate from clinical records and retain a residual risk of re-identification.

### **IPD sharing plan summary**

Available on request