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Original Article

Survey on the Approval and Use of Group 1 Priority Antibiotics at a Provincial Hospital in Vietnam

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Abstract: Objective: To analyze the approval process and usage patterns of Group 1 priority antibiotics, namely vancomycin, injectable linezolid, and colistin at Thai Nguyen A Hospital. Methods: A retrospective cross-sectional study was conducted among patients administered Group 1 priority antibiotics for over 72 hours, using inpatient medical records from July to December 2023. Approval procedure: i) Physicians must submit an Antibiotic Use Request Form (AURF) to the Pharmacy Department prior to prescribing these antibiotics, and ii) Clinical Pharmacists check the AURF and may additionally monitor or retrospectively review cases without prior AURF submission. Results: In 172 patients, Group 1 antibiotics were predominantly utilized for Gram-positive bacteria (90.63%). Regarding dosing, 85.71% of colistin loading doses and 100% of linezolid cases complied with guidelines. However, while 75.0% of vancomycin maintenance doses were appropriate, only 12.5% of patients received an adequate loading dose. In total, 79.07% of patients improved or cured. Clinical pharmacists executed 62 interventions, primarily focused on therapeutic monitoring (50.0%) and regimen adjustments (41.9%). Vancomycin necessitated the most frequent therapy adjustments, while interventions for linezolid and colistin concentrated on monitoring side effects and assessing renal function, respectively. Conclusion: Group 1 priority antibiotics were generally used appropriately, resulting in favorable clinical outcomes. The results highlight the critical role of clinical pharmacist interventions in enhancing antimicrobial stewardship to optimize the use of high-priority antibiotics.

Keywords: Group 1 antibiotics, antibiotic stewardship, pharmacist interventions.

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1. Introduction

In recent years, infections due to multidrug-resistant (MDR) bacteria, including Gram-negative *Acinetobacter baumannii, Pseudomonas aeruginosa, Klebsiella pneumoniae, E. coli*, and Gram-positive MRSA - have increased [1]. These infections are frequently severe, associated with elevated death rates, extended hospitalizations, and significant healthcare expenditures.

To address this, the World Health Organization (WHO) advocates for the establishment of Antimicrobial Stewardship (AMS) programs to maintain the efficacy of antibiotics, especially those classified as "last-resort" or "reserve" medicines [1][2]. WHO introduced the AWaRe classification in 2019, categorizing antibiotics into three groups: Access, Watch, and Reserve. Reserve antibiotics such as linezolid, teicoplanin, fosfomycin, and colistin are designated for use in the treatment of confirmed or suspected MDR infections [3].

In 2020, the Vietnamese Ministry of Health issued Decision No. 5631/BYT-QĐ, introducing a list of 18 priority antibiotics (Group 1) and 2 antibiotics requiring monitoring (Group 2) for hospital use. According to this regulation, the use of these priority antibiotics must be guided by institutional protocols and requires approval through a clinical pharmacist-led intervention process. This includes the completion of a prescription approval form and multidisciplinary consultation prior to administration.

Clinical pharmacy interventions are integral to AMS, with evidence demonstrating their impact on cost reduction and patient outcomes [4]. For instance, Sanjeev Singh et al., (2019) developed criteria for the use of reserve antibiotics, resulting in a 14.4% decrease in average monthly antibiotic expenditures [5]. Seah V. X. F. et al., (2017) indicated that measures, including the cessation of unneeded antibiotics (35%), transition to narrower-spectrum drugs (32%), and optimization of dose (17%), resulted in statistically significant decreases in patient mortality [6].

At Thai Nguyen A Hospital, a first-class provincial facility in Vietnam, antibiotics account for a significant and increasing proportion of the hospital's total drug expenditures, especially among priority antibiotics. The hospital introduced a Prescribing Procedure for Restricted Antibiotics in January 2018. Under this system, the use of listed antibiotics must be carefully considered by the physician and approved in advance by clinical pharmacists and hospital leadership through an Antibiotic Use Request Form (AURF). In addition, hospital guidelines for the use of vancomycin and colistin have been established. Therefore, this study was conducted to analyze the current approval process and usage patterns of Group 1 priority antibiotics - specifically vancomycin, injectable linezolid, and colistin at Thai Nguyen A Hospital.

2. Methods and Subjects

2.1. Study Population

Inpatient medical records from July 2023 to December 2023, including at least one prescription of a Group 1 priority antibiotic (vancomycin, injectable linezolid, or colistin), along with an AURF and clinical pharmacist monitoring data.

- Inclusion criteria: Medical records of patients administered vancomycin, injectable linezolid, or colistin for a duration of 72 hours or more.
- Exclusion criteria: Records with antibiotic use duration of less than 72 hours.

2.2. Study Design

Cross-sectional, retrospective descriptive study utilizing inpatient medical records and clinical pharmacy intervention records.

2.3. Study Procedure

- **Approval process**: Prior to administering vancomycin, linezolid, or colistin, physicians are required to submit a paper-based AURF to the

Pharmacy Department. The pharmacist reviews, advises, and documents the approval. Pharmacists may provide additional advice on indications or monitor the patient. If no AURF was previously filed, a retrospective review and documentation were conducted.

- **Renal function**: Assessed using the Cockcroft-Gault equation for patients with complete records of both serum creatinine and body weight [7].

- **Appropriateness of antibiotics use**: Vancomycin and colistin: Evaluated based on the hospital's treatment guidelines, which were developed based on the National Drug Formulary and the Summary of Product Characteristics (SmPC) (Supplementary Table 1,2). Linezolid: Assessed according to the drug SmPC.

2.4. Data Analysis

Data were analyzed using SPSS (version 22.0) and Microsoft Excel. Continuous variables exhibiting a normal distribution were presented as mean ± standard deviation (SD). Non-normally distributed continuous variables were reported as median and interquartile range (IQR). Categorical variables were represented as frequencies and percentages (%).

Table 1. Patient characteristics

Characteristic	Results (N = 172)
Age (years), median [IQR]	**45 [7–62]**
Gender, n (%)	
Male	*98 (56.98%)*
Female	*74 (43.02%)*
Treatment department, n (%)	
	46 (26.74%)
ICU	*38 (22.09%)*
Trauma surgery	*54 (31.4%)*
Pediatrics	*10 (5.81%)*
Urology surgery	*6 (3.49%)*
Infectious diseases	*18 (10.47%)*
Other departments	
Renal function (ml/min), median [IQR], n (%, N = 157)	**68.19 [47.45–89.4]**
≥90	*39 (24.84%)*
60–89	*58 (36.94%)*
30–59	*41 (26.11%)*
15–29	*12 (7.64%)*
<15	*7 (4.47%)*
Length of stay (days), median [IQR]	**14 [11–20]**
Infection types, n (%)	
Hospital/Ventilator-associated pneumonia	*58 (33.72%)*
Community-acquired pneumonia	
Urinary tract infection	*2 (1.16%)*
Meningitis	
Skin and soft tissue infections	*12 (6.98%)*
Surgical site infection	*2 (1.16%)*
Septic shock	*48 (27.91%)*
Sepsis	*2 (1.63%)*
	6 (3.49%)
	42 (24.42%)

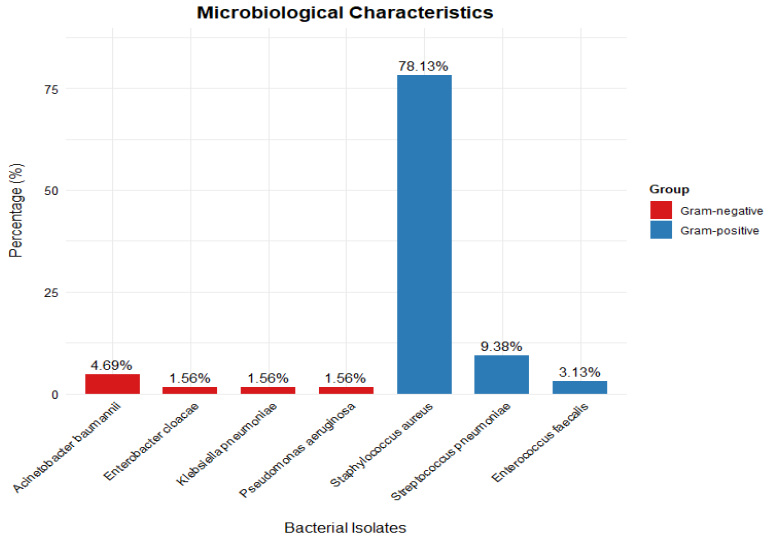


Figure 1. Microbiological characteristics.

2.5. Microbiological Characteristics

Out of 172 patients, 160 (93.02%) had microbiological testing performed, with bacteria identified in 128 cases (74.42%). The predominant specimen types yielding positive cultures were sputum (25.25%), pus (24.24%), and blood (21.21%). Of 128 bacterial isolates, Gram-positive bacteria comprised the majority (90.63%), with the most frequently identified species being *Staphylococcus aureus* (78.13%), *Streptococcus pneumoniae* (9.38%), and *Enterococcus faecalis* (3.13%).

Among Gram-negative isolates, the most common species were *Acinetobacter baumannii* (4.69%), followed by *Enterobacter cloacae* (1.56%), *Klebsiella pneumoniae* (1.56%), and *Pseudomonas aeruginosa* (1.56%).

2.6. Characteristics of Antibiotic Dosing

Colistin was administered with a loading dose in 63.63% of patients, of whom 85.71% adhered to hospital guidelines; the most common loading dose was 6 MIU. All patients received a maintenance dose 12 hours later, most frequently 8 MIU/day (36.36%). Among adults, 12.5% received a guideline-compliant loading dose of vancomycin (1000 mg or 1500 mg), and 75% received maintenance doses aligned with the guidelines, predominantly 1000 mg. In pediatric patients, all initial doses were compliant, with 30–45 mg/kg/day being the most utilized (66.67%). All linezolid regimens followed hospital guidelines, typically 600 mg every 12 hours. Results are presented in Table 2.

2.7. Clinical Pharmacist Interventions

A total of 117 antibiotic use request forms were reviewed, of which 62 cases (53%) were intervened clinically and followed-up by pharmacists. Details of interventions related to vancomycin, injectable linezolid, and colistin are shown in Table 3.

Among the 62 interventions involving priority antibiotics, the predominant categories were treatment adjustment (41.94%) and treatment monitoring (50%). The most common intervention types were: indication (17.74%), dosing (12.9%), followed by adjustments in infusion time, additional inflammatory markers monitoring, limiting treatment duration, monitoring for adverse effects, and renal function - each comprising around 10%.

Vancomycin was most frequently associated with interventions on indication, dose, and infusion duration, exceeding 20%. For linezolid, adverse effect monitoring was the most common (26.67%), while colistin interventions mostly focused on renal function monitoring (20.83%) and indication adjustments (16.67%).

Table 2. Antibiotic Dosing Practices and Compliance with Hospital Guidelines

Characteristic	Colistin (N = 22)	Vancomycin - Adults (N = 16)	Vancomycin - Pediatric (N = 30)	Linezolid (N = 104)
Loading dose usage	63.63%	12.5%	Not applicable	Not applicable
Loading dose comply with hospital guideline	85.71%	100%	-	-
Interval between loading and maintenance dose	Every 12 h (100%)	Every 12 h (87.5%)	-	-
Common maintenance dose	8 MIU/day (36.36%)	1000 mg (75%)	30 - 45 mg/kg/day (66.67%)	600mg/dose
Dosing frequency	2 times/day (100%)	Every 12 h (87.5%) every 8h (12.5%)	N/A	Every 12 h (100%)
Compliance with hospital maintenance dose guideline	72.73%	75%	66.67%	100%
Administration method	IV intermittent infusion (100%)	IV intermittent infusion (100%)	IV intermittent infusion (100%)	IV intermittent infusion (100%)
Continuous infusion	No	No	No	No

Table 3. Clinical pharmacist interventions characteristics

Interventions	COL, n (%, N = 24)	VAN, n (%, N = 23)	LIN, n (%, N = 15)	Total, n (%, N = 62)
1. Treatment Modifications	9 (37.50)	15 (65.22)	2 (13.33)	26 (41.94)
Indication adjustment	4 (16.67)	5 (21.74)	2 (13.33)	11 (17.4)
- Change drug	-	2 (8.7)	-	2 (3.23)
- Add drug	2 (8.33)	-	-	2 (3.23)
- Stop drug	-	1 (4.35)	-	1 (1.61)
- Deny approval	2 (8.33)	2 (8.7)	2 (13.33)	6 (9.68)
Dose regimen change	3 (12.5)	5 (21.74)	-	8 (12.9)
- Loading dose	2 (8.33)	4 (17.39)	-	6 (9.68)
- Maintenance dose	1 (4.17)	1 (4.35)	-	2 (3.23)
- Change infusion time	2 (8.33)	5 (21.74)	-	7 (11.3)
2. Treatment Monitoring	13 (54.17)	6 (26.09)	12 (80.0)	31 (50.0)
- Limit usage duration	-	2 (8.7)	3 (20)	5 (8.06)
- Monitor ADRs	1 (4.17)	-	4 (26.67)	5 (8.06)
- Monitor renal function	5 (20.83)	-	-	5 (8.06)
- Order microbiological test	4 (16.67)	2 (8.7)	1 (6.67)	7 (11.3)
- Monitor inflammatory markers	3 (12.5)	2 (8.7)	4 (26.67)	9 (14.51)
3. Additional Documentation	2 (8.33)	2 (8.7)	1 (6.67)	5 (8.06)
Total	24 (100)	23 (100)	15 (100)	62 (100)

2.8. Treatment Outcomes

The majority of patients showed improvement, with a combined cure and improvement rate of 79.07%. Meanwhile, 15.12% had deterioration or exhibited no improvement, and 5.81% were either discharged or transferred. The clinical response was observed in the majority of cases, with 23.26% attaining complete recovery and 54.65% partial improvement. Follow-up cultures were performed in 46.63% of patients, of which 57.14% had no microbiological response. Details of treatment outcomes are presented in Figure 2.

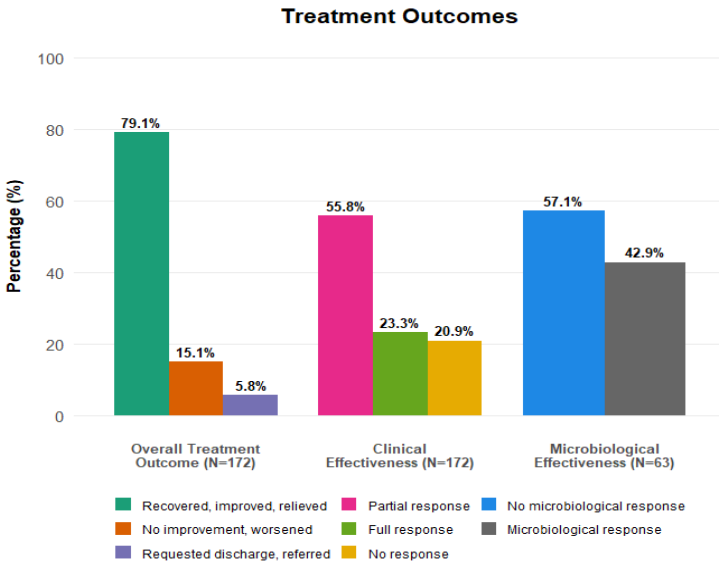


Figure 2. Treatment outcomes.

3. Discussion

Among the 172 patients studied, 56.98% were male, with a median age of 45 years (IQR: 7 - 62), which is lower than in other studies [8, 9] owing to a greater number (31%) of pediatric patients. Renal function varied widely, with 38% of patients showing renal impairment (Crcl < 60 mL/min), similar to Do et al. study (2014), which reported 27.1% of patients with impaired renal function [10]. Given that both colistin and vancomycin are renally excreted, individualizing dosage is crucial; yet, the absence of therapeutic drug monitoring for vancomycin makes dosing adjustments more challenging. Patients primarily received treatment in Pediatrics, ICU, and Trauma Surgery, with prevalent infections including hospital-acquired pneumonia, bloodstream infections, and skin/soft tissue infections, which were conditions warranting the use of last-resort antibiotics.

Microbiological testing was conducted in 93.02% of patients. Antibiotic susceptibility testing was performed in 95.31% of cases, facilitating the appropriate antibiotic use and preserve last-line agents. Among 128 bacterial isolates, Gram-positive bacteria predominated (90.63%), with *Staphylococcus aureus* constituting the majority (78.13%), followed by *Streptococcus pneumoniae* and *Enterococcus faecalis*. Gram-negative pathogens were rare, with *Acinetobacter baumannii* being the most common.

Regarding drug dosage, current evidence indicates that the absence of a loading dose for colistin or vancomycin in adults delays the attainment of therapeutic level [11]. In our study, 63.63% of patients were administered a colistin loading dose, while 69.56% received one for

vancomycin. These figures are lower than those reported by Nguyen et al., (2023) [12] but exceed the rates observed in international studies lacking pharmacist intervention (e.g., 5% and 10% in Philips 2015 and 2018) [13, 14]. This highlights the necessity for clinicians to focus more on the appropriate use of loading doses to optimize treatment outcomes.

Regarding clinical pharmacist intervention, a total of 117 AURFs were approved prior to antibiotic administration. Clinical pharmacists intervened in 62 cases (53%), either at the initial approval stage or during treatment monitoring. Among these interventions, the most common were treatment adjustments (41.94%) and ongoing monitoring (50%), consistent with previous findings, which reported similar rates of interventions involving dose changes, drug substitutions, or discontinuations. Vancomycin accounted for the highest proportion of interventions (over 20%), mainly related to indication, dosing, and infusion time. For linezolid, 26.67% of interventions involved monitoring for adverse effects, while for colistin, key interventions focused on renal function monitoring (20.83%) and appropriate indications (16.67%).

Throughout this period, all AURFs were processed manually using paper forms, as no digital system existed for approval or drug use monitoring. Owing to insufficient clinical pharmacy personnel, data had to be manually compiled from clinical logs and Google Forms. To ease the workload and enhance efficiency, integrating information technology for the automatic reporting of medication use, clinical signs, laboratory data, and microbiological features is recommended. This could also aid physicians in making more informed prescribing decisions [5].

4. Conclusion

Group 1 priority antibiotics were generally used appropriately, resulting in favorable clinical outcomes for the majority of patients. Pharmacist interventions highlight the necessity of maintaining antimicrobial stewardship strategies and incorporating digital tools to enhance the efficiency of the approval process.

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Supplementary Table 1. Hospital guideline on vancomycin dosing

Patients	Dosing
Adults	Loading: 25–30 mg/kg; Maintenance: 15–20 mg/kg every 8–12 h; Drug response: 48–72 h; Endocarditis: ≥3 weeks
Children ≥1 month	10 mg/kg every 6 h; Max 2 g/day
Neonates <1 week	15 mg/kg first dose; then 10 mg/kg every 12 h
Neonates 1 week–1 month	15 mg/kg first dose; then 10 mg/kg every 8 h
Renal Impairment – General	Loading 15 mg/kg; Daily dose = 15 × CrCl; Anuric: 1 g every 7–10 days

Supplementary Table 2a. Hospital guideline on colistin loading dose

MIC ≤1 mg/L		1 mg/L<MIC≤2 mg/L	
Weight (kg)	Loading Dose (MIU)	Weight (kg)	Loading Dose (MIU)
30-39	2	≤30	4
40-54	3	>30−40	5
55-69	4	>40−50	6
70-89	5	>50−60	7
≥90	6	>60−70	8
		>70	9

Supplementary Table 2b. Hospital guideline on colistin maintenance dose

Creatinine Clearance (CrCl) (mL/min)	Maintenance Dose
<15	3 MIU every 24 hours
15-29	2 MIU every 12 hours
30-49	3 MIU every 12 hours
50-79	4 MIU every 12 hours
>80	3 MIU every 8 hours
HD	2 MIU every 24 hours, plus 1 MIU post-dialysis
CRRRT	3 MIU every 8 hours