Research Title:
Comparison of therapeutic recommendations generated by OneChoice Plus® with the therapeutic recommendations provided by infectious disease specialists for the treatment of bacteremia and urinary tract infections in hospitalized patients at HNERM during the period October to December 2025.

Type of Protocol:
Institutional (X) Collaborative ( ) Extra-institutional ( ) Undergraduate thesis ( )

Study Site:
Health facility: Edgardo Rebagliati Martins National Hospital
Department: Lima **Province:** Lima
Research Center (if applicable): Not applicable
Field of study: Infectious Diseases

Investigators

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Abstract

Introduction:
The emergence of machine learning (ML)–based tools has enabled the development of models that suggest antimicrobial treatments based on microbiological, epidemiological, and clinical patterns. Systems such as OneChoice Plus (Akrstone Medical Solutions) have demonstrated the ability to integrate into antimicrobial stewardship programs (ASPs), improving therapeutic adequacy and reducing inappropriate antibiotic use. However, there is limited evidence directly comparing these recommendations with those issued by infectious disease specialists in Latin American contexts characterized by high bacterial resistance.

Objective:
To compare ML-generated therapeutic recommendations with those issued by infectious disease specialists for the treatment of bacteremia and urinary tract infections in hospitalized patients at HNERM.

Methods:
Analytical cross-sectional observational study including patients with confirmed bacteremia or urinary tract infection during October–December 2025. ML recommendations (OneChoice Plus) will be compared with specialist recommendations. Concordance will be assessed using Kappa statistics and agreement proportions. Analysis will be performed using STATA v17.

Introduction

Antimicrobial resistance (AMR) is one of the greatest global public health threats according to WHO, currently responsible for more than 1.27 million direct annual deaths and 4.95 million associated deaths (1). This burden particularly affects regions with limited resources and high antibiotic pressure, such as Latin America, where the prevalence of ESBL-producing Enterobacterales ranges from 40–60% in several countries, and the spread of KPC continues to increase (2,3).

In Peru, several studies have documented a sustained increase in resistance to third-generation cephalosporins, fluoroquinolones, and carbapenems, particularly in high-complexity hospitals, thereby complicating the management of severe infections such as bacteremia and complicated urinary tract infections (4,5). This scenario increases mortality, prolongs hospital stays, and raises both institutional and health-system costs (6,7).

Correct antibiotic selection is one of the most relevant determinants of prognosis in patients with severe infections. Evidence shows that inadequate empirical therapy increases mortality by 2- to 3-fold in bacteremia caused by resistant pathogens (8,9,10). In this context, the role of infectious disease specialists is essential, as their involvement improves therapeutic adequacy, reduces inappropriate prescriptions, and decreases clinical complications (11,12).

However, increasing microbiological complexity, growing clinical data volume, and healthcare workload have driven the need for complementary tools based on artificial intelligence (AI) and machine learning (ML). These technologies enable analysis of large volumes of real-time data by integrating epidemiological patterns, resistance profiles, host characteristics, and laboratory data (13).

Among these tools, OneChoice Plus (Akrstone Medical Solutions) is an ML model that generates personalized antibiotic recommendations based on microorganisms, resistance profiles, and patient data. Recent studies have shown that OneChoice improves therapeutic adequacy, reduces prescriber variability, and can be effectively integrated into Antimicrobial Stewardship Programs (ASPs) (14,15,16). A recent meta-analysis of AI platforms for antimicrobial therapy reported significant reductions in inappropriate prescriptions and improvements in treatment-optimization time (17,18).

Despite these advances, a significant gap remains in Peru: ML-generated recommendations have never been directly compared with infectious disease specialists' decisions in a national high-complexity hospital. This comparison is crucial because the adoption of such technologies depends on demonstrating that their recommendations are consistent, safe, and comparable to the gold standard: specialist clinical decision-making (16).

This study, therefore, seeks to systematically evaluate concordance between ML-based therapeutic recommendations and those generated by infectious disease specialists at HNERM, analyzing not only agreement levels but also factors associated with discordance and the potential clinical impact of such differences. Generating local evidence will enable an assessment of the practical utility of these technologies in contexts of high bacterial resistance.

Problem Statement

Antimicrobial selection in severe infections, such as bacteremia and complicated urinary tract infections, is an increasing clinical challenge due to the rising prevalence of resistance mechanisms, including ESBL, AmpC, KPC, and NDM, which are widely distributed in Latin American hospitals (2,19). At HNERM, the burden of ESBL- and carbapenem-resistant Enterobacterales is among the highest in the country, creating significant difficulty in selecting adequate empirical therapy (annual report from the HNERM Microbiological Map – Microbiology Service; unpublished data).

The central problem is that empirical treatment adequacy depends on multiple factors, including local epidemiology, microbiological profile, comorbidities, clinical severity, and prior antibiotic exposure, among others. Simultaneous processing of all this information can lead to clinical variability and potential therapeutic errors, even among experienced professionals (20).

Machine learning tools promise to reduce this variability by generating standardized, evidence-based, context-adapted recommendations (16). However, their real clinical usefulness in Peruvian hospitals has not yet been evaluated.

Thus arises the central question:
To what extent are ML-generated therapeutic recommendations concordant with those issued by infectious disease specialists at HNERM for the treatment of bacteremia and urinary tract infections?

The answer will help determine whether AI can safely complement clinical decision-making, optimize ASP resources, and reduce healthcare workload in a high-complexity hospital.

Objectives

General Objective
To compare machine-learning-based therapeutic recommendations with recommendations by infectious disease specialists for the treatment of bacteremia and urinary tract infections at HNERM.

Specific Objectives
• Describe the clinical-epidemiological characteristics of patients with bacteremia and urinary tract infections.
• Determine whether the empirical treatment received was adequate or inadequate.
• Evaluate concordance and discordance between ML-based and specialist therapeutic recommendations in cases of bacteremia.
• Evaluate concordance and discordance between both types of recommendations in urinary tract infections.

Materials and Methods

Study Design
Analytical ambispective observational study, following STROBE guidelines (21).

Population and Sample

Population: Hospitalized patients at HNERM with confirmed bacteremia or urinary tract infection during the study period.

Sampling: Consecutive non-probabilistic sampling of all cases meeting inclusion criteria.

Sample size: All episodes occurring between October–December 2025 will be included.

Inclusion Criteria

• Hospitalized patients at HNERM between October and December 2025.
• Confirmed diagnosis of:
  – Bacteremia with positive blood culture.
  – Urinary infection with significant urine culture ($\geq 10^5$ CFU/mL or according to clinical judgment).
• Case evaluated by an infectious disease specialist.
• Availability of complete clinical and microbiological data.

Exclusion Criteria

• Contaminated cultures (biological sample invaded by microorganisms during collection or processing, representing a false positive and not a true infection).
• Patients without infectious disease evaluation.
• Patients without ML-generated recommendation (technical errors or incomplete data).
• Readmissions of the same patient within the study period (only the first episode will be considered).

Operational Definition of Variables:

Table 1: Variable Operationalization Table

Variable	Operational Definition	Type	Escala
Age	Years completed at the time of diagnosis	Numéric	Ratio
Sex	Male / Female according to medical history	Categorical	Nominal
Type of infection	Bacteremia / Urinary tract infection	Categorical	Nominal
Causating microorganism	Microbiological isolation	Categorical	Nominal
Antimicrobial resistance	Profile according to antibiogram	Categorical	Nominal
Empirical treatment	Antibiotic(s) administered initially: Appropriate (the chosen antibiotic has coverage against the identified germ) Adequate (the antibiotic is appropriate but following the ProA guidelines) Inappropriate (the empirical treatment does NOT cover the identified germ)"	Categorical	Nominal
Recomendation for Machine Learning	Antibiotic suggested by OneChoice Plus	Categorical	Nominal

Specialist Recommendation	Antibiotic indicated by infectious disease specialist	Categorical	Nominal
Concordance	Antibiotic: AWARE (Access, Watch and Reserve) Dose, Interval, Duration of therapy	Categorical	Nominal
SOFA Severity	SOFA Severity at the time of Bacteremia or UTI diagnosis	Numeric	Ordinal
Hospital Mortality	Deceased/Not deceased	Categorical	Binary

Procedures and Techniques:

A search will be conducted in the microbiology records (blood cultures and urine cultures) and in the ESSI database of EsSalud. The database will be anonymized by assigning codes to identify each case. The recommendations provided by the ML system and the recommendations issued by Infectious Diseases Specialists will be obtained from the EsSalud hospital management system. This data, along with the remaining variables, will be collected in an Excel spreadsheet.

Analysis Plan

The analysis will be performed using STATA v17. In the descriptive analysis, categorical variables will be presented as absolute frequencies and percentages; numerical variables, if normally distributed, as mean ± SD; if non-normal, as medians. Normality will be assessed using the Shapiro–Wilk test.

For analytical analysis, ML vs. specialist concordance will be evaluated using Cohen's kappa index, overall agreement percentage, and agreement by infection type. Factors associated with discordance will be analyzed using bivariate and multivariate logistic regression, reporting ORs and 95% CIs. For the secondary clinical impact analysis, empirical therapy will be classified as adequate or inadequate, and in-hospital mortality will be assessed (χ^2 test or Fisher's exact test), with a significance level of $p < 0.05$.

Limitations and Feasibility

Limitations
• Information bias: incomplete data in medical records.
• Unmeasured confounding: clinical variables not documented.
• Selection bias: single-center study.
• Technological limitation: ML model depends on completeness of the dataset.

Feasibility
• Data availability: complete electronic records.
• Resources: trained investigators.
• Cost: low; funded by the authors.

Ethical Considerations

• Based on the Declaration of Helsinki and the Peruvian General Health Law.
• Data will be anonymized.
• Consent exemption applies due to retrospective, minimal-risk study design.
• Review and approval by the Institutional Ethics Committee.

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