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Effect of a multimodal intervention in general and digestive surgery wards on carbapenem use and antimicrobial resistance: protocol for a prospective, quasi-experimental interrupted time-series study

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ABSTRACT

Introduction Infections are particularly common among hospitalised patients in surgical wards. Carbapenem antibiotics, major drivers of antimicrobial resistance, are frequently prescribed in this setting, often inappropriately and for unnecessarily prolonged durations. International guidelines emphasise the need for comprehensive multimodal antimicrobial stewardship programmes to optimise antibiotic use; however, evidence supporting their routine application in surgical wards remains scarce and is mostly derived from retrospective analyses or single-component interventions. This study aims to evaluate the impact of an integrated, multimodal antimicrobial stewardship intervention on carbapenem consumption, antimicrobial resistance patterns and stewardship-related outcomes in surgical wards, with a concurrent focus on maintaining patient safety and clinical effectiveness.

Methods and analysis We conducted a single-centre, quasi-experimental interrupted time-series study among adult patients admitted to the general and digestive surgery wards of a tertiary-care Spanish hospital. The study includes a retrospective pre-intervention period (1 January 2022–31 December 2023) and a prospective intervention period (1 April 2024–31 March 2026). The multimodal antimicrobial stewardship intervention comprises educational activities, updated local guidelines delivered via a dedicated web-based platform and mobile application, PAF on carbapenem prescriptions and structured reassessment of β-lactam allergy labels. The primary outcome is the temporal trend in monthly carbapenem consumption, expressed as defined daily doses per 100 patient-days. Secondary outcomes include temporal trends of monthly carbapenem days of therapy per 100 patient-days, overall antibiotic consumption, the proportion of patients receiving carbapenems and clinical safety outcomes (length of hospital stay, in-hospital mortality and 30-day readmission rates). In addition, the acceptance of stewardship recommendations, the accuracy of β-lactam allergy labelling and the monthly incidence of selected antimicrobial-resistant organisms, including *Enterococcus faecium* bloodstream infection and *Clostridioides difficile* infection, will be analysed. Aggregated data from routine clinical practice are extracted from electronic medical records, and pharmacy and microbiology databases, supplemented by anonymous surveys. Interrupted time-series regression models will be applied to assess changes in trends attributable to the intervention.

Ethics and dissemination Approval for the protocol was granted by the Clinical Research Ethics Committee of Bellvitge University Hospital (PR332/23). The protocol complies with European and national data protection

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A prospective interrupted time-series design allows assessment of changes in trends following a system-level intervention.
⇒ A pragmatic, multimodal antimicrobial stewardship intervention embedded in routine clinical care enhances clinical relevance, although the effects of individual components cannot be isolated.
⇒ The focus on general and digestive surgery, using standardised antimicrobial consumption, microbiological and process outcomes, provides a comprehensive evaluation in a high-impact but under-represented setting.
⇒ The single-centre design without a concurrent control group may limit generalisability and allow residual confounding.
⇒ Despite the robustness of the interrupted time-series approach, unmeasured changes in case-mix, clinical practice or healthcare activity during the study period may influence the observed results.

regulations. Findings will be disseminated through scientific conferences and publication in peer-reviewed journals.

INTRODUCTION

Antimicrobial resistance (AMR) is a major global health challenge with profound clinical, economic and social implications.[1–3] In response, the WHO and other international agencies have developed coordinated, cross-sectoral 'One Health' action plans to address the growing threat.[3 4] Within Europe, AMR is projected to be responsible for 33 000 deaths annually by 2050.[1]

Excessive and inappropriate use of antibiotics remains the primary driver of AMR.[2 3] In hospital settings, a substantial proportion of patients receive antimicrobial therapy, with inappropriate prescribing rates approaching 50%.[5] Antimicrobial stewardship programmes (ASPs) have emerged as a key strategy to optimise antimicrobial use and improve patient outcomes.[6 7] Among available interventions, prospective audit and feedback (PAF) is considered one of the most effective approaches, allowing post-prescription review and targeted recommendations by stewardship teams.[8] Systematic reviews have shown that ASP interventions can reduce antimicrobial consumption, AMR and healthcare-associated infections.[9 10]

In addition to PAF, other strategies such as educational interventions and systematic reassessment of reported β-lactam allergies play an important role. Educational initiatives may contribute to sustained improvements in prescribing practices, although they remain underrepresented in the literature, particularly multidisciplinary settings.[11] Similarly, inappropriate penicillin allergy labels are associated with worse clinical outcomes and increased use of broad-spectrum agents, reinforcing the importance of allergy delabelling within ASP frameworks.[12 13]

While intensive care units have traditionally been the primary focus of antimicrobial stewardship interventions,[14] surgical wards represent a relevant but comparatively understudied setting. Many common surgical conditions are infectious in nature, and healthcare-associated infections are among the most frequent complications in general and digestive surgery.[15–18] In this context, inappropriate antibiotic use, often driven by prolonged treatment durations and poor adherence to guidelines,[17] remains common despite evidence supporting shorter and effective treatment courses in intra-abdominal infections.[19 20] In parallel, carbapenem consumption has increased steadily in many centres,[21] contributing to the emergence of carbapenemase-producing organisms, a major threat in AMR.

However, existing studies evaluating antimicrobial stewardship interventions in surgical patients present important methodological limitations. Many rely on retrospective designs or simple before-after approaches that do not adequately account for underlying temporal trends or confounding factors.[9 22] In addition, most interventions have focused on single components, whereas real-world ASPs are inherently multimodal. As a result, there is a lack of robust prospective evidence evaluating the impact of multimodal stewardship interventions in surgical wards. These limitations make it difficult to distinguish the true effect of stewardship interventions from underlying temporal trends.

To address these gaps, we designed a prospective quasi-experimental interrupted time-series study to evaluate the impact of a structured multimodal antimicrobial stewardship intervention in general and digestive surgery wards. This approach enables the assessment of both immediate and sustained effects while accounting for pre-existing trends.[23] We hypothesise that this strategy will reduce carbapenem consumption and AMR rates without adversely affecting clinical outcomes.

METHODS AND ANALYSIS

Study design

This is a prospective, single-centre, quasi-experimental interrupted time-series study with two predefined periods: a retrospective pre-intervention period (1 January 2022–31 December 2023) and an active intervention period (1 April 2024–31 March 2026) following implementation of a multimodal ASP. This design allows for the estimation of changes in trends in antibiotic use and AMR outcomes, while accounting for pre-existing temporal trends and adjusting for seasonal variation.

Study setting and population

The study is being conducted at Bellvitge University Hospital, Barcelona, Spain, a tertiary-care public hospital within the Spanish National Healthcare System. The hospital provides care to a large urban population and includes a high volume of complex surgical admissions. This setting has been identified as a high carbapenem-consuming environment with an increasing incidence of infections caused by carbapenemase-producing organisms, which supports the implementation of targeted antimicrobial stewardship interventions focusing on broad-spectrum antibiotic use.

The study population consists of adult patients (>18 years old) admitted to the general and digestive surgical wards. The intervention is being implemented by a multidisciplinary antimicrobial stewardship team comprising specialists in infectious diseases, clinical microbiology and hospital pharmacy, in collaboration with general surgeons, allergists and nursing staff.

Intervention

During the intervention period, a multimodal antimicrobial stewardship bundle is implemented. All components of the intervention are predefined prior to the start of the prospective phase and progressively implemented throughout the intervention period. The multimodal intervention includes (figure 1):

- Educational interventions targeting surgeons in general and digestive surgery, physicians in the

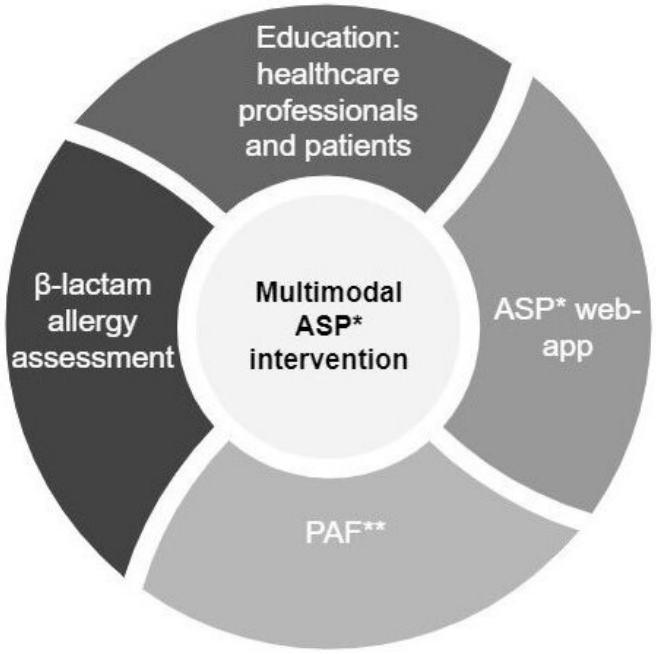

Figure 1 Multimodal ASP intervention. *ASP, Antimicrobial Stewardship Programme; **PAF, prospective audit and feedback.

emergency department and nursing staff. These sessions cover core antimicrobial stewardship principles, local epidemiology, updated therapeutic guidelines, recommended treatment durations, β-lactam allergy assessment, appropriate specimen collection, identification of candidates for intravenous-to-oral switch and optimisation of treatment duration. Surgeons and emergency physicians receive one initial session followed by annual refresher sessions, while nursing staff participate in one initial and one final session. The impact of these activities is assessed through voluntary and anonymous surveys administered at the beginning and end of the intervention period.

- Patient education consisting of the distribution of an informational leaflet addressing appropriate antibiotic use and prevention of healthcare-related infections. The leaflet includes an optional anonymous survey to assess patients' knowledge and perceptions.
- Educational materials in inpatient wards, including visual aids and infographics summarising key antimicrobial stewardship principles and providing checklists to support daily clinical decision-making.
- An ASP web-based platform and mobile application, providing real-time access to updated clinical guidelines, training materials, local antimicrobial consumption and resistance data, and decision-support tools. These include structured empirical treatment recommendations and guidance on treatment duration, intravenous-to-oral switch and microbiological sampling.
- PAF targeting carbapenem prescriptions. Patients receiving carbapenems are identified daily through electronic prescribing systems. Cases are initially reviewed by a clinical pharmacist and subsequently discussed in a multidisciplinary team involving infectious diseases physicians and microbiology specialists, with direct input from the surgeon responsible for the patient. Recommendations are then formulated and documented in the electronic medical record, including suggestions for de-escalation, discontinuation or optimisation of therapy. These recommendations are non-compulsory, and final decisions regarding antimicrobial treatment remain the responsibility of the attending clinical team.
- Systematic β-lactam allergy assessment in patients receiving carbapenem therapy. Allergy labels are reviewed using an institutional algorithm based on clinical history. When appropriate, inaccurate allergy labels are removed or patients are referred to allergy specialists for further evaluation.

Outcomes

The primary outcome is the temporal trend in monthly carbapenem consumption, measured as defined daily doses (DDD) per 100 patient-days. Secondary pharmacological outcomes include monthly trends in carbapenem days of therapy (DOT) per 100 patient-days, total antibiotic consumption measured as DDD and DOT per 100 patient-days, and the proportion of patients receiving carbapenems.

Stewardship-related process outcomes will include the acceptance and type of antimicrobial stewardship recommendations, categorised as maintenance of therapy, de-escalation, discontinuation and recommendations for additional diagnostic procedures (including imaging studies or microbiological cultures). Maintenance of therapy will be recommended when the prescribed antimicrobial regimen is considered appropriate, either due to adherence to local empirical guidelines or based on the patient's clinical condition. These categories are predefined and consistently applied throughout the study period. Data on the acceptance or non-acceptance of antimicrobial stewardship recommendations will be extracted from Silicon, the hospital's electronic prescribing system.

Microbiological outcomes will include the incidence of healthcare-associated infections caused by multidrug-resistant Gram-negative bacilli, *Enterococcus faecium* bloodstream infections and *Clostridioides difficile* infection.

Additional process outcomes will include the prevalence and appropriateness of β-lactam allergy labelling and the proportion of patients safely delabelled.

Clinical safety outcomes will also be assessed to ensure that reductions in carbapenem consumption are not associated with adverse patient outcomes, including length of hospital stay, in-hospital mortality and 30-day readmission rates.

Sample size

Formal sample size calculation is not applicable to interrupted time-series designs. While methodological

guidance for monthly time-series data recommends at least 12 data points before and 12 after the intervention to allow meaningful adjustment for seasonality, the use of monthly outcome measures in this study provides 24 points per period, a substantially larger number of time points, thereby ensuring adequate power to detect changes in level and trend.[23]

Microbiology studies

Clinical samples are processed at the hospital's accredited Clinical Microbiology Laboratory using standardised routine methods. Bacterial identification is performed by matrix-assisted laser desorption-ionisation time-of-flight mass spectrometry, and antimicrobial susceptibility testing is conducted using automated systems in accordance with European Committee on Antimicrobial Susceptibility Testing (EUCAST) standards applicable at the time of testing. Carbapenem resistance is defined according to EUCAST clinical breakpoints, with carbapenemase production confirmed using phenotypic and/or molecular methods as per laboratory protocols. The incidence of healthcare-associated infections will be assessed according to European Centre for Disease Prevention and Control criteria, defined as infections not present or incubating at the time of hospital admission and typically occurring ≥48 hours after admission.[24] In this study, microorganisms considered multidrug-resistant include extended-spectrum β-lactamase-producing *Klebsiella pneumoniae*, carbapenemase-producing *K. pneumoniae*, carbapenemase-producing *Enterobacter* spp, extensively drug-resistant *Pseudomonas aeruginosa*, and carbapenemase-producing *P. aeruginosa*. Detection of *E. faecium* bloodstream infection includes molecular identification of vanA/vanB genes when appropriate. *C. difficile* infection is diagnosed using routine immunoassays and/or molecular assays according to institutional algorithms. Only the first clinically relevant isolate per patient is included. Incidence rates are calculated per 1000 patient-days using ward-level denominators.

Data collection and analysis plan

All analyses will be conducted using aggregated data obtained from institutional sources; no individual-level data will be collected. Aggregated antimicrobial consumption and antimicrobial stewardship data will be collected through the hospital SAP-BO application. This electronic surveillance tool, developed by the Catalan Institute of Health and implemented in 2018, enables real-time monitoring of antimicrobial therapy in hospitalised patients. Integrated with electronic medical and nursing records, SAP-BO supports timely screening based on predefined criteria and provides antimicrobial use metrics to support stewardship activities and evaluate ASP impact. Aggregated demographic and clinical characteristics will be obtained from electronic medical records and summarised by study period, including age, sex, primary diagnosis, patient complexity index, using appropriate descriptive statistics.

For the primary outcome, interrupted time-series (ITS) analysis will be performed to evaluate trends in carbapenem use (DDD/100 patient-days) before and after the intervention. Segmented regression models with an appropriate link function will be used, incorporating terms for time, intervention phase (pre/post) and the interaction between time and intervention to estimate baseline trends, immediate changes in level and changes in trend following the intervention. Models will be adjusted for relevant covariates. Autocorrelation of residuals will be assessed using the Durbin-Watson test and, if present, appropriately accounted for. In addition, a complementary pre-post comparison will be conducted using a t-test or Wilcoxon rank-sum test, as appropriate. As an exploratory analysis, joinpoint regression will be applied to identify potential time points at which significant changes in trend occur during the post-intervention phase.

Secondary outcomes, including antimicrobial consumption, stewardship indicators and incidence rates of healthcare-associated infections caused by multidrug-resistant organisms, *E. faecium* bloodstream infections and *C. difficile* infection, will be analysed using the same ITS approach where sufficient temporal data are available. In case of sparse monthly data or a high proportion of zero-event months, outcomes will be aggregated annually and analysed using Poisson or negative binomial regression models, as appropriate, with the number of stays as a model offset. Complementary pre-post comparisons will be performed as appropriate, using the Student's t-test or Wilcoxon rank-sum test for continuous variables and the χ^2 test or Fisher's exact test for categorical variables.

Clinical safety outcomes considered as length of hospital stay, in-hospital mortality and 30-day readmission rates will be analysed using pre-post comparisons, applying the same statistical tests as described for the secondary outcomes

Secondary antimicrobial stewardship implementation outcomes, including the number, type and acceptance of stewardship recommendations, as well as the prevalence and appropriateness of β-lactam allergy labelling and the proportion of patients safely delabelled, will be summarised descriptively. Voluntary and anonymous survey data collected from healthcare professionals and patients will be analysed descriptively.

All the analyses will be stratified by sex when relevant. All analyses will be performed using R software (V.4.2.2 or later).

Patient and public involvement

Patients were involved at an early stage through a focus group of individuals with prior admission to the general and digestive surgery wards. They contributed to the co-design of an informational leaflet on antibiotic use, ensuring that its content and format reflected patient perspectives, priorities and needs, and informing the research question. The leaflet includes a QR code linking to an anonymous survey assessing patients' knowledge

and perceptions of antibiotic use. All admitted patients are invited to participate voluntarily.

Patients were not involved in recruitment or conduct beyond this, and participation imposes minimal burden due to the short, anonymous nature of the survey. Results will be shared through social media and other accessible channels for the hospital population.

ETHICS AND DISSEMINATION

This study uses aggregated, non-identifiable data derived from routine clinical records, surveys and institutional information systems. No individual-level patient data or biological samples are collected specifically for research purposes. Surveys administered to healthcare professionals and patients are anonymous and voluntary.

Approval for the protocol was granted by the Clinical Research Ethics Committee of Bellvitge University Hospital (PR332/23), which waived the requirement for informed consent due to the exclusive use of aggregated, non-identifiable data.

All procedures comply with applicable Spanish and European data protection regulations and Good Clinical Practice guidelines. Data are stored in secure institutional databases, with access restricted to authorised members of the research team, and confidentiality of patients and participating healthcare professionals is ensured throughout the study.

Publication plan

Manuscripts arising from this study will be prepared in accordance with the predefined analysis plan and under the supervision of the study statisticians. Results will be submitted for publication in peer-reviewed scientific journals and may be presented at national and international scientific conferences.

Authorship and contributorship will follow the recommendations of the International Committee of Medical Journal Editors.

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Contributors All authors contributed to the study concept and design. IO, ES, AP, NS, NP, GA-A and JC contributed to the study design. NV-P, IO, AP, ES, NS and AS-L were responsible for case identification and data collection. JP performed the statistical analysis. NV-P, IO and JC drafted the manuscript and critically revised it for important intellectual content. All authors reviewed and approved the final version of the manuscript. NV-P is the guarantor of the study. As the authors are not native English speakers, ChatGPT was used to assist in improving and optimising the English language of the manuscript. The authors take full responsibility for the content.

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Competing interests AP received support for attending meetings and/or travel from Takeda, Chiesi and Sanofi. JC received honouraria from MSD for educational activities. The rest of the authors declare that they have no competing interests.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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