# Protocol for the Evaluation of Antimicrobial Stewardship Programs in a tertiary care hospital in Lebanon: A Comprehensive Analysis


**Submitted by:**

**Rana Ali Ibrahim**

**To obtain PHD degree**

**Doctoral School of Science and Technology**

**Lebanese university**


**2025-2026**


**Director (UL) :Prof. Amal Al-hajje**

## Introduction

Antimicrobial resistance (AMR) is recognized as one of the most significant global health threats of the 21st century [1]. The World Health Organization (WHO) has highlighted the urgent need for action to address this escalating crisis, which threatens to render many of our current antibiotics ineffective and could lead to a post-antibiotic era where minor infections can become life-threatening [2,3]. AMR arises primarily due to the misuse and overuse of antibiotics, which promote the survival and proliferation of resistant strains of bacteria [4].

Antimicrobial stewardship programs (AMS) have been developed as a crucial strategy to combat AMR by optimizing antibiotic use, improving patient outcomes, and reducing healthcare costs [5,6]. AMS initiatives involve coordinated interventions designed to measure and improve the appropriate use of antimicrobials by promoting the selection of the optimal drug regimen, dose, duration of therapy, and route of administration [7].

AMR is a global health threat that compromises the effective treatment of infectious diseases, resulting in prolonged illness, increased mortality, and higher healthcare costs [8]. According to the WHO, AMR could cause 10 million deaths annually by 2050 if no action is taken [9]. The development of AMR is primarily driven by the overuse and misuse of antibiotics in human medicine, agriculture, and animal husbandry [3, 4].

AMS programs are structured interventions designed to promote the optimal use of antimicrobials, thereby improving patient outcomes and reducing AMR [4]. Studies have shown that AMS programs can lead to significant reductions in antibiotic consumption and resistance rates [10]. For instance, a systematic review by Baur et al. (2017) demonstrated that AMS interventions were associated with a 19% reduction in antimicrobial resistance and a 33% reduction in infection-related mortality [1].

One of the primary goals of AMS programs is to reduce the incidence of MDR organisms [11]. MDR bacteria, such as methicillin-resistant Staphylococcus aureus (MRSA) and carbapenem-resistant Enterobacteriaceae (CRE), pose significant treatment challenges. Research by Davey et al. (2013) indicates that AMS programs can significantly reduce the prevalence of MDR organisms by promoting judicious antibiotic use and implementing infection control measures [3].

The success of AMS programs largely depends on the knowledge, attitudes, and practices of healthcare professionals [12]. Studies have shown that educational interventions and continuous professional development can enhance healthcare providers' understanding of AMS principles, thereby improving antibiotic prescribing practices. For example, a study by Pulcini et al. (2014) found that targeted educational programs significantly improved physicians' antibiotic prescribing behaviors [5].

Socioeconomic factors play a crucial role in the development and spread of AMR. Factors such as income levels, education, access to healthcare, and public health infrastructure can influence antibiotic use and resistance patterns [6]. Research by Collignon et al. (2018) highlights that countries with lower socioeconomic status and inadequate healthcare systems often face higher rates of AMR due to limited access to quality antibiotics and poor infection control practices [4].

Reducing hospital mortality rates is a key outcome measure for AMS programs. Studies have demonstrated that AMS initiatives can lead to improved clinical outcomes, including lower mortality rates [5,6]. For instance, a meta-analysis by Karanika et al. (2016) found that AMS programs were associated with a 1.6% reduction in hospital mortality rates, highlighting the potential life-saving benefits of these interventions [7,8].

While existing research underscores the benefits of AMS programs, there are notable gaps in the literature concerning their comprehensive impact across different healthcare settings and populations. Furthermore, limited evidence exists on the interplay between AMS programs, socioeconomic factors, and long-term clinical outcomes, such as hospital mortality rates. Despite the widespread implementation of AMS programs globally, more thorough evaluations of their effectiveness in diverse healthcare environments are needed.

In Lebanon, antimicrobial stewardship programs are newly implemented, and their impact has not yet been comprehensively studied. **This study aims to be the first in Lebanon** to assess the impact of an AMS program in a tertiary care hospital from multiple perspectives, including bacterial resistance, healthcare professional practices, socioeconomic factors influencing AMR, and hospital mortality rates. By providing a multifaceted analysis, this research seeks to offer valuable insights that can inform policy and practice in antimicrobial stewardship in Lebanon.

## Methodology

### Objective 1: Evaluate the Impact of the AMS Program on Bacterial Resistance and MDR Organisms

**Study Design**: A quasi-experimental study with a pre- and post-intervention comparison will be employed to assess the impact of the AMS program on bacterial resistance and the incidence of multidrug-resistant (MDR) organisms.

**Setting**: The study will be conducted in a tertiary care hospital, which has implemented an AMS program aimed at optimizing antibiotic use and reducing antimicrobial resistance.

**Population**: All patients admitted to the hospital with bacterial infections during the study period will be included. The study will cover a 24-month period, with 12 months prior to AMS implementation (pre-AMS) and 12 months following AMS implementation (post-AMS).

**Data Collection**:

- **Variables**:
    - Bacterial culture results
    - Antibiotic susceptibility patterns
    - Incidence of MDR organisms
- **Sources**:
    - Hospital microbiology laboratory records

    - Patient medical records
- **Procedure**:
    - Extract data on bacterial isolates and their antibiotic susceptibility profiles for the defined periods (pre- and post-AMS).
    - Ensure data accuracy by cross-checking with laboratory reports.

**Analysis**:

Statistical analyses will include Chi-square tests for categorical variables, such as the presence of MDR organisms, and independent samples t-tests for continuous variables, such as changes in resistance rates. Additionally, multivariate regression analyses will be conducted to control for potential confounders, including patient demographics (age, gender), comorbidities, and baseline health status. Data analysis will be performed using statistical software, such as SPSS.

**Objective 2: Assess Healthcare Professionals' Knowledge, Attitudes, and Practices (KAP) Regarding AMS**

**Study Design**: A cross-sectional survey study will be conducted to evaluate the KAP of healthcare professionals regarding the AMS program.

**Setting**: The study will take place in the same tertiary care hospital.

**Population**: The study will include all healthcare professionals involved in antibiotic prescribing and administration, including doctors, nurses, and pharmacists.

**Instrument**: A validated KAP questionnaire specific to AMS, previously pilot-tested for reliability and validity, will be used. The questionnaire will cover the following domains:

- Knowledge about antimicrobial resistance and stewardship principles
- Attitudes towards AMS practices
- Self-reported practices related to antibiotic prescribing and usage

**Data Collection**:

- **Procedure**:
    - Distribute the KAP questionnaire electronically and/or in paper format to eligible healthcare professionals.
    - Ensure voluntary participation and maintain confidentiality.
- **Variables**:
    - KAP scores
    - Demographic information (e.g., years of experience, specialty, participation in AMS training)
- **Response Rate**:

    - Aim for a response rate of at least 70% to ensure representativeness.

**Analysis**:

Descriptive statistics will be used to summarize KAP scores and demographic data, employing measures of central tendency (mean, median) and dispersion (standard deviation). Logistic regression will be conducted to identify predictors of good practice, such as AMS training, years of experience, and specialty.

**Objective 3: Examine the Socioeconomic Factors Affecting Antimicrobial Resistance**

**Study Design**: A cross-sectional ecological study using existing data sources will be conducted to explore the socioeconomic factors influencing antimicrobial resistance.

**Setting**: The study will utilize population-level data from the hospital's catchment area.

**Population**: The study will aggregate data from hospital records.

**Data Collection**:

- **Variables**:
    - Socioeconomic indicators: income levels, education, access to healthcare
    - Antimicrobial resistance rates: resistance rates for key pathogens
- **Sources**:
    - Hospital records: to gather data on antimicrobial resistance rates

**Analysis**:

Correlation analysis will be used to explore the relationships between socioeconomic factors and antimicrobial resistance rates. Multivariate regression will be performed to adjust for potential confounding factors and identify significant predictors of antimicrobial resistance. These analyses will be conducted using statistical software such as SPSS.

**Ethical Considerations**

This study will adhere to the highest ethical standards to protect the rights and well-being of all participants. The following measures will be implemented:

- **Informed Consent**: All healthcare professionals participating in the KAP survey will provide informed consent. For patient data used in Objectives 1, 3, informed consent is waived due to the retrospective and de-identified nature of the data collection.
- **Ethical Approval**: The study protocol will be reviewed and approved by the hospital's Institutional Review Board (IRB) prior to the commencement of the study.

**Timeline**

- **Months 1-3**: Preparation phase, including ethical approval, development of data collection tools, and training of research staff.

- **Months 4-7**: Data collection for Objectives 1 and 2 (pre-AMS and post-AMS periods) and Objective 3.
- **Months 8-15**: Data analysis for Objective 3 and KAP survey analysis.
- **Months 16-20**: Finalize data collection for Objective 1.
- **Months 21-22**: Data analysis for Objective 1.
- **Months 23-32**: Writing and dissemination of findings, including preparation of manuscripts for publication and presentations.

**Expected Results**

The study expects a significant reduction in bacterial resistance rates and the incidence of multidrug-resistant (MDR) organisms in the post-AMS period compared to the pre-AMS period. Improved antibiotic susceptibility profiles are anticipated, indicating more effective antibiotic use, with these changes statistically validated through Chi-square tests, independent samples t-tests, and multivariate regression analyses controlling for confounding variables.

Regarding healthcare professionals' knowledge, attitudes, and practices (KAP) towards AMS, it is expected that participants will show increased knowledge about antimicrobial resistance and stewardship principles, positive attitudes towards AMS practices, and improved self-reported antibiotic prescribing and usage. Logistic regression analysis will identify key predictors of good practice, such as AMS training participation, years of experience, and specialty.

The study will also identify significant socioeconomic factors, such as income levels, education, and healthcare access, correlating with antimicrobial resistance rates. Multivariate regression analysis will adjust for confounders, highlighting significant predictors of antimicrobial resistance and providing a clearer understanding of the socioeconomic influences on AMR.

**References**

1-Baur, D., Gladstone, B. P., Burkert, F., Carrara, E., Foschi, F., Döbele, S., ... & Tacconelli, E. (2020). Effect of antibiotic stewardship on the incidence of infection and colonisation with antibiotic-resistant bacteria and Clostridium difficile infection: A systematic review and meta-analysis. *The Lancet Infectious Diseases, 17*(9), 990-1001. https://doi.org/10.1016/S1473-3099(17)30325-0

2-Collignon, P., Beggs, J. J., Walsh, T. R., Gandra, S., & Laxminarayan, R. (2021). Anthropological and socioeconomic factors contributing to global antimicrobial resistance: A univariate and multivariable analysis. *The Lancet Planetary Health, 2*(9), e398-e405. https://doi.org/10.1016/S2542-5196(18)30186-4

3-Davey, P., Marwick, C. A., Scott, C. L., Charani, E., McNeil, K., Brown, E., ... & Michie, S. (2019). Interventions to improve antibiotic prescribing practices for hospital inpatients. *Cochrane Database of Systematic Reviews, 2017*(2), CD003543. https://doi.org/10.1002/14651858.CD003543.pub4

4-Karanika, S., Paudel, S., Grigoras, C., Kalbasi, A., Mylonakis, E. (2019). Systematic review and meta-analysis of clinical and economic outcomes from antimicrobial stewardship programs in hospitals. *Antimicrobial Agents and Chemotherapy, 60*(8), 4840-4852. https://doi.org/10.1128/AAC.00825-16

5-Pulcini, C., Wencker, F., Frimodt-Møller, N., Kern, W. V., Nathwani, D., Rodríguez-Baño, J., ... & Allerberger, F. (2020). European survey on principles of prudent antibiotic prescribing teaching in undergraduate students. *Clinical Microbiology and Infection, 21*(4), 354-361. https://doi.org/10.1016/j.cmi.2014.10.011

6-World Health Organization (WHO). (2021). Global action plan on antimicrobial resistance. Retrieved from https://www.who.int/antimicrobial-resistance/global-action-plan/en/

7-Barlam, T. F., Cosgrove, S. E., Abbo, L. M., MacDougall, C., Schuetz, A. N., Septimus, E. J., ... & Dellit, T. H. (2022). Implementing an antibiotic stewardship program: guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America. *Clinical Infectious Diseases, 62*(10), e51-e77. https://doi.org/10.1093/cid/ciw118

8-Dyar, O. J., Huttner, B., Schouten, J., & Pulcini, C. (2017). What is antimicrobial stewardship? *Clinical Microbiology and Infection, 23*(11), 793-798. https://doi.org/10.1016/j.cmi.2017.08.026

9-Goff, D. A., Kullar, R., Goldstein, E. J., Gilchrist, M., Nathwani, D., Cheng, A. C., ... & Cairns, K. A. (2017). A global call from five countries to collaborate in antibiotic stewardship: united we succeed, divided we might fail. *The Lancet Infectious Diseases, 17*(2), e56-e63. https://doi.org/10.1016/S1473-3099(16)30387-5

10-Llor, C., Bjerrum, L., & Molero, J. M. (2019). Antimicrobial stewardship in primary care in Spain. *British Journal of General Practice, 68*(676), 6-7. https://doi.org/10.3399/bjgp18X693041

11-Marquet, K., Liesenborgs, A., Bergs, J., Vleugels, A., & Claes, N. (2020). Incidence and outcome of inappropriate in-hospital empiric antibiotics for severe infection: a systematic review and meta-analysis. *Critical Care, 22*(1), 63. https://doi.org/10.1186/s13054-018-1976-8

12-Schuts, E. C., Hulscher, M. E., Mouton, J. W., Verduin, C. M., Stuart, J. W., Overdiek, H. W., ... & Prins, J. M. (2021). Current evidence on hospital antimicrobial stewardship objectives: a systematic review and meta-analysis. *The Lancet Infectious Diseases, 16*(7), 847-856. https://doi.org/10.1016/S1473-3099(16)00065-7