METHODOLOGY

Study Site: - The study is to be carried out at the inpatient setting of a private tertiary care referral hospital at the Malabar region of Kerala. The Al-Shifa hospital Pvt. Ltd is a 550 bedded, multidisciplinary tertiary level referral hospital situated in Perinthalmanna, Malappuram District of Kerala. The various departments hospital include general medicine, obstetrics and gynaecology, paediatrics and neonatal, neurosciences, orthopaedics, neurosurgery, etc.

Study Design: - A prospective interventional study will be carried out among the inpatients of general medicine department in order to develop and establish an Antimicrobial Stewardship Programme (ASP) and thereby reducing the consumption of the Anti-Microbial Agent (AMA) and the chances of emergence of resistance.

Inclusion Criteria: - The inpatients from general medicine department with antibiotics prescribed are included in this study.

Exclusion Criteria: - The inpatients with no antibiotics prescribed from general medicine department are excluded from this study.

Study Tools: - The following study tools are using in the present research work, they are

1. Data collection form for antimicrobial resistance/susceptibility surveillance.
   This form is designed to collect the details for antimicrobial susceptibility surveillance. The form consists of the details like, Patient Demographics, Site of infection, Nature of specimen collected, Infectious organism, Sensitivity pattern of microorganism, Strain of microorganism. The details are to be obtained from microbiology department after specimen collection and identification of pathogen and susceptibility testing.

2. Baseline Data Assessment Form.
   The base line data assessment form helps, to better understand current antimicrobial practice and experience. With this data from different departments such as medical departments, pharmacy, microbiology, quality assurance and other departments will be collected.

3. Antimicrobial Stewardship Program Data Evaluation Form.
   This form is used in order to collect all the necessary information relevant to the study. This form consists of the details like;
   Patients demographics such as name, age, sex, body weight, Medication Record Department (MRD) number, date of admission (DOA), date of discharge (DOD), department, diagnosis, location, age category, physician.
Microbiology data, i.e. culture and sensitivity data which consist of service, collected specimen, collection date, reporting date, test; test is within the hospital or outside the hospital, isolated organisms, and sensitive drugs, intermediately sensitive and resistant drugs. Antibiotic drug chart consist of name, indication, dose, frequency, duration of therapy, starting date, stopping date, total unit, unit cost and total costs and also the discharged medications, number of broad spectrum antibiotics, number of narrow spectrum antibiotics, conversion of IV to oral formulations, how many days taken for conversion, number of parenteral AMA for discharged patients, number of drugs without culture and sensitivity, number of deescalated drugs, surgery, duration of therapy before and after the surgery and empirical therapy responded or not. The medication errors reporting part is classified as prescription error, administration error and dispensing error and classification of each error. Intervention and recommendations documentation chart consist of date, description of error, recommended intervention and number of performed intervention.

**Statistical Techniques:** -All the statistical analysis will be carried out using Statistical Package for Social Sciences (SPSS) software. Numerical data will be expressed as mean and standard deviation. Frequency distribution of parameter like gender, department, type of infection and organism isolated are also to be analysed. For the categorical variables, frequencies and percentage will be calculated with the Pearson Chi square test. For comparison of pre and post interventions t test will be used.

**WORK PLAN**

The research work is to be carried out in different steps as follows,

1. Assessment of current practice
2. Development of Antimicrobial Stewardship Program
3. Development of antibiotic formulary and antibiogram
4. Implementation of ASP
5. Assessment the impact of ASP

Using different types data collection forms, designed during the study data will be collected. The data collected will be evaluated and antibiogram will be developed for the individual microorganisms using WHONET software, followed by the consumption of antimicrobial agents will be calculated using antimicrobial consumption tool. Guideline for the conversion of Intra Venous to Per Oral antimicrobial agents, educational notes for the de-escalation therapy, medication error is to be developed and then it is approved by the administrative authorities of the hospital. As a part of ASP implementation WHO antimicrobial resistance surveillance software has to be installed in the hospital and the guideline, educational notes will provided to physicians, in different departments. In the implementation period recommendations will be provided for the conversion of IV to PO antimicrobial agents as well as for the reduction of medication errors.

Then in the post implementation period data will collected and evaluated. Then a Comparison the data collected in the pre-ASP period and post-ASP period to assess the impact of antimicrobial stewardship programme (ASP). The data include strength of population selected, sex distribution, age distribution and categorization, number of culture and sensitivity tests performed per patient, length of stay within the hospital, net cost per patient, number of broad spectrum antimicrobial agents/patient, number of narrow spectrum antimicrobial agents/patients, parenteral antimicrobial agents / patients, number of patients discharged with parenteral AMA etc. The errors related to antimicrobial use after NCCMERP categorization will be analyse. Finally comparison of the resistance profile of antimicrobial agents and antimicrobial agents consumed will be done. The compared data of each strategies and parameters will evaluate using appropriate statistical tool.

**SIGNIFICANCE OF THE RESEARCH**

Antimicrobial stewardship programs in hospitals seek to optimize antimicrobial usage in order to improve individual patient care. Inappropriate use of antimicrobial drug is an important public health threat because it damages our ability to effectively treat the infections. So a careful and responsible approach should be implemented at regional and
international levels. In health care environment, effort should cornerstone on, accurate diagnosis, early treatment, wise use of antimicrobials, and breaking the spread of resistance. In India the infectious disease burden is among the highest in the world and recent report showed the inappropriate and irrational use of antimicrobial agents against these diseases, which led to increase in development of antimicrobial resistance.

So the current need is to develop a robust antimicrobial stewardship programme which would enhance clinical outcomes, optimize antimicrobial usage, and health care cost. This should be developed in each hospital at local level and national level. Effective antimicrobial stewardship programme have been shown to improve the appropriateness of antimicrobial usage.