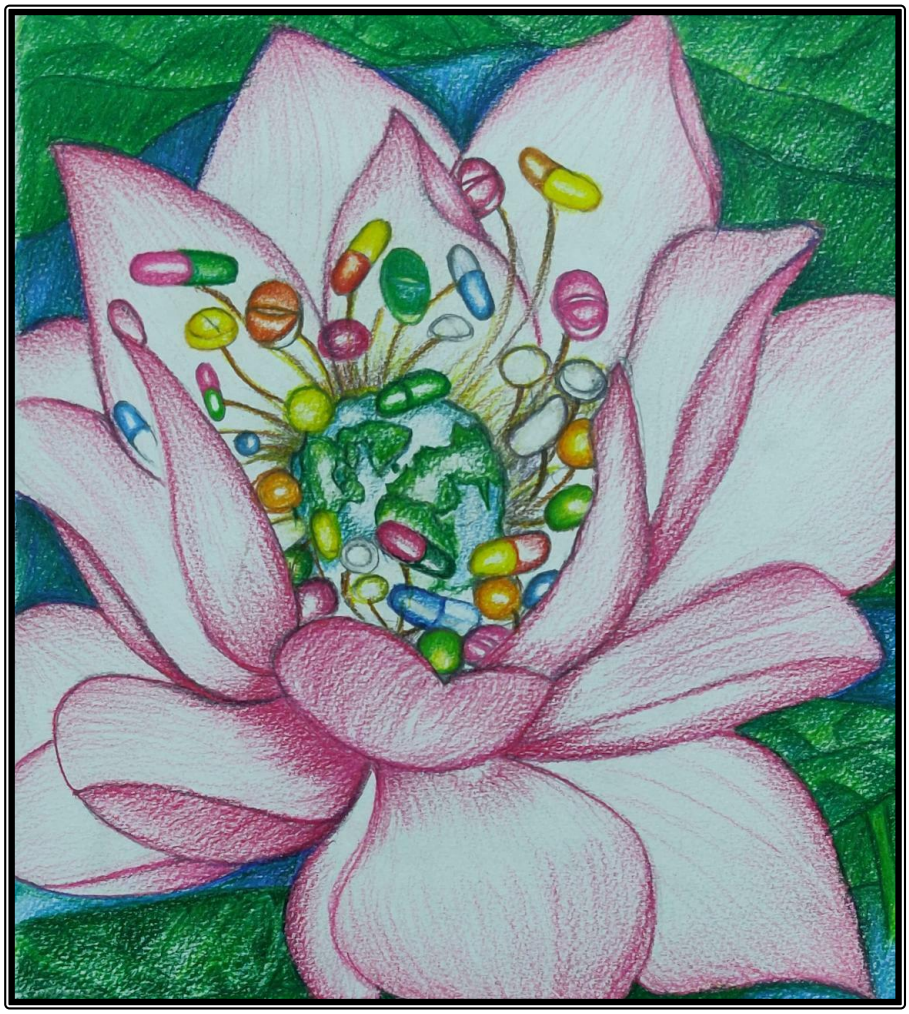
Are antimicrobials appropriately used in public health facilities as per the treatment guidelines for antimicrobial use in common syndromes?



Operations Research Report
Tamil Nadu Health Systems Reforms Program
By

Department of Community Medicine
ESIC Medical College and PGIMSR, KK Nagar, Chennai 78

Cover Art:
In Indian Philosophy the lotus symbolizes the seat of the intellect and the ability to distinguish between good and bad. This art depicts the importance of using antimicrobials judiciously and rationally in order to protect them and prevent antimicrobial resistance. The antimicrobials are depicted as the seeds of the future generations. The Cover Art was hand drawn and coloured with pencil shades by Dr. Ajith Kumar Ponnambalam (+919677374152).

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DEPARTMENT OF COMMUNITY MEDICINE

FINAL PROJECT REPORT

Are antimicrobials appropriately used in public health facilities as per the treatment guidelines for antimicrobial use in common syndromes?

Submitted to

The TNHSRP – Operational Research

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List of Abbreviations

ADD	Acute Diarrheal Disease
AIIMS	All India Institute of Medical Sciences
AMR	Antimicrobial Resistance
AMRSN	Antimicrobial Resistance Surveillance and Research Network
AMS	Antimicrobial Stewardship
AMSC	Antimicrobial Stewardship Committee
AMSP	Antimicrobial Stewardship Program
ARI	Acute Respiratory Infection
ASPIC	Antimicrobial Stewardship Prevention and Infection and Control
ATC	Anatomical Therapeutic Classification
AWaRe	Access, Watch, Reserve
CMC	Christian Medical College
DDD	Defined Daily Dose
GAP - AMR	Global Action Plan on Antimicrobial Resistance
GH	Government Hospital
GPPS	Global Point Prevalence Survey
HDI	Human Development Index
HIC	High Income Countries
ICMR	Indian Council of Medical Research
IP	Inpatient
IV	Intravenous
JIPMER	Jawaharlal Institute of Postgraduate Medical Education and Research
LMIC	Low and Middle Income Countries
MDR-TB	Multidrug Resistant Tuberculosis
NAP-AMR	National Action Plan on Antimicrobial Resistance
NDM	New Delhi Metallobetalactamase
NEDL	National Essential Drug List
NPTEL	National Programme on Technology Enhanced Learning
OP	Outpatient
PGI	Post Graduate Institute
STG	Standard Treatment Guidelines
UTI	Urinary Tract infection
WHO	World Health Organization

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Executive Summary

Antimicrobials are an important medical invention of the 20th century and have drastically contributed to the epidemiological transition. However, the recent years have seen the rapid emergence of antimicrobial resistance. One of the biggest contributors to antimicrobial resistance is indiscriminate and inappropriate use of antimicrobials. This study was conducted to evaluate the appropriateness of use of antimicrobials in public health facilities in Tamil Nadu using the ICMR standard treatment guidelines for antimicrobial use in common syndromes as the standard. Six districts were purposively sampled based on the Human Development Index of 2017, namely Trichy, Tirunelveli, Pudukkottai, Salem, Theni and Villupuram. One medical college, one district and one subdistrict hospital were sampled from each district. In these facilities evaluation of appropriateness of antimicrobial use was done by facility level assessment of policies and practices of antimicrobial use, an in-patient case sheet audit and outpatient prescription audit for antimicrobial use in the departments of general medicine, general surgery, obstetrics, gynecology, pediatrics and orthopedics. The study found that a high proportion of in-patients in all the health facilities were on antimicrobials (40-88%). The district and sub-district hospitals had a higher proportion of in-patient antimicrobial use than the medical colleges. In the in-patient setting there was a very high use of third generation cephalosporins (~40 DDDs per 1000 bed days). In some district hospitals the use was as high as 100 DDDs per 1000 bed days. Cefotaxime, Ceftriaxone, Amoxycillin, Doxycycline and Ciprofloxacin comprised 90% of the consumption of antimicrobials in terms of DDDs per 1000 bed days. The utilization of Access group of antimicrobials namely, Amoxycillin, Ciprofloxacin and Doxycycline were less than half of the Watch group of antimicrobials namely Cefotaxime and Ceftriaxone, leading to a poor Access to Watch ratio. Utilization of antimicrobials in DDDs per 1000 bed days was higher in the departments of general medicine, general surgery, compared to obstetrics, gynecology, paediatrics and orthopaedics. On

assessment of appropriateness of use of antimicrobials as per the ICMR standard treatment guidelines it was found that 98% were inappropriately used. The commonest type of inappropriate use was use of unnecessarily broad-spectrum antibiotics deviating from the ICMR guidelines. In surgical departments, the surgical prophylaxis was inappropriate in terms of the choice, dose and duration of the antimicrobial used. There was a high use of antimicrobials for normal vaginal deliveries in all health facilities. In the out-patient prescription audit, there was very poor documentation of diagnosis. Analysis of antimicrobial prescription against the clinical history suggesting an infection showed that almost twice the number of patients who had a history suggestive of infection were prescribed antimicrobials. Assessment of facility level policies and practices revealed that many facilities had an antimicrobial formulary which was in adherence to the National Essential Drug List. Stock out status was reported for common antimicrobials in 9 of the 18 surveyed facilities. Eleven of the 18 facilities reported following a standard treatment guideline for antimicrobial use. Ten of the 18 facilities had a copy of the ICMR standard treatment guidelines. A pattern of decreasing use of Watch group antimicrobials, increasing use of Access use antimicrobials and better antimicrobial policy and practices score was observed with increasing Human Development Index of the districts. There is a need to establish routine surveillance of antimicrobial use in terms of DDDs per 1000 bed days in all health facilities. A facility level antimicrobial stewardship committee must be established in all health facilities to regulate antimicrobial use. Training and capacity building on antimicrobial use, especially surgical prophylaxis practices must be enhanced.

Are antimicrobials appropriately used in public health facilities as per the treatment guidelines for antimicrobial use in common syndromes?

Introduction

Public health importance of antimicrobials

Discovery of antimicrobials has been one of the most important advances in medicine. Antimicrobials are a group of chemical substances that inhibit the growth of microorganisms. They help controlling the infections in humans and are at times even lifesaving. Antimicrobials are specifically biological substances produced by other living organisms that act against microorganisms and thus help treat infections. These antimicrobials selectively harm the infecting organism without inducing much harm to the human host. The discovery of Penicillin by Alexander Fleming in 1928 was the landmark in the history of antimicrobials.(1) The period extending from 1950 to 1970 marked the golden era of antimicrobials when several new antimicrobials were discovered.(2) They revolutionized the treatment of infectious diseases. In many countries after the discovery and extensive use of antimicrobials, infectious diseases ceased to be the major cause of morbidity and mortality and it was replaced by the epidemiological transition to high prevalence of non-communicable diseases like diabetes, hypertension, cardiovascular diseases and cancer. Antimicrobials and vaccines have played a major role in this epidemiological transition in developed countries.(3,4) In low and middle income countries like India, this epidemiological transition is taking place now. However, there are several new emerging and re-emerging infectious diseases that are coming up in the recent times.(5) These infections along with the development of antimicrobial resistance now post a major threat to global health.

Global problem of antimicrobial resistance

Emergence of antimicrobial resistance is a global public health problem. It is a significant threat to the gains that were achieved during the antimicrobial era. Microbes develop resistance to antimicrobials as an adaptive response. Once they develop resistance the antimicrobials cease to be effective against them. The resistance can be natural resistance against the antimicrobial, acquired genetic mutations in the microbes conferring them resistance to the antimicrobial, transfer of genetic resistance from one microbe to another through gene sharing and acquiring resistance through selection pressure due to indiscriminate and inappropriate use of antimicrobials. Infections caused by resistant microbes are difficult to treat and often prove fatal. Since the infection persists for longer duration of time due to lack of effective treatment, it also has more chances of spreading in the community.(6)

The problem of antimicrobial resistance is global and not localized to any region. In the United States the Centres for Disease Control reports that at least 2.8 million people get infected each year by resistant microbes and about 35,000 due annually due to resistant infections.(7)

Multi Drug Resistant Tuberculosis (MDR-TB) is a major infection that leads to high levels of morbidity and mortality. The global incidence of MDR-TB is 3% of all newly diagnosed patients and 18% of all re-treatment patients. In countries with high TB burden like India, this leads to staggering number of patients who are difficult to treat with routine medications. (8) Other important resistant microbes are chloroquine resistant falciparum malaria, methicillin resistant staphylococcus aureus, extended spectrum beta lactamase producing gram negative bacteria, carbapenem resistant Enterobacteriaceae, all of which can cause deadly infections.(9) Today with increasing use of technology and interventions for various diseases such as cardiac conditions, there is a heavy reliance on antimicrobials to prevent infections. But the emergence

of antimicrobial resistance leads to problems in applying these technologies and interventions for improving the health status of people.

Antimicrobial resistance is a major public health problem because of some important reasons. Resistant microbes are difficult to treat and remain infective for longer periods of time. This increases the potential for transmission of the resistant microbe. Also this warrants the use of higher antimicrobials which are more expensive. This increase in duration of hospitalization or treatment and use of more expensive antimicrobials increases the cost of treatment. The emergence of antimicrobial resistance makes more infectious diseases difficult to treat and control.(9) This increases the global burden of diseases.(10) Along with emerging resistance, many microbes are also becoming more virulent.(11) This combination of high virulence and high antimicrobial resistance has led to a major problem of infectious diseases globally. The other major problem is that pharmaceutical companies are hesitating to invest in development of newer antimicrobials. This is because the life of a new antimicrobial is very short, as the microbes develop resistance very fast.(12) Antimicrobial resistance is a major stumbling block to achieving the Sustainable Development Goals.(13) It also poses hindrance to provision of good primary health care.

Antimicrobial resistance – the Indian scenario

The problem of antimicrobial resistance is very significant in India.(14,15) The crude infectious diseases mortality rate in India is 416 per 100,000 population and this is two times greater than that in the United States.(16) The New Delhi Metallo beta lactamase enzyme was first reported in 2008 in India and is now present globally.(17) E. coli isolated in India, now show a high level of resistance to common antimicrobials such as Ampicillin, Nalidixic Acid and Co trimoxazole. Slowly resistance to third generation cephalosporins and fluoroquinolones

has also increased.(18) In 2013, studies showed that 10% of the E. coli isolates were also carbapenem resistant. Similarly, fluoroquinolone resistance among salmonella species has increased to as high as 30%.(19) A recent study from Mumbai showed that 66% of surgical site infections are caused by gram negative bacteria and a significant proportion of them are resistant to many common antimicrobials. Higher antimicrobials like colistin are increasingly being used in many tertiary care hospitals in India to treat resistant microbes.(20) A study from Tamil Nadu showed a high prevalence of carbapenem resistance among klebsiella isolates especially from pus and urine and a very high prevalence of aztreonam and fluoroquinolone resistance among E. coli. (21) Factors that lead to emergence of antimicrobial resistance in India are very similar to those globally. Indiscriminate and inappropriate use of antimicrobials is a common reason.

Factors contributing to antimicrobial resistance

A brief overview of emergence of antimicrobial resistance is important to gain a sound grasp of the factors that influence emergence of antimicrobial resistance. Antimicrobial resistance emerges in the microorganism through genetic mutations. Mutations of this kind happen very frequently, but such resistance mutations also lead to a reduction in fitness of the microorganism. Therefore, they are not propagated through subsequent generations of the microorganism. There is a need for selection pressure, which is some factor which provides the organism a survival advantage, in order for the resistance mutation to be transmitted across generations. Drastic genetic shifts often do not cause this kind of resistance traits. It is the gradual genetic drifts which cause them. (22) Apart from these forms of acquired resistance, bacteria have also been known to horizontally transfer the resistance gene to other closely related bacteria that share the same ecosystem. There are several settings which provide the typical environment that favours this kind of horizontal resistance transfer. These include

sewage treatment plants, livestock, poultry, and water bodies. Therefore use of and presence of antimicrobials in these environments can favour emergence and horizontal transfer of resistance genes. The development and propagation of antimicrobial resistance in the environment is dependent on four factors namely emergence of new mutations in the organism, mobilization of these new mutations into mobile genetic elements, transfer of these new mutations to human pathogens, and dissemination of this new mutation to the human microbiome.(23) Any factors human, medical or environmental that favours these four factors can promote emergence of antimicrobial resistance.

One of the greatest contributors to the emergence of antimicrobial resistance is high use of antimicrobials. Changes in antimicrobial use are associated with changes in prevalence of antimicrobial resistance. Resistant microbes are more common in hospital acquired infections. Those patients who have received antimicrobials previously are more likely to develop infections with resistant microbes. Hospitals that have a high rate of antimicrobial use also have high rates of antimicrobial resistance.(24) Patients who are on longer duration of antimicrobial use have a greater risk of antimicrobial infections. Irrational use of antimicrobials including inappropriate indication, dose, frequency and duration can all contribute to emergence of antimicrobial resistance. Low vaccine coverage rates and vaccine hesitancy contributes to increased infections and therefore increased use of antimicrobials. (25) Lack of proper water, sanitation, hygiene and infection prevention practices can worsen the antimicrobial resistance problem. Apart from the medical industry, antimicrobials are also over-used in agriculture, livestock rearing, through the food chain, and through waste water from all these operations. (26) There is a need to implement public health measures to stall the relentless emergence of antimicrobial resistance.

Antimicrobial stewardship initiatives

The World Health Assembly in 2015 endorsed the Global Action Plan on Antimicrobial Resistance (GAP-AMR).(27) In 2017, the High Level meeting of the General Assembly of the UN also committed that AMR is a global threat and need to be addressed urgently. According to the global action plan, there are five strategic objectives to be achieved to limit the global problem of antimicrobial resistance namely

(1) Improve awareness and understanding of AMR through effective communication, education and training.
(2) Strengthen knowledge and evidence base through surveillance and research
(3) Reduce incidence of infections through effective sanitation, hygiene and infection prevention measures
(4) Optimize the use of antimicrobial medicines in human and animal health
(5) Develop the economic case for sustainable investment that takes account of the needs of all countries and increase investment in new medicines, diagnostic tools, vaccines and other interventions.

To meet the objective 4 mentioned above one of the most important intervention is Antimicrobial Stewardship (AMS).(28) Antimicrobial Stewardship is defined as interventions that target optimization of antimicrobial use, improve patient outcomes, reduce antimicrobial resistance, reduce health care associated infections and reduce overall health care costs. The goals of AMS are to optimize the prescription of antimicrobials, to promote behaviour change in prescription and dispensing practices, to improve quality of care and patient outcomes, to reduce unnecessary health care costs, to reduce emergence of antimicrobial resistance, to prolong the life span of antimicrobials, to limit adverse economic impact of antimicrobial

resistance, and to promote rational use of antimicrobials.(28) The principles of AMS are shown in Figure 1.

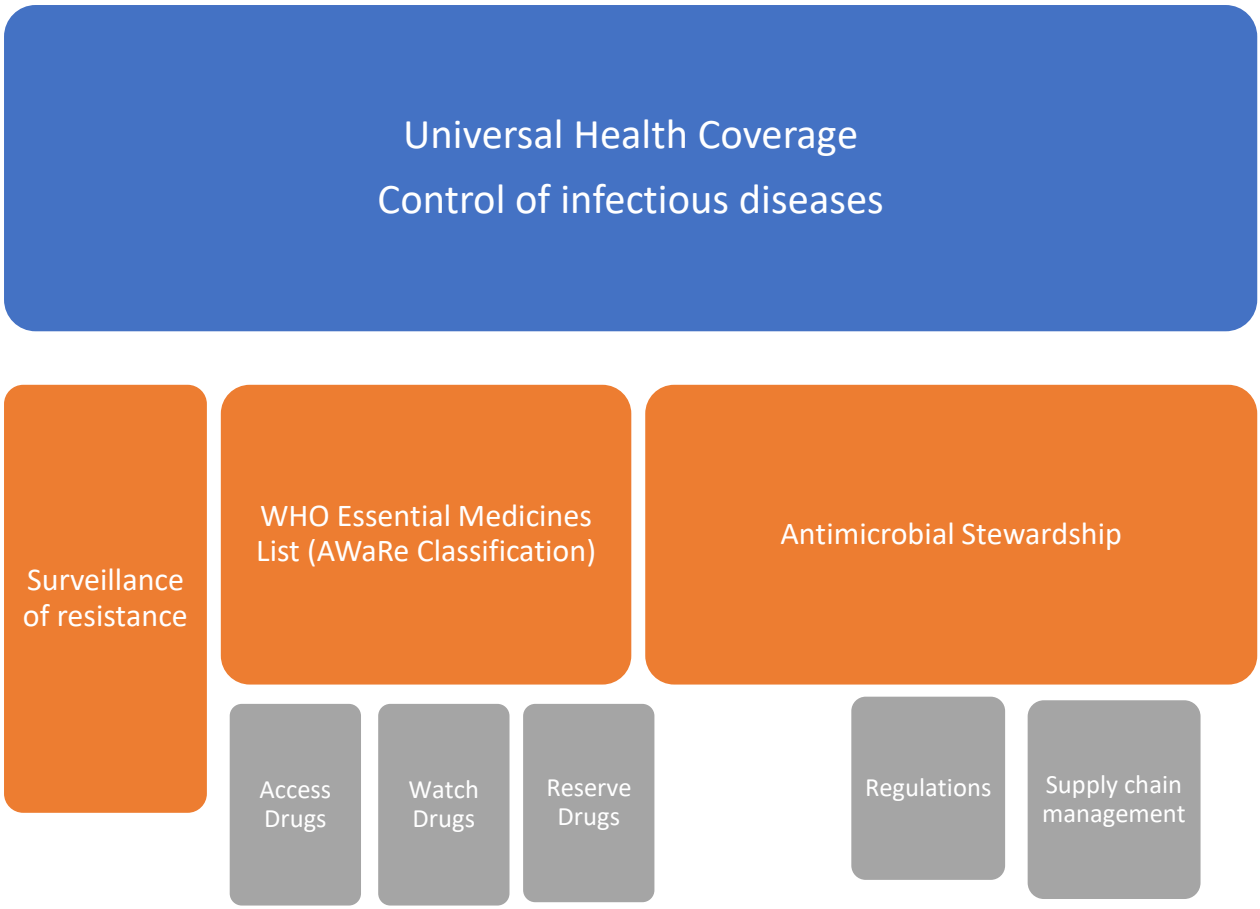

Figure 1: Universal health coverage for infectious diseases can be ensured by active surveillance of antimicrobial resistance, implementation of the WHO Essential Medicines list of access, watch and restrict antimicrobials, and implementation of antimicrobial stewardship through regulation of antimicrobial use and management of supply chain of antimicrobials.

The World Health Organization proposes several important strategies for AMS at the national level. These include:

1. Prioritizing AMS in the health policy of countries. The government of countries must endorse antimicrobial stewardship as an important intervention to reduce antimicrobial resistance.

2. Setting up technical working groups at national level to advice and oversee the implementation of antimicrobial stewardship initiatives at the country level.
3. Regular monitoring and evaluation of the antimicrobial stewardship initiatives at the national level and suggestion of course correction and modifications to improve the implementation.
4. Integrating the AWaRe classification (Access, Watch and Reserve) of antimicrobials into the National Essential Medicines list.
5. Developing national, regional and local standard treatment guidelines for use of antimicrobials according to the AWaRe classification by the WHO.
6. Regulation of antimicrobial manufacture, distribution and sale, regulating fixed drug combination of antimicrobials and strictly regulating sale only on prescription.
7. Ensuring good manufacturing practices of antimicrobials. Regulation of laboratories and manufacturing units through periodic inspections.
8. Creating public awareness about antimicrobials and antimicrobial resistance thus ensuring rational and proper use of antimicrobials.
9. Education and training of all health care providers on antimicrobials, prescription practices, antimicrobial resistance and antimicrobial stewardship.
10. Establishment of surveillance of antimicrobial use, antimicrobial resistance and antimicrobial stewardship practices in all health facilities in the nation.
11. Access to diagnostic tests to detect infections, antimicrobial sensitivity and resistance patterns.

The Global Action Plan on AMR proposes four important indicators to monitor the implementation of antimicrobial stewardship initiates in countries. These include,

Use of antimicrobials in humans, access to antimicrobials, appropriate use of antimicrobials and optimization of antimicrobial use and regulation.

At the health facility level the antimicrobial stewardship initiatives include:

1. Setting up of a antimicrobial stewardship committee at the facility and allocation of specific budget for the operation of this committee.
2. The AMS team must be multidisciplinary including more than 2 health care professionals, nurses, pharmacists, physicians and administrative staff.
3. The AMS team and the Infection Control Committee must collaborate and work together.
4. Regular audits and reports must be performed and reported.
5. The facility must have an up-to-date standard treatment guidelines for antimicrobial use.
6. Advice and feedback from AMS team members must be sought and accessible to all clinical prescribers of antimicrobials.
7. The AMS team must conduct regular ward rounds and oversee the antimicrobial use in the facility.
8. The health facility must have a WHO AWaRe compliant antimicrobial drug formulary.
9. There must be restrictive prescription regulations on Restricted antimicrobials like double prescriptions, or authorization by an approved prescriber.
10. Laboratory and imaging services must be strengthened to support the AMS initiatives.
11. Education and Training of all health care providers on antimicrobial prescription, antimicrobial resistance and antimicrobial stewardship.
12. Periodic antimicrobial prescription and use audit at the health facility level and departmental level.

13. Monitoring the quantity and types of antimicrobials frequently used in the health facility.
14. Monitoring antimicrobial sensitivity and resistance patterns.
15. The antimicrobial prescription audit reports must be shared with all prescribers.

The AWaRe classification is a useful antimicrobial regulation intervention proposed by the World Health Organization.(29) According to this classification antimicrobials are classified into Access, Watch and Reserve. This classification is shown in Figure 2.

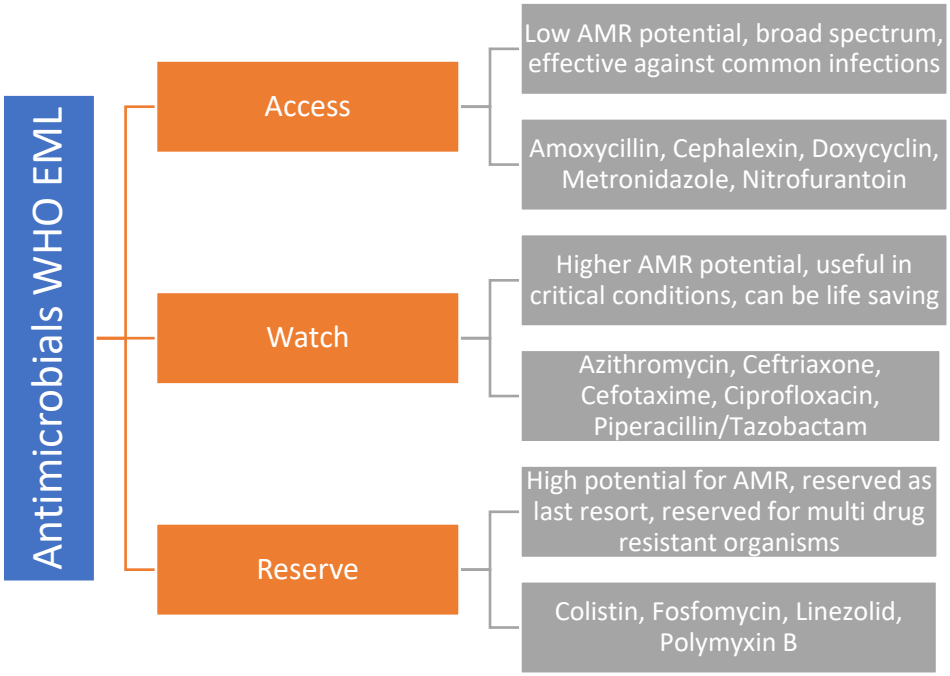

Figure 2: This is the AWaRe classification of antimicrobials where Access antimicrobials are to be made freely accessible as they cover common infectious conditions, Watch antimicrobials have a greater potential for antimicrobial resistance and hence should be regulated and Reserve antimicrobials are the last resort drugs reserved for multi drug resistant organisms.

Specific activities recommended by the WHO for antimicrobial stewardship in a health facility include(28):

1. Reduce over-prescription of antimicrobials. Often antimicrobials are prescribed for fever without an evidence of a local infection, viral infections, other inflammatory conditions which is unnecessary. This can be regulated and prevented.
2. Regulation of use of Watch and Reserve antimicrobials. Often, Watch antimicrobials are used in health facilities as they tend to be broad spectrum. This should be monitored and regulated.
3. Avoiding unnecessary combination antimicrobials.
4. Avoiding wrong antimicrobial choice, dose, dosing interval, duration and route of administration by wide dissemination of antimicrobial standard treatment guidelines.
5. Delaying administration or starting of antimicrobials is known to reduce unnecessary use of antimicrobials.
6. Review of empiric antimicrobial prescription after 48 hours of starting them to decide on stopping or changing the antimicrobials.
7. De-escalation of antimicrobials based on standard treatment guidelines or microbiological culture reports.
8. Early switch of IV to oral antimicrobials when indicated.
9. Dispending Reserve antimicrobials only on approval by the AMS committee.

Health facilities can plan and implement these measures to ensure antimicrobial stewardship. The antimicrobial stewardship committee can be overall in charge of these interventions. It can have subcommittees which take charge of specific antimicrobial stewardship activities.

Antimicrobial stewardship in India

The Indian Council of Medical Research (ICMR) released the Antimicrobial Stewardship Program Guidelines in the years 2018. (30)The guidelines proposed active strategies, supplemental strategies, and other strategies for antimicrobial stewardship.

Active Strategies:

1. Prospective antimicrobial prescription audits and feedback. The audit will help check and improve appropriate prescription of antimicrobials with respect to drug choice, dose, frequency, duration and route of administration.
2. Formulary restriction and preauthorization. This is an effective method to reduce and regulate antimicrobial use. This is done by placing a policy requirement that if higher antimicrobials are prescribed it requires authorization by a member of the antimicrobial stewardship committee.

Supplemental Strategies:

1. Education and Training. Training all health care providers on antimicrobials, antimicrobial prescription, antimicrobial resistance and antimicrobial stewardship will improve antimicrobial use. Education and training will supplement active strategies of regulation of antimicrobial use.
2. Facility specific standard treatment guidelines for antimicrobial use in common syndromes.
3. Antimicrobial cycling is the process of periodically changing the antimicrobials used in the facility to prevent the development of antimicrobial resistance. It will introduce diversity in the antimicrobials used and hence offload the selection pressure that leads to antimicrobial resistance.
4. Antimicrobial order forms can significantly regulate the prescription patterns as the prescribers have to provide justification in these forms for starting antimicrobials.

5. Measure of antimicrobial use by periodically measuring and reporting the Defined Daily Dose DDD per 1000 patient days as defined by the WHOs Anatomical Therapeutic Classification (ATC) system can help keep a tab on use of antimicrobials.
6. Optimization of dose, duration, frequency and route of administration.
7. Review of antimicrobials after 48 hours of initiation to either stop or deescalate.
8. Early switch from parenteral to oral therapy when indicated.
9. Electronic medical records and electronic prescription practices can substantially help in regulating antimicrobial use.
10. Strengthening of microbiology laboratory to provide appropriate culture and sensitivity reports.

The guidelines recommend formation of antimicrobial stewardship teams which comprise of the medical superintendent or director of the health facility, pharmacist, microbiologist, infection prevention and control committee member, and other health care providers. (30)

The Antimicrobial Resistance Surveillance and Research Network (AMRSN) was established across the country in 2013 and this has been following the data on antimicrobial sensitivity and resistance patterns in various parts of the country.(31) This data supplements the AMSP initiatives. Following the setting up of this surveillance network ICMR provided guidelines for antimicrobial stewardship. ICMR also launched the Antimicrobial Stewardship Prevention of Infection and Control (ASPIC) programme which trains physicians, nurses and pharmacists on antimicrobial stewardship, infection prevention and control.(32)

In a tertiary care centre in Kochi, Kerala a multidisciplinary antimicrobial stewardship intervention was implemented. The intervention comprised of establishment of institutional standard treatment guidelines for antimicrobial use and a post prescription antimicrobial prescription audit. The intervention was instrumental in rectifying inappropriate antimicrobial use in 2776 instances in the 1 year period of implementation. The DDDs/1000 patient days reduced substantially following the intervention. This study showed the feasibility and effectiveness of such antimicrobial stewardship initiatives in India. (33) In a survey of 25 health facilities in India, 60% of them reported implementing antimicrobial stewardship activities. The AMSP activities were mainly led by clinical microbiologists. Monitoring of antimicrobial use was performed in 14 of these 25 centres and 13 of those 14 centres performed antimicrobial prescription audits. Twelve of them gave feedback to the prescribers and 10 of them even reported to the AMSP team of the respective hospitals. Nine of the surveyed centres did a regular review of all patients on antimicrobials to decide on stopping or de-escalation. DDD per 1000 patient days monitoring of the antimicrobial use in the hospital was performed by 9 of these facilities.(34) These findings indicate that there is a need for strengthening of AMSP initiatives across health facilities in India.

ICMR Standard Treatment Guidelines for antimicrobial use in common syndromes

The Indian Council of Medical Research, in keeping with the need to implement antimicrobial stewardship activities across health facilities in the country, released the first edition of the Standard Treatment Guidelines for antimicrobial use in common syndromes. This was informed by the data from the Antimicrobial Resistance Surveillance and Research Network (AMRSN). These guidelines propose the following steps for rational use of antimicrobials. (35)

Step 1: Making an appropriate clinical diagnosis considering whether it is an infection, and what possible non-infectious causes could explain the fever.

Step 2: Limiting empiric antimicrobial therapy to the most serious cases of infection. Empiric antimicrobials are indicated only for

a. Febrile neutropenia
b. Severe sepsis and septic shock
c. Community Acquired Pneumonia
d. Ventilator Associated Pneumonia
e. Necrotizing fasciitis

Step 3: Suspecting and identifying the microbe. Identifying the fever syndrome, predicting possible microbes associated with the syndrome and identifying the local sensitivity and resistance patterns.

Step 4: Choosing the appropriate antimicrobial. Based on the identified microbe starting the appropriate antimicrobial in appropriate dose, frequency, duration and route of administration taking into consideration appropriate pharmacokinetic and pharmacodynamic parameters according to comorbidities.

Step 5: De-escalation / modification. Based on culture and antimicrobial sensitivity patterns, de-escalation and modification of antimicrobials. Changing combination antimicrobials to single antimicrobial, changing broad spectrum to narrow specific spectrum, and changing parenteral to oral antimicrobials.

Step 6: Stop antimicrobials in the following clinical situations. Viral respiratory infections, skin and soft tissue infections, asymptomatic bacteriuria, low grade fever, microbial colonization and culture contamination.

Step 7: Reduce duration of therapy. Optimal duration of therapy must be followed such as, community acquired pneumonia for 5 days, hospital acquired pneumonia for 8 days, skin and

soft issue infections for 5 days, cystitis for 3-5 days, pyelonephritis for 5-14 days, catheter associated UTI for 7 days, and surgical prophylaxis single dose.

Step 8: Optimizing the dose based on pharmacodynamic and pharmacokinetic parameters specific to various comorbidities such as chronic kidney disease.

The document provides clear specific guidelines on management of acute fever, sepsis, respiratory tract infections, intra-abdominal infections, skin and soft tissue infections, bone and joint, central nervous system, urinary tract, hospital acquired, pelvic, endocarditis infections and infections in the immunocompromised. This guidelines has further been updated and revised in 2019. (35)

Evaluation of antimicrobial sensitivity and resistance patterns

While antimicrobial stewardship initiatives focus on periodic evaluation of use of antimicrobials in health facilities through audits, there is also a need to periodically evaluate overall antimicrobial use at state and national level to steer the large scale antimicrobial stewardship initiatives towards positive outcomes. These methods of evaluation of antimicrobial use include review of case sheets and prescriptions to evaluate appropriateness of antimicrobial use, survey of antimicrobial stewardship committee members regarding functions of AMSP in the health facilities, tracking of sale and dispensing of antimicrobials according to DDD per 1000 person days of hospital stay in various health facilities, and surveillance of antimicrobial sensitivity and resistance patterns in the health facilities. Other indirect indicators for evaluation of antimicrobial use include, antimicrobial use in food production, volume of antimicrobials used to promote growth of poultry and cattle, levels of antimicrobials in water, sewage and soil. Evaluation of infection prevention and control activities such as immunization rate, access to primary care services, access to sanitation and

toilet facilities, childhood and under 5 mortality rate, animal immunization rates, farm sanitation laws, and rate of hospital acquired infection. (36–39)

WHO prescribed method of evaluation of antimicrobial use

The World Health Organization recommends three broad categories of indicators at the level of health care facilities to evaluate appropriate use of antimicrobials.

These include facility level policies and systems to ensure appropriate use of antimicrobials, physician level practices and systems that ensure rational use of antimicrobials, at the level of the provision of health care where the nurses and other staff administer and give these antimicrobials to the patients and finally at the level of patients and communities where the antimicrobials are used. Figure 1 represents this conceptual framework for evaluation.

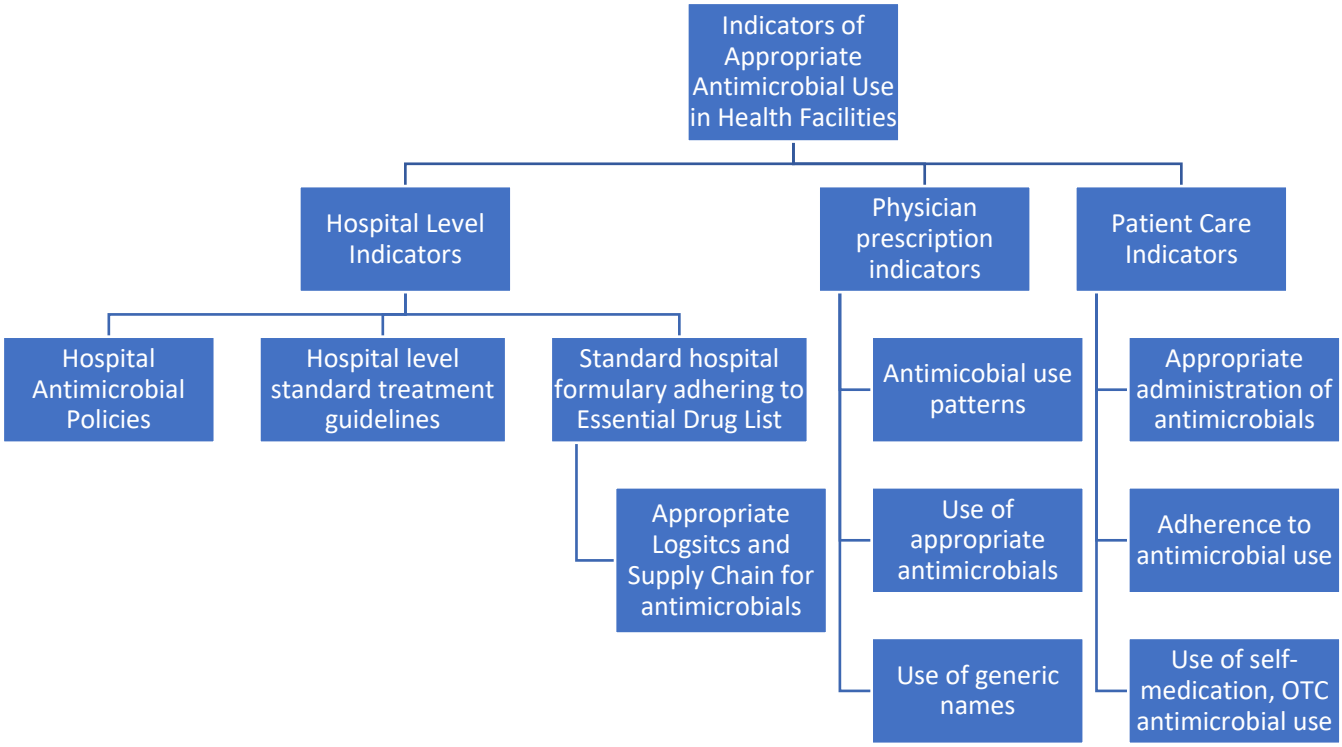

Figure 3: Framework for evaluation of appropriateness of antimicrobial use in health facilities

Indicators for measurement

Hospital Indicators – To be evaluated at hospital level

1. Does a standard treatment guideline exist for treatment of common infectious diseases?
2. Number of diseases for which the hospital has STG ____
3. Is there an approved hospital formulary?
4. Total number of antimicrobials included in the approved hospital formulary or essential medicine list ____
5. Availability of a set of important antimicrobials in the hospital pharmacy _____%
6. Average number of days that these important antimicrobials are out of stock ____days / month
7. Expenditure on antimicrobials as a percentage of total hospital medicine expenditure

Prescribing Indicators – To be evaluated through audit of a random sample of case sheets

1. Percentage of case sheets with one or more antimicrobials prescribed
2. Average number of antimicrobials prescribed per case sheet in which any antimicrobial was prescribed
3. Percentage of antimicrobials prescribed consistent with hospital formulary or essential medicine list
4. Average cost of antimicrobials prescribed per hospitalization in which antimicrobials were prescribed
5. Average duration of prescribed antimicrobial treatment
6. Percentage of patients with pneumonia prescribed antimicrobials as per STG
7. Percentage of antimicrobials prescribed with generic name

Patient Care Indicators & Supplemental Indicators – to be evaluated through audit of a random sample of case sheets and patients

1. Percentage of doses of prescribed antimicrobials administered
2. The average duration of hospital stay of patients who received antimicrobials
3. Percentage of antimicrobial drug sensitivity tests reported per hospital admission with curative antimicrobial prescribed

Objectives

1. To evaluate the appropriateness of antimicrobial use in public health facilities in Tamil Nadu at the facility, prescription, patient care and patient level as per the ICMR standard treatment guidelines for antimicrobial use, 2019
2. To categorize the various health facilities and the districts based on the appropriateness of antimicrobial use as per the ICMR standard treatment guidelines for antimicrobial use, 2019

Methods

Study Setting

The study was conducted in the secondary and tertiary level public health facilities in Tamil Nadu. Based on the Human Development Index (HDI) the districts were classified into high, middle and low performance districts.(40) Two districts were randomly sampled from each level of performance. One tertiary care medical college teaching hospital, one District Hospital and one sub-district level hospital was sampled from each selected district, thus giving rise to a sample of 18 health facilities. Table 1 shows the list of sampled districts and the randomly sampled health facilities from each district.

Table 1.1: District-wise list of health facilities sampled for the study

District	HDI	Tertiary Hospital	Secondary Hospitals
Tirunelveli	High	Government Tirunelveli Medical College and Hospital	• Government Headquarters Hospital, Tenkasi • Government Hospital, Ambasamudram
Thiruchirapalli	High	KAP Vishwanathan Government Medical College and Hospital	• Government Hospital, Srirangam • Government Hospital, Musiri
Salem	Medium	Government Mohan Kumaramangalam Medical College and Hospital	• Government Hospital, Attur • Government Hospital, Omalur
Pudukkottai	Medium	Government Pudukkottai Medical College and Hospital	• Government Hospital, Aranthangi • Government Hospital, Iluppur
Villupuram	Low	Government Villupuram Medical College and Hospital	• Government Hospital, Tindivanam • Government Hospital, Vikravandi
Theni	Low	Government Theni Medical College and Hospital	• Government Hospital, Bodinayakanur • Government Hospital, Periyakulam

Sampling and Sample Size

Assuming the prevalence of appropriate antimicrobial prescriptions in case sheets to be 50%, for a 95% confidence level and 10% relative precision of estimate, the sample size is 400. Using a design effect of 2 to account for multistage sampling, the total sample size is 800. In 6 districts with 3 health facilities per district (1 tertiary care and 2 district level facilities) there will totally be 18 health facilities. Including 5 departments in each facility there will be a total of 90 departments. From each department roughly 9 case sheets with antimicrobials should be included in the sample. Assuming about 50% of the case sheets will have antimicrobials in them, this will require sampling at least 20 case sheets from each department in each health facility.

For the out-patient prescription audit, assuming a prevalence of appropriate antimicrobial use to be 50%, for a 95% confidence level and 10% relative precision, the sample size required is 400. Accounting for a design effect of 2, the required sample size is 800. If 20% of OP prescriptions have an antimicrobial, a total of 4000 OP prescriptions must be studied to obtain 800 with antimicrobials in them. This would give rise to approximately 250 OP prescriptions from each of the 18 health facilities.

Data Collection Method

Trained research assistants and field investigators were sent to the various health facilities. They performed the following activities during data collection

Health Facility Level Assessment

- The research assistants interviewed the Chief Medical Officer / Medical Superintendent of the facility to gather data about the antimicrobial policy, hospital infection control policy, hospital drug formulary, essential drug list, standard treatment guidelines for common infectious diseases followed in the hospital.
- The research assistants interviewed the Medical Officer of the Department of Microbiology (laboratory services) and gathered information about hospital infection control policies, antimicrobial sensitivity patterns and policies for antimicrobial resistance prevention
- The investigators also contacted the Medical Officer of the Department of General Medicine to collect data about standard treatment guidelines for common infectious diseases.

Inpatient Prescription Assessment

The field investigators sampled consecutive 20 case sheets each admitted currently in the hospital in the following departments – General Medicine, General Surgery, Obstetrics, Gynecology, Paediatrics, Orthopaedics. Details of antimicrobials were extracted from these case sheets. The 2019 ICMR standard treatment guidelines were followed for assessing appropriateness of therapy for those infections for which the guidance is available.

Patient Care Indicators

A consecutive sample of 20 in-patients admitted in the hospitals (secondary and tertiary care) in various departments (General Medicine, General Surgery, Obstetrics, Gyencology, Paediatrics, Orthopaedics, all inclusive) were interviewed and their case sheets reviewed to understand regarding receipt of antimicrobials.

Outpatient Prescription Audit

In the tertiary, and secondary level facilities, 250 patients visiting the respective OPD were consecutively sampled for the out-patient prescription audit regarding antimicrobials. The 2019 ICMR guidelines for appropriateness of antimicrobial prescriptions was used.

Data Analysis

Antimicrobial Utilization Analysis: The antimicrobial utilization was analysed by calculating the Defined Daily Dose (DDD) of each antimicrobial per 1000 bed days for each facility.(41) The formula used was

$$\textbf{DDD / 1000 bed days} = \frac{\text{No. of units of antimicrobial administered in the facility in the survey period} * 1000}{\text{DDD} * \text{total number of patients studied}}$$

Analysis of Appropriateness of antimicrobial use: Using the ICMR standard treatment guidelines for antimicrobial use in common syndromes, a researcher coded the drug choice, dose, dosing interval and duration of the antimicrobials used in OP and IP settings as appropriate (1) and inappropriate (0). If diagnosis was not available or was incomplete, the coding was avoided. The coding chart is shown in the Table given below. It is adapted from the ICMR guidelines for antimicrobial use.

Table 1.2: Coding chart for appropriateness of antimicrobial use as per ICMR standard treatment guidelines for antimicrobial use in common syndromes

S.No	Disease diagnosis	Antimicrobial of choice
1	Typhoid fever	Cefixime, Ceftriaxone, Ciprofloxacin, Chloramphenicol
2	Suspected gram positive infections – community acquired pneumonia, pharyngitis, bacterial sinusitis	Cefazolin, Cloxacillin, Amoxycillin + clavulanate
3	Suspected gram negative infections – urinary tract infections, pyelonephritis, intra abdominal infections, cholecystitis, cholangitis, liver abscess	Cefaperazone + Sulbactam, Piperacillin + tazobactam, Fluoroquinolone
4	Rickettsial Infections	Doxycycline, Azithromycin
5	Leptospirosis	Penicillin, Doxycycline, Ceftriaxone
6	Vivax Malaria	Chloroquin, Artemether Lumefantrine
7	Falciparum Malaria	Artemether and Lumefantrine
8	Skin and soft tissue infections – cellulitis, necrotizing fasciitis	Cefazolin, Cefalexin, Amoxycillin + clavulanate, Clinidamycin
9	Bacterial CNS infections – meningitis, meningoencephalitis	Ceftriaxone, Amoxycillin + Clavulanate, Meropenem
10	Surgical prophylaxis – clean wound	Single dose cefazolin
11	Surgical prophylaxis – clean contaminated wound	Cefazolin or Ceftriaxone
12	Surgical prophylaxis – contaminated wound	Cefotaxime + Metronidazole, Metrindazole + Aminoglycoside / Fluoroquinolone
13	Surgery – dirty infected wound	Cefazolin + Metronidazole, Cefotaxime + Aminoglycoside / Fluoroquinolone
14	Surgical site infections	Piperacillin + Tazobactam Ceftriaxone + Metronidazole Ciprofloxacin + Metronidazole
15	Hospital Acquired Pneumonia, Ventilator Associated Pneumonia	Cefaperazone + Sulbactam Piperacillin + Tazobactam
16	Vaginal delivery following PROM, chorioamnionitis	Ampicillin, Cefazolin
17	Vaginal delivery with 3rd degree and complete perineal tear	Cefazolin + Metronidazole
18	Cesarean Section	Cefazolin single dose
19	Peurperal sepsis and septic abortion	Piperacillin + Tazobactam

Table 1.3: Standard doses of antimicrobials

Antimicrobials	Dose, duration and route of administration
Cotrimoxazole	1 DS tab BD
Azithromycin	500 mg PO OD
Ceftriaxone	2 g IV OD
Cefixime	20 mg / Kg / Day
Chloramphenicol	500 mg QID
Ciprofloxacin	750 mg BD
Cefazolin	2 g IV Q8H
Cloxacillin	2 g IV Q6H
Amoxicillin + Clavulanate	1.2 g IV Q8H
Piperacillin + Tazobactam	4.5 g IV Q6H
Cefoperazone + Sulbactam	3 g IV Q12 H
Imipenem	1 g IV Q8H
Meropenem	1 g IV Q8H
Doxycycline	100 mg PO or IV BD
Penicillin G	20 Lakh IV Q4H

Ethical Considerations:

The study was reviewed and approved by the Institutional Ethics Committee of the ESIC Medical College and PGIMSR, KK Nagar, Chennai 600078 on 04.05.2021 through the IEC No. IEC/2021/1/03. Written informed consent was obtained from all the patients in both the outpatient and in-patient settings. Adequate privacy was provided during the interviews. Confidentiality of the patient data was maintained throughout the study. Name and personal identifying information was not collected during the audit.

Results

The results are presented in three section, the In-patient antimicrobial case sheet audit findings, the outpatient antimicrobial prescription audit findings and finally the health facility level evaluation of policy and systems in place for appropriate antimicrobial use.

In Patient Antimicrobial Case Sheet Audit

Table 2.1: Characteristics of the study sample for IP case sheet audit N = 1832

S.No	Characteristic	Category	Number (%)
1	District	Trichy	300 (16.37)
		Villupuram	306 (16.70)
		Salem	326 (17.79)
		Pudukkottai	300 (16.37)
		Theni	300 (16.37)
		Tirunelveli	300 (16.37)
2	Department	General Medicine	526 (29)
		General Surgery	353 (19)
		Obstetrics	265 (14)
		Gynecology	158 (09)
		Pediatrics	281 (15)
		Orthopedics	249 (14)
3	Age Groups	< 25 yrs	620 (33.8)
		26 – 40 yrs	473 (25.8)
		41 – 60 yrs	511 (27.8)
		>60 yrs	228 (12.4)
4	Gender	Male	920 (50.2)
		Female	912 (49.8)
5	Comorbidities	Diabetes	168 (09)
		Hypertension	187 (10)
		Heart Disease	45 (03)
		COPD	23 (01)
		Asthma	30 (02)
		Kidney Disease	33 (02)

A total of 1832 in patient case sheets were audited. Approximately three hundred case sheets were audited in each district. The age distribution of the study population revealed about 12.4% in the age above 60 years. About 53.6% were between the age groups of 26-60 years. There was almost an equal distribution of men and women. The most common comorbid condition noticed was hypertension, followed by diabetes.

Table 2.2: Clinical Characteristics of the surveyed in-patients

S.No	Characteristic	Categories	Number (%)
1	Central Venous Line	Yes	13 (0.70)
2	Peripheral Venous Line	Yes	1462 (79.80)
3	Endotracheal Tube	Yes	06 (0.32)
4	Tracheostomy	Yes	04 (0.21)
5	Urinary Catheter	Yes	102 (5.56)
6	Intercostal drainage tube		19 (1.03)
7	Colostomy		02 (0.10)
10	Is a clear diagnosis documented?	Yes	1799 (98)

The clinical characteristics of the in patients who were surveyed were noted. It was noticed that about 98% of the audited case sheets had a clearly documented diagnosis. The details of various catheters, tubes and interventions were noted to understand the probability of invasive procedures in these patients and the chance of hospital acquired infection due to these invasive procedures. It was noticed that the most frequent invasive intervention among the in-patients was a peripheral venous line in about 80% of the patients. The second most common invasive intervention was a urinary catheter in 5.5% of the in patients. The other invasive interventions were less common.

Table 2.3: Antimicrobial IP Case Sheet Audit Findings – Appropriateness of Antimicrobial Use as per ICMR STG for antimicrobial use

S.No	District	Health Facility	Patients with documented diagnosis n (%)	Patients with diagnosis of an infection n (%)	Patients for whom cultures were sent n (%)	Patients on antimicrobials n (%)	Patients with appropriate antimicrobials (as per ICMR guidelines) n (%)
1	Trichy	Medical College (n=212)	212 (100)	40(28.43)	n/c	109 (51.41)	0
		Srirangam GH (n=38)	37 (97.36)	1 (2.7)	n/c	36 (94.73)	0
		Musiri GH (n=50)	47 (94)	12 (24)	n/c	33 (66)	0
2	Villupuram	Medical College (n=212)	212 (100)	38 (19)	1 (2.6)	137 (68.5)	0
		Vikravandi GH (n=51)	51 (100)	25 (49)	0	40 (78.4)	1 (1.96)
		Tindivanam GH (n=55)	55 (100)	34 (62)	0	46 (83.63)	0
3	Salem	Medical College (n=201)	200 (99.5)	100 (50)	4 (4)	143 (71.14)	0
		Omalur GH (n=50)	50 (100)	22 (44)	3 (13.6)	40 (80)	0
		Attur GH (n=75)	75 (100)	23 (31)	0	61 (81.33)	0
4	Pudukkottai	Medical College (n=200)	200 (100)	36 (18)	4 (11.1)	80 (40)	3 (3.75)

		Iluppur GH (n=50)	50 (100)	13 (26)	0	25 (50)	0
		Aranthangi GH (n=50)	43 (86)	16 (32)	0	29 (58)	0
5	Theni	Medical College (n=200)	200 (100)	96 (48)	n/c	107 (53.5)	6 (5.60)
		Bodinayakanur GH (n=60)	39 (65)	10 (16)	n/c	34 (56)	0
		Periyakulam GH (n=40)	40 (100)	20 (50)	n/c	38 (76)	0
6	Tirunelveli	Medical College (n=200)	200 (100)	65 (32.5)	28 (43)	138 (69)	3 (2.17)
		Tenkasi GH (n=50)	50 (100)	22 (44)	3 (13.6)	43 (86)	1 (2)
		Ambasamudram GH (n=50)	50 (100)	13 (26)	0	44 (88)	0

n/c – data not captured accurately

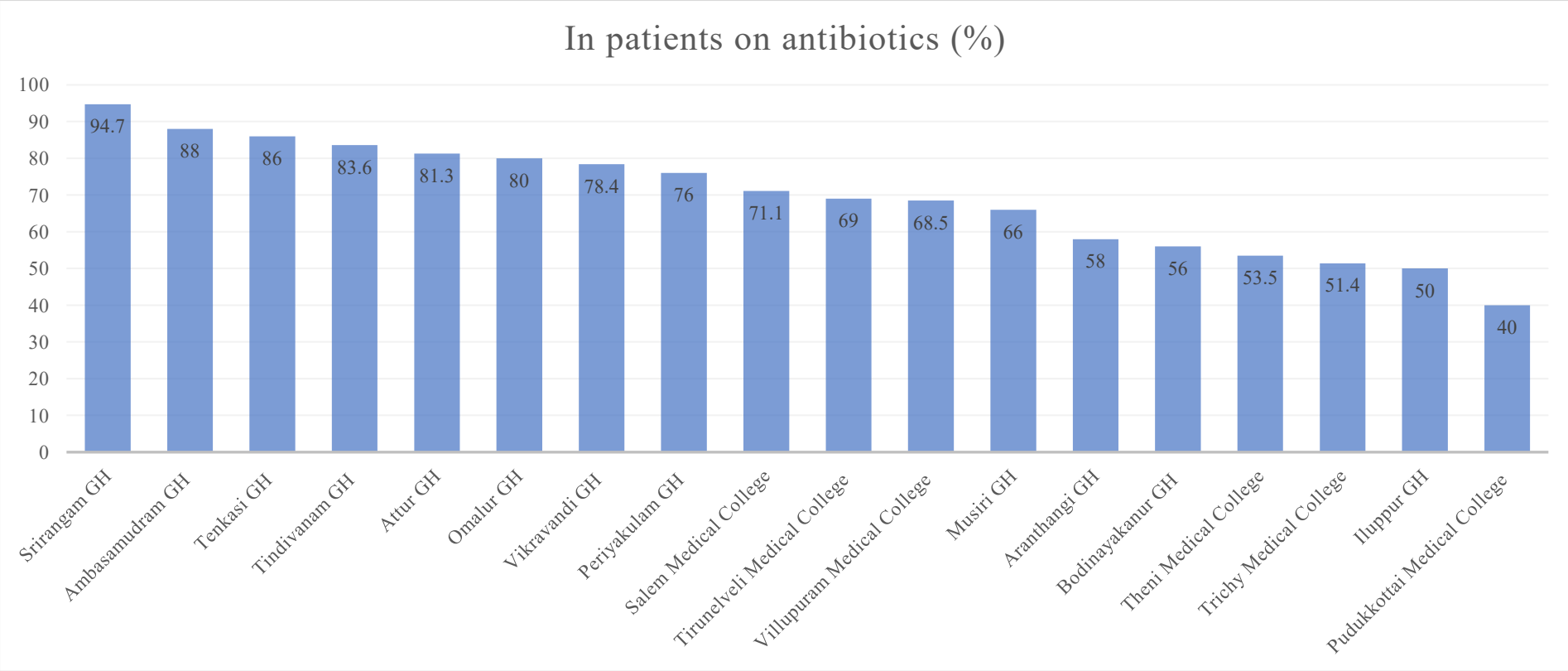

Figure 4: This figure shows the proportion of in patients who were on antimicrobials in each of the 18 surveyed health facilities.

Among the in-patient case sheets that were audited, it was noticed that a majority of the case sheets had a documented diagnosis. However, it was noteworthy that in Aranthangi GH (86%) and Bodinayakanur GH (65%) fewer case sheets had a clear diagnosis. Based on the diagnosis, the proportion of in-patient case sheets with an infective cause for admission ranged between 2 – 50%. However, the proportion of in-patients who were on antimicrobials ranged between 40-95%. It was noticed that Srirangam GH, Ambasamudram GH, Tenkasi GH, Tindivanam GH, Attur GH and Omalur GH had a very high proportion of patients on antimicrobials (above 80%). Salem, Tirunelveli and Villupuram Medical Colleges had an antimicrobial use of about 68-72%. Theni, Trichy and Pudukkottai Medical Colleges had a low rate of antimicrobial use of around 40-55%. This data is shown in Table 1.3 and Figure 4.

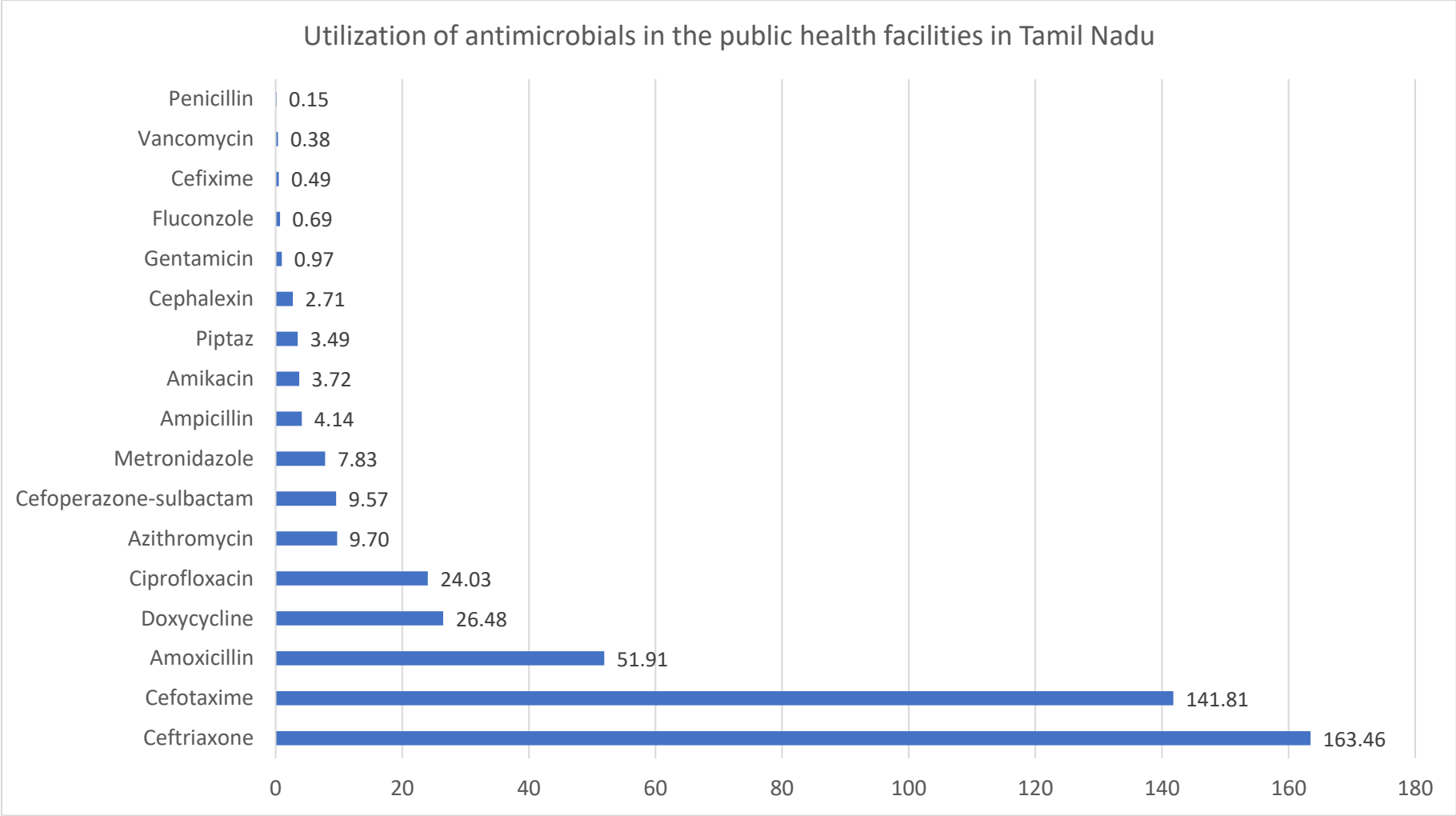

Figure 5: Defined Daily Dose of antimicrobials per 1000 bed days in the 18 health facilities surveyed

Table 2.4: Antimicrobial IP Case Sheet Audit Findings – Defined Daily Dose of antimicrobials per 1000 bed days used in the health facilities

	Pudukkottai Medical college	Illupur GH	Aranthangi GH	Trichy Medical college	Srirangam GH	Musiri GH	Tirunelveli Medical College	Ambasamudram GH	Tenkasi GH	Salem Medical College	Omalur GH	Attur GH	Theni Medical College	Bodinayakanur GH	Periyakulum GH	Villupuram Medical College	Vikravandi GH	Tindivanam GH
Amoxicillin	11.67	30.00	113.33	20.45	100.86	106.67	38.17	60.00	13.33	26.51	13.33	166.63	19.17	2.22	31.25	84.96	26.13	69.69
Ampicillin	0.00	0.00	0.00	0.00	0.00	0.00	27.08	30.00	4.33	0.00	0.00	0.00	0.00	0.00	0.00	2.16	0.00	10.91
Penicillin	0.00	0.00	0.00	0.00	0.00	0.00	1.39	0.00	0.00	0.00	0.00	0.00	0.69	0.00	0.00	0.66	0.00	0.00
Cefotaxime	73.38	120.00	140.00	118.00	269.68	182.50	30.00	44.00	191.00	212.47	260.00	233.61	31.25	56.26	147.50	151.19	169.05	122.72
Ceftriaxone	42.50	60.00	40.00	94.40	39.47	0.00	258.88	460.00	199.00	24.85	100.00	26.66	303.80	141.70	488.75	97.77	227.36	337.24
Piperacillin Tazobactam	0.00	0.00	0.00	9.10	0.00	12.86	4.82	0.00	12.86	8.79	0.00	0.00	14.46	0.00	0.00	0.00	0.00	0.00
Cefoperazone-sulbactam	0.00	0.00	0.00	0.00	0.00	0.00	68.75	0.00	0.00	59.64	20.00	13.33	0.00	0.00	0.00	10.62	0.00	0.00
Ciprofloxacin	17.00	44.00	0.00	1.89	26.31	70.00	12.00	80.00	20.00	14.91	20.00	13.33	5.00	0.00	0.00	33.04	56.84	18.18
Azithromycin	83.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	66.67	0.00	16.67	0.00	0.00	7.87	0.00	0.00
Amikacin	0.00	0.00	0.00	2.36	0.00	0.00	5.00	0.00	0.00	59.64	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Doxycycline	15.00	80.00	60.00	18.88	0.00	40.00	50.00	40.00	40.00	0.00	0.00	26.66	10.00	0.00	0.00	2.36	39.20	54.54
Metronidazole	2.50	0.00	0.00	19.59	0.00	6.00	3.00	18.00	0.00	2.24	20.00	6.67	3.75	12.50	3.75	19.59	9.80	13.64
Cephalexin	0.25	0.00	0.00	3.54	6.58	0.00	26.25	7.50	0.00	1.24	0.00	0.00	1.25	0.00	0.00	2.25	0.00	0.00

The drug utilization of various antimicrobials was calculated for the different public health facilities as DDDs per 1000 bed days as indicated in the methods section. The DDDs were obtained from the WHO list. As seen in Figure 5, Ceftriaxone, Cefotaxime, Amoxycillin, Doxycycline, and Ciprofloxacin contribute to 90% of all the DDDs utilized in the public health facilities. This is the DU90% of antimicrobials in the public health facilities in Tamil Nadu. Two of these drugs, Ceftriaxone, Cefotaxime are higher generation Cephalosporins with a broad spectrum and are in the Watch group according to the AWaRe classification. The other three in the DU90% namely, Amoxycillin, Doxycycline and Ciprofloxacin are in the Access group slated for liberal use. Figure 6 represents the use of higher generation Cephalosporins among the various public health facilities in Tamil Nadu. It is seen that some District hospitals such as Omalur GH, Vikravandi GH, Ambasamudram GH, Periyakulam GH and Musiri GH are utilizing more higher generation cephalosporins than all the tertiary care centres. The DU90% had three Access group of antimicrobials namely, Amoxycillin, Doxycyline and Ciprofloxacin. It was noticed that the utilization of these Access group antimicrobials in all the health facilities was very low. Musiri GH, Attur GH, Ambai GH and Aranthangi GH were using some of these antimicrobials. But, Omalur GH, Periyakulam GH and Bodinayakanur GH was not using much of the Access antimicrobials, whereas they were using large amounts of the higher antimicrobials.

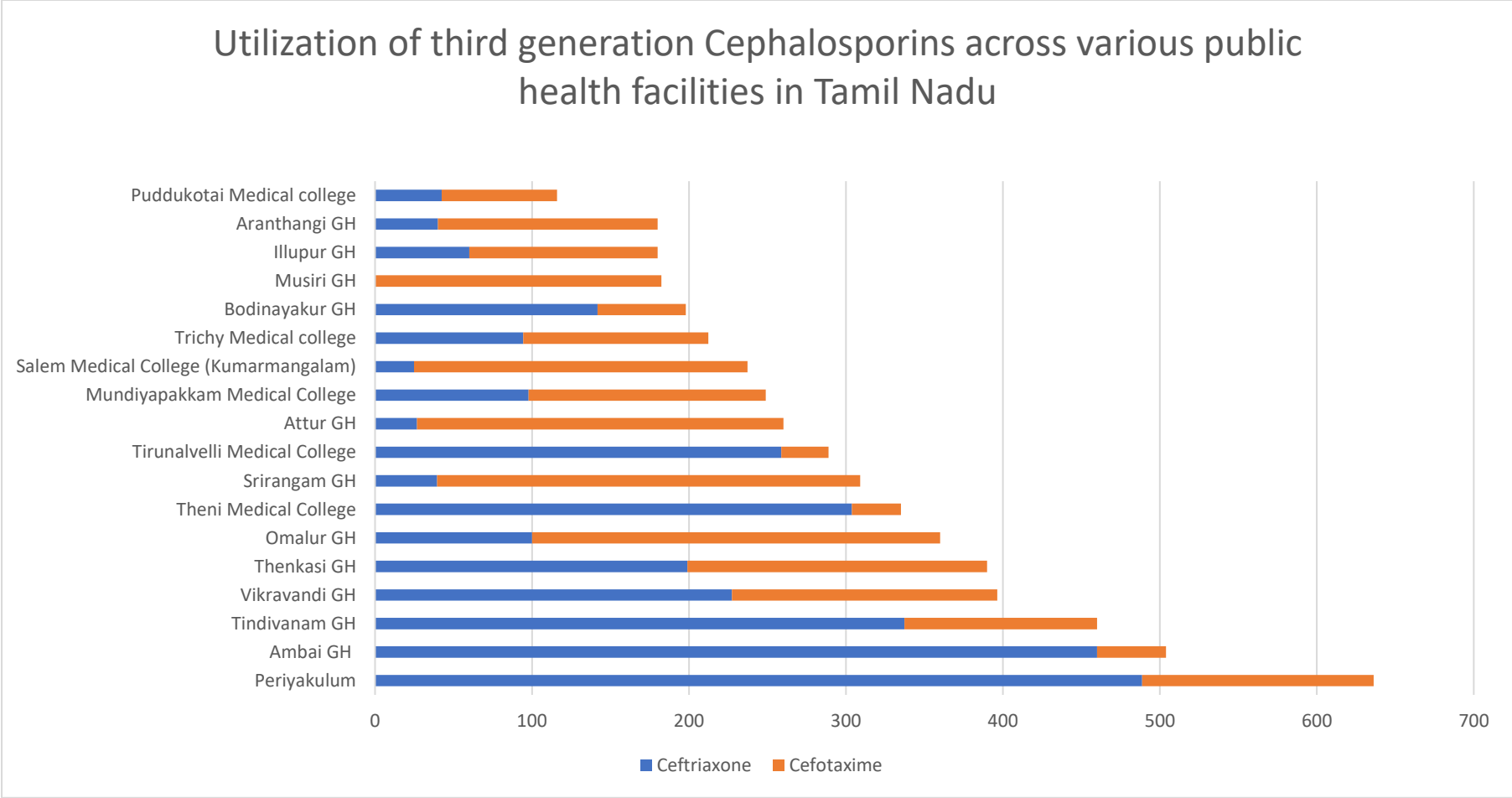

Figure 6: Utilization of higher generation cephalosporins across various public health facilities, shows that some district hospitals utilize these drugs more than tertiary care hospitals.

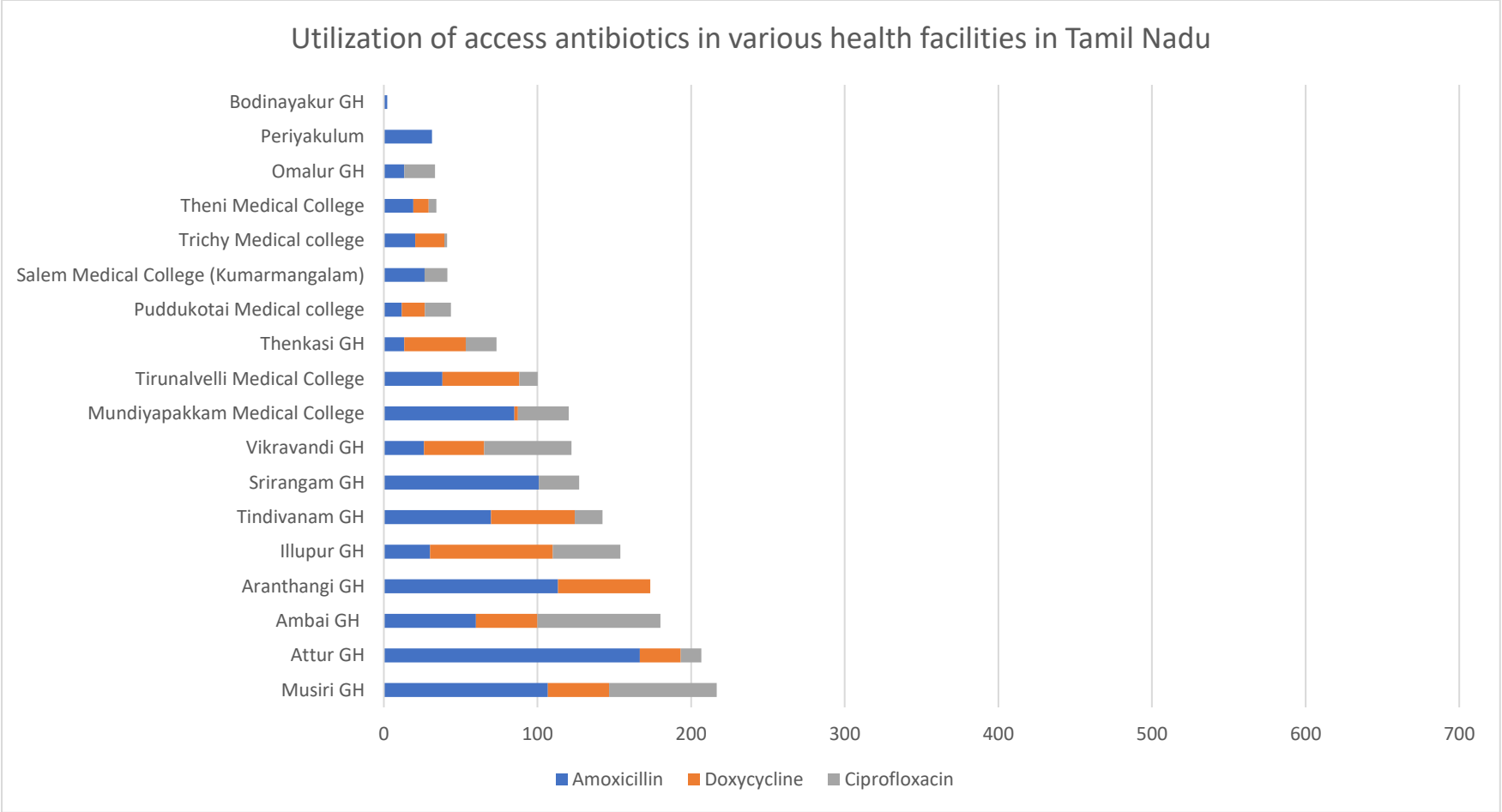

Figure 7: Utilization of Access group of antimicrobials in various public health facilities in Tamil Nadu showing that the use of these antimicrobials is very low even in district hospitals.

Table 2.5: Antimicrobial IP Case Sheet Audit Findings – Defined Daily Dose of antimicrobials per 1000 bed days used in the various departments

S.No	Antibiotic name	General Medicine	General Surgery	Obstetrics	Paediatrics	Orthopaedics	Gynaecology
1	Ceftriaxone	45.66	26.08	6.63	6.79	8.64	2.78
2	Cefotaxime	34.97	17.24	13.46	7.84	4.68	3
3	Amoxicillin	6.24	3.21	9.78	1.52	2.78	0.75
4	Doxycycline	10.92	0	0	1.4	0.48	1.8
5	Ciprofloxacin	6.92	3.68	0	0.28	0.48	0.6
6	Cefoperazone-Sulbactam	3.64	3.06	0.52	0.14	2.64	0.11
7	Azithromycin	0	7	0.43	0.93	0	0
8	Amikacin	0	7	0.43	0.93	0	0
9	Metronidazole	2.73	0.93	0.59	0	0.07	0.68

The utilization of antimicrobials was highest in the department of General Medicine, with high utilization of Ceftriaxone, Doxycycline and Cefotaxime. A similar pattern was noticed in General Surgery where there was a high utilization of Ceftriaxone and Cefotaxime. The utilization of antimicrobials was much lower in the departments of Obstetrics, Gynecology, Pediatrics and Orthopedics. This is seen in Table 2.5 and Figure 8.

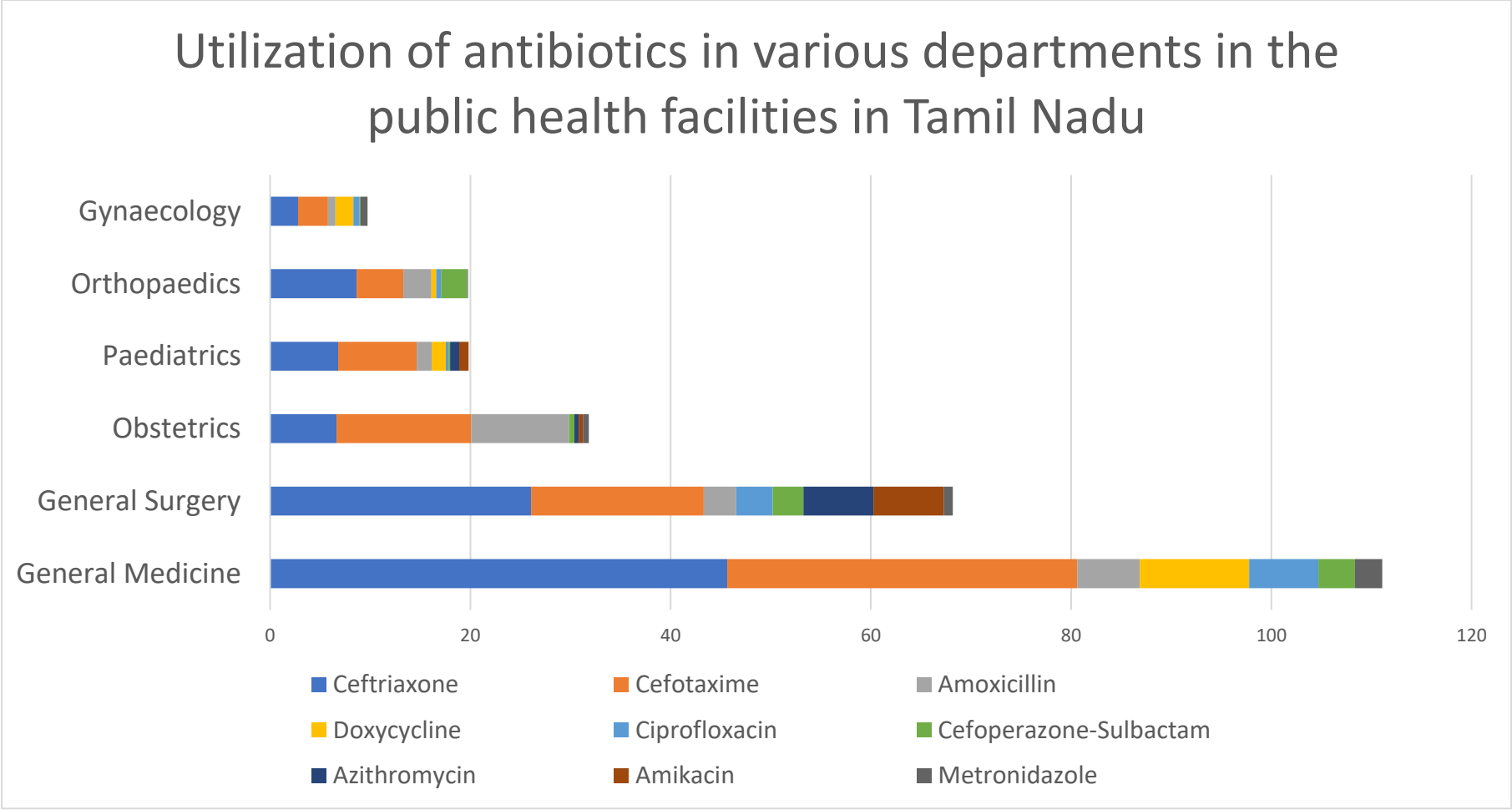

Figure 8: Utilization of antimicrobials in various departments in public health facilities in Tamil Nadu. This shows that General Surgery, General Medicine and Gynaecology have higher utilization of all antimicrobials and Paediatrics has the least utilization.

The appropriateness of antimicrobial use was assessed by using the ICMR standard treatment guidelines as a reference. The appropriateness was assessed based on

a. Appropriateness of drug choice
b. Appropriateness of drug dose
c. Appropriateness of drug dosing interval

A total of 1160 / 1183 (98%) patients on antimicrobials were inappropriate.

Table 2.6: Types of inappropriate antimicrobial choice in various departments

S.No	Department	Type of inappropriate drug choice	Number of patients (%)
1	General Medicine (N = 325)	Inappropriate broad spectrum empiric antimicrobial	212 (65.2%)
		Antimicrobial for non-infective diagnosis	113 (34.8%)
2	General Surgery (N = 145)	Inappropriate broad spectrum surgical prophylaxis	100 (68.9%)
		Wrong antimicrobial choice for infective diagnosis	45 (31.1%)
3	Obstetrics and Gynaecology (N = 265)	Inappropriate broad spectrum surgical prophylaxis for caesarean section	180 (67.9%)
		Inappropriate use of broad spectrum antimicrobials for normal delivery	85 (32.1%)
4	Paediatrics (N = 177)	Inappropriate use of broad spectrum empiric antimicrobials	177 (100%)
5	Orthopaedics (N = 248)	Inappropriate broad spectrum surgical prophylaxis	200 (80.6%)
		Wrong antimicrobial choice for infective diagnosis	48 (19.4%)

It is noticed that in the surgical departments of General Surgery, Orthopaedic Surgery and Obstetrics and Gynaecology, the commonest type of inappropriate antimicrobial use was unnecessary use of broad spectrum antimicrobials (Higher generation Cephalosporins) for surgical prophylaxis for clean and clean contaminated surgeries. In General Medicine and Paediatrics the most common type of inappropriate antimicrobial use was broad spectrum antimicrobial use that was not appropriate for the infective syndrome. This is shown in Table 2.6.

Analysis of appropriateness of the drug dose was performed assuming that the prescribed antimicrobial was of appropriate choice. The appropriateness of antimicrobial dose is shown in Figure 9.

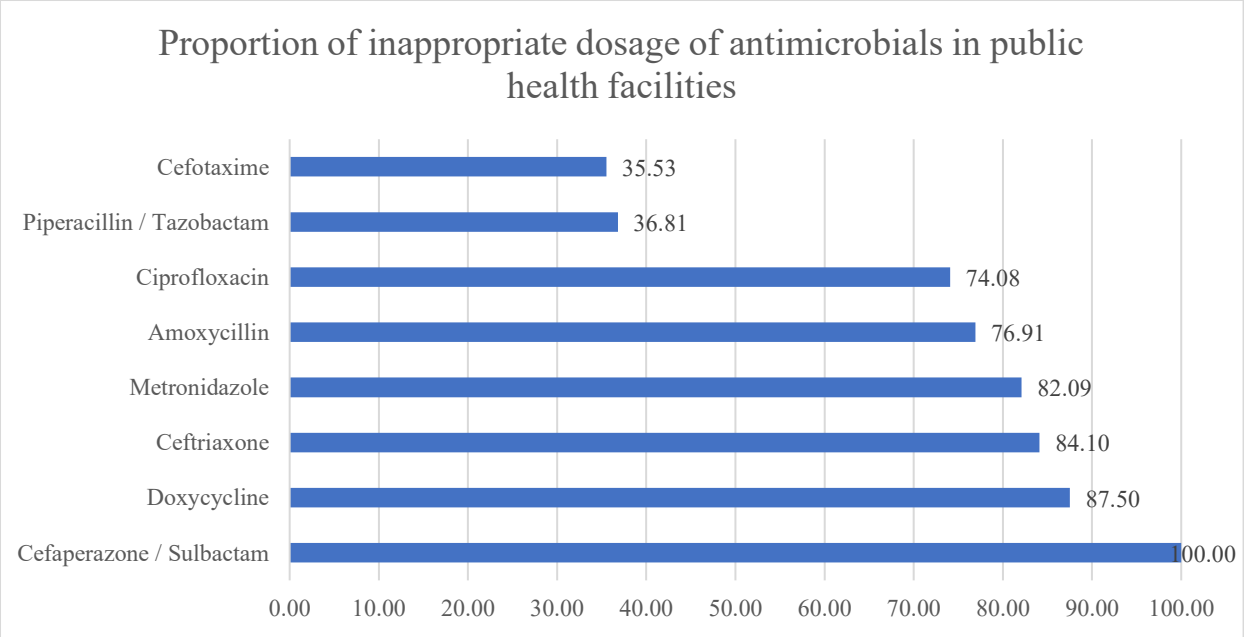

Figure 9: Proportion of inpatients where the antimicrobial was prescribed with inappropriate dose.

It is noticed that Cefaperazone / Sulbactam was always prescribed with inappropriate dose, whereas Cefotaxime was prescribed with inappropriate dose only in 35% of the occasions. Even a common antimicrobial such as Amoxycillin was prescribed with inappropriate dose in 77% of the occasions.

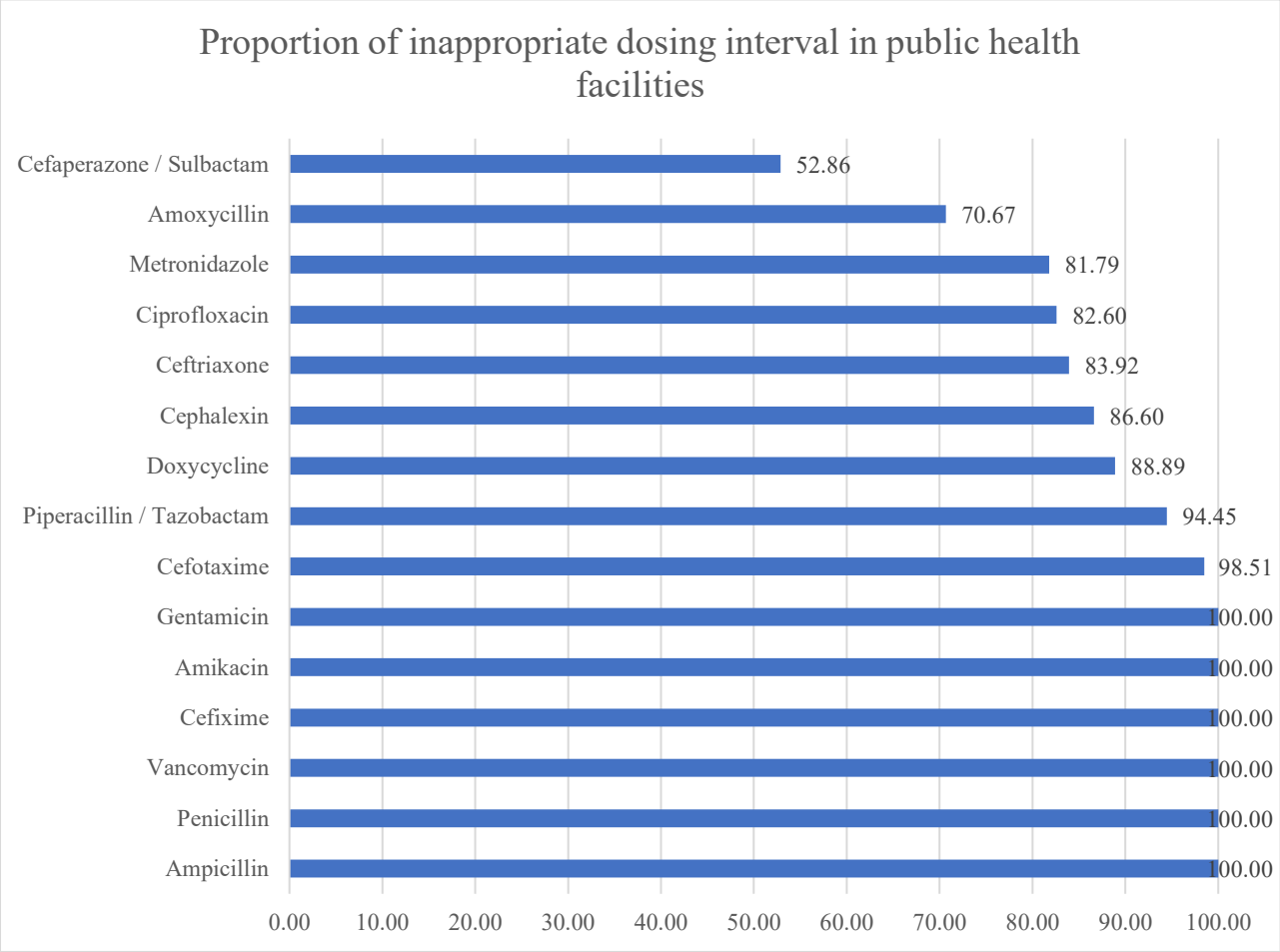

Figure 10: Proportion of inpatients who were prescribed inappropriate dosing interval

The appropriateness of the dosing interval was also assessed assuming that the antimicrobial choice was appropriate. It was noticed that dosing interval was inappropriate for common antimicrobials such as Ampicillin, Penicillin, Amikacin and Gentamicin. However the utilization of these antimicrobials was also very low.

Out Patient Antimicrobial Prescription Audit

Table 2.7: Characteristics of the study sample for OP Prescription audit (N = 4495)

S.No	Characteristic	Category	Number (%)
1	District	Trichy	749 (16.7%)
		Villupuram	752 (16.7%)
		Salem	752 (16.7%)
		Pudukkottai	743 (16.7%)
		Theni	749 (16.7%)
		Tirunelveli	750 (16.7%)
2	Department	General OP	3594 (80.0%)
		General Surgery	66 (1.5%)
		Obstetrics and Gynecology	370 (8.2%)
		Pediatrics	389 (8.7%)
		Orthopedics	76 (1.7%)
3	Age Groups	< 25 yrs	1115 (24.8%)
		26 – 40 yrs	891 (19.8%)
		41 – 60 yrs	1669 (37.1%)
		>60 yrs	820 (18.2%)
4	Gender	Male	2204 (49.0%)
		Female	2290 (50.9%)
		Transgender	1 (0.1%)
5	Diagnosis	Non-Infectious Diagnosis	3584 (79.7%)
		Acute Diarrheal Disease	11 (0.2%)
		Acute Febrile Illness	188 (4.2%)
		Foot Ulcer	20 (0.4%)
		Lower Respiratory Infection	3 (0.1%)
		Otitis Media	5 (0.1%)
		Tuberculosis	1 (.0%)
		Upper Respiratory Infection	487 (10.8%)
		Urinary Tract Infection	36 (0.8%)
		Viral Illness	1 (.0%)
		White Discharge	1 (.0%)

Most of the district hospitals did not have special out patient units for the various departments. So it can be seen that 80% of the sample was from General Out Patient department. It was also noticed that about 80% of the patients came for non-infectious diagnoses to the OP. Among the infectious diagnosis, upper respiratory infection and acute undifferentiated fever were the most common. These characteristics are shown in Table 2.7.

Table 2.8: Antimicrobial OP Prescription Audit Findings

S.No	District	Hospital	No. of patients with documented diagnosis n (%)	No. of patients with history suggestive of an infection n (%)	No. of patients for whom cultures were sent n (%)	No. of patients on antimicrobials n (%)
1	Trichy	Medical College n = 251	0 (0%)	38(15.1%)	4 (1.6%)	219(87.3%)
		Srirangam GH n = 250	5 (2%)	11 (4.4%)	14(5.6%)	155(62%)
		Musiri GH n = 249	49 (19.7%)	62(24.9%)	1 (0.4%)	122(49%)
2	Villupuram	Medical College n = 248	42 (16.9%)	34 (13.7%)	0 (0%)	117(47.1%)
		Vikravandi GH n = 257	3 (1.2%)	81(31.5%)	0 (0%)	92(35.8%)
		Tindivanam GH n = 248	82 (33.1%)	92(37.1%)	0 (0%)	112(45.2%)
3	Salem	Medical College n = 250	250 (100%)	21(8.4%)	5 (2%)	63(25.2%)
		Omalur GH n = 250	213 (85.2%)	60(24%)	26(10.4%)	102(40.8%)
		Attur GH n = 250	170 (68%)	103(41.2%)	18(7.2%)	202(80.8%)
4	Pudukkottai	Medical College n = 249	11 (4.4%)	0 (0%)	8 (3.2%)	99(39.8%)
		Iluppur GH n =245	2 (0.8%)	0 (0%)	0 (0%)	75(30.6%)
		Aranthangi GH n =249	0 (0%)	0 (0%)	0 (0%)	133(53.4%)
5	Theni	Medical College n = 250	191 (76.4%)	51 (20.4%)	29(11.6%)	229(91.6%)
		Bodinayakanur GH n = 250	4 (1.6%)	26 (10.4%)	3 (1.2%)	82(32.8%)
		Periyakulam GH n = 250	7 (2.8%)	95 (38%)	22 (8.8%)	219(87.6%)
6	Tirunelveli	Medical College n = 250	227 (90.8%)	10 (4%)	0 (0%)	93(37.2%)
		Tenkasi GH n =249	1 (0.4%)	47(18.8%)	1 (0.4%)	111(44.6%)
		Ambasamudram GH n = 250	8 (3.2%)	28(11.2%)	0 (0%)	78(31.2%)

It was noticed that in Salem Medical College there was a 100% documentation of diagnosis in the OP slip. Other than Pudukkottai, Villupuram and Trichy Medical Colleges all other colleges had a reasonably good level of documentation of diagnosis in the OP notes. In the district hospitals Attur GH was the only facility which had a good amount of documentation of diagnosis (68%) in the OP notes. This is shown in Table 2.8.

In Figure 11 it is seen that Theni Medical College, Periyakulam GH and Trichy Medical College had a very high percentage of out patients who were started on antimicrobials. The proportion of out patients started on antimicrobials was least in Salem Medical College, Illupur GH and Ambasamudram GH. The other important point noted in this figure is that the proportion of patients started on antimicrobials was very high compared to the proportion of patients who had features suggestive of infection. In Pudukkottai Medical College, Tirunelveli Medical College, Aranthangi GH and Srirangam GH this difference between proportion of patients with features suggestive of infection and proportion of patients on antimicrobials was highest.

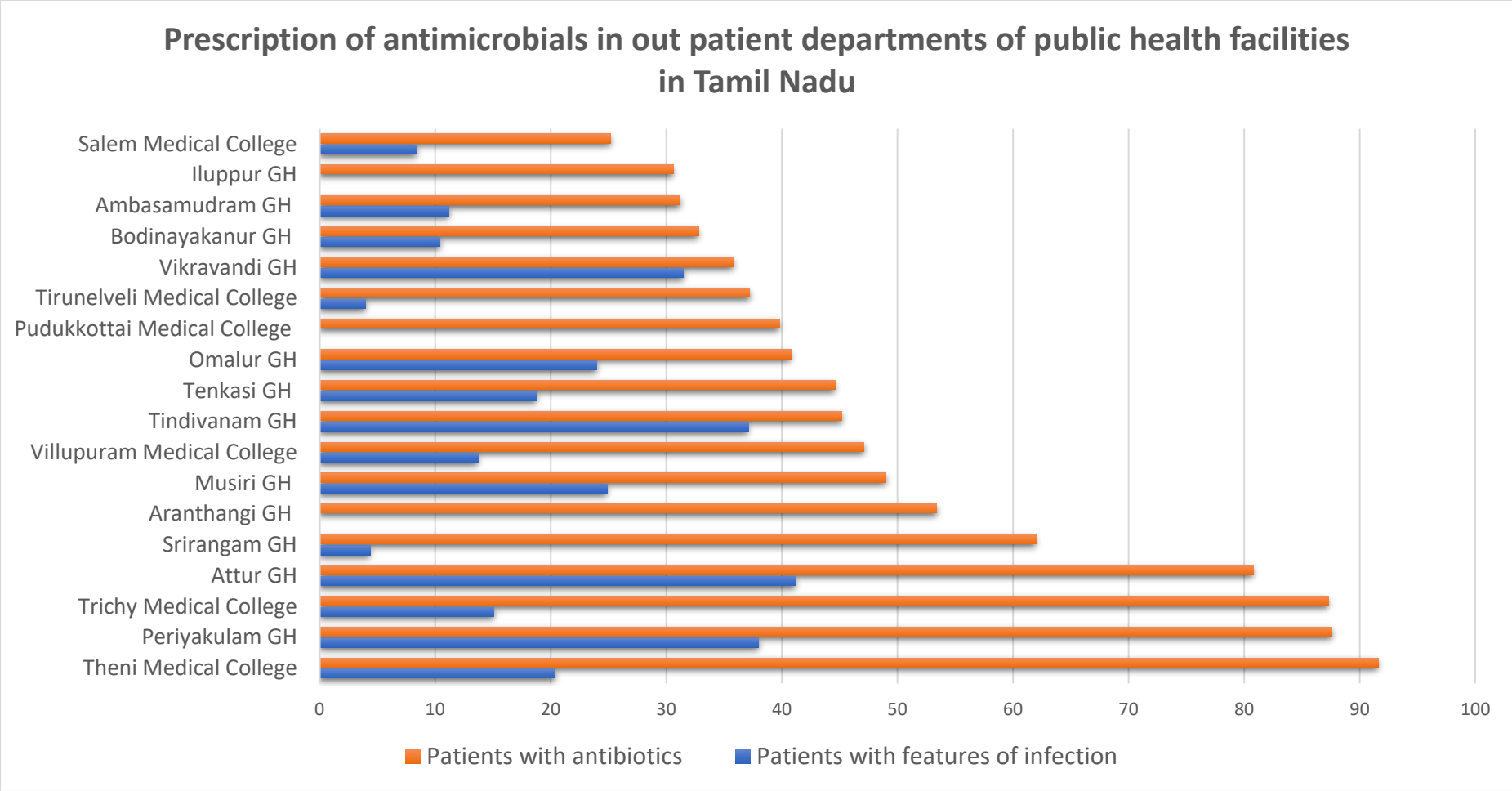

Figure 11: This figure shows the proportion of patients attending the OP who had features suggestive of an infection and the proportion who were on antimicrobials

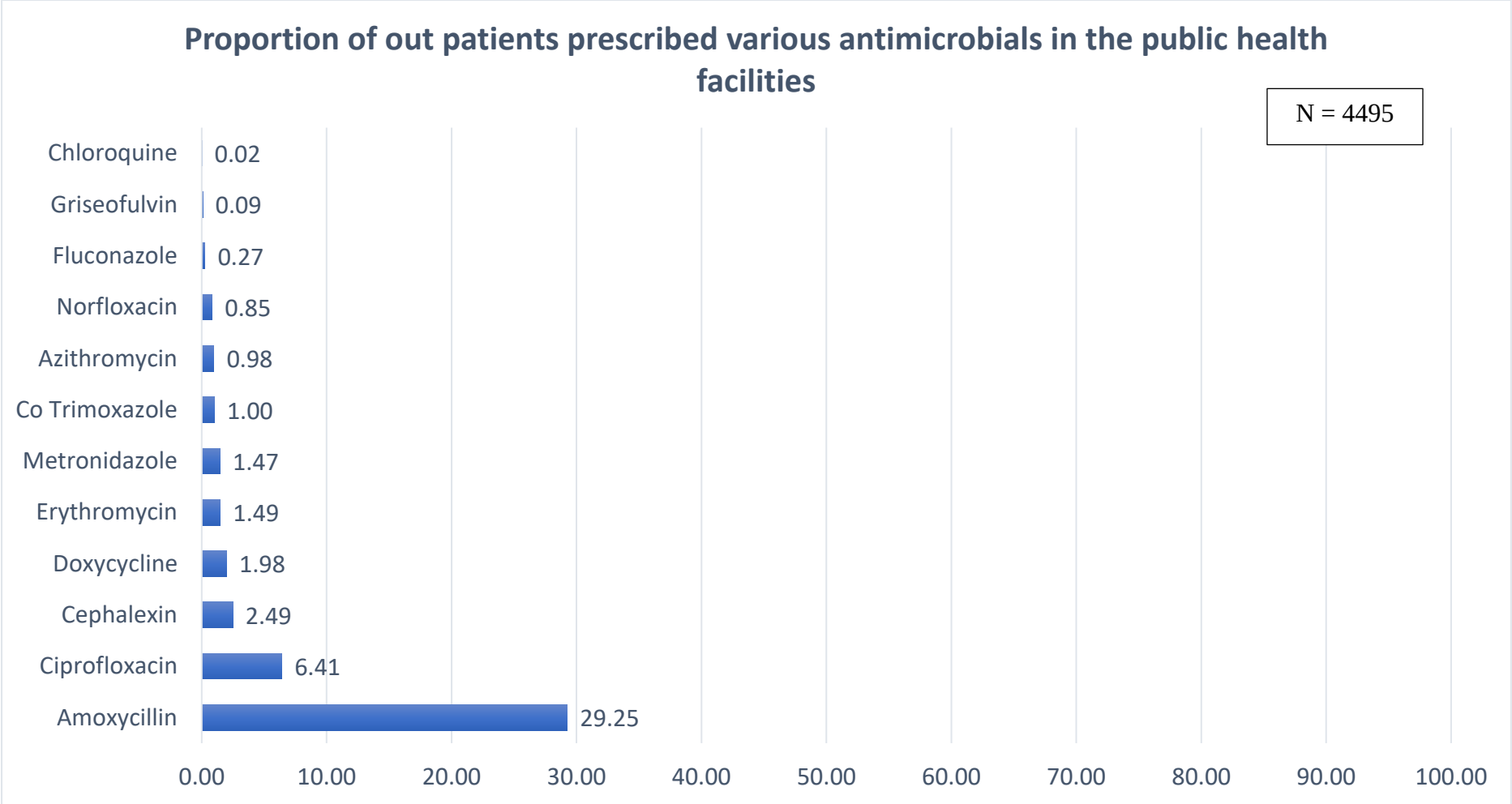

Figure 12: This graph shows that the most frequently prescribed antimicrobial in public health facilities is Amoxycillin and the next most frequently used in Ciprofloxacin.

In the outpatient facilities, the most commonly prescribed antimicrobial was Amoxycillin. This was followed by Ciprofloxacin, Cephalexin and Doxycycline. It was not possible to perform an assessment of appropriateness of use of these antimicrobials as most of the outpatient prescriptions did not have a documented diagnosis. Assuming that the antimicrobials prescribed were appropriate, an analysis of appropriateness of dose and dosing interval was performed.

There was a prevalence of almost 100% inappropriate dose of Amoxycillin and Metronidazole in most public health facilities. The level of inappropriate dose of antimicrobials was least for Ciprofloxacin, Norfloxacin and Doxycycline. This is shown in Figure 13 and Table 2.9.

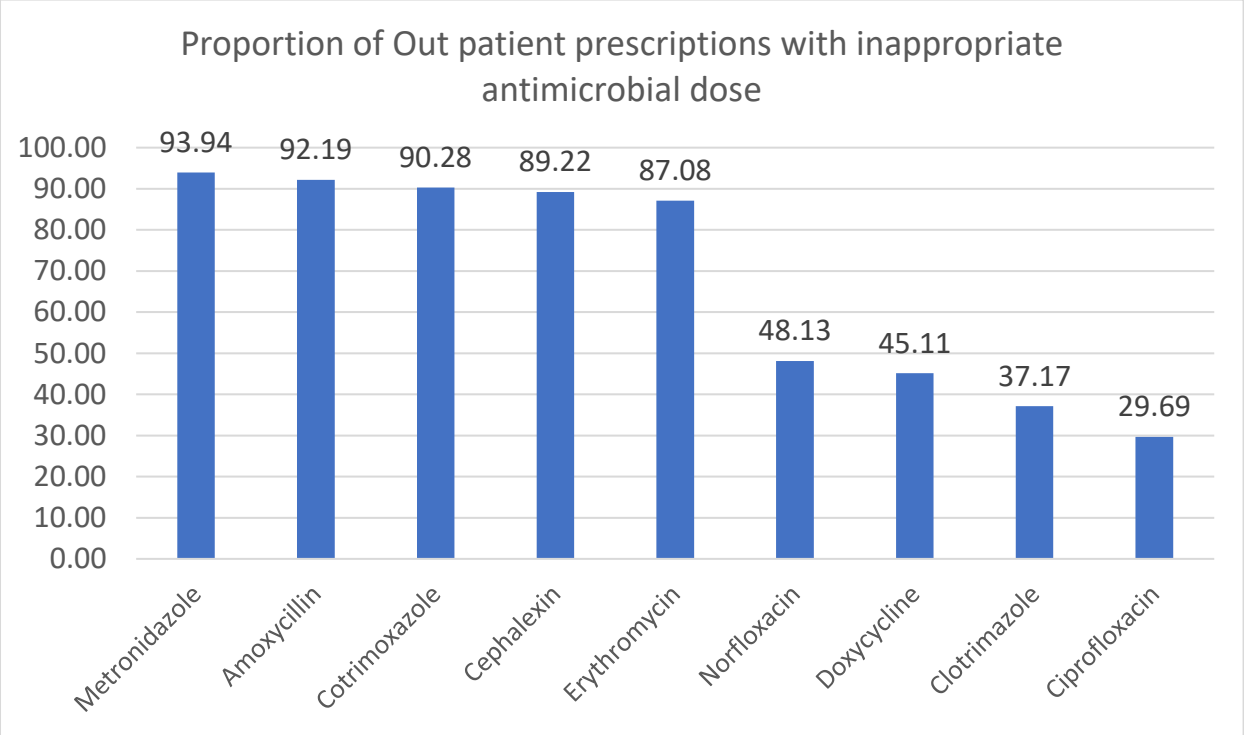

Figure 13: Proportion of outpatient antimicrobial prescriptions with inappropriate dose

Table 2.9: Inappropriate dose of antimicrobials as per ICMR guidelines in outpatient prescriptions

S.No	Antimicrobial	Trichy Medical College	Musiri GH	Srirangam GH	Villupuram Medical College	Vikravandi GH	Tindivanam GH	Salem Medical College	Attur GH	Omalur GH	Pudukkottai Medical College	Aranthangi GH	Iluppur GH	Theni Medical College	Bodinayakanur GH	Periyakulam GH	Tirunelveli Medical College	Ambasamudram GH	Tenkasi GH
1	Amoxycillin	73 (100%)	50 (98%)	24 (100%)	44 (74.6%)	31 (86.1%)	57 (79.2%)	19 (100%)	71 (80.7%)	60 (100%)	5 (100%)	2 (100%)	4 (100%)	153 (100%)	34 (100%)	158 (99.4%)	18 (58.1%)	48 (100%)	40 (83.3%)
2	Cotrimoxazole	NA	NA	NA	1 (100%)	3 (75%)	NA	NA	14 (100%)	2 (66.7%)	NA	1 (100%)	NA	NA	NA	NA	NA	NA	5 (100%)
3	Cephalexin	1(100%)	2(100%)	6(75.0%)	3(100%)	26(96.3%)	1(50%)	NA	3(100%)	2(100%)	1(100%)	NA	NA	6(100%)	NA	9(100%)	2(50%)	5(100%)	7(77.8%)
4	Ciprofloxacin	2(11.8%)	3(30%)	2(33.3%)	0%	1(50%)	0%	NA	1(14.3%)	NA	0%	NA	NA	0%	14(56.0)	10(27.8%)	0%	0%	3(14.3%)
5	Norfloxacin	1(11.1)	0%	0%	2(33.3%)	NA	1(100%)	NA	NA	NA	NA	NA	NA	NA	NA	NA	0%	NA	NA
6	Erythromycin	NA	NA	NA	NA	NA	3(100%)	1(100%)	10(83.3%)	14(100%)	NA	3(100%)	NA	NA	0	NA	1(33.3%)	1(100%)	8(80%)
7	Doxycycline	0%	1(33.3%)	2(40%)	0	NA	0	3(30%)	3(75%)	1(12.5%)	NA	NA	0%	0%	3(75%)	0%	0%	1(50%)	0%
8	Clotrimazole	0%	11(84.6%)	1(20%)	3(13.6%)	1(50%)	0%	1(4.8%)	12(50%)	NA	NA	NA	NA	NA	NA	NA	NA	0%	NA
9	Metronidazole	11(100%)	3(100%)	1(100%)	4(100%)	NA	6(54.5%)	1(100%)	1(100%)	NA	NA	NA	NA	15(100%)	2(100%)	3(100%)	1(100%)	1(100%)	2(66.7%)

NA – Not Assessed

Table 2.10: Inappropriate dosing interval of antimicrobials as per ICMR guidelines in outpatient prescriptions

S.No	Antimicrobial	Trichy Medical College	Musiri GH	Srirangam GH	Villupuram Medical College	Vikravandi GH	Tindivanam GH	Salem Medical College	Attur GH	Omalur GH	Pudukkottai Medical College	Aranthangi GH	Iluppur GH	Theni Medical College	Bodinayakanur GH	Periyakulam GH	Tirunelveli Medical College	Ambasamudram GH	Tenkasi GH
1	Amoxycillin	71(97.3%)	30(58.8%)	10(41.7%)	38(64.4%)	33(91.7%)	46(63.9%)	12(63.2%)	50(56.8%)	57(95%)	1(20%)	0	3(75%)	81(52.9%)	29(85.3%)	128(80.5%)	13(41.9%)	41(85.4%)	31(64.6%)
2	Cotrimoxazole	NA	NA	NA	0	3(75%)	NA	NA	5(35.7%)	1(33.3%)	NA	1(100%)	NA	NA	NA	NA	NA	NA	0
3	Cephalexin	1(100%)	1(50%)	6(75%)	2(66.7%)	27(100%)	2(100%)	NA	1(33.3%)	2(100%)	1(100%)	NA	NA	5(83.3%)	NA	5(55.6%)	2(50%)	5(100%)	7(77.8%)
4	Ciprofloxacin	2(11.8%)	3(30%)	1(16.7%)	2(40%)	1(50%)	0	NA	2(28.6)	NA	1(16.7%)	NA	NA	5(13.9%)	8(32%)	2(5.6%)	3(23.1%)	1(16.7%)	3(14.3%)
5	Erythromycin	NA	NA	NA	NA	NA	3(100%)	1(100%)	11(91.7%)	13(92.9%)	NA	2(66.7%)	NA	NA	1(100 %)	NA	2(66.7%)	0	9(90%)
6	Doxycycline	0	2(66.7%)	2(40%)	1(50%)	NA	5(35.7%)	2(20%)	1(25%)	1(12.5%)	NA	NA	0	1(50%)	1(25%)	0	1(50%)	0	0
7	Metronidazole	8(72.7%)	0	1(100%)	4(100%)	NA	5(45.5%)	0	0	NA	NA	NA	NA	4(26.7%)	1(50%)	3(100%)	0	0	1(33.3%)

NA – Not Assessed

It was noticed that majority of the antimicrobials prescribed in the outpatient facilities were prescribed with inappropriate dosing interval. Inappropriate dosing interval was highest for Amoxycillin and Cephalexin, and it was lowest for Ciprofloxacin, Doxycycline.

Facility level assessment of antimicrobial use policies and practices

Table 2.11: Description of the surveyed health facilities

Health Facility	Data Collected on	Bed Capacity	OP attendance per day over past week	In patients over past week	Bed Occupancy Rate over past week (%)
Villupuram Medical College	03.09.21	1500	3000	1500	100
Vikravandi GH	28.08.21	60	400	15	70
Tindivanam GH	22.09.21	50	1200	50	85
Salem Medical College	01.11.21	1642	3500	1800	100
Attur GH	09.10.21	300	1800	250	90
Omalur GH	19.10.21	62	600	150	100
Trichy Medical College	06.09.21	1703	5000	500	29
Srirangam GH	26.08.21	157	600	90	57
Musiri GH	07.10.21	68	400	55	81
Pudukkottai Medical College	30.09.21	1635	1200	1000	55
Iluppur GH	15.09.21	104	800	20	20
Aranthangi GH	02.11.21	225	800	200	89
Tirunelveli Medical College	25.08.21	2047	2173	1453	71
Ambasamudram GH	17.09.21	125	650	80	75
Tenkasi GH	27.09.21	557	1250	375	100
Theni Medical College	22.09.21	826	500	200	60
Bodinayakanur GH	21.10.21	296	700	35	65
Periyakulam GH	11.10.21	86	1400	80	90

Tirunelveli Medical College was the hospital with the largest bed capacity among the tertiary care centres. Among the secondary care centres, Tenkasi GH had a 557 bed capacity and this was closely followed by Attur GH with a 300 bed capacity. Among all the Medical Colleges Villupuram Medical College and Salem Medical College had 100% bed occupancy in the week prior to data collection, whereas many of the district hospitals had lesser bed occupancy rates with Illupur GH having the lowest bed occupancy of 20% over the past week.

Based on the presence of policies for antimicrobial use in the various health facilities they were given scoring. Based on these scores the health facilities were ranked. This ranking is shown in Figure 14.

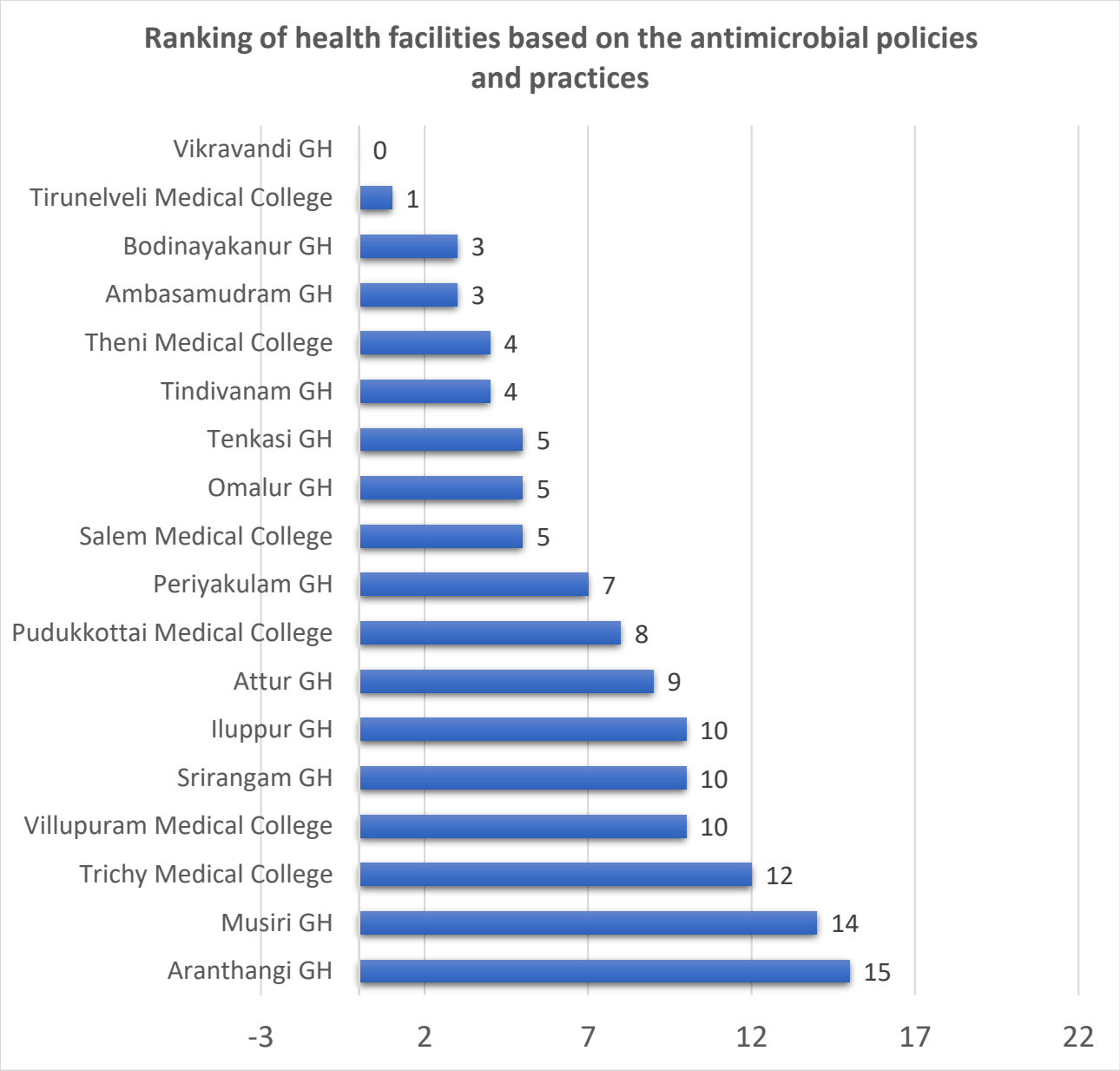

Figure 14: Ranking of health facilities based on antimicrobial policies and practices

Table 2.12: Scoring of public health facilities based on various antimicrobial policies and practices in the health facilities

Antimicrobial Policies and Practices	Villupuram Medical College	Vikravandi GH	Tindivanam GH	Salem Medical College	Attur GH	Omalur GH	Trichy Medical College	Srirangam GH	Musiri GH	Pudukkottai Medical College	Iluppur GH	Aranthangi GH	Tirunelveli Medical College	Ambasamudram GH	Tenkasi GH	Theni Medical College	Bodinayakanur GH	Periyakulam GH
Presence of antimicrobial formulary in the facility	0	0	0	0	0	1	0	1	1	1	1	1	0	1	1	0	1	1
Is the formulary based on National Essential Drug List	0	0	0	0	0	0	0	1	1	1	1	1	0	1	1	0	1	1
Is there stock of all antimicrobials in the formulary on the day of the survey?	0	0	0	0	0	0	0	1	1	1	1	1	0	1	1	0	1	1
Do you have antimicrobial guidelines specific to susceptibility patterns in your facility?	1	0	1	0	1	1	1	1	1	1	1	1	0	0	0	1	0	0
Do you have any restrictions in place for antimicrobial prescriptions?	0	0	0	0	1	1	1	1	0	0	0	1	1	0	0	0	0	0
Do you have a copy of ICMR guidelines for antimicrobial use?	0	0	1	1	0	1	1	1	1	1	1	1	0	0	0	1	0	0
Do you use any other guidelines for antimicrobial use?	1	0	1	1	1	0	0	0	0	0	0	0	0	0	0	1	0	0
Do you have written antimicrobial prescription policies?	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0
Do you have a written policy to document diagnosis while prescribing antimicrobials?	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Do you have written policy to send for cultures while prescribing antimicrobials?	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Do you have a written policy of routine de-escalation of antimicrobials in inpatients?	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Do you have a written policy for limiting the duration of antimicrobial use in the facility?	0	0	0	0	0	0	1	0	1	0	1	1	0	0	0	0	0	0
Do you have a written policy of obtaining authorization for prescribing restricted antimicrobials?	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Do you have a written policy to review all in patient antimicrobial prescriptions after 48 hours?	1	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	1
Do you train the doctors on antimicrobial use and antimicrobial resistance?	1	0	0	0	1	0	0	0	1	0	0	1	0	0	1	0	0	0
Do you train the nurses on antimicrobial use and antimicrobial resistance?	0	0	0	0	1	0	1	0	1	0	0	1	0	0	1	0	0	0
Do you conduct routine antimicrobial OP prescription audits?	1	0	0	1	1	0	1	1	1	0	1	1	0	0	0	1	0	1
Do you conduct routine antimicrobial IP case sheet audits?	1	0	0	1	1	0	1	1	1	0	1	1	0	0	0	0	0	1
Do you communicate your audit findings to the prescribing physicians?	1	0	0	1	0	0	1	1	1	0	1	1	0	0	0	0	0	1
Do you perform assessment of antimicrobial utilization as DDD units?	1	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0
Do you report antimicrobial utilization as DDDs per hospital operation denominators?	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Do you have electronic drug ordering system in the facility?	1	0	1	0	1	0	1	1	1	1	1	1	0	0	0	0	0	0

About 10 of the health facilities have antimicrobial formulary which is based on the National Essential Drug List. Eleven facilities have specific guidelines for antimicrobial use based on local sensitivity patterns. Only ten facilities had the copy of ICMR standard treatment guidelines. But the number of facilities which have written antimicrobial stewardship policies is very less, some policies is as low as 1 facility and some in up to 5 facilities. Only 4-5 facilities have an antimicrobial de-escalation or 48 hour review policy. Ten health facilities had routine antimicrobial audits in OP and IP settings. Only four facilities did assessment of antimicrobial utilization based on DDDs and only one of them reported it relative to hospital operation indicators. Nine health facilities had an electronic drug ordering system. Based on this scoring, the facilities were ranked. It was noticed that Aranthangi GH was the top ranking facility with respect to antimicrobial policies. Vikravandi GH had the least score and was ranked the lowest.

Ranking of public health facilities and districts based on antimicrobial use

For the purpose of this study, point prevalence of antimicrobial use in the public health facilities and at the district level was considered as a surrogate marker of appropriateness of antimicrobial use. (42) Sampling weights were applied to the proportion of antimicrobial prescriptions at the outpatient and in patient settings and the weighted point prevalence estimates calculated. These were used to rank the health facilities and the districts.

Protocol for assigning sampling weights for estimation of point prevalence of antimicrobial prescription in health facilities and districts:

Estimation of weighted point prevalence at facility level:

Data on antimicrobial prescription that was available

- Total number of patients who have been prescribed antimicrobials in each facility
- Total sample surveyed in each facility

Data on facility patient load

- Total OP attendance per day
- Total IP per day

Assumptions

- During the 15 day survey period in a facility there is likely to be a change in in patients 3 times in medical college assuming an average 5 day in patient stay and a change in in patients 4 times in a District Hospital assuming an average of 3-4 days in patient stay. This assumption was used to compute the total population of in patients from which the sample was drawn.
- During the 15 day survey period it was assumed that a patient had at least one repeat visit and this assumption was used to calculate the total population of out patients from which the sample was drawn.

Sample Weight = N/n = Total population / sample size

After assigning the sample weights, a proportional weight was assigned to the IP point prevalence and OP point prevalence to make them weighted prevalence estimates.

Total sample weight of IP and OP in a facility = OP sampling weight + IP sampling weight

Proportional weight of OP sample = OP sampling weight / (OP sampling weight + IP sampling weight)

Proportion weight of IP sample = IP sampling weight / (OP sampling weight + IP sampling weight)

Weighted Point Prevalence Estimate of Antimicrobial Prescription in a facility = Proportional weight of OP sample * OP point prevalence estimate + Proportional weight of IP sample * IP Point prevalence estimate

The weighted point prevalence at the facility level are shown in Table 2.13 and Table 2.14.

Estimation of point prevalence at district level:

Weight assigned for Medical College = 1 (as there is only one medical college in each district)

Weight assigned for District Hospital = Total no. of district hospitals in the district / 2 (sampled district hospitals)

The number of district hospitals in each of the districts were - Trichy (5), Tirunelveli (6), Salem (12), Villupuram (7), Theni (5), Pudukkottai (13)

Weighted Point Prevalence of antimicrobial use in a district = Proportional weight of Medical College * Weighted point prevalence in medical college + Proportional weight of District Hospital * Average weighted point prevalence of two district hospitals

The estimated point prevalence at the district level is shown in Table 2.15.

Table 2.13: Sampling weight for Outpatient and Inpatient point prevalence of antimicrobial use

Health Facility	Observed Point Prevalence Estimate IP	Observed Point Prevalence Estimate OP	IP Sample Size	OP Sample Size	IP admission per day	OP attendance per day	Total IP over survey period	Total OP over survey period	IP Sample Weight	OP Sample Weight
Trichy Medical College	51.4	87.3	212	251	500	5000	1500	35000	7.075	139.442
Srirangam GH	94.7	62	38	250	90	600	360	4200	9.474	16.800
Musiri GH	66	49	50	249	55	400	220	2800	4.400	11.245
Tirunelveli Medical College	69	37.2	200	250	1453	2173	4359	15211	21.795	60.844
Ambasamudram GH	88	31.2	50	250	80	650	320	4550	6.400	18.200
Tenkasi GH	86	44.6	50	249	375	1250	1500	8750	30.000	35.141
Salem Medical College	71.1	25.2	201	250	1800	3500	5400	24500	26.866	98.000
Attur GH	81.3	80.8	75	250	250	1800	1000	12600	13.333	50.400
Omalur GH	80	40.8	50	250	150	600	600	4200	12.000	16.800
Villupuram Medical College	68.5	47.1	212	248	1500	3000	4500	21000	21.226	84.677
Vikravandi GH	78.4	35.8	51	257	15	400	60	2800	1.176	10.895
Tindivanam GH	83.6	45.2	55	248	50	1200	200	8400	3.636	33.871
Theni Medical College	53.5	91.6	200	250	200	500	600	3500	3.000	14.000
Bodinayakanur GH	56	32.8	60	250	35	700	140	4900	2.333	19.600
Periyakulam GH	76	87.6	40	250	80	1400	320	9800	8.000	39.200
Pudukkottai Medical College	40	39.8	200	249	1000	1200	3000	8400	15.000	33.735
Aranthangi GH	58	53.4	50	249	200	800	800	5600	16.000	22.490
Iluppur GH	50	30.6	50	245	20	800	80	5600	1.600	22.857

Table 2.14: Weighted point prevalence of antimicrobial use in public health facilities

Health Facility	Observed Point Prevalence Estimate IP	Observed Point Prevalence Estimate OP	IP Sample Weight	OP Sample Weight	Total Weight	IP Weight Proportion	OP Weight Proportion	Weighted Point Prevalence
Trichy Medical College	51.4	87.3	7.075	139.442	146.518	0.048	0.952	85.57
Srirangam GH	94.7	62	9.474	16.800	26.274	0.361	0.639	73.79
Musiri GH	66	49	4.400	11.245	15.645	0.281	0.719	53.78
Tirunelveli Medical College	69	37.2	21.795	60.844	82.639	0.264	0.736	45.59
Ambasamudram GH	88	31.2	6.400	18.200	24.600	0.260	0.740	45.98
Tenkasi GH	86	44.6	30.000	35.141	65.141	0.461	0.539	63.67
Salem Medical College	71.1	25.2	26.866	98.000	124.866	0.215	0.785	35.08
Attur GH	81.3	80.8	13.333	50.400	63.733	0.209	0.791	80.90
Omalur GH	80	40.8	12.000	16.800	28.800	0.417	0.583	57.13
Villupuram Medical College	68.5	47.1	21.226	84.677	105.904	0.200	0.800	51.39
Vikravandi GH	78.4	35.8	1.176	10.895	12.071	0.097	0.903	39.95
Tindivanam GH	83.6	45.2	3.636	33.871	37.507	0.097	0.903	48.92
Theni Medical College	53.5	91.6	3.000	14.000	17.000	0.176	0.824	84.88
Bodinayakanur GH	56	32.8	2.333	19.600	21.933	0.106	0.894	35.27
Periyakulam GH	76	87.6	8.000	39.200	47.200	0.169	0.831	85.63
Pudukkottai Medical College	40	39.8	15.000	33.735	48.735	0.308	0.692	39.86
Aranthangi GH	58	53.4	16.000	22.490	38.490	0.416	0.584	55.31
Iluppur GH	50	30.6	1.600	22.857	24.457	0.065	0.935	31.87

Table 2.15: Weighted point prevalence of antimicrobial use in health facilities and districts

District	Health Facility	Weighted Point Prevalence	Districtwise Weighted Point Prevalence
Trichy	Trichy Medical College	85.57	70.01
	Srirangam GH	73.79	
	Musiri GH	53.78	
Tirunelveli	Tirunelveli Medical College	45.59	52.51
	Ambasamudram GH	45.98	
	Tenkasi GH	63.67	
Salem	Salem Medical College	35.08	64.17
	Attur GH	80.90	
	Omalur GH	57.13	
Villupuram	Villupuram Medical College	51.39	45.98
	Vikravandi GH	39.95	
	Tindivanam GH	48.92	
Theni	Theni Medical College	84.88	67.43
	Bodinayakanur GH	35.27	
	Periyakulam GH	85.63	
Pudukkottai	Pudukkottai Medical College	39.86	43.09
	Aranthangi GH	55.31	
	Iluppur GH	31.87	

Based on the weighted pointed prevalence estimates at the facility and district levels, the facilities and districts were ranked. This is shown in Figure 15 and Figure 16.

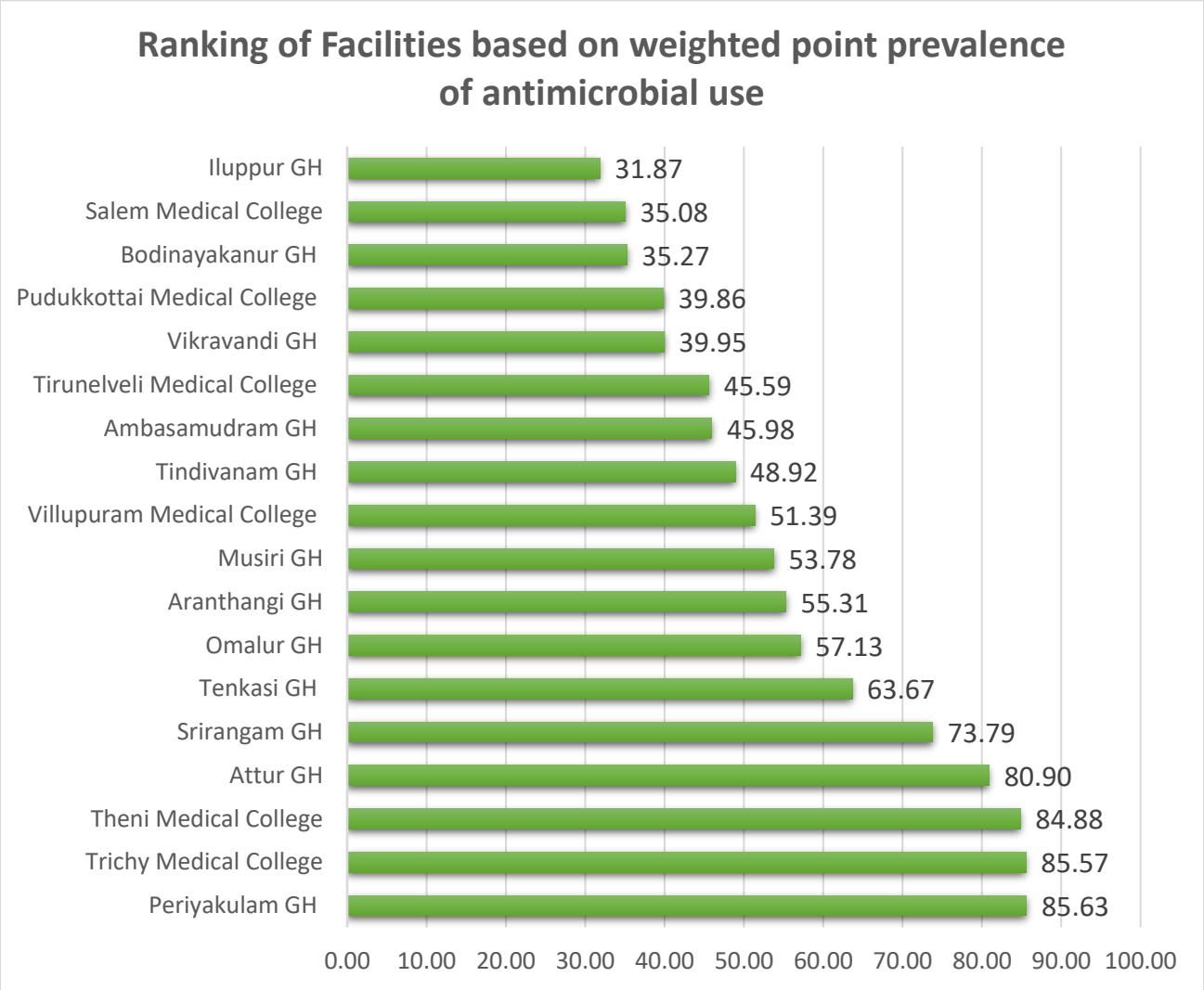

Figure 15: This figure shows the ranking of the public health facilities based on the quantum of antimicrobial use with Periyakulam GH having the highest point prevalence estimate and Illupur GH having the least.

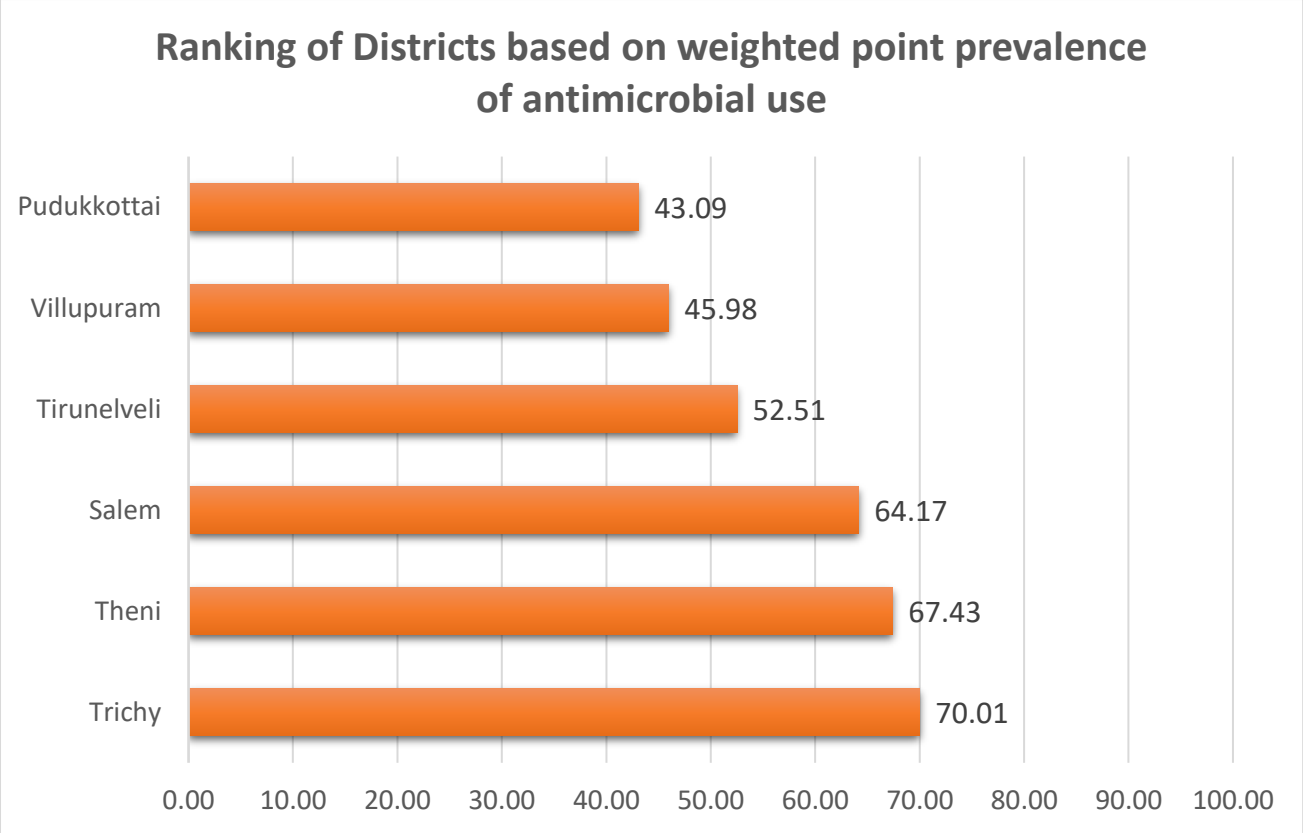

Figure 16: This figure shows the ranking of the districts based on the point prevalence of antimicrobial use and it is seen that Trichy has the highest use of antimicrobials, whereas Pudukkottai has the least.

Association between Human Development Index and Antimicrobial use

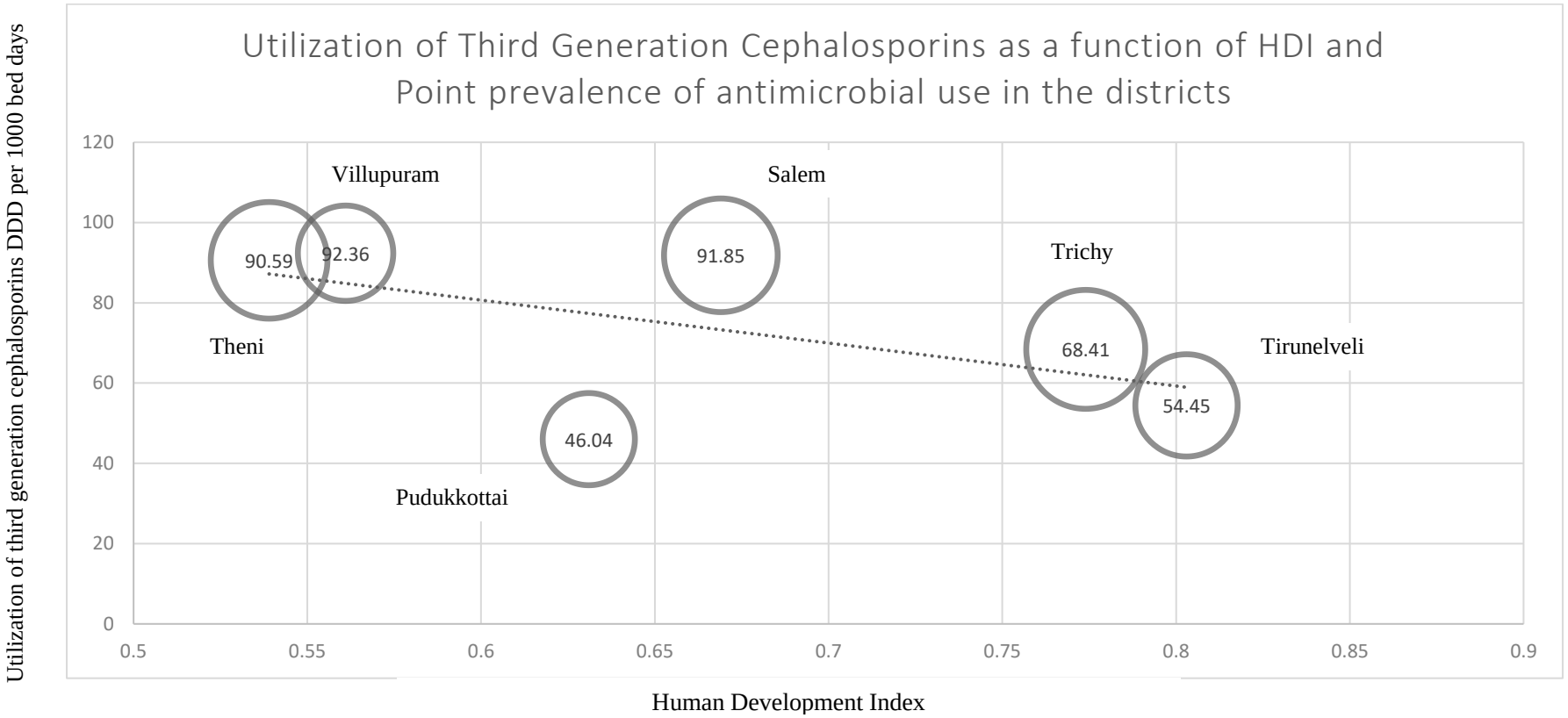

Figure 17: Association between Human Development Index, Utilization of third generation cephalosporins in the districts and weighted point prevalence estimate of antimicrobial use in the districts showing that use of higher antimicrobials reduces with increasing HDI. The bubble size indicates the weighted point prevalence of antimicrobial use.

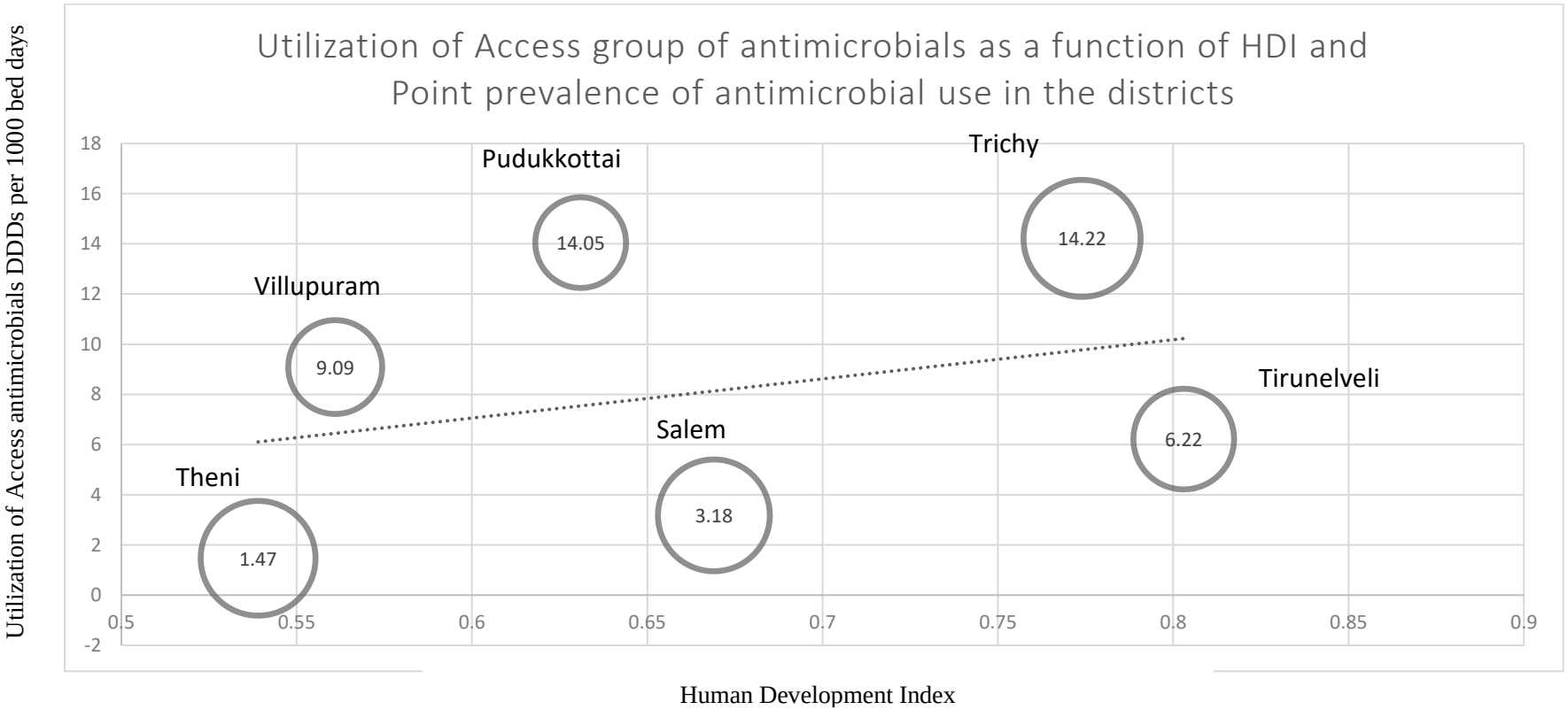

Figure 18: Association between Human Development Index, utilization of Access group of antimicrobials and weighted point prevalence estimate of antimicrobial use in the respective districts showing that use of access group antimicrobials increases with increasing HDI. The bubble size indicates the weighted point prevalence of antimicrobial use.

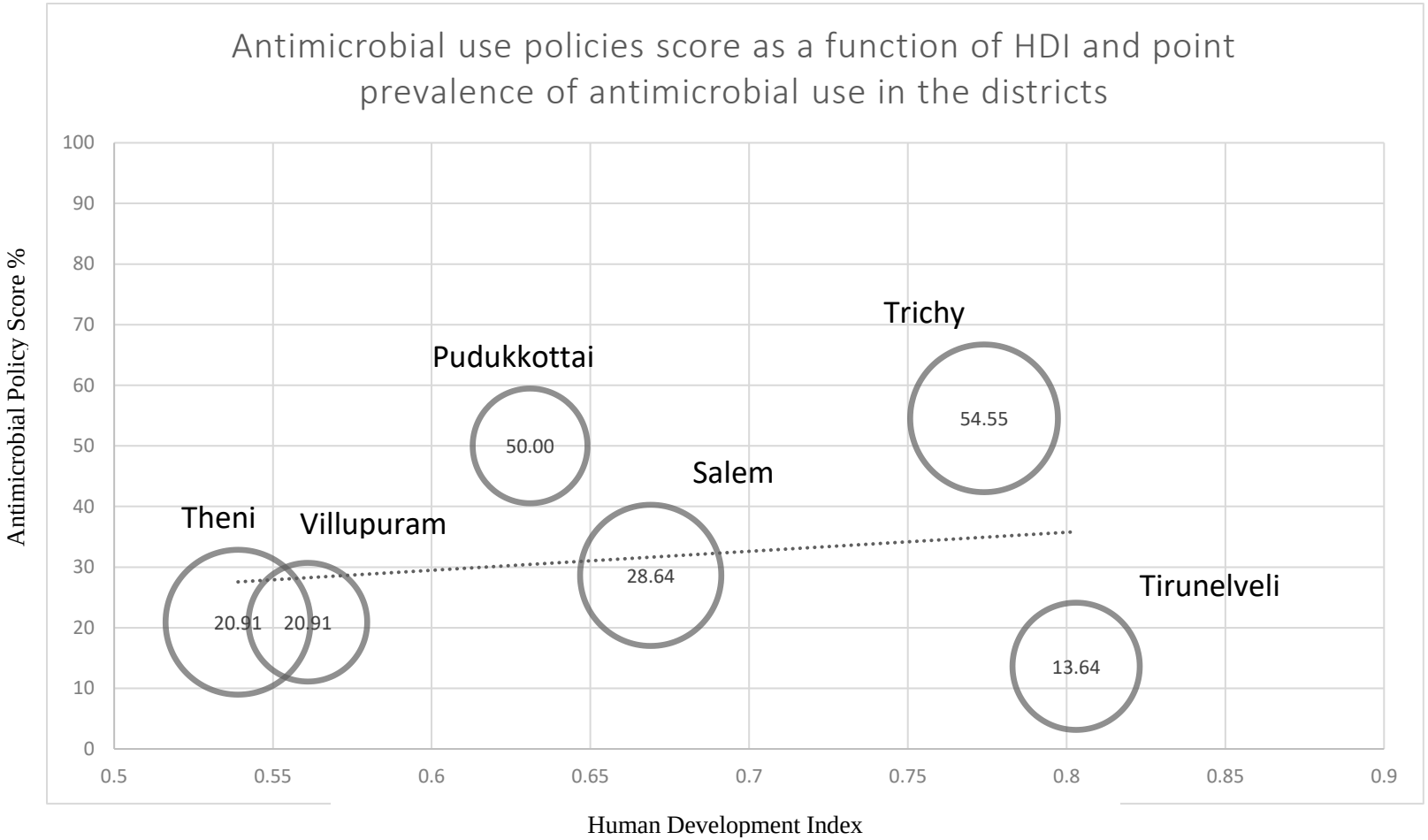

Figure 19: Association between Human Development Index, Score on antimicrobial policies at the district level and weighted point prevalence estimate of antimicrobial use showing that there is an increase in the antimicrobial policies scores with increasing HDI. The bubble size indicates the weighted point prevalence of antimicrobial use.

A trend of decreasing utilization of third generation cephalosporins with increasing human development index of the district was observed. The utilization of access group of antimicrobials including amoxycillin, cirprofloxacin and doxycycline increased with increasing human development index. Also the overall district level score of antimicrobial policies that were present in the health facilities also increased with increasing human development index. Therefore a pattern of association between the level of development of the district and utilization of antimicrobials was observed.

Discussion

Summary of important findings

This study evaluated the appropriateness of antimicrobial use in a sample of public health facilities of Tamil Nadu under three main headings namely, an inpatient case sheet audit, an outpatient prescription audit and assessment of facility level policies and practices with respect to antimicrobial use.

- Other than Bodinayakanur GH and Aranthangi GH, the documentation of a clear diagnosis in the case sheets was very high (>90%) in all facilities.
- The inpatient case sheet audit revealed a very high proportion of inpatients on antimicrobials in almost all the District Hospitals except Ilupur GH and Aranthangi GH which had lower use.
- Among the medical colleges, the proportion of patients on antimicrobials was very high in Salem, Tirunelveli and Villupuram Medical Colleges, whereas it was relatively lower in Pudukkottai, Theni and Trichy Medical Colleges.
- It was noted that across all the health facilities the proportion of patients on antimicrobials was double the proportion of patients with a diagnosis of an infectious disease.
- Utilization of antimicrobials in DDDs per 1000 bed days revealed that in the inpatient setting there was a very high utilization of third generation Cephalosporins, Cefotaxime and Ceftriaxone.
- Among all the health facilities the top antimicrobials which comprised of 90% of the total utilization in DDDs per 1000 bed days included Cefotaxime, Ceftriaxone, Amoxycillin, Doxycycline and Ciprofloxacin.

- It was noticed that the District Hospitals, especially Omalur, Vikravandi, Ambasamudram, Bodinayakanur, Tindivanam, Srirangam and Attur GH had a very high utilization of third generation Cephalosporins.
- The Medical Colleges had a relatively lesser utilization of third generation Cephalosporins compared to these District Hospitals.
- The utilization of the Access Group of antimicrobials as per the WHO AWaRe classification, namely Amoxycillin, Ciprofloxacin and Doxycycline was less than half of the use of third generation Cephalosporins in the inpatient settings.
- The utilization of antimicrobials in DDDs per 1000 bed days was higher among the departments of General Medicine and General Surgery compared to Obstetrics, Gynecology, Orthopaedics and Paediatrics.
- On assessment of appropriateness of antimicrobial choice in the in-patient setting, it was noticed that 98% were inappropriate.
- In General Medicine there was a high prescription of inappropriately broad spectrum antimicrobial (third generation Cephalosporin) for a non-specific clinical condition.
- In the surgical departments such as General Surgery, Gynecology and Orthopaedics there was inappropriate use of broad spectrum antimicrobials (third generation Cephalosporins) for surgical prophylaxis.
- It was also noticed that in obstetrics department there was high use of broad spectrum antimicrobials for routine normal delivery, which was not indicated.
- Even in common Access group of antimicrobials such as Amoxycillin, Ciprofloxacin and Doxycycline, there was a 70-80% inappropriate dose.
- The dosing interval was inappropriate in 75-80% of the prescriptions of Amoxycillin, Doxycycline, Ciprofloxacin and Metronidazole.

- The outpatient prescription audit revealed that 80% of the out patients came for non-infectious conditions. However, there was very poor documented diagnosis in the out patient records and so a thorough audit of appropriateness could not be performed. Salem Medical College, Omalur GH, Attur GH, Theni Medical College and Tirunelveli Medical College had a clear documentation of the diagnosis in the OP records.
- It was noticed that almost twice the number of patients were on antimicrobials compared to the number of patients who had a condition suggestive of an infection from the history.
- In the outpatient department, the most frequently prescribed antimicrobial was Amoxycillin which was prescribed for 30% of the outpatients. Following Amoxycillin, Ciprofloxacin, Cephalexin and Doxycycline were the top antimicrobials used among outpatients.
- Assessment of appropriateness of drug choice was not possible as a clear documentation of diagnosis was not available in most cases.
- Inappropriate drug dose was present for 93% of prescriptions of Metronidazole, 92% of prescription of Amoxycillin and 30% of prescription of Ciprofloxacin.
- Among the outpatient prescriptions inappropriate dosing interval was very common for Amoxycillin and Cephalexin. Inappropriate dosing interval was least for Ciprofloxacin and Doxycycline.
- Assessment of the facility level policies and practices of antimicrobial use revealed many facilities had an antimicrobial formulary and this formulary was as per the National Essential Drug List.
- Nine of the facilities reported stock-outs of essential antimicrobials at the time of the assessment.

- Eleven of the 18 facilities had local guidelines for antimicrobial use based on the local sensitivity patterns.
- Ten of the facilities had a copy of the ICMR standard treatment guidelines on antimicrobial use in common syndromes.
- The existence and implementation of specific antimicrobial use policies and antimicrobial stewardship interventions was very poor and present only in a few facilities.
- The monitoring of antimicrobial utilization by DDDs and by DDDs per hospital operation indicators was not being performed in most health facilities.
- Among the Medical Colleges, Trichy and Theni Medical Colleges have a high use of antimicrobials, Villupuram and Tirunelveli Medical Colleges have a moderate use and Salem and Pudukkottai Medical Colleges have a low use.
- Among the District Hospitals, Iluppur, Bodi and Vikravandi GH have low levels of antimicrobial use, Musiri, Omalur and Aranthangi GH have moderate levels of use and Srirangam, Attur and Periyakulam GH have a high use.
- Among the districts Villupuram and Pudukkottai have low utilization of antimicrobials, while Salem and Tirunelveli have a moderate utilization and Theni and Trichy have very high utilization.
- A trend of decreasing use of third generation cephalosporins, increasing use of access antimicrobials and higher antimicrobial policies score was observed with increasing Human Development Index of the districts.

Overuse of antimicrobials in inpatient and outpatient settings

A Global Point Prevalence Survey (GPPS) of 303 health facilities across 53 countries indicated that 34.4% received at least one antimicrobial. The top three antimicrobials prescribed were Penicillin plus beta lactamase inhibitor, third generation Cephalosporins and Fluoroquinolones. The diagnosis justifying the prescription of antimicrobial was present in only 77% of the antimicrobial prescriptions. In this global survey in East and South Asia, the most utilized antimicrobial was Penicillin with beta lactamase inhibitor followed by third generation Cephalosporins. (43) This pattern is very different from the one observed in this study in Tamil Nadu. Penicillin with beta lactamase inhibitor is not available in the formulary of most of the health facilities. It is not used routinely. Instead it is the third generation Cephalosporins which are used extensively.

A Point Prevalence Survey was conducted in India in 16 tertiary care facilities. Of all the surveyed patients 57.4% received at least one antimicrobial on the day of the survey. In the Global Point Prevalence Survey (GPPS) reported earlier the East and South Asia region showed an antimicrobial use of 48.2%.(43) Another survey performed in eastern India showed an antimicrobial use of 62% in 2014 and 69% in 2017.(44) All these data show a high use of antimicrobials in inpatient facilities in India compared to global standards. The current survey conducted among 18 health facilities in Tamil Nadu among 1832 in patients showed an alarmingly high figure of 64.5%. This is comparable with the high prevalence of antimicrobial use in hospital settings in eastern India. This high prevalence of antimicrobial use is a matter of great concern.

Secondary data analysis of Standardized Patient interactions done in India, Kenya and China revealed that there is a high level of prescription of antimicrobials in primary care.

Antimicrobial prescriptions were given inappropriately in 50% of interactions in India, 50% in Kenya and only 28% in China. Antimicrobial overuse was significantly lower in urban areas compared to rural. It was higher among qualified practitioners compared to non-qualified. The prevalence of antimicrobial overuse was greatest for presumptive TB cases compared to other tracer diseases. While access antimicrobials were the most overused in Kenya, in India watch antimicrobials including Fluoroquinolones and Cephalosporins were excessively used.(45) A systematic review and meta-analysis of antimicrobial prescription in low and middle income countries (LMIC) revealed that the pooled prevalence of proportion of antimicrobial prescription in primary care setting was 52%.(46) In another surveillance of antimicrobial prescriptions done in Vellore in South India, it was found that the proportion of patients who were prescribed antimicrobials over a 2 year period of surveillance was 40.9%. The most frequently prescribed antimicrobials were Fluoroquinolones and Penicillin.(47) In another study of practice of antimicrobial prescriptions in outpatient private practice in India, it was found that there were 412 prescriptions per 1000 persons per year, which roughly translates to 41% per year.(48) In yet another study of point prevalence of antimicrobial prescriptions in outpatient settings in New Delhi, it was found that 39% of patients attending public health facilities and 43% of patients attending private clinics were prescribed antimicrobials.(49) A study from Uttar Pradesh, India showed an alarmingly high use of antimicrobials of 81% in primary and secondary care levels. The study reported that fever routinely prompted the prescription of antimicrobials irrespective of reason for the fever. (50)In this study the point prevalence of prescription of antimicrobials in the outpatient settings was 51.2%. This is comparable to other studies reported above. However, the proportion of antimicrobial prescriptions that were inappropriate was very high. Moreover, this study did not assess use of antimicrobials in the private sector.

Several factors influenced the misuse of antimicrobials. Poor regulation of prescriptions, unregulated supply of antimicrobials, and lack of a clearly documented policy on antimicrobial prescription led to overuse. Various prescriber level factors such as diagnostic uncertainty, time constraints and poor accessibility of laboratory facilities led to overuse of antimicrobials. Lack of periodic training of prescribers was a major problem that led to inappropriate use of antimicrobials.(51)

Overuse of antimicrobials is the most common and important reason for emergence of antimicrobial resistance. Treatment of resistant microbes requires higher end antimicrobials which have serious adverse effects as well as cost much more than routine antimicrobials. Overuse of antimicrobials also alters the antimicrobial flora of the body. This has serious consequences. It can lead to overgrowth of clostridium difficile and its associated diarrhoea.

High utilization of third generation Cephalosporins

A study using quarterly national sample survey of antimicrobial use in 76 countries showed that the consumption of Watch category of antimicrobials, which are broad spectrum antimicrobials, increased by 90% between 2000 – 2015 whereas, the utilization of Access category of antimicrobials increased only by 26.2%. The rise in use of Watch antimicrobials was steeper in Low and Middle Income Countries (165%) compared to High Income Countries (28%). The Access-to-Watch ratio reduced by 46.7% in LMIC and 16.7% in HIC. (52)

The WHO has set a global target of 60% of all national antimicrobial consumption to be Access group of antimicrobials by 2023. However, this seems to be very difficult to achieve with the existing use of Watch category of antimicrobials. This seems to be a major problem especially in LMICs. Two possible reasons could be operating to influence the increase in higher

antimicrobial consumption in LMIC settings. Firstly, the unregulated use of antimicrobials in a context of lack of adequate stewardship could be leading to unregulated use of higher antimicrobials. Second important reason could be the emergence of antimicrobial resistance and therefore prescribers being forced to resort to higher antimicrobials. (53)

A study from Thailand showed that among children there was a high overall antimicrobial prescription rate of 46% and parenteral third generation cephalosporins were prescribed in 68% of all children. (54) A study from Mumbai, India showed that the use of third generation cephalosporins was very high in the general medicine and general surgery departments. Among all drugs prescribed for a sample of 600 patients, 19% were antimicrobials, and of the antimicrobials 37% were third generation cephalosporins. Of these about 40% were empirical prescriptions. (55) In another study from Pune it was noticed that third generation cephalosporins were empirically prescribed for 65% of the patients. Among all the antimicrobials prescribed in the hospital 63% were third generation cephalosporins, with Ceftriaxone being the most common. (56)

This high use of third generation cephalosporins is likely to lead to several complications. A study showed that patients with cephalosporin resistant Enterobacteriaceae infections had higher mortality, longer duration of hospital stay and higher health care cost compared to sensitive infections. (57) In a study in a tertiary care hospital in Kerala it was seen that most of the cephalosporin prescription was definite and accompanied by a culture report (45%), followed by empirical use as per standard guidelines (32%) and in a small proportion it was prophylactic (23%). The cephalosporins were inappropriate in 11% of the prescriptions. Wrong indication, wrong duration of therapy and lack of de-escalation were the most important reasons for inappropriateness.(58)

High and indiscriminate use of third generation cephalosporins was also observed in this study. This pattern is similar to the high use of third generation cephalosporins that has been observed all over India and in most LMICs.

Inappropriate use of antimicrobials for surgical prophylaxis

One of the most common cause for inappropriate antimicrobial use is inappropriate use of broad spectrum antimicrobials for prophylaxis before surgery. The ICMR Standard Treatment Guidelines recommend single dose of Cephazolin just before the incision for clean and clean contaminated surgeries. It was noticed in this study that majority of the patients undergoing clean and clean contaminated surgeries in public health facilities in Tamil Nadu were receiving prolonged courses of third generation cephalosporins.

An audit of antimicrobial prescriptions for surgical prophylaxis done in Ahmedabad showed that the mean duration of antimicrobial prophylaxis pre-operatively was 0.75 days and mean duration post operatively was 3.33 days. The most frequently prescribed antimicrobial for surgical prophylaxis was third generation cephalosporins (65%). The prescription was inappropriate in 52% of the patients. This showed a very high prevalence of inappropriate surgical antimicrobial prophylaxis. (59) Another study in a tertiary care hospital in New Delhi revealed that surgical antimicrobial prophylaxis was given for 86% of all surgeries although only 67% required it. Third generation cephalosporins were the most commonly prescribed and they were given for an extended period of 5 days post operatively. Thus surgical antimicrobial prophylaxis was inappropriate in terms of choice of antimicrobial, timing of administration as well as duration. (60) A study in a medical college teaching hospital in Kerala showed that third generation cephalosporins were used for surgical prophylaxis in 100% of patients intravenously. In addition 30% of the patients received Amikacin and Metronidazole. The post-

operative use of antimicrobials was extended to 36 hours or more in 96% of the patients. (61) Another study from Bengaluru showed that 48% of the antimicrobials of surgical patients were of inappropriate choice. (62) The current audit of antimicrobial use in department of general surgery in the various public health facilities showed a high use of broad spectrum third generation cephalosporins for prolonged duration. This further adds to the data on high prevalence of inappropriate surgical prophylaxis.

Antimicrobial stewardship policies and their implementation

The Antimicrobial Stewardship, Prevention of Infection and Control (ASPIC) program by the Indian Council of Medical Research was put together to bring clinical pharmacologists, clinical microbiologists and other clinicians together to work towards antimicrobial stewardship. The main goals of this ASPIC program is to prevent the emergence of antimicrobial resistance and to prevent hospital acquired infections. The program involves training the experts from these specialties from 20 different institutions each year to carry out the activities to achieve these goals. (63)

A study carried out by the Indian Council of Medical Research in 2014 showed that though many public and private hospitals had the antimicrobial stewardship policy documents with them, the practice of these policies was rare. Antimicrobial audits were not performed routinely by the facilities.(64) The ASPIC was established in the same year. A systematic review done in 2020 showed that even after implementation of the ASPIC and widespread awareness about antimicrobial resistance and stewardship activities, the implementation of antimicrobial stewardship is still in a very poor state in the country. (65)

Several other important interventions have also been performed in India to ensure antimicrobial stewardship and reduction of antimicrobial resistance. The Chennai Declaration was signed in 2012 by the Clinical Infectious Diseases Society in which it was decided to adopt a national level policy to tackle the problem of antimicrobial resistance. The declaration stated the need for an easy to implement national level policy to handle antimicrobial resistance. (66)

The National Action Plan on Antimicrobial Resistance was drafted by the Core Working Group on Antimicrobial Resistance constituted by the Ministry of Health and Family Welfare of the Government of India in 2016. The strategic objectives of the NAP-AMR is aligned with the GAP-AMR objectives of the WHO. The core objectives of the NAP-AMR include:

1. Improving awareness and understanding of AMR through effective communication, education and training
2. Strengthening knowledge and evidence through surveillance
3. Reducing the incidence of infections through effective infection prevention and control activities
4. Optimizing the use of antimicrobials in health, animals and foods
5. Promoting investments for AMR activities, research and innovation
6. Strengthening India's leadership on AMR

This study is focused on the fourth objective which is optimizing the use of antimicrobials in health. The NAP-AMR has drafted the following activities for optimizing the use of antimicrobials in health care.

Ensure uninterrupted access to high quality antimicrobials: The NAP-AMR envisages strengthening drug regulation, regulation of sale of antimicrobials Over The Counter, regulation of the manufacture and distribution of substandard antimicrobials, and establishing

quality management systems in antimicrobial production and distribution. The NAP also focuses on strengthening the logistics and supply chain of antimicrobials to ensure uninterrupted supply to all health facilities.

Establishment of National Surveillance System for Antimicrobial use: Surveillance of antimicrobial use at health facilities and at district, state and national levels, surveillance of antimicrobial consumption among humans, animals and agricultural sector, monitoring the consumption of antimicrobials in health facilities.

Antimicrobial stewardship in human health: Establishment of antimicrobial stewardship committees in all health facilities, develop national guidelines for antimicrobial use, developing resources for antimicrobial stewardship programs, training of health facilities for antimicrobial stewardship, establishing a monitoring and evaluation framework for antimicrobial stewardship in health facilities, improving antimicrobial use at the community level. (67)

The Antimicrobial Resistance Surveillance and Research Network (AMRSN) was set up by the ICMR in 2013. It collates the incidence of drug resistant infections and patterns of antimicrobial resistance among pathogens of human importance. This network focuses on six main pathogenic microbes and their resistance namely Enterobacteriaceae causing sepsis, Gram negative non fermenters, Enteric fever pathogens, Diarrheagenic bacteria, Gram positive staphylococci and enterococci, and fungal pathogens. The main goals of AMRSN are to establish a network of hospitals to monitor the trends of antimicrobial susceptibility and testing, molecular testing and gene mapping of resistance pathogens, dissemination of information on drug resistant pathogens to stakeholders and creation of data management system for data collection and analysis. The Nodal centres in this network are AIIMS, New Delhi, PGI,

Chandigarh, JIPMER, Puducherry and CMC, Vellore. In addition there are 15 regional centres. (68)

The Indian Council of Medical Research released the Antimicrobial Stewardship Programme guidelines in 2017. Some of the stewardship strategies proposed by this guidelines include ensuring appropriate antimicrobial therapy, ensuring appropriate surgical prophylaxis, developing and implementing standard treatment guidelines, performing prospective audits and providing feedback to prescribers, maintaining a strict antimicrobial formulary at facility level and ensuring that it adheres to the National Essential Drugs List, pre-authorization of certain Watch and Reserve antimicrobials, education and training of prescribers, ensuring establishment of good microbiology laboratory support and effective monitoring and evaluation. Other supplemental stewardship initiatives include measures of antimicrobial consumption in DDDs per hospital performance indicators and monitoring them, escalation / de-escalation of antimicrobials, switch from parenteral to oral therapy at the earliest possible time, and optimization of dose and duration of therapy. (30) The ICMR also released the Standard Treatment Guidelines for antimicrobial use in common syndromes in the year 2019. (35)

In this study it was found that most of the important interventions of antimicrobial stewardship were weak or non-existent in the public health facilities that were surveyed. This indicated that antimicrobial stewardship was in a very nascent stage in the public health facilities in Tamil Nadu. The only strategies that were present in several of the facilities was a robust drug formulary of antimicrobials that adhered to the national essentials drugs list and a local antimicrobial prescription policy based on sensitivity patterns in the facility. All the other interventions were rare in the surveyed facilities.

Level of socio-economic development and antimicrobial use patterns

In this study it was observed that districts such as Tirunelvei and Trichy which are more developed as per the Human Development Index had better patterns of antimicrobial use compared to Salem, Pudukkottai which had medium HDI and Theni, Villupuram, which had lower HDI. This pattern of socio-economic development having an impact on antimicrobial use has been observed in previous studies and reports.(69) Increasing socio-economic development reduces the risk of more serious infectious diseases, as it provides a relatively better quality of life and safer environmental conditions. Therefore utilization of antimicrobials is reduced in these better developed districts. Moreover, stricter regulatory mechanisms and stewardship policies are present in these better developed districts as observed in this study. This directly translates to better patterns of antimicrobial use.

Recommendations:

Based on this research study there are several important recommendations. There are recommendations for antimicrobial use at the prescriber level, at the facility level and at the health system level.

Recommendations at prescriber level:

- Knowledge of antimicrobial resistance and antimicrobial stewardship must be made a core competency for recruitment and promotion of all faculty in the teaching hospitals. Certification of competency in antimicrobial prescription and antimicrobial resistance must be made compulsory for promotions of medical officers in District Hospitals.
- Online training courses must be developed specifically for the Indian context in collaboration with NPTEL and ICMR and this must be made mandatory for all government medical officers.
- A detailed assessment of the awareness, attitudes and prescription patterns of individual prescribers of antimicrobials must be performed at the state level. This assessment must guide planning and implementation of education and training activities for prescribers.
- All medical officers must be required to take the Antimicrobial Self-Assessment Toolkit and assess their own preparedness to prescribe antimicrobials. The feedback from this toolkit must be reviewed and appropriate training provided to the medical officers.

Recommendations at the health facility level:

- Each health facility must set up its own Antimicrobial Stewardship Committee.
    - *Composition of AMS Committee in Medical Colleges:*

      Clinical Pharmacologist, Clinical Microbiologist, General Medicine specialist, General Surgery specialist, Obstetrics and Gynecology specialist, Paediatrics specialist, Pharmacist, Nursing Superintendent
    - *Composition of AMS Committee in District Hospitals:*

      General Medicine specialist, General Surgery specialist, Obstetrics and Gynecology specialist, Paediatrics specialist, Pharmacist, Nursing Superintendent
- This AMS committee must meet monthly. It must have a documented minutes of meeting each month.
- During the meetings the AMS committee must discuss the following:
    - Antimicrobial sensitivity and susceptibility patterns in the previous month
    - Utilization of antimicrobials in DDDs
    - Utilization of Access antimicrobials and Watch and Reserve antimicrobials
    - Discussion of cases where reserve antimicrobials were used
- The AMS committee must also perform periodic ward rounds to inspect the review of antimicrobial prescriptions, review of prescribed antimicrobials after 48 hours, escalation / de-escalation practices, switch from parenteral to oral antimicrobials.
- The AMS committee must commission periodic OP audits and IP case sheet audits for antimicrobial use
- The AMS committee must organize quarterly training for all staff including doctors, nurses, nursing assistants and orderlies on antimicrobial prescription, antimicrobial resistance and antimicrobial stewardship

- Periodic audit of antimicrobial prescriptions in OP and IP settings must be performed. These audits must have a standard data extraction format which includes diagnosis, specific indication for antimicrobials, whether culture and sensitivity patterns were obtained, name of antimicrobial, dose, dosing interval, duration and route of administration. It must also contain details of whether the antimicrobial choice was reviewed after 48 hours for escalation / de-escalation decision and whether it was considered for switch from parenteral to oral formulation.
- There must be an antimicrobial audit board displayed in a public location accessible to all doctors, nurses and other prescribers of antimicrobials. The findings of the periodic audits must be displayed in this audit board. The format for display of audit findings must also be standardized.
- Audit findings must also be communicated individually to the department heads who in turn must communicate it to all the doctors and nurses in the health facility.
- The audit must specifically focus on use of third generation cephalosporins (as this was found to be very high and indiscriminate in many health facilities).
- The audit must also specifically look for antimicrobial use in surgical prophylaxis and provide constructive feedback on appropriateness of antimicrobial use for surgical prophylaxis.
- The audit must also closely review use of antimicrobials for normal delivery.
- The pharmacist must prepare a monthly report of the utilization of various antimicrobials in DDDs per 1000 bed days.
- This utilization report must be shared with the antimicrobial stewardship committee.
- The utilization of important Access, Watch and Reserve group of antimicrobials in each facility must be displayed in the form of an ongoing graph and it must be monitored

Recommendations at the Health System level:

- A multidisciplinary expert committee must be formed at the state level to discuss and provide recommendations on the key antimicrobial use issues observed in the study. These issues include
    - Overuse of antimicrobials in all health facilities including district, subdistrict and medical college teaching hospitals
    - Overuse of third generation cephalosporins
    - Inappropriate use of antimicrobials
    - Inappropriate use of antimicrobials in surgical prophylaxis
- This multidisciplinary expert committee must comprise of experts in infectious diseases, surgeons, physicians, pharmacologists, microbiologists and internists.
- The multidisciplinary expert committee must be given the task of arriving at a consensus decision on implementation of antimicrobial stewardship interventions in the health facilities, methods to regulate antimicrobial use to avoid overuse and inappropriate use, methods to regulate use of third generation cephalosporins and most appropriate surgical prophylaxis to be used.
- State level surveillance of antimicrobial use, antimicrobial stewardship interventions and antimicrobial resistance patterns must be established at Nodal Centres and several smaller regional centres. This surveillance data must be used to determine empirical antimicrobial guidelines.

Conclusions:

This study of appropriateness of antimicrobial use in public health facilities in Tamil Nadu found that there was widespread high point prevalence of use of antimicrobials in both the in patient and outpatient settings. In the inpatient settings third generation cephalosporins, which belong to Watch group according to the WHO AWaRe classification were used extensively compared to Amoxycillin, Ciprofloxacin or Doxycycline which are Access group of antimicrobials, which is a disturbing pattern. There was overuse of third generation cephalosporins for routine surgical prophylaxis which was against the standard guidelines for surgical prophylaxis. Inappropriately high utilization of antimicrobials for normal vaginal delivery was also observed. In the outpatient settings there was excessive inappropriate use of Amoxycillin and there was a high prevalence of inappropriate dose, dosing interval and duration of antimicrobial use. Most of the health facilities lacked any proper antimicrobial stewardship practices to regulate the use of antimicrobials. Therefore, the study concludes that the current situation of antimicrobial use in public health facilities is a ticking time-bomb for development of aggressive antimicrobial resistance. There is an immediate need to intervene and establish rigorous antimicrobial stewardship involving the health facilities at the ground level to avert the massive development of antimicrobial resistance.

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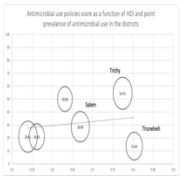


ESIC Medical College and PGIMSR, KK Nagar, Chennai 78
OR - Tamil Nadu Health System Reform Program

Are antimicrobials appropriately used in public health facilities as per the treatment guidelines for antimicrobial use in common syndromes?

Data Extraction form – In Patient Case Sheet Antimicrobial Audit

1. Date of Survey:
2. Gender of the Patient: Male / Female / Others
3. Age of the patient: _____
4. Hospital Name: _____
5. District: Thirunelveli / Theni / Salem / Pudukkottai / Trichy / Villupuram
6. Department: Gen Med / Gen Surg / Ob / Gyn / Paeds / Ortho
7. Date of Admission:
8. Diagnosis: _____ / Not Documented
9. Surgery or procedures done (including normal delivery, instrumental delivery, caesarean section):

   _____

   _____

   _____
10. Does the patient have any of the following?
    a. Is the patient on a central intravenous line? Yes / No
    b. Is the patient on a peripheral intravenous line? Yes / No
    c. Is the patient on a urinary catheter? Yes / No
    d. Is the patient on endotracheal tube? Yes / No
    e. Is the patient on tracheostomy? Yes / No
    f. ICD tube? Yes / No
    g. Colostomy bag? Yes / No
11. Comorbid conditions:
    a. Diabetes? Yes / No

b. Hypertension? Yes / No
c. CAD? Yes / No
d. Asthma? Yes / No
e. COPD? Yes / No
f. Any other medical comorbidities?

_____

12. Is there a temperature chart documented? Yes / No
13. Does the prescription in the case sheet have any antimicrobials? Yes / No
14. List the antimicrobials with dose, frequency , route of administration and duration (nth day)

Name of antimicrobial	Dose (in mg)	Frequency (number of times a day)	Route of administration (oral / parenteral)	Date of Starting	Date of stopping (if applicable)	Ask the patient – Did you receive this drug in the last 24 hours?	If yes, how many times in the last 24 hours?

15. Are generic names used for antimicrobial prescription? Yes / No
16. Has any sample been sent for culture? Yes / No
17. If yes, which sample
    a. Blood
    b. Urine

c. Tissue
d. Pus
e. Swab
f. Others _____

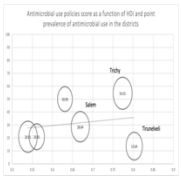
18. Has culture report been obtained? Yes / No
19. What did the culture grow?

_____

_____

_____

20. Is a sensitivity pattern reported? Yes / No
21. Have antimicrobials been changed after culture report? Yes / No
22. Is the antimicrobial used appropriate as per the ICMR STG of 2017? (refer the ICMR 2017 STG and mark the response) Yes / No
23. Is the dose appropriate as per the antimicrobial that is prescribed? Yes / No
24. Is the duration of antimicrobial prescription appropriate as per the ICMR STG of 2017? Yes / No



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Are antimicrobials appropriately used in public health facilities as per the treatment guidelines for antimicrobial use in common syndromes?

Data Extraction form – Outpatient Prescription Antimicrobial Audit

1. Date of Survey:
2. Gender of the Patient: Male / Female / Others
3. Age of the patient: _____
4. Hospital Name: _____
5. District: Thirunelveli / Theni / Salem / Pudukkottai / Trichy / Villupuram
6. Department: Gen Med / Gen Surg / Ob / Gyn / Paeds / Ortho
7. Diagnosis: _____ / Not documented
8. Comorbid conditions:
    a. Diabetes? Yes / No
    b. Hypertension? Yes / No
    c. CAD? Yes / No
    d. Asthma? Yes / No
    e. COPD? Yes / No
    f. Any other medical comorbidities?

    _____
9. Does the prescription have any antimicrobials? Yes / No
10. List the antimicrobials with dose and duration

    _____

    _____

    _____

    _____
11. Has any sample been sent for culture? Yes / No
12. If yes, which sample
    a. Blood

b. Urine
c. Tissue
d. Pus
e. Swab
f. Others _____

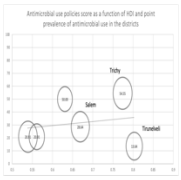
13. Has culture report been obtained? Yes / No
14. What did the culture grow?

_____

_____

_____

15. Is a sensitivity pattern reported? Yes / No
16. Have antimicrobials been changed after culture report? Yes / No
17. If no, why not?
    a. Sensitive to current antimicrobials
    b. Not sensitive to any antimicrobials available in the hospital
    c. Not clearly documented
18. Check the antimicrobials with the patient. Are they the same as in the prescription? Yes / No
19. Are there enough number of tablets / capsules to cover the dosage, frequency and duration prescribed? Yes / No
20. Is the antimicrobial used appropriate as per the ICMR STG of 2017? (refer the ICMR 2017 STG and mark the response) Yes / No
21. Is the dose appropriate as per the antimicrobial that is prescribed? Yes / No
22. Is the duration of antimicrobial prescription appropriate as per the ICMR STG of 2017? Yes / No



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Interview Checklist for Hospital Level Antimicrobial Use Indicators – MS/DMS/RMO

Infrastructure for Antimicrobial Stewardship

1. Does your facility have a functioning Hospital Infection Prevention & Control Committee? Yes / No
2. Details of Committee
    a. How many members? _____
    b. How often does it meet?
    c. When did the committee meet last?
    d. Is there a nurse in the committee?
    e. Is there an clinical infectious diseases specialist (General Medicine) in the committee?
    f. Is there a microbiologist in the committee?
3. Does your facility have a functioning committee on pharmacovigilance? Yes / No
    a. How many members? _____
    b. How often does it meet?
    c. When did the committee meet last?
    d. Is there a nurse in the committee?
    e. Is there an clinical specialist (General Medicine) in the committee?
    f. Is there a pharmacologist in the committee?

4. Does your facility have microbiological laboratory/division within the hospital? Yes / No
5. If no, Does your facility have access to microbiological services outside the hospital? Yes / No
6. Does your facility have an antimicrobial stewardship committee? Yes / No
    a. How many members? _____
    b. How often does it meet?
    c. When did the committee meet last?
    d. Is there a nurse in the committee?
    e. Is there an clinical specialist (General Medicine) in the committee?

7. Could you describe the infrastructural challenges faced in ensuring appropriate use of antimicrobials in your hospital?

_____

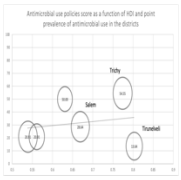
Could you describe the additional infrastructure support from the health system that you would require to ensure appropriate antimicrobial use in your health facility?

Policy and Practices for appropriate use of antimicrobials

8. Does your facility have an antimicrobial formulary (including unrestricted and restricted antimicrobials) updated continuously?
9. Is your antimicrobial formulary based on the National Essential Drug List?
10. Does your facility have a local antimicrobial guideline specific for your facility?
11. Are your local antimicrobial guidelines based on local antimicrobial susceptibility to assist with antimicrobial selection for common clinical conditions?
12. Do you have any restrictions in place for prescription of antimicrobials? (e.g., only authorized persons can sign antimicrobial prescriptions, only certain antimicrobials can be prescribed by certain groups of doctors, all antimicrobial prescriptions must be signed by prescribing doctor and an authorized person etc.)
13. Does you facility have a copy of the ICMR standard treatment guidelines for antimicrobial use in common syndromes?
14. Do you have any other STG for antimicrobial use?
15. Which one of the STG for antimicrobial use do you have?
16. Does your facility have a written policy that requires prescribers to document an indication in the medical record or during order entry for all antimicrobial prescriptions?
17. Does your facility have a written policy that requires prescribers to order appropriate microbiological tests before prescribing antimicrobials?
18. Is there a formal procedure for a physician, pharmacist, nurse or other staff member to review the appropriateness of an antimicrobial at or after 48 hours from the initial order (post-prescription review)?
19. How is this implemented? Details?
20. Have your doctors undergone training on antimicrobial prescription and antimicrobial resistance?
21. Have your nurses undergone training on antimicrobial administration and antimicrobial resistance?
22. Does your facility have a policy that encourages conversion from parenteral to oral antimicrobials as early as possible?
23. Does your facility have a policy that encourages minimizing the overall duration of antimicrobial use?
24. Do you have electronic drug ordering system in your hospital?
25. Do you have electronic health records?

Monitoring and feedback regarding appropriate use of antimicrobials

26. Does your facility audit whether the indication is captured in the medical record for all antimicrobial prescriptions?
27. Does your facility audit or review surgical antimicrobial prophylaxis choice and duration?
28. Are results of antimicrobial audits or reviews communicated directly with prescribers?
29. Does your facility monitor antimicrobial use by grams (Defined Daily Dose [DDD]) or counts (Days of Therapy [DOT]) of antimicrobial(s) by patient per day?
30. Is monitored antimicrobial use reported by hospital activity denominator (by number of admissions/discharges or by number of bed-days/patient-days)?
31. How many blood cultures have been tested in the past year?
32. List of antimicrobials out of stock at the facility during the survey period.



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Are antimicrobials appropriately used in public health facilities as per the treatment guidelines for antimicrobial use in common syndromes?

அறிமுகம்

நான் _____, இ.எஸ்.ஐ.சி மருத்துவக் கல்லூரி மற்றும் பி.ஜி.ஐ.எம்.எஸ்.ஆர்., சென்னையில் பணி செய்கிறேன். தமிழ்நாட்டில் உள்ள பொது சுகாதார மையங்களில் ஆண்டிபயாடிக் மருந்துகளின் சரியான பயன்பாட்டைப் புரிந்துகொள்வதற்கான பணி எனக்கு வழங்கப்பட்டுள்ளது. இந்த தகவலை தமிழ்நாட்டின் பல்வேறு சுகாதார மையங்களில் உள்ள நோயாளிகளிடமிருந்து சேகரித்து பொது சுகாதார மையங்களில் ஆண்டிபயாடிக் மருந்துகளின் பயன்பாட்டை மேம்படுத்துவதற்கான பரிந்துரைகளுடன் ஒரு அறிக்கையை சமர்ப்பிக்க விரும்புகிறேன்.

ஆராய்ச்சியின் நோக்கம்

ஆண்டிபயாடிக் என்பது மனித உடலில் தொற்றும் பாக்டீரியா மற்றும் பிற நுண்ணுயிரிகளை கொல்ல பயன்படும் மருந்துகள். இந்த நுண்ணுயிரிகளை கொல்வதன் மூலம் ஆண்டிபயாடிக் மருந்துகள் மனிதர்கள் நோயிலிருந்து மீள உதவுகின்றன. தொற்று நோய்களை எதிர்த்துப் போராட ஆண்டிபயாடிக் மருந்துகள் மிகவும் பயனுள்ள கருவிகள். இருப்பினும், அவை எப்போதும் சரியான முறையில் பயன்படுத்தப்படுவதில்லை. சில நேரங்களில் தவறான ஆண்டிபயாடிக் மருந்துகள் பரிந்துரைக்கப்படுகின்றன, சில நேரங்களில் தவறான அளவு பரிந்துரைக்கப்படுகிறது மற்றும் சில நேரங்களில் நோயாளிகள் முழு பரிந்துரைக்கப்பட்ட காலத்திற்கு நுண்ணுயிர் எதிர்ப்பிகளின் பயன்பாட்டை முடிக்க மாட்டார்கள். இந்த நடைமுறைகள் ஆண்டிபயாடிக் மருந்துகளுக்கு பாக்டீரியாவின் எதிர்ப்பு வெளிப்படுவதற்கு வழிவகுக்கிறது, அதாவது இந்த ஆண்டிபயாடிக் மருந்துகளால் இந்த பாக்டீரியாக்களை இனி கொல்ல முடியாது. இது மிகவும் ஆபத்தான நிலைமை, ஏனெனில் எதிர்காலத்தில் நுண்ணுயிரிகளை எதிர்த்துப் போராடுவதற்கான கருவிகள் எதுவும் நம்மிடம் இருக்காது. எனவே, ஆண்டிபயாடிக் மருந்துகளின் சரியான பயன்பாட்டை ஊக்குவிக்க வேண்டிய அவசியம் உள்ளது. தற்போதுள்ள ஆண்டிபயாடிக் பயன்பாட்டு முறைகள் என்ன, அவை தமிழகத்தில் பொது சுகாதார மையங்களில் சரியான முறையில் பயன்படுத்தப்படுகின்றனவா இல்லையா என்பதைப் புரிந்துகொள்ள இந்த ஆய்வு வடிவமைக்கப்பட்டுள்ளது.

ஆராய்ச்சி வகை

இந்த ஆய்வில் உங்கள் நோய் விவரங்கள், மருத்துவமனையில் தங்களுக்கு எடுக்கப்பட்ட சோதனைகள், நீங்கள் ஆண்டிபயாடிக் மருந்துகள் பயன்படுத்தினீர்களா இல்லையா மற்றும் பயன்படுத்தப்பட்ட ஆண்டிபயாடிக் மருந்துகளின் விவரங்களுக்கு உங்கள் மருத்துவமனை கேஸ் ஷீட்டுகளை ஆராய்வது அடங்கும்.

பங்கேற்பாளர் தேர்வு

ஆண்டிபயாடிக் பயன்பாட்டு முறைகளைப் புரிந்து கொள்ள, ஆராய்ச்சியின் போது மருத்துவமனையில் அனுமதிக்கப்பட்ட நோயாளிகளின் கேஸ் ஷீட்டுகளை நாங்கள் பரிசோதிக்க வேண்டும். பங்கேற்க நீங்கள் தோராயமாக தேர்வு செய்யப்பட்டுள்ளீர்கள்.

தன்னார்வ பங்கேற்பு

இந்த ஆய்வில் பங்கேற்பது முற்றிலும் தன்னார்வமானது. நீங்கள் ஆய்வில் பங்கேற்கிறீர்களா இல்லையா என்பதைப் பொருட்படுத்தாமல், முன்பு போலவே அதே சிகிச்சையையும் தொடர்ந்து பெறுவீர்கள்.

நடைமுறைகள் மற்றும் நெறிமுறை

இந்த ஆய்வில் பங்கேற்க நீங்கள் ஒப்புக்கொண்டால், உங்கள் கேஸ் ஷீட்டை நாங்கள் கவனமாக படிப்போம். உங்கள் மருத்துவ வரலாறு, பரிசோதனை முடிவுகள், ஆய்வக சோதனை முடிவுகள், ஸ்கேன் முடிவுகள் மற்றும் சிகிச்சை விவரங்களை நாங்கள் குறித்துக்கொள்வோம். உங்கள் நோயை நாங்கள் சரிபார்த்து, நீங்கள் பெற்ற சிகிச்சையை இந்திய மருத்துவ ஆராய்ச்சி கவுன்சில் பரிந்துரைத்த தரமான சிகிச்சை வழிகாட்டுதல்களுடன் ஒப்பிடுவோம். நீங்கள் தற்போது பெறும் சிகிச்சையில் நாங்கள் தலையிட மாட்டோம், மேலும் உங்கள் மீது கூடுதல் சோதனைகள் அல்லது நடைமுறைகளைச் செய்ய மாட்டோம்.

ஆராய்ச்சியின் போது, நாங்கள் உங்களுடன் அடிக்கடி தொடர்பு கொள்ளத் தேவையில்லை. நாங்கள் உங்களை ஒரு முறை சந்திப்போம், ஆய்வை விளக்கி உங்கள் ஒப்புதலைப் பெறுவோம். உங்கள் கேஸ் ஷீட்டிகளை நாங்கள் மதிப்பாய்வு செய்து முக்கியமான புள்ளிகளைக் குரித்துக்கொள்வோம். அதனுடன், ஆய்வு முடிக்கப்படும்.

அபாயங்கள்
உங்கள் நோய் மற்றும் ஆண்டிபயாடிக் மருந்து பயன்பாடு பற்றிய தகவல்களைப் பிரித்தெடுக்க உங்கள் கேஸ் ஷீட்டுகளை நாங்கள் பயன்படுத்துவதால், உங்கள் மருத்துவத் தகவலின் இரகசியத்தன்மையை மீறும் ஒரு சிறிய ஆபத்து உள்ளது. உங்கள் ரகசியத்தன்மையைப் பாதுகாக்க நாங்கள் முயற்சிப்போம், மேலும் நீங்கள் பெறும் சிகிச்சையை நாங்கள் தொந்தரவு செய்யாதபடி நாங்கள் கேஸ் ஷீட்டுகளைஅதிக நேரம் வைத்திருக்கவில்லை என்பதை உறுதி செய்வோம்.

நன்மைகள்
இந்த ஆய்வில் பங்கேற்பதன் மூலம் நீங்கள் எந்த நேரடி நன்மைகளையும் பெற வாய்ப்பில்லை. இருப்பினும், உங்கள் தரவிலிருந்து பெறப்பட்ட அறிவு எதிர்கால நோயாளிகளுக்கு ஆண்டிபயாடிக் மருந்துகளின் சிறந்த பயன்பாட்டைத் திட்டமிட உதவும்.

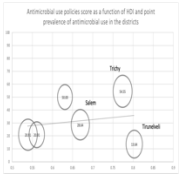
ரகசியத்தன்மை
இந்த ஆய்வின் போது உங்களிடமிருந்து பெறப்பட்ட தகவல்கள் ரகசியமாக வைக்கப்படும். உங்கள் கேஸ் ஷீட்டில் இருந்து தகவல்களைப் பிரித்தெடுக்கும்போது, உங்கள் பெயரையும் பிற தனிப்பட்ட அடையாளம் காணும் தகவலையும் நாங்கள் சேகரிக்க மாட்டோம். மறைகுறியாக்கப்பட்ட மற்றும் பாஸ்வேர்டால் பாதுகாக்கப்பட்ட மென்பொருளில் தரவு சேகரிக்கப்படும், அவை ஆராய்ச்சியாளர்களுக்கு மட்டுமே அணுகக்கூடியதாக இருக்கும்.

முடிவுகளைப் பகிர்தல்
இந்த ஆராய்ச்சியின் கண்டுபிடிப்புகள் பொது சுகாதார மையங்களில் ஆண்டிப்யாடிக் மருந்துகளின் பயன்பாட்டை மேம்படுத்த உதவும் வகையில் தமிழக சுகாதார அமைப்புடன் பகிரப்படும். இருப்பினும், கண்டுபிடிப்புகளைப் பகிரும்போது, உங்கள் ரகசியத்தன்மையை நாங்கள் பாதுகாப்போம்.

யாரைத் தொடர்பு கொள்ள வேண்டும்
இந்த ஆய்வு தொடர்பான ஏதேனும் சந்தேகங்கள் அல்லது கேள்விகள் இருந்தால், நீங்கள் முதன்மை புலனாய்வாளரான விஜயபிரசாத் கோபிசந்திரனை (+91 9445226806) தொடர்பு கொள்ளலாம்.

பகுதி II: ஒப்புதல் சான்றிதழ்
மேற்கூறிய தகவல்களை நான் படித்திருக்கிறேன், அல்லது அது எனக்கு வாசிக்கப்பட்டுள்ளது. அதைப் பற்றி கேள்விகளைக் கேட்க எனக்கு வாய்ப்பு கிடைத்தது, நான் கேட்ட அனைத்து கேள்விகளுக்கும் எனது திருப்திக்கு பதிலளிக்கப்பட்டுள்ளன. இந்த ஆராய்ச்சியில் பங்கேற்பாளராக பங்கேற்க நான் தானாக முன்வந்து ஒப்புக்கொள்கிறேன்.
பங்கேற்பாளரின் பெயர் _____
பங்கேற்பாளரின் கையொப்பம் _____
தேதி _____
நாள் / மாதம் / ஆண்டு

ஆய்வாளரின் பெயர் _____
ஆய்வாளரின் கையொப்பம் _____
தேதி _____
நாள் / மாதம் / ஆண்டு



ESIC Medical College and PGIMSR, KK Nagar, Chennai 78
OR - Tamil Nadu Health System Reform

Are antimicrobials appropriately used in public health facilities as per the treatment guidelines for antimicrobial use in common syndromes?

Informed Consent form for health care providers in health facilities

Introduction
I am _____, working for the ESIC Medical College and PGIMSR, Chennai. I have been given the assignment to understand appropriate use of antimicrobials in public health facilities in Tamil Nadu. I intend to collect this information from health care providers

(medical superintendent / resident medical officers / nursing superintendents / doctors / nurses) in various health facilities in Tamil Nadu and submit a report with recommendations to improve the use of antimicrobials in public health facilities.

Purpose of the research

Antimicrobials are very useful tools to fight infectious diseases. However, they are not always used appropriately. Sometimes wrong antimicrobials are prescribed, sometimes wrong dosage is prescribed and sometimes patients do not complete the use of antimicrobials for the full prescribed period. These practices lead to emergence of resistance of the bacteria to the antimicrobials, which means that these antimicrobials can no longer be effective against these bacteria. This is a very dangerous conditions, as we may end up not having any tools to fight micro-organisms in the future. Therefore, there is a need to encourage correct use of antimicrobials. This study has been designed to understand what the existing antimicrobial use patterns are and whether they are being used appropriately or not in public health facilities in Tamil Nadu.

Type of Research

This research will involve interviewing you with a few questions to understand antimicrobial use patterns in your hospital.

Participant selection

To understand the antimicrobial use patterns in the state, we have sampled a few health facilities. Your health facility has been sampled and you are invited to participate in this study from your health facility.

Procedures and Protocol

If you consent to participate in this study, we will conduct a detailed interview with you. During this interview we will ask you specific questions regarding antimicrobial policies, antimicrobial procurement, antimicrobial stocks in the pharmacy, standard treatment guidelines followed for use of antimicrobials, and appropriate use of antimicrobials. We will be audio recording the interviews. Then we will transcribe these interviews and analyze them. The total duration of the interview is not likely to be more than 30 mins.

Risks

As we will be conducting an interview for about 30 minutes, we may be briefly interrupting your work. We will ensure that we fix up the most convenient time for the interview so that we don't hamper your routine work. We will carefully protect your confidentiality and will not reveal sensitive information revealed by you during the interview.

Benefits

You are unlikely to receive any direct benefits from participating in this study. However, knowledge gained from your data will help plan better use of antimicrobials for future patients.

Confidentiality

Information obtained from you during this study will be kept confidential. The data will be collected in encrypted and password protected software which will be accessible only to the researchers.

Sharing the Results

The findings of this research will be shared with the Tamil Nadu health system in order to help them improve the use of antimicrobials in the public health facilities. However, while sharing the findings, we will protect your confidentiality.

Who to Contact

If you have any doubts or questions related to this study, you may contact the principal investigator, Vijayaprasad Gopichandran (+91 9445226806).

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been

answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the procedures to be followed in the study.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Photo Gallery

Meeting with Dean and College Council in Theni Medical College for the research project

Field Staff collecting data in the health facilities

Research team with Dean, Pudukkottai Medical College

Interview with Medical Superintendent and Nursing Staff in Musiri GH