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**Appropriateness of Antimicrobial Therapy and Associated factors at
Zewditu Memorial Hospital Inpatient setting: Retrospective cross-
sectional study**

A thesis paper to be submitted to Tikur Anbessa Specialized Hospital,
ECCM Department as a Partial fulfillment of the requirement for a post-
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Acronym

AAU	Addis Ababa University
AFEM	African Federation of Emergency Medicine
AMR	antimicrobial resistance
CKD	Chronic Kidney Disease
CNS	Central nervous system
ETH	Ethiopian
ESTG	Ethiopian standard treatment guidelines
EONS	Early Onset Neonatal Sepsis
HURH	Hawassa University Referral Hospital
ICU	Intensive Care Unit
JUCSH	Jimma University specialized hospital
LRTI	Lower respiratory tract infection
MDO	Multiple dose omitted
SDO	Single dose omitted
TASH	Tikur Anbessa Specialized Hospital
ZMH	Zewditu Memorial Hospital

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Abstract

Background: Misuse and unnecessary antimicrobial therapy is becoming more widespread and results in antimicrobial resistance all over the world. Despite this, antibiotics are being used inappropriately specially in the inpatient setting.

Objective: A hospital-based cross-sectional study was conducted in medical ward and ICU OF ZMH from March, 2024 to May, 2024. Data were collected using Kobo tool box which contains each patient's socio-demographic characteristics, diagnosis, antimicrobials given to the patients. Patient selection was through systematic random sampling technique of patients' charts for whom antibiotics were administered. The data was analyzed using SPSS software version 26.

Results: A total of 257 patients during the study period who were taking antimicrobials were reviewed. This study reveals that antimicrobials were administered for majority of the cases based on empiric diagnosis (74.3%). The major reason for which antibiotics were prescribed were lower respiratory tract infections (LRTI) accounting for 47.9% of the cases (N=123,) followed by gastrointestinal infections (n=14, 5.4%). 184(71.6%) of the patients had interruption of antibiotic administration during treatment period (either a single or multiple doses of antibiotics were omitted). In 144(56%) of the patients either the dose, route of administration, frequency or duration of antibiotic therapy was inappropriate. Residence outside Addis (P=0.036) and having comorbidities (P=0.03) were the factors which are independent determinants of inappropriate antimicrobial use .

Conclusion: Antimicrobials were among the most commonly administered drugs for patients who were admitted to Medical ward and ICU. Most patients were being exposed to inappropriate antimicrobial therapy. Comorbidities and residence were the two factors that were found to have significant association with inappropriate antimicrobial usage.

INTRODUCTION

Background

Even though, the development of various antimicrobials to treat infections was one of the best achievements in human history, this is being challenged by the growing burden of resistance to already available antimicrobials throughout the entire world. This antimicrobial resistance is being associated with significant increase in morbidity and mortality of patients. According to WHO reports in 2019, 1.3 million deaths were directly attributed to resistance of microbes to already existing antimicrobial therapy. Even if, it is impossible to fully overcome the problem, reducing inappropriate use of antimicrobials will significantly down play the prevalence.

In order to decrease the unnecessary use of antibiotics, global efforts must be made with the involvement of each country stakeholders and should recognize the available over the counter antibiotics in most parts of the world. This is crucial since in most of low income countries, there are just only few Doctors and other health professionals in the community. In such setups, over the counter medications are associated with misuse of antimicrobials.

Statement of the problem

Inappropriate administration of antimicrobials significantly increase the risk of antibiotic resistance which pose great risk even for treating minor infections. This put a heavy burden on the health system especially on developing country like Ethiopia were there are not much options of antibiotic choices to treat patients.

No country in this world is immune of antimicrobial resistance and the presence of poverty makes the situation even worse. For example, absence of access to clean water, sanitation and hygiene, and even the financial issues when patients get sick is becoming a huge burden on the health care system.

Irrational use of antimicrobials is associated with resistant microbial emergence. In spite of this, antimicrobial agents are commonly given in the inpatient setting. In one study done in Ethiopia, The study revealed that antimicrobials were prescribed for most of the patients (88.9%) based on empiric diagnosis without culture result. The diagnosis made for antibiotic use were pneumonia in 16.8% of the cases and EONS in 14.0% of the patients. Ceftriaxone was the antibiotic most commonly used (84.9%) among the single therapeutic agents, whereas ceftriaxone and metronidazole (23.5%) were the antibiotics that were used most frequently as a combination therapy.

Even though, there are previous studies on appropriateness of antibiotic therapy in our country, the studies only focus in pediatric population. Furthermore, I couldn't get comprehensive publications that correlates AMR with patterns of antibiotic/s prescription. Furthermore, none of the studies looks for antiviral and antifungal prescription pattern. As result, This study will provide details on both overall antimicrobial prescription pattern and magnitude of AMR. There is also a growing concern for increased pattern of resistance of microbes to already existing antibiotics as time goes by, including to carbapenems.

Additionally, For the last couple of years culture was done to majority of patients admitted to Zewditu Memorial Hospital which was not the trend before. Therefore, this study will be conducted with no difficulty regarding getting culture result of patients admitted to the ICU. The implementation of EMR system in the hospital will give me easy access on antibiotics administered, their specific duration and mode of administration.

Significance of the study

Despite a clear alarming situation from WHO that misuse of antibiotics and/or improper selection of antimicrobial as one of the major reason for the growing burden of AMR, there isn't much done to control its prevalence especially in developing countries like Ethiopia. This is partly because the real crisis of antibiotics resistance on the health system, the economy of the country and the outcome of patients with AMR in particular, is not well studied.

Therefore, this study will help us to influence misuse/improper choice of antibiotics, to develop updated guidelines on AMR and inform health professionals regarding the broader picture of antimicrobial resistant on patients outcome. Additionally, this study will clearly shows in what chaotic situation we are, the burden on the patients and the possible ways out.

The study can also be a great input to policy makers and other responsible stake holders such as Ministry of Health, CDC, WHO, World Bank and all others who show their concern on this burning issue. Such stake holders will aid in developing local strategies to limit the problem as like WHO's one health initiatives.

Literature Review.

The irrational use of antibiotics is one of the many, in fact the major contributor of antimicrobial resistance across all countries. This misuse and the concomitant rapid growth of AMR is a well-known accepted threat to human health, sustainable growth and development.

Antimicrobial resistance needs utmost attention due to associated increase in morbidity and mortality. It affects people of all age categories in all regions of the world whether high income, middle income or low income countries but the highest burden is seen in middle and low income countries. Such problems create high socioeconomic crisis. According to WHO estimate, about 1.7 million deaths all over the world were attributed to bacterial infections which are resistant to already existing antimicrobials.

Irrational use of antimicrobials is associated with resistant microbial emergence. In spite of this, antimicrobial agents are commonly given in the inpatient setting. In one study done in Ethiopia, The study revealed that antimicrobials were prescribed for most of the patients (88.9%) based on empiric diagnosis without culture result. The diagnosis made for antibiotic use were pneumonia in 16.8% of the cases and EONS in 14.0% of the patients. Ceftriaxone was the antibiotic most commonly used (84.9%) among the single therapeutic agents, whereas ceftriaxone and metronidazole (23.5%) were the antibiotics that were used most frequently as a combination therapy.

One of the main strategies to combat antimicrobial resistance is surveillance. Its lack leads to ineffective policies and waste of resources. It is important to understand the pattern of antimicrobials utilization and associated resistance in order to identify priority areas, to plan for interventions and to monitor the response to the interventions.

A major problem behind administering inappropriate antimicrobials is lack of enough diagnostic workup for early identifications of the organisms. This results in utilizations of antibiotics empirically. Additionally, culture and sensitivity results take significant time which causes physicians no choice but to treat empirically.

OBJECTIVE

General Objective

Appropriateness of antimicrobial therapy and associated factors at Zewditu Memorial Hospital Inpatient setting: Retrospective cross-sectional study

Specific Objective

To assess appropriateness of antimicrobial prescription pattern

To assess the outcome of patients treated with antimicrobials.

To explore the magnitude of AMR.

METHODOLOGY

Study area and Period

The study was conducted at Zewditu Memorial Hospital which is located in Addis Ababa, the capital city of Ethiopia and the head quarter of African Union. ZMH is located in central Addis Ababa. The hospital provides various clinical services including emergency health care, inpatient and outpatient health care, ICU, Ophthalmology, Psychiatry, surgery, laboratory, maternal and child health services. Recently, the hospital is building a new building which has separate ICU's for pediatric and adult patients.

Study Design

The cross-sectional study was employed by collecting primary data from medical records or a retrospective chart review was used.

Population

Source Population

All those patients admitted to Zewditu Memorial Hospital Medical ward and ICU during the study period.

Study Population

All patients admitted to Zewditu Memorial Hospital inpatient and received antimicrobial treatment during the study period.

Study Unit

Patients in ZMH Medical ward and ICU who were receiving antimicrobials.

Sampling Frame

Inclusion Criteria

Patients in ZMH inpatient setting who received antimicrobial therapy.

Exclusion Criteria

Admitted patients who were not on antimicrobial

Pediatric patients at ICU

Culture result which is considered from skin or other contaminant.

Sample size determination and sampling technique

A whole sampling technique was used which include all patients taking antimicrobial and who were admitted to ZMH from March 01/2022 to May 30/2024 and who fulfill the Inclusion criteria. But the minimum sample size for the study will be determined using single population proportion formula because the proportion of Trends of empirical antibiotics prescription and outcome of patients with AMR is not known and there is no similar study done previously in Ethiopia:

$$N = \frac{(Z_{\alpha/2})^2 \times p(1-p)}{d^2}$$

Where:

N= sample size required

$Z_{\alpha/2}$ = Critical value=1.96

d= marginal error =0.02

P - is taken as 50%

$$n = \frac{(1.96)^2 \times (0.889) \cdot (1-0.889)}{(0.02)^2}$$

$$= 947.71=948$$

Since the source of population is less than 10,000, population correction formula is used to determine adjusted minimum sample size.

$$n_{adj} = \frac{n}{(1+(n/N))}$$

Where; n = initial sample size (948)

N = total number of source population (305)

$$n_{adj} = \frac{948}{(1+(948/305))}$$
$$= 230.76=231$$

The sample size for this study after adding 10% contingency rate will be 257

Study Variables

Dependent Variables

Appropriateness of antimicrobial prescription pattern

Independent variables

Age

Sex

Socioeconomic status

Diagnostic investigation results

Focus of the infection

Hospital length of stay

Operational definitions

Antibiotic resistance-the resistance of microbes to medications administered which is proven by culture result.

Appropriateness of antimicrobial therapy (AAT)- means the right indication plus an appropriate pattern of antibiotic administration, which includes dose, duration, frequency and route of administration.

Data collection tool, Methods and Procedures

Two data collectors and two supervisors who are senior physicians with ample experience on the field were allocated. Data collection is through a pre-structured questionnaire which is prepared by modifying a research questionnaire from previously published research paper.

Result Dissemination Plan

The study result will be submitted to Addis Ababa University, School of Medicine-Department of ECCM in both soft and hard copy. The research paper might also used for presentation purpose in conferences such as AFEM and others.

Ethical Consideration

The research proposal will be submitted to AAU, School of Medicine and ZMH ethical review committee in order to get a written legal ethical clearance. When permission is granted, the data collection will commence.

Results

Socio-demographic characteristics

A total of 257 patients during the study period who were taking antimicrobial/s were analyzed and evaluated for appropriateness of antimicrobial prescription pattern at Zewditu Memorial Hospital Medical ward and ICU. Among them, 160(62.3%) were male and 217 (84.4%) of the patients were from Medical ward. The mean age of the study population is 47.07 with age range between 15 to 100. Regarding their

residence, 242(94.2%) of the patients came from Addis Ababa while the rest of them came from Oromia Region.

Regarding their payment status, 42.8%(N=110) of the patients pay out of pocket for their treatment (self-care) while 78(30.4%) had community based health insurance, 53(20.6%) were exempted, 4(1.6%) were partially exempted (patients who sustained RTA), 5(1.9%) were labeled as social, 3(1.2%) were staff and 4(1.6%) of them had unknown payment status.

Table 1

Socio-demographic Characteristics	Frequency	Percent
Male	160	62.3
Female	97	37.7
Residence		
From Addis Ababa	242	94.2
Out Side Addis Ababa	15	5.8
Ward		
Medical ward	217	84.4
ICU	40	15.6

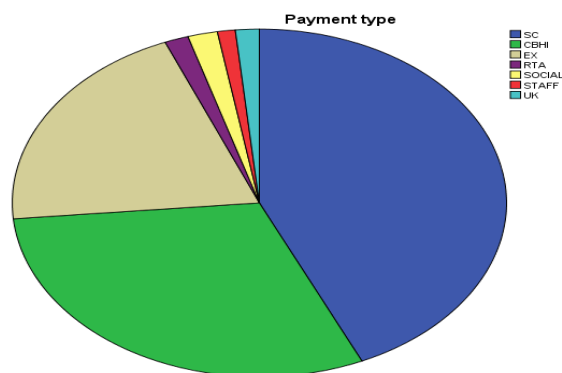


Figure 1-Payment status of

patients.

Type of Diagnosis, Culture result and Drugs prescription pattern

191(74.3%) of the patients were taking antibiotics empirically while the rest of them were taking either definitive(based on culture result) or prophylactically each accounting for 63(24.5%) and 3(1.2%) respectively. For patients who were taking definitive or targeted therapy, 42(66.67%) of them had their antibiotics revised after

culture result and the rest of them continued with empirical antibiotic choice. In general, for 34(13.2%) of the patients admitted during the study period, antibiotics were revised regardless of their culture status (before culture result).

In majority of the patients (N=123, 47.9%), the focus of infection was lower respiratory tract alone and LRTI concomitantly with one or more other systems accounts for 74 % (N=191) of the cases. Gastrointestinal tract infections alone accounts for 14(5.4%), CNS infections alone 9(3.5%), relapsing fever with or without systemic involvement 10(3.9%) and 2(0.8%) for skin infections. 4(1.2%) taking antibiotics for prophylaxis, and 4(1.2%) for unspecified or undocumented reason. In 53(20.62%) of the cases, there was involvement of two or more organ systems.

Culture was sent only for 81(31.5%) of patients and 38(46.91%) of them had positive culture result while others has shown no growth. The commonest source of culture was blood which accounts for 71.6%(N=58) of the cases. In 30.86%(N=25) of the patients culture was done from Urine, in 25.93%(N=21) of them Sputum was the source of culture, In 8.64%(N=7) of them Tracheal aspirate was the source of culture. Other rare sources of culture includes Pleural fluid, Body fluid and cerebrospinal fluid (CSF).

Regarding health care associated infection, 30(11.67%) of the patients had developed hospital acquired infection (HAP) and 3(1.17%) developed ventilator associated pneumonia (VAP).

Comorbidities and Length of Stay

175(68.1%) of the patients had one or more comorbidities. Hypertension was the commonest comorbidity found and followed by Heart Failure, Diabetes mellitus, chronic kidney disease and old stroke respectively.

Others include COPD, HIV/AIDS, Asthma, Malignancy, Hyperthyroidism/Hypothyroidism, Post TB fibrosis, chronic liver disease, ulcerative colitis, Epilepsy, peptic ulcer disease, benign prostatic hyperplasia and unspecified Psychiatric illness. The minimum length of stay was 2 days where as the maximum length of stay was 87 days.

Appropriateness of antimicrobial therapy

184(71.6%) of the patients had interruption of antibiotic administration during treatment period (either a single or multiple doses of antibiotics were omitted). In 144(56%) of the patients either the dose, route of administration, frequency or duration of antibiotic therapy was inappropriate.

The intravenous route of the administration account for most (75.3%) of the antimicrobials. The most common PO antibiotic given during discharge was cotrimoxazole(48.6%). The minimum duration of antibiotic therapy was single dose(stat) and the maximum duration of therapy was 49 days. 15.2 % (N=39) of the patients had history of antibiotic use in the past three months.

Harrison Textbook of Internal Medicine, Up-to-date online, Tintinalli's 9th edition and ESTG for general hospitals were used as references.

Concomitant antiviral and antifungal Medications

16(6.2%) of the patients were taking anti-fungal medications concomitantly and Cryptococcal Meningitis was the commonest diagnosis made to use antifungal. None has fungal culture done during their treatment period. 25(9.7%) were also taking antiviral treatment with viral meningoencephalitis being the commonest admission diagnosis made(N=12, 48%).

Factors Associated with Appropriateness of Antibiotic Therapy

The appropriateness of antibiotic therapy among patients admitted to medical ward and ICU was associated with several factors. There was more inappropriate antibiotics administration in patients from medical ward than ICU. (AOR=4.837, 95% CI=2.145– 10.911, P=0.001). Significant associations were also observed between the appropriateness of antibiotic therapy and both the residence and comorbidities. Patients from outside Addis Ababa had higher level of inappropriate antimicrobial therapy (AOR=9.612 CI=1.159-79.68, P=0.036). Regarding their comorbidities, Patients with comorbidities are likely to have antimicrobial treatment interruption compared to those without comorbidities (AOR=6.81 95% CI 3.135-15.00 P=0.03).

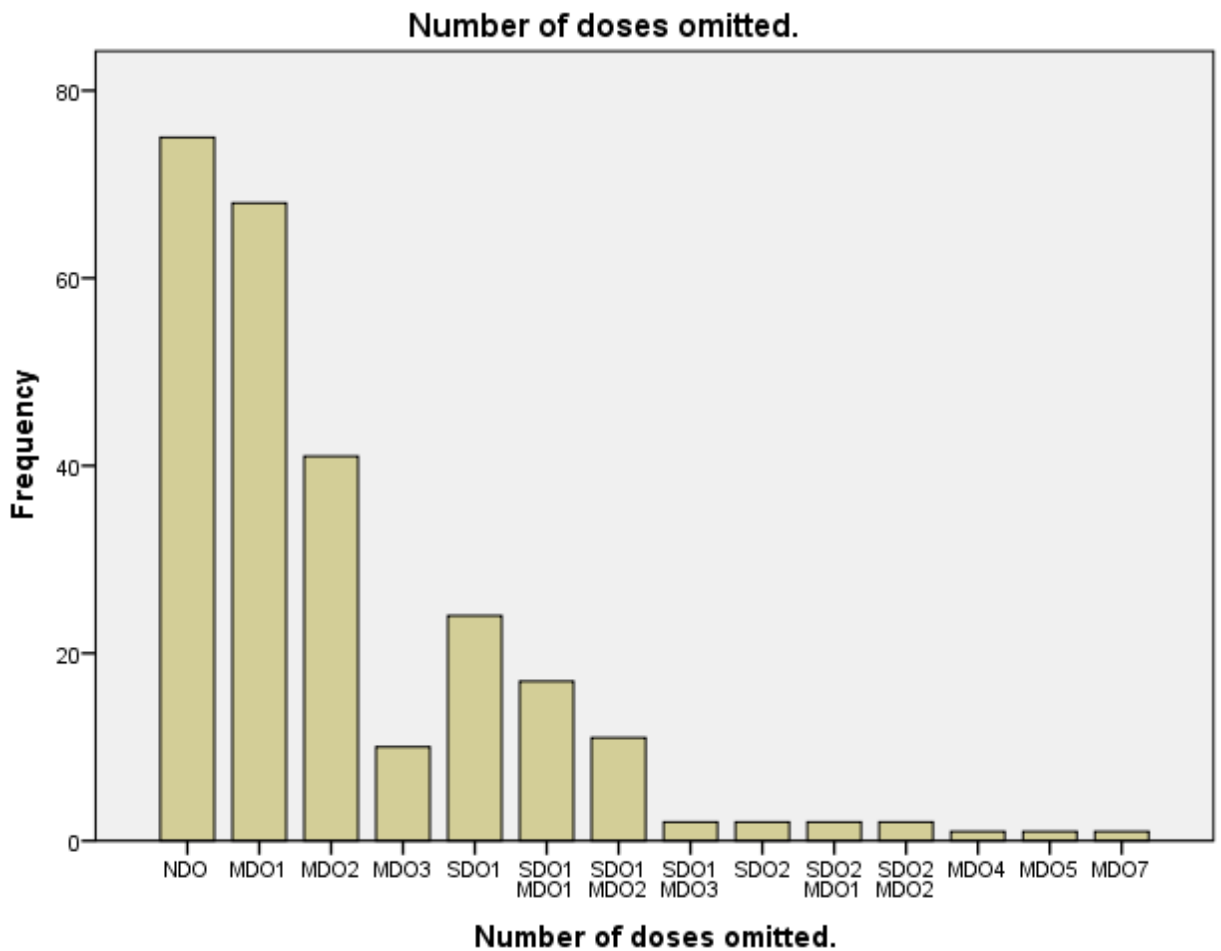
Table 2

Number of doses omitted		
	Frequency	Percent
NDO	75	29.2
MDO1	68	26.5
MDO2	41	16.0
MDO3	10	3.9
SDO1	24	9.3
SDO1 MDO1	17	6.6
SDO1 MDO2	11	4.3
SDO1 MDO3	2	.8
SDO2	2	.8
SDO2 MDO1	2	.8
SDO2 MDO2	2	.8

MDO4	1	.4
MDO5	1	.4
MDO7	1	.4
Total	257	100.0

NDO=no dose omitted, SDO-single dose omitted, MDO-multiple dose omitted(ex. SDO1- for 1 drug single dose omitted, MDO3- For 3 of the drugs multiple doses omitted)

Figure 2



Reason for Antibiotic omission

The main reason for antibiotic omission is due to lack of the prescribed medication followed by patient refusal, patients absence at bedside and financial issues to buy the drugs. Other reasons mentioned include no IV line to administer antibiotics and no IV fluids to dilute the medications.

Table 3

Reason for omission	Frequency	Percent
No omission	73	28.4
Medication not available	149	57.8
Medication not available + patient refusal	10	3.9
Medication not available + patient absent	8	3.1
Financial reason	6	2.3
Patient refusal	4	1.6
Medication not available + no IV line	2	0.8
Patient absent	1	0.4
Medication not available + Patient refusal + no IV fluid to dilute medications	1	0.4
Medication not available + Patient refusal + patient absent	1	0.4
Medication not available + Financial reason + Patient absent	1	0.4
Medication not available + Financial reason	1	0.4

Outcome

Regarding their outcome, 207(80.5%) of the patients during the study period were discharged improved while 39(15.2%) of them died, 5(2%) left against medical advice, 4(1.6%) disappeared from medical ward and ICU, 1(0.4%) transferred to other hospital and, 1(0.4%) had unknown discharge status.

Discussion

In this study, males patients account for the majority the cases (n=160, 62.3%), and came from Addis Ababa (n=24294.2%). Majority of the patients pay out of pocket for their treatment (n=108, 42%) while 78(30.4%) had community based health insurance.

In this study, lower respiratory tract infection alone was the commonest focus of infection accounting for 123(47.9%) of the cases. LRTI concomitantly with one or

more other systems accounts for 74% (N=191) of the cases. This is followed by gastrointestinal tract infections alone account for 14(5.4%) and CNS infections alone 9(3.5%). These results are almost comparable with other studies done in Shenan Gibe Hospital, where the main diagnosis for antibiotic use were pneumonia (n=125, 38.5%), sepsis (n=49, 15.2%), and acute gastroenteritis (n=41, 12.7%).

Majority of the patients (n=226, 87.9%) were treated with a combination of two or more antibiotics, while the rest of them 31 (12.1%) were treated with monotherapy. The highest number of antibiotics used for a single patient was ten, which was higher than in the study conducted in HURH, where it was found to be three, and JUCSH, where it was found to be four.

Multivariable logistic regression analysis of the study revealed that inappropriate antimicrobial therapy was significantly associated with residence and comorbidities. There was higher inappropriate drug therapy in patients from outside Addis than patients outside Addis Ababa (AOR=9.612 CI=1.159-79.68, P=0.036).

Conclusion

Antimicrobials were among the most commonly administered medications for patients who were admitted to Medical ward and ICU. Most patients were being exposed to inappropriate antimicrobial therapy. Comorbidities and residence were the factors that were found to be significantly associated with inappropriate antimicrobial usage.

Recommendations

Majority of antimicrobials were administered empirically which needs to be supported by culture result. Therefore, Proper evaluation of patients and sending laboratory for culture before initiations of antimicrobials is crucial. Additionally, period evaluation of the culture results of the hospital should be used to assess the appropriate utilization of antibiotics. Hospital based regulation of patient antibiotic therapy monitoring system has to be established. Effective communication between treating Physicians and nurses is also very essential.

Disclosure

The author has no conflicts of interest in this research paper.

Questionnaires

- 1) Identification Number.....
- 2) Age.....
- 3) Sex
- 4) Residence

- A. Addis Ababa
 - B. Outside Addis Ababa(specify).....
- 5) Focus of the infection
- A. URT
 - B. LRT
 - C. CVS
 - D. GI
 - E. GUS
 - F. CNS
 - G. Wound
 - H. Other specify.....

Diagnosis Made for Antibiotic Use.....

- 6) What type of Antibiotic/s therapy is the patient receiving?
- A. Empirical
 - B. Targeted(definitive)
 - C. Prophylactic
- 7) Administration of antibiotic 1(Dose, route of administration, frequency, duration,)...
- 8) Administration of antibiotic 2(Dose, route of administration, frequency, duration,)...
- 9) Administration of antibiotic 3(Dose, route of administration, frequency, duration,)...
- 10) Administration of antibiotic 4(Dose, route of administration, frequency, duration,)...
- 11) If the patient is receiving more than 4 antibiotics, write down here.....
- 12) Was the antibiotics revised before culture result
- A. Yes
 - B. No
- 13) If yes....
- A. Administration of antibiotic 1(Dose, route of administration, frequency, duration,)...

- B. Administration of antibiotic 2(Dose, route of administration, frequency, duration,)...
- C. If the patient is receiving more than 2 revised antibiotics, write down here.....
- 14) Was the antibiotics revised after culture result
 - A. Yes
 - B. No
- 15) If yes....
 - A. Administration of antibiotic 1(Dose, route of administration, frequency, duration,)...
 - B. Administration of antibiotic 2(Dose, route of administration, frequency, duration)...
 - C. If the patient was receiving more than 2 revised antibiotics, write down here.....
- 16) Was there financial constraints to order the necessary antibiotics
 - A. Yes
 - B. No
- 17) If yes, to what antibiotic/s did you down grade?.....
- 18) What is the culture result?
 - A. There is growth
 - B. No growth
 - C. Not done
- 19) If there is growth
 - A. What organism/s are grown in the culture result.....
 - B. To which antibiotics are they resistant.....
- 20) To which antibiotics are they sensitive.....
- 21) Was there any interruption of antibiotics during treatment period?
 - A. Yes
 - B. No
 - C. If Yes....For how long?.....Why?.....
- 22) Length of stay at ED.....
- 23) Length of stay at wards.....
- 24) Length of stay at ICU.....

- 25) Total length of stay at the hospital.....
- 26) Does the patient has any comorbidities
- A. Yes
 - B. No
- 27) If yes, What comorbidities?
- A. DM
 - B. HTN
 - C. HF
 - D. Old stroke
 - E. MI
 - F. CKD
 - G. Other specify.....
- 28) Outcome of the patient
- A. Discharged improved
 - B. Bed ridden
 - C. Died
 - D. Vegetative
 - E. Other specify.....
- 29) For patients in the ICU, Was the patient on Mechanical Ventilator
- A. Yes
 - B. No
- 30) If Yes, for how long?
- 31) Was the patient hospitalized in the past 3 months
- A. Yes
 - B. No
- 32) Was the patient taking any antibiotics in the past 3 months?
- A. Yes
 - B. No

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