

Antibiotics Treatment in Surgical Ward of a Tertiary Care Hospital in Reference to National Essential Medicine List of India 2022- An Observational Study

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Abstract:

Background: National list of Essential Medicine (NLEM) is a list of medicines, in order to increase the compliance through access to safe, effective, quality, and affordability of essential drugs. Essential medicine should be available in sufficient quantities to the patients for common diseases to control the drug resistance and economic burden to the government.

Purpose: Our objective of the study is to observe the gap in balancing the essentiality, availability, and cost-effectiveness of antibiotics supplied and administered in the department of surgery in a tertiary care Government hospital.

Methods: Antibiotics supplied in the surgical wards for three consecutive months were observed and analyzed whether or not they were in accordance with NLEM 2022 and AwaRe list. This study was done in Rajendra Institute of Medical Sciences, Ranchi, and Jharkhand, India.

Results: Medicines which were supplied in the surgery ward were efficient to cover common surgical diseases. The Gap exists in total amount of antimicrobial drugs administered, and also in accordance with NLEM 2022 and AwaRe grouping.

Conclusion: It is essential to maintain supply chain of low cost and effective antibiotics in the wards in sufficient quantity and in regular periodicity, as per culture and sensitivity report of the patients. Supply of packets of complete course of drug for the disease to each patient, followed by audit of compliance by Pharmacologists on regular basis will help in reducing the drug resistance.

Keywords: National list of essential medicine (NLEM-2022), antibiotics, surgical ward.

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Introduction

Essential medicines list of drugs is to satisfy the priority health care needs of the population for cost-effective quality treatment. The drugs listed in NLEM are considered scheduled drugs under Drugs Price Control Order (DPCO) and their prices are regulated by National Pharmaceutical Pricing Authority (NPPA) to ensure affordability. India developed its first essential medicine list in 1996 [1].

In 2018, the Standing National Committee on Medicine (SNCM) was constituted to review and revise the National List of Essential Medicine. Committee has submitted its final report in the month of September 2022 and Government of India has accepted the recommendations of the committee in toto and adopted the NLEM 2022. Twenty-seven sections of drug classes are mentioned in National List of Essential Medicines (NLEM) 2022. NLEM is a dynamic document and is revised in a few years

on a regular basis considering the changes in public health priorities and also on advancement in pharmaceutical knowledge. NLEM was formulated first in 1996 in India and then revised in year 2002, 2011 and 2015.

Present revised NLEM list released as the fifth list in September 2022, after a gap of 7 years [3]. Within this gap between NLEM 2015 and NLEM 2022, the WHO revised its EML three times (every 2 years) and each revision comprised 90 modifications on an average [4].

Present WHO Model List of Essential Medicine is 23rd list, published in 2023 [5].

Formation of the Indian NLEM 2022

The parameters of NLEM state that a drug must be essential, and the disease included for the treatment purpose must be a public health concern [3]. The

drug should have proven efficacy- safety, cost effectiveness and safety. Should have good compliance and an acceptable risk-benefit ratio. The drugs that are included are single medicine and not a fixed- dose combination unless the combination is rational and has a proven benefit. The drugs are also grouped based on their requirement in a primary, secondary, or tertiary care facility. Lastly, the drug should be included in the current guideline for the treatment of concerned disease and drug should be licensed in India.

On the other hand, a drug would be deleted from the list If- (a) it is banned in India (b) there are reports of concerns of the safety profile (c) a drug with better efficacy- safety profile or cost-effectiveness is now available (d) the disease for which the drug used, is no longer a public concern in India or (e) in case of antimicrobial drugs, the drug has been rendered ineffective due to resistance. As of now 156 nations published NLEM. Indian NLEM (2022) contains 384 drugs, with 28 antibiotics. Thirty four drugs from previous list have been dropped and 26 new drugs have been added. Growing from 348 in NLEM 2011 and 376 in NLEM 2015, the present list consists of 384 drugs[6].

Concept of Essential Medicine

1. Essential medicine must always be available in adequate quantities and at affordable price.
2. The process of selection of essential medicine based on (1) relevance to the pattern of prevalent diseases, (2) proven efficacy and safety, (3) adequate scientific data and evidence of performance in a variety of settings, (4) adequate quality, (5) favourable cost-benefit ratio, (6) desirable pharmacokinetic properties [7].

To enhance the credibility of Indian health care system, procurement and delivery systems of essential medicines have to be strengthened through government commitment, careful selection, adequate public sector financing, efficient distribution systems, control on taxes and duties, and inculcating a culture of rational use of medicines in current and future prescribers[8].

Limitations of NLEM (India 2022):

1. NLEM should include drugs with high cost like anticancer drugs, hematopoietic hormones for, increasing cases of renal diseases.
2. The antibacterial agents are not categorized as access, watch and reserve (AwaRe) group.

3. Should be more aligned with the concept of Essential medicines[9].

Concept of WHO EML 2021

WHO published the first model list of essential medicines in 1977 [10].

Over 130 countries use the WHO model of EML to develop their national essential medicine list and to guide their purchasing decision. A total of 591 medicines and 103 therapeutic equivalents are listed. Out of this, 261 medicines are antibiotics. Among the list of antibiotics, access group drugs are 85, watch group drugs are 147 and reserve group drugs are 29.

This AwaRe classification of antibiotics was developed in 2017 by the WHO expert committee on selection and use of essential medicines as a tool to support antibiotic Stewardship efforts at local, national, and global levels. The current versions, updated in July 2023, are the 23rd Essential Medicine List (EML) and the 9th Essential Medicine List for Children (EMLc)

Material and Method

It is a Cross- Sectional observational study. Antibiotics are listed which are supplied in general surgery wards of Rajendra Institute of Medical Science, Ranchi, Jharkhand (INDIA). Total beds in the department of surgery is 198, excluding burn ward and surgery ICU beds.

Data were taken every month, starting from March 2023 to May 2023. All the beds were occupied. The average number of the patients who were not given antibiotics were 10.

Aim and Objective:

1. To see whether antibiotics used in surgery ward are in accordance with NLEM INDIA 2022 or not.
2. To identify essential antibiotics, this must be supplied in sufficient quantity in ward to prevent antibiotics resistance.

Inclusion and Exclusion Criteria:

Antibiotics included are those, supplied for patients admitted in surgery ward for routine surgical cases and excluded the antibiotics supplied for patient admitted in ICU and burn ward of department of general surgery.

Observation:

Table 1: Antibiotics supplied to number of patients in the Department of Surgery, in the month of March to May 2023

Medicine Administered	March	April	May
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Inj. Piperacillin+ Tazobactam	22	21	23
Inj. Cefoperazone- Sulbactam	30	32	31
Inj. Ceftriaxone+ Sulbactam	16	15	17
Inj. Ceftriaxone	11	10	12
Inj. Cefoperazone	4	5	3
Inj. Meropenem	9	8	10
Inj. Amikacin	16	17	15
Inj. Amoxyclav	21	20	22
Inj. Metrogyl	34	35	33
Inf. Ciprofloxacin	25	23	24
Total No. Of Patients	188	186	190

Table 2: Percentage of those drugs supplied not enlisted in EML

Medicine administered	No. of patients	Percentage of drug administered	Listed in EML
Inj. Cefoperazone- Sulbactam	30	15.96 %	NO
Inj. Piperacillin+ Tazobactam	22	11.70%	Yes
Inj. Ceftriaxone+ Sulbactam	16	8.51%	No
Inj. Ceftriaxone	11	5.85%	Yes
Inj. Cefoperazone	4	2.13%	No
Inj. Meropenem	9	4.79%	Yes
Inj. Amikacin	16	8.51%	Yes
Inj. Amoxyclav	21	11.17%	Yes
Inf. Metrogyl	34	18.08%	Yes
Inf. Ciprofloxacin	25	13.29%	Yes
Total No. Of Patients	188	100%	

Out of 198 patients, 10 patients were not prescribed any antibiotics. One hundred eighty-eight patients were given antibiotic.

Table 3: Defined Daily Dose of drug used

ATC classification	ATC Drugs	Defined Daily Dose
	Cefoperazon+Sulbactum	2gm+1 gm
JO1CR05	Piperacillin +Tazobactum	12gm+1500mg
J01DD04	Ceftriaxone	2 gm
J01DD62	Ceftriaxone+Sulbactum	2gm+1gm
J01DD12	Cefoperazone	2 gm
J01DH02	Meropenem	3gm
J01GB06	Amikacin	1gm
J01CR02	Amoxyclav	1gm+250mg
J01XD01	Metrogyl	1200mg

ATC=Anatomical Therapeutic Chemical

To facilitate the ability to compare consumption information across time and geography, a technical unit of measurement was created for use in conjunction with the ATC classification. It is referred as the Defined Daily Dose (DDD) and assigned to each drug at the 5th level. It is defined by the ATC as the assumed average maintenance dose per day for a drug used for its main indication in

adults. For antibiotics, the main indication is moderate to severe infections.

Defined Daily Dose are useful for measuring and comparing volumes of drug used. DDD should not be considered as the 'correct' dose but as an international compromise on review of available documentation.

Table 4: Standard Antimicrobial dosage regimen of Superficial Soft Tissue Infections:

S.No.	Antibiotics	Doses, duration and route of administration
1	Cefazolin	1-2gm IV q8h
2	Cefalexin	750mg BD,500mg TID
3	Amoxicillin-Clavulanate	Oral:1gm BD/ IV1.2gmTDS
4	Clindamycin	600-900 mg IV 8 hourly
5	Piperacillin- Tazobactam + Clindamycine	IV 4.5gm 6 hourly (PT), +IV600mgTDS
6	Ciprofloxacin	IV 750 mg q12 hourly
7	Doxycyclin	IV 200 mg stat followed by 100mg 1-0-1

8	Amoxicillin- Clavulanate	1gm BD
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Discussion

In surgery department the usual antibiotics available for patients Amikacin, Amoxicillin- clavulanic acid, Cefoperazone single or in combination, Cefoperazone- sulbactam, Ceftriaxone or Ceftriaxone with sulbactam, Metronidazole, Ciprofloxacin and Piperacillin- tazobactam.

Among these, AwaRe group drugs are Amikacin, Amoxicillin-clavulanic acid and Metronidazole infusion. Watch group antibiotics are Injection Cefotaxime, Ceftriaxone, Cefoperazone, Infusion Ciprofloxacin, and Injection Piperacillin-tazobactam. The reserve group antibiotics are Injection Meropenem, Ceftazidime and Linezolid which is listed in EML 2022.

Among these only Meropenem is supplied on regular basis. Among β -lactams, cefotaxime, ceftazidime, ceftriaxone, piperacillin-tazobactam and meropenem are available. Injection Benzathine penicillin and injection benzylpenicillin not supplied. Oral antibiotics as cloxacillin, cefixime, cefazolin, cefadroxil are not supplied in the department. Only capsule amoxicillin and tablet amoxicillin+clavulanic acid is supplied. Oral dosage forms of cefadroxil and cefixime, azithromycin, cefuroxime and co-trimoxazole, cloxacillin are not supplied. List of drugs supplied is sufficient to cover wide range on infections. The drugs are distributed based on availability of drugs on a particular day leaving behind the actual requirements of different drugs on that particular day. The drug which is prescribed to a patient in a surgical ward should be supplied in full course, meaning thereby if a drug is given twice daily, then the minimum duration prescribed is 5 days, then total of 10 complete dosages should be prescribed for the patient.

Common Surgical Diseases Which Need Antibiotics:

(A) Antibiotics For Skin And Soft Tissue Infection: In cellulitis along with Cefazolin or Cefalexin /Amoxicillin-clavulanate, clindamycin is required. But it is not supplied regularly. It is also required in cases of necrotising fasciitis, frequently encountered in our hospital. In necrotising fasciitis caused by *Aeromonas / vulnificus* suspected when there is history of exposure to fresh water or salt water, Access group tablet ciprofloxacin 500mg, tablet Doxycycline 100mg is mandatory for treatment, but it unavailable in hospital.

(B) Antibiotics For Diabetic Foot Ulcer: Clarithromycin is indicated but it is unavailable in surgery department.

(C) Antibiotics Required For Deep Neck Infections: Cases of Suppurative parotitis and

Ludwig's angina are admitted in department are required Clindamycin.

(D) Antibiotics Used For Peritonitis: Too many options are here, among access group 85 drugs, watch group 134 drugs and in reserve group 26 drugs are listed in WHO AWaRe classification.

Injection Amoxicillin+clavulanic acid, Amikacin injection, Metronidazole infusion are available in ward, these are access group antibiotics, also, watch group antibiotics supplied in abundance- Ciprofloxacin, Ceftriaxone, Cefoperazone, Cefotaxime. Injection Streptomycin is irregular in supply, it must be supplied without interruption, for cases of abdominal tuberculosis. Injection form of Rifampicin is also not available, but oral Rifampicin is available.

(E) Antibiotics for Intestinal Obstruction

1. Metronidazole, 2. Vancomycin

Vancomycin is not supplied in surgery department.

This type of situation is also seen in other parts of our country. The availability of some essential medicines was found sub optimal and needs to be improved[11].

Conclusion

The measure for supply dependent prescription of medicine will decrease the probable development of drug resistance and it will lead to increased compliance and full utilization of effectiveness of drug.

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