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Original Research Article

A study on the contents of prescription of the in-patients of a tertiary care hospital, Manipur

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ABSTRACT

Background: Appropriate medications are the backbone for effective control of infections and diseases. Objective of the study was to analyse the prescriptions relating to national list of essential medicines (NLEM) of a tertiary care hospital.
Methods: Data was collected from 525 case sheets of the surgical in-patients for a period of 1 year which included total number of drugs prescribed, single (NLEM/non-NLEM) drugs, fixed dose combinations (NLEM/non-NLEM) drugs, most common drugs (NLEM/non-NLEM), route of administration, ADR/ADE and herbal drugs. Descriptive statistics was used for analysis of the data.
Results: The total number of drugs observed in the case sheets was 2575. Out of the total drugs, 1942 drugs (75.4%) were from the list of NLEM (2022) while 633(24.6%) drugs were of non-NLEM. 266 drugs (10.33%) were generic drugs and 2309 drugs (89.67%) were proprietary drugs. The total number of single drug was 1839 (NLEM, 1805 + non-NLEM, 34) and that of the total FDC was 736 (NLEM, 137 + non-NLEM, 599). The most common drugs which were prescribed were analgesics: paracetamol 517 (NLEM); diclofenac supp.14 (non-NLEM), antibiotics: ceftriaxone 258 (NLEM, 14.5%), cefpodoxime proxetil 3 (non-NLEM, 8.9%), antihypertensive: telmisartan 13 (NLEM, 0.7%), non-NLEM nil, anti-diabetics: metformin 15 (NLEM, 0.8%), dapagliflozin 6 (non-NLEM, 16.7%), and gastroprotective drugs: pantoprazole 493 (NLEM, 27%), non-NLEM nil.
Conclusions: Non-NLEM drugs should be prescribed only when there is definite advantages of the same over the NLEM drugs. Prescription of proprietary FDC drugs, factors for non-availability and under-prescription of NLEM drugs should be highlighted through CME coupled with awareness about the aim and objectives of the NLEM during clinical practice to the prescribers.

Keywords: NLEM, Non-NLEM, FDC, ADR, ADE, CME

INTRODUCTION

The World Health Organization (WHO) and the Indian Council of Medical Research (ICMR) advised the health care professionals- doctors and paramedics to prescribe/use the drugs/medicines which are approved/listed in the national list of essential medicines (NLEM) and also to prescribe the drugs of generic name because these drugs are available all over the country at cheaper rates.[1-3] The treatment/management of the patients shall be at the lower side and there shall be cost-effectiveness of the patients/physicians/authorities/policy makers.[4] This will improve the policy of rational use of medicines (RUM) and discard the irrational use of medicine and the banned fixed dose combination (FDC) drugs.[5]

The NLEM which was prepared with the aim and objective of cost-effectiveness treatment may be useless if the prescribers are not prescribing the drugs as per the guidelines of the WHO/ICMR.[6]

Unfortunately, many studies on drug utilization and prescription pattern have highlighted the problem of under-utilization of the NLEM. The present authors also came across the non-compliance of the NLEM policy during their studies in 2022-2023. The problem is prevalent across the globe particularly in the developing countries.

As such, this study was conducted to accentuate the concepts of rational use of medicine with the available NLEM.

METHODS

Study design and setting

It is a retrospective cross-sectional observational study conducted in the premises of Shija Academy of Health Sciences, Langol.

Data collection

Purposive sampling was used to study the cases. From the population of in-patients, surgical in-patients were selected for reflecting the pattern of drug usage. Then, consecutive enrolment of the case sheets of in-patients of surgery, obstetrics and gynaecology, otolaryngorhinology and orthopaedics for the period November 2021-November 2022 were done resulting in a total of 525 case sheets.

These were examined after obtaining permission of the medical superintendent, Shija Hospitals and Research Institute Pvt. Ltd.

Collected data included total number of drugs prescribed, single (NLEM/non-NLEM) drugs, FDCs (NLEM/Non-NLEM) drugs, most common drugs (NLEM/Non-NLEM), route of administration, ADR/ADE and herbal drugs if any in a predesigned format.

Inclusion criteria

All Case sheets of in-patients of SHRI were included in the study

Exclusion criteria

All case sheets with left against medical advice (LAMA) and those with incomplete prescriptions were excluded from the study.

Data analysis

Descriptive statistics was used for analysis of the data.

Ethical considerations

Ethical clearance was obtained from the institutional ethical committee of SHRI with the order no. IEC/SHRI/22 dated 17 November 2022.

RESULTS

The total number of case sheets which was examined during November 2021 to November 2022 (365 days) was 525.

Age group of 31-40 years (22.3%) was mostly admitted with females (58.5%) exceeding males (41.5%) in the department of surgery (57.7%) on an average duration of 3.8 days hospital stay as depicted in Table 1.

Table 1: Demographic data.

Variables	Number of patients	Percentages (%)
Age (in years)		
0-10	41	7.8
11-20	37	7
21-30	99	18.9
31-40	117	22.3
41-50	89	17
51-60	71	13.5
>60	71	13.5
Gender		
Male	218	41.5
Female	307	58.5
Departments		
Surgery	303	57.7
Obstetrics and gynaecology	100	19.1
Otolaryngorhinology	20	3.8
Orthopaedics	102	19.4
Duration of hospital stay (days)	525	3.8

The total number of drugs which were observed in those case sheets was 2575. Out of the total, drugs 1942 (75.4%) were from the list of NLEM (2022) while 633 (24.6%) drugs were of non-NLEM. 266 drugs (10.33%) were generic drugs and 2309 drugs (89.67%) was proprietary or branded drugs. The total number of single drug was 1839 (NLEM 1805 + non-NLEM 34) and that of the total FDC was 736 (NLEM 137 + non-NLEM 599). The most common drugs which were prescribed were paracetamol 517(NLEM, 28.7%); diclofenac supp. 14 (non-NLEM, 41.2%), ceftriaxone 258 (NLEM, 14.5%), cefpodoxime proxetil 3 (non-NLEM,8.9%), antihypertensive: telmisartan 13 (NLEM, 0.7%), non-NLEM nil, anti-diabetics: metformin 15 (NLEM, 0.8%), dapagliflozin 6 (non-NLEM, 16.7%), and gastroprotective drugs: pantoprazole 493 (NLEM, 27%), non-NLEM nil as depicted in Table 2.

Regarding the common FDC drugs which were observed among the analgesics were zerodol-SP (aceclofenac+ paracetamol+ serratiopeptidase) 98, 16.3% and the antibiotics injection Hituf 4.5 (piperacillin+ tazobactam) 91, 66.4% from NLEM; tablet VICEF-CV (cefixime+ clavulanic acid) 105, 17.6% as shown in Table 3.

Table 2: NLEM and NLEM (single drug).

NLEM section	Drug class	NLEM single	%	Non-NLEM single	%
2.1.5	Analgesics	Paracetamol (517)	28.7	Diclofenac supp (14)	41.2
2.1.2		Diclofenac (114)	6.3	Buprenorphine patch (2)	
2.2.3		Tramadol (231)	12.7	Pentazocine (2)	5.9
17.4.2		Hyoscine butylbromide (22)	1.2	Etoricoxib (1)	5.9
2.2.1		Fentanyl (3)	0.2	Ropivacaine (1)	2.9
17.4.1		Dicyclomine (1)	0.1		
6.2.11	Antibiotics	Ceftriaxone (258)	14.5	Cefpodoxime proxetil (3)	8.9
6.2.2.9		Metronidazole (48)	2.6	Cefoperazone (1)	2.9
6.4.1		Amikacin (39)	2.1		
6.4.10		Levofloxacin (26)	1.5		
6.2.18		Cefixime (4)	0.2		
6.4.11		Linezolid (4)	0.2		
6.2.2.2		Cefuroxime (2)	0.11		
10.3.7	Anti-htn	Telmisartan (13)	0.72	Nil	
10.3.3		Hydrochlorothiazide (6)	0.33		
10.3.1		Amlodipine (5)	0.3		
18.3.1.6	Anti-diabetics	Metformin (15)	0.8	Nil	
18.3.14	Multivitamins	Long-acting insulin (3)	0.2		
		Nil		Nil	
17.1.2	Gastro-protective drugs	Pantoprazole (493)	27.3	Nil	
3.3	Anti-allergy	Dexamethasone (1)	0.01	Nil	
17.4	Anti-spasmodics	Nil		Drotaverine (1)	2.9
1.4	Muscle relaxants	Nil		Flavoxate (1)	2.9
5.1	Anti-convulsants	Nil		Pregabalin (2)	5.9

Table 3: NLEM and non-NLEM (FDC).

NLEM section	Drug class	NLEM FDC	%	Non- NLEM FDC	%
2	Analgesics	Nil		Aceclofenac + paracetamol + serratiopeptidase (98)	16.3
				Aceclofenac + paracetamol (40)	6.7
				Ibuprofen + paracetamol (26)	4.3
				Diclofenac + serratiopeptidase (22)	3.7
				Tramadol + paracetamol (5)	0.8
				Dicyclomine + paracetamol (4)	0.7
				Camylofin + paracetamol (4)	0.7
6.2.1.2	Antibiotics	Piperacillin + tazobactam (91)	66.4	Cefixime + clav. acid (105)	17.6
6.2.1.13		Amoxcillin + clava acid (46)	33.6	Ceftriaxone + tazobactam (67)	11.2
				Ceftriazone + sulbactam (32)	5.4
				Ofloxacin + ornidazole (3)	0.5
				Meropenem + sulbactam (2)	0.3
10	Anti-HTN	Nil		Nil	
18	Anti-diabetes	Nil		Nil	
26	Multivitamins	Nil		Thiamine mononitrate + riboflavin + pyridoxine hydrochloride + cyanocobalamin + nicotinamide + calcium	31.7

NLEM section	Drug class	NLEM FDC	%	Non- NLEM FDC	%
				pantothenate (190)	
17.1.2	Gastroprotective drugs	Nil		Nil	
3.3	Anti -allergy	Nil		Phenylephrine + chlorphenamine maleate (1)	0.1

The route of administration of the drugs was on the nature/conditions of the diseases/patients. The routes were highlighted as intravenous 1886 (73.25%), oral 670 (26.01%), rectal 14 (0.55%), s/c 3 (0.12%), topical 2 (0.07%) respectively. The patients were of surgical cases which were both acute and emergency situations and also operated and post-operative cases as shown in Table 4.

Table 4: Routes of administration.

Route	Total	%
Oral		
Tablets	650	26.01
Liquid	20	
Total	670	
Parenteral		
i/v	1771	73.25
i/m	115	
Total	1886	
Rectal		
Suppositories	14	0.55
s/c	3	0.12
Topical		
Cutaneous	2	0.07

The most frequently prescribed drugs were as follows as shown in Table 5: vitamins and minerals - tab neurobion forte (31.7%) from non-NLEM; topicals - buprenorphine patch (5.5%) from non-NLEM; gastroprotective drugs - inj. pan 40 (27%) from NLEM; antibiotics - inj. xone (4.5) from NLEM; tab vicef-CV (17.6%) from non-NLEM; analgesics (opioids) - inj. tramazac (12.9) from NLEM; analgesics (non-opioids) - inj. diclonac 6.5% from NLEM; diclofenac supp. (38.9%) from non-NLEM; anti-allergy - inj. dexamethasone (0.05%); and anti-diabetics - inj glargine (0.01).

The clinicians prescribed most of the common drugs in their proprietary names viz., tab zerodol-P, and injection megmadol as shown in Table 6.

The NLEM list of 2015/2019 was revised. 26 drugs were deleted under different categories and 34 drugs were added under different categories. A revised list of NLEM was published in 2022.

In this study, it was observed that the clinicians prescribed amikacin, cefuroxime, buprenorphine and insulin glargine which were included in the revised list while chlorpheniramine which was excluded from NLEM 2022 was still prescribed as shown in Table 7.

Table 5: Most frequently used drugs.

Particulars	NLEM	Non-NLEM
Vitamin and minerals	Nil	Tab. neurobion forte (31.7%)
Topicals	Nil	Buprenorphine patch (5.5%)
Anti-ulcer	I/V pantoprazole (27%)	Nil
Antibiotics	I/V ceftriaxone (4.5%)	Tab. cefixime + clav. acid (17.6%)
Analgesic (opioids)	I/V tramadol (12.9%)	Nil
Analgesic (non-opioids)	I/V diclofenac (6.5%)	Diclofenac supp (38.9%)
Anti-allergy	I/V dexamethasone 0.05%	Nil
Anti-diabetics	Long-acting insulin (0.1%)	Nil
Anti-hypertensive	Telmisartan	Nil

Table 6: Common proprietary drugs.

Drug class	Brand name
Analgesics	Tab. zerodol-P, tab. zerodol-SP, inj. megmadol
Antibiotics	Inj. xone, inj. hituf 4.5, tab. taxim-O, tab vicef-CV
Anti-hypertensives	Tab. amlodac, tab. telma 40
Antidiabetics	Tab. gluconorm-SR
Multivitamins	Tab. neurobion forte
Gastro-protective	Inj. pan 40
Anti-allergy	Syp. coriminic
Antispasmodics	Tab. spasmonorm
Anticonvulsants	Tab. pregabalin 75
Muscle relaxants	Tab. zerodol-MR

It is established that the clinicians have adequate knowledge of ADR/ADE. However, their attitude towards practicing reporting of ADR/ADE under Pharmacovigilance Program of India is not sufficient as reflected on the examination of 525 case sheets where in not a single case of ADR/ADE was noted/reported.

Table 7: Use of drugs added and deleted from NLEM 2022.

Class	Drugs newly added	Drugs excluded	Tot-al
Antibacterial	Amikacin, cefuroxime	Nil	2
Analgesics	Buprenorphine	Nil	1
Anti-diabetics	Insulin glargine	Nil	3
Anti-allergy	Nil	Chlorpheniramine	1

DISCUSSION

On examination of the previous studies, it was observed that many prescribers under-utilised the NLEM. This may be due to inadequate training.[7,8] A total of NLEM 1942 (75.4%), non-NLEM 633 (24.6%) drugs were observed to be prescribed. Drug utilization studies of many investigators revealed the non-NLEM drugs usage between 10% to 75%.[4,9] The most frequently prescribed non-NLEM single drug in this study was Diclofenac supp and fixed dose combination drug was aceclofenac+ paracetamol+ serratiopeptidase.

The prescription of vitamins and minerals 190 (31.7%) is low as observed in other studies. These are required in cases of deficiency. On the other hand, the availability of large number of FDCs of vitamins and minerals facilitates the misuse and over-prescriptions without scientific rationale.[10,11]

The present study is done under the objectives of the essential medicine list (WHO and India). The NLEM list of 2015 was revised by the standing national committee on medicines with the deletion of 26 drugs and addition of 34 drugs. A revised NLEM list was published as NLEM 2022.[12]

The findings of the previous studies showed that the prescribers are not aware of the importance of the essential medicine list and decision of the policy makers. The average number of drugs per prescription was 3.7 (NLEM) and 1.2 (non-NLEM). Such type of observations was reported by many researchers.[1] The single drug preparation of Paracetamol from NLEM was the most commonly used while multivitamin combination namely tablet neurobion forte was the most common from non-NLEM.

Vitamins and minerals were prescribed for the probable cause of deficiency cases only. This group is not included in the NLEM. However, a large number of preparations of such drugs both as single and FDC viz., vitamin B_{12} + folic acid/iron or vitamin B_{12} + iron + folic acid are marketed in the country. The clinicians are influenced by the medical representatives/MNC leading to misuse and overprescription without valid reasons. The clinicians were not aware of the salts of the drug viz., zinc with oxide/sulfate/acetate or calcium lactate/aspartate/carbonate. Such type of drugs was not observed in this study.

Regarding the alternative drugs, herbal preparations were not prescribed and also not included in the NLEM too.

Regarding the ADR/ADE, not a single case was observed or reported in this study as the prescribers did not have sufficient attitude and practice of ADR/ADE despite accounting good knowledge. This was similar to another recent study.[13]

Limitations

The study was done with the inpatients case sheets of a few departments for a period of one year. The case sheets were also of the patients treated and admitted in the paying wards. This observation may not be able to depict the expected scenario of the understanding and utilization of the NLEM on a larger scale.

CONCLUSION

Non-NLEM drugs may be allowed to be prescribed only when there is a definite advantage of the drug over the NLEM drugs. Prescribers are always advised to prescribe the older drugs instead of newer drugs (cetirizine to levocetirizine, omeprazole to pantoprazole). There shall be restriction of prescription of branded FDC drugs and seriously view the factors for the non-availability and under-prescription of NLEM drugs. It is suggested to make the NLEM drugs easily accessible to the general population and to highlight the knowledge of the prescribers about the NLEM drugs through CME coupled with awareness about the aim and objectives of the NLEM during clinical practice.

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