Drug Utilization Study On Antibiotics In The Department Of Medicine At A Tertiary Care Hospital: A Retrospective Observational Cohort Study

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***Abstract*- Objective:** The aim of the study was to evaluate the utilization and prescription pattern of antibiotics in the department of general medicine for ensuring the rational drug therapy. **Method:** A retrospective observational cohort study was conducted over a period of six months in a tertiary care hospital enrolling 250 patients. Case records were retrospectively reviewed for the demographic data, clinical presentation, investigational management and outcomes. Data analysis were conducted using Microsoft Excel 2010, SPSS (Version 1.0.0.1406). **Results:** In the study most commonly prescribed antibiotics were cephalosporins / sulbactam followed by meropenem. Total 13 ADR were reported. The overall cost of prescription was reduced to 19.14% if the proposed alternate 1 category of brands were used and 33.17% reduction with alternate 2 category of brands, which would help in minimizing the patient expenditure.

Conclusion: This study provided an insight into the drug utilization pattern of Antibiotics and the rationality behind the antibiotic usage. ADRs are common occurrence, but are often not recognized, even if they are recognized they are underreported as many are unaware about the clinical importance. The total cost reduction of 19.14% and 33.17% with alternate brands of drugs shows that effective cost reduction strategies could reduce the cost of therapy which will in turn improve patient compliance and reduces the economic burden.

***Index Terms*-** Drug utilisation evaluation, antibiotics, prescribing pattern, adverse drug reaction, Pharmacoeconomics.

I. INTRODUCTION

Drug utilization evaluation DUE is effective method of accessing the appropriateness of various medication used. DUE is a structured process to analyses the pattern of drug administration in various hospital settings. DUE will improve patient outcome by maintaining the interventions. Polypharmacy, irrational drug choice, incorrect drug dose, drug interaction re the contributing factor to increased morbidity, mortality and health care expenses. The antibiotics are the most commonly used class of drug in healthcare settings and they are really important to used optimally otherwise treatment outcome will interfere by resistant pathogen. The inappropriate use of antibiotics may leads increase the development of drug resistance, increased healthcare expenses and serious s adverse drug reaction. DUE can help to access the drug related problems, preventing the development of drug resistance organism and control Pharmacoeconomics of treatment. Therefore this study was planned to identify the prescribing pattern of antibiotic, adverse drug reaction of antibiotic and Pharmacoeconomics of antibiotic.

II. MATERIALS AND METHODS

Study Site: General Medicine Department.
Study Design: Retrospective observational study
Study Duration: 6 Months
Minimum Sample Size Required: 185

III. METHOD

The data was collected retrospectively for 6 months period from general medicine department. Case records was retrospectively reviewed from MRD for demographic data, clinical presentations, investigations, management, adverse reactions, Co-morbidities associated and any interventions. The case records were individually screened to access the prescription pattern of antibiotics. The adverse effect of antibiotic were monitored by collecting the ADR that is already reported and also suspected ADR accessed by clinical pharmacist while data collection.

The DDD is the assumed average maintenance dose per for a drug used for its main indication in adult. DDD/ patient per 100 days of 5 commonly prescribed antibiotics was calculated and it provides the estimate of drugs consumption in the general medicine department.

The cost minimization analysis of most commonly prescribed antibiotics in the general medicine department was accessed by analyzing the prescribed brands of antibiotics prescribed in the hospitals with other brands of the same antibiotics which is manufactured by top 10 pharmaceutical companies in India.

IV. STATISTICAL ANALYSIS

In this study, SPSS was used to compare the cost of prescribed antibiotics to alternatives of same class. Data analyzed using Microsoft excel 2010. Other statistical tools like ANOVA and Chi-square were also used in this study.

V. RESULTS

Among the study population 54% (n=135) were females and 46% (n=115) were males and majority of the patients were in the age group of 41-60years (n=91,36.4%) followed by 61-80 years (n=81(32.4%)). There was no significant difference in the antibiotic exposure (p=0.72316) with respect to age (P value = >0.05).

A total of 14 different types of diagnosis were subjected to antibiotic prescription. The respiratory tract infections (n=181, (58.76%)) was the most common diagnosis for which antibiotics prescribed, out of these 109 cases were COVID 19 followed by urinary tract infection (n=28, (9%)) (**Table no:1**).

The average number of antibiotics per prescription was 1.744 +/-0.875479 (Mean+/- SD). Parenteral antibiotics were mostly prescribed 70.64% (n=308) than oral Antibiotics 29.36%(n=128) (**Table no: 2**).

Among the antibiotics prescribed, Cephalosporin class of antibiotics (n=120,29%) was commonly prescribed followed by carbapenem (n=69, 17%), Macrolide (n=68, (16%)). Among cephalosporin antibiotics, third generation antibiotic Cefoperazone/sulbactam (n=86,(21%)) was widely prescribed followed by meropenem (n=69, (17%)), azithromycin (n=64, (15%)) (**Table no:3**).

13 ADRs were recorded in which 3 were reported ADRs **(Table no:4)** and 10 were suspected ADRs **(Table no:5**). A total of 10 ADRs were with Beta-lactams (Piperacillin + Tazobactam, Cefoperazone + Sulbactam, Ceftriaxone) (76.92%) followed by Macrolides (Azithromycin) 2(15.38%), Aminoglycosides (Amikacin) 1 (7.69%). Most ADRs reported were mild to moderate based on Hartwig scale and found to be possible based on Naranjo's scale. Chi- square test was done to find the association of ADRs with severity and preventability and the results shows that there was a no significant association between the severity. [X^2 (1,13) = 2.3593, P = 0.124541] and preventability [X^2 (1,13) = 0.96515152, P = 0.325892)] in reported and suspected ADRs **(Table no:6,7)**.

The most commonly prescribed 5 antibiotics were classified using the ATC classification system and drug utilization was measured as DDD/patient per 100 days. Cefoperazone+ sulbactam (J01DD62) was the most commonly prescribed antibiotic with DDD/patient per 100 days value (25.55) followed by meropenem (J01DH02) with DDD/patient per100 days value 0f 23 **(Table no:8)**.

Cost minimization analysis shows a potential reduction in cost of prescription **(figure no:1**), if there was an intervention. The overall cost of prescription was reduced to 19.14% if the proposed alternate 1 category of brands were used and 33.17% reduction with alternate 2 category of brands (**Table no:9)**.

Table NO:1 INDICATION FOR ANTIBIOTICS PRESCRIBED

DISEASE	**FREQUENCY**	**%FREQUENCY**
Respiratory tract Infection	182	59.0%
Cellulitis	14	4.5%
Renal Disease	14	4.5%
Urinary tract Infection	28	9%

CNS Disorder	6	1.9%
GIT Disorder	25	8.1%
Acute Labyrinthitis	2	0.6%
Gingivitis	1	0.32%
Dengue	18	5.8%
Hepatic Disease	5	1.6%
Leptospirosis	3	0.9%
Sepsis	3	0.9%
CVD	7	2.2%
Total	**N=308**	**100%**

TABLE NO: 2 WHO PRECRIBING INDICATION OF ANTIBIOTICS

PRESCRIBING INDICATORS	RESULT	WHO STANDARD VALUE
Average number of Antibiotics per prescription *	1.744+/-0.875479	1.6-1.8
Percentage of antibiotics prescribed by generic name*	7.79%	100%
Percentage of antibiotics prescribed by brand name*	92.20%	0%
Percentage of antibiotics from essential medicine list*	81.4814%	100%
Mono therapy of antibiotics	48.4%	<30%
Percentage of antibiotics with injection*	70.64%	20.0-26.8

*WHO core drug indicators, *Mean+/-SD. All other values are represented in percentage*

TABLE NO: 3 COMMONLY PRESCRIBED ANTIBIOTICS

ANTIBIOTICS	**FREQUENCY**	**RELATIVE FREQUENCY**
Amoxicillin + Clavulanic acid	8	1.92%
Piperacillin + Tazobactam	51	12.28%
Azithromycin	64	15.42%
Cefoperazone + Sulbactam	86	20.72%
Meropenem	69	16.62%
Levofloxacin	12	2.89%
Amikacin	37	8.91%
Cefoperazone +Tazobactam	1	0.24%
Moxifloxacin	6	1.44%

Cefuroxime	21	5.06%
Clarithromycin	4	0.96%
Linezolid	15	3.61%
Ceftriaxone	3	0.722%
Nitrofurantoin	1	0.24%
Sulfamethoxazole + Trimethoprim	3	0.72%
Clindamycin	5	1.20%
Ofloxacin	1	0.24%
Norfloxacin	7	1.68%
Cefpodoxime	3	0.72%
Doxycycline	2	0.48%
Crystalline Penicillin	2	0.48%
Cefixime	2	0.48%
Cefotaxime	2	0.48%
Cefepime	1	0.24%
Cefalexin	1	0.24%
Rifaximin	6	1.44%
Mupirocin	2	0.48%
Total	**N=415**	**100%**

TABLE NO:4 REPORTED ADVERSE DRUG REACTION

Drug	**Dosage form**	**Reaction**	**WHO CAUSLITY**	**NARNJO**	**Severity**	**Preventability**
Amikacin	Injection	Elevated Creatinine	Possible	Possible	Mild	Probably Preventable
Cefoperazone+ Tazobactam	Injection	Rashes	Possible	Probable	Moderate	Definitely Preventable
Piperacillin + Tazobactam	Injection	Rashes	Possible	Probable	Moderate	Probably Preventable

TABLE NO:5 SUSPECTED ADVERSE DRUG REACTION

Drug	Dosage Form	Reaction	WHO CAUSALIT Y	NARANJO	Severity	Preventability
Piperacillin +Tazobactam	Injection	Anemia	Possible	Possible	Mild	Probably Preventable
Azithromycin	Oral	Liver Enzyme Elevation	Possible	Possible	Mild	Probably Preventable
Cefoperazone +Sulbactam	Injection	Anemia	Possible	Possible	Mild	Probably Preventable
Ceftriaxone	Injection	Rashes	Possible	Possible	Moderate	Definitely Preventable
Piperacillin+ Tazobactam	Injection	Elevated BUN	Possible	Possible	Moderate	Probably Preventable

Cefoperazone + Sulbactam	Injection	Elevated Creatinine	Possible	Probable	Mild	Probably Preventable
Cefoperazone + Sulbactam	Injection	Elevated Total Count	Possible	Probable	Mild	Probably Preventable
Cefoperazone + Sulbactam	Injection	Decreases Hb	Possible	Possible	Mild	Probably Preventable
Cefoperazone +Sulbactam	Injection	Diarrhea	Possible	Possible	Mild	Probably Preventable
Azithromycin	Oral	Liver Enzyme Elevation	Possible	Possible	Mild	Probably Preventable

TABLE NO:6 ASSOSIATION OF SEVERITY OF ADR BY CHISQUARE TEST

	MILD	MODERATE	TOTAL
REPORTED ADR	1	2	3
SUSPECTED ADR	8	2	10
TOTAL	9	4	13
CHI-SQUARE TEST			
PEARSON CHI-SQUARE	df	P-VALUE	
2.3593	1	0.124541	

TABLE NO:7 ASSOSIATION OF PREVENTABILITY OF ADR BY CHISQUARE TEST

	MILD	MODERATE	TOTAL
REPORTED ADR	2	1	3
SUSPECTED ADR	9	1	10
TOTAL	11	2	13
CHI-SQUARE TEST			
PEARSON CHI-SQUARE	df	P-VALUE	
0.9652	1	0.325892	

TABLE NO:8 ATC CODE AND DDD/PATIENTS OF MOST COMMONLY PRESCRIBED 5 ANTIBIOTICS

DRUG	**ROUTE**	**DDD (gram)**	**PDD**	**ATC CODE**	**DDD/ PATIENT**	**DDD /patient per day**	**DDD/ patient per 100 days**
PIPERACILLIN TAZOBACTA M	PARENTER AL	14	12.32	J01CR05	1.0420	0.1780	17.80
CEFOPERAZO NE SULBACTAM	PARENTER AL	4	4.25	J01DD62	1.248	0.2555	25.55
MEROPENAM	PARENTERAL	3	4.24	J01DH02	1.68	0.2336	23.36
AZITHROMYC IN	PARENTERAL ORAL	0.5 0.3	0.05 0.84	J01FA10	0.956	0.23119	23.119
AMIKACIN	PARENTERAL	1	0.34	J01GB06	0.152	0.0443	4.43

FIGUR NO:1 PERCENTAGE COST REDUCTION COMPARISON

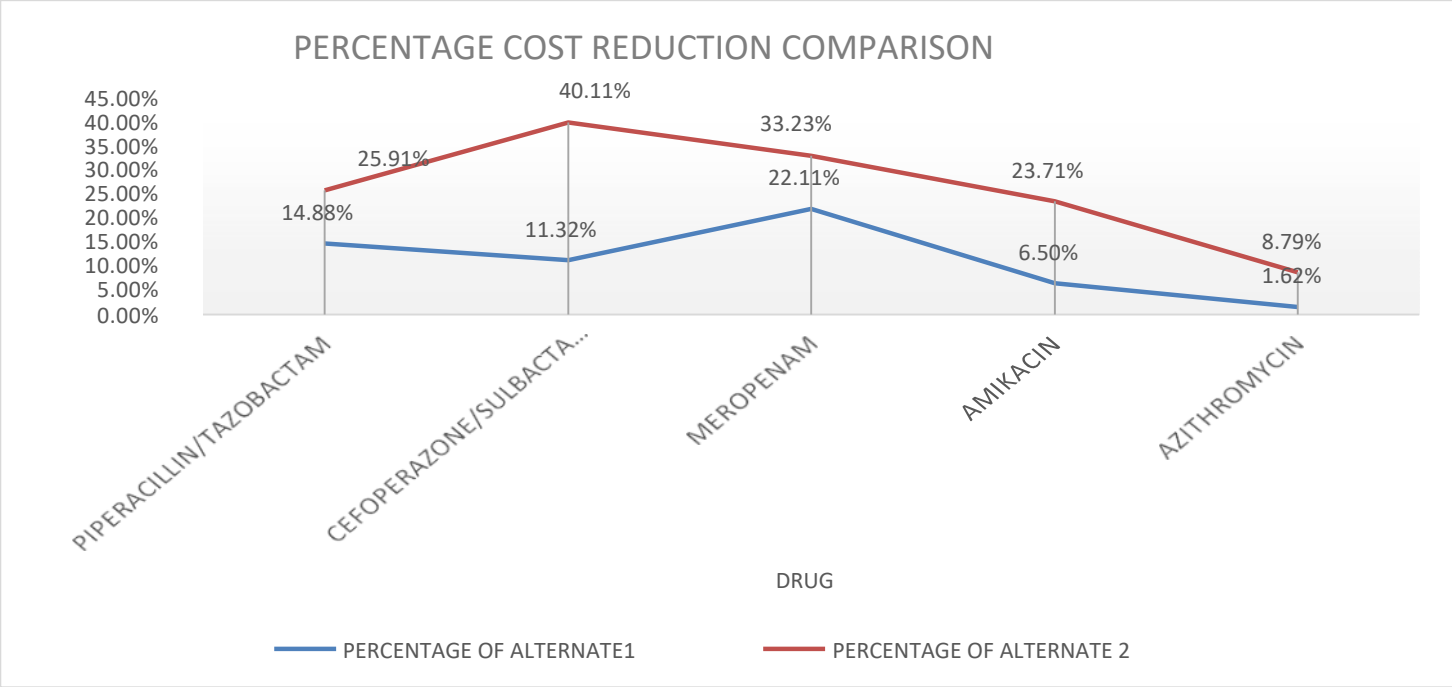

TABLE NO:8 COST MINIMISATION ANALYSIS OF ANTIBIOTICS BY ANOVA

DRUG	Percentage of alternate 1 from actual cost	Percentage of alternate 2 from actual cost
Piperacillin + Tazobactam	14.88%	25.91%
Cefoperazone + Sulbactam	11.32%	40.11%
Meropenem	22.11%	33.23%
Amikacin	6.5%	23.71%
Azithromycin	1.62%	8.79%
Total	19.154%	33.17%

	Mean Square	F	P-value
Between Groups	0.087385	13.13068	0.000952
Within Groups	0.006655		

VI. DISCUSSION

The current study reveals that majority of the patients (n=91,36.4%) were in the group of 41-60 year, followed by 61-80 year (n= 8,32.4%). Similar study conducted by Hussain M et al (2014) also found that most of prescriptions were in age group of 46-60 years. [6]

In current study, number of antibiotics prescribed were compared with age groups and found that most of the patients belongs to 41-60 years of age. Majority of them were prescribed with 1-2 antibiotics and also compare with groups. The study reports that difference in number of antibiotics consumption was found to be statistically significant (F (2,9) =11.61822, P=0.00321).

The current study report shows total of 14 different types of diagnosis were subjected to antibiotic prescription. The respiratory tract infections (n =181,58.76%) was the most common diagnosis for which antibiotics prescribed, out of these 109 cases were COVID 19 followed by urinary tract infection (n=28,9%). Similar to the study conducted by Chem ED et al (2018), Respiratory tract infection was the main diagnosis for which antibiotics were prescribed. Similar study by Lim Y et al (2012) have also reported respiratory tract infection as the most common indication for antibiotic prescription. [7, 8]

A total of 19 different types of comorbidities were observed from Sample. Out of which 97(32.9%) was diabetes mellitus followed by hypertension 84 (28.5%), hypothyroidism 25 (8.5%). Similar study conducted by Pushpalatha S et al (2020) found that most of the patients had diabetes mellitus and the study conducted by Gowthami et al (2016) was also found to have almost same results. [9,10]

The reports on the antibiotic frequency in patient with comorbidity, it was observed that 1-2 antibiotics were prescribed in 132(83.54%) and 3-4 antibiotics in 24 (16.18%) and 5-6 antibiotics in 2 (1.265 %) patients with comorbid condition. In case of patients without comorbid condition 1-2 antibiotics were prescribed in 72 patients (78.26%) followed by 3-4 antibiotics were 16 (17.39%). Therefore, we can observe that the antibiotics frequency in patients with comorbid condition exceeds the patients without comorbid condition. Similar study conducted by Ternhag A et al (2014) found that comorbidity was a strong factor that determine the number of antibiotic prescriptions. [11]

The Cefoperazone /Sulbactam (n=86,20.72%), Meropenem (n=69,16.62%), Azithromycin (n=64,15.42%), Piperacillin/Tazobactam (n=51,12.28%), Amikacin (n=37,8.91%) were the five most frequently prescribed antibiotics. In contrast, a study conducted by Meher B. R et al (2014) shows piperacillin/tazobactam was the most commonly prescribed antibiotics. [12]
The Cephalosporin class of antibiotics were the most commonly prescribed (n=120,28.91%) followed by carbapenem(n=69,16.62%), macrolide(n=68,16.38%), penicillin(n=61,14.69%). This observation was similar to a study conducted by Venugopal D et al (2014) which also found that cephalosporins were mostly prescribed to inpatients. [13]

The average number of antibiotics per prescription ranges from 1.722+/-0.8755279(mean+/-SD). A high rate of prescribing antibiotics using brand name was observed in this study. The average percentage of antibiotics prescribed by generic name, brand name was 7.79%, 92.20% respectively. The percentage of antibiotics prescribed from essential medicine list was found to be 81.4814%. The percentage of parenteral antibiotics use was 70.64% and the study was compared with study by Kanishk K et al (2018) where it was reported that the average number of prescriptions was 8.44. Percentage of drugs prescribed by generic name was 33% of drugs with essential drug list was 66.16. [14]

The majority of the antibiotics prescribed were in the Watch followed by Access, Reserve. Of 25 antibiotics prescribed, 7 were Access,15 is Watch, and 1 Reserve. High consumption of watch-group antibiotics was observed in the study. Similar observation was reported by a study by Nguyen NV et al (2020). [13]

The maximum number of ADRs were reported with Beta-lactams (Piperacillin Tazobactam, Cefoperazone + Sulbactam, Ceftriaxone) 10 (76.92%) followed by Macrolides (Azithromycin) 2(15.38%), Aminoglycosides (Amikacin) 1 (7.69%) which was similar to a study conducted by Dhar K et al (2015) which noted that most ADR were reported by ceftriaxone and therapeutic Class of Antibiotics Implicated to cause ADR was beta lactams.[15]

Out of 13 ADR, 3 were reported (23%) by clinicians (**Table no:4)** and 10 were possible ADR suspected by Student Investigators **(Table no:5)**. This observation indicates the role of clinical pharmacist in identifying suspected ADRs. Active involvement of clinical pharmacist and Pharm D students in medication review helps in improving therapeutic outcomes.

An assessment of ADR by WHO causality assessment scale showed possible ADR among the patients which was similar to a study conducted by Dhar K et al (2015) also showed that majority of ADR were possible. Preventability of ADRs was assessed using the modified Shumock and Thornton method. Using the scale, results revealed that 85% ADRs were probably preventable while 15% were definitely preventable. The causality assessment of reported ADRs as per the Naranjo scale and revealed that 69% were possible, 31% were probable ,0% were definite and unlikely. These data correlated with the study of Starveva et al (2008), Priyadharssini et al (2011) which showed that majority of them were possible followed by probable. [16,17]

In this study, it is observed that in reported ADR mild and moderate were 1 and 2 respectively while in case of suspected ADR mild and moderate were 8 and 2 respectively. The result of chi-square shows that there was no significant association between severity and ADRs [X^2 (1,13) =2.3593, P = 0.124541]. The result of chi-square test on association between preventability and ADR showed that there is no significant association [X^2 (1,13) = 0.96515152, P = 0.325892)].

The most commonly prescribed 5 antibiotics were classified using the ATC classification system and drug utilization was measured as DDD/patient per 100 days. Cefoperazone+ sulbactam (J01DD62) was the most commonly prescribed antibiotic with DDD/patient per 100 days value (25.55) followed by meropenem (J01DH02) with DDD/patient per100 days value of 23. In contrast, a study conducted by Patel SR et al (2015) shows that Cefoperazone + sulbactam was the most commonly prescribed antibiotics with DDD/patient per 100 days value of 11.86 followed by amoxicillin + clavulanic acid with DDD/patient per 100 days value of 5.42.

The actual antibiotic cost reduction found in total antibiotics with respect to alternate 1 and 2. The substantial reduction in cost of prescription can be done by performing cost minimization analysis (CMA) for antibiotics. Cost minimization analysis shows a potential reduction in cost of prescription, if there was an intervention. The overall cost of prescription was reduced to 19.14% if the proposed alternate 1 category of brands were used and 33.17% reduction with alternate 2 category of brands. The result could be compared with a study conducted by Sathish VD et al (2019) which observed that 18.4% cost reduced from actual cost and 4.29% overall cost reduction of the prescription.[18]

The percentage of cost reduction was analyzed and observed that the antibiotic piperacillin + tazobactam had a cost reduction of 14.8% and 25.91% when we use alternate brands 1 and 2 respectively. The antibiotic Cefoperazone + Sulbactam had cost reduction of 11.32% and 40.11% respectively. The antibiotic Meropenem had cost reduction of 22.11% and 33.23% respectively. The antibiotic Amikacin had cost reduction of 6.5% and 23.71% respectively. The antibiotic Azithromycin had cost reduction of 1.62% and 8.79%% respectively.

Careful assessment of antibiotic brands has the potential to reduce the cost of antibiotics. Further evaluation and interventions should also consider health outcome such as morbidity, quality of life and mortality.

The influence of CMA in antibiotic were studied using ANOVA. The difference between the alternate 1 and alternate 2 are statistically significant. (F (2,12) =11.61822, P-value = 0.000952). Similar result was reported by a study conducted by Giwa A et al, (2008). [19]

VII. CONCLUSION

The purpose of the study was to assess the drug utilization and prescription pattern of antibiotic usage. In our study, 250 prescriptions were analysed according to WHO indicators; ADRs were analysed and cost minimization analysis was done. Cefoperazone /sulbactam was the most commonly prescribed drug. A total of 13 ADRs were found, reported (3) and suspected (10) and were assessed using WHO causality, Naranjo, severity and preventability scales. ADRs are common occurrence but they are not often recognized. Even if they are recognized they are underreported as many are unaware about the clinical importance. The total cost reduction of 19.14% and 33.17% with alternate brands of drugs shows that effective cost reduction strategies could reduce the cost of therapy which would in turn improve patient compliance and reduces the economic burden.

Our results shows that an active intervention by a clinical pharmacist in process of antibiotic prescription will improve the rational use of antibiotics by reducing the cost.

The clinical pharmacist can provide their services by doing clinical interventions, inspecting patient care area and nursing station regarding antibiotics. To maintain a professional competence pharmacist should play an active role by obtaining patients medication history and also maintain accurate reports of antibiotics as a part of DUE to reduce morbidity and mortality and economic burden of therapy. Therefore, Implementation of multidisciplinary healthcare team including clinical pharmacist (Pharm D) will be beneficial to achieve the rational use of medicine, increase patient safety and to contribute for cost reduction related to medical prescribing.

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