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**CLINICAL ANALYSIS OF MEDICATION INAPPROPRIATENESS /MEDICATION
ERRORS IN TERTIARY CARE SETTING OF HYDERABAD, SINDH, PAKISTAN**

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ABSTRACT

Objective: Inappropriate medications and even medication errors presents today as a fact at hospitals that no longer can be repudiate and it is sometimes has become so frequent and deep-seated in medical practice, it throws an overwhelming burden on health care systems as well as on patients, and because of that studying, classifying, analyzing and trying to eliminate them has become an urgent obligation in medical, clinical as well as pharmaceutical fields.

Methodology: This research study correlates between Pharmaceutical, Pharmacological and Biopharmaceutical sciences, along with Clinical Investigative studies in order to evaluate, analyze, assess and categorize medication use. A total of 340 sample/case was recruited through random sampling technique from different wards of the tertiary care hospital of Hyderabad Pakistan (240 from Medicine wards and 100 from Surgery wards) than samples were evaluated on the basis of collected prescription, transcription, and administration errors.

Results: Up to this moment 340 cases were collected and about 2234 drugs were to be assessed. Out of which 70.5% (n=240) sample were collected from various Medical Wards, while 29.5% (n=100) case was collected from major general surgery, Ortho and traumatology wards. The

primarily results analysis of 698 drug from 110 cases 62.72% (n=69) of them was male & 37.27% (n=41) was female. Generally, the total number of inappropriate medication or errors was enormous representing 45.56% (n=318) of total analyzed sample from various General Medical Units. Majority of errors was Mild with 65.72% (n=209) which represents lack of following of the prescriptions & medical safety guidelines, Moderate errors scored 22.01% (n=70), While Sever errors scored 8.17% (n=26) and completely improper medication was 3.14% (n=10) only.

Conclusion: Overmedication was clearly present in most of the cases and anti-biotic misuse was detected too many times. Although errors itself might not cause imminent threat to the patient's life, the long-term consequences of it might do. Overuse of injections was clearly present despite the fact it increases the risks of blood borne diseases transfusion.

Keywords: Medication Inappropriateness, Clinical and Pharmaceutical Investigations, Errors, Wards

INTRODUCTION

The main goal of drug therapy is to reach intelligible therapeutic outcomes, improve patients' quality of life, and reduce or even eliminate possible and imminent risks. But unfortunately inappropriate medical assessment medication errors stand as a major obstacle during health care providing process. It can be defined as any medical or clinical practice that combines both the actions which is based on medical evidences, along with experts' professional opinion in order to optimize health care and treatments outcomes¹⁻². Medication inappropriateness or errors may defined as Inappropriate medication/errors commonly involves errors in dosing, medication, improper medication, unspecific dosing, dispensing/labeling errors,

dose adjustment mistakes etc. To sum up we can describe it as an unsuitable as well as improper medication that might be given or prescribed to the patient by medical practitioner during health care providing proses.

The European Medication Agency has described medication errors as "unintended mistakes occur during the processes of prescribing, dispensing and administration of a medicine that could cause harm to a patient³. They are the most common preventable cause of undesired adverse events in medication practice and presents a major public health burden". According to the United states Pharmacopeia (USP) already defined medication errors as "any

preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer”⁴. So we can combine both definitions and describe it as any preventable events which occurs during the process of prescribing, dispensing, and administration of the drugs that might cause harm or lead to harmful results on patient’s health or even disturbed their clinical situation.

Inappropriate medication or errors might occurs due to many reasons like lack of knowledge or information of the therapy or about the patients’ history, lack of professional behavior between the medical staff, unclear communication methods or language, poor hand writing, lack of passion and motivation, repetitive interruption, complicated clinical situation, work accumulation, overload and the most important of all stress.

The impact of inappropriate medications or medication errors on health care system as well as on patients’ health is utterly huge. Some reports of the British Medical Association stated that; almost a 250 thousands patients every year are admitted to hospitals suffering from an at least one adverse drug reaction (ADR) related to medication errors in the UK, costing around

£466 million each year⁵⁻⁶. At the same time some studies in the US concluded that thousands of deaths, millions of hospitalizations, and huge a number of medical incidences were originated by inappropriate drug use or correlated to them. And it has been assumed that by intercepting medication errors and its consequences, it is attainable to lessen the total spending cost of public health on mopping up the damage of medication errors by almost \$4 billion⁵. It had been also assumed that the problems which are correlated to medication errors causes or leads to around 30% of hospitalizations in the UK and the USA. While in Germany almost 50% of patients receive more than six drugs per day which opens the door for errors, overmedications and other undesired effects⁷⁻⁹.

The main goals of this study is to identify the medication errors and its causes, to analyze the frequency of medication errors, to study and analyze its consequences and the burden it throws on the patients as well as on the health care system, to classify errors according to the degree of seriousness. And above all to design/develop assessment plan in order to evaluate medication appropriateness or suitability during health care providing process, by which implanting this plan of assessment will reduce medical

related events and save health care cost. As well as it might provide a background for future studies which is to be conducted in the same field?

METHODOLOGY OF THE STUDY

This research study is a descriptive study based on a clinical retrospective analysis of records, medical charts, and prescriptions. A concise and comprehensive medical sheets was designed based on detailed history, local examination, labs reports, clinical examination and evaluation to collect the required medical information. Then designed a frame work for assessment of medication

effectiveness, suitability and appropriateness by which I have developed an assessment plan combines both Explicit and Implicit Criteria properties of clinical assessment at the same time, using specific as well as flexible techniques.

A total of 340 sample/case was recruited through random sampling technique from different wards of the tertiary care Hospital of Hyderabad Pakistan (240 from Medicine wards and 100 from Surgery wards). After samples than evaluated the collected prescription, transcription, and administration errors was investigated.

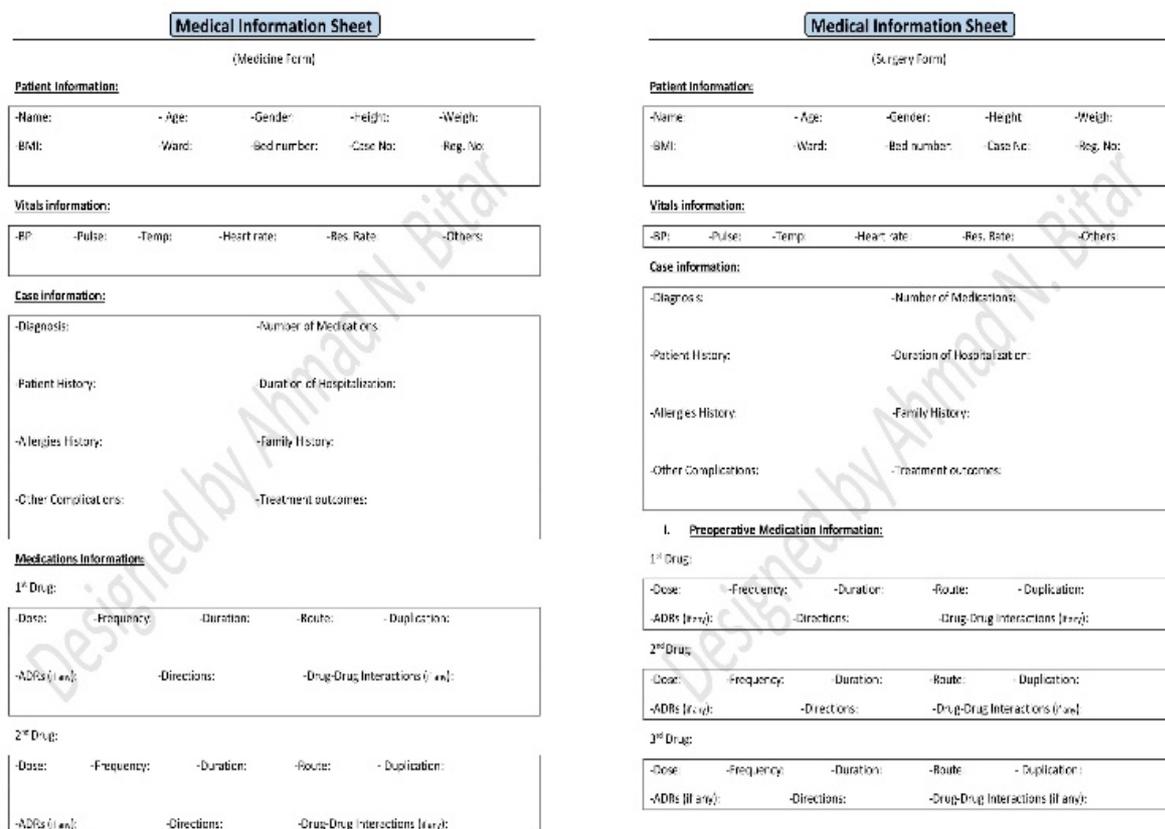


Figure: 1.1.comprehensive Medical Information Sheets.

Clinical Assessment plan:

The research clinical assessment plan was divided into three major stages each of which consisted of multiple steps. The first stage was started with the collection of the required cases and information using comprehensive medical information sheets developed for medicine ward samples in 1st step, and then the 2nd step was sampling from surgery wards using information sheets which was also specified for surgical unites.

The second and the major stage was about analyzing and evaluation of the drugs which was also divided into four steps. The 1st step was marks calculation based on the designed

clinical assessment questionnaire of 14 point each point carry (1 to 3) marks, the total score will be counted the lowest score is the better while the highest score is the worst, then in 2nd step the total score of each drug will be put against evaluation scale of five classes in which proper medication will be 14 and completely improper will be 30 marks or more, 3rd step is correlation and analysis, and 4th is leveling, evaluation and outcomes analysis.

Finally the 3rd stage was about errors classification, analysis and categorization according to the degree of seriousness, and clinical outcomes of each error from (0-6).

Medication Appropriateness Assessment Questionnaire					
-Drug:	-Drug Number:	-Case Number:			
1st Assessment Step:					
1. Is there an indication for the drug?	Yes 1	2	No 3	Comments	
2. Is the medication effective for the condition?	Yes 1	2	No 3	Comments	
3. Is the dosage correct (Size/Frequency)?	Yes 1	2	No 3	Comments	
4. Are the directions correct?	Yes 1	2	No 3	Comments	
5. Are the directions practical?	Yes 1	2	No 3	Comments	
6. Are there any drug-drug interactions?	No 1	2	Yes 3	Comments	
7. Are there any drug condition interactions?	No 1	2	Yes 3	Comments	
8. Is there a duplication with any other drug?	No 1	2	Yes 3	Comments	
9. Is the duration of treatment proper?	Yes 1	2	No 3	Comments	
10. Is this an expensive drug compared to others?	No 1	2	Yes 3	Comments	
11. Is there any preventable ADRs?	No 1	2	Yes 3	Comments	
12. Is there any Contra-indications?	No 1	2	Yes 3	Comments	
13. Is this an incomplete Chart/Prescription?	No 1	2	Yes 3	Comments	
2nd Assessment Step:					
14. Is there any unexpected miscellaneous errors?	No 1	2	Yes 3	Comments	
3rd Assessment Step:					
15. Evaluation Scale Score:	Proper (14)	Mild (15-19)	Moderate (20-24)	Sever (25-29)	Improper (30+)
4th Assessment Step:					
16. At what stage the error has occurred?	Prescription	Transcription	Administration		
17. Is this probably caused by poor illegible hand writing?	Yes	No			
18. Is this probably caused due medical abbreviation usage?	Yes	No			
19. Which medical professional were involved in?	Physicians	Nurses	Pharmacists		
5th Assessment Step:					
20. According the following scale, how serious is this error?	1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10.				
21. At what level it can be considered?	0 - 1 - 2 - 3 - 4 - 5 - 6.				
22. Does it cause permanent damage to the patient?	Yes	No			
23. Does it cause significant financial burden on patients?	Yes	No			
24. Does it cause significant burden on health care system?	Yes	No			
25. Is overall medication course proper?	Proper	Under/over medication	Other		

Figure: 1.2. Medication Appropriateness Assessment Questionnaire.

Clinical Categorization and Evaluation:

The appropriateness of the prescribed drugs will be assessed using START/STOPP criteria⁸⁻¹⁰, Integrated Management of Childhood Illness (IMCI)¹¹⁻¹², and Medication Appropriateness Index (MAI)¹³, which is very approvable reliability indicator that has been used very openly to intercept medical errors more than any other set of medical assessment criteria, and it proved to be able to support proper actions to improve health care providing process. Finally errors and inappropriate medications will be grouped and categorized according to their degree of severity/seriousness (weather it is harmless, causing a significant damage, or even might lead to death), and outcomes using the following classification¹⁴⁻¹⁷:

Degree 0: errors occurred and resolved by medical personnel.

Degree 1: errors appeared but did not cause any significant harm to the patient.

Degree 2: errors appeared and led to clinical monitoring but did not cause a significant change in patients' clinical situation.

Degree 3: errors appeared causing disturbance in clinical situation, or required more laboratory test or monitoring, but it is reversible and did not lead to permanent harmful consequences.

Degree 4: errors appeared and required intensive care, or even increased duration of treatment.

Degree 5: errors appeared causing a perpetual irreversible damage to the patients' health.

Degree 6: overwhelming errors appeared leading to the death of patient.

RESULTS ANALYSIS**General Research Summary:**

A total of 340 sample/case was recruited through random sampling technique from different wards of the Liaquat University Hospital, Hyderabad/Jamshoro. Out of which 70.5% (n=240) of the samples were collected from various Medical Wards (including general medicine units, pediatric units, cardiology units, and pulmonary ward), and 29.5% (n=100) were from Surgical Wards (including general surgical units, surgical pediatric units, orthopedic and traumatology units). Out of them 57.94% (n=197) sample were male and 43.16% (n=143) were female. The total Number of drugs to be assessed is 2234 each of which will take about 20 min to be assessed properly. Form Medicine Wards 1661 drug will be assessed, While from Surgery 573 drug will assessed including pre and post-surgical medications.

Size wise distribution of samples:

The lion share of samples went to the general medicine wards (unit I, II, III, and IV) representing 32.35% (n=110) of the total number of samples collected, pediatric units and cardiology wards each of them occupied 16.17% (n=55) of total number, while pulmonary, pediatric surgery orthopedic and traumatology wards took only 7.35% (n=25), and at the same time general surgical units (I, II, III, IV) together accounted for 15% (n=25) of samples total number.

Primary results analysis and discussion of 110 case:

The results analysis which will be presented in this paper will include general medicine wards samples which is accounted for 32.35% (n=110) of total samples and contained 698 drug representing 31.24% of total drugs number, and the total number of errors which have been encountered was 318 error representing 45.55% out of total number of drugs which was prescriber in medicine wards. From this sample of 110 case the majority of patient were male with 62.72% (n=69), while female patients were 37.27% (n=41) only.

1st assessment step of the presented sample: In this step drug is to be assessed by passing through the medical assessment questionnaire.

The following clustered bar chart represents the distribution of errors after assessment its clear here that incomplete chart or prescription was sky rocketing in all four medical units especially medical unit one accounting for almost one third of total number of errors, then comes indication errors by which majority of them after analysis turned out to be due to supplementation drugs errors, antibiotic misuse, and ulcers medication overuse. Also major drug-drug interactions errors were present in a significant way indicating lack of knowledge about them among medical professional. On average more than 6 drugs were prescribed to each patient at the same time.

Kidney and liver diseases:

Out of 110 case 19.09% (n=21) of them were suffering from kidney or liver diseases and sometimes from both, as their major reason of hospitalization or even as complication due to their medical condition or previous illness. Almost one fifth of them have died (n=4) during hospitalization.

The major issue here is the contraindicated medication which was prescribed to them mistakenly causing some serious damage to patients in critical conditions.

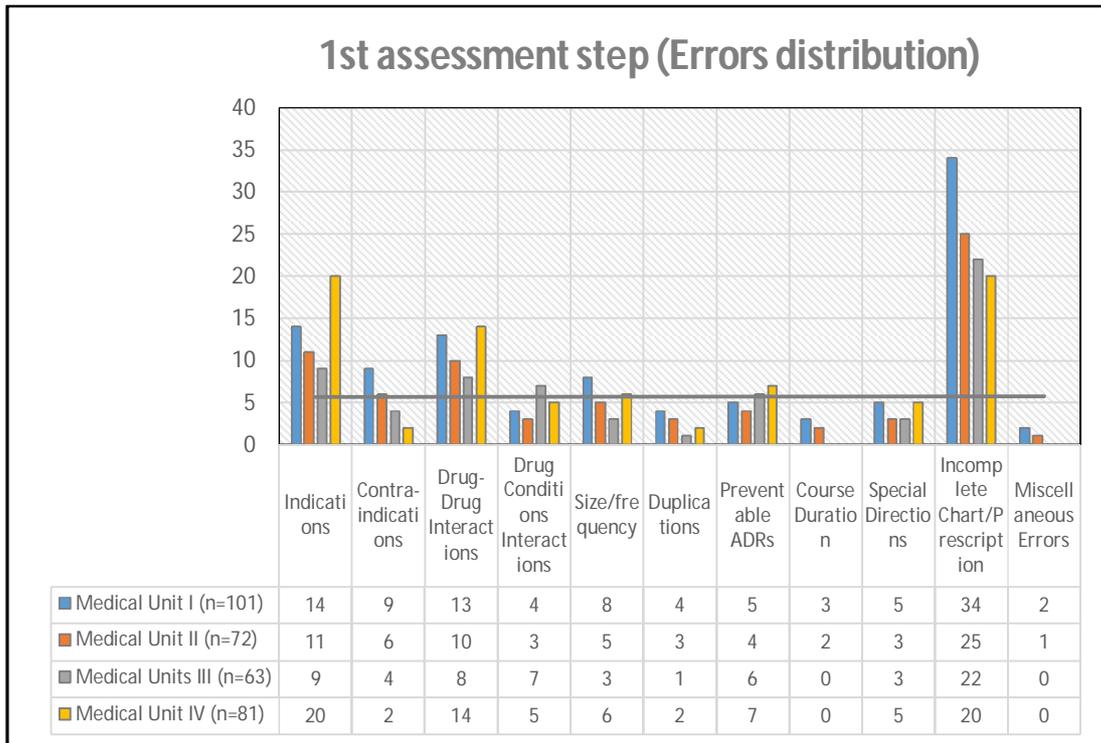


Figure: 2.1. Medication Errors Distribution.

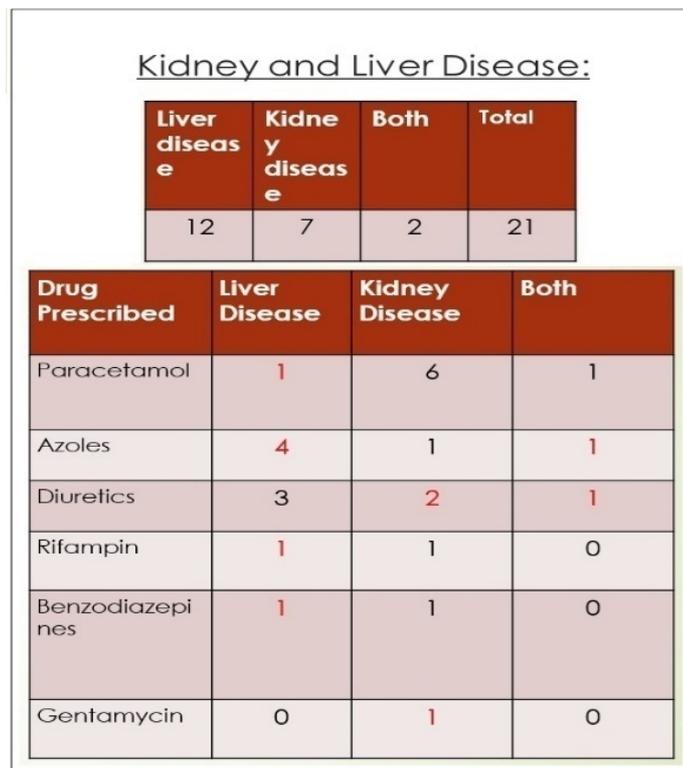


Figure: 2.2. Kidney and Liver Toxicity

2nd Assessment Step of the presented sample:

This step include scaling, after 1st step the total score of mark obtained by each drug will be put against the evaluation scale of five categories as the following:

- If drug scored 14 it will be proper medication.
- If it scored between (15 to19) it will be considered mild error.

- If the score was from (20 to 24) it will be Moderate error.
- While if the score was from (25 to 30) the error will be considered sever.
- Finally any score from 30 and above then the drug will be considered totally improper.

On the following chart we see there is huge amount of errors representing 45.55% (n=318), Majority of errors were mild.

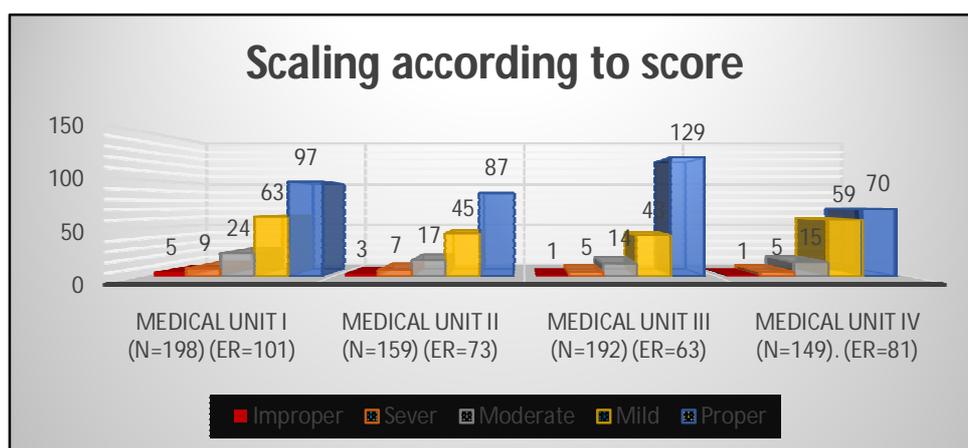


Figure: 3.1. Errors Distribution According to Evaluation Scale.

Death toll analysis:

The following radar chart represents death which was encountered in medical units I, II, III, and IV. The total number of deaths occurred was 21 distributed as following (medical unit-I =8, medical unit-II=4, medical unit-III=5, and medical unit-IV=4). By correlating the number of errors after scaling and its seriousness occurred in each

unit and number of deaths encountered in each of them, it is clearly visible here that medical unit I was accounted for the highest number of prescribed medication, significantly the highest of errors, and also with highest number of deaths. And the maximum number of deaths occurred due chronic liver diseases with 6 deaths accounting for almost one third of deaths.

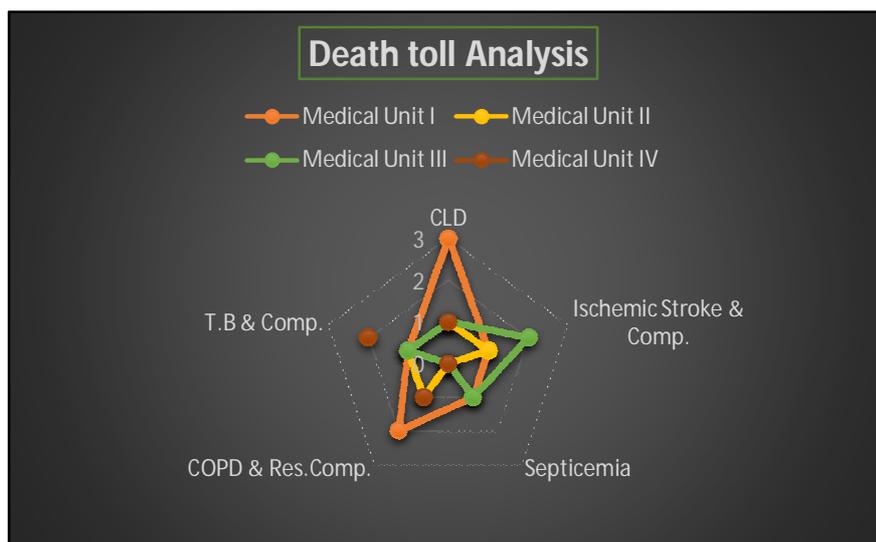


Figure: 3.2. The Deaths That Occurred and its Analysis.

Disease complications analysis:

During this study too many sever diseases was encountered like liver diseases, malignancies, ischemic, stroke, COPD, DM, RTIs, UTIs, TB and meningitis. They are to be discussed in details thesis along with poisoning cases, but what deserved notifying or discussing was that all patient who were suffering from COPD, were at the same time

patients of DM and all of them were male patients.

As we know lung disease is much more common in males than females which is clear, but the association of DM with COPD is not established before and it opens the door for investigations about the pathophysiological correlation between both diseases.

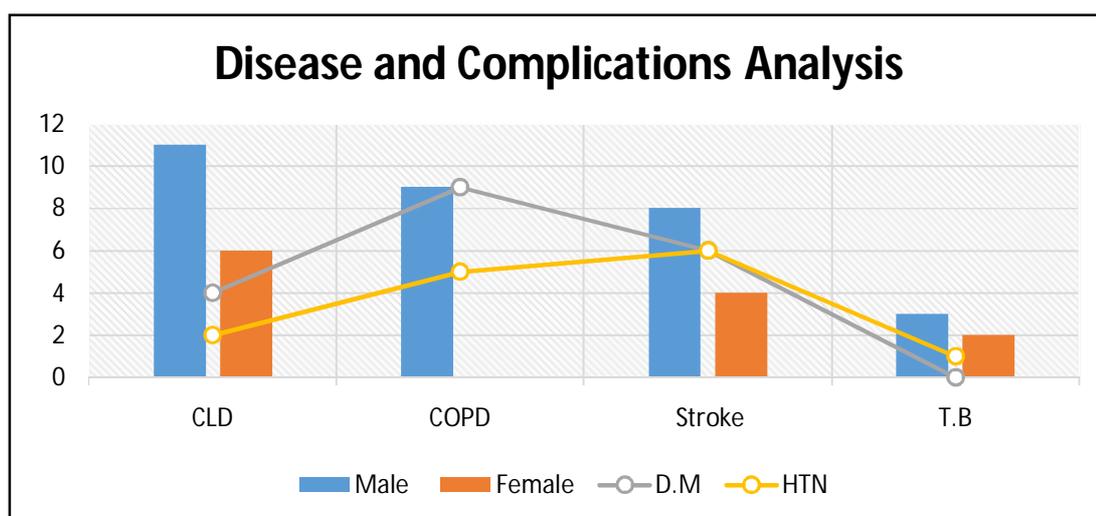


Figure: 3.3. Linking Complications with diseases.

3rd assessment step of the presented sample:

During this step analysis of causes was done, majority of errors occurred during the process of prescription accounting for almost 65% which was done by medical officers and physicians, medical abbreviation errors were clearly significant during administration process and was committed by nurses which indicate that there is lack of back ground between nurse staff about them. Although very bad hand writing was encountered multiple time, it did not cause a significant damage.

4th assessment step of the presented sample:

Overmedication was detect too many times with total number of 41 case especially in medical unit-I which was accounted for more than one third of them 39.02% (n=16) case. Although all units remained between one to five life-threatening errors and significant errors, medical unit-I scored the highest number for both.

While under medication detected three times only, all three cases were cases of poisoning specially antidotes errors. Which suggest lack of practical background about poisoning among medical practitioners and especially house officers?

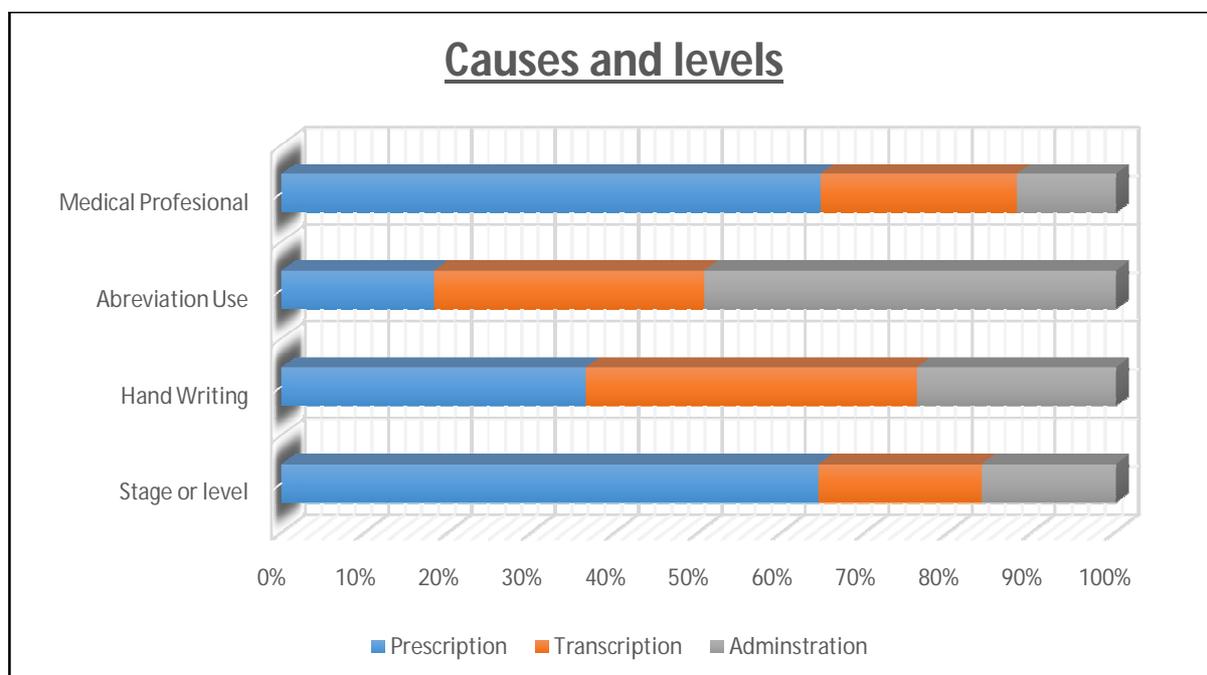


Figure:4.1. Distribution According to Stage

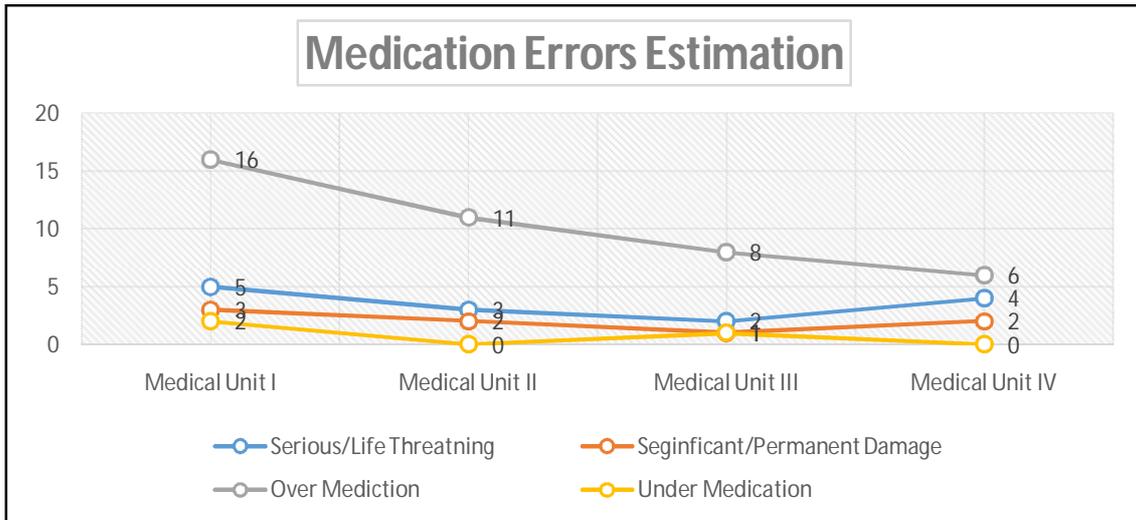


Figure 5.1: Estimation of Medication Errors.

Categorization:

Errors then were categorized and classified according to the degree of seriousness from 0 to 6. Despite the fact that most of errors concentrated in the first three categories, it

opens the door for more serious errors. In fact our major concern is about 3rd degree onward because those represented the amount of damage caused to patients during health care providing process.

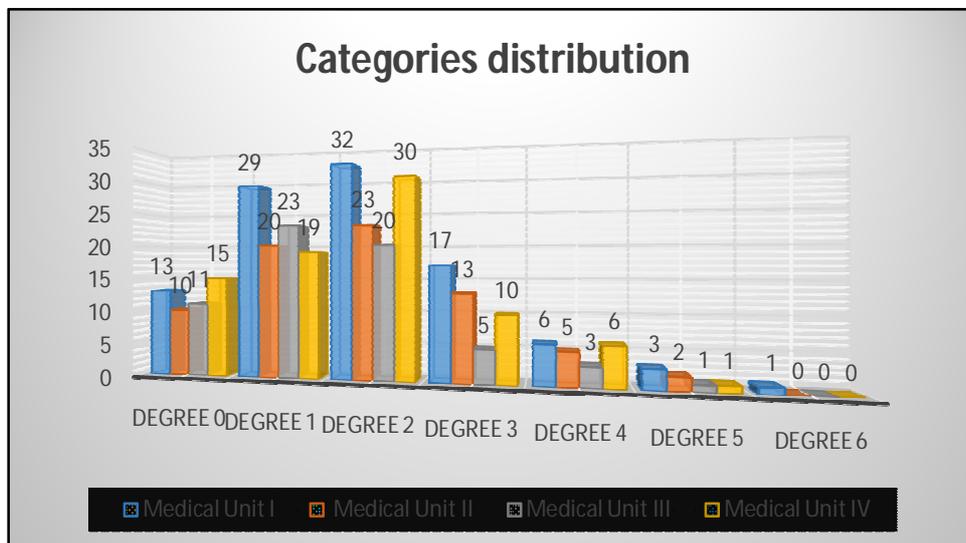


Figure: 6.1. Categorization of Errors Based on Severity and Outcomes.

Statistical analysis:

The statistical analysis was done using SPSS 20th edition. The frequencies and descriptive

analysis of errors indicated that the range of errors was 10, sum 318, mean 2.8909 and with standard deviation (S.D) of 1.814.

Table 1.1: Descriptive Statistics

	N	Range	Minimum	Maximum	Sum	Mean	Std. Deviation
Total number of medication	110	15.00	2.00	17.00	698.00	6.3455	2.66281
Total Number of errors	110	10.00	.00	10.00	318.00	2.8909	1.81404
Valid N (listwise)	110						

After conducting correlation analysis it revealed that there is a significant positive relationship between errors and number of medication, $r(108)=0.798$, $P=0.001$.

Table 1.2: Correlations

		Total number of medication	Total Number of errors	Male/Female
Total number of medication	Pearson Correlation	1	.798**	.006
	Sig. (2-tailed)		.000	.951
	N	110	110	110
Total Number of errors	Pearson Correlation	.798**	1	.036
	Sig. (2-tailed)	.000		.708
	N	110	110	110
Male/Female	Pearson Correlation	.006	.036	1
	Sig. (2-tailed)	.951	.708	
	N	110	110	110

** Correlation is significant at the 0.01 level (2-tailed).

And by presenting this data on a scattered blotting graph it indicated that there is a clear linear correlation ship between errors and medication.

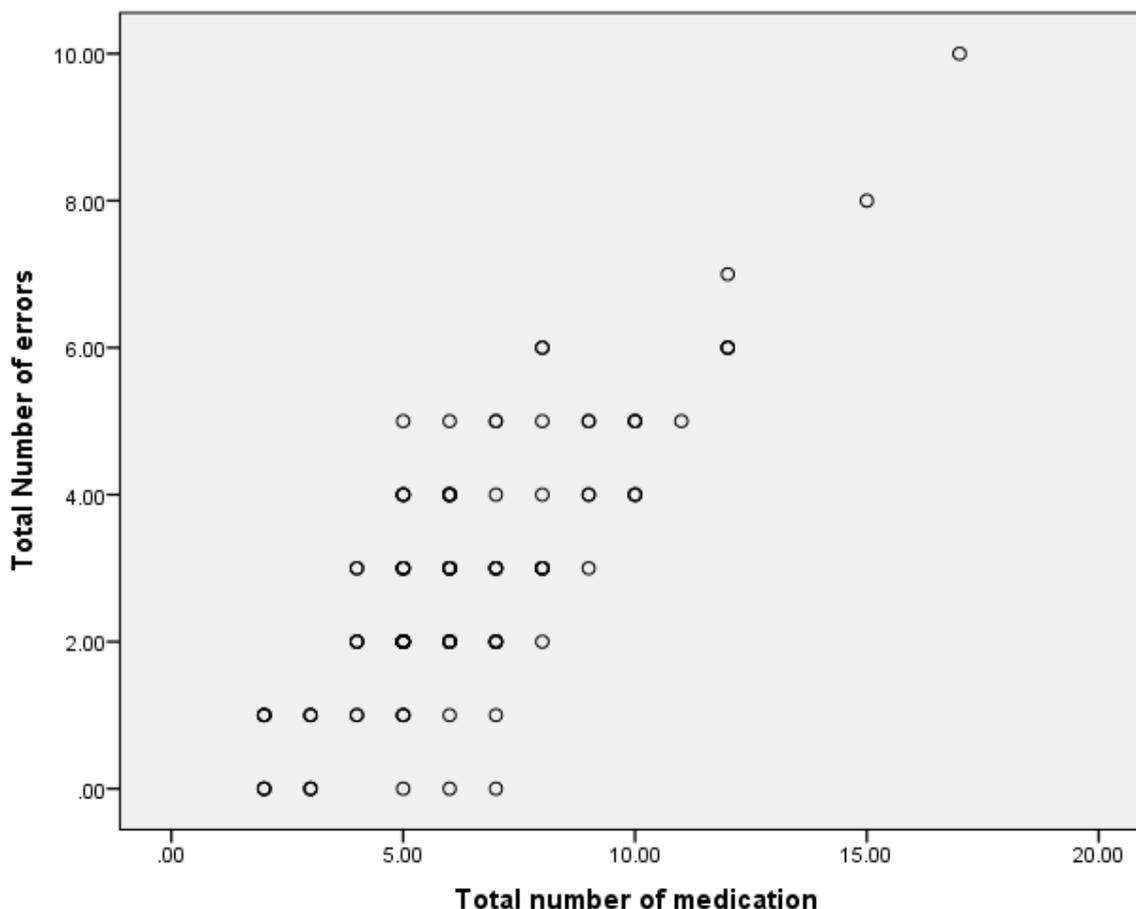


Figure 7.1

CONCLUSION

Overmedication was clearly present in most of the cases and anti-biotic misuse was detected too many times. The doses were not adjusted even in case of renal and liver impairment or diseases. Overuse of IV/IM route in general medicine units was detected too many times even when patient in a perfectly proper condition for Oral medication. Which increases the risks of blood bore diseases transfusion? The study also suggest that there might be a Pathophysiological correlation between D.M and COPD, because all patient of COPD were suffering from D.M. Anyhow this topic will be thoroughly studied during the assessment of pulmonary ward cases, and maybe in an independent pilot study will be conducted about it. Although errors itself sometimes might not cause imminent threat or death, the long-term consequences of it might do, it also has been detected that the highest number of poly pharmacy medications, was associated with high number of errors as well as with largest number of deaths specifically in medical unit-I, it was the worst of medication appropriateness the highest in errors and also in deaths rate as compared to other medical units. At the end of the day all of us seeks help at health facilities to relief our pain and

reduce our suffering and none of us or our beloved once want to be in situation where he/she goes medical facilities to be cured and instead of that comes back with the burden of medical mistake or error.

Conflict of Interest:

There is no any conflict of interest.

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