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CLINICAL ASSESSMENT, EVALUATION, AND CATEGORIZATION OF MEDICATION ERRORS

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ABSTRACT

Objectives: Tertiary care settings are the ultimate breeding grounds for medication errors which are usually unpredictable and can be overwhelmingly serious. Medication errors are not only affecting the patients' condition but also can totally halt the treatment process. In fact, whenever errors increase the trust in any health care system will be decreased. This study aimed at identifying medication errors and its causes, analyzing its prevalence, and tried to classify medication errors according to their degree of seriousness. This research also aimed at developing a practical mechanism to assess prescribed drugs and detect errors.

Methods: This is an investigative descriptive retrospective clinical analysis of 340 patients conducted using a combination of explicit as well as implicit methods of clinical assessment. Assessment and evaluation plan for each prescribed drug consisted of three major stages and multiple steps, in which medication were tested and evaluated using especially designed and carefully built tools. **Results:** A total of 2234 prescribed drugs were assessed in this study (medicine=1661, surgery=573). Errors were detected in in 36.34% of drugs, majority of which were mild 58.74%, while serious errors accounted for about 12% and incomplete prescription represented 36.69% of all detected errors. The highest mean SD for prescribed drugs (7.44±1.93)

and errors (4.08±1.1) was the in pulmonary ward. 74.13% of errors occurred in prescription stage and overprescribing was detected in 95 profile. After stratified categorization based on seriousness, 80.41% of errors clustered in the first low risk three categories and 2.33% of errors in D5 and D6 were life threatening.

Conclusion: Medication errors were extremely ubiquitous among the recruited sample. Although incomplete chart/prescription mostly was not a serious error, it opened the door for more significant and really dangerous errors. Almost all errors were preventable and prescribing errors were the most dominant.

Keywords: Medication Errors; Clinical Assessment; Evaluation of Medication Errors; and Medication Error Categorization

1. INTRODUCTION

Drug therapy aims at achieving tangible therapeutic results, enhance patients' quality of life, and at the same time strives to reduce the any possible risks. However, medication errors stands as a major obstacle hindering the provided treatments, casting its shadow on patients' quality of life, and shackling health care systems with huge burdens.

Justified and wise medical practice which is based on proper medical evidences as well as experts' professional decisions can be called as appropriate treatment [1]. On other hand, medication errors can described according to Food and Drugs Administration (FDA) of the United State of America 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"*[2]. The European Medicine Agency (EMA) defined medication errors as *"unintended mistakes occurs during the processes of prescribing, dispensing and administration of a medicine that could cause harm to a patient"* [4].

In a nutshell, medication errors can be describe as any preventable events or inappropriate actions that might occur throughout various steps of health care providing process (prescribing, dispensing, transcription, administration) [3]. That includes errors which are caused by lack of communications, lack of knowledge, lack of experiences, unprofessionalism, poor hand writing, information missing, interest absence, frequent interruptions, overload errors, and errors caused due to stress or anxiety.

Medication errors throw an utterly huge burden on health care systems, society, and on the patients' life. According to the

National Health Service (NHS), the most recent reports on medication reports revealed that the cost of medication errors widely varied form £67.93 up to £6,927,078.96 [5], with an average cost to mitigate its adverse effects fluctuating around £466 million per year [6]. Over 237 million errors per year were detected in England alone out of which 28% had serious consequences, and it was estimated that adverse drug reaction caused by medication errors cost the NHS about £98.5 million in 2017 alone; leading to 712 deaths and prompting to 1708 more [5].

In the United State of America (USA) it has been revealed that thousands of deaths and millions of hospital admissions were caused by medication errors. It has been concluded that preventing medication errors will reduce the cost of health medical spending by $4 billion [6, 7], in fact in the US medication errors were responsible for about 30% of all hospitalizations [7].

Medication errors have a big impact on health care system as well as on patients' health conditions. Its effect can differ dramatically from minor almost intangible events to major devastating incidents. Errors consequences can be wide, serious, and complicated; leading to reduced trust in health care system, building a remarkable increase in health care cost, casting a huge financial deficit, increasing the prevalence and complexity of adverse drug reactions (ADR), causing unexpected interactions, and even some times leading to patient's death [10].

Since there is a lack of reports about medication errors in undeveloped countries. This study is shedding some light on medication errors at tertiary care setting of Hyderabad, Pakistan. Prescribed medication were evaluated, errors stages were identified, the prevalence of errors was analyzed, and on bases of severity it was accordingly classified using especially designed clinical assessment plans, scaling method, and evaluation plan.

2. RESEARCH METHODOLOGY

This research is an investigative descriptive retrospective clinical analysis of the available patients' records. Which was conducted using a combination of explicit as well as implicit methods of clinical assessment which is considered to be effective, specific, and flexible at the same time. After receiving a confirmed ethical approval from the concerned departments. Information was collected from patients' detailed history, prescription records, laboratories reports, patients' charts, conducted investigative test, clinical bedside examination reports, as well as hospital database. In order to collect the required information especially designed

collection tools were used, and comprehensive medical information sheets were designed for medicine specialties and for surgical once.

The samples [340 patients (240 patients from medicine wards, 100 from various surgical wards)] were recruited using random sampling techniques from various wards and departments of Liaquat University Hospital and Civil Hospital of Hyderabad. Then cases were assessed and medication errors were identified if occurred at any stage of health providing process including drug prescription, transcription, dispensing, and administration. Medication appropriateness for all patients was assessed against the most recent reports and guidelines.

2.1.Assessment and Evaluation Plan:

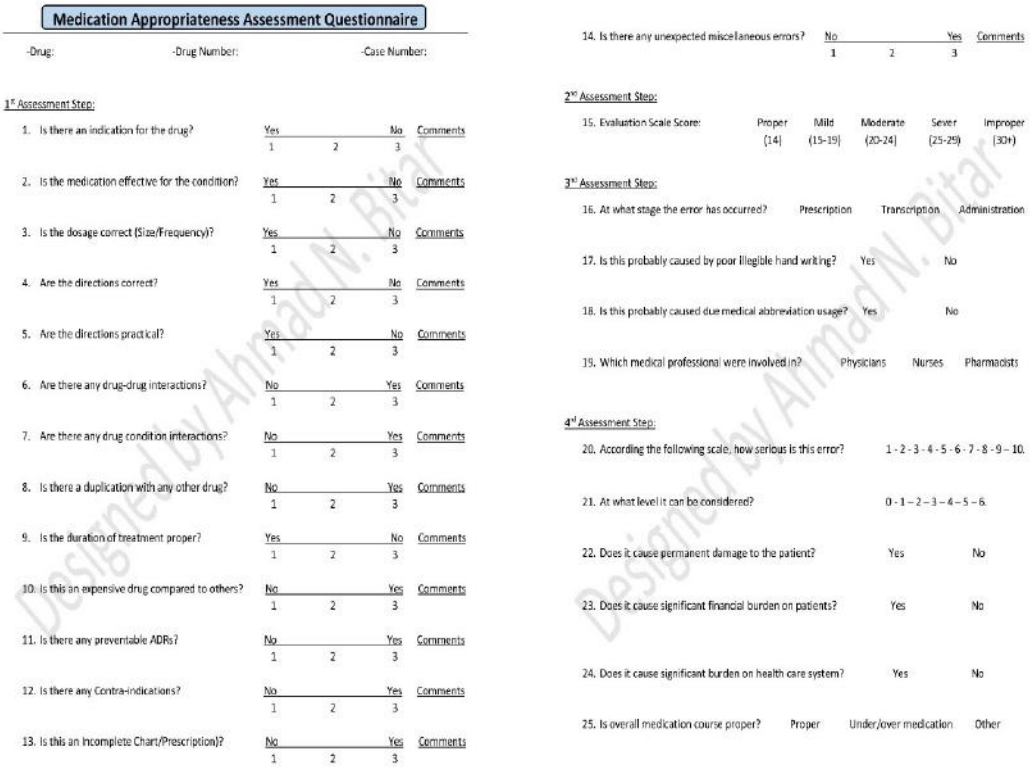
Evaluation plan for each drug consisted of three major stages and multiple steps. The first stage was sample and data collection from various wards, units, and departments of the above mentioned hospitals using the especially designed surgical and medical information sheets. The most important stage was the second one, it was divided into multiple steps concentrating on suitability evaluation and drug assessment. The 1st step of the second stage was primary assessment in which the score of each assessed drug was calculated using the designed assessment questionnaire (MAAQ) *Fig.1* then the total score obtained by each drug was tested against the constructed evaluation scale of medication appropriateness. A panel of experts verified the designed questionnaires and evaluated its contents.

To calculate the scores, drugs were assessed against fourteen questions each of which carrieda marking system from 1 to 3 and overall score ranged from 14 up to 42, and the lower the score the more suitable the drug. Then in the 2nd step the obtained scores were assessed against the evaluation score which was categorized as following: 1. Proper medication use (14) points. 2. Mildly inappropriate use (15-19) point. 3. Moderately inappropriate use (20-24) points. 4. Severely inappropriate use (25-29) points. 5. Completely improper (30+) points.

In 3rd step data or information related to errors were assessed and analyzed. That included correlation and analysis of errors linked information like level of errors, causes of medication errors, which medical practitioner were involved in errors, etc. 4th and final step of the second stage concentrated on ME evaluation for seriousness, consequences, harmful effect, ultimate outcomes, burden, and whether there is over/under medication.

The third stage was all about clinical classification of medication errors according to the degree of error seriousness using a specifically constructed 7 levels criterion as following: 1. Zero Degree (D0): included errors resolved by medical staff before giving the drug to the patient. 2. First Degree (D1): minor error events occurred without causing any harm. 3. Second Degree (D2): errors required clinical monitoring but without causing any significant changes in patient's medical condition. 4. Third Degree (D3): reversible errors that caused clinical disturbance without permanent damage. 5. Forth Degree (D4): errors required hospitalization or intensive care and increased treatment duration. 6. Fifth Degree (D5): errors caused permanent irreversible damage. 7. Sixth Degree (D6): overwhelming errors led to death.

In this study any hospitalized patients whether male or female aged from three years up to seventy five years were included in the study, while newborns, infants, very old patients, and non-hospitalized patients were excluded from the study. Special populations like patients with malignancies, genetic disorders, or rare conditions were also excluded.



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
14. Is there any unexpected miscellaneous errors?	No 1	2	Yes 3	Comments

2nd Assessment Step:

15. Evaluation Scale Score: Proper (14) Mild (15-19) Moderate (20-24) Sever (25-29) Improper (30+)

3rd 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

4th 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: Medication Appropriateness Assessment Questionnaire (MAAQ)

3. RESULTS

A total of 340 patients were included majority of them were male 57.94% (n=197), most of patient from both gender were clustering in 61-75 age group combined representing 67.05% (n=228). A total of 2234 prescribed drug were assessed in this study vast majority of them were encountered in various medicine wards (n=1661) while the remaining (n=573) were collected from various surgical wards. The most prevalent type of errors encountered was incomplete drug prescription which represented 36.69% (ER=298) of all detected errors (ER=812). 19.33% (ER=157) of the detected errors were in prescribed drug strength and frequency, while indication errors accounted for 0.9.97% (81 ER), drug interactions were detected (ER=66) representing 08.12% and the remaining seven categories combined together accounted for the remaining 25.86% (ER=210) **(Table 1)**.

Table 1: Medication Errors Distribution

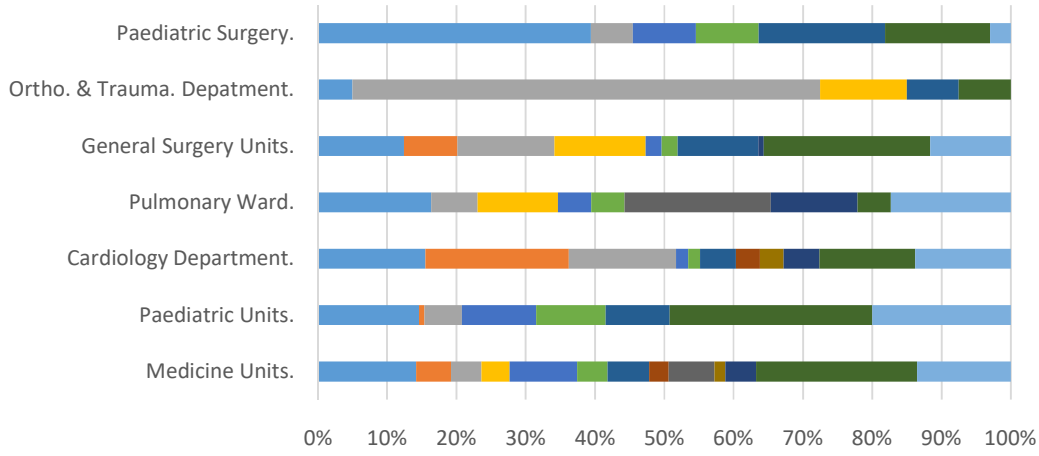
	Medical Units I, II, III, and IV (n=110).	Paediatric Units I, and II (n=55).	Cardiology Department (n=55).	Pulmonary Ward (n=25).	General Surgery Units (n=50).	Ortho. And Trauma. (n=25).	Paediatric Surgery (n=25).
Indications	54	7	2	12	5	1	0
Contra-Indications.	21	2	4	5	3	2	1
Drug-Drug Interaction	45	4	3	2	3	5	4
Drug Condition Interactions	19	5	1	3	5	2	0
Strength/Frequency	22	34	18	23	38	12	10
Duplications	10	9	5	8	5	3	0
Preventable ADRs	22	6	3	7	4	4	2
Course Duration	5	1	0	4	3	0	0
Special Directions	16	4	1	2	3	0	0
Incomplete Chart/prescription	101	53	24	31	64	12	13
miscellaneous	3	1	1	5	0	0	0
Total number of errors/Total number of drugs.	318/698	126/380	62/397	102/186	133/330	41/105	30/138

Despite the fact that cardiology department was the second highest in term of number of prescribed drugs with mean SD of 7.21±2.98 per patient, it was the lowest in term of encountered errors with 1.12±0.2 per patient. In general medicine units the mean SD was 6.34±2.01 for prescribed drugs, while in term of the number of errors the mean SD was 2.89±0.8. Orthopedic and traumatology department was the lowest in term of drug prescribing with 4.20±0.42 mean SD **(Table 2)**.

Table 2: Prescribed drugs and medication errors mean SD as per ward, unit, or department

	Prescribed Drugs	Medication Errors
General Medicine Units	6.34±2.01	2.89±0.8
Paediatric Units	6.90±1.33	2.29±0.63
Cardiology Department	7.21±2.98	1.12±0.2
Pulmonary Ward	7.44±1.93	4.08±1.1
General Surgical Units	6.60±1.5	2.60±0.42
Paediateric Surgery Ward	5.52±0.3	1.20±0.12
Orthopedic & Traumatology Department.	4.20±0.42	1.64±0.7

Medication Errors were encountered in every unit, department, or ward. The most common errors were in supplementation drugs, unnecessary prescribed drugs, including many incomplete prescriptions representing more than one fifth of all errors **Figure.2**.



	Medicine Units.	Paediatric Units.	Cardiology Department.	Pulmonary Ward.	General Surgery Units.	Ortho. & Trauma. Depatment.	Paediatric Surgery.
Antibiotics & Antifungal	45	19	9	17	16	2	13
Diuretics & Antihypertensive	16	1	12	0	10	0	0
NSAID & Antipyretic	14	7	9	7	18	27	2
Steroidal Drugs	13	0	0	12	17	5	0
GIT Ulcer Drugs	31	14	1	5	3	0	3
Bronchodilators and antitussive	14	13	1	5	3	0	3
sedative, hypnotics, & anticonvulsants	19	12	3	0	15	3	6
Cardiogeic & life Suportive Drugs	9	0	2	0	0	0	0
T.B and Antimalarial	21	0	0	22	0	0	0
Anticoagulants and Antiplatelets	5	0	2	0	0	0	0
Hypoglycemic Drugs	14	0	3	13	1	0	0
supplementation Drugs	74	38	8	5	31	3	5
Other Drugs	43	26	8	18	15	0	1

Figure 2: Distribution Analysis of Medication Errors

Errors in antibiotics were the also prevalent and more serious and they have been accounted for about 15% of errors, also antibiotic multidrug resistance has been detected 5 times in this study due overprescribing habit of antibiotic in Pakistan. Errors in T.B drugs were significantly more serious and with higher impact on patients' health condition since T.B treatment can take 6 to 10 months. Error

in drug with narrow therapeutic index and highly toxic drugs like cardiogenic, anticoagulants, life supportive drugs were detected only 11 and 7 times respectively. Parenteral routes were extensively over used and overprescribing was the general norm in all wards and departments except for the pediatric surgery.

Errors occurred in 36.34% of all assessed drugs (ER=812) out of 2234 prescribed drug. According to the assessment plan and the developed evaluation scale it was clear that medical units alone were accounted for 39.16% (ER=318), while in term of the number of prescribed drugs medical unites represented about one third of all prescribed drugs (PD=698) **Figure 3**.

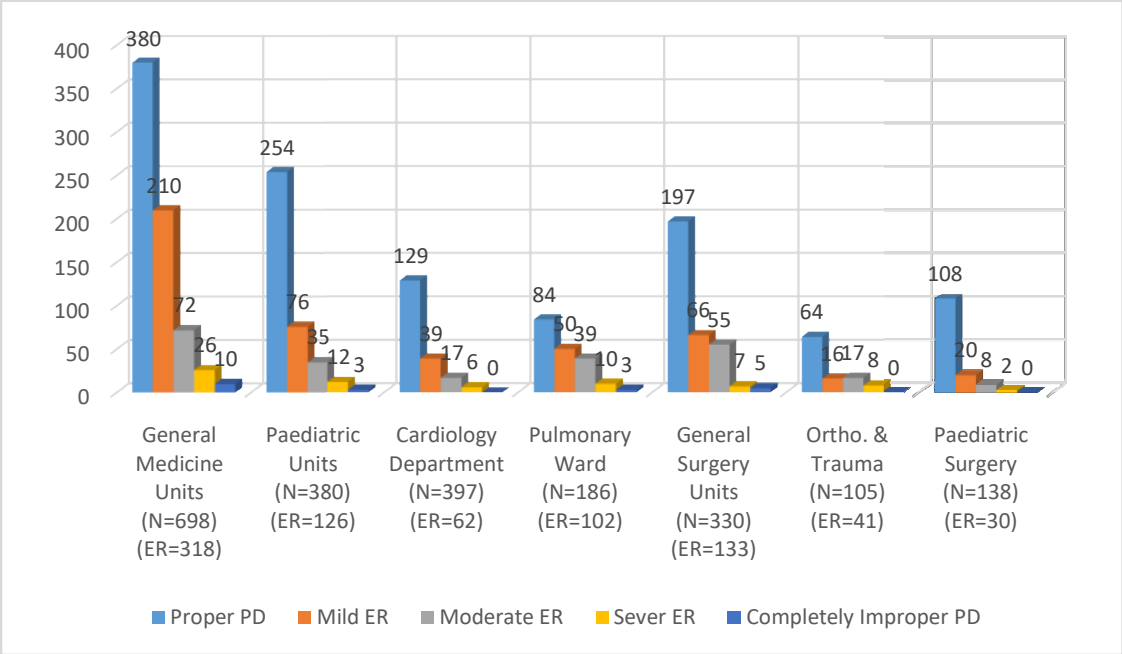


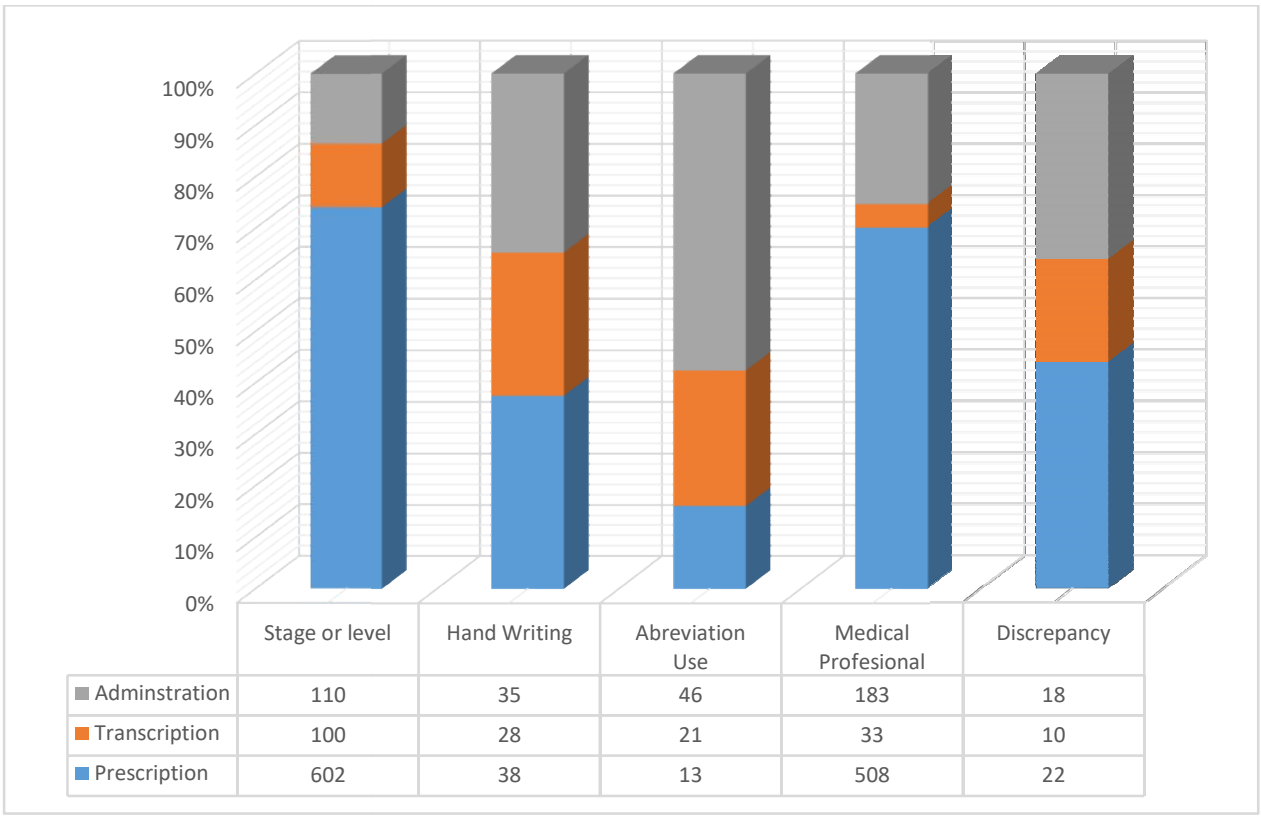
Figure 3: Scaling and errors categorization on the bases of evaluation score

Also, a very significant number of errors was detected in general surgery, pediatric ward, and pulmonary department with [16.37% (ER=133), 15.51% (ER=126), and 12.56% (ER=102)] respectively, and the rest of included departments or wards shared the remaining 16.37%.

The vast majority of errors were mild accounting for 58.74% (ER=477) of all detected errors, while errors considered as moderate detected in 289 PD occupying 35.59% of all errors. The most dangerous and fatal errors were in sever and completely improper PD and they were accounting for more than 11% of all errors with 08.74%

(ER=71) for sever errors and 02.58% (ER=21) for improper PD.

Information regarding causes of errors, their stage/level, and the responsible medical professional were collected and analyzed in the third step of the research. The results showed that 74.13% (ER=602) of the encountered errors were in the prescribing phase, the errors that were spotted in transcription phase represented 12.31% (ER=100), while errors at administration level accounted for 13.54% (ER=110). ME linked to poor hand writing were ranging from 25%-35% during health care providing steps, 58.97% of errors caused by medical abbreviation use were in drug administration step, inappropriate prescribing by physicians was detected in 508 drug representing 62.56% of all errors, while nurses and pharmacist were responsible for 22.53% (ER=183) and 0.4.06% (ER=33) respectively and the origins of the remaining 10.83% of errors were not clearly identified **Figure 4**.



	Stage or level	Hand Writing	Abreviation Use	Medical Profesional	Discrepancy
Adminstration	110	35	46	183	18
Transcription	100	28	21	33	10
Prescription	602	38	13	508	22

Figure 4: Distribution of errors based on the occurrence level

Discrepancies in medical record were also detected 50 times appearing in many forms varying from simple mismatch in files and registers/records to extreme lack of documentation of the provided medication and patient history.

Overmedication was highly prevalent and occurred in 95 cases accounting 27.94% of the recruited sample, majority of them were detected in general medicine wards **Figure 5**.

Life threatening errors occurred 40 times (04.92%) and errors associated with permanent damage to patient's health detected 16 times (0.019%) only. Medication errors associated or linked to significant and serious outcomes showed an almost steady linear trend lines at 40% drifting from 2 to 10 errors among the various units, wards, and departments included in the study.

After errors stratification it was found that most of the encountered errors were relatively with low seriousness level and were congregating in the first three categories. All three categories combined together were accounting for 80.41% (ER=653) of all errors [D0 (ER=146), D1 (ER=256), and D2 (ER=251)] these three categories included errors which were either interrupted and solved by medical staff, were not associated with harmful effect on patients' health, or did not cause clinical disturbance to patient's condition **Figure 6**.

In the third degree (D3), 95 errors were detected and it included errors which led to reversible serious harmful side effects or clinically significant events and even though such a type of errors only accounted for 11.69% of all errors they presented a high risk factor for more serious or fatal complications. Errors with significant serious outcomes, which required a special care to mitigate the damage they might cause, required hospitalization, or even were responsible for increased duration of hospital admission were accounted for 5.54% (ER=45), in the fifth degree (D5) errors with permanent irreversible damage were expressed and it were detected 16 times only accounting for 1.97%, while errors which are linked to patient death or contributed in fatal events appeared three times and presented in D6 category.

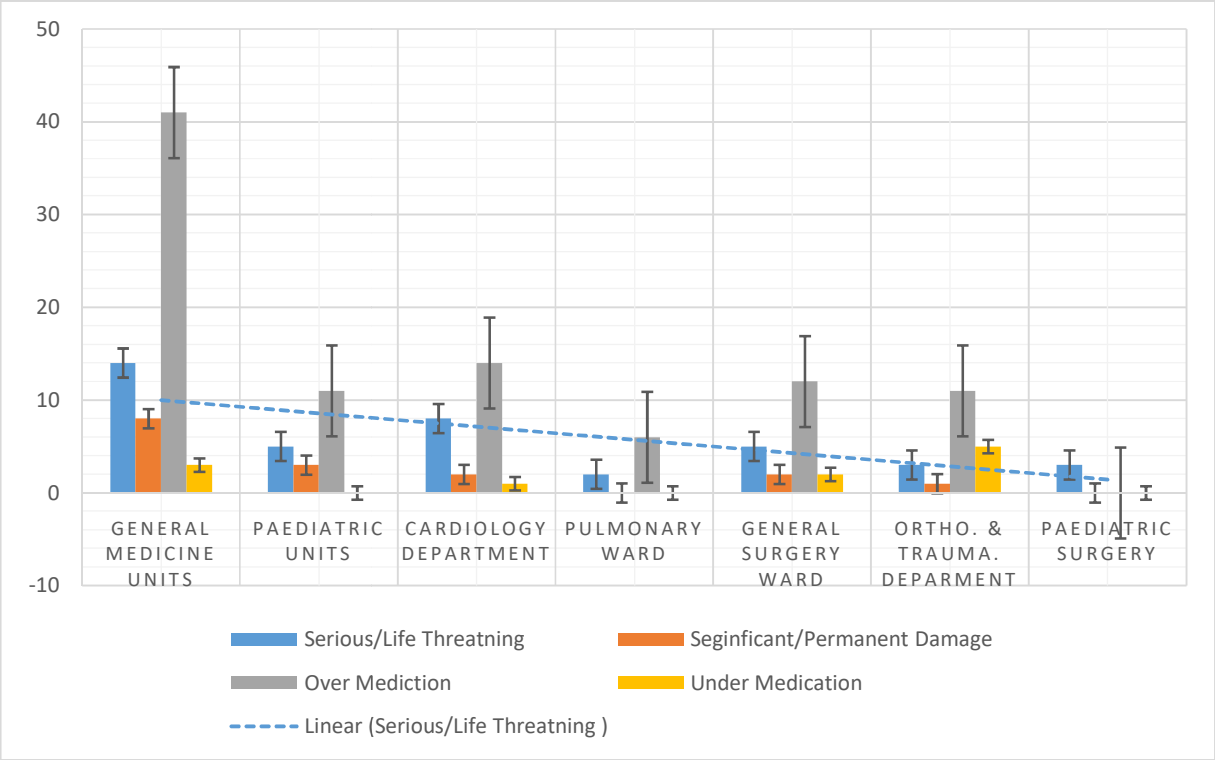


Figure 5: Appraisal of Medication Errors

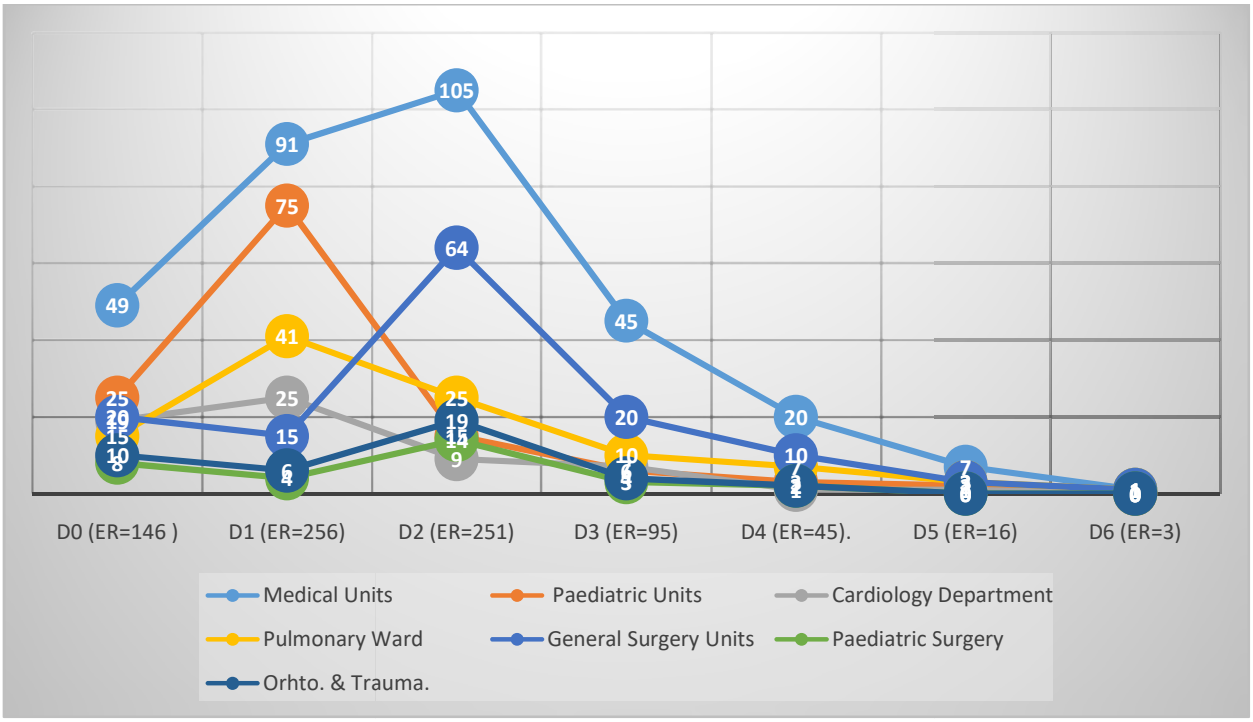


Figure 6: Stratified Categorization of errors based on severity outcomes and consequences

4. DISCUSSION

Male patients represented almost 60% of the all recruited sample which can be explained by the current cultural obstacles in Pakistan regarding female hospitalizations and due to lack of personal privacy in government hospitals, and about 70%of the patients were above 60 years old. It was noticed in previous studies that most of errors mostly occurred in elder patients above 65 years of old and in patients who were suffering from chronic conditions and that appeared to be the case in this study [11].

In term of number of the prescribed medication it was shown in other study that elderly patients above 60 years in care on average received 8 drugs [12], which seems to be not so far from the finding of this study for example in pulmonary ward patients the mean SD was 7.44±1.93 and the mean SD for medication errors was 4.08±1.1. Except for cardiology department the general norm was the higher the number of prescribed drugs the higher the risks for medication errors. It was also found that elder patients were at higher risks for medication errors as compared to other population.

According to *Barber et al*, in the UK almost 40% of patient at nursing homes were victims of medication errors [13], and the most prevalent errors were "incomplete information" or "incomplete prescription", in Pakistan according to the conducted study incomplete chart/prescription represented 36.69% of all errors detected and it was also the most common type of errors. While errors in strength and frequencies accounted for about 20% which was significantly lower than what was detected in Barber et al study (37.9%),overmedication/overprescribing was present in 27.94% of the cases which was higher than what was found in the UK(23.5%) [13]. The high prevalence in medication errors in medicine wards and units can be explained by the complexity of medical condition usually older patients suffer from and work overload in these departments.

Over medication was the general norm in all categories and wards. Antibiotics overprescribing detected in almost all units and wards included in the study and even T.B medication were overprescribed in some incidents. Bacterial resistance was detected multiple times and it is thought to be due to antibiotic overuse and misuse, which is thought to be contributing to the encountered resistance and also increased the risk for more future bacterial resistance events. Indication errors, contraindication errors, and drug interaction errors indicated lack of proper knowledge about drugs or lack of

commitment to guidelines among prescribing staff.

General medicine units are vital and among the most important parts of any tertiary care setting, yet the prevalence of errors in medicine units was significantly high with almost three errors per patient on average. Most of errors in medicine wards were linked to prescribers mostly physicians since the vast majority of them occurred in prescribing stage; and that seems to be significantly higher than what was concluded in *Ashcroft et al.* study which was conducted in the UK by the INH; in which it was found that 8.8% of newly prescribed drugs were associated with errors [14].

Even though the patients in cardiology department are usually in more critical status, receive a high number of medication, and suffer from more than one medical complication; it was the lowest in term of errors ubiquity with mean SD of 1.12±0.2. Which can be attributed to the well planning, good administration, recurrent evaluation, as well as the continuous monitoring which were good in this department. This results was almost identical to what has been detected in India (1.2) [15],In contrast, the rates of adverse events and medical errors were significantly lower in Japan with 20.2% [16], while in the UK more serious errors were linked to cardiovascular group [14].

Discrepancies in files were detected in all stages and levels of health care providing processes. Types of discrepancy varied from mismatching of patients' history with present to omission errors and providing drugs without proper documentation. In other studies drug reconciliation utilizing the available information that was collected from several sources and good communication were found to reduce the amount of discrepancies and increase the accuracy at transition points among care team [14, 17, and 18].

5. CONCLUSION

Errors appeared in more than one third of all prescribed drugs (36.34%), majority of which were mild 58.74% (n=477 ER), while serious errors accounted for about 12% only. Errors were prevalent among the recruited sample and it was the highest in pulmonary ward, while the lowest one was in cardiology department. Incomplete chart and prescription was the most common type of errors and preventable serious errors represented a significant portion of the encountered errors. Errors occurred in prescribing process were the most dominant in term of error levels. More than three quarters of errors were categorized in the first

three categories of seriousness while life threatening errors represented only 2.33% of errors.

Conflicts of interest

The authors declare no conflict of interest.

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