Title: A Study of Role of Clinical Pharmacist in Medication Review and Patient Education.

Shah Jainam V.[a], Patni Kalyani N.[a], Dr. Deshpande Shrikalp S.[a], Dr. Patel Varsha J. [b].

a: Department of Pharmacology and Clinical Pharmacy, K. B. Institute of Pharmaceutical Education and Research (KBIPER),Gandhinagar, Gujarat, India.

b: Chair-person, Research Department, Dr. Jivraj Mehta Smarak Health Foundation, Bakeri Medical Research Centre, Ahmedabad Gujarat India.

Email-Id – jainam1810@gmail.com

Contact details: (M) 8401345788, 9173197229

Abstract:

Purpose: Identifying, preventing, and resolving the Drug Related Problems (DRPs) is an important issue in healthcare process. Factors leading to DRPs are social pressure to prescribers, inadequate patients' knowledge regarding therapy, structure of health system and pharmaceutical marketing. **Method:** Fifty adult patients including both genders were recruited for this study. DRPs were assessed using PCNE classification Version 5.01 and patient knowledge was assessed before and after providing education. DRP occurrence was correlated with age, gender, number of drugs prescribed and co-morbid conditions. The patient's knowledge regarding disease, therapy and life-style were assessed. For this, the medication related points were more focused such as name, strength, dose, schedule, possible ADRs, etc. **Results:** The maximum positive correlation was found between DRPs and number of drugs (0.42). Drug interaction is a major factor leading to DRPs in case of polypharmacy. Out of all the classes included in PCNE classification, drug choice was a major problem. The highest number of DRPs was found in the age group of 51 to 60 years i.e. 25 DRPs. Among both the genders, relatively more DRPs were found in females. After education, there was a considerable increase in patients' knowledge by 156.73%. **Conclusion:** Thus it is concluded from study that if clinical pharmacist proclaims a role in the assessment of DRPs it seems better to focus on the identification, evaluation and prevention of patient- and prescriber- related problems. Clinical pharmacist can also increase patient's knowledge and awareness by providing counselling leading to reduction in DRPs to a greater extent.

Key Words: Drug Related Problem (DRP); Patient Education; Clinical Pharmacist; PCNE; Medication Review.

Introduction: -

Identifying, preventing, and resolving the Drug Related Problems (DRPs) is an important issue in the healthcare process. [1] The term 'Drug Related Problem' is not unique for a problem with pharmacotherapy. Other terms have been proposed. For instance 'drug-therapy problem' is often used too, and was introduced by the group of Cipolle, Morley and Strand. Krska introduced the term 'Pharmaceutical Care Issue' in 2002. That term is sometimes used in the UK. Fernandez-Llimos*et al.* recently proposed 'pharmacotherapy failure', corresponding to negative clinical outcomes resulting from the use or the lack of use of medicines. [2] Despite many efforts enforce the rational use of drugs; number of studies has reported the drug induces health-problems. Factors involving in this, are, social pressure to prescribers, the structure of health system, and pharmaceutical marketing. Patients also play an important role in giving rise to the above stated issue.

The large scale use of drugs may create situation that do not follow pharmacotherapeutical principles. These situations are classified as drug-related problems (DRPs). [3] Another way to say the DRP is problems related to the use of approved drugs can be summarized with the term DRP. [4] It is stated that the drugs and drug therapy will enhance the health-related quality of life, and are intended to cure, prevent or diagnose diseases, sign or symptom. Yet, the flip side is that the improper or inappropriate use of drugs can be harmful and could evoke new adverse symptoms, be the cause of patient's morbidity and even mortality. [4, 5]

DRPs include all the issues that may potentially affect the successful outcome of the pharmacotherapy in a particular patient, in a medication error, adverse drug reaction and adverse drug event. According to a study performed by Hohmann C. et al in Germany, up to 27% of all hospitals, prescribing errors can be attributed to incomplete medication histories at the time of admission. [1] Other factors are administration errors, drug-drug, drug-disease, drug- food, drug-test interaction. There is a growing interest in identifying and as well as resolving the DRPs at the time of admission or and at discharge. The provision of providing medication information is among the most fundamental responsibilities of pharmacists. The information can be either patient specific, as an integral part of pharmaceutical care, or to relative to a group of patients. [6]

As the medical practice changes in complexity and sophistication, the importance of patient education is being increasingly recognized as an essential component of high quality medical care. "Patient education" refers to the educational experiences planned for the patient by professional personnel as a component of his care. [7] Patient education has a critical importance. From an ideal patient education, physician may gain satisfaction in having an impact on the health of their patients, and they benefit from an enhanced relationship with their educated patients. [8]

Patient education programs to support patient participation in disease management have been proposed as an important strategy in limiting the growing burden of chronic diseases. [9] It has been observed that for many disease or disorder, patients are re-admitted to the hospitals. Enhanced patient education strategies are critical ways for hospitals to reduce readmission rates. [10]

Methodology-

The approval for the conduct of the research was obtained from Institutional Ethics Committee, Dr. Jivraj Mehta Smarak Health Foundation & Bakeri Medical Research Centre, Ahmedabad.

According to convenient sampling technique, 50 adult patients (18 to 65 yrs.) of both gender, admitted in the medical ward for at least two days up to discharge were included in the study. Patients taking medicine for more than 3 diseases and those patients with history of surgery within 6 months were excluded. Patients discharged with incomplete data and patients who did not provide information were considered as withdrawal/dropout patients. Informed consent was obtained. Medical records of the patients were recorded in the CRF.

The Medication Review was done in accordance to PCNE (Pharmaceutical Care Network Europe) Classification for Drug Related Problems, Version 5.01. [11] The main parameters with their respective sub-parts which were taken into consideration are: Adverse Drug Reaction including Toxicity, Allergic Reaction and Side effect; Drug Choice including Inappropriate drug, Inappropriate dosage form, Prescribed drug not indicated, Indicated drug not prescribed, Drug therapy duplication and Contraindicated drug; Drug Dosing including Dose too low/frequency not enough, Dose too high/frequency too often and Duration inappropriate; Drug Use including wrong dose taken, wrong drug taken, drug not at all taken, incorrect storage and incorrect administration; interactions including Drug-drug, Drug-disease and Drug-food; Others (Included in PE) including patient dissatisfied with therapy, insufficient awareness of health and disease, unclear complaints, clarification necessary and therapy failure (Reasons unknown) and technical including unreadable prescription.

For assessment of ADRs, only those ADR which were reported by the hospital staff were considered. Drug interactions were assessed by using Medscape Multi-drug Interaction Checker Application. Version: 3.2.2. [12] For patient Education assessment, list of 20 elements was prepared and patients were asked the same elements pre and post counselling, to assess the level of knowledge of patients related to their own drug therapy.

Patient education was divided into 2 parts i.e. first 8 sub domains i.e. Name, Strength, Dose, Schedule, Administration, Expected Duration, Indication, Possible ADRs; and remaining 12 sub domains including : Minimum Required Duration, Drug Interactions, Food Interactions, Herb Interaction, Storage, Missed Dose, Benefits of Completing Therapy, Medication Adherence, Special Monitoring, Special Precautions (If Any) and Life-style Modifications. First 8 sub domains are of greater significance as these should be known to the patient. Remaining 12 sub domains should be informed to the patient by health care provider either physician or pharmacist or nurse.

A grading system was developed for assessment of education. For the first eight sub domains of patient education, total of 2 points would be given for complete knowledge. 1 point each will be given for inadequate knowledge and 0 point will be given if the patient doesn't know about the sub domain. For the remaining 12 sub domains, 1 point for complete knowledge and 0 point will be given if the patient doesn't know or having inadequate knowledge about the sub domain of patient education assessment. The baseline scores and scores after patient education were compared. After the data was collected; average, percentage and correlation coefficient were obtained using Microsoft office and SPSS version 16.

Results

Total 104 DRPs were identified in 50 patients, of which, drug selection problem was found in total 49, drug dosing issue 7 times and 35 times Drug-drug interactions. Other Category of DRPs were 10 and technical errors- 3.(Table 1) Age wise distribution of variables in Table 2 suggests that highest number of drugs were prescribed in age group of 51-60 years with highest number of DRPs as well found to be 25. The Gender difference and relation to DRPs can be observed in Table 2. The drug-drug interactions were found frequently with aspirin, levofloxacin, quetiapine, metoprolol, rifampicin and spironolactone. (Table 3)

Correlation coefficient between Age of patients and Number of DRPs was 0.1348 and correlation between number of drugs and Number of DRPs was 0.4218.

Patient education was assessed at pre-education and post-education points. The overall % increase was 156.73% and t-test value was 21.83 as shown in Table 4. This shows significant increase in post education score of patients.

Discussion:

It has been known that drugs may directly cause or contribute to hospital admissions when the numbers of drugs are increased. [13]According to the pharmaceutical care network Europe (PCNE), a DRP is defined as an event or circumstance involving drug therapy that actually or potentially interferes with the desired health outcomes [2]DRPs such as medication errors and adverse drug reactions are relatively common in hospitalized patients and can result in patient morbidity and mortality. [14] There are several classification systems for DRPs, some of them are by Strand et al, a consensus group in Granada, the Pharmaceutical Care Network Europe (PCNE), and Apoteket AB (National Corporation of Pharmacies in Sweden).[15]

PCNE classification system has a broader perspective and includes process-related factors, for instance, patients' knowledge of health and diseases and administrative problems together. [15] The PCNE classification was validated using Cronbach's alpha which is found to be 0.477 for the current set-up. Suggesting that PCNE classification can be used after the required modifications for our patient population.

DRPs can occur throughout the entire medication process and represent risk factors for adverse drug reactions and events. [16] Historically, adverse drug reactions have been the focus of most studies related to drug-induced morbidity, but they form only a small part of drug-related problems. [14]Clinical pharmacists can combine current diagnoses, laboratory values, medical history and prescribing guidelines with the current pharmacotherapy of a patient. Thus clinical pharmacist can possibly detect and help in resolving more DRPs than any other computerized systems such as Computerized Physician Order Entry systems (CPOE) or Clinical Decision Support System (CDSS).[17] There are many studies that signify the role of clinical pharmacist services in patient care. [13, 17, 18]

In our study, the occurrence of DRPs correlated with age, gender, polypharmacy and number of co-morbidities. A similar study was carried out by Courtman BJ [13] et al, in which correlation of variables like age, gender and polypharmacy was established with increase in DRPs. Another research carried out by Vinks TH, et al emphasized the role of pharmacist in the identification, assessment and prevention of DRPs in elderly patients. They also focused on polypharmacy (six or more concomitantly) leading to DRPs. [19]A study by Prasanna Dahal et al, concluded that polypharmacy, co-morbidities and patient age are the factors leading to DRPs. [18]

As far as age related DRPs are concerned the maximum number of patients was in the age group of 51 years to 60 years-10 and highest numbers of DRPs were seen (25 DRPs) in this group. Maximum numbers of drugs were prescribed in this group- 153 drugs meaning an average of 15 drugs per patient. This was followed by the age group of 61 years to 70 years in which the number of DRPs and the number of Drugs prescribed are 24 and 103 respectively. In this age group, number of co-morbid conditions are 25 that is the highest amongst the population groups. This indicates that patients aged 51years and above are at higher risk of developing DRPs as compared to other groups; the reason behind this can be multiple co-morbid conditions, polypharmacy, inadequate knowledge about the disease, etc. The correlation coefficient of age v/s DRPs was found to be 0.13 indicating a positive correlation between the two variables. Thus as age increases, chances of DRPs will also increase.

As the age progresses, co-morbid conditions increase and as a result number of prescribed drugs increase; eventually leading to increase in DRPs. Polypharmacy can be considered as important factor for causing DRPs. There is a positive correlation between numbers of drugs prescribed at a time and DRPs, main reason being drug-drug interactions.

Total 124 major and significant drug-drug interactions were identified, out of which 3 were intentional\beneficial. Drug-drug interactions can lead to decrease or increase in a drug's effect; eventually causing sub-therapeutic or supra-therapeutic dose. Thus to reduce occurrence of drug-drug interactions, pharmacokinetics and pharmacodynamic properties of drugs should be kept in mind as DRPs are mostly dependent of chemical and physical properties of the drug and as a consequence are often more difficult to influence and to prevent. [19]

To prevent these drug interactions, several methods can be selected. First and foremost is to check the pharmacokinetic properties of each drugs and if the half-lives of the drugs are not crossed over, they can be administered at different timings. Another method is to give an alternative therapy to the patients. As observed in Table 3, propranolol and glimepiride when administered concomitantly, propranolol decreases effects of glimepiride by pharmacodynamic antagonism. This is significant interaction and has to be monitored closely. Here in this case, to avoid such interaction, alternative therapy can be given such as replacing the drug propranolol by metoprolol. Such methods if employed, the drug interactions can be prevented and optimum therapy can be provided to each patients.

Gender is also considered as a factor responsible for DRPs. The mean number of DRP found in females was 2.7 while that in males was 1.9. This clearly states that DRPs can occur more frequently in females as compared to males.

The factors focused in the study such as polypharmacy, drug interactions, lack of patients' knowledge about the disease, etc. can be identified by the clinical pharmacist and by the help of physician, DRPs can be resolved. Thus suffering of patients can be decreased, their hospital stay can be minimized, economic burden can also be reduced and rational use of medicine can be increased. [14, 16] The fact that most of the DRPs can be identified by pharmacists lends support to actively including clinical pharmacists in the therapeutic healthcare team. [2] This can help physicians in making therapy related decisions. Pharmacists can also help the physician by keeping them updated about recent and new therapy related information, which can eventually reduce drug related problems. Patient-related DRPs as well as prescriber-related DRPs depends in some degree on human factors, like for instance: knowledge, education, attitude and awareness. [19] It is difficult to increase the role of pharmacists in therapy related decision making because chances of acceptance of their recommendations and its implementation are less. A study performed by Celin AT et al, in 2012 revealed that the acceptance rate of pharmacists' recommendations was 97% while their implementation was only 70%. [20] If the pharmacist proclaims a role in the assessment of DRPs it seems better to focus on the identification, evaluation and prevention of patient- and prescriber- related problems. [17]

Patient's knowledge is an important parameter that is associated with DRPs. U.S. Department of Health and Human Services, 1990 has recognized patient education tool as a critical one for achievement of therapeutic goal, as the complexity and sophistication of medical care has changed over the time period. Lack of knowledge of health and diseases, unhealthy life-style have been closely linked to leading cause of death. [21] Providing education to patients regarding their disease, drugs therapy as well as life-style changes have been acknowledged as a part of the Clinical/Hospital pharmacist's duties. Many studies have reported that participation of pharmacists in drug therapy management aids in patient's adherence to drug therapy leading to cost-effectiveness of therapy. [22]

An ideal patient education provided to patient, which gives physician a satisfaction of having positive impact on the health of their patients. This benefits physicians from an enhanced relationship with their educated patients. In addition, it may help create an environment of trust, improved doctor-patient relationship and increased patient's role in health care, all of which leading to increase in patient satisfaction. [21] Providing patient education yields a positive impact on patient compliance, therapeutic outcomes and quality of life of patients in many chronic illnesses. [21]

In this study there was increase in patient score after education by 156.73% meaning a significance difference between pre and post education knowledge. Providing the counselling to patients related to their drug therapy increases their basic knowledge regarding their drugs and its appropriate use. It also imparts positive effect on the medication adherences and decreases the chances of ADRs and side effects of the drug, leading to better therapeutic outcomes.

A study by Cunningham G. et al, performed two phase trial in which they first assessed the incidence rate of DRPs without preventive strategies in elderly patients and subsequently phase two after applying preventive strategies reported that providing educational intervention reduces the number and incidence of DRPs and Drug-related hospitalization and concluded that continued program of education might be effective in reduction of incidence of DRPs relating to NSAIDs. [23] Another study from India also demonstrated positive effect on Knowledge, Attitude and Practice post patient education in diseases like Diabetes and hypertension. [24]A study in South India by in Chronic Kidney Disease (CKD) patients identified DRPs according to simplified IASER methodology and provided pharmacist intervention on three segments namely: Pharmacotherapeutic recommendation, Preventive Pharmaceutical care and Educational Pharmaceutical care. They reported that continual identification, intervention and resolution of DRPs in CKD could be a vital role in achieving better therapeutic outcome. [25]

A study conducted by us in 2015 for diabetic out-patients in community setting in which HbA1c of 55 diabetic patients was assessed at baseline and at end-point of study after three months of patient counselling regarding disease, drug use and life-style changes reported that clinical pharmacist's intervention improves therapeutic outcomes. [26] A similar study also concluded that even short pharmaceutical care program relating to patient education reduces the glycemic indices of diabetic patients thus improving their quality of life. Education also helps in achieving personalized therapeutic goal of individual patients. [27]

Conclusion:

It is evident that identification of DRPs and providing pharmacist intervention in patient education results in achieving higher and better therapeutic outcomes. Pharmacist is a unique and undisputed part of healthcare team and utilization of their therapeutic skills leads to betterment of healthcare system benefiting not only patients but also physicians as well. A continuing system of identification, intervention and resolution of DRPs is an effective method for an appropriate patient-centred healthcare system.

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Tables

Table 1: Total DRPs found in each class of PCNE (n=50)

DRP Class	Adverse Drug Reaction	Drug choice	Drug dosing	Drug use	Interactions	Others*	Technical	Total Pt DRP
Total DRPs	0	49	7	0	35	10	3	104

***Others: -** Patient dissatisfied with therapy, insufficient awareness of health and disease, Unclear complains-clarification necessary, Therapy failure (Reasons unknown).

Table 2: Distribution of variables(n=50)

Age Group	Gender of Patients	No. Of Patients	No. of Co morbid Conditions		No. Drugs prescribed		No. of DRPs found	
			Average Per Patient	Total	Average Per Patient	Total	Average Per Patient	Total
18-21	Male	3	2.00	6	10.33	31	1.00	3
	Female	0	0	0	0.00	0	0.00	0
21-30	Male	3	1.67	5	11.00	33	2.00	6
	Female	2	2.50	5	16.00	32	2.50	5
31-40	Male	6	1.17	7	8.50	51	1.17	7
	Female	1	2.00	2	14.00	14	4.00	4
41-50	Male	7	1.43	10	12.29	**86**	1.29	9
	Female	1	3.00	3	8.00	8	4.00	4
51-60	Male	6	1.83	11	14.00	84	2.67	16
	Female	4	2.00	8	17.25	69	2.25	9
61-70	Male	7	2.57	**18**	11.43	80	2.57	**18**
	Female	2	**3.50**	7	11.50	23	3.00	6
71-80	Male	2	2.50	5	11.00	22	2.00	4
	Female	2	1.00	2	12.50	25	1.50	3
81-90	Male	3	1.67	5	16.00	48	2.00	6
	Female	1	2.00	2	16.00	16	4.00	4
Average (n=50)				**1.92**		**12.44**		**2.08**
Total		**50**	**30.83**	**96.00**	**189.80**	**622.00**	**35.94**	**104.00**

Table 3: Drug - Drug Interactions (n=50)

Interacting Drug	Precipitating Drug
Alprazolam	Baclofen
Aluminium Hydroxide	Digoxin Ferrous Fumarate Ursodiol
Amlodipine	Rifaximine Tamsulosin
Aspirin	Amoxyclav Carvediol furosemide Glimepiride Hydrochlorthiaz ide methylprednisol one Metoprolol prazosin Ramipril Telmisartan Terbutaline Torsemide
Atorvastatin	Azithromycin Fosphenytoin
Azithromycin	Fosphenytoin Ondansetron
Budesonide	Dexamethasone Theophyllin
Calcium	Isoniazide Propranolol Ursodiol Metoprolol
Carbidopa	hydrochlorthiaz ide
Cinnarazine	Alprazolam
Clonidine	Atenolol Prazosin
Cyclosporin	Mycophenolate Mofetil
Escitalopram	Aspirin Clopidogrel Moxifloxacin
Esomeprazole	clopidogrel
Furosemide	Metolazone
Insulin	Glimepiride
Isoniazide	Alprazolam Dexamethasone
Levofloxacin	Digoxin Fosphenytoin Glimepride Hydrochlorthi--azide Insulin Metformin Ondansatron Telmisartan
Losartan	Aspirin Furosemide Spironolactone
Metaloxone	Tramadol
Methylpredni s-olone	clopidogrel Enoxaparin Moxifloxacin
Metoprolol	Aluminium Hydroxide Clonidine Furosemide Nifedipine Spironolactone Terbutaline Torsemide
Moxifloxacin	Escitalopram Magnesium - Sulfate Ondansetron
Pantoprazole	Clopidogrel Digoxin Ferrous Fumarate Rifaximin Theophyllin
Phenytoin	Pantoprazoe
Piracetam	Clopidogrel
Prazosin	metoprolol Nifedipine tamsulosin
Propranolol	Glimepride Torsemide
Quetiapine	Azithromycin Fosphenytoin Levofloxacin Lorazepam
Rabeprazole	cefpodoxime Cefuroxime Clopidogrel
Ramipril	Glimepride Insulin Torsemide
Rifampicin	Alprazolam Dexamethas-one Glimepride Pantoprazole Paracetamol Propranolol Zolpidem
Sodium Bicarbonate	Metoprolol Rosuvastatin
Spironolacto -ne	Atorvastatin Digoxin Furosemide Prednisolone Propranolol Torsemide
Telmisartan	Atenlol Atorvastatin

Dexamethasone	Alprazolam Moxifloxacin Ondansetron Theophyllin		**Nifedipine**	Alprazolam Atorvastatin Digoxin Nebivolol Prednisolone			
Digoxin	Furosemide Metoprolol		**Ofloxacin**	Ondensatron		**Terbutaline**	Torsemide
			Ondansetron	Escitalopram			
Intentional/Beneficial Interactions:							
Aspirin + Clopidogrel			**Insulin + Metformin**			**Insulin + Sitagliptin**	

Table 4: Result of Patient Education.(n=50)

Patient Education	8 points		12 Points		Total 20	
	Pre-Edu	Post-Edu	Pre-Edu	Post-Edu	Pre-Edu	Post-Edu
Average	7.56	11.06	4.16	7.38	11.74	18.4
% Increase Post Education	146.3%		177.4%		156.73%	
T-test	14.57		16.6		21.83	

Statistical Correlation:

The two-tailed P value is less than 0.0001 at t = 21.80 and DF=-47. This shows that there is an extreme statistical significant difference exists in the pre-education and post-education group of the patients.