

# Evaluation of Patient Counselling by Pharm D Students using a validated Medication Counselling Evaluation Tool in Patients with Type 2 Diabetes Mellitus

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**Abstract:-** One of the prime learning outcomes for Pharm.D graduates is medication-related counselling expertise. Evaluation of counselling is essential to assess the effectiveness of counselling, identify areas of improvement and refining student's counselling skills. Further, testing the evaluation tool in patients with specific disease conditions like T2DM, systemic hypertension etc., allows better analysis of the tool.

The study objectives was to evaluate medication counselling abilities of Pharm.D students using a validated medication counselling evaluation tool in patients with Type 2 Diabetes Mellitus and identify the key areas of improvement.

Initially, Medication Counselling Checklist (MCC), emphasizing various medication counselling points on T2DM medications was prepared. Patients with T2DM, selected for the study were counseled for their drugs prescribed during discharge. The counselling performance was evaluated using the validated tool and scores were awarded to respective students. The MCC, patient profile forms, documentation forms and graded evaluation tool for every patient counseled were collated as student's workbook. Analysis of data was performed and key areas of improvement related to both provision of medication counselling by Pharm.D students and medication counselling evaluation tool were identified and discussed.

Total of 61 patients with Type 2 DM were counselled. Out of all the patients, presence of other clinical conditions such as systemic hypertension, coronary artery disease, chronic kidney disease etc., were observed. The most common anti-diabetic medications for

which counselling provided were insulin analogues, biguanides, DPP-4 inhibitors, sulfonyl ureas, and SGLT-2 inhibitors. Using the evaluation tool, all parameters were graded based on the student's performance and total scores were summed up for each counseling session. The scores obtained in specific elements such as Introduction, Professional competence, Counselling session, Communication ability and Closure of the session were evaluated specifically. It was evident that pharmacists' expertise in professional competence sector and possess good communication skills, while few components of counselling session requires improvement.

Outcome of the study provides a visualisation of calibre of pharmacists in patient counselling. Medication counselling abilities of Pharm.D students could be further enhanced in terms of their professional competence and quality of medication counselling.

**Keywords:-** Medication Counselling Checklist; Discharge Medication Counselling Evaluation.

## I. INTRODUCTION

One of the key learning outcomes for Pharm.D graduates is medication-related counselling expertise, which is included in the Doctoral Pharmacy programmes across the world. Well-structured and formal medication counselling sessions paralleled by the assessment of students' ability to communicate and provide effective patient education and medication counselling is necessary to ensure students are ready to enter practice. Evaluation of counselling is essential to assess the effectiveness of counselling, identify areas of improvement and to raise the quality of medication counselling for refining student's counselling skills, enhance

medication compliance and to achieve better therapeutic outcomes.

Adherence to a healthy lifestyle and medication compliance can have a positive impact on the course of chronic diseases like diabetes management. Diabetes Mellitus (DM) is a group of metabolic disorders characterized by hyperglycemia and decreased insulin sensitivity. It is associated with abnormalities in carbohydrate, fat and protein metabolism, and results in chronic complications including micro-vascular, macro-vascular, and neuropathic disorders. The worldwide prevalence of DM has risen dramatically over the past two decades. It has been projected that the number of individuals with DM will continue to increase in the near future.

According to WHO, non-communicable diseases accounted for 74% of deaths globally in 2019, of which, diabetes resulted in 1.6 million deaths, thus becoming the ninth leading cause of death globally. Diabetes Mellitus is one of the largest global health emergencies of this century, ranking among the 10 leading causes of mortality.[1] Over 1 million deaths per year can be attributed to diabetes alone, making it the ninth leading cause of mortality. In 2017, approximately 462 million individuals were affected by Type 2 Diabetes Mellitus, corresponding to 6.28% of the world's population, or a prevalence rate of 6059 cases per 100,000. These numbers are estimated to increase to 700 million people with diabetes and 548 million people with Impaired Glucose Tolerance by 2045, which represents a 51% increase compared to 2019.[2] In India, the prevalence of Diabetes has raised from 7.1% in 2009 to 8.9% in 2019.[1] Thus, necessitating certain lifestyle modifications and medication adherence to achieve control of glycemic levels and improved quality of life for patients with Type 2 Diabetes Mellitus. Effective communication between pharmacist and patient has been identified as a critical component of medication adherence.

A simple comprehensive instrument which allows precise evaluation of various components of medication counselling has been developed and validated recently. Systematic evaluation of medication counselling in Type 2 Diabetes Mellitus patients by using this validated medication counselling evaluation tool may be helpful in bringing medication-related counselling abilities in Pharm.D students. Moreover, the checklist-based approach in this study may foster student's medication counselling expertise, specific to those medications used to treat Type 2 Diabetes Mellitus.

## II. OBJECTIVES

To evaluate medication counselling abilities of Pharm.D students in patients with Type 2 Diabetes Mellitus by following a checklist based approach and identifying the key areas of improvement.

## III. METHODOLOGY

A prospective study was performed at the General Medicine department of a 1000 bedded private corporate hospital over a period of six months. The study was done with 61 in-patients with Type 2 diabetes mellitus after obtaining ethical clearance, while critically ill patients and patients not willing to participate in the study were excluded.

The methodology includes the following 3 stages:

- Preparation of Medication counselling checklist (MCC) for anti-diabetic medications and provision of medication counselling to patients with Type 2 Diabetes mellitus.
- Evaluation of medication counselling with the validated tool and preparation of student's workbook.
- Identifying the key areas of improvement related to provision of medication counselling by Pharm.D students.

### A. Preparation of MCC for anti-diabetic medications and provision of medication counselling

The MCC, which is a comprehensive checklist emphasising various medication counselling points on Type 2 Diabetes Mellitus medications was prepared initially to ensure that adequate information and instructions regarding prescribed medications are included, and that none of the important elements are missed during the medication counselling session. It was thus developed with consensus from clinical guide, institutional guide and other experts in the field of Medicine and Pharmacy. It ensures that students convey all necessary information about the prescribed medicines to the patients. The British National Formulary (BNF), the American Hospital Formulary Service-Drug Information (AHFS-DI), and the Micromedex database were used as primary sources of medication-related information, such as indications, directions for use, storage, adverse drug reactions (ADRs), drug interactions, as well as warnings and precautions such as driving restrictions, risks associated with abrupt discontinuations, advice regarding alcohol abstinence when necessary and laboratory monitoring requirements with specific medications.

### B. Evaluation of medication counselling with the validated tool and preparation of student's workbook

After the preparation of the MCC, the students provided medication counselling to patients with Type 2 Diabetes Mellitus. Patients were notified about the discharge medication counselling and prior consent was obtained. The ability to perform medication counselling effectively by the students was then evaluated using a validated medication counselling evaluation tool.

Completed student's workbook contains the MCC, patient profile forms, patient counselling documentation forms and the score sheets of the students.

### C. Identifying key areas of improvement

The specific elements of a medication counselling session with respect to the pharmacist's introduction, professional competence, accuracy of medicine information provided during the counselling session, various essential qualities demonstrating the student's communication ability, and his/her approach towards closing the medication counselling session were evaluated critically and specific elements that need improvement were identified and discussed with the pharmacist before giving subsequent medication counselling.

In addition, any criteria in the medication counselling evaluation tool that needs further modification was identified through critical analysis of the cumulative performance reports of the medication counselling and discussed with expert faculty assessors at the end of the study period.

## IV. RESULTS

Discharge medication counselling was provided by Pharm.D students for 61 patients with Type 2 Diabetes Mellitus and was evaluated by using a validated medication counselling evaluation tool. The results of the study are detailed below –

### D. Preparation of MCC for Type 2 diabetes mellitus

The "Medication Counselling Checklist" (MCC) focusing on Type 2 Diabetes Mellitus was prepared initially, emphasising various medication counselling points on Type 2 Diabetes Mellitus medications including commonly prescribed oral hypoglycemic agents of all classes such as Sulfonylureas, Biguanides, SGLT-2 inhibitors, DPP-4 inhibitors etc., and insulin analogues inclusive of short acting, intermediate acting, long acting as well as combination insulin formulations.

Micromedex database was used as primary source for medication-related information, such as indications, dosage, directions for use, possible side effects / adverse drug reactions, potential interaction with drugs / food administered concurrently, contra-indications, warnings / precautions, self monitoring techniques, storage specifications and other specific drug related information. The British National Formulary (BNF) and the American Hospital Formulary Service-Drug Information (AHFS-DI) were used as secondary reference sources.

The MCC was prepared for the purpose of aiding the pharmacists in comprehension of drug information and enhancing accuracy of information provided to patients. It carries all necessary drug related information that is required for patient counselling and hence, serves as a reference for counselling pharmacists.

### E. Provision of medication counselling for Type 2 diabetes mellitus patients

A total of 61 in-patients, who were selected, based on inclusion and exclusion criteria of the study were monitored and were counselled for their anti-diabetic drugs prescribed during discharge. Informed consent was obtained from each patient prior to providing medication counselling. Patient information forms were given and patients were made aware of all study related components concerning the patients. The mean age of patients who were counselled was  $60.70 \pm 12.70$  years (range of 17-87 years), out of which 24 (39.3%) patients were old aged (above 60 years), 36 (59%) patients were adults (36-65 years) and 1 (1.6%) patient was late adolescence (15-35 years).

The demographic details of patients counselled are presented in **Table 1**.

**Table 1 : Demographic details of the discharged patients (N=61)**

S.No	AGE GROUP (in years)	No. OF PATIENTS	MEAN AGE (yrs) $\pm$ SD	GENDER	No. OF ANTI-DIABETIC DRUGS PRESCRIBED (n=91)
1	Early adulthood (15-35)	1	$60.70 \pm 12.70$	Male 39  Female 22	2
2	Adulthood (36-50)	12			19
3	Late adulthood (51-65)	24			31
4	Young old (66-74)	19			29
5	Old (75-84)	4			8
6	Very old (Greater than 85)	1			2

Out of 61 patients with T2-DM, presence of other clinical conditions such as systemic hypertension (20.8%), coronary artery disease (7.1%), chronic kidney disease (4.3%), cerebrovascular accident (3.5%), anaemia (3.5%), myocardial infarction (3.5%) etc., were noted.

The most common anti-diabetic medications for which counselling provided were insulin analogues (39.5 %), biguanides (24.8 %), DPP-4 inhibitors (18.6 %), sulfonylureas (16.2 %) and SGLT – 2 inhibitors (0.7%), which is presented in **Table 2**.

**Table 2: Details of anti-diabetic medications prescribed (n=129)**

S.No	DRUG CATEGORIES	No. OF DRUGS	PERCENTAGE
1	INSULIN ANALOGS	51	39.5 %
2	BIGUANIDES	32	24.8 %
3	DPP-4 INHIBITORS	24	18.6 %
4	SULFONYL UREAS	21	16.2 %
5	SGLT-2 INHIBITORS	1	0.7 %

Other classes of medications such as Anti-hypertensives (11.7 %), anti-ulcer drugs (7.37 %), anti-hyperlipidemic drugs (6.23 %), anti-platelet agents (5.67%), antibiotics (4.34 %), NSAIDs (5.03%) etc were concomitantly prescribed in the study subjects.

Initial drug related information were studied with the prepared MCC as a reference. Counselling was performed by making appropriate use of patient profile, assessing their understanding about disease and drugs, providing drug related information and verifying patient's level of understanding by receiving feedback. Counselling session was directed by the students by addressing actual concerns of the patients with empathetic behavior and understandable language.

#### *F. Evaluation of anti-diabetic medication counselling using validated medication counselling evaluation tool*

The student's counselling performance was assessed by observing the session and grading various parameters included in the evaluation tool used. Areas of assessment include the student's introduction to the patient, professional competence, accuracy of drug information, effective communication abilities and session closure method. Activities were judged and scores were allotted according to

the performance standard, from 0 points to 5 points indicating poor to excellent performance.

Using the medication counselling evaluation tool, all the parameters were graded based on the student's performance and total scores were summed up for each counselling session. The overall evaluation of patient medication counselling was performed by applying the obtained total scores with following grading criteria, mentioned in **Table 3**.

**Table 3 : Grading criteria for the scores**

PERCENTAGE SCORES OBTAINED	PERFORMANCE QUALITY
0 – 20 %	Poor
21 – 40 %	Below average
41 – 60 %	Average
61 – 80 %	Good
81 – 100 %	Excellent

Average scores received in each component and their percentages are set out below in **Table 4**, which assists in recognising the areas of improvement in medication counselling.

**Table 4: Scores obtained in specific elements of medication counselling session**

Part	Maximum points	Average points	Percentage of points
Introduction	6	6	100 %
Professional competence	20	17.27	86.35%
Counselling session	65	47.16	72.55 %
Communication ability	35	31.36	89.60 %
Closure of the session	25	21.78	86.80 %

#### *G. Submission of completed workbook*

The student's workbook gives an account of details of patients counselled, respective documentation forms and graded evaluation tools, which serve as basis for inferring results of the study. Patient profile forms comprising of patient's demographic details, past medical & medication histories, current clinical conditions, diagnosis, treatment plans, drugs administered and discharge medications were documented. Documentation forms were filed, which surveys the activities performed before/ during the counselling session. Particulars such as date of counselling, counselling steps followed, points covered during counselling, barriers involved, usage of counselling aids were set forth. Rated counselling evaluation forms were enclosed for each patient's discharge medication counselling and scores thus obtained in elements covered by the evaluation tool were compared and studied.

#### *H. Identifying key areas of quality improvement in medication counselling process*

The specific elements of medication counselling session with respect to the pharmacist's introduction, professional competence, accuracy of medicine information provided during the counselling session, various essential qualities demonstrating the student's communication ability and his/her approach towards closing the medication counselling session were evaluated critically. Reports of cumulative scores obtained in all specific aspects evaluated were assessed and the areas that demand significant improvement were recognised.

From detailed comparison of all sections, it is apparent that pharmacists expertise in professional competence sector and possess good communication skills, while few components of Part-3, ie., counselling session requires improvement. The sectors namely usage of visual aids like pictograms, devices etc., presenting product information

leaflets/ pamphlets are to be given attention. Added information on potential / possible drug interactions for oral hypo-glycemic agents are to be improved, which eventually results in better patient understanding, stronger drug compliance and finer quality of life.

## V. DISCUSSION

The rise in the global prevalence of diabetes posed a great challenge to health-care system. Medication non-adherence is the most common issue observed in the management of diabetes because of complex and lifelong therapy.[3]In order to provide the best care, a pharmacist should develop and build a relationship with each patient. In doing so, the patient will feel more confident and comfortable in providing their medical history to the pharmacist, allowing the pharmacist to gather proper tools and information needed to provide best counselling. Patients with Type 2 diabetes need to be educated and counseled on how to prevent both acute and chronic complications common in diabetes to obtain desired glycemic control and live improved quality of life. It has been found that patients with knowledge of their disease including their treatment methods have high likelihood to succeed in managing the disease conditions. The main objective of this study is to evaluate clinical pharmacists' educational and counseling ability on diabetic patients by using this medication counseling evaluation tool.

In the first category of introduction, the student's ability to communicate the purpose of counselling session was evaluated using the medication counselling evaluation tool. This involves pharmacists self introduction, identifying patient or attender, checking comfort of the patient and enquires the expected time and consent for the session. This shows the pharmacists professional and educational ability required for the counseling.

In the second category, viz, professional competence, usage of patient profile and assessing the patient's understanding of their diabetic condition were identified. Assessment of the patient's understanding about what the doctor informed the patient was assessed and also informs any other complications were involved. Maintain professional competence allows individuals to continue to learn throughout their career, to develop their educational skills regarding patient medication counseling by using this medication counseling evaluation tool.

In the third category, the most common elements included in the evaluation tool were medication name, indication of the medication, direction for use, side effects, potential precautions and warnings, interactions and missed dose instructions. Specific information regarding storage and usage methods of various types of insulin such as pre-filled pens, cartridges, vials and insulin syringes were elaborated. Advices on lifestyle modifications were provided and medication's relationship to glycemic control and HbA1c levels were explained. Techniques for self monitoring of glucose levels were taught for better monitoring of blood glucose levels.

Open questions give the patient the opportunity to speak as much as possible, while on the other hand, the pharmacist gets the opportunity to understand patient's knowledge. Using language that is understandable by the patient and displaying effective non-verbal behavior such as maintaining eye contact, professional body language etc., are important characteristics of counseling pharmacists. Identifying appropriate / real concerns of the patient and addressing them with facts in a logical order plays an essential role in patient's perception on their anti-diabetic medications.

Closure of counseling was provided by summarizing key points of information on the anti-diabetic drugs prescribed and about the disease condition. Sufficient time for raising queries by the patient was given, which results in clear understanding of information conveyed. Degree of patient understanding is verified by procuring feedback from patients which also helps to improve pharmacist's approach. Data of demographic details, contact details, disease conditions and medication plans were collected along with the pharmacist's comments about the patient's individual drug therapy and were documented. These data assist the health care professionals in further follow up sessions.

According to the study done by *Narayana Goruntla et al. (2019)*, Pharmacist directed patient counselling combined with message reminder showed a greater effect on the improvement of medication adherence and control of glycemia, blood pressure and lipid profile in diabetes. [3]

It has been proved in the literature that appropriate counseling is as important as the appropriateness of the dispensed medication itself. Several studies have emphasized the importance of adequate information provision to assure the patient's adherence and indicated that provision of adequate information on medications is associated with better patient adherence.[4]

## VI. CONCLUSION

In the sight of increasing prevalence of Diabetes Mellitus and comorbidities, medication counselling for diabetic patients is crucial. Evaluation of counselling by Pharm.D students assisted in perceiving strengths and weaknesses of counselling. Medication counselling abilities of Pharm.D students could be further enhanced in terms of quality of medication counselling by following a check-list based approach and evaluation using a validated tool.

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