

# Impact of Structured Diabetes Pharmaceutical Care Training on Practices of Community Pharmacist

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## Abstract

**Objectives:** The diabetes epidemic in India has placed it in the second position in having the largest number (77 million) of adults with diabetes, worldwide. Diabetes is a chronic progressive disease that can be effectively controlled by medication adherence, monitoring and managing well on regular basis. A well-trained pharmacist can help the patients to achieve good glycaemic control by providing them pharmaceutical care. This study aims to evaluate the effect of tailored diabetes pharmaceutical-care training on the practices of pharmacists and the subsequent impact on patients' clinical outcomes. **Methods:** A prospective interventional quantitative study was conducted to assess the impact on Knowledge, Attitude and Practice (KAP) levels of community pharmacists after providing diabetes pharmaceutical care training. The selected trained pharmacists enrolled type-2 diabetes patients to assess the practice component further, by observing patients' outcomes in terms of knowledge, attitude, practices along with clinical outcomes in terms of glycemic control, post pharmaceutical care provision. A descriptive analysis and statistical evaluation, using SPSS Version 21. **Key Findings:** Significantly improved outcomes were observed across all the pharmacist participants in terms of KAP levels, from baseline to post-interventional training ( $p < 0.0001$ ). Also, a considerable impact on patients' knowledge, awareness, practices and clinical outcomes was noted in the intervention group. Clinically there was a significant reduction in fasting blood glucose levels, postprandial blood glucose levels, HbA<sub>1c</sub> and control in systolic and diastolic blood pressure ( $p < 0.05$ ) was also observed. **Conclusion:** Community pharmacists who had completed structured training in diabetes care could practice pharmaceutical-care well and help patients with type-2 diabetes in achieving good glycemic control.

**Key words:** Diabetes, Pharmaceutical care, Community pharmacist, Training, Impact.

## INTRODUCTION

Community pharmacists come across patients with diabetes frequently than other health care workers thus making them the most accessible to patients with diabetes, among all other health care professionals.<sup>[1]</sup> Pharmaceutical Care (PhC) has impacted diabetes-related outcomes, patient and provider satisfaction as well as cost management of the disease in a very positive way.<sup>[2]</sup>

Results from many studies suggest that intensive treatment; regular monitoring and glycemic control of diabetic patient with diabetes leads to significant reductions in risk of micro and macro-vascular complications like retinopathy, nephropathy, neuropathy, dyslipidemia and cardiovascular disease, thus decreasing the cost of diabetes management and thereby improving the overall quality of life of the patients.<sup>[3-5]</sup> Being unable to receive sufficient appropriate education related to diabetes management, patients are unable to maintain sustained glycemic control; thus preventable diabetes-related complications are left unchecked.<sup>[6-8]</sup> Lack of knowledge and inadequate pharmaceutical care practices has led to non-adherence, uncontrolled hyperglycemic conditions with the risk of future complications in patients.<sup>[9]</sup>

The pandemic of diabetes is spreading like wildfire, especially among developing countries. The IDF Diabetes Atlas 9<sup>th</sup> edition 2019 shows that

463 million adults are currently living with diabetes worldwide. Seventy-seven million Indian adults have diabetes, making it the second-largest nation housing this disease worldwide. It is predicted that India will be the country with most of the patients with diabetes estimated as 578 million people (10.2% of the population), by 2030, followed by China and the USA if stringent measures are not taken to curb the disease.<sup>[10,11]</sup>

From being a predominantly farming nation a few decades ago to being a nation with extremely rapid urbanization and industrialization, the lifestyle and society of India have undergone drastic changes. Diabetes once considered a rich man's disease is now affecting those from every stratum of society. Genetic predisposition, central obesity (greater abdominal adiposity), increased sedentary work, fast food culture, as well as insulin resistance have put Indians at risk for diabetes according to population studies.<sup>[12]</sup>

Community pharmacists assist in the monitoring and management of a patient with diabetes diabetic patients in developed nations.<sup>[13]</sup> However, in most developing nations, including India, the community pharmacists do not play an adequate role in diabetic care other than dispensing medicines to the patients. Indian patients with diabetes urgently need additional care services from their community. A well-trained community pharmacist equipped with

knowledge and skills along with a positive inclination to providing diabetic care will be a significant asset to the health care system in India.<sup>[14-16]</sup>

There are virtually no significant data or studies that assess the depth of knowledge and effective practices of community pharmacists focused on diabetes in India.<sup>[17]</sup> Hence there is a pressing need to assess the knowledge, attitude and practices of community pharmacists. This will help in designing targeted educational training for them to enhance their practices in providing diabetic care to patients.

## METHODS

### Approvals and Permissions

The study was conducted in Pune district of Maharashtra state, western India, over 18 months following the approval of the Institutional Ethics Committee BVDUMC/IEC/74 and seeking permission from higher authorities of participant pharmacists belonging to Government (Govt.) and Non-Government (Non-Govt.) sectors. Permission to conduct the study was granted by the respective authorities of participants: Director of Primary Health Care Centre, Civil Surgeon of District Hospital, Regional head of Chemist and Druggist Association and Managing Authority of Super Specialty Private Hospital.

### Participants

This prospective, interventional quantitative study was designed to evaluate Knowledge, Attitude and Practices (KAP) levels of community pharmacists with regards to Diabetes Pharmaceutical Care and subsequently train them on Diabetes Pharmaceutical Care. Post-training the participants were further evaluated to see the impact of such training on their KAP enhancement. Additionally, the practice component was further evaluated by seeing the impact on patient outcomes. For this, few of these trained Pharmacists were selected and were asked to enroll the patients and provide them Diabetes PhC services in terms of Patient education, monitor their glucose levels and collect their clinical data with regards to glucose levels, blood pressure, HbA<sub>1c</sub> and lipid levels before and after providing PhC services.

The Govt sector participants belonged to Primary Healthcare Centers (PHC) and District Hospitals, whereas the non-Government sector participants were from community medical shops and private hospitals of Pune district. The eligible pharmacists, held at least a Diploma in Pharmacy (a proper primary education for Pharmacists in India), were registered with the state pharmacy council and were mandatorily involved in dispensing. Pharmacists performing activities other than dispensing were excluded. All participants volunteered to participate in this educational training program on the invitation.

The general practices of Government and Non-government pharmacists in India are not the same; they differ in a few of their roles and areas of practice. However, dispensing the medicine on the doctor's prescription to the patients is the common practice done regularly by both.

For assessment of practice component, the selected pharmacists enrolled patients with diabetes type-2 as per the following eligibility criteria: patients with type 2 diabetes of either sex, above 35 years of age, patients associated with hypertension as comorbidity, patients who were willing to cooperate. Those with type-1 diabetes, diabetic pregnant women, critically ill diabetes patients and patients with other comorbidities apart from hypertension were excluded from the study.

The patients were enrolled by the few selected pharmacists after identifying and informing them about the study and taking their voluntary consent. The pharmacists allocated the patients into two groups. One group of patients were managed in standard practice (Non-Intervention group), whereas the other group of patients was provided structured and tailored information related to diabetes care (Intervention group). Each participating pharmacist was needed to enroll at least 2-4 patients consecutively.

The educational program on diabetes, medication and lifestyle changes was conducted through face-to-face discussions between pharmacists and patients on the pharmacist's premises. Each educational session lasted approximately 45-60 min for each patient in the intervention group. The essential components of the educational program were standardized, although the pharmacist tailored the material to the patient's drug therapy and existing knowledge of diabetes.

### Materials

A 50-item questionnaire in English for pharmacists and a 25-item questionnaire in English and Local language Marathi for patient participants comprising of questions to assess the Knowledge, Attitude and Practice components related to diabetes pharmaceutical care and diabetes management was designed and developed respectively. Both pre-and post-training questionnaires possessed the same set of multiple-choice questions. Standard literature was used for reference to develop the components of the questionnaires. The questionnaires were adapted to suit local requirements. The content review and approval were done by the experienced professors of the clinical pharmacy department and specialty physicians of the teaching hospital. The questionnaire also included preliminary questions to capture the demographic details of the respondents.

A training manual on diabetes pharmaceutical care was developed for training and educating the pharmacists. The content was developed by referring textbooks, similar training manuals, published literature, online standard training modules and diabetes guidelines which were further adapted to local needs. The main components included in the training manual are presented in Figure 1. Contents of the manual were reviewed and approved by the senior faculty of the pharmacy practice department and experts from community pharmacy settings and specialty physicians.

### Procedure

#### Pharmacist outcome measures

A one-day workshop on diabetes pharmaceutical care training and education was organized for invited participants at their respective institutes. The KAP questionnaire was administered before training and responses to the KAP questionnaire were collected. After this, actual training on diabetes pharmaceutical-care was given to the participants in three different sessions, as stated in Figure 1. A 90-min session was conducted by the principal investigator and expert educators from the Clinical pharmacy field. The sessions were conducted using power-point presentations, blackboard explanations and audio-visual aids. The training was conducted as group-interaction, followed by question-answer sessions and face-to-face discussions and a feedback system at the end of each training session. The post-training impact on knowledge, attitude and practices was assessed by administering the same questionnaire after three months to the same set of pharmacists. Additionally, the practice component was further assessed by evaluating the impact of diabetes pharmaceutical care training on the patient's outcome.

## Patient outcome measures

The eligible patients were enrolled by the selected, trained pharmacists across various settings. The patients who fulfilled the study criteria were equally allocated to an intervention group and a Non-Intervention group by the pharmacists after taking their consent. The Pharmacists or the caregivers of the patients who were literate enough translated or read the KAP questionnaire in the local language and explained, in case the patient was illiterate and noted the response on being their half.

In the Intervention Group, the patient's objective and subjective data like demographics, clinical and biochemical data along with medication details, were collected in a patient profile proforma by the pharmacists at their settings. The base values of the following parameters: Blood Pressures BP (systolic) and DBP (diastolic), Fasting Blood Glucose (FBG), Post Prandial Blood Glucose (PPBG), Glycosylated Hemoglobin (HbA<sub>1c</sub>) and lipid levels were collected on their first visit. Also, the Knowledge, Attitude and Practices pre-questionnaire was administered to the patients before counseling. Based on the patient's knowledge, attitude and practice responses; the pharmacist provided tailored counseling/education to the patients. Pharmaceutical care through diabetes education mainly covered information on their diabetes, glycemic control, medication information, instructions on the lifestyle that needed modifications and dietary advice. At the next follow up visit (approx. after six months period), Clinical and Biochemical Data was again collected along with post-questionnaire administration to patients. Based on the post-questionnaire response, counseling was again provided by the pharmacist as needed.

The same procedure was conducted on the patients enrolled in Non-Intervention group participants as that performed on the Interventional group and required data was collected, except that no intervention in the form of any patient education or counseling was ever provided at any stage to these participants.

Review of prescription refills, feedback from the patient through the interview and glucose levels as indicators were used to assess the medication adherence qualitatively. Patients were asked by the Pharmacists to get back their empty strips or bottles in the follow-up visit to reconcile the dispensed units. The respective pharmacists did consult with Doctors of patients, in case of any adverse reactions, glycemic variations, drug-related problems, uncontrolled conditions, progression into complications, for lab test recommendations and any other diagnosis or treatment-related actions required.

The data were collected from patient records, patient files and prescriptions, electronic records and laboratory assessment records. The pharmacists also collected data that helped to recognize drug-related discrepancies and the need for medication modification. The pharmacist traced the patient's clinical and general progress via follow-up appointments scheduled approximately three months apart. For comparison and assessment, only one follow-up visit's data were included for analysis for clinical parameters as per study design.

## Evaluation

Each correct response to the question was given a score of one; the total score was evaluated per participant while evaluating the pre and post KAP questionnaire responses. The difference between the baseline and post-intervention KAP levels of pharmacists and patients was assessed statistically and compared to understanding the improvements or any changes. Patient's Clinical data were compared from baseline to follow up visits and statistically analyzed and compared for any changes for both groups.

The statistical software SPSS Version 21 was used for the assessment of outcomes. The continuous variables were presented as Mean  $\pm$  Standard deviation (SD) with descriptive analysis. The difference in the means of parameters was compared among the groups and pre and post interventions by using students' unpaired "t" test. The *p*-value of  $<0.05$  was considered significant.

## RESULTS

### Demographic details

Four hundred pharmacists were invited to participate in the study; out of which 55 participants dropped out due to lack of time to manage both the training and their regular activities; finally, 345 attended and completed the pre-KAP assessment and Diabetes Pharmaceutical Care training.

Out of these trained pharmacists, 200 pharmacists from different settings were selected for an additional subset study, that enrolled type 2 diabetes patients to assess the practice component further in terms of improvement in KAP level and clinical outcomes in patients. Out of 200 trained pharmacists, 100 pharmacists were from Govt. and 100 from the Non-Govt sector.

All 345 pharmacists belonged to the age range of 35 to 49 years (Mean  $\pm$  SD of 35.78  $\pm$  9.03), male participants to female ratio were 2:1, 80% pharmacists were Diploma in Pharmacy qualified, 18% had Bachelor in Pharmacy qualification and very few participants were having postgraduate degrees in pharmacy. Over 70% of pharmacists were having work experience of more than ten years; and the maximum participants (58%) were from a private sector community pharmacy. All the 345 pharmacists received and completed Pharmaceutical care training in diabetes and KAP questionnaire assessment pre-and post-training (Table 1).

**Table 1: Demographic parameters of Pharmacists recruited for training (n=345).**

Parameters		Numbers (%)
Gender	Males	236 (68.40)
	Females	109 (31.60)
Qualification	D. Pharm	271 (78.55)
	B. Pharm	62 (17.97)
	D. and B. Pharm	02(0.005)
	M. Pharm	10(2.8)
Age (years)	Mean $\pm$ sd	35.78 $\pm$ 9.03
Experience (years)	Mean $\pm$ sd	9.33 $\pm$ 8.30
Number of Pharmacist participants from various settings (n=345)	Community	200 (57.97)
	Pvt. Hospital	50 (14.49)
	PHC	55 (15.94)
	Govt. Hospital	40 (11.59)
Number of Type 2 diabetes patients enrolled by Pharmacists (n=385)	Community	170 (44.15)
	Pvt Hospital	100 (25.97)
	PHC	75 (19.48)
	Govt. Hospital	40 (10.38)

**Table 2: Demographic parameters of Patients enrolled for practice assessment (n=260).**

Variables	Non-Intervention n (%) out of 130	Intervention n (%) out of 130	P Value
<b>Age groups</b>			
Below 35	04 (3)	00 (0)	0.739 ( $p > 0.05$ )
36-49	27 (21)	26 (20)	
50-69	67 (52)	75 (58)	
Above 69	32 (24)	29 (22)	
Mean $\pm$ SD	57.23 $\pm$ 15.71	58.28 $\pm$ 16.20	
<b>Gender</b>			
Male	58 (45)	61 (47)	0.874 ( $p > 0.05$ )
Female	72 (55)	69 (53)	
<b>Duration of Diabetes</b>			
Below 5 years	34 (26)	36 (28)	0.999 ( $p > 0.05$ )
5-10 years	56 (43)	60 (46)	
11-20 years	36 (28)	31 (24)	
Above 20 years	04 (3)	26 (2)	
<b>Mean <math>\pm</math> SD</b>	9.06 $\pm$ 12.78	8.54 $\pm$ 14.35	
<b>Family history of DM</b>			
Positive	31 (24)	34 (26)	0.79 ( $p > 0.05$ )
Negative	99 (76)	96 (74)	
<b>Occupation</b>			
Employed	55 (42)	51 (39)	0.999 ( $p > 0.05$ )
Unemployed	75 (58)	79 (61)	
<b>Level of Education</b>			
Illiterate	65 (50)	44 (34)	0.999 ( $p > 0.05$ )
School	42 (32)	45 (35)	
College	23 (18)	41 (31)	
<b>Type of Area</b>			
Rural	88.4v(68)	79 (61)	0.999 ( $p > 0.05$ )
Urban	41.6 (32)	51 (39)	

The trained pharmacists identified 385 patients of type-2 diabetes for practice assessment study, of which 270 were identified by Non-Govt. sector pharmacists which were found to be eligible, whereas 115 patients identified by Govt-sector pharmacists for study, were not found to be qualified due to various reasons like not willing to consent, all inclusion criteria were not met and base level HbA<sub>1c</sub> values were not available. Out of qualified 270 patients enrolled, 135 were allocated in the intervention group and 135 in the non-intervention group who continued with the study. Out of 270 enrolled patients, only 260 were included in the final analysis since ten patients were lost to follow up after their first visit.

Among 270 enrolled patients, the age range of the maximum participants in both the non-intervention and intervention group was above 36 years, with mean  $\pm$  sd age range of 37.23  $\pm$  15.71 and 38.28  $\pm$  16.20 years respectively ( $p > 0.05$ ). All the participant patients were taking on an average of two oral medicines for the treatment of diabetes, besides most of the patients were taking an average of two other drugs for hypertension. The male to female ratio in the non-intervention group was 1:1.5 and in the intervention group, it was 1:1.3 ( $p > 0.05$ ). Among both the groups, the non-interventional group showed an average duration of diabetes for about 9.06  $\pm$  12.78 years and the intervention test group showed an average duration of diabetes of 8.5  $\pm$  14.35 years. Family history for diabetes was found to be positive in 24% of patients in the non-interventional group and 26% of patients in the intervention group. More than half of the patients (68%) were living in rural areas and 32% of patients were from urban areas in the non-interventional group and in the intervention group 61% of patients were living in rural areas and 39% of patients were from urban areas in both groups, patients were moderately literate. Thus demographically, both Non-Intervention and intervention group patients were uniform and matching concerning all parameters (Table 2).

Among 345 participants, a very significant increase in the level of diabetic pharmaceutical care-related knowledge, attitude and practice components among all the participants across both Govt and Non-Govt pharmacists was observed post-training. The structured training had significantly helped in increasing the knowledge component from baseline 7.58  $\pm$  4.09 to 17.09  $\pm$  5.77, attitude component from 2.05  $\pm$  2.27 to 6.26  $\pm$  3.34 and practice component from 0.65  $\pm$  1.04 to 1.69  $\pm$  1.83 post-training interventions in all pharmacists, (Table 3).

### Clinical and KAP Measures outcomes in Patients

Table 4, provides a comparison of impact, on various clinical and KAP parameters related to non-intervention and intervention group participants, from baseline to follow-up visit. Among 260 enrolled diabetes patients, a significant decrease compared to baseline was observed in all assessed

**Table 3: Effects of Diabetes Pharmaceutical Care training on KAP\* among the different groups of pharmacists (n=345).**

Setting ↓	Knowledge (K)			Attitude (A)			Practices (P)		
	Pre score	Post score	p-value	Pre score	Post score	p-value	Pre score	Post score	p-value
ALL	7.58 $\pm$ 4.09	17.09 $\pm$ 5.77	<0.0001*	2.05 $\pm$ 2.27	6.26 $\pm$ 3.34	<0.0001*	0.65 $\pm$ 1.04	1.69 $\pm$ 1.83	<0.0001*
Community Pharmacists	7.86 $\pm$ 4.01	17.07 $\pm$ 5.45	<0.0001*	2.64 $\pm$ 2.51	7.00 $\pm$ 3.06	<0.0001*	0.89 $\pm$ 1.17	2.13 $\pm$ 2.08	<0.0001*
Pvt. Hospital Pharmacists	7.02 $\pm$ 4.06	17.38 $\pm$ 6.21	<0.0001*	1.03 $\pm$ 1.33	5.66 $\pm$ 3.97	<0.0001*	0.6 $\pm$ 0.95	1.51 $\pm$ 1.49	<0.001*
PHC govt. Pharmacists	6.93 $\pm$ 3.50	17.27 $\pm$ 5.97	<0.0001*	1.54 $\pm$ 1.98	4.87 $\pm$ 3.02	<0.0001*	0.27 $\pm$ 0.62	0.89 $\pm$ 0.98	<0.001*
Govt. Hospital Pharmacists	7.80 $\pm$ 5.14	16.63 $\pm$ 6.67	<0.0001*	1.09 $\pm$ 1.27	5.23 $\pm$ 3.28	<0.0001*	0.13 $\pm$ 0.40	0.83 $\pm$ 0.93	<0.001*

**Table 4: Effect of Diabetes Pharmaceutical Care practices on patients in terms of Clinical parameters and KAP outcomes measures (n=260).**

Parameters	Non-Intervention (n=130)	Intervention (n=130)	P Values amongst groups
FBG 1 <sup>ST</sup> PRE	158.82 ± 2.64 (30.69)	167.93 ± 3.64	0.0439*
FBG 2 <sup>ND</sup> POST	169.13 ± 2.83 (32.84)	148.92 ± 2.40	<0.0001*
P VALUES (pre and post)	<0.0082*	<0.0001*	
PPBS 1 <sup>ST</sup> PRE	221.11 ± 4.95	234.56 ± 6.42	0.0983
PPBS 2 <sup>ND</sup> POST	256.19 ± 5.49	209.43 ± 4.94	0.0003*
P VALUES (pre and post)	0.0622	<0.0021*	
SYSTOLIC BP 1 <sup>ST</sup> PRE	136.79 ± 1.08 (12.55)	138.75 ± 1.17	0.2194
SYSTOLIC BP 2 <sup>ND</sup> POST	135.47 ± 1.19 (13.84)	131.64 ± 0.81	0.0084*
P VALUES (pre and post)	0.4124	<0.0001*	
DIASTOLIC BP 1 <sup>ST</sup> PRE	85.50 ± 0.70	84.34 ± 0.92	0.3175
DIASTOLIC B 2 <sup>ND</sup> POST	87.10 ± 0.61	82.03 ± 0.64	<0.0001*
P VALUES (pre and post)	0.0850	<0.0404*	
HbA <sub>1c</sub> 1 <sup>st</sup>	10.20 ± 2.30	9.39 ± 2.30	0.0878
HbA <sub>1c</sub> 2 <sup>nd</sup>	10.11 ± 2.50	8.43 ± 1.88	0.0160*
P VALUES (pre and post)	0.5124	0.00451*	
PRE-KAP Score	4.85 ± 0.23	6.36 ± 0.29	0.0001*
POST-KAP Score	4.70 ± 0.24	15.54 ± 0.32	<0.0001*
P VALUES (pre and post)	0.6515	<0.0001*	

**Figure 1: Components of the Diabetes Training Manual.**

The pharmacists were trained in 3 sessions each per month using the manual. (Each session of 90 min)
<b>Session 1</b>
Steps for providing Diabetes pharmaceutical-care to Patients <b>Overview on Diabetes</b> The pharmacists were given a basic overview of diabetes, types and classification, clinical symptoms and signs, diagnosis and complications of diabetes, goals of diabetes management and treatment of hypoglycemia.
<b>Blood Glucose Monitoring</b> Information on the normal and abnormal glucose levels and their clinical significance, how to monitor blood glucose levels, how to use a blood glucose meter, when to check blood glucose and target levels.
<b>Session 2</b>
<b>Insulin:</b> The pharmacists were trained on how insulin works in the body, various types of insulin preparations, dosing-schedules and adjustments of insulin, how to use, store, mix and inject insulin.
<b>Oral Medications for Diabetes</b> This section covered the different options to treat diabetes with oral medications and combinations, how they work, their potential side effects and drug interactions, how to take them correctly, monitoring parameters if any and tailored patient counseling steps.
<b>Session 3</b>
<b>Monitoring parameters</b> The pharmacists were made aware of the clinical importance of monitoring blood glucose, blood pressure and hemoglobin A <sub>1c</sub> , urine testing and lipids.
<b>Avoiding Long-Term Complications</b> This section described lifestyle modifications in terms of diet and exercises and the precautions to prevent the body systems that can be damaged by diabetes.

clinical parameters in the intervention group: decrease in FBG ( $p < 0.0001^*$ ), followed by a significant decrease in PPBG levels ( $p < 0.0021^*$ ), a significant decrease in systolic blood pressure ( $p < 0.0001^*$ ) and a reasonable reduction in diastolic blood pressure ( $p < 0.0404^*$ ). Also, the mean percentage of HbA<sub>1c</sub> levels after six months of intervention showed a moderate decrease of approximately 0.96% ( $p < 0.0404^*$ ) compared with baseline in the intervention group. Followed to this a very significant increase in the overall knowledge, attitude and practices of the patients enrolled was noticed from  $6.36 \pm 0.29$  to  $15.54 \pm 0.32$ , comparatively.

Whereas in the group, all the clinical parameters PPBS, SBP, DBP and HbA<sub>1c</sub> were found to have either remained more or less unchanged or increased and deteriorated further from baseline. However, fasting glucose levels (FBG) were shown to have decreased significantly ( $< 0.0082^*$ ) in the non-intervention group. In terms of KAP levels, no significant improvement was observed compared to baseline,  $p > 0.05$  (Table 4).

## DISCUSSION

The broad range of data collected in the present study allowed a comprehensive assessment of the potential benefits of structured and tailored interventions done with regards to pharmacists and patients. Overall, a very significant and positive impact was observed across all the evaluated parameters of pharmacists and patients under study.

Enhanced outcomes of KAP were observed across all the participants post-training. Increment in knowledge about the topic, gaining complete therapeutic insight about diabetes, understanding how to perform the pharmaceutical care in their setting and provision of tailored patient care was advantageous for the participants after undergoing training. Since more than 80% of participants had just a basic pharmacy education, a Diploma course which is of two years with scarcely any clinical component exposure in India, they were less confident initially due to lack of knowledge and not inclined to impart Pharmaceutical care before the interventional training. Similar studies conducted by Adepu R and Battaglia JN, *et al.* have also proven that participation in such structured educational training helped pharmacists in specializing in diabetes therapy which led to gaining confidence to counsel the patients. Consequently, it helped patients in gaining skills in self-management due to awareness and they started managing their conditions well.<sup>[17,18]</sup>

Pharmacists gave the feedback that the main barriers which they face apart from lack of clinical knowledge were no time for counseling patients, high workload, non-availability of skilled staff and lack of motivation to give Pharmaceutical care training in the Indian scenario. Studies conducted by Ayadurai S and Datar A *et al.* reported similar findings that shortage of time, insufficient staff, lack of therapeutic knowledge leading to low confidence levels, inadequate reimbursement, working constraints, lack of designated space to provide counseling due to the physical design of the pharmacy and lack of training were the main reasons for non-provision of pharmaceutical care.<sup>[19,20]</sup>

In this study the assessment of KAP scoring in patients discovered that there was a significant decrease in knowledge; attitude and practices from the baseline and final visit in the non-intervention group ( $p > 0.05$ ) whereas in the intervention group there was a significant increase in the same, post pharmaceutical care services received. Statistical analysis shows that the impact on the intervention group was statistically significant ( $p < 0.0001$ ). This outcome is similar to the study conducted by Noohu Abdulla Khan *et al.* which also indicated that improvement in diabetic patients' knowledge, awareness and attitude towards the disease was improved post Pharmaceutical care and lead to better glycaemic control.<sup>[21]</sup>

Concerning the patient's clinical outcomes, it was found that in the intervention group, KAP scores were higher and significant glycaemic control was achieved after six months compared to baseline. The factors responsible for the improvement of diabetes control in the overall population could be attributed to improved patient-pharmacist communication driven by the educational intervention, better understanding of medication and treatment as well as useful lifestyle habits which were also proved in other similar studies.<sup>[22]</sup> In terms of demographic parameters like age, gender, duration of diabetes, family history, occupation, education level and civilization of diabetes for both groups; statistical analysis indicated that the groups were well matched ( $p > 0.05$ ) which is similar to the study conducted by Shanmugam Sriram *et al.*<sup>[23]</sup>

A significant improvement in patients' clinical outcomes was noted in the intervention group such as a reduction in fasting blood glucose levels, postprandial blood glucose levels, Hb1Ac and better control in systolic and diastolic blood pressure. In this study, there was a significant decrease in fasting blood glucose between the baseline and final visits of patients which is a similar finding to the study conducted by Chidambaram Dhandapani *et al.* that showed significant improvement in FBG in the test group, compared to the Non-Intervention group.

These results provide clinical evidence that pharmaceutical care has a positive

role in type 2 diabetes management due to close assessment of glycaemic levels periodically and solving drug-related problems of patients by coordination with treating physician. Furthermore, our findings show that there was a significant decrease in postprandial blood glucose in the intervention group ( $p < 0.001$ ) which is similar to the study conducted by Chidambaram Dhandapani *et al.* which shows that educating the pharmacists to provide pharmaceutical care and follow up calls with patients proved beneficial in reducing mean PPBS levels significantly.<sup>[24]</sup>

This study shows that there was a significant decrease in systolic and diastolic blood pressure in the intervention group which is similar to the study conducted by Winifred Aitalege Ojjeabu *et al.* which also shows that the mean values of systolic and diastolic blood pressure were significantly decreased in both groups.<sup>[25,26]</sup> This attributed to patients having diabetes with hypertension in the intervention group were also educated about the importance of controlling hypertension that can prevent the development of future complications. However, in the non-intervention group, there was an increase of about one unit from baseline in the mean value of systolic blood pressure since they were not aware of the importance of controlling blood pressure along with their diabetes.

The reductions in HbA<sub>1c</sub> levels (average of 0.96 %) among the patients from the intervention group after six months post-intervention are an encouraging achievement with meaningful clinical consequences. Similar findings were seen among 26 RCTs reported by Michiels Y, *et al.* which assessed HbA<sub>1c</sub> levels, 24 of them showed a 0.18-2.1% decrease in HbA<sub>1c</sub> levels, after an average interval of 3–12 months, between the non-intervention and the intervention group.<sup>[27]</sup>

We believe that the intervention group patients in our study showed improved glycaemic control because they understood their disease and its treatment better, which brought out an active change in the way they managed their day to day choices of diet and adhered to medication advice received from their pharmacists. Twenty-five studies comprising 2997 persons with diabetes confirmed that education on diabetes and its complications, medication adherence, lifestyle and education about self-management skills provided by pharmacists led to a reduction of HbA<sub>1c</sub> levels with a mean of 0.75% in a span of 6 months. Similar findings are supported by the studies done by Ali MK, Krapek Ket and Iqbal MZ *et al.*<sup>[28-30]</sup>

Our data thus strongly supports the hypothesis that structured training can have a positive impact on community pharmacist's practices in delivering effective diabetes pharmaceutical care and patients are benefited by achieving successful glycaemic control.

## Limitations

Our study had some limitations. The outcome in terms of actual practices is mainly related to non-government community pharmacists since pharmacists from the hospital and government sector had unavoidable barriers due to which they could not successfully provide the required PhC services. These barriers need to be further studied to find an appropriate solution so that all settings from both sector pharmacists can provide such services and maximum patient benefit can be achieved. We could not assess specific parameters like the lipid levels in patients due to the unavailability of lipid profiles of maximum patients at the base level and also in follow up visits. It is expected that the PhC services need to be continuously conducted in routine even once the study complete, but it is difficult to monitor in the absence of regulatory controls, monitoring systems and official mandates.

## CONCLUSION

The study concluded that well-trained pharmacists could have a beneficial impact on the care of patients with type 2 diabetes. The structured training proved to be a useful tool to up-skill pharmacists and improve their knowledge and confidence in practicing diabetes care. Pharmacists viewed the training as relevant and beneficial in facilitating the provision of tailored, evidence-based interventions in diabetes care. Patients could gain appropriate knowledge of diabetes and its management from pharmacist-led education imparted to them. It consequently could help patients in monitoring and daily management of diabetes in appropriate manner to achieve glycaemic control successfully.

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## CONFLICT OF INTEREST

The authors declare that they have no conflict of interest to disclose.

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