Clinical Pharmacist Intervention on the Outcomes in Outpatients with Type 2 Diabetes Mellitus, Hypertension, and Dyslipidaemia and Its Impact on Cardiovascular Diseases

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ABSTRACT

Objective: The objectives of the study were to evaluate the effect of the intervention of a clinical pharmacist on glycemic control, Blood Pressure, and lipid profile for patients with coexistence of type 2 diabetes mellitus, hypertension, and dyslipidemia in the outpatient department of a tertiary care hospital. It also evaluates the impact of these interventions on the risk management for cardiovascular events and the frequency of hospitalization. **Methods:** A prospective randomized controlled study conducted in the outpatient department of a tertiary care hospital. Based on inclusion-exclusion criteria they were randomly divided equally into interventional group and usual care group. The patients in the former group participated in a clinical pharmacist-led care program that provided all pharmacist care. Blood data was collected at the baseline and the end of the study. The main outcomes measure was changed in the primary parameters associated with the disease. The impact of this risk factor management on cardiovascular events and subsequent hospitalization was also measured. **Results:** No significant differences were noted in demographic and basic clinical data at the baseline between the interventional group and the usual care group. At the end of the study patients in the interventional group showed good glycemic control, normalized lipid profile, and blood pressure. A significant reduction in the occurrence of cardiovascular events and hospitalization was also observed in the interventional group. **Conclusion:** The study showed significant improvements in glycemic control, blood pressure, lipid levels, and reduced cardiovascular events, and improved clinical characteristics and self-care management.

INTRODUCTION:

Drug use is a complex process that leads to an increased number of drug-related problems at various levels involving prescribers, patients, pharmacists, and pharmaceutical industry [1]. In response to the growing need for enhancing the effectiveness, safety, and precision of drug therapy, the profession of pharmacy is required to evolve new functions and responsibilities for pharmacy practitioners to promote rational drug use.

Hypertension, dyslipidemia, and diabetes are found to be the major risk factors for cardiovascular morbidity and mortality. The prevalence and management status of these cardiovascular risk factors are not been fully described, yet this population increases worldwide presenting challenges even to primary health insurance services [2]. Knowledge of the current magnitude of hypertension, dyslipidemia, and diabetes in this population is important for healthcare resource allocation, disease management, and education [3].

Most people who have diabetes, high blood pressure, and high cholesterol have difficulty in managing all three conditions; indeed, success is fleeting for those who do manage all three. But among those individuals that achieved simultaneous control of their conditions, few were able to maintain it at either institution.

The management of these three conditions is complex, requiring continuous medical care by health care professionals and considerable self-care efforts by patients. In patients with these complex diseases, the medication regimens are often complex therefore appropriate use of medication, adherence to medications, and lifestyle modifications are important factors that influence the outcomes of the treatment.

Clinical Pharmacist-led pharmaceutical care is a new concept getting momentum in healthcare management [4]. The mission of pharmaceutical care is to provide medications as well as other healthcare services to help people to get the best results. It involves activities to identify and resolve drug-related problems as well as encouraging proper use of medication and promoting general health and education resulting in better therapeutic outcomes by their patient-focused interventions. As experts in drug therapy pharmacists can excel in drug selection and patient education along with a multidisciplinary healthcare team for better care of the patients [5,6].

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Clinical Pharmacists can play a vital role to improve the treatment as well as lifestyle modifications and economic benefits to the best of our knowledge no such pharmaceutical care program is reported in our community [7]. Clinical Pharmacy is practiced in many countries and makes a significant contribution to improving drug therapy and patient care [8]. India is a country with significant problems with medication use but still, very recently Indian pharmacists are not educated and trained in inpatient care. With the introduction of Pharm D and post-graduation programs in pharmacy practice, pharmacist now enters clinical services.

Clinical pharmacists are specially educated and trained practitioners who provide direct patient care and involvement in comprehensive medication management. Clinical pharmacists are already gained significant worldwide acceptance as an important healthcare team member for patient care in the ambulatory and acute care of the patients [5]. They focus on the optimization of the use of medication, adjustment of the doses, monitoring, and identification of adverse drug reactions, and economic efficiency. Many studies demonstrated the clinical and economic benefits of clinical pharmacists in hospital settings.

The benefit of drug therapy is found to be based on the rational use of drugs. The rational use in turn largely depends on patient compliance. This is an area where a clinical pharmacist can be involved in the appropriate use of drugs in inpatient care. Periodic clinical review and evaluation of the drug effect by clinical investigational data improve the treatment and the therapeutic outcome. Therefore, these types of studies will result in better drug administration and patient care.

With the changes in the complexity and sophistication of medical practice, the importance of patient education is increasingly recognized as an essential component for enhanced medical care. Patient education is the educational experiences planned by professional healthcare members for the patient [9]. Patient educational programs to support patient participation in disease management have been proposed as an important strategy in reducing the increasing load of chronic diseases. It has been observed that even after treatment with the best regimens, patients are readmitted to the hospital due to improper use of the prescribed medicines [10]. The readmission can be reduced to a great extent by patient education programs.

Despite new medications and specific care of type-2 diabetes controlling glycemic parameters, blood pressure, and lipid profile the control over these remains insufficient.

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Improvement in medication adherence and self-care activities are associated with control in patients with diabetes, hypertension, and dyslipidemia. Pharmaceutical care programs led by pharmacists in previous studies carried out in different settings have shown improvement in the control of these diseases [11,12,13].

A very few studies were conducted in India where a large number of patients have chronic diseases like hypertension, dyslipidemia, and diabetes mellitus. Also, studies were conducted to evaluate glycemic control as well as blood pressure and lipid control separately. But the intervention of all three conditions and assessment of the effect of the interventions in these diseases and their impact on cardiovascular disease is first of its kind in a clinical pharmacy setting.

The main purpose of this study is to evaluate the effect of intervention by a clinical pharmacist on the clinical outcomes of glycemic control, blood pressure, lipid profile, body mass index, waist circumference for a patient with the co-existence of type-2 diabetes, hypertension, and Dyslipidaemia throughout 12-months in the outpatient setting of a tertiary care hospital and its impact on the cardiovascular complications and hospitalizations. In this study, we aim evaluation of the impact of the intervention of clinical pharmacists on outpatients with hypertension, dyslipidemia, and diabetes mellitus and its effect on cardiovascular diseases and hospitalizations.

MATERIALS AND METHOD:

Selection of the subjects:

Patients above 18 years of age belonging to either gender, diagnosed with type – 2 diabetes mellitus, hypertension, and hyperlipidemia for not more than 2 years were selected. Patients above 70 years are not included due to comorbid conditions and inability to adhere to the therapeutic regimen due to psychological factors. Patients with severe renal and hepatic dysfunctions were also excluded.

The study design:

The study was designed as a prospective, randomized controlled research. It was carried out in a tertiary care multidisciplinary teaching hospital. Ethical clearance was obtained from the institutional ethical committee of the hospital where the study was carried out. Patients diagnosed with all three disease conditions of type-2 diabetes mellitus, hypertension and

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dyslipidemia were selected from the outpatient department of general medicine. The study was conducted for 12 months. Subjects were selected based on exclusion inclusion criteria and they were monitored. Patients who expressed willingness to participate in the study and otherwise satisfied the eligibility requirements were selected and the study details were well explained to all the participating patients and the duly signed informed consent was obtained. The selected patients were grouped randomly into interventional and usual care groups. The different intervention steps and the protocol of the study were explained to the patients included in the interventional group whereas the usual care group was directed to follow their normal treatment protocol.

The multifaceted interventions for the patients in the interventional group were comprised of two sessions, face-to-face care by an interview and counseling followed by a telephonic follow-up program. The interventional group was given regular six face-to-face informative sessions during one year during their regular visit to the outpatient department for review. During this session, the clinical pharmacist performed a 30 minutes face to face interaction and counseling. This included the following

Evaluation and providing basic knowledge about diabetes, hypertension, dyslipidemia, and cardiovascular diseases which included factors that are found to be seriously affected and possible occurrence of cardiac events.

Evaluation of the previous medication uses and the experiences, if necessary, it was tailored with advice.

Utilizing medication administration supports like pill counter and leaflets containing detailed information about the drug,

Patient information leaflets containing information regarding the disease, symptoms, laboratory tests required and lifestyle modifications to be made were prepared and supplied and pictures showing health educations, and

Correcting any misunderstandings about the disease or medications and associated lifestyle modification.

During this interview, the evaluations were made regarding the progress of the intervention, and detailed counseling and educations were given regarding the medications, adherence,

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self-care activities, and also the lifestyle modifications recommended. The patients were also given time to ask questions related to their disease, therapy and clear the doubts.

During the second session, the patients were given regular 12 follow-up interventions in the study. The patients were contacted over the telephone and guidance was given regarding the rational use of medications. The telepharmacy was mainly focused on the adherence of the patient to the medications.

Patient counseling is performed by the clinical pharmacist utilizing the telepharmacy pursuance and performed the following: -

Assessment of the medication adherence,

Encouragement and reminders with tailored advice, and

Clarifying any misunderstandings or misconceptions.

All the patients participated in all the proceedings. A few patients were shifted their place of work and accordingly discontinued from the study as they are relocated. Some patients due to their comorbid conditions shifted their treatment to other specialty hospitals. All these patients discontinued their study with prior intimation to the study supervisor. No mortality was reported in the complete period of the study in either group of patients.

Data Collection

All demographic details were collected. At the start and end of the study, blood samples were collected to evaluate the biomarkers such as fasting blood sugar, HbA1c, TC, LDL-C, HDL-C, and TG. Arrangements were made to measure the Systolic Blood Pressure and Diastolic Blood Pressure during the visit of the study population at the outpatient department. At the beginning and end of the proceedings of the study questionnaires were given and explained to answer for the adherence and self-care activities Adherence was measured using Morisky adherence test and self-care activities by using standardized questionnaire formats. Measurements were taken for the body mass of the patient in the outpatient department. The waste circumference of the patient was also measured in the outpatient department.

The main outcomes were measured concerning chronic diseases. The changes in the hyperglycemia were measured as variations in HbA1c, fasting blood sugar level. The changes in the systolic blood pressure (SBP) and diastolic blood pressure (DBP) were also assessed.

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The clinical changes in the lipid profile parameters were calculated based on the changes in the value of total cholesterol, Low-Density Lipoprotein - Cholesterol (LDL-C), High-Density Lipoprotein - Cholesterol (HDL-C), and triglycerides (TGs). Medication adherence is self-reported by using standardized self-reporting proforma. The body weight and the activities such as diet, exercise, self-monitoring of blood glucose, and foot were also monitored using self-assessment methods. The impact of these disease conditions on cardiovascular diseases was studied. The hospitalization due to cardiovascular complications was also recorded. The changes in quality of life were closely monitored.

Measurements were made in the outcome of the interventions from baseline to the completion of the study were evaluated using statistical analysis. The demographic data and the baseline characteristics were summarized descriptively. Continuous variables were analyzed using unpaired t-test and categorical data were analyzed by using chi-square test at the baseline as well as by the end of the study at 5% significance. All differences were tested at p=5.

RESULTS AND DISCUSSION:

RESULTS:

During this study a clinical pharmacist optimized the pharmacotherapy and involved in the design of medication regimens, the clinical pharmacy services, and interventional parameters are assessed and the results reflected the successful use of the strategies in this context.

One of the most important barriers of pharmaceutical care in India was the attitude of the physician towards the patient care process and the lack of effective clinical training for the pharmacists [14]. But the present study demonstrates the significance of clinical pharmacists in improving therapeutic outcomes in medical outpatients.

Clinical pharmacist intervention resulted in a significant improvement in HbA1c, fasting blood glucose, blood pressure, and lipid profile. This has reduced the occurrence of associated heart diseases and related hospitalization.

Study Population

A total of 220 eligible patients attending the outpatient clinic of a tertiary care hospital has participated in the study. Out of 220 patients, 110 were randomly included in the intervention group and110 were in the usual care group. During the study, 04 patients from the

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intervention group and 06 patients from the usual care group were discontinued due to personal reasons.

Therefore, 106 patients in the intervention group and 104 patients in the usual group, accounting for a total of 210 patients completed the study.

Patient Characteristics at Baseline

Gender, age, education, and employment are represented in Table-1. Statistical analysis indicated that there was no significant difference in the patient characteristics between the intervention groups versus the usual care group.

TABLE NO. 1: DEMOGRAPHIC CHARACTERISTICS

Demographic characteristics	Usual care group N=104	Interventional group N=106	p-value
Gender			
Male	44(42.3)	41(38.7)	0.592
Female	60(57.7)	65(61.3)	
Age group			
41-45	04(3.8)	03(2.8)	
46-50	18(17.3)	19(17.9)	
51-55	20(19.2)	21(19.8)	
56-60	36(34.6)	38(35.8)	0.950
61-65	20(19.2)	21(19.8)	
66-70	06(5.8)	04(3.8)	
Education			
Elementary	14(13.5)	14(13.2)	
Primary	18(17.3)	18(17.0)	
Secondary	22(21.2)	25(23.6)	
Graduate	28(26.9)	26(24.5)	
Postgraduate	12(11.5)	14(13.2)	0.994
Professional	10(9.6)	09(8.5)	
Employment			
Employed	32(30.8)	43(40.6)	0.979
Unemployed	72(69.2)	63(59.4)	

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Biomedical Outcomes

Glycemic control

At the baseline assessment, the HbA1c values were similar for both interventional and usual care groups. But at the end of the study, the HbA1c value was reduced from 8.56% to 7.36% in the interventional group whereas in the usual care group it was reduced from 8.71% to 8.57% (Table-2).

Comparing with the usual care group, the interventional group patients achieved a greater reduction in the HbA1c values at the end of the study. It was observed that in the intervention group the percentage of patient reached the American Diabetes Association goal (HbA1c< 7) was significantly higher compared to the usual care group.

The average fasting blood sugar was reduced from 208mg/dL to 186mg/dL in the interventional group and 211mg/dL to 198mg/dL in the usual care group (Table-3, Fig-2).

Both the group showed significant reductions in fasting blood sugar levels. But the reduction in the interventional group was significantly larger than the usual care group at the end of the study because of the impact of the interventions by the clinical pharmacist.

The most important finding related to the blood sugar monitoring was that 37 percent of the interventional group achieved the ADA target in the 12 months of follow-up. The reduction in the fasting blood sugar level of both groups of diabetes patients further proved that pharmaceutical care can result in a significant improvement in glycemic control in multiple clinical morbid conditions.

Systolic and Diastolic Blood Pressure

At the baseline, the mean SBP in the interventional group and usual care groups were 140.86mm Hg and 143.00 mmHg respectively. It was reduced to 125.81mmHg and 134.78 mmHg at the end of the study. (Table-2)

The mean DBP was 91.03mm Hg and 91.19 mmHg at the baseline in the interventional group and usual care group respectively. It was reduced to 82.03mmHg and 85.27 mmHg at the end of the study. (Table-2)

There was a decrease in the SBP and DBP in both the groups but the interventional group showed more reduction at the end of the study compared to the usual care group. The

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percentage of patients in the interventional group who achieved the ADA goals for SBP/DBP (140/90) significantly higher than the usual care group in this study.

TABLE NO. 2: OUTCOMES IN KEY BIOMEDICAL VALUES AT BASELINE AND END OF STUDY WITHIN & BETWEEN GROUPS.

Outcome measures	Interventional group				Usual care group				Group mean difference
	Baseline Mean+SD (Median)	End of Study Mean+SD (Median)	Mean Difference	P-Value	Baseline Mean+SD (Median)	Mean+SD (Median)	Mean Difference	P-Value	
Fasting Blood Sugar(mg/dL)	209.62±13.60 (208.0)	182.571±4.91 (186.0)	27.06	0.00	211.831±1.91 (212.0)	200,68±17.19 (198.0)	11.144	0.001	-15.912
HbA1c (%)	8.56±0.69 (8.5)	7.360±.76 (7.2)	01.196	0.00	8,710±.74 (8.7)	8.570±.95 (8.5)	0.136	0.136	-1.061
Systolic BP (mm Hg)	140.86±5.05 (141.0)	125.81±4.51 (126.0)	15.05	0.00	143.00±6.19 (142.0)	134.78±5.57 (134.0)	8.221	0.0001	-6.826
Diastolic BP (mm Hg)	91.031±.84 (91.0)	82.043±.25 (82.0)	08.99	0.00	91.19±1.96 (91.0)	85.273±.35 (86.0)	5.923	0.000	-3.067
Total Cholesterol (mg/dL)	209.53±6.17 (209.0)	188.59±8.71 (190.0)	20.93	0.00	209.71±6,81 (209.0)	197.24±15.14 (195.0)	7.904	0.000	-8.463
Triglycerides (mg/dL)	157.58±8.91 (157.0)	138.25±15.22 (137.0)	19.32	0.00	155.04±4.86 (155.0)	154.88±4.91 (155.0)	0.150	0.117	-11.417
LDL-C (mg/dL)	124.516±.89 (124.0)	111.58±8.95 (112.0)	12.93	0.00	127.86±9.57 (127.0)	121.66±13.56 (120.0)		0.001	-6.742
HDL-C (mg/dL)	42.08±6.29 (41)	48.993±.70 (49.0)	-06.92	0.005	39.894±.89 (40.0)	39.98±4.91 (40.5)	0.087	0.07	6.829

A1c=haemoglobin A1c, BP=BoodPressure, LDL-C Low-Density Cholesterol, HDL-C= High-Density Cholesterol.

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Lipid Profile

The Total Cholesterol, Triglyceride, and LDL-C values decreased in all the patients belonging to both interventional and usual care groups at the end of the study. Similarly, there was an improvement in the HDL level in the patients belonging to an interventional group. But values were not increased marginally in the usual care group (Table-2).

Significant differences in lipid control were observed between the interventional group and the usual care group. The total cholesterol, triglycerides, and LDL were significantly reduced in both the group. But there was a significant reduction in the interventional group compared to the usual care group indicating the impact of clinical pharmacist intervention. The HDL level was not much increased in the usual care group, but there was a significant improvement in the HDL value in the interventional group.

Cardiovascular diseases

All the patients who have participated in the study reported no cardiovascular diseases at the baseline. But at the end of the study, 11 patients and 02 patients were found to have cardiovascular diseases in the interventional group and usual care group respectively. The patients with cardiovascular diseases were significantly higher in the usual care group compared to the interventional group.

 It was found that 15 patients from the interventional group and 04 patients from the usual care group were admitted to the hospital due to cardiovascular and associated diseases. The group analysis showed a significant reduction in the intervention group and usual care group for hospitalization due to cardiovascular diseases [Table 3].

Our results showed that the efficiency of clinical pharmacists on individual components of cardiovascular risks resulted in improved healthcare. In the study, significant improvements in blood sugar levels, hypertension, dyslipidemia, smoking cessation, and alcoholic habits resulted in the reduced cardiovascular events in the interventional group.

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TABLE NO. 3: OUTCOMES IN CVD AND HOSPITALIZATION AT BASELINE AND END OF STUDY

Clinical Characteristics	Usual care group			Interventional group			Group Analysis p-value
	Number (%)	Number (%)	p value	Number (%)	Number (%)	p value	
Cardiovascular diseases	00(0)	15(14.4)	0.000	00(00)	04(03.8)	0.131	0.003
Hospitalization	00(00)	11(10.6)	0.000	00(00)	02(01.9)	0.230	0.007

DISCUSSION:

During the study, the clinical pharmacist was involved in patient counseling and patient education to optimize the pharmacotherapy. This has created an awareness on the patient not only in the appropriate use of medication but also about their lifestyle modifications. The study also made an impact on the usual care group with their contacts with the intervention group members.

Diabetes is a lifelong disease and the constant increasing incidents of diabetes make the healthcare community more liable for effective management programs [15]. One of the most important parameters used to assess the blood glucose level is a measurement of HbA1c and fasting blood glucose levels. HbA1c is a measure of glycosylated hemoglobin (HbA1c). It is an important blood test that determines the management of diabetes. The test provides an average measurement of blood glucose over a 6 to 12 weeks period. It is mainly used in conjunction with home glucose monitoring to make treatment adjustments for the better control of diabetes [16].

In this study, the HbA1c value did not differ much in the usual care group whereas in the interventional group it was significantly reduced. The changes in the interventional group also showed significant differences when compared to the usual care group, justifying the effect of the intervention of clinical pharmacists in inpatient care. The improvement in the HbA1c in the study may be due to the integrated effect on optimizing the prescribed pharmacotherapy, individualized education in various self-care activities, enhanced adherence, and regular follow-up by interactions and telephonically by the clinical pharmacist.

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The present study yielded a significant reduction in both systolic and diastolic blood pressure in patients belonging to the interventional group compared to the usual care group. Since the patients in both groups were prescribed with the almost similar antihypertensive class of medications the findings pointed out that the strategies like patient education about the therapy and associated changes in the lifestyle modifications and medication adherence resulted in an improvement in blood pressure control of hypertensive patients in the interventional group and usual care group.

Some studies showed a significant reduction in total cholesterol, LDL, and triglycerides [17]. But in our study, we were able to achieve a significant difference in all the lipid profiles. This was found to be due to patient education about the need for change in lifestyle behaviors related to food habits which may have influenced lipid control positively.

Cardiovascular diseases and the associated risk factors are considered the important public problem in healthcare worldwide. So, controlling the risk factors and reducing cardiovascular events is of prime concern in healthcare [18]. Many interventions are promoted in the healthcare sector to achieve this goal. It was observed that risk factors associated with cardiovascular diseases are mainly hypertension, blood glucose, Dyslipidaemia, and smoking [19]. All these factors were found to remain poorly identified and controlled in the modern scenario. Our results showed that the efficiency of clinical pharmacists on individual components of cardiovascular risks resulted in improved healthcare. In the study, significant improvements in blood sugar levels, hypertension, dyslipidemia, smoking cessation, and alcoholic habits resulted in the reduced cardiovascular events in the interventional group.

CONCLUSION:

This is a first of its kind of study performed to assess the impact of clinical pharmacists on the final clinical outcome of the clinical pharmacist intervention in patients who have all the major chronic diseases namely diabetes, hypertension, and hyperlipidemia, and high risk for cardiovascular diseases and associated complications.

During this study a clinical pharmacist optimized the pharmacotherapy and involved in the design of medication regimens, the clinical pharmacy services, and interventional parameters are assessed and the results reflected the successful use of the strategies in this context. One of the most important barriers to pharmaceutical care in India was that the attitude of the physician towards the patient care process and the lack of effective clinical training for the

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pharmacist. But due to the introduction of a new clinically oriented pharmacy educational program and the intensive clinical training with other healthcare providers encouraged the clinical pharmacists to work in the clinical setup and attracted increased acceptance and appreciation from other members of the healthcare particularly the physicians. The present study demonstrated the significance of clinical pharmacists in improving therapeutic outcomes in medical outpatients.

Clinical pharmacist intervention resulted in a significant improvement in HbA1c, fasting blood glucose, blood pressure, and lipid profile. This has reduced the occurrence of associated heart diseases and related hospitalization.

The pharmaceutical care provided by the pharmacist through patient counseling and education provides not only a positive approach in the patient towards the therapy but also improves their lifestyle and knowledge about the disease condition. Therefore, these services of the clinical pharmacists have to be encouraged. The data represent the rural population which limits its extrapolation to other areas on mixed population. This in the future will help the medical care team to consider the integrated pharmacist-led services which result in increased patient satisfaction with care. This also will improve the safety, quality, and cost of the personalized and complex treatment regimens in chronic disease management. The total number of patients involved in the study was small, but they show a very promising beginning of the clinical pharmacist-led disease management program in which clinical pharmacists are actively involved in the clinical activities in the multidisciplinary health care team.

The future scope of Clinical Pharmacy services found to be bright in India. The starting and establishment of the Pharm D program equip the clinical pharmacists with knowledge and skill to capable of involving in patient-oriented pharmaceutical care. These pharmacists are associated with clinicians and other health care team members more than community pharmacists. Therefore, hospital-oriented patient care by clinical pharmacists is going to serve the healthcare sector in the future.

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