

ASSESSMENT OF PHARMACEUTICAL CARE SERVICES ON HEALTH RELATED QOL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS – A PROSPECTIVE INTERVENTIONAL STUDY

BALAI AH S.^{1*}, TIRUPA M.¹, NARAYANA G.², MOHANRAJ R.², Y. PADMANABHA REDDY³

¹Student, Pharm. D, Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education and Research, Anantapur, A.P, India, ²Professor & Principal, Raghavendra Institute of Pharmaceutical Education and Research, Anantapur, A.P, India. Email: chinnabalu362@gmail.com

Received: 16 May 2014 Revised and Accepted: 28 June 2014

ABSTRACT

Background: In the last three decades role of pharmacist has changed dramatically. Patient counselling by pharmacist deals with providing information to the patients regarding the disease, Medications and lifestyle modifications. Diabetes mellitus (DM) is a severe medical and social problem that affects patient's general wellbeing. Despite of the advances in understanding the disease and its management, the morbidity and mortality rate are in rise.

Objective: To study the impact of pharmaceutical care services on quality of life in type 2 diabetes mellitus. To improve the knowledge, practice and attitude, Quality of life of patients towards disease management.

Methods: This is a prospective intervention study. It was carried out to determine the quality of life, based on which patients were counselled regarding disease, medication, nutrition, exercise, insulin, foot care, eye care, personal hygiene, self monitoring of glucose and self care. Out of 80 patients, who are having diabetes mellitus and given patient counseling again collected after 1st and 2nd month. The paired t-test in Graph Pad InStat was used for statistical calculation.

Results: The overall KAP scores for diabetes patients between test of baseline and final follow up was statistically significant ($P < 0.001$). The test group has shown increased medication adherence than control which shows the importance of patient counseling.

Conclusion: The study concluded that pharmacist mediated patient counseling and the disease, medications and lifestyle modifications will improve the knowledge, attitude and practice, Quality of life and Glycemic control.

Keywords: Patient counseling, KAP, Patient information leaflet and. Quality of life.

INTRODUCTION

Diabetes mellitus (DM) is a severe medical and social problem that affects patients general well being. Patient counselling by pharmacist deals with providing information to the patients regarding the disease, medications and lifestyle modifications. It has been shown to improve therapeutic outcomes [1].

The World Health Organization (WHO) has established two main objectives in caring for diabetic patients: first, maintain the health and quality of life of individuals with diabetes through effective patient care and education and second, treat and prevent complications of the disease which should decrease morbidity and mortality as well as reduce the treatment lost [2].

Prevalence and incidence of diabetes among adults is high, varying between 2.8 percent to 4 percent in the year 2000. This number is expected to grow, resulting in over 350 million persons with diabetes world-wide in 2030 [3].

The number of people with diabetes mellitus (DM) is steadily increasing in Southeast Asia due to population growth, aging, urbanization, and the increasing prevalence of obesity as well as physical inactivity (WHO and IDF, 2004).

Similarly, for India this increase is estimated to be 58%, from 51 million people in 2010 to 87 million in 2030. The impacts of T2DM are considerable: as a lifelong disease, it increases morbidity and mortality and decreases the quality of life. Accordingly, morbidity and mortality in India there are 109 thousand deaths in 2004, 1,157 million years of life lost in 2004, 2.263 million Disability Adjusted Life Years (DALY) in India during 2004 [4].

The prevalence of DM is dramatically rising worldwide; 171 million people suffered from diabetes in 2000, and it is expected that this figure will double to 366 million by 2030 [5].

The incidence increases with age, which, together with ageing of the population and possibly also with the high prevalence of overweight and obesity, will lead to a serious growth in the demand for diabetes-related health care [6].

During the last 20 years, the focus of community hospitals and pharmacies has shifted from a product centred approach to patient-centred activities. This was the result of a growing awareness that not only the quality of the drug itself, but also that of pharmacotherapy are key in the effectiveness and safety.

These issues, for example medication surveillance and patient education on compliance, a consequence of this shift, and due to the impact of diabetes on public health, the interest in interventions involving pharmacists in diabetes care has improved [5], [7].

Hyperglycaemia the hallmark of diabetes mellitus is associated with many different symptoms, which can be classified into short-term or long-term complications.

Acute symptoms of untreated diabetes include thirst, weight loss, polyuria and blurred vision. Severe hyperglycemia can result in fatal diabetic keto-acidosis. Long-term complications include retinopathy, nephropathy and neuropathy.

Furthermore, Type 2 diabetes mellitus is associated with a two to three fold increased risk of cardiovascular disease. Especially the long-term complications of diabetes are associated with high morbidity, high cost and decrease in quality of life.

Poverty, non-compliance, lack of knowledge and poor follow ups are the factors observed in poor glycemic control [8]. Individuals with poor management of diabetes are at a greater risk of developing long term micro and macro vascular complications that lead to the damage of end organs such as kidney, heart, brain and eyes, affects the direct and indirect health care costs and overall quality of life [9].

The clinical pharmacy grew with the concept of pharmaceutical care or patient centred pharmacist care, the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve the patients' quality of life. It involves the pharmacist's decision to avoid, initiate, maintain, or discontinue drug therapy, both of prescription and non-prescription drugs. It is thus practiced in collaboration with patients, physicians, nurses, and other health care workers. The ultimate goal of pharmaceutical care is to optimize the drug therapy and improve a patient's quality of life.

Pharmacists are in a prime position to ensure that use of medications by the patients safely and appropriately. These outcomes can be achieved by influencing the cure of the disease, elimination or reduction of symptoms, arresting or slowing the disease progress, prevention and diagnosis of disease or desired alterations in the physiological process. Patient counselling is an important means for achieving pharmaceutical care. It is defined as providing medication related information orally or in written form to the patients or their representatives, on topics like direction of use, advice on side effects, precautions, and storage, diet and life style modifications [3]. Patient counseling is interactive in nature and involves a one-to-one interaction between a pharmacist and a patient and/or caregiver [4]. The ultimate goal of counseling is to provide information directed at encouraging safe and appropriate use of medications, thereby enhancing therapeutic outcomes [10].

Another important role of pharmacist is always being available to answer the questions of the patients. Overall, it is the pharmacist's role to help a diabetic patient in the best possible way to cope with their disease [11].

MATERIALS AND METHODS

Study site: Department of General Medicine of a 300 bedded secondary care referral hospital located in Anantapur, A.P in South India.

Study design: Prospective Interventional study.

Study period: The prospective interventional study was conducted over a period of 6 months October 2013 – April 2014

Study sample: 80 patients

Study criteria:

Inclusion Criteria

- ✚ Patients of either sex aged above 40 years
- ✚ Presence of signs and symptoms which are suspected to have diabetes
- ✚ Patients who give consent to participate in this study

Exclusion Criteria

- ✚ Patients who are not willing to or unable to give consent to participate in study
- ✚ Patients who are Pregnant and Paediatrics

Sources of Data

All necessary data was collected from the following sources

1. Patient data collection form
2. Patient case history
3. Patient prescriptions
3. Laboratory data
4. Treatment profiles
5. Microbiological data
6. Patient counselling details - (Quality of life index, Patients KAP profile).

Consent from hospital Authority

The study was approved by the Hospital authority, by submitting a profoma of the study which includes the objectives, methodology, and the study was conducted with the expert guidance of seniors and junior physicians of the department selected.

Literature Survey

The literatures supporting the study were gathered from various sources such as British Medical Journal, American Medical Journal, Journal of Clinical Pharmacy and Therapeutics, Journal of Pharmacy Practice, The Annals of pharmacotherapy, Journal of national medical association, Indian journal on medical microbiology

Statistical Tool

The paired t-test in Graph Pad InStat was used for statistical calculation. **P value* < 0.001 was considered statistically significant.

Study procedure:

The formal permission from Hospital Medical director and Head of the Department of General medicine is going to obtain prior to initiation of the study. Personal meetings with the Head of the Department of General medicine, with a request to allow for Patient Counselling. After obtaining informed consent from the patient baseline parameters (age, gender, social status, economic status, and diagnosis and drug usage) were obtained by using a suitable data collection form. A total of 80 subjects who are having diabetes are enrolled in our study. The sample was divided into test (44) and control (36). All the baseline parameters are equally distributed in both test and control with a *p* value more than 0.05. The study was divided into baseline, 1st visit, and 2nd visit with a difference of two months for each visit. At base line after getting demography data, KAP scores and Quality of life score and blood glucose levels were obtained by KAP questionnaire for specialized formulations. After obtaining of baseline KAP, Quality of life scores and blood glucose levels, patient counselling was conducted in test group by oral and PIL. After counselling the scores were obtained in both test and control groups on 1st, 2nd visit with counselling of test group in their respective visits.

RESULTS

The present study involved 80 (100 %) as the sample, who participated and responded. Demographic details of the participants involved in the study was categorized based on gender and age distribution, the results of which were thoroughly analyzed and reported in Table 1.

Table 1: Demographic Details

S. No.	Age (Years)	Males	Females	No of Patients	% Patients
01	40-50	16	14	30	37.5
02	51-60	13	12	25	31.25
03	61-70	6	4	10	12.5
04	71-80	4	3	7	8.75
05	>80	3	5	8	10
Total		45 (56.25 %)	35 (43.75 %)	80	100

Figure 1 shows that the distribution of diabetic cases according to the sex. Out of 80 cases 45 cases were male (56.25%) and 35 cases were female (43.75%). In all age groups of Diabetic cases was more in males compared to females.

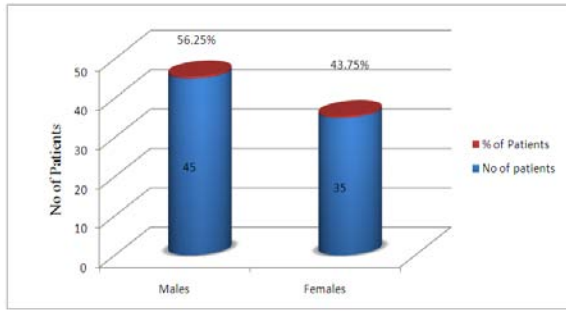


Fig. 1: Diabetic Cases Distribution Gender Basis

Patients were categorized based on socio-economic status, results of which were thoroughly analyzed and reported in Table 2

Table 2: Socio-economic status of patients

S. No.	Socio-economic Status	No of Patients	% Patients
01	Low	42	52.5
02	Middle	30	37.5
03	High	08	10

The details of medications distribution in study population is systematically analyzed and reported in Table 3.

Table 3: Distribution of medications in patients

S. No.	Distribution of drugs in patients	No of Patients	% of Patients
01	Metformin	18	22.5
02	Sulfonylureas + Metformin	38	47.5
03	Insulin + Sulfonyl/Metformin	22	27.5
04	Thiazolidinediones	02	2.5
05	Not on any drugs	-	-

Table 4: Duration of disease in patients

S. No.	Years	No. of Patients	% Patients
01	< 1	21	26.25
02	1 – 5	35	43.75
03	5 – 10	17	21.25
04	> 10	07	8.75

Figure 2 Shows the educational status of the patients enrolled in the study.

Major co-morbidities of the study population along with Type 2 diabetes mellitus were clearly assessed and the results are reported in Table 5.

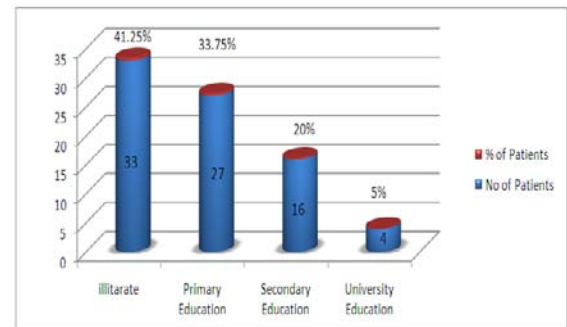


Fig. 2: Educational status of the patients

The disease duration of the patients, out of 80 cases 26.25% cases were having disease duration of < 1year, 43.75% cases were having disease duration of 1-5 years, 17 21.25% cases were having disease duration of 5-10 years and 8.75% patients were having disease duration of greater than 10 years, results are reported in Table 4.

Table 5: Co-morbidities of the patients

S. No.	Major co-morbidity	Males	Females	Total	% of Patients
01	T2DM	22	16	38	47.5
02	T2DM + HTN	11	09	20	25
03	T2DM + HTN + Hypothyroidism	01	02	03	3.75
04	T2DM + Asthma	05	02	07	8.75
05	T2DM + UTI	00	04	04	5
06	T2DM + Nephropathy	01	-	01	1.25
07	T2DM + Hypokalaemia	01	-	01	1.25

Patients were also categorized based on their social history (alcohol & smoking habits), results are reported in Table 6

Table 6: Patients social history

S. No.	Social history	No of patients	% of Patients
01	Smoking	18	22.5
02	Alcohol	04	5
03	Smoking+ Alcohol	27	33.75
04	Tobacco	06	7.5
05	None	25	31.25

Table 7 shows the KAP values of both test and control group of baseline and final follow up visit on diabetes mellitus patients. At the final follow up visit there is a significant improvement in the KAP scores with a *P-value of 0.001.

*P value < 0.05 is significant and *P<0.001 is highly significant (Paired t test)

BL = Base Line, FF= Final Follow up

Comparison of responses to QOL questionnaire was given on Table 8 and the mean scores of the entire different group for various

dimensions were mentioned. Physical endurances were 10.40±22.67 before counseling and Social work was 22.18±31.75 in after counseling. The highest mean score in the domain Diet Tolerance 63.12±1.47 before counseling and after counseling 79.53±14.84.

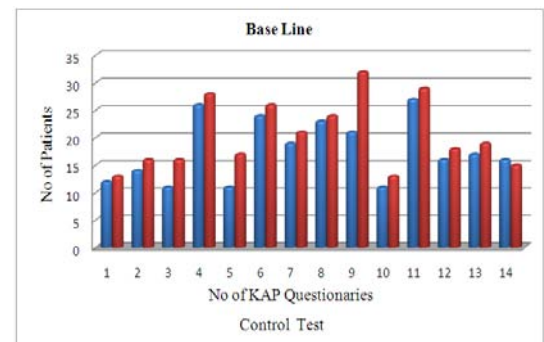


Fig. 3: Comparison of responses between Control and Test on KAP on Baseline

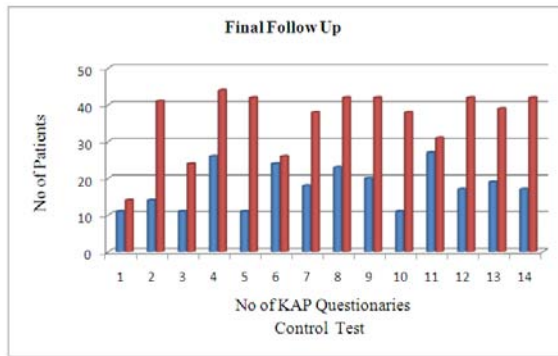


Fig. 4: Comparison of responses between Control and Test on KAP on Follow up

Figure 5 and Figure 6 reports the responses of counseling outcome in patients under control and test based on fasting blood glucose levels (FBG) and Post Prandial Blood Glucose levels (PPBS).

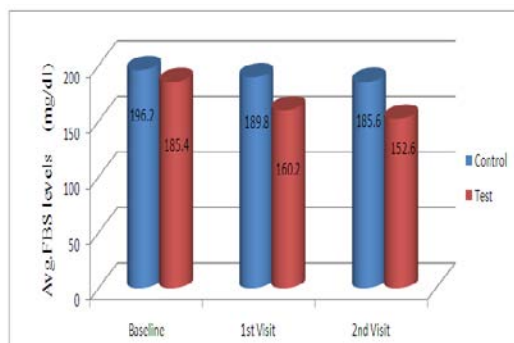


Fig. 5: Response on counseling outcome in patients on FBG levels

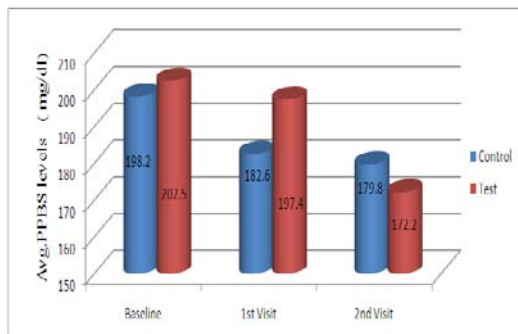


Fig. 6: Response on counseling outcome in patients on PPBS levels

DISCUSSION

In the current study, the demographic details of patients enrolled into the study shows that the majority are females and are housewives and are dependent on their family members or relatives for refilling the prescriptions and information. According to this study the diabetic prevalence was found to be high in patients of above 40 (37.5%) year's age group in our study. In all age groups of Diabetic cases were more in males compared to females. Age group of 50 to 60 years with average disease duration of 1-5 years.

Therapeutic management of patients enrolled in the study reveal that the patients were either on monotherapy (either Sulfonylureas or Metformin) or on dual therapy (combination of Sulfonylureas or Metformin). Patients who were only on diet and lifestyle modification for managing their diabetes showed greater improvement in blood glucose control and improved quality of life with education. The prevalence of Diabetic cases was found to more in the age of 40 years. According to this study the diabetic

prevalence was found to be high in patients of above 40 (37.5%) year's age group. Out of 80 cases 45 cases were male (56.25%) and 35 cases were female (43.75%). In all age groups of Diabetic cases was more in males compared to females.

The socio economic status of the patients was found to be in 42 cases were lower socio economic, 30 cases were middle socio economic and 08 cases were high socio economic. Results are based upon the patient annual income as low socio economic is >50,000, middle range is up to 1, 00,000 and high means that above 1, 00,000 rupees. The educational status of the patients enrolled in the study. Out of 80 cases 33(41.25%) cases are with Illiterates (no formal education) followed by 27(33.75%) cases with primary education followed by 16(20%) patients with secondary education followed by 4(5%) Cases with university level education.

Social history shows that 18 (22.5%) cases were having smoking, 27 (33.75%) cases were having smoking with alcohol consumption, 25 (31.25%) cases were not having any social history and 06 (7.5%) patients were having tobacco chewing habits

Disease distribution in study subjects found to be 38 (47.5%) cases were having Type-2 DM and 20 (25%) cases having Type-2 DM with Asthma and remaining percentages are type 2 diabetes with urinary tract infection, nephropathy, and hypokalemia respectively.

The distribution of drugs in diabetic patients are as follows 18 (22.5%) cases are on metformin and 38 (47.5%) cases are on combination of sulfonylurea's and metformin and 22 (27.5%) cases are on insulin and sulfonylurea's / metformin and 02 (2.5%) cases on thiazolidinediones.

In this study, based on KAP questionnaire evaluation there was improvement in knowledge of the patients regarding basic concepts of the disease like accurate method for monitoring glucose control and the necessity of checking blood sugar at least once in a month, effect on different organs by untreated diabetes, importance of foot care in diabetes patients, management of hypoglycemic episodes etc after providing patient education.

KAP values of both test and control group of baseline and final follow up visit on diabetes mellitus patients. At the final follow up visit there is a significant improvement in the KAP scores with a *P-value of 0.001.

The F & P diabetic specific questionnaire was used to assess the QoL of the enrolled diabetic patients. All domains of the QoL instrument were affected in diabetes patients included in the study groups. Significant improvement ($p < 0.05$) in the overall QOL was observed in the test group compared to the baseline.

The overall QOL of both test and control groups were similar (*P value > 0.05) at the baseline. However a non significant improvement in the overall QOL was observed in the first follow up and a significant improvement in the overall QOL was observed in the first and final follow up. In the 1st and 2nd follow up there was significant improvement in the QOL (*P value < 0.05) when compared with the baseline. This was due to the fact that patient education influenced in proper glycemic control, which has reduced the diabetic symptoms that improved the patient's enjoyment in day-to-day activities. The fasting blood glucose of the patients was non-significant (*P value > 0.05) at the baseline. At the end of the visits the test group showed significant (*P > 0.05) reduction in FBS from baseline to the final follow up. This significant change is due to the influence of patient education and counseling aids that helped the patients to understand more about the long term complications of poorly managed diabetes that in turn improved their compliance, diet maintenance and life style modifications. The fasting blood glucose levels of the patients. Initially at the baseline visit the control group average FBG levels of the patients was found to be 196.2mg/dl, at the 1st visit average FBG was 189.8 mg/dl, at the 2nd visit the average FBG was found to be 185.6 mg/dl and. Similarly Post Prandial blood glucose (PPBS) level of the patients are 198.2 mg/dl was base line and 1st and 2nd visits are 182.6 & 179.8 mg/dl. In test group also obtained the baseline, 1st and 2nd visit of FBS and PPBS levels are 185.4mg/dl, 160.2mg/dl and 152.6mg/dl and 207.5mg/dl, 197.4mg/dl, 172.2mg/dl respectively. From the above

graph gradual decrease in the FBG&PPBS of patients can be seen from the base line to second visit which shows the improved

condition of the patients and it indicates the effect of counseling on the disease.

Table 7: Knowledge, Attitude and Practice (K A P) Questionnaire Responses

S. No.	K A P Questions	Control		Test	
		B L	F F	B L	F F
01	Diabetes is a condition in which blood sugar levels is higher than the normal	20	21	24	44
02	1. Diabetes is caused due to increased intake of sugar or 2. sugar products	20	22	20	41
03	Knowledge about the symptoms of diseases	25	25	24	44
04	3. Most accurate methods of monitoring glucose control 4. is checking blood sugar	28	29	22	42
05	5. Blood sugar and urine sugar tests tell about your 6. control of diabetes	30	34	30	41
06	Do you accept that a diabetic patient should have regular blood glucose checking at least once in a month?	31	33	32	43
07	7. Do you know that suitable dietary changes; regular 8. exercise and other lifestyle modifications are essential for 9. blood glucose control?	14	16	18	31
08	Regular exercise improves blood circulation and there by helps in utilization of excess amount of glucose by tissues	11	13	11	36
09	Do you know that diabetic patients need not take care of their foot?	14	15	16	32
10	Footwear includes keeping your foot clean and wearing footwear of proper size with more comfort	20	20	18	36
11	Smoking and alcohol drinking can worsen your diabetic conditions	30	31	32	43
12	Do you know that diabetic patients may experience blurred vision, confusion and sweating, increase heart beat due to fall in blood glucose than normal?	10	13	12	38
13	In order to overcome the above situation, the patients should eat a teaspoonful sugar or a sugar candy	13	14	14	26
14	Health education is not important to control diabetes	12	12	16	44
	*P - Value	0.015		0.001	

The Comparisons of responses between Control and Test Groups in baseline and Final follow up of KAP Questionnaires are reported in Figure 3 and Figure 4 respectively.

Table 8: Comparison of Responses to QoL questionnaires before and after counseling

S. No.	Dimension	Average QOL mean		*P-value
		Before counseling	After counseling	
01	General Health	55.93±14.62	50.13±13.63	0.0128
02	Symptoms Bothered	50.73±16.51	32.26±14.56	0.001
03	Financial Worries	62.5±19.28	54.06±16.48	0.0001
04	Treatment Satisfaction	52.81±9.53	57.81±7.724	0.001
05	Emotional Mental Health	55.93±7.94	61.25±12.51	0.0003
06	Physical Endurances	10.40±22.67	50.35±21.56	0.0001
07	Diet Tolerance	63.12±1.47	79.53±14.84	0.001
08	Social Work	30.62±33.51	22.18±31.75	0.0035
09	Overall QoL	51.15±6.74	47.75±9.39	0.0002

CONCLUSION

Diabetes mellitus is a chronic disorder which will limit patient's routine activities in terms of physical, social, psychological status. Pharmacist plays a major role in management of chronic disorders by providing Pharmaceutical care service. The present six month study also demonstrated the positive influence of patient counseling on knowledge, attitude and practices, various domains of quality of life and clinical and physiological parameters of diabetes mellitus. Our study concludes that pharmacist mediated individualised pharmaceutical care services have a positive impact on KAP, HRQOL, Glycemic control, and medication adherence which improves the therapeutic outcome of the patients.

CONFLICT OF INTERESTS

Declared None

ACKNOWLEDGEMENTS

The authors would like to thank Dr. Y.Padmanabha Reddy, Professor and Principal Raghavendra Institute of Pharmaceutical Education and Research (RIPER), Dr. Rama Keshava Reddy, H.O.D, Department of General Medicine, RDT Hospitals Bathalapalli and Dr. Mohanraj Rathinavelu, Assistant Professor, Department of Pharmacy Practice, RIPER for their valuable guidance and constant support.

REFERENCES

1. Marc A, Ronald E, Bruce H, P. Redekop Ken, Health related quality of life and treatment satisfaction in Dutch patients with type 2 diabetes diabetes care. J Diabetes Care. 2002;(25):458-63.
2. O. WH. guidelines Management of Diabetes mellitus-Standards of care and clinical practice guidelines. J Diabetes Care.

3. Dekker JM, van der Kraan M, Nijpels G, de Vegt F, Kostense PJ, Stehouwer CDA, *et al.* [Estimate of the number of new patients with type 2 diabetes mellitus in the Netherlands: at least 65,000 per year in the age group of 50 years and above]. *J Ned Tijdschr Geneesk* 2003;147(29):1419-23.
4. Mohan V, Sandeep S *et al.* Epidemiology of type of diabetes: indian scenario. *Indian J of Medical Res* 2007.
5. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. *J Diabetes Care* 2004;27(5):1047-53.
6. Aekplakorn *et al.* Thai Multicenter Research Group on Diabetes Mellitus. *J Diabetes Care* 1994;2003.
7. King H, Aubert RE, Herman WH. Global burden of diabetes, 1995-2025: prevalence, numerical estimates, and projections. *J Diabetes Care* 1998;21(9):1414-31.
8. Marc A, Ronald P, Guy E, Bruce H. Redekop Ken, Health related quality of life and treatment satisfaction in Dutch patients with type 2 diabetes. *J Diabetes care* 2002;25:458-63.
9. Jonsson B, Type, II. Revealing the cost of diabetes in Europe. *J Diabetologia* 2002;45:S5-12.
10. I. USP medication counseling behaviour guideline. USP DI update volumes I and the United States. *J Pharmacopeia Convention Inc* 17391748.1997:664-75.
11. Kannel WB, Mc Gee DL. Diabetes and cardiovascular disease. The Framingham study. *J of the American Medical Association* 1979;241(19):2035-8.