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Are We Treating the Right People? Are We Treating the People Right? Health Status, Knowledge and Quality of Life amongst Patients with Diabetes at a Specialized Clinic at Kamuzu Central Hospital, Malawi

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Authors' contributions

First and last author contributed equally to the manuscript. Author ATY conducted the fieldwork, compiled, analyzed the data and wrote the manuscript. Author FN planned, developed the study protocol and supervised the study; reviewed the data and wrote parts of the manuscript. Author YM contributed significantly to the study protocol and reviewed and edited the manuscript. Author CB supported the QoL assessment and reviewed/edited the manuscript. Author TB gave the statistical advice for the statistical analysis. Author MZ supervised the research. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Aims: To describe health status, knowledge and quality of life among patients with diabetes mellitus attending a tertiary hospital in the capital of Malawi.

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Study Design: A cross-sectional observational study among randomly selected adult patients with diabetes.
Place and Duration of Study: Diabetes clinic, outpatients department, department of Medicine, Kamuzu Central Hospital, Lilongwe, Malawi between April 2014 and May 2014.
Methodology: We included 271 randomly selected patients (82 men, 189 women; age range 18-86 years) with diabetes mellitus. Socio-demographic characteristics, clinical status, glycosylated hemoglobin (HbA1C), comorbidities and medical history were assessed beside diabetes specific knowledge and subjective quality of life (QoL).
Results: There were 77% classified as having type 2 diabetes vs. 23% type 1 diabetes. In 4% tuberculosis (TB) was suspected and prevalence of human immunodeficiency virus (HIV) was 13.6%. Level of education was high in 52%. Mean HbA1C was 7.1% and 15.9% had an HbA1c <5.5%. HbA1C was significantly higher in type 1 vs. type 2 diabetes (P < .001). Mean body mass index (BMI) was 30.1 kg/m^2. The mean BMI for females 31.4 kg/m2 (SD 5.9) was significantly higher than that for males 26.9 kg/m^2 (SD 4.6), (P = .001). Arterial hypertension was diagnosed in 61% and 52% had a systolic blood pressure >= 140 mmHg and/or diastolic blood pressure >= 90 mmHg. Among all participants, 23% had estimated glomerular filtration rate (eGFR) corresponding to stage 3 and above chronic kidney diseases (CKD). The majority of patients (62%) could not name their diabetes type or causes; 75% of participants expressed a significant fair overall QoL.
Conclusion: The clinic was dominated by well-educated adipose females with relatively adequately controlled HbA1c and patients, who might have no diabetes. Patients with acute metabolic diabetes complications were underrepresented. Subjects showed a fair subjective QoL. Clinic function and focus as a specialized tertiary care center require re-definition.

Keywords: Diabetes care; diabetes complications; quality of life; Sub-Saharan Africa; Malawi.

ABBREVIATIONS

ACEI : Angiotensin Converting Enzyme Inhibitors
BMI : Body Mass Index
COMREC : College of Medicine Research and Ethics Committee
BP : Blood Pressure
DC : Diabetes Clinic
DM : Diabetes Mellitus
DN : Diabetes Nephropathy
DR : Diabetes Retinopathy
ED : Erectile Dysfunction
FBS : Fasting Blood Sugar
GFR : Glomerular Filtration Rate
HbA1C : Glycosylated Haemoglobin
HDL : High Density Lipoprotein
HDU : High Dependency Unit
HIV/AIDS : Human Immunodeficiency Virus infection and Acquired Immune Deficiency Syndrome
KAP : Knowledge, Attitude and Practice
KCH : Kamuzu Central Hospital
LDL : Low Density Lipoprotein
NCDs : Non-Communicable Diseases
OAD : Oral Anti-Diabetic Drugs
OGTT : Oral Glucose Tolerance Test
QoL : Quality of Life
TAG : Triglyceride
WHO : World Health organization

1. INTRODUCTION

Non-communicable diseases are well documented as causing significant mortality and morbidity [1]. Diabetes mellitus (DM) is considered a serious non-communicable disease and a leading factor for developing cardiovascular diseases [2]. The global prevalence of diabetes in 2013 reached approximately 382 million and is expected to increase by 55% by 2035 [2]. Diabetes treatment places a significant burden on a country's economy through indirect costs of reduced productivity as a result of patients' disability, especially in Africa [3].

Poverty-related illnesses, e.g., malaria, tuberculosis and human immunodeficiency virus infection and acquired immune deficiency syndrome have demanded most healthcare attention and funding in sub-Saharan Africa over the last decades; however, chronic diseases like diabetes mellitus now require equally attention in both urban and rural areas [4].

Malawi is one of the poorest countries in the world [5]. Diabetes prevalence in Malawi is increasingly similar to the world's average (5.26% vs. 8.3% respectively) [6,7]. Little is known about the demographic characteristics, health status, disease specific knowledge and subjective quality of life of patients with diabetes in Malawi. Only one study explored diabetes patients in Queen Elisabeth Hospital in Blantyre in 2010 [8]. The health care policies in Malawi emphasise infectious diseases and this is where most of the money on health care is spent. Meanwhile, for non-communicable diseases like diabetes, small affordable changes in the healthcare system and lifestyle of individuals can make a huge difference. In order to change the mindset of policy makers and those affected by diabetes, knowledge is required on who suffers from diabetes, how healthy are they and what is the impact of the disease on their quality of life. Poor quality of life affects the socioeconomic status of individuals and may have a negative impact on the economic development of a nation.

Malawi' s current National non communicable diseases Action Plan calls for the conduction of epidemiological and operational research for CVDs, diabetes and chronic respiratory diseases to address knowledge gap and to develop appropriate action [6].

This study reports and describes demographic characteristics, associated health problems, knowledge profile and QoL profile of patients with diabetes at an outpatient service at Kamuzu Central Hospital (KCH), Lilongwe, Malawi.

2. METHODOLOGY

In a cross-sectional observational design, participants were randomly selected over a period of six consecutive clinic days; patients were eligible if they were adults (>18 years), diagnosed with type 1 or type 2 diabetes, registered and receiving care at the diabetes clinic (DC). Consents were obtained.

During a clinic day on Tuesday, all patients received usually a number upon arrival. Using a random number generator (Microsoft excel), a subset of patients was selected. If after being initially selected, patients declined to participate or did not meet eligibility criteria, they were substituted with subsequent patients. After randomization and consent procedures, another numbered recruitment cards were distributed.

An appointment for a study clinic the following Saturday was made for an interview and clinical examination. Patients received reimbursement for their transportation costs and a snack. All staff involved in the interviews and/or in the clinical examinations followed standardized procedures. Patients' recruitment and data collection was curried out between first of April-sixth of May.

2.1 Study Site

Kamuzu Central Hospital is a regional referral, university teaching hospital in the central region of Malawi. It is serving a population of approximately five million [9]. The medical department offers in- and outpatient medical care. In January 2014 there were a total of 1156 patients. They were registered as attended the DC in the Electronic Medical Record (EMR) system by Baobab Health Company [10]. Since year 2000, DC was held once weekly. Due to increased demand in 2014 it runs twice weekly (Personal observation).

Organized by a nurse and a clerk, DC operates from 8:00 am until 13:00. During waiting time, a retired nurse gives non-standardized short sessions on health education about diabetes symptoms and complications. Sessions cover diabetes and hypertension management, diabetes complications, nutrition charts and preventive measures like foot care. During each clinic day, medical doctors and clinical officers

examine approximately 60-80 patients. The medical review is usually brief and symptoms-oriented. There is no specific protocol for patients' management. Medicines like oral anti-diabetic Drugs (OAD) or insulin are prescribed for up to three months depending on availability in the pharmacy. Diagnosis of type 1 or type 2 diabetes and other types of diabetes like type 3 is based on clinical symptoms and age. Diagnosis is documented in a health passport book. The study was carried out between April and May 2014.

2.2 Questionnaire

Questionnaire included core questions about demographics, health profile, and past medical history and current medication. It is based on Malawi's world health organization (WHO) NCD STEPS Survey Questionnaire [11]. Assessment of knowledge, attitude, and practice based on the National diabetes education program survey of the public's knowledge, attitudes, and practices related to diabetes [12]. Questions also included the preferred sources of diabetes information, knowledge of preventive health measures, number of hypoglycemic events requiring assistance in the last three months, consultation with traditional healers or use of herbal medicine in the last 12 months. Assessment of QoL was based on the WHO-Quality of Life BREF (WHOQOL-BREF) [13] Questionnaire. They are divided into four domains. They are graded as follows: scores on each domain—good (> mean +1 standard deviation [SD]), fair (mean ±1 SD) or poor (< mean -1 SD) [14].

2.3 Anthropometric Measurements

Height was measured to the nearest 0.5 cm with a calibrated scale attached to the wall. A bathroom scale measured weight calibrated in kilograms (kg) from 0-150 kg with the subject in light clothing and without shoes. The scales were assessed prior to each clinic. Waist circumference was measured to the nearest 0.5 cm using a flexible tape in upright position with abducted arms over the umbilicus and the bottom edge of the measuring tape on the top of the hipbone during normal expiration. Thresholds for central obesity by waist circumference were >94 cm for males or >80 cm for females [15].

2.4 Clinical Examinations

Blood pressure (BP) was measured using two manual sphygmomanometers. Measurements were performed between 08:00 and 10:00 to avoid daytime variations after a 15-minute rest in a seated position and right arm at heart level. Two measurements were performed with a 5-minute interval. If the difference between the measurements exceeded 5 millimeter of mercury (mmHg), a third measurement was performed; the average value of the two higher readings was calculated. BP readings were classified using the strata developed for hypertension by the American Heart Association. Patients with high BP records were referred to the emergency room and then to the hypertension clinic. Peripheral neuropathy (PNP) and vibration sensation were assessed using a 10" tuning fork C 64/C 128 Hz. Diabetes foot syndrome was assessed by clinical inspection. Diabetes retinopathy (DR) was assessed by two trained ophthalmology clinical officers. They used a direct ophthalmoscope examination after pupil dilatation.

2.5 Laboratory Tests

Fasting blood sugar (FBS) was tested using a glucometer (Standard Diagnostics CHECK GOLD© glucometer from Standard Diagnostics Inc.) for a capillary blood sample. HbA1C level, Serum creatinine and lipid profile were determined in the hospital's laboratory by qualified lab-technicians using ERBA XL 200© machine (ERBA diagnostic Mannheim, Germany). We defined the presence of hypercholesterolemia if the total cholesterol (TC) > 200 mg/dl, high low density lipoprotein (LDL) if > 100 mg/dl, hypertriglyceridemia if triglyceride (TAG) > 150 mg/dl and high density lipoprotein (HDL) was low if the value < 40 mg/dl. Proteinuria and glycosuria were tested using urine dipsticks. All tests were performed according to the manufacturer's instructions.

2.6 Data Management and Statistical Analysis

Data were entered into an excel spreadsheet. Descriptive statistics were analyzed using Statistical Package for the Social Sciences (SPSS 21). Means, medians, and proportions were calculated and SD and correlation (Pearson's) were used to interpret the results. Associations were considered significant at $P \leq .05$. A linear regression model was tested to explore predictors of overall QoL; logistic regression was analyzed to explore patients' QoL associated with several variables.

3. RESULTS AND DISCUSSION

3.1 Results

A total of 534 individuals were screened for eligibility, 14% were excluded because of being minors and have declined consent. Seven percent dropped out by not attending the study clinic the following Saturdays resulting in an overall number of 271 (70% female) participants (Fig. 1).

3.1.1 Demographic data

Basic demographic findings are presented in Table 1. Twenty –eight percent were employees while 31% had no jobs and 11% were unable to work. 3% were housekeepers. Unemployed subjects above retirement age (55 years) accounted for 22%, among them there were 11% officially retired subjects. Students were 2%.

3.1.2Prescription and supply of diabetes medication

In total, 98% attended the clinic primarily for medication refill. Only 2% were referral cases. There was no diabetes emergencies cases reported. In all, 73% were receiving OAD, insulin was prescribed to 23%, 2% were on combination therapy (OAD and insulin) and 3% controlled their diabetes through diet. Four patients (8%) classified as type 1 diabetes in their health passport but received OAD. Half of the subjects (50%) received all their diabetes medication as prescribed at the hospital pharmacy, whereas 48% patients received only some and 2% patients did not receive any. Half of the patients (51%) were able to buy prescribed medications from a private pharmacy/shop vs. 45% were not and 2% were able to buy some.

3.1.3 Presence of arterial hypertension and cardiovascular comorbidities

Arterial hypertension was the most frequent diagnosed comorbidity in 61%, 54% of them received angiotensin-converting enzyme inhibitors and 10% received Beta-Blockers. The second common comorbidity was cerebral stroke in 4% then angina pectoris in 3% and myocardial infarct in 1.4%. There were 65% of males who complained of erectile dysfunction.

3.1.4 Presence of chronic infectious diseases

Based on clinical symptoms, TB was suspected in 4%. HIV prevalence was 13.6% and 92% of them received antiretroviral therapy.

3.1.5 Parameters of glycemic control

The mean HbA1C level for all participants was 7.1%, (max/min = 12.6/3.1) see Table 2. Significant differences in HbA1C levels were found between patients classified as type 1 and those with type 2 DM (mean HbA1C 7.8% vs. 6.9%, $P < .001$) and between patients treated with insulin compared to those treated with OAD (7.8% vs7.1%, $P = .01$) see Table 3.

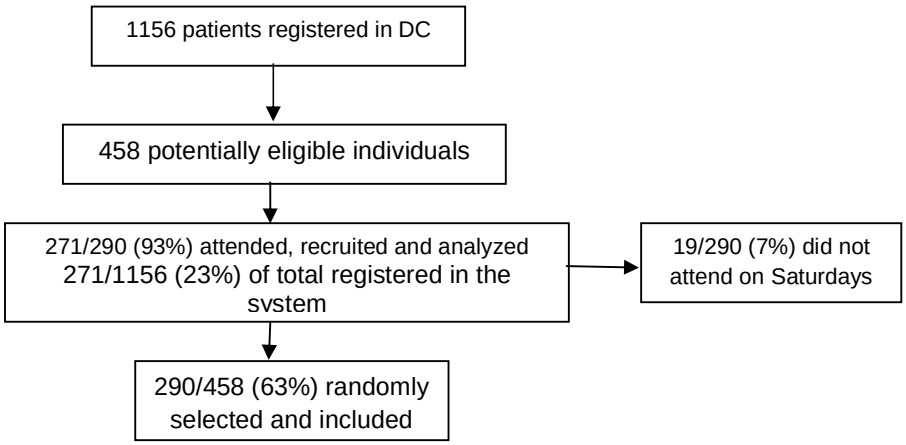

Fig. 1. Patient recruitment process

Table 1. Characteristics of study participants by type of diagnosed diabetes

n	n (%)	Type 1 DM (%)	Type 2 DM (%)	*P* value
	271	62	209	
Mean Age in years and (SD)	53.4 (12.5)	48 (15.4)	55 (11.1)	
Gender; female (%)	189; (70)	35; (56.45)	132; (73.6)	
Education				
Had not attended school	24 (9)			
Standard 1-5 years	44 (16)			
Standard 6-8 years	63 (23)			
Secondary and above	140 (52)			
Duration of DM (%)				
<1 year	50 (18.45)	4 (6.4)	46 (6.45)	
1-3 years	45 (16.61)	8 (12.9)	37 (12.9)	
3-6 years	54 (19.93)	12 (12.35)	42 (19.35)	
6-9 years	45 (16.61)	12 (19.35)	33 (19.35)	
More than 10 years	51 (18.82)	15 (24.19)	36 (24.19)	
More than 20 years	26 (10.6)	11 (17.74)	15 (18.18)	
Diabetes medication				
Oral medication	197 (73)	4 (8)	193 (92)	
Insulin	61 (23)	56 (89)	8 (2)	
Both	4 (2)	1	1	
Non/ on diet	9 (3)	1	8 (4)	
Mean BMI kg/m^2	30.1	28.5	30.5	
F (%)/m (%) = 31.4 (5.9%) / 26.9 (4.6%)				
PNP (m/f)	66 (25/41)	14	52	
Diabetes foot (m/f)	5 (3/2)	2	3	
DR	51 (20)	11 (18)	40 (19)	
Laboratory Tests:				
Mean HbA1C % (SD)	7.1 ± 1.7	7.8 ± 1.7	6.9 ±1.6	< .001
FBS (SD)	166 ± 83.8	185 ±97.5	160 ±78.6	= .05
Glycosuria (%)	80 (29.5)	27 (43.5)	53 (25.3)	= .03
Creatinine mg/dl (SD)	1.01 ±0.32	0.99 ±0.23	1.02 ±0,34	= .51
Proteinuria (%)	152 (56.4)	38 (61.2)	115 (55)	= .33
Diabetes-specific knowledge, attitude and practice				
Know name of diagnosed diabetes (%	102 (37.6)	32 (51.6)	70 (33.4)	<0.001

Table 2. Interpretations of various ranges of tested HbA1c levels

HbA1C level	n.	Mean FBS	%	Interpretation
< 6.5%	91	120 mg/dl	33.5 %	< 6.5% (possibility of frequent hypoglycaemia or misdiagnosis/non-diabetics or impaired glucose tolerance test)
> 6.5%	180	190 mg/dl	66.4 %	> 6.5% (confirmation of diagnosis)
< 5.5%	43	121 mg/dl	15.9 %	Low
5.5– 7.5%	117	147 mg/dl	43.2 %	Good
7.5– 10%	97	205 mg/dl	35.8 %	Poorly controlled
≥ 10%	14	196 mg/dl	5.1 %	Very poorly controlled

Table 3: HbA1C distribution by diabetes therapy

Diabetes medication	n.	Mean HbA1C	SD	Minimum	Q1	Q3	Median	Maximum
OAD	198	7.1	1.68	3.1	5.9	8.1	7	12.6
Insulin	60	7.8	1.64	4.10	6.6	8.9	7.85	1.19
OAD and Insulin	4	6.7	1.09	5.60	5.8	7.6	6.7	7.9
Diet only	9	5.4	1.14	3.3	5	5.9	5.2	7.5

A total of 90/271 (33%) participants presented with an FBS higher than 180 mg/dl. The majority of them were female (64%), but FBS did not differ significantly different between gender (*P* = .11) or types of DM (*P* = .05). In this group of subjects, mean age was 51 years (SD 14.79) and mean HbA1C was 8.07% (SD 1.64). Of this group, 24% had PNP and 22% had retinopathy. There was a positive moderate correlation between HbA1C and FBS (*P* < .001), while there was no association between HbA1C and BMI (*P* = .09). Glycosuria was significantly more frequently found in females (*P* = .01), patients with type 2 diabetes (*P* = .03) and those with HbA1C >7.5% (*P* < .001).

3.1.6 Dyslipidemia

The most frequently prescribed medication were anti-dyslipidemia drugs (mostly statins) in 56%. Females had significantly higher LDL levels than males (*P* = .02). Patients with type 2 diabetes had a significantly higher LDL and TGL levels than those with type 1 (*P* = .04 and *P* = .02 respectively).

3.1.7 Presence diabetes complications

Diabetes Retinopathy of any degree was diagnosed in 20% (n=51,) of the total group out of which 75% (n= 38) were classified to require immediate laser therapy. PNP was clinically diagnosed in, 24%. There was no association found between duration of diabetes, HbA1C, FBS and presence of neuropathy. More than half of the participants 152/271 (56.4%) had proteinuria. Patients with a previously diagnosed arterial hypertension had a significant higher creatinine level (*P* < .001) than those who had not. More than a quarter of all patients showed eGFR levels during this single test equivalent to CKD stages 3 to 5 (Table 4).

3.1.8 Diabetes-specific knowledge, attitude, practice and subjective QoL

Patients knowing their type of diabetes have a higher level of education, i.e., 78% reached secondary or above education level, and significantly could type 1 diabetes respondents name their disease correctly compared to those with type 2 DM (52% vs. 33%), *P* = .001. Logistic regression test showed that only level of education had a significant influence on the knowledge of type of diabetes (*P* = .004).

A percentage of 41% did not know what causes either type 1 or type 2 DM, 27% mentioned a high sugar diet as the main cause, while only 4% believed that obesity was a major cause of diabetes, while 8% mentioned heredity. Polyuria was the most commonly mentioned symptom of diabetes by 68%. A percentage of 30% saw PNP as the most common complication. Blindness, diabetes retinopathy and lower limb amputation were mentioned by only 13%, 7% mentioned cardiovascular diseases. Out of the total, 62% believed that losing weight is the best way to avoid/reduce diabetes complications, while only 7% mentioned increased physical activity to do so.

The HbA1C test was known by only 4% as a test for glycemic control. Out of the total, 60% preferred medical doctors to be their main source of diabetes education/health information. Around 20% reported to have visited traditional healers and/or taken herbal medicine to manage their diabetes at the time of their interview. Overall, participants expressed a fair QoL (Fig. 2). A correlation coefficient test showed that the risk of having a low subjective overall QoL was higher in patients with diagnosed arterial hypertension, *P* = .06.

3.2 Discussion

This is the first study in Malawi that assesses the health status of diabetic patients registered in a diabetes clinic together with diabetes specific knowledge, attitude and practice and a disease subjective QoL. The assessment of the health status in the study considerably exceeded the level of the routinely performed physical examination at the clinic. The study highlights achievements and challenges for the future development of diabetes care at a central hospital level in Malawi. Main findings are the predominance of well-educated, obese females diagnosed with diabetes, the high percentage of diagnosed and uncontrolled arterial hypertension, the high percentage of diabetes nephropathy and retinopathy and underrepresentation of patients with acute severe diabetes emergencies like ketoacidosis in diabetes type 1. The composition of the patients may represent a specific risk profile for the “urban, well- educated and economically better off” part of society in Lilongwe. However it stands in contrast to findings of the STEPS survey [11], which for instance shows a higher percentage of males affected by diabetes compared to females. Access for other people in need may be limited with regards to distance. The current clinical classification of diabetes type 1 and type 2 led to some apparent misclassification or uncorrected documentation results. For example, among six

patients classified as type 1, the study showed that they were taking OAD. These findings require review of the already registered patients and implementation of a standardized clinical and laboratory tests, which could be supported by the already available though not fully functioning EMR system.

The relatively adequate controlled mean HbA1C level might be influenced by attending a large proportion of patients who might have impaired glucose tolerance but no diabetes. This is illustrated by the fact that one third of the recruited registered patients had HbA1C levels below 6.5%.

3.2.1 Comorbidities

Arterial hypertension was the most frequent comorbidity and higher than that found in the Blantyre study in 2010 [8].

3.2.2 Non-Diabetes medication

Statins represents the highest prescription rate found among patients with type 2 diabetes compared to other six sub-Saharan African countries (11.7%) in 2012 [16]. Females had significantly higher LDL levels than males. This might be because that obesity is common among females and is almost always associated with a higher LDL and triglycerides as part of the metabolic syndrome [15].

3.2.3 Chronic infectious disease

Prevalence of suspected patients with TB was higher (4%) than 2012 WHO-reported cases (22/1000 [2%]) in the general population of Malawi [17] an observation that might support the higher risk of TB among patients with Diabetes [18]. So far TB screening had not been part of the routine evaluation of diabetes patients in DC.

HIV/AIDS prevalence was similar to the finding of a previous study in Malawi in 2010 [8] (13.6% vs. 14%). It is remarkable that 92 % of patients were on ART compared to just 16% in the previous study reflecting the successful scale up effort in Malawi [8].

Table 4. Distribution of positive proteinuria tests for the corresponding CKD stages according to eGFR test

CKD	Number of patients	Presence of proteinuria**	%
Stage 1	56	30	54%
Stage 2	152	88	58%
Stage 3	56	32	57%
Stage 4	5	3	60%
Renal failure	2	0	0%

*** Proteinuria percentage represents the percentage of patients in each stage group*

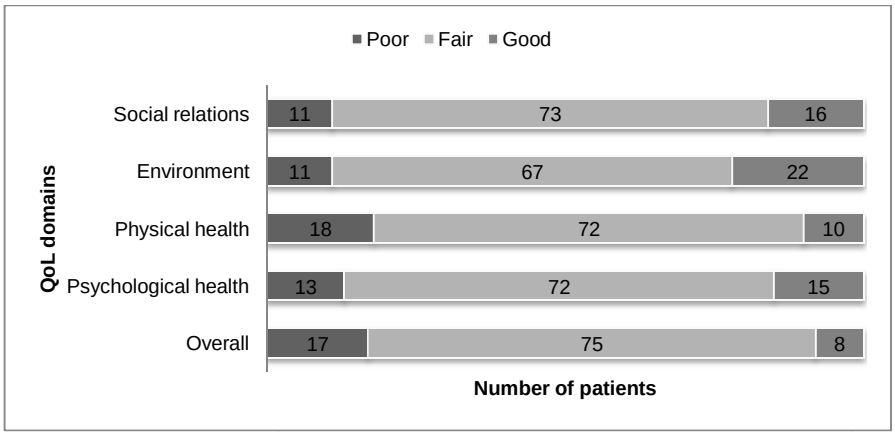

Fig. 2. Grades distribution of overall and four domains by total study population

3.2.4 Reason for attendance

Patients primarily used the facility to refill their anti-diabetes drugs – a reason stated by 98%. Apparently, the setting played a limited role for medical consultation and physical examinations, health education or as a referral center. Medication refill, BP and blood glucose measurements could be decentralized to facilities with lower levels of care.

3.2.5 Glycemic control

The median FBS was lower than that found in the 2010 study in Blantyre (166 mg/dl vs. 182.7 mg/dl) [8]. This might be due to the introduction of metformin as a first-line drug of choice for the treatment of type 2 DM after the study of Blantyre was conducted [8].

Likewise the HbA1C level of 7.1% might refer to an improvement of the glycemic control compared to the 2010 study in Blantyre where the HbA1c was 9.4% [8]. Compared to those in a previous study in 2012 in six sub-Saharan African countries there was 43.6% with an HbA1c > 8.5%, while in this study it was 27.1% [16]. To further scrutinize the level of glycemic control we determined mean HbA1C levels after excluding patients with levels less than 5.5% who most likely do not have diabetes. The mean HbA1C for the remaining total group was 7.65%, and 8.14% and 7.48% for type 1 and type 2 respectively.

Patients with type 1 diabetes were significantly less well controlled compared to those with type 2 DM (average HbA1C: 7.9% vs. 6.9%). The reason might be shortage of insulin supply resulting in an irregular or reduced dosing. The lack of self-monitoring by glucometer or blood glucose tests and hence lack of dose adjustment could play a role. Lastly storage conditions required for optimal insulin effect might be not optimal.

While the vast majority (92%) of patients with type 2 DM taking OAD showed good glycemic control (mean HbA1C 7.1%), dyslipidemia was less controlled. This is shown by the recorded higher prevalence of hypercholesterolemia, hypertriglyceridemia, high LDL and low HDL in comparison to those with type 1 DM.

3.2.6 Complications

The stages of diabetes retinopathy were advanced and they were not associated with gender, age, type of diabetes, longer duration of diabetes, presence of arterial hypertension or adequacy of diabetes control (FBS, HbA1C), in contrast to Cohen's et al. study in 2010 [8]. Surprisingly, PNP prevalence was half the rate that had been found in a previous study in sub-Saharan African countries in 2012 (24% vs. 48.41%) [16].

Although we did not -by single measurement - confirm a diagnosis of Chronic Kidney Disease (CKD), it remains a finding of major concern that 23% of the patients had eGFR corresponding with CKD stage 3 and higher and that proteinuria was detected in more than half of the patients (56.4%). This finding requires more follow up and closer monitoring of renal function to prevent end stage renal disease.

3.2.7 Knowledge, attitude, practice and subjective QoL

The very limited knowledge about HbA1C testing was expected due to unavailability of HbA1C test in the facility. It was an encouraging information that more than half of the participants (62%) believed that weight loss is helpful in diabetes management. It is noteworthy that a considerable fraction of the subjects had recently tried traditional medicine compared to those who had done so in the last 12 months (20% vs. 4%). This needs to be considered since there might be drug interaction with herbal medicines.

Surprisingly the assessment of QoL revealed that three quarters of patients with diabetes had a fair overall subjective QoL. While in another study in Kilimanjaro in 2002 found that half of diabetes patients perceived their disease as big psychological problem [19]. On the other hand, this study further supported the results found by older study in 2006 in Nigeria [20] that patients living with DM have a relatively good QoL.

3.2.8 Limitations

We recognize the limitations of our study. First, since this study took place in the largest tertiary hospital in the capital of Malawi, the profile of the capital's population shaped the profile of the recruited sample. Many patients with complicated diabetes in faraway villages may find it difficult to reach the services offered in the facility.

Second, due to the cross sectional design, sample size was based on feasibility with the aim to recruit a sample of at least 10% of the total

number of registered patients, which was reached. Yet we cannot entirely exclude a selection bias and the results cannot be generalized beyond this clinic setting, which, however, plays a very important role for diabetes care in Malawi.

4. CONCLUSION

We conclude from our findings that the clinic serves in particular a very specific group of patients with diabetes and metabolic syndrome. It seems that patients with more acute unstable metabolic emergencies of diabetes are not adequately represented in the clinic. This group does not reflect the pattern of the epidemiological findings concerning diabetes from the STEPS survey [11], which shows for example a majority of males. Since KCH is a central hospital, which is supposed to play a major role in diabetes care for Malawi, however this pattern should be reflected. Future efforts of the clinic should aim for better access and referrals for patients who need a special diabetes care including those coming from rural areas.

Due to large number of patients, a focused clinical care seems not to be feasible. It is advisable to re-consider the function of the clinic at a tertiary care level. For example, prescription of OAD could be managed at a lower level. Admission and discharge to the clinic should be re-defined as well as the function and content of follow up visits. These could focus on investigations that are usually not available at lower levels of health care such as HbA1C test, renal function test or the diagnosis of retinopathy. A structured referral system for diabetic patients from the lower levels of health care for extended investigations e.g. annual fundoscopy; renal function testing could be introduced.

Furthermore, a structured patients' education should be introduced and could be more individualized for patients requiring insulin and those on OAD. Young type 1 diabetes patients could be managed together in the pediatric department for a specific training for self-management.

CONSENT

All authors declare that written informed consent was obtained from the patients (or other approved parties) for publication of this case report and accompanying images.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

Protocols received institutional review board approval from the ethics committee at Heidelberg University, Germany and the College of Medicine Research and Ethics Committee (COMREC), University of Malawi (Appendix 1 and 2 respectively). The study was supported technically and financially from ESTHER-MAGNET Project.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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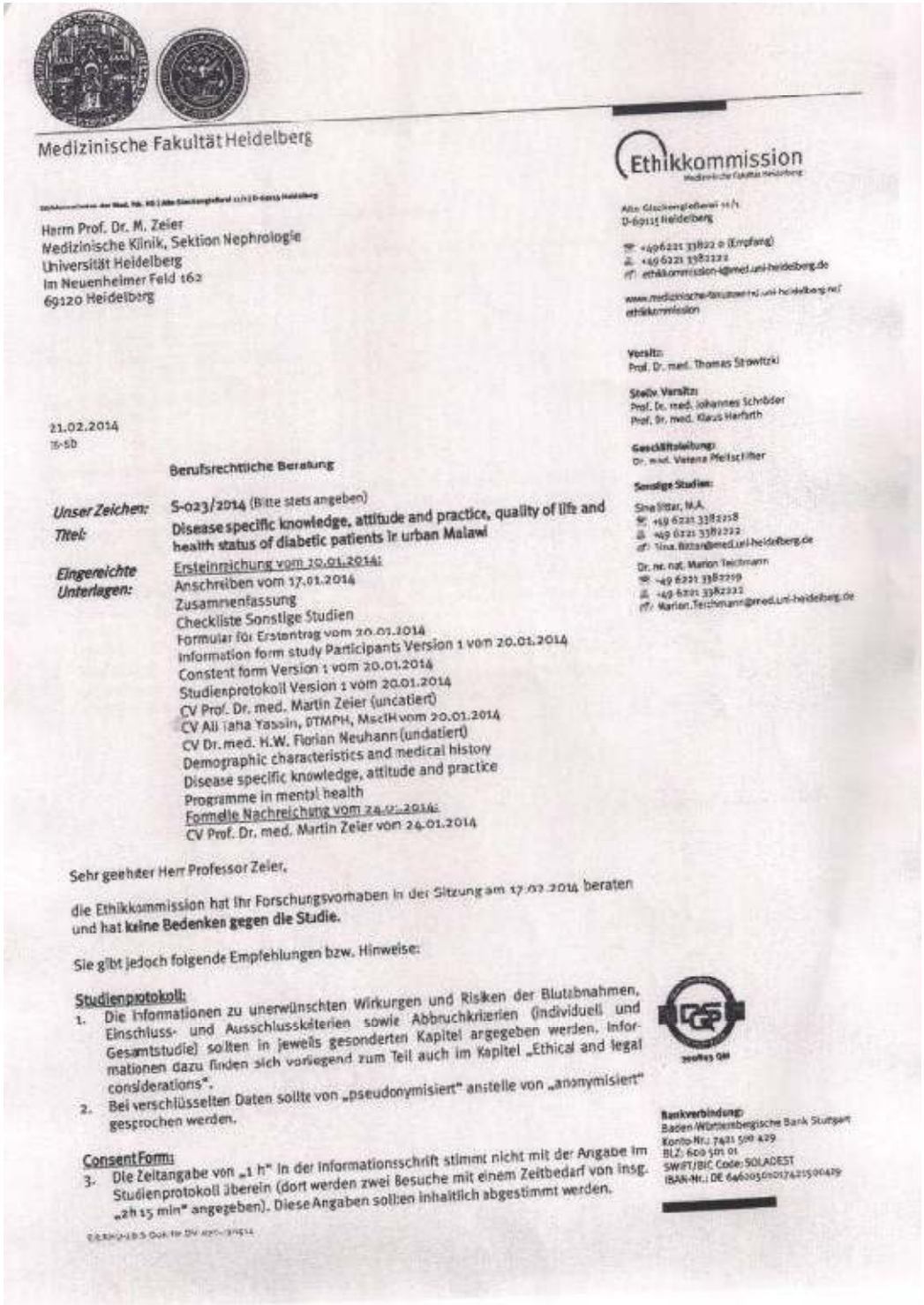
APPENDIX 1



Medizinische Fakultät Heidelberg

Ethikkommission

Herrn Prof. Dr. M. Zeier
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21.02.2014
ts-sb

Berufsrechtliche Beratung

Unser Zeichen: S-023/2014 (Bitte stets angeben)
Titel: **Disease specific knowledge, attitude and practice, quality of life and health status of diabetic patients in urban Malawi**

Eingereichte Unterlagen:
Ersteinreichung vom 20.01.2014:
Anschreiben vom 17.01.2014
Zusammenfassung
Checkliste Sonstige Studien
Formular für Erstantrag vom 20.01.2014
Information form study Participants Version 1 vom 20.01.2014
Content form Version 1 vom 20.01.2014
Studienprotokoll Version 1 vom 20.01.2014
CV Prof. Dr. med. Martin Zeier (uncatiert)
CV Ali Jana Yassin, DTMPH, MscIH vom 20.01.2014
CV Dr.med. H.W. Florian Neuhann (undatiert)
Demographic characteristics and medical history
Disease specific knowledge, attitude and practice
Programme in mental health
Formelle Nachreichung vom 24.01.2014:
CV Prof. Dr. med. Martin Zeier von 24.01.2014

Sehr geehrter Herr Professor Zeier,

die Ethikkommission hat Ihr Forschungsvorhaben in der Sitzung am 17.02.2014 beraten und hat **keine Bedenken gegen die Studie.**

Sie gibt jedoch folgende Empfehlungen bzw. Hinweise:

Studienprotokoll:
1. Die Informationen zu unerwünschten Wirkungen und Risiken der Blutabnahmen, Einschluss- und Ausschlusskriterien sowie Abbruchkriterien (individuell und Gesamtstudie) sollten in jeweils gesonderten Kapitel angegeben werden. Informationen dazu finden sich vorliegend zum Teil auch im Kapitel „Ethical and legal considerations".
2. Bei verschlüsselten Daten sollte von „pseudonymisiert" anstelle von „anonymisiert" gesprochen werden.

Consent Form:
3. Die Zeitangabe von „1 h" in der Informationsschrift stimmt nicht mit der Angabe im Studienprotokoll überein (dort werden zwei Besuche mit einem Zeitbedarf von insg. „2h 15 min" angegeben). Diese Angaben sollten inhaltlich abgestimmt werden.

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Wir wünschen Ihnen bei der Durchführung der Studie viel Erfolg.

Bitte leiten Sie das Ergebnis der berufsrechtlichen Beratung und die studienrelevante Korrespondenz allen teilnehmenden Ärzten in unserem Zuständigkeitsbereich weiter.

Mit freundlichen Grüßen

Prof. Dr. med. Thomas Strowitzki
Vorsitzender

Allgemeine Hinweise:

- Änderungen in Organisation und Ablauf der Studie sind der Kommission, zusammen mit einer Bewertung der Nutzer-Risiko-Relation, umgehend mitzuteilen. Sowohl die **Antragsnummer** als auch die **geänderten Passagen** sollten in den betreffenden Unterlagen **deutlich gekennzeichnet** sein, da anderenfalls keine zügige Bearbeitung möglich ist.
- Die Ethikkommission der Medizinischen Fakultät Heidelberg arbeitet gemäß den nationalen gesetzlichen Bestimmungen und den ICH-GCP-Richtlinien. Ihren Beratungen liegt die Deklaration des Weltärztebundes von Helsinki in der jeweils aktuellen Fassung zugrunde.
- Unabhängig von Beratungsergebnis macht die Ethikkommission Sie darauf aufmerksam, dass die ethische und rechtliche Verantwortung für die Durchführung einer Studie beim Leiter der Studie und bei allen teilnehmenden Ärzten liegt.

S-033/2014

APPENDIX 2

UNIVERSITY OF MALAWI

CERTIFICATE OF ETHICS APPROVAL

This is to certify that the College of Medicine Research and Ethics Committee (COMREC) has reviewed and approved a study entitled:

P.02/13/1530 – Disease specific knowledge, attitude and practice, quality of life health status of diabetic patients in urban Malawi by Dr. A. Taha Yassin

On 16 May 2014

As you proceed with the implementation of your study, we would like you to adhere to international ethical guidelines, national guidelines and all requirements by COMREC as indicated on the next page

Dr. V. Mwapasa- Chairperson (COMREC) Date

Peer-review history:
The peer review history for this paper can be accessed here:
http://sciencedomain.org/review-history/14268