# DIETARY KNOWLEDGE, ATTITUDE AND PRACTICES OF DIABETIC PATIENTS AT NSAMBYA HOSPITAL KAMPALA; UGANDA.

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# SUBMITTED TO THE UNIVERSITY OF STELLENBOSCH

In partial fulfillment of requirements for the degree in:

Masters of Medicine in Family Medicine ( MMed Fam-Med).

HREC Number: S12/08/223.

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# Declaration

I, the undersigned, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree. I also declare that ethical approval for the study was obtained from the Health Research Ethics Committee of Stellenbosch University (Reference number: \$12/08/223).

Signature: Date: 25 02 2015

## **ABSTRACT**

#### Introduction

Diabetes Mellitus (DM) is on the increase globally and deemed to be at epidemic levels in Sub Saharan Africa. Lifestyle modification particularly following an appropriate dietary pattern is a cornerstone of management. One's knowledge, attitude and practices (KAP) as well as culture and values influence one's ability to make the required lifestyle changes. This study was carried out to establish the dietary KAP of diabetic patients attending the diabetic clinic of Nsambya hospital a tertiary private not for profit hospital in Kampala Uganda.

## Methods

A convenient sample of 236 patients was used. Their dietary KAP was assessed using a locally modified version of the American Diabetes Association (ADA) Diabetes Self Management Assessment Research Tool (D-SMART) with some other questions from the University of Michigan Diabetes Research and Training Centre attitude, knowledge and practice questions. The modified version was validated by two local endocrinologists. The 24 hour diet recall method was also used to assess the participants' regularity and/or frequency of meals and also to find out the commonest components of their diet.

## **Results**

67.4% of the respondents were older than 46 years of age and 63.1% were females. The females had a mean knowledge score of 57.4 (out of 60) and the males 54.1. Marital status and level of education were found to positively influence one's knowledge. 82.7% of the respondents had the correct attitude towards DM and its management with marital status found to be the most positively contributing factor. All the respondents had poor scores on the practices section.

## Conclusion

There is a gap between the knowledge/attitudes and the practices of the patients at Nsambya. More effective methods of delivery of the Diabetes Self Management Education (DSME) need to be used and longer term intervention programs established. Further studies especially those exploring factors affecting the DM dietary practices need to be done.

#### INTRODUCTION

Diabetes mellitus (DM) now deemed to be at epidemic levels in Sub Saharan Africa is on the increase worldwide. In 2010 its prevalence in Africa was estimated at 12.1 million, and is expected to rise to about 23.9 million by 2030<sup>1</sup>.

The greatest relative increase in the prevalence of DM in the period 2000-2030 is expected to be in the developing countries including Sub Saharan Africa<sup>2</sup>. This is attributed to increasing urbanization and physical inactivity plus increase in the proportion of the general population that is older than 60 years. Overall, although the prevalence of DM is higher in men, it has been reported that more women have DM<sup>2</sup>. It is postulated that this is due to a bigger number of women older than 60 years and the increasing prevalence of DM with age. In developing countries, most DM patients are in the 45-64 year range. However, it is estimated that by 2030 DM patients older than 64 years will be more than 82 million in the developing countries<sup>2</sup>.

The demographic profile of Uganda of 2013 has estimated that there is a similar trend with more women among people older than 60 years<sup>3</sup>.

In managing type 2 diabetes (T2DM), lifestyle modification, particularly formulating an appropriate dietary pattern, is accepted as a cornerstone of treatment. However, adherence to healthy lifestyle changes continues to be a major problem. Studies have shown that adherence is about 50% for medications in chronic diseases and much lower for lifestyle prescriptions. A study done in Egypt revealed that good adherence to diabetic self management (dietary instructions) was reported in 41.7% of adult patients<sup>4</sup>.

The required lifestyle changes in managing DM are influenced by one's knowledge, attitudes and practices (KAP) and one's culture and values<sup>5</sup>. Therefore these important psychosocial determinants need to be incorporated in effective strategies to manage diabetes since they are major determinant variables to compliance to diabetes treatment regimens<sup>6</sup>.

A study done in Uganda showed that despite having accurate beliefs about DM, many T2DM patients had poor metabolic control. There was a reported significant lack of healthy food choices affected largely by culture and inadequate income<sup>7</sup>. This study recommended that in such an environment where medications are not purchased consistently, relying on lifestyle and self-care strategies is critical<sup>7</sup>.

One writer has reported that most difficulties in the management of DM in Ugandan patients revolve around diet<sup>8</sup>. Being able to understand the patients' KAP on diet and address it may therefore help to improve DM care outcomes.

Patients have been found to predominantly rely on health care workers (HCWs) for their daily DM management problems<sup>9</sup>. Equipped with the knowledge of the local patients' KAP, the HCWs involved in the care of DM patients may be able to generate more patient-centered interventions.

Thus this research set out to establish the dietary KAP of DM patients at Nsambya hospital the teaching hospital for Nkozi University offering Masters of Medicine programs in Internal medicine, pediatrics, surgery and obstetrics and gynecology. The hospital runs a diabetic clinic of an estimated 1000 active patients. This is currently run by an Internist, registrars in internal medicine, medical officers, two diabetic nurses and a senior nursing officer of the out-patient department.

#### **MATERIALS AND METHODS**

This was a cross sectional descriptive study. The study population was patients older than 18 years of age with the diagnosis of diabetes made at least one year prior to the study.

#### **Ethics statement**

Ethical approval was obtained from both the Stellenbosch University health research ethical committee (HREC) and the Nsambya hospital ethical review board.

Informed consent (written or verbal) was obtained from every participant by the research assistant.

#### **Data collection**

The diabetic nurse, the sister in-charge of the out patients' department and a nursing aide from the general medical ward collected the data after a brief training by the researcher and the Internist in-charge of the clinic.

Using Raosoft's online sample size calculator with an estimated population of 1000 patients (the currently recorded active members at the clinic which is a combination of both type 1 and type 2 DM), a sample size of 278 was calculated to give a 95% confidence level and 5% margin of error<sup>10</sup>. Convenience sampling was used. Every eligible patient was approached as he/she waited to see the doctor in the outpatient clinic for his/her routine monthly follow up appointments over a period of 8months. Each patient was approached personally for consent to take part in the study. This was after the nurse in charge of the clinic had made a general announcement about the study to everyone present.

Although Nsambya hospital is at the tertiary level, the patients attending the DM clinic are not only those with complications but are mostly regular uncomplicated DM patients.

The questionnaire used was a locally modified version of the American Diabetes Association Diabetes Self Management Assessment Research Tool (D-SMART)<sup>11</sup> with some additions from the University of Michigan diabetes research and training centre attitude, knowledge and practice questionnaire<sup>12</sup> that were relevant to the study. The modifications made to the original questions were to make them locally relevant for example with the names of the foods. The modified questionnaire was validated by 2 local endocrinologists. The questionnaire was then translated into the main spoken local language (Luganda). Both versions were piloted with 7 patients at the same clinic for suitability, with only a few modifications in the phrasing of some questions, especially in the local language version.

# The questionnaire had 4 components:

The first captured demographics of: age, sex, marital status, living arrangement, education level, employment status, and if any other family member had diabetes. These variables were included because studies have shown that psychological and social factors impact on adherence to any treatment regimen including diet for DM patients. Family relationships have been reported to play an important role in the management of DM. Greater levels of social support, particularly DM-related support from spouses and other family members have been associated with better regimen adherence<sup>13</sup>.

The second part with 12 questions assessed for knowledge about: the cause and complications of diabetes, which foods to eat or not to and if how food is prepared matters. There were also questions comparing the importance of diet, medication and exercise in the management of diabetes.

The third part assessed attitude with a total of 9 questions. 3 closed questions focusing on: dietary instructions, alcohol usage and exercise (as compared to diet) as part of self care management in the treatment of DM. These had answers of either Yes, No or I do not know. The next 6 were statements focused on the patient's ability to manage their diet with a Likert scale ranging from strongly agree to strongly disagree.

The fourth part about practice had 8 statements that also had responses on the Likert scale ranging from not at all able/no I do not to very frequently/most of the time. The last part was an open-ended question asking the patients to record what they had eaten and drunk in the past 24 hours (24 hour diet recall).

The data was collected from March 2013 to the end of October 2013. Most questionnaires were administered by the research assistants. A few were filled in by the patients themselves. For the patients who could speak/ understand neither English nor Luganda, the interview was

done through an interpreter who was the person accompanying the patient to the clinic even for interpretation in the doctor's consultation.

# **Analysis**

From the knowledge section, each correct question was assigned a mark of 5 and a wrong one zero. The total score was then converted into percentages and everyone with 50% or more was deemed to have a good amount of knowledge.

The Likert scale answers from the attitude section were collapsed into 3 broad categories of "agree", "disagree" or neutral to ease statistical analysis. Those that indicated a positive attitude to DM or its management were deemed correct while those that indicated a negative attitude were deemed wrong. Anyone who got 5 or more correct statements (out of 9) including the answers to the closed questions was assigned a good attitude and anyone with less than 5 correct answers was deemed to have a poor attitude.

The answers from the practices section were divided into 2 broad categories of either yes or no. Those that exhibited a practice that increases the risk of DM complications or of poor management were deemed wrong answers and those that were in line with proper DM dietary management were taken as correct answers. Anyone who scored 5 (out of 8) or more correct answers was assigned to good practices and one with less than 5 as one with poor practices.

Data were analyzed using SPSS version 18. All statistical tests were performed using a p value of ≤ 0.05 as the level of significance. Chi-square and student t- tests were used to compare groups. Correlation between variables was assessed using Pearson correlation coefficients. Stepwise linear regression analysis was used to examine the simultaneous effect of various patient characteristics on the knowledge attitude and practices.

#### **RESULTS**

A total of 250 questionnaires were filled in but only 236 had all the questions in all the sections completed. These were used in the analysis giving a 94.4% response rate. This sample size allowed a 5.58% margin of error which remains within the acceptable limits. Therefore the final sample of 236 does not detract from the statistical power of the study. In the last 4weeks of the data collection, most of the people attending the clinic were either those that had already participated in the study or those newly diagnosed (less than a year after the diagnosis).

Table 1 shows the demographic characteristics of the respondents:

Variable	N(%)
Age	

18-24	13(5.5)	
25-31	4(1.7)	
32-38	19(8.1)	
39-45	41(17.4)	
46 and above	159(67.4)	
Sex		
Female	149(63.1)	
Male	87(36.9)	
Marital status		
Single	43(18.2)	
Married	146(61.9)	
Divorced	13(5.5)	
Widowed	31(13.1)	
Cohabiting	3(1.3)	
Living		
arrangements		
Living alone	8(3.4)	
Living with	225(96.6)	
someone		
<b>Education Level</b>		
Illiterate	8(3.4)	
Primary	81(34.6)	
Secondary	80(34.2)	
Tertiary	65(27.8)	
Employment		
status		
Formal	99(44.0)	
employment	) ) ( <del>+4</del> .0)	
Casual labor	37(16.4)	
Unemployed	89(39.6)	
Any other family		
member with		
diabetes		
Yes	117(50.9)	
No	113(49.1)	

The median age was 54 years.

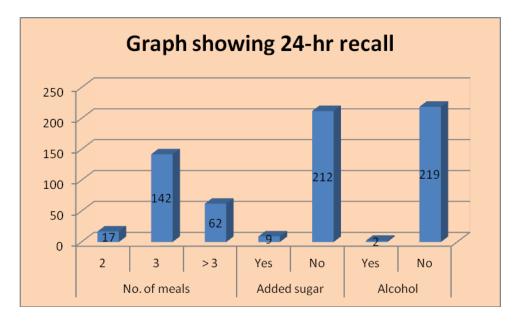
Overall, the mean knowledge score of the respondents was 54%. The median score for the females was 60% while that for the men was 50%. Using the bi-variate analysis, marital status and level of education were shown to significantly affect the patients' knowledge positively. The other variables of: age, sex, living arrangement, employment status and whether there was another family member with DM did not show any statistically significant correlation to knowledge.

Concerning attitude, most (82.7%) of the respondents had a good attitude towards the dietary management of DM. Using the bi-variate analysis, a patient's marital status was found to be a significant contributor to a good attitude. Notably one's education status did not show any correlation with how well one scored from the attitude questions.

In regard to practice as part of dietary management of DM, all the respondents had poor practices this being more in the females (73.2% had poor practice scores) and the older(46 years and above) patients(78.6% had poor practice scores), despite these having scored highest on the knowledge questions.

Stepwise linear regression for the total knowledge, attitude and practice scores was done but no variable was found to significantly predict the total practice score.

From the 24-hour diet recall accounts, 15 people of the 236 that completed all the other sections on the questionnaire (6.36%) did not respond. The graph below shows the results from this account.



The local diet most of the people eat comprises of: plantain, rice, Irish or sweet potatoes, corn, cassava and other starches like yams. The sauce is mainly legumes (beans and peas) groundnut paste, vegetables (like egg plant, cabbage and other green vegetables) and meat (beef, chicken,

fish and pork). Although these can comfortably be included in a diabetic diet if in the correct amounts or portions, 13 of the respondents (5.5%) reported having had more than 3 sources of carbohydrates in one meal.

#### DISCUSSION

The demographics of the respondents show that the clinic has mostly females and most of them were older than 46 years. This is similar to findings in other studies<sup>2,14-16</sup>. A study done in a Ugandan rural regional referral hospital, found that 61% of the people attending the DM clinic were females and almost half of them were in the 40-59 year age range<sup>17</sup>.

Generally, respondents had a good amount of knowledge about dietary management as indicated by the good mean knowledge score. They also had a good attitude towards dietary management.

The good knowledge and attitude scores are seemingly not translated into good practice since there is no direct correlation with good practice concerning dietary management. Other studies have shown similar findings <sup>15,16,18</sup>.

The gap between knowledge and a corresponding change in practice is a well known phenomenon in healthcare 19. Regarding diabetic self management education (DSME) this can be due to different reasons including the way the information is transmitted to the patients, the frequency of doing this and the contact hours each patient actually gets with the HCW delivering the DSME<sup>20</sup>. The presentation of the information to the patient should include various interventions involving patient empowerment like modeling, individual goal setting and those involving participation and collaboration<sup>21</sup>. Since the mode of presentation at the study site is mainly didactic, the HCWs involved in the DSME need to make use of some of the above interventions that empower the patients. Another factor affecting the effectiveness of an intervention in DSME is the contact time spent with the patients, with an average of 23.6 hours of contact between the educator and patient being found to achieve a 1% reduction in glycated hemoglobin (HbA1C) one of the markers of DM control<sup>20</sup>. Although the this study was not able to determine the exact contact time between the HCWs and patients in the DSME, it was observed that the DSME was delivered to all the patients as a group in a 15-20 minute session as they waited to see the doctor. The effects of a DSME diminish with time and only regular reinforcement or repetition of an intervention has been shown to improve knowledge levels at even long term intervals. This could then also eventually influence practice as DSME has been demonstrated to help improve HbA1C both in the short and long term<sup>22</sup>. The patients at the study site initially get one on one DSME sessions with the diabetic nurse if the diagnosis is first made while admitted on the medical ward (for any reason). In the outpatient clinic, those that the doctor deems deficient in the general knowledge of T2DM self care are referred to the

diabetic nurse to arrange repetition of the DSME. However the nurse reports that very few patients turn up for this. She suggests that this is probably because these sessions are set for the next day after the clinic and so few are able to return. The other time T2DM patients get a chance for DSME repetition is if they are admitted to the medical ward for any reason after the initial diagnosis. This is usually by the diabetic nurse who also works on the medical ward.

Although most of the locally available foods can correctly be part of the diabetic diet, the issue of quantity and correct portions of each food type for a particular meal still needs to be emphasized as indicated from this study that some of the respondents were having almost all their energy needs from carbohydrates (more than 3 carbohydrates in one meal).

The 24 hour diet recall method was used to give an idea about the regularity and/or frequency of meals plus the common components of the respondents' diets. It showed that many patients (142 of the 221) take 3 meals a day which is a recommended practice in the dietary management of DM except for those on insulin who may also need to have snacks between the main meals<sup>23</sup>. Snacking was reported in 28% of those who did the 24 hour recall. The interview was not able to identify if this was the appropriate snacking recommended for patients on insulin.

# **STUDY LIMITATIONS**

The use of interpreters who were the patients' attendants in some instances could have caused misrepresentation of information. This could have been a source of error most probably affecting the open statements on the Likert scale under the attitude section with falsely positive answers being given.

Most of the interviews were carried out by the two nurses that generally run the clinic and this could have been a source of bias with the patients answering the questions according to what they have been taught as opposed to the reality in their lives.

With convenience sampling used, only those well motivated in self care as part of management for T2DM patients may have consented to take part in the study. These might be the ones with better knowledge and attitude scores, leaving out those with knowledge deficits and/or with poor attitude.

Since the final sample size was smaller than the calculated number that would give a 95% confidence interval, this reduces the power of this study giving an error margin of 5.58% and reducing the ability to generalize the findings to other populations.

#### CONCLUSION

This study shows that there is a gap between the patients' dietary knowledge/attitude and practices. Good knowledge and attitude scores are not translated into good practices. More effective methods of presenting the diabetic self management education (DSME) that empower the patients for behavior change like brief behavior change counseling and modeling need to be used in this setting. The group teaching sessions also need to be made more effective with longer times assigned to them and working with smaller groups. These have been found to be more effective in positively influencing lifestyle modifications<sup>24</sup>. Longer term intervention programs need to be established to ensure that the patients retain the acquired knowledge needed to be used to empower them for eventual changes towards good dietary practices. Also, since most DSME programs have been found to have a positive impact on behavior only in the short term<sup>25</sup> regular reinforcement needs to be systematically done to ensure sustained behavioral changes. Further studies particularly those exploring factors affecting the dietary practices of the DM patients also need to be done so that these can be directly addressed to help improve the dietary management of DM.

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#### **APPENDICES**

# Appendix 1

# **Questionnaire on Diabetes Mellitus**

Section A: Demographics

Age.....

Sex: Female Male

Marital status: Single Married Divorced Widowed Cohabiting

**Living arrangements**: Living alone Living with someone

**Education level**: Illiterate Primary Secondary Tertiary

Employment status: Formal employment, Casual laborer, Unemployed

Is there any other family member with diabetes? Yes No

# **Section B: Knowledge**

- 1. What effect does unsweetened fruit juice have on your blood sugar?
  - Lowers it
  - Raises it
  - Has no effect
- 2. Which of these should not be used if you sense that your blood sugar is low?
  - 3 pieces of chocolate
  - Half a cup of orange juice
  - 1 cup of soft drink(soda)
  - 1 cup of full cream cow's milk
- 3. Which of the following is a free food?
  - Any unsweetened food
  - Any diabetic food
  - Any food labeled sugar free
  - Any food with less than 20 calories/serving
- 4. Which of the following is highest in fat?
  - Low fat milk
  - Orange juice

- Corn
- Honey
- 5. Which of the following is highest in carbohydrates?
  - Roasted chicken
  - Chocolate
  - Baked potato
  - Peanut butter( ground nut paste)
- 6. The diabetic diet is:
  - The way most Ugandans eat
  - A healthy diet for most people
  - Too high in carbohydrates for most people
  - Too high in proteins for most people
- 7. Eating food low in fat reduces the diabetic patients' risk for
  - Nerve disease
  - Kidney disease
  - Heart disease
  - Eve disease
- 8. Eating too much sugar and other sweet foods is a cause of Diabetes mellitus
  - Yes
  - No
  - I don't know
- 9. Medication is more important than diet and exercise to control my Diabetes
  - Yes
  - No
  - I don't know
- 10. The way I prepare my food is as important as the foods I eat
  - Yes
  - No
  - I don't know
- 11. Diabetic diet consists of mainly specially prepared foods
  - Yes
  - No
  - I don't know
- 12. Maintaining a healthy weight isn't important in the management of diabetes.
  - Yes
  - No
  - I don't know

#### Section C: Attitude

- 13. Dietary instructions should be written out even if the diabetic patient is illiterate. Someone at home should be available to interpret it for him/her.
  - Yes
  - No
  - I don't know
- 14. Being drunk while on diabetic drugs is not a serious problem
  - Yes
  - No
  - I don't know
- 15. Diet and exercise are not as important as treatment in control of Diabetes
  - Yes
  - No
  - I don't know

Select one of the following options as a response to each of the questions below

Responses: Strongly agree Agree Neutral Disagree Strongly disagree

(a) (b) (c) (d) (e)

# In general, I believe that:

- 16.I know what parts of controlling my diet as part of the management of diabetes I'm satisfied with
- 16. I know what parts of controlling my diet as part of management of diabetes I'm dissatisfied with
- 17. I know what parts of controlling my diet as part of management of diabetes I'm ready to change
- 18. I can motivate myself to manage my diet
- 19. I know enough about myself as a person to make dietary choices that are right for me
- 20. I know the barriers to managing my diet as part of my management of diabetes

## **Section C: Practice**

For the questions below, answer using the scale of 0 to 7, where 0 means none, and 7 means frequently

21. In the past 1 week how often have you missed or skipped meals?

0	1	2	3	4	5	6	7		
Not at al	I						Very fre	equently	
22. In the past 1 week how often have you overeaten (eaten more than you know you should)?								?(k	
0	1	2	3	4	5	6	7		
Not at al	I					1	Very fre	equently	
23. In the past 1 week how often have you eaten high fat foods like fried animal protein?									
0	1	2	3	4	5	6	7		
Not at al	I						Very fr	requently	
24. Pleas	se circle th	e numbe	r that in	dicates h	now able	you are	e to fit o	dietary management into	
your	life in a po	ositive ma	anner						
0	1	2	3	4	5	6	7		
Not							Very	able	
At all abl	le								
25. How much do you involve your family in helping you follow a meal plan?									
0		2	3	4	5	6	7		
Not at al				_			•	often	
	empower	•		-			•	foods?	
0		2	3	4	5	6	7		
Not at al							•	well.	
	-	you eat o	nly that	which is	availabl	e or onl	y what	you can afford irrespective	e
	ntent?								
0		2	3	4	5	6	7		
No I do r	not						Most	of the time.	
		s diabete	s interfe	ere with	or preve	nt you f	from do	oing your normal daily	
	ities?								
0		2	3	4	5	6	7		
No it do								n of the time	
29. May	vou please	e write do	own the	food and	d drinks	taken ir	the las	st 24 hours indicating the	

amounts taken and the quantities of each (24hr recall method).

# Appendix 2

#### **CONSENT FORM:**

**TITLE OF THE RESEARCH PROJECT**: DIETARY KNOWLEDGE, ATTITUDE AND PRACTICES OF DIABETIC PATIENTS AT NSAMBYA HOSPITAL KAMPALA; UGANDA.

REFERENCE NUMBER: \$12/08/223.

PRINCIPAL INVESTIGATOR: Dr. Conrad Ntaate

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You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

## What is this research study all about?

This study will be carried out at Nsambya hospital in Kampala. It is a study that seeks to understand the knowledge, attitudes and practices (KAP) concerning diet of diabetic patients attending the diabetic clinic at the hospital. Since dietary management is a big component of the self care in management of diabetes, an understanding of the patients dietary KAP will help the diabetics' health care team to develop better management package for the people in this region.

The study will be done through interviews with the patients who will voluntarily consent to take part in the study. These will be selected from those attending the clinic at the hospital.

The convenient sampling method will be used, patients being approached as they wait to see the doctor for their scheduled monthly reviews.

### Why have you been invited to participate?

You have been invited to participate in his study because you a part of the group of people that qualify to be in the study and you have also already shown willingness to take part in this by accepting to follow up from the initial verbal invitation.

# What will your responsibilities be?

Your responsibility will be to answer the questions set out in the questionnaire either on your own or by someone reading them out to you and then him/her writing down your answer. You will be the one to choose from the two methods how this is done.

# Will you benefit from taking part in this research?

There are no direct (personal) benefits to you for taking part in this study but the information we get will be shared with your health care team and it will help them improve the management of diabetic patients at this hospital.

Are there in risks involved in your taking part in this research?

There are no risks involved in your taking part in this study.

If you do not agree to take part, what alternatives do you have? (This will not apply to this study since there is no intervention planned)

#### Who will have access to your medical records?

The information collected will only be accessible to the study team when it has just been collected and thereafter it will be coded in a way that you cannot be identified even if one saw that information.

What will happen in the unlikely event of some form injury occurring as a direct result of your taking part in this research study? (This too does not apply to this study).

Will you be paid to take part in this study and are there any costs involved?

You are not going to be paid for taking part in this study.

Is there anything else that you should know or do? (This too does not apply because there is no intervention and no part of the study affects the patients' usual management).

You will receive a copy of this information and consent form for your own records.

## **Declaration by participant**

By signing below, I ...... agree to take part in a research study entitled (insert title of study).

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is voluntary and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signature of interpreter	Signature of witness
Signature of investigator	Signature of witness
Signed at ( <i>place</i> )	on ( <i>date</i> ) 2013.
• I did/did not use a interpreter. (If a in sign the declaration below.	terpreter is used then the interpreter must
<ul> <li>I am satisfied that he/she adequately under discussed above</li> </ul>	understands all aspects of the research, as
<ul> <li>I encouraged him/her to ask questions as</li> </ul>	nd took adequate time to answer them.
I explained the information in this docum	nent to
I <i>(name)</i> dec	clare that:
Declaration by investigator	
Signature of participant	Signature of witness
Signed at ( <i>place</i> )	on ( <i>date</i> ) 2013.