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Review Article

Designing of Proforma to Study Diabetes Mellitus: A Systematic Approach

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Abstract

Diabetes mellitus has been recognized as a metabolic disorder presently troubling the world, posing a great socio-economic burden to many nations. Over the past two decades the worldwide prevalence of diabetes has risen from an estimated 30 million cases in 1985 to 177 million in 2000. 17 million deaths occur every year worldwide due to diabetes unawareness approximating to 2 in every 10 deaths. World Health Organization projects that diabetes will be the 7th leading cause of death affecting 360 million people by 2030. More than 80% of diabetes deaths occur in low- and middle-income countries like India, Bangladesh, Nepal, Pakistan etc. It is estimated that 61.3 million people aged 20 - 79 years live with diabetes in India (2016 estimate), which is expected to increase to 101.2 million by 2030. However all of these data are based on small random studies done in some regions of country. Even a multi-centre studies that have been done, have several limitations. In brief the data on diabetes complications and population study on the prevalence of diabetes is even scarcer. Thus, there is a need for development of an easy and precise questionnaire which will have enormous public health impact and help government plan makers to take action against diabetes in India. The objective of this project is to increase diabetes awareness in terms of precautions, diagnosis and treatment. This review covers the rationale behind every question asked for better patient compliance and cooperation, so that diabetes cannot only be detected but monitored correctly and accurately without hit and trial of medication as per patients schedule and eating habits.

Keywords: *Diabetes Mellitus; Fatigue; Polydypsia; Population*

Introduction

Diabetes can affect numerous parts of the body and is associated with solemn complications, such as heart disease and stroke, blind-ness, kidney failure, and lower-limb amputation. Some complications, particularly micro vascular (e.g. eye, kidney, and nerve) disease, can be reduced with good glucose control. Also, early finding and treatment of complications can prevent progression, so monitoring with dilated eye exams, urine tests, and foot exams is essential. Because the risk of cardiovascular disease is increased in diabetes and predia-betes, blood pressure and lipid management, along with smoking cessation, are principally important. By working mutually, people with diagnosed diabetes, their support network, and their health care providers can reduce the occurrence of these and other complications [1].

According to the World Diabetes Atlas, India is predictable to have around 51 million people with diabetes. However, these data are based on minute sporadic studies done in some parts of the country. Even a few multi-centre studies that have been done, have numerous restrictions such as sample selection criteria, age selection, place selection etc. Also, marked heterogeneity between States limits the gen-eralizability of consequences. Other studies done at diverse time periods also lack identical methodology, do not take into contemplation ethnic differences and have insufficient coverage [1,2]. Thus, till date there has been no nationwide study on the prevalence of diabetes which is accurately representative of India as a whole. Moreover, the records on diabetes complications are even scarcer. Therefore, there is an urgent need for a large well-planned countrywide study, which could provide trustworthy nationwide data, not only on prevalence of diabetes, but also on complications of diabetes and pre-diabetes, in India. A study of this nature will have massive public health impact and help guidelines makers to take action against diabetes in India [2,3].

India is a vast, heterogeneous country with an estimated population of 1.1 billion people, a complex socio-political history, dialects and ethnicity, immense diversity of culture, communal and privately-funded health infrastructure, and challenging demands on human and structural resources. These factors together negate a single policy solution for the whole country and this underscores the importance of generating a robust, representative base of evidence that documents burdens of disease, identifies vulnerable populations and draws attention to disease determinants [3,4].

In India, approximately 742 million people live in rural areas [4,5] where alertness of chronic diseases is awfully low [6] and the ratio of known-to-unknown diabetes is 1:3 (compared to 1:1 in urban areas) [7]. Basic estimates suggest that type 2 diabetes prevalence in urban areas is much higher (approximately 25 - 50%) than in rural areas [8,9]. Although trend data are now signifying that diabetes prevalence in rural areas is speedily catching up with the urban estimates.

In addition, given that the awesome majority of India's population lives in rural areas and that there is a upper ratio of undiagnosed cases, the load of diabetes and NCDs may be much greater. Also, divergences in disease outcomes are directly related to large disparities in human and infrastructural resource provision between rural and urban areas [10,11]. Consequently, the Government of India's National Rural Health Mission will benefit greatly from more precise estimates of diabetes and NCD burden in all States of India.

Here is the proposed questionnaire sample for study of diabetic and non–diabetic patient or even prediabetes:

Proposed Project Title: Designing a Pro-forma to study Diabetes and Associated Complications

Dear Participant,

You are invited to participate in a survey I am conducting for a (course title e.g. M. Pharm.) project at (Institute's name). The Supervisor of this project is (Supervisor's name). This is an educational survey to know the current status of diabetes mellitus in (name of the region). All information that you provide through your participation in this study will be kept confidential. The data collected through this study will be used for educational, research and publication (if any) purpose. There are no known or anticipated risks to participation in this study.

Important Information

1. The questionnaire contains total 6 sections spread in 8 pages including this page.
2. It may take approximately 60 minutes to complete this questionnaire.
3. Please read the questionnaire carefully before answering the questions.
4. If you would like to write additional comments about the study, please feel free to do so.
5. If you need any assistance to understand any part of this questionnaire or you need any help to fill this questionnaire, kindly feel free to ask.

Focus of the project: (In this section you can write the aim of the proposed study: E.g. From this study I will try to propose what precautions/measures can be taken to prevent diabetes mellitus and associated complications. Also we expect to conclude the reasons, which are the measure cause for diabetes mellitus and associated complications.

Should you have any comments or concerns resulting about your participation in this study, please contact **(Supervisor's name) at (Supervisor's Address, Contact number and E-mail).**

Thank you in advance for your co-operation in my research.
Name and signature of the investigator:
Email and contact number

Consent of the participant: This survey is conducted on me with my consent. I am participating in this survey voluntarily without any pressure or monetary or any other benefit. The information provided here is correct as per best of my knowledge.

Date: Signature of the participant

The rationale/justification/basis for asking every question included in different sections of this questionnaire is written with the question asked.

Survey Questionnaire

Section 1: General Information of the Participant

Question	Rationale
Name of patient Sex: Zodiac: Date of birth: Mobile no.: Telephone no.: Email:	1. This term is used here to identify whether the patient is male or female. This paper also includes the number of males or females suffering from diabetes and prevalence of diabetes in them. In past studies it was concluded that the males are more prone to diabetes than female. 2. Zodiac in our study is mentioned in order to find that whether Zodiac signs have any correlation in the prevalence of diabetes. For example people born in winter are exposed to different weather conditions to the people born in summer season. 3. Patient's date of birth is important to mention to identify the current of patient. 4**.** State is mentioned here to get the knowledge of climatic condition whether the state is near/far from topic of Cancer.
Current address: City: State/Province: Country: ZIP Code	The 'top three' countries with the maximum prevalence of diabetes are India, China, and the USA. Large increases in prevalence are also expected mostly in countries such as Bangladesh, Brazil, Indonesia, Japan, and Pakistan [12]. From this question the investigator may wish to assess that effect of place on the epidemiology of diabetes. Ethnicity typically also refers to culture within a culture-that is, a group of people with a common or shared identity, living within a larger, mainstream group [13]. The incidence of type 1 diabetes is highest in the temperate regions (about 30 to 35 cases per 100000 children per year) and declines progressively towards the equator. High prevalence is noted within populations from these regions even when distributed in other parts of the world [14].
Educational Qualification	Patient's qualification study is important to find out whether the patient has some knowledge regarding the disease, like the patient from science field will be more familiar with the term as compare to uneducated/arts stream.
Marital status (a) Married (b) Single (c) Other….....	Patient circadian rhythm is important to analyze its disease status example patient wake up time before sunrise or after sunrise. It is used to study whether the married people is more prone to diabetes than unmarried.
Total number of members in your family? At what time you wake up? At what time you go to bed in the night? Do you take a nap in the afternoon? Average time spent in the bed per day? Before diabetes: Day hours Night: hours After diabetes: Day hours Night: hours	A sleep duration of 6 hours or less or 9 hours or more is associated with increased prevalence of DM and IGT [15].
When did get you diagnose with diabetes?	About one third of all people with diabetes do not know they have the disease [16].
And why did you get it diagnose?	Type 2 diabetes often does not have any symptoms [16].
Indicate which type of diabetes you possess: Diabetes type 1 OR Diabetes type 2	Type 2 diabetes is much more common than type 1 diabetes, and accounts for around 90% of all diabetes worldwide [17].
Have you found change in blood pressure after diagnosis of diabetes? Yes/ No	People with diabetes are twice as likely to develop heart disease as someone without diabetes. Good control of diabetes significantly reduces the risk of developing complications and prevents complications from getting worse [16].
If yes, What type of change? Increased/ Decreased And How much changed? …..... mm/ Hg	
Have you ever fainted or loss of consciousness after diagnosis of diabetes, even for a short time? Yes/ No If yes, then how many times? In your view, what was the reason for fainting or loss of consciousness?	

Section 2: Medical Condition of the Participants

Question	Rationale
1. Any other chronic condition apart from diabetes you possess: (a) High cholesterol (b) High blood pressure (c) Heart disease Type: …… (d) Lung disease Type: …… (e) Other chronic condition, please specify…… 2. How many points will you give to your health condition on the scale of 1-4? 1.Excellent 2.Good 3.Bad 4.Worst	1. Approximately one-third of patients with diabetes have diagnosable psychological problems at some point during their lifetime [18]. 2. Affective and anxiety disorders are the most common diagnoses and occur significantly more often in patients with diabetes than in the general U.S. population [18]. 3. Major depression affects approximately one of every five patients with diabetes and severely impairs quality of life and all aspects of functioning [19].
3. Do you feel fatigue continuously? Yes/No 4. Describe your fatigue in the past two weeks on the scale of 1-4: a) No fatigue b) Little fatigue c) Very fatigue d) Severe fatigue	1. Many of the chronic complications associated with diabetes are associated with fatigue. Diabetes is the leading cause of end-stage renal disease (ESRD) in the United States [20]. 2. Anemia, the major side effect of impaired kidney function, results in increased fatigue [21]. 3. Among patients undergoing dialysis for treatment of ESRD, symptoms (including fatigue) negatively affected quality of life and were significantly worse among the patients with diabetes than those without diabetes [22].
Do you feel continuous body pain? Describe the pain in body/body parts in the past two weeks on the scale of 1-4: a) No pain b) Little pain c) Intense pain d) Severe pain Do you feel shortness or difficulty in breathing? Describe your shortness / difficulty in breathing in the past two weeks on the scale of 1-4: a)No b) Little c) More d) Severe	The lung is also a target organ for diabetic microangiopathy in patients with both type 1 and type 2 diabetes. And decrements in lung function have been reported among patients with diabetes over the past two decades [23]. Decrements in the lung function of patients with diabetes are believed to be the consequence of biochemical alterations in the connective tissue constituents of the lung, particularly collagen and elastin, as well as microangiopathy due to the nonenzymatic glycosylation of proteins induced by chronic hyperglycemia [24].
9. Any change observed in your wound healing capacity, after diagnosis of diabetes? 1. Decreased 2. Increased 3. Not change 10. Have you noticed any of the following symptoms in last two weeks? Answer in Yes/ No/Don't know a. Increased thirst b. Dry mouth c. Change in appetite? Increased/ Decreased d. Nausea or vomiting e. Abdominal pain f. Severely high blood sugar g. Severely high blood pressure h. Morning headaches? i. Nightmares? j. Night sweats?	People who generally sweat excessively, day and night, may have a condition called hyperhidrosis. The main conditions and medications that can cause night sweats is hypoglycemia (low blood sugar), which is commonly associated with diabetes and taking insulin [25]. Night time low blood sugars can cause more than bad dreams - restless sleep and headaches upon awakening are common complaints [26]. Diabetes causes fluctuations in the body temperature and this is the reason why long term diabetic patients experience a sudden increase and drop in their body temperature. Night sweats are the body's response to stabilize its temperature [27].
k. Lightheadness? Yes/No/Don't know l. Shaking or weakness?	Hypoglycemia can occur as a side effect of some diabetes medications, including insulin and oral diabetes medications-pills-that increase insulin production [28]. Dizziness is a common complaint in persons with diabetes, and may be caused by low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), or autonomic dysfunction [29].

Section 3: Daily Activities

Question	Rationale
Do you take breakfast? Yes/ No If yes, what is the time of your breakfast? If no, please give the reasons for not having the breakfast? Time of your lunch? Time of your dinner? Any other meal? If yes, how many times in between lunch and dinner? …… Any other meal after dinner? Yes/ No If yes, then what was the time of it? …..p.m. Amount of salt and spice you like to intake? Low Normal High	1. This means that a person who has worked with a dietitian and a diabetes treatment team to figure out how many grams of carbohydrate they can eat throughout the day can decide at any given meal what they will eat. 2. Because each gram of fat contains 9 calories (while a gram of protein or carbohydrate contains only 4 calories), fat gram counting as a means of losing weight becomes an additional nutritional tool for many patients.
Do you exercise? Yes / No How many times in a day and week? Time duration of exercise How much time you spend in exercise per day?.....hours. Type of exercise (walking/ stretching/ cycling/ swimming / any others……)	Diabetes can be prevented. Thirty minutes of moderate-intensity physical activity on most days and a healthy diet can drastically reduce the risk of developing type 2 diabetes [30]. If you are at risk, type 2 diabetes can be prevented with moderate weight loss (10 - 15 pounds) and 30 minutes of moderate physical activity (such as brisk walking) each day [16].
Food habit: Vegetarian/ Non-vegetarian Any change in food habits after diagnosis of Diabetes? Yes/ No What type of change specify? Specify the name/type of food which you generally eat in (a) Breakfast: (b) Lunch: (c) Dinner: (d) Between the meals: Do you smoke? Yes/ No Do you consume alcohol? Yes/ No Do you take narcotics? Yes/ No Any other addiction? Yes/ No Is any of your family members' diabetic? If yes, please mention the relation …… How many times you get up to urinate at- Day……..Times Night ……Times Do you feel pain in bladder during urination? Yes/ No	

Section 4: Personality and Medical Care

Question	Rationale
Your body weight (in kg) Before diabetes After diabetes Your height ……..feet ……inches ……	For the calculation of Basal Metabolic Index of the patient.
Do you monitor your body weight regularly? Yes/ No If yes, then at what interval?	These questions are directly related to the patient awareness.
What was your body weight when you were diagnosed with diabetes? Do you feel any change in your physical efficiency after diagnosis of diabetes? Increased/ Decreased/No change If increased/ decreased, kindly describe? a. Do you feel any difficulty in vision? Yes/ No b. Any other problem associated with eyes? c. If yes, kindly describe d. Since when (a/b): Before diabetes After diabetes Do you feel any change in your memory status after diagnosis of diabetes? Yes/ No a. If yes, kindly describe b. How the diabetes is affecting your mental condition(like depression/negative thinking)	Lack of awareness about diabetes, combined with insufficient access to health services, can lead to complications such as blindness, amputation and kidney failure [31]. Diabetes is the leading cause of blindness in working-age adults [16].
Do you regularly visit the physician after diagnosis of diabetes? In the past 6 months, how many times did you go to the hospital emergency department? What was the purpose of your visit? Total number of physicians visited for the management of diabetes In the past 6 months, how many times were you hospitalized for a night or longer? When and why? When did you get your eyes examined last time (for example glaucoma or for any other problem)? Why? How many times did the doctor or nurse examine your feet in the last 6 months? When was the last time you had your blood examined? (For checking your sugar level) Have you observed any eye, heart, kidney, skin, liver, memory related problems after diagnosis of diabetes? Yes/ No If yes, kindly mention the time interval of these complications after diagnosis of diabetes? Have you been diagnosed with any other disease after diagnosis of diabetes? Yes/ No If yes, kindly mention: Do you take any substitute of sugar, such as Sugarfree? Yes/ No If yes, kindly mention:	Peoples are not aware about substitute of sugar, because they may use Gur, sugar-cane etc. Sometimes people used saccharine, aspartame etc. which are carcinogenic for human body.

Describe your diet

Type of Food	Subtype	Before Diagnosis		After Diagnosis	
		Quantity (In gm/no.)	Calories (kcal)	Quantity (In gm/no.)	Calories (kcal)
Chapattis/Poori/Paratha					
Rice and Pulses					
Vegetables					
Juices					
Namkeen, Sweets					
Chat, Fast food					
Milk products					
Any Nonveg					
Any other					

Rational

- The important message is that with proper education and within the context of healthy eating, a person with diabetes can eat anything a person without diabetes eats [32].
- Now many patients are being taught to focus on how many total grams of carbohydrate they can eat throughout the day at each meal and snack, and still keep their blood glucose under good control. Well-controlled blood glucose is a top priority because other research studies have concluded that all people with diabetes can cut their risk of developing diabetes complications such as heart disease, stroke, kidney and eye disease, nerve damage, and more, by keeping their blood glucose as closely controlled as possible.
- This means that a person who has worked with a dietitian and a diabetes treatment team to figure out how many grams of carbohydrate they can eat throughout the day can decide at any given meal what they will eat [33].

Rational

Question	Rationale
Individual income	Diabetes costs $174 billion annually, including $116 billion in direct medical expenses [16]. Estimation for the determination of ratio of patient family total expenditure with respect to the cost on medicine
Total family income	
Total monthly expenditure on:- 1.Medicine 2. Household 3. Other	
Occupation (Business/ Service/ Homemaker/ Student/ Any other) Working hours a day Nature of work: Laborious/Hard/Easy/ Mental	Estimating prevalence of diabetes in a population associated with occupation is more likely to suggest a type of work with more mental work than physical work. The most affected people are software engineers followed by doctors and businessmen. The incidence of diabetes has also affected a certain section of the society like women belonging to the upper strata and who are house wives. So associating diabetes with occupation is difficult since it depends more on the food intake physical exercise and attitude of the individual [34]. Occupational stress is associated with the incidence of T2MD; the higher the degree of stress, the greater the risk of T2MD [35].
Types of medicines consumed by you	
Till now total cost of your treatment including diagnosed test and reports	

Name of medicines prescribed

Brand name	Generic name	Manufacturer name	Dose

11. Name of the diagnostic tests performed for management of diabetes and investigation of associated problems:

……

12. Name and address of the physicians who gave you satisfactory treatment: ……

……

Section 6: Participant View

Do you feel that diabetes can be controlled? Yes/ No

If yes then how?

Any other comment? ……

Rationale: Patient psychological condition is very important.

Have you ever participated in this type of survey? Yes/ No

1. If yes, then please describe
2. Are you satisfied with this survey? Yes/ No

If No kindly suggest some more points which should me mentioned in the questionnaire.

This space has been left blank intentionally so that the participant can write additional comments here, about his/her disease, and this study.

Comments of the Surveyor

Conclusion

Diabetes is one of the most costly diseases ever in both human and economic terms. To reduce today's burden and that on future generations, it is in everyone's interest that cost-effective measures to prevent diabetes are identified and implemented.

According to IDF and WHO figures, there are at least 387 million people with diabetes means every one people out of 12 lives with diabetes. Worldwide, 80% of them whom are in developing countries [1]. If nothing is done to slow down the epidemic, by 2025 the overall number of people with diabetes will have increased to 300 million. In 2014 4.9 million deaths from diabetes in India i.e. in every 7 seconds 1 people died by diabetes. In India 66.847 million people diagnosed by diabetes, and 35.49569 people have undiagnosed diabetes, whose cost is 94.96 USD per person. It is very interesting thing that 1 in 2 people with Diabetes do not know they have it.

Type 2 diabetes accounts for 90 to 95% of all diabetes. The growth rate of Type 2 diabetes is explosive in the overall population and it is estimated that more than 50% of people in this group are not diagnosed.

Authors Contribution

Mr. Mayank Malaiya collected the data from patients, Dr Aakanchha Jain and Dr. Sourabh Jain helped in arranging the data for communication and manuscript formatting, Dr. Dharmendra Jain contributed to in bringing this new idea of diabetes patient care in the form of manuscript, discussion and creating the questionnaire.

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Conflict of Interest

All the authors report no conflict of interest.

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