Screening of Tuberculosis patients for Diabetes Mellitus: Pilot project

Training module for RNTCP staff

Central TB Division, Directorate General of Health Services,
Ministry of Health & Family welfare
Government Of India

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Acknowledgements

1. Global and National Burden of Tuberculosis and Diabetes

1.1. Global Burden of Disease:

There are 7 billion people estimated to be living in the world.

The most recent estimates of tuberculosis (TB) are from the WHO Global Tuberculosis Report 2011 which report data for 2010 [1]. In 2010, there were 8.8 million incident cases of TB (range 8.5 – 9.2 million) and between 1.2- 1.5 million deaths from TB (including TB deaths among HIV-infected people). Of these 8.8 million TB cases, only 5.7 million (65%) were notified. Treatment success for new smear-positive pulmonary TB cases for the cohort in 2009 was 87%.

The most recent estimates of the global burden of diabetes mellitus (DM) come from the 2011 Diabetes Atlas of the International Diabetes Federation [2]. In 2011, there were an estimated 366 million cases of DM globally, and by 2030 it is expected that this number will have risen to 552 million. 80% of people with DM live in low- and middle-income countries and 50% of all people with DM (183 million) are undiagnosed. It is estimated that DM caused 4.6 million deaths in 2011.

1.2. National Burden of Disease:

India is a country with 1.2 billion people (or 17.5% of the world population).

India has the largest number of TB cases in the world (estimated at 2.0 million per annum) with an incidence rate of 168/100,000 per year for 2009 [3]. The national case detection rate for new smear positive cases was 72% in 2010. Treatment success for new smear-positive pulmonary TB cases for the cohort in 2009 was 88%, slightly higher than the global average.

As a consequence of urbanization as well as social and economic development, there has been a rapidly growing epidemic of diabetes mellitus (DM) [2,4]. Available data suggest that an estimated 11% of urban people and 3% of rural people above the age of 15 years have DM. Among them about half in rural areas and one third in urban areas are unaware that they have DM. Most recent estimates from the International Diabetes Federation put the number of persons with diabetes mellitus at 61.3 million

(10% of the adult population), with a further 77 million having impaired glucose tolerance.

2. Interactions between Tuberculosis and Diabetes

2.1. Global:

The recent medical literature on the interactions between Tuberculosis and Diabetes has shown that [5,6,7,8,9].

- People with a weak immune system, as a result of chronic diseases such as diabetes, are at a higher risk of progressing from latent to active TB
- People with diabetes have a 2-3 times higher risk of TB compared to people without diabetes
- About 10% of TB cases globally are linked to diabetes
- A large proportion of people with diabetes as well as TB is not diagnosed, or is diagnosed too late. Early detection can help improve care and control of both
- All people with TB should be screened for DM particularly in settings with high DM prevalence
- DM can lengthen the time to sputum culture conversion and theoretically this could lead to the development of drug resistance if a 4-drug regimen in the intensive phase of therapy is changed after 2 months to a 2-drug regimen in the presence of culture-positive TB.
- People with diabetes who are diagnosed with TB have a higher risk of death during TB treatment and of TB relapse after treatment. WHO-recommended TB treatments should be rigorously implemented for people with TB/DM.
- DM is complicated by the presence of infectious diseases, including TB. It is important that proper care for diabetes is provided to those that are suffering from TB/DM.
- It has been argued that good glycemic control in TB patients can improve treatment outcomes.

However the precise mechanisms by which the interactions take place are still not clear.

2.2. National:

Epidemiological surveys and studies have been completed and published or are currently being conducted in India on the association between DM and TB. Epidemiological models using 2000 data in India have shown that DM accounts for 20% of smear-positive pulmonary TB [10] and recent analyses have indicated that the increase in DM prevalence in India has been an important obstacle to reducing TB incidence in the country [11].

In Tamil Nadu, crude prevalence rates of diabetes and pre-diabetes in TB patients were found to be 25% and 24% respectively with rates in the general population being 10% diabetes and 8% pre-diabetes. A comparison of different methods of screening for diabetes (fasting blood glucose, oral glucose tolerance test and HBA_{1C}) showed the fasting blood glucose to be the more cost-efficient.

In a study from the state of Kerala, 44% of the TB patients were found to have diabetes (as compared to a prevalence of 16%-20% diabetes in the general population) - 23% of the TB patients had self-reported diabetes, and 21% were newly diagnosed to have diabetes on measurement of HBA_{1C} (> 6.5%).

These works suggests high levels of DM in patients with TB in the states of Tamil Nadu and Kerala. This may have an important effect on TB treatment outcomes by lengthening the time to sputum culture conversion, increasing death rates and increasing the risk of recurrent TB after successful completion of TB treatment [9]. This association may also theoretically lead to the development of multi-drug resistant TB (TB resistant to rifampicin and isoniazid).

The epidemiological and clinical interactions between TB and DM are similar to that between TB and HIV [12]. The impact of these interactions, though different in magnitude at individual level may even out at population level due to higher prevalence of DM in the population. The similarity of interactions provides an opportunity for application of lessons learnt in TB-HIV collaboration to TB-DM collaboration as well.

3. Global Response to the Care and Control of TB and Diabetes

An important step in the fight against DM and TB has been the development of a WHO-Union Framework for Collaborative activities to guide policy makers and implementers in reducing the dual burden of DM and TB (**Table 1**). This was developed through a 2-year consultative process, with WHO giving clearance to develop a Framework rather than Guidelines due to lack of strong evidence to support some of the suggested interventions. The Framework was released in August 2011, and will serve as a guide to help policy makers and implementers to move forward to combat the looming epidemic [13]. It will be important to ensure that interventions are delivered within the context of general health systems and take account of other chronic non-communicable diseases, and that engagement is sought both with and from civil society.

One of the important activities of the Collaborative Framework is the routine implementation of bi-directional screening of the two diseases [14]. The ways of screening, recording and reporting for the two diseases in routine health care settings are not well determined, and these knowledge gaps need to be addressed [14,15].

4. National Response to the Care and Control of TB and Diabetes

A national stakeholders meeting was held in Delhi, India, (October 2011) between The Union, WHO, World Diabetes Foundation (WDF), and national diabetes, non-communicable disease and tuberculosis authorities to review and discuss linkages between diabetes mellitus (DM) and tuberculosis (TB), the need for bi-directional screening and the WHO-Union Collaborative Framework. At the national stakeholders' meeting it was agreed that the feasibility of bi-directional screening should be assessed as pilot projects within routine health care services.

5. Aim and Objectives of the Pilot Project

The aim of the current project is to assess the feasibility and results of screening tuberculosis (TB) patients for diabetes mellitus (DM) within the routine health care setting.

Specific objectives are:-

a) To actively screen TB patients for DM
b) To refer those suspected or diagnosed with DM to appropriate diabetes care
c) To record and report on the screening data.

6. Methods for the Pilot Project

6.1. Patients:

All TB patients who have been consecutively diagnosed and registered under RNTCP will be screened for Diabetes. This includes patients with new and previously treated TB, and stratified into smear-positive pulmonary TB, smear-negative pulmonary TB and extrapulmonary TB.

6.2. Screening Intervention and Diagnosis of Diabetes:

The screening for DM will follow the guidelines stipulated by the National Programme for prevention and control of Cancer, Diabetes, Cardiovascular Diseases and Stoke (NPCDCS) in India [16]. Those guidelines stipulate that a fasting blood glucose be carried out using a finger prick and glucometer with cut-off thresholds in line with those recommended by the World Health Organization.

Screening TB patients for DM should be conducted as early as possible after diagnosis of TB; but can be done at any time during the course of TB treatment. Because of the difficulties in getting TB patients to first come to the clinic in a fasting state, TB patients will be initially screened with a random blood glucose (RBG) using a glucometer. If the RBG is less than 110 mg/dl, this is a normal result and no further tests need be carried out. If the RBG is at or greater than 110mg/dl, this might indicate an abnormal glucose state and there is a possibility of DM. The patient will be asked

to return in a fasting state, and a fasting blood glucose (FBG) will be carried out. A fasting blood glucose (FBG) at or greater than 126 mg/dl indicates DM. The screening procedure and criteria for diagnosis of DM is summarized in **Table 2** and the procedure of conducting the test is provided in **Table 3**.

6.3. Who will do the glucometer test?

The testing will be done by a person designated and trained for the purpose at every peripheral health institution (PHI). Though this would vary from site to site the following general principles would apply. Wherever, NPCDCS is being implemented, the ANM (Auxiliary Nurse Midwife) has been trained to use glucometer and screen people for DM. The same personnel would test TB patients. In case, this mechanism is not available, the laboratory technician working in the PHI will be trained to do the test. If a PHI does not have a laboratory technician, then either the staff Nurse or any other staff designated by the MO-PHI will be trained to do the test.

6.4. Referrals of TB patients with DM to diabetes care:

In the sites involved, TB patients identified with known DM or with a FBG at or higher than 126 mg/dl will be referred to diabetes services using a referral form (see **Table 4**) for definite diagnosis, care and treatment. A referral and feedback mechanism will be developed to enable timely exchange of information. Good cooperation and collaboration will need to be developed between the two sets of staff working in the different service areas.

6.5. Recording and reporting:

Templates for the quarterly recording and reporting on the results of DM screening in TB patients are shown in the Annexes. The quarterly reporting form and the data to be reported are shown in **Appendix 1a** and the instructions for filling the report are shown in **Appendix 1b.** The parallel register for recording the DM screening tests and data to be captured are shown in **Appendix 2a,** and the explanations for how this register is completed are shown in **Appendix 2b.**

Modifications will be made to the **TB treatment cards** to capture the following information.

1. Current smoker: Yes/No
2. Already known diabetic: Yes/No
3. RBG value with date:
4. FBG value with date:
5. Newly diagnosed diabetic: Yes/No
6. Referred to DM care with date: Yes/No
7. Reached DM care with date: Yes/No

A seal incorporating the above details will be prepared and printed on all the TB treatment cards used in the PHI. The responsibility for collecting the information and updating the treatment card will rest with the institutional DOT provider of the PHI. This information from the treatment card will then be captured by the Senior Treatment Supervisor (STS) of the respective TB unit in the TB-DM register (**Appendix 2**).

The quarterly reports will be prepared on the cohort of registered patients (including transfer-in patients and those registered under Non-DOTS) by the STS (**Appendix 1**). The project will commence in the first quarter of 2012 (January-March) and continue until third quarter of 2012 (July-September), and quarterly recording and reporting will occur for each quarter, with results collated and reported one month after the end of the quarter. TB patients will be followed-up through their TB treatment to assess treatment outcomes, disaggregated by DM status. Quarterly reporting will therefore be done for Q1-2012; Q2-2012; Q3-2012.

6.6. Supervision:

The entire process will be periodically supervised by the District TB Officer (DTO) and concerned RNTCP consultant once in a month.

6.7. Justification and Implications

With the launch of the WHO and Union Collaborative Framework for the care and control of Diabetes and Tuberculosis, it is important that countries with a high dual burden of the two diseases work out how best to screen for each disease within the routine health services. Screening for diabetes in TB clinics should lead to better and

earlier detection of DM, earlier and better treatment of DM (which might have gone unrecognised) and anticipated improved clinical outcomes on anti-TB treatment. This should be of benefit not only to India and also for the global community.

7. Exercises

There are two exercises at the back of this manual to be undertaken by the participants. Instructions on how to complete the exercises are shown on the appropriate pages.

8. References

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15. Harries AD, Murray MB, Jeon CY, Ottmani SE, Lonnroth K, et al. (2010) Defining the research agenda to reduce the joint burden of disease from diabetes mellitus and tuberculosis. Trop Med Int Health 15: 659-663.
16. Directorate General of Health Services MoHFW Government of India (2009) National Programme for prevention and control of Cancer, Diabetes, CVD and Stroke (NPCDCS): Operational Guidelines. New Delhi.

Tables

Table 1: Collaborative activities to reduce the dual burden of TB and DM

A. Establish the mechanisms for collaboration

A.1. Set up means of coordinating DM and TB activities
A.2. Conduct surveillance of TB disease prevalence in DM patients in medium and high-TB burden settings
A.3. Conduct surveillance of DM prevalence in TB patients in all countries
A.4. Conduct monitoring and evaluation of collaborative DM and TB activities

B. Detect and manage TB in patients with DM

B.1. Intensify detection of TB disease among DM patients
B.2. Ensure TB infection control in health care settings where DM is managed
B.3. Ensure high quality TB treatment and management in people with DM

C. Detect and manage DM in patients with TB

C.1. Screen TB patients for DM
C.2. Ensure high quality DM management among TB patients

TB = tuberculosis; DM = diabetes mellitus

Table 2: Screening for Diabetes and making the diagnosis of Diabetes

At first visit: time of registration or close to starting TB treatment

Screen first with a random blood glucose (RBG) using glucometer at any time.
- If the RBG is less than 110 mg/dl, then no further action is needed
- If the RBG is 110 mg/dl or greater, then do a second screen at next visit

Next visit:

Screen second with a fasting blood glucose (FBG) using glucometer.
- If FBG is less than 110 mg/dl, then this is normal
- If FBG is 110 – 125 mg/dl, then this indicates impaired glucose tolerance
- If FBG is 126 mg/dl or higher, then this indicates **Diabetes mellitus**

Table 3: Diabetes Screening by Strip method (NPCDCS guidelines)

Things Needed:

- A glucometer
- Test strips
- A lancet
- A notebook
- A pen

Steps:

1. Take out the glucometer and place on a flat surface.

2. Remove a test strip from the container and place in the glucometer. One end will need to face the top of the glucometer; usually it has a darker coloured line on it. This is where the blood will be placed for testing.

3. Turn on your glucometer.

4. Use a lancet to pierce the skin and obtain blood from the tip of a finger.

5. Place the blood sample on the test strip. The test strip package will have exact instructions, including blood sample size. Usually, this is accomplished by placing the blood drop against the edge or top of the strip.

6. Watch the glucometer screen. It should show a "waiting" or "processing" symbol, and will emit a beep when the sample has been tested. The results will be displayed as a number on the screen.

7. Record your test results in your notebook and pass this information to Medical officer.

Table 4: Referral form for TB patients referred to Diabetes care clinics

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Referral to Diabetes Care
(To be filled in duplicate by PHI MO. One copy for patient, one for record)

Dear doctor,

I am referring a TB patient under anti-TB treatment who has been diagnosed to be having diabetes mellitus (details below) to your centre for further evaluation and treatment for dm. Please provide feedback on the same form and send it through the patient.

- Name:
- Age:
- Sex:
- Fasting blood glucose(value and date):
- Date of starting TB treatment:

Referring Doctor: *Contact Phone #:*

Name & signature: *Date: _____*

Name & address of the PHI:

Details regarding Diabetes Care
(To be filled by the DM treating physician and sent to the referring PHI through the patient)

Patient started on diabetes treatment: yes/no

If yes, provide details of treatment

If no, reason:

Additional information:

Name & signature of the DM treating physician   *Date*

Annexes

Annex 1a: Quarterly Report of Diabetes Screening in TB Patients

Quarter =   **Year =**

a	Number of TB patients registered	
b	Number of current smokers (smoked in last 1 month)	
c	Number already known with Diabetes Mellitus (DM)	
d	Number not known to have DM at the time of screening (a-c)	
e	Of 'd', Number screened with Random Blood Glucose	
f	Of 'e', Number with Random Blood Glucose ≥ 110 mg/dl	
g	Of 'f', Number screened with Fasting Blood Glucose	
h	Of 'g', Number newly diagnosed with DM (FBG ≥ 126 mg/dl)	
i	Total number of DM (c+h)	
j	Of 'i', Number referred to Diabetes Care	
k	Of 'j', Number reached to Diabetes Care	

Quarterly Report completed one month after end of the quarter

Annex 1b: Instructions for preparing Quarterly Report

	Indicator	Explanation
a	Number of TB patients registered	Count the total number of TB patients registered in the quarter. (Column 1 of TB-DM register)
b	Number of current smokers (smoked in last 1 month)	Count the total number of 'Y' in column 2 of TB-DM register.
c	Number already known with Diabetes Mellitus (DM)	Count the total number of 'Y' in column 3 of TB-DM register.
d	Number not known to have DM at the time of screening (a-c)	This is obtained by subtracting number of TB patients with previously known DM (c) from total TB patients registered (a).
e	Of 'd', Number screened with Random Blood Glucose	Count the total number of 'Y' in column 4 of TB-DM register. Please note that this cannot be greater than 'd'.
f	Of 'e', Number with Random Blood Glucose $\geq$ 110 mg/dl	Count in column 5 the number of entries greater than or equal to 110.
g	Of 'f', Number screened with Fasting Blood Glucose	Count the total number of 'Y' in column 6 of TB-DM register. Please note that this cannot be greater than 'f'.
h	Of 'g', Number newly diagnosed with DM (FBG $\geq$ 126 mg/dl)	Count in column 7 the number of entries greater than or equal to 126.
i	Total number of DM (c+h)	This is obtained by adding number of newly diagnosed DM (h) and previously known DM (c)
j	Of 'i', Number referred to Diabetes Care	Count the total number of 'Y' in column 9 of TB-DM register. Please note that this cannot be greater than 'i'.
k	Of 'j', Number reached to Diabetes Care	Count the total number of 'Y' in column 10 of TB-DM register. Please note that this cannot be greater than 'j'.

Annex 2a: DM Screening Register for Tuberculosis Patients (TB-DM register)

Quarter _____   **Year _____**

1	2	3	Complete these columns only if answer to column 3 is 'No'					9	10
			4	5	6	7	8		
TB Number	Current Smoker Y/N	**Known DM Y/N**	Screen with RBG Y/N (Date)	Result of RBG (mg/dl)	Screen with FBG Y/N (Date)	Result of FBG (mg/dl)	**New DM Y/N**	Referred to DM care Y/N (Date)	Reached DM Care Y/N (Date)

Current Smoker = smoked cigarettes/bidis in the last one month
DM = diabetes mellitus; RBG = Random Blood Glucose; FBG = Fasting Blood Glucose; Y-Yes; N-No
If Known DM (column 3) is 'Y', then write NA (Not applicable) in columns 4-8
If Known DM (column 3) is 'N', then screen for DM
If RBG ≥ 110 mg/dl, do second screen with FBG at next visit
If FBG ≥ 126 mg/dl, diagnosis = Diabetes Mellitus

Annex 2b: Instructions for recording in TB-DM register

Column No	Explanation	Source
1	TB Number will be serially numbered as per the TB register (starting 1 from January 1, 2012).	TB register
2	If the TB patient has been smoking cigarettes or bidis (even once) in the last one month, he will be considered as current smoker and recorded as 'Y', or else 'N'.	TB treatment card
3	If the patient was already diagnosed with Diabetes Mellitus or on anti-diabetic treatment, then record 'Y'; or else record 'N'. The documented evidence is required to confirm the diagnosis or treatment with oral hypoglycemics or insulin. If the patient is already diagnosed to be DM before current screening, i.e., column 3 is 'Y', then write NA (for Not applicable) in columns 4-8. If the answer is "N", then proceed with blood glucose screening	TB treatment card
4	If RBG has been done, write 'Y' and the date (dd/mm/yy) when Random Blood Glucose was done; else write 'N'.	TB treatment card
5	Write the value of RBG (in mg/dl); If RBG ≥ 110 mg/dl, do second screen with FBG at next visit	TB treatment card
6	If FBG has been done, write 'Y' and the date (dd/mm/yy) when Fasting Blood Glucose was done; else write 'N'.	TB treatment card
7	Write the value of FBG (in mg/dl); If FBG ≥ 126 mg/dl, diagnosis of Diabetes Mellitus is made.	TB treatment card
8	If FBG ≥ 126 mg/dl, diagnosis = Diabetes Mellitus and mention 'Y'; else record 'N'	TB treatment card
9	All TB patients with Diabetes Mellitus (whether newly diagnosed or previously known) will be referred to diabetic care using the referral form (Table 3). If the patient has been referred, mention 'Y' the date of referral (dd/mm/yy) in this column. If the patients has not been referred, mention 'N'	TB treatment card
10	If the TB patient with DM (whether newly diagnosed or previously known case) has reached the health institution where DM care is provided, (based on the feedback on the referral form in Table 3), mention 'Y' and the date of reaching (dd/mm/yy) the institution where anti-diabetic treatment is provided. If there is no feedback, mention 'N'.	TB treatment card

Exercises

Exercise 1: Entering patient data to the DM screening register for TB patients

Instructions:
- Participants need one copy of the DM screening register for TB patients
- There are 5 patients listed here
- Read out their details and ask the participants to complete the 5 rows of the Register

	Patient 1	**Patient 2**	**Patient 3**	**Patient 4**	**Patient 5**
TB Reg. Number	14	15	16	17	18
Name	Patel	Singh	Krishna	Dupeet	Reddy
Date of TB Registration	6-10-2011	7-10-2011	7-10-2011	9-10-2011	12-10-2011
Current Smoking	Y	N	N	Y	N
Known DM	N	N	N	N	Y
Screen RBG Date	6-10-2011	7-10-2011	7-10-2011	9-11-2011	NA
Result RBG	100	110	140	156	NA
Screen FBG Date		9-11-2011	5-11-2011	3.1.2012	NA
Result FBG		100	126	140	NA
New Diagnosis DM	N	N	Y	Y	N
Refer to DM care Date	N	N	Y 1-12-2011	Y 3-1-2012	Y 2-1-2012
Reached DM care Date	N	N	Y 1-12-2011	Y 4-1-2012	N

Exercise 2: Cohort reporting of DM screening in TB patients

Instructions for the Participants:
Take the following two pages of completed rows from the Register on DM screening in TB patients.
There are 20 patients and use their data to complete the cohort reporting form

DIABETES (DM) SCREENING REGISTER FOR TUBERCULOSIS PATIENTS

Quarter 4   **Year 2011**

1	2	3	Complete these columns only if answer to column 3 is 'No'					9	10
			4	5	6	7	8		
TB Number	Current Smoker Y/N	**Known DM Y/N**	Screen with RBG Y/N (Date)	Result of RBG (mg/dl)	Screen with FBG Y/N (Date)	Result of FBG (mg/dl)	**New DM Y/N**	Referred to DM care Y/N (Date)	Reached DM Care Y/N (Date)
14	Y	N	Y (12-10-2011)	78			N		
21	N	N	Y (13-10-2011)	81			N		
15	N	N	Y (11-10-2011)	195	Y (12-11-2011)	145	Y	Y (12-11-2011)	Y (15-11-2011)
16	N	N	Y (11-10-2011)	108			N		
22	Y	N	Y (14-10-2011)	115	Y (21-11-2011)	110	N		
23	N	N	Y (15-10-2011)	144	Y (23-11-2011)	136	Y	Y (12-12-2011)	N
18	N	N	Y (13-10-2011)	80			N		
20	N	N	Y (12-10-2011)	149	Y (24-10-2011)	142	Y	Y (24-10-2011)	N
19	Y	Y	NA	NA	NA	NA	Y	Y	N
17	N	N	Y (11-10-2011)	87			N		

DIABETES (DM) SCREENING REGISTER FOR TUBERCULOSIS PATIENTS

Quarter 4   **Year 2011**

1	2	3	Complete these columns only if answer to column 3 is 'No'					9	10
			4	5	6	7	8		
TB Number	Current Smoker Y/N	**Known DM Y/N**	Screen with RBG Y/N (Date)	Result of RBG (mg/dl)	Screen with FBG Y/N (Date)	Result of FBG (mg/dl)	**New DM Y/N**	Referred to DM care Y/N (Date)	Reached DM Care Y/N (Date)
24	Y	N	Y (24-10-2011)	92			N		
25	N	N	Y (25-10-2011)	98			N		
26	N	N	Y (26-10-2011)	171	Y (12-11-2011)	142	Y	Y (22-11-2011)	Y (25-11-2011)
27	N	N	Y (27-10-2011)	105			N		
28	N	N	Y (27-10-2011)	122	Y (21-11-2011)	116	N		
29	N	N	Y (27-10-2011)	148	Y (23-11-2011)	138	Y	Y (23-11-2011)	Y (23-11-2011)
30	N	N	Y (28-10-2011)	91			N		
31	N	N	Y (28-10-2011)	149	Y (24-11-2011)	164	Y	Y (24-11-2011)	Y (24-11-2011)
32	Y	Y	NA	NA	NA	NA	N	Y (24-11-2011)	Y (24-11-2011)
33	N	N	Y (29-10-2011)	100			N		

Current Smoker = smoked cigarettes/bidis in the last one month
DM = diabetes mellitus; RBG = Random Blood Glucose; FBG = Fasting Blood Glucose; Y-Yes; N-No
If Known DM (column 3) is 'Y', then write NA (Not applicable) in columns 4-8
If Known DM (column 3) is 'N', then screen for DM
If RBG ≥ 110 mg/dl, do second screen with FBG at next visit
If FBG ≥ 126 mg/dl, diagnosis = Diabetes Mellitus