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ORIGINAL RESEARCH

The role of Diabetes mellitus comorbidity on Tuberculosis treatment outcomes in Nepal: A prospective cohort study

Roshan Kumar Mahato[1], Wongsa Laohasiriwong[1], Rajendra Koju[2]

[1] Faculty of Public Health, Khon Kaen University, Khon Kaen, Thailand;
[2] Kathmandu University School of Medical Sciences, Department of Internal Medicine, Dhulikhel Hospital, Kathmandu University Hospital, Nepal.

Corresponding author: Assist Prof. Dr. Roshan Kumar Mahato;
Address: Faculty of Public Health, Khon Kaen University, Khon Kaen, Thailand;
E-mail: mahatoroshank@kusms.edu.np

Abstract

Aim: The Objective of this study was to assess the effect of Diabetes Mellitus (DM) on treatment outcomes of tuberculosis (TB) patients in the Central Development Region of Nepal.
Methods: A prospective cohort study was conducted in central Nepal. The study population of n=408 was consecutively recruited from treatment centers of all 19 districts of central Nepal. The TB cases (n=306) and TB with DM (n=102) cases were followed up for the estimation of blood glucose level, HbA1c level, and sputum examination on 2, 5, and 6 months after TB treatment started. The Generalized Estimating Equation (GEE) was performed to identify the risk ratio among TB and TB with DM cases on treatment outcome.
Results: Our study identified that the magnitude of treatment failure among the tuberculosis cases was 19.7% (95% CI: 17.44-21.95). The GEE analysis observed that factors associated with the treatment failure had uncontrolled DM (HbA1C ≥7 %) (adj.RR=5.24, 95% CI: 2.58-10.62, P value <0.001), aged ≥ 45 (adj.RR= 6.13, 95% CI: 2.55-14.76, P value <0.001), had inadequate financial status (adj.RR= 2.33, 95% CI: 1.07-5.06, P value 0.033) and had prior TB (adj.RR=2.33, 95% CI: 1.09-4.97, P value 0.028) respectively.
Conclusion: The prevalence of worsening TB treatment among patients with TB and DM was significantly higher than those who had TB only. Poor glycaemic control, increasing age, inadequate financial status, and previous history of tuberculosis were strong predictors of worsening tuberculosis treatment outcomes.

Keywords: *Central Nepal, Generalized Estimating Equation, Glycaemic control, Tuberculosis with Diabetes mellitus.*

Conflict of interest: None declared.

Ethical approval: The Ethics Committee in Human Research of Khon Kaen University, Khon Kaen, Thailand (HE612209), the Nepal Health Research Council (2640) and Institutional Review Committee (Protocol approved number 01/18), Kathmandu University School of Medical Sciences, Dhulikhel, Nepal had approved to conduct this study.

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Introduction

Nepal is passing through a phase of epidemiological transition from a higher prevalence of communicable diseases to non-communicable diseases (NCDs). It is currently suffering from a double burden of diseases. Various small studies from different parts of the country on diverse populations have shown varying prevalence rates of type 2 diabetes mellitus ranging from 6.3 to 8.5%. However, a systematic review and meta-analysis from 2000 to 2014 illustrate that the prevalence of type 2 diabetes reached a minimum of 1.4% to a maximum of 19.0%. The pooled prevalence of type 2 diabetes was 8.4% (95% CI: 6.2-10.5%). In addition, prevalence of type 2 diabetes in urban and rural populations was 8.1% (95% CI: 7.3-8.9%) and 1.0% (95% CI: 0.7-1.3%), respectively (1). TB patients beginning TB treatment with Diabetes comorbidity experience tardy regain of body mass and haemoglobin (2,3), which are essential for the profound recovery from both diseases (4). In addition, previous studies have revealed that Diabetes may weaken sputum conversion (2,5-7), cure and increase the risk of relapse (4,8,9), and raise the risk of anti-TB drug resistance as well (10,11). Furthermore, a recent study observed that TB with DM was associated with some critical socio-demographic factors, including age, unemployment, literacy, and polluted environment (12). A study from Nepal has also illustrated the prevalence of Diabetes among Tuberculosis patients, which was 9.1% among older age TB patients, tobacco users, people with high-income status, and a history of high blood pressure (8,13). Therefore, this present study aimed to identify the role of DM on the treatment response among TB patients in the Central Development Region of Nepal.

Methods

A prospective cohort study was conducted by administrating a structured questionnaire among the TB and TB with DM cases. In addition, we examined their blood glucose level, HbA1c level, and sputum grade 2, 5, and 6 months after starting treatment of TB to identify the treatment outcome of TB.

Study population

A total sample of 408 patients was estimated to be required by taking reference of risk ratio 2.93 of non-cure rate (28.65%) among the TB DM cases from a previous study (5). 408 TB cases were collected from the National Tuberculosis Centre and treatment centers of all 19 districts of the (Central Development Region) CDR, Nepal, and were examined for a blood glucose level. After that, 102 TB patients with Diabetes were considered cases, and 306 non-diabetes Tuberculosis patients were considered controls. Since six patients died and one got severe cancer during the study period, finally, 401 TB cases were followed up to identify treatment outcomes. Simultaneously, Body Mass Index (BMI) and blood glucose level were measured, and the sputum status was checked to determine treatment outcomes in two, five, and six months after starting treatment. The respondents who met the essential requirement for their family within the year of treatment were considered to have a good financial status.

Data Collection

The data was collected by using a structured questionnaire (Annex I). In addition, signs and symptoms of the tuberculosis cases were documented before the beginning of TB treatment, and additional history was obtained for the presence of DM or DM treatment, previous TB treatment, TB contacts, other comorbidities, and medication used.

Similarly, the patients were followed monthly during the intensive phase and bi-monthly after that. History, physical examination, blood testing, and microscopic examination were repeated after the intensive phase (at two months), five months, and at the end of treatment (at six months). TB program-specific definitions were used to classify

treatment response and outcome. TB registerswere cross-checked to ensure the quality of collected data.

Statistical analysis

All collected data were entered in Epi-Data (Version 3.1) and transferred to STATA (Version 13, Stata Corporation, College Station, TX USA) for analysis. The data collected after the respondents' follow-up in 2, 5, and 6 months were analysed using GEE to identify the risk ratio amongst the TB and TB with DM cases on treatment outcomes.

Results

Table 1 illustrates the characteristics of TB and TB with DM patients at 2, 5, and 6 months of the treatment period. The respondents (TB and TB with DM) aged ≥ 45 years old seemed to raise the non-curing rate from 43.30% at two months, 45.88% at five months, and 51.90% at six months of treatment. In addition, the tuberculosis patients living in rural areas were observed to fail sputum conversion at six months of treatment compared with two months of treatment, i.e., 12.50% to 11.49%, respectively.

Table 1. Characteristics of TB patients at 2, 5 and 6 months of treatment (n=401)

Characteristics	2 Months		5 months		6 months	
	Cured	Not cured	Cured	Not cured	Cured	Not cured
Gender						
Male	185 (60.86)	64 (65.98)	192 (60.76)	57 (67.06)	192 (59.63)	57 (72.15)
Female	119 (39.14)	33 (34.02)	124 (39.24)	28 (32.94)	130 (40.37)	22 (27.85)
Age (years)						
<45	204 (67.11)	55 (56.70)	213 (67.41)	46 (54.12)	221 (68.63)	38 (48.10)
≥ 45	100 (32.89)	42 (43.30)	103 (32.59)	39 (45.88)	101 (31.37)	41 (51.90)
Marital status						
Single	106 (34.87)	26 (26.80)	109 (34.49)	23 (27.06)	114 (35.40)	18 (22.78)
Married	198 (65.13)	71 (73.20)	207 (65.51)	62 (72.94)	208 (64.60)	61 (77.22)
Place of residence						
Urban	266 (87.50)	81 (83.51)	278 (87.97)	69 (81.18)	285 (88.51)	62 (78.48)
Rural	38 (12.50)	16 (16.49)	38 (12.03)	16 (18.82)	37 (11.49)	17 (21.52)
Employment						
Unemployed	69 (22.70)	27 (27.84)	71 (22.47)	25 (29.41)	70 (21.74)	26 (32.91)
Employed	235 (77.30)	70 (72.16)	245 (77.53)	60 (70.59)	252 (78.26)	53 (67.09)
Financial Status						
Adequate	216 (71.05)	66 (68.04)	225 (71.20)	57 (67.06)	223 (72.36)	49 (62.03)
Inadequate	88 (28.95)	31 (31.96)	91 (28.80)	28 (32.94)	89 (27.64)	30 (37.97)
History of Prior TB						
No	243 (79.93)	69 (71.13)	247 (78.16)	65 (76.47)	256 (79.50)	56 (70.89)
Yes	61 (20.07)	28 (28.87)	69 (21.84)	20 (23.53)	66 (20.50)	23 (29.11)
Treatment category						
Cat I	254 (83.55)	73 (75.26)	262 (82.91)	65 (76.47)	272 (84.47)	55 (69.62)
Cat II & Cat III	50 (16.45)	24 (24.74)	54 (17.09)	20 (23.53)	50 (15.53)	24 (30.38)
Drug resistant Status						
None	274 (90.13)	82 (84.54)	284 (89.87)	72 (84.71)	291 (90.37)	65 (82.28)
Any or Multi drug resistance	30 (9.87)	15 (15.46)	32 (10.13)	13 (15.29)	31 (9.63)	14 (17.72)
Initially Screened for DM						
No	285 (93.75)	88 (90.72)	298 (94.30)	75 (88.24)	307 (95.34)	66 (83.54)
Yes	19 (6.25)	9 (9.28)	18 (5.70)	10 (11.76)	15 (4.66)	13 (16.46)
History of Smoking						
Never	166 (54.61)	53 (54.64)	174 (55.06)	45 (52.94)	183 (56.83)	36 (45.57)
Ever Smoke but now quitted	138 (45.39)	44 (45.36)	142 (44.94)	40 (47.06)	139 (43.17)	43 (54.43)

Characteristics	2 Months		5 months		6 months	
	Cured	Not cured	Cured	Not cured	Cured	Not cured
History of alcohol consumption						
Never	186 (61.18)	52 (53.61)	195 (61.71)	43 (50.59)	204 (63.35)	34 (43.04)
Ever Drunk but now quitted	118 (38.82)	45 (46.39)	121 (38.29)	42 (49.41)	118 (36.65)	45 (56.96)
Type of house						
Cement	250 (82.24)	76 (78.35)	261 (82.59)	65 (76.47)	268 (83.23)	58 (73.42)
Mud/Brick	54 (17.76)	21 (21.65)	55(17.41)	20 (23.53)	54 (16.77)	21 (26.58)
Type of the floor						
Cement	265 (87.17)	80 (82.47)	276 (87.34)	69 (81.18)	284 (88.20)	61 (77.22)
Mud/Brick	39 (12.83)	17 (17.53)	40 (12.66)	16 (18.82)	38 (11.80)	18 (22.78)
Type of wall						
Cement	250 (82.24)	76 (78.35)	261 (82.59)	65 (76.47)	269 (83.54)	57 (72.15)
Mud/Brick	54 (17.76)	21 (21.65)	55 (17.41)	20 (23.53)	53 (16.46)	22 (27.85)
Blood Glucose level						
< 200 mg/dl	240 (78.95)	66 (68.04)	246 (77.85)	60 (70.59)	254 (78.88)	52 (65.82)
≥ 200mg/dl	64 (21.05)	31 (31.96)	70 (22.15)	25 (29.41)	68 (21.12)	27 (34.18)
Blood Glucose level of TB DM only						
< 200 mg/dl	46 (71.88)	18 (58.06)	55 (78.57)	9 (36.00)	54 (79.41)	10 (37.04)
≥ 200mg/dl	18 (28.13)	13 (41.94)	15 (21.43)	16 (64.00)	14 (20.59)	17 (62.96)
HbA1c Level of TB DM only						
< 7%	52 (81.25)	22 (70.97)	63 (90.00)	11 (44.00)	60 (88.24)	14 (51.85)
≥7%	12 (18.75)	9 (29.03)	7 (10.00)	14 (56.00)	8 (11.76)	13 (48.15)
BMI (Kg/m^2) of TB DM only						
<18.5	28 (43.75)	15 (48.39)	30 (42.86)	13 (52.00)	28 (41.18)	15 (55.56)
≥18.5	36 (56.25)	16 (51.61)	40 (57.14)	12 (48.00)	40 (58.82)	12 (44.44)

The increasing blood glucose levels among the TB with DM cases at 2, 5, and 6 months of the treatment period revealed a curing failure with 41.94%, 64.00%, and 62.96%, respectively. Similarly, an uncontrolled HbA1c level is also responsible for increasing the no-curing rate from 2 months (29.03%) to 5 months (56.00%). On the other hand, a raising BMI (Body Mass Index) level from low to normal was observed that enhanced the TB curing rate from 2 months (56.25%) to 6 months (58.82%) (Table 1).

Risk factors of the failure of treatment outcome: using the Generalized Estimating Equations model (GEE)

In this study, we analysed the risk factors for failure in treatment outcomes using the GEE model for repeated measures of the outcomes. It could identify that uncontrolled Diabetes during the treatment period (≥7 %) was one of the major risk factors of failure in TB treatment outcome (adj.RR=5.24, 95% CI: 2.58-10.62, P-value <0.001) as well as other risk factors including; age ≥ 45 yrs. (adj.RR=6.13, 95% CI: 2.55-14.76, P-value <0.001), inadequate financial status (adj.RR=2.33, 95% CI: 1.07-5.06, P-value 0.033) and history of prior tuberculosis (adj.RR=2.33, 95% CI: 1.09-4.97, P-value 0.028) respectively (Table 2).

Table 2. Risk Factors of Failure of Treatment Outcome among TB Patients Using the Generalized Estimating Equations Model

Factors	2 months		5 Months		Six months		Adj. (RR)	95% CI	P-Value
	n	% *	n	% *	n	% *			
HbA1c Level									<0.001
< 7 %	22	70.97	11	44.00	14	51.85	1	1	
≥7 %	9	29.03	14	56.00	13	48.15	5.24	2.58-10.62	

Factors	2 months		5 Months		Six months		Adj. (RR)	95% CI	P-Value
	n	% *	n	% *	n	% *			
Age (years)									<0.001
<45	55	56.70	46	54.12	38	48.10	1	1	
≥ 45	42	4330	39	45.88	41	51.90	6.13	2.55-14.76	
Financial Status									0.033
Adequate	66	68.04	57	67.06	49	62.03	1	1	
Inadequate	31	31.96	28	32.94	30	37.97	2.33	1.07-5.06	
History of Prior TB									0.028
No	69	71.13	65	76.47	56	70.89	1	1	
Yes	28	28.87	20	23.53	23	29.11	2.33	1.09-4.97	

Discussion

The prevalence of DM with TB will continue to increase, given the projected global expansion of DM. However, to our knowledge, this is the first study on this region that has been performed to identify the treatment outcomes of tuberculosis cases associated with DM. The data presented in this prospective cohort study show that a total of 401 respondents from both TB and TB with DM cases were observed until the last month of the tuberculosis treatment period, of which 79 or 19.7% (95% CI: 15.79-23.61) were not cured. A study conducted in Taiwan observed similarly 17.0% of treatment failure (14). A study conducted in the urban setting of Indonesia revealed that 22.2% of the DM patients with TB had positive sputum smears after the treatment period (15). In Pakistan, nearly one-third (33.6%) of study participants who had a previous history of tuberculosis was not cured (16). In addition, more than two-thirds of the respondents were delayed in seeking treatment (≥ 7 days). In addition, most of the respondents who failed to cure visited more than two health facilities for their diagnosis. This might be due to some health providers being unable to diagnose TB as well as Diabetes in the same place.

In our setting, we determined the role of DM and other risk factors on TB treatment outcome 2, 5 & 6 months of comprehensive treatment of our tuberculosis cohort. The sputum conversion guides the duration of TB treatment and infectivity of the patient but delayed conversion is also associated with an increased risk of relapse. While most studies outside the Middle East (16) have shown no relationship between DM and conversion at the end of 2 months, we considered a more extended observation period of 6 months.

Up to one-third of the world's population is infected with Mycobacterium tuberculosis; however, not all of those infected develop active TB because, usually, the immune system contains the germ. However, in some people, the bacteria remain dormant. They could become active, causing disease at later stages, especially those with risk factors such as old age, Diabetes, and other immunosuppressive treatments (7). So, after controlling the confounding factors, uncontrolled DM and five more risk factors showed an effect on the failure of TB treatment. The respondents who had uncontrolled DM with ≥7 % of HbA1c on two months of treatment were more than five times at risk of failing therapy. A systematic review found that uncontrolled DM (HbA1c ≥7) was a significant risk factor for positive sputum culture after two months (17). Another multicentre study conducted in South Korea revealed similar findings (18). Therefore, close monitoring of blood glucose and clinical conditions of TB patients with DM during the treatment period is crucial (19). Respondents aged ≥ 45 years had a greater risk of deteriorating TB treatment outcomes. A similar result has been observed by studies conducted in Indonesia (15), Taiwan (14), and Malaysia (2). Similarly,

inadequate financial status was also associated with failure of treatment. However, a study conducted in Kuala Lumpur, Malaysia, revealed no significant difference in the economic situation between both groups (2).

Furthermore, history of prior tuberculosis is doubling the effect of the non-curing rate of tuberculosis, supported by a study conducted in Malaysia: the authors observed that patients with a previous history of tuberculosis treatment were found to be three times more likely to have sputum smear non-conversion compared with those without prior exposure to tuberculosis (2). So, the reason might be a previous infection may induce initial cavitation and increase the extent of residual lesions of the lung (20).

Conclusion

This study outcome was a stepping-stone towards getting free of TB despite being diabetic. Our study observed that poorly controlled DM, increasing age, inadequate financial status, and previous history of tuberculosis were strong predictors of tuberculosis treatment failure. Therefore, a regular DM screening program would enhance TB control and reduce the burden of TB in Nepal. The National Tuberculosis Program (NTP) should establish a policy on collaboration with the private sector by setting up a referral system and providing basic knowledge on tuberculosis and Diabetes.

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ANNEX I: QUESTIONNAIRE FOR PARTICIPANTS

"The role of diabetes mellitus co-morbidity on tuberculosis treatment outcomes in Nepal: A Prospective Cohort Study"

General information:

CRF Number: ☐☐☐

Date of the interview: |……..| ….....| ……...| [Day | Month | Year]

Name of district: _____

Part A: Socio-demographic characteristics		**Code**
A1	Gender ☐ 1. Male ☐ 2. Female	A1
A2	Your age …….. Years old (full Year) What is your date of births? |……..| ….....| ……...| [Day | Month | Year]	A2….....
A3	Number of household members in your family?.....	A3……
A4	Marital status ☐ 1. Single ☐ 2. Married ☐ 3. Separated ☐ 4. Divorced	A4
A5	Place of residence ☐ 1. Urban ☐ 2. Rural ☐ 3. Homeless/displaced	A5
A6	What is your educational attainment? ☐ 1. No formal education ☐ 2. Primary ☐ 3. Secondary ☐ 4. High school or equivalence ☐ 5. Bachelor or equivalence ☐ 6. Higher than Bachelor degree	A6
A7	What is your main occupation? ☐ 1. None ☐ 2. Housewife ☐ 3. Student ☐ 4. Farmer ☐ 5. Unskilled worker ☐ 6. Employee ☐ 7. Business ☐ 8. Government officer ☐ 9. Other please specify ……	A7 A79xxx
A8	What is your average family monthly income …… NPR	A8……
A9	What is your average monthly income …… NPR	A9……
A10	What is your average monthly expense ……NPR	A10….
A11	What is your financial situation? ☐ 1. Not Enough ☐ 2. Not Enough with debt	A11

Part A: Socio-demographic characteristics		**Code**
	☐ 3. Enough with no saving ☐ 4. Enough with saving	

Part B: Health Status and History of Disease		
B1	Height …… cm	B1…..
B2	Weight ……kg	B2…..
B3	Systolic Blood Pressure …….mmHg	B3…..
B4	Diastolic Blood Pressure …….mmHg	B4…..
B5	What are the signs/ symptoms that make you to see the health personnel? **(Can choose more than one options)** ☐ 1. Cough ☐ 2. Fever ☐ 3. Loss of Weight ☐ 4. Haemoptysis ☐ 5. Chest pain ☐ 6. Other please specify ……	B51 B52 B53 B54 B55 B65xx
B6	History of Prior TB ☐ 1. No ☐ 2. Yes	B6
B7	If yes, where did you get the initial TB diagnosis? ☐ 1. Public Centre ☐ 2. Private Centre	B7
B8	Who made your initial TB diagnosis? ☐ 1. Paramedic's ☐ 2. Medical Officer ☐ 3. Chest specialist ☐ 4. Other please specify ……	B8
B9	Family history of TB ☐ 1. No ☐ 2. Yes	B9
B10	Date of first TB diagnosis? |……..| ….....| ……...| [Day | Month | Year]	B10
B11	How long does it take to get diagnosed with TB since having signs/ symptoms of TB…….(days)	B11….
B12	Number of health facilities visited before initial TB diagnosis ……..	B12….
B13	Which of the following investigations was performed to diagnose TB? **(Can choose more than one options)** ☐ 1. Sputum examination ☐ 2. X-ray ☐ 3. Gene-Xpert ☐ 4. PCR ☐ 5. Mountex Test ☐ 6. Other please specify ……	B13 1 B132 B133 B134 B135 B136x
B14	Sputum grade ☐ 1. + ☐ 2. ++ ☐ 3. +++	B14
B15	Type of TB ☐ 1. Positive sputum ☐ 2. Negative sputum ☐ 3. Extra pulmonary	B15

Part B: Health Status and History of Disease		
B16	Treatment of category ☐ 1. Cat I ☐ 2. Cat II ☐ 3. Cat III	B16
B17	**Stage of treatment period** |……..| ….....| [Day | Month]	B17
B18	In addition to tuberculosis, what other disease(s) has the patient been diagnosed? **(Can choose more than one options)** ☐ 1. None ☐ 2. Hypertension/ Cardiovascular ☐ 3. Diabetes ☐ 4. Diabetes ☐ 5. HIV/AIDS	B181 B182 B183 B184 B185
B19	Do you have any type of drug resistant? ☐ 1. None ☐ 2. Any drug resistance ☐ 3. Multi drug resistance	B19
B20	Have you been screened for Diabetes till date? **(If No, then jump to Q C1)** ☐ 1. No ☐ 2. Yes	B20
B21	If you have DM, which type of DM you have? ☐ 1. Type 1 ☐ 2. Type2	B21
B22	Do you have any type of diabetic comorbidity? **(Can choose more than one options)** ☐ 1. None ☐ 2. Hypertension/ Cardiovascular ☐ 3. TB ☐ 4. Cancer ☐ 5. HIV/AIDS ☐ 6. Any other diseases, please specify ……	B221 B222 B223 B224 B225 B226x
B23	Do you have any type DM complication? **(Can choose more than one options)** ☐ 1. None ☐ 2. CVD ☐ 3. Nephropathy ☐ 4. Neuropathy ☐ 5. Retinopathy ☐ 6. Hearing Impairment ☐ 7. Any other diseases, please specify ……	B231 B232 B233 B234 B235 B236 B237x
B24	If, previously diagnosed date of first DM diagnosis? |……..| ….....| ……...| [Day | Month | Year]	B24
B25	If you have DM since how long you are getting treatment? …… months	B25….
B26	Mode of DM treatment? **(Can choose more than one options)** ☐ 1. Dietary control ☐ 2. Oral glycaemic control ☐ 3. Insulin Injection ☐ 4. Health education ☐ 5. Health Counselling ☐ 6. Exercise	B261 B262 B263 B264 B265 B266

Part B: Health Status and History of Disease		
	☐ 7. Any other diseases, please specify ……	B267x
Part C: Behavioural and Environmental factors		
C1	History of smoking ☐ 1. Never ☐ 2. Currently ☐ 3. Ever smoke but now quitted	C1
C2	If smoke, since how long ……months	C2
C3	If quit, since how long ……months	C3
C4	If currently smoke, specify amount of daily consumption ……. (number of cigarettes/day)	C4….
C5	History of alcohol consumption ☐ 1. Never ☐ 2. Currently ☐ 3. Ever drunk but now quitted	C5
C6	If currently drink, since how long ……months	C6….
C7	If quit, since how long ……months	C7….
C9	What type of house do you have? ☐ 1. Cement ☐ 2. Mud/Brick ☐ 3. Other please specify ……	C33
C10	What is the type of the floor? ☐ 1. Cement ☐ 2. Mud/Brick ☐ 3. Other please specify ……	C34
C11	What type of wall do you have? ☐ 1. Cement ☐ 2. Mud/Brick ☐ 3. Other please specify ……	C35

Chart assessment tool

Date of assessment: |……..| ….....| ……...| [Day | Month | Year]

Name of the DOTS centre: _____

Description	Initial	2 months	5 months	6 months
Blood Glucose level				
Fasting				
Random				
HbA_{1c} Level				
Sputum grade				
Weight				
Height				
SBP				
DBP				