

# Pre-Diagnosis and Diagnosis Cost Associated before Initiation of Directly Observed Treatment, Short Course Regimen in Urban Pokhara, Nepal

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## ABSTRACT

**Background:** TB is disease that falls disproportionately in low income nation and the poor's. Many studies were available that assessed the Pre-treatment and treatment cost of TB but none of these literature differentiates pre-diagnosis and diagnosis cost of TB. This study assessed both Pre-diagnosis and Diagnosis cost of Tuberculosis.

**Materials and Methods:** An Institutional cross sectional study of all the patients (70) in intensive phase of Urban-DOTS regimen were included in study. Microsoft Excel was used for data entry and cleaning and analysis was done through SPSS version 16.0. P-value less than 0.05 were taken as the cut-off values for Non- Parametric test of statistical significance between the variables.

**Results:** Of 70 patients, majority were male 46 (65.7%), non-migrants 36 (51.4%), non-poor household member 39 (55.7%) and 55(76%) cope with household income and saving. The Median Pre-diagnosis and Diagnosis cost was \$ 74.61 (23.87 – 165.70) and \$ 15.38 (5.20 – 187.50) respectively. Total cost for the patients before initiation of DOTS regimen were associated with household income group, diagnostic centre, number of health care provider, and coping mechanisms (P < 0.05).

**Conclusion:** The median total cost before initiation of DOTS regimen was \$ 87.13 (36.336 – 332.00) and accounted 3.45% (0.99 – 9.09) of median annual household income of the patients. The study urges for the medical insurances, medical compensations and active case finding approaches that ultimately reduce the cost of TB before the initiation of DOTS regimen.

**Keywords:** TB, Pre-Diagnosis, Diagnosis, Cost, DOTS

## INTRODUCTION

World Health Organization (WHO) estimated that every year 100 million people get into poverty and other 150 million suffered due to payment made for health service. <sup>(1)</sup> In low income nation where 90% population lived, 10% cases entail ruinous cost. <sup>(2)</sup> In the resource deprived and social solidarity absent condition patients and their families are escorted to economic burden due to the illness. Studies found that TB the

disease that falls disproportionately to the poor put household on risk of impoverishment. A review literature reported that total economic burden due catastrophic cost (more than 10% of annual households income) to the household of patients is dominated by the indirect cost elements. <sup>(3)</sup> Illness cost effects on treatment seeking behavior and produce catastrophic effects on the household level. A household victimized from the catastrophic payment

has to sacrifice other basic needs (such as food, school fees) or sell off assets or to bring upon debt at cost of mitigating with economic consequences of direct and indirect cost of Tuberculosis (TB).<sup>(4)</sup>

In low and middle income countries mean total cost varies from \$55 to \$ 8198. Contribution of both un-weighted average direct medical cost and un-weighted average non-medical cost on total cost was equal. Foregone income due to TB contributes 60 % (range 16-94%) of total cost. Economic cost before the treatment of the TB is equal to the cost after the initiation of treatment.<sup>(5)</sup> Out of pocket expenditure is the major source of financing for contributing the health care cost. Affordability or ability to pay for essential major services like health has been one of the major challenges in developing countries.<sup>(6)</sup> Beside unaffordable user fees, foregone income of both patients and caretakers has become a great challenge of for patients centered health care management. So a household has to face double burden of cost alleviated due to disease. Cost of the treatment has made a significant impact on the health inequalities among the people living on the same periphery of the health facilities. NFHS III India revealed that despite the centralization of the health facilities in cities, intra-urban inequalities are worsening.<sup>(7)</sup>

Despite Directly Observed Treatment Short Course (DOTS) approach India with fee diagnosis and treatment in South Indian TB patients annually bear more than \$ 3 billion as out-pocket expenditure.<sup>(8)</sup> In its rural Uganda Pre-diagnosis cost account half of the monetary cost and huge time lost lead to significant increase in cost due to foregone income before the diagnosis of TB<sup>(9)</sup> whereas the pre-diagnosis cost has the share of the more than 80% of the total cost of TB in Nigeria.<sup>(10)</sup>

Nepal has the huge burden of TB and massive investment has been done by different government and non-government organization by providing free direct

diagnosis and treatment cost. Many studies in TB conducted but very few contain the economic aspects of TB from patient's perspective. And none of them differentiate the pre-diagnosis cost with diagnosis cost. A patient cost is an integral function of health care financing system and the accessibility of the diagnosis is reflected by the Pre-diagnosis cost.<sup>(11)</sup> The objective of this study was to figure out direct out-of-pocket expenditures and indirect costs due to foregone income and differentiate it based on pre-diagnosis and diagnosis phase of TB treatment process of confirmed patients in Pokhara, a urban setting of western Nepal.

## MATERIALS AND METHODS

**Study design:** The study design was Institution based descriptive cross-sectional on all TB patients in the intensive phase of treatment at health facilities in Pokhara Sub-metropolitan city. It was carried between June and July 2014.

**Study Setting:** The study area Pokhara, headquarter of Western Development Region of Nepal has area of 55.22 square kilometer with the population of 264,991.<sup>(12)</sup> In Pokhara the treatment service other than DOTS approach was not recommended. The treatment was provided through 12 DOTS centre: 1- Private Hospital, 2- Private Clinics and 1-DPHO DOTS, 1-Health post and others through Municipality wards offices. All of them are provided services under Urban DOTS centre.

**Participants:** List of the patients and the respective 12 DOTs centre were obtained from the District Public Health office of Kaski District and all the eligible patients were interviewed.

### Inclusion criteria:

- TB patients aged 15 years old
- Patients on Intensive phase of treatment were included because to minimize the recall bias. They cost can be more comparable because they seek the health facilities at the same time

### Exclusion criteria

- Currently hospitalized patients
- Not willing to respond

**Data Collection:** The data used was collected through interview from a survey of all eligible patients from 12 DOTS centre under Urban DOTS Pokhara. The data was collected from 70 patients using the structure questionnaire and through observation of TB card of the patients. Data was collected while the patients were visiting to the DOTS centre for drug. The survey's design is described below:

**Development of the questionnaire:** The Tool to Estimate Patients' Costs questionnaire that had been developed by KNCV Tuberculosis Foundation was taken as the major part of questionnaire. (13) The questions that provided the cost before the

initiation of treatment were adopted in the questionnaire.

**Data entry and analysis:** Data was first entered through Ms-Excel by three people and checked to remove interpersonal error. Data cleaning was done through Ms-Excel. Data Analysis was done through SPSS version 16. Normality test was done by using Shapiro-Wilk test. Due to the limited sample size and violation of assumption of Parametric test, Non-Parametric Statistics were used for the analysis of data. For evaluation the total cost before the initiation of treatment among different groups Mann Whitney U test and Kruskal Wallis H test were used. Box-Plot was used to symmetric nature of the data among groups.

**Ethical Consideration:** Informed Consent was obtained from District Public Health Office, Kaski, Urban DOTS Centers and Patients visiting DOTS centers.

**Table 1: Definitions used in this study**

Sn	Variable	Definition
1.	Pre-diagnosis Cost	Defined as the cost incurred between the onset of symptoms and the diagnosis of TB
2.	Diagnosis Cost	Defined as the cost incurred at the time of diagnosis of the disease
3.	Direct Cost	Out of Pocket cost for the payment of the health services and those incurred on the way during the access of health services. This includes Administrative cost, Test Cost, Radiological cost, drug cost, Travel cost, Food cost and Accommodation cost.
4.	Indirect Cost	Foregone income due to illness and monetary value of the time spend while undertaking the health services.
5.	Coping Cost	Cost incurred by patients or household to cope with the health services cost by borrowing money or selling household assets. And is estimated adding (if both events occur otherwise the value of single event) interest paid for the borrowing and the loss incurred due to sell off assets.
6.	Patients Cost	The cost incurred by the patients for rendering the health services
7.	Guardian Cost	The cost incurred by the Guardian/caretaker for helping the patients
8.	Poor patients	The patients whose total annual income is equal or less than median annual income of the patients (\$2495) is called poor patient. The patients whose total annual income is more than the median annual income of the patients is called Non-Poor patients.
9.	Poor Household	The household whose total income is less or equal to median annual income of the households (\$3120) is Poor household. The household whose annual income is more than the median annual household income is non Poor Household.
10.	Total cost before the initiation of Treatment	Cost before the initiation of DOTS treatment. It is estimated by summing Pre-diagnosis and Diagnosis cost.

## RESULTS

All total 70 eligible patients in intensive phase of Urban DOTS of Pokhara were interviewed for the study. Table 2 provides the socio-demographic and clinical characteristics of the patients.

The study includes higher proportion (65.7%) of male, 40% of patients were more than 35 years of age and nearly half of the patients were migrants. Only one third of patients after the initiation of symptoms have visited government health facilities

and majority of the patients (57.1%) have been correctly diagnosed as TB patients from governmental health institute whereas more than one fourth patients have to be hospitalized for the diagnosis of TB.

When asking about the number of provider 68.6% reported that they visited more than one health care provider (hospitals, clinics, Health post) and 70% of the patients visited more than one time for the health care services before treatment phase.

**Table 2: General Characteristics of Patients**

<b>Variables</b>	<b>Total (%)</b>
<b>Gender</b>	
Male	46 (65.7)
Female	24 (34.3)
<b>Age in Years</b>	
≤35	42(60)
>35	28(40)
<b>Migrants</b>	
Yes	34 (48.6)
No	36 (51.4)
<b>No. of family Member</b>	
≤4	43 (61.4)
>4	27 (38.6)
<b>Education level</b>	
No formal Education	7 (10)
Primary/Lower Secondary	33 (47.1)
Secondary/Higher Secondary	22 (31.5)
Graduate and Above	8 (11.4)
<b>Occupation</b>	
Sales/services	16 (22.8)
Agriculture	5 (7.2)
Household	7 (10)
Production/construction	21 (30)
Other (Students and Unemployed)	21(30)
<b>Patients Income Group</b>	
Poor patient	35 (50)
Non-Poor Patients	35 (50)
<b>Household Income Group*</b>	
Poor Household	31(44.3)
Non-Poor Household	39(55.7)
<b>Primary Earner</b>	
Patient	37 (59)
Others (Unmarried and Widows)	33 (41)
<b>Medical Insurance</b>	
Yes	0 (0)
No	70(100)
<b>Type of TB</b>	
Smear Positive Pulmonary TB	36 (51.4)
Smear Negative Pulmonary TB	9 (12.9)
Extra Pulmonary TB	25 (35.7)
<b>HIV Status</b>	
Yes	3 (4.3)
No	67 (95.7)
<b>First Contact for health services</b>	
Government	23 (33)
Non-Government	47 (67)
<b>Diagnostic Centre*</b>	
Government	40 (57.1)
Non-Government	30 (42.9)
<b>Hospitalized*</b>	
Yes	15 (21.4)
No	55 (78.6)
<b>Traditional Healer</b>	
Yes	3 (4.3)
NO	67 (95.7)
<b>Delay</b>	
No Delay	35(50)
Delay	35(50)
<b>Number of Health Service Provider</b>	
One	22 (31.4)
More than One	48 (68.6)
<b>Frequency of Visit to Health Service Provider</b>	
One	21 (30)
More than One	49 (70)
<b>Coping Mechanism</b>	
Household Income and Savings	55 (78.6)
Borrowing along with Household income and saving	12 (17.1)
Selling of assets with borrowing and household income and saving	3 (4.3)

**Table 3: Association between characteristics of Patients and Total cost prior to initiation of DOTS Regimen**

Variables	Median Total Cost (US Dollar-\$)	Mann Whitney Test Statistics	P-value
<b>Gender</b>			
Male	56.82(36.16-173.90)	467	0.301
Female	118.2(40.89-395.46)		
<b>Age in Years</b>			
≤35	62.36(34.54-350.35)	553	0.686
>35	96.20(38.85-282.10)		
<b>Migrants</b>			
Yes	56.812(36.16-173.90)	511	0.241
No	209.17(33.12-392.70)		
<b>No of family Member</b>			
≤4	118.97(40.48-349.47)	479	0.227
>4	51.06(29.97-300.70)		
<b>Education level</b>			
No formal Education	60.18(7.87-107.00)	3.341**	0.343
Primary/Lower Secondary	67.44(35.87-305.73)		
Secondary/Higher Secondary	159.39(39.44-416.55)		
Graduate and Above	216.67(24.01-391.69)		
<b>Occupation</b>			
Sales/services	56.20(19.06-319.86)	.593**	0.968
Agriculture	247.60(8.62-415.95)		
Household	60.18(38.25-241.98)		
Production/construction	92.03(42.76-420.60)		
Other	78.37(37.39-373.06)		
<b>Primary Earner</b>			
Patient	100.39(39.36-337.90)	579	0.722
Others	67.44(33.49-327.00)		
<b>Type of TB</b>			
Smear Positive Pulmonary TB	59.82(30.33-291)	3.056*	0.215
Smear Negative Pulmonary TB	219.4(65.12-974.06)		
Extra Pulmonary TB	117.58(38.67-320.36)		
<b>HIV Status</b>			
Yes	1812.90(40.61-2862.00)	47	0.131 <sup>#</sup>
No	82.22(35.57-300.70)		
<b>Traditional Healer</b>			
Yes	621.62(54.25-2862.00)	45	0.116 <sup>#</sup>
No	82.23(35.58-300.80)		
<b>Patients Income Group</b>			
Poor patient	56.34(31.40-241.98)	496	0.171
Non-Poor Patients	145.64(40.96-413.51)		
<b>Household Income Group*</b>			
Poor Household	51.056(23.94-118.97)	395	0.014
Non-Poor Household	211.03(40.61-413.51)		
<b>Delay</b>			
No Delay	56.34(20.97-349.37)	533	0.354
Delay	165.77(40.96-326.23)		
<b>First Contact for health services</b>			
Government	92.03(38.26-287.42)	367	0.70
Non-Government	182.23(19.36-353.30)		
<b>Diagnostic Facility*</b>			
Government	50.12(130.34-154.07)	301	<0.001
Non-Government	274.76(63.34-577.14)		
<b>Hospitalized*</b>			
Yes	413.52(353.40-730.89)	45	<0.001
No	51.06(29.98-165.77)		
<b>Number of Health Service Provider*</b>			
One	33.80(15.29-290.73)	331	0.013
More than One	132.30(48.82-352.32)		
<b>Number of Visit to Health Service Provider</b>			
One	40.97(15.29-333.27)	373	0.070
More than One	119.97(46.65-337.80)		
<b>Coping Mechanism*</b>			
Household Income and Savings only	57.27(29.66-264.69)	8.704**	0.013 <sup>#</sup>
Borrowing and Household saving	215.20(54.98-742.67)		
All	350.30(100.38-2862.00)		

# Fisher Exact Test P-value

\*Significant variable at 0.05 level of significance

\*\* Kurskal-Wallis H Test statistic

Similarly 60% of the patients were primary income earner for the family, 44.3% patients were from poor household and beside using household saving and income. Majority of patients (78.6%) used household income and saving where as 17.1% remaining patients borrowed money from others (neighbors, friends, financial institutes) along with household income and saving for coping with the cost of TB before initiation of treatment. Furthermore 4.3% claimed that they sold assets along with borrowing and usage of household saving and income.

The above table 3 illustrated the role of the characteristics of the patients in determining the total cost of TB before the diagnosis of TB. There is no statistical difference in the median total cost before the initiation of DOTS by socio-economic characteristics of the patients: Gender, age, migrant status, educational status, occupational status, and primary earner of the family and patients income groups. But only the household income affected the median total cost (P-value=0.014, Mann-Whitney U value=395). The median cost of the patient (\$ 211.03) from non-poor family was significantly greater than the median cost (\$ 51.056) of the poor family.

Similarly health seeking and medical characteristics of the patients: Type of TB, HIV status, delay, contact with traditional healer, institute for first contact after symptoms and number of visit for seeking health services did not play significant role in determining the total cost before the initiation of treatment. As far as hospitalization is concern there was a significant difference in the median cost of hospitalized and non-hospitalized patients. (P-value<0.01, Mann-Whitney U Value=45). The median cost for hospitalized and non-hospitalized patients was \$413.52 and \$52.06 respectively. Similarly the cost for patient that have visited more than one health care provider (\$33.80) was statistically higher than patients those who have visited only one provider (\$=132.30) (P-value=0.0013, Mann-Whitney U value=331). Coping mechanism of the patients have a significant impact on the total cost. The cost of the patients who used household income and saving for seeking diagnosis was only \$ 57.27 whereas the patients who have borrowed money along with using household was \$ 215.20. The median cost of the patients who sold household assets along with borrowing and using household income and saving was \$ 350.30.

**Table 4: Total patients' and Guardian costs on Pre-diagnosis and Diagnosis phase of TB care**

	N	US (Dollar)	Median Percentage out of Total Annual Household Income
<b>Median Pre-diagnosis Cost</b>			
Patients Direct Cost	49	57.90(23.06-140.80)	
Guardian Direct Cost	23	2.49(1.38-13.37)	
Patients Indirect cost	34	37.38(7.45-89.36)	
Guardian Indirect cost	23	2.37(0.72-3.49)	
Total Pre-diagnosis Cost	49	74.61(23.87-165.70)	2.75(1.03-4.93)
<b>Median diagnosis Cost</b>			
Patients direct Cost	70	6.29(0.62-131.80)	
Guardian direct Cost	49	0.40(0.21-46.80)	
Patients Indirect Cost	70	7.1(4.28-14.84)	
Guardian Indirect Cost	49	0.63(0.37-3.72)	
Median Total Diagnosis Cost	70	15.38(5.20-187.50)	0.53(0.26-3.51)
<b>Coping Cost other than household saving and Income</b>	15	4.12(0.62-16.42)	0.13 (0.01-0.057)
<b>Median Total Cost before DOTS regimen</b>	70	87.13(36.16-332.00)	3.45(0.99-9.09)

Only 49 patients had undergone Pre-diagnosis test which illustrated that 21 (70-49) patients had been diagnosis as TB on their first visit to health institute. The Pre-diagnosis cost direct cost of the patients was

\$ 57.9 followed by Pre-diagnosis cost of the Guardian with only \$ 2.49. Similarly the patients direct Pre-diagnosis median cost was \$ 37.38 whereas Guardian Indirect cost was \$2.37. All together totals pre-diagnosis

median cost was \$ 74.61 with 2.75 median percentage of total household annual income.

At the time of diagnosis median direct cost paid by patients was \$ 6.29 whereas median direct diagnosis cost paid by Guardian was \$ 0.40. Similarly median indirect diagnosis cost bore by patients and Guardian worth \$7.1 and \$0.63. The total median Diagnosis costs attributed worth \$ 15.85 and shared 2.75% as the median percentage of total household income. All together 15 patients had to cope with cost by borrowing and selling assets. The median value of coping cost was \$4.12. Its median percentage of the income sacrificed for coping with the cost is 0.13 % of total household annual income.

In aggregate median total cost for the patients before the initiation of DOTS regimen accounted \$ 87.13. The median percentage of the income that patients had lost for the disease before the initiation of DOTS was 3.45%.

## DISCUSSION

This study demonstrates the burden faced by TB patients before initiation of DOTS regimen. Unlike other studies it segregated the cost before commencement of DOTS regimen into Pre-diagnosis and Diagnosis cost. The study shows that the medical and non-medical costs for the diagnosis of the disease are mandatory in Nepal. Although National TB control program mentions diagnosis cost of TB as free<sup>(14)</sup> but study indicates that patients are bound to pay certain amount of user fee charge even in governmental health institute. When the diagnosis is done on through DOTS centre of District public health office patients are charged with NPR 10 (around \$ 0.1) as a ticket charge. But when the patients undergo diagnosis through other government and other private health centers then they have to pay for administrative charge, and medical charge as in other disease.

In study almost 70% patients had to visit for more than one time for the

diagnosis of disease whereas about 68% patients have visited more than single health provider till the diagnosis of disease. This shopping around for the diagnosis, rendering private health care, and other medical and travel cost are the determinants for high cost of disease.<sup>(15)</sup> In matter relating to health seeking behavior, 67% people visited private health care provider as first visit after symptoms get noticed. But majority of patients were truly identified as TB patients only after rendering government institute. It indicates the better quality of government health institute regarding diagnosis of TB. Nearly half of the patients were migrants. And there was no significant contribution of migration status of patients. But it's important to consider that there are several ways in which migrants have to bear the brunt of living cost at greater scale than do inhabitant of the local area where treatment is being sought. These living costs for migrants go beyond loss of income and medical cost. They include higher cost of food, rent, traveling cost etc.

In India patients pay considerable amount before reaching the free diagnosis and treatment service provided through government institute. Before initiation of treatment patients among governmental health organization paid at least Indian INR 200 (around \$3.279) while patients among Private organization paid 6.5 times more than patients at governmental health organization.<sup>(16)</sup>

TB patients' faced substantial cost before and during the diagnosis of the disease. Guardian also sacrificed certain amount through direct cost and loss of income while rendering the health services for patients. Generally the priority of cost measurement in disease treatment process is focused on direct medical cost. The monetary value of pre-diagnosis indirect cost was equivalent to 65% of patients direct medical cost. But diagnosis indirect cost was found to be higher than diagnosis direct cost. Indirect cost in the study was found to be of significant value due to the inability to work and loss of work time

while rendering the services. It manifests that indirect cost rendering health services have the significant role on cost acceleration during pretreatment phase. In Uganda higher work lost was found before the diagnosis of TB. (17) Patient income doesn't determine the pretreatment cost. But due to disease income of patients is affected by productivity loss and raise in amount overdue. More than 50% of work day's loss due to TB occurred during pre-treatment phase and was reported as indirect indicator for patients delay for getting appropriated diagnosis. (16)

Beside using household Income and saving, study identified that 25% patients have to borrowing money or sell of household asset or both as coping mechanism with the high cost. It's the sign that household might undergo severe debt and lose of assets till the effective treatment of disease. According to Ramachandran R et.al cited by Dennis A. Ahlburg, in Tamil Nadu 67% of rural household 75% of urban households went on debt due to tuberculosis. In the same article Dennis A Ahlburg also mentioned that study of Pyerfound that in Bangladesh, household has to sale the assets followed by the credit creation due to loan as the response to the medical expense of the disease. Coping mechanism makes household more vulnerable to long term implication like future shocks, infant mortality and morbidity due to reduces food consumption and obstruct the economic recovery of the household. (18)

Studies in Nigeria and Kenya that clubbed Pre-diagnosis and Diagnosis cost together in the name of Pre-diagnosis/ Diagnosis cost. In Nigeria age group, HIV status and income status of the patients have contributed significantly on the pretreatment cost which is not supported by finding in this study and the study at Kenya. (10;19) Unlike the finding in Nigeria, this study demonstrates that non-poor household paid less than poor household during the rendering of proper diagnosis of disease. (10)

Household expenditure on health is not only the indicator for the economic prosperity of the household; it also indicates the accessibility of the country people towards the health. The study found that median annual income of the household of the patients was \$3120 and spent 3.34% of it till the identification of disease. Similarly, median annual income of the patients was \$2495 and median expenditure till the effective diagnosis of TB \$ 87.43. In Bangladesh proportion of the expenditure for only patients for effective diagnosis washing her than of cumulative cost of patients and Guardian at this study. The average total loss before effective treatment was \$245 whereas the annual household income was \$780. (20)

This study has several biases. Due to the cross sectional nature of the study patients has to recall the past events of the cost. Most of the patients were employed in informal sector and do don't have any fixed level of income. As the cost calculation and loss of the time value of money are based on the self-reported repose by the patients, chance of getting influenced by reporting and recall bias. Due to limited size of the participants and non-parametric statistics used may raise the question on the rigorousness of the findings. Based on the availability on more infrastructure and relatively higher per-capita income of the people at this study area makes the urban as economically advantageous. So the inference drawn from this study may not be applicable to other urban setting of the country.

## CONCLUSIONS

The study identified significant economic burden on Patients and households by Pre-diagnosis and Diagnosis cost produced by TB. In order to reduce the burden study appeals for introduction of social security schemes like medical insurance, compensations of medical and non-medical cost for migrants, poor, marginalized and other vulnerable communities. In addition to this,

government should also focus on passive case finding techniques that reduce patients delay and frequencies of shopping around the health centers for the effective diagnosis of TB.

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