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Conducted by

SAARC Member States

(2020-2024)

SAARC TB and HIV/AIDS Centre

CONTENTS

This volume contains: (Research 2020-2024)

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FOREWORD

Tuberculosis (TB) and HIV/AIDS remain public health challenges across the SAARC region, profoundly affecting millions of individuals and their communities. Between 2020 and 2024, this period has been further complicated by the COVID-19 pandemic which disrupted essential TB and HIV services and posed unprecedented obstacles to healthcare delivery and disease control efforts.

This comprehensive compilation of research and evaluation studies from 2020 to 2024 reflects a critical examination of the evolving epidemiology, service delivery challenges, and socio-economic impacts associated with TB and HIV/AIDS in the region. It includes pivotal assessments of catastrophic costs incurred by TB patients and their families, prevalence and risk behaviors related to HIV among marginalized populations such as prisoners, the effects of COVID-19 on TB case finding and treatment adherence, and the nutritional status of TB patients under support programs.

The findings emphasize the urgency of strengthening healthcare systems, advancing integrated care models for TB and HIV, and enhancing social protection mechanisms to mitigate the financial and psychological burdens on affected populations. Moreover, the research highlights the necessity of adaptive strategies and partnerships to sustain progress amidst concurrent public health crises.

The SAARC Tuberculosis and HIV/AIDS Centre (STAC) is steadfast in its commitment to support member countries through coordinated research, capacity building, and evidence-based policymaking. Through dissemination of these valuable insights and lessons learned, this report aspires to guide policymakers, healthcare providers, implementers, and researchers in their collective efforts to overcome challenges and drive toward the goal of ending TB and HIV/AIDS in the region.

We extend our sincere appreciation to all researchers, national programs, frontline health workers, and partner organizations whose dedication and collaboration have been instrumental in generating this knowledge and advancing public health priorities in South Asia.

23.8.2025

Dr. Anuj Bhattachan
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CATASTROPHIC COST INCURRED BY THE TB PATIENTS AND THEIR FAMILIES AND THE PREDICTORS OF CATASTROPHIC COST – SURVEY AMONG THE PATIENTS ATTENDING TB CLINICS IN SRI LANKA

2020

CATASTROPHIC COST INCURRED BY THE TB PATIENTS AND THEIR FAMILIES AND THE PREDICTORS OF CATASTROPHIC COST – SURVEY AMONG THE PATIENTS ATTENDING TB CLINICS IN SRI LANKA

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1. Background:

TB is the second leading infectious killer after COVID-19 and the 13th leading cause of death worldwide. It was also the leading killer of people with HIV and a major cause of deaths related to antimicrobial resistance (1). Millions of people continue to fall sick with TB each year. In 2020, an estimated 9.9 million (8.9-10.9 million) people fell ill with TB worldwide, of which 5.5 million were men, 3.3 million were women and 1.1 million were children. People living with HIV accounted for 8% of the total. There were cases in all countries and age groups, but overall 90% were adults (aged ≥15 years) who could contribute to the generation of household income in many ways (1).

TB is a disease which is closely related to social determinants of health and therefore it is said to be the disease of poor and marginalized. The major social determinants of TB include food insecurity, malnutrition, poor housing and environmental conditions, as well as financial, geographic and cultural barriers to health care access (3). At the household level, TB is mostly associated with smoking, alcohol consumption, low body mass index, lower level of personal education, unemployment, and lower household wealth (4). Therefore, higher incidences of TB are more likely to be in societies with high economic inequalities and low Socioeconomic Status (SES), and where people suffer from food insecurity and malnutrition. This is further evidenced in countries with high human development index, low child mortality and better access to improved sanitation the incidence of TB has been falling more quickly (5).

Similarly, the impact of TB on the social and economic development of a country is also considerable. Globally, Tuberculosis is most prevalent among the age group of 15–54, which is the most economically productive sector of the population (6, 7). The disease can therefore cause enormous economic and social disruption by reducing both labour supply and productivity. This shows that socio-economic development and TB is very closely linked with each other causing a viscous cycle.

When a patient with tuberculosis experience productivity loss causing loss of income is forced to spend on medical and other cost related to diagnosis and management of TB that particular patient will be overburdened economically leading to further deterioration of SES. Evidence suggests that the average expenditure incurred by patients in low- and middle-income countries on diagnosis and treatment of TB ranges from $55 to $8198 (8). In countries where government

spending on health is low and with a larger presence of

private players, patients may be forced to spend out-of-pocket (OOP) to meet the expenditure on health (9). OOP is the direct payment made by individuals at the time of service use for health services and nonmedical payments (such as transportation, accommodation, food charges), excluding prepayment for health services in the form of taxes or specific insurance premiums (10). The share of OOP in total health expenditure is a proxy measure of the degree to which people lack financial protection and, when it exceeds 40%, is termed as catastrophic expenditure (CHE) (10).

In 2014, the 67th World Health Assembly adopted a resolution to make the world free of TB by the year 2035. WHO's "End TB Strategy" provides a holistic overview of this resolution and has four principles and three pillars (11). The three high-level target indicators of the End TB Strategy are reductions in TB deaths by 95%, reductions in the TB incidence rate by 90% from 2015 level and the percentage of TB patients and their households experiencing catastrophic costs being maintained at zero. These indicators and targets are relevant to all countries, with interim milestones to be achieved by 2020, 2025 and 2030. By the end of 2019, at the global level, most of the WHO regions and many high TB burden countries were not on track to reach the End TB Strategy's 2020 milestones (20% reduction in TB incidence rate, 35% reduction in the number of TB deaths and reduction in the households experiencing catastrophic costs to 0%) (11).

Catastrophic health expenditures is defined as out-of-pocket expenditure for health care that exceeds a specified proportion of household income, with the consequence that the household may have to sacrifice the consumption of other goods and services necessary for their wellbeing (12-14). Catastrophic health expenditures do not necessarily mean high health care costs. Relatively small expenditures for common illnesses may have serious financial implications for poor households (15, 16). Over recent years, the World Health Organization (WHO) has promoted the concept of universal health coverage (UHC), emphasizing the need for access to services at an affordable cost to protect households from CHE (17).

The catastrophic costs indicator is a new inclusion in the End TB Strategy, in recognition of the fundamental role of costs as a significant impediment to accessing health care services and completing TB treatment. Despite the fact that TB diagnosis and care is provided free of charge in many countries, a number of studies have demonstrated that TB patients incur significant costs when accessing diagnostic and treatment services (18).

These costs can create barriers to accessing health care potentially leading to delayed TB diagnosis, ongoing transmission of TB in communities, poor TB treatment outcomes, excess mortality, and

impoverishment. In addition, these costs often affect the poorest groups in society the most, further placing individuals and families in a debilitating cycle of poverty and illness.

However, in view of the End TB Strategy, it is now recommended to measure catastrophic costs, incurred when the total costs exceed 20% of the annual household income (11). It is wider than catastrophic expenditure and includes indirect costs such as income loss related to time lost from work or loss of employment in addition to direct costs. Patients and families resort to some coping strategies to balance the costs incurred towards healthcare (19). The magnitude of the burden posed by the costs and the coping strategies adopted by the families determines the level of impoverishment.

2. **Justification:**

Sri Lanka is a lower-middle-income country with a GDP per capita of USD 3,853 (2019) and a total population of 21.8 million. Following 30 years of civil war that ended in 2009, the economy grew at an average 5.3 percent during the period 2010-2019. Sri Lankan health and social indicators rank among the highest in South Asia and compare favourably with those in middle-income countries. Economic growth has translated into shared prosperity with the national poverty headcount ratio declining from 15.3 percent in 2006/07 to 4.1 percent in 2016. Extreme poverty is rare and concentrated in some geographical pockets; however, a relatively large share of the population subsists on slightly more than the poverty line (20).

Sri Lanka has a well-developed free health care system and spend 3% of the GDP on health (21). Under universal health coverage, accessibility to health care services is highly ensured in the country. However, people have the freedom to choose the health care provider and may end up in either public sector or private sector according to their need and preference. When public sector is considered, people can choose the preferred care provider which range from primary care service provider to tertiary care service provider. However, the private sector provides around one–half of outpatient curative care and around 5–10% of inpatient care. Most private healthcare is paid for by individuals out of pocket, as health insurance is not widely available. Patients usually have to pay private institutions up-front for treatment (21). It was found that 0.1% or approximately 14 000

people are being pushed into poverty because of out-of-pocket health spending and 5.3% of people spent more than 10% of their household's total expenditure on health care (22).

When it comes to TB services, accessibility and affordability of TB services has been ensured from the past by decentralising TB diagnostic and treatment facilities in Sri Lanka. TB diagnostic services are provided for the patients via 26 District Chest Clinic (DCC) Laboratories and 170 microscopic centres situated in different types of general health care institutions and these services are free of charge.

Further, first line and second line drugs are provided only by the National TB Programme (NTP) via its 26 DCCs and 108 branch clinics to maximize the accessibility of the patients. Directly Observed Treatment (DOT) by a DOT provider in the neighbourhood of the patient supplies drugs during the intensive phase of the treatment thus minimizing transport cost incurred by the patients. Nutrition supplementation as well as TB allowance for the patients with low- income categories would also provide an additional support to resist the burden incurred by indirect costs during the treatment period. Special paid TB leave for government employee secure health and income source of the workers during this period.

As stated above, if the patient chooses a private provider as the first contact point or later in the course of pre- diagnosis, the patient has to bear all the expenses including consultation fee, investigation cost and other direct non-medical cost until the proper diagnosis is made as tuberculosis. In the absence of an insurance coverage, this will create an additional out of pocket expenditure to patients which sometime might push them in to poverty if they are already in the low-income category. Similarly, once the diagnosis is made some of these patients especially who engage in jobs in the private sector might lose their jobs until treatment is completed and this situation might push the patient and the family in to impoverishment if they don't have any additional income sources. Those who are self-employed would follow the same scenario if this is the sole source of income to the particular household. Therefore, although the NTP services are free of charge catastrophic cost incurred by the TB patients in Sri Lanka cannot be predicted unless the patient care pathway and the consequences of TB diagnosis on family income are well studied.

Sri Lanka has committed to reach the End TB targets by the year 2025, advancing the global targeted year of 2035. Being one of the targets, Sri Lanka needs to put more effort to bring down the percentage of households experiencing catastrophic cost due to TB to 0% by the year 2020. However, a costing study to evaluate the baselines value in 2015 or thereafter has not been carried out and therefore conducting a costing study to estimate the percentage of families experiencing catastrophic cost due to TB is a timely need. This will further aid to monitor the yearly change until the country reaches the End TB targets.

General objective:

To describe TB related direct and indirect cost and to estimate the catastrophic cost incurred by the drug sensitive and drug resistance TB patients and their families and to determine the predictors of catastrophic cost due to TB

Specific objectives:

1. To describe TB related direct and indirect cost incurred by the drug sensitive TB patients in the pre-treatment period, intensive phase of treatment, and continuation phase of treatment
2. To estimate the catastrophic cost incurred by the drug sensitive TB patients during the TB episode
3. To describe social protection, coping strategies and the social consequences related to TB among drug sensitive TB patients
4. To determine the predictors of catastrophic cost due to TB among drug sensitive TB patients

3. Methodology

The study method is adapted based on the handbook developed by the WHO on Tuberculosis patient cost surveys

3.1 ***Study Design:*** Longitudinal study design to achieve the objectives 1 to 4

3.2 Study setting

Component 1: The study was conducted in all 9 provinces. The district with the highest TB case load was selected purposively from each province. This was decided considering the fact of recruitment of adequate sample and completion of the study within a limited time period.
Thus, Colombo, Kandy, Galle, Rathnapura, Kurunegala, Anuradhapura, Badulla, Jaffna and Kalmunai were selected to conduct the study.

3.3 Study period

The period of data collection was from September to December 2021

3.4 Study population

All drug sensitive TB patients registered for treatment at the selected district institutions (both pulmonary and extra pulmonary TB patients; both new and re-treatment TB patients)
Inclusion Criteria: All patients (including children accompanied by a parent/guardian)**.**
Exclusion Criteria: Following groups will be excluded

- Patients who cannot communicate rationally due to mental sub normality/psychiatric disorders unless they are presented with their guardians

- Patients who were in orphanages, elderly homes, prisons and other types of care homes

3.5 Sample size calculation

TB diagnosis and follow up services are provided via 26 DCCs and 108 branch clinics in the island. Currently, local data on the proportion of drug sensitive TB patients and their families who incurred catastrophic cost due to TB is not available. Assuming the proportion of drug sensitive TB patients who incurred catastrophic cost due to TB as 50%, the minimum sample size (n) required for the study will be calculated as follow (24),

$n = [DEFF*Np(1-p)]/ [(d2/Z21-\alpha/2*(N-1) +p*(1-p)]$

Where n – Crude sample size

Z – Standard Normal Deviate (SND) for chosen confidence level (1.96)

p – estimated proportion of TB patients who incurred catastrophic cost due to TB (50%) CI- Confidence level (95%)
d – Absolute precision on either side of the proportion p (d) (5%) DEF- Design effect (for cluster surveys - DEFF) (1.8)
N- Total Population size (for finite population correction factor) (8500)

The sample size required would be 662 subjects. When adjusted for a 10% non-response rate, the final sample size required to be interviewed would be 736 (662/0.9) patients.
Cluster size =15, Number of clusters= 736/15= 49, when rounded off, 50 clusters

3.6 *Sampling*

Component 1: The study followed a cluster sampling technique. This technique is used as each district is conducting branch clinics apart from the main DCCs and TB patients are diagnosed and followed up in these clinics as well. Therefore, each selected district is having more than one institution to provide TB care.

Considering low numbers of case detection in some districts, the district with the highest case detection in each province will be selected for the study.

Clusters were allocated proportionately to the number of cases notified/detected annually by each selected district (Table 1).

Clusters were allocated within the district according to the probability proportional to size of the detected TB cases (annual) by each institution within the district

Once the cluster allocation was completed, study units were selected by recruiting consecutive drug sensitive TB patients attending DCCs and the branch clinics.

As there were two data collection points, the first sample was recruited when the patients were registered for treatment. Same size of sample was recruited when the patients attended at the

completion of the intensive phase of treatment. (New patients at the end of 2nd month and retreatment patients at the end of 3rd month).

Table 1. Cluster allocation according to the districts selected

Province	**District**	**Number of TB patients detected in 2019**	**Number of clusters**	**Number of patients**
Western	Colombo	2024	21	315
Central	Kandy	620	6	90
Southern	Galle	404	4	60
Northern	Jaffna	272	3	45
Eastern	Kalmunai	164	2	30
North-Western	Kurunegala	443	5	75
North Central	Anuradhapura	242	2	30
Uva	Badulla	280	3	45
Sabaragamuwa	Rathnapura	394	4	60
	Total	**4843**	**49**	**750**

3.7 Study Instruments

Data collection was done using a structured **interviewer administered questionnaire**. It was administered in both Sinhalese and Tamil languages. The questionnaire was developed in English and then it was translated to Sinhalese and Tamil followed by back translation to English to assess the retention of the original meaning. Expert opinion from the Consultant Respiratory Physicians, Health Economists and public health specialists was taken during the development of the questionnaire. The face and content validity of the questionnaire was ensured. This Questionnaire is comprised of three main components

1.Component A- Demographic and socio-economic question

2. Component B- Information on TB and other comorbidities

3. Component C- TB related costs (pre-treatment, intensive phase, and continuation phase)

A second study instrument was used to validate the data collected at the interview. As there was a follow up period after each recruitment point, the patients were given a diary

to write weekly costs incurred by the patients and the family in relation to the disease itself. Patients were instructed to update the diary daily by including all direct and indirect medical cost related to the management of the disease.

3.8 Pretesting of the questionnaire

Pre-testing of the questionnaire was done in a sample of patients (5% of the total sample size= 38 patients) who were attending District Chest clinic Gampaha and the necessary changes were made

thereafter.

3.9 *Details of data collectors / training and supervision of data collectors:*

Data collection was done by the specially recruited data collectors, who are pre-interns following calling for applications and interview-based selection from the selected districts. This reduced the language barriers specific to each area. An interviewer guide was prepared. Based on the guide, data collectors underwent a training where the research was explained to them and the questionnaire was discussed in detail, including what information needs to be obtained from the participants and the registers. Training was done by the PI and the other investigators. The training was conducted at national level after calling all the data collectors in to one place. Training included presentations and hands on session at Central Chest Clinic Colombo. Importance of maintaining privacy for contact information was explained to them. The communication methods and the obtaining the informed consent were also emphasized. The importance of maintaining courtesy, respect and patience while obtaining sensitive information from the patients were explained. The data collectors were regularly supervised by the investigators to ensure the necessary information was obtained in the correct manner.

3.10 Data Collection

All diagnosed TB patients are registered in the District TB register by the Nursing Officers. All new patients thus registered, eligible and consented (Information sheet was provided to each and every patient and subsequently verbal consent was obtained) for the study were recruited as study participants by the data collectors. Consecutive patients who were registered for treatment were recruited to **facilitate fair subject selection.**

Two samples of patients were recruited at two time points. First sample when the patients were registered for treatment. Similar sample was recruited from the patients who were

attending the clinic on completion of intensive phase. Data collection was done using a google form.

In the first group, the data collection was done at the point of recruitment. Retrospective data collection about the cost on the pre-treatment phase was collected together with sociodemographic and disease information. The same group of patients were interviewed after one and two months during their follow up visits to the clinic to estimate the cost due to TB during the intensive phase (Figure 1). Although retrospective data was collected by asking patients (bills were checked only if available) during prospective data collection patients were also given a diary to update TB related direct and indirect cost weekly and the data were validated when they presented for the interview.

In the second group, the data collection on sociodemographic and disease was done at the end of the intensive phase. This group of patients were interviewed after one and two months of continuation phase during their follow up visits to the clinic to estimate the cost due to TB during the continuation phase (Figure 1). Patients were also given a diary to update TB related cost weekly to validate the data collected in the interview.

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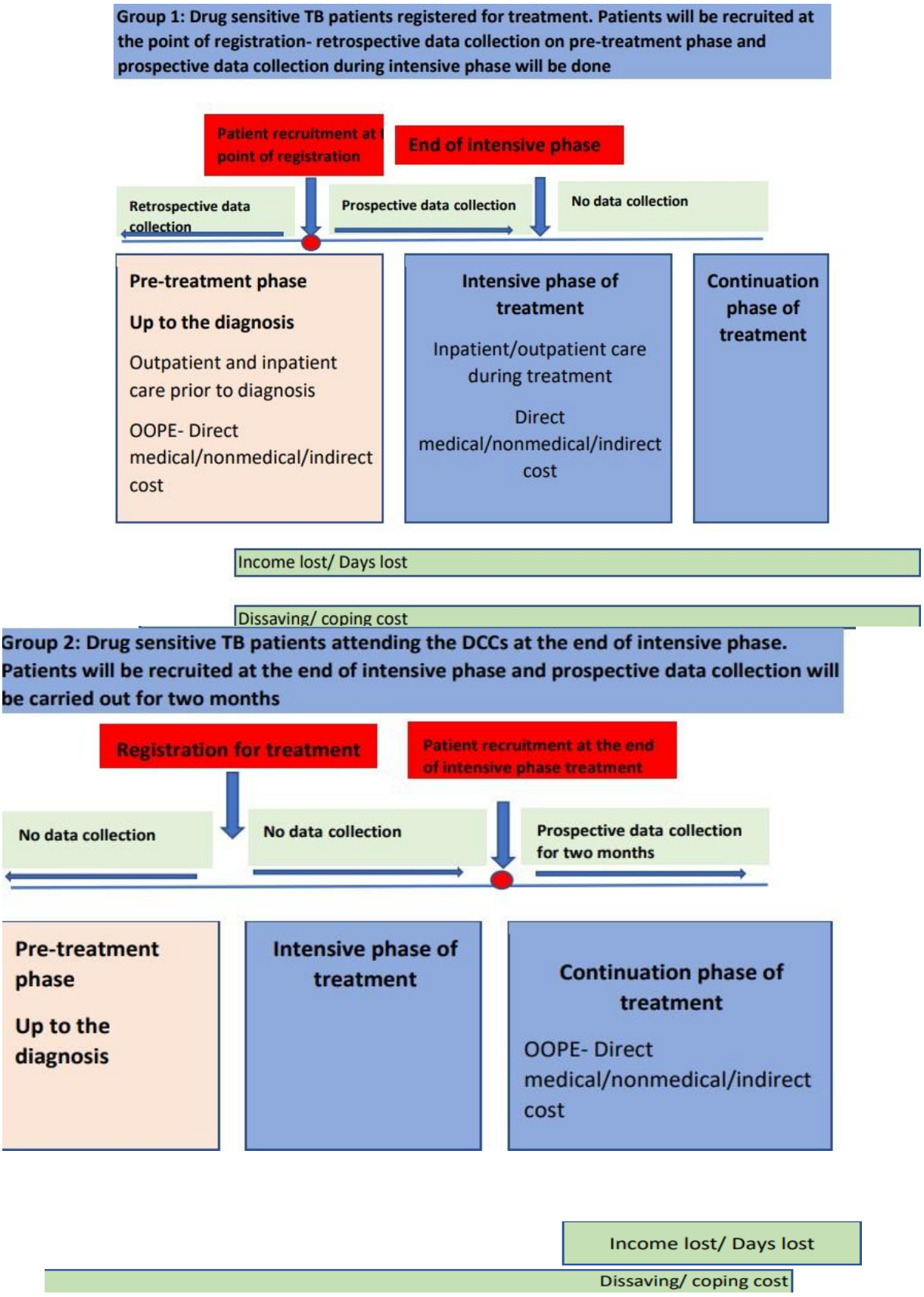


Figure 1. Schematic representation of recruitment and data collection

As the study intends to estimate TB related cost, following a single group from the time of registration up to treatment completion was not feasible. Therefore, based on WHO recommendations two samples of equal size were recruited as described above. The cost estimation for the period in the continuation phase was done after extrapolating the gathered two months costs for the entire period.

After introducing themselves and the objective of the study, and the benefits to the country, the data collectors provided the information sheet to all the participants and explained. Explanation in the native language improved the comprehensibility and before getting the signature all the participants were inquired whether they have understood the procedures. The informed written consent from the patients, guardians was taken thereafter. Face to face interviews were conducted in a quiet area allocated for the same purpose after the patient finishes all routine registration procedures, before the health education and counselling session. Special precautions were taken to minimize the disturbance to the clinic activities.

As this is a clinic setup all basic medications for many ailments are available. As most of the patients are having respiratory problems nebulization facilities, other treatment facilities inhaled steroids etc are available in

the clinic. Similarly, to attend any psychological problems some Chest Clinics have designated counsellors, and some have Nursing Officers trained for counselling. Arrangements were made to refer to psychological support services in the absence of a designated counsellor.

3.11 Quality Assurance

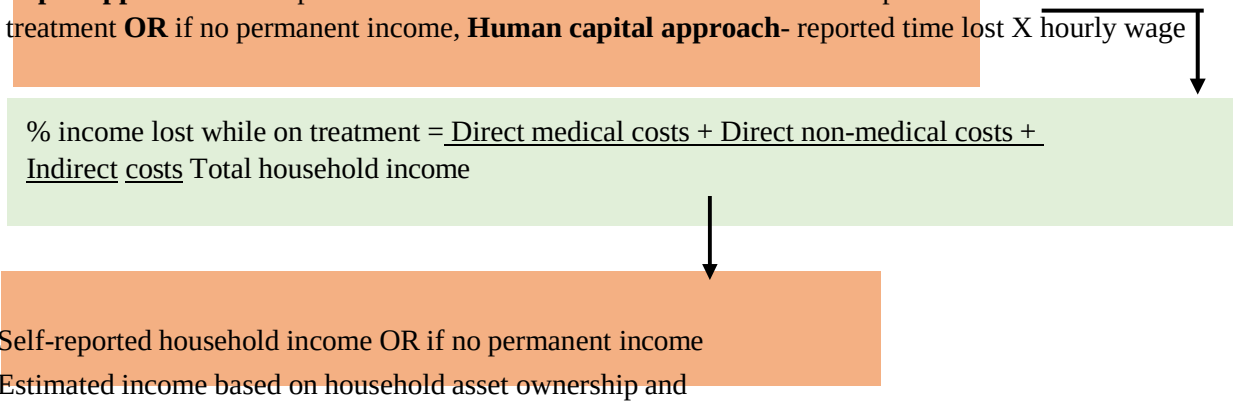
The risk of interviewer bias is minimum as most of the information are objective and not subjective. In addition, to minimize the inter-interviewer error, interviewers were given clear instructions and a thorough training on administering the questionnaire, so that, almost a similar approach could be adopted by all interviewers. By collecting data from new patients who just registered for treatment recall bias on pre-treatment period was minimized. Retrospective data collection after follow-up period was validated by maintaining the patient diary on TB related cost.

3.12 Data analysis

We used SPSS statistical software (version 24) to analyze the data. Initially, it was ensured that there's no significant socioeconomic difference between the groups recruited at two time points. Univariate data analysis was done to provide descriptive information on the direct and indirect medical cost and the indirect cost related to TB.

Catastrophic cost was calculated as follow

Output approach: self-reported household income before TB minus self-reported household income during TB treatment **OR** if no permanent income, **Human capital approach**- reported time lost X hourly wage



Bivariate analysis provided the evidence on significant associated factors. Multivariate analysis was utilized to assess the predictors of catastrophic cost after controlling the confounding effect. We determined the statistical significance of differences using a two- sided $P < 0.05$.

3.13 Definition of the variables

Direct Medical	Costs incurred during pre-diagnosis, hospitalization, medical visit, for directly observed treatment (DOT) visit, or a visit to pick up TB drugs. For hospitalizations and visits, the survey further breaks these costs down by activity: bed day charges, consultation fees, radiography, medicines, laboratory tests, and other procedures if the patient has spent on it
Indirect Medical Cost	Costs include the cost of transportation to and from a medical visit and the cost of food that the patient (and their accompanying household members) had to purchase while travelling to a health facility. This includes food required during hospitalization or food and nutritional supplements recommended and additional to the regular food.
Indirect Cost	Indirect costs are either the income that patients report losing during treatment or through a measure of the opportunity cost for seeking or being in care, that is a valuation of time "lost" for the patient and their household members throughout the TB episode. Measured by

	self-reported household income lost by estimating the change of income before the onset of symptoms and the point of data collection **OR** If no permanent income, reported time use while seeking and receiving care during the TB episode (in hours) multiplied by an individual hourly income. Children are by default given an hourly wage of zero, and instead estimated hourly income data for the caregiver(s) are used.
Household	A small group of persons who share the same living accommodation, who pool some, or all, of their income and wealth and who consume certain types of goods and services collectively, mainly housing and food
Coping	Borrowing funds or selling assets to finance, for example, health care Expenditure
Social protection	An integrated set of policies and programmes (including social assistance, labour market programmes and social insurance) providing minimum income security in the event of illness or other external and unforeseen event, which aims for poverty reduction, and sustainable and inclusive economic growth

Social assistance	Refers to in-kind or cash transfers, including disability grants, cash transfers for poor or vulnerable populations, or other types of benefits such as food packages or transport vouchers that are non-contributory.
Social insurance	A contributory scheme, usually compulsory, that pools funds from individuals and provides benefits to those contributing, in accordance with specified rules, against risk. The benefit is guaranteed through contributions without any type of need- or means-testing
TB episode	The period of time from "self-reported onset of TB-related symptoms", until end of treatment or death. The basic extrapolation technique proposed in this survey assumes 100% treatment completion
Social consequences	Includes social exclusion, divorce, children dropping out of school, etc
Catastrophic total costs due to TB	Total costs borne by patients in tuberculosis treatment, exceeding a given threshold (e.g. 20%) of the household's annual pre-TB income

4. Ethical and Administrative Requirements

Informed written consent of the participants was taken after explaining the objectives and probable outcomes of the study.

All patients included in the study were informed that this is for a research project, and any person who didn't wish to participate were considered as non-respondents. Patients were given the option to volunteer to participate in this study. Subjects had the opportunity to ask questions and inquire about the study questions, and also, they had the freedom to step down from the interview at any time or refrain from answering any question they might not wish to respond to.

Study participant didn't receive monetary allowances for participation, and it was informed to them before getting the informed consent. Refreshment were provided for the participants.

Their anonymity and confidentiality were maintained. Contact details of the patients were gathered in order to contact them in follow up visits in case if they fail to visit the treatment center. All information obtained were stored in a strictly confidential manner, and only the investigators are having the access to the information. Electronic version of the data base was password secured and the data sheets were kept under lock and key.

4. Results:

Out of 750 participants, 634 responded with a response rate of 84.5%.

4.1 Socio-demographic characteristics of the study participants

Table 1: Distribution of study participants by socio-demographic and other characteristics

	Frequency (n = 634)	Percentage
Age (years).		
0 – 14	19	3.0
15 – 24	58	9.1
25 – 34	71	11.2
35-44	102	16.1
45-54	125	19.7
55-64	162	25.6
65 and above	97	15.3
Gender.		
Male.	372	58.7
Female.	262	41.3
Ethnicity.		
Sinhala.	397	62.6
Tamil.	129	20.3
Muslim.	106	16.7
Burgher.	2	0.4
Religion.		
Buddhism.	376	59.2
Hinduism.	106	16.7
Islam.	106	16.7
Roman catholic/Christian	46	7.3
Marital status.		
Married.	481	75.9
Unmarried.	126	19.8
Divorced/separated	13	2.1
Widowed	14	2.2
Level of Education		
No formal education	19	3
Grade 1- 5	76	12
Grade 6 -11	172	27.1
Grade O/L (Ordinary level- Grade 11 exam)	175	27.6
Grade 12-13	32	5
GCE A/L	109	17.2
Higher Education/PG	51	8
Employment status before being diagnosed a TB		
Employed	356	56.2
Not employed	278	43.8

	Frequency (n = 634)	Percentage
Household income (Monthly in LKR)		
<30,000	175	27.6
30,001-60,000	408	64.4

60,001-90,000	31	4.9
90,001-120,000	8	1.3
120,001-150,000	7	1.1
>150,000	5	0.8
Presence of one or more comorbidities		
Yes	312	49.2
No	322	50.8
Household size		
Living alone	42	6.6
2-3 members	179	28.2
4-5 members	318	50.2
6-7 members	80	12.6
8 or more members	15	2.4
Any other members in the household currently suffering from TB		
Yes	32	5
No	602	95

Table 2. Distribution of study participants by job loss after being diagnosed as TB

	Frequency (n = 356)	**Percentage**
Loss of job after being diagnosed as TB		
Yes	110	30.9
No	246	69.1

4.1. TB related direct and indirect cost incurred by the drug sensitive TB patients

Table 3. Distribution of study participants by cost incurred during the TB episode

Cost category	**Phase of TB episode**			
	Pre-treatment	Intensive phase	Continuation phase	Total Episode
Direct medical cost	4,517,404	295,840	50,800	4,864,044 (16,213 USD) 25.5 USD per patient
Indirect Medical Cost	815,077	664,325	1,962,024.00	3,441,426 (11,471 USD) 18 USD per patient
Indirect cost	236,334	6,072,450	11,827,400.00	18,136,184 (60,453 USD) 95.3 USD per patient
Total cost (LKR)	5,568,815	7,032,615	13,840,224.00	26,441,654 (81,706 USD)
Cost per patient	8783.62	11,092.45	21,830	41,706
Cost per patient (USD)	26.7	33.81	66.5	127

As per the Table, during pre-treatment phase the highest cost was due to direct medical cost which included consultation fee, payment for private hospitals, investigation etc. However, the direct medical cost reduced considerably during intensive and continuation phase as TB patients are provided free health services including drugs once the diagnosis is made. The total cost during intensive and continuation phase have gone up mainly due to indirect cost which includes daily loss of wage for the patient and the bystander during hospital stay and clinic visit and the income loss due to loss of jobs among one third of patients who were occupied previously prior to the TB episode. The information given by the patient was crosschecked with the diary given at the registration.

	Frequency (n = 634)	Percentage
Cost incurred as a proportion of annual income		
Up to 10%	487	76.8
10.1% to 20%	40	6.4
20.1% to 30%	50	7.9
30.1% to 40%	32	5.0
40.1% to 50%	19	3.0
>50%	6	0.9

4.2 catastrophic cost incurred by the drug sensitive TB patients during the TB episode

Table 4. Distribution of study participants by proportionate cost from the total household income

As per the table, majority (83.2%) spent less than 20% of their annual income for the expenditure caused due to TB episode. Hence, the proportion of households that spent > 20% of their household income or the households that experience catastrophic cost due to TB is 16.8%

4.3 Coping strategies, social protection and the social consequences related to TB

4.3.1 Coping strategies

When the patients were inquired whether they could manage the cost with the household income, majority, 61.2% (n=388) responded saying that they could cover the expenses with h ousehold income (Table 5).

	Frequency (n = 634)	Percentage
Ability to cover the expenses with household Income		
Yes	388	61.2
No	246	38.8

Table 5. Distribution of study participants by ability to cover the expenses with household income

When different types of coping strategies were inquired from the patients, 14.4% (n=91) responded

saying that they have taken bank loans, 29% (n=184) had borrowed loans from relatives, 5.8% (n=37) had sold one of their assets, 13.4% (n=85) had pawned their jewelries, and 46.1% (n=292) had used their savings (Table 6)

Table 6. Distribution of study participants by coping strategies

4.3.2 Social protection:

With regards to social protection, 9.6% (n=61) of the participants responded saying that they have insurance coverage, while 116 (18.3%) said that they received TB allowance. Only a minority, 3.2% (n=20) of patients said that they received funding support from local donors. Of the study participants, 30.4% (n=193) had received "Thriposha" as nutrition supplementation.

	Frequency (n = 634)	Percentage
Insurance coverage		
Yes	61	9.6
No	573	90.4
Receipt of TB allowance		
Yes	116	18.3
No	518	81.7
Funding from local donors		
Yes	20	3.2
No	614	94.2
Nutrition supplementation		
Yes	193	30.4
No	441	69.6

Table 7. Distribution of study participants by availability of social protection strategies

	Frequency (n = 634)	Percentage
Bank loans		
Yes	91	14.4
No	543	85.6
Loans from relatives		
Yes	184	29.0
No	450	71.0
Sale of the assets		
Yes	37	5.8
No	597	94.2
Pawning of jewelries		
Yes	85	13.4
No	549	86.6
Use of savings		
Yes	294	46.3
No savings/ not used savings	340	53.7

4.3.3 Social Consequences:

Of the study participants who were employed, 110 (30.8%) responded saying that their occupation is always affected due to the diseases and they either resigned or lost the job due to different reasons. Around 65 (18.3%) patients said that it was often/sometimes

	Frequency (n = 634)	Percentage
Impact of the disease on day-to-day personal Activities		
Always affected (all 7 days)	58	9.1
Often affected (5-6 days)	103	16.2
Sometimes affected (3-4 days)	156	24.6
Rarely affected (1-2 days)	154	24.3
Not affected at all	163	25.7

affected while 169 (47.5%) said that it was rarely affected and 12 (3.4%) responded saying it was not affected at all (Table 8).

Table 8. Distribution of study participants by the response on impact of the disease on occupation

When the impact of the disease on day-to-day personal activities was inquired, majority, 25.7% (n=163) responded saying it didn't affect the day-to-day activities at all. Only 58 (n=9.1%) patients said that the day-to-day activities were always affected because of the disease (Table 9).

Table 9. Distribution of study participants by the response on impact of the disease on day-to-day personal activities

When the patients were inquired whether the disease has affected attending the day-to- day activities of their children, 376 patients who had children responded. Only 5 patients (n=1.4) responded saying it was always affected while the majority, 63.5% (n=239) stated

	Frequency (n = 356	Percentage
Impact of the disease on occupation		
Always affected (resigned or lost the job)	110	30.8
Often/sometimes affected (4 days or more)	65	18.3
Rarely affected (1 to 3 days per week)	169	47.5
Not affected at all	12	3.4

that the disease didn't affect attending the day to activities of their children (Table 10). Table 10. Distribution of study participants by the response on impact of the disease on attending day to day activities of children

When the patients were inquired about their psychological well-being such as feeling sad, do not feel

like engaging day to day activities, getting angry etc, the way they responded is depicted in Table 11. Majority, 27% (n=171) responded saying that they sometimes felt sad as they got the disease. However, majority, 33.8% (n=214) stated that they never felt like not engaging in day-to-day activities, cleaning themselves and eating. When the patients were inquired whether they cannot fall asleep until late night or wake up very early, majority, 40.1% (n=254) responded saying that they never experienced it. Further, majority responded saying that sometimes they don't feel like eating (n=202, 31.9%), got angry with family members and close friends more often than before (n=210, 33.1%) and couldn't enjoy the activities that they enjoyed before (n=236, 37.2%) as depicted in Table 10.

Table 10. Distribution of study participants by the response on statement related to psychological wellbeing.

	Frequency (n = 376)	**Percentage**
Impact of the disease on day-to-day activities of Children		
Always affected	5	1.4
Often affected	11	2.9
Sometimes affected	35	9.3
Rarely affected	86	22.9
Not affected at all	239	63.5

Of the 417 participants who responded to the question on sexual activity, majority expressed that they rarely experienced that they couldn't engage in sexual activity with the spouse as before (Table 11).

Table 11. Distribution of study participants by the perception on engagement in sexual activities

	Frequency (n = 634)	**Percentage**
Do you feel sad most of the time in the day		
Always	22	3.5
Often	93	14.7
Sometimes	171	27.0
Rarely	181	28.5
Never	167	26.3
Do not feel like engaging in day-today activities like cleaning yourself and eating		
Always	29	4.6
Often	75	11.8
Sometimes	127	20.0
Rarely	189	29.8
Never	214	33.8
Cannot fall asleep until late night or wake up very Early		
Always	60	9.5
Often	73	11.5

Sometimes	145	22.9
Rarely	102	16.1
Never	254	40.1
Don't feel like eating		
Always	96	15.1
Often	86	13.6
Sometimes	202	31.9
Rarely	132	20.8
Never	118	18.6
Gets angry with family members/ close friends more often than before		
Always	53	8.4
Often	54	8.5
Sometimes	210	33.1
Rarely	130	20.5
Never	187	29.5
Cannot enjoy the activities you enjoyed before		
Always	52	8.2
Often	96	15.1
Sometimes	236	37.2
Rarely	156	24.6
Never	94	14.8

Under social consequences, patients were further inquired about perceived stigma and discrimination. Of the total participants, 132 (20.8%) responded saying that they were treated differently due to current illness at any point up to the date of interview while majority, 47.9%

	Frequency (n = 417)	**Percentage**
Could not engage in sexual activities as before		
Always	23	5.5
Often	24	5.6
Sometimes	136	32.6
Rarely	171	41.0
Never	63	15.1

(n=304) responded saying "No" to this. However, 198 (31.8%) participants didn't respond to this question.

Table 12. Distribution of study participants by the response on whether they were treated differently at any point in the illness

When the patients who were responded were asked to give their views on different aspects of perceived stigma and discrimination on a Likert scale, they responded differently. Majority responded saying that they never (n=201; 46.1%) felt that people were not talking to them, but majority stated that sometimes (n=136;31.9%) they felt that people were trying to avoid them.

	Frequency (n = 634)	Percentage
Whether you were treated differently		
Yes	132	20.8
No	304	48.0
No response	198	31.2

However, when the patients were inquired whether they felt that they were a burden to the family, 177 (27.9%) participants responded saying that sometimes they felt it while 136 (31.2%) never felt it. Another 148 (34%) responded saying that they sometimes felt that their families treated them differently after the illness while around one third never felt it (Table 13)

Table 13. Distribution of study participants by the response on different aspects of perceived stigma and discrimination

	Frequency (n = 436)	Percentage
Do you feel as if people were not talking to you as they used to do?		
Always	27	6.2
Often	31	7.1
Sometimes	96	22.0
Rarely	81	18.6
Never	201	46.1
Do you feel as if people were trying to avoid you?		
Always	51	11.7
Often	46	10.6
Sometimes	136	31.9
Rarely	105	24.0
Never	95	21.8
Do you feel as if you were a burden to the family?		
Always	18	4.1
Often	28	6.4
Sometimes	177	27.9
Rarely	77	17.7
Never	136	31.2
Do you feel that your family was treated differently after your illness?		
Always	12	2.8
Often	25	5.7
Sometimes	148	34.0
Rarely	124	28.4
Never	127	29.1

5. Association between selected factors and catastrophic cost due to TB among drug sensitive TB patients

Before analyzing the significant predictors of catastrophic cost due to TB, bivariate analysis was carried out to find out the factors that are significantly associated with TB. Selected socio-demographic, disease related, coping strategies and sector of initial treatment seeking were identified to explore the association with cost due to TB

Table 14. Association between selected socio-demographic factors and catastrophic cost due to TB

	Experienced catastrophic cost (n=107)		**Not experienced catastrophic cost (n=527)**		**Total (n=634)**		**Level of significance**
	N	%	n	%	n	%	
Age category (years)							$X^2 = 5.53$ df = 1 p = 0.019
0-14 and ≥65	11	9.5	105	90.5	116	100	
15 to 64	96	18.5	422	81.5	518	100	
Gender							$X^2 = 8.13$ df = 1 p =0.005
Male	76	20.4	296	79.6	372	100	
Female	31	11.8	231	88.2	262	100	
Ethnicity							
Sinhala	59	14.9	338	85.1	397	100	$X^2 = 3.075$ df = 1 p = 0.051
Non-Sinhala	48	16.9	189	79.7	237	100	
Marital status							
Married	91	18.9	390	81.1	481	100	$X^2 = 5.924$ df = 1 p = 0.013
Unmarried/single/ Divorced	16	10.5	137	89.5	153	100	
Monthly income							
≤Rs.60,000	102	17.5	481	82.5	583	100	$X^2 = 1.397$ df = 1 p =0. 237
>Rs.60 000	5	9.8	46	90.2	51	100	
Level of Education							
Up to O/L	86	19.4	357	80.6	443	100	$X^2 = 6.742$ df = 1 p =0. 011
Grade 12/13 and Above	21	11.0	170	89.0	191	100	
Status of employment before the diagnosis							$X^2 = 55.6$ df = 1 p <0. 001
No	12	4.3	266	95.7	278	100	
Yes	95	26.7	261	83.7	356	100	

As per Table 14, significantly higher proportion of patients aged between 15 to 64 years (n=95; 18.5%; p=0.019) experienced catastrophic cost due to TB compared to children and elderly

(65years and above) (n=11; 9.5%) grouped together. Proportion of males (n=76; 20.4%) who experienced catastrophic cost due to TB is significantly higher (p=0.005) than females (n=31; 11.8%), whereas patients who were married experienced significantly higher catastrophic cost due to TB compared to those who were single, separated and divorced grouped together (n=16; 10.5%). Further, a greater proportion of those who were studied up to O/L experienced catastrophic cost due to TB compared to those who educated from grade 12 and above (n=21;11%) and the difference was significant. It is worthwhile to note that, of those who were employed before being diagnosed as TB, 26.7% (n=95) experienced catastrophic cost whereas only 4.3% (n=12) of those who were not employed before experienced catastrophic cost due to TB. And the difference was significant.

Of the 356 patients who were employed before, 30.9% (n=110) lost their jobs after being diagnosed as TB. Hence, the association between status of employment and the catastrophic cost due to TB after the diagnosis was further explored (Table 15).

Table 15. Association between employment status after being diagnosed as TB and catastrophic cost due to TB among those who were employed before

	Experienced catastrophic cost (n=107)		**Not experienced catastrophic cost (n=527)**		**Total (n=356)**		**Level of significance**
	n	%	n	%	n	%	
Employment status after being diagnosed as TB							$X^2 = 251.4$ df = 1 $p < 0.001$
Yes	4	1.6	242	98.4	246	100	
No	91	82.7	19	17.3	110	100	

It was found that significantly higher proportion (82.7%; n=91) of those who were not employed after being diagnosed/ treated as TB experienced catastrophic cost compared to those who didn't lose their jobs (n=4; 1.6%).

As lost of employment/ earning has been a significant factor for catastrophic cost due to TB, further analysis was carried out to explore the association between the cost due to TB with those who were employed and lost their jobs while amalgamating those who were employed but not lost their jobs and those who were not employed before. This analysis also revealed a significant association between those who were employed and lost their jobs with catastrophic cost due to TB compared to those who were not employed and employed but didn't lose their jobs combined together.

Table 16. Association between loss of job and catastrophic cost due to TB

	Experienced catastrophic cost (n=107)		Not experienced catastrophic cost (n=527)		Total (n=634)		Level of significance
	n	%	n	%	n	%	
Employment status							$X^2 = 411.38$ df = 1 $p < 0.001$
Lost the job	91	82.7	19	17.3	110	100	
Non employed + didn't lose the job	16	3.1	508	96.9	524	100	

The association between household size and catastrophic cost due to TB is depicted in Table 17. It was found that the households with up to 4 members had experienced higher proportion (18.2; n=75) of catastrophic cost due to TB compared to the households with 5 or more members (14.5%; n=32). However, this difference was not significant.

Table 17. Association between household size and catastrophic cost due to TB

	Experienced catastrophic cost (n=107)		Not experienced catastrophic cost (n=527)		Total (n=634)		Level of significance
	N	%	n	%	n	%	
Household size							$X^2 = 1.390$ df = 1 p =0.297
Up to 4 members	75	18.2	338	81.8	413	100	
Five or more members	32	14.5	189	85.5	221	100	

Table 18 includes the association between the cost due to TB and the type of TB, presence of co-morbidities, and household members currently diagnosed as TB. As per the analysis, only the patients who had Chronic Lung Diseases (CLDs) as a comorbidity demonstrated significant association with catastrophic cost due to TB. Around 29.6% (n=21) of patients who had CLDs as a comorbidity experienced catastrophic cost due to TB compared to the patients who didn't experience CLD, 15.3% (n=86) and the difference was significant.

Table 18. Association between status of TB and other diseases and cost due to TB

	Experienced catastrophic cost (n=107)		Not experienced catastrophic cost (n=527)		Total (n=634)		Level of significance
	n	%	n	%	n	%	
Type of TB							
PTB	89	17.2	428	82.8	517	100	$X^2 = 0.228$ df = 1 p = 0.683
EPTB	18	15.4	99	84.9	117	100	
Presence of one or more comorbidities							$X^2 = 1.285$ df = 1 p =0.289
Yes	58	18.6	254	81.4	312	100	
No	49	15.2	273	84.8	322	100	
Presence of DM							
Yes	45	17.4	213	82.6	258	100	$X^2 = 0.099$ df = 1 p = 0.748
No	62	16.5	314	83.5	376	100	
Presence of CLD							
Yes	21	29.6	50	70.4	71	100	$X^2 = 9.193$ df = 1 p = 0.004
No	86	15.3	477	84.7	563	100	
Household members with TB							$X^2 = 1.346$ df = 1 p =0. 237
Yes	8	24.2	25	75.8	33	100	
No	99	16.5	502	83.5	601	100	

Table 19 shows the association between different coping strategies adopted by the patients and the catastrophic cost due to TB. As per the table, significantly higher proportions of patients who borrowed loans from relatives (32.1%, n=59; p<0.001) and who pawned jewelries (29.6%; n=21; p=0.004) had experienced catastrophic cost due to TB compared to those who didn't practice particular coping strategies.

Table 19. Association between coping strategies adopted by the patients and catastrophic cost due to TB

	Experienced catastrophic cost (n=107)		Not experienced catastrophic cost (n=527)		Total (n=634)		Level of significance
	N	%	n	%	n	%	
Bank loans							
Yes	15	16.3	77	83.7	92	100	$X^2 = 0.025$

No	92	17.0	450	83.0	542	100	df = 1 p = 1.00
Loans from relatives							X^2 = 42.62 df = 1 p <0.000
Yes	59	32.1	125	67.9	184	100	
No	48	10.7	402	89.3	450	100	
Sales of assets							
Yes	3	8.1	34	91.9	37	100	X^2 = 2.154 df = 1 p = 0.101
No	104	17.4	493	82.6	597	100	
Pawning of jewelries							X^2 = 9.193 df = 1 p = 0.004
Yes	21	29.6	50	70.4	71	100	
No	86	15.3	477	84.7	563	100	
Savings							
Use of savings	48	16.3	246	83.7	294	100	X^2 =0.118 df = 1 p =0. 751
No savings/not used savings	59	17.4	281	82.6	340	100	

The association between catastrophic cost due to TB and the type of facility the patient has visited initially was analyzed and depicted in Table 20. Accordingly, a significant association was noted between the type of facility visited and the catastrophic cost due to TB. Overall, 22.2% of patients who visited private hospital had experienced catastrophic cost due to TB while it was 19.7% for those who first visited the family doctor. Among those who visited DCC it was 1.4% whereas other government hospitals it was 16.7%.

Table 20. Association between the type of facilities first visited and catastrophic cost due to TB

	Experienced catastrophic cost (n=107)		Not experienced catastrophic cost (n=527)		Total (n=634)		Level of significance
	n	%	n	%	n	%	
The type of facility first visited							$X^2 = 20.18$ df = 4 p <0.001
Aayurveda hospital	1	100	0	0	1	100	
District Chest Clinics	1	1.4	71	98.6	72	100	
Government hospitals other than DCC	43	16.7	214	83.3	257	100	
Family doctor	44	19.7	179	80.3	223	100	
Private hospitals	18	22.2	63	77.8	81	100	

Analysis of the association between catastrophic cost due to TB and the sector to which the patient visited first revealed that significantly higher proportion of patients who visited the private sector (20.4%; n=62; p=0.026) initially had experienced catastrophic cost due to TB compared to those who visited government sector (13.6%; n=45) Table 21.

Table 21. Association between the type of facilities first visited and catastrophic cost due to TB

	Experienced catastrophic cost (n=107)		Not experienced catastrophic cost (n=527)		Total (n=634)		Level of significance
	n	%	n	%	n	%	
Health sector that the patient first visited							$X^2 = 5.152$ df = 1 p= 0.026
Government Sector	45	13.6	285	86.4	330	100	
Private sector	62	20.4	242	79.6	304	100	

Although 10 factors were showed a significant association in the bivariate analysis, when the logistic regression was performed to adjust the confounding effect, only 4 factors were categorized as predictors of catastrophic cost. Losing the jobs, taking loans from relatives, pawning jewelries, seeking initial care in private sector significantly increase the risk of

catastrophic cost due to TB (Table 22).

Table 22. Predictors of catastrophic cost due to TB

Variables in the Equation									
								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	Age category	.949	.562	2.851	1	.091	2.582	.859	7.766
	Gender category	-.068	.405	.028	1	.867	.934	.422	2.068
	Ethnic cat	-.409	.412	.986	1	.321	.664	.296	1.489
	Marital status	-.055	.495	.012	1	.912	.946	.359	2.498
	Education	-.507	.463	1.201	1	.273	.602	.243	1.492
	CLD	.546	.537	1.034	1	.309	1.726	.603	4.947
	Loss of job	**5.309**	**.458**	**134.309**	**1**	**.000**	**202.24**	**82.39**	**496.42**
	Loans from relatives	**1.396**	**.410**	**11.617**	**1**	**.001**	**4.041**	**1.810**	**9.020**
	Pawning of jewelries	**1.183**	**.495**	**5.696**	**1**	**.017**	**3.263**	**1.235**	**8.617**
	Sector – initial care	**1.055**	**.419**	**6.349**	**1**	**.012**	**2.872**	**1.264**	**6.523**
	Constant	1.303	.927	1.974	1	.160	3.680		

a. Variable(s) entered on step 1: age_recat, @1.2.Gender, Ethnic_cat, Maritalcat, Educationcat, @1.8cAsthmaCOPD, joblost, @4.2.2.Loansfromrelatives, @4.2.5.PawningJwelleries, sectorcat.

Discussion:

Tuberculosis is an infectious disease that highly related to many socioeconomical determinants such as poor nutrition, overcrowding, poor housing, which ultimately link to economic determinant, that is the financial stability of the community. This is pictured in the global TB burden where the developed world reports very low TB incidence while the developing countries are still struggling to overcome the inbuilt challenges of the disease. Similarly, the consequences of the disease on the socioeconomical background of the families and the communities is detrimental. Therefore, the WHO End TB targets include "Zero" catastrophic cost as one of the indicators that should be achieved by 2035 and the same is expected to achieve by 2030 under SDG targets. Therefore, this study primarily aimed to describe the TB related costs at different stages of TB care cascade, to assess the percentage of TB patients and their households that ended up in catastrophic cost due to TB and also to explore the aspects of social protection, coping strategies, and the social consequences and finally to identify the predictors of catastrophic cost due to TB.

The study was a descriptive cross-sectional study among 750 drug sensitive TB patients, covering all 9 provinces. Patients were recruited at two points in TB care cascade, one cohort at the registration and the second cohort at the end of the intensive phase. This design was adopted as per the WHO guidance document and after getting technical advice from the relevant experts in the field of health economics. The cohort of patients recruited at the registration was subjected to retrospective data

collection about the pre-treatment period. Although the memory bias at this point was a concern, it was minimized by asking the patients to provide evidence and also the costs quoted by the patients for investigation were crosschecked with the available market rates. During prospective data collection, the validity of data was preserved by asking the patients to record all expenses in a diary.

The sample included majority male patients with a female to male ratio of 1.4 and around 41% are representing the age group of 55 years and above which are comparable to national figures, 1.8 of female to male ratio and 45% of age group 55years and above. Just over 50% of the study participants had studied up to Ordinary level and this indirectly shows the real socioeconomic background of the affected population. Around 56% of the study population were employed prior to the diagnosis and majority of families get an income of around 30,000 to 60,000 LKR which also shows the poor socio-economic background of the study population. Nearly 50% of the patients are suffering from one or more comorbidities indicating the cost for the patients is not purely for TB but also for other diseases, especially if they don't seek care from the state sector.

The patients in Sri Lanka are opted with many choices if they need to seek health care services. They could choose the private sector, state sector or even Ayurvedic sector as the primary health care provider. As per the TB patient pathway survey, nearly 40% of patients initially seek care at the private sector and the majority go to part time private practitioners (Patient Pathway Analysis, Survey report NPTCCD, 2019). This evidence is further supported by the results of current study which shows that the highest direct cost incurred by the patients was during the pre-treatment period. This includes costs for investigations, hospital stays in the private sector, antibiotics and other medicines. This also show the increasing trend of people seeking care in private sector and also support findings of Sri Lanka health system review that the majority (95%) of inward care is provided by the public sector and around 50% of outpatient care is provided by the private sector. Though Sri Lanka's out of pocket expenditure as a share of current health expenditure fluctuated substantially in recent years, it tended to increase through 2002 - 2021 period ending at 43.6 % in 2021. However, the direct medical cost during the intensive and continuation phase was the minimum and this reflects the free health services especially the free treatment services provided by the National TB programme. In Sri Lanka, only the NTP provides TB drugs and it is free of charge. Even the patients diagnosed in the private sector are catered and therefore the direct medical cost per patient was 25.5USD in this study and it is only 20% of total cost per patient.

The highest indirect medical cost was observed during continuation phase, which is for 4 months. However, it is only 18 USD per patient indicating only 15% of total expenditure per patient. Out of all types of costs, the indirect cost was the highest and it shows an increase over the TB cascade, the lowest during pre-treatment and the highest during continuation phase. The contribution of indirect cost to the total cost is considerable and it is 75%. This is slightly higher than the proportion of indirect cost as the total cost for TB in Bangaladesh which is 68% (25). This clearly indicates the loss of income over the care cascade especially towards continuation phase. Loss of income due to job loss may have

contributed immensely as 30% of study participants who were occupied previously had lost their jobs after being diagnosed as TB. In contrast, the Thailand TB catastrophic cost survey showed that the highest cost was due to direct non-medical costs and the indirect cost was the second highest (26). Total cost during the entire episode per patient was 127 USD in the current study which is slightly higher than the cost incurred by TB patients in Bangaladesh which is 124 USD. However, the total cost incurred by a TB patient in Thailand was 903 USD and this study sample also included the Drug resistance patients. Present study revealed that 16.8% of TB patients and their families have experienced catastrophic cost due to TB whereas in the Thailand study it was 29.6%. The findings of current study showed that the government should put additional effort to minimize cost due to TB.

When considered the health expenditure as a total, it was revealed that 5 percent (2016) of the population incurs catastrophic health expenditure measured as out-of-pocket spending exceeding 10% of household consumption or income.

Although the majority of patients had responded saying that they could manage the expenses with the household income, patients used different mechanisms as coping strategies, while only less than 50% had used their savings. They used different mechanisms such as borrowing loans from banks, relatives and pawning their jewelries. It was mentioned that Pledging jewels and borrowing money were major coping strategies in an Indian study (27). All TB patients had been provided TB allowance from the past and the amount is varied from LKR 5000 to 1000 depending on the province as the allowance is funded by the provincial council funds. However, less than one fifth of the study had responded saying that they receive TB allowance. This scenario should be further explored to find out the reasons why the smaller number of patients were funded with TB allowance, whether due to challenges in providing provincial allocation due to existed economic crisis. On the other hand, only 9.2% of patients had insurance coverage and in Si Lanka, mostly the people working in private sector are opted with health insurance. Further, the standard is to provide nutrition supplementation for all TB patients and it is funded by the government. However, only one third of the patients had received nutrition supplementation.

When it comes to social consequences, impact on the disease on earning is the most affected area. Around one-third of the patients responded saying the illness had an impact on their occupation and they either resigned or lost the job due to different reasons. An Ethiopian study also found that TB patients mean productivity and income reduced by 37 and 10 %, respectively, compared with pre-treatment level, while mean household expenditure increased by 33 % and working hours reduced by 78 % due to TB illness (28). However, the disease didn't affect the day-to-day activities much as per the findings, but one third of them sometimes felt like not eating, got angry with family members and

friends and couldn't enjoy the activities that they enjoyed before. Further, more than 40% of them felt sad (always, often or sometimes). This denotes a considerable proportion is expressing that their psychological wellbeing is not perfect which needs attention on counselling, mindfulness practices and other strategies that could uplift their psychological wellbeing. Stigma and discrimination was not a major concern as per the study findings, however over quarter of patients sometimes felt that they were treated differently.

When considering the association of certain factors with catastrophic cost, persons of male gender, age group between 15 to 54 years, married and those who were employed before the diagnosis of TB

showed significantly higher proportion of catastrophic cost due to TB. This is being further reflected in the finding, out of 356 patients who were employed before, 30.9% (n=110) lost their jobs after being diagnosed as TB. It was found that significantly higher proportion (82.7%; n=91) of those who were not employed after being diagnosed/ treated as TB experienced catastrophic cost compared to those who didn't lose their jobs (n=4; 1.6%). The scenario could be explained by the fact that those who are economically active and earning for the family would get the diseases the economical consequence is significant and the situation is worsened when they lose their jobs. They should look after the family and in parallel need to spend on their illness. This is why, all TB patients irrespective of their previous work history should receive social protection in terms of money and nutrition. Previously, the patients will receive TB allowance only when the grama Niladaari certified that he or she is under low-income category, however later on this policy was changed and all TB patients are eligible for TB allowance. Further, presence of chronic lung diseases, borrowing loans from relatives and pawning jewelries and initial visit to private sector also showed a significant association with catastrophic cost. Of these factors, loss of job, sector of initial care seeking, pawning of jewelries and borrowing loans from relatives appeared as predictors of catastrophic cost in the risk prediction model and very importantly loss of job is the strongest predictors out of all. Therefore, it is worth while to inquire the patient about their economic situation at each visit and to identify those who have the potential risk of ending up in catastrophic cost to offer customized social protection methods to them. Bangaladesh study suggested that the risk of CHE increased among male patients with smear-negative TB and delayed enrolling in the DOTS (25). A systematic review on catastrophic cost due to TB and its predictors revealed that that country, drug sensitivity, and Human immune-deficiency Virus (HIV) co-infection were the main predictors of such costs. However, current study only included drug sensitive TB patients and Sri Lanka being a country with very low number of HIV-TB co-infection present study sample didn't include such patients, when the patients were randomly chosen from the district.

Conclusions:

1. The highest direct medical cost is observed during pre-treatment period of TB episode
2. The highest indirect medical cost and the indirect costs are observed during continuation phase of TB treatment
3. On average, a TB patient spend around 127 USD during the entire TB episode
4. The catastrophic cost due to TB experienced by the TB patients and their households is 16.8%
5. Of the coping strategies', higher proportions of patients adopted use of savings and or loans from relatives
6. Existing social protection methods for TB patients, such as insurance policy, TB allowance, funding from local donors etc are suboptimal
7. Impact of the disease on occupation, and day to routine is minimum
8. Around 20% of patients had either always or often experience psychological consequences
9. Proportion of patients who always or often perceived stigma and discrimination is around 10-20%
10. Although there are several factors significantly associated with catastrophic cost due to TB, loss of job, taking loans from relatives, pawning of jewelries and initial care from private sector were found to be the predictors of catastrophic cost due to TB

Recommendations:

- To reduce pre-treatment cost facilitation of TB diagnosis as the outpatient departments should be done to minimize late diagnosis which will reduce hospital admission and unnecessary cost.
- Strengthen private public partnership to enable TB diagnosis at private sector so that additional cost incurred during private sector care during pre-treatment could be minimized
- Monitor the families who encounter catastrophic cost using a tool and targeted support should be provided for those patients
- Target the patients who lost their jobs and who are in debt and provide more support for them
- Streamline already available social protection methods, such as TB allowance and nutritional support,

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Assessment of HIV Prevalence among Prison Population in Nepal 2021

Final Report

Assessment of HIV Prevalence among Prison Population in Nepal

Submitted To

SAARC Tuberculosis and HIV/AIDS Centre (*STAC*)
Thimi, Bhaktapur,
Bagmati Province, Nepal

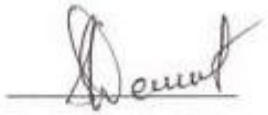
Acknowledgment

It is our pleasure to share with you the first-ever report on Assessment of HIV prevalence among Prison Population in Nepal. The study was conducted with the technical support from National Centre for AIDS and STD Control (NCASC) and financial support from SAARC Tuberculosis and HIV/AIDS Centre (STAC). We would like to thank Central Diagnostic Laboratory (CDL) for conducting external quality assessment of the biological specimens. The study aimed at generating the evidence about the prevalence of HIV and Syphilis among the prison population and to assess the HIV risk behavior, knowledge.

We are grateful to all the participants from the prison who spent their valuable time with us for the interview, provided blood sample for testing and shared their experiences with the study team. Without their support and cooperation, the study would not have been completed.

We like to acknowledge the support from Director General (DG), Department of Prison Management (DPM), Mr. Drona Pokharel, Jailor Mr. Laxmi Prasad Baskota, (Under Secretary), Central Jail, and Kalpana Gyawali (Sr. AHW). Finally we would like to acknowledge dedication and hard work of the principal investigator, research assistants, laboratory assistants and counselors. This report is a collaborative study by NCACS, STAC and SAIFRN-Nepal.

We believe that the findings of this survey will be valuable for the policy makers, program planners and implementing agencies to plan the new program and revise the strategies to address the HIV epidemic of Nepal, especially in the prison population.



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AIDS: Acquired immune deficiency Syndrome

AIDS: Acquired immunodeficiency syndrome

HBV: Hepatitis B Virus

HCV: Hepatitis C Virus

HIV: Human Immunodeficiency Virus

NCASC: National Centre for AIDS and STD Control

NHSP: National HIV Strategic Plan

PWID: People Who Inject Drugs

SDG: Sustainable Development Goal

STAC: SAARC Tuberculosis and HIV/AIDS Centre

STI: Sexually Transmitted Infections

WHO: World Health Organization

Summary

HIV is the leading causes of morbidity and mortality and continues to represent major global public health concerns. Few would disprove that the most neglected and vulnerable of all populations in the global HIV/AIDS response are people who are incarcerated. The objective of the study was to determine the prevalence of HIV and syphilis among prison population and assess the HIV related risk behaviors, knowledge and uptake of different interventions among prison population. A cross-sectional descriptive study was carried out among 377 prison inmates in central prison of Kathmandu, Nepal. All total of 328 male and 49 female were recruited in this study. The prevalence of HIV was found to be 1.9% (7/377) (95% CI: 1.97-2.00) and syphilis 0.5% among the total participants (377). Before being imprisoned 40.3% (n=152) respondents had used any kind of drug (oral and injecting) whereas 11.7% (n=44) of the respondent used to inject drug. Out of 319 respondents who ever had sexual intercourse, 126 (39.5%) of the respondents had sexual intercourse with female sex workers. Only 71 (56.3%) of them had used condom. Of the total prisoners 324 (85.9%) had heard about HIV/AIDS. Overall 130 (34.5%) had previously tested for HIV. For limiting the transmission of HIV and Syphilis, screening of HIV among prisoners should be conducted at the first entry of prisoners in prison. The prevalence and risk factors of HIV infection should be considered by policy makers for initiating harm reduction programs and forming the HIV guidelines in prisons.

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Background:

HIV is the leading causes of morbidity and mortality and continues to represent major global public health concerns.[1] Few would disprove that the most neglected and vulnerable of all populations in the global HIV/AIDS response are people who are incarcerated[2]. Prison populations are at high risk of HIV infections as a consequence of risk factors that are in play both before incarceration and once in prison where there are frequent opportunities for further transmission as they have little or no access to HIV treatment, prevention, and care. It is also due to their legal status by the result of which they are discriminated against by the criminal justice system. Globally, about 10·2 million men, women, and children are in prisons, detention, or some form of government custody at any given time[3]. Various studies suggest that the period following release could be a key prevention target for reducing the transmission of HIV and HCV among PWID (People who inject drugs). Prisoners are at risk of acquiring; human immunodeficiency virus (HIV), hepatitis B and C virus (HBV and HCV) infections due to their lifestyles and high risk behavior, that includes; illicit drug injection use inside or outside the prison, unsafe sex, multiple sexual partners and homosexuality. In addition, prison inmates are affected by; prevailing social health problems, illegal behavior, and limited educational opportunities[1]

Many individuals who are incarcerated are at greatest risk of these infections, whether because of injection drug use for HIV and viral hepatitis. However, prisons not only pose a threat to the health of people incarcerated within them. They also pose a risk to staff and to the population at large, because detainees are not a static population, but move around the prison system and back and forth from the outside world. The risks particularly lie at the interface between prisons and society outside4. Prisons act as incubators for tuberculosis and HIV, because they are associated with higher levels of infection than in the surrounding populations and yet many countries like Nepal have fragmented policy responses to these interlinked issues—prisons, HIV, viral hepatitis, and tuberculosis—and interruptions of surveillance and treatment during transitions.

Access to healthcare in prison is an increasing public health concern that should be included in the public health agenda. All over the world, the prevalence of sexually transmitted infections (STIs) and blood-borne infections is higher among the imprisoned population than in the general population. Communicable diseases can not only be spread within prisons but also outside. Indeed, visitors and correctional staff are in contact with people deprived from their liberty and may be infected by these communicable diseases. Moreover, inmates who are not treated in prison can spread their disease after release. The high prevalence of these infections can be influenced by factors that precede imprisonment. These factors include low socioeconomic status, high-risk sexual behaviors, limited access to health care and injecting drug use. During imprisonment,

[1] https://www.thelancet.com/action/showPdf?pii=S1473-3099%2818%2930469-9
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3437455/
[3] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30892-3/fulltext
4https://www.thelancet.com/action/showPdf?pii=S0140-6736%2816%2930466-4

inmates face other important risk factors: overcrowding, sharing contaminated objects or risky sexual intercourses. All these factors can contribute to the infection Human immunodeficiency virus (HIV), hepatitis B virus (HBV) and syphilis[5].

However, the magnitude and mechanism of this elevated risk following incarceration is not well understood, and there is scarce empirical evidence to support existing modeling, inform policy change, or aid in the development of interventions that target this period of risk. To improve the evidence based interventions we need a study to quantify the association between incarceration history, either past or recent, and HIV or HCV acquisition risk among PWID[6].

Internationally prisons are considered high risk environments for the transmission of HIV for several reasons, including:

- A large number of inmates coming from and returning to high risk environments;
- Activities such as injecting drug use, tattooing and unsafe sexual practices (consensual or otherwise) with limited availability of clean injecting equipment and condoms; and
- Epidemics of STIs such as syphilis, coupled with inadequate treatment of them, leading to a higher risk of transmitting HIV through sexual activity

HIV is a priority program of government of Nepal led by National Center for AIDS and STD Control (NCASC), under Ministry of Health and population. It has set targets and indicators for fast tracking the AIDS response by 2021, also known as 90-90-90 target which states that 90% of all people living with HIV will know their HIV status, 90% of diagnosed HIV positive people will receive sustained antiretroviral therapy and 90% of all people receiving antiretroviral therapy will have viral load suppressed. Along with this vertical transmission of HIV will be eliminated where mothers and alive and well, congenital syphilis is eliminated and new infection of HIV is reduced by 75%. This is in line with the Sustainable Development Goal (SDG) target 3.3, "End the epidemic of AIDS" by 2030.

Key population remains the main focus of the National HIV Strategic Plan (NHSP) 2016-2021.One of the key populations of HIV are prison population. Prison populations are also at risk of HIV and STI transmission. The priority targeted prevention intervention among prison inmates are behavior change intervention, including provision of condoms, HIV testing and counseling, diagnosis and treatment of STIs.

Global Scenario:

UNAIDS estimated that people in prison are on average five times more likely to be living with HIV compared with adults who are not incarcerated. The World Health Organization (WHO) estimates the difference to be even starker, suggesting prisoners are 15 times more

[5]http://scielo.isciii.es/pdf/sanipe/v20n2/1575-0620-sanipe-20-02-47.pdf
[6]https://www.thelancet.com/action/showPdf?pii=S1473-3099%2818%2930469-9

likely to be HIV-positive than those who are not in imprisoned. Prisons are characterized by higher risks for the transmission of infectious diseases including HIV, along with limited access to health services.[8]Of an estimated 10.2 million people incarcerated worldwide, estimated midpoint of the number infected was 389 000 with HIV (3.8%). Overall, prevalence of HIV infection was substantially higher in prison populations than in surrounding communities, especially where there are generalized HIV epidemics, such as

in sub-Saharan Africa, and where there is a high prevalence of injection drug use, such as in Eastern Europe and central Asia. (Dolan k et al., 2016).

In a study conducted in Ghana, 281 inmates tested from all the 3 prisons, HIV seroprevalence was 19.2 %, 17.4 % had HBsAg, HCV seroprevalence was 19.2 % and of the 82 officers tested from all the 3 prisons, HIV seroprevalence was 8.5 %. (Adjei A A et al., 2006) After Sub-Saharan Africa, the regions with the largest number of people living with HIV are Asia and the Pacific. At the end of 2015, there were an estimated 5.1 million people living with HIV across this region. There has been a slow progress in reducing number of new HIV infected cases in recent years, and also there are rising epidemics in some countries[7] In a study conducted in Pakistan, the prevalence rate among prisoners with HIV infection has been estimated 2.2% while, in a review study in India, it has estimated about 1.7%. (Kate Dolan & Sarah Larney., 2010)

Scenario of Nepal:

The first HIV infection in Nepal was identified in 1988. The potential for the spread of HIV in Nepal is large because of extensive use of commercial sex workers, high rates of sexually transmitted diseases, low levels of condom use, and pockets of intravenous drug users.[11] (Hikmat Bahadur Raya, 2018) As of July 2020, the HIV prevalence among adults (15-49 years) is below 0.13% in 2020 and there are an estimated total of 29,503 people living with HIV. Out of that, 59.6% 17587 are males and 40.38% 11916 are females and 0.96% are transgender. Furthermore, out of total people living with HIV around 4 percent are aged 0-14 years[10] (HIV Epidemic Update of Nepal, 2020, NCASC)

IBBS Survey estimated the prevalence of HIV among street-based children and youths was found to be 0.86 percent. Among 350 participants, 288 (82.3%) were male, and 62 (17.7%) were female. Overall 6.6 percent of the street involved children and youth were found to be as injecting drug users. Almost a half (48.6%) of the street involved children and youth never had sexual intercourse, and 28.3 percent of them had first sexual intercourse much earlier at 7 to 14 years of age.[12](IBBS Survey, 2016)

7http://scielo.isciii.es/pdf/sanipe/v20n2/1575-0620-sanipe-20-02-47.pdf
8 https://www.avert.org/professionals/hiv-social-issues/key-affected-populations/prisoners#footnote10_99ek7je
9 HIV in Indian prisons: Risk behaviour, prevalence, prevention & treatment. Kate Dolan & Sarah Larney., 2010)
10 http://ncasc.gov.np/WAD2020/Factsheet-2020-S.pdf
11 https://www.oatext.com/global-and-national-trends-of-hiv-aids.php
12 Integrated Biological and Behavioral Surveillance (IBBS) Survey among Street-Involved Children and Youths in Three Districts of Kathmandu Valley of Nepal, 2016

Rationale/justification:

Different studies suggest that the prevalence of HIV, Hepatitis C virus (HCV), hepatitis B virus (HBV), and tuberculosis is higher in prison population that in the general population because of different factor related to criminalization of drug use and sex work, and the detention of key population at high risk of HIV (people who use drug, men who have sex with men, male sex workers, female sex workers) and overcrowding for tuberculosis. Prison setting fuels the risk factor for the spread of HIV, HCV, HBV and tuberculosis and then transmitted to the community after prisoners are released. The results generated from this survey provided crucial evidence for utilization by policymakers, program planners,

and implementers to mobilize the national HIV response towards ending HIV in Nepal. Nevertheless, our vision for the generated study findings was to provide policymakers and program managers with evidence to develop targeted intervention strategies for different groups of PWID.

Objectives:

The objectives of this study were as follows:

General Objective:

To determine the prevalence of HIV and syphilis among prison population in Kathmandu, Nepal.

Specific Objective:

To assess the HIV related risk behaviors, knowledge and uptake of different interventions among prison population in Kathmandu, Nepal.

Methods and Methodology:

Study design:

A cross-sectional descriptive study was carried out among 377 prison inmates. Blood amples were tested from prison inmates to determine HIV and syphilis prevalence as per the national program algorithm. The socio-demographic and behavioral data was collected to assess risk behaviors and uptake of different interventions by using a structured questionnaire.

Study population and area:

This study included both male and female prison inmates aged 18 years or above from central prisons of Kathmandu. Those who were < 18 years of age; did not give consent; had other comorbid conditions were excluded from the study.

Sample size:

A total of 377 prison inmates who fulfilled the selection criteria were randomly selected from central prison and included in the study. The minimum sample size required of 359 was based on the following parameters: population size of the central prison (N)-3344, and the confidence level at 95% ($Z_{1-\alpha}$=1.96). Considering the 5% non-response rate, the total sample size for the study was 377.

Review of literatures:

We reviewed national and international published articles and literatures related to HIV infection among the prison population. The literatures were used for comparison and interpretation of results. National HIV Prevention and control strategies was reviewed and linked to the results.

Sampling:

Firstly, a list of total prison inmates in the central prisons was prepared. Secondly, the number of prison inmates per prison for the study was determined based on proportion of the prison inmates in each prison. Lastly, among the prison inmates in prison, required numbers of participants above 18 years of age were selected randomly.

Blood sample collection and testing:
Before collecting blood sample, each participant was explained about the objective and procedures of the study and consent was taken. The data and blood sample was collected only from those participants who voluntarily consented to participate in the study. After taking all aseptic precautions, blood sample of 2ml was collected by laboratory technician. The blood was then tested for HIV and syphilis according to national protocol using standard test kits following the 2020 HIV Testing and Treatment Guidelines. All positive samples reactive for HIV and syphilis and 10% negative were sent to Central Diagnostic Laboratory (CDL) Kamalpokhari for external quality assurance (EQA). The test results were later provided to the study participants with pre-and post-test counseling in a confidential manner by qualified and trained counselors. All participants with a positive test result went under counseling and medical consultation and were referred for follow up in specialized service for treatment for HIV.

Data collection technique:
Prisoners who were invited to participate in the survey were given an explanation about the aims, procedure, advantages and impact of being involved. After explaining the survey, prisoners could choose to not participate and if they wanted to be involved they had to consent verbally. A witness signed the consent form to protect the participants' identity. Inmates were excluded if they: could not read the consent; had profound intellectual disabilities; had acute mental illness; could not be safely moved to the interview area according to prison officials; were unavailable due to being transferred, in court or hospital; or refused to provide consent. Data collection included demographic characteristics, sexual behavior, drug use, knowledge about HIV and use of programs related to HIV and drug use. The interview was conducted using standard questionnaire. After respondents completed the questionnaire, a blood sample was taken for testing for HIV and syphilis.

Ethical issues:
For the ethical consideration the proposal was submitted to Nepal Health Research Council (NHRC), Kathmandu and approval was taken from NHRC. Written permission was taken from the Central jail authority. The entire respondents were informed about the purpose, effectiveness of the study and a written consent was taken from them. Confidentiality was ensured throughout the study process and quality control systems for collection of both biological and behavioral data was ensured.

Criteria for sample selection:
Eligibility criteria for this study:

- 18 years and above
- Lived in the central prison of Kathmandu where the survey was being conducted
- Nepalese citizenship
- Be physically and mentally able to understand.
- Could be safely moved to the interview area according to prison officials; were available for the interview; or provided consent.

Data collection tools:
The study used questionnaire for a face-to-face interview and forms to collect the results of HIV, syphilis tests through test kit.

Potential Biases:
Due to the face-to-face interview, self-reported HIV risk behavior was prone to social desirability bias which was minimized by the non-collection of personal identifiers and by conducting anonymous interviews.

Supervision and monitoring:
The joint monitoring team was formed including different experts (lab, clinician, public health expert, epidemiologist etc.) to monitor the fieldwork. Monitoring of fieldwork was planned in different phases of the survey (initial, mid and end) and monitoring team used standard monitoring checklist during supervision and monitoring visit.

Plan for data management and analysis:
Data Quality Management and Analysis: During the day-to-day operations of the survey, the field supervisor recorded the following: The number of individuals who refused to participate; the number of participants who were found to be ineligible; the number of participants completing the interviews who refused to become recruiters. In order to effectively carry out daily monitoring, the site supervisor used the checklist (refer to protocol for detail information).

After the completion of data collection, it was reviewed, organized, coded, entered and analyzed by using the SPSS version- 20 and MS Excel 2007. Descriptive and inferential analysis was computed. The findings were presented using tables and diagrams based on the objectives of study. The survey was descriptive and data was summarized as frequency and percentages.

Findings

History of drug use among the respondents

Ever Used Any Drugs
From the table it is observed that 40.3% (n=152) of the respondents have used drugs before among which 43.6 % (n=143) were male and 18.4% (n=9) were female. Similarly, 59.7% (n=225) of the respondents have not used any drugs among which 56.45% (n=185) were male and 81.6 % (n=40) were female. (Table 1)

Used Injecting Drugs
11.7% (n=44) of the respondents have used injecting drugs among which 12.5% (n=41) were male and 6.1% (n=3) were female. Likewise, 88.3% (n=333) of the respondents have not used injecting drugs among which 87.5% (n=287) were male and 93.9% (n=46) were female. (Table 1)

Age when started Injecting
The mean age of the respondents when started injecting was 20±5 (n=44). The mean age of male when started injecting was 20±5 (n=41) and the mean age of female when started injecting was 17±3 (n=3). (Table 1)

No of person together when injecting

The no. of respondents injecting alone was 7 (15.9%) among which 6 (14.6%) were male and 1 (33.3%) was female. The no. of respondents injecting 1 to 2 people together was 20 (45.5%) among which 19 (46.3%) were male and 1 (33.3%) was female. The no. of respondents injecting 3 to 5 people together was 13 (29.5%) among which all i.e. 13 (31.7%) were male. The no. of respondents injecting more than 5 people together were 3 (6.8%) among which 2 (4.9%) were male and 1 (33.3%) was female. The number of respondents not knowing was 1 (2.3%) among which all i.e. 1 (2.4%) was male. (Table 1)

Shared Needles while Injecting

13.6% (n=6) of the respondents shared needles while injecting, among which 14.6% (n=6) were male and 0 were female. 86.4% (n=38) of the respondents have not shared needles while injecting among which 85.4% (n=35) were male and 100% (n=3) were female. (Table 1)

Syringe/ Needle cleaned

100% (n=6) of the respondents have cleaned syringe/needle among which all 100% (n=6) were male. (Table 1)

Source of Syringe/Needle

63.6% (n=28) of the respondents bought syringe/needle from medical among which 65.9% (n=27) were male and 33.3% (n=1) were female. 11.4% (n=5) of the respondents borrowed syringe/needle from friend among which 9.8% (n=4) were male and 33.3% (n=1) were female. 2.3% (n=1) of the respondents self-created syringe/needle among which all respondents 2.4% (n=1) were male. 6.8% (n=3) of the respondents receive syringes from Drop in center (DIC), among which all 7.3% (n=3) were male. 15.9% (n=7) of the respondents received the syringe/needles from other sources among which 14.6% (n=6) were male and 33.3% (n=1) were female. (Table 1)

Disposal of used Syringe

22.7% (n=10) of the respondents dispose syringe in open area among which 22.0% (n=9) were male and 33.3% (n=1) were female. 6.8% (n=3) of the respondents dispose syringe in toilet among which 7.3% (n=3) were male. 38.6% (n=17) of the respondents dispose syringe in rubbish bin among which 36.6% (n=15) were male and 66.7% (n=2) were female. 9.1% (n=4) of the respondents dispose syringe in NGO/DIC among which 9.8% (n=4) were male. No female respondents dispose the syringe in NGO/DIC. 22.7% (n=10) of the respondents dispose syringe in other places among which 24.4% (n=10) were male. (Table 1)

Table 1: History of drug use among the respondents

Variable Name	Male		Female		Total	
	(N)	(%)	(N)	(%)	(N)	(F)
Ever Used Any Drugs						
Yes	143	43.6	9	18.4	152	40.3
No	185	56.4	40	81.6	225	59.7
Used Injecting Drugs						
Yes	41	12.5	3	6.1	44	11.7
No	287	87.5	46	93.9	333	88.3

Age when started Injecting									
Mean ± SD		41	20±5		3	17±3		44	20±5
No of person together when injecting									
Alone		6	14.6		1	33.3		7	15.9
1 to 2 person		19	46.3		1	33.3		20	45.5
3 to 5 person		13	31.7		0	0.0		13	29.5
More than 5 person		2	4.9		1	33.3		3	6.8
Don't Know		1	2.4		0	0.0		1	2.3
Shared Needles while Injecting									
Yes		6	14.6		0	0.0		6	13.6
No		35	85.4		3	100.0		38	86.4
Syringe/ Needle cleaned									
Yes		6	100		0	0.0		6	100
No		0	0.0		0	0.0		0	0.0
Source of Syringe/Needle									
Bought from Medical		27	65.9		1	33.3		28	63.6
Borrowed from Friend		4	9.8		1	33.3		5	11.4
Self-creation		1	2.4		0	0		1	2.3
Crop In Center (DIC)		3	7.3		0	0		3	6.8
Other		6	14.6		1	33.3		7	15.9
Disposal of used Syringe									
Open area		9	22.0		1	33.3		10	22.7
Toilet		3	7.3		0	0.0		3	6.8
Rubbish bin		15	36.6		2	66.7		17	38.6
NGO/DIC		4	9.8		0	0		4	9.1
Other		10	24.4		0	0		10	22.7

Sexual history of the respondents

Ever had sexual intercourse: Majority of the respondent had sexual intercourse (95%) among them 97.3% were male and 79.6% were female. However only 5% respondent did not have sexual intercourse, among which male were 2.7% and female were 20.4%. (Table 2)

Sexual Intercourse with FSW: Around 62.3% respondent had no sexual intercourse with FSW, among which 59.9% were male and 82.1% were female. Along with that 12.8% female and 0.3% male did not respond to the question. (Table 2)

Condoms used while intercourse with FSW: In a question regarding condom use while intercourse with FSW, more than half of the total respondent (57%) answered that they used condom, among them all of the female who had intercourse with FSW used condom whereas only 56.3% male used condom. About 40.5% of the male did not use condom while intercourse with FSW, whereas, 2.4% of the male had no knowledge. (Table 2)

Last time you had sexual intercourse (Partner): All female respondent had sexual intercourse with male partner last time whereas about 98.7% male had intercourse with female and 0.6% male had intercourse with male in the last intercourse. (Table 2)

Type of sex partner during last intercourse: Around 68.2% of the total respondent answered that they had their last intercourse with regular sex partner among which female (74.4%) were higher in percentage to have intercourse with regular sex partner than male respondent (67.4%). The reason for this was there were more male respondent having sex with casual sex partner which is 23.5%, almost 3 times more than female respondent (5.1%). Around 8.2% male respondent paid someone money or goods for sex and only 0.3% male received money or goods for sex. However, female respondent did not receive or provide money or goods for sex. (Table 2)

Type of sex during last intercourse: Around 93% of total respondent said that they had vaginal sex during last intercourse among which 93.4% were male and 92.3% were female. Only 2.6% female and 0.9% male had anal sex whereas 4.4% male respondent had both anal and vaginal sex during last intercourse. Around 0.3% male respondent answered other types of sexual activity. (Table 2)

Ever used condom during sexual intercourse: More than half of the total respondent (54.7%) used condom during sexual intercourse in their life time, among which 58.3% were male and 25.6% were female. (Table 2)

How often do you use condom: Among the total respondent who used condom during sexual intercourse only 14.6% used condom every time, among them 14.4% were male and 20% were female. Majority of respondent (66.2%) used condom sometimes which is similar in response to male (66.5%) and female (60%). About 16% male and 20% female used condom almost every time during sexual intercourse whereas 2.1% male never used condom. (Table 2)

Condom used in last sexual intercourse: More than half of the total respondent (55.6%) did not use condom during their last sexual intercourse among them 40% were female and 56.4% were male whereas 39.9% of the total respondent did not use condom during last sexual intercourse among which 39.9% were male and 40% were female. (Table 2)

Taken drugs in last sexual intercourse: Majority of respondent and their partner (75.4%) did not take drugs during last intercourse among which 74.6% were male and 82.1% were female whereas 4.2% of the respondent and their partner took drugs among which 4.4% were male and 2.6% were female. About 14.8% of the respondent used drugs during last sexual intercourse among which 16.3% were male and 2.6% were female. About 3.9% of the respondent answered that their partner used drugs during last sexual intercourse among which 3.1% were male and 10.3% were female. (Table 2)

Table 2: Sexual history of the respondents

Variable Name	Male			Female			Total	
	(N)	(%)		(N)	(%)		(N)	(F)
Ever had sexual intercourse								
Yes	319	97.3		39	79.6		358	95.0
No	9	2.7		10	20.4		19	5.0
Sexual intercourse with FSW								
Yes	126	39.5		2	5.1		128	35.8
No	191	59.9		32	82.1		223	62.3
Don't Know	1	0.3		0	0.0		1	0.3
No response	1	0.3		5	12.8		6	1.7
Condom used while intercourse with FSW (n=128)								
Yes	71	56.3		2	100		73	57.0
No	51	40.5		0	0.0		51	39.8
Don't Know	3	2.4		0	0.0		3	2.3
No response	1	0.8		0	0.0		1	0.8
last time you had sexual intercourse (Partner)								
Man	2	0.6		39	100		41	11.5
Women	315	98.7		0	0.0		315	88.0
Don't know	1	0.3		0	0.0		1	0.3
No response	1	0.3		0	0.0		1	0.3
Last time type of sex partner								
Regular sex partner	215	67.4		29	74.4		244	68.2
Casual sex partner	75	23.5		2	5.1		77	21.5
Someone I paid money or goods for sex	26	8.2		0	0.0		26	7.3
Someone who gave me money or goods for sex	1	0.3		0	0.0		1	0.3
Other	1	0.3		0	0.0		1	0.3
No response	1	0.3		8	20.5		9	2.5
Type of sex in last time								
Vaginal sex	298	93.4		36	92.3		334	93.3

Anal Sex	3	0.9		1	2.6		4	1.1
Both vaginal and anal	14	4.4		0	0.0		14	3.9
Other	1	0.3		0	0.0		1	0.3
No response	3	0.9		2	5.1		5	1.4
Ever used condom during sexual intercourse								
Yes	186	58.3		10	25.6		196	54.7
No	131	41.1		29	74.4		160	44.7
Don't Know	1	0.3		0	0.0		1	0.3
No response	1	0.3		0	0.0		1	0.3
How often use condom								
Every Time	27	14.4		2	20.0		29	14.6
Almost Every time	30	16.0		2	20.0		32	16.2
Sometimes	125	66.5		6	60.0		131	66.2
Never Used	4	2.1		0	0.0		4	2.0
No response	2	1.1		0	0.0		2	1.0
Condom used in last sexual intercourse								
Yes	75	39.9		4	40.0		79	39.9
No	106	56.4		4	40.0		110	55.6
Don't Know	4	2.1		2	20.0		6	3.0
No response	3	1.6		0	0.0		3	1.5
Taken drugs in last sexual intercourse								
I took drugs	52	16.3		1	2.6		53	14.8
My partner took drugs	10	3.1		4	10.3		14	3.9
We both took drugs	14	4.4		1	2.6		15	4.2
We both did not take drugs	238	74.6		32	82.1		270	75.4
Don't Know	2	0.6		0	0.0		2	0.6
No response	3	0.9		1	2.6		4	1.1

Knowledge about STI among the respondents

Sexually transmitted diseases: Two-third of the total respondent (71.9%) have heard about sexually transmitted diseases among which 72.3% were male and 69.4% were female, whereas one-third of the respondent (24.7%) have not heard about sexually transmitted diseases. (Table 3)

Experience of following symptoms in past 12 months: Majority of respondent (61.3%) did not experience any symptoms in past 12 months. Among the respondent who have experienced some symptoms, 5% (4.5% male, 0.5% female) experienced intense pain (burning sensation) during urination, 0.8% (0.5% male, 0.3% female) experienced warts in the anal area, 1.6% (1.6 % male, 0% female) experienced sores or ulcers in the genital area, 1.9% experienced abnormal discharge from the penis (specific for men), 0.3% (0.3% male, 0% female) experienced abnormal discharge from the anus, 1.3% (1.1% male, 0.3% female) experienced bumps/ swelling in the anal area, 1.6% women experienced vaginal

discharge 0.8% women experienced pain in the lower abdomen. (Table 3)

Table 3: Knowledge about STI among the respondents

Variable Name	Male			Female			Total	
	(N)	(%)		(N)	(%)		(N)	(F)
Heard about sexual transmitted diseases								
Yes	237	72.3		34	69.4		271	71.9
No	80	24.4		13	26.5		93	24.7
Don't Know	9	2.7		1	2.0		10	2.7
No response	2	0.6		1	2.0		3	3
Past 12 months experienced following symptoms								
Intense pain (burning sensation) during urination	17	4.5		2	0.5		19	5.0
Warts in the anal area	2	0.5		1	0.3		3	0.8
Sores or ulcers in the genital area	6	1.6		0	0.0		6	1.6
Abnormal discharge from the penis (specific for men)	7	1.9		0	0.0		7	1.9
Abnormal discharge from the anus	1	0.3		0	0.0		1	0.3
Bumps/ swelling in the anal area	4	1.1		1	0.3		5	1.3
Vaginal discharge (specific for women)	0	0.0		6	1.6		6	1.6
Pain in the lower abdomen (Specific for women)	0	0.0		3	0.8		3	0.8
No Sign / Symptoms experienced	209	55.4		22	5.8		231	61.3
Other	6	1.6		0	0.0		6	1.6
Don't Know	5	1.3		0	0.0		5	1.3
No response	74	19.6		14	3.7		88	23.3

Knowledge about HIV/AIDS among the respondents

Heard about HIV: Majority of the respondent (85.9%) have heard about HIV among them 86% were female and 85.7% were female whereas 11.7% respondent have not heard about HIV among which 11.3% were male and 14.3% were female. (Table 4)

Condom use protection from HIV: About 68.4% respondent answered that condom use protects form HIV among which 66.8% were male and 79.6% were female. About 13.3% of the total respondent answered that condom does not protect from HIV among which 14.3% were male and 6.1% were female. (Table 4)

Get HIV from Mosquito bite: Majority of respondent (44.6%) said that Mosquito bite does not cause HIV, among them 44.8% were male and 42.9% were female. Around 36.1% had incorrect knowledge about mosquito bite causing HIV among which 36% were male and 36.7% were female. (Table 4)

Healthy looking person can be infected with HIV: Majority of respondent (68.2%) knew that healthy looking person can be infected with HIV among which 68.0% were male and 69.4% were female. Whereas 21.5% of the respondent didn't know among

which 20.4% were male and 28.6% were female. (Table 4)

Having one uninfected faithful sex partner: More than half of the respondent (59.9%) answered that having one uninfected faithful sex partner can stop from getting infected from HIV among which 59.8% were male and 61.2% were female. About 18% of the respondent didn't know among which 17.1% were male and 20.4% were female. (Table 4)

Abstaining from sexual intercourse: About 43.5% of the respondent said that they had abstain from sexual intercourse can help to stop from getting infected with HIV among which 43.3% were male and 44.9% were female whereas 38.8% did not comply with the statement and responded otherwise among which 16.5% were male and 20.4% were female. (Table 4)

By sharing meals with someone who is infected with HIV: About 71.1% respondent answered that sharing meal with someone who is infected with HIV will not infect them with HIV, among which 72.3% were male and 63.3% were female, whereas 13.8% respondent answered that sharing meal with someone who is infected with HIV can cause HIV, among which 12.2% were male and 24.5% were female. (Table 4)

Sharing needle with someone who is already infected: About 87.5% of the respondent believed that sharing needle with someone who is infected with HIV can transmit HIV, among which 86.9% were male and 91.8% female whereas 1.5% male respondent believed that sharing needle with someone already infected will not transmit HIV. Around 10% of the total respondent did know. (Table 4)

Know anyone who is infected with HIV or who has died of AIDS: About 49.3% of the respondent did not know anyone who is infected with HIV or who has dies of AIDS, among which 42.4% were male and 22.4% were female. Whereas 39% knew someone who is infected with HIV or who has died of AIDS, among which 42.4% were male and 22.4% were female. (Table 4)

Table 4: Knowledge about HIV/AIDS among the respondents

Variable Name	**Male**		**Female**			**Total**	
	(N)	**(%)**	**(N)**	**(%)**		**(N)**	**(F)**
Heard about HIV							
Yes	282	86.0	42	85.7		324	85.9
No	37	11.3	7	14.3		44	11.7
Don't Know	9	2.7	0	0.0		9	2.4
Condom use protection from HIV							
Yes (Correct)	219	66.8	39	79.6		258	68.4
No (Incorrect)	47	14.3	3	6.1		50	13.3
Don't Know (Incorrect)	59	18.0	7	14.3		66	17.5
No response (Incorrect)	3	0.9	0	0.0		3	0.8
Get HIV from Mosquito bite							
Yes (Incorrect)	118	36.0	18	36.7		136	36.1

No (Correct)	147	44.8	21	42.9		168	44.6
Don't Know (Incorrect)	59	18.0	10	20.4		69	18.3
No response (Incorrect)	4	1.2	0	0.0		4	1.1
Healthy looking person can be infected with HIV							
Yes (Correct)	223	68.0	34	69.4		257	68.2
No (Incorrect)	32	9.8	1	2.0		33	8.8
Don't Know (Incorrect)	67	20.4	14	28.6		81	21.5
No response (Incorrect)	6	1.8	0	0.0		6	1.6
Having one uninfected faithful sex partner							
Yes (Correct)	196	59.8	30	61.2		226	59.9
No (Incorrect)	67	20.4	9	18.4		76	20.2
Don't Know (Incorrect)	58	17.1	10	20.4		68	18.0
No response (Incorrect)	7	2.1	0	0.0		7	1.9
Abstaining from Sexual intercourse							
Yes (Incorrect)	142	43.3	22	44.9		164	43.5
No (Correct)	131	39.9	15	30.6		146	38.7
Don't Know (Incorrect)	54	16.5	10	20.4		64	17.0
No response (Incorrect)	1	0.3	2	4.1		3	0.8

By sharing meals with someone who is infected with HIV							
Yes (Incorrect)	40	12.2	12	24.5		52	13.8
No (Correct)	237	72,3	31	63.3		268	71.1
Don't Know (Incorrect)	48	14.6	5	10.2		53	14.1
No response (Incorrect)	3	0.9	1	2.0		4	1.1
Sharing needle with someone who is already infected							
Yes (Correct)	285	86.9	45	91.8		330	87.5
No (Incorrect)	5	1.5	0	0.0		5	1.3
Don't Know (Incorrect)	34	10.4	4	8.2		38	10.1
No response (Incorrect)	4	1.2	0	0.0		4	1.1
Know anyone who is infected with HIV or who has died of AIDS							
Yes	139	42.4	11	22.4		150	39.8
No	152	46.3	34	69.4		186	49.3
Don't Know	36	11.0	4	8.2		40	10.6
No response	1	0.3	0	0.0		1	0.3

Confirmatory result from laboratory diagnosis:

From the study we found that there were 7 participants i.e. 1.9% who were found to be positive for HIV. (Table 5)

Table 5: Laboratory diagnosis for HIV

HIV Diagnosis	Frequency	Percent
Positive	7	1.9
Negative	370	98.1
Total	377	100.0

From the study we found that there were 2 participants i.e. 0.5 % who were found to be positive for syphilis. (Table 6)

Table 6: Laboratory diagnosis for Syphilis

Syphilis Diagnosis	Frequency	Percent
Positive	2	0.5
Negative	375	99.5
Total	377	100.0

Among Male samples: (N=328)

Among the male samples (N=328) there were 6 participants i.e. 1.8% who were found to be positive for HIV. (Table 7)

Table 7: Result of HIV from laboratory diagnosis among total male sample: (N=328)

HIV result from laboratory diagnosis	Frequency	Percent
Positive	6	1.8
Negative	322	98.2
Total	328	100.0

Among Female samples: (N=49)

Among the female samples (N=49) there were 1 participant i.e. 2.0% was found to be positive for HIV. (Table 8)

Table 8: Result of HIV from laboratory diagnosis among total female sample: (N=49)

HIV result from laboratory diagnosis	Frequency	Percent
Positive	1	2.0
Negative	48	98.0
Total	49	100.0

Among the participants who injected drug before imprisonment the prevalence of HIV was found to be 4.5%. Similarly, among participants who had sexual intercourse with sex workers the prevalence of HIV was found to be 2.3%. Among participants who had usedcondom during sexual intercourse before imprisonment 1.5% had HIV positive result. Likewise, 1.9% of the HIV positive cases had female sex partners. (Table 9)

Table 9: Summary HIV prevalence based on risk behavior

Risk factors	Number (N=377)	HIV positive (N=7)
Injected drug use before imprisonment	44 (11.67%)	2 (4.5%)
Sexual intercourse with sex worker before imprisonment	128 (33.95%)	3 (2.3%)
Use of condom during sexual intercourse before imprisonment	196 (52%)	3 (1.5%)
Sex partner (female)	315 (83.6)	6 (1.9%)

Participants were asked about their knowledge of HIV/AIDS. Among the participants who had heard of HIV/AIDS, 1.85% had HIV positive result. Similarly, 1.16% and 1.77% of the participants who had HIV positive result had known that condom prevents from HIV infection and that HIV can be prevented having sex with only one partner. (Table 10)

Table 10: Summary "knowledge of HIV/AIDS"

Particulars	Number (N=377)	HIV positive (N=7)
Heard of HIV/AIDS	324 (85.94%)	6 (1.85%)
Knows that condom prevents from HIV infection	258 (68.44%)	3 (1.16%)
Knows that HIV can be prevented having sex with only one partner	226 (59.95%)	4 (1.77%)

History of HIV testing among the respondents:

Participants were asked about their confidential HIV test in the community 52.3% (Male 54.9% and Female 34.7%) that they can have confidential HIV test. 50.1% (Male 52.1 and 36.7%) of the participants knew where to go for HIV test. 34.5% (35.4% and 28.6) of the participants had tested for HIV previously. (Table 11)

Table 11: History of HIV testing among the respondents

Variable Name	Male		Female		Total	
	(N)	(%)	(N)	(%)	(N)	(F)
Can someone have confidential HIV test in your community						
Yes	180	54.9	17	34.7	197	52.3
No	109	33.2	30	61.2	139	36.9
Don't Know	39	11.9	1	2.0	40	10.6
No response	0	0.0	1	2.0	1	0.3
Know where to go for HIV test						
Yes	171	52.1	18	36.7	189	50.1
No	98	29.9	30	61.2	128	34.0
Don't Know	56	17.1	0	0.0	56	14.9
No response	3	0.9	1	2.0	4	1.1

Ever had HIV test									
Yes		116	35.4		14	28.6		130	34.5
No		209	63.7		32	65.3		241	63.9
Don't Know		1	0.3		1	2.0		2	0.5
No response		2	0.6		2	4.1		4	1.1

Background Characteristics of the participants and HIV status:

Age Group: The prevalence of HIV as found to be different among different age groups. The prevalence in different age group i.e. 18-24, 25-34, 35-44 and 50 and higher was 2.4%, 1.2%, 3.0% and 2.6% respectively. (Table 12)

Average Income: The prevalence of HIV among different income group i.e. No income was 3.1%, 1-15000 was 3.1% and 2.1% for those having income greater than 45000. (Table 12)

Education: The prevalence of HIV among different education group was 2.7%, for illiterate, 6.7%, for Informal education, 3.3%, for 1-5 (primary education) and 1.1 %, for 9-10 (secondary education). (Table 12)

Marital status: The prevalence of HIV among single/never married was 2.2% and among married 1.8% among married. (Table 12)

Years in prison: The prevalence of HIV among prisoners who were imprisoned for 1 to 2 years was 3.9% and who were imprisoned for >2 to 5 year was 1.8%. (Table 12)

Case: The prevalence of HIV among prisoners from different cases was drug 1.3%, homicide 1.1%, rape 3.8%, robbery/theft 2.3% and smuggling/kidnap/forest 4.5%. (Table 12)

Injected Drug: The prevalence of HIV among prisoners who had injected drug before imprisonment was 4.5%. (Table 12)

Ever had sexual intercourse: The prevalence of HIV among prisoners who had sexual intercourse before imprisonment was 1.7%. (Table 12)

Ever had sexual intercourse with sex worker: The prevalence of HIV among prisoners who ever had sexual intercourse with sex worker before imprisonment was 2.3%. (Table 12)

Table 12: Background Characteristics of the participants and HIV status

Variable	Positive	Negative	Total
Age Group			
18-24	2 (2.4)	83 (97.6)	85 (100.0)
25-34	2 (1.2)	167 (98.8)	169 (100.0)
35-44	2 (3.0)	65 (97.0)	67 (100.0)
45-49	0 (0.0)	17 (100.0)	17 (100.0)
50 and higher	1 (2.6)	38 (97.4)	39 (100.0)

Average Income			
No any Income	3 (3.1)	93 (96.9)	96 (100.0)
1 – 15000	3 (3.1)	94 (96.9)	97 (100.0)
15001 – 30000	0 (0.0)	108 (100.0)	108 (100.0)
30001 – 45000	0 (0.0)	29 (200.0)	29 (100.0)
Greater than 45000	1 (2.1)	46 (97.9)	47 (100.0)
Education			
Illiterate	1 (2.7)	36 (97.3)	37 (100.0)
Informal Education	2 (6.7)	28 (93.3)	30 (100.0)
1- 5 (Primary Education)	3 (3.3)	87 (96.7)	90 (100.0)
6-8 (Lower secondary)	0 (0.0)	54 (100.0)	54 (100.0)
9-10 (Secondary Education)	1 (1.1)	90 (98.9)	91 (100.0)
11-12 (Higher Secondary)	0 (0.0)	53 (100.0)	53 (100.0)
Graduate and Higher	0 (0.0)	22 (100.0)	22 (100.0)
Marital Status			
Single, Never Married	3 (2.2)	134 (97.8)	137 (100.0)
Married	4 (1.8)	216 (98.2)	220 (100.0)
Divorced	0 (0.0)	8 (100.0)	8 (100.0)
Permanently Separated	0 (0.0)	4 (100.0)	4 (100.0)
Widow/ Widower	0 (0.0)	5 (100.0)	5 (100.0)
Other (Specify)	0 (0.0)	3 (100.0)	3 (100.0)
Years in Prison			
< 1 year	0 (0.0)	46 (100.0)	46 (100.0)
1 to 2 year	6 (3.9)	148 (96.1)	154 (100.0)
>2 to 5 year	1 (1.8)	56 (98.2)	57 (100.0)
>5 to 10 year	0 (0.0)	47 (100.0)	47 (100.0)
More than 10 year	0 (0.0)	68 (100.0)	68 (100.0)
Case			
Drug	1 (1.3)	79 (98.8)	80 (100.0)
Homicide	1 (1.1)	93 (98.9)	94 (100.0)

Rape	3 (3.8)	77 (96.3)	80 (100.0)
No response (NA)	0 (0.0)	11 (100.0)	11 (100.0)
Banking	0 (0.0)	10 (100.0)	10 (100.0)
Robbery/Theft	1 (2.3)	43 (97.7)	44 (100.0)
Polygamy	0 (0.0)	11 (100.0)	11 (100.0)
Smuggling/Kidnap/Forest	1 (4.5)	21 (95.5)	22 (100.0)
Fraud	0 (0.0)	15 (100.0)	15 (100.0)
Other (Specify)	0 (0.0)	10 (100.0)	10 (10.0.0)
Injected Drug			
Yes	2 (4.5)	42 (95.5)	44 (100.0)
No	5 (1.5)	328 (98.5)	333 (100.0)
Ever had sexual intercourse			
Yes	6 (1.7)	352 (98.3)	358 (100.0)
No	1 (5.3)	18 (94.7)	19 (100.0)
Ever had sexual intercourse with sex worker			
Yes	3 (2.3)	125 (97.7)	128 (100.0)
No	3 (1.3)	220 (98.7)	223 (100.0)
Don't Know	0 (0.0)	1 (100.0)	1 (100.0)
No response	0 (0.0)	6 (100.0)	6 (100.0)

Knowledge of HIV/AIDS and HIV status:

The table shows the relationship between knowledge related to HIV/AIDS and prevalence of HIV cases. It was observed that among the respondents 1.5% of the positive cases had heard about disease called HIV and 4.5% of the positive cases had not heard about HIV.

Regarding protecting oneself from HIV by using condom during sexual act 1.2% of the positive case had correct knowledge and 2.4% had incorrect knowledge. Participants were asked if a person can het HIV from mosquito bites, it was observed that 1.2% of the positive cases had correct knowledge and 3.4% of the positive cases had incorrect knowledge.

Participants were asked if healthy looking person can be infected with HIV, 1.2% of the positive cases had correct knowledge and 3.3% of the positive cases had incorrect knowledge. Similarly, respondents were asked if S/he can protect oneself from HIV by having only one uninfected faithful partner, 1.8% positive cases had correct knowledge and 2.0% of the positive cases had incorrect knowledge. Participants were asked if S/he can protect oneself from HIV, by abstaining from sexual intercourse, 0.7% of the positive cases had correct knowledge whereas 2.6% of the positive cases had incorrect knowledge.

They were further asked if a person get HIV by sharing a meal with someone who is infected, 1.9% of positive cases had correct knowledge and 1.8% of the positive cases had incorrect knowledge. Participants were asked if a person can get HIV, by getting injection with a needle that was already used by someone else who is infected, 1.5% of the positive cases had correct knowledge and 4.3% of the positive cases had incorrect knowledge. (Table 13)

Table 13: Knowledge of HIV/AIDS and HIV status:

Variable	Positive	Negative	Total
Heard of the disease called HIV or AIDS			
Yes	5 (1.5)	319 (98.5)	324 (100.0)
No	2 (4.5)	42 (95.5)	44 (100.0)
Don't Know	0 (0.0)	9 (100.0)	9 (100.0)
Protect oneself from HIV by using Condom during sexual act			
Correct knowledge	3 (1.2)	255 (98.8)	258 (100.0)
Incorrect knowledge	4 (3.4)	115 (96.6)	119 (100.0)
Can a person get HIV from mosquito bites			
Correct knowledge	4 (2.4)	164 (97.6)	168 (100.0)
Incorrect knowledge	3 (1.4)	206 (98.6)	209 (100.0)
Healthy looking person can be infected with HIV			
Correct knowledge	3 (1.2)	254 (98.8)	257 (100.0)
Incorrect knowledge	4 (3.3)	116 (96.7)	120 (100.0)
Can protect oneself from HIV by having only one uninfected faithful partner			
Correct knowledge	4 (1.8)	222 (98.2)	226 (100.0)
Incorrect knowledge	3 (2.0)	148 (98.0)	151 (100.0)
Can protect oneself from HIV, by abstaining from sexual intercourse			
Correct knowledge	1 (0.7)	145 (99.3)	146 (100.0)
Incorrect knowledge	6 (2.6)	225 (97.4)	231 (100.0)
Can a person get HIV by sharing a meal with someone who is infected			
Correct knowledge	5 (1.9)	263 (98.1)	268 (100.0)
Incorrect knowledge	2 (1.8)	107 (98.2)	109 (100.0)
Can a person get HIV, by getting injection with a needle that was already used by someone else who is infected			
Correct knowledge	5 (1.5)	325 (98.5)	330 (100.0)
Incorrect knowledge	2 (4.3)	45 (95.7)	47 (100.0)

Overall knowledge Score:

Overall knowledge score was calculated using the 7 questions related to knowledge of HIV/AIDS. The mean of the knowledge score was 0.6264±0.2736. Knowledge score was further grouped into three categories, poor knowledge, average knowledge and good knowledge. Poor knowledge was categorized as score (< mean – SD) or <0.35, Average knowledge was categorized as score (mean – SD to mean + SD) or 0.35 to 0.90, and Good

knowledge was categorized as (>mean + SD) or > 0.90.

From the overall knowledge score it was observed that 3.6% of positive cases had poor knowledge, 1.4% of positive cases had average knowledge and 2.4% of the positive cases had good knowledge. (Table 14)

Table 14: Overall knowledge score:

Overall Knowledge	Positive	Negative	Total
Poor Knowledge	2 (3.6)	54 (96.4)	56 (100.0)
Average Knowledge	4 (1.4)	276 (98.6)	280 (100.0)
Good Knowledge	1 (2.4)	40 (97.6)	41 (100.0)
Total	7 (1.9)	370 (98.1)	377 (100.0)
Overall knowledge score	(X ± SD) (0.6264 ± 0.2736)		

Result of bivariate and multivariate logistic regression:

Bivariate and multivariate regression was carried out for two dependent variables. Participants who had injected drug before imprisonment and participants who had sexual intercourse with sex worker before imprisonment. Those participants who had injected drug and had sexual intercourse with sex worker were coded as 1 and those who had not were coded as 0. Independent variables for the analysis were, age, sex, education, income, marital status, cast and case for imprisonment.

Participants who injected drug before imprisonment:

In the bivariate analysis three independent variables i.e. marital status, education and case for imprisonment showed significant relationship. Whereas in the multivariate analysis, case of prisoner for imprisonment had significant relationship with those who injected drug. It showed that participants who were imprisoned due to cases other than drugs had low chance of injecting drugs before imprisonment. The odds ratio of cases other than drugs are homicide 0.14 (CI 0.05-0.43) (P<0.01), rape 0.16 (CI 0.05-0.51) (P<0.01), other (theft/fraud/smuggling etc) 0.24 (CI 0.10-0.58) (P<0.01) respectively. (Table 15)

Participants who had sexual intercourse with sex worker before imprisonment:

In the bivariate analysis four independent variables i.e. age, sex, education and average income showed significant relationship. Whereas in the multivariate analysis, sex, education and income had significant relationship with participants who had sexual intercourse with sex workers before imprisonment. Males were 12.63 (CI 2.84-56.24) times likely (P<0.01) to have sex with sex workers compared to females. Those who had informal education and lower secondary education were 4.00 (CI 1.19-13.52) (P<0.01) and 4.80 (CI 1.57-14.66) (P<0.01) times likely to have sex with sex workers compared to illiterate. Likewise, those who had income range up to 15000 Nrs were 2.71 (CI 1.34-5.52) (P<0.01) times likely to have sex with sex workers compared to those who had no income. (Table 15)

Table 15: Bivariate and multivariate regression for participants who ever injected drug and participants who have sexual intercourse with sex worker with background characteristics of the respondents:

Background Characteristics	Participants who injected drug before imprisonment		Participants who had sexual intercourse with Sex worker before imprisonment	
	UOR (CI)	AOR (CI)	UOR (CI)	AOR (CI)
Age Group				
18-24	1.00	1.00	1.00	1.00
25-34	1.28 (0.60-2.72)	1.46 (0.59-3.62)	1.92* (1.07-3.43)	1.80 (0.92-3.52)
35-44	0.66 (0.23-1.89)	0.81 (0.23-2.86)	1.57 (0.77-3.18)	1.53 (0.64-3.68)
45 and higher	-	-	0.73 (0.32-1.63)	0.68 (0.25-1.84)
Sex				
Female	1.00	1.00	1.00	1.00
Male	2.19 (0.65-7.37)	2.51 (0.63-9.90)	12.08*** (2.86-51.00)	12.63** (2.84-56.24)
Marital Status				
Single, Never Married	1.00	1.00	1.00	1.00
Married/Divorced/Separated/Other etc	0.39** (0.20-0.73)	0.68 (0.31-1.49)	0.90 (0.57-1.41)	1.06 (0.59-1.90)
Education				
Illiterate	1.00	1.00	1.00	1.00
Informal education	0.60 (0.05-7.00)	0.39 (0.03-5.60)	3.94** (1.26-12.30)	4.00* (1.19-13.52)
1-5 (Primary Education)	2.44 (0.51-11.58)	1.92 (0.35-10.42)	2.50 (0.93-6.73)	2.43 (0.85-6.94)
6-8 (Lower secondary)	1.03 (0.16-6.48)	0.67 (0.9-4.87)	5.04** (1.79-14.20)	4.80** (1.57-14.66)
9-10 (Secondary Education)	4.93* (1.09-22.29)	3.14 (0.58-17.01)	2.14 (0.79-5.76)	1.85 (0.63-5.43)
Higher than secondary education	1.80 (0.36-9.14)	1.01 (0.17-6.07)	2.02 (0.73-5.59)	2.12 (0.70-6.40)

Income				
No any Income	1.00	1.00	1.00	1.00
1- 15000	1.20 (0.51-2.82)	2.45 (0.89-6.74)	2.27* (1.20-4.29)	2.71** (1.34-5.52)
15001-30000	1.06 (0.45-2.49)	1.20 (0.45-3.18)	2.02 *(1.09-3.75)	1.78 (0.92-3.45)
Greater than 30000	0.78 (0.29-2.13)	0.63 (0.19-2.07)	1.36 (0.68-2.71)	1.26 (0.58-2.73)
Cast				
Upper cast group	1.00	1.00	1.00	1.00
Dalit	0.36 (0.10-1.28)	0.31 (0.07-1.34)	0.78 (0.41-1.45)	0.77 (0.35-1.70)
Disadvantage janajatis	0.93 (0.44-1.95)	1.22 (0.50-2.95)	0.75 (0.39-1.43)	0.98 (0.53-1.84)
Other (Non dalit terai/Religious minorities/Advantage Janajati	0.79 (0.33-1.92)	0.92 (0.32-2.60)	0.58 (0.32-1.05)	0.79 (0.39-1.60)
Case				
Drugs	1.00	1.00	1.00	1.00
Homicide	0.13*** (0.05-0.36)	0.14** (0.05-0.43)	0.80 (0.40-1.59)	0.71 (0.35-1.47)
Rape	0.12*** (0.04-0.37)	0.16** (0.05-0.51)	0.91 (0.53-1.56)	0.62 (0.30-1.27)
Other (Theft/Fraud/Smuggling etc)	0.23*** (0.11-0.50)	0.24** (0.10-0.58)	0.89 (0.48-1.66)	0.66 (0.34-1.29)

* P<0.05, **P<0.01, ***P<0.001

Conclusion:

A cross-sectional descriptive study was carried out among 377 prison inmates in central prison of Kathmandu, Nepal. All total of 328 male and 49 female were recruited in this study. Among the total respondents, majority 24.9% respondents were imprisoned due to homicide case, 21.2% due to drugs case followed by 21.2% rape case. Of the total prisoners 324 (85.9%) had heard about HIV/AIDS. Overall 130 (34.5%) had tested for HIV. The confirmatory result from laboratory diagnosis revealed that among the total population 7 (seven) cases had HIV positive result. This gives the prevalence of 1.9% among the total prison population (n=377). Among the male prisoners (n=328) the prevalence of HIV was found to be 1.8% i.e.6 (six) cases. Likewise, among the female prisoners (n=49) the prevalence of HIV was found to be 2.0% i.e. 1 (one) case. Regarding the prevalence of syphilis it was found to be 0.5% (2) among the total participants.

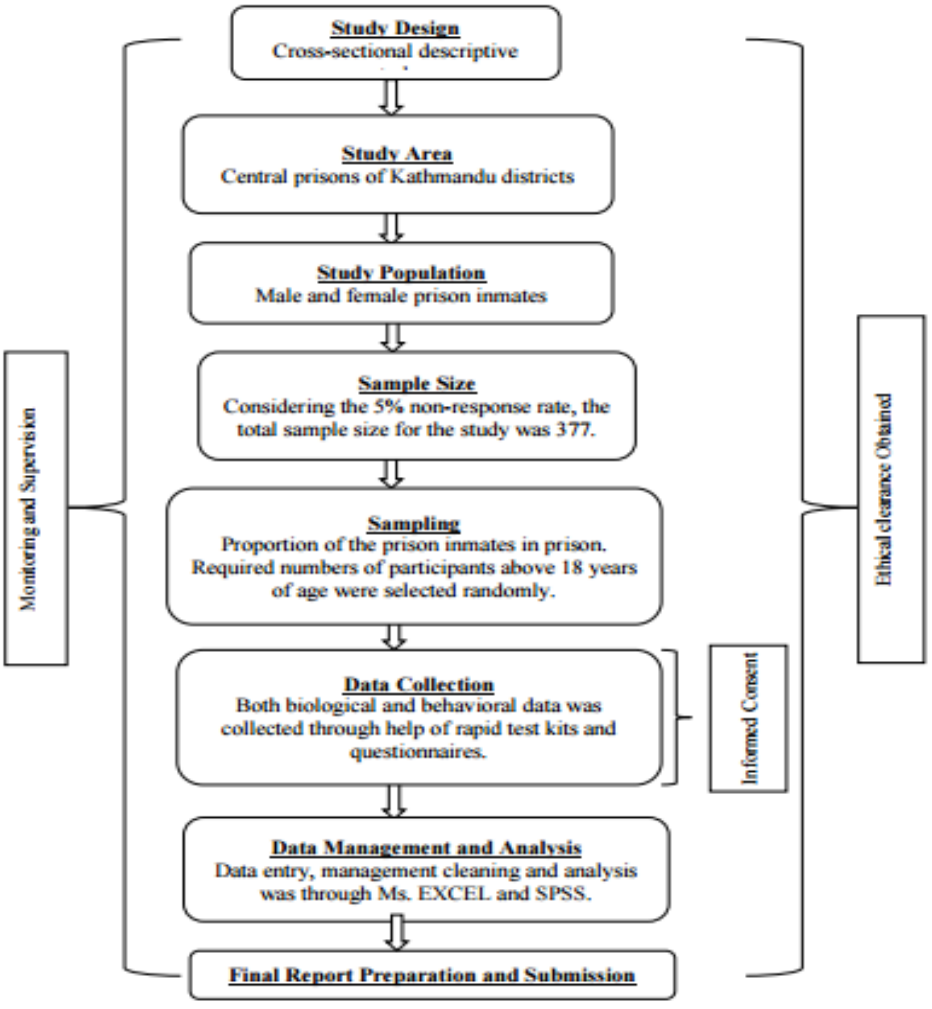
Recommendation:

We would like to recommend National Center for AIDS and STI Control Center, SAARC Tuberculosis and HIV/AIDS Centre (STAC), Department of prison management (DPM) and Central prison that screening of HIV among prisoners should be conducted at the first entry of prisoners in prison.

The prevalence and risk factor of HIV infection should be considered by policy makers for initiating harm reduction program and forming the HIV guideline in prisons.

ANNEXURE:

Annex 1: Methodology Framework



Annex 2: Supporting Documents:

Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 1620

25 December 2020

Dr. Sudha Devkota

Principal Investigators, National Centre for AIDS & STD Control

Dr. Bibek Kumar Lal

Principal Investigators, SAARC TB and HIV/AIDS Centre

Ref: Approval of research proposal

Dear Dr. Devkota and Dr. Lal,

This is to certify that the following protocol and related documents have been granted approval by the Ethical Review Board, NHRC for implementation.

If the researcher requires transfer of the bio-samples to other countries, the investigator should apply to the NHRC for the permission. The researchers will not be allowed to ship any raw/crude human biomaterial outside the country, only extracted and amplified samples can be taken to laboratories outside of Nepal for specific study, as per the protocol submitted and approved by the NHRC. The remaining samples of the lab should be destroyed as per standard operating procedure and the process should be documented and informed to the NHRC timely.

ERB Protocol No	808/2020 P	**Sponsor Protocol No**	NA
Principal Investigator/s	Dr. Sudha Devkota Dr. Bibek Kumar Lal	**Sponsor Institute**	SAARC TB and HIV/AIDS Centre
Title	Assessment of HIV Prevalence among Prison Population in Kathmandu valley Nepal		
Protocol Version No	NA	**Version Date**	NA
ICF Version No. (V.N.)	NA	**Version Date**	NA
Other Documents 1. Data collection tools 2. Acceptance letter from the study sites 3. Donor agreement letter			
Members of research team	1. Dr. Rabeya Sultana 2. Dr. Keshab Deuba 3. Mr. Lok Raj Pandey		
Study Site	Kathmandu and Lalitpur Districts		

Tel: +977 1 4254220, Fax: +977 1 4262469, Ramshah Path, PO Box: 7626, Kathmandu, Nepal
Website: http://www.nhrc.gov.np, E-mail: nhrc@nhrc.gov.np

Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 1620

Type of Review	☐	**Expedited**	**Duration of Approval** 25 December 2020 to 25 December 2021	**Frequency of continuing review**
	√	Full Board		
	Meeting Date: 23 December 2020			
Total budget of research	**$ 14,113.00**			
Ethical review processing fee	**$ 423.39**			

Investigator Responsibilities

- Any amendments shall be approved from the ERB before implementing them
- Submit Serious Adverse Events (SAE) and Suspected Unexpected Serious Adverse Reaction (SUSAR) reports to the ERB within 48hours
- Submit progress report every 3 months
- Submit final report after completion of protocol procedures at the study site
- Report protocol deviation / violation within 7 days
- Comply with all relevant international and NHRC guidelines
- Abide by the principles of Good Clinical Practice and ethical conduct of the research

If you have any questions, please contact the Ethical Review M & E Section at NHRC.

Thanking you,

Dr. Pradip Gyanwali
Member Secretary
(Executive Chief)

Tel: +977 1 4254220, Fax: +977 1 4262469, Ramshah Path, PO Box: 7626, Kathmandu, Nepal
Website: http://www.nhrc.gov.np, E-mail: nhrc@nhrc.gov.np

नेपाल सरकार
गृह मंत्रालय
कारागार व्यवस्थापन विभाग
कालिकास्थान, काठमाडौं ।

पत्र संख्या : २०७७/०७८
चलानी नं. : ८६३

फोन : ४४४४५५२
फयाक्स : ४४४४५५३
मिति : २०७७।०८।३०

विषय– सहजीकरण गरिदिने सम्वन्धमा ।

श्री कारागार कार्यालय,
जगन्नाथदेल, डिल्लीबजार काठमाडौं
नख्खु, ललितपुर ।

प्रस्तुत विषयमा राष्ट्रिय एड्स तथा यौनरोग नियन्त्रण केन्द्रद्वारा काठमाडौं उपत्यकास्थित कारागारहरुमा रहेका कैदीवन्दीहरुमा एच.आई.भी. तथा यौनरोग सम्वन्धी अवस्था विश्लेषणका लागि स्याफ्रन नेपालको प्राविधिक सहयोगमा संचालन गर्ने अनुसन्धानात्मक कार्यमा समन्वय गरिदिन अनुरोध भै आएकोले कारागारको दैनिक प्रशासनिक कार्य एवं सुरक्षा व्यवस्थामा प्रतिकूल असर नपर्ने गरी उक्त कार्यमा आवश्यक सहजीकरण गरिदिन हुन आदेशानुसार अनुरोध छ ।

(देवर्षि सापकोटा)
शाखा अधिकृत

बोधार्थ
श्री राष्ट्रिय एड्स तथा यौनरोग नियन्त्रण केन्द्र,
टेकु, काठमाडौं :- आवश्यक समन्वय गर्नहुन ।

Study Team Members

Principal Investigators Dr. Sudha Devkota Dr. Bibek Kumar Lal

Co-Principal investigators

Dr. Rabeya Sultana Dr. Keshab Deuba Mr. Lok Raj Pandey

Consultant

Dr. Megha Raj Banjara

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Ms. Shweta Rawal Mr. Rishav Pokharel

Mr. Prithutam Bhattarai

Field Survey Team Members

Mr. Shailesh Bista Mr. Laxman Kharel Mr. Subodh Aryal

Mr. Man Bahadur Thapa Mr. Parmananda Choudhary Ms. Nilam Kapali

Administration Support

Ms. Sukirty Poudel

QUESTIONNAIRE

HIV and Syphilis Prevalence and Risk Behaviour Survey among Prisoners in Nepal 2020

Section 1: Demographics

Thank you for your consent. Remember that you can refuse to answer questions if you want to. For some questions if you do not know the exact answer, try to estimate it as best as you can. This completes the exercise. Please continue with the survey.				
101	ID No of Respondent			
102	What was your sex?	Male …….. Female …….. Third gender ……. Other (*Specify*)___ Don't know ……... No response ……..	1 2 3 96 98 99	
103	If third gender, How would you describe yourself?	Gay/ homosexual …….. Lesbian ……..……..……. Bisexual ……..……..…… Transgender ……..…… Other (*Specify*)_____ Don't know ……..……. No response ……..……	2 3 4 5 96 98 99	
104	What is your current age (completed years)? (If less age is less than 18 years end the interview)	__ __		
105	What is your educational status?	Illiterate ……..……..… Informal education …….. Grade1 ……..……..……. Grade2 ……..……..…….. Grade3 ……..……..…….. Grade4 ……..……..…….. Grade5 ……..……..…….. Grade6 ……..……..…….. Grade7 ……..……..…….. Grade8……..……..…… Grade9 ……..……..…….. Grade10 ……..……..…… Intermediate passed or equivalent …… Graduate…… Post Graduate and above… Don't know …… No response ……	0 18 1 2 3 4 5 6 7 8 9 10 12 15 17 98 99	

106	What is your caste? (*Specify*)___ *[Instruction to interviewer]: Please check the coding categories of caste and enter correct coding in the ethnic group.* (*Note: coding categories of caste/ethnic group)* **1. Dalit** • Hill: Kami, Damai,Sarkii, Gaine,Badi • Terai: Chamar,Mushar,Dhusah/Paswan,Tatma, Khatway,Bantar,Dom, Chidimar, Dhobi,Halkhor **2. Disadvantaged Janajatis** • Hill : Magar, Tamang, Rai, Limbu, Sherpa, Bhote, Walung, Byansi, Hyolomo, Garrti/Bhujel, Kuumal, Sunsar, Baramu, Pahari,Yakkah, Chhantal, Jirel,Darai,DuraMajhi,Danuwar,Thami,Lepcha Chepang, Bote, Raji,Hayu,Raute,Kusunda, • Terai: Tharu,Dhanuk,Rajbansi,Tajpuriya, Gangai,Dhimarl,Meche, Kisan, MundaSanthal/Satar,Dhangad/Jhangad, Koche, Pattarkatta/Kusbadiay **3. Disavantagednon-dalitTeraicastegroups:** Yadav, Teli,Kalwar,Sudhi,Sonar,Lohar, Koiri,Kurmi, Kanu,Haluwai, Hajam/Thakur,Badhe,Bahae,RajbaKewat, Mallah,Nuniya, Kumhar,Kahar, Lodhar, Bing/Banda, Bhediyar, Mali,Kumar,Dhunia **4. ReligiousMinorities:** Muslims,Churoute **5. RelatiivelyadvantagedJanajatis** :Newar,Thakali,Gurung **6. Uppercastegroups** :Brahman(hill),Chhetri, Thakuri,Sanyasi,Brahman(Terai),Rajput,Kayastha,Ba niya, Marwadi,Jaine,Nuraang,Bengali	Dalit …… Disadvantaged Janajatis … Disadvantaged non-dalit Terai caste groups …… Religious Minorities …… Relatively advantaged Janajatis…… …… Upper caste groups …… Don't know …… No response……	1 2 3 4 5 6 98 99	
107	What is your current relationship status?	Single, Never married …….. Married ……. Divorced/Permanently separated …….. Widow/Widower ……. Others (*Specify*)___ Don't know …….. No response …….	1 2 3 4 96 98 99	

108	Did you had any income source?	Yes …… No ……. Don't know ……... No response ……..	1 2 98 99	*If no/ Don't know go to Q 110*
109	In an average how much is your total individual income per month (before being imprisonment)? *(Income from all sources of income)*	Nrs:_____		
110	Are you arrestee or prisoner?	Arrestee …….... Prisoner …….	1 2	
111	If you are prisoner, How long **have you** been imprisoned for **this/current sentence**?	< 1 year ……. 1 - 2 years ……. > 2 - 5 years …….. >5 - 10 years ……. More than 10 years ……...	1 2 3 4 5	
112	How long **will you** be in prison for this sentence?	< 1 year …… 1 - 2 years …… >2 - 5 years …….. >5 - 10 years …… More than 10 year ……...	1 2 3 4 5	
113	What is your case?	Drugs …… Criminal …… Corruption …… Terrorist …… Rape …….. Others (*Specify*)_____	1 2 3 4 5 96	*If Other than Drugs skip to Q 116*
114	If your case is related to drugs, what was your role?	User …….. Distributor …… User and distributor …….. Producer…… Others (*Specify*)_____	1 2 3 4 96	
115	Have you been imprisoned due to drug related cases before also (including recent sentence) ?	If Yes, times Never been imprisoned due to drug related case	1 2	
116	Have you been in prison before also (including recent sentence) ?	If Yes, times No.....	1 2	

Section 2: Drugs Use

We are going to ask you some questions related to drug use before you were imprisoned.				
201	Have you ever used drugs such as; marijuana, heroin, amphetamine, cocain, ecstasy, etc.?	No ……. Yes ……	0 1	
202	Have you ever injected drugs?	No ……. Yes ……	0→ 1	*If No Go to Q 301*

203	If you have injected drug. How old were you when you injected drugs for the first time?	… Years Don't Know..... No response.....	 98 99	
204	When did you last time inject drugs?	. days ago OR . years ago		
205	**The last time you injected,** how many persons also inject with you?	. person(s) Inject alone ..... Don't Know..... No response.....	1 2 98 99	
206	**The last time you injected,** did you use a used needle and syringe or did you give a used needle and syringe to others (sharing needles)?	No …… Yes …… Don't Know..... No response.....	0 1 98 99	*If No Go to Q 209*
207	**If "Yes",** did you clean the needle and syringe?	No …… Yes…… Don't Know..... No response.....	0 1 98 99	*If No Go to Q 209*
208	**If "Yes"**, what did you use for washing/cleaning the needle and syringe?	Water …… Alcohol or liquor …….. Soap …….. Bleach ……... Others (*Specify*)_____	1 2 3 4 5	
209	**The last time you injecting,** where did you get the needle and syringe?	Purchase from medical shop….. Borrow/rent from friend ……... Self creation …….. Public needle (used by other) ... DIC (Drop In Center) ……... Others (*Specify*)_____	1 2 3 4 5 96	
210	Where did you throw away used needle and syringe that was **used last time**?	Open area …….. Toilet …… Rubbish bin …….. DIC of NGO ……. Others (*Specify*)_____	1 2 3 4 96	

Section 3: Sexual History/ Recall Sexual Behavior/Sexual Partners and Condom Use

Thank you. Now we will ask you some questions about Sexual History/ Recall Sexual Behavior/Sexual Partners and Condom Use these are related to the events before you were imprisoned.				
301	Have you ever had sexual intercourse? *[Instruction to interviewer]: With sexual intercourse we mean either vaginal sex or anal sex OR, with vaginal sex we mean a penis enters a vagina OR, with*	Yes ……..… No …….. Don't know …… No response ……	1 2 98 99	*If No/ Don't know Go to*

	anal sex we mean a penis enters a person's anus. (For the interviewer only)			*Q 401*
302	Did you have a sexual intercourse with a female sex worker?	Yes ……. No …….. Don't know …… No response ……	1 2 98 99	*If No/ Don't know Go to Q 304*
303	Did you use Condom during sexual intercourse with a female sex worker?	Yes ……. No …….. Don't know …… No response ……	1 2 98 99	
304	When was the last time you had sexual intercourse?	.....Days …..... Months …..... Years Don't know …… No response ……	1 2 3 98 99	
Now we are going to ask few questions about your sexual partners. A regular sex partner is someone you are committed to, for example your spouse, live-in sex partner, girlfriend or boyfriend. There is no payment or exchange of goods or services for sex with these partners. A casual partner is a man or woman you have sex with but don't feel committed to. There is no payment or exchange of goods and services for sex with casual partners.				
305	The last time you had sexual intercourse was your sex partner a man, a woman, a transgender, or another person?	Man …… Woman …….. Transgender ……... Other (*Specify*)_____ Don't know …… No response ……	1 2 3 96 98 99	
306	The last time you had sexual intercourse what kind of sex partner was that person?	Regular sex partner ……. Casual sex partner …….. Someone I paid money or goods for sex …….. Someone who gave me money or goods for sex ……..	1 2 3 4 96 98	

		Other (*Specify*)_____ Don't know …… No response ……	99	
307	The last time you had sexual intercourse, what kind of sex did you have with your sex partner?	Vaginal sex …… Anal sex …….. Both vaginal and anal …… Other (*Specify*)_____ Don't know …… No response ……	1 2 3 96 98 99	
308	Have you ever used condom during sexual intercourse?	Yes …….. No …….. Don't know …… No response ……	1 2 98 99	*If No/ Don't know Go to Q 311*
309	How often did you use condom with your sex partner?	Every Time …… Almost Every time …… Sometimes …….. Never Used …… Don't Know …… No response ……	1 2 3 4 98 99	
310	Did you use condom during your last sexual intercourse?	Yes …….. No …….. Don't know …… No response ……	1 2 98 99	
311	The last time you had sexual intercourse, did you or your partner take drugs to get high before you had sex?	I took drugs …… My partner took drugs …… We both took drugs …… We both did not take drugs … Don't know …… No response ……	1 2 3 4 98 99	

Section 4: Knowledge on STIs and HIV

Thank you. Next we will ask some questions about your knowledge on STIs and HIV.				
401	Have you ever heard of diseases that can be transmitted through sexual intercourse?	Yes …….. No ……... Don't know …… No response ……	1 2 98 99	
402	In the past 12 months, have you experienced any of the following symptoms: (*Please read out the symptoms*) *(Multiple answers possible)*	Intense pain (burning sensation) during urination…. Warts in the anal area …… Sores or ulcers in the genital area …… Abnormal discharge from the penis (specific for men) ……. Abnormal discharge from the anus ……	1 2 3 4 5	*If No*

		Bumps/swelling in the anal area …….	6	*Symptoms observed go to Q 406*
		Vaginal discharge (specific for women) …….	7	
		Pain in the lower abdomen(specific for women)	8	
		No symptoms observed …….	9	
		Other (*Specify*)_____	96	
		None ……...	97	
		Don't know ……	98	
		No response ……	99	
403	In the past 12 months, have you been diagnosed with any symptoms related to sexually transmitted infection (STI) that you just mentioned?	Yes …….	1	If No/Don't know Go to Q 406
		No ……..	2	
		Don't know ……	98	
		No response ……	99	
404	Did you receive treatment from a medical doctor or other medical professional the last time in past 12 months when you were diagnosed with a STI?	Yes …….	1	If No/Don't know Go to Q 406
		No ……..	2	
		Don't know ……	98	
		No response ……	99	
405	The last time you were diagnosed in the past 12 months with a STI, from where did you receive treatment?	Government hospital ……..	1	
		Private hospital/Nursing Home ……..	2	
		Community based hospital ….	3	
		Private clinic/lab …….....	4	
		PMTCT site ……	5	
		HTC site …….	6	

		STI clinic …… Others (*Specify*)_____ Don't know …… No response ……	7 96 98 99	
406	Have you heard of the disease called HIV or AIDS?	Yes …… No …….. Don't know …… No response ……	1 2 98 99	
407	Can a person protect himself/herself from HIV by using a condom correctly during each sexual act? (*HIV is the virus that causes AIDS*)	Yes …… No …….. Don't know …… No response ……	1 2 98 99	
408	Can a person get HIV, from mosquito bites?	Yes …… No …….. Don't know …… No response ……	1 2 98 99	
409	Do you think a healthy-looking person can be infected with HIV?	Yes …… No …….. Don't know …… No response ……	1 2 98 99	
410	Can a person protect himself/herself from HIV, by having only one uninfected faithful sex partner?	Yes …… No …….. Don't know …… No response ……	1 2 98 99	
411	Can a person protect himself/herself from HIV, by abstaining from sexual intercourse?	Yes …… No …….. Don't know …… No response ……	1 2 98 99	
412	Can a person get HIV, by sharing a meal with someone who is infected?	Yes …… No …….. Don't know …… No response ……	1 2 98 99	
413	Can a person get HIV, by getting injections with a needle that was already used by someone else who is infected?	Yes …… No …….. Don't know …… No response ……	1 2 98 99	
414	Do you know anyone who is infected with HIV or who has died of AIDS?	Yes …… No …….. Don't know …… No response ……	1 2 98 99	

Section 5: HIV Testing

We will now ask you few questions on HIV testing. Remember that your responses will be kept confidential and will not be shared with anyone.

501	Is it possible in your community for someone to have a confidential HIV test?	Yes …….	1	
		No ……..	2	
		Don't know ……	98	
		No response ……	99	
502	Do you know where to go for HIV test?	Yes …….	1	
		No ……..	2	
		Don't know ……	98	
		No response ……	99	
503	Have you ever had an HIV test?	Yes …….	1	*If No/Don't know End*
		No ……..	2	
		Don't know …… No response ……	98 99	
504	Have you ever had HIV test in Prison?	Yes …….	1	*If yes go to 509 (If No/Don't know End)*
		No ……..	2	
		Don't know ……	98	
		No response ……	99	
505	Did you voluntarily take up the HIV test, or were you required to have the test?	Voluntary ……...	1	
		Required …….	2	
		Don't know ……..	98	
		No response ……	99	
506	When did you last test for HIV?	Within 6 months …….	1	*If Before 12 months go to Q 507*
		Between 7-12 months ……	2	
		Before 12 months ……	3	
		Don't know ……..	98	
		No response …….	99	
507	How many times have you undergone for HIV test within the past 12 months?	_____Times	98	
		Don't know …….. No response ……..	99	
508	Do you know your HIV status from your last HIV test?	Yes …….	1	*If No End*
		No ……..	2	
		Don't know ……	98	
		No response ……	99	
509	We will keep your answers confidential and	HIV Positive ……	1	*If*

	will not share with anyone. If it is possible to answer what was the result of your last HIV test?	HIV Negative …….. Uncertain …….. Don't know ……. No response ……..	2 3 98 99	*Negative / Uncertain/ Don't know End*
510	Are you receiving Anti-retro Viral Therapy (ART)? *(ART is the use of HIV medicines to treat HIV infection.)*	Yes ……. No …….. Don't know …… No response ……	1 2 98 99	*If yes, End*
511	Why are you not enroll in ART, even after knowing you are HIV positive? *(Multiple answers possible)*	Felt I was healthy ……... Others might know ……. Had to pay …….. Bad attitude of healthcare provider …….. Long waiting time …….. Long Distance …….... Others (*Specify*)_____ Don't know ……..... No response …….....	1 2 3 4 5 6 96 98 99	

Thank you for the interview. Hereafter, we will now move to our second phase of the survey and would kindly like request you to contact the lab assistant for further test.

HIV and Syphilis Prevalence and Risk Behaviour Survey among Prisoners in Nepal 2021

Report for Rapid Test

ID No of Respondent: _____ Date: ____/____/ _____

LABORATORY REPORT-RAPID TESTS			
Test Name		**Result**	
1.	Determine™ HIV-1/2	[ ] REACTIVE	[ ] NON REACTIVE
2.	Uni- Gold™ HIV	[ ] REACTIVE	[ ] NON REACTIVE
3.	Stat Pak HIV-1/2	[ ] REACTIVE	[ ] NON REACTIVE
4.	Syphilis	[ ] REACTIVE	[ ] NON REACTIVE

FINAL RESULTS:

HIV FINAL RESULT: *(To be reported to client)*		
[ ] POSITIVE	**[ ] NEGATIVE**	**[ ] IN-CONCLUSIVE**

SYPHILIS FINAL RESULT:		
[ ] POSITIVE	**[ ] NEGATIVE**	**[ ] IN-CONCLUSIVE**

NOTE: *A negative result does not necessarily indicate that the individual is not infected. If the individual had unprotected sex, shared injecting equipment, or received unscreened blood products, or had an occupational exposure in either the three month period before the test was performed or after blood was drawn, they may be infected. The HIV antibody test may not detect recently acquired HIV infection.*

_____

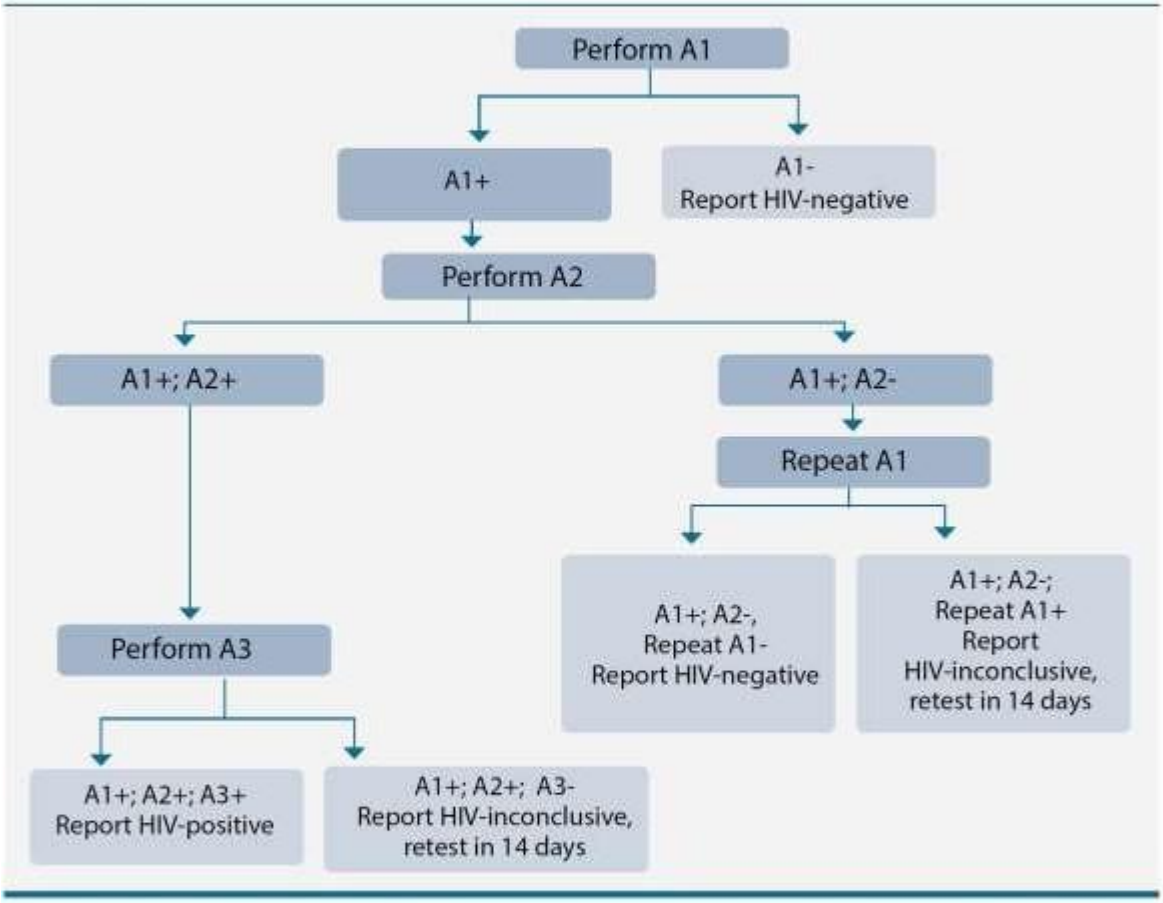
Authorized Signature

Assay 1 (A1)	Assay 2 (A2)	Assay 3 (A3)
Determine HIV- 1/2 *	Uni-Gold HIV	HIV 1/2 Stat-Pak
Enzyme-linked immunosorbent assay (ELISA)		

** The national programme recommends Determine HIV 1/2 as A1. Higher centres may use ELISA as A1.*

The testing algorithm shown in Fig. 1.4 will be used for HIV testing by the national programme.

FIGURE 1.4: National HIV testing algorithm



- All individuals are tested on Assay 1 (A1). Anyone with a non-reactive test result (A1–) is reported as HIV negative.
- Individuals who are reactive on Assay 1 (A1+) should then be tested on a separate and distinct Assay 2 (A2).
- Individuals who are reactive on both Assay 1 and Assay 2 (A1+; A2+) should then be tested on a separate and distinct Assay 3 (A3).
  - Report as HIV positive if Assay 3 is reactive (A1+; A2+; A3+).
  - Report as HIV inconclusive if Assay 3 is non-reactive (A1+; A2+; A3–). The individual should be asked to return in 14 days for additional testing.
- Individuals who are reactive on Assay 1 but non-reactive on Assay 2 (A1+; A2–) should be repeat tested on Assay 1.
  - If repeat Assay 1 is non-reactive (A1+; A2–; repeat A1–), the status should be reported as HIV negative;
  - If repeat Assay 1 is reactive (A1+; A2–; repeat A1+), the status should be reported as HIV inconclusive, and the individual asked to return in 14 days for additional testing.

Piloting of active tuberculosis case finding in the most risk populated district of Nepal to trace the missing cases "A situation Analysis" SAARC Tuberculosis and HIV/AIDS Centre National Tuberculosis Control Centre December 2020

Piloting of active tuberculosis case finding in the most risk populated district of Nepal to trace the missing cases "A situation Analysis"

SAARC Tuberculosis and HIV/AIDS Centre

National Tuberculosis Control Centre

December 2020

Government of Nepal
Ministry of Health and Population
Department of Health Services
National Tuberculosis Control Center

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ACKNOWLEDGMENT

The situation analysis of active TB case finding in the most risk-populated district of Nepal was carried out in the four districts (Kathmandu, Lalitpur, Bhaktapur, and Tanahun) in the year 2020 in collaboration with the National Tuberculosis Control Centre (NTCC), with the intent to appraise the current situation of the National Tuberculosis Program of Nepal, focusing on the active case finding of TB. Additionally, it aimed to identify barriers and challenges of the program, and suggest possible solutions. While the assessment could not be conducted as originally envisaged, due to the restrictions caused by the COVID-19 pandemic, we are satisfied that the exercise has been fruitful and has yielded invaluable information.

I would like to express my deepest appreciation to all those who supported to complete this assessment. I would like to acknowledge the crucial role of NTCC Director Dr. Anuj Bhattachan for his support and guidance during the assessment. Similarly, I am thankful for the help provided by the NTCC, PMER section chief Mr. Mukti Khanal for his guidance, suggestion, and support during the fieldwork and preparation of the report. I am also thankful for the support from Ms. Basundara Sharma Aryal, Senior Public Health Officer, and Mr. Pushpa Raj Joshi, Statistical Officer of NTCC.

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Dr. Bibek Kumar Lal

Director

ABBREVIATION

ACF	=	Active Case Finding
ACSM	=	Advocacy, Communication, and Social Mobilization
AIDS	=	Acquired Immune-Deficiency Syndrome
DOTS	=	Directly Observed Treatment Short course
EP	=	Extra Pulmonary
EQA	=	External Quality Assurance
FNAC	=	Fine Needle Aspiration Cytology
HIV	=	Human Immune-deficiency Virus
INGO	=	International Non-Governmental Organization
JANTRA	=	Japan-Nepal Health and Tuberculosis Research Association
MoHP	=	Ministry of Health and Population
PME	=	Planning, Monitoring, and Evaluation
NGO	=	Non-Governmental Organization
NTCC	=	National Tuberculosis Control Centre
OPD	=	Out Patient Department
PBC	=	Pulmonary Bacteriologically Confirmed
PCD	=	Pulmonary Clinically Diagnosed
PPE	=	Personal Protective Equipment
PPM	=	Public Private Mix
SPSS	=	Statistical Program for Social Sciences
STAC	=	SAARC Tuberculosis and HIV/AIDS Centre
TB	=	Tuberculosis
WHO	=	World Health Organization

EXECUTIVE SUMMARY

It is areport on the situation analysis of piloting of active TB case finding in the most risk-populated districtof Nepal to trace the missing TB cases and development guidelines. The situation analysis was carried out in the four districts (Kathmandu, Lalitpur, Bhaktapur, and Tanahun) of Nepal in the year 2020 in collaboration with the National Tuberculosis Control Centre (NTCC). The purpose of the situation analysis is to describe the current situation of the National Tuberculosis Program at the community level especially focusing on the active case finding of TB. Likewise, it aims to identify barriers and challenges of the program and determine the possible solutions to improve the National TB Program at the community level. We interviewed TB patients, health workers, lab personnel, and outreach workers in the community for the data collection. The data were analyzed and interpreted using SPSS version 16.0.

Current situation of TB services at the community

There are more male TB patients than females. About one-third of TB patients are in the 15- 24 age group. Mostof the TB patients belong to Janajati ethnic group. Likewise, most of the TB patients have completed the secondary level of education in situation analysis districts. More than half of the TB patients, i.e. 66 percent were diagnosed from government lab facilities. Similarly, the most common method of TB diagnosis is sputum microscopy so far. Around 68.9 percent of the patients were diagnosed by sputum microscopy.The average number of quality sputum samples is 6.1 per 10 samples in laboratories of Kathmandu valley while 4.2 number of quality samples in Tanahun.

Nearly 50 percent of the TB patients did not seek health services for more than 4 weeks after being sick.The preponderance of the TB patients had treatment for their symptoms before TB diagnosis. Among them, nearly half of the patients had visited private pharmacies, and more than one-fourth of the patients seek services from private health facilities.More than one-third of TB patients received medicine for cough particularly cough syrup, nearly one- third received antibiotics, and 23 percent received fever. About 80.3 percent of the patients were informed about the possibility of having TB.About 61.6 of the patients have sought services from the same health care provider and about one-third of the patients had

soughtservices from multiple providers in different health facilities.About one-fourth of the TB patients took more than 4 weeks to get a diagnosis after seeking their first health services.Around 66 percent of the TB patients who went for health services took more than one month for getting

a TB diagnosis.The majority of the sputum sample is transported by patients themselves, 60 percent of the sputum are transported by family members, about 40 percent by outreach works, 20 percent by health workers, and 10 percent by female community health volunteers.All the laboratory personnel requests the next sputum sample if they receive a poor quality sample in the Kathmandu valley. Unlike, about half of laboratory workers in the Tanahun district perform the test without considering the quality of the test.

There was a delay in TB diagnosis among half of the TB patients. The major reasons for the deferral are patients are not aware of the severity of symptoms, difficulty in assessing health services, not having previous satisfactory experience, lockdown, and other reasons. There was no contact tracing of more than one-third of TB patients. The major reasons for not doing contact tracing are the perception that family members without any symptoms do not need sputum tests, and 24 percent of the patients do know about the importance of contact tracing.

Impact of COVID-19 in TB

The average number of OPD visits slightly increases from Baishak and reaches a peak in Shrawan, and then declines to respective months. The number of sputum tests in Baishak and Jestha month is very low, after Ashar, the number of sputum microscopy tests had gradually increased and had reached a peak in Ashoj. The highest mean number of TB patients diagnosed for both districts is in the Shrawan month and the lowest in the Baishak month. The average number of TB patients enrolled in the DOTS centre is highest in the Shrawan in Kathmandu valley and Tanahun.

The health workers, including lab personnel and outreach workers, haveexperienced a delay in sputum collection in all the districts during lockdown and travel restrictions. The main reasons for the delay no contact tracing of the patient, no sputum courier,the lab personnel is also unavailable at the facilities, and some of the diagnostic facilities were closed from a certain time. Along with that, health workers had to provide TB medicine from 2 weeks to

months to the patients. Home-based treatment could be a challenge for treatment adherence despite most of the health workers are confident about the treatment adherence of patients. Besides, the pandemic situation has affected the follow-up sputum examination. There is a low number of follow- up test during the strict lockdown and travel restrictions. Some of the health workers were compelled to provide TB treatment for longer due to delay in sputum follow up examination.

Conclusion

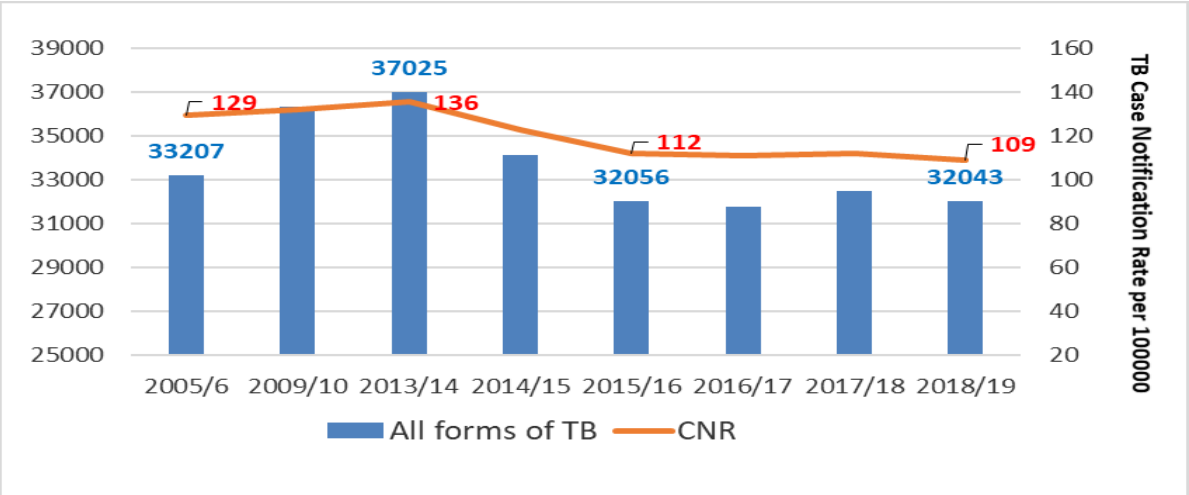
Despite the expansion of molecular diagnosis, a substantial proportion of TB patients are diagnosed from sputum microscopy. Although the first preference of patients is private pharmacies and facilities for initial health services, the majority of them are diagnosed in government health facilities. There is a delay in TB diagnosis, which is further deferred by COVID-19. Besides, health workers in the clinic had to provide medicine for a long time because of no sputum follow- up examination of TB patients. Therefore, it is pivotal to expand and improve the functionality of molecular diagnosis, including Gene Xpert with dedicated laboratory staff. There should be focused PPM activities in the major urban areas to decrease the delay of TB diagnosis. In addition, we need to explore and expand the use of digital technologies in TB service delivery. For instance, developing a digital system for monitoring the TB treatment in homes of TB patients.

CHAPTER I: INTRODUCTION

1. Introduction

Tuberculosis (TB) is a public health problem in Nepal. Since the implementation of DOTS in 1996, TB-related morbidity and mortality had been reduced. Around, one hundred and seventeen thousand, 117,000 (88,000 – 145,000) people with TB disease are living in Nepal. (NTCC, 2020) However, there is an unacceptable drop in the TB incidence rate. (TB factsheet, 2015) The case notification rate continued to remain constant for the last five years and show a minor decline in the last three years. (NTCC, 2019) The major reasons for not rise in the case notification rate and the decline in incidence rate are, there are still a high number of undiagnosed TB cases, especially among the vulnerable groups, hard to reach population.

Figure 1: Trend of case notification rate and notified annual notified TB cases



Source: NTP Annual Report, 2019

The National Tuberculosis Control Centre (NTCC) aims to end TB by 2050, incorporating active TB case finding in the most risk population as a strategic intervention. NTCC has implemented the activities in high burden 38 districts of Nepal. Active TB case finding is the systematic identification of people with suspected active TB, in a predetermined target group, using tests, examinations, or other procedures that can be applied rapidly. Among those whose screening is positive, the diagnosis needs to be established by one or several diagnostic tests and additional clinical assessm [101] which together have high accuracy. The unprecedented coronavirus pandemic seriously affects TB services like diagnosis, treatment, follow up, and preventive activities, including active TB case finding in the community.

Therefore, it is pivotal to assess the situation to provide the best quality TB services, including active TB case finding in the emergency or crisis, which will help to improve TB notifications, decreasing transmission, and trace the missing TB cases in the community. Furthermore, the situation analysis helps to identify the specific needs and tasks for integrated community-based TB activities as well as analysis of the alternatives about the best solution for the future and the establishment of strategy. It involves information gathering at all levels to analyze and understand the existing situation. Japan-Nepal Health and Tuberculosis Research Association (JANTRA) conducted the situation analysis under the supervision and monitoring from NTCC and the funding from STAC (SAARC TB and HIV/AIDS Centre). JANTRA worked in close coordination with district hospitals, DOTS center, microscopic center, gene Xpert center, and the community.

2. Objectives

- To assess the situation of the national tuberculosis program focusing on active case finding activities in four districts of Nepal
- To determine the main barriers to better delivery of TB services
- To identify the solutions to improve the active TB case finding at the community level

CHAPTER II: METHODOLOGY

Research design

It is a descriptive study, which describes the current situation of TB care and support activities at the community level. The situation analysis was carried out by collecting the data in TB services such as diagnosis, treatment, and follow up and preventive services related indicators.

Study area

The situationanalysis wasoperated in Kathmandu, Bhaktapur, Lalitpur, and Tanahun of Nepal. The selected districts are high burden districts of TB and active case finding activities have been implemented under Global Fund and NTCC in the hard to reach populations.

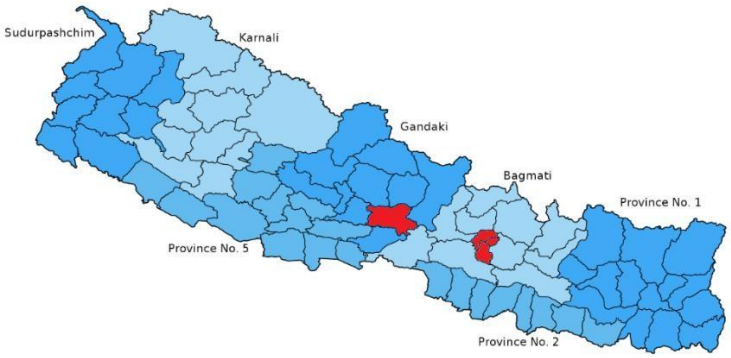


Figure 2: Study sites

Sampling design

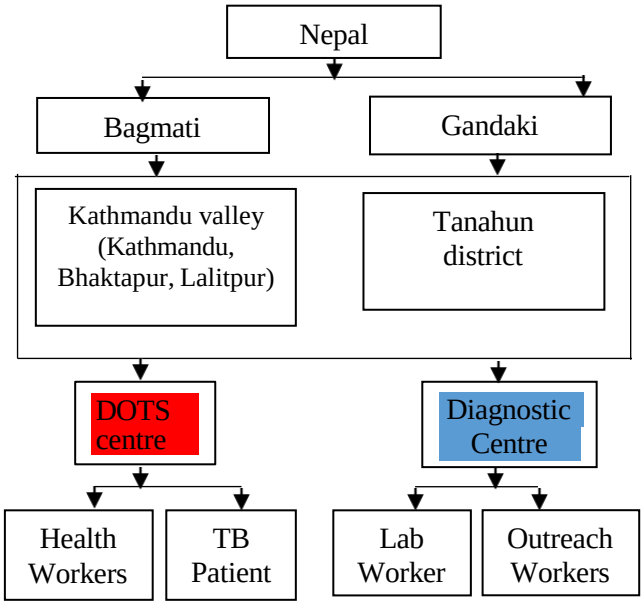


Figure 3: Sampling frame of the study

required number of TB patients for the interview from each DOTS centre. Data was collected in 19 DOTS centre, 10 Lab linked lab facilities, and 10 outreach workers of linked lab facilities.

Sample size

The sample to describe the situation analysis of TB and address the study objectives are as

follows. A totalof 19 health workers, 10 Laboratory workers, and 10 outreach workers were included for the data collection.

The sample size for TB patients is calculated as per

$N=z^2p\ (1-p)/d^2$

Where,

Proportion of PBC (p) =70%

Permissible error (d)=0.09

$n= 1.96^2*0.7*0.3/(0.09)^2=104$

Considering 2% Non response rate, Total sample size **=106**

Inclusion and exclusion criteria

The inclusion and exclusion criteria for selecting the study participants and sites are described in the table below:

Table 1: Inclusion and exclusion criteria

Study participants	**Inclusion criteria**	**Exclusion criteria**
Health facilities/ Health Workers	• A health facility that is currently providing DOTS services • Health workers who is working as a TB focal person	• Health facility that is not providing DOTS services • A health worker who is not involved in TB services
Laboratory Worker/facilities	• Laboratory facility that is providing TB diagnostic facilities • Laboratory facilities that have linked DOTS centre for sputum transportation • Laboratory worker who is responsible for providing TB diagnostic services	• Laboratory facility that is providing TB diagnostic facilities for at least the last six months • Laboratory worker who is involved in TB diagnostic services for at least the last six months
Outreach workers	• Outreach worker working for active TB cases finding under the Global fund program	• Outreach reach workers who are not involved in the TB program, currently
TB patient	• The under TB treatment patients • Pulmonary bacteriologically confirmed cases	• The cured or completed TB patient • Extra-pulmonary • Pulmonary clinically diagnosed

Operational definitions

Active TB case finding

Active case finding requires systematic screening and clinical evaluation of persons who are at high risk of developing TB, such as people who are contacts of someone who was diagnosed with TB.

Vulnerable populations

Prisoners, migrants, and socially marginalized people are particularly vulnerable because of the increased exposure associated with their living conditions.

Delay in TB diagnosis

It is the time interval between the onset of symptoms and confirmation of TB in the patient. This includes patient delay and health system delay. Patient delay: Period from the onset of the first symptom(s) related to pulmonary TB such as cough, fever, and chest pain to the first medical consultation. Health system delay: Period from the first consultation to the date of diagnosis. Diagnostic delay was categorized using a cutoff value of 4 weeks by considering an acceptable patient delay and health system delay of 2 weeks each.

Contact tracing

Contact tracing is a process,which involves finding and counseling, testing, and treatment if necessary to the people who are in close contact of TB patients.

Good Quality of sputum

Sputum specimen that is mucous/ purulent without saliva and food particles

Data collection methods

We collected both qualitative and quantitative data. The primary data was collected from TB patients, health workers, laboratory workers, and outreach workers using a semi-structured questionnaire. The secondary data was collected from the DOTS center and diagnostic facilities on monthly OPD visits, the number of sputum test and TB patients enrolled in the DOTScenter by observing the records and registers of the facilities. The primary data was collected using a face-to-face interview at the health facilities with all the study participants. We carried out a face-to-face interview in a structured way. Among the TB patients, we conducted an exit interview with those who came for TB medicine at the DOTS center.

Data collection tools

The situation analysis team constructed separate semi-structured questionnaires for health workers, laboratory workers, outreach workers, and TB patients.The technical team of STAC revised the tools. Then, each set of questionnaire was pre-tested after incorporating the feedback and suggestions from the technical team. The approvedtools after correcting the deviations in the questionnaire were used for data collection.

Quality assurance

The research assistant was trained for two days in the interview technique, ethical issues, data collection and cleaning process. The research assistants were mobilized to collect the information at the field level after exposing them in pre-testing. The research coordinator was responsible to monitor all the field level activities. The team leader was responsible for overall all the activities, including coordination with STAC, NTCC, and the district. The technical team from STAC closely monitored and supervised the data collection to ensure completeness and accuracy of data.Regular communication, including progress meetings, was carried out to identify the deviations and take corrective actions as soon as possible during the situation analysis.

Ethical consideration

As this was a program evaluation, we have taken written permission from the national program of Nepal. We had inception meeting with NTCC before the operationalization of the situation analysis. We had taken the approval to visit the health facilities and review the registers. Then, we coordinated with the focal person of health facilities and get their permission for the data collection.

Before the data collection, the research assistant took written consent from all the study participants after explaining the objectives of the situation analysis and data collection. The participation of all the participants was voluntary and no one was forced to participate in the situation analysis. No personnel identifiers of the participants were included in the data analysis to maintain the confidentiality of the participants. Besides, participants were not subjected to harm in any way whatsoever. In addition, the anonymity of individuals and health facilities was ensured.

Time period

This situation analysis was done from August- December 2020.

Processing and analysis of data

Each variable was coded into a limited number of categories and classes. The edited data was entered in SPSS version 16.0. The data was classified based on attributes.

Categorical variables including gender, occupation, ethnic groups, religion, and geographic location of patients were summarized with proportions, whereas the continuous variables were summarized with average values. The simple tables were prepared to analyze one or more

independents variables and cross-tabulation was prepared for the interrelation of two or more variables.After the tabulation of the data descriptive statistics such as measures of central tendency, measures of dispersion were used for further analysis.

The qualitative data were analyzed by scaling of the respondents response. The research assistant read the statements several times to identify similar and/or close opinions. The consolidated similar or connected information to get summarized and categorized groups of statements. After that, the study team reviewed the data, discussed it within the groups, and then categorized it into one statement with similar meaning, and then the data were summarized and analyzed.We presented the different statements in the frequency table.

The categorical scale data, where our respondents were subjected to rank the items in the questionnaire, includesthe rating of the quality of sputum and their confidence level for the home-based treatment. For the rank items data, each item contains a score. Responses indicating the least possible reason for the delay receive the lowest score of 1 and the most possible cause of delay is receive the highest score of 6. Then, the total score for each statement was obtained by adding the score received from each participant. For instance,

Total sum item (Xi) $= SP_2 + SP_2 \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots + SP_{19}$

where,

S= score (number)

P=Participants

X=items

The total score was calculated and the statement with the highest score was rated as the most possible reason for the delay in TB diagnosis and treatment.

For the rating scale with five points or ten points. The score was given for each points. The mean score was calculated and compared between the districts.

CHAPTER III: FINDINGS

3.1 Situation of TB patients

Age and sex distribution of TB Patients

The population pyramid illustrates the age and sex distribution of TB patients that were included in the situation analysis. The bulk of TB patients are in the age group of 20 to 30 years in both gender.

Figure 4: Age and sex distribution of TB patients

Background information about TB patients

A total of 106 the total TB patient, nearly one-third i.e. 28.3 percent of the patients are from the Tanahun district while 71.7 percent of the participants were from Kathmandu valley. Around 73.6 percent of the TB patients were in the continuation phase whereas 26.4 percent were in the intensive phase. Nearly one-third of the TB patients (28.9%) were students in Kathmandu valley. Nearly one-fourth of the patients were employed in service, 18.4 percent were unemployed, and 19.7 percent were employed in the informal sector. While 3.3 percent of the TB patients were students in Tanahun. Only 6.7 percent of the patient was employed in service, 26.7 percent were employed in the informal sector. In both districts, most of the TB patients belong to Janjati ethnic groups. 17.1 percent of the patients were Bhramin/Chhetri in Kathmandu valley, while the proportion of Bharmin/Chhettri in Tanahun is 13.3 percent. More than one-fourth of the TB patients in Tanahun were from Dalit ethnic group whereas only 3.9 percent of the TB patients were from Dalit ethnic group in Kathmandu. The majority of the TB patients were Hindus in both of the districts, which is followed by Buddhism, Christian, and Muslims.

More than one third (35.5%) of the TB patients had completed higher secondary school in Kathmandu valley. Likewise, just above one-third (32.9%) has completed primary secondary,

13.2 percent are literate, and the same percent of TB patients are illiterate and the least proportion of 5.3 percent had completed advanced/university education level. Dissimilarly, 40 percent of the TB patients had completed only primary level schooling, more than one- third of the patients are illiterate, 13.3 percent are literate and around 10 percent had higher secondary schooling and none of them have achieved advanced/university-level education.

The predominance of the TB patients i.e. 83 percent in Tanahun district was married, 10 percent were never married and 6.7 percent were widow and widower while on contrary, around half the patients were married, 40.8 percent were never married and 1.3 percent were widow/widower.

Table 2: Socio-economic status of TB patients

	Name of district		
Occupation	**Kathmandu valley (n=76)**	**Tanahun (n=30)**	**Total**
Service	19.7%	6.7%	16.0%
Business small	5.3%	3.3%	4.7%
Business Factory/Industry	3.9%		2.8%
Housewife	3.9%	10.0%	5.7%
Employed in informal sector	19.7%	26.7%	21.7%
Unemployed	18.4%	46.7%	26.4%
Students	28.9%	3.3%	21.7%
Others		3.3%	0.9%
Educational Status			
Advanced/University	5.30%	0%	3.80%
Higher secondary	35.50%	10.00%	28.30%
Primary -Secondary	32.90%	40.00%	34.90%
No formal education/Literate	13.20%	13.30%	13.20%
Illiterate	13.20%	36.70%	19.80%
Ethnic Groups			
Dalit	3.9%	26.7%	10.4%
Janajati	71.1%	56.7%	67.0%
Madeshi	1.3%	0%	.9%
Muslims	1.3%	0%	.9%
Bharmin/Chettri	17.1%	13.3%	16.0%
Others	5.3%	3.3%	4.7%
Religion			
Hindu	64.5%	86.7%	70.8%
Buddhism	28.9%	6.7%	22.6%
Muslims	1.3%		.9%
Christian	5.3%	6.7%	5.7%
Marital status			
Single-Never married	40.8%	10.0%	32.1%
Married	57.9%	83.3%	65.1%

Widow/widower	1.3%	6.7%	2.8%
TB treatment			
Intensive Phase	21.1%	40.0%	26.4%
Continuation Phase	78.9%	60.0%	73.6%
Total	**100.0%**	**100.0%**	**100.0%**

Diagnostic health facilities

More than half (66%) of the TB patients were diagnosed from government lab facilities, nearly a fifth(19.8%) of the patients were diagnosed from private lab facilities, 19.8 percent were diagnosed from NGO/INGOs lab, and 1.9 percent from other health facilities. The major health facility for TB diagnosis is sputum microscopy in both districts. However, there is a significant difference in other places for TB diagnosis in the districts.The most common method of TB diagnosis is sputum microscopic so far. Around 68.9 percent of the TB have been diagnosed with sputum microscopy, about one-third (28.5%) of the TB have been diagnosed with Gene Xpert and nearly 2 percent of the pulmonary TB cases have been diagnosed from culture.

Table 3: Diagnostic Health Facilities and tools of diagnosis

	Name of district		
Diagnostic facilities	**Kathmandu valley (n=76)**	**Tanahun (n=30)**	**Total**
Government lab facilities	63.2%	73.3%	66.0%
NGO/INGOs lab Facilities	17.1%	0%	12.3%
Private lab facilities	18.4%	23.3%	19.8%
Others	1.3%	3.3%	1.9%
Total	100.0%	100.0%	100.0%
	District		**Total (n=106)**
Tools of diagnosis	**Kathmandu valley (n=76)**	**Tanahun (n=30)**	
Microscopy	63.2%	83.3%	68.9%
Gene Xpert	35.5%	10.0%	28.3%
Culture	0%	3.3%	.9%
Other	1.3%	3.3%	1.9%
Total	100.0%	100.0%	100.0%

Timespan in the patients pathway to TB diagnosis and treatment

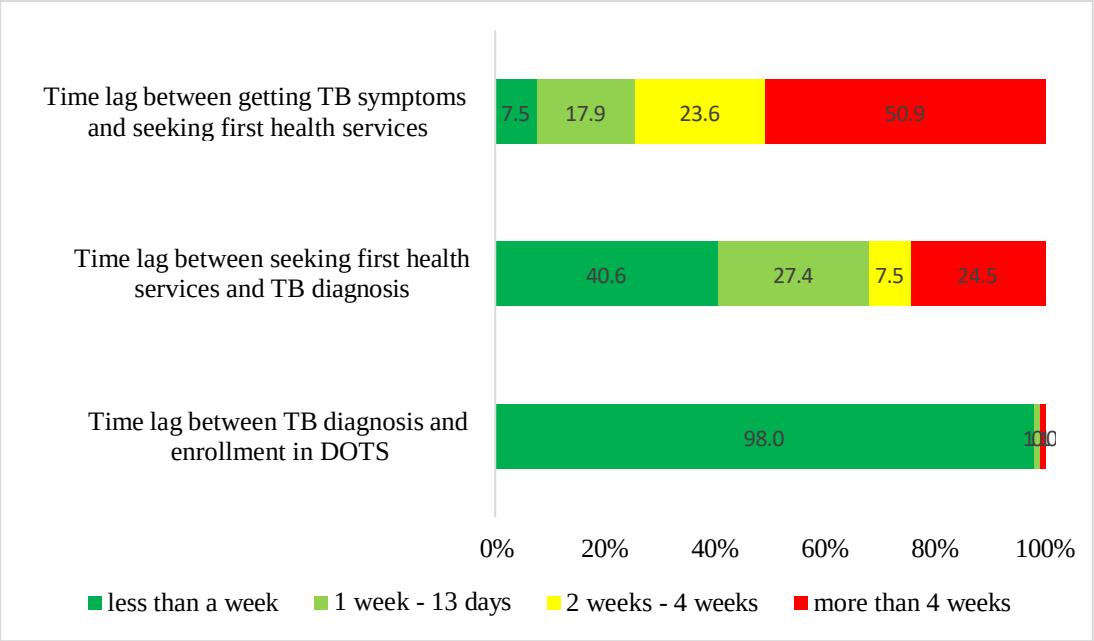
Nearly 60 percent of the TB patients in did not seek health services for more than 4 weeks after getting TB sign and symptoms. More than one-fifth (23.6%) of the patients waited for 2 to 4 weeks for seeking health services. Nearly 18 percent waited for 1 to 2 weeks while 7.5 percent seek health services within one week of getting TB signs and symptoms.

About 24.5 percent of the patients got TB diagnosis after 4 weeks of seeking first health services. Around 40.6 percent took less than a week to get TB diagnosis after visiting the

health services, nearly one-third took upto 13 days, and about 7.5 percent took 15 days to 30 days to get a TB diagnosis after reaching the health services.

About 98 percent of patients were enrolled in DOTS centre within a week of getting TB diagnosis. About 2 percent were enrolled after the 2 weeks of TB diagnosis. This indicates there is high time lag for seeking health services indicating patient delay in TB diagnosis.

Figure 5: Timespan in TB diagnosis and treatment



Delay in diagnosis

About 61.2 percent of productive age groups had a delay in TB diagnosis. Likewise, 69.1 percent of employed TB patients had a deferral in diagnosis. A similar proportion of patients with formal education and never-married patients had a delay in TB diagnosis. The proportion of delay in TB diagnosis is higher in females compared to males. Similarly, the deferral is higher among never married in comparison to married TB patients. Correspondingly, the percentage of delay is higher in migrants compared to local residents. The delay of diagnosis is higher in the Kathmandu valley compared to Tanahun.

Table 4: Delay in TB diagnosis

	Delay in TB Diagnosis		
Age group	**No (n=43)**	**Yes (n=63)**	**P value**
<=14 years (n=2)	50.0%	50.0%	0.76
15-59 years (n=85)	38.8%	61.2%	
>=60 years (n=19)	47.4%	52.6%	
Occupation status			

Employed (n=55)	30.9%	69.1%	0.06*
Unemployed (n=28)	57.1%	42.9%	
Students (n=23)	43.5%	56.5%	
Educational status			
Formal education (n=71)	39.4%	60.6%	0.73
Informal education/illiterate (n=35)	42.9%	57.1%	
Marital status			
Never married (n=34)	38.2%	61.8%	0.73
Married (n=72)	41.7%	58.3%	
Migrants			
No (n=60)	41.7%	58.3%	0.79
Yes (n=46)	39.1%	60.9%	
Ethnic groups			
Dalit (n=11)	36.4%	63.6%	0.88
Janajati (n=71)	40.8%	59.2%	
Madeshi (n=1)	0%	100.0%	
Muslims (n=1)	0%	100.0%	
Bharmin/Chettri (n=17)	47.1%	52.9%	
Others (n=5)	40.0%	60.0%	
Religion			
Hindu (n=75)	41.3%	58.7%	0.83
Buddhism (n=24)	41.7%	58.3%	
Muslims (n=1)	0%	100.0%	
Christian (n=6)	33.3%	66.7%	
Gender			
Male	44.3%	55.7%	0.36
Female	35.6%	64.4%	
Districts			
Kathmandu valley (n=76)	38.2%	61.8%	0.42
Tanahun (n=30)	46.7%	53.3%	

Note:Chi-Square test of the proportion for the significant difference at 0.1 (*), 0.05(**)

Pursuing treatment before TB diagnosis

The preponderance of the TB patients (82%) had seek treatment for their symptoms before the TB diagnosis. The proportion of receiving treatment is higher in patients of Kathmandu valley in comparison to the patients of Tanahun district.

Figure 6: Seeking treatment from private and public health facilities before TB diagnosis

Initial health facilities visited by patients and their services

Among the total patients who had treatment before TB diagnosis, nearly half (45%) of the patients had visited private pharmacies, and more than one-fourth of the patients seek services from private health facilities for the first time. However, there is a huge variation between Kathmanduvalley and Tanahun district. None of the patients visited private pharmacies in Tanahaun while 58.1 percent of the patients visited private pharmacies in the Kathmandu valley.

Likewise, the majority of the patient'ssymptoms (73.8%) have not improved and remainedthe same despite taking medicine from the health facilities. About 80.3 percent of the patients were informed about the possibility of having TB.

Among the total TB patients who were informed about the possibility of TB, nearly half (50%) of the patients were taught about the possibility of TB in the first visit to the health facilities, 25 percent were shared in the second and consecutive visit to the health facilities.

Table 5: Facilities for initial health-seeking related to TB diagnosis and their services

Facilities for seeking care	Name of district		Total
	Kathmandu valley (n=62)	Tanahun (n=18)	
Ayurveda dispensary	1.6%		1.3%
Medical colleges and Hospital	3.2%	11.1%	5.0%
Private health facility	32.3%	11.1%	27.5%
Private pharmacy	58.1%	0%	45.0%
Public health facilities	3.2%	5.6%	3.8%
Effect in symptoms of TB			
Improved	21.0%	44.4%	26.3%
Worsened	24.2%	11.1%	21.3%
Same	54.8%	44.4%	52.5%
Informed about possibility of TB			
Yes	80.6%	94.4%	83.8%
No	19.4%	5.6%	16.3%

Information about chances of TB	Kathmandu valley (n=50)	Tanahun (n=17)	Total
First visit	40.0%	69.2%	48.8%
Second visit	26.7%	23.1%	25.6%
After second visit	33.3%	7.7%	25.6%
Total	100.0%	100.0%	100.0%

Health facility for seeking initial health services

The ample number of people pursue health services from the private sector, which includes

both private pharmacies and private clinics and physicians. The practice of seeking initial health services from the private sector decreases with age. There are significant differences in visiting the private sector and public facilities between employed and unemployed, where most of the unemployed choose public facilities for seeking health services. Likewise, patients with higher education are more likely to visit private facilities compared to less educated patients. Conversely, there are no weighty differences in practices of seeking care between genders, ethnic groups and based on migration. A substantial proportion of patients who were diagnosed from government health facilities had an initial visit to the private sector. Besides, some proportion of patients diagnosed from the private sector had visited public facilities indicating, the essentiality of coordination and cross-referral mechanism between government and private health facilities.

Table 6: Health facility from seeking initial health services

	Health facilities for seeking first health services		
Age group**	**Public health facilities**	**Private health facilities**	**P Value**
<=14 years (n=1)	0.0%	100.0%	0.000
15-59 years (n=67)	10.4%	89.6%	
>=60 years (n=12)	58.3%	41.7%	
Occupation**			
Employed (n=43)	14.0%	86.0%	0.006
Unemployed (n=16)	43.8%	56.3%	
Students (n=21)	4.8%	95.2%	
Education*			
Formal education (n=57)	12.3%	87.7%	0.053
Informal education/illiterate (n=23)	30.4%	69.6%	
Gender			
Male (n=46)	19.6%	80.4%	0.570
Female (n=34)	14.7%	85.3%	
Migrants			
No	20.0%	80.0%	0.505
Yes	14.3%	85.7%	
Ethnic groups			
Dalit (n=7)	14.3%	85.7%	0.737
Janajati (n=53)	17.0%	83.0%	
Madeshi (n=1)	0.0%	100.0%	
Bharmin/Chhettri (n=15)	26.7%	73.3%	
Others (n=4)	0.0%	100.0%	
Religion			
Hindu (n=59)	20.3%	79.7%	0.354
Buddhism (n=17)	5.9%	94.1%	
Christian (n=4)	25.0%	75.0%	

Marital status**			
Never married (n=30)	0.0%	100.0%	0.001
Married (n=50)	28.0%	72.0%	
Diagnosis centre			
Government Lab facilities (n=55)	14.5%	85.5%	0.536
NGO/INGOs Lab Facilities (n=8)	12.5%	87.5%	
Private Lab facilities(n=14)	28.6%	71.4%	
Others(n=3)	33.3%	66.7%	

Note:Chi-Square test of the proportion for the significant difference at 0.1 (*), 0.05(**)

Causes of delay diagnosis among TB patients

The major factors for delay in diagnosis are patients are not aware of the severity of symptoms, difficulty in assessing health services, not having previous satisfactory experience. The travel restriction due to COVID 19 has contributed to nearly 13 percent in the delay diagnosis.

Table 7: Reasons for delay in TB diagnosis

Causes of delay diagnosis	Frequency	Percent	Percent of Cases
Not aware of the severity of symptoms	21	33.30%	36.80%
Financial difficulties	6	9.50%	10.50%
Lack of time	3	4.80%	5.30%
Difficulty in accessing the health services	7	11.10%	12.30%
Not having a previous satisfactory experience	12	19.00%	21.10%
Lockdown/	8	12.70%	14.00%
Others	6	9.50%	10.50%
Total	63	100.00%	110.50%

Duration, approach, and expenditureto reach TB treatment centre

The average time to reach the treatment centre is nearly half an hour i.e. 35 minutes. Patients in Tanahun havea higher average time to reach the treatment centre than Kathmandu valley.The mean time to reach the TB treatment center by walking is about 27 minutes; it takes about 50 minutes in public transportation and about 20 minutes in private transportation for the TB patients.On the average NRs. 105 rupees is required for transportation in Tanahun district who uses public transportation while it requires 51 rupees in Kathmandu valley.

Table 8: Average minutes to reach TB treatment centre

District	Mean time	Frequency	Std. Deviation
Kathmandu valley	21.55	76	25.34
Tanahun	47.33	30	47.72

Total	28.84	106	34.98
Mode of transportation of TB patients	**Mean time**	**Frequency**	**Std. Deviation**
Walking	27.25	68	32.28
Public transportation	49.33	15	50.20
Private transportation	20.22	23	26.30

Total	28.85	106	34.98
District	**Mean cost**	**Frequency**	**Std. Deviation**
Kathmandu valley	51.42	7	10.69
Tanahun	105	6	116.91
Total	76.15	13	80.78

Calendar of visiting DOTS centre

Despite of the National guideline to provide medicine up to one month to a TB patients, the majority (66%) of the TB patients visit weekly to receive TB treatment. Only about 14 percent of the patients visit daily for TB treatment.

Table 9: Calendar of visiting DOTS centre

	District		**Total**
Visit to DOTS centre	**Kathmandu valley**	**Tanahun**	
Daily	13.20%	16.70%	14.20%
Weekly	76.30%	40.00%	66.00%
fortnightly	6.60%	16.70%	9.40%
Monthly	3.90%	26.70%	10.40%
Total	100.00%	100.00%	100.00%

Contact tracing

More than one third (35%) of contacts of TB patients are not examined for sputum test.The proportion of contact tracing increases with age. For instance, all contacts of patients of <=14 years have 100% contact tracing, while about 66 percent of patients of 15-59 years has contact tracing and >=60 years had only 55 percent of contact have been tested for TB. Likewise, the highest percentage of contact tracing is among students and the lowest among unemployed. There is no significant difference in the proportion of contact tracing based on educational status.The contact tracing is slightly higher in females compared to males. There are substantial variations in the proportion of contact tracing in different ethnic groups. In contrast to that, there are no differences in the fraction of contact tracing in patients with a family history of TB and migrated TB patients.A higher proportion of TB patients contacts in the Tanahun district are not tested for TB compared to Kathmandu valley.

Table 10: Contact tracing of TB patient's family members

	Contact tracing of family members		
Age groups	**Yes**	**No**	**P value**
<=14 years (n=2)	100.0%	0%	0.40
15-59 years (n=85)	65.8%	34.2%	

>=60 years (n=19)	55.6%	44.4%	
Occupation status			
Employed (n=55)	66.7%	33.3%	0.13
Unemployed (n=28)	50.0%	50.0%	
Students (n=23)	77.3%	22.7%	
Educational status			
Formal education (n=71)	63.8%	36.2%	0.78
Informal education/illiterate (n=35)	66.7%	33.3%	
Marital status			
Never married (n=34)	75.8%	24.2%	0.10
Married (n=72)	59.1%	40.9%	
Gender			
Male (n=61)	61.0%	39.0%	0.35
Female (n=45)	70.0%	30.0%	
Ethnic groups			
Dalit (n=11)	72.7%	27.3%	0.63
Janajati (n=71)	64.6%	35.4%	
Madeshi (n=1)	100.0%		
Muslims (n=1)	100.0%		
Bharmin/Chettri (n=17)	50.0%	50.0%	
Others (n=5)	80.0%	20.0%	
Family members with TB history			
No (n=55)	64.3%	35.7%	0.60
Yes (n=51)	65.1%	34.9%	
Migrants patients			
No (n=60)	65.3%	34.7%	0.89
Yes (n=46)	64.0%	36.0%	
Districts			
Kathmandu Valley	69.60%	30.40%	0.12
Tanahun	53.30%	46.70%	

Note:Chi-Square test of the proportion for the significant difference at 0.1 (*), 0.05(**)

Elucidations for not doing contact tracing of TB patients

More than one-third (35%) of the patient whose contacts are not tested for TB said that their family members do not have any symptoms so; they were not tested for TB. About 24 percent of the patients do know about the need for contact tracing.

Table 11: Reasons for not doing contact tracing

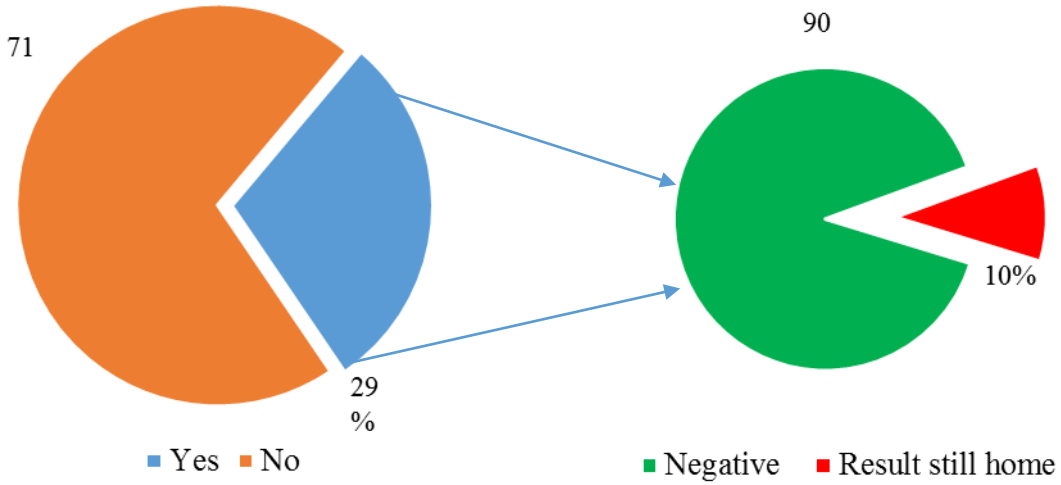
Elucidations for not doing contact tracing	Frequency	Percent
Because forget to bring sputum	1	3%
Don't know about contact tracing	8	24%
Family members don't have any symptoms	12	35%
Health workers have not asked to do the test	3	9%

I leave alone	2	6%
Lack of time	5	15%
Recently registered TB patients	2	6%
Social stigma in the community	1	3%
Total	34	100%

COVID 19 test of TB patients

Nearlyone-third(29%) of the TB patients had been tested for coronavirus in both of the districts. All the TB patients were negative for coronavirus so far as while 15 percent of patients have not received a report to date.

Figure 7: COVID 19 test of TB patients

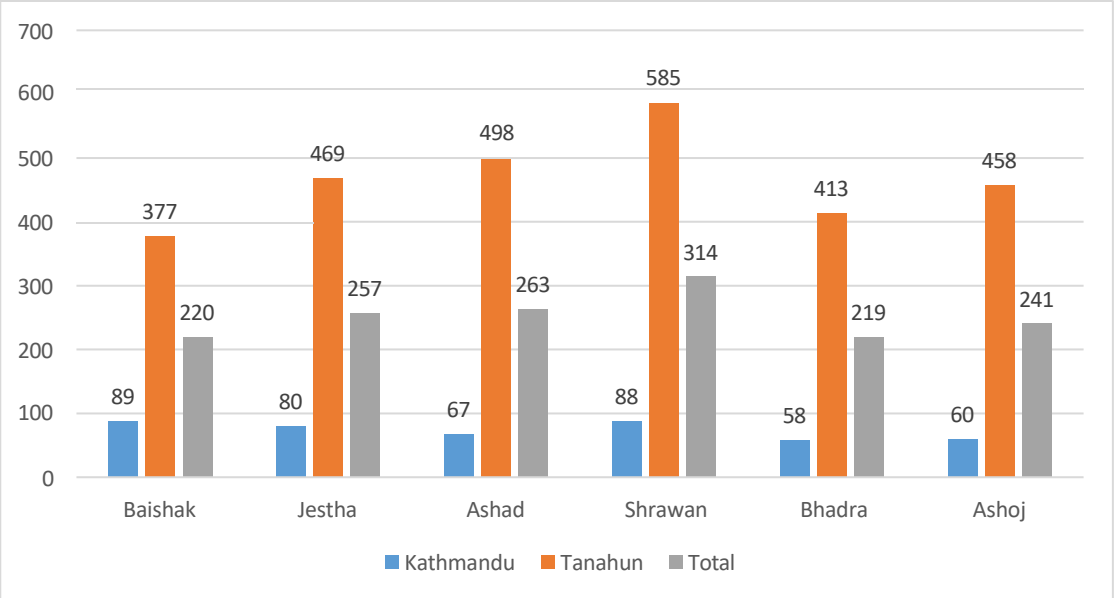


3.2 Current situation of TB diagnostics and treatment services

The trend of OPD visit in the health facilities for six months

The average number of OPD visits slightly increases from Baishak and reaches a topmost in Shrawan, and then declines to respective months. The mean of OPD visits in Tanahun is significantly higher compared to Kathmandu valley. It shows OPD visits in health facilities of Tanahun are higher than health facilities of Kathmandu valley. It could be because most of the data in Kathmandu was collected from Urban Health Clinics rather than health posts and Primary health care centers.

Figure 8: The average number of OPD visit in the health facilities

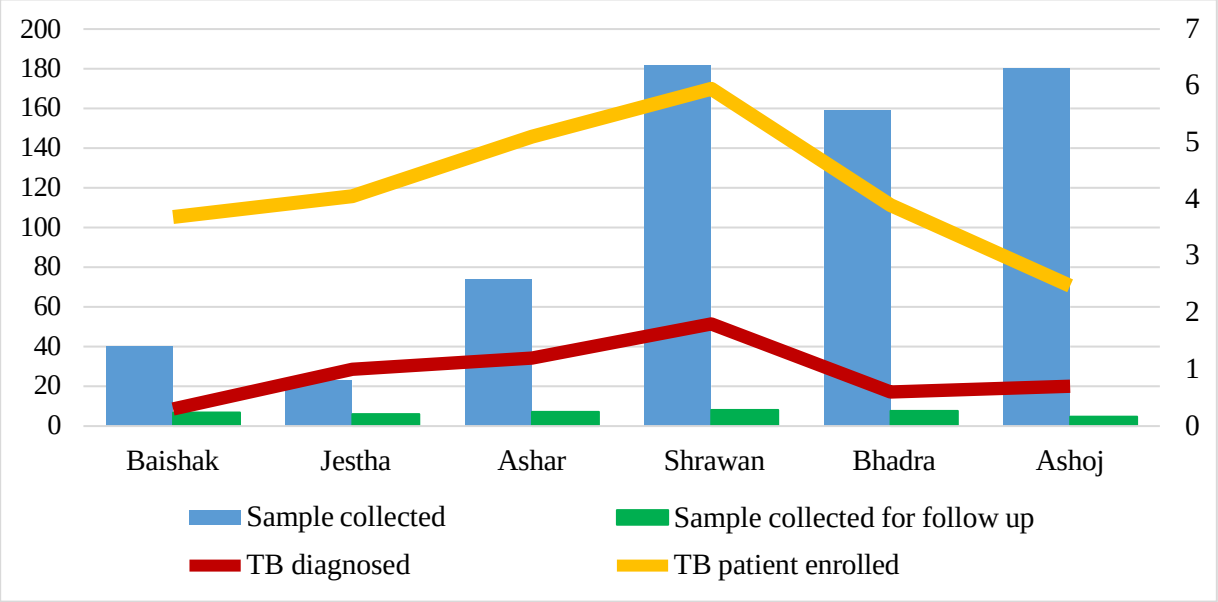


Trend of sputum test, diagnosis, and treatment enrollment for six months

The line graph on the number of sputum microscopy tests in the last six months in the selected laboratories reveals the number of sputum tests in Baishak and Jestha month is very low, after Ashar the number of sputum microscopy test had gradually increased and had reached a peak in Ashoj.

The average number of sputum microscopy tests for follow-up examination illustrates the stationary trend from Baishak to Ashoj.The average number of TB patients enrolled in the DOTS centre is highest in the Shrawan month in both of the study districts while lowest in the Baishak month. After reaching the crest in Shrawan the TB patient's enrollment has decreased in the following months. Besides, the graph exemplifiesthe highest mean number of TB patient's diagnosed is in the Shrawan month and the lowest in the Baishak month. It also reveals there is significant higher number of TB patient enrolled in TB treatment compared to TB diagnosis.

Figure 9: Trend of sample collection, follow test, TB diagnosis and enrollment



Health facilities referring patients to the diagnostic facilities

Most of the microscopic centers(90.0%) obtaina referral from public health facilities like health posts, primary health care centers. About 16.7 percent of the private pharmacies and private physician referring patients for TB diagnosis, which indicated, limited functional linkage between private sector and TB diagnostic facilities.

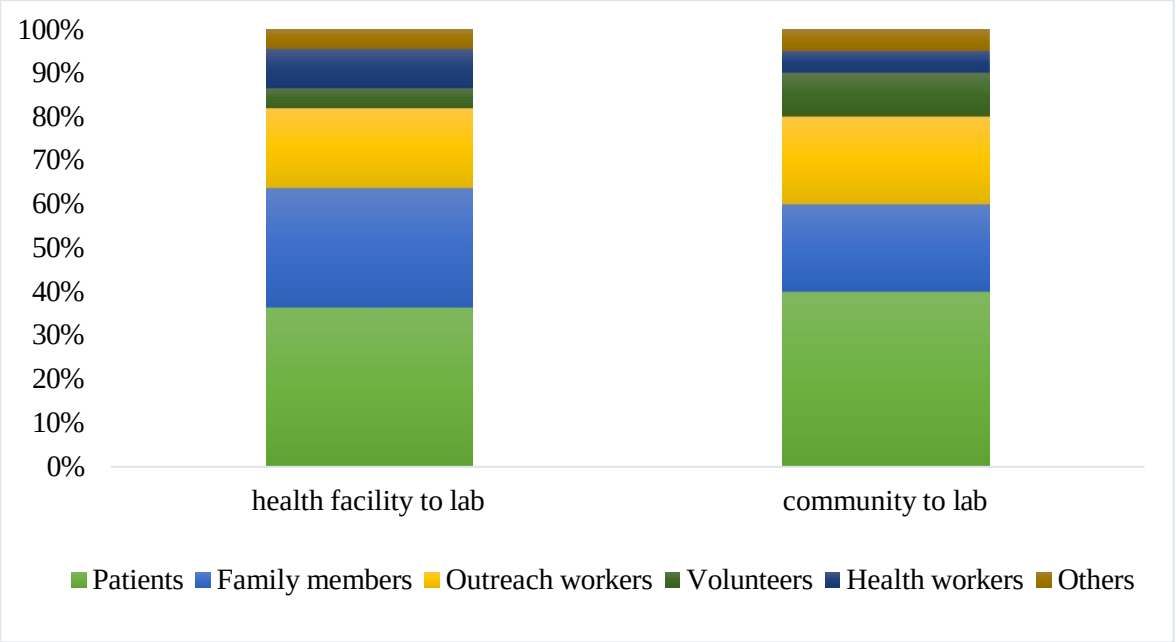
Table 12: Health facilities referring for the TB diagnosis

Receive referrals for TB diagnosis			
	Responses		
Health facilities	N	Percent	**Percent of Cases**
Public facilities	9	50.0%	90.0%
Private doctors	3	16.7%	30.0%
NGO facilities	3	16.7%	30.0%
Private Pharmacies	3	16.7%	30.0%
Total	18	100.0%	180.0%

Sample transportation from health facility and community to diagnostic facilities

The graph indicates patients and their family members transport the sputum sample to designated lab facilities from health facilities and communities. more sputum is transported from the community. Female community health volunteers transport sputum samples from the community to the lab. Similarly, health workers also transport sputum samples from the health facility to the lab.

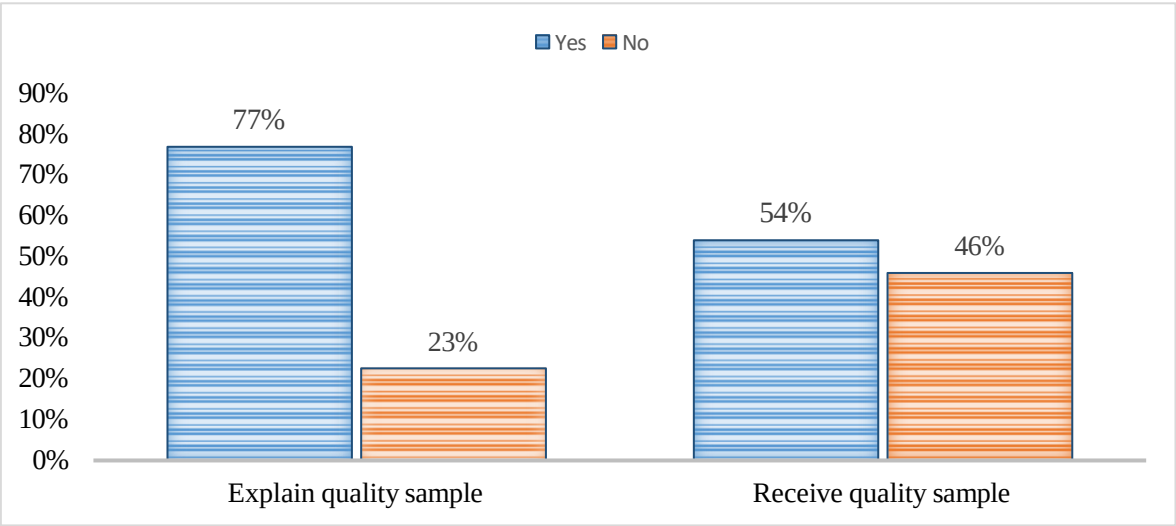
Figure 10: Sample transportation from community and health facilities to Laboratory



Patients getting instruction on quality sputum collection and laboratory worker receivingquality sample

The figure demonstrates the comparative view of the proportion of patients who received an instruction on the process of quality sputum and laboratory workers receiving quality sputum at the diagnostic facilities. The substantial proportion of patients was explained about the process of quality sputum. However, a significant lower proportion i.e. around 54 percent of the sputum sample were of good quality for the sputum test.

Figure 11: Differences in getting instruction and proactive on qualitysputum sample collection



Laboratory worker's practice to poor quality sputum sample

All the laboratory personnel requests the next sputum sample if they receive a poor quality sample in Kathmandu. Unlike, about half of laboratory workers in the Tanahun district perform the test without considering the quality of the test. About 16.7 percent for the follow-up test and 33.33 percent of laboratory workers during contact tracing perform the test without considering the quality of the sample in Kathmandu valley as well.

Table 13: Laboratory worker's practice to poor quality sputum

Sputum sample for initial TB diagnosis	District		Total
	Kathmandu valley	Tanahun	
Perform the test without considering the quality		50.0%	20.0%
Request for next sputum sample	100.0%	50.0%	80.0%
Sputum sample for follow up of TB treatment			
Perform the test without considering the quality	16.7%	25.0%	20.0%
Request for next sputum sample	83.3%	50.0%	70.0%
Others		25.0%	10.0%
Sputum sample for contact tracing			
Perform the test, without considering the quality	33.3%	75.0%	50.0%
Request for next sputum sample	66.7%	25.0%	50.0%
Total	100.0%	100.0%	100.0%

Retaining of sputum quality during transportation and storage

About half (50%) of the laboratory workers believe that cold chain is maintained during sputum transportation in Kathmandu whereas only 25 percent of laboratory workers believes cold chain is maintained during transportation. Around 80 percent of the laboratory has a refrigerator for sputum sample storage in Kathmandu while around 75 percent of the lab facilities havea refrigerator for sputum sample storage in Tanahun. Likewise, about (50%) half of the diagnostic facilities have faced the problem of reagent shortage at least one time in the last six months at a minimum of one week.

Table 14: Retaining of sputum quality during transportation and storage

Transportation maintainingtemperature	District		Total
	Kathmandu valley	Tanahun	
Yes	50.0%	25.0%	40.0%
No	50.0%	75.0%	60.0%
Store in refrigerator			
Yes	83.3%	75.0%	80.0%
No	16.7%	25.0%	20.0%

Shortages for reagents/cartridge over the last 6 months			
Yes	66.7%	25.0%	50.0%
No	33.3%	75.0%	50.0%
Total	100.0%	100.0%	100.0%

ContentsinTB education and counseling by health workers

All the health workers provide education and counseling about treatment adherence, 94.7 percent of health workers educate patients about TB symptoms. One of the concerning factors is still only 63.2 percent of the health worker provide education about TB and HIV infection.

Table 15: Contents in TB education and counseling

TB education and counseling	Responses		Percent of Cases
	N	Percent	
TB symptoms	18	16.4%	94.7%
Treatment adherence	19	17.3%	100.0%
Contact screening	17	15.5%	89.5%
Treatment side effects	17	15.5%	89.5%
TB and HIV	12	10.9%	63.2%
Healthy lifestyle and nutrition	19	17.3%	100.0%
Others	8	7.3%	42.1%
Total	110	100.0%	578.9%

3.3 Current TB services at the community level

Health worker's notion on TB screening in a vulnerable population of the communities

More than one third (36.8%) of the health workers assumed that the vulnerable population has been approached for TB screening while 40% of the outreach worker presumed of the vulnerable population has not been approached for TB screening. The table below indicates significant variation on the assumption about TB screening in Kathmandu valley and the Tanahun district.

Table 16: TB screening in a vulnerable population

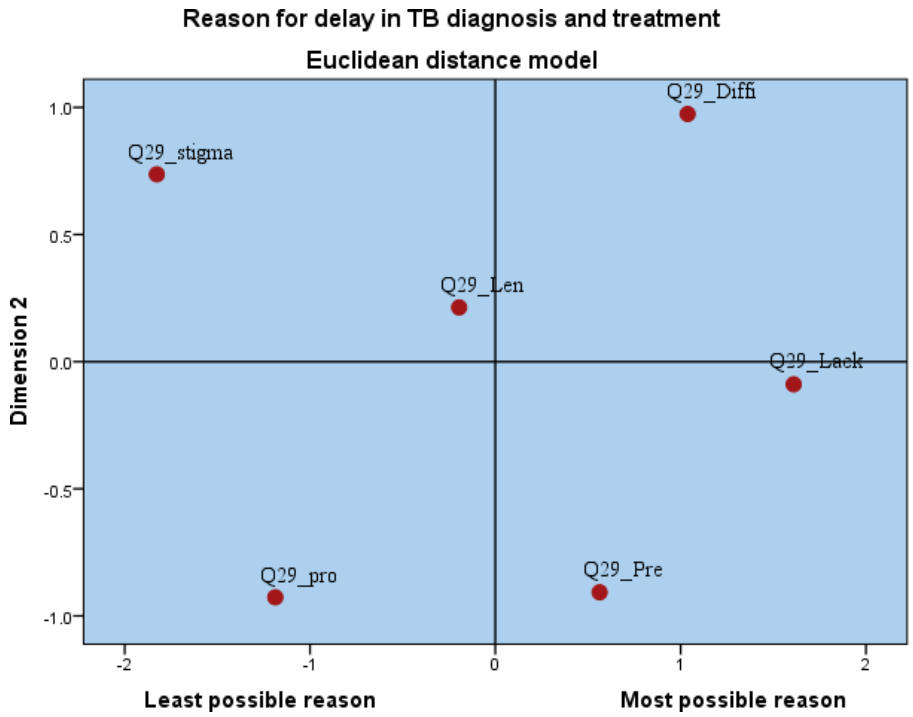
Health workers	Frequency	Percent
Yes	7	36.8
No	12	63.2
Total	19	100
Outreach workers		
Yes	4	40
No	6	60
Total	10	100

Health worker's perspective on factors related todelay in TB diagnosis and treatment

The main reasons for the delay in TB treatment for the health workers is lack of awareness of tuberculosis among TB patients, followed by patient preference to seek health services from private providers, and difficulty in accessing public health services, higher length of services in the health facilities including delay in diagnostic services.The laboratory workers perceive that patient difficulty in assessing the health services is the major reason for the delay of diagnosis, followed by patient preference to seek health services from informal health providers. In addition, the long duration of the sputum sample test and lack of knowledge contributes to the delay in diagnosis. According to outreach workers,the main reason for the delay in TB diagnosis is a preference to go informal health care private health facilities followed by patient difficulty in accessing government health services, followed by long time for sputum test and patient preference to seek health services from informal/private health providers.

Figure 12: Health worker's perspective on reasons for delay in TB diagnosis and treatment

Note:



Stress=0.0623, RSQ= 0.965

3.4 Impact of COVID-19 in TB services

Modification of working hours during a pandemic situation

About 90 percent of the outreach workers have changed their working pattern in the pandemic. Likewise, about 70 percent of the diagnostic facilities had modified their working hours and nearly 60 percent of DOTS centre has changed the working hours in the pandemic.

More than half (57.1%) of laboratory workers worked for more hours than before pandemic situation while 28.6 percent worked on alternative days and 14.3 percent lab was closed for a certain time and then worked in the normal calendar. Likewise, among health workers 45.5% worked for more hours on days particularly more engaged in contact tracing of COVID 19, 36.4% worked on alternate days. Similarly, 56% did not have any fieldwork due to travel restriction and about 44% did work of sample collection and contact whenever there is information about TB patients from health workers.

Table 17: Modification of working hours during a pandemic situation

	Health care providers		
Modification of working hours	**Health workers (n=19)**	**Lab personnel (n=10)**	**Outreach workers (n=10)**
Yes	57.9%	70.0%	90.0%
No	42.1%	30.0%	10.0%
Total	100.0%	100.0%	100.0%
Health care providers	**Health workers (n=11)**	**Lab personnel (n=7)**	**Outreach worker (n=9)**
Work for more hours in a day	45.50%	57.10%	0%
Work for fewer hours in a day	36.40%	0%	0%
Work on alternate days	18.20%	28.60%	0%
Others	0%	14.30%	0%
Didn't had fieldwork	0%	0%	56%
Only travel, when there is a call from a health worker	0%	0%	44%
Total	100%	100%	100%

Management of presumptive TB patients and follow up examination of under treatment TB patients in the health facility

The majority of the health workers i.e. 73.7 percent referred the patients to nearby diagnostic facilities, about 15.8 percent of health workers suggested to go private facilities for a follow-up examination, while 10.5 percent just continue the medicine, as they did not have any options for follow up examination. Nearly half of the health workers i.e. 47.4 percent had

referred the presumptive patients to nearby diagnostic facilities, more than one-fourth of the health workers facilitated sample collection and transportation through outreach workers, about 10.5 percent referred to private lab facilities and a similar proportion of health workers provided antibiotics for 15 days and few of them asked the patients once the situation is normal.

Table 18: Management of presumptive TB patients and follow up examination in the health facility

Management of diagnosis of presumptive TB in this pandemic	District		Total
	Kathmandu	Tanahun	
Refer presumptive patient to nearby diagnosis facility	46.2%	50.0%	47.4%
Ask to come once the situation is normal	7.7%	0.0%	5.3%
Refer to private lab	7.7%	16.7%	10.5%
Facilitate sample transport by ORW	23.1%	33.3%	26.3%
Others	15.4%	0.0%	10.5%
Total	100.0%	100.0%	100.0%
Manage to follow up examination of under treatment patient			
Just continue the medicine	7.7%	16.7%	10.5%
Refer to near diagnostic facility	76.9%	66.7%	73.7%
Others	15.4%	16.7%	15.8%
Total	100.0%	100.0%	100.0%

Delay of TB services due to pandemic situation

Almost all the outreach workers (90%) presumed there is a delay in TB services due to the pandemic situation. About 80 percent of the lab personnel believe there is a delay in TB services. On contrary to these about 42.1 percent of the health workers think there are TB services.

Table 19: Delay of TB services due to Pandemic situation

Delay	Category of respondents			Total
	Health workers (n=19)	Lab personnel (n=10)	Outreach workers (n=10)	
Yes	42.1%	80.0%	90.0%	64.1%
No	57.9%	20.0%	10.0%	35.9%
Total	100.0%	100.0%	100.0%	100.0%

Factors for the delay in TB diagnosis and treatment during the pandemic

The major reason forthe delay is patientsdo not want to visit the health facilities due to the perceived risk of coronavirus. Besides, health facilities were not fully functional during the

pandemic situation.The majority of the health workers thought due to travel restrictions, there has been a delay in the sputum sample collection. Besides, the health workers also believe that, due to no contact tracing of the patient, there has been a delay in sputum sample collection. In addition, the lab personnel is unavailable at the facilities and some of the diagnostic facilities were closed fora certain time. The major reason for the delay is travel restriction, as patients and the outreach workers could not travel from one place to another place.

Table 20: Factors for the delay in TB diagnosis during the pandemic

Laboratory Worker	**Frequency**	**Percent**
Health facilities provide emergency services only and lack of staff in the facilities	2	20%
Travel restriction and no sample courier	1	10%
Because of the risk of COVID 19, patient doesn't want to come to health facilities	7	70%
Outreach Worker		
Travel restriction and no movement of people	6	60%
Community people were afraid to give a sample and health workers were afraid to collect sputum and patient don't want to come to the health facility	4	40%
Health workers		
Travel restriction	8	53%
No contact tracing	3	20%
Afraid to seek health services from facilities due to perceived risk of coronavirus	2	13%
The designated lab was completely closed for a certain time	1	70%
Only a few staff in the clinic and laboratory	1	70%

CHAPTER IV: STRENGTH, CHALLENGES AND RECOMMENDATIONS

Strengths

There is a wider expansion of DOTS centre, including hard to reach populationin all the assessment district. Even during the lockdown and travel restriction, NTP has ensured all the TB patients had their medicine. Furthermore, almost all the patients are enrolled in the DOTS centre within a week of diagnosis, which is one of the strength of the National Tuberculosis Program.

Challenges to TB services and care at community level

According to the health care providers still, around forty percent of the vulnerable population in the community are not screened for TB on regular basis.On top of that, around half of the TB patients did not seek medical help for more than 4 weeks. The first choice for medical help is private pharmacies (45%), followed by private clinics (27.5%). At the private pharmacies and clinics, they

receive treatment based on the symptoms. As the symptoms get worse or health conditions do not improve, then only they are referred to as sputum tests for TB. These all factors play a crucial role in the delay in TB diagnosis. The major reason for the patient's delay is not aware of the severity of symptoms that most of the patients think hemoptysis is the major symptom of TB. In addition, there isa limited number of molecular diagnosis facilities or unavailability of diagnostic tools in the districts. Thus, asubstantial number of TB patients are diagnosed from sputum microscopy. Besides, about fifty percent of the sputum samples are of poor quality. Lab personnel tests the sputum sample without considering the quality, particularly for follow-up examination and contact tracing samples.

However, the accessibility of TB treatment services is a huge challenge because patients have to travel for around 50 minutes to reach the DOTS center in the hilly areas. Additionally, around 40 percent of the TB patient's contacts are not traced for sputum test.

Challenges due to COVID 19 pandemic in the TB services at the community level

The travel restriction measures contribute to the delay in TB diagnosis. About one-fifth of the delay was due to lockdown/travel restrictions. Health workers in the clinic had to prolong the TB treatment due to no sputum follow-up examination of TB patients in time. The health workers, including laboratory personnel, were fully occupied in COVID 19 and could not focus on the TB program except providing medicine to TB patients.The number of OPD visits

to health facilities was less (40-50%), as patients were afraid of going to the health facilities due to the perceived risk of coronavirus.Outreach workers have to refer presumptive TB patients to a private lab because government lab facilities were fully occupied for COVID 19 test.

Recommendations

It is essential to carry out mapping of vulnerable populations in the districts to identify hotspots area for the intensive screening of TB and organize ACSM activities in the community to aware of TB signs and symptoms and the importance of early TB tests. Consequently, expand and improve the functionality of molecular diagnosis, including Gene Xpert with dedicated laboratory staff. It is pivotal to provide program-based orientation/training to the lab personnel, health workers, outreach workers, female community about the process of collecting quality sputum samples. Besides, the National TB program need to strengthen QCA activities.In addition, it is essential to continue prioritizing PPM activities (engagement of private pharmacies) in the major urban areas to decrease the delay of TB diagnosis. Likewise, we need to expand and improve community-based DOTS with clear terms of references for local-level health authorities including local partners. Correspondingly, improve monitoring of contact tracing activities by introducing the

standard checklist.It is crucial to make provision for joint planning with the local level government including local-level stakeholders.

ANNEXES I: WORK PLAN

Activity	Timeline																			
	August				September				October				November				December			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Consensus on the project sites																				
Inception meeting																				
Finalization of tools and methods																				
Orientation of the field team, including tools and methods																				
Coordination with the concerned authorities in the district																				
Field work																				
Monitoring and Evaluation																				
Preparation of report																				
Project completion dissemination workshop																				
Publications of report																				

ANNEXES II:PHOTOS

	 पुरानडिहि नगर

ResearchProject Report

TheimpactofCOVID-19pandemiconDirectlyObservedTreatment Short-Courses (DOTS) program for

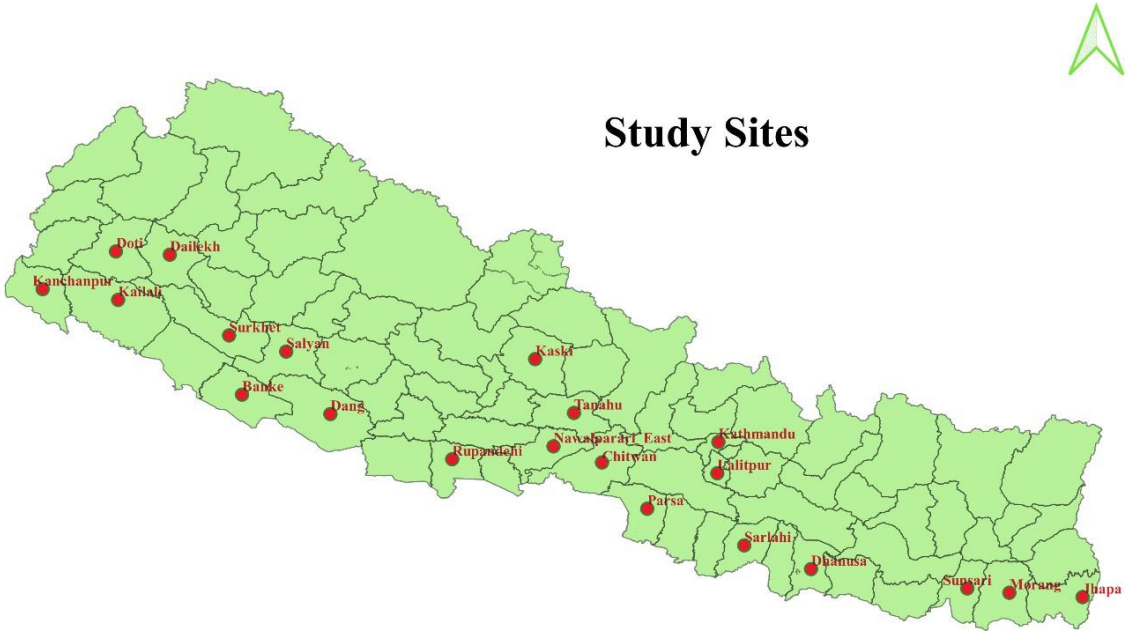
Submitted By

DhulikhelHospital,KathmanduUniversity

Hospital Dhulikhel, Kavre

Research Project Report

The impact of COVID-19 pandemic on Directly Observed Treatment Short-Courses (DOTS) program for Tuberculosis in Nepal



Submitted By

Dhulikhel Hospital, Kathmandu University

Hospital Dhulikhel, Kavre

ABBREVIATION

ATT	Anti-Tuberculosis
DOTS	Directly Observed Treatment Short-Course
EP	Extra-Pulmonary
HO	Health Officer
KII	Key Informant Interview
IRC	Institutional Review Committee
KUSMS	Kathmandu University School of Medical Sciences
MDR	Multi-Drug Resistance
NHRC	Nepal Health Research Council
NTCC	Nepal Tuberculosis Control Center
OPD	Out Patient Department
SAARC	South Asian Association for Regional Cooperation
TB	Tuberculosis
XDR	Extensively Drug-Resistance
WHO	World Health Organization

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Acknowledgment

It is our great pleasure to present the report of a research project entitled, “The impact of COVID-19 pandemic on Directly Observed Treatment Short-Course (DOTS) program for Tuberculosis in Nepal”. This report was prepared by the core research team of the project led by Principal Investigator: Dr. Biraj Karmacharya, Director, Department of Public Health, Community Programs and Global Engagement, Kathmandu University. The report was drafted and prepared by Ms. Ruby Shrestha (DH, KUH) and reviewed by the research team: Dr Ranju Kharel (IOM, TU), Dr. Sanjeeta Sitaula (IOM, TU) and Dr Anadi K.C. (Birat Aankha Aspatal).

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EXECUTIVE SUMMARY

The research study was funded by SAARC Tuberculosis and HIV/AIDS Center (STAC) Nepal, technically supported by National Tuberculosis Control Center (NTCC) and implemented by Dhulikhel University Kathmandu University. The study aimed to understand the impact of COVID-19 pandemic on Tuberculosis patients and Tuberculosis program in Nepal by focusing on the usage of the DOTS clinics. It also identified the facilitators and barriers to usage of COVID-19 pandemic in Nepal.

Tuberculosis remains a major public health program in Nepal and requires surveillance, clinical assessment, confirmation of diagnosis and supervised treatment regimens for effective management. The COVID-19 pandemic has led to change in prioritization which has affected many aspects including the functioning of tuberculosis control programs. Geographically, most TB cases in 2018 were in the WHO regions of South-East Asia accounting for a total of 44%. South Asia, continues to suffer from the burden of TB because of poverty, gender inequality, vulnerability, inaccessibility, inadequate lab resource, discrimination and marginalization. It needed our attention more than ever, but significant resources are now being diverted from TB to COVID-19 management. These may lead to grave consequences for existing and undiagnosed TB patients globally, particularly in TB endemic countries like Nepal which is still battling with the age long disease of TB.

We aimed to assess the challenges due to COVID- 19 pandemic on management of tuberculosis, mainly the usage of DOTS (Directly Observed Treatment Short-Course) Clinics in the form ATT (Anti-tuberculosis treatment) adherence (compliance) to the patients along with facilitators and barriers to strengthen DOTS services. We analyzed the pre-COVID, during-COVID and post COVID data from the DOTS centers (n=21), from the 21 districts of all seven provinces to determine the average (mean difference) of ATT adherence to TB patients as measured by the percentage of day medicines were taken. Additionally, qualitative interviews of the patients enrolled in DOTS centers (n= 117), in charges at the DOTS Centers (n=35), health-coordinators from corresponding municipalities (n=21) and TB focal persons and health office chiefs from corresponding district (n=37), TB focal persons at corresponding provinces (n=6), and TB focal persons at central level (n=2) were conducted to understand the perspectives on the facilitators and barriers to strengthen DOTS services during critical times like COVID-19. A thematic analysis approach was used for data analysis purposes, to determine both patients and health providers' perspective on the barriers and facilitators of COVID-19 pandemic on DOTS program. A checklist questionnaire was prepared which was asked with the respective DOTS in charge at the DOTS facilities to understand the trend of usage of DOTS clinics throughout COVID-19 pandemic.

The total number of TB patients were concentrated in Bagmati province followed by Lumbini and Gandaki, with least in Karnali province. Approximately 57% were male patients, with majority belonging to Brahmin/Chhetri ethnicity, followed by Janajati. Majority of the patients belonged to the age group 20 to

30 years with least from 0 to 10 years and above 80 years' age group. Majority of the TB cases were newly diagnosed and detected with PBC and EP. A total 217 KIIs were conducted in the study, including 117 patients, 35 DOTS facility in-charges and focal person, 21 health coordinators, 38 health officers and 6 provincial health officers. The highest percentage of patients interviewed were housewives followed by unemployed patients with the least percentage of foreign returnees. Majority of TB patients had pre-information on COVID-19 pandemic and were aware of the prevention measures. DOTS focal person and staff maintained social distancing and preventive measures in the health facilities during COVID-19 pandemic.

To monitor the DOTS usage during COVID-19 pandemic, we used a checklist on essential TB services. The checklist was categorized into six sections: Information on DOTS centers, Treatment and Management, Diagnosis of Tuberculosis, Drug Management, Information Management and Program Management. Although 20 out of 21 DOTS centers agreed to provide necessary information, most of the patient treatment cards were either missing or not completely filled, with huge missing data. The study reported a mean difference in ATT adherence during the first lockdown stage between all three stages: Pre-lockdown, During Lockdown and Post-Lockdown stage, however no significance difference was observed during the second lockdown stage. The total number of TB patients under ATT immediately decreased after the first lockdown which continued to decrease until the second lockdown stage. The average number of patients slightly increased post second lockdown. Similarly, GeneXpert and microscopy service slightly decrease after the first lockdown due to unavailability of staff. Although reporting and recording tools were available in the majority of the DOTS centers, only one in ten health workers reported to have updated reporting format and observed discrepancies in online reporting systems.

TB patients experienced difficulty in traveling to health facilities due to unavailability of public transportation because of strict social restriction during lockdown. Furthermore, both TB patients and health staff admitted to constant fear of transmission of COVID-19 particularly due to crowding in the health facilities. Anxiety and stress were commonly mentioned by the TB patients during COVID-19 pandemic due loss of job, insufficient funds to support additional diet and fear of constant availability of TB medicines in the health facilities. Although, majority of the DOTS centers reported to have managed to provide timely TB medicine to the TB patients, occasionally, lab services were interrupted due to transfer of laboratory staff for the COVID duty. Health providers faced difficulties in service provision,

primarily due to additional COVID-19 responsibilities, lack of infrastructure and equipment, and restriction to movement. They were also demotivated due to insufficient incentives during COVID-19 pandemic. Overall, health providers were unprepared for the sudden onset of COVID-19 pandemic, resulting in priority shifting towards COVID-19 management. This has overshadowed and hampered the regular programs including the National Tuberculosis Program at the national level. Fear of transmission was commonly observed among patients included in the study, which could reduce the adherence of the DOTS services. Similarly, due to close down of OPD services during lockdown period, TB cases possibly could be missed from the follow up services and diagnosis of TB services could be delayed resulting in decreased case notification and identification. The government strictly instructed the public to avoid gathering during COVID-19 pandemic, which has reduced the community TB programs including awareness programs, and active screening of TB cases. In such cases, TB cases could be hidden within the community and possibly failed to be detected leading to spread of cases in the community.

The disruption of TB programs seemed to have high impacts on the highly vulnerable population, particularly old age populations with less source of income and difficult access to health facilities. TB patients with low sources of income also mentioned difficulty to consume additional nutritious food during the treatment period either due to loss of job or low source of income in the family. Health providers felt

the need to prioritize vulnerable TB patients and provide nutritional support to the patients during treatment duration. They also suggested exploring the possibility of providing transportation cost or transportation facility for the patients with difficult access to health facilities during pandemic. Overall health system should be prepared for any kind of pandemic in future with proper planning and resources. Health providers seemed more confident during the second wave of COVID-19 pandemic, as most of them had experienced from earlier management and had allocated resources accordingly.

Clinical care for diseases like tuberculosis that require daily care are impacted hard by scenarios like COVID-19. The preparedness for such circumstances needs to be done considering the needs of the patients and the health providers. The government and concerned authorities should prioritize marginalized patients and need to explore the possibility of supporting them during a pandemic situation. For TB patients, the possibility of incentives or transportation facilities could be helpful for the patients with low source of income and difficult access to health facilities. Taking into consideration the working patient groups, it is essential to explore the possibility to expand DOTS services on weekend and post office hours so that patients don't have to miss their work hours. Work Shift could be explored for the staff at DOTS centers during the pandemic, allocating their time for both pandemic management and regular program services. Microscopy centers in rural areas should be expanded in future. We believe this study provided valuable information to the policy makers about the effects of COVID-19 pandemic on diseases and can act as a model to assess the situation of other infectious diseases (like HIV) and noninfectious diseases (Diabetes, Chronic Kidney diseases etc.). We hope the result of this study can help in formulating strategies to facilitate the treatment strategy for the patients.

1. INTRODUCTION

1.1 Background

Tuberculosis (TB) is an infectious disease caused by the bacillus Mycobacterium tuberculosis which primarily affects the lungs (pulmonary TB) and other sites (extra pulmonary TB). It is one of the major public health problems in the country causing around 7000 deaths annually (1). Nepal National TB program has been successful in meeting the global targets of the millennium development goals and was embarking on an ambitious journey to address the targets of END TB strategy which aims to end the global TB epidemic by 2035 and eliminate TB by 2050. But there seems to be a barrier in the achievement of the Nepal National TB program due to the COVID-19 pandemic caused by severe acute respiratory syndrome coronavirus (SARS-CoV-2).

Similar to TB, it is predominantly a respiratory illness and the symptoms can range from asymptomatic, common cold to more severe disease including pneumonia and acute respiratory distress syndrome (2,3). The mode of human-to-human transmission is via droplet infections which are either inhaled or enter the body by touching infected surfaces. As the world is struggling to tackle the COVID-19 crisis, which is overwhelming the health care systems, all aspects of healthcare delivery including programs to control diseases like Tuberculosis are being adversely affected.

The first case of COVID 19 positive cases in Nepal was confirmed on 23 January 2020 and despite all the measures to control the transmission of disease, the number of cases escalated(4). A country-wide lockdown came into effect on 24 March 2020 and ended on 21 July 2020(5).

The COVID 19 health crisis has caused a massive disruption worldwide in diagnosing and treating people with deadly but preventable diseases with the developing countries being affected the most. A meta-analysis of 8 studies, which analyzed data from over 46,000 Chinese patients, found that the most common comorbidities among subjects with COVID-19 were hypertension (17% ± 7), diabetes (8% ± 6), cardiovascular diseases (5% ± 4) and chronic respiratory diseases (2% ± 0)(6). Patients with chronic diseases especially in developing countries are at higher risk of death because of the current COVID-19 crisis due to difficulty in accessing health care due to prioritization to COVID-19, overburdened health care facilities and the lockdown effects.

Reports from other countries have clearly depicted the adverse role of COVID-19 pandemic in the management of TB patients due to various factors like prioritization of services, availability of drugs, the possibility of increased disease transmission or disease susceptibility among TB patients, and the problems caused by co-morbidity (7-10). The economic impact of this global pandemic has been particularly harmful to the most marginalized, and impoverished communities, leading to increase in poverty and malnutrition, both of which are major risk factors that predispose to TB in rural and urban communities (7). In India, the lockdown has resulted in decrease in TB notification rate by up to 80% which has a risk of a large number of cases remaining undiagnosed, and untreated, further fueling TB transmission rates among household contacts (7). A modeling analysis by STOP TB partnership estimated that the global TB incidence and deaths in 2021 would increase significantly implying a setback of at least 5 to 8 years in the fight against TB, due to the COVID-19 pandemic (9).

The challenges faced by patients of suspected or confirmed TB are closure of out-patient departments (OPD) at various hospitals, poor access to treatment, refusal by government and private hospitals, difficulty in reaching Direct Observed Treatment Short-course (DOTS) centers by patient and medical staff due to limited transport (8). Patients who are multidrug resistant tuberculosis (MDR) and are on injectable medications for TB e.g. Amikacin or Streptomycin are facing real challenges for injection administration. There is evidence suggesting that patients with latent TB and established disease have an increased risk of the SARS-CoV-2 infection and predisposition towards developing severe COVID-19 pneumonia which further complicates the situation (2,11).

1.2 PURPOSE

In this study we aimed to assess the impact of COVID-19 on Tuberculosis patients and tuberculosis programs in Nepal by focusing on the usage of DOTS clinic (as measured by the number of new patients and compliance to treatment of previously diagnosed cases) during COVID-19 pandemic which were

further classified into three phases: Pre-lockdown phase, during lock-down phase and post-lock down phase. We also determined the facilitators and barriers to usage of DOTS services during COVID-19 by using a structured questionnaire. This was a mixed method study where we interviewed patients, DOTS clinic in charges, health providers, and related health officials (Health Offices, Province officials, head of NTCC) to find out the difficulties encountered and possible solution to help curb the tide of TB in the era of COVID-19 pandemic. This study can be a supporting evidence to the policy makers about the effects of COVID-19 pandemic on diseases like TB and should be able to act as a model to assess the situation of other infectious diseases (like HIV) and noninfectious diseases (Diabetes, Chronic Kidney diseases etc.).

Furthermore, the result of this study can help in formulating strategies to facilitate the treatment strategy for the patients.

1.3 SIGNIFICANCE/RATIONALE

Tuberculosis is a communicable disease that is a major cause of ill health, one of the top 10 causes of death worldwide and the leading cause of death from a single infectious agent (ranking above HIV/AIDS)
(12). Globally, an estimated 10.0 million (range, 9.0–11.1 million) people fell ill with TB in 2018. The WHO End TB Strategy defines milestones (for 2020 and 2025) and targets (for 2030 and 2035) for reductions in TB cases and deaths. The targets for 2030 are a 90% reduction in the number of TB deaths and an 80% reduction in the TB incidence rate (new cases per 100 000 populations per year) compared with levels in 2015. The milestones for 2020 are a 35% reduction in the number of TB deaths and a 20% reduction in the TB incidence rate (12). But the End TB Strategy milestones for 2020 and 2025 can only be achieved if TB diagnosis, treatment and prevention services are provided within the context of progress towards universal health coverage (UHC), and if there is multisector action to address the broader determinants that influence TB epidemics and their socioeconomic impact (13). However, the global attack by SARS-CoV-2 virus will have a major impact upon the progress towards UHC.

Geographically, most TB cases in 2018 were in the WHO regions of South-East Asia accounting for a total of 44%(12). SAARC had adopted WHO's Global Stop TB Partnership strategy which envisions a TB-free world. For it, the strategic directions for TB Control are grounded in six principles, out of which one was the commitment to high quality DOTS that would provide diagnostic services and treatment with effective anti-tubercular drugs. But the strategic plans have been badly affected by the COVID-19. Although recent achievements of SAARC partners in TB Control are encouraging, there is need to ensure effective implementation of TB control activities, to intensify advocacy, social mobilization, partnership, research and inter-sectoral efforts to achieve the target of ending the TB epidemic by 2030. However, COVID-19 pandemic assumed to have a huge impact upon these TB control activities and there could be difficulties to achieve targets.

South Asia, continues to suffer from the burden of TB because of poverty, gender inequality, vulnerability, inaccessibility, inadequate lab resource, discrimination and marginalization (8). It

needed our attention more than ever, but significant resources are now being diverted from TB to COVID-19 management. These may lead to grave consequences for existing and undiagnosed TB patients globally, particularly in TB endemic countries like Nepal which is still battling with the age long disease of TB. COVID-19 has claimed lives of many Nepalese, caused disruption to economic, as well as social life, and

the ability and internal resilience of Nepal to cope is a matter of concern. The lockdown, minimal mobility, social stigmatization, decline in human resources, unavailability of transportation to reach the DOTS center to obtain the ATT restrain can lead to a reduction in quality of TB care and worse outcomes in Nepalese scenario.

Though the World TB Day of 2020 was celebrated on 24th March with the slogan of **"It's time for Action- It's time to End TB"**, the achievement of this aim seems to be eclipsed due to Coronavirus in Nepal. Instead, there could be an increase in the gap between the number of new cases reported and the estimated incident cases in 2020 due to a combination of underreporting of detected cases and under diagnosis (i.e., people with TB do not access health care or are not diagnosed when they do). Thus, the hope to END TB seems far ahead than expected.

Herein, we employed both qualitative and quantitative method to understand the impact of COVID-19 in Nepal in regard to diagnosis and treatment of TB cases, conduction of TB control programs, prioritization of services, availability of drugs, the effect on hard-to-reach and low-income communities and the role of stigmatization, the possibility of increased disease transmission or disease susceptibility. In summary, COVID-19 pandemic could have impacted the health services in Nepal through three ways. **First,** it could reduce the access to health services because of the prolonged lockdowns and hindrances in mobility. **Second,** it might shift the attention of health professionals and officials to COVID-19 letting other health conditions be undermined. **Third,** it could have impacted on the timely supplies of other health materials like medicines. We anticipate that this must have led to severe impact on the DOTS services.

1.4 General Objective

To determine the effect of COVID-19 Pandemic on DOTS services in Nepal

1.5 Specific objectives

Aim 1: To determine the usage of DOTS clinics (as measured by the number of patients and compliance to treatment) before and during and post COVID-19 lockdown in 2021

Aim 2: To determine facilitators and barriers to strengthen DOTS services during COVID-19

2. METHODOLOGY

2.1 Study design

The study design employed a mixed method approach. Both quantitative and qualitative methods were applied to achieve the study objectives. The secondary data was purposely collected from the DOTS registries and respective patient cards at selected DOTS centers to determine the adherence of TB treatment during the study duration. We collected following information:

- Basic clinical characteristics of the patients
- Basic demographic characteristics of the patients: age, sex, address, ethnicity
- Total number of new patients enrolled in the DOTS program
- Total number of TB cases with COVID-19
- Compliance to treatment based on DOTS center visit and where applicable refill of the medications. (The compliance was being designed as percentages determined in terms of percentage)

We conducted key informant interviews of the TB patients and health providers to understand the facilitators and barriers of TB treatment during pandemic. We included both first and second lockdown phase in the study and categorized each phase further into pre-lockdown, lockdown and post lockdown phase as follows:

Period 1: First Lockdown

Pre-Lockdown Phase	15/10/2076 to 15/12/2076
Lockdown Phase	16/12/2076 to 15/03/2077
Post Lockdown Phase	16/02/2077 to 15/04/2077

Period 2: Second Lockdown

Pre-Lockdown Phase	15/11/2077 to 15/01/2078
Lockdown Phase	16/01/2078 to 15/03/2078
Post Lockdown Phase	16/03/2078 to 15/05/2078

2.2 Study Site

The study was conducted in all seven provinces of Nepal. We selected three districts from each province

based on following criteria:

- Total number of COVID cases at district level (May 2020 to December 2020)
- Total notified TB cases at district level (FY 2075/76)

All districts were ranked based on the total reported number of COVID cases. Similarly, districts were separately ranked based on total notified TB cases. The individual rank for each district obtained from two above mentioned criteria was then averaged. From each province, the districts with the top three average ranks were selected. Likewise, DOTS centers with the highest number of TB notification cases were purposely selected from each selected district (hence 21 in total). Similarly, corresponding municipalities were also purposely selected in the study.

Following are the list of selected sites in the study: List1: List of Study Sites

Province	Districts	Local Authority	Type	DOTS Centers
1	Morang	Biratnagar Sub-Metropolitan City	Metropolitan cities	NATA
	Sunsari	Dharan Sub-Metropolitan City	Sub-metropolita n cities	BPKIHS
	Jhapa	Damak Municipality	Municipality	Damak HP
2	Sarlahi	Lalbandi Municipality	Municipality	Lalbandi PHC
	Parsa	Birgunj Sub-Metropolitan City	Sub Metropolitan	National Medical College
	Dhanusa	Janakpur Sub-Metropolitan City	Sub Metropolitan	District Clinic Janakpur
3	Kathmandu	Kathmandu Metropolitan city	Metroplitan	GENETUP,TB Hos.

	Chitwan	Bharatpur Metropolitan city	Metroplitan	DPHO Clinic
	Lalitpur	Lalitpur Metropolitan City	Metroplitan	Patan Hospital
4	Kaski	Pokhara Metropolitan City	Metropolitan	DPHO DOTS
	Tanahu	Byas Municipality	Municipality	Damauli district H
	Nawalparasi East	Kawasoti Municipality	Municipality	Shivmandir HP
5	Rupandehi	Butwal Sub-Metropolitan City	Sub-metropolitan cities	Lumbini Zonal HOS
	Banke	Kohalpur Municipality	Municipality	Kohalpur HP
	Dang	Ghorahi Sub-Metropolitan City	Sub-metropolitan cities	Rapti Sub Regional Hospital
6	Surkhet	Birendranagar Municipality	Municipality	Katkuwa HP
	Salyan	Chhatreshwori Rural Municipality	Rural Municipality	Chhayachhetra HP
	Dailekh	Narayan Municipality	Municipality	District Hospital, Da
7	Kailali	Dhangadhi Sub-Metropolitan City	Sub-Metroplitan	Seti Z H
	Kanchanpur	Bhimdatta Municipality	Municipality	Mahakali Zonal Hospital
	Doti	Dipayal Silgadi Municipality	Municipality	District Hospital, Do

2.3 Study Population

The study population were TB Patients and Health Service Providers. We employed TB patients either taking or completed anti-tuberculosis treatment at selected DOTS centers within the defined study period. Likewise, from the provider's side, health professionals responsible for providing TB services at selected study sites were selected.

2.3.1. Inclusion Criteria

- TB patient under ATT at selected DOTS center.
- Patients whose ATT treatment included within the study duration

2.3.2. Exclusion Criteria

- Non-consenting individuals
- Patients whose treatment period did not fall under study duration.
- Patient below age of 16 years

We conducted **Key -Informant Interviews (KIIs)** to get an in-depth understanding on facilitators and barriers to strengthen DOTS services during COVID-19.

The key informants were allocated as follows: <u>At each DOTS center:</u>

- 6 patients (hence a total of 126)
- 1 DOTS Center in charge (hence a total of 21)
- 1 Health facility in charge (hence a total of 21) <u>At the corresponding municipality</u>
- 1 health coordinator (hence a total of 21) <u>At the corresponding district</u>
- 1 District Health Officer (hence a total of 21)
- 1 Focal Person for Tuberculosis (hence a total of 21)

<u>At the corresponding province</u>

- 1 official involved in the planning, monitoring and procurement section (hence a total of 7) <u>At the central level</u>
  - 1 official from the National Tuberculosis Control Center
  - 1 official from the Ministry of Health and Population

All interviews were conducted by trained research assistants (n=7) under the guidance of the research team as well as the research coordinator. All the interviews were audiotaped and transcribed verbatim into Nepali language. The recorded files were securely stored in a password-protected file in an encrypted folder that was accessible only to the researcher. No personal identifiers were mentioned in the digital files. Each interview lasted from 10 minutes to one hour. The interviews were conducted in private with no one else present.

We categorized the interview analyzes into two categories: Patients, and Health providers. We used inductive coding to identify themes from the interviews. Before coding, each transcript was individually read by the investigator to get a sense of the entire interview. The transcripts were thoroughly read line by line. The text was then divided into meaning units such as phrases, quotes and presented in as a meaningful unit i.e. code.

The codes were generated manually which were categorized into themes based on the patterns of the codes. The themes were reviewed and revised during analysis. The finalized theme was then manually entered in the coding framework which was prepared by the team in excel format. The relevant codes for each theme were also manually coded and filled in the coding framework. Data were then analyzed using a thematic framework method first to understand their perception on the impact of COVID-19 on DOTS services, and then to gain their perspectives on what might be the facilitators and barriers to strengthen the DOTS services during COVID-19 pandemic.

2.4 Sampling method

Aim 1:

Purposive sampling technique was employed to sample the TB patients taking anti-tuberculosis drugs from the respective DOTS center based on following study duration:

Period 1: First Lockdown	
Pre-Lockdown Phase	15/10/2076 to 15/12/2076
Lockdown Phase	16/12/2076 to 15/03/2077
Post Lockdown Phase	16/02/2077 to 15/04/2077
Period 2: Second Lockdown	
Pre-Lockdown Phase	15/11/2077 to 15/01/2078
Lockdown Phase	16/01/2078 to 15/03/2078
Post Lockdown Phase	16/03/2078 to 15/05/2078

Selected patients' information was collected from the individual patient treatment card at the respective DOTS center.

Aim 2:

Patients undergoing ATT at selected DOTS centers were conveniently selected from the DOTS registries. Similarly, DOTS in charge/ Health In-charge of selected DOTS facilities were interviewed in the study. Likewise, TB focal person at municipality level, TB focal person and Health Office Chief at health office level were also purposely selected from the corresponding municipalities and health offices. At the central level, TB focal personals at respective provinces were interviewed in the study, along with the TB program representatives from NTCC and MoHP.

2.5 Data collection technique

Aim 1:

The secondary data collected from the selected DOTS centers covered following information:

- Basic clinical characteristics of the patients: type of regimen, indication, comorbidities
- Basic demographic characteristics of the patients: age, sex, address, ethnicity
- Total number of new patients enrolled in the DOTS program
- Compliance to treatment based on DOTS center visit and where applicable refill of the medications. (The compliance will be designed as percentages determined in terms of percentage)

This information was directly entered into electronic semi- structured questionnaires (Kobo Toolbox) for further analysis.

Aim 2:

Semi-structured key-informant interviews were conducted with TB patients undergoing DOTS therapy and health care providers who were directly involved in DOTS program services under KII guidelines. The aim of the interviews was to explore the perceived facilitators and barriers in smooth functions of services by both service providers (health workers) and service utilizers(patients). National Tuberculosis Management Guidelines 2019 Nepal was referred to develop the KII guide. The interview tried to understand the impact of COVID-19 pandemic from patient and providers' perspectives.

We used the iterative process by discussing each interview shortly after it was completed and making suggestions for future interviews, with subsequent interviews probing more deeply into themes emerging in earlier interviews. Furthermore, we pre-contacted patients for the interview and requested them to visit the DOTS center on the interview day. Those patients who did not arrive at DOTS centers on the interview day were followed up and interviewed via phone. Upon follow up, if the participant did not respond, they were automatically dropped from the study.

Similarly, health providers were also pre-informed about the study. On the interview day, with their consent, interviews were conducted, ensuring confidentiality. If the health providers were not available in their respective work station on the interview day, the participants were followed up via phone and were requested for the phone interview. Upon denial, the health providers were withdrawn from the study. The detailed list of Key Informant Interviews is mentioned in Annex.

2.6 Research Variables

2.6.1. Dependent variables

We selected main outcome of the study as average (mean difference) in ATT adherence (compliance) of

the TB Patients as the dependent variables: It was calculated as percentage of total number of days ATT were swollen under direct observation to total number of days ATT were supposed to be taken.

2.6.2. Exposure variable:

The exposure variable was selected as the time periods of lock-down, pre-lockdown and post-lockdown stage.

2.7 Data Analysis

Aim 1:

We presented categorical data using frequency and percentage and continuous data with means and standard deviation. We studied the association of the percentage of average (mean difference) ATT adherence by DOTS to the TB patients between three lockdown stages for each lockdown period using the ANOVA test. We performed the statistical analysis using R (version 4.0.3) with R Studio (version 1.2).

Aim 2:

All recorded KIIs were transcribed verbatim into Nepali and were reviewed against the audio recording for potential discrepancies or incomplete data. Codes were generated to depict the pattern of responses in the transcript. A thematic analysis approach (27) was used for data analysis. We used inductive and deductive coding for analysis. First, we started with a set of predetermined codes as per our prior knowledge and then added new codes after reviewing interview transcripts. The researcher read through the transcripts several times to familiarize with the data. The text was then divided into meaningful units, such as phrases and quotes, and the meaningful units were then condensed. The condensed meaningful units were then abstracted and labeled with codes. Codes were compared on the basis of differences and similarities and sorted into categories. The categories were further discussed by the investigators for identification and formulation of themes. Verbatim quotes were presented in *italics* after translating into English.

2.8 Ethical Consideration

The study protocol was approved by the Nepal Health Research Council (NHRC), Ref. No.: 2939 and the institute review committee of Kathmandu University School of Medical Sciences Institutional Review Committee (KUSMS- IRC), Approval number: 66-2021. Before recruiting the participants, we informed them about research details such as objectives, their role in study, the risk and benefits of participating in the study, data confidentiality and voluntary nature of the participation. After ensuring that the participants understood the information, we obtained written consent for in-person interview and obtained verbal consent for phone interview. Data was collected anonymously and kept confidential in a password protected computer.

3. RESULTS

Total 1369 data was compiled through secondary data collection from the selected DOTS center's TB patient cards. Out of total patients, only 43% of patients were female. The total number of registered TB patients were concentrated in Bagmati, Lumbini and Gandaki province with the lowest reported from Karnali province.

Demographics of the total TB patients

Table 1: Total number of patients registered in respective provinces

Province	**F**		**M**		
	F	**%**	**f**	**%**	**Total**
1	59	10	102	13	161(12%)
2	48	8	68	9	116(8%)
Bagmati	190	33	200	25	390(28%)
Gandaki	81	14	119	15	200(15%)
Lumbini	163	28	197	25	360(26%)
Karnali	1	0	7	1	8(1%)
Sudur-Pashchim	42	7	92	12	134(10%)
Total	**584**	**100**	**785**	**100**	**1369**

Majority (38%) of the patients included in the study belonged to Brahmin/Chettri ethnicity followed by Janajati. Likewise, the majority of patients were found to be in the active population groups including age 20 to 50 years, with mean age 38 years. Approximately 96% of the total registered patients did not have previous treatment history, and the majority of the patients were reported as a new patient category (92%). PBC and EP tuberculosis cases were the most reported TB cases.

Table 2: Demographic structure of the patients

	f	**%**
Ethnicity		

Brahmin/Chhetri		503	38
Dalit		133	10
Janajati		439	33
Madhesi		152	11
Others		108	8
Total		**1335**	**100**
Age Group			
0-10	24		2
11-20		184	14
21-30		372	28
31-40		229	17
41-50		158	12
51-60		122	9
61-70		132	10
71-80	79		6
80 and above	41		3
Total		**1341**	**100**
Previous History			
Yes	47		4

No	1290	96
Total	**1337**	**100**

Disease Classification		
EP	545	40
PBC	749	56
PCB	54	4
Total	**1348**	**100**
Type of Patient		
New	1229	92
Other previously treated	11	1
Relapse	69	5
Treatment after Failure	10	1
Treatment after loss to follow up	9	1
Unknown previously treated patients	8	1

Organizational Data on Essential TB services

We prepared a checklist of essential TB services to assess and monitor the organization status of the TB program during the first and second lockdown phase. The checklist was categorized into six sections: Information on DOTS centers, Treatment and Management, Diagnosis of Tuberculosis, Drug Management, Information Management and Program Management. We asked a structured, closed-ended questionnaire/checklist to the respective DOTS center in-charge/Health Facility in-charge on diagnosis of tuberculosis, drug management, information management and program management. The responses were coded and analyzed. 'Yes' response was coded 1 and 'No' as 0 respectively. The value for each response from all 20 DOTS centers were added and presented as the total percentage for each indicator for all six study phases. The detailed information is presented in Table 3. Total 20 DOTS centers agreed to participate and provided the information required for the study. Research Assistant filled in the checklist based on observation and interaction with the available health providers at respective DOTS centers.

We collected the relevant information based on a checklist for both first and second lockdown. Each lockdown phase was further divided into pre-lockdown phase, during lockdown phase and post-lockdown phase. The total number of patients under ATT treatment reduced immediately after the first lockdown and

remained on the lower side till the end of the second lockdown stage. Similarly, we observed a slight increase in the average number of patients enrolled in the treatment post second lockdown stage.

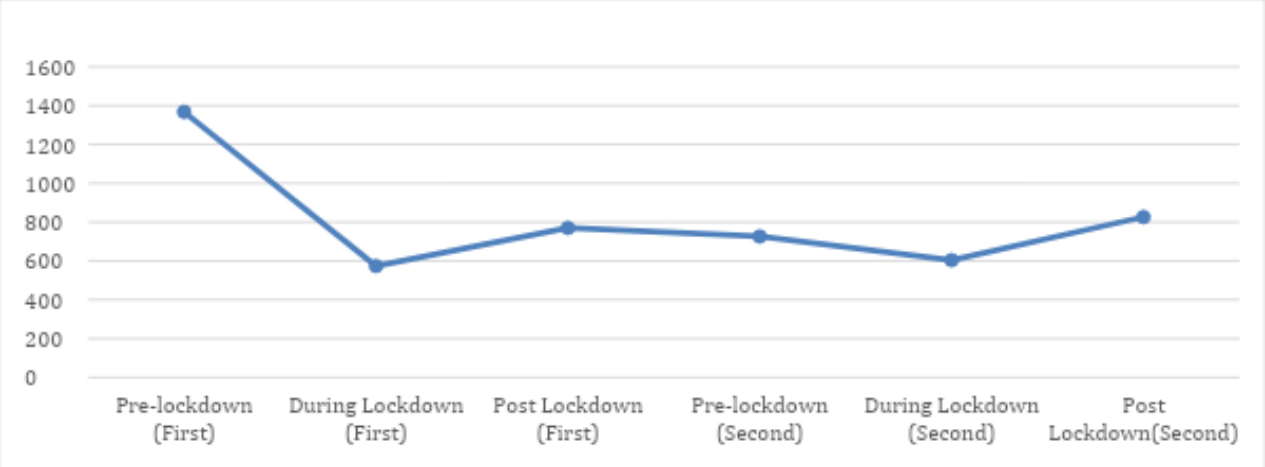

Figure 1: Total number of patients given drugs at selected DOTS centers

Out of total 20 DOTS centers, a higher percentage of the DOTS centers reported on availability of sputum microscopy and GeneXpert services during pre-lockdown stage which reduced especially during the first lockdown period primarily due to unavailability of staff and required equipment. Similarly, the majority percentage of health providers mentioned lesser availability of adequate drugs particularly during both lockdown stages.

Majority of percentage of health providers reported availability of adequate reporting and recording tools, however only one in ten health providers reported to have updated treatment cards during lockdown till post second lockdown period. Similarly, the monthly reporting was not reported on time, with a decrease in average percentage of reporting during the first lockdown. Although approximately 65% of health providers reported availability of functioning online reporting systems, one in ten health providers observed discrepancies in online reporting systems (HMIS). Likewise, the majority of TB related health programs were not conducted due to COVID-19 pandemic.

Table 3: Checklist on Organization management of TB program

	Pre-lockdown (First) (%)	During Lockdown (First) (%)	Post Lockdown (First) (%)	Pre-lockdown (Second) (%)	During Lockdown (Second)	Post Lockdown(Second) (%)

(%)

Diagnosis of Tuberculosis						
Availability of sputum microscopy	85	65	85	80	7	75
Availability of GeneXpert	62	55	57	65	5	65
Working condition of microscopy or GX service (YES/NO)	60	40	60	55	6	70
Availability of reagents/consumables/cartridge in the facility (YES/NO)	76	75	76	75	6	75
Follow-up of TB patients (YES/NO)	75	60	80	70	7	75
Drug Management						
Availability adequate drugs (YES/NO)	90	85	86	95	8	85
Information Management						
Availability of adequate R&R tools at HF?	90	85	95	100	9	70

(Register/Treatment Card/HMIS 9.3/others						
Were treatment cards updated? (YES/NO)	0	5	40	5	10	40
Did HF report on a monthly basis to HMIS? (YES/NO)	90	75	80	95	85	90
Any discrepancies between record and report (HMIS) (YES/NO)	10	5	5	10	10	10
Is the online reporting system (DHIS/GX/MDR/eTB) functioning? (YES/NO)	50	60	60	70	65	75
Program Management						
Allocation of TB focal person? (YES/NO)	90	90	85	90	85	90
Interruption of regular programs due to COVID-19 pandemic? (YES/NO)	15	25	15	10	20	15

Finding regarding Treatment Adherence (%) of TB Patient

The ANOVA test was performed to compare the effect of lockdown stages on ATT adherence for both first and second lockdown phases. The treatment adherence was calculated in percentage for all three lockdown stages.

First Lockdown Phase

A one-way ANOVA revealed that there was a statistically significant difference in mean ATT adherence percentage between at least two lockdown stages i.e. F= 4.7, p=0.009. Tukey's HSD test for multiple comparison found that the mean value of ATT adherence was significantly different between pre-lockdown stage and post-lockdown stage (p= 0.002, 95% C.I. = [2.81, 16.36]) and between post-lockdown stage and lockdown stage (p=0.03, 95% C.I. = [-18.67, -0.41]). There

was no statistically significant difference in mean ATT adherence between pre-lockdown stage and post-lockdown stage between pre-lockdown stage and lockdown stage (p= 0.99, 95% C.I. = [-9.77, 9.92]). The mean ATT adherence decrease by 7% from pre-lockdown stage during lockdown stage which further decreased by approximately 4% post lockdown stage.

Table Summary

First Lockdown Phase(ATT Adherence)	Count	Sum	Average	Variance
Pre- lockdown	73	6970.850831	95.49111	115.1696
Lockdown	118	10496.95342	88.95723	461.4209
Post-lockdown	50	4234.489883	84.6898	649.0927

Table 4: Anova Test

Source of Variation	Sum of Squares	df	Mean Square	F	P-value
Between Groups	3738.709179	2	1869.355	4.728821	0.009683993
Within Groups	94084.00624	238	395.311		
Total					

97822.7154

1 240

Table 5: Post Hoc Test

Lockdown Stages	Mean Difference	Lower Bound	Upper Bound	p value
Pre-lockdown – Lockdown	0.076854	-9.77346	9.927171	0.999813
Pre-lockdown - Post-Lockdown	9.622084	2.88093	16.36324	0.002548
Post-lockdown – Lockdown	-9.54523	-18.6738	-0.41667	0.038055

Second Lockdown Phase

For the second lockdown phase, the below mentioned one-way ANOVA analysis revealed that there was no statistically significant difference in mean ATT adherence percentage between at least two lockdown stages i.e. F= 2.9, p=0.05. Similarly, the mean ATT adherence decreased by approximately 6.5% from pre-lockdown stage during lockdown stage and increased by 8.5% post lockdown stage.

Table Summary

Second Lockdown Phase(ATT Adherence)	Count	Sum	Average	Variance
Pre- lockdown	27	2417.334	89.53088	415.2526
Lockdown	89	7400.883	83.15599	642.9596
Post-lockdown	52	4763.736	91.61032	82.58826

Table 6: Anova Test

Source of Variation	Sum of Squares	df	Mean Square	F	P-value
Between Groups	2586.406	2	1293.203	2.980604	0.053503
Within Groups	71589.01	165	433.8728		
Total	74175.42	167			

We further performed an independent t-test to compare the mean ATT adherence difference

between the first and second lockdown phases for all three lockdown stages. There was no significant difference in

mean ATT adherence between first lockdown phase and second lockdown phase for the pre-lockdown stage (p=0.06). Similarly, there was no significant difference in mean ATT adherence between first lockdown phase and second lockdown phase for both lockdown stage (0.07) and post-lockdown stage (0.06).

Table 6: T-Test between the mean adherence during pre-lockdown stages

Pre- Lockdown stage	Count	Mean	Variance	p-value
First Lockdown	73	95.49111	115.1696	0.060911
Second Lockdown	27	89.53088	415.2526	

Table 7: T-Test between the mean adherence during lockdown stages

Lockdown Phase	Count	Mean	Variance	p-value
First Lockdown	118	88.95723	461.4209	0.076681
Second Lockdown	89	83.15599	642.9596	

Table 8: T-Test between the mean adherence during pre-lockdown stages

Post-Lockdown Phase	Count	Mean	Variance	p-value
First Lockdown	50	84.6898	649.0927	0.068577
Second Lockdown	52	91.61032	82.58826	

Demographics of the interviews conducted

We conducted a total 217 KIIs in between the data collection period (mid-July till mid-November 2021). A total 117 patients, 35 DOTS facility in-charges and focal person, 21 health coordinators, 38 health officers from health offices, and 6 health professionals from provincial health offices participated in the study.

Out of total 117 patients interviewed, majority of the participants were male (59%) and belonged to the active age group i.e. 20-50 years. Patients below 16 years of age were not included in the study. Although the highest percentage of the participants were reported as housewives, approximately 14% of participants were

unemployed followed by other occupations including service jobs, student and self-employed.

Knowledge on COVID-19

TB Patients participating in the interview were assessed on their knowledge on COVID-19 pandemic. Patients were asked about the signs and symptoms of COVID-19 and its preventive measures. Majority of patients had pre-information on COVID-19 pandemic via Television, radio and social media. Patients could easily mention the signs and symptoms of COVID-19 including fever, headache, cough, sore throat, back pain and cold symptoms. Although, DOTS centers itself did not conduct preventive programs and awareness specifically for TB patients, patients were requested to maintain social distance, wear masks and use sanitization. Two meters' distance were maintained during DOTS center visits and patients reported to wear masks and followed COVID-19 safety measures while visiting the DOTS center. Health facilities also established hand washing stations, likewise, posters and pamphlets were posted in the health facilities to create awareness.

Table 9: Demographic status of patients interviewed in the study

	F		M			
Age Group	**f**	**%**	**f**	**%**	**Total**	**%**
0-10	0	0	0	0	0	0
11-20	4	8	2	3	6	5
21-30	17	35	16	23	33	28
31-40	12	25	9	13	21	18
41-50	9	19	14	20	23	20
51-60	4	8	15	22	19	16
61-70	1	2	9	13	10	9
71-80	1	2	3	4	4	3

80 and above	0	0	1	1	1	1
Total	**48**	**100.00**	**69**	**100.00**	**117**	**100.00**

Occupation	**F**	**%**
Business	6	5.41
Farmer	11	9.91
Foreign returnee	1	0.90
Housewife	18	16.22
Labor	10	9.01
Retired	4	3.60
Self employed	12	10.81
Service	13	11.71
Student	12	10.81
Unemployed	16	14.41
Others	8	7.21
Total	**111**	**100.00**

Impact Assessment (Barriers)

Semi-structured questions were designed to assess the impact of COVID-19 pandemic with patients and health providers. Majority of the patients interviewed had difficulty in traveling to the health centers during the lockdown period due to strict lockdown measures. Patients also feared of COVID-19 infection during health facility visits. A number of patients also lost jobs due to COVID-19 pandemic and had difficulty meeting the end meet. It was difficult for the patients to get a sufficient diet during the pandemic due to loss of jobs and low income. Following are the barriers mentioned by the patients:

Patient's Perspective

Barriers to DOTS Services during lockdown from Patients' Perspectives

A. Difficulty in commute to Health Care Facility/DOTS centers

The majority of patients had difficulty in traveling to health facilities due to:

- Strict restrictions on mobility during the lockdown

  "If we came with a patient's card, we could get the medicine. But they don't give us medicine without the card. Also, the police didn't allow us to travel without a card".

- Unavailability of public transportation for traveling to the healthcare facility

  "It *was difficult for us to come here as there was no public transportation. I had to pay RS 500 to get to the health facility. My home is 9km far away from here.".*

  The strict restriction during the lockdown stage induced frustration, and anxiety among patients.

- Frustration

  A TB patient mentioned, "Sometimes, it was frustrating commuting every day to get medicine at the health facility during a pandemic., I used to get angry at the situation but what to do, we had to get the medicine".

B. Fear

Patients experienced fear of transmission of COVID-19 while traveling to DOTS centers due to:

- Preconceived notions of co-morbidity between COVID-19 and Tuberculosis given similar signs and symptoms of both diseases. Patients also considered themselves with weak immunity and highly susceptible to COVID-19 infection.
- Crowding as there are higher chances of COVID-19 infections.

  "I was very afraid to visit the health facility during lockdown. I was worried if I would get COVID infected via contaminated air in the hospital".

- Fear of getting infected via health care workers, as they are daily exposed to numerous other patients in the health facility.

C. Anxiety

At times, health providers experienced anxiety among TB patients regarding the sufficient availability of medicines and the continuation of laboratory services.

A DOTS provider mentioned, "Patients were anxious if the health facility will operate, whether they will get medicines and repeatedly asked if they would get medicine in future. We counseled them and ensured the availability of medicines".

D. Financial Burden

Although, Government of Nepal is committed to provide all TB medicines free of cost at all DOTS centers, patients from poor economic backgrounds were found to be affected during the lockdown period. Health providers mentioned patients could not visit health facilities as they did not have enough money to commute.

"My husband lost his job during COVID. We've small scale bee farming for now. I don't get sufficient nutrition for the treatment".

E. Lack of laboratory services in the health facility

During interviews with patients and providers, both reported laboratory services were affected during COVID-19 pandemic. Although TB medicines were regularly provided to TB patients, the majority of DOTS centers could not continue their regular laboratory services during the lockdown period.

"We got timely medicine but the laboratory service was irregular. During the lockdown period, I was asked to perform my laboratory diagnosis from outside. There is no laboratory service available here. They asked us to visit other health facilities".

F. Non-functioning equipment in the health facility

In some cases, regardless of availability of the laboratory staff and services, laboratory equipment was not functioning. The patients were mostly asked to visit other health facilities for the laboratory test.

"The service is irregular here. The machine is not working today. So they've asked me to visit other health facilities for my regular testing".

Social Stigma

Although, majority of patients did not feel stigma against TB infection neither from the family nor the society, a very few patients mentioned differences in family's behavior during the TB treatment period. A group of patients did not expose their disease condition outside their household and maintain confidentiality, which they believed prevented them from any kind of discrimination in the society. However, the majority of patients regardless of their location, reported full support particularly from family members and spouses during the treatment period.

"I got full support from my family. I didn't feel any differences. We didn't inform anyone in the society

about my condition. It remained confidential. If anyone asked me, I would say, I've chest pain. Nobody knew I was TB infected".

"Nobody from my family supported me. Rather TB hospital supported me and provided me with incentives".

"It is nothing like that. There is no stigma related to TB in society. Medicines are easily available. I visit the health facility, get my medicine and return back home".

Facilitators to DOTS Services from Patients' Perspectives

Majority of TB patients felt difficulty traveling to health facilities during lockdown due to strict social restrictions. Patients suggested to continue to provide monthly supply of DOTS medicine in future as well. Patients also felt the need to prioritize the vulnerable patients in the rural areas and provide vehicle service, incentives. Similarly, staff were suggested to be present timely during their duty hours.

A. Monthly supply of TB medicine

Majority of patients in the interview explained their difficulty and fear while traveling to DOTS centers and suggested the concerned authority to approve for at least bi-monthly or monthly supply of TB medicine.

"Weekly medicine is provided for now but it should be supplied at least for a month or two. Only then will it be easier for us".

B. Timely availability of medicine and health staffs

Patients recommended DOTS centers should not be closed during lockdown period and staff should be regularly available to provide the services.

"The thing is during COVID time, available services and medicines should be provided timely. Staff should be available whenever patients visit with difficulties".

C. Prioritize rural areas and economically poor TB patients

Although patients residing at urban areas comparatively had lesser issues with traveling and availability of medicine, patients with less financial means and traveling longer distances to health facilities were found to be mostly affected during COVID-19 pandemic. Patients suggested prioritizing the vulnerable groups and managing vehicle services to visit health facilities during the lockdown period.

"Easy access should be provided to TB patients living in the rural municipalities. People from that place should also be provided medicine from here, as it is not provided".

"Government should provide the medicine of tuberculosis to all the health organizations in rural and remote areas. Lab facilities like Sputum check-ups, blood tests should be available".

D. Incentives for TB patients with less source of income

TB patients with less economic sources were financially affected during COVID-19 pandemic. TB patients did not have enough money to get sufficient nutrients and suggested an incentives scheme to get the nutrition required for the TB patients.

E. Door to door service

Majority of patients recommended exploring the possibility for easy access to medicine. Door to door facility for the supply of TB medicine was one of the most recommended preferences by the interviewees.

"The patients faced a lot of problems during curfew and lockdown, so I suggest the medicine must be locally provided and if possible, medicines must be supplied Door to Door and if financial support could be provided to needy one that could be a lot better".

F. DOTS for old age patients

Among all age groups, elderly and old aged TB patients were reported to be mostly affected during COVID-19 pandemic. Furthermore, the old age population usually are found to be financially deprived. It was recommended to prioritize old age TB patients during pandemic situations.

All TB patients can't visit the DOTS center on a daily basis. Although, under the DOTS program, patients should consume medicine under the direct supervision of health staff in the health facility, practically it is difficult. Most of the TB patients are old aged and they are normally poor and don't have any income sources. If they get the medicine at home, or if they can get the medicine from the nearby health facility, it will be way easier for them".

Health Providers Perspective

Barriers to DOTS Services: Perspectives from Health Care Providers (DOTS In-charge, Health Coordinator at local level, and TB focal person at District Health offices)

A. Additional Responsibilities

Most of the health providers at the DOTS center, in particular laboratory staff, were assigned to perform additional COVID-19 management duties. While few of providers' regular duties were completely shifted, few had to juggle between their COVID management duties and the DOTS program. In both cases, the DOTS program was hampered, as the whole focus was shifted towards COVID-19 management. Laboratory services were disturbed as many laboratory staff were shifted for COVID-19 testing. TB laboratory services remained closed for a while in many circumstances. Health providers at DOTS centers reported difficulty in reporting and recording due to unavailability of staff. Similarly, health providers also mentioned occasional shortage of medicines, lack of equipment, and shortage of masks. Due to lack of incentive from the

Government, staff were demotivated to perform duties.

At municipal level and health offices, health providers experience reduction in TB case findings due to limited community engagement and COVID-19 restrictions measures. Regular TB programs in particular those requiring gathering including meetings, training, awareness programs were hampered during pandemic. This has also led to insufficient monitoring and supervision activities. Majority of health providers agreed on insufficient preparedness for the COVID-19 pandemic management. The sudden onset of COVID-19 pandemic led to shadow regular health programs including the National Tuberculosis program.

Following are the barriers mentioned by the health providers:

"Last year and this year too, we had limited manpower. We had limited paramedics and they were sent to COVID hospital to assist. I was even asked to duty at COVID hospital by the higher administration of the hospital and I had to follow their orders which is why there were considerable effects on DOTS services".

"As in the Lockdown period, I was in health Desk Duty too, where people who come from foreign countries need to look after. And at the same time, I used to come to the tuberculosis clinic and if there was a patient, I used to provide medicine".

B. Fear of Transmission

The frontline health care providers experienced fear of transmission of COVID-19 infection due to crowding in the health care facilities on most occasions. They also mentioned not having enough space in the health facility for maintaining social distancing.

"The room is congested here. In addition, the standard criteria for DOTS rooms like proper ventilation, proper airflow is not maintained. I fear I might be at risk but still I am supposed to do my duty".

C. Lack of coordination between health providers and healthcare system

Health providers at the local level and district level experienced a lack of coordination in terms of TB program management. While health coordinators at the local level were overburdened by the piles of roles and responsibilities of health programs, health officers complained of not allocating enough programs at the district level.

"We have to travel for supervision in different areas in the district but we don't have bikes. Only limited money is allocated for supervision and the central office queries us on our performance. The budget is provided to the local level and they complain to us".

"The main reason is, in the past, all the programs were conducted directly under the Health and Population Department. But now, these programs are handled by municipalities, and the Health and Population Department acts only as a bridge and works only as a coordinator. So, it is difficult to organize different programs".

"The government suggested canceling all training programs and meetings during the pandemic. On Asar, all of the sudden, we were asked to conduct health activities, maintaining social distance and following preventive measures. But due to limited time, we encountered several problems".

D. Lack of priority and motivation from higher level

Tertiary hospitals were occupied with various health programs and with a larger number of patients. In such cases TB programs are often not prioritized by the higher authority, resulting in poor service delivery for the TB patients.

"*Medicines don't come here directly. Even if it comes, they will send us different medicines in huge quantities. Another thing is doctors don't follow the regimen. They don't follow regiment guidelines and go with another treatment. So, the amount of supply is not enough due to higher prescriptions. We ask formedicine quarterly. So, these things are very difficult. We informed this issue to the higher authority but they did not listen to us".*

E. Hampered Regular Program

Regular programs including awareness campaigns, contact tracing, case identification and findings, follow-up, meetings, and workshops were halted during the COVID-19 pandemic, primarily due to shifting the focus on COVID-19 management and social restrictions. Disruption of these services has impacted on less case identification and diagnosis of TB patients. Furthermore, the laboratory services were disturbed.

"*Contact tracing was interrupted in between lockdowns. I stopped contact tracing for a month. Case findings were affected as patients were not diagnosed. The government also recommended everyone to stay indoors, so such hidden cases could not be identified".*

F. Changes DOTS Guideline for COVID-19 pandemic

Although the principal component of the DOTS program is to provide medicine to the patients under direct observation of health staff, the concept of DOTS was not feasible during the COVID-19 pandemic. Considering the risk of transmission of infection in the health facility and difficulty in getting transportation during COVID-19 restriction, patients were allowed to take sufficient medicine for one to two weeks depending on their access to the health facility. This has highlighted the probable chances of patients missing to intake medicines on a daily basis and follow up on laboratory diagnosis.

"The thing is, everyone runs into each other. Both general patients and TB patients visit the health facility for the check-up and medicines. Considering TB as a communicable disease, there is a risk of transmitting TB to general patients which is why it was not possible to ask patients to visit the DOTS center on a regular basis".

"Due to COVID restrictions and lockdown, it is very difficult to follow the DOTS protocol and provide medicine to the patients under direct observation every time".

G. Closed Health Facility

Few health facilities were reported closed for a certain duration during the lockdown period which has hampered the regular DOTS program. The facilities were closed to prevent crowding in absence of open space and sufficient infrastructure to maintain social distancing. The closure of the health facility has definitely impacted on disruption of laboratory services and diagnosis of tuberculosis cases.

During the closure of the health facilities, registered TB patients were referred to other functioning health facilities. However, in absence of trained TB staff and required infrastructure, DOTS services were interrupted at times. Patients were also reported to have missed their regular follow-up check-ups and reported to continue with the regiment without any follow-up check-ups.

"Last year, our DOTS services were handed over to the Urban health clinic as our health facility was closed for a while. They could not report and record properly as they had limited knowledge. They were not trained. All of a sudden, they were asked to provide service by the local government. It was not their negligence. But we had an error in recording and reporting. For example, for PBC cases, to report the case as cured, it is necessary to test the sputum of the patient on the 5th and last month of the treatment but it was not tested".

H. Irregular TB services

DOTS program dedicated staff were either transferred to the COVID management team or were doing dual jobs. In such a scenario, health facilities remained closed in many DOTS centers, while the services were disturbed in the remaining centers.

"DOTS center was closed, some paramedics were assigned to the COVID hospital, whereas some other staff, including me, were assigned to the emergency ward. So, we carried out our services from the emergency ward".

"The main issue was on follow-up services. The patients were required to test the sputum in the second and third months but most of the patients did not because they could not travel. They used to call and inform us that they could not visit. What could we do? We simply provided medicine and continued the service".

I.Insufficient Supply of Medicines

Although medicine was not a major issue in most of the DOTS issues, occasional interruption and difficulties in supplies of TB medicines were reported by the DOTS centers.

"Occasionally, medicine supplies were interrupted. We had to coordinate and visit the local government office for the medicine. It was a problem then".

"The ratio of patients to medicine is relatively high here. So, it's difficult to manage the supply of medicine to all patients".

"We had some medicines on the stock. But occasionally, medicines were delayed and we had to visit the municipality office to get those medicines".

J. Insufficient TB Budget

Regular supervision and monitoring of TB programs were hampered due to insufficient allocation of budget for the supervision and monitoring at the health office level.

"Although the district office tries to help us, due to the limited budget they can't. That is why there is an issue with the coordination and implementation of the program. The coordination mechanism has changed, maybe the problems might have arisen because of that".

K. Focus Shifted on COVID response

The government of Nepal shifted its priority towards COVID-19 management right from the start of COVID-19 pandemic. This has definitely hampered and shadowed regular health programs including

DOTS programs. Health staff were asked to assist COVID-19 management duties at all working levels. The sudden shift of priorities without any proper plan has created challenges for the regular health programs.

"Our whole workforce is shifted towards COVID-19 management. Because of that, COVID is our priority which is why the TB program is shadowed for now".

"The government of Nepal has advised us to focus on the COVID pandemic and we have to dedicate our time to that. We cannot allocate staff for door-to-door visits for the case identification. The new case finding of TB is definitely impacted".

Facilitators to DOTS Services from Health Providers' Perspectives

Health providers emphasized on timely availability of registers and medicines for the smooth management of TB programs in future. In addition, most health providers felt the need for refresher training, supervision and guidance to get updated with the new reporting format. A health provider mentioned the need to focus and categorize the clusters of patients based on their needs and economic status. Many patients lost their jobs during COVID-19 pandemic, creating employment opportunities that can support the patient to meet their end. Similarly, laboratory services including microscopy services should be expanded and available for rural areas for easy access of rural population.

A. Counseling and Awareness

Providers at all levels including DOTS center, local government office and health office have jointly mentioned better management of the health programs in the second year of pandemic than the first year.

Health staff are more confident and believe proper counseling and awareness is essential for the TB patients to reduce patients fear and anxiety along with the use of Personal Protective equipment.

"Provide counseling and awareness to the patients. Speak with positivity and try to make them understand the situation. That is what can be done".

"Ask them to wear PPE such as masks and sanitizer. Also, suggest they maintain distance and drink hot water. Counsel and ask them to remain calm. If patients follow precaution measures, everything will be fine".

"The situation is better this year as we shared pamphlets about COVID 19 and did some counseling as well. Also, the awareness programs conducted by the government have helped".

B. Early management and supply of Medicines

Learning from the previous year experience, providers at municipalities reported to have provided medicine earlier to ensure regular supply of medicines.

"We provided medicine earlier than usual during the second lockdown period. The central office also sends

us the supplies in a timely manner. So, there were lesser issues than previous lockdown":

C. Staff management for DOTS

Likewise, DOTS centers are mentioned to have lesser issues than the first year of the pandemic, as they now have a staffing plan for both COVID-19 and DOTS duty in their health facilities.

"If the total number of TB staff is around 2 to 3, then we can allocate staff for COVID duty and swab collection, and the remaining two can stay here and provide the services. That is why we did not havproblems this year".

D. Allocation of TB program for the Health Officer

Coordination, reporting and implementation of DOTS program has slightly changed post the induction of a new three tier government structure in Nepal. The job responsibilities of health staff especially at municipality level and district level have changed. These changes might have questioned the effective implementations of regular programs. TB focal persons at the health office have recommended sharing DOTS program responsibilities for its effective management.

"My suggestion is that the central office should provide the TB program to health offices like before. The local government has not been able to implement the program effectively as we did. Providing authority

to the local government is like weakening the program. Therefore, I would like to request through you to the central office to provide the TB program to us for its effective management".

E. Training for HF staffs

Amidst pandemic, the working modalities of the health staff have definitely changed due to the new normal way of living post COVID-19 pandemic. Therefore, the health staff recommended providing relevant training on management of patients post COVID pandemic. They believe such training will enhance their skills and they will be able to perform better.

"If we are provided with training, we will be able to provide effective counseling and services. It will be really helpful for us".

F. Prioritize DOTS program

Post COVID-19 pandemic, regular programs are getting back on track and health staff are more committed toward their normal job responsibilities.

"I've already communicated. I will be looking over the DOTS program. I will prioritize it and if possible, I will do duty in the emergency department as well so that DOTS services are not affected. We've been prioritizing the DOTS program this lockdown period and paramedics will also not be transferred for emergency duties".

"I have asked the administration to let me work in the DOTS center and find some other staff for the emergency department. Paramedics aren't sent to COVID hospital anymore. The situation is good now".

G. Easy Transportation

As transportation was the major issue reported by both patients and providers during the pandemic, it seems essential to focus on exploring possible ways to make the transport facility accessible. Door to Door services, managing transport facilities for patients and community involvements were few possible solutions recommended during the study.

"*In case some patients find it difficult to travel, the social mobilizers from Bagmati Sewa Samaj collect the sputum from the health center and bring it here for test and provide the test results to the patients".*

"I think, for high-risk areas, it is essential to provide either transport facilities for the patients or collect sputum from each patient. It will be easier for patients".

"If we could provide door to door medicine for the TB patients either via FCHV or Community Health Volunteers, the risk of transmitting TB would decrease".

H. Infrastructure

The importance of proper and functioning infrastructure cannot be stressed more during pandemic. Many DOTS centers were reported to close due to insufficient infrastructure. In a few cases, due to non-functioning medical equipment, patients were referred to other health facilities.

"The room is congested here. As it is an MDR sub center, if we had a bed for patients in the facility, it would have been easier to screen the patients".

I. Risk Allowance for TB staff

A provider mentioned, **"***Furthermore, it would be better if the government provided a risk allowance to motivate people working in these risky environments. As this is the first place all the patients, as well as visitors, encounter in the institute, there is a chance of spreading the infection from patients to visitors".*

J. Proper Guideline and orientation for Clinicians

A DOTS in-charge mentioned*, "Meetings should be conducted with responsible persons. They need to know about the guidelines, how medicine is reaching clinics, and ways of treatment. As they are highly educated, it is not our duty to provide the knowledge. NTC should directly contact and coordinate with responsible persons and conduct meetings. Early preparedness is very weak. As high authority become irresponsible as they should think about this".*

K. Allocation of TB dedicated human resource

Although TB focal person is allocated in the majority of the DOTS center, in few cases, particularly in private organization, TB focal staff were shifted for other COVID responsibilities hampering the regular DOTS program. So it is essential to have a dedicated TB focal person all the time in the DOTS center.

"Every organization should allocate a separate TB dedicated staff. We also have insufficient human resources

L. Effective management of DOTS program

"It is important to ensure proper access to medicine in case of any emergency in the future". Everything should be well managed including the supply and distribution of medicines, for which we need to be trained manpower. Training should be provided, refreshment training should be planned as the regiment keeps on changing. A contingency planning should be prepared to give continuity to our health program during an emergency. Integrated training should be designed and the local government should take the lead. There is a lack of manpower at the local level and it is difficult to implement programs. It is essential to have a contingency plan and train our human resources".

4. DISCUSSION

This study explored the impacts of COVID-19 pandemic on DOTS program from both patients and provider's perspective respectively. Both DOTS and TB programs of Nepal have been severely disrupted by COVID-19 pandemic. TB patients experienced difficulty in traveling to the health facility due to lack of transportation facilities and strict social restriction and movement. TB patients also struggled to access TB services, due to unavailability of transportation, fear of COVID-19 infection, reduced health facility opening hours and unavailability of laboratory services. Meanwhile, providers faced difficulties in service provision, primarily due to additional COVID-19 responsibilities, lack of infrastructure and equipment, and restriction to movement. Health providers reported to be demotivated due to insufficient incentives during COVID-19 pandemic. Overall, health providers reported to be unprepared for the sudden onset of COVID-19 pandemic, resulting in priority shifting towards COVID-19 management. This has overshadowed and hampered the regular programs including the National Tuberculosis Program at the national level.

COVID-19 pandemic has directly hampered regular health programs including TB program, as both human and economic health resources have been re-allocated for COVID-19 pandemic management (25). It has been highly prioritized across the world, causing disruption in the diagnosis and treatment of several health conditions and canceling many outpatient activities and elective procedures (26). In this study, unavailability of laboratory services and shut down of the facilities is linked to unavailability of staff either due to COVID-19 related sickness, self-isolation or redeployment of staff for the COVID duties. Redeployment in European National Reference TB Laboratory affected operations of nearly 30% of the laboratories in March and April. A smaller number of laboratories (<10%) experienced problems procuring personal protective equipment (PPE), and laboratory space constraints (27). Many European TB National Reference Laboratories reported to be directly involved in the COVID-19 response in

various capacities including antibody testing, and contact tracing scaling up overall COVID-19 testing (29).

The disruption of TB programs directed to highly vulnerable populations and restrictions to personal mobility combined with diagnosis delay may have negatively impacted vulnerable populations and household transmission, respectively (29). This study also highlights old age and hard to reach poor TB patients who were found to be impacted directly due to social restriction and lack of income source during COVID-19 pandemic. A study mentioned a likely increase in catastrophic costs (>20% of household annual income) for TB patients as an effect of an increase in poverty and inequality, during COVID-19 pandemic, resulting in inability to access TB health (24). Increase in poor living conditions and malnutrition can also lead to increase in TB cases in the future.

In this study, we observed that patients feared to visit health facilities mostly due to fear of crowding and infections. Moreover, providers also reported constant fear of transmission due to insufficient space and equipment in the health facility for the treatment of patients. Overcrowding in the health facilities promotes further propagation of both diseases and immune-compromised patients including TB patients are more prone to contract these infections (30). Patients also explained about their fear of co-infection between TB and COVID-19, considering the symptoms similarity between the two diseases and preferred not to visit health facilities for the regular medicines. Spread among household contacts is also an important concern due to close interactions fostered by home confinement. Similar observation was experienced in India, where the diagnosis of TB was delayed, as most non- emergency services were suspended and access to private sector healthcare was also reduced. This resulted in decreased case notification and identification. The notification rate in three highest burdens of TB: India, Philippines, and Indonesia was reduced by approximately 25% during the pandemic period from January to June 2020 as compared to the same period in the year 2019(30). Similarly, a rapid assessment conducted by NTCC also found a decline in the identification of new cases and had impacts from sputum courier, diagnosis, enrolment, and follow up including recording/reporting (30). In our study, we also observed a decline in the number of total TB patients in the health facilities. The study also concluded, mean difference in the adherence to the treatment between the different phases of COVID-19 pandemic during first lockdown stage, however no mean difference in the ATT adherence was observed during second lockdown. The result could suggest better management of TB program during second lockdown phase, possibly due to prior experience of COVID-19 pandemic during first lockdown phase. The health providers were also found more confident in service delivery during second lockdown phase due to prior experience and knowledge on COVID-19 management, and pre-planning. On the other hand, TB patients like general public could be more aware on COVID-19 pandemic and could have lesser fear of visiting health facilities.

Apart from laboratory services, outpatient departments were not functional in many hospitals during the lockdown period, resulting in disruption in follow up, and reporting of TB cases. Furthermore, extensive

counseling and motivation is needed and allocated for TB patients according to the National Tuberculosis Program to deal with the disease, and its side effects. The entire process came to a standstill with the implementation of lockdown. Fewer referrals and less screening and testing means that people potentially infected with TB could be at risk of not only falling sick and dying from the disease, but they also risk spreading TB to others, including the drug- resistant strains (32).

In many countries across the world, social distancing and movement restrictions have helped in flattening the COVID-19 incidence curve, however, these interventions have caused reduction in TB case findings and identifications. In Malaysia, a 9% reduction of TB cases was reported in between January to May 2020(22). Similarly, in the Philippines, TB case findings were discontinued as priority of health was shifted to COVID-19 and GeneXpert platform in the selected TB laboratories were re-assigned to COVID-19 screening, the TB program was shadowed and limited (22). The study also showed reduction in the average total number of patients under TB treatment during the lockdown period. However, no significant changes were observed in terms of mean adherence of ATT patients during different phases of lockdown stages for both first and second lockdown. This could be due to incomplete data on adherence which was compiled from the TB patient card. Furthermore, the availability of TB Budget might be lowered than previous years, with resources diverted to COVID 19 mitigation. Health providers in the study reported less resource allocation for TB projects in Nepal, which is similar to the reports of half of high TB burden countries who reported significant decrease in TB funding with reallocation of TB funding to the COVID-19 response (24).

5. STRENGTHS AND LIMITATIONS

This study has several strengths. To our knowledge, this is the first study that has investigated the impact of COVID-19 on DOTS services utilizing qualitative and quantitative approaches. This study thus sheds light on the critical issues surrounding the impact of COVID-19, mainly the lockdown, on important services like DOTS. It also provides an in-depth perspective on the barriers and facilitators to strengthen DOTS services during such times, from the patients, providers and other related officials. DOTS centers and corresponding health offices were selected based on the highest case notification rate of TB and CI of COVID-19; this might not be representative of the overall population utilizing DOTS services. However, the representation from seven provinces, and the allocation of three different districts in each province should make the findings fairly generalizable. Ideally the comparison of compliance data of each patient during pre-lockdown phase, lockdown phase and post lockdown phase gives more accurate information compared to comparison of average compliance during each period. Similarly, while interviewing, participants were asked questions based on their previous experience during COVID-19 pandemic, which could have led to the possibility of recall bias in the study. However, it was minimized through appropriate structuring of the questionnaire and training interviewers. The participants could have been cautious during interviews and try to portray good or bad health practices causing social desirable bias which was minimized carefully by choosing appropriate words and keeping it anonymous. Likewise, the patient treatment cards from the selected DOTS centers were either incomplete or missing, this could have led to missing useful information. Despite these, we believe that the findings provide important information for future programs and policies not just for DOTS services but also for other diseases that require regular care during critical times like pandemic and other unforeseen, prolonged disasters.

6. CONCLUSION AND RECOMMENDATIONS

In Nepal, COVID-19 pandemic hampered regular health programs including TB programs at all levels. Although the study only reported mean adherences differences for the first lockdown phase, with strict social restrictions and closure of OPD services, TB case identification rate is assumed to be reduced by the health care providers. COVID-19 restriction could also lead to failure to screen TB patients, which could lead to spread of TB cases and related complications in the community. Similarly, reporting and recording activities, follow-up of patients for the laboratory diagnosis were severely affected during COVID-19 pandemic, increasing the risk of missing patients.

Majority of the patients complained about difficulty in commuting to the health facility in particular during the lockdown period. The unavailability of public transportation, strict social restriction in particular mobility were common problems encountered by the patients during lockdown/curfew. Furthermore, both TB patients and health staff admitted to constant fear of transmission of COVID-19 particularly due to crowding in the health facilities. Although, majority of the DOTS centers reported to have managed to provide timely TB medicine to the TB patients, occasionally, lab services were interrupted due to transfer of laboratory staff for the COVID duty. Furthermore, few DOTS centers were also reported closed either due to insufficient staff or COVID-19 infections among health workers. The interruption of DOTS services has not only hampered regular activities such as counseling, meetings and training programs but is believed to decrease case findings, contact tracing, follow up diagnosis and mostly error in reporting and recording.

Coordination was the major issue reported during the interview. While the new induction of three tier government structures has shifted roles and responsibilities in between the three levels of government bodies, there seems to be a lack of coordination and communication. Furthermore, due to insufficient TB budget, regular monitoring and supervision programs were halted at district level.

With the sudden onset of COVID-19 pandemic, in absence of an early preparedness plan and guideline, the whole priority seems to have been shifted on COVID-19 management. The sudden shift of such priority has not only shadowed regular health programs including DOTS programs but also has challenged the whole health system to maintain the existing status of other health programs. Although providers seem to be more confident than the first year of pandemic in terms of service delivery, there are challenges which need to be addressed immediately for the effective implementation of DOTS program.

Based on the study, here are some key recommendations.

- Given the vulnerability of the elderly, poor and marginalized communities to TB, it is recommended to prioritize vulnerable groups in TB control programs. Tailored interventions and support services should be designed to cater the needs of marginalized and vulnerable TB patients.
- Engaging communities in active case finding initiative is advisable for early detection and treatment. This could be accelerated through implementing awareness campaigns within communities and encouraging individuals to seek timely medical attention.
- To improve early diagnosis and accessibility to test facilities, there should be concerted efforts to expand microscopy centers in pocket areas with higher prevalence of TB.
- It is imperative to ensure that DOTS facilities have adequate infrastructure for patient consultation, check-up and social distancing if required. This measure is essential for safeguarding the health of both patients and health workers.
- Exploring the possibility of providing skill-based training for TB patients can empower them to secure a source of income post-treatment and will also contribute to reducing stigma associated with TB.
- To increase the accessibility to DOTS services, considering the expansion of operational hours, including weekends and post office hours, would benefit individuals who may face challenges in accessing healthcare during standard working hours.

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Annex
List of participants in the study

Patients and TB in-charge (DOTS Centers)	Health Coordinator (Municipality)	TB focal Person (Health Office)	Province Health Directorate	TB focal person (Central Level)
Province 1				
NATA ● Patients-6 ● DOTS In-charge - 1 ● Health Incharge- 1	Biratnagar Metropolitan City ● Health Coordinator-1	Morang TB Focal person- 1 Chief – 1	TB focal person - 1	MoHP- 1 NTCC- 1
Damak Hospital ● Patients-6 ● DOTS In-charge - 1 ● Health Incharge- 1	Damak Municipality ● Health Coordinator-1	Jhapa TB Focal person- 1 Chief – 1		
BPKIH ● Patients-6 ● DOTS In-charge - 1 ● Health Incharge- 1	Dharan Sub-Metropolitan City ● Health Coordinator-1	Sunsari TB Focal person- 1 Chief – 1		

Province 2				
Lalbandi PHC ● Patients-6 ● DOTS In-charge - 1 ● Health Incharge- 1	Lalbandi Municipality ● Health Coordinator-1	Sarlahi TB Focal person- 1 Chief – 0	TB focal person - 1	
National Medical College ● Patients-6 ● DOTS In-charge - 1 ● Health Incharge- 1	Birgunj Sub-Metro Municipality ● Health Coordinator-1	Parsa TB Focal person- 1 Chief – 1		
District Clinic Janakpur, Dhanusa ● Patients-6 ● DOTS In-charge - 1 ● Health Incharge- 1	Janakpur Sub-Metropolitan City ● Health Coordinator-1	Dhanusa TB Focal person- 1 Chief – 1		
Province 3				
Genetup Hospital ● Patients-6 ● DOTS In-charge - 1 ● Health Incharge- 1	Kathmandu Metropolitan City ● Health Coordinator-1	Kathmandu TB Focal person- 1 Chief – 0	TB focal person - 1	

KIST Medical College ● Patients-6 ● DOTS In-charge -1 ● Health Incharge- 0	Lalitpur Metropolitan City ● Health Coordinator-1	Lalitpur TB Focal person- 1 Chief – 1		
DPHO Clinic Bharatpur ● Patients-6 ● DOTS In-charge -1 ● Health Incharge- 1	Bharatpur Metropolitan City ● Health Coordinator-1	Chitwan TB Focal person- 1 Chief – 1		
Province 4				
DPHO DOTS Kaski ● Patients-6 ● DOTS In-charge -1 ● Health Incharge- 0	Pokhara Metropolitan City ● Health Coordinator-1	Kaski TB Focal person- 1 Chief – 1	TB focal person - 1	
Damauli District Hospital ● Patients-6 ● DOTS In-charge -1 ● Health Incharge- 1	Byas Municipality ● Health Coordinator-1	Tanahu TB Focal person- 1 Chief – 1		
Shiv Mandir Health Post ● Patients-6 ● DOTS In-charge -1	Kawasoti Municipality ● Health Coordinator-1	Nawalparasi East TB Focal person- 0		
● Health Incharge- 1		Chief – 1		
Province 5				

Lumbini Zonal Hospital • Patients-6 • DOTS In-charge -1 • Health Incharge- 1	Butwal Sub-Metropolitan City • Health Coordinator-1	Rupandehi TB Focal person- 1 Chief – 0	TB focal person - 1	
Kohalpur Health Post • Patients-6 • DOTS In-charge -1 • Health Incharge- 1	Kohalpur Municipality • Health Coordinator-1	Banke TB Focal person- 1 Chief – 1		
Rapti Academy Health Science • Patients-6 • DOTS In-charge -1 • Health Incharge- 1	Ghorahi Sub-Metropolitan City • Health Coordinator-1	Dang TB Focal person- 1 Chief – 1		
Province 6				
Katkuwa Health Post • Patients-6 • DOTS In-charge -1 • Health Incharge- 1	Birendranagar Municipality • Health Coordinator-1	Surkhet TB Focal person- 1 Chief – 0	TB focal person - 1	
ChayaChetra Health Post • Patients-2 • DOTS Incharge- 0 • Health Incharge -1	Chakreshwari Rural Municipality • Health Coordinator-1	Salyan TB Focal person- 1 Chief – 1		
District Hospital Dailekh • Patients-6 • DOTS In-charge - 1 • Health Incharge- 0	Narayan Municipality • Health Coordinator-1	Dailekh TB Focal person- 1 Chief – 1		

Province 7				
Seti Zonal Hospital • Patients-6 • DOTS In-charge - 1 • Health Incharge- 0	Dhangadhi Sub-Metropolitan City • Health Coordinator-1	Kailali TB Focal person- 0 Chief – 1	TB focal person - 0	
Mahakali Zonal Hopsital • Patients-6 • DOTS In-charge - 1 • Health Incharge- 1	Bhimdatta Municipality • Health Coordinator-1	Kanchanpur TB Focal person- 1 Chief – 1		
Doti District Hospital • Patients-6 • DOTS In-charge - 1 • Health Incharge- 1	Dipayal Silgadhi Municipality • Health Coordinator-1	Doti 192 TB Focal person- 1 Chief – 1		

Patients and Health providers' perspective on barriers and facilitators of DOTS services during pandemic

Patients perspectives on barrier to DOTS services during COVID-19 pandemic	**Health Providers perspectives on barrier to DOTS services during COVID-19 pandemic**
Difficulty in commute to Health Care Facility/DOTS centers due to • Strict restrictions on mobility during the lockdown • Unavailability of public transportation for traveling to the healthcare facility	Additional Responsibilities due to COVID-19 pandemic

Fear ● Fear of crowding in the health facilities, as there are higher chances of COVID-19 infections ● Fear of getting infected via health care workers ● Fear of getting infected with COVID-19 as a result of co-morbidity	Fear of COVID-19 transmission
and poor health condition of patients	
Delusion, Anxiety and Mental Stress ● Regarding the sufficient availability of medicines and the continuation of laboratory services ● To get services from other health facilities	Lack of coordination between health providers and healthcare system
Irritation and Frustration ● Irritation on the need to visit health facility during COVID-19 pandemic ● Frustration on the disease status and need to be safe during pandemic	Lack of priority and motivation from a higher level 193
Financial Burden ● Insufficient money to commute to health facilities ● Insufficient income source due to loss of job ● Insufficient money for additional diet and treatment	Hampered Regular Program
Lack of regular laboratory services in the health facility ● Unavailability of laboratory staffs due to COVID duty ● Unavailability of staffs due to COVID-19 infection	Changes in DOTS guideline for COVID-19 pandemic
Non-functioning equipment in the health facilities	Closed Health Facility

● Unavailability of laboratory chemicals and equipment during lockdown period due to lack of supply	
Additional Responsibilities due to COVID-19 pandemic Stigma	Irregular TB services
Fear of COVID-19 transmission	Insufficient Supply of Medicines
Lack of coordination between health providers and healthcare system	Insufficient TB Budget
Lack of priority and motivation from a higher level	Focus Shifted on COVID response

Patients perspectives on solution to improve DOTS services during COVID-19 pandemic
Continue monthly supply of TB medicines
Timely availability of medicine and health staffs
Prioritize rural areas and economically poor TB patients
Incentives for TB patients with less source of income
Door to door services Prioritize old age patients

Health Providers perspectives on solution to improve DOTS services during COVID-19 pandemic
Counseling and Awareness
Fear of COVID-19 transmission Early management and supply of Medicines
Staff management for DOTS services
Allocation of TB program for the Health Officer Training of HF staffs
Prioritize DOTS program
Easy Transportation services
Infrastructure
Risk allowance for TB staffs
Proper guideline and orientation for Clinicians

Allocation of TB dedicated human resources
Effective management of DOTS program

Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 2939

Date: 27 April 2021

Dr. Bibek Kumar Lal

Principal Investigator, SAARC Tuberculosis and HIV/AIDS Center, Thimi

Dr. Biraj Man Karmacharya

Principal Investigator, Kathmandu University School of Medical Sciences, Nepal

Ref: Approval of research proposal

Dear Dr. Lal and Dr. Karmacharya,

This is to certify that the following protocol and related documents have been reviewed and granted approval by the Expedited Review Sub-Committee for implementation.

ERB Protocol Registration No.	226/2021 P	**Sponsor Protocol No**	NA
Principal Investigator/s	Dr. Bibek Kumar Lal Dr. Biraj Man Karmacharya	**Sponsor Institution**	SAARC Tuberculosis and HIV/AIDS Centre
Title	The Impact of COVID-19 pandemic on directly observed treatment short course (DOTS) program for tuberculosis in Nepal		
Protocol Version No	NA	**Version Date**	NA
Other Documents	1. Data collection tools 2. No objection letter from NTCC 3. Donor agreement letter	**Risk Category**	Minimal risk
Study Team Member	Dr. Sanjeeta Sitaula, Ms. Ruby Maka Shrestha, Dr. Ranju Kharel Sitaula, Dr. Anadi Khatri KC and Dr. Virendra Singh Salhotra		
Expedited Review	Proposal ☑ Amendment ☐ Re-submitted ☐ **Meeting Date:** 19 April 2021	**Duration of Approval** 27 April 2021 to 27 April 2022	**Frequency of continuing review**

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Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.:

Total budget of research	**NRs 20,33,695.00**
Ethical review processing fee	**NRs 61,010.85**

Investigator Responsibilities :

- Any amendments shall be approved from the ERB before implementing them
- Submit progress report every 3 months
- Submit final report after completion of protocol procedures at the study site
- Report protocol deviation / violation within 7 days
- Comply with all relevant international and NHRC guidelines
- Abide by the principles of Good Clinical Practice and ethical conduct of the research

If you have any questions, please contact the Ethical Review M & E Section at NHRC.

Thanking you,

Dr. Pradip Gyanwali
Member Secretary
(Executive Chief)

KATHMANDU UNIVERSITY
SCHOOL OF MEDICAL SCIENCES

Date: August 02, 2021

To,

Dr. Biraj Man Karmacharya
Principal Investigator
Kathmandu University School of Medical Sciences
Dhulikhel, Kavre

Subject: Approval of Research Proposal

Dear Dr. Karmacharya

This is to certify that the following protocol and related documents have been reviewed and granted approval by Institutional Review Committee, Kathmandu University School of Medical Sciences (IRC, KUSMS) for implementation on 01 August, 2021.

IRC-KUSMS Approval No.	**66/2021**	Duration of Approval	01 August, 2022
Principal Investigator	Dr. Biraj Man Karmacharya	Sponsor Institute	N/A
Title	**The impact of COVID-19 pandemic on Directly Observed Treatment Short-Courses (DOTS) program for Tuberculosis in Nepal.**		
Other Members of Research Team (Co- Investigator)	Rajnu Kharel, Sanjeeta Sitaula Anadi Khatri, Ruby Maka Shrestha		
IRC-KUSMS, Administrative fee	Rs. 500.00		
Chairperson of IRC-KUSMS	**Name**	**Date**	
	Prof. Dr. Dipak Shrestha	August 02, 2021	
Investigator Responsibilities: ➢ Comply with all relevant International and NHRC guidelines. ➢ Submit final report after completion of protocol at IRC-KUSMS.			

If you have any questions, please contact the IRC-KUSMS section at Kathmandu University School of Medical Sciences/ Kathmandu University Hospital.

With best regards,

Dr. Rajeev Shrestha
Member Secretary, IRC-KUSMS

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Tools of the Study

Qualitative Data Collection Tools

- **KIIs questionnaire for TB Patients**
- **KIIs questionnaire for DOTS focal person/ Health In-charge**
- **KIIs questionnaire for Health Coordinator or TB focal person at Municipality level or TB focal person and Chief Health Officer at Health Offices**
- **KIIs questionnaire for TB focal person at Province Health Directorate Office**
- **KIIs questionnaire for TB focal person at NTCC**
- **KIIs questionnaire for TB focal person at MoHP**

Quantitative Data Collection Tools

- **Checklist of essential TB services during COVID-19 pandemic**
- **Individual Questionnaire for TB patients**

SARS-COV-2 and TB co-infection among current TB patients in Chennai, India

Final Report

Submitted to

SAARC Tuberculosis and HIV/AIDS Center (STAC) Sanothimi, Bhaktapur

Submitted by

ICMR-National Institute for research IN TUBERCULOSIS

28th February 2024

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Executive Summary

During the COVID-19 pandemic, bidirectional screening of patients was recommended among TB and COVID-19 patients owing to the overlap of the respiratory symptoms. In this study, we studied the co-existence of COVID-19 along with TB among the TB patients who visited NTEP clinics in Chennai. Of the 384 bacteriologically confirmed TB cases, 22 of them were tested positive for SARS-CoV-2 by Standard Q COVID-19 Antigen test. In this study, we also compared the treatment outcomes for both co-infected and only TB groups along with comparison of their baseline characteristics. Among the limited cases of TB-COVID-19 co- infection, we did not observe any significant differences between the two groups in treatment outcomes and/or clinical characteristics. As a high TB burden country with infant BCG vaccination program in place, more studies are required to validate the effect of COVID-19 infection among bacteriologically confirmed TB cases.

In conclusion, the study showed a rate of co-infection with COVID-19 and tuberculosis to be 5.7%, there was no significant difference in the favorable treatment outcome of patient with TB alone and TB plus COVID-19 group.

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1.1 Background and Rationale

Before the arrival of the COVID-19 pandemic, tuberculosis (TB) continued its rank as the primary cause of death with contagious conditions everywhere [1]. The development of the novel corona virus (COVID-19) has bestowed a significant challenge in the 21st century, developing weak impacts on health, demographics, and public aspects [2]. The symptoms of COVID-19 closely resemble those of TB and other extensive infections. Consequently, co-infection of SARS-CoV-2 with other viruses, bacteria, and fungi frequently complicates the prevention, diagnosis, and control strategies for COVID-19. Both COVID-19 and TB primarily affect the human respiratory tract, specifically the bronchi, and are transmitted through aerosol droplets from an infected person to a healthy individual [3,4]. COVID-19 pandemic, resulting from the novel corona virus SARS-CoV-2, varies from a mild cold to more severe cases such as pneumonia [5,6]. Human-to-human transmission primarily occurs through droplet infections, either by inhaling respiratory droplets or touching surfaces contaminated with the virus.

Tuberculosis (TB) continues to be widespread in various regions worldwide, standing as significant contributor to mortality in India [7]. India grapples with the simultaneous challenges posed by both COVID-19 and TB. The concern lies in the possibility that, as attention and resources are diverted to address the immediate health crisis of COVID-19, there could be a setback in the treatment of TB patients. This setback might lead to a surge in TB cases once lockdown restrictions are eased. It is imperative to effectively manage the response to the COVID-19 pandemic while ensuring the uninterrupted continuity of essential national TB programs [8].

The World Health Organization (WHO) has issued recommendations on managing the effects of COVID-19 on tuberculosis (TB) [9]. WHO proposes utilizing the capabilities of National TB Elimination Program (NTEP) to promptly conduct testing and contact tracing in response to

COVID-19. Additionally, WHO advocates for the adoption of digital technologies to provide remote care and assistance to individuals with TB. In 2018, the United Nations pledged to eradicate the global tuberculosis (TB) epidemic by 2030 through the "End TB" strategy. This initiative aimed at an 80% reduction in TB incidence, a 90% decrease in deaths, and the elimination of catastrophic costs for households affected by TB. India declared its commitment to achieving TB elimination within its borders by 2025, surpassing the UN's target by five years [10]. Lockdowns and periods of elevated COVID-19 prevalence and hospital strain have been associated with a decline in the case notification ratio. This ratio represents the primary and immediate impact of the spread of COVID-19 on tuberculosis (TB) transmission dynamics [11]. To control the spread of SARS-CoV-2, countries worldwide enforced lockdowns, mandating people to stay indoors. This resulted in several repercussions. The similarity in symptoms between TB and COVID-19 might have led to a delay in considering TB, as many individuals could have linked comparable symptoms to COVID-19 and chosen to wait it out. Moreover, the existing stigma associated with TB, combined with the additional stigma surrounding COVID- 19, and could have discouraged people from seeking testing, even when experiencing symptoms shared by both diseases. [12,13]. The present study will carry out SARS-CoV-2 screening among TB patients in sputum samples transported to ICMR-NIRT as part of TB diagnostics.

1.2 Objectives:

A. To describe the co-existence of SARS-COV2 and Mycobacterium tuberculosis in sputum samples of TB patients attending National Tuberculosis Elimination Program (NTEP) clinics in South India.

B. To compare the treatment outcomes between coinfected patients (SARS-COV2 and Mycobacterium tuberculosis) and Mycobacterium tuberculosis infected patients from Nikshay database.

Methodology

2.1. Study design: Anonymized, non-interventional study on TB and SARS COV2 co-infection.

2.2 Study population: Stored sputum samples for a period of three months (February 2021 to April 2021) was included in the study form the NTEP sites under ICMR-NIRT.

2.3 Eligibility criteria: All sputum sample received at ICMR-NIRT as part of NTEP-TB

diagnostics algorithm for TB diagnostics. (Fig: 1)

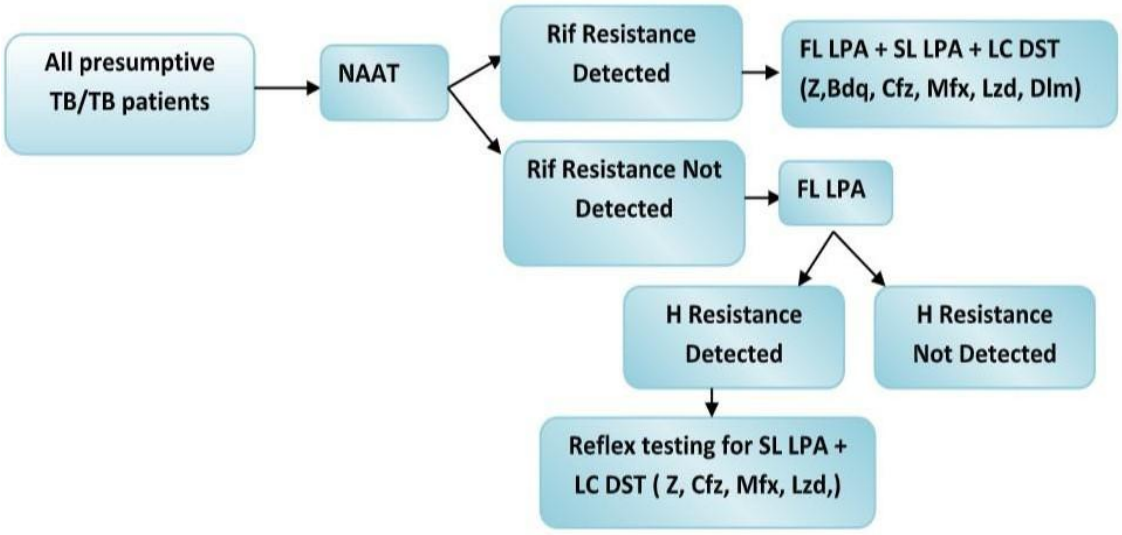


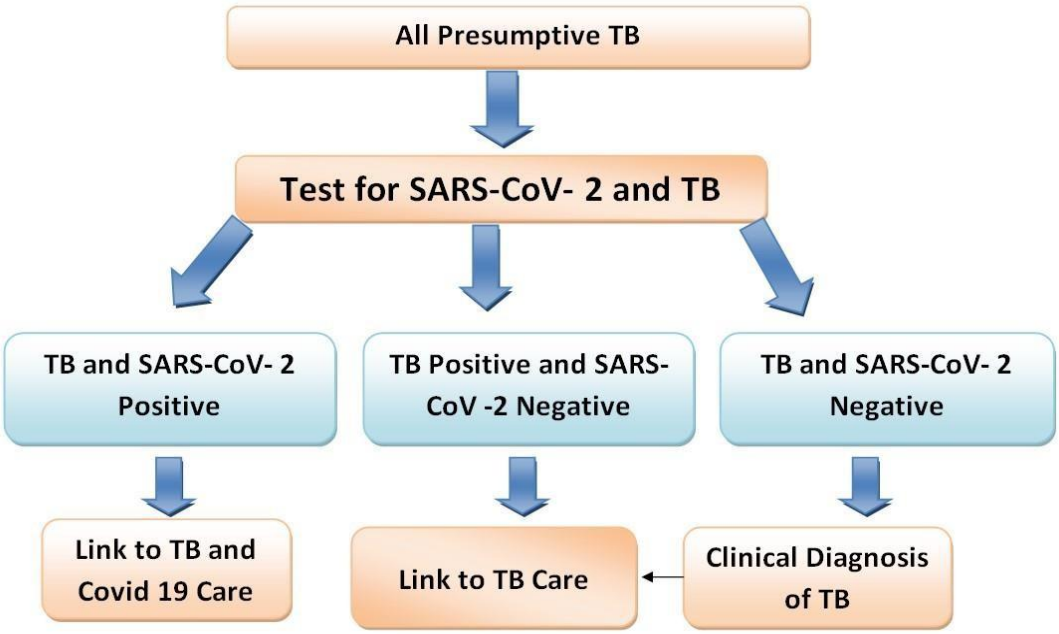
Fig: 1: Algorithm for TB diagnostics TB: Tuberculosis, NAAT: Nucleic Acid Amplification Test, Rif: Rifampicin, FL LPA: First Line -Line Probe Assay, SL LPA: Second Line –Line Probe Assay, LC DST: Liquid Culture Drug Susceptibility Test, Z: Pyrazinamide, Bdq: Bedaquiline, Cfx: Clofazimine, Mfx: Moxifloxacin, Lzd: Linezolid, Dlm: Delamanid, H: Isoniazid Diagnostic laboratories for tuberculosis (TB) are being upgraded to NAAT. This enhancemen enables the provision of NAAT for all individuals suspected of having TB right from the initial diagnostic stage. Based on the NAAT result subsequent tests will be conducted to gather additional information or refine the diagnostic process as needed.

2.4 NTEP-NRL-NIRT (NTEP-National reference Laboratory-NIRT). The bacteriology department at ICMR-NIRT is a national reference laboratory and as part of the program, sputum samples positive by any nucleic acid amplification test (NAAT) CBNAAT/Truenat from the linked district (five district of Chennai, Kanchipuram, Tiruvallur and Vellore) are transported to ICMR-NIRT for 1st Line LPA (Line probe assay) for detection of resistance to Isoniazid and Rifampicin. If resistance is detected then they are also put up for culture and 2nd Line LPA is performed for detection of resistance to Fluroquinolone and Aminoglycosides.

2.5 Study procedures

All newly diagnosed TB patients was tested for SARS-CoV-2 infection. The data relating to date of TB diagnosis and Nikshay number was recorded for the request form.

Figure 2: Algorithm for testing of SARS-CoV-2 among TB patients in NIRT Chennai, India.



STANDARD Q COVID-19 Ag Test was used in the study for screening sputum samples for the **SARS-COV-2 infection.** STANDARD Q COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens of SARS- CoV-2 present in human nasopharyngeal specimens. This product is intended for healthcare professionals at the clinical setup and point of care sites, as an aid to early diagnosis of SARS- CoV-2 infection in patient with clinical symptoms of SARS-CoV-2 infection. It providesonly an initial screening test result. STANDARD Q COVID-19 Ag Test has two pre-coated lines, ―C‖ Control line,

―T‖ Test line on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any specimens. Mouse monoclonal anti- SARS-CoV-2 antibody is coated on the test line region and mouse monoclonal anti-Chicken IgG antibody is coated on the control line region. Mouse monoclonal anti-SARS- CoV-2 antibody conjugated with color

particles are used as detectors for SARS-CoV-2 antigen device. During the test, SARS-CoV-2 antigen in the specimen interact with monoclonal anti- SARS-CoV-2 antibody conjugated with color particles making antigen-antibody color particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the mouse monoclonal anti-SARS-CoV-2 antibody. A colored test line would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. The intensity of colored test line will vary depending upon the amount of SARS-CoV-2 antigen present in the specimen. If SARS- CoV-2 antigens are not present in the specimen, then no color appears in the test line. The control line is used for procedural control and should always

appear if the test procedure is performed properly and the test reagents of the control line are working. All positive and faint bands with the screening test was tested by RT- PCR as a gold standard test for comparison.

3. Statistical considerations

3.1 Sample size: The study population consists of all TB positive sputum samples received and stored at ICMR-NIRT, Chennai. We will collect basic demographic, epidemiological, microbiological, and clinical information (including outcomes) on TB and COVID-19 patients during the study period from available NTEP database. The prevalence of TB among Covid-19 patients has been found to be 0.37 - 4.47 % among different studies. Considering this reference and assuming that 95% confidence level and 20% relative precision, a minimum sample size required would be 384 TB positive patients.

3.2 Data collection and Analysis:

We have included all reported TB cases in the samples sent to us and stored from February 2021 to April 2021. COVID-19 cases were confirmed with positive real-time reverse transcription polymerase chain reaction (RT-PCR) from ICMR certified laboratory. Information on TB confirmed

cases was collected from Nikshay and filled out electronically in an Excel sheet.

Nikshay: NIKSHAY (http://nikshay.gov.in) is a web enabled application, which facilitates the monitoring of universal access to TB patients' data by all stakeholders. The system has been developed jointly by the Central TB Division of Ministry of Health and Family Welfare and National Informatics Centre (NIC).Ni-kshay is used by health functionaries at various levels across the country both in the public and private sector, to register cases under their care, order various types of tests from Labs across the country, record treatment details, monitor treatment adherence and to transfer cases between care providers.

4. Ethical considerations:

This is laboratory study and was carried out on the de-identified sputum samples, the data was be stored using study ID numbers. The study proposal was be submitted to Institutional Ethics Committees and started once the approval was in place (NIRT-IEC: 2021 030).

5. Results:

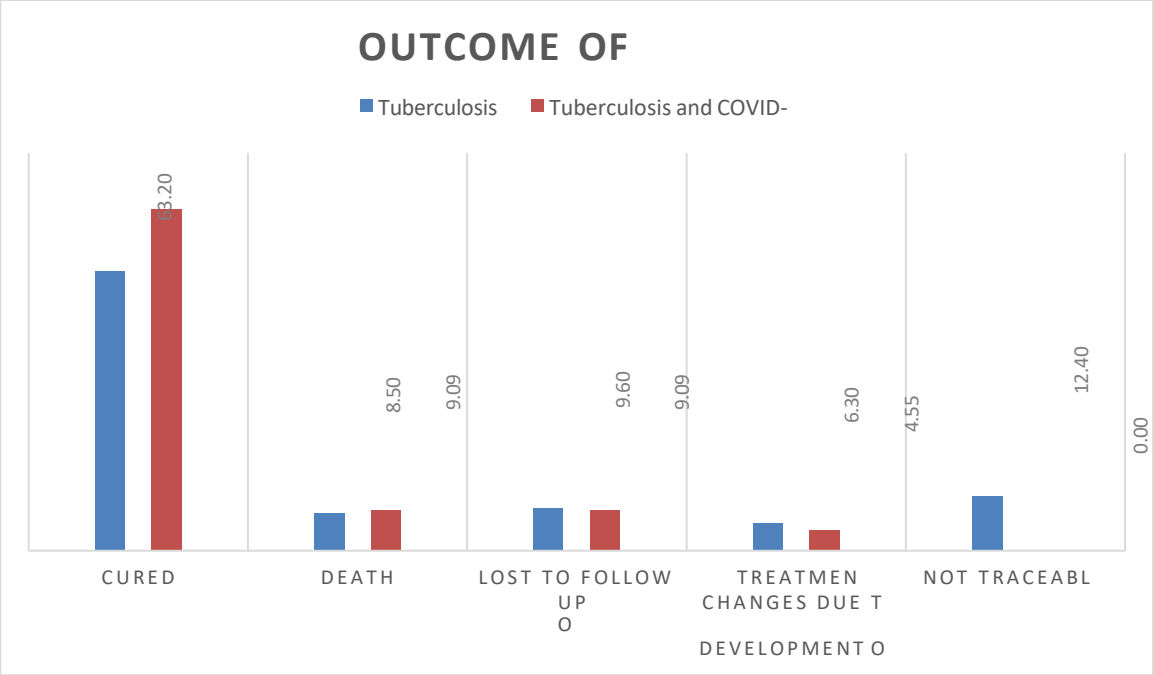
Of these 384 patients (i.e., 88 females, 296 males), the population of men was almost three times that of women. Except for patients whose mean age was not reported (8 patients) and non-adult ones (4 patients), the mean age of adult patients was 53.59 years for the TB-COVID group and 45.36 years for the only TB group (Table 1).

All the samples were tested by GeneXpert and were included if positive, no rifampicin resistance was detected, INH resistance was seen in one TB with COVID. In the TB alone group, 19 patients had rifampicin resistance was detected (11 MDR-TB and 8 Mono RIF resistance-TB), INH mono resistance was seen 19 patients.

Outcome based analysis: A total of 17 (77.27%) patients were cured in the TB with COVID-19 patient group and 5 patients show unfavorable outcome ranging from death (2, 9.1%), lost to follow up (2, 9.1%), and treatment changes due to development of resistance (1, 4.5%). The distribution of diabetic patients in the TB with COVID-19 patient group was diabetic (8, 47.05%) and non-

diabetic (9, 52.9%) among the cured patients and there was no association of diabetic patients with unfavorable outcome as both the patient died of TB was nondiabetic.

Figure 3: Outcome of the Tuberculosis and Tuberculosis plus Covid-19 group



A total of 230 (63.2%) patients were cured in the only TB patient group and 132 patients show unfavorable outcome ranging from death (31, 8.5%), lost to follow up (35, 9.6%), treatment changes due to development of resistance (23, 6.3%) and not traceable (43, 11.8%) (Fig 3). The distribution of diabetic patients in the only TB patient group was diabetic (135, 37.3%) and non- diabetic (221, 61.0%) among the patients with unfavorable outcome (132, 36.5%) and there was no association of diabetic patients with unfavorable outcome (Death 31, 8.5%) as both the diabetic (12, 3.2%) and non-diabetic (18, 4.9%) has no significant difference.

The TB-COVID-19 patients with higher rate of coinfection were seen in male, belonged to older age groups and with more co-morbidity. These determinants of death are similar to those described for mono-disease TB.

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Characteristics		**Tuberculosis and COVID-19 (22)**	**Tuberculosis (362)**
Age (Mean/Median)		53.59/53	45.36/47
Height		45.13/48	46.6/45
Weight		156.59/156	155.38/155
Gender	**Male**	18 (81.8%)	278 (76.8%)
	Female	4 (18.2%)	84 (23.2%)
Socio-economic status	**APL**	0.0	4 (1.1%)
	BPL	16 (72.7%)	285 (78.7%)
	Unknown	6 (27.3%)	73 (20.2%)
Diabetes	**Diabetic**	11 (50%)	135 (37.3%)
	Non-Diabetic	11 (50%)	221 (61.0%)
	Unknown	0.0	6 (1.65%)
Smoking	**Smoker**	7 (31.8%)	94 (26.0%)
	Non-Smoker	15 (68.2%)	232 (64.1%)

	Unknown	0.0	36 (9.9 %)
Alcohol	**Alcoholic**	9 (40.9%)	119 (32.9%)
	Non-Alcoholic	13 (59.1%)	199 (54.9%)
	Unknown	0.0	44 (12.2%)
HIV Status	**Non-Reactive**	22 (100%)	335 (92.5%)
	Reactive	0.0	6 (1.7%)
	Unknown	0.0	21 (5.8%)

Data is presented both in number and percentage as indicated. APL: Above poverty level BPL: Below poverty Level, HIV: human immunodeficiency virus

5. Discussion

The data on the impact of COVID-19 severity on treatment outcome of TB is unclear and literature reports are often conflicting. The management of co-infected patients is complicated as there are pharmacokinetic interactions between several drugs used for the therapy of SARS-CoV-2 infection and the treatment of TB [14]. There is a moderate level of evidence indicating that individuals co-infected with COVID-19 and TB are at a higher risk of experiencing severe disease or mortality compared to those solely affected by COVID-19. As a precautionary measure, it may be advisable to incorporate routine screening for TB among suspected or confirmed cases of COVID-19 in countries facing a high burden of TB.[15].

Various research studies have delved into the consequences of the COVID-19 pandemic on tuberculosis (TB). According to a previous report, the shock triggered by COVID-19 may significantly influence the occurrence and mortality associated with tuberculosis, with a prolonged timeline for a return to normalcy in these aspects.[16]. Changes in blood cell parameters are linked to an adverse treatment outcome. TB-COVID-19 co-infection is correlated with a higher mortality

rate, particularly among individuals of older age, those with a history of smoking or current smokers, individuals with a history of drug abuse, and those with co-existing non-communicable diseases. [17].

Our study observed 22 cases of TB-COVID-19 co-infection among 384 TB patients with symptoms who were tested positive by NAAT. A lower incidence of COVID-19 was observed in regions with higher tuberculosis (TB) incidence and widespread Bacillus Calmette-Guérin (BCG) vaccine coverage. This finding encourages additional exploration into the pathogenesis and immune response of COVID-19 [18]. While combating the COVID-19 pandemic, it is crucial not to overlook the importance of vigilance and proper management of tuberculosis (TB). TB remains a significant infectious cause of mortality globally, and addressing it appropriately is imperative.[19]. In a previous study, an annual decline of approximately 2% in the prevalence and incidence of tuberculosis (TB) from 2020 to 2025, both in the presence and absence of COVID-19. While an overall reduction is observed, it lacks statistical significance, suggesting that COVID-19 has not significantly influenced TB in Tamil Nadu [20].

Our study compared the gender, age, co-morbidities, social habits, socioeconomic status between the two groups but we did not find any significant differences. This could be due to the limited co-infection cases observed in our study. Statistically significant factors contributing to the severity of disease in patients with TB-COVID-19 include female gender, presence of fever, dyspnea, pulmonary bilateral TB lesions, and the presence of three or more

co-morbidities. To accurately differentiate between COVID-19 and TB, it is crucial to conduct rapid molecular testing and computed tomography, especially given the similar clinical characteristics of both diseases. Additionally, bilateral pulmonary TB lesions and the presence of co-morbidities should be recognized as risk factors for the development of severe COVID-19.[21].

Concerning the risk of morbidity and mortality, various risk scores for COVID-19, as well as independent risk factors for tuberculosis (TB), have been identified. These factors include age,

poverty, malnutrition, and co-morbidities such as HIV co-infection and diabetes. Ongoing global TB-COVID-19 studies are anticipated to furnish additional evidence and insights into the interplay of these factors, further contributing to our understanding of the risks associated with these diseases. [22]. Research findings indicate that common symptoms in TB-COVID-19 co-infection include fever, cough, hypotension, altered blood cell count, and abnormal liver enzymes, along with lower hemoglobin levels. Unfavorable treatment outcomes are associated with alterations in blood cell parameters. However, no significant differences in treatment outcomes were observed in the TB-COVID-19 co-infection group in comparison to only TB group. In previous study, a higher death rate was observed TB- COVID-19 co-infection, particularly among individuals of older age, those with a history of smoking, drug abuse, and co-morbidity of non-communicable diseases. Conversely, HIV patients exhibit a lower death rate, possibly attributed to the impact of antiviral drugs. Further investigations into immune cell function in HIV patients are warranted for a comprehensive understanding.[17].

Individuals at a heightened risk of experiencing severe COVID-19 or facing a higher likelihood of mortality often share specific characteristics. These include advanced age, male

sex, and the presence of underlying health issues like cardiovascular disease (CVD), obesity, and either type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM).[23, 24]. Diabetes Mellitus elevates the risk of contracting Tuberculosis (TB) disease by approximately threefold, doubling the likelihood of death during TB treatment and contributing to other unfavorable treatment outcomes. Additionally, diabetes may heighten the risk of latent infection with Mycobacterium tuberculosis (LTBI).[25]. In contrast to other research, our study reveals no statistically significant association between co morbidities and SARS-CoV-2 or tuberculosis (TB).

6. Conclusion:

The study showed a rate of co-infection with COVID-19 and tuberculosis to be 5.7%, there was no

significant difference in the favorable treatment outcome of patient with TB alone and TB plus COVID-19 group. **As** patients reported similar symptoms, it advisable for health services to screen patients for both diseases whenever possible, taking advantage of the possibility to obtain imaging rapidly and stimulating adoption of rapid molecular testing for TB and COVID-19. Although our study does not provide specific data on this, it seems clinically advisable to treat both conditions as soon as possible following international recommendations.

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Morbidity and Mortality Related to COVID-19 among HIV Infected Individuals in Selected ART Sites of Kathmandu Valley

2021

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Final Report

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We believe that the findings of this survey will be valuable for the policy makers, program planners and implementing agencies to plan the new program and revise the strategies to address the situation of COVID-19 among the People Living with HIV in Nepal.

-Study Team SAIFRN, Nepal

Executive Summary

HIV is a one of the priority program of government of Nepal led by National Center for AIDS and STD Control (NCASC), under Ministry of Health and population. COVID-19 pandemic has caused major disruptions in the implementation of health services and; diverting most of the resources and efforts to contain the COVID-19 pandemic also fuel the underachievement of activities of different

health programme, including achievement of national HIV programme (NCASC, 2020). The objectives of this study are to determine the morbidity and mortality of COVID-19 among HIV infected individuals in selected Antiretroviral Therapy (ART) sites of Kathmandu valley, to assess the health outcomes of COVID-19 among People living with HIV (PLHIV) and to assess the impact of COVID-19 in receiving care services by People living with HIV.

This was a cross-sectional survey among people living with HIV, ART focal person and key informants. A mixed method approach was used for data collection. The sample size for the study was 388 who were tested for COVID-19. Most of the participants 39.2% were found to be in the age group of 36-45 and 57.7% were male. Prevalence of COVID-19 among surveyed HIV infected individuals was 12.1%. Prevalence of COVID-19 among HIV infected individuals registered at seven selected ART sites and as recorded at ART sites was 1.6%. Percentage of deaths among PLHIV due to COVID-19 was 0.068% and case fatality rate of COVID-19 among PLHIV was 4.2%. Findings related to ART service at the time of COVID-19 revealed that total of 7.5% participants had to cancel ART appointment due to COVID lockdown whereas 4.4% of the total participants had face shortage of diagnosis and drugs for HIV/AIDS treatment. Maximum number of participants i.e. 86.6% had received multiple months dispensing of ART at the time of COVID-19.

In conclusion, it is important to focus on prevention strategies to mitigate spread of COVID-19 among PLHIV and uninterrupted access to ART services should be provided to PLHIV in a time of such pandemic in the future.

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Abbreviations

AIDS : Acquired immune deficiency Syndrome

ART **:** Antiretroviral Therapy

COVID-19 **:** Coronavirus Disease of 2019

HIV : Human Immunodeficiency Virus

MoHP : Ministry of Health and Population

NCASC : National Centre for AIDS and STD Control

PLHIV **:** People living with HIV

RT-PCR **:** Reverse Transcription–Polymerase Chain Reaction

SDG : Sustainable Development Goal

STAC **:** SAARC Tuberculosis and HIV/AIDS Centre

WHO : World Health Organization

Introduction

1.1 Background

COVID-19 has imposed great threat to low and middle income countries including Nepal. The fragile health system and availability of limited resources are vital challenges to cope with this large-scale outbreak and to mitigate its consequences (Koirala et al., 2020). Government of Nepal (GoN) declared lockdown across the country on 24 March and enforced self and home quarantine of two weeks for the people visiting Nepal. Ministry of Health and Population (MoHP) has developed guidelines "Interim Guideline for COVID and other health care services of COVID-19 epidemic", "Responding to COVID-19: Health sector preparedness, response and lessons learnt". The guideline provides information to health facilities on how to manage the COVID-19 cases. It guides different health services for the diagnosis and management of COVID-19 cases, basic counseling and referral service, isolation, sample collection and referral services, and case management (MoHP, 2020). Nepal Medical Council developed a guideline named "Interim Guidance for Infection Prevention and Control when COVID-19 is suspected" with the purpose to guide health care professionals while providing services to suspected cases or COVID-19 patients in health facilities (Nepal Medical

Council, 2018), "COVID-19 triage/management algorithm for PHC" (Nepal Medical Council, 2021), "Interim intensive care unit (ICU) protocol for the care of patients with COVID-19" (Nepal Medical Council, 2020). MoHP endorsed "Pocket Book for Infection Prevention and Control Measures for COVID-19" and "Guidelines for COVID-19 Case Investigation and Contact Tracing Team Deployment". Furthermore, MoHP has developed "Health Sector Emergency Response Plan COVID-19" to strengthen the health system response to counter the COVID-19 pandemic. It includes strategic approaches and interventions such as public health and social measures, hospital based interventions, management of human resources and logistic and fund management. The fear of the disease and lock down imposed by the government to prevent the disease spread has resulted cessation of public health programmes both from the providers site and the public. Studies from other countries have reported the impact of the COVID-19 pandemic on mental health and quality of life of the people (Zhang et al., 2020). Although different strategies and measures have been employed for COVID-19 control in Nepal, there is no evidence available till date on such measures including lock down and travel restrictions have impact on health care of the people living with HIV. These impact of COVID-19 on people, health system have not been assessed till date. Further, how people, local health facilities and local government cope up with COVID- 19, what are their preparedness and what should be done in the future to combat such pandemic are largely unavailable.

HIV is a priority program of government of Nepal led by National Center for AIDS and STD Control (NCASC), under Ministry of Health and population. Different countries, including

Nepal, implemented several strategies including quarantine of suspected cases, isolation of positive COVID-19 cases, contact tracing etc to contain the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). One of the important strategies adopted against coronavirus disease 2019 (COVID-19) was the announcement of national-wide shelter in place so-called lockdown. COVID-19 pandemic has caused major disruptions in the implementation of health services and; diverting most of the resources and efforts to contain the COVID-19 pandemic also fuel the underachievement of activities of different health programme, including achievement of national HIV programme (NCASC, 2020). Further, PLHIV are immunosuppressed and prone to several infections including SARS-CoV-2. However, there is no information available regarding morbidity and mortality of COVID-19 among HIV infected individuals. Studies conducted in India revealed that a similar clinical and epidemiological profile of COVID-19 among PLHIV with other group of people (Patel et al, 2021, Pujari et al, 2021). A study from India also showed that COVID-19 restrictions had an impact on access to HIV testing services. There was high acceptance of multi-month dispensing (MMD) and community-based services support provided by health workers (Pollard et al, 2021). However, very limited information is available on COVID-19 among HIV infected individuals from the SAARC countries. Such information on prevalence of COVID-19 among PLHIV, and impact of COVID-19 and lock down on service delivery will provide holistic evidence which will be useful for developing strategies to cope such pandemic in future.

1.2 Rationale

Qualitative studies conducted in different parts of Nepal revealed that supply of essential medicine, maternity services and immunization were found to be the most affected areas of health care delivery during the lockdown (Singh et al, 2021, Khatiwada et al, 2021). Interruption of delivery of

health care in Nepal caused by COVID-19 could cause adverse consequences for the health of people beyond those from COVID-19 itself. Causes of such disruption could include COVID-19-related morbidity and mortality, hospital and health facility closures or reduced service availability, and physical distancing and other measures put in place to combat the virus spread. There could be huge impact of COVID-19 in case detection and treatment of HIV/AIDS. Further, there could be low or limited service delivery and implementation of control programmes.

Sustainable Development Goal (SDG) target 3.3, states "End the epidemic of AIDS" by 2030. NCASC has set targets and indicators for fast tracking the AIDS response by 2021, also known as 90-90-90 target which states that 90% of all people living with HIV will know their HIV status, 90% of diagnosed HIV positive people will receive sustained antiretroviral therapy and 90% of all people receiving antiretroviral therapy will have viral load suppressed. Along with this, vertical transmission of HIV will be eliminated where mothers are alive and well, congenital syphilis is eliminated and new infection of HIV is reduced by 75%.

This priority disease control programme could be badly impacted during COVID-19 pandemic and lock down. There could be morbid cases of COVID-19 among HIV infected individuals. Since, HIV infected are immune compromised, COVID-19 infection could be fatal among those individuals. There is no information available on morbidity and mortality of COVID-19 among HIV infected individuals. If such information is available that could be useful for preventing morbidity and mortality among immune compromised patients from pandemic diseases. There is the need to identify the impact of COVID-19 to mitigate the gaps created so as to achieve set target. The analysis of impact of COVID-19 pandemic on health of the HIV infected people, impact in providing and receiving public health services and medical services due to lock down and travel restrictions imposed by the government would provide better picture to develop strategies to the probable next peak or outbreak or pandemic of similar nature in the future.

There is a growing concern that the immune suppressing nature of HIV may make people living with HIV AIDS more susceptible SARS coronavirus infection. People living with HIV AIDS with low CD4 count and not on anti-retroviral therapy (ART) have the greatest risk of contracting severe symptoms of COVID-19 which may lead to death among this group. Therefore, this study was conducted to determine the morbidity and mortality of HIV infected individuals due to COVID-19 in selected ART sites of Kathmandu valley and assess the impact of COVID-19 in receiving care services by PLHIV. The study would provide the burden of COVID-19 among PLHIV that can be applicable to run the programmes smoothly in similar pandemics/outbreaks of similar nature in the future.

1.3 Objectives

1. To determine the morbidity and mortality of COVID-19 among HIV infected individuals in selected ART sites of Kathmandu valley.
2. To assess the health outcomes of COVID-19 among people living with HIV.
3. To assess the impact of COVID-19 in receiving care services by people living with HIV.

1.4 Operational Definitions

Morbidity: For this study, morbidity has been defined as the prevalence of COVID-19 among PLHIV, duration of illness due to COVID-19 and severity of illness (hospitalization, oxygen requirement in hospital, ICU admission and requirement of ventilators).
Health Outcomes: It includes appearance of symptoms after COVID-19 test result, Mortality, severity of illness.
Multiple months dispensing: According to national guideline, multiple doses of ART is provided for one month to PLHIV. In our study we considered more than one month dispensing as multiple months dispensing of ART.

Methods

2.1 Study design

This was a cross-sectional survey conducted among people living with HIV, ART focal persons and key informants. Mixed method including qualitative and quantitative approaches was used for data collection.

2.2 Study sites

The study was conducted in selected seven ART sites of Kathmandu valley. (Table 1)

2.3 Study population

Those people who are living with HIV (PLHIV), who are registered in respective ART sites and taking ART and who had tested for COVID-19 were the study population. However, some of the respondents had not tested for COVID-19 were also included from some sites to obtain information on effect of COVDI-19 on getting ART services. Further, key informant interview (KII) was conducted with program managers including Director, Medical officer of NCASC. ART focal persons of ART sites were interviewed to assess the functionalities of the control programme and care services during COVID-19 pandemic.

2.4 Sample size and sampling

Sample size was calculated using the Cochran's formula for cross-sectional study.

Sample size (N)=$Z^2PQ/D2$
Where, Z= Z score value of standard normal variable at 95% confidence level. (1.96)
P= Estimated prevalence = 50% (As prevalence of COVID positive cases was unknown for PLHIV in Nepal)
D= 0.05 (5% margin of error)
Therefore, required sample size was 385 ~388.

Site specific sample size was calculated based on Probability Proportionate to Size (PPS). The site specific sample size has been given in table below. In the sites all COVID-19 tested PLHIV

were selected for the interview to assess the impact of COVID-19 in receiving care. The site specific sample size was approximately proportionate to the number of PLHIV receiving ART in the specific sites. Some of the sites had no PLHIV meeting the inclusion criteria (i.e. those who had tested from COVID-19), therefore the desired number of samples from that site was not obtained.

All PLHIV registered at seven ART sites in Kathmandu valley were included for mortality and morbidity determination due to COVID-19.

Key Informant Interview (KII) with director of NCASC, and interview of In-charge of ART service site was conducted.

Table 1: ART site specific sample distribution

S.N.	Name of ART sites	District	Number of PHIV receiving ART (Male)	umber of PLHIV ceiving ART (Female)	Total Number of PLHIV receiving ART	Actual sample size taken
1	Sukra Raj Tropical and Infectious Disease Hospital (Teku) ART Site	Kathmandu	1123	870	1993	214
2	Bir Hospital ART Site	Kathmandu	306	184	490	87
3	Sparsa Nepal ART Site	Lalitpur	276	119	395	66
4	Bhaktapur District Hospital AR T Site	Bhaktapur	54	23	77	9
5	Maiti Nepal ART Site	Kathmandu	10	35	45	5
6	Paropakar Maternity Hospital ART Site	Kathmandu	61	67	128	7
7	Kanti Children's Hospital ART Site	Kathmandu	18	9	27	0
	Total		1848	1307	3155	388

**Note: When adequate number of sample was not captured from the particular ART site as stated, next ART site was considered to fulfill the sample target. (As of June 01, 2021)*

Description of ART Sites

Sukra Raj Tropical and Infectious Disease Hospital (STIDH) ART Site: STIDH is a public hospital in Teku, Kathmandu. It is the only hospital in Nepal especially designated for the treatment of tropical and infectious diseases. The hospital was established in 1933. ART Site was established within the hospital premises in 2004. It is one of the sites having highest number of registered PLHIV.

Bir Hospital ART Site: Bir Hospital is the oldest and one of the busiest hospitals in Nepal. It is located at the center of Kathmandu city. ART Site was established within the hospital premises in 2008.

Sparsa Nepal ART Site: Society for Positive Atmosphere and Related Support to HIV and AIDS is a community supported NGO working in the area of HIV and AIDS since 2002 and registered in 2004. ART site within SPARSHA Nepal was established in 2005.

Bhaktapur District Hospital ART Site: Bhaktapur Hospital is the oldest hospital of Nepal. Today it has a proud history of 125 years and the first hospital of Nepal where the practice of modern medicine commenced. It is established with a motive “Care to Cure”. It began as an idea of a patient-oriented, socially responsible center, making superior quality healthcare services

convenient and accessible for the community it serves. It aims to meet all healthcare needs of the nation through unparalleled patient care and wellness programs. ART Site was established within the hospital in 2013.

Maiti Nepal ART Site: Maiti Nepal an organization devoted to combating human trafficking including violence against women and children; is engaged in protection, rescue and rehabilitation of survivors of trafficking by promoting their human rights in diversified avenues. Activities include awareness campaigns among general public, people with low level of awareness, school and college students, parliamentarians, law enforcement agencies, Village Development Committees, and concerned agencies. ART site within Maiti Nepal was established in 2007.

Paropakar Maternity Hospital ART Site: Paropakar Maternity and Women's Hospital, also known as Prasuti Griha, is the first maternity hospital of Nepal. It is located on Maternity Hospital Road, in Thapathali, Kathmandu, Nepal. ART Site was established within the hospital in 2017.

Kanti Children's Hospital ART Site: (Est 2006) Kanti Children's Hospital (Kanti Baal Aspatal) is a pediatric hospital in Maharajgunj, Kathmandu, Nepal. ART Site was established within the hospital in 2006.

2.5 Variables and indicators

Variables: Age, Sex, Education, Income, Marital Status, Place of residence, COVID-19 status, symptoms, place of treatment, outcome of treatment, CD4 count, Viral load, Availability of ART and TB drugs, Availability of health professionals, reporting of the cases, number of patients diagnosed and treated, illness due to COVID-19, mortality.

2.6 Inclusion and exclusion criteria

Inclusion:

Those clients and service providers who agreed to participate in the study. PLHIV who had tested for COVID-19 by RT-PCR/Antigen/Antibody test. **Exclusion:**

Those who refused to participate were excluded from the study.

2.7 Data collection

2.7.1 Coordination with NCASC and ART sites

This study was conducted in collaboration with NCASC and ART centers within Kathmandu valley. Seven ART centers of Kathmandu valley were selected for data collection. SAIFRN coordinated with in-charge of ART centers for management of study according to plan.

2.7.2 Determination of COVID-19 morbidity among PLHIV

All of the PLHIV receiving ART from ART sites were approached for collection of data on COVID-19 mortality and morbidity. PLHIV were approached at ART centers during the day of their visit to collect data about their COVID-19 test status and the result through face to face interview. Participants who cannot be contacted at ART centers were contacted through telephonic interview. The contact telephone numbers were obtained from ART register. They were asked about their COVID-19 test status and the result of the test. Those tested with RT- PCR/Antigen/Antibody test and found as COVID -19 positive were included in calculation of morbidity. Morbidity indicators include the prevalence of COVID-19 among PLHIV, duration of illness due to COVID-19 and severity of illness (hospitalization, oxygen requirement in hospital, ICU admission and requirement of ventilators). The study included COVID-19 tested cases among PLHIV since the report of first case of COVID-19 in Nepal i.e. 23 January, 2020 to the date of data collection.

2.7.3 Determination of COVID-19 mortality among PLHIV

COVID-19 mortality related data were collected from peer contact, ART service provider, COVID -19 treating clinicians' tracking record etc. These data were confirmed through death audit or verbal autopsy with immediate family members.

2.7.4 Interview of PLHIV to assess the impact of COVID-19

During the visit of ART site the total number of PLHIV receiving ART were obtained through ART focal person/in-charge. All 388 COVID-19 tested PLHIV during the time of data collection from seven ART centers of Kathmandu valley were interviewed to assess the impact of COVID-19. They were explained about the aims, procedure, advantages and impact of being involved in the study. Consent from the participants was obtained. Interview of each participant took about 20 minutes. Interview was conducted by research assistants having work experience sociology, public health and HIV/AIDS.

2.7.5 Assessment of impact of COVID-19 at service level

Key informant interview of director of NCASC was conducted to collect data on the impact of COVID-19 in providing services as well as the mitigation measures taken. In addition, interview of in-charge of all 7 ART sites was conducted to collect data on HIV diagnosis, treatment, response and reporting status during COVID-19 pandemic and supply chain management. Interview was conducted by research assistants having work experience sociology and public health.

2.7.6 Validity of the collected data

The data on COVID-19 test, positivity status and deaths were found recorded in the ART sites. The PLHIV identified through records were interviewed and further confirmed regarding COVID-19 test and the results. Death data were verified through verbal autopsy.

2.8 Selection of research assistants and orientation

Four research assistants with previous relevant research/data collection experience were involved in the study. One day orientation programme was conducted in Lalitpur for the research assistants on research protocol, procedure of the study, ethical issues of research, and revision on questionnaires and tools. Mock interview was conducted among the research assistants during the orientation session.

2.9 Study tools

Standard questionnaires were used for data collection (Appendix).

2.10 Supervision of the research activities

The monitoring team of clinician, public health expert and study team member from SAIFRN-Nepal monitored the fieldwork. Monitoring of fieldwork was conducted and monitoring team used standard monitoring checklist during supervision and monitoring visit.

2.11 Ethical issues

Ethical approval (Regd. No. 462/2021 P) was taken from Nepal Health Research Council (NHRC). Written/verbal consent was obtained from the participants before interview. This survey included only interview of the participants. It did not include any sensitive issues and biological sample collection. The survey participants were explained of purpose, procedure, right to participate and withdraw, benefits, confidentiality of data, right not to participate and contact information before taking written consent. Consent was voluntary. The participants could withdraw their participation at any time. Very few (i.e. 3) of the respondents dropped in the middle of the interview. All the collected questionnaires/forms were kept confidential and there was no identification of the participant in the report.

2.12 Data management and analysis

After the completion of data collection, it was reviewed, organized, coded, entered and analyzed by using the SPSS and MS Excel. Descriptive and inferential analysis was computed. The finding has been presented using tables and figures based on the objectives of the study. The survey was descriptive and data have been summarized as counts and percentages. The qualitative data were translated and transcribed according to themes. The qualitative data has been presented on the following themes: early response activities were conducted at time of COVID-19, experience related to diagnosis and treatment of HIV during the time of COVID-19, experience related to supply of medicine and logistics during the time of COVID-19, experience related to service available at ART during the time of COVID-19, feedbacks for smooth functioning of ART at time of such pandemics etc. Further, supply the commodities, early response activities, weaknesses, mitigation measures taken by NCASC at the time of CVODI-19 and lockdown.

Results

The findings of the study are based on the responses provided by PLHIV who were registered at 7 selected ART centers of Kathmandu valley. The total number of samples recruited for the study was 388, in some variables there was no response from the participants.

3.1 Background characteristics of the participants

Among 7 ART centers within Kathmandu valley, maximum number of participants were recruited from Teku ART site i.e. 214 (55.2%). Similarly, 87 (22.4%) were recruited from Bir Hospital and 66 (17.0%) were recruited from Sparsha Nepal. Whereas, there were no participants from Kanti Children Hospital ART center who had tested for COVID-19 at time of the study (Table 2).

The mean age of survey participants was 40 years (S.D.=10). Maximum participants were from 36-45

years (39.2%), followed by 46-55 years (21.6%). Likewise, the least number of participants were from age group of more than 55 years (4.6%) and less than 25 years (10.3%).

Among 388 participants responded, there were 224 (57.7%) males, 163 (42.0%) females and 1 third gender (Table 2).

Most of the participants (89.9%) were from inside the Kathmandu valley and 10.1% were from outside the Kathmandu valley.

Maximum numbers of participants were married i.e. 285 (73.5%) whereas 63 (16.2%) were un- married, 22 (5.7%) single/widowed, 16 (4.1%) separated and one in living together relationship. Education background of the respondents revealed that most of the respondents (23.5%) had secondary level (Grade 9-10) schooling, followed by lower secondary (19.8%). 45 (11.6%) participants were illiterate (Table 2).

The occupations of the respondent were categorized in two groups employed and unemployed. The category employed included participants (61.9%) who were engaged in occupations- service (private/government), business, daily wage/ labor and agriculture. Whereas, the category unemployed included participants (27.8%) who had no jobs, who were housewife and who were students (Table 2).

The numbers of participants for the monthly income analysis were included from those who were employed only. Maximum participants (39.2%) had income range from 15001 to 25000 followed by 27.1% had income rage of 10001-15000. The participants with income range 10000 and less were 37 (15.4%) (Table 2).

Table 2: Background characteristics of the respondents

Variables	Number (N=388)	Percent
ART sites		
STIDH Teku	214	55.2
Sparsha Nepal	66	17.0
Bir Hospital	87	22.4
Bhaktapur ART Center	9	2.3
Prashuti Griha ART Center	7	1.8
Kanti Child Hospital ART Center (No COVID-19 tested)	0	0.0
Maiti Nepal	5	1.3
Age group (in years)		
≤ 25	40	10.3
26-35	79	20.4
36-45	152	39.2
46-55	84	21.6
More than 55	18	4.6
No response	15	3.9
Mean ± SD	40±10	
Gender of the respondent		
Male	224	57.7
Female	163	42.0
Third gender	1	0.3
Residence		

Inside Kathmandu valley	349	89.9
Outside Kathmandu valley	39	10.1
Marital status		
Married	285	73.5
Unmarried	63	16.2
Separated	16	4.1
Single/Widowed	22	5.7
Other (living together)	1	0.3
No response	1	0.3

Education level		
Illiterate	45	11.6
Primary (Grade 1-5)	78	20.1
Lower secondary (Grade 6-8)	77	19.8
Secondary (Grade 9-10)	91	23.5
Higher Secondary (Grade 11-12)	66	17.0
Bachelors and above	18	4.6
No response	13	3.4
Occupation		
None	57	14.7
Service (private/government)	136	35.1
Business	55	14.2
Housewife	40	10.3
Agriculture	10	2.6
Daily wage/ labor	39	10.1
Student	11	2.8
No response	40	10.3
Employment status		
Employed	240	61.9
Unemployed	108	27.8
No response	40	10.3
(Unemployed: Student, Housewife, No any job)		
Monthly income (if employed)		
10000 and Less	37	15.4
10001-15000	65	27.1
15001-25000	94	39.2
More than 25000	43	17.9
No response	1	0.4

3.2 *Findings related to ART and HIV diagnosis*

It was found that 56 (14.4%) participants started their ART after COVID-19 pandemic whereas 314 (80.9%) started their ART before COVID-19 pandemic. Most of the respondents (27.1%) had started their ART 6 to 10 years ago, followed by those started within 2 years (22.7%) (Table 3).

Respondents were asked about their place of diagnosis of HIV. Maximum participants (77.6%) were diagnosed in government facility followed by NGO (12.9%) and private health facilities (7.0%) (Table 3).

Most of the participants (127, 32.7%) have had diagnosed HIV more than 10 years ago. Similarly, 90 (23.3%) had HIV diagnosed 6-10 years ago, followed by 73 (18.8%) 2-5 years ago and 73 (18.8%) within 2 years ago (Table 3).

Table 3: Findings related to ART and HIV diagnosis

Variables	Number (N=388)	Percent
ART started status		
ART started after COVID-19	56	14.4

ART started before COVID-19	314	80.9
Don't know	3	0.8
No response	15	3.9
ART initiation time (in years ago)		
Within 2 years	88	22.7
2-5 years ago	81	20.9
6-10 years ago	105	27.1
More than 10 years ago	96	24.7
Don't know	3	0.8
No response	15	3.9
Place of HIV diagnosis		
Government	301	77.6
Private	27	7.0
NGO	50	12.9
No response	10	2.6
HIV diagnosis (in years ago)		
Within 2 years	76	19.6
2-5 years ago	73	18.8
6-10 years ago	90	23.3
More than 10 years ago	127	32.7
Don't know	1	0.3
No response	21	5.4

3.3 Findings related to COVID-19 and PLHIV receiving ART

It was observed that out of 388 participants, 47 (12.1%) have positive COVID-19 test result (Table 4).

Out of 47 individuals who had positive COVID-19 result, 34 (72.3%) experienced any type of symptoms of COVID-19 whereas 13 (27.7%) did not experience any symptoms. Most of the symptoms experienced by the COVID-19 positive participants were common cold/cough, fever, body pain, chest pain, and headache (Table 4).

COVID-19 positive participants were asked about their place of treatment. Maximum respondents (36, 76.6%) said that they had treatment at home, whereas 8 (17.0%) were treated at hospitals. Most of the participants (17, 36.2%) have had their treatment from doctors (Table 4).

Table 4: Findings related to COVID-19 and PLHIV receiving ART

Particulars	**Number (N=388)**	**Percent**
Result of COVID-19 test		
Positive	47	12.1
Negative	341	87.9
Symptoms related to COVID-19		
Yes	34	72.3
No	13	27.7
Symptoms *(Multiple response answers)*		
Common cold / cough	17	22.4
Fever	22	28.9
Body pain	14	18.4

Chest pain	5	6.6
Headache	5	6.6
Tasteless	4	5.3
Breathlessness	4	5.3
No smell	2	2.6
Diarrhea	3	3.9
Place of treatment for COVID-19		
Home	36	76.6
Hospital	8	17.0
Pharmacy	2	4.3
Other	1	2.1
If in hospital, treated in OPD		
Yes	4	50.0
No	4	50.0
If in hospital, require oxygen		
Yes	5	
No	3	
If in hospital, admitted in ICU		
Yes	3	
No	5	
If in hospital, require ventilator		
Yes	0	
No	8	
After being COVID-19 positive, days to obtain negative result (in days)		
Min-Max	7-60	
Median	13 days	
Time it took to experience feeling ill (in days)		
Min-Max	1-14	
Median	3 days	

Time it took to visit the doctor/health professional (In days)		
Min-Max	1-30	
Median	2 days	
Time it took to get diagnosed and treatment (in days)		
Min-Max	1-22	
Median	2 days	
Person treated COVID-19		
Doctor	17	36.2
Health workers	4	8.5
Pharmacy	7	14.9
Self	9	19.1
No response	10	21.3

The COVID-19 infected PLHIV received treatment services within 2 days of diagnosing positive of COVID-19. They contacted hospital/doctor after 3 days of feeling ill. In average, the COVID- 19 infected individual recovered in 13 days.

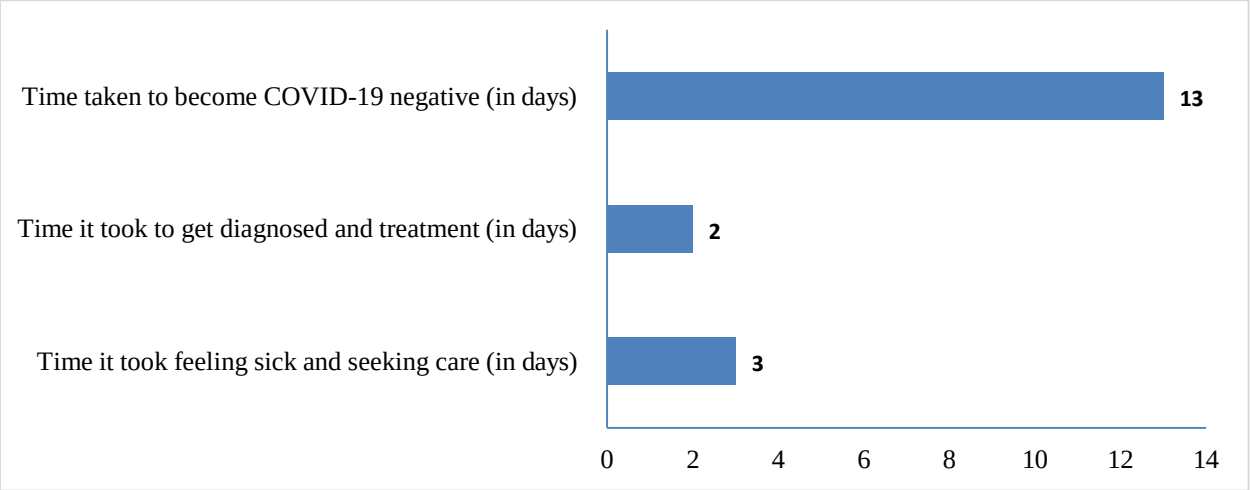

Figure 1: Median days taken for seeking COVID-19 related services for COVID-19 positive participants

3.4 Findings related to ART services at the time of COVID-19

Participants were asked if they hand to cancel their ART appointment due to COVID-19 lockdown, about 29 (7.5%) said yes. The main reason for cancelation of appointment was that the hospitals and clinics were closed due to COVID-19 and doctors and health professionals were unavailable.

Participants of the study were asked if they had faced any shortage of diagnosis and drugs for HIV/AIDS treatment at COVID-19 lockdown period, 17 (4.4%) of the respondents faced

shortage of drugs for HIV/AIDS treatment whereas 2 (0.5%) of the participants had partially experienced this problem.

Majority of the respondents 336 (86.6%) had received multiple months dispensing of ART at the time of COVID-19 pandemic for more than one months. 26 (6.7%) of the participants had interrupted ART treatment at time of COVID-19 (Figure 5).

About 52% of the participants said that health workers visited their house to provide ART drugs during the time of COVID-19 lockdown.

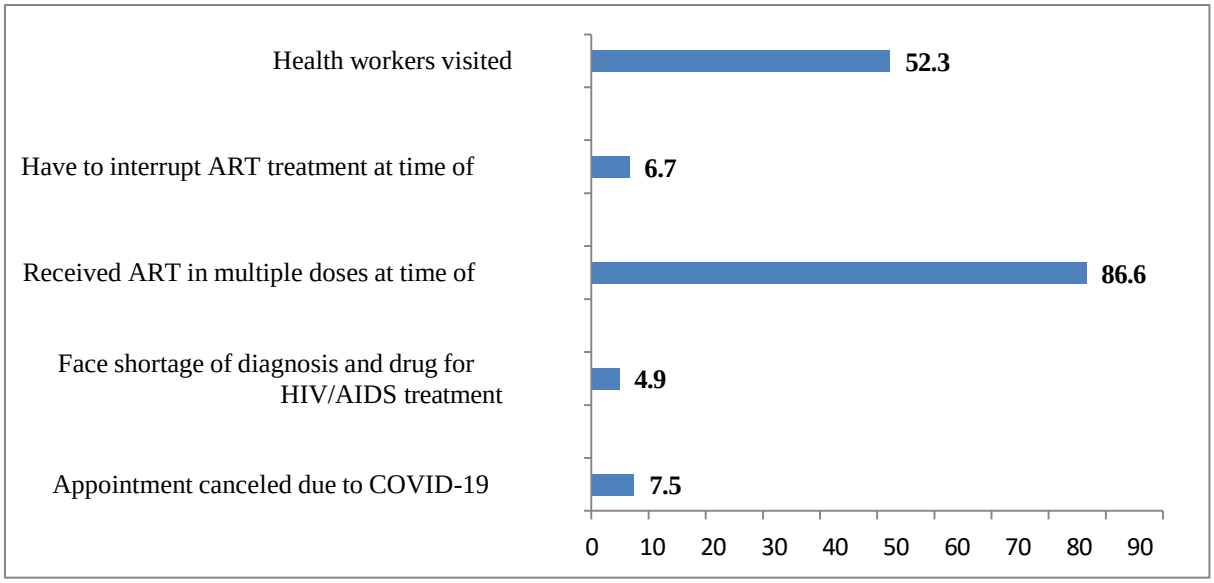

Figure 2: ART services at the time of COVID-19

3.5 Findings from interview with ART focal person

A total of 640 new cases of HIV minimum-0, maximum-307 cases were diagnosed in seven ART sites from initiation of COVID-19 upto the time of data collection (December 2021). Before COVID-19 pandemic, these seven sites had total 3612 HIV cases with minimum-1 to maximum-1997 cases. In maximum cases, 24 hours was taken for confirmatory diagnosis of HIV infection during the time of COVID-19. PLHIV suffered from COVID-19 and took ART during that time were 71 (Table 5).

Table 5: Findings from interview with ART focal person

Variables	Number
Number of HIV diagnosed at the time of COVID-19 till data collection	
Min-Max	0-307
Sum	640
Cumulative number of HIV diagnosed before COVID-19	
Min-Max	1-1997
Sum	3612

Time for diagnosis confirmation at the time of COVID-19	
Min-Max	4-24 hrs
Mode	24 hrs
Average number of PLHIV receiving ART service at time of COVID-19 per month	
Min-Max	10-1302
Mean	365
Number of PLHIV taking ART infected with COVID-19	
Min-Max	0-47
Mean	10.1
Sum	71
Number of PLHIV taking ART died with COVID-19	
Sum	3

"Identified clients prior to lockdown who cannot come to ART at lockdown" - *ART Focal Person, SPARSHA Nepal ART*

"Provide Health Education Counselling like COVID-19, HIV/AIDS and Communicable disease, Provide COVID-19 Vaccine, Food and General Medicine" – *ART Focal Person, Maiti Nepal ART*

Experience related to diagnosis and treatment of HIV during the time of COVID-19

During the time of COVID-19 activities related to Diagnosis and treatment was conducted according to Government rules and guidelines. In the ART centers the work was running smoothly before COVID-19 lockdown, health workers were using mask and other personal protective equipment's. There was good environment to work and easy to stay in contact with patients.

"Freely working before but now alert situation using mask to do work" - *ART Focal Person, Bir Hospital ART*

"Good Environment to work, Easy to stay in contact with patients" – *ART Focal person, Paropakar Maternity ART*

"Treatment was fruitful and response of client was positive" – *ART Focal Person, Maiti Nepal ART*

Experience related to supply of medicine and logistics during the time of COVID-19

Supply of medicine and logistics were supplied according to Government rules. There was no difference in COVID-19 and time before COVID-19. Some problems were experienced due to un-timely supply of logistics. In some ART sites stock medicine was available so difficulty was

not experienced.

“Extra quantity of mask, PPE, gloves required” - *ART Focal Person, Bir Hospital ART*

“Not timely supply of logistics” – *ART Focal Person Kanti Child Hospital ART*

“No difference in COVID19 time and before” – *ART Focal person, Paropakar Maternity ART*

“We had Stock medicine so we didn’t felt difficulty” – *ART Focal Person, Maiti Nepal ART*

Experience related to service available at ART during the time of COVID-19

Due to lockdown it was hard to contact all PLHIV receiving ART. Lack of manpower, lab test and viral load delayed. Problem was experienced in HIV/AIDS campaigning and awareness programs, field movement, and counseling. Safety of the health workers and peer educators was minimized. Mental health threats associated with pandemic and restrictions were felt to both health workers and clients. Extra quantity of mask, sanitizers, gloves and PPE was required.

“No campaigning, no field movement, problem in counseling” – *ART Focal Person Bhaktapur*

“Not enough time to patients, not able to do counselling, to be safe ourselves” - *ART Focal Person, Bir Hospital ART*

“Lack of manpower, lab test or viral load delayed” - *ART Focal Person, SPARSHA Nepal ART*

“Due to lockdown hard to contact all PLHIV receiving ART” – *ART Focal person, Paropakar Maternity ART*

“We couldn’t attend training, Mental health threats associated with pandemic and restrictions” – *ART Focal Person, Maiti Nepal ART*

Feedbacks for smooth functioning of ART at time of such pandemics

- Coordination with organizations and NGOs working on HIV/AIDS,
- Group counseling of PLHIV maintaining social distance, and PPE in small groups rather than individual (As individual counseling takes more time)
- Effective community mobilization through peer educator based community approach.
- ART was provided to clients for multiple months.
- There was lack of space experienced at ART sites, enough space should be provided to ART centers at time of such pandemic.
- PPE should be provided and managed for clients and health care providers.
- Health insurance should be provided to health workers and clients if possible.
- Vaccination should be easily available for high risk population.
- ART should be provided to patients for 5-6 months.
- Information related to COVID-19, HIV/AIDS, TB and other co-infections should be provided to clients at time of such pandemics.
- Home delivery of ART medicine should be provided smoothly and should be

properly managed. Use of safety measures such as PPE, masks, gloves and sanitizers should be used by the person in-charge of home delivery.

3.6 Information from key informant interview from Director, NCASC

ART service was identified as the essential health service and, so all ART centers were functioning during the COVID-19 Pandemic. NCASC was able to supply all the HIV commodities to the ART centers during this period. There were no constraints for supply of any HIV related commodities to ART centers.

For supplying the commodities on time, follow up with ART centers for the timely report were done (not receiving sites). Yes, reports for supply were received on time due to follow up with centers (from where reports not provided).

Due to COVID-19 many important programs like trainings, meetings, prevention related activities were hampered due to restriction in movement and gathering. Prevention programs were unable to reach key populations, so awareness, HIV testing, HIV diagnosis was hampered and for PLHIV on treatment, VL testing was decreased due to limitation in movement (VL sample could not be transported).

The weakness of the HIV/AIDS control program during the COVID-19 pandemic were, unable to reach key populations, so awareness, HIV testing, HIV diagnosis was hampered and for PLHIV on treatment VL testing was decreased due to limitation in movement (VL sample could not be transported).

To mitigate the impact of COVID-19, NCASC in coordination with stakeholders developed Interim Guidance for HIV program during COVID-19 and supported implement the prevention activities by promoting HIV Self-testing, takeaway OST medicines to retain the clients, ART medicine distribution by CHBC and peer navigators deployed to clients who cannot visit ART center. There is no need to change in policy or regulations, but preparation for emergency management is required. The need of buffer stock of HIV related commodities is needed to ensure stock of all commodities.

3.7 COVID-19 positive status and background characteristics of the respondents

Among 388 surveyed participants tested for COVID-19 by PCR or antigen test, 47 (12.1%) were positive for COVID-19. The proportion of COVID-19 among surveyed HIV infected individuals was 12.1%. As recorded in ART sites, the prevalence of COVID-19 among PLHIV was 1.6% (71/4367). 3 cases of PLHIV died due to COVID-19 as recorded in ART sites and verified by verbal autopsy. The case fatality rate of COVID-19 among PLHIV was 4.2% (Table 6).

Table 6: Prevalence of COVID-19 among PLHIV visiting ART center of Kathmandu valley

Particulars	Value	Percent
Proportion of COVID-19 among surveyed HIV infected individuals	47/388*100	12.1
Prevalence of COVID-19 among HIV infected individuals as recorded in ART sites	71/4367*100	1.6
Percentage of deaths among PLHIV due to COVID-19	3/4367*100	0.068
Case fatality rate of COVID-19 among PLHIV	3/71*100	4.2

The COVID-19 positive status of the participant was cross tabulated with the age group of the respondent. It is found that the participants higher than 26 years had slightly high prevalence of COVID-19 status. The prevalence among 25 and less aged population was 7.5%. There was no significant

relationship observed between age group and COVID-19 positive population.

The gender of the population revealed that 16.6% female and 8.9% male participants had COVID-19. There was significant association between gender and COVID-19 positive population when third gender which had only single case was omitted from the analysis.

The prevalence of COVID-19 was slightly higher among the participants who were single/widowed (13.6%) followed by married (12.3%) and unmarried (11.1%). There was no significant association observed between marital status and COVID-19 positive population.

Occupation and COVID-19 positive status of the HIV infected individuals revealed that prevalence of COVID-19 was high among students (27.3%) followed by housewife (25.0%), service providers (14.0%). There was significant association between occupation and COVID-19 positive population.

The occupation of the respondent were categorized into two groups employed and unemployed. The category employed included participants who were engaged in occupation like service (private/government), business, daily wage/labor and agriculture. Whereas, the category unemployed included participants who had no jobs, who were housewife and were students. Unemployed participants had slightly higher COVID-19 prevalence (16.7%) than among employed (10.8%). There was no significant association between employment status and COVID-19 positive population (Table 7).

Table 7: COVID-19 status among PLHIV based on background characteristics

Variables	**Positive (n=47)**		**Negative (n= 341)**		**Total (n=388)**	
	(N)	**(%)**	**(N)**	**(%)**	**(N)**	**(%)**
Age group (years)						
≤ 25	3	7.5	37	92.5	40	100.0
26-35 years	11	13.9	68	86.1	79	100.0
36-45 years	20	13.2	132	86.8	152	100.0
46-55 years	11	13.1	73	86.9	84	100.0
More than 55 years	2	11.1	16	88.9	18	100.0
No response	0	0.0	15	100.0	15	100.0
Gender						
Male	20	8.9	204	91.1	224	100.0
Female	27	16.6	136	83.4	163	100.0
Third Gender	0	0.0	1	100.0	1	100.0
Residence						

The COVID-19 positive status of the participants and place of HIV diagnosis showed that most of the participants who had COVID-19 infection were diagnosed at government

Inside Kathmandu valley	47	13.5	302	86.5	349	100.0
Outside Kathmandu valley	0	0.0	39	100.0	39	100.0
Marital status						
Married	35	12.3	250	87.7	285	100.0
Unmarried	7	11.1	56	88.9	63	100.0
Separated	1	6.3	15	93.8	16	100.0
Single/widowed	3	13.6	19	86.4	22	100.0
Other (living together)	1	100.0	0	0.0	1	100.0
No response	0	0.00	1	100.0	1	100.0
Education						
Illiterate	4	8.9	41	91.1	45	100.0
Primary (1-5)	14	17.9	64	82.1	78	100.0
Lower Secondary (6-8)	11	14.3	66	85.7	77	100.0
Secondary (9-10)	7	7.7	84	92.3	91	100.0
Higher Secondary (11-12)	6	9.1	60	90.9	66	100.0
Bachelors and above	3	16.7	15	83.3	18	100.0
No response	2	15.4	11	84.6	13	100.0
Occupation						
None	5	8.8	52	91.2	57	100.0
Service (private/government)	19	14.0	117	86.0	136	100.0
Business	5	9.1	50	90.9	55	100.0
Housewife	10	25.0	30	75.0	40	100.0
Agriculture	0	0.0	10	100.0	10	100.0
Daily wage/labor	2	5.1	37	94.9	39	100.0
Student	3	27.3	8	72.7	11	100.0
No response	3	7.5	37	92.5	40	100.0
Employment status						
Employed	26	10.8	214	89.2	240	100.0
Unemployed	18	16.7	90	83.3	108	100.0
No response	3	7.5	37	92.5	37	100.0

hospital.

COVID-19 positive was found higher (18.4%) among the participants who had no multiple months dispensing of ART. Likewise, maximum number of participants visited by health workers had COVID-19 positive result (Table 8).

Table 8: COVID-19 status according to PLHIV and ART related characteristics

Variables	**Positive (n=47)**		**Negative (n=341)**		**Total (n=388)**	
	N	**%**	**N**	**%**	**N**	**%**
Place of HIV diagnosis						

Government	41	13.6	260	86.4	301	100.0
Private	1	3.7	26	96.3	27	100.0
NGO	2	4.0	48	96.0	50	100.0
No response	3	30.0	7	70.0	10	100.0
HIV diagnosis (in years ago)						
Within 2 years of the survey	2	2.6	74	97.4	76	100.0
2-5 years ago	9	12.3	64	87.7	73	100.0
6-10 years ago	16	17.8	74	82.2	90	100.0
More than 10 years ago	12	9.4	115	90.6	127	100.0
Don’t know	1	100.0	0	0.0	1	100.0
No response	7	33.3	14	66.7	21	100.0
ART initiation time (in years ago)						
Within 2 years of the survey	3	3.4	85	96.6	88	100.0
2-5 years ago	11	13.6	70	86.4	81	100.0
6-10 years ago	15	14.3	90	85.7	105	100.0
More than 10 years ago	15	15.6	81	84.4	96	100.0
Don’t know	0	0.0	3	100.0	3	100.0
No response	3	20.0	12	80.0	15	100.0
ART started time before/during COVID-19						
ART started after COVID-19	1	1.8	55	98.2	56	100.0
ART started before COVID-19	43	13.7	271	86.3	314	100.0
Don’t know	0	0.0	3	100.0	3	100.0
No response	3	20.0	12	80.0	15	100.0
Received multiple months dispensing of ART						
Yes	38	11.3	298	88.7	336	100.0
No	9	18.4	40	81.6	49	100.0
No response	0	0.0	3	100.0	3	100.0
PLHIV who received ART from health worker at house						
Yes	37	18.2	166	81.8	203	100.0
No	9	5.0	170	95.0	179	100.0
No response	1	16.7	5	83.3	6	100.0
Number of times of health workers visiting House						
1	8	10.7	67	89.3	75	100.0
2	11	17.5	52	82.5	63	100.0
3 and more	17	27.0	46	73.0	63	100.0
No response	1	50.0	1	50.0	2	100.0

Multivariate analysis (Table 9) was carried out for the selected independent variables with

dependent variable COVID-19 positive PLHIV. Compared to ≤ 25 years age group, it was found that other age group had comparatively higher COVID-19 positive cases but no significant relationship was observed. Compared to the male the odds of having COVID-19 positive among female was 1.43 (0.62-3.28). Though significance was seen in bivariate analysis it was not found significant in multivariate analysis.

Married participants as compared to those who were unmarried, separated, single and living together, the chances of having COVID-19 was slightly higher, but no significant relationship was found. Those who were employed had less odds of having COVID-19 as compared to unemployed. As compared to illiterate participants, the chance of having COVID-19 was higher among those who had primary, lower secondary and higher secondary education in contrast the chances were lower among those who had secondary education.

Table 9: Bivariate and multivariate analysis of COVID-19 positive participants with background characteristics of the respondents

Variables	**Crude OR**	**Adjusted OR**
	OR (CI)	**OR (CI)**
Age group (years)		
≤ 25	1.00	1.00
26-35 years	1.96 (0.52-7.60)	1.15 (0.21-6.49)
36-45 years	1.87 (0.53-6.64)	1.08 (0.19-6.37)
46-55 years	1.86 (0.49-7.07)	1.11 (0.17-7.28)
More than 55 years	1.54 (0.24-10.13)	1.52 (0.14-16.47)
Gender		
Male	1.00	1.00
Female	2.03* (1.09-3.76)	1.43 (0.62-3.28)
Marital status		
Married	1.00	1.00
Unmarried	1.12 (0.47-2.56)	0.61 (0.18-2.10)
Separated/Single/Other	1.18 (0.35-4.00)	0.43 (0.08-2.44)

Education		
Illiterate	1.00	1.00
Primary (1-5)	2.24 (0.69-7.26)	1.66 (0.40-6.98)
Lower Secondary (6-8)	1.71 (0.51-5.72)	1.81 (0.40-8.08)
Secondary (9-10)	0.85 (0.26-3.08)	0.73 (0.15-3.57)
Higher Secondary (11-12) and above	1.23 (0.36-4.24)	1.23 (0.25-6.02)
Employment status		
Employed	0.61 (0.32-1.16)	0.63 (0.28-1.41)
Unemployed	1.00	1.00
Received multiple doses of ART		
No	1.00	1.00
Yes	0.57 (0.26-1.26)	0.31* (0.10-0.92)
House Visit ART		
No	1.00	1.00
Yes	4.21*** (1.97-8.99)	5.70***(2.25-14.47)
ART initiation time (in years ago)		
Within 2 years	1.00	1.00
2-5 years ago	4.45* (1.19-16.59)	4.88* (1.22-19.59)
6-10 years ago	4.72* (1.32-16.89)	4.01* (1.01-15.86)
More than 10 years ago	5.25* (1.46-18.80)	3.88 (0.95-15.74)

*Abbreviation: OR- Odds Ratio, CI- Confidence Interval, * P<0.05, **P<0.01, ***P<0.001*
Dependent variable: PLHIV having positive COVID-19 status.
Note: No response variables and those categories in the variables having "zero" for the positive cases were not included in the bivariate and multivariate analysis to compute the Odds Ratio. Some of the variables have been recoded.
Note: Due to auto correlation (>0.45) between HIV diagnoses (in years ago), ART initiation time (in years ago) and ART started time before/during COVID-19. ART started time before/during COVID-19 was only included in the bivariate and multivariate analysis.

Discussion

ART sites from Kathmandu valley were selected for the study as there had been the highest number of registered PLHIV. This study found that the mean age of survey participants was 40±10 years, in contrast, mean age was more than this in a study conducted by Gervasoni et al (2020). The female participants were also in significant proportion in this study.

This study found that 12% of PLHIV participating in the study had positive COVID-19 test result. According to the records of ART sites, the prevalence rate of COVID-19 among PLHIV was 1.6%. The nationwide prevalence of COVID-19 in Nepal is around 3.3% (MoHP 2022). This indicates that the burden of COVID-19 among PLHIV is relatively less as than compared to general population. The studies conducted by Del Amo et al. (2020), Vizcarra et al. (2020), Huang etal. (2020), and H€arter et al. (2020), also reported less prevalence of COVID-19 among PLHIV. The study conducted in USA by Park et al. (2020) found similar prevalence rate of COVID 19 among PLHIV as to our study. Meta-analysis article published in Scientific Reports by Ssentongo et al., (2021) revealed significantly high morbidity and mortality from COVID-19 among HIV positive persons. Advanced disease, low CD4 count, chronic conditions associated with HIV are related factors for high morbidity of COVID-19 among PLHIV. The beneficial effects of tenefovir and protease inhibitors remain inconclusive.

In our study the percentage of death among PLHIV due to COVID-19 was 0.068 and case fatality rate as 4.2%. Although there were only 3 deaths in our study, CFR among PLHIV due to COVID-19 was comparatively higher than the national CFR (1.2%). The study conducted in UK revealed that PLHIV had higher risk of COVID-19 deaths than those without HIV (Bhaskaran et al., 2021). All three death cases were male which cannot be explained by limited data.

Among the COVID-19 positive individual's majority of them had experienced symptoms. The common symptoms according to retrospective reports of participants were fever, cough/common-cold, body pain, chest pain and headache. Studies conducted in India revealed that a similar clinical and epidemiological profile of COVID-19 among PLHIV with other group of people (Patel et al, 2021; Pujari et al, 2021; Huang et al., 2020). In our study we have not captured data based on WHO criteria. However we have information on appearance of symptoms, hospitalizations, oxygen required, ICU admission and ventilator support. The findings of our study showed that slightly higher rates of hospitalization and admission to ICU among COVID-19 positive patients with HIV; however, none of them required ventilator support. The study conducted by Nagarakanti et al., 2021 revealed that 9% of PLHIV with COVID-19 required ICU and 9% of them required ventilator support.

The age wise distribution of the participants showed that majority of PLHIV were in the age group 36-45 years followed by 46-55 years and 26-35 years. Regarding the age of the individual and COVID-19 positive status, the present study showed insignificant relationship. However, a study conducted by Hoffmann et al. (2021) showed significant relationship between 50 years or older population and COVID-19.

This study revealed that COVID-19 was almost double among females as compared to males. However, other studies by Hoffmann et al. (2020), Sigel et al. (2020), Vizcarra et al. (2020), Dandachi D et al.(2020), and H€arter et al. (2020) revealed that COVID-19 was seen higher among the males then females.

The reported mean duration of illness by PLHIV with COVID-19 was 13 days, in some cases up to 60 days. The mean duration of illness is similar with general population. A study conducted by Huang et al. (2020), reported that confirmed COVID-19 cases in PLHIV can shed virus up to 30 days.

According to the reports of ART focal persons, "diagnosis of HIV was done early and medicine was kept in stock by ART sites" during the COVID-19 pandemic. In contrast to this statement, few of the PLHIV reported that they had to interrupt ART treatment (6.7%) and faced shortage of drugs (4.9%) at the time of COVID-19.

A total of 640 new cases of HIV minimum-0, maximum-307 cases were diagnosed in seven ART sites from initiation of COVID-19 up to the time of data collection (December 2021). Before COVID-19 pandemic, these seven sites had cumulative total of 3612 HIV cases with minimum-1 to maximum-1997 cases. We did not collect the data on the number of follow-up test of PLHIV canceled due to COVID-19.

ART sites practiced multiple months dispensing of ART to their registered PLHIV. Although,

we have not assessed the acceptability of this practice, but there was high acceptance of multi-month dispensing (MMD) and community-based services support provided by health workers in India (Pollard et al, 2021). Strong monitoring mechanism should be in place in case of supply of multiple months dispensing of antiretroviral drugs during emergency. This can be done through proper counseling, follow up telephone calls or visit by health workers to ensure compliance.

Response by National Center for AIDS and STD Control (NCASC) was found satisfactory during the COVID-19 pandemic; NCASC was able to supply all the HIV commodities to the ART centers during this period. However, prevention programs were unable to reach key populations.

Limitations

- Although all 8 ART sites within Kathmandu valley were originally planned to be included in the study; however, TUTH could not be included and during the time of study no individuals were tested of COVID-19 in Kanti Children Hospital ART site.
- Our study focused only on ART sites, but there could be deaths of PLHIV due to COVID-19 in the community. Some of such deaths might be unreported to ART sites.

Conclusion and Recommendations

There was no high burden of COVID-19 among PLHIV. COVID-19 infection rate was higher in 25-40 years aged PLHIV, similar to other population, but it was not statistically significant. COVID-19 infection rate was significantly higher in females than males. The mortality rate was 0.068% among all the PLHIV registered at 7 ART sites of Kathmandu valley, which is less than the other population. CFR due to COVID-19 (4.2%) was found to be higher than that of the other population (1.2%). Duration of recovery from COVID-19 in PLHIV was similar to other population. High proportion of PLHIV (84.1%) received multiple months dispensing of ART during the time of COVID-19. Very less proportion of PLHIV (7.6%) had to cancel ART appointment due to COVID-19. Health care services at ART sites were continued, HIV commodities were supplied continuously whereas public health services at communities were interrupted.

The following recommendations have been made from the study

- Programme directed to protect PLHIV from COVID-19 infection need to be initiated since the fatality rate is high among PLHIV.
- Specific measures should be taken in order to continue ART as essential health service in emergency so that immunocompromised PLHIV would be least affected by the pandemics.
- Strong monitoring mechanism should be in place in case of supply of multiple months dispensing of antiretroviral drugs during emergency. This can be done through proper counseling, follow up telephone calls or visit by health workers to ensure compliance.
- Measures to ensure continued public health services to the community should be taken using universal prevention measures.

- Further research is required to investigate high case fatality rate among PLHIV and high rate of COVID-19 among female than male.

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Appendix-I
Ethical Approval

Government of Nepal
Nepal Health Research Council (NHRC)
Estd. 1991

Ref. No.: 322

Date: 24 August 2021

Dr. Megha Raj Banjara
Principal Investigator
Tribhuvan University, Kathmandu

Ref: Approval of research proposal

Dear Dr. Banjara,

This is to certify that the following protocol and related documents have been reviewed and granted approval by the Expedited Review Sub-Committee for implementation.

ERB Protocol Registration No./ Submitted Date	462/2021 P 28 July 2021	**Sponsor Protocol No**	NA
Principal Investigator/s	Dr. Megha Raj Banjara	**Sponsor Institution**	SAARC Tuberculosis and HIV/AIDS Center (STAC)
Title	Morbidity and mortality related to COVID-19 among HIV infected individuals in selected ART sites of Kathmandu valley		
Protocol Version No	NA	**Version Date**	NA
Other Documents	1. Data collection tools 2. Acceptance letter from the study site 3. Donor agreement letter	**Risk Category**	Minimal risk
Study Team Member	1. Dr. Bikash Lamichhane 2. Dr. Bhim Acharya 3. Ms. Shweta Rawal 4. Mr. Prithutam Bhattarai 5. Mr. Rishav Pokharel		
Expedited Review	Proposal √ Amendment Re-submitted **Meeting Date:** 12 August 2021	**Duration of Approval** 24 August 2021 to 24 August 2022	**Frequency of continuing review**

Tel: +977 1 4254220, Fax: +977 1 4262469, Ramshah Path, PO Box: 7626, Kathmandu, Nepal
Website: http://www.nhrc.gov.np, E-mail: nhrc@nhrc.gov.np

Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 322

Total budget of research	**NRs 9,01,900.00**
Ethical review processing fee	**NRs 10,000.00**

Investigator Responsibilities :

- Any amendments shall be approved from the ERB before implementing them
- Submit progress report every 3 months
- Submit final report after completion of protocol procedures at the study site
- Report protocol deviation / violation within 7 days
- Comply with all relevant international and NHRC guidelines
- Abide by the principles of Good Clinical Practice and ethical conduct of the research

If you have any questions, please contact the Ethical Review M & E Section at NHRC.

Thanking you,

Dr. Pradip Gyanwali
Member Secretary
(Executive Chief)

Tel: +977 1 4254220, Fax: +977 1 4262469, Ramshah Path, PO Box: 7626, Kathmandu, Nepal
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Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 1462

15 December 2021

Dr. Megha Raj Banjara
Principal Investigator
Tribhuvan University

Subject: **Approval of requested Amendment for a** study entitled **Morbidity and mortality related to COVID-19 among HIV infected individuals in selected ART sites of Kathmandu Valley (Reg no. 462/2021, Approved on 12 August 2021)**

Dear Dr. Banjara,

The meeting of the Expedited Review Sub-Committee of Nepal Health Research Council held on 10 December 2021 discussed the amendment requested on 25 November 2021. The meeting has approved the amendment to remove Tribhuvan University Teaching Hospital (TUTH) as one of the study sites as data could not be collected from the site because of low number of patients attending in TUTH during data collection period.

If you have any queries, please feel free to contact the Ethical Review M & E Section of NHRC.

Thanking you!

Dr. Pradip Gyanwali
Member Secretary

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Appendix-III
Letter of Support from NCASC

Government of Nepal
Ministry of Health and Population
National Centre for AIDS & STD Control

4261653
4262753
4258219
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Email: ncasc@ncasc.gov.np
Website: www.ncasc.gov.np
Taku, Kathmandu, Nepal

Ref. No. : 078/79/99

Date: 24th August, 2021

To whom it may concern

This is to inform that NCASC has no objection in study titled " Morbidity and mortality related to COVID-19 among HIV infected individuals in selected ART sites of Kathmandu Valley" conducted by SAIFRN-Nepal in close collaboration with SAARC Tuberculosis Research Center (STAC) and National Centre for AIDS and STD control (NCASC).

Dr. Sudha Devkota
Director

"ASSESSMENT OF NUTRITIONAL STATUS OF THE PULMONARY TB PATIENTS WHO HAVE RECEIVED NIKSHAY POSHAN YOJANA SCHEME RESIDING IN RAMANAGARA DISTRICT, INDIA BY USING N-TB MOBILE APPLICATION- A CROSS-SECTIONAL STUDY"

“ASSESSMENT OF NUTRITIONAL STATUS OF THE PULMONARY TB PATIENTS WHO HAVE RECEIVED NIKSHAY POSHAN YOJANA SCHEME RESIDING IN RAMANAGARA DISTRICT, INDIA BY USING N-TB MOBILE APPLICATION- A CROSS-SECTIONAL STUDY”

FINAL REPORT

This report is prepared by:

Principle Investigator	**Dr Santosh K. Yatnatti** Assistant Professor Department of Community Medicine CDSIMER, Karnataka
Co-investigators	**Dr Sanjay Kumar Mattoo** Jt Dir (Sr CMO-NFSG), Central TB Division, Ministry of HFW / Dte.GHS, Govt. of India
	Dr Manasa A. R. Assistant Professor Department of Community Medicine CDSIMER, Karnataka
	Dr Sushma J. Senior Resident Department of Community Medicine CDSIMER, Karnataka
	Dr Kumar K. District Tuberculosis Officer Ramanagara District
Project Mentor	**Dr Sharath B. N.** Chairman State TB OR Cell Karnataka & Professor, Department of Community Medicine ESIC Medical College, Bangalore
Technical Assistance	**Dr Shazia Anjum** Medical Consultant Karnataka State HQ World Health Organization NTEP Technical Support Network

ACKNOWLEDGEMENTS:

We would like to wholeheartedly thank the Director and the entire team at STAC (SAARC Tuberculosis and HIV/AIDS Centre) for providing us the opportunity and for funding this project. We would also take this opportunity to thank Dr. Sudarshan Mandal, Deputy Director General, Head Central TB Division, Project Director, NTEP Government of India and the whole Central TB division team of Government of India for their constant support and providing the Letter of Support without which we could not have applied for the SAARC TB project. We would also like to thank our respected Chairman Dr Hemachandra Sagar, Vice- Chairman Dr Premachandra Sagar, CDSIMER, Dayanand Sagar University for their vision and support. We would also like to thank The Principal and Dean, Dr A. C. Ashok, Special Officer, Dr Madan S. Gaikwad, Medical Director Dr Rajagopalan S, of CDSIMER, Dayanand Sagar University for their encouragement. We would also like to thank Dr M Sundar, Head of the department and to all the faculty, of department of Community Medicine, CDSIMER for their co-operation. We would like to thank the chairman's and the team of Institutional Scientific Committee and Institutional Ethical Committee for their support. We would also like to thank Dr. K.T. Venkatesh Murthy and Dr. Manju Prakash for helping us out with translation and back translation of the questionnaires, informed consent form and participation information sheet. We thank our project Statistician, Mr. Narayanaswamy D. M. for timely support and coordination. We also want to thank Mr. Venkat Raju, account manager and Mr. Manjunath, IT support officer, CDSIMER for there contribution. We extend our thanks to our data collectors, Mrs. Kavya.S, Mr. Puneeth S. K, and Mr. A.C. Keerthiraj. We would also like to thank Mr. Shivashekar STS Kanakapura, Mr. Lokesh, Senior Health Inspector Kanakapura, Mr. Shreenivash, STS Ramanagara, Mr. Shekar TBHV Ramanagara, Mr. Krishnegowda, SHI Ramanagara, Mr. Lakshmeesh, STS Channapattana, Mr. Dhananjay. TBHV Channapattana TU, Mr. Lingaraju, SHI Channapattana TU, Mr. Girish STLS Channapattana TU,Mr. Shivanna STS MAGADI TU, Shivakumar SHI MAGADI. TU, Mr. Pramod STS Harohalli TU, Mr. Siril DPC, Ramanagara DTO OFFICE, Mrs PAVITRA, Data Entry operator, Ramanagara office, Mr. Shivananjaiah TB/HIV Supervisor, Ramanagara, Mr. Nagaraj STLS Kanakapura for helping us in data collection, mobilising the study participants, helping to arrange the venue thereby contributing for the successful completion of this project.

CONTENTS

List of Abbreviations

AFB	Acid Fast Bacilli
ANC	Antenatal Case
ASHA	Accredited Social Health Activist

BMI	Body Mass Index
CBNAAT	Cartridge Based Nucleic Acid Amplification Test
CDSIMER	Dr Chandramma Dayanand Sagar Institute of Medical Education and Research Centre
CI	Confidence Interval
COVID-19	Corona Virus Disease
DBT	Direct Benefit Transfer
DMC	Designated Microscopic Centre
DOTS	Directly Observed Treatment Short course
DRTB	Drug Resistant Tuberculosis
DTO	District Tuberculosis Officer
HIV	Human Immunodeficiency Virus
IEC	**Institutional Ethics Committee**
IQR	Inter-quartile Range
MTB	Mycobacterium Tuberculosis
NPY	Nikshay Poshan Yojana
NTEP	National Tuberculosis Elimination Program
PPPS	Probability Proportion to Population Size
RNTCP	Revised National Tuberculosis Control Program
RR	Relative Risk
SD	Standard Deviation
SES	Socio-Economic Status
SHI	Senior Health Inspector
SPSS	Statistical Package for the Social Sciences
STLS	Senior Tuberculosis Laboratory Supervisor
STS	Senior Treatment Supervisor
TBHV	Tuberculosis Health Visitor
TU	Tuberculosis Unit
UHTC	Urban Health and Training Centre
WHO	World Health Organization

EXECUTIVE SUMMARY

Every year, millions of people fall sick with tuberculosis. India is one of the WHO's list of 30 high TB burden countries which accounts for 87% of the world's cases. Role of nutrition in the cure of tuberculosis has been long proved. Gap between the expected proportion of successful TB outcome and the actual number could be due to many reasons, one of which could be the ineffective assessment of nutritional status of these patients.

Global efforts to combat TB have led to witness various strategies and innovations accelerating the process towards eliminating TB. One such initiative by the government of India is the provision of nutritional support to the individuals affected with TB disease, which was named as Nikshay Poshan Yojana (NPY). Though NPY scheme was started in April 2018 providing monthly financial incentive for nutritional support, there is a need to assess the utilization pattern of this amount received. At the same time, it is very essential to regularly assess the nutritional status of these patients to guide & counsel them on the quality and quantity of nutritional requirement to fasten their recovery. This was identified as a key area to explore in our present study.

We conducted a cross sectional study with an objective to assess the nutritional status of TB patients using N-TB application. N-TB mobile application was launched in coordination with WHO, RNTCP and Yeneopya University to simplify nutritional assessment by calculating BMI using height and weight of the patients and also for counselling and care of patients with tuberculosis in India. Another objective of our study was to determine the factors associated with utilization pattern of Nikshay Poshan Yojana. A total of 270 patients with pulmonary TB who had received incentives for all 6 months were included in the study. Representative sample from all five TB units of Ramanagara district were considered. Our results revealed that among 143 underweight study subjects at the time of diagnosis, 31.5% (45) attained normal BMI, and 1.4% (2) became overweight, while the majority 67.1% (96) remained underweight at the end of 6 months of treatment. It was found that there was statistically significant association between nutritional status at the end of 6 months and age group, gender, marital status and presence of co-morbidity. However, there was no statistically significant association between education, religion, family size, socio-economic status, history of Covid infection and previous history of TB. We emphasize on the timely delivery of NPY before declaration of treatment outcome so that we will be able to better appreciate the improved nutritional status. Periodic nutritional assessment coupled with nutritional counseling of TB patients will further increase favorable treatment outcomes. In addition, implementation of effective communication skills in managing TB patients will contribute to successful elimination of TB.

1. TITLE OF THE RESEARCH PROPOSAL:

"Assessment of nutritional status of the pulmonary TB patients who have received Nikshay Poshan Yojana scheme residing in Ramanagara district, India by using N-TB mobile application- A cross-sectional study"

2. INTRODUCTION/BACKGROUND:

Tuberculosis is a curable and preventable disease yet continues to be one among the leading top 10 causes of death worldwide. The burden has further been aggravated with the emerging COVID-19 pandemic. An estimated 10 million people fell ill with TB in 2020 according to Global Tuberculosis Report 2021. India being the TB capital of the world with 26% of the global TB population poses similar challenges faced by the developing countries. India is committed to achieve TB elimination by 2025. (1,2) Pulmonary tuberculosis is the most common type of TB and constitutes 72% of all TB cases

in India and 68% in Karnataka. (3) About 85% of people who develop TB disease can be successfully treated with a 6-month drug regimen. Already cured or patients who have completed treatment are also at the risk of contracting infection in future. (2) The prevalence of TB in developed countries is declining due to better living and economic conditions, whereas the developing countries still continue to thrive with TB disease due to many factors like catastrophic expenditure, under nutrition, vulnerable populations, associated co- morbid conditions etc. (4,5) The estimated numbers of cases attributable to undernutrition alone was 2.2 million. (6) Undernutrition is a risk factor for development of latent TB infection into active TB disease and also escalates malnutrition. (7) WHO has made nutrition screening, assessment and management as integral components of TB treatment and care because of the clear bidirectional causal link between undernutrition and active TB. (1) The role of a nutritious diet is imperative in the fight against TB. In fact, in most TB cases the patient is either very weak or extremely poor to afford a diet rich in nutrients. (8,9) Nutritional supplementation in TB patients has shown good outcomes with respect to sputum conversion rates, higher cure and completion rates and better outcomes. (10) In 2018, India came up with "Nikshay Poshan Yojana" (NPY)a scheme to meet the nutritional requirements of TB patients it is one of the DBT schemes of NTEP. (6,7,10,11) This is a direct benefit scheme, wherein all the TB patients (Drug sensitive and Drug Resistant TB) are provided with a benefit of cash of INR 500(≈ USD 8) per month

for complete treatment period. The beneficiary will receive the benefit directly electronically to their respective bank accounts. Along with social protection and nutritional support, the main focus of the NPY is to help the TB patients to complete their treatment. (12) Karnataka, a south Indian state started to implement this since 2018 along with other states of India and the details are being updated in NIKSHAY, an online portal database of the TB patients in India. (6,7,10,11) 62% of eligible beneficiaries in India have been benefitted by NPY, whereas in Karnataka it is 74%.

(3) At the same time in 2018. N-TB mobile application was launched in coordination with WHO, RNTCP and Yeneopya University to simplify nutritional assessment, counselling and care of patients with tuberculosis in India. (13) However, as per the knowledge of the investigators NTB application is not being utilized for assessing the nutritional status of TB patients in Ramanagara district and there are limited studies which has assessed the nutritional status of the TB patients post Nikshay Poshan Yojana scheme utilization.

3. REVIEW OF LITREATURE:

TB and Malnutrition

In a study among 1,717,655 Norwegians, individuals >15-years old were followed for 8– 19 years as part of a radiographic screening program. The relative risk of tuberculosis among persons in the lowest body mass index (BMI) category was found to be more than five-fold higher than the group in the highest BMI category, and it was independent of sex, age and radiographic findings. (16) In another study, it was noted that tuberculosis patients were respectively 11 and 7 times more likely to have a BMI <18.5 and mid-arm circumference < 24 cm. (17)

A study by Paton et al. found that nutritional counseling with provision of supplements when started during the initial phase of tuberculosis treatment, produced a significant increase in body weight, total lean mass and physical function after six weeks thus indicating that nutritional supplementation may help to improve outcome in tuberculosis patients. (18)

It has been documented that body weight in patients with tuberculosis acts as a predictor of response to treatment and the patients who were underweight during the course of disease are expected to gain weight during successful treatment. Possible association between weight changes during treatment and treatment outcome has been investigated in a study conducted by Khajedaluee, M et al in Iran. The impact of weight changes during treatment was compared in patients whose outcomes were declared as cured, completed treatment, treatment failure and death and the differences were statistically significant between the four groups ($p < 0.03$). (19)

In a report from Chattisgarh state among 1695 adult pulmonary TB patients, 90 per cent were found to have some degree of undernutrition. At diagnosis, majority of patients (80% women and 67% men) had evidence of severe chronic undernutrition. Half of men had weight less than 42 kgs while majority of the women were less than 34 kgs. Many patients had levels of undernutrition that were incompatible with life. Nearly half of the women had severe undernutrition at the end of treatment. Moreover, severe undernutrition at diagnosis was shown to be associated with a 2-fold increased risk of death. (14) Studies have also shown that patients with a poor nutritional status at the end of treatment are likely to have poor performance status because of poor muscle strength with an increased risk of TB relapse after completion of therapy. (15)

According to India Tuberculosis Report 2021, the risk of Tuberculosis increases by about 14% for each unit reduction in BMI and the risk of recurrence is four times compared to those individuals with normal weight. It was also documented that only $1/3^{rd}$ of men and $1/4^{th}$ of women had normal range BMI after successful TB treatment. (3) Co-existence of Tuberculosis and under nutrition is observed in many parts of India among patients with active TB, especially those with pulmonary TB. (20)

NTB application

N-TB is a mobile-based application that has been developed by Yenepoya medical college in partnership with Government of India & World Health Organisation for assessing the nutritional status in the NTEP. Along with estimation of BMI, the app can also be used to classify the severity of undernutrition, thus easing the triage and clinical actions based on the BMI. The app also indicates desirable body weight corresponding to a BMI of 21 kg/m^2 and the daily caloric and protein intake for underweight patients with active TB. Dietary counseling for TB patients, information on the major food groups, emphasis an adequate and balanced diet from locally available foods for nutritional recovery of TB patients are some of the added benefits for the patients with TB, provided in the N-TB application. (13)

Nikshay Poshan Yojana: Implementation, challenges and utilization.

A study done by Abhay S et al. (4) titled 'I am on treatment since 5 months but I have not received any money': coverage, delays and implementation challenges of 'Direct Benefit Transfer' for tuberculosis patients – a mixed-methods study from South India, revealed that only 50% utilized the DBT scheme and the barriers to not utilizing these schemes included non-availability, rejection because the patient is rich, lack of knowledge and technical issues in the website portal.

A cross-sectional study was conducted by Rajesh Kumar et al among patients registered for TB treatment at Ladosarai and Mehrauli DOTS centre between July-September 2018 to explore the ways the incentives were utilised by the patients. All patients received their nutritional incentive during last months of continuous phase of treatment and therefore

reported its non-utilization during the course of treatment that could have attributed to the treatment outcome of these patients. (10)

J Begum et al., in their retrospective cross-sectional study conducted among TB patients reported that, only 68.2% of the TB patients that received direct benefit transfer (DBT) for nutritional support withdrew the money by themselves, 20% got it with the help of healthcare workers (ASHA) and 11.8% patients got it done by their spouse/father/family member. The majority (76%) of them spent the money on buying food for nutrition, while the rest 24% spent it on personal and family needs. However, the beneficiaries did not express satisfaction regarding the adequacy of the amount received to meet their nutritional requirements. The authors found a significant association of BMI and literacy with the utilization of scheme (P value < 0.05). But occupation, socio-economic status, age and gender

had no relation with the utilisation of the scheme. 91.5% of the beneficiaries were aware of the cash incentive given as per Nikshay Poshan Yojana, and those who were aware mostly got the information from the healthcare workers (84.3%), followed by neighbours (3.6%), friends & family (2.4%) and media (1.2%). Out of all the patients who were aware of the scheme, only 17 (22.4%) had their money deposited in their respective accounts and the rest 59 (77.6%) did not get any sort of money till the end of study period. The association between literacy status and utilization of the scheme in terms of knowledge about money deposition and using it for their nutrition was found statistically significant. (21)

Rohit et al., conducted a study among the patients that received cash incentive for nutrition under NPY scheme. 78.5% of them received at least one incentive of cash incentive. Among those received, the median (IQR) duration between treatment initiation and receipt of first incentive was 74 days (41–165). In 25.2% of the patients, the first incentive was received after ascertainment of their treatment outcome. (12)

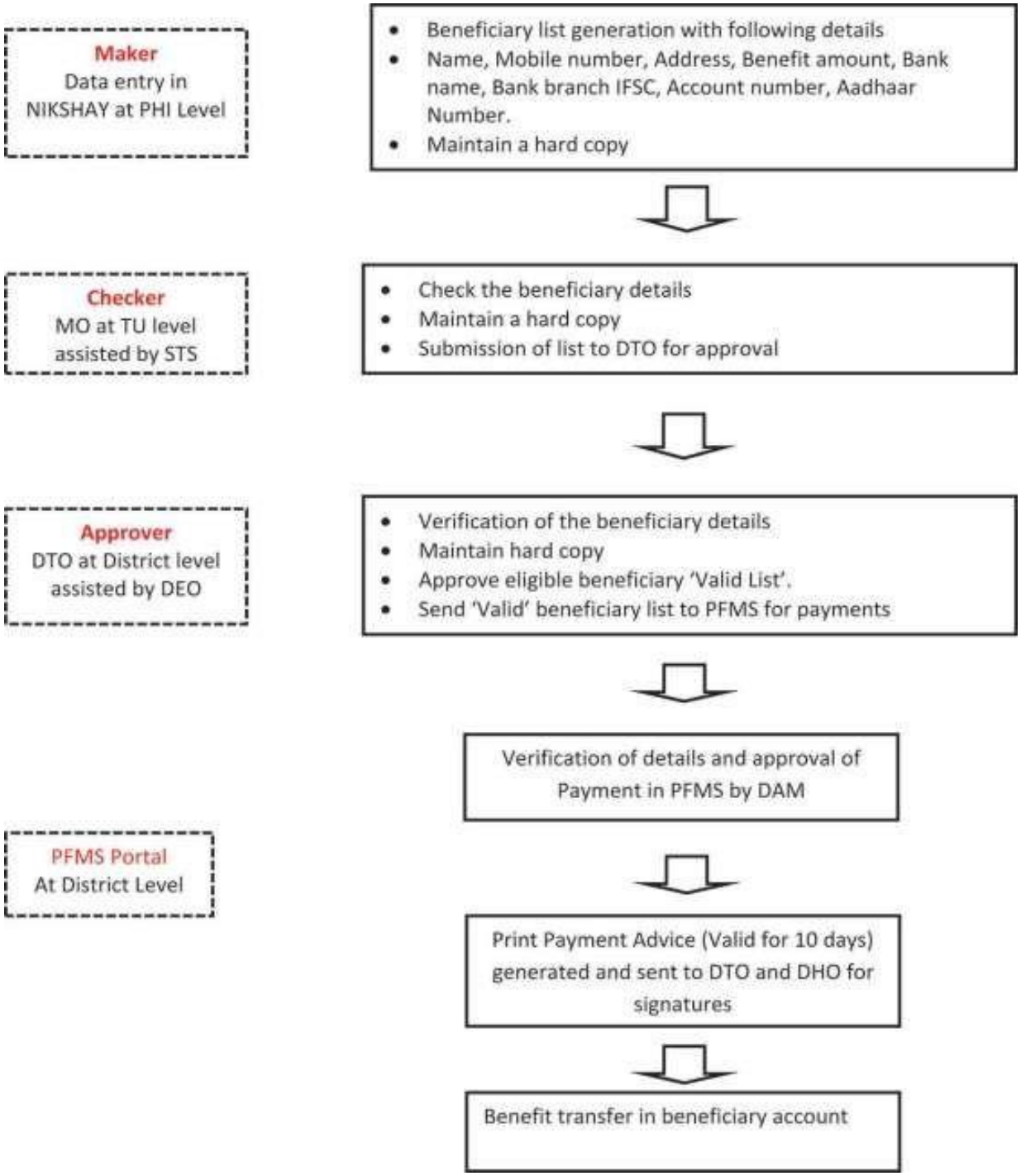
Another study was conducted by BH Patel et al., in Vadodara of western India to assess the coverage and to explore enablers and challenges in implementation of direct benefit transfer scheme for patients with tuberculosis. The study reported that 42.2% of the participants had received at least one incentive. Significantly more patients from the public sector had received DBT compared with those from private sector (adj RR=16.3; 95%CI 11.6 to 23.0). Among public sector patients, 7.3% (49/671) had received first incentive

within 2months of treatment initiation. Median (IQR) time of receipt of first incentive was
5.2 (3.4, 7.4) months. Treatment in private sector, residing outside city limits and being HIV non-reactive were significantly ($p<0.001$) associated with longer time to receive the incentive. The enabling factors for utilization of DBT scheme was availability of funds, human resource and logistics. However, the barriers were non availability of bank accounts, resistance to share personal information and decreased support from private treatment providers. (6)

A recent study by J D. Dave and M P. Rupani among 426 patients with drug-sensitive pulmonary TB to determine the association between non-receipt of DBT and unfavorable treatment outcomes reported that majority (91%) of the patients had successful treatment outcomes, 15% of patients were tobacco smokers, 26% were tobacco chewers, 5% consumed alcohol, 4% were HIV positive and 9% had diabetes. 46% received the first incentive late and 49% received the last incentive after their treatment

completion. Non- receipt of DBT, being unemployed and HIV positive status were significantly predicting unfavorable treatment outcomes. The study also revealed that most of the patients receiving DBT used it for its intended purpose, however, they felt that it was insufficient to cover the nutritional costs. The challenges on the DBT program as perceived by the NTEP functionaries was described in five categories such as improper bank account, delay in release of funds, patient factors and unintended use of the incentives. (22)

DBT Process: The process of transfer of incentive to the patient from the time of diagnosis is explained in the flow chart below:



4.HYPOTHESIS / RESEARCH QUESTION:

Is there any effect of NPY scheme on the nutritional status of the patients with pulmonary tuberculosis?

5. OBJECTIVES OF STUDY:

1) To determine the Proportion of pulmonary TB patients who utilized NPY scheme.

2) To assess the nutritional status of the pulmonary TB patients who utilized the NPY scheme using N-TB mobile application.

3) To determine the factors associated with utilization of NPY scheme and spending pattern of the amount received by the pulmonary TB patients.

6. METHODOLOGY:

6.1 Study design: A cross-sectional study

6.2 Study setting: Study was conducted in

Country: India

State: Karnataka- A southern state in India

District: Ramanagara- A Southern District in Karnataka

Sites: 5 Tuberculosis Units-Ramanagara, Harohalli, Channapattana, Kanakpura and Magadi

6.3 Study period: 6 Months (August 1st 2021– January 31st 2022)

6.4 Study population:

Pulmonary Tuberculosis patients who were residing in Ramanagara District was selected for the study.

Inclusion criteria: All notified Pulmonary TB patients who had utilized 6 incentives of NPY scheme irrespective of the outcome in 2020 financial year (1st April 2020 to March 31st 2021) was included. Only Pulmonary TB cases were taken because most of the cases will be cured within the period of 6 months. This will ensure homogenicity and make the comparison purpose easier.

Exclusion criteria: Those patients who were not willing to participate and were unable to comprehend & respond was excluded. Pediatric Pulmonary TB patients were excluded as the N-TB application is designed only for adult population. Pregnant and lactating mothers were excluded as the BMI cannot be taken into consideration as it is a physiological process. Also, DRTB patients and Extra pulmonary TB patients were

excluded from the study as the duration of the treatment and DBT benefit is variable.

6.5 Method of data collection:

Primary data: collected through interviewing the TB patients using the proforma

Secondary data: Patient data on DBT extracted from NIKSHAY portal and treatment cards of TB patients

The participants were explained about the nature and the purpose of the study and written informed consent was obtained prior to data collection.

6.6 Data collection tool

A predesigned, pretested semi-structural questionnaire was used to collect information from the study participant. The content validity of the study was measured by sharing the questionnaire with the subject-matter experts and then asking them to provide feedback on how well each question measures the construct in question. Their feedback was later analyzed and informed decisions was made about the effectiveness of each question. Pretesting was done by pilot study, translation and back translation by subject experts. Series of meetings were held between the experts, investigators and data collectors in order to finalize the questionnaire. The questionnaire consisted of six sections:

Section I: Comprised of questions related to socio-demographic details of the study subjects

Section II: Comprised of questions related to TB diagnostic details of the study subjects

Section III: Comprised of questions related to TB treatment adherence

Section IV: Comprised of questions related to Nutritional incentives received by the study subjects

Section V: Comprised of questions related to utilization pattern of the incentives received by the study subjects

Section VI: Comprised of questions related to nutritional assessment of the study subjects

Outcome/Exposure variables: Proportion of patients with pulmonary TB utilizing NPY scheme and their nutritional status.

6.7 Operational definition of certain terms used in the study

For purposes of this study, the following operational definitions had been adopted (23)

Pulmonary Tuberculosis patient:

Microbiologically confirmed TB:

Presumptive TB patient with biological specimen positive for AFB, or positive for MTB on culture, or positive for TB through Quality Assured Rapid Diagnostic molecular test.

Clinically diagnosed TB case:

Presumptive TB patient who is not microbiologically confirmed, but diagnosed with active TB by a clinician on the basis of X-ray, histopathology or clinical signs with a decisionto treat the patient with a full course of Anti-TB treatment.

Definitions and classification used for Occupation- International Standard Classification of Occupations (ISCO)

A *job* is defined in ISCO-08 as "a set of tasks and duties performed, or meant to be performed, by one person, including for an employer or in self-employment". *Occupation* refers to the kind of work performed in a job. The concept of *occupation* is defined as a "set of jobs whose main tasks and duties are characterized by a high degree of similarity". A person may be associated with an occupation through the main job currently held, a second job, a future job or a job previously held.
Skill is defined as the ability to carry out the tasks and duties of a given job. For the purposes of ISCO-08, two dimensions of skill are used to arrange occupations into groups. These are s*kill level* and s*kill specialization.*
Skill level is defined as a function of the complexity and range of tasks and duties to be performed in an occupation. Skill level is measured operationally by considering one or more of: the nature of the work performed in an occupation in relation to the characteristic tasks and duties defined for each ISCO-08 skill level;the level of formal education defined in terms of the International Standard Classification of Education (ISCED-97) (UNESCO, 1997) required for competent performance of the tasks and duties involved; and the amount of informal on-the-job training and/or previous experience in a related occupation required for competent performance of these tasks and duties.

Skill levels

Statistics by occupation are presented in ILOSTAT according to both the categories of the latest version of the ISCO available and broad skill levels, based on the following correspondence table:

Broad skill level	ISCO-08	ISCO-88
Skill levels 3 and 4 (hi	1. Managers	1. Legislators, senior officials and managers
	2. Professionals	2. Professionals
	3. Technicians and associate professionals	3. Technicians and associate professionals
Skill level 2 (medium)	4. Clerical support workers	4. Clerks
	5. Service and sales workers	5. Service workers and shop and market sale workers
	6. Skilled agricultural, forestry and fishery workers	6. Skilled agricultural and fishery workers
	7. Craft and related trades workers	7. Craft and related trades workers
	8. Plant and machine operators, and assemblers	8. Plant and machine operators and assemble
Skill level 1 (low)	9. Elementary occupations	9. Elementary occupations
Armed forces	0. Armed forces occupations	0. Armed forces
Not elsewhere classifi	X. Not elsewhere classified	X. Not elsewhere classified

Definitions and classification of Education

LITERACY STATUS[24]:

The maximum level of educational qualification attained was recorded and was defined as follows:

a. **Illiterate:** A person who could not read or write. This category also includes those who could only sign or reproduce some writing mechanically without any meaning.

b. **Primary School**: Those who had studied up to 4^{th} standard.

c. **Middle School:** Those who had studied from 5^{th} to 7^{th} standard.

d. **High School:** Those who had studied from 8^{th} to 10^{th} standard.

e. **Intermediate/Diploma:** A person who has studied 11^{th} and 12^{th} year of formal education referred to as Pre-university College in state board or A person who has completed a Diploma course in any field.

f. **Graduate:** A person who had obtained degree from any university.

g. **Postgraduate:** A person who had obtained postgraduate degree from any university.

6.8 Sample size:

Based on the utilization rate of NPY as 42.2% from a study done by Bharath Kumar H P et al.,(6) using the formula

$n=Z^2 pq/d^2$ where,

Z = relative deviate (1.96 at 95% confidence)

p = prevalence (42.2)

q = 100-p=100-42.2

= 57.8

d = Absolute precision =15%

n = 245

Considering a non-response rate of 10% the total calculated sample size will 245+25=**270.**

6.9 Process of selecting the cases:

Total number of patients who enrolled between April 2020 – March 2021

N= 999

Excluding:
1. Age < 18 yrs
2. Drug Resistant TB cases
3. Extrapulmonary cases
4. ANC cases

Those who received atleast one incentive

N= 660

Those who received 6 incentives/ 3000 rupees

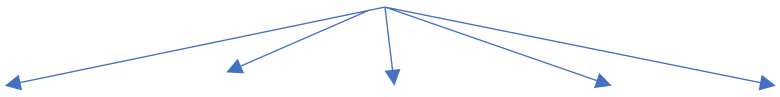
N= 536

Excluding:
1. Phone switched off/ Not reachable/ Wrong number [n=158 (70%)]
2. Patient not available [n=23 (10%)]
3. Patient not interested/ refused to participate [n=31 (14%)]
4. Did not turn up on the day of interview [n= 14 (6%)]

Study subjects who fulfilled the inclusion & exclusion criteria

N=304

Study subjects that were supposed to be selected according to PPPS from 5 different Talukas were N=270



Ramanagara	Channapatna	Kanakapura	Harohalli	Magadi
(n=84)	(n=62)	(n=54)	(n=35)	(n=35)

However, we could reach the following samples because there were many non- responders in other TUs. So we had to compensate from other available TUs.

Ramanagara	Channapatna	Kanakapura	Harohalli	Magadi
(n=86)	(n=49)	(n=72)	(n=30)	(n=33)

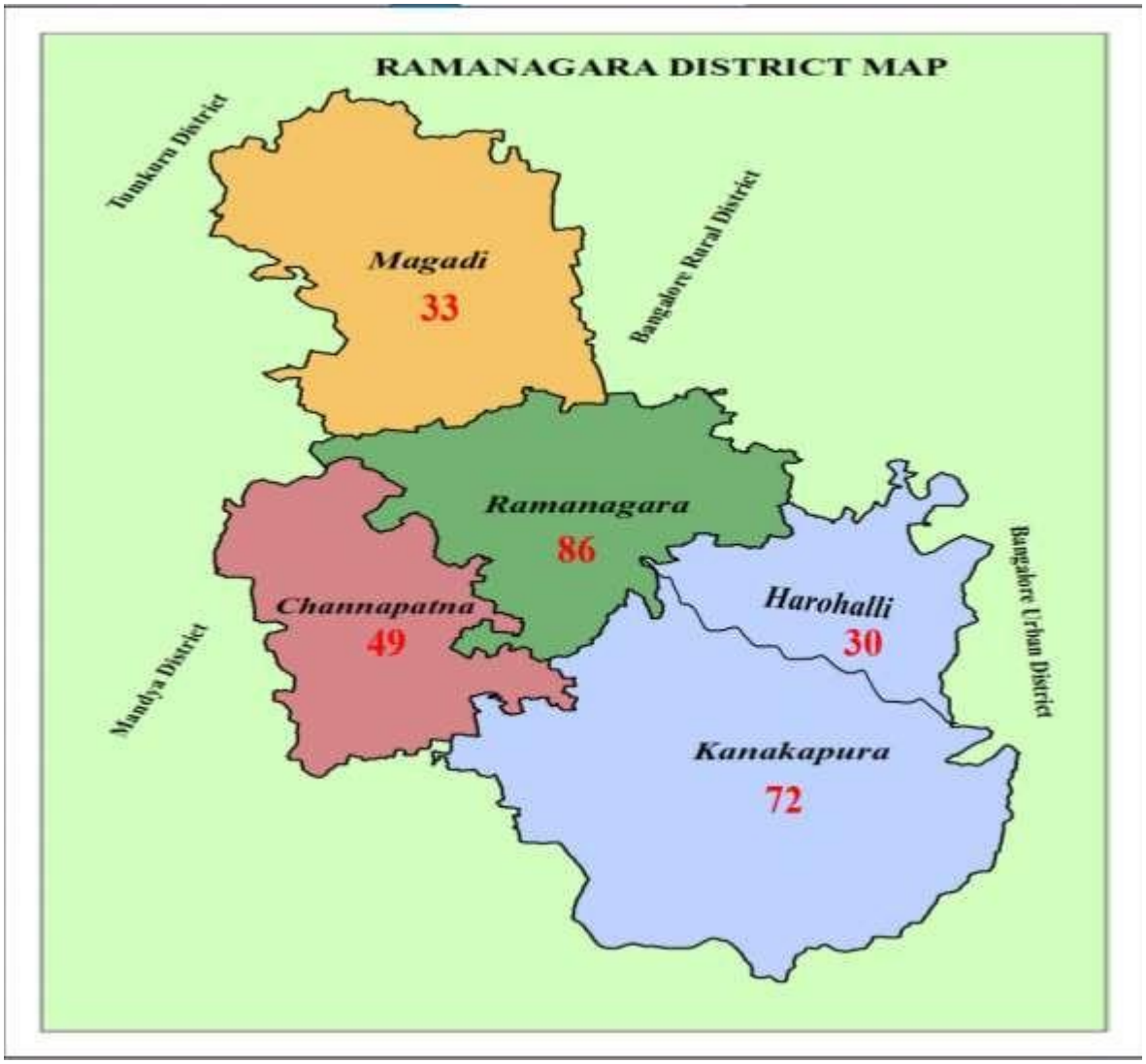


Figure 1: Ramanagara district map showing number of study subjects recruited in each taluka.

Data collection technique:

Initially, we had planned for door-to-door survey for collecting the data. However, during the pilot study, we found the following barriers:

1) Stigma about the disease among the study subjects

2) Study subjects did not want their family members, neighbors and friends to know about their disease.
3) They were interested to participate in the study but not at their homes.

Therefore, after doing the pilot study and consulting with the experts & district TB officials, we shifted the approach from door-to-door survey to camp approach.

The camp approach comprised of the following:

Step I: Collection of data, anthropometric measurements and distribution of study incentive by the data collectors & field investigators.

Step II: Medical examination by the Principal Investigator.

Step III: Health education talk by district TB staff and investigators of the study.

Figure 2, 3 & 4: Data collection, free health check-up and awareness talk on TB at UHTC, CDSIMER, Kanakapura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NATIONAL TB ELIMINATION PROGRAMME
Shot on OnePlus

Figure 5: Data collection at Ramanagara District Hospital

Figure 6 & 7: Data collection at Magadi government hospital

Figure 8 & 9: Data collection at Sri shakthi Bhavana, Channapatna

Figure 10 & 11: Meeting with Expert, Investigators and data collectors

6.10 Sampling:

a. **Sampling technique:** Study subjects were selected according to Probability Proportional to Population Size (PPPS) from 5 different Talukas – Ramanagara, Channapatna, Kanakapura, Harohalli & Magadi

b. **Details of clinical examination:** Not applicable. Only anthropometric measurements were done details in section 7.11.

c. **Validation study tool**: Pilot study was done to pretest and validate the questionnaire.

d. **Randomization**: Not applicable.

6.11 Anthropometric measurements:

We took the details of patient's weight at the time of diagnosis from their TB cards. 85% of them had their height details mentioned in the TB cards. For the rest of the participants, the height measured at the time of interview was considered.

Weight measurement

Weight was recorded using analogue weighing scale with accuracy up-to 100grams (Samso). The weighing machine was calibrated before start of each data collection session. The participant was made to stand still and upright with weight evenly distributed between two feet.

Height measurement

Height was measured using a wall mounted, easy-to-use and portable Staturemeter made of non-stretchable tape with an accuracy of 0.1 cm. It is mounted at a known height (200 centimeters) on the wall with a flat surface underneath. The participants were made to stand without the shoes on. Heels was slightly separated with weight borne evenly on both feet. Knees

straight with the back of head, shoulder blades, buttocks and heels were brought in contact with the wall and head in Frankfurt plane (the line joining floor of external auditory meatus to the lower margin of the orbit) and bi-auricular plane being horizontal. The horizontal blade of the staturemeter was then brought straight on the head and height was noted.

With the details of weight and height available at three different points (i.e., at the time of diagnosis, at the end of 6 months of treatment and at the time of diagnosis), N-TB mobile app was used to calculate BMI at the time of diagnosis, at the end of 6 months of treatment and at the time of interview as shown in the figure below to calculate BMI. (13)

Figure 12. Screenshots of the N-TB mobile application

6.12 ETHICAL ISSUES:

- Institutional ethical committee approval was obtained. **IEC No. CDSIMER/MR./0022/IEC/2021**

- The study subjects were telephonically informed about the study. They were free to discuss regarding their participation in the study with their family members and appropriate time slot were fixed according to the convenience of the participants. On the day of the data collection the study subjects were first explained about the study using participant information sheet and written informed consent was taken.

7. RESULTS

All the data collected were compiled and entered into a Microsoft Excel worksheet. The data

Descriptive statistics like Mean, SD, and Percentages were calculated.

To find the association between the attributes chi-square test is used, to find the significant change of variables due to intervention Wilcoxon signed-rank test is applied, and Friedman's test is applied to see the progress of BMI from diagnosis to at the time of interview.

The normality of the data was tested using Shapiro-Wilk test. The data was analyzed using Statistical software SPSS 20.0.

Table1: General Details of the study area

	No. of Study subjects	**Percent**
Informant – Self	270	100.0
Name of TU	**No. of Study subjects**	**Percent**
Ramanagara	86	31.9
Kanakapura	72	26.7
Channapatna	49	18.1
Magadi	33	12.2
Harohalli	30	11.1

All the information is collected through direct interviews of the study subjects of 270 sample size, the majority of the respondents were from Ramanagara TU 31.9% (86), followed by Kanakapura TU of 26.7% (72), and 18.1% (49) from Channapatna TU, 12.2% (33) from Magadi TU and 11.1% (30) from Harohalli TU.

Table 2: Age-Gender distribution of the study subjects

Age-Group (Years)	**Male**		**Female**		**Total**	
	n	**%**	**N**	**%**	**n**	**%**
18-20	5	2.6	7	9.3	12	4.4
21-30	13	6.7	21	28.0	34	12.6
31-40	34	17.4	19	25.3	53	19.6
41-50	40	20.5	16	21.3	56	20.7
51-60	49	25.1	8	10.7	57	21.1
61-70	41	21.0	4	5.3	45	16.7
71-80	12	6.2	0	0.0	12	4.4

≥ 81	1	0.5	0	0.0	1	0.4
Total	195	72.2	75	27.8	270	100.0
	Descriptive Statistics					
Min	Max	Mean	SD	Median	Mode	Q1-Q3
18	90	47.3	15.7	48	60	36-60

The majority of the individuals were in the age group of 51-60 21.1% (57), age-group of 41-50 years was 20.7% (56), and 31-40 years was 19.6% (53). With a median age of 48 years and interquartile range of (36-60) years. Among the respondents 72.2% (195) are males and 27.8%

(75) are females, majority of the males were in the age group of 51-60 years 25.1% (49) and the majority of the females were in the age group of 21-30 years 28% (21). Least number of study subjects were seen in the age group of ≥ 81 years in males i.e., 0.5% (1)

Table 3: Socio-demographic profile of the study subjects

Religion	**No. of Study Subjects**	**Percent**
Hindu	250	92.6
Muslim	19	7.0
Christian	1	0.4
Education*	**No. of Study Subjects**	**Percent**
Illiterate	115	42.6
Primary school certificate	35	13.0
Middle school certificate	30	11.1
High school certificate	58	21.5
Intermediate/Diploma	16	5.9
Graduate	16	5.9
Marital Status	**No. of Study Subjects**	**Percent**
Married	232	85.9
Unmarried	38	14.1
Occupation*	**No. of Study Subjects**	**Percent**
Unemployed	63	23.3
Clerks	2	0.7
Craft And Related Trade Workers	2	0.7

Elementary Occupation	20	7.4
Legislators, Senior Officials, Managers	1	0.4
Plant And Machine Operators and Assemblers	10	3.7
Professionals	1	0.4
Skilled Agricultural and Fishery Workers	109	40.4
Skilled Workers, Shop and Market Sales Worker	58	21.5
Technicians And Associate Professionals	4	1.5
No. of People in the Family	**No. of Study Subjects**	**Percent**
≤ 4	188	69.6
≥ 5	82	30.4
Socio Economic Status	**No. of Study Subjects**	**Percent**
I (7533 and above)	5	1.9
II (3766-7532)	43	15.9
III (2260-3765)	98	36.3
IV (1130-2259)	99	36.7
V (1129 and below)	25	9.3
Total	270	100.0

*Education and Occupation was classified according to Modified Kuppuswamy Scale 2021(24)

In the study it was found that 92.6% (250) were Hindu religion, 7% (19) were Muslim religion and 0.4% (1) were Christian religion.

Among the study subjects 42.6% (115) were illiterate, 21.5% (58) were high school, 13% (35) were primary school, 11.1% (30) were middle school, and intermediate/diploma was 5.9% (16) and graduation was 5.9% (16).

Among the study subjects, 85.9% (232) were married and 14.1% (38) were unmarried.

Among the study subjects, agricultural/fishery workers were found to be the majority of 40.4% (109), 23.3% (63) were unemployed and skilled workers/shops/market sales workers were found to be 21.5% (58).

The distribution of family members in a family was in the range of 1 to 15. The family size of ≤ 4 members was the majority of 69.6% (188) and ≥ 5 members were 30.4% (82).

The socio-economic status of the study subjects is assessed and it was found that 36.7% (99) belonged to class IV SES, 36.3% (98) belonged to class III SES, 15.9% (43) belonged to class II SES, 9.3% (25) belonged to class V SES and 1.9% (5) belonged to class I SES as per modified BG Prasad classification.

Table 4: Clinical Profile of the study subjects

Comorbidity Status	**n (270)**	**Percent**
Yes	96	35.6
No	174	64.4
Comorbidity	**n (96)**	**Percent**

Diabetes	79	82.3
Hypertension	29	30.2
Bronchial Asthma	4	4.2
HIV	2	2.1
Cancer	1	1.0
Heart Disease	1	1.0
Social Habits	**n (270)**	**Percent**
Smoking	41	15.2
Alcohol	21	7.8
Total	62	23.0
Frequency of social habits	**Smoking n(%)**	**Alcohol n(%)**
Daily	36 (87.8)	12 (57.1)
More than once in a week	2 (4.9)	7 (33.3)
Once in a month	2 (4.9)	1 (4.8)
More than once in a month	1 (2.4)	1 (4.8)
Total	41 (100.0)	21 (100.0)
History of COVID Infected	**n (270)**	**Percent**
Yes	4	1.5
No	266	98.5
COVID Vaccination Status	**n (270)**	**Percent**
Yes (1 Dose)	235	87.0
No	35	12.0
Previous History of TB	**n (270)**	**Percent**
Yes	41	15.2
No	229	84.8
Previous History of TB in Family	**n (270)**	**Percent**
Yes	49	18.1
No	221	81.9

In the study, it was found that 35.6% (96) were had at least one comorbid condition, and diabetes was the major comorbid seen i.e., 82.3% (79), followed by hypertension 30.2% (29) and Bronchial Asthma 4.2%

(4), HIV was 2.1% (2) and 1% (1) of cancer and heart disease

The social habits in the study subjects were evaluated, 23% (62) had social habits, smoking was the major social habit of 15.2% (41), and alcohol of 7.8% (21) among the study subjects. The frequency of smoking was found to be daily in

87.8% (36), 4.9% (2) was found to be more than once in a week, once in a month 4.9% (2), and more than once in a month 2.4% (1). The frequency of alcohol was found to be daily in 57.1% (12), more than once in a week in 33.3% (7), Once and More than once in a month was 4.8% (1) each.

The history of COVID infection was found in 1.5% (4), and COVID vaccination status was 87.0% (235) received 1 dose of vaccination among the study subjects.

The previous history of TB was seen in 15.2% (41) of the study subjects, and the previous history of TB in a family member was seen in 18.1% (49) of the study subjects.

Table 5: Diagnosis and Treatment adherence profile of the study subjects

Place of Diagnosis	**n (270)**	**Percent**
Public	269	99.6
Private	1	0.4
Mode of Diagnosis	**n (270)**	**Percent**
CBNAAT	267	98.9
Chest X-ray	3	1.1
The interval between sample collection & diagnosis	**n (270)**	**Percent**
Less than a week	266	98.5
More than a week	4	1.5
The interval between the onset of symptom & initiatio of treatment for TB	**n (270)**	**Percent**
Less than 2 weeks	269	99.6
1 Month	1	0.4
Treatment Interruption	**n (270)**	**Percent**
Yes	4	1.5
No	266	98.5
Reason for Treatment Interruption	**n (4)**	**Percent**
Out of Station	2	50.0
Jaundice	1	25.0
Alcoholic	1	25.0
Total	4	100.0
History of Severe Side Effects	**n (270)**	**Percent**
Yes	14	5.2
No	256	94.8
Side Effects	**n (14)**	**Percent**
Vomiting	11	78.6
Tiredness	3	21.4

Giddiness	1	7.1
Allergy	1	7.1
Total	270	100
Follow up Visits by TBHV/STS	**n (270)**	**Percent**
Yes	257	95.2
No	13	4.8
Frequency of Visits	**n (257)**	**Percent**
Once a month	255	99.2
Once in 3 months	2	0.8

In the study, it was found that 99.6% (269) were diagnosed at the public lab and 0.4% (1) were diagnosed at the private lab. CBNAAT was the method of diagnosis in the majority of the study subjects 98.9%
(267) and 1.1% (3) Chest X-ray. The interval between sample collection and diagnosis was less than a week in 98.5% (288) study subjects and more than a week in 1.5% (4) study subjects. The interval
between the onset of symptoms and initiation of treatment for TB was less than 2 weeks in 99.6% (269) and 1 month in 0.4% (1) study subjects. The treatment interruption was found in 1.5% (4), and among them, the reason for interruption was out of the station in 50% (2) and jaundice and alcoholic were 25%

(1) each.

The history of severe side effects is assessed and was found to be 5.2% (14) had side effects, among them vomiting of 78.6% (11), 21.4% (3) of tiredness, and 7.1% (1) of each giddiness and allergy.

The follow-up visits by TBHV/STS are seen in 95.2% (257) of study subjects and 99.2% (255) once in a month and 0.8% (2) once in 3 months.

Table 6: Nutritional Incentives received details of the study subjects

Aware about Nikshay Poshana Yojana	**n (270)**	**Percent**
Yes	77	28.5
No	193	71.5
Source of Awareness about NPY	**n (77)**	**Percent**
STS (Senior TB Supervisor)	45	58.4
TBHV (TB Health Visitor)	17	22.1
ASHA	11	14.3
MO (Medical Officers)	4	5.2

Total	77	100.0
Details of the money received?	**n (270)**	**Percent**
Received in the First incentive	265	98.1
Received in the Second incentive	260	96.3
Received in the Third incentive	254	94.1
Received in the Fourth incentive	226	83.7
Received in the Fifth incentive	206	76.3
Received in the Sixth incentive	169	62.6
During the Six Months of time	**n (270)**	**Percent**
Fully Received (Rs.3000)	194	71.9
Partially Received (≤ Rs.2500)	76	28.1
Name of Tuberculosis Unit	**n=270 (%)**	**Fully Received within 6 months (n=194) (%)**
Ramanagara	86 (31.9)	68 (79.1)
Kanakapura	72 (26.7)	44 (61.1)
Channapatna	49 (18.1)	43 (87.8)
Magadi	33 (12.2)	22 (66.7)
Harohalli	30 (11.1)	17 (56.7)
Utilization Pattern	**n (270)**	**Percent**
Nutritional Purposes	240	88.9
Medicines	30	11.1

Among the study subjects, only 28.5% (77) are aware of nikshay poshana yojana, of which the source of awareness majority was STS 58.4% (45), 22.1% (17) was TBHV, 14.3% (11) was ASHA worker and 5.2% (4) was medical officers.

With regards to the incentives received incentive wise, in the first incentive 98.1% (265) have received incentives in the range (Rs.500-2000), in the second incentive 96.3% (260) have received incentives in the range (Rs.500-1000),

in the third incentive 94.1% (254) have received incentives in the range (Rs.500-1000), in the fourth incentive 83.7% (226) have received incentives in the range (Rs.500-1500), in the fifth incentive 76.3% (206) have received incentives in the range (Rs.500-1000), and in the sixth incentive 62.6% (169) have received incentives in the range (Rs.500-3000). During the first six months of duration, only 71.9% (194) have received full incentives of Rs.3000 within six months and 28.1% (76) have received partial incentives in the range (≤ Rs.2500) and have received the remaining amount after

the sixth months.

The Ramanagara TU was the highest study subjects 31.9% (86) of which 79.1% (68) have received full incentives within the six months. In the Kanakapura TU study subject were 26.7% (72) of which

61.1%

(44) have received full incentives within the six months. In the Channapatna TU, study subject were 18.1% (49) of which 87.8% (43) have received full incentives within the six months and was the highest among the TU's. In the Magadi TU study subject were 12.2% (33) of which 66.7% (22) have received full incentives within the six months. In the Harohalli TU study subject were 11.1% (30) of which 56.7%

(17) have received full incentives within the six months.

Among the study subjects, 88.9% (240) utilized NPY for nutritional purposes, and 11.1% (30) utilized for medicines.

Table 7: Nutritional details of the study subjects

Among the study subjects, 95.2% (257) were non-vegetarian and vegetarians were 4.8% (13). And Nutritional Support from any Voluntary Organizations was taken by 7% (19).

At the time of diagnosis, BMI was normal in 41.9% (113) subjects. 4.8% (13) were overweight, and 0.4%

(1) was obese. Mild underweight was seen in 17.4% (47) subjects, moderately underweight was 10.7% (29), severely underweight was 13.7% (37) and extremely underweight was 11.1% (30).

At 6 months after the diagnosis, BMI was normal in 51.9% (140) subjects. 10.4% (28) were overweight, and 1.1% (3) obese. Mild underweight was seen in 14.4% (39) subjects, moderately underweight was 10% (27), severely underweight was 10.7% (29), and extremely underweight was 1.5% (4).

At the time of interview, BMI was normal in 51.1% (138) subjects. 14.8% (40) were overweight and 3.0% (8) were obese. Mild underweight was seen in 13.3% (36) subjects, moderately underweight was 7.0% (19), severely underweight was 5.6% (15) and extremely underweight was 5.2% (14).

Table 8: BMI at the time of diagnosis and at the end of 6 months.

	BMI at the end of 6 months					
BMI at the time of Diagnosis	Underweight (99, 36.7%)		Normal body weight (14 51.9%)		Overweight (31, 11.5	
	n	**%**	**N**	**%**	**n**	**%**
Underweight (143, 53.0%)	96	67.1	45	31.5	2	1.4
Normal body weight (113, 41.9%)	3	2.7	95	84.1	15	13.3
Overweight (14, 5.2%)	0	0.0	0	0.0	14	100.0

Among 143 underweight study subjects at the time of diagnosis, 31.5% (45) gained normal BMI, and 1.4% (2) became overweight at the 6th-month, while the majority 67.1% (96) remained underweight.

Among 113 normal body weight study subjects at the time of diagnosis, the majority 84.1% (95) remained normal BMI, and 13.3% (15) were overweight at the 6th-month, while the 2.7% (3) reduced to underweight.

Among the 14 overweight study subjects at the time of diagnosis, they remained to be overweight at the end of 6 months.

Table 9: Association between Nutritional status at the end of 6 months and demographic profile of the study subjects

BMI	**Underweight (99)**		**Normal body weight (140)**		**Overweight (31)**		**Total (270)**		**Chi-square test**	**p-value**
Age-Group (Years)	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**		
18-24	16	16.2	10	7.1	3	9.7	29	10.7	9.516#	0.0494*
25-48	47	47.5	51	36.4	12	38.7	110	40.7		
> 48	36	36.4	79	56.4	16	51.6	131	48.5		
Gender										
Male	77	77.8	103	73.6	15	48.4	195	72.2	10.429	0.0054*
Female	22	22.2	37	26.4	16	51.6	75	27.8		

Marital Status										
Married	77	77.8	126	90.0	29	93.5	232	85.9	7.307#	0.0259*
Unmarried	22	22.2	14	10.0	2	6.5	38	14.1		
Education										
Illiterate	42	42.4	61	43.6	12	38.7	115	42.6	1.496#	0.8273
Primary/High School	42	42.4	66	47.1	15	48.4	123	45.6		
Intermediate/Graduate	15	15.2	13	9.3	4	12.9	32	11.9		
Religion										
Hindu	87	87.9	136	97.1	27	87.1	250	92.6	7.343#	0.1188
Muslim	11	11.1	4	2.9	4	12.9	19	7.0		
Christian	1	1.0	0	0.0	0	0.0	1	0.4		
Family Size										
≤ 4	74	74.7	95	67.9	19	61.3	188	69.6	2.454	0.2931
≥ 5	25	25.3	45	32.1	12	38.7	82	30.4		
Socio Economic Status										
I / II/ III	55	55.6	73	52.1	18	58.1	146	54.1	0.497	0.7799
IV/V	44	44.4	67	47.9	13	41.9	124	45.9		
Name of TU										
Ramanagara	36	36.4	40	28.6	10	32.3	86	31.9	--	--
Kanakapura	27	27.3	39	27.9	6	19.4	72	26.7		
Channapatna	9	9.1	30	21.4	10	32.3	49	18.1		
Magadi	14	14.1	17	12.1	2	6.5	33	12.2		
Harohalli	13	13.1	14	10.0	14	45.2	41	15.2		
Total	99	100.0	140	100.0	42	135.5	281	104.1		

*#Yates Chi-square test *Statistically significant p<0.05*

It was found that there was statistically significant association between nutritional status at the end of 6 months and age group, gender and marital status.

However, there was no statistically significant association between education, religion, family size and socio-economic status.

Table 10: Association between Nutritional status at the end of 6 months and clinical profile of the study subjects

BMI	Underweight (99)		Normal body weight (140)		Overweight (31)		Total (270)		Chi-square test	p-value
Co-morbidity	**n**	**%**	**n**	**%**	**N**	**%**	**n**	**%**		
Yes	18	18.2	59	42.1	19	61.3	96	35.6	24.653	0.000 (<0.05)
No	81	81.8	81	57.9	12	38.7	174	64.4		
Diabetes Mellitus										
Yes	11	11.1	53	37.9	18	58.1	82	30.4	32.319	0.000 (<0.05)
No	88	88.9	87	62.1	13	41.9	188	69.6		
Hypertension										
Yes	8	8.1	14	10.0	7	22.6	29	10.7	5.344	0.0691
No	91	91.9	126	90.0	24	77.4	241	89.3		
COVID Infection										
Yes	1	1.0	2	1.4	1	3.2	4	1.5	0.093#	0.9545
No	98	99.0	138	98.6	30	96.8	266	98.5		
Previous History of TB										
Yes	21	21.2	17	12.1	3	9.7	41	15.2	3.493#	0.1744
No	78	78.8	123	87.9	28	90.3	229	84.8		
Family History of TB										
Yes	27	27.3	21	15.0	1	3.2	49	18.1	9.382#	0.0092
No	72	72.7	119	85.0	30	96.8	221	81.9		

#Yates Chi-square test **Statistically significant p<0.05*

**p<0.05 is considered statistically significant and there is an association between the two attributes.*

It was found that there was statistically significant association between nutritional status at the end of 6 months and presence of co-morbidity, Diabetic study subjects and family history of TB.

However, there was no statistically significant association between nutritional status and hypertensive study subjects, history of Covid infection and previous history of TB.

Table 11: Association between Nutritional status at the end of 6 months and habits/treatment profile of the study subjects

	Underweight (99)		Normal body weight (140)		Overweight (31)		Total (270)		Chi-square test	p-value
Alcohol	**n**	**%**	**n**	**%**	**n**	**%**	**N**	**%**		
Yes	11	11.1	9	6.4	1	3.2	21	7.8	1.669#	0.434
No	88	88.9	131	93.6	30	96.8	249	92.2		
Smoking										
Yes	20	20.2	20	14.3	1	3.2	41	15.2	4.173#	0.1241
No	79	79.8	120	85.7	30	96.8	229	84.8		
The interval between sample collection & diagnosis										
Less than a week	99	100.0	136	97.1	31	100.0	266	98.5	1.645#	0.4393
More than a week	0	0.0	4	2.9	0	0.0	4	1.5		
The interval between the onset of symptom & initiation of treatment for TB										
Less than 2 weeks	98	99.0	140	100.0	31	100.0	269	99.6	1.346#	0.5101
1 Month	1	1.0	0	0.0	0	0.0	1	0.4		
Treatment Interruption										
Yes	2	2.0	2	1.4	0	0.0	4	1.5	0.093#	0.9545
No	97	98.0	138	98.6	31	100.0	266	98.5		
History of Severe Side Effects										
Yes	7	7.1	6	4.3	1	3.2	14	5.2	0.475#	0.7885
No	92	92.9	134	95.7	30	96.8	256	94.8		

#Yates Chi-square test

There was no statistically significant association between nutritional status and consumption of alcohol, tobacco, interval between sample collection and diagnosis, interval between onset of symptoms and initiation of treatment, treatment interruption and history of severe side effects.

Table 12: Association between Nutritional status at the end of 6 months and incentives by NPY of the study subjects

	Underweight (84)		Normal body weight (138)		Overweight (48)		Total (270)		Chi-square test	p-value
Follow up Visits by TBHV/STS	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**		
Yes	95	96.0	135	96.4	27	87.1	257	95.2	3.092#	0.213
No	4	4.0	5	3.6	4	12.9	13	4.8		
Aware about Nikshay Poshana Yojana										
Yes	32	32.3	40	28.6	5	16.1	77	28.5	2.301#	0.3164
No	67	67.7	100	71.4	26	83.9	193	71.5		
Nutritional incentive received during the Six Months duration										
Fully Received (Rs.3000)	67	67.7	103	73.6	24	77.4	194	71.9	1.533	0.4646
Partially Received (≤ Rs.2500)	32	32.3	37	26.4	7	22.6	76	28.1		
Utilization Pattern										
Nutritional Purposes	85	85.9	125	89.3	30	96.8	240	88.9	1.874#	0.3918
Other Purposes	14	14.1	15	10.7	1	3.2	30	11.1		
Diet										
Non-Vegetarian	96	97.0	133	95.0	28	90.3	257	95.2	1.077#	0.5836
Vegetarian	3	3.0	7	5.0	3	9.7	13	4.8		
Nutritional Support from any Voluntary Organizations										
Yes	5	5.1	13	9.3	1	3.2	19	7.0	1.327#	0.515
No	94	94.9	127	90.7	30	96.8	251	93.0		

#Yates Chi-square test

There was no statistically significant association between nutritional status and follow-up visits by TBHV/STS, awareness about NPY, nutritional incentive received in 6 months duration, utilization pattern, diet and Nutritional support from any Voluntary Organizations.

Table 13: Odds ratios depicting the factors associated with underweight and normal/overweight.

BMI	Underweight (99)	Normal & Over body weight	Odds ratio	95 % CI	z statistic	p-value

			(140)					
Age-Group (Years)	**n**	**%**	**n**	**%**				
≤48	63	63.6	76	44.4	2.1875	1.3154 to 3.6377	3.017	0.0026
>48	36	36.4	95	55.6				
Gender								
Male	77	77.8	118	69.0	1.572	0.8854 to 2.7911	1.545	0.1225
Female	22	22.2	53	31.0				
Marital Status								
Married	77	77.8	155	90.6	0.3613	0.1795 to 0.7272	2.852	0.0043
Unmarried	22	22.2	16	9.4				
Education								
Illiterate	42	42.4	73	42.7	0.9892	0.5996 to 1.6320	0.043	0.966
Educated	57	57.6	98	57.3				
Family Size								
≤ 4	74	74.7	114	66.7	1.48	0.8507 to 2.5749	1.388	0.1653
≥ 5	25	25.3	57	33.3				
Socio Economic Status								
I / II/ III	55	55.6	91	53.2	1.0989	0.6683 to 1.8070	0.372	0.7102
IV/V	44	44.4	80	46.8				
Co-morbidity								
Yes	18	18.2	78	45.6	0.265	0.1465 to 0.4793	4.391	< 0.0001
No	81	81.8	93	54.4				
Diabetes Mellitus								
Yes	11	11.1	71	41.5	0.176	0.0877 to 0.3534	4.886	< 0.0001
No	88	88.9	100	58.5				
Hypertension								
Yes	8	8.1	21	12.3	0.6279	0.2671 to 1.4765	1.067	0.2861
No	91	91.9	150	87.7				
COVID Infection								
Yes	1	1.0	3	1.8	0.5714	0.0586 to 5.569	0.482	0.63
No	98	99.0	168	98.2				
Previous History of TB								
Yes	21	21.2	20	11.7	2.0327	1.0395 to 3.9748	2.073	0.0381
No	78	78.8	151	88.3				
Family History of TB								
Yes	27	27.3	22	12.9	2.5398	1.3536 to 4.7654	2.903	0.0037
No	72	72.7	149	87.1				

Alcohol	Underweight (99) n(%)		Normal & Over body weight (140) n(%)		Odds ratio	95 % CI	z statistic	p-value
Yes	11	11.1	10	5.8	2.0125	0.8224 to 4.9250	1.532	0.1256
No	88	88.9	161	94.2				
Smoking								
Yes	20	20.2	21	12.3	1.8083	0.9251 to 3.5348	1.732	0.0832
No	79	79.8	150	87.7				
The interval between sample collection & diagnosis								
Less than a week	99	100.0	167	97.7	5.3463	0.2848 to 100.3543	1.121	0.2625
More than a week	0	0.0	4	2.3				
The interval between the onset of symptom & initiation of treatment for TB								
Less than 2 weeks	98	99.0	171	100.0	0.1914	0.0077 to 4.7451	1.009	0.3128
1 Month	1	1.0	0	0.0				
Treatment Interruption								
Yes	2	2.0	2	1.2	1.7423	0.2416 to 12.5664	0.551	0.5818
No	97	98.0	169	98.8				
History of Severe Side Effects								
Yes	7	7.1	7	4.1	1.7826	0.6064 to 5.2404	1.051	0.2934
No	92	92.9	164	95.9				
Follow up Visits by TBHV/STS								
Yes	95	96.0	162	94.7	1.3194	0.3955 to 4.4015	0.451	0.652
No	4	4.0	9	5.3				
Aware about Nikshay Poshana Yojana								
Yes	32	32.3	45	26.3	1.3373	0.7781 to 2.2983	1.052	0.2928
No	67	67.7	126	73.7				
During the Six Months of time								
Fully Received (Rs.3000)	67	67.7	127	74.3	0.7254	0.4214 to 1.2486	1.159	0.2466
Partially Received (≤Rs2500)	32	32.3	44	25.7				
Utilization Pattern								
Nutritional Purposes	85	85.9	155	90.6	0.6267	0.2918 to 1.3462	1.198	0.231
Other Purposes	14	14.1	16	9.4				

Diet								
Non-Vegetarian	96	97.0	161	94.2	1.9876	0.5337 to 7.4014	1.024	0.3058

	Descriptive Statistics			Paired Differences				
BMI	**Mean**	**SD**	**Median**	**Mean**	**SD**	**Median**	**Q1**	**Q3**
At Diagnc	18.6	3.7	18.2	1.54	1.77	1.3	0.8	2.0
After 6th Mo	20.2	3.8	19.6					
BMI at 6th-Mor	**n (%)**	**Mean Rank**		**Sum of Ranks**		**Wilcoxon Signed Rank Test**	**p-value**	
Decrea	14 (5.2)	148.0		2072.0		-12.274	0.000 (< 0.05)	
Increa	246 (91.1)	129.5		31856.0				
Const	10 (3.7)							
Vegetarian	3	3.0	10	5.8				
Nutritional Support from any Voluntary Organizations								
Yes	5	5.1	14	8.2	0.5965	0.2082 to 1.7091	0.962	0.336
No	94	94.9	157	91.8				

It was seen that factors like age group, gender, family size, socio economic status, previous history of TB, Family history of TB, alcohol, smoking, diet, the interval between onset of symptoms and initiation of TB treatment, treatment interruption, follow-up visit, awareness about NPY, and history of side effects had an odds ratio of more than 1. This implies that all these factors had higher outcomes on BMI status.

Table 14: Comparison of BMI after receiving the Nikshay Poshana Yojana among the study subjects

The mean BMI at the time of diagnosis was 18.6±3.7kg and the mean BMI after the 6th month was 20.2±3.8 kg. The mean change in BMI was 1.54±1.77kg and the median change in BMI was 1.3 with interquartile range (0.8 to 2.0). 3.7% (10) study subjects had reported no change in BMI at the end of 6 months, 5.2% (14) study subjects reported decrease in BMI and 91.1% (246) study subjects reported increase in BMI at the end of 6 months.

The BMI was tested for principles of normality using Shapiro-Wilk test where it was observed that p-value was <0.05 at 3 point of time, hence non-parametric test was applied.

On applying Wilcoxon signed-rank test it was found that $Z = -12.274$ and $p < 0.05$, implying statistically significant change in BMI at the end of 6 months of treatment.

Fig 13: Bar chart depicting BMI at the time of diagnosis and at the end of 6 months

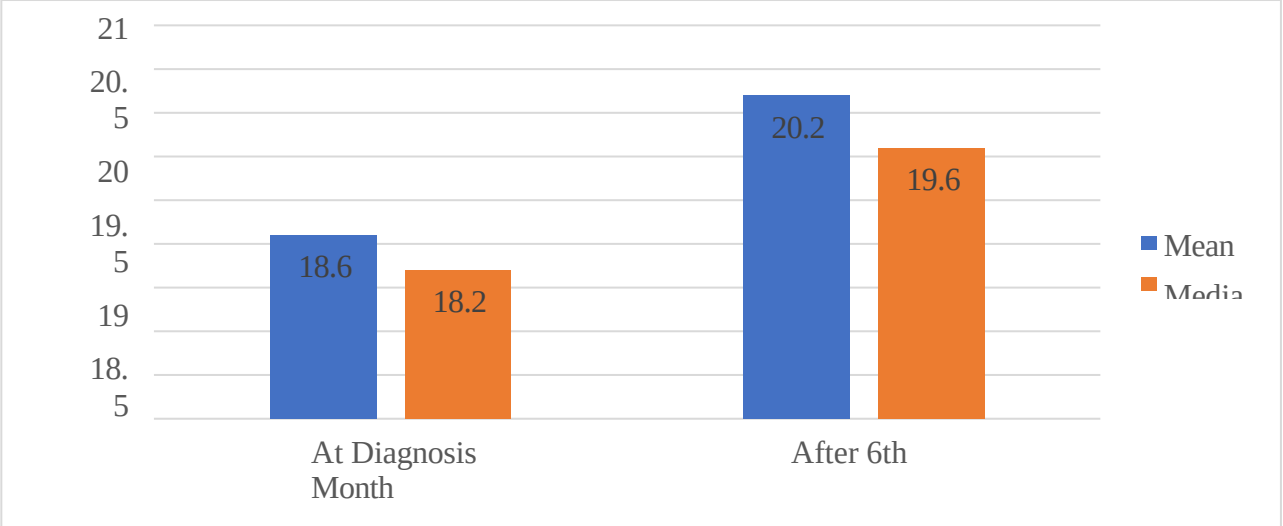

Table 15: Comparison of BMI at the time of diagnosis, at the end of 6 months and at the time of interview in the study subjects

BMI	Min	Max	Mean	SD	Median	IQR (Q1-Q	Mean Ra	Friedman Test (chi- squa	p- value
at Diagnosis	10.1	34.2	18.6	3.7	18.2	16.0-21.2	1.21	274.12	0.000 (<0.05)
at 6th Month	11.5	35.6	20.2	3.8	19.6	17.3-22.7	2.28		
at the time of the Interview	11.8	42.0	21.1	4.6	20.9	18.0-23.9	2.51		

The median with IQR at the time of diagnosis was 18.2 (16.0-21.2), after the 6th month 19.6 (17.3-22.7), and at the of interview 20.9 (18.0-23.9) with mean rank 1.21, 2.28, 2.51 respectively. There was a statistically significant difference in the BMI from the time of diagnosis, at the end of 6 months of treatment and at the time of the interview, Friedman's chi-square =274.12 with p=0.000 <0.05. This has been represented using the Box and Whisker plot given below (Fig 3)

It was found that there was no change in the weight at the time of interview compared to weight at diagnosis in 8.9% (24) subjects, weight was increased in 81.5% (220) subjects and 9.6% (26) subjects had

decrease in weight.

Fig 14: Box and Whisker plot showing the mean, median with inter quartile range values of the BMI at the time of diagnosis, at the end of 6 months and at the time of interview

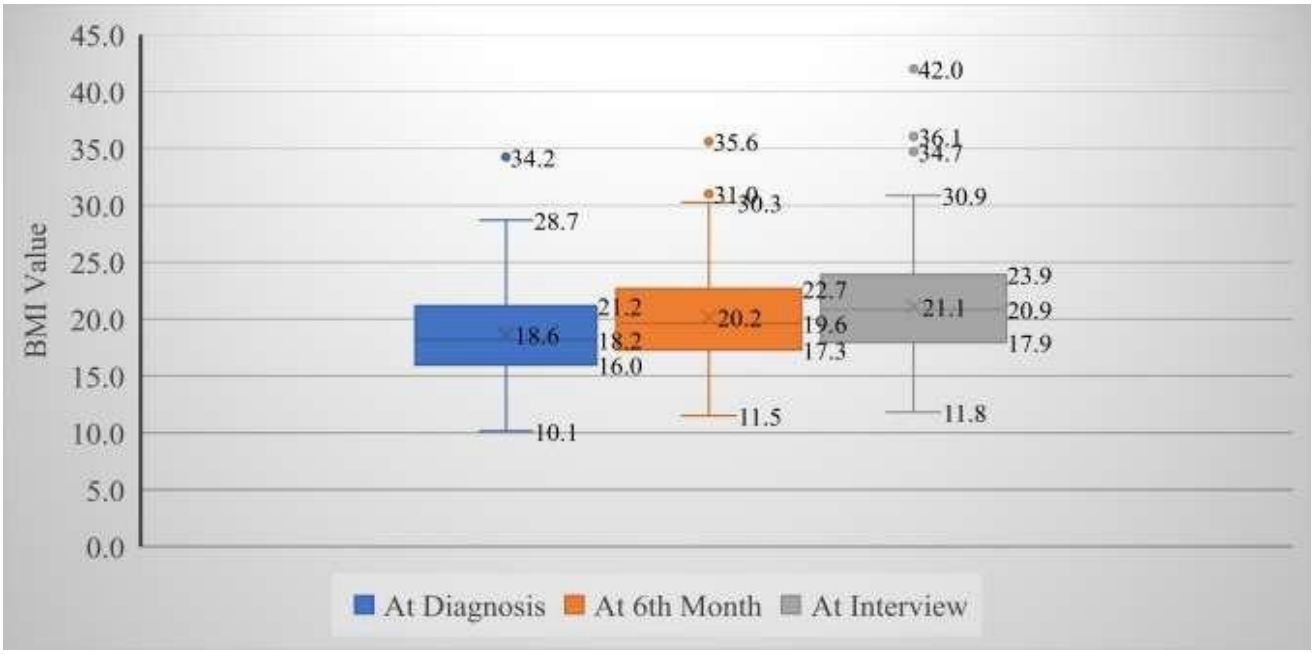

Table 16: Comparison of historical data of NPY Utilization of District of Ramanagara

Year	Eligible TB Patients	who received NPY	Percentage
2018-2019	1085	598	55.1%
2019-2020	1555	974	62.63%
2020-2021	999	660	66.06%

The historical data revealed that the NPY utilization has substantially increased from the year 2018 with 55.1% to 2019 with 62.63% and 2020 with 66.06%.

8. DISCUSSION

Our study showed that majority of the individuals were in the age group of 51-60 (21.1), with a median age of 48 years and interquartile range of (36-60) years. Among the respondents 72.2% were males and 27.8% were females. Many young females had TB in our study maybe because of more prevalence of

under nutrition among this age group. Majority of the subjects (36.7%) belonged to class IV SES, 36.3% belonged to class III as per modified BG Prasad classification and occupation of majority of the study subjects was agriculture/fishery (40.4%). However, the socio-demographic data of the study done by J Begam et al., showed that a majority (44%) of the participants were in the age group of 41–60 yrs and were males (63.8%). The socio-economic status calculated using the modified Kuppuswamy scale showed that a majority belonged to the upper lower class (83.1%). (21) In a study conducted by MP Poornima et al., the median age of the study participants was 36 years (24–49 years). The majority (62%) of the patients were males, 36% were unemployed, and 71% belonged to below the poverty line. Most of them belonged to the class III socioeconomic status according to the modified BG Prasad classification (25)

In our study, majority (85%) of the cases were newly diagnosed. Similar finding was reported by MP Poornima et al., where 94% of the cases were newly diagnosed (26). Patel BH et al., and MP Poornima et al., in their study reported that nearly 58% and 52.5% of patients had sought a public health care facility respectively (26,6). In contrast, our study revealed that 99.6% of the participants in our study were diagnosed in public sector. The reason for more patients being diagnosed in public sector could be that all TB patients are diagnosed and notified under NTEP. Even in the private sector, once the patient has any of the TB symptoms, they are referred to public DMC for further management. Another reason for the increase in diagnosis of TB cases in public sector in our study can be attributed to the active case finding from the government or might be due to the underreporting/decreased participation of private practitioners. Also, this may be due to the differences in study population.

Bhargava A et al., reported in their study that majority of patients (80% women and 67% men) at diagnosis had evidence of severe chronic under nutrition and half of men had weight less than 42 kg while majority of the women were less than 34 kg. (18) Similar to this study, our study revealed that majority of the subjects (52.9%) were underweight, mild underweight was seen in 17.4% of the subjects, 10.7% were moderately undernourished, 13.7% were severely undernourished and extreme underweight was seen in 11.1% of the subjects. BMI was normal in 41.9% of the subjects. 4.8% were overweight and 0.4% were obese.

Khajedaluee, M et al., compared the impact of weight changes during treatment in patients whose outcomes were declared as cured, completed treatment, treatment failure and death and the differences were statistically significant between the four groups ($p < 0.03$). (17) However, in our study, there was no statistically significant association between nutritional status and treatment interruption and history of severe side effects.

In our study only 28.5% were aware of Nikshay Poshan Yojana, of which the major source of awareness was STS (58.4%) followed by TBHV (22.1%), ASHA worker (14.3%) and medical officers (5.2%). The proportion of subjects aware of NPY scheme were found to be only 28.5% in our study which could be because the subjects were not familiar with the name of the scheme "NPY". However, all of them knew about the 500 Rs cash incentive provided by NTEP through DBT for each month of TB treatment till the completion of treatment. In contrast, in a study done by J Begum et al., 91.5% of the beneficiaries were aware of the cash incentive given as per Nikshay Poshan Yojana and those who were aware mostly got the information from the healthcare workers (84.3%), followed by neighbours (3.6%), friends and family (2.4%), and media (1.2%). (21) Another study found television to be the main source of information on tuberculosis. (27)

With regard to the incentives received in our study, 98.1 % received first installment during the treatment period, which is more when compared to studies done by Rohit A et al., and Patel BH et al where 78.5% and 42.2% received first installment during the treatment period (6,12). In our study, 28.1% of the subjects did not receive the money completely during the 6 months of
treatment. A study done by Kumar R et al., reported that 47.3% of the study subjects did not receive any incentive during the period of treatment. (10) Gross delays in disbursing the money was documented by Rohit A et al., with nearly 25% of the patients receiving the money after treatment outcomes have occurred. (12) Delayed payment in such patients has resulted in non-utilization of the incentive for nutrition support during the period of treatment, defeating the purpose of the scheme and suboptimal implementation of NPY.

In our study, 72% of the subjects received incentives on time and majority of them (89%) utilized it for nutritional purposes. Similarly, 76% of the participants in the study by Rohit A et al., spent the money on buying food for nutrition, while the rest 24% spent it on personal and family need fulfillments. However, the beneficiaries did not express satisfaction regarding the adequacy of the amount received to meet their nutritional requirements. (10) Similar findings were reported in a study by Patel BH et al where patients had spent the money buying milk, fruits and food from the incentives received through NPY. (6) In contrast, Kumar R et al reported non utilization of NPY among the study subjects through out the treatment period due to delay in receiving payment. (10) In our study, 7% of the participants received nutritional support from any voluntary organizations. However, we do not know the utilization of the support provided by voluntary organizations.

Our study showed that there was a statistically significant difference in the BMI of the participants from the time of diagnosis to the time of the interview. Also, age, gender and marital status had a statistically significant association with BMI. However, we did not find a statistically significant association between BMI & education, religion, family size and socio-economic status which is almost similar to a study done by J Begum et al. (21)

In a retrospective cohort study done by J D. Dave and M P. Rupani to determine the association between non-receipt of DBT and unfavorable treatment outcomes,15% of patients were tobacco smokers, 5% consumed alcohol, 4% were HIV positive and 9% had diabetes. Our study also showed similar findings, where 15.2 % study subjects were tobacco smokers, 7.8% consumed alcohol, 1% were HIV positive and 29.2% were Diabetics. (22). However, we have no information about diabetic management or specific diet of patients with TB and diabetes among our study participants.

The challenges and barriers faced during the study is depicted in Fig. 15 and Fig. 16.

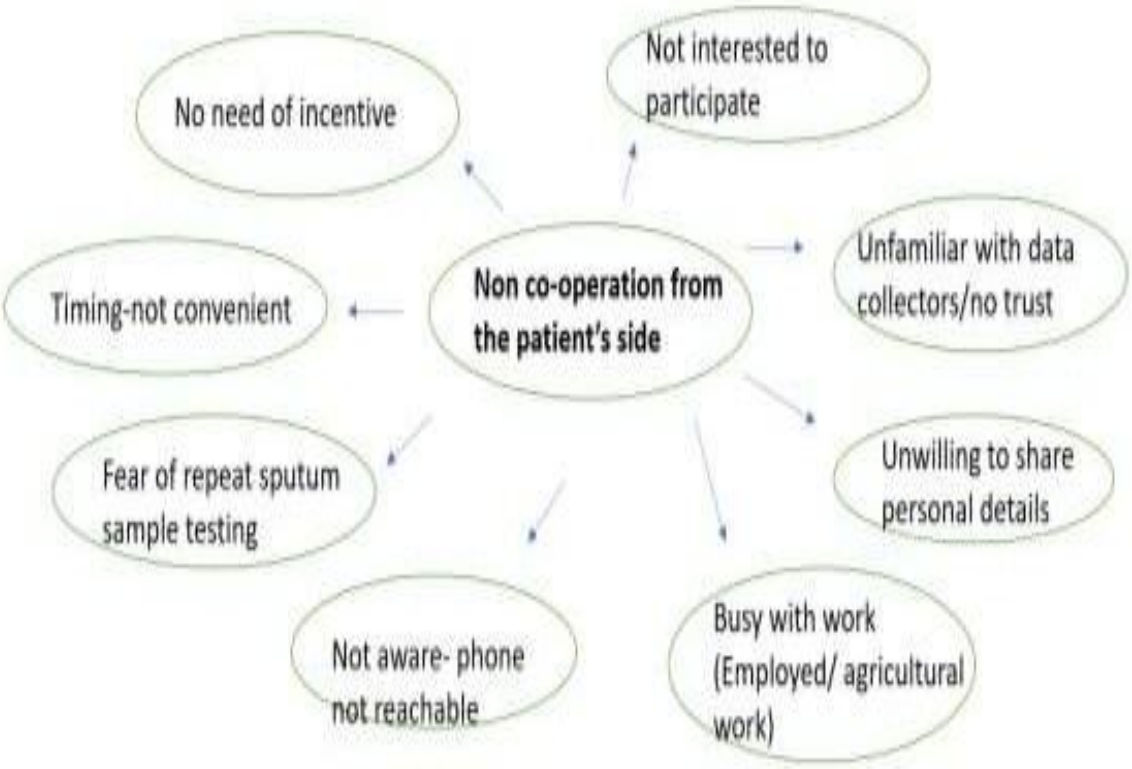

Fig.15: Non-cooperation to participate in study from the study subjects.

Fig.16: Fear of stigmatization to participate in study from the study subjects.

The following strategies were adopted to overcome few of the challenges, which are depicted in Fig17.

Fig.17: Importance of building trust with study subjects to participate in the study

In the study done by J Begum et al., it was found that patient's illiteracy and ignorance, stigma attached with the disease, non-cooperation of patients and the lack of effective follow-up were some of the challenges. (21) Similarly, in our study non-cooperation from patient side and fear of stigmatization were some of the main challenges. However, building trust among the patients with effective communication showing empathy and involving NTEP staff were identified as some of the strategies to overcome these challenges.

9. Conclusion

We conclude that the majority of the study participants utilized the NPY scheme as per the proposed purpose of the program. But, few of them received the final incentive of NPY after the completion of treatment which compromised the intended purpose. Therefore, timely delivery of NPY scheme is of paramount importance. The nutritional status (BMI) of majority of the study subjects showed significant improvement in BMI at the time of diagnosis, at the end of 6 months of treatment and at the time of interview. However, the increase in BMI cannot be solely attributed to the utilization of NPY scheme only. In addition, periodic nutritional assessment coupled with nutritional counselling would contribute towards achieving the purpose of NPY scheme. Non-cooperation, fear of stigmatization was some of the major challenges, which could be overcome by building trust among the patients through effective implementation of Behavior Change Communication in the community.

10. Strengths of the study:

- The data collection was done in all the 5 Tuberculosis Units of Ramanagara District, thereby ensuring equal representation from all parts of the district.

- For all the study subjects, a comprehensive approach was used wherein they had one to one interaction with data collector, medical examination by the investigator and health awareness by the NTEP officials.

- Both the primary and secondary data were reviewed at the time of the interview.

11. Limitations of the study:

- The patient will start gaining weight as soon as he is started on Anti Tubercular Treatment with increase in his/her appetite. Therefore scientifically, the weight gain cannot be attributed solely to the incentives provided through NPY scheme.

- Almost 90% of the study subjects have reported that the incentive was used for buying nutritional foods, however we do not have any proof for the same and it is purely based on the history given by the study subjects.

- The N-TB application, which was used for our study was based on the WHO classification of BMI and it was not specific to the South Asian standards.

12. Recommendations:

- Since stigmatization of TB patients is very much prevalent, health education and awareness in the community is the need of the hour.

- Body language, good communication skills, knowledge about the diseases and sensitivity of the data collectors towards the issue will result in successful rapport building with the TB patients.

- Nutritional incentives should be disbursed on time at regular intervals to the TB patients for it to be impactful, otherwise it will defeat the purpose of the program.

If we invest in nutrition, we can have better outcome and end TB by 2035

Policy and practical implications:

India contributes the maximum number of TB cases among high-burden countries and the country's National TB Programme has been a signatory and leading example in following the 'End TB' strategy. The National Strategic Plan for TB Control focuses on reducing the catastrophic expenditure to zero in the country. In resonance with the rationale, Nikshay Poshan Yojana intervention was rolled all over India to promote nutrition in patients affected with TB. This study provides the baseline information about the Proportion of pulmonary TB patients utilizing NPY scheme and their nutritional status. The findings of the present study suggest that the cash incentives provided under NPY were utilized by the patients for the intended purpose which was reflected in the improved nutritional status of these patients. Thus, similar intervention could be adopted by other member countries with increased burden of TB to improve the nutritional status of TB patients which will ensure better treatment outcomes.

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14. ANNEXURES

ANNEXURE I: IEC APPROVAL LETTER

CDSIMER
Dr. Chandramma Dayananda Sagar Institute of Medical Education and Research
(Shri of Dayananda Sagar University)

INSTITUTIONAL ETHICS COMMITTEE

(Regn. .....)

Chairperson
Shri. M N Vidyashankar

Member Secretary
Dr. Pratibha D Nadig

Basic Medical Scientist
Dr. Sunil S More

Legal Member
Shri. Arvind Moorchung

Clinical Members
Dr. S. Rajagopalan
Dr. Nithin M D
Dr. Yashaswini L S
Dr. Amita Mukhopadhyay

Social Scientist / Ethicist
Smt. Durga Unnikrishnan

Lay Person
Mr. Sheik Alaudeen M S

Appellate Authority
Dr. A.C. Ashok

Certificate of approval from CDSIMER-IEC

Date: 04.10.2021

To

Dr.Santosh K Yatnatti,

Principal Investigator,

Department of Community Medicine, CDSIMER

Study Ref: CDSIMER/MR/0022/IEC/2021

Dear Dr. Santosh K Yatnatti

CDSIMER-IEC reviewed and discussed your application received from Internal Scientific Committee to conduct the research study entitled "Assessment of the nutritional status of pulmonary TB patients who have received Nikshay Poshan Yojana scheme residing in Ramanagar District, India by using N-TB mobile application-a cross sectional study" during the CDSIMER IEC meeting held on dated 24-09-2021 between 2.00 pm to 3.30 pm at Board room, G Block, Dr. Chandramma Dayanand Sagar Institute of Medical Education and Research (CDSIMER)

The following documents were reviewed:

1. Revised Study Protocol
2. Informed consent form with translation in Kannada Language
3. Questionnaire
4. Research reference articles
5. Budget details

The following members of the CDSIMER-IEC were present at the meeting

Sl No	Name	Designation
1	Shri. M N Vidyashankar	Chairperson
2	Dr. Pratibha D Nadig	Member secretary
3	Dr. Sunil S More	Basic Medical Scientist
4	Shri. Arvind Moorchung	Legal Member
5	Dr. S Rajagopalan	Clinical Member
6	Dr. Manju Prakash	Clinical Member
7	Dr. Yashaswini L S	Clinical Member
8	Dr. Amita Mukhopadhyay	Clinical Member
9	Smt. Durga Unnikrishnan	Social Scientist/Ethicist
10	Mr. Sheik Alaudeen M S	Lay Person
11	Dr. A.C. Ashok	Appellate Authority

The study is **APPROVED** in its revised presented form.

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CDSIMER
Dr. Chandramma Dayananda Sagar Institute of Medical Education and Research
Unit of Dayananda Sagar University

INSTITUTIONAL ETHICS COMMITTEE

(Regn. .....)

Following points must be noted:

1. CDSIMER IEC should be informed of the date commencement of study and submit quarterly progress reports.
2. PI and other investigator should co-operate with CDSIMER IEC, which may monitor study from time to time.
3. New information or any SAE, which could affect this study, must be communicated to CDSIMER IEC and sponsors (If applicable). The PI should report SAEs occurred for CDSIMER IEC approved studies within 24 hrs of the occurrence of the SAE.
4. In the event of any protocol amendments, CDSIMER IEC must be informed and the amendments should be highlighted in clear terms as follows:

a) The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project (Page No., Clause No. etc.)
b) The PI must comment how proposed amendment will affect the ongoing study
c) Alteration in the budgetary status, staff requirement should be clearly indicated and the revised budget form should be submitted.
d) If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval,
e) If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
f) If there are any amendments in the trial design, these must be incorporated in the protocol and other study document. These revised documents should be submitted for approval of the CDSIMER IEC, only then can they be implemented.
g) Approval for amendment changes must be obtained prior to implementation of changes.
h) The amendment is unlikely to be approved by the CDSIMER IEC unless all the above information is provided.

5. Any deviation/violation/waiver in the protocol must be informed to the CDSIMER IEC.

If project initiation not done in next 1 year from the date of approval from CDSIMER IEC, further extension will not be granted and it will require resubmission to CDSIMER IEC.

Thanks and Regards,

Dr.Pratibha Nadig

Member Secretary

Member Secretary
CDSIMER - IEC
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Devarakaggalahalli, Harohalli,
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ANNEXURE II: INFORMED CONSENT FORM

Informed Consent Form

Title of the research proposal:

"Assessment of nutritional status of pulmonary TB patients who have received Nikshay Poshan Yojana scheme residing in Ramanagara district, India by using N-TB mobile application- A cross-sectional study"

Research team

Dr. Santosh K Yatnatti, Department of Community Medicine, CDSIMER

Dr. Sanjay Kumar Mattoo, Joint Director Central TB Division, India,

Dr. Manasa A. R, Department of Community Medicine, CDSIMER

Dr. Sushma J, Department of Community Medicine, CDSIMER

Dr. Kumar K, District Tuberculosis Officer, Ramanagara

I aged _____years resident of _____ with Nikshay ID _____hereby give consent to participate in the above mentioned study.

I have been explained about the nature and purpose of this study. I have been explained all these details in my native language. I have signed this consent voluntarily, out of my free will, without any pressure and in my full senses as this study does not involve any investigations and interventions. I have understood the possible risks and the benefits that might arise due to my enrolment. I have been given adequate time to decide on my enrolment and implications of my consenting. Have been given time and opportunity to ask clarifications and questions from the investigator. The investigator has provided me with their contact details and I understand that I can contact them any time for further clarifications about the protocol. I hereby state that my decision to participate in this study is free from coercion or undue inducements.

The semi structured questionnaire consists of the information about the socio demographic part and, spending pattern of Nikshay Poshan Yojana and assessment of nutritional status.

The information will be confidential and will not be shared with anyone else. The comprehension of the patient will be assessed before collecting the data.

The risk level of this research is considered to be minimal. By taking part in the study, I will come to know my nutritional status and I will be provided with nutritional advice. Also, Rs 500 will be given for my nutritional upliftment.

I have also been explained that if I refuse right from the beginning, my health care rights will not be affected in anyway. I have freedom not to answer any particular question which I feel uncomfortable to answer. I also understand that I have the right to withdraw at any point of time before the study completion if I feel there is any compromise in my rights as a TB patient.

I have been assured that privacy will be respected and the data collected from me will be kept confidential and will be shared only by members of the research team, ethics committee and regulatory authorities. No one else shall be privy to my details.

I have also understood that the researchers might want to present findings from the study or publish them in a scientific periodical or submit reports to the concerned authorities. I have been assured that in such situations my privacy and confidentiality will not be compromised.

I have also understood that either a copy of the informed consent document or a copy of the participant information sheet (in my native language) can be kept by me for future reference.

Nikshay ID & Signature of participant with date

PI's Signature,

PI, contact details
Dr. Santosh K Yatnatti
Assistant Professor
Dept. of Community Medicine
CDSIMER
Mobile Number: 9480276111
Email ID: sky.sant@gmail.com

Place

Date

ANNEXURE III: PARTICIPANT INFORMATION SHEET

PARTICIPANT INFORMATION SHEET

Title of the research Proposal

"Assessment of nutritional status of pulmonary TB patients who have received Nikshay Poshan Yojana scheme residing in Ramanagara district, India by using N-TB mobile application- A cross-sectional study"

Research team

Dr. Santosh K Yatnatti, Department of Community Medicine, CDSIMER

Dr. Sanjay Kumar Mattoo, Joint Director Central TB Division, India,

Dr. Manasa A. R, Department of Community Medicine, CDSIMER

Dr. Sushma J, Department of Community Medicine, CDSIMER

Dr. Kumar K, District Tuberculosis Officer, Ramanagara

Purpose of the study:

Tuberculosis is one of the leading five diseases causing mortality in Karnataka State. In 2010, Ramanagara district was one of the low performing districts with respect to TB indicators in Karnataka. Therefore, our current study will help to strengthen and fill the gaps by assessing the nutritional status and the outcome or utilization of NPY, thereby creating awareness to each and every tuberculosis patient which the team is going to come across during the process of current study.

Duration of participation:

Process of filling up the questionnaire and anthropometric measurement will take about 20-30 minutes of your time.

Why are you being selected?

You are invited to take part in research about "Assessment of nutritional status of pulmonary TB patients who have received Nikshay Poshan Yojana scheme residing in Ramanagara district, India by using N-TB mobile application- A cross-sectional study" as you are one of the beneficiaries of Nikshay Poshan Yojana.

ANNEXURE IV: QUESTIONNAIRE

"Assessment of the nutritional status of pulmonary TB patients who have received Nikshay Poshan Yojana scheme residing in Ramanagara district, India by using N- TB mobile application- A cross-sectional study"

Date of interview:
Name of the Data Collector:

General details:

1. Nikshay ID: 2. Informant: a) Self b) Others
3. Age: 4. Gender: a) Male b) FEmale
5. Contact number:
6. Religion: a) Hindu b) Muslim c) Christian d) Others
7. Education: a) Profession or Honours b) Graduate c) Intermediate or diploma d) High school certificate e) Middle school certificate f) Primary school certificate g) Illiterate
8. Marital status: a) Married b) Unmarried c) Divorced d) Widowed
9. Occupation: a) Legislators, Senior Officials & Managers b) Professionals c) Technicians and Associate Professionals d) Clerks e) Skilled Workers and Shop & Market Sales Workers f) Skilled Agricultural & Fishery Workers g) Craft & Related Trade Workers h) Plant & Machine Operators and Assemblers
10. Number of family members:
11. Per capita monthly income:
12. Socioeconomic status (Modified B G Prasad Classification):

a) I (7533 and above) b) II (3766-7532) c) III (2260-3765) d) IV (1130-2259)

e) V (1129 and Below)

Diagnosis details:

13. Any Comorbidities: a) Diabetes b) Hypertension c) HIV d) Bronchial asthma e) None f) Others_____
14. Previous history of TB: Yes/No
15. History of TB in the family: Yes/No
16. Alcohol consumption: Yes/No.
16 (a) If Yes, Frequency: i) Daily ii) More than once in a week iii) More than once in a month iv) once in a month v) occasionally
17. Smoking: Yes/No. If Yes,
17. (a) If yes, Frequency: i) Daily/almost daily ii) Weekly iii) Monthly iv) once or twice in year v) never
18. Name of the DMC:
19. Name of the TU: a) Harohalli b) Kanakapura c) Ramanagara d) Chanpatna e) Magadi
20. Place of diagnosis: a) Public b) Private
21. Mode of diagnosis: CBNAAT/Sputum smear microscopy/LPA/Chest X-ray/CT/others
22. Interval between sample collection and diagnosis: a) < a week b) > a week
23. Interval between the onset of symptom and initiation of treatment for TB: a) < two week b) 1 month c) > a month

Treatment adherence details:

24. Treatment interruption if yes, specify duration and reason
25. History of severe side effects: Yes/No.
a) If Yes, mention type and duration ----------
26. Follow up visits by TBHV/STS: Yes/No, If yes, how frequently?
a) once a month b) once in 3 months c) once in 6 months
27. Treatment outcome: Cured/ Treatment completed/ Treatment failure

Nutritional incentives:

28. Are you aware of Nikshay Poshana Yojana? Yes/No.
29. How did you come to know about Nikshay Poshan Yojana? MO/STS/TBHV/ASHA/AWW/Family and Friends/Others……
30. Details of the money received?

Instalment	Date	Amount received
First		
Second		
Third		
Fourth		
Fifth		
Sixth		

31. How many times did you receive it?

Utilization pattern:

32. How did you utilize the financial incentive?
a. For nutritional purposes
b. For other purposes

If for other purposes, tick for the appropriate response (Multiple responses possible)
i) To repay debt
ii) To buy alcohol
iii) To buy tobacco (smoke forming and smokeless)
iv) To buy Medicines
v) To undergo Lab tests
vi) To pay rent
vii) Others
33. How do you think NPY benefitted you?

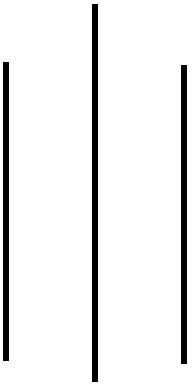
Nutritional assessment:

34. Type of diet: Vegetarian/ Non vegetarian
35. Nutritional support from any voluntary organizations/Anganwadi/School health scheme: Yes/No.
36. Height (In cms):
37. Weight (In Kg):
a. At the time of diagnosis: b) After 6months of NPY:
c) Weight gain during the 6 months of NPY: Yes/No, if yes how many kgs___
38. BMI (Kg/m2):
a. At the time of diagnosis: i) Extreme underweight ii) Severe underweight iii) Moderate underweight iv) Mild underweight v) Normal vi) Overweight vii)Obese
b. After 6months of NPY: i) Extreme underweight ii) Severe underweight iii) Moderate underweight iv) Mild underweight v) Normal vi) Overweight vii)Obese

Bidirectional Screening of Tuberculosis and Diabetes mellitus patients in the Gandaki Province of Nepal

2024

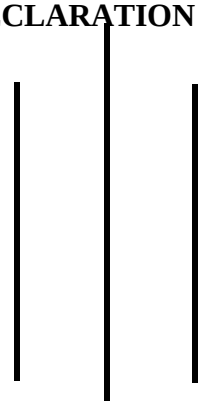
Bidirectional Screening of Tuberculosis and Diabetes mellitus patients in the Gandaki Province of Nepal



SUBMITTED TO

SAARC Tuberculosis and HIV/AIDS Centre
Thimi, Bhaktapur
Nepal

SELF-DECLARATION



SUBITTED BY

Mr. Manmohan Mishra (Principal Investigator)

Asst. Prof. Srijana Paudel (Co-Investigator)

Dr. Naveen Prakash Shah (Co-Investigator)

Mrs. Sushila Baral (Co-Investigator)

Mr. Rajesh Kumar Yadav (Co-Investigator)

This research project entitled "**Bidirectional Screening of Tuberculosis and Diabetes mellitus patients in the Gandaki Province of Nepal**" is original, unpublished, independent work by the authors. The data mentioned in the research has been generated during research work and are genuine. The results embodied in this research, researchers have not been submitted to any other institution or university for obtaining any degree or financial benefits.

……..

Signature

Mr. Manmohan Mishra
Director
Provincial Public Health Laboratory
Gandaki Province
Date: 29th November, 2024

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The success of this study and the completion of this report are undoubtedly the results of the earnest efforts put forth by many individuals. First and foremost, I am greatly thankful to SAARC Tuberculosis and HIV/AIDS Centre, Thimi, Bhaktapur for providing us with the research grant, and gratefully acknowledge the ethical review board, Nepal Health Research Council for the ethical clearance.

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At last, but not the least, I want to impart a vote of thanks to provincial Public Health Laboratory, Gandaki province, for their cooperation and support during data

collection. I would like to acknowledge, all the participants who participated in the study without which the study would not have been possible.

……..

Signature

Mr. Manmohan Mishra

Director

Provincial Public Health Laboratory

Gandaki Province

Date: 29th November, 2024

ABSTRACT

Background: Nepal faces a rising burden of non-communicable diseases (NCDs), particularly Diabetes. TB patients face an increased risk of developing diabetes due to factors such as prolonged inflammation, medication side effects, and lifestyle changes during treatment. Conversely, diabetes patients have a heightened susceptibility to TB due to compromised immune function, making them more susceptible to infection. Active screening for both diseases can reduce TB transmission and prevent the development of complications of DM.

Objective: The study aims to determine the prevalence of tuberculosis among diabetes patients and diabetes among tuberculosis patients and its associated factors.

Methods: The study design was hospital based quantitative cross-sectional study. Diabetes mellitus patients visiting provincial public health laboratory, Pokhara academy of Health Sciences and tuberculosis patients visiting Tuberculosis treatment center were reached as a respondent. Systematic random sampling was done. Written informed consent was taken. Data analysis was performed using descriptive statistics, binary and multiple logistic regression analysis through SPSS ver.22.

Results: The prevalence of diabetes mellitus patients among tuberculosis patients was 12.20% and tuberculosis among diabetes mellitus patients was 14.40%. Age, co- morbid conditions, HIV status was found to be predictors having diabetes among TB patients whereas, education status, presence of TB symptoms was found to be predictors having tuberculosis among diabetes mellitus patients.

Conclusions and Recommendations: The study concludes nearly one in tenth respondents had tuberculosis among diabetes mellitus patients and vice versa. Encourage diabetes patients to attend regular follow-up visits to monitor tuberculosis and tuberculosis patients for diabetes is crucial. The research contributes to the evidence base that informs policies and practices and help to understand

the necessity of integrated screening and management strategies to address the dual burden of TB and DM effectively.

Keywords: Prevalence, Diabetes mellitus, Tuberculosis, Nepal

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CHAPTER I - INTRODUCTION

1.1 Background

Tuberculosis remains a considerable global public health problem, mainly affecting poor and vulnerable populations. Tuberculosis is a highly infectious and chronic disease caused by the bacillus mycobacterium tuberculosis (1), which infect almost all body tissues and organs, but pulmonary tuberculosis (PTB) is the most common form.(2) Diabetes and tuberculosis both are considered as public health problems across the world as well as in Nepal. The association between TB & diabetes are known historically from 18th century onwards and numerous research has been conducted in a more scientific manner.(3)

Diabetes has been associated with a two-to-three fold risk of tuberculosis and a twofold risk of death during TB treatment.(4) With a stronger association in the presence of other risk factors. The probability of developing TB disease is much higher among people with diabetes. As estimated 371,000 TB cases were attributed to diabetes globally in 2021. In addition, DM is known to increase the risk of active TB approximately three fold, and contributes to adverse TB treatment outcomes such as death, treatment failure, relapse and even adverse drug interactions.(5,6)

Nepal is currently ranked thirty among high DR TB burden countries.(7) Nearly half of all cases remain undiagnosed and improving case-detection is an important target for the National TB Control Program (NTP).(1) In Nepal, there is also a growing burden of non-communicable diseases (NCDs), especially diabetes. In the fiscal year 2079/80, government health services treated 312,370 diabetes patients, excluding those treated in private healthcare facilities.(8)

To provide guidance to countries grappling with the dual burden of TB and DM, the World Health Organization (WHO) and the International Union Against TB and Lung Disease (The Union) developed a framework for collaborative TB–DM activities in 2011.(9) Under this framework, one of the key recommended activities is to establish mechanisms for collaboration between public health programs providing TB and DM diagnostic and treatment services. This includes conducting bidirectional screening, i.e., routine screening of all TB patients for DM and all DM patients for TB, and linking patients with coexisting diseases to appropriate care.

Several countries in Asia and Africa have formulated policies and are implementing bidirectional screening.(10,11) Tuberculosis (TB) is alarming, marking a reversal of the progress made over a century. This resurgence highlights the threat of antimicrobial resistance (AMR) and disproportionately affects vulnerable populations, exacerbating existing social inequalities. TB

patients face an increased risk of developing diabetes due to factors such as prolonged inflammation, medication side effects, and lifestyle changes during treatment. Conversely, diabetes patients have a heightened susceptibility to TB due to compromised immune function, making them more susceptible to infection. Active screening for both diseases can reduce TB transmission and prevent the development of complications of DM.

1.2 Problem Statement

Diabetes mellitus (DM) and tuberculosis (TB) are both serious health threats, and they have a complex relationship. Converging epidemics of non-communicable disease like DM (DM) and an infectious disease like tuberculosis (TB) is a double burden.(12) Diabetes rose from 108 million in 1980 to 422 million in 2014; there was a 3% increase in diabetes mortality rates by age between 2000 and 2019.(13) From an estimated prevalence of 463 million in 2019, it is estimated to increase to 578 million in 2030, and 700 million in 2045.(12)

Diabetes is rapidly growing public health problem affecting millions of people worldwide. WHO agreed to halt the rise in diabetes and obesity by 2025.(14) People with DM are at a higher risk of developing TB and experiencing more severe condition and adverse treatment outcomes. DM can increase the risk of TB by three fold. Evidence from different research shows that DM can increase the odds of developing Multi Drug resistant TB (MDR-TB). In 2020, an estimated 370 000 (UI: 150 000 - 680 000) new cases of TB were attributable to diabetes.(15)

In 2019, just over 15% of people with TB were estimated to have diabetes globally, compared with 9.3% among the general adult population (aged 20-79 years). This equates to about 1.5 million people with TB and diabetes who required coordinated care and follow-up to optimize the management of both conditions.

Different research articles had shown bidirectional screening is needed to improve prevention and care of tuberculosis and diabetes mellitus.(16,17) Diabetes mellitus risk was substantially raised among individuals with a history of TB disease.(18)

A study done in South India by B.C Prakash et al. shows 9% of diabetes patients were diagnosed with tuberculosis. Another study done by Regmi H.S et al. shows 8% diabetes patients were positive for tuberculosis.(19)

An intensive case finding of tuberculosis and diabetes mellitus- bidirectional screening of patients attending a tertiary teaching hospital in Rural Telangana, India by Sannithi K.et.al found 14.8% diabetes patients were positive for tuberculosis.(20)

A study conducted by Jeon and Murray, individuals with diabetes mellitus are two to three times more likely to develop active tuberculosis compared to those without diabetes. A study done in Northeast Ethiopia found prevalence of tuberculosis in 6.2% among diabetic patients. (21) The study done by

Mahishale V. shows 2.6% of the diabetes mellitus patients had tuberculosis. The link between DM and TB is prominent in developing countries where TB is endemic and burden of DM is increasing.(17) The frequency of diabetes among pulmonary T.B patients in the study was found to be 34.3% of which 29.9% were known DM cases and 4.4% were newly diagnosed.(16)

The prevalence of DM was found to be 18% (n=36). Increasing age ($p<0.000$), male sex ($p=0.04$), low BMI ($p=0.02$), family history of TB ($p=0.017$) was found significantly associated with DM-TB in the study done in tertiary health care center, Hyderabad among adult tuberculosis patients.(22) The study aims to assess the prevalence of diabetes and tuberculosis and its associated factors among the tuberculosis and diabetes patients respectively residing in Gandaki province of Nepal.

1.3 Objectives

1.3.1 General Objective

To assess the prevalence of diabetes and tuberculosis and its associated factors among the tuberculosis and diabetes patients respectively residing in Gandaki province of Nepal.

1.3.2 Specific Objectives

- To determine the prevalence of tuberculosis among diabetes patients.
- To assess the prevalence of Diabetes among tuberculosis patients.
- To identify factors associated with TB among diabetes patients and diabetes among TB patients.

1.4 Conceptual Framework

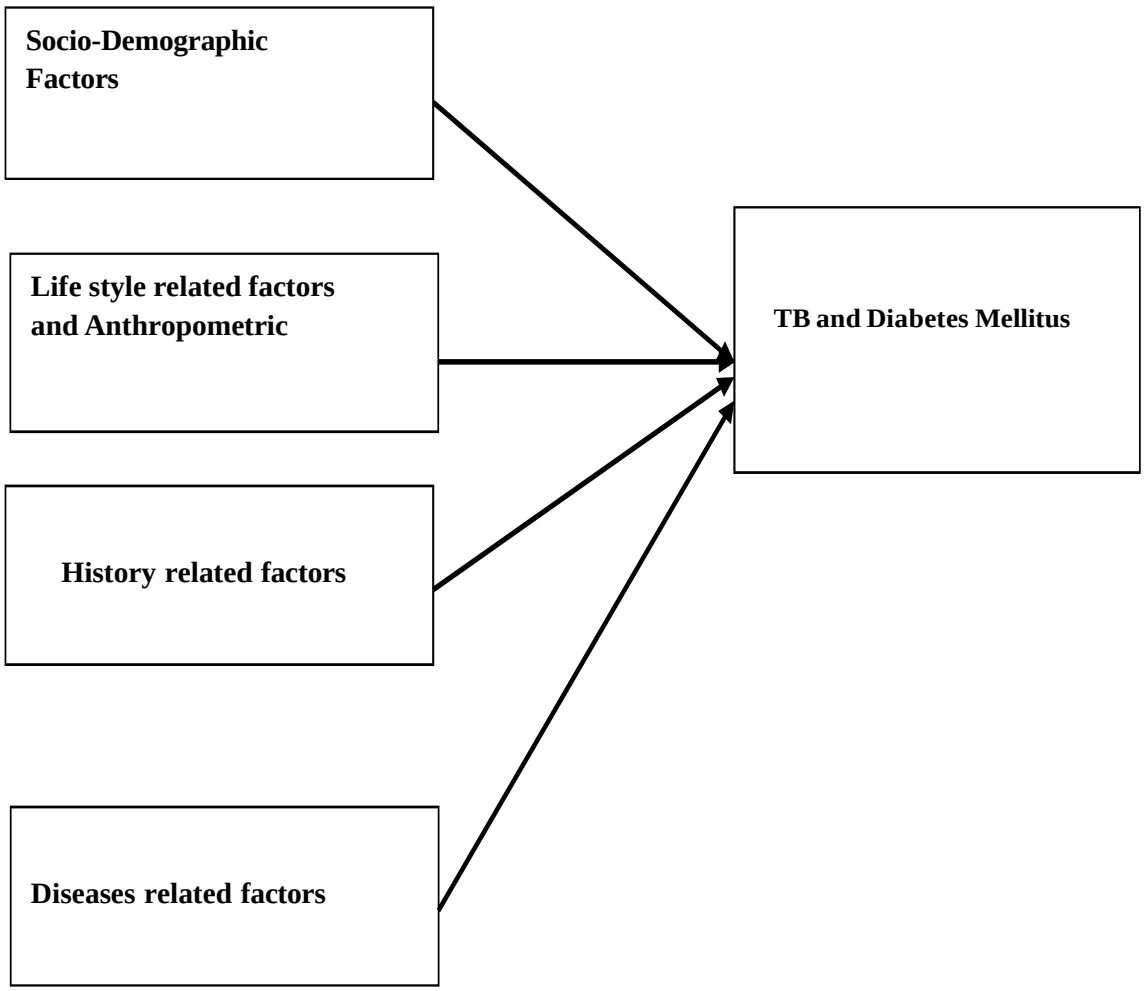

Figure 1: Conceptual Framework Study Variables

- Socio-demographic and economic variables:

Age, Sex, Religion, Ethnicity, Marital status, Family types, Residence, Educational status, Occupation, Family income, enrolment in health insurance

- Lifestyle and behavioral variables:

History and current status of smoking, History and current status of consuming alcohol, physical exercise

- Anthropometric variables: Body Mass Index
- Disease related variables:

Family history of Tuberculosis, Received TB treatment services, Contact with TB patients,

Family history of diabetes mellitus, Knowledge on symptoms of disease, Treatment category, Types of tuberculosis and diabetes, experienced side effects, co-morbid condition, HIV status, DM diagnosed method, Diabetes mellitus status based on sugar level of RBS, DM Status based

on sugar level of HBA1C.

1.5 Research Questions

- What are the factors associated with prevalence of diabetes mellitus and tuberculosis among the tuberculosis and diabetes patients?

CHAPTER II- METHODOLOGY

The research methodology adopted all procedural steps to explore the information that reflect the objectives of the study. The various aspects of the research methodology are discussed under the following headings.

2.1 Study Design

The study design was a hospital-based cross-sectional study done among the diabetes mellitus patients and tuberculosis patients attending provincial public health laboratory and Tuberculosis treatment center of Gandaki province respectively was conducted. All TB patients and DM patients diagnosed with diabetes mellitus and tuberculosis respectively was assessed with laboratory test HbA1C and FPG for diabetes and Gene Xpert for tuberculosis.

2.2 Study Methods

Study method was quantitative. Semi structured questionnaire was used for collecting primary data through face-to-face interview.

2.3 Study Process (Flow Diagram)

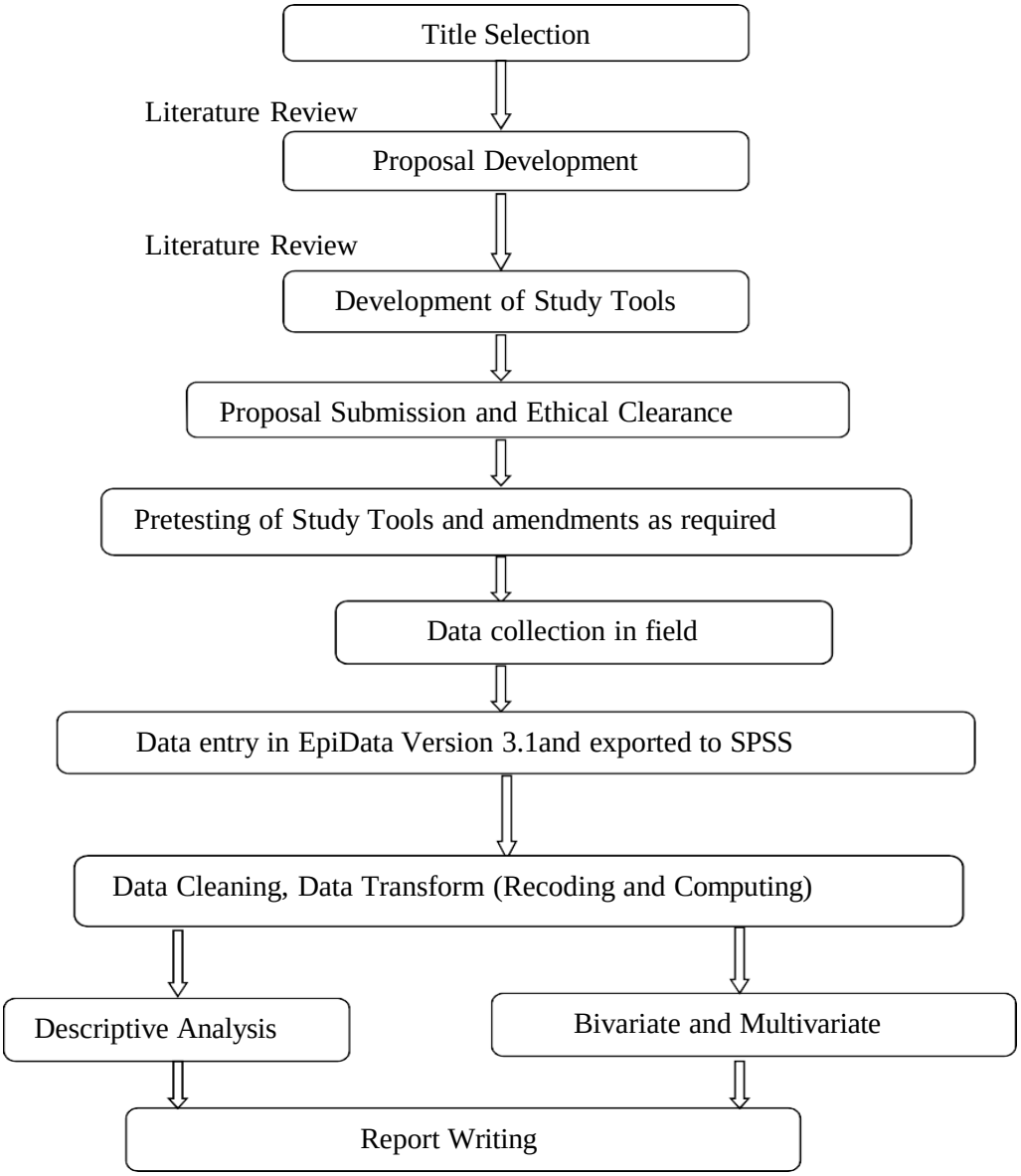

Figure 2: Study Process

2.3 Study Population, Site and Its Justification

The study population was Diabetic patients having age more than 18 years. The study was conducted in selected tertiary care hospital of Gandaki Province i.e. Western Regional hospital, Pokhara Academy of Health Sciences, Provincial public Health Laboratory and Tuberculosis treatment center. The study was conducted in Pokhara Metropolitan. Kaski has HDI 0.567 which is 3rd rank in whole country. Pokhara metropolitan is second most developed city after Kathmandu metropolitan. Prevalence of DM and tuberculosis is higher in urban area so, Pokhara metropolitan has been chosen as study area.

2.4 Study unit:

Patients with diabetes mellitus visiting Provincial public health laboratory and Pokhara Academy of health sciences and tuberculosis visiting Tuberculosis treatment center of Gandaki province.

2.5 Inclusion and Exclusion criteria

Respondents who were above 18 years and had diabetes mellitus and tuberculosis and willingness to participate in the study were included in the study. In regards of diabetes among TB, patients who had diagnosed diabetes already and refuse to provide blood for RBG/HbA1C test were excluded. Regarding TB among diabetes mellitus patients who were already on TB medication and refuse to provide sputum for gene xpert test were excluded.

2.6 Sampling Methods / Techniques

A random sampling technique was used. Steps of sampling:

1. Selection of the tertiary care hospitals which has highest diabetes patients flow was selected for study which is provincial public health laboratory (provincial lab) and Western Regional Hospital, Pokhara academy of health sciences and tuberculosis treatment centers where all tuberculosis patients was enrolled were selected.
2. All the diabetes patients and tuberculosis patients visiting to the selected institutions were entered in one register to make a sampling frame of the data collection period. With the help of the excel, the random number was generated previously and was save in laptop. With the help of generated number, the patients who falls under the extracted random number were selected as a respondent.

2.7 Sample size

Sample size is calculated by using the following formula:

Diabetes among tuberculosis patients

$n = Z^2pq/d^2$ Where,

Z= value of standard normal distribution in 1.96 level of significant with 95% confidence level

(p= 11.9% Prevalence Diabetes among Tuberculosis patients of Nepal is 11.9%.(23) so the

required p= 0.119

q = (1- p) = (1-0.119) = 0.881

d = desirable error 0.05 (5% margin of error) Now putting

the values,

$$n = \frac{z^2pq}{d^2}$$

$$n = \frac{1.96^2 0.119 * 0.881}{0.005^2}$$

n=161.099≈162

Assuming the Non response rate (NR) of 10% sample size,

Final sample size (n_2) = $\frac{n}{1-NR}$

$$\frac{162}{1-10/100}$$

= 180

Required respondents = 180

So the investigator aims to focus study by 180 samples following the calculation above.

Tuberculosis among Diabetes patients

$n= Z^2pq/d^2$ Where,

Z= value of standard normal distribution in 1.96 level of significant with 95% confidence level

(p= 11.9% Prevalence tuberculosis among Diabetes patients of India is 9%.(24) so the required

p= 0.119

q = (1- p) = (1-0.119) = 0.881

d = desirable error 0.05 (5% margin of error)

Now putting the values,

$n= \frac{z^2pq}{d^2}$

$n= \frac{1.96^2 0.119 * 0.881}{0.005^2}$

n=161.08≈162

Assuming the non-response rate (NR) of 10% sample size,

Final sample size (n_2) = $\frac{n}{1-NR}$

$$\frac{162}{1-10/100}$$

= 180

Required respondents = 180

So the investigator aims to focus study by 180 samples following the calculation above.

2.8 Data Collection Technique / Methods

The data was collected through quantitative approach. Data was collected from the diabetes patients and tuberculosis patients using interview schedule in Nepali version at one point in time for each of the patients. A schedule was divided into four sections. The first section includes the socio-demographic and economic characteristics, life style and behavior related

information. The second section focus on the anthropometric measures. Third section includes disease related variables.

Firstly, formal permission was taken from the Provincial public health laboratory, tuberculosis treatment center and Pokhara academy of health sciences. Informed consent was taken from the respondents before starting data collection. Respondents were made clear about the purpose of study, benefits of the study and assured about the privacy and confidentiality of the information. The interview was conducted considering comfort for the respondents like; sitting arrangement, polite voice and leading question was not asked. Face to face interview, review of treatment cared.

Data was entered in the EPI-DATA version 3.1 and all the entered data was transferred in Statistical Package for Social Sciences (SPSS-22 version) for the further analysis. Based on the objectives, data was analyzed. The data was analyzed by using descriptive and inferential statistics.

2.9 Validity and Reliability of the Study Tools:

- Questionnaire was constructed after the review of the related literature, reference of various research papers was taken.
- Back translation of the questionnaire was done in Nepali language and again into English language.
- Pretesting was done in Urban Health Center to 10 per cent of respondents and questionnaire was modified as per need.
- After the data collection, immediate editing was done to correct the mistake that occurs during the data collection.
- During data entry, error was minimized, through EPI-DATA.
- Use of probing questions to reduce recall bias.
- Respondents were asked in native language to make them clear what they are being asked. In order to get exact information, questionnaire was made practicable and convenient adequate counseling was done

2.10 Limitation of the Study

The study was limited only in one hospital and only at provincial lab and couldn't be generalized nationally.

2.11 Plan for Data Management and Analysis:

Data was entered in the EPI-DATA version 3.1 and all the entered data was transferred in Statistical Package for Social Sciences (SPSS-22 version) for the further analysis. Based on the objectives, data was analyzed. The data was analyzed by using descriptive and inferential statistics followed by multivariate analysis. Multivariate logistic regression model was carried out to identify the most independent. The odds ratio and 95% CI was reported while showing the association. This result was considered significant

at 5% level i.e. p value (<0.05).

2.12 Plan for Dissemination of Research Results

A complete research report will be submitted to provincial public health laboratory, tuberculosis treatment center, Pokhara academy of health sciences. Presentation will be conducted to concern authorities for implementation of the research results. Scientific dissemination will be done through publish research paper in SAARC Journal of Tuberculosis, Lungs Disease and HIV/AIDS and presentation in national and international forum/ conferences.

2.13 Ethical Considerations

2.13.1 Ethical Review

Approval was obtained from all the selected institutions and ethical approval was obtained from the ethical review board of Nepal Health Research Council (NHRC) (Ref no. 329)

2.13.2 Informed Consent

Diabetes mellitus patients and tuberculosis patients aged 18 years and above were considered as the study respondents.

Before the conduction of study, purpose of study was clearly explained and respondents was assured that the information given by them was kept confidential and only used for research purpose. Interview was conducted only after taking written informed consent from the respondents. Each respondent was given right to withdraw from the study at any time during the interview as per their wish and interest. Questions were not asked in a way that hurts their dignity. Respondents were selected without any discrimination of ethnicity, age, occupation, socio-economic status and religion.

2.13.3 Benefits to respondents and handling of possible risks

All respondents were informed about no any risk in participating under study. After collecting data, for individuals benefit counseling and information was provided on which they have queries.

CHAPTER III-RESULTS

This research was aimed to study the prevalence of diabetes mellitus patients and tuberculosis among tuberculosis and diabetes mellitus patients respectively of Gandaki province of Nepal. Out of 180 interview schedules, all the respondents respond to the questionnaire. The analysis was done with reference to the objectives of the study. The results of this study based on quantitative analysis are presented below.

Univariate Analysis

Part: I Diabetes among TB Patients

Table 1: Socio-demographic characteristics of the TB respondents

Characteristics	Frequency (n)	Percentage (%)
Treatment/Referral Facilities		
Government Hospital	118	65.6
Private Hospital	58	32.2
Pharmacy	4	2.2
Sex		
Male	114	63.3
Female	66	36.7
Age		
18-40 Year	89	49.1
41-60 Years	47	26.1
>61 Years	44	24.4
Mean=45.17, S.D=19.029, Min=18, Max=92		
Religion		
Hinduism	128	71.1
Buddhism	45	25.0
Christianity	7	3.9
Ethnicity		
Dalit	41	22.8
Disadvantaged Non Dalit Terai Caste	3	1.7
Disadvantaged Janjati	2	1.1
Religious Minorities	1	0.6
Upper Caste Groups	60	33.3
Relatively Advantaged Janajati	73	40.6
Marital Status		
Married	128	71.1
Unmarried	41	22.8
Widowed	11	6.1
Family Type		
Nuclear	112	62.2
Joint	68	37.8
Residence		
Urban	141	78.3
Rural	39	21.7

More than three-fifth (65.6%) of respondents were referred from government hospital. More than three fifth (63.3%) were male. About half (49.1%) of respondents were of age group 18-40 years. Most (71.1%) of the respondents follow Hinduism. One –third (33.3%) of respondents were upper caste groups. Most (71,1%) of the respondents were married. Nearly two-third (62.2%) belongs to Nuclear family. Majority of respondents reside in urban areas is illustrated in Table 1.

Table 2: Socio-economic characteristics of the TB respondents

Characteristics	Frequency (n)	Percentage (%)
Educational Status		
Illiterate	42	23.3
Non Formal Education	23	12.8

Primary Education (1-8 Class)	31	17.2
Secondary Education (9-12 Class)	63	35.0
Higher Education (Completion of Bachelor or Above)	21	11.7
Occupation		
Unemployed	65	36.1
Employee	30	16.7
Farmer	26	14.4
Students	23	12.8
Daily Labor	9	5.0
Government Job	2	1.1
Business	10	5.6
Others (Abroad, Driver, Housewife, Pension)	15	8.3
Family Monthly Income		
<NRs17000	34	18.9
NRs17000-25000	31	17.2
≥NRs25000	115	63.9
Min=2000, Max=500000		
Enrolment in Health Insurance Scheme		
No	120	66.7
Yes	60	33.3

Table 2 shows socio economic characteristic of the TB respondents. One-fourth (23.3%) of the respondents were illiterate. One third (36.1%) were unemployed, very few (1.1%) were engaged in government job. More than two-third (66.7%) were not enrolled in health insurance scheme.

Table 3: Lifestyle and behavioural related characteristics of TB respondents

Characteristics	**Frequency (n)**	**Percentage (%)**
History of smoking? (n=180)		
Yes	80	44.4
No	100	55.6
Current consumption of smoking? (n=180)		
Yes	17	9.4
No	163	90.6
History of alcohol drinking? (n=180)		
Yes	88	48.9
No	92	51.1
Current consumption of alcohol? (n=180)		
Yes	18	10.0
Occasionally	7	3.9
No	155	86.1
Do you do Physical exercises? (n=18)		
Yes	21	11.7
No	159	88.3
If yes, then how many minutes? (n=21)		
< 40 Minutes	13	61.9
≥40 Minutes	8	38.1

Table 3 shows lifestyle and behavioural related characteristics of TB respondents. More than half (55.6%) of the respondents didn't have history of smoking where recently one in tenth (9.4%) of respondent's smoke. More than half (51.1%) of respondents had no history of drinking alcohol where one in tenth (10%) consume alcohol in present days. Majority (88.3%) of respondents do physical exercise.

Table 4: Anthropometric related findings of TB respondents

Characteristics	Frequency (n)	Percentage (%)
Body mass index group (kg/m2)		
Underweight (<19)	59	32.8
Normal weight (19-24.9)	91	50.6
Overweight (25-29.9)	26	14.4
Obesity (30-34.9)	4	2.2

Table 4 revealed about half (50.6%) of the respondents had normal body mass index followed by underweight (32.9%). Very few (2.2%) of the respondents were obese.

Table 5: Family history of TB respondents

Characteristics	Frequency (n)	Percentage (%)
Family history of TB		
No	141	78.3
Yes	39	21.7
If Yes who are diagnosed as TB (n=39)		
Father	11	28.2
Husband	5	12.8
Grand mother	4	10.3
Mother	3	7.7
Grand father	3	7.7
Brother	3	7.7
Son	2	5.1
Sister	2	5.1
Father and mother	2	7.7
Daughter	2	5.1
Wife	1	2.6
Ever Received TB Treatment Service		
No	151	83.9
Yes	29	16.1
If yes, what type of TB treatment (n=29)		
DS TB	27	93.1
DR TB	2	6.9
Contact with any TB patients		
No	159	88.3
Yes	21	11.7
Family history of DM		
No	148	82.2
Yes	32	17.8
If Yes who are diagnosed as DM (n=32)		

Father	13	40.6
Mother	6	18.8
Husband	3	9.4
Son	3	9.4
Wife	2	6.3
Brother	1	3.1
Daughter	1	3.1
Father and Sister	1	3.1
Grand father	1	3.1
Sister	1	3.1

Table 5 shows one fifth (21.7%) of respondents had family history of tuberculosis. Nearly one-fifth (16.1%) had ever received tuberculosis treatment service. Majority (82.2%) of respondents had no history of diabetes mellitus.

Table 6: Disease related findings of TB patients

Characteristics	**Frequency (n)**	**Percentage (%)**
Know about the Symptoms of TB		
No	38	21.1
Yes	142	78.9
Symptoms of TB **(Multiple Response)		
Cough with expectoration	96	70.6
Chest Pain	37	27.2
Low grade fever	49	36.0
Blood in sputum	18	13.2
Loss of appetite	39	28.7
Loss of weight	33	24.3
Treatment Category		
New	153	85.0
Relapse	26	14.4
Treatment after failure	1	0.6
Type of TB		
Pulmonary (PBC)	117	65.0
Pulmonary (PCD)	15	26.7
Extra Pulmonary (EP)	48	26.7
Experienced side effects		
No	141	78.3
Yes	39	21.7
Comorbidities other than TB		
Yes	47	26.1
No	133	73.9
If yes, What diseases (n=47)		
COPD	14	29.8
Hypertension	8	17.0
HIV	4	8.5
Kidney	2	4.3
Thyroid	3	6.4
Hepatitis-B	2	4.3
Liver Problem	2	4.3
Arthritis	1	2.1
Asthma	1	2.1
Asthma, HIV and Heart	1	2.1

CVD	1	2.1
Epilepsy	1	2.1
Hepatitis-B and HIV	1	2.1
Hypertension and HIV	1	2.1
Hypertension and Thyroid	1	2.1
Lungs	1	2.1
Uric acid	1	2.1
HIV Status		
Negative	169	93.9
Positive	11	6.1

Table 6 shows most of the respondents (78.9%) knew about the symptoms of TB. Majority (85%) were newly diagnosed followed by relapse (14.4%). 65% had pulmonary (PBC). Most (78.3%) of respondents didn't experienced side effects. 26.1% of respondents had other co-morbid diseases other than TB in which, (29.8%) had COPD followed by hypertension (17%). Two-third (66.7%) of the respondents didn't have any co-morbid conditions other than diabetes mellitus. Majority (93.9%) of respondents had HIV status negative.

Table 7: Diabetes Mellitus related findings of TB patients

Characteristics	**Frequency (n)**	**Percentage (%)**
DM Diagnosed Method		
RBG	98	54.4
Both (RBS & HBA1C)	82	45.6
DM Status based on sugar level of RBS		
Normal (<110 mg/dl)	98	54.4
Abnormal (≥110 mg/dl)	82	45.6
DM Status based on Sugar level of HBA1C (n=82)		
Normal (<6.0%)	60	33.3
Pre-Diabetes (6.0%-6.4%)	4	2.2
Diabetes (≥6.5%)	18	10.0
Prevalence of diabetes among TB patients		
Non-Diabetes	158	87.8
Diabetes	22	12.2
Category of DM Status (n=22)		
Pre-Diabetes	4	18.18
Diabetes	18	81.82

Table 7 shows about diabetes Mellitus related findings of TB patients. More than half (54.4%) of respondents were diagnosed diabetes mellitus through RBG method. More than one in tenth (12.2%) of the respondents had diabetes among tuberculosis patients in which 81.82% were diabetes and 18.18% had pre diabetes.

Figure 3: Prevalence of Diabetes among tuberculosis patients

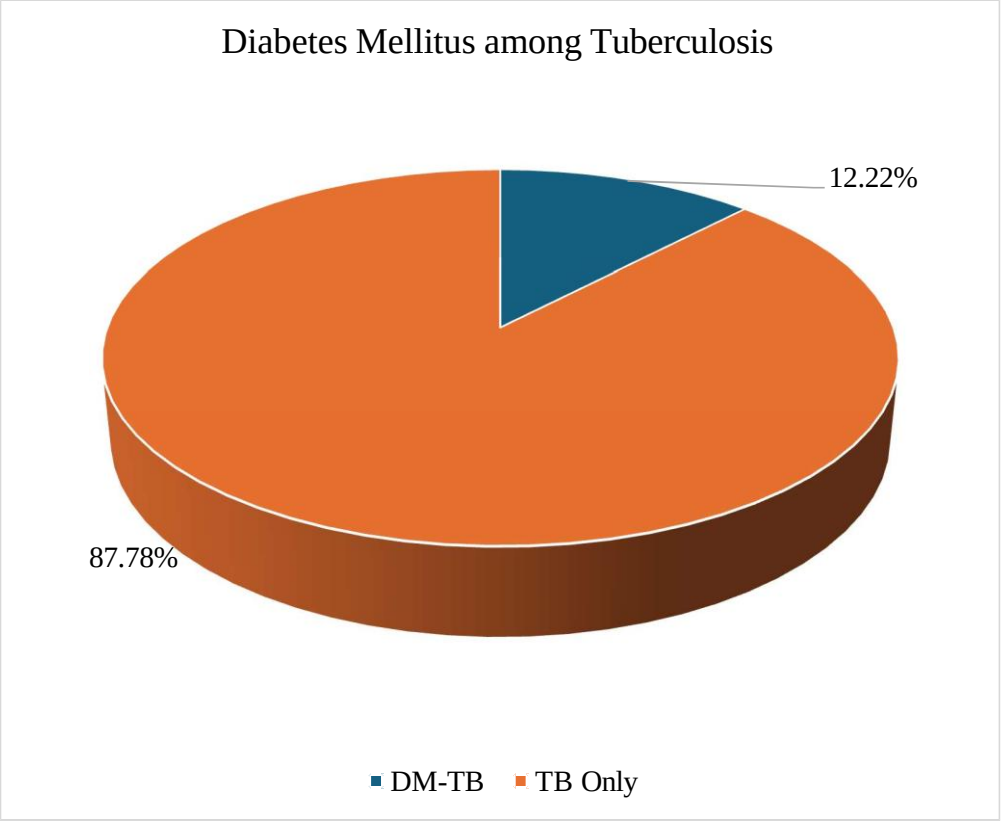

Figure 3 shows prevalence of diabetes among tuberculosis patients on which 12.2% had diabetes.

Bivariate Logistic Regression

Table 8: Association between socio-demographic and economic characteristics of diabetes among TB patients

Characteristics	Tuberculosis		p-value	UOR	95%CI
	TB only n(%)	TB-DM n(%)			
Sex					
Male	96 (84.2)	18 (15.8)	0.004*	2.906	0.939-8.992
Female	62 (93.9)	4 (6.1)		**1**	**Ref**
Age					
<45 Years	99 (98.0)	2 (2.0)	0.0001*	**1**	**Ref**
≥45 Years	59 (74.7)	20 (25.3)		16.780	3.786-74.368
BMI					
Underweight	51 (86.4)	8 (13.6)	0.702	1.199	0.473-3.040
Normal	107 (88.4)	14 (11.6)		**1**	**Ref**
Education Status					
Illiterate	35 (83.3)	7 (16.7)	0.315	1.640	0.620-4.337
Literate and above	123 (89.1)	15 (10.9)		**1**	**Ref**
Religion					
Hinduism	117 (91.4)	11 (8.6)	0.020*	**1**	**Ref**
Non-Hinduism	41 (78.8)	11 (21.2)		2.854	1.151-7.077
Ethnicity					

Relatively Advantaged Janajati	59 (80.8)	14 (19.2)	0.019*	2.939	1.163-7.417
Non- Relatively Advantaged Janajati	99 (92.5)	8 (7.5)		**1**	**Ref**
Family Type					
Nuclear	100 (89.3)	12 (10.7)	0.428	**1**	**Ref**
Joint	58 (85.3)	10 (14.7)		1.437	0.585-3.532
Residence					
Urban	122 (86.5)	19 (13.5)	0.329	1.869	0.523-6.676
Rural	36 (92.3)	3 (7.7)		**1**	**Ref**
Occupational Status					
Unemployed	57 (87.7)	8 (12.3)	0.645	**1**	**Ref**
Employee	101 (87.8)	14 (12.2)		0.988	0.391-2.497
Family Income					
<NRs45000	121 (86.4)	19 (13.6)	0.301	1.937	0.543-6.911
>NRs45000	37 (92.5)	3 (7.5)		**1**	**Ref**
Health Insurance Status					
No	104 (86.7)	16 (13.3)	0.520	1.385	0.512-3.742
Yes	54 (90.0)	6 (10.0)		**1**	**Ref**

Different independent variables like sex, age, religion, and ethnicity were found statistically associated with presence of diabetes mellitus. Males are more likely to have DM (UOR = 2.906, 95% CI: 0.939–8.992) compared to females. Individuals aged ≥45 years are significantly more likely to have DM (UOR = 16.780, 95% CI: 3.786– 74.368) compared to those aged <45 years. Relatively advantaged janajati individuals have higher odds (UOR = 2.939, 95% CI: 1.163-7.417) of having DM compared to non- relatively advantaged janajati individuals. Age is the strongest predictor of diabetes, with individuals aged ≥45 being at significantly greater risk. Variables such as BMI, family income, and residence, often associated with diabetes mellitus, did not show significant associations in this analysis.

Table 9: Association between behavioural factors and diseases characteristics of diabetes among TB patients

Characteristics	Tuberculosis		p-value	UOR	95%CI
	TB only n(%)	DM-TB n(%)			
History of Smoking Status					
No	91 (91.0)	9 (9.0)	0.140	**1**	**Ref**
Yes	67 (83.8)	13 (16.2)		1.962	0.792-4.857
History of Alcohol					
No	84 (91.3)	8 (8.7)	0.140	**1**	**Ref**
Yes	74 (84.1)	14 (15.9)		1.986	0.789-5.000
Family History of TB					
No	123 (87.2)	18 (12.8)	0.672	**1**	**Ref**
Yes	35 (89.7)	4 (10.3)		0.781	0.248-2.458
Prior Treated of TB					
No	131 (86.8)	20 (13.2)	0.339	**1**	**Ref**
Yes	27 (93.1)	2 (6.9)		0.485	0.107-2.199
Do you have TB symptoms					
No	32 (84.2)	6 (15.8)	0.363	1.477	0.353-4.076
Yes	126 (88.7)	16 (11.3)		**1**	**Ref**
Co-morbidities other than TB					
No	122 (91.7)	11 (8.3)	0.006*	**1**	**Ref**
Yes	36 (76.6)	11 (23.4)		3.389	1.358-8.459
Experienced of side effect					
No	123 (89.4)	15 (10.6)	0.217	**1**	**Ref**
Yes	32 (82.1)	7 (17.9)		1.837	0.691-4.883
Family History of DM					
No	132 (89.2)	16 (10.8)	0.214	**1**	**Ref**
Yes	26 (81.2)	6 (18.8)		1.904	0.681-5.323
Nutrition Status					
Underweight (<19)	51 (86.4)	8 (13.6)	0.702	1.199	0.473-3.040
Normal (≥19)	107 (88.4)	14 (11.6)		**1**	**Ref**

HIV status					
Negative	152 (89.9)	17 (10.1)	0.001*	**1**	**Ref**
Positive	6 (54.5)	5 (45.5)		7.451	2.054- 27.022

Table 9 shows association between behavioural factors and diseases characteristics of diabetes among TB patients. History of smoking, history of alcohol, family history of TB, prior treated of Tuberculosis, having Tuberculosis symptoms, experienced of side effects, family history of DM, nutrition status was not found statistical association with presence of diabetes among tuberculosis patients. Having co-morbid conditions, HIV status was found statistically significantly associated with presence of diabetes among tuberculosis patients.

Table 10: Adjusted relationship of explanatory variables with diabetes among TB Patients

Characteristics	**P-value**	**AOR**	**95%, CI**
Sex			
Male	0.604	1.427	0.372-5.475
Female		**1**	**Ref**
Age			
<45 Years		**1**	**Ref**
>45 Years	0.001*	16.907	3.198-89.386
Religion			
Hinduism		**1**	**Ref**
Non-Hinduism	0.947	1.048	0.261-4.207
Ethnicity			
Relatively Advantaged Janajati	0.110	3.234	0.768-13.617
Non- Relatively Advantaged Janajati		**1**	**Ref**
Co-morbidities other than TB			
No	0.037*	**1**	**Ref**
Yes		8.504	1.138-63.565
HIV status			
Negative	0.013*	**1**	**Ref**
Positive		8.527	1.558-46.680

Table 10 shows the predictors for presence of diabetes among tuberculosis patients. Respondents who had age more than 45 years were more likely to had diabetes (p 0.001, OR 16.907, CI 3.198-89.386). Respondents who had other co-morbid conditions were more likely to had diabetes (p 0.037, OR 8.504, CI 1.138-63.565) compared with respondents with no-co morbid conditions.

Part: II Result

TB among Diabetes Patients

Table 11: Socio-demographic characteristics of the DM respondents

Characteristics	**Frequency (n)**	**Percentage (%)**
Treatment Facilities		
Government Hospital	106	58.9
Private Hospital	54	30.0
Pharmacy	20	11.1

Sex		
Male	106	58.9
Female	74	41.1
Age		
18-40 Years	17	9.4
41-60 Years	75	41.7
>61 Years	88	48.9
Mean=59.04, S.D=14.58, Min=23, Max=86		
Religion		
Hinduism	141	78.3
Buddhism	38	21.1
Christianity	1	0.6
Ethnicity		
Dalit	20	11.1
Disadvantaged Non Dalit Terai Caste	0	0
Disadvantaged Janajati	1	0.6
Religious Minorities	1	0.6
Upper Caste Groups	83	46.1
Relatively Advantaged Janajati	75	41.7
Marital Status		
Married	155	86.1
Unmarried	8	4.4
Widowed	17	9.4
Family Type		
Nuclear	74	41.1
Joint	102	56.7
Extended	4	2.2
Residence		
Urban	135	75.0
Rural	45	25.0

About three-fifth (58.9%) of respondents were referred from government hospital. Nearly three fifth (58.9%) were male. About half (48.9%) of respondents were of age group above 61 years. Most (78.3%) of the respondents follow Hinduism. More than one –third (46.1%) of respondents belongs to upper caste groups. Most (86.1%) of the respondents were married. More than half (56.7%) belongs to Joint family. Most of respondents (75%) reside in urban areas is illustrated in Table 11.

Table 12: Socio-economic characteris 355 **the DM respondents**

Characteristics	Frequency (n)	Percentage (%)
Educational Status		
Illiterate	66	36.7
Non Formal Education	39	21.7
Primary Education (1-8 Class)	31	17.2
Secondary Education (9-12 Class)	37	20.6
Higher Education (Completion of Bachelor or Above)	7	3.9
Occupation		
Unemployed	112	62.2
Employee	27	15.0
Farmer	7	3.9
Students	2	1.1
Daily Labor	1	0.6

Government Job	2	1.1
Business	29	16.1
Others (Abroad, Driver, Housewife, Pension)		
Family Monthly Income		
<NRs17000	12	6.7
NRs17000-25000	26	14.4
≥NRs25000	142	78.9
Mean=54316.67, S.D=35000.794, Min=10000, Max=300000		
Enrolment in Health Insurance Scheme		
No	91	50.6
Yes	89	49.4

Table 12 shows socio economic characteristic of the DM respondents. More than one- third (36.7%) of the respondents were illiterate. Around two-third (62.2%) were unemployed, very few (1.1%) were engaged in government job. Nearly half (49.4%) of the respondents were enrolled in health insurance scheme.

Table 13: Lifestyle and behavioural related characteristics of DM respondents

Characteristics	**Frequency (n)**	**Percentage (%)**
History of smoking? (n=180)		
Yes	56	31.1
No	124	68.9
Current consumption of smoking? (n=180)		
Yes	41	22.8
No	139	77.2
History of alcohol drinking? (n=180)		
Yes	70	38.9
No	110	61.1
Current consumption of alcohol? (n=180)		
Yes	11	6.1
Occasionally	25	13.9
No	144	80.0
Do you do Physical exercises? (n=180)		
Yes	57	31.7
No	123	68.3
If yes, then how many minutes? (n=57)		
< 40 Minutes	39	68.4
≥40 Minutes	18	31.6

Table 13 shows lifestyle and behavioural related characteristics of DM respondents. More than two-third (68.9%) of the respondents didn't have history of smoking where recently two in tenth (22.8%) of respondent's smoke. More than half (61.1%) of respondents had no history of drinking alcohol where very few (6.1%) consume alcohol in present days. Majority two-third (68.3%) of respondents do physical exercise.

Table 14: Anthropometric related findings of DM respondents

Characteristics	Frequency (n)	Percentage (%)
Body mass index group (kg/m2)		
Underweight (<19)	13	7.2
Normal weight (19-24.9)	124	68.9
Overweight (25-29.9)	31	17.2
Obesity (30-34.9)	12	6.7

Table 14 revealed about more than two-third (68.9%) of the respondents had normal body mass index followed by overweight (17.2%). Very few (6.7%) of the respondents were obese.

Table 15: Family history of DM respondents

Characteristics	Frequency (n)	Percentage (%)
Family history of TB		
No	172	95.6
Yes	8	4.4
If Yes who are diagnosed as TB (n=8)		
Father	4	50.0
Husband	1	12.5
Mother	1	12.5
Brother	1	12.5
Daughter	1	12.5
Ever Received TB Treatment Service		
No	168	93.3
Yes	12	6.7
If yes, what type of TB treatment (n=12)		
PBC	10	83.3
PCD	2	16.7
Contact with any TB patients		
No	175	97.2
Yes	5	2.8
Family history of DM		
No	157	87.2
Yes	23	12.8
If Yes who are diagnosed as DM (n=23)		
Father	4	17.4
Mother and Mother	2	8.7
Husband	4	17.4
Son	4	17.4
Wife	3	13.0
Brother	2	8.7
Daughter	1	4.3
Sister	2	8.7
Son and Daughter	1	4.3

Table 15 shows very few (4.4%) of respondents had family history of tuberculosis among diabetes mellitus patients. Majority (93.3%) of respondents didn't ever received tuberculosis treatment service. Majority (87.2%) of respondents had no family history of diabetes mellitus.

Table 16: Disease related findings of DM patients

Characteristics	Frequency (n)	Percentage (%)
Know about the Symptoms of TB		
No	80	44.4
Yes	100	55.6
Symptoms of TB **(Multiple Response)		
Cough with expectoration	75	83.3
Chest Pain	31	34.4
Loss of appetite	10	11.1
Loss of weight	9	10.0
Low grade fever	7	7.8
Blood in sputum	6	6.7
Types of DM		
Type-I	40	22.2
Type-II	140	77.8
Types of medication		
Oral hypoglycemic	97	53.9
Both	48	26.7
Insulin	35	19.4
Duration time for Medication of Diabetes in Year		
≤5 Years	111	61.7
> 5 Years	69	38.3
Experienced side effects		
No	137	76.1
Yes	43	23.9
If yes, what types of side effects (n=43)		
Vision Problem	10	23.3
Frequent Urination	8	18.6
Chest Pain	7	16.3
Joint Pain	7	16.3
Liver Problem	6	14.0
Kidney Problem	2	4.7
Weakness	2	4.7
CVD	1	2.3
Comorbidities other than DM		
Yes	79	43.9
No	101	56.1
If yes, what types of diseases (n=79)		
Hypertension	37	46.8
CVD	14	17.7
Thyroid	9	11.4
Asthma	8	10.1
Kidney Problem	5	6.3
CVD and Hypertension	2	2.5
Thyroid and Hypertension	2	2.5
Asthma and Hypertension	1	1.3
HIV Status		
Negative	180	100.0

Table 16 shows more than half of respondents (55.6%) knew about the symptoms of TB. Majority (83.3%) had cough with expectoration, followed by chest pain (34.4%). Majority (77.8%) of

respondents were Type II diabetes. Nearly two-third (61.7%) of respondents were under medication of diabetes less than five years. Majority (76.1%) didn't experienced side effects. 43.9% of respondents had other co-morbid diseases other than diabetes mellitus in which, 46.8% had hypertension followed by CVD (17.7%).

Table 17: Age wise findings of type of DM patients

Age in Years	DM patients		Total
	Type I n, (%)	Type II n, (%)	
18-30 Years	6 (60.0)	5 (40.0)	10
30-40 Years	4 (57.1)	3 (42.9)	7
40-50 Years	9 (42.9)	12 (57.1)	21
50-60 Years	14 (28.6)	35 (71.4)	49
60-70 Years	6 (13.3)	39 (86.7)	45
70-80 Years	1 (2.6)	37 (97.4)	38
≥80 Years	0 (0.0)	10 (100.0)	10
Total	40 (22.2)	140 (77.8)	

Table 17 shows age wise findings of type of DM patients. Type I diabetes is more prevalent in younger age groups (18-40 years), making up the majority in these groups. Type II diabetes becomes dominant from age 40 onward, with its prevalence increasing significantly in older age groups. By age 70-80 years and beyond, almost all patients have Type II diabetes.

Table 18: TB related findings of Diabetes patients

Characteristics	Frequency(n)	Percentage (%)
TB Diagnosed Method		
Rapid Molecular Test	180	100.0
Gene-xpert Result at Diagnosis		
MTB Not Detected	154	85.6
MTB Detected High	12	6.7
MTB Detected Low	9	5.0
MTB Detected Medium	3	1.7
MTB Detected Indeterminant	2	1.1
Prevalence of TB among Diabetes patients		
Positive	26	14.4
Negative	154	85.6

Table 18 shows TB related findings of Diabetes patients. Among 180 diabetes patients, all were diagnosed using the Rapid Molecular Test. Gene-Xpert results showed that 85.6% had MTB not detected, while 14.4% tested positive for TB. Among those with

MTB detected, 6.7% had high levels, 5.0% low levels, 1.7% medium levels, and 1.1% indeterminate results. The overall prevalence of TB among diabetes patients was 14.4%.

Figure 4: Prevalence of tuberculosis among Diabetes patients

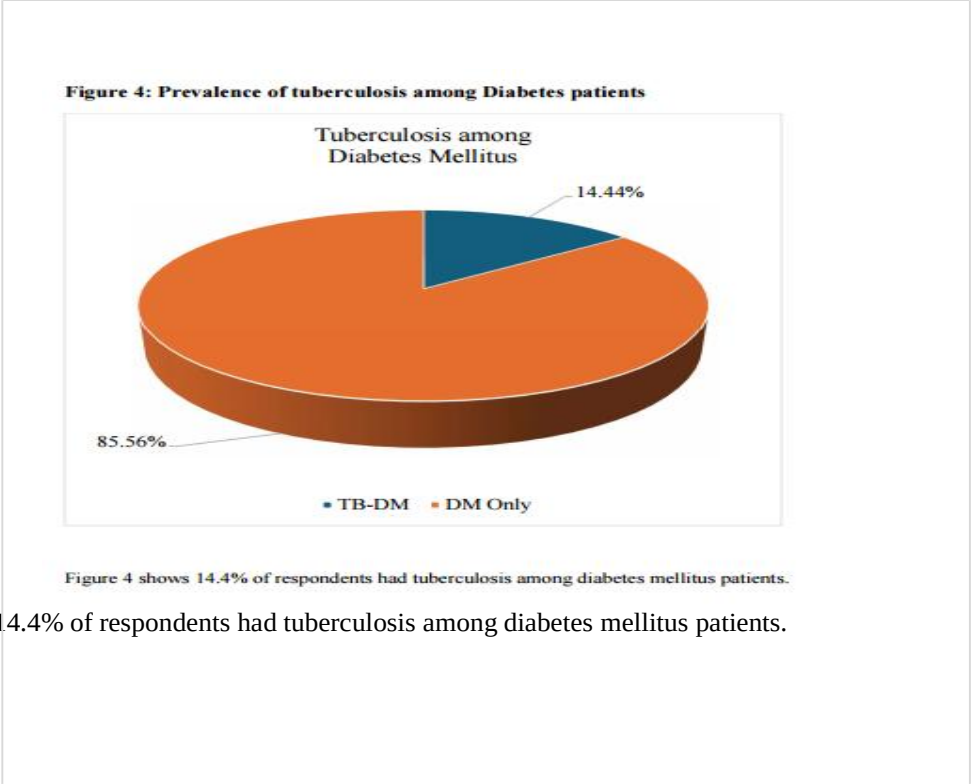

Figure 4 shows 14.4% of respondents had tuberculosis among diabetes mellitus patients.

Table 19: Association between socio-demographic and economic characteristics of TB among Diabetes Patients

Characteristics	Diabetes Mellitus		p-value	UOR	95%CI
	DM only n(%)	DM-TB n(%)			
Sex					
Male	84 (79.2)	22 (20.8)	0.004*	4.583	1.508-13.929
Female	70 (94.6)	4 (5.4)		**1**	**Ref**
Age					
<45 Years	23 (76.7)	7 (23.3)	0.129	0477	0.180-1.261
>45 Years	131 (87.3)	19 (12.7)		**1**	**Ref**
BMI					
Normal	116 (84.7)	21 (15.3)	0.546	1.376	0.485-3.900
Overweight	38 (88.4)	5 (11.6)		**1**	**Ref**
Education Status					
Illiterate	62 (93.9)	4 (6.1)	0.015*	**1**	**Ref**
Literate and above	92 (80.7)	22 (19.3)		3.707	1.218-11.280
Religion					
Hinduism	121 (85.8)	20 (14.2)	0.850	**1**	**Ref**
Non-Hinduism	33 (84.6)	6 (15.4)		1.100	0.409-2.961
Ethnicity					
Relatively Advantaged Janajati	61 (81.3)	14 (18.7)	0.173	1.779	0.771-4.103
Non- Relatively Advantaged Janajati	93 (88.6)	12 (11.4)		**1**	**Ref**
Family Types					
Nuclear	67 (90.5)	7 (9.5)	0.112	**1**	**Ref**

Joint	87 (82.1)	19 (17.9)		2.090	0.830-5.262
Residence					
Urban	121 (89.6)	14 (10.4)	0.007*	**1**	**Ref**
Rural	33 (73.3)	12 (26.7)		3.143	1.328-7.440
Marital Status					
Married	134 (86.5)	21 (13.5)	0.394	0.627	0.212-1.851
Unmarried	20 (80.0)	5 (20.0)		**1**	**Ref**
Occupational Status					
Unemployed	100 (89.3)	12 (10.7)	0.068	**1**	**Ref**
Employee	54 (79.4)	14 (20.6)		2.160	0.934-5.000
Family Income					
<NRs 45000	66 (79.5)	17 (20.5)	0.033*	2.519	1.057-6.004
>NRs 45000	88 (90.7)	9 (9.3)		**1**	**Ref**
Health Insurance Status					
No	75 (82.4)	16 (17.6)	0.226	1.685	0.720-3.947
Yes	79 (82.1)	10 (11.2)		**1**	**Ref**

Table 19 shows that different independent variables like sex, education status, residence, family income were found statistically associated with presence of tuberculosis. Males are more likely to have tuberculosis (UOR=4.583, 95% CI: 1.508-

13.929) compared to females. Individuals who were literate were significantly more likely to have tuberculosis (UOR=3.707, 95% CI: 1.218-11.280) compared to those illiterate. People residing in rural areas were more likely to had tuberculosis (p 0.007, UOR= 3.143, CI1.328-7.440)

Variables such as age, BMI, religion, ethnicity, family type, marital status, occupation status, health insurance status, did not show significant associations in this study.

Table 20: Association between Behavioural factors and diseases characteristics of TB among diabetes Patients

Characteristics	Diabetes Mellitus		p-value	UOR	95%CI
	DM Only n(%)	DM-TB n(%)			
History of Smoking Status					
No	112 (90.3)	12 (9.7)	0.007*	**1**	**Ref**
Yes	42 (75.0)	14 (25.0)		3.111	1.331-7.269
History of Alcohol					
No	97 (88.2)	12 (11.8)	0.209	**1**	**Ref**
Yes	57 (81.4)	13 (18.6)		1.702	0.738-3.924
Physical Exercise					
No	102 (82.9)	21 (17.1)	0.141	2.141	0.764-6.003
Yes	52 (91.2)	5 (8.8)		**1**	**Ref**
Family History of TB					
No	147 (85.5)	25 (14.5)	0.873	**1**	**Ref**
Yes	7 (87.5)	1 (12.5)		0.840	0.099-7.124
Prior Treated of TB					
No	144 (85.7)	24 (14.3)	0.821	**1**	**Ref**
Yes	10 (83.3)	2 (16.7)		1.200	0.248-5.817
Do you have TB symptoms					
No	74 (92.5)	6 (7.5)	0.018*	**1**	**Ref**
Yes	80 (80.0)	20 (20.0)		3.083	1.174-8.097
Family History of Diabetes					
No	134 (85.4)	23 (14.6)	0.838	1.144	0.314-4.164
Yes	20 (87.0)	3 (13.0)		**1**	**Ref**
Types of Diabetes					
Type I	23 (82.5)	7 (17.5)	0.533	1.351	0.523-3.487
Type II	121 (86.4)	19 (13.6)		**1**	**Ref**
Co-morbidities status					
No	90 (89.1)	11 (10.9)	0.125	**1**	**Ref**

Yes	64 (81.0)	15 (19.0)		1.918	0.827-4.448
Experienced of side effect					
No	121 (88.3)	16 (11.7)	0.060	**1**	**Ref**
Yes	33 (76.7)	10 (23.3)		2.292	0.952-5.519
Nutritional Status					
Normal (<25)	116 (84.7)	21 (15.3)	0.547	1.376	0.485-3.900
Overweight (≥25)	38 (88.4)	5 (11.6)		**1**	**Ref**

Table 20 shows association between behavioural factors and diseases characteristics of tuberculosis among diabetes mellitus patients. History of smoking, Having Tuberculosis symptoms were found statistically significantly associated with presence

of tuberculosis among diabetes patients. History of alcohol, physical exercise, family history of TB, prior treated of TB, family history of DM, types of diabetes, co- morbidities status, experienced side effect, nutrition status were not found statistical association with presence of tuberculosis among diabetes patients

Table 21: Adjusted relationship of explanatory variables with TB among DM patients

Characteristics	**P-value**	**AOR**	**95%,CI**
Sex			
Male	0.180	2.322	0.678-7.957
Female		**1**	**Ref**
Education Status			
Illiterate	0.033*	**1**	**Ref**
Literate and above		4.048	1.119-14.639
Residence			
Urban	0.212	**1**	**Ref**
Rural		1.921	0.689-5.354
Family Income			
<NRs45000	0.073	2.465	0.918-6.619
>NRs45000		**1**	**Ref**
History of Smoking Status			
No	0.052	**1**	**Ref**
Yes		2.684	0.990-7.278
Presence of TB symptoms			
No	0.019*	**1**	**Ref**
Yes		3.744	1.237-11.332

Table 21 shows the predictors for presence of tuberculosis among diabetes patients. Education status, having tuberculosis symptoms were found to be predictors for presence of TB among DM patients. Respondents

who were literate were more likely (p 0.033, AOR 4.048, CI 1.119-14.639) to had tuberculosis among diabetes mellitus patients

Figure 5: Flowchart of the bidirectional screening for TB and Diabetes in Gandaki Province

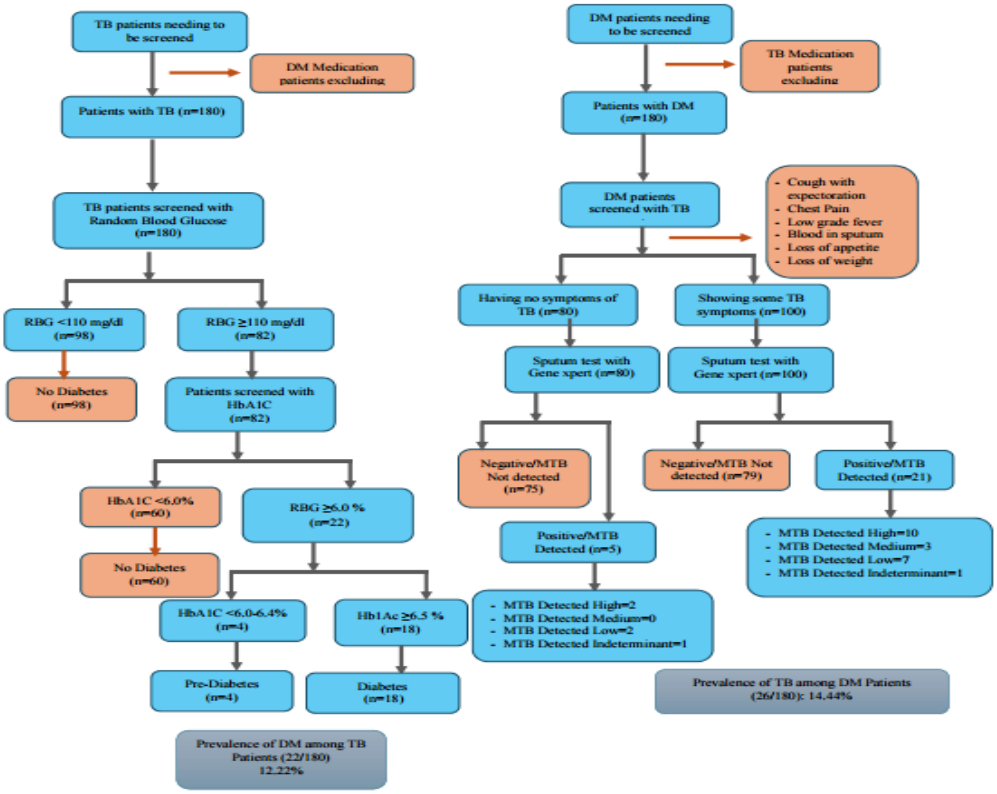

Figure 5 shows a bidirectional screening process for tuberculosis (TB) and diabetes mellitus (DM). Among 180 TB patients., all patients had been screened with RBG from which, 98 patients were identified as non-diabetic (RBG <110mg/dl) and 82 patients had been diagnosed with diabetes with RBG ≥ 110 mg/dL, Further HbA1c test was performed among 82 TB patients which revealed 60 without diabetes (HbA1c < 6.0%), 22 with diabetes (4 with pre-diabetes (HbA1c 6.0–6.4%), and 18 with diabetes (HbA1c

≥ 6.5%). Likewise, among 180 DM patients, they were undergone through gene xpert test. Of which, 154 had negative, 26 had positive MTB (Mycobacterium tuberculosis). The prevalence of TB among DM patients was 14.44%. The prevalence of DM among TB Patients was 12.22%. The analysis highlights the significant comorbidity between TB and DM, emphasizing the importance of integrated screening.

CHAPTER IV-DISCUSSION

This study determines the prevalence of diabetes mellitus among Tuberculosis patients and its associated risk factors and prevalence of tuberculosis among diabetes mellitus patients. The findings of this study provide important insights into the program management of TB-DM co-morbidity, and have several health policy implications.

As, non-communicable diseases like diabetes mellitus continues to remain high despite numerous efforts had been made. Meanwhile tuberculosis incident rate is also increasing. Prevalence of diabetes influences incidence of tuberculosis and mortality.(15)

Many research had revealed that tuberculosis and diabetes mellitus are a co-morbid conditions which are mutually influential. Diabetes mellitus is a risk factor for tuberculosis and diabetes mellitus patients are three times more likely to get tuberculosis than the general population which worsen the quality of life of a patients. It has also effect on Tuberculosis treatment outcomes leading to longer duration of treatment, high risk of relapse and aroused other different complications If a patients had both diseases, they are prone to cause more diseases as they have low immune system. TB–DM comorbidity which has become a major global public health concern and a critical public health challenge in low- and middle-income countries. This conditions had increase the necessity of bi-directional screening for both diseases which is also recommended by World health Organization, World diabetes foundation and international union against tuberculosis and lung diseases. (15,25)

Conducting bidirectional screening helps 367 ly detection of tuberculosis among diabetes mellitus patients and vice versa and it also assists with an integrated approach to the management of co-morbidity which ultimately reduce the economic burden of the patients and support in maintaining quality of life.

Tuberculosis among Diabetes mellitus patients

People living with diabetes mellitus are three times more likely to develop TB, and an increase in diabetes mellitus predisposes people to develop Tuberculosis.(26)

Our study shows the prevalence of tuberculosis among diabetes mellitus patients was 14.40% which is similar with the study done in South India by B.C Prakash et al.(19)

and Regmi H.S et al and Sannithi K et al. which shows 9%, 8 % and 14.8% diabetes patients were positive for tuberculosis. (20,27)

Another study done by Jeon and Murray shows diabetes mellitus patients have a two- three times higher risk of developing active TB compared to non-diabetics. This heightened risk is attributed to immune dysfunction caused by diabetes.(15,28)

A study done in Northeast Ethiopia found prevalence of TB in 6.2% among diabetic patients.(21) Another contrast findings were found in the study done by Mahishale V.
(29) which shows 2.6% of the diabetes mellitus patients had tuberculosis.

Associated Factors

Our study shows male patients with diabetes mellitus had test positive for tuberculosis. Male were more likely to develop TB compare to female which coincide with the study done in Eastern Nepal by Regmi H.S.(27)

The present study found no statistical association with history of alcohol however, respondents who consume alcohol are more likely to had diabetes mellitus with tuberculosis which is a fact that alcohol play a significant role as risk factor which is supported by the study done by Narasimhan P, et al.(30)

Another study conducted in northwest Ethiopia by Gedfew M, et al. which shows history of alcohol consumption was significantly associated with TB. Patients with a history of alcohol consumption were four times as likely to develop TB than patients with no history of TB. Variations across studies may stem from differences in sample sizes, study settings, follow-up durations, and the socio-demographic characteristics of the respondents.(31)

Our study found no statistical association between residence and TB among DM (p 0.212, OR 1.921) in multivariate analysis where in bivariate analysis residence was found statistically associated with presence of tuberculosis among diabetes mellitus patients. People residing in rural areas were more likely to had tuberculosis (p 0.007, OR 3.143, CI 1.328-7.440) which contradicts with the findings of study done in Northeast Ethiopia by Amare H, et al found people residing in urban areas were independently associated with development of active TB in people living with DM (AOR: 5.5; 95% CI: 1.07–28.20).(32)

This may be attributed to differences in socio-demographic characteristics Furthermore, the predominance of rural residents among the respondents could have contributed to challenges such as limited access to healthcare facilities, potentially might influence the outcomes.

Our study found no statistical association of history of TB (p 0.821), contact with TB patient in family (p 0.873) which contradicts with the findings of study done in northeast Ethiopia which shows history of TB (AOR: 13.4; 95% CI: 2.74–65.73), contact with TB patients in the family (AOR: 9.4; 95% CI: 1.822–48.50) were independently associated with the development of active TB in people living with DM.(32)

Diabetes Mellitus among Tuberculosis

Our study found diabetes mellitus among TB was 12.20% which is similar to the study done in

Kathmandu valley by Thapa B et al which shows 9.1%.(33). In the study, some of the cases were self-reported cases too where, self-reported cases had been excluded in our study. Another study done in Malawi by John LZ Nyirenda et al. and Mahishale V et al shows 9.4% and 15.96% of Tuberculosis patients were diagnosed as diabetes mellitus.(31) (36) Contrasts findings was found in the study done in South India by B.C Prakash et al, Rajaa S et al and Bhavana L, et al. which shows 2.9%, 39% and 18% were newly diagnosed cases of diabetes mellitus among the tuberculosis patients.(19,22,35) Similar findings was found in the study done in Morang, Eastern Nepal by Sharma B et al which found 11.9% diabetes mellitus among tuberculosis patients.(36)

Associated factors

In terms of gender, prevalence of diabetes in more in male tuberculosis patient. Men are more likely to engage in behaviors such as smoking and alcohol use, both of which exacerbate diabetes risk and increase vulnerability to TB infection. Our study found male are more prone to diabetes as, TB prevalence is more among male compared to female as, as it is immune compromise diseases, co-morbid condition exist among the tuberculosis patients which is similar to the findings of the study done by Thapa B,et al.(33), Rajaa S. et al and Bhavana L, et al.(22,33,35)

Regarding age, age is the strongest predictor of any diseases. As increasing in age, risk factor for many diseases also increase, including chronic diseases, infections. Ageing is associated with a progressive degeneration of the tissues, which has a negative impact on the structure and function of vital organs and is among the most important known risk factors for most chronic diseases. Our study findings also resembles with this condition where respondents above 45 years were more likely to had diabetes among tuberculosis patients which is also supported by the study done by Thapa B, et al.(33,37), Rajaa S.et al., BC Prakash et al.and Bhavana L, et al.(19,22,33,35)

In multi variate analysis, age with more than 45 years, having co-morbid conditions and HIV patients tested as positive were more likely to develop diabetes mellitus. A significant association was observed with age >45 years ($p=0.001$), with an odds ratio of 16.907 (95% CI: 3.198–89.386), suggesting older TB patients are more likely to have diabetes. This is consistent with established evidence that diabetes prevalence increases with age due to metabolic changes and prolonged exposure to risk factors.(37)

In our study underweight TB patients were more likely to had diabetes contradicts with the findings of research done by Rajaa S et.al which found obese TB patients had significantly higher risk of having DM compared with those with normal BMI.(35)

Tuberculosis patients with low family income were more likely to had diabetes due to the intricate relationship between socioeconomic status and health. Economic disadvantage influences multiple factors that increase diabetes risk which is supported by the study done by Hwang J et al., Chen Yu et.al, Kim et.al(38–40) found that individuals in the lowest income quartile were about one and half times more likely to develop diabetes compared to those in higher-income.(41) Our study found age more than 45 years , co-morbidities condition were significant predictor of diabetes among tuberculosis patients contradicts with the findings of study done by Sharma B et al(36) which shows current alcohol consumer as the significant predictor of diabetes among the tuberculosis patient

The study has several strengths. We comprehensively covered a vast majority of patients visiting the tertiary hospital of a province, provincial public health laboratory of province and tuberculosis treatment center of Gandaki province.

Despite of several strengths, our study has some limitations. The patients in our study were recruited from three major provincial and federal-level laboratories and hospitals, which may limit the generalizability of the findings to similar healthcare settings. Additionally, as the study utilized data from public health facilities, the sample may be skewed toward individuals with positive health-seeking behavior, potentially underrepresenting the broader population of TB and diabetes mellitus patients in the community. Lastly, the cross-sectional design of the study precludes establishing causal relationships between demographic, anthropometric, or behavioral factors and diabetes mellitus.

CHAPTER V- CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusion

The study concludes nearly one in tenth of the patients had co-morbid condition TB and diabetes among diabetes and Tuberculosis patients respectively. It is important to screen DM patients for TB and TB patients for DM in routine setting, as it results in high rates of detection of co-morbid conditions. HIV was found to be significant factor among TB and diabetes patients. With increasing age, respondents were more likely to had TB and Diabetes. One-fifth of patients who had type I diabetes had tuberculosis. Diabetic patients who had risky behavior like smoking were more prone to had tuberculosis.

5.2 Recommendations

Encourage diabetes patients to attend regular follow-up visits to monitor tuberculosis timely and tuberculosis patients for diabetes mellitus is crucial. Early identification can lead to proactive management strategies and prevent complications.

Health authorities and healthcare providers should focus on those age factors to prevent co-morbid conditions. Screening program should be conducted focusing the elderly population.

Routine screening program should be conducted among TB and diabetes mellitus patients for the identification of DM and TB. This approach support to increase the case notification and identify the missing cases of TB.

Gantt Chart:

S.N.	Activities	Weeks																			
		July, 2024				Aug, 2024				Sep, 2024				Oct, 2024				Nov,2024			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
1	Topic Selection																				
2	Proposal Development																				
3	Preparing research tools																				
4	Ethical Approval																				
5	Pre- testing																				
6	Data Collection																				
7	Data editing, coding and entry																				
8	Data Analysis																				
9	Draft Report																				
10	Final report and Submission																				

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ANNEX I: INFORMED CONSENT

Namaskar!

Aim for a research study on **"Bidirectional Screening of Tuberculosis and Diabetes Patients in the Gandaki Province of Nepal".** Please provide real information to my questions. The answers which you provide me are only used for research purposes. I assure you that we will maintain your privacy of information is each stage of research. I can only involve you after getting your consent and during the interview your freedom to quite from the interview if you feel discomfort to questions or other problems. For the interview session, it will take 10-15 minutes to collect the information and Sputum or blood will take 5 minute. I hope you are willing to participate in this interview because your participation and your view are the most important for research and researcher.

I agree in this research and interested to participate. Yes ☐ No ☐ Signature of Participant…… Signature of researcher ……

Date…… Date…… If illiterate

Thumb print of Participant

Left Thumb Right Thumb

Signature of witness

……..

Date……

If you have any queries regarding this research please inform me at manmohanmishra.nepal@gmail.com, srijanapaudel21@gmail.com and or directly you can call me on 9847586476/9856088135

Form ID No: ……..

Registration number:	Phone Number:
Date of Treatment:	
From where did you diagnosed the conditions (TB/Diabetes)	1. Government …… 2. Private hospital……. 3. Pharmacy……..
Date of Interview:	

Research Questions (TB among DM)

Particular about patients

Name:	Sex: a. Male b. Female Age: Years
Permanent District:	M/RM:
Weight: kg	Height: cm

Section A: Socio-demographic and economic factors

A.1	Education status	1. Unable to read and write 2. Able to read and write 3. Primary (1-8) 4. Secondary (9-12) 5. College and above
A.2	Religion	1. Hinduism 2. Buddhism 3. Islam 4. Christianity 5. Other (specify)
A.3	Ethnicity	1. Dalit 2. Disadvantaged Non-Dalit Terai Caste 3. Disadvantaged Janajati 4. Religious Minorities 5. Upper Caste groups 6. Relatively advantaged janagati 7. Others (specify)……
A.4	Marital status	1. Married 2. Unmarried 3. Divorced 4. Widowed 5. Separated
A.5	Family type	1. Nuclear family 2. Joint family 3.Extended family
A.6	Occupation	1. Unemployed 2. Employee 3. Farmer 4. Students 5. Daily labour6. Government job 7. Business 7. Others (specify)……..
A.7	Residence	1. Urban 2. Rural
A.8	Family income	… NRs
A.9	Enrollment health insurance status	0. No 1. Yes

Section B: Behavioral related Factors

B.1	History of smoking?	0. No 1. Yes **(if No, skip Q B.4)**
B.2	Current consumption of smoking?	0. No 1. Yes 2. Occasionally
B.3A	If yes, how do you take smoke?	…… Per day
B.4	History of alcohol?	0. No 1. Yes **(if No, skip Q B.7)**
B.5	Current consumption of alcohol?	0. No 1. Yes 2. Occasionally
B.6A	Duration of start of drinking alcohol	_____month / Year
B.7	Do you do physical exercise?	0. No 1. Yes
B.7A	If yes, than how minutes?	… min per day

C.History factors

C.1	Do any of your family members have a history of diabetes?	0. No 1. Yes **(if No, skip Q C.2)**
C.1A	If yes, Who in your family has been diagnosed?	_____
C.2	Do any of your family members have a history of tuberculosis?	0. No 1. Yes **(if No, skip Q C.3)**
C.2A	If yes, Who in your family has been diagnosed with TB?	_____
C.3	Did you receive any TB treatment before?	0. No 1. Yes **(if No, skip Q C.4)**
C.3A	If yes	1. DS TB (PBC, PCD &EP) 2. DR TB
C.4	Have you been in close contact with someone diagnosed with tuberculosis recently?	0. No 1. Yes
C.5	Do you have any symptoms resembled with tuberculosis?	0. No 1. Yes
C.6	If yes, which symptoms do you have?	1. Cough with expectoration 2. Chest pain 3. Low grade fever 4. Blood in Sputum 5. Loss of appetite 6. Loss of weight 7. Others (specify)

D. Disease related factors

D.1	Types of DM	1. Type I 2. Type II
D.2	Which types of medication	1. Oral 2. Injectable 3. Both
D.3	How long have you been started DM Treatment?	… Months
D.4	Have you Experienced any side effects with DM Medicine?	0. No 1. Yes (if yes, what is)……
D.5	Have any diseases been diagnosed other than DM?	0. No 1. Yes (if yes, what is)……
D.6	HIV status	1. Negative 2. Positive 3.Unknown

E. Report

E.1	From which method TB diagnosis is done?	1. Microscope 2. Rapid molecular test
E.2	TB Result	Result:
E.3	TB status	0. Negative 1. Positive

Form ID No: ……..

Research Questions (DM among TB)

Registration number	Phone Number:
Date of registration no	
From where did you diagnosed the conditions (TB)	1. Government …… 2. Private hospital……. 3. Pharmacy……..
Date of Interview:	

Particular about patients

Name:	Sex: a. Male b. Female Age: Years
Permanent District:	M/RM:
Weight: kg	Height: cm

Section A: Socio-demographic and economic factors

A.1	Education status	1. Unable to read and write 2. Able to read and write 3. Primary (1-8) 4. Secondary (9-12) 5. College and above
A.2	Religion	1. Hinduism 2. Buddhism 3. Islam 4. Christianity 5. Other (specify)
A.3	Ethnicity	1. Dalit 2. Disadvantaged Non-Dalit Terai Caste 3. Disadvantaged Janajati 4. Religious Minorities 5. Upper Caste groups 6. Relatively advantaged janagati 7. Others (specify)……
A.4	Marital status	1. Married 2. Unmarried 3. Divorced 4. Widowed 5. Separated
A.5	Family type	1. Nuclear family 2. Joint family 3.Extended family
A.6	Occupation	1. Unemployed 2. Employee 3. Farmer 4. Students 5. Daily labour 6. Government job 7. Business 8. Others (specify)……..
A.7	Residence	1. Urban 2. Rural
A.8	Family income	… NRs
A.9	Enrollment health insurance status	0. No 1. Yes

B. Behavioral related Factors

B.1	History of smoking?	0. No 1. Yes **(if No, skip Q B.4)**

B.2	Current consumption of smoking?	0. No 1. Yes
B.3	If yes, how do you take smoke?	…… Per day
B.4	History of alcohol?	0. No 1. Yes
B.5	Current consumption of alcohol?	0. No 1. Yes 2. Occasionally
B.6	Duration of start of drinking alcohol	_____month / Year
B.7	Do you do physical exercise?	0. No 1. Yes **(if No, skip Q B.7)**
B.7A	If yes, than how minutes?	… min per day

C. History factors

C.1	Do any of your family members have a history of tuberculosis?	0. No 1. Yes **(if No, skip Q C.2)**
C.1A	If yes, Who in your family has been diagnosed with TB?	_____
C.2	Did you receive any TB treatment before?	0. No 1. Yes **(if No, skip Q C.3)**
C.2A	If yes	1. DS TB(PBC, PCD &EP) 2. DR TB
C.3	Have you been in close contact with someone diagnosed with tuberculosis recently?	0. No 1. Yes
C.5	Do you have any symptoms resembled with tuberculosis?	0. No 1. Yes
C.6	If yes, which symptoms do you have?	1. Cough with expectoration 2. Chest pain 3. Low grade fever 4. Blood in Sputum 5. Loss of appetite 6. Loss of weight 7. Others (specify)
C.7	Do any of your family members have a history of diabetes?	0. No 1. Yes **(if No skip Q D.1)**
C.7A	If yes, Who in your family has been diagnosed?	_____

D. Disease related factors

D.1	What types of TB treatment are you receiving?	1. New 2. Relapse 3. Failure 4. Loss to follow up 5. Transfer in 6. Unknown 7. Others (specify)
D.2	Types of TB	1. Pulmonary (PBC / PCD) 2. Extra Pulmonary

D.3	How long have you been enrolled in DOTS?	… Months
D.4	Have you Experienced any side effects with TB Medicine?	1. No 1. Yes (if yes, what is)……
D.5	Have any diseases been diagnosed other than TB?	0. No 1. Yes (if yes, what is)……
D.6	HIV status	1. Negative 2. Positive 3.Unknown

E. Report

E.1	From which method DM diagnosis is done?	1. RBG 2. HBA1C (if RBG more than (>110 mg/dl)
E.2	DM Result (Sugar level)	……
E.3	DM status	0. Normal (<110 mg/dl) 1. Abnormal (>110 mg/dl)

ANNEX III: IRC Letter

Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 329

	Review Date: 25 August 2024	25 August 2024 to 24 August 2025 **This approval will be valid for one year**	NA
Total budget of research	**NRs 12,78,000.00**		
Ethical review processing fee	**NRs 38,340.00**		

Investigator Responsibilities

- If you do not start the project within 3 months of this letter, please contact the Ethical Review M & E Section at NHRC
- Any amendments shall be approved from the ERB before implementing them
- Submit progress report every 6 months
- Submit final report after completion of protocol procedures at the study site
- Comply with all relevant international and NHRC guidelines
- Abide by the principles of Good Clinical Practice and ethical conduct of the research

If you have any questions, please contact the Ethical Review M & E Section at NHRC.

Thanking you,

.....

Dr. Pramod Joshi
Member Secretary

Tel: +977 1 5354220,5327460, Ramshah Path, PO Box: 7626, Kathmandu, Nepal
Website: http://www.nhrc.org.np, E-mail: nhrc@nhrc.org.np

Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 329

25 August 2024

Mr. Man Mohan Mishra
Principal Investigator
Provincial Public Health Laboratory, Gandaki Province Pokhara
Pokhara

Ref: Approval of research protocol

Dear Mr. Mishra,

This is to certify that the following protocol and related documents have been reviewed and granted approval through the expedited review process for its implementation.

Protocol Registration No/ Submitted Date	351_2024 3 July 2024	**Sponsor Protocol No**	NA
Principal Investigator/s	Mr. Man Mohan Mishra	**Sponsor Institution**	STAC
Title	Bidirectional Screening of Tuberculosis and Diabetes Patients in the Gandaki Province of Nepal		
Protocol Version No	NA	**Version Date**	NA
Other Documents	1. Data collection tools 2. Informed Consent Form 3. Sponsor agreement letter 4. Support letter 5. Conflict of Interest (CoI) 6. Ethics Training Certificate 7. Role and responsibilities 8. Work plan	**Risk Category**	Minimal risk
Co-Investigator/s	1. Srijana Paudel 2. Sushila Baral 3. Rajesh Kumar Yadav 4. Naveen Prakash Shah		
Study Site	Diabetic patients aged more than 18 years. The study will be conducted in Provincial Public Health laboratory, Gandaki Province and Tuberculosis Treatment Center, Gandaki Province		

Type of Review	✓	**Expedited**	**Timeline of study** 25 August 2024 to November 2024 **Duration of Approval**	**Frequency of continuing review**
		Full Board		

Tel: +977 1 5354220,5327460, Ramshah Path, PO Box: 7626, Kathmandu, Nepal
Website: http://www.nhrc.org.np, E-mail: nhrc@nhrc.org.np

ANNEX IV: Support Letter for Data Collection

Government of Nepal
Ministry of Health and Population
Department of Health Service
National Tuberculosis Control Center
Thimi, Bhaktapur

Phone no. 6630706
6630033
Fax no. 6635986
Website:www.nepalnt.gov.np

Ref. no. 518

Date: 9th May, 2024

To,
The Director
SAARC Tuberculosis and HIV/AIDS Centre
Thimi, Bhaktapur, Nepal

Letter for support

Dear Sir,

It gives me a great pleasure to know that Mr. Man Mohan Mishra; Director General of Provincial Public Health Laboratory, as a principle investigator is applying research grant jointly with co-investigator Dr. Naveen Prasad Shah; Chief ConsultantChest Physician of National Tuberculosis Centre for SAARC Tuberculosis and HIV/AIDS Centre Small Grants Scheme for Operation/Implementation Research to tackle the threat of Drug Resistance Tuberculosis in your institution and entitled**"Bidirectional Screening of Tuberculosis and Diabetes Patients in the Gandaki Province of Nepal"**.

Weassure that National Tuberculosis Centre, Ministry of Health and Population, Nepal will provide sufficient coordination and other necessary support for research work, if his team will get research grant then the research activities and findings will be useful to tackle double burden of communicable and non-communicable diseases in single situation and better care and support to Tuberculosis among Diabetes and Diabetes among Tuberculosis patients in Gandaki Province of Nepal.

In Gandaki province, numerous cases of tuberculosis have been missing, requiring urgent attention. Additionally, there is a high prevalence of non-communicable diseases in the region. Conducting research will aid in identifying both non-communicable diseases and missing tuberculosis cases, aligning with the goal of ending TB. Furthermore, the presence of a well-equipped tuberculosis center and a provincial public health laboratory facilitates the diagnosis of these cases.

.....Naveen.....
Dr. Naveen Prakash Shah
Acting Director

ANNEX V: Acceptance of the Research Proposal

SAARC Tuberculosis and HIV/AIDS Centre
Thimi, Bhaktapur, P.O. Box No. 9517, Kathmandu, Nepal
Tel. No.: 00977-1-6632601, 6631048, 6632477, Fax No.: 6634379, E-mail: director@saarctb.org, Website: www.saarctb.org

STAC/SSRG/2024/ 157

To,
Assit. Prof. Srijana Paudel
c/o Dr. Naveen Prakash Shah
National Tuberculosis Control Centre (NTCC)
Thimi, Bhaktapur

19 June 2024

Subject: Acceptance of the Research Proposal

Dear Ms. Paudel,

I am happy to inform you that your research proposal titled **"Bidirectional Screening of Tuberculosis and Diabetes Patients in the Gandaki Province of Nepal"** has been accepted by the Centre.

You are requested to acknowledge the receipt of this letter and to come forward to sign the agreement paper with SAARC TB and HIV/AIDS Centre (STAC) as soon as possible

Thank you for your co-operation.

With regards,

Yours sincerely,

Dr. Manisha Rawal
Director, STAC

ANNEX V: Agreement Letter

Agreement Between

SAARC Tuberculosis and HIV/AIDS Centre

and

Ms. Srijana Paudel (Co-Investigator), Gandaki Province, Nepal

With reference to Expression of Interest announced by SAARC Tuberculosis and HIV/AIDS Centre (hereafter referred to as STAC) through website dated 15 May 2024 to conduct Small Research Grant.

The proposal submitted by **Dr. Srijana Paudel (Co-Investigator), Gandaki Province, Nepal** has been accepted and this contract is signed between STAC and Dr. Srijana Paudel.

For the Study: "Bidirectional Screening of Tuberculosis and Diabetes Patients in the Gandaki Province of Nepal"

The Terms and Conditions for the consultant/ firm are mentioned below:

Durations:

The research will commence from the date of signing the contract and is expected to be completed by 30th November 2024, unless extended by mutual agreement without any financial liabilities on both parties.

Research Objectives:

To determine and asses the prevalence of Tuberculosis among Diabetes patients and identify factors associated with TB among Diabetes patients and Diabetes among TB patients.

Ownership of Work Product:

All reports, materials, and documents produced in the course of performing the research shall remain under the ownership of STAC.

Deliverables:

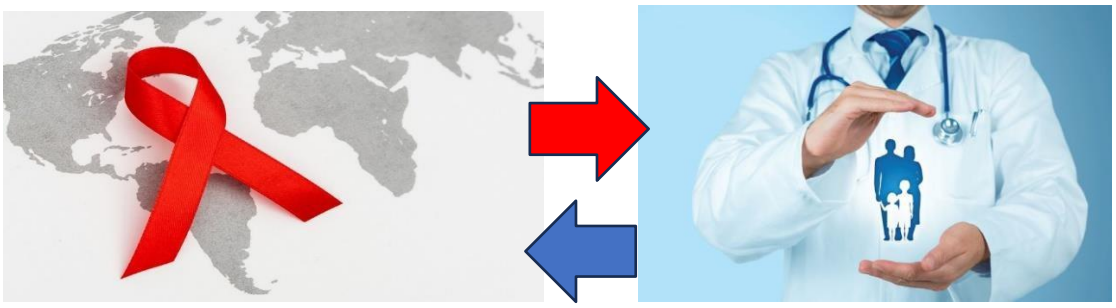
1. Completion of the study as per enclosed protocol
2. Submission of the technical and financial report of the study in the stipulated time period.
3. Publication of original article in SAARC Journal of Tuberculosis, Lung Diseases and HIV/AIDS.

Understanding Health Insurance Accessibility for People Living with HIV/AIDS in Kathmandu

2024

Report on

Understanding Health Insurance Accessibility for People Living with HIV/AIDS in Kathmandu Valley: Barriers, Attitudes and Policy Recommendations



Submitted to:

SAARC TB and HIV/AIDS Centre (STAC)

Submitted on: *December 13, 2024* **Submitted**

by: *PI: Nanda Kishor Adhikari*

Co- PI: Regan Ranjit

SAARC

SOCIAL DEVELOPMENT & PROMOTION CENTRE

ACKNOWLEDGEMENT

We would like to express our sincere gratitude to all those who have contributed to the successful completion of our research entitled "**Understanding Health Insurance Accessibility for People Living with HIV/AIDS in Kathmandu Valley: Barriers, Attitudes and Policy Recommendations**" Their immense support, guidance, and encouragement have been invaluable along the way throughout this project.

We are particularly indebted to the SAART Tuberculosis and HIV/AIDS Center (STAC), Thimi for their unwavering support and cooperation throughout this assessment. We would like to extend our heartfelt thanks to Dr. Anuj Bhattachan, Director, Dr. Manisha Rawal, Former Director and Dr. Prajjwal Pyakurel, Research Officer, for their continuous encouragement, insightful feedback and collaborative efforts. Their commitment has significantly contributed to the success of this research.

We would also like to thank the Nepal Health Research Council (NHRC) for timely providing ethical clearance.

We acknowledge the invaluable contributions of the ART Centers (Bhaktapur Hospital, Sparsha Nepal, Bir Hospital, and Teku Hospital) in facilitating this research and grateful to the focal persons from the National Center for AIDS and STD Control (NCASC), National Health Insurance Board, Public District Health Offices (Kathmandu, Lalitpur and Bhaktapur), ART Centers in the Kathmandu valley, and various Civil Society Organizations (NAP+N, Sneha Samaj, Sathi Samuha, Parichaya Samaj, SACTS, Blue Diamond Society, NFWLHIV, and municipal HIV focal person) for their support and collaboration. We would also like to thank National Health Training Centre (NHTC) for providing the hall to conduct Draft report sharing meeting and attending in that program.

Finally, we extend our heartfelt thanks to all the participants who generously shared their time and insights that became the backbone of this study. Their willingness to participate in this study has been instrumental in its success. We are also deeply grateful to our dedicated research team, whose hard work and commitment have made this research possible.

EXECUTIVE SUMMARY

People living with HIV (PLHIV) in Nepal have limited access to health insurance, despite improvements in care and treatment. These services align with the 95-95-95 targets of the UNAIDS-established goals to monitor the fight against the HIV/AIDS epidemic by 2030. Despite the fact that HIV treatment is free in Nepal, people living with HIV (PLHIV) still have to deal with the diagnosis and treatment of opportunistic infections, non-communicable diseases, and other complications brought on by advanced

HIV.

The objective of the research is to develop a comprehensive understanding of the accessibility and effectiveness of health insurance programs for people living with HIV/AIDS in Nepal and formulate recommendations for enhancing their access to wider coverage and services.

This research employs a mixed methods approach integrating both qualitative and quantitative data collection methods. Four Focus Group Discussions (FGDs) and 25 In- Depth Interviews (IDIs) were conducted for the qualitative component, while a survey was administered to 150 PLHIV to gather quantitative data. Stratified random sampling was utilized for the survey and purposive sampling was applied for the qualitative research. A team of four research assistants, supervised by a field coordinator, was mobilized to carry out data collection.

The results of both quantitative and qualitative data provide important new information about how the Nepalese government's free health insurance program for people living with HIV is perceived, used, and hindered. Although the program is well-known and has a well- known reputation, the data also point to significant shortcomings and difficulties that must be resolved for increased efficacy and accessibility. This study highlights significant progress and ongoing challenges in implementing the free health insurance scheme for PLHIV in Nepal. The findings reveal notable benefits in terms of financial relief and improved access to health services while exposing limitations such as incomplete coverage, stigma, and logistical barriers.

In conclusion, even if the free health insurance program has significantly reduced and capable of reducing the costs related to medical care, resolving the gaps and obstacles found is essential to realizing its full potential. This program, which lowers out-of- pocket costs for necessary services, has been a lifeline for many. Expanding the coverage to include more comprehensive healthcare needs—particularly mental health and chronic conditions—is necessary to improve its efficacy. Enhancing service delivery, maintaining confidentiality, and streamlining the enrollment procedure would also help PLHIV obtain healthcare. Strengthening this program will enable PLHIV to achieve better health outcomes, manage their condition with dignity, and enjoy an improved quality of life.

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ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
COVID	Corona Virus
IDI	In- depth Interview
FGD	Focus Group Discussion
HIV	Human immunodeficiency Virus
MSM	Men who have sex with men
NCASC	National Centre for AIDS and STD Control
NFWLHIV	National Federation of Women Living with HIV
NGO	Non- Government Organization
NHTC	National Health Training Centre

PLHIV	People Living with HI
PWID	People who inject drugs
SAARC	South Asian Association for Regional Cooperation
SDPC	Social Development and Promotion Centre
STAC	SAARC Tuberculosis and HIV/AIDS Centre
STD	Sexually Transmission Disease
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS

1. INTRODUCTION

1.1. Background

HIV/AIDS remains a significant public health concern globally, including in Nepal. Despite advancements in treatment and care, access to health insurance for people living with HIV (PLHIV) in Nepal is limited. This research aims to identify and analyse the barriers preventing PLHIV from accessing free health insurance in Nepal and identifying gaps in the coverage of services through insurance programs.

According to UNAIDS 2024, there were over 39.9 million HIV-positive individuals worldwide at the end of 2023. Approximately 1.3 million new cases of HIV infection and 630,000 deaths from AIDS-related causes occurred in the same year. Sub-Saharan Africa remains the most severely affected region, with 30.7 million people living with HIV, accounting for two-thirds of the global total. Eastern Europe and Central Asia have also seen a significant increase in HIV infections in recent years. Women and girls accounted for 53% of all HIV infections in 2023, with young women aged 15-24 in sub-Saharan Africa being twice as likely to be living with HIV compared to young men of the same age. Additionally, there were about 1.4 million children (0-14 years) living with HIV as of 2021.

By the end of 2023, 30.7 million people were accessing antiretroviral therapy (ART), a significant increase from 7.8 million in 2010. Despite this progress, 5.4 million people who need ART are still not accessing it. The Joint United Nations Programme on HIV/AIDS

(UNAIDS) aims to end the AIDS epidemic as a public health threat by 2030, with key targets including ensuring that 95% of people living with HIV know their status, 95% of those who know their status are on treatment, and 95% of those on treatment achieve viral suppression. As of 2023, 86% of people living with HIV knew their status, 77% were accessing treatment, and 93% of people accessing treatment were virally suppressed. These statistics illustrate both the progress made and the ongoing challenges in the global fight against HIV/AIDS (Global HIV statistics factsheet 2024).

As of 2023, the SAARC region faces substantial challenges in achieving the UNAIDS 95-95-95 target goals for HIV/AIDS. In this region, India shows relatively better progress, with around 77% of people living with HIV aware of their status, and approximately 65% of those diagnosed receiving ART (Malik M et al., 2023). However, other countries like Pakistan and Bangladesh lag significantly behind, with lower percentages in both diagnosis and treatment. The region as a whole is still struggling to reach the second and third 95s, with barriers such as social stigma, discrimination, and inadequate healthcare infrastructure impeding progress. While some progress has been made, intensified efforts and strategic interventions are essential for the SAARC countries to meet the 95-95-95 targets and effectively control the HIV/AIDS epidemic.

In Nepal, HIV testing and counselling, anti-retroviral treatment (ART) and viral load testing services are free of charge. These services correspond to addressing 95-95-95 targets of goals established by UNAIDS to track progress in combating the HIV/AIDS epidemic by 2030. Even though treatment of HIV is free in Nepal, PLHIV have the burden of diagnosis and management of opportunistic infections, non-communicable diseases and other complications that result from HIV in its advanced stage. While advancements in HIV treatment have significantly improved the prognosis of PLHIV, accessing and adhering to treatment can still pose substantial financial burdens for individuals and healthcare systems. Beyond medication, PLHIV require consistent monitoring, laboratory tests and routine clinical visits. These healthcare services contribute to the overall cost burden, especially for those without adequate health insurance coverage. In Nepal, the Government initiated free health insurance scheme for PLHIV from 2020 amid COVID 19 pandemic and so far, there are around 17,000 PLHIV enrolled in the scheme allowing a PLHIV and up to four other family members to be covered under insurance plan. The health insurance coverage includes a range of services such as outpatient department (OPD) services, emergency services, inpatient (hospitalization) services, diagnostic tests (Eg. laboratory tests, X-rays, ultrasounds, MRIs, CT scans),

prescribed medications in a convenience bag, surgeries and assistive devices like spectacles, hearing aids, white canes and crutches within specified price limits. However, the coverage excludes cosmetic surgery, basic healthcare, high-cost

dental treatments, artificial abortion, artificial insemination services and free drugs provided by Nepal Government.

Despite the free health insurance schemes' initiation, the coverage for PLHIVs varies depending on government policies, available resources, and partnerships with international organizations and Civil Society Organizations. Not all districts and health facilities where ART services are run have initiated the policy. Government health insurance's schemes have limited coverage, particularly for specialized treatments, medications, and procedures. This has resulted in out-of-pocket expenses for PLHIVs seeking healthcare services not covered by the insurance.

In Nepal, PLHIV face significant out-of-pocket expenditures for their healthcare needs, which pose substantial financial burdens. Despite government efforts to provide free antiretroviral therapy (ART) through public health facilities, many PLHIV still incur costs for associated healthcare services. These include expenses for transportation to healthcare centres, additional medications, diagnostic tests, and managing opportunistic infections. A study conducted by the Joint United Nations Programme on HIV/AIDS (UNAIDS) revealed that out-of-pocket health expenditures can be particularly high in rural areas, where access to healthcare services is limited, leading to higher travel costs and additional logistical expenses. These financial challenges often result in delayed treatment, poorer health outcomes, and increased vulnerability among PLHIV (Alvi et al., 2020). Strengthening financial protection mechanisms and expanding access to comprehensive healthcare services are crucial steps towards alleviating the economic burden on PLHIV in Nepal.

The Kathmandu Valley, which includes the Kathmandu, Lalitpur, and Bhaktapur districts, has reported varying statistics on HIV/AIDS. As of recent data, Valley accounted for approximately 18% of Nepal's total HIV cases, with Kathmandu district alone recording the highest number of cases. The prevalence rate among key populations, such as men who have sex with men (MSM) and people who inject drugs (PWID), is notably higher in urban areas like Kathmandu due to factors such as mobility, higher-risk behaviours and limited access to healthcare services. Efforts by the National Centre for AIDS and STD Control (NCASC) and NGOs have

significantly expanded HIV testing and treatment services, with around 70% of diagnosed individuals in the valley receiving antiretroviral therapy (ART). Despite progress, stigma remains a significant barrier to HIV prevention and care in the Kathmandu Valley, emphasizing the need for continued advocacy and targeted interventions.

1.2 Rationale

The Kathmandu Valley, as the economic and healthcare hub of Nepal, hosts a significant proportion of PLHIV in the country. This concentration is largely due to high migration rates, with many individuals from rural areas moving to the valley in search of employment and access to better healthcare services, including HIV/AIDS care. Consequently, understanding the accessibility of health insurance for PLHIV in this region is critical, as the health system here serves a large and diverse population with specific healthcare needs.

While there has been notable progress in expanding health insurance coverage in Nepal, particularly in urban areas like Kathmandu, challenges remain in ensuring that PLHIV can fully benefit from these schemes. Health insurance policies often do not fully address the unique and long-term healthcare needs of PLHIV, such as mental health support and specific testing services. Additionally. stigma, discrimination and financial barriers may further limit access to care for this population.

Given the concentration of PLHIV in the Kathmandu Valley, this research aims to identify the barriers they face in accessing health insurance and healthcare services. By exploring the attitudes of PLHIV and healthcare providers, this study will highlight key issues within the current health insurance system and offer policy recommendations to improve accessibility and inclusivity for this vulnerable group.

1.3 Research Objectives:

General Objective:

- To develop a comprehensive understanding of the accessibility and effectiveness of health insurance programs for people living with HIV/AIDS in Nepal and formulate recommendations for enhancing their access to wider coverage and services.

Specific Objective:

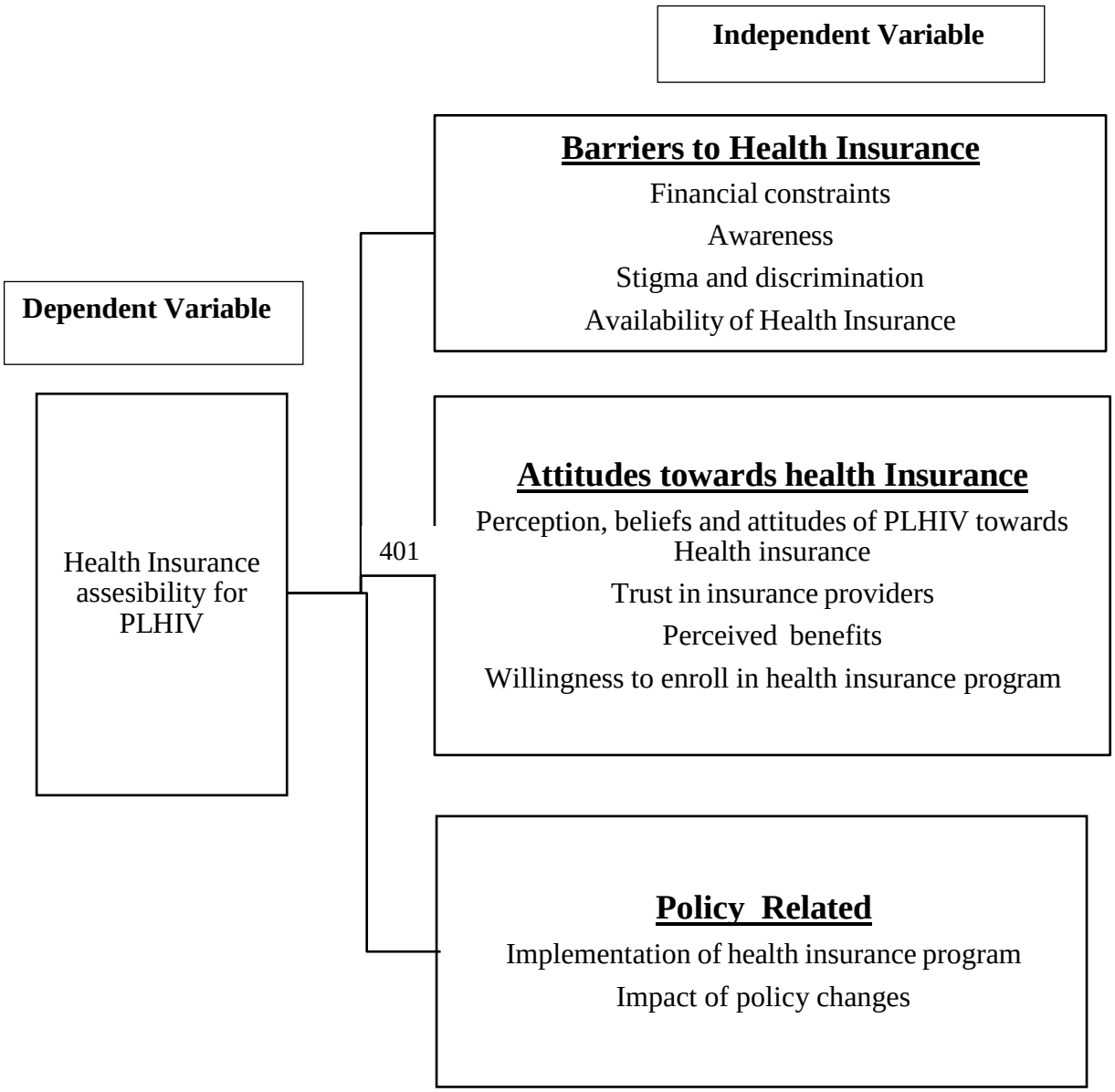
- To explore the perceptions, knowledge, and attitudes of PLHIV towards health insurance schemes and their coverage in an urban context.

- To identify socioeconomic, cultural and structural barriers hindering PLHIV from enrolling in health insurance programs.

- To determine issues and challenges associated with the free health insurance scheme for PLHIV in Kathmandu Valley.

- To propose recommendations to policymakers and stakeholders for improving access to health insurance and its coverage for PLHIV in Kathmandu Valley.

1.4 Variables



2. METHODOLOGY

2.1. Research Design

This research utilized a mixed-method approach comprising both qualitative and quantitative methods.

Qualitative Research Design

For qualitative methods, in-depth interviews and focus group discussions were conducted with PLHIV, healthcare providers, policymakers, and representatives from Nepal Government Health Insurance Board. Semi- structured interview guidelines were used to explore- perception, attitude and barriers. The interviews and discussions were audio-recorded using the dedicated recorders and transcribed and translated prior to data analysis. Those transcripts were analysed using a thematic approach. The text from the interviews and FGDs was organized, coded and grouped into relevant themes using the NVivo 12 Pro qualitative data management software.

Quantitative Research Design

For quantitative methods, individuals living with HIV/AIDS were surveyed. Furthermore, socio-demographic and socio-economic information to assess the living condition of PLHIV was evaluated. Moreover, the questions related to knowledge regarding health insurance and provision made within the health insurance scheme for PLHIV and barriers in enrolment and utilization of free health insurance provided by the Government of Nepal was included.

2.2. Number of participants and justification

For the quantitative study, 150 participants (PLHIV) were enrolled from the Kathmandu, Bhaktapur and Lalitpur districts. For the qualitative study, 4 focused group discussions were held and from 4 different ART centres 6-8 PLHIV participated in each discussion. 25 IDIs were conducted with people working in the sector of HIV/AIDS and the Nepal Government health insurance board. IDI was primarily focused on gaining the deeper understanding and having insight from a diverse group of populations working in HIV/AIDS and health insurance board. The interviews were conducted with one representative each from NCASC and health insurance board

office, health insurance facilitator and HIV/AIDS focal person from the health office of each district (Kathmandu, Bhaktapur and Lalitpur) as policymakers and policy implementors, 6 healthcare providers from ART centres, 10 representatives from civil society organisations working in the field of HIV/ AIDS and one municipal HIV/AIDS focal person.

2.3. Study site and its justification

Kathmandu valley (Kathmandu, Lalitpur and Bhaktapur district) of Nepal was purposefully selected as study sites as these districts have a significant number of PLHIV. Sample population from this area represent the other urban areas of Nepal because of the heterogenous settlement of the population.

2.4. Study population

PLHIV, representatives and officials from relevant government bodies and civil society members working in the sector of HIV/AIDS and Nepal Government Health Insurance Board.

2.5. Sampling unit

Individual

2.6. Sample size

For the quantitative survey we used the formula $n= z^2pq/d^2$

where, z= z score value of standard normal variable at 95% confidence level (1.96), P= estimated prevalence =0.088 D = 0/05 (5% Margin of error). The sample size was 123, estimating 20% non-response rate, our final sample was 150. And the sample size was divided proportionately in three districts. Similarly, for qualitative study, four FGDs were conducted with 8 participants each from 4 different ART centres and the selection of 25 participants to conduct IDIs.

SN	Name of ART Site	Province	District
1	Bhaktapur District Hospital	Bagmati	Bhaktapur
2	Sparsha Nepal, Sanepa	Bagmati	Lalitpur
3	Bir Hospital	Bagmati	Kathmandu
4	Sukra Raj Tropical and Infection Disease Control Hospital	Bagmati	Kathmandu

2.7. Sampling Technique:

As a researcher, we wanted to ensure that our study represented the diverse experiences of PLHIV in the Kathmandu Valley. We knew that PLHIV comes from different backgrounds- they vary in age, gender, income, and where they live. To truly understand the challenges, they face in accessing health insurance, we needed to include voices from all these different groups.

To achieve this, we used a method called stratified random sampling for the survey. First, we divided the population into smaller groups (or "strata") based on important characteristics like age, gender, socioeconomic status, and location. We created groups such as young women, middle-aged men and those living in urban or peri-urban areas. Once these groups were established, we randomly selected participants from each group. This ensured that everyone had a fair chance of being included in the study, and it helped us gather input from a wide variety of people. By doing this, we made sure our study wasn't skewed toward one specific group but instead captured the full range of experiences within the PLHIV community.

This approach allowed us to compare how different groups faced unique challenges. For example, we could analyze whether older participants had different barriers to health insurance than younger ones or whether men and women encountered distinct issues. By carefully planning our sampling in this way, we aimed to produce findings that were both fair and representative of the whole community.

For qualitative data, a purposive sampling technique was followed.

2.8. Criteria for sample selection

2.8.1.Inclusion Criteria:

- Only individuals who voluntarily participated and provided written consent were included in the study. This included PLHIV, health insurance and HIV/AIDS-related service providers.
- Only PLHIV aged 18 years and above who resided in the Kathmandu Valley, whether

temporarily or permanently, were included in the study.

- Only participants above 18 years of age and residing in the Kathmandu Valley were included in the study.

2.8.2. Exclusion Criteria:

- Participants unwilling to provide written consent were excluded from the study.

2.9. Data Collection

Data Collection Technique:

Surveys among PLHIV were carried out to get quantitative data. FGDs and IDIs with PLHIV, HIV/AIDS service providers, and the Nepal Government Health Insurance Board were carried out to acquire qualitative data.

Data Collection Tool:

A questionnaire tailored to gather quantitative data in alignment with predefined objectives was formulated. Quantitative survey data was acquired using KOBO-collect. To capture qualitative data, distinct semi-structured interview guidelines were crafted for both IDI and FGD. Interviews and discussions were documented utilizing an audio recorder. Prior to data collection, we pretested data collection tools and made necessary change as required.

2.10. Data management and analysis

The data collected from the survey was systematically reviewed, organized, coded, and entered into Kobo-Collect and downloaded in SPSS and MS Excel format for analysis. Both descriptive and inferential analyses was performed and study findings were presented using tables aligned with the study objectives. The survey was primarily descriptive, and data was summarized in terms of counts and percentages.

The qualitative data was transcribed and translated into English by the research team members. The reflexive thematic approach was used to identify, analyse, and interpret themes. The team of researcher first generated the coding framework after going through the transcripts. QSR NVivo ver.12, the qualitative data management software was used for coding and data analysis. Following coding, a thorough analysis was conducted to interpret the data, extracting meaningful insights and patterns, ultimately leading to data-driven conclusions.

2.11. Validity and Reliability of the tools

All questionnaires utilized in this survey underwent validation among the population similar to the study population. Questions was derived from the established guidelines, and pre-testing was conducted to ensure the reliability and validity of the study tools. The pretest was done snowball sampling in Teku among 15 PLHIV who were residing outside Kathmandu valley using snowball sampling to avoid duplication between pretesting and survey conduction and made necessary change as required.

Selection of research assistants and orientation

Four research assistants with previous experience in field of research and data collection, particularly in the field of HIV/AIDS, were selected to engage in this study. A comprehensive one-day orientation program was conducted in the training hall of Social Development and Promotion Centre (SDPC) to familiarize the research assistants with the research protocol, study procedures, ethical considerations, and the administration of questionnaires and assessment tools.

Supervision of the research activities

Effective supervision of research activities is vital for ensuring integrity, quality, and ethical conduct. Robust supervision facilitates adherence to ethical standards, promotes collaboration, and helps overcome challenges. This proposal prioritized

thorough and attentive joint supervision by principle and co-investigators and central team of SDPC and STAC to ensure the success and impact of the research activities.

Survey Team

SN	Name	Position	Qualification	Experience in year	Responsible for

1.	Mr. Nanda Kishor Adhikari	**Principal Investigator**	Master's in Science	22 years	Planning and designing of overall survey, coordination with related government line agencies, stakeholders and STAC, Supervision of data collection & analysis and finalizing of report and lead in dissemination
2.	Mr. Regan Ranjit	Co-Investigator	MSc. In Global Health PGD in Research	8 years	Support in designing of the survey, development of tools and questionnaires, training of supervisors and research assistants, sampling of the sites and data analysis.
3.	Ms. Trishna Jha	Field Coordinator	Bachelor in Public Health	10 years	Coordination with related stakeholders of IDIs & FGDs, day to day communication with and supervision of research assistants, data entry supervision and verification, support in preliminary data analysis

4.	Bishnu Prasad Khatiwoda, Shri Krishna Basnet, Ganga Prasad Poudel, Babi Acharya	Research assistants (4)	At least bachelor level of health sciences	-	Collection field data, data entry, verification of data, conducting IDIs & FGDs

2.12. Ethical Considerations:

Any activities or behavior of assessment team were not harmed to any aspect of life of the respondent/participants. Following processes and tasks were adopted to consider the ethical aspects of the participants:

- Ethical approval was received from NHRC Kathmandu, Nepal through the approval letter with the reference number of 312.
- A written consent form was filled up before scientific data collection and after explaining about the purpose of the study. None of the participants were forced to respond. Responses were completely on their interest.
- Confidentially was fully maintained. Full name of the participants were not collected as a mandatory part of the data collection. For the survey, a unique code was assigned to each participant prior to data entry. Research assistants were assigned unique alphabetic identifiers (A-D) with each assistant providing a sequential number starting from 1 (eg. A1, B1 etc). Similarly for IDIs, unique codes were assigned to the notes of IDIs, using the format "IDI_PLHIV_HI" followed by a sequential number starting from 01 (eg. IDI_PLHIV_HI_01). These codes were provide prior to transcription to ensure confidentiality and anonymity during the data handling and analysis process.

2.13. Draft report sharing meeting:

A draft report sharing meeting was held on December 10, 2024, at the National Health Training Centre (NHTC) hall in Teku. The meeting was attended by Dr. Anuj Bhattachan

(Director, STAC), Dr. Prajjwal Pyakurel (Research Officer, STAC), Dr. Madhab Prasad Lamsal (Senior Health Administrator, NHTC), Mr. Sanjeeb Kr. Jha (Statistician, STAC) and other key stakeholders involved in the field of HIV including the team of SDPC.

3. RESULT

A. Findings of Quantitative survey

The result section presents descriptive and inferential analysis of Health insurance among PLHIV. Based on sample size estimation, the questionnaire was shared among 150 participants.

3.1 Socio-demographic Information

The table below shows the socio- demographic table.

Table 1: Age of respondent (n=150)

Characteristics	Frequency(n)	Percentage (%)
18-24	16	10.67
24-30	15	10
30-36	23	15.33
36-43	31	20.67
43-50	32	21.33
50-57	20	13.33
57-64	12	8
64-71	1	0.67
Total	150	100

Table 1 summarizes the age distribution of participants in the research study. Out of a total sample majority of the participant were middle age. It has mean- 40.81 and median- 42.

Table 2: Sex of respondent (n=150)

Characteristics	Frequency(n)	Percentage (%)
Male	91	60.67
Female	59	39.33
Total	150	100

Table 2 summarizes the gender distribution of participants in the research study. Out of a total sample, 60.67% were male, while 39.33% ere female. This breakdown highlights the gender composition of the study population, with males representing the majority.

Table 3: Religion of respondents (n=150)

Characteristics	Frequency(n)	Percentage (%)
Hindu	105	70
Buddhist	27	18
Christian	14	9.33
Muslim	3	2
Other	1	0.67
Total	150	100

Table 3 illustrates the religious composition of participants in the study. Among the total sample, the majority identified as Hindu, comprising 70%. Buddhists made up 18%, followed by Christians at 9.33%, Muslims at 2% and other religion 0.67%. This distribution reflects the diverse religious affiliation within the study population.

Table 4: Ethnicity of respondents (n=150)

Characteristics	Frequency(n)	Percentage (%)
Janajati	77	51.33
Bramhin/ Chhetri	60	40
Dalit	6	4
Madhesi	5	3.33
Muslim	2	1.33
Total	150	100

Table 4 illustrates the ethnic composition of the study participants. Of the sampled, the majority were Janajati, comprising 51.33%. Bramhin/Chhetri followed with 40%, while Dalit participants accounted for 4%. Madhesi participants represented 3.33%, and Muslim participants made up 1.33%. This distribution highlights the diverse ethnic backgrounds of the study population.

Table 5: Marital Status of respondents (n=150)

Characteristics	Frequency(n	Percentage (%
Married	91	60.67
Unmarried	34	22.67
Separated	11	7.33
Widow/ Widower	10	6.67
Divorced	2	1.33
Living Together	2	1.33

Total	150	100

Table 5 represents the marital status distribution of the study participants. Out of a total of 150 participants, the majority were married, comprising 60.67%. Unmarried individuals accounted for 22.67%, while 7.33% were separated. Widow/widower participants made up 6.67% and both divorced and living-together individuals each constituted 1.33%.

Table 6: Main Occupation of respondents (n=150)

Characteristics	**Frequency(n**	**Percentage (%**
Non- government job	37	24.67
Others (Labor, Driver, Dancer, Cook, Security Guard)	34	22.67
Household work	19	12.67
Business	15	10
Self-owned	13	8.67
Unemployment	12	8
Student	8	5.33
Agriculture	7	4.67
Not willing to answer	3	2
Government job	1	0.67
Retired	1	0.67
Total	150	100

Table 6 represents the occupational distribution of the study participants. The largest group, representing 24.67%, reported working in non-government jobs. A significant portion, 22.67%, fell into "others" category. Household work accounted for 12.67%, followed by business activities at 10% and self-owned ventures at 8.67%. Unemployment was reported by 7.33%, while students and those engaged in agriculture each represented 5.33%. 2% of them were unwilling to answer and 1 participant each were government job holders and retirees.

Table 7: Highest academic of respondents (n=150)

Characteristics	**Frequency(n)**	**Percentage (%)**
Basic education	49	32.67
Secondary Level	47	31.33
Illiterate	19	12.67
Highest Secondary Level	18	12

Bachelor	13	8.67
Unwilling to answer	2	1.33
Other	1	0.67
Master Level	1	0.67
Total	150	100

Table 7 shows that most participants had basic education (32.67%) which includes primary level or could read and write with no formal education or secondary-level education (31.33%). Smaller proportions were illiterate (12.67%) or had higher education, with Bachelor's degrees at 8.67%. Meanwhile, one of the participants holds the master level.

3.2 Information about Health Insurance

Table 8: Information about Health Insurance Program of Nepal Government (n=150)

Characteristics	Frequency(n	Percentage (%
Yes	142	94.67
No	8	5.33
Total	150	100

Table 8 shows participants' awareness of the Health Insurance Program offered by the Nepal Government. The majority, 142 out of 150 participants, indicated "Yes", signifying that they had information about the program, while only 8 participants responded "No", indicating a lack of awareness.

Table 9: Enroll in Health Insurance scheme. (n=150)

Characteristics	Frequency(n	Percentage (%
Yes	139	92.67
No	11	7.33
Total	150	100

Table 9 presents data on participants' enrollment in the health insurance scheme. A significant majority, 92.67%, reported being enrolled while 7.33% indicated they were not enrolled in the scheme.

Table 10: Source of Health Insurance. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Government	133	88.67
Private	6	4

Total	139	92.67

Table 10 shows the sources of health insurance among participants. The majority, 88.67%, have health insurance through existing government schemes, while 4% are covered by private insurance.

Table 11: Payment of Health Insurance. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Free Health Insurance Scheme for PLHIV	134	89.33
Saving/ Salary	5	3.33
Total	139	92.67

Table 11 illustrates the payment methods for health insurance among participants. A significant majority, 89.33%, reported being covered under the free health insurance scheme for PLHIV. A smaller proportion, 3.33%, indicated that they paid for health insurance through their savings or salary.

Table 12: Health Insurance necessary for PLHIV. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	144	96
No	6	4
Total	150	100

Table 12 shows the perceived necessity of health insurance for PLHIV. A large majority, 96%, believe that health insurance is necessary for PLHIV, while 4% disagree.

Table 13: Information about the free Health Insurance scheme for PLHIV from Nepal Government. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	146	97.33
No	4	2.67
Total	150	100

Table 13 represents participants' awareness of the free health insurance scheme for PLHIV provided by the Nepal Government. A vast majority, 97.33%, reported having information about the scheme, while 2.67% indicated they were unaware.

3.3 Utilization of Free Health Insurance

Table 14: Has not Enrolled in Health Insurance scheme. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Others	9	6
Do not fall sick often	2	1.33
Total	11	7.33

Table 14 shows that 6% of the participant has not enroll in health insurance scheme as they were not aware about the scheme at the time of survey or while enrolling in scheme. Likewise 1.33% responded that they do not prefer to enroll as they do not fall sick often.

Table 15: Source of information about free Health Insurance scheme for PLHIV. (n=150)

Characteristics (MR)	Frequency(n)	Percentage (%)
Government Office	135	90
Friends/ Relatives/ Neighbor	7	4.67
Other	7	4.67
Social media (Facebook, Instagram and other)	3	2
Electronic Media (TV and radio)	2	1.33

Table 15 shows the source of information about the free health insurance scheme for PLHIV. The majority, 90%, received information from government offices. A smaller proportion, 4.67%, learned about the scheme through friends, relatives or neighbors while 7 participants cited "Other sources. Meanwhile, Social media platforms and electronic media shares 2% and 1.33% respectively

Table 16: Enroll in free Health Insurance from Nepal Government. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	136	90.67
No	14	9.33
Total	150	100

Table 16 presents the enrollment status in the free health insurance scheme provided by the Nepal Government. A majority, 90.67%, have enrolled in the scheme while 9.33% have not enrolled. Furthermore, 3 of the participants explained that they had been enrolled in the scheme but waiting for it to be matured to utilize the service.

Table 17: Feels that free Health Insurance has reduced the economic burden. (n=150)

Characteristics	Frequency(n	Percentage (%
Yes	138	92

No	12	8
Total	150	100

Table 17 shows participants' views on whether the free health insurance scheme has reduced their economic burden. A large majority, 92%, feel that the scheme has alleviated their financial strain, while 8% believe it has not made a significant difference.

Table 18: Knowledge about the amount annually that Health Insurance covers. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	105	70
No	45	30
Total	150	100

Table 18 shows participants' have knowledge about the amount that is annually covered by health insurance. A large majority, 70%, knows about the amount, while 30% are found to be unaware the amount that is covered by the insurance.

Table 19: Feels that the amount annually provided by free Health Insurance is enough. (n=150)

Characteristics	Frequency(n	Percentage (%
Yes	9	61.33
No	4	29.33
Don't know	1	9.34
Total	15	100

Table 19 shows that 61.33%, feel that the amount annually provided by free health insurance is enough, 29.33% believe it is not enough while 9.34% are found to be unaware about it.

Table 20: Feel benefitted by free Health Insurance. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	134	89.33
No	16	10.67
Total	150	100

Table 20 illustrates participants' perception of the benefits of the free health insurance scheme in their life. A majority, 89.33% feel that they have benefited from the scheme, while 10.67% do not feel the same.

Table 21: Free Health Insurance has cover required health services (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	110	73.33
No	40	26.67
Total	150	100

Table 21 shows whether the free health insurance scheme cover the required services where a majority, 73.33%, believe that the scheme covers the necessary services, while 26.67% feel that it does not cover.

Table 22: Want to continue to utilize free Health Insurance scheme. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	136	90.67
No	0	0
Don’t know	14	9.33
Total	150	100

Table 22 shows that 90.67%, want to continue to utilize free health insurance, while 9.33% don’t know about the continuation and discontinuation of the scheme.

Table 23: Have paid the services that were not covered by Insurance. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	61	40.67
No	89	59.33
Total	150	100

Table 23 shows that 40.67%, have paid for the services that were not covered by insurance like some medicines, Dental treatment, Thyroid, gastritis, derma, Orthopedic Eye Treatment, Mental health, USG and other test biopsy, CT scan, Accidents, Gynecology diagnosis while 59.33% didn’t pay for it.

Table 24: Although the services were covered by Health Insurance, have to take the service from other institution due to unavailability of services. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	30	20
No	120	80
Total	150	100

Table 24 shows that 20%, have taken services from the other institute due to unavailability of the

services that was not covered in health insurance, while 80% didn't take the services from the other institute.

3.4 Issues of Health Insurance

Table 25: Faced difficulty while being enrolled in free health insurance (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	18	12
No	132	88
Total	150	100

Table 25 presents the participants' experiences with enrolling in the free health insurance scheme. A small percentage, 12%, faced difficulties during the enrollment process, while the majority, 88%, did not encounter any issues.

The difficulties faced during enrollment are the long waiting time, difference in name in ART and National Identity Card and the unavailability of the insurance card in time.

Table 26: Face difficulty to identify as PLHIV while being enrolled. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	17	11.33
No	133	88.67
Total	150	100

Table 26 shows that the participants' experiences in identifying as PLHIV during the enrollment process for the free health insurance scheme. A small percentage, 11.33%, faced difficulty in identify as PLHIV while the majority, 88.67%, did not experience any such challenges.

The difficulty faced identifying as PLHIV are feeling shy and difficult, humiliation and fear of disclose.

Table 27: Utilized service through free Health Insurance. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	118	78.67
No	32	21.33
Total	150	100

Table 27 shows that utilization of services through the free health insurance scheme. A majority, 78.67%, have used the services, while 21.33% have not utilized them.

Table 28: Receive the service easily. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	106	70.67
No	12	8
Total	118	78.67

Table 28 presents participants' experiences with receiving services through the free health insurance scheme. A majority, 70.67%, found it easy to access the services, while a smaller proportion, 8% still faced challenges in receiving the services.

The difficulty faced in receiving services are not getting medicine in time, referral system is time consuming and lengthy, process is not systematic.

Table 29: Free Health Insurance scheme made easy access to health services. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	137	91.33
No	13	8.67
Total	150	100

Table 29 shows that majority, 91.33%, feel that the Free health insurance scheme made easy access to health services, while 8.67% believe it has not made easy access.

Table 30: Perceive free Health Insurance as best alternative to reduce financial burden. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	133	88.67
No	3	2
Don't Know	14	9.33
Total	150	100

Table 30 shows 88.67% perceive free health insurance as best alternative to reduce financial burden, while 2% don't perceive and 9.33% don't know about it.

Table 31: Refer free Health Insurance scheme to other PLHIV. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	139	92.67
No	3	2
Don't Know	8	5.33
Total	150	100

Table 31 shows that majority, 92.67%, will refer free health insurance scheme to other PLHIV, while 2% would not refer and 5.33% don't know about it.

Table 32: Feels that need to change anything in this policy. (n=150)

Characteristics	Frequency(n)	Percentage (%)
Yes	58	38.67
No	92	61.33
Total	150	100

Table 32 shows that while a majority of participants 61.33% believed that the free health insurance policy does not need any changes, 38.67% still feel that adjustments or improvements are necessary. This indicates that a significant portion of the participants believes there are areas within the policy that could be enhanced.

B. Findings of Qualitative data (IDI)

3.5 Perceptions, Knowledge, and Attitudes Towards Health Insurance

I. General Awareness

Majority of the respondents are aware of and had some knowledge about the free health insurance scheme provided by the Nepal government as mentioned by one of the participants:

"Yes, I have information. I got this information from the initiation of NCASC and ART Centres."- IDI_PLHIV_HI_11

Furthermore, Interviewees demonstrated awareness of the free health insurance program for PLHIV, often learning about it through official sources. For example, stated, IDI_PLHIV_HI_13 explained, *"I knew this information from the National Health Insurance Board, meeting of NCASC, and different related organizations."*

II. Importance of Health Insurance

Respondents generally recognized the importance of health insurance for PLHIV, particularly in covering essential tests and treatments as mentioned by:

"Health insurance is necessary to feel secure due to automatic review. It is also necessary for blood tests. The cost of medicine will be covered by insurance." - ***IDI_PLHIV_HI_02***

Furthermore, interviewees emphasized that health insurance is essential, particularly for financially vulnerable populations such as PLHIV. ***IDI_PLHIV_HI_11*** noted, *"Health*

insurance is necessary for all but most for PLHIV, which makes it easier for them to receive services." This sentiment was echoed by ***IDI_PLHIV_HI_24***, who highlighted the insurance's role in providing "relief and convenience" to financially struggling patients.

III. Perception of Coverage

While the policy is valued, there is concern that it does not cover all necessary health services, especially for opportunistic infections as mentioned by one of the participants:

"No, it does not include accidental treatment, heart disease, special treatment, surgery, and blood tests for other diseases." - ***IDI_PLHIV_HI_10***

Many interviewees felt that the insurance coverage is insufficient. ***IDI_PLHIV_HI_13*** shared, *"Most of the problems are covered, but not all, like the equipment required for operations is not included. We have to buy our operation gown. How to bear that cost?"* Similarly, ***IDI_PLHIV_HI_17*** stated, *"The free health insurance program doesn't cover most health problems of PLHIV/AIDS."*

3.6. Socioeconomic Barriers to Enrollment

I. Financial Challenges

Socioeconomic hardships often impede enrollment, with many PLHIV struggling to cover additional costs not included in insurance, such as transportation and non-covered medications. One of the participants mentioned:

"There will be expense in T/T, OPD tickets… problem in bus fare, buying medicine." - ***IDI_PLHIV_HI_08***

In Addition, financial constraints are a significant barrier to enrollment, especially as PLHIV often experience heightened economic vulnerability. ***IDI_PLHIV_HI_20*** stated, *"Most of the infected people are financially weak, so it's difficult to pay for health insurance,"* while ***IDI_PLHIV_HI_21*** highlighted the additional impact of *"lack of employment opportunities."*

II. Employment Constraints

Due to stigma and weakened immunity, PLHIV may face challenges in securing employment, exacerbating financial difficulties. As mentioned by one of the participants:

"They cannot do heavy work as they are physically and mentally weak. So, they avoid work."

- IDI_PLHIV_HI_03

Furthermore, interviewees noted that limited job opportunities exacerbate financial barriers. ***IDI_PLHIV_HI_21*** commented on the *"financial and mental weakness"* that comes with economic hardship, often aggravated by the social stigma attached to HIV status, making it even more challenging for PLHIV to gain employment.

III. Uncovered Health Needs

Financial burden is heightened by health insurance limitations, which exclude treatments for chronic conditions, mental health, and major surgeries. One of the participants mentioned:

"It only covers general diseases... but not opportunistic infections." - ***IDI_PLHIV_HI_06***

Furthermore, there are significant gaps in coverage, particularly for health needs outside direct HIV treatment. ***IDI_PLHIV_HI_18*** stated, *"All health problems are not covered, like mental health and chronic diseases,"* pointing to an important aspect of unmet health needs among PLHIV. It shows the need to aware about the services covered by scheme.

3.7. Social Barriers

I. Stigma and Privacy Concerns

Fears of disclosure and social stigma prevent many from enrolling in health insurance or utilizing its services, with concerns about confidentiality breaches in healthcare facilities. One of the participants mentioned:

"There is leakage in privacy... less chance of privacy near residence, so there is a problem." - ***IDI_PLHIV_HI_05***

In-addition**,** Stigma remains a profound barrier, deterring many PLHIV from enrolling in health insurance due to fear of exposure. ***IDI_PLHIV_HI_12*** stated, *"The patients fear disclosure and social stigma,"* and ***IDI_PLHIV_HI_22*** added, *"Fear of disclosure in the community and self-stigmatization."*

II. Discrimination by Healthcare Providers

Instances of prejudice, such as health workers taking extra precautions, discouraging PLHIV from seeking treatment. One of the participants mentioned:

"Even health workers hesitate to provide health treatments… using double gloves." ***IDI_PLHIV_HI_01***

In-Addition, discrimination by healthcare providers also hinders PLHIV from fully utilizing health services. ***IDI_PLHIV_HI_21*** reported that *"Patients are often treated with discrimination and negative attitudes,"* while also mentioning *"more attention than needed,"* which may stem from biased perceptions.

III. Documentation Issues

Enrollment can be hindered by lack of identification documents or inconsistent records between ART centers and official documents. One of the participants mentioned:

"There is a problem on registration... if there is no citizenship or birth certificate." - ***IDI_PLHIV_HI_09***

3.8 Challenges with Health Insurance Utilization

I. Limited Coverage of Health Conditions

Limited coverage of essential treatments was a common concern. ***IDI_PLHIV_HI_24*** highlighted that *"Insurance doesn't cover all health problems; essential treatments are often excluded."* ***IDI_PLHIV_HI_20*** echoed this sentiment, stating that *"Dental and skin diseases are not covered."*.

Critical health needs such as mental health services, chronic disease management, and advanced surgeries are excluded from the scheme, limiting its usefulness. One of the participants mentioned:

"The free health insurance program does not cover most health problems of PLHIV like heart, liver, cancer, mental health." - ***IDI_PLHIV_HI_01***

II. Referral and Access Issues

The referral system creates significant barriers, particularly in remote areas where services are limited. ***IDI_PLHIV_HI_11*** described it as *"difficulties, especially for remote areas,"* and ***IDI_PLHIV_HI_12*** mentioned the *"limited availability of medicines and tests due to referral issues."*

Referral systems can compromise confidentiality and require PLHIV to visit multiple centers, increasing the difficulty and cost of receiving treatment. One of the participants mentioned:

"There is a problem in referral… the referred center would know about the PLHIV patients,

which broke confidentiality." - ***IDI_PLHIV_HI_*04**

III. Availability and Timeliness of Services

Delays in service provision impact the timely utilization of health insurance benefits. ***IDI_PLHIV_HI_*04** pointed out that *"Not all medicines are available on time,"* while ***IDI_PLHIV_HI_*23** emphasized the need for *"timely funding from the Health Insurance Board." Furthermore,* long waiting times and limited access points make it hard for PLHIV to use health services efficiently. One of the participants mentioned:

"There is a long queue for ticket, billing, and stamping... delays in services." - ***IDI_PLHIV_HI_07***

3.9 Impact of Health Insurance on Health and Well-being

I. Improved Health Behavior

Health insurance has positively influenced PLHIV health behaviors, encouraging timely check-ups and reducing the risk of severe complications. Few of the participants mentioned:

"It has increased self-esteem… health check-ups and medicine are covered, helping individuals to stay healthy." - ***IDI_PLHIV_HI_02***

"*PLHIV insurance has enabled regular health check-ups, positively impacting health behavior.*" ***IDI_PLHIV_HI_21***

II. Financial Relief and Mental Well-being

The scheme reduces financial stress for PLHIV, aiding in both physical and mental well-being by making essential services more accessible. Few of the participants mentioned:

"The financial burden will be reduced due to health insurance... timely treatment helps in better diagnosis and reduced stress." - ***IDI_PLHIV_HI_07***

"Reduced the financial burden, helping PLHIV cope better"- ***IDI_PLHIV_HI_24***

3.10 Recommendations for Policy Improvement

I. Increase Coverage Limits and Scope

Expanding the insurance coverage to include chronic disease treatments, advanced medical procedures, and mental health support is widely recommended. While some also emphasized the need of including family members in insurance scheme. Few of the participants

mentioned:

"The amount of NPR 1 lakh should be increased to NPR 5 lakh… the policy should cover mental health and chronic conditions." - ***IDI_PLHIV_HI_08***

"Including family members of infected persons should be advocated."- ***IDI_PLHIV_HI_19***

II. Simplify Access and Expand Service Locations

Improving service availability by increasing ART centers and streamlining the referral process is suggested to ensure easier access to treatment. One of the participants mentioned:

"The number of ART centers should be increased… remove the referral system for convenience." - ***IDI_PLHIV_HI_01***

Furthermore one of the participants suggested *"The CD4 counting machine should be available in nearest health facilities. It is currently available from two health facilities only in Nepal"* - ***IDI_PLHIV_HI_05***

III. Enhance Awareness and Reduce Stigma

Comprehensive training and awareness campaigns for healthcare workers and communities are proposed to address stigma and privacy concerns. One of the participants mentioned:

"There should be orientation on health insurance policy… BCC materials for stigma reduction should be developed." - ***IDI_PLHIV_HI_03***

C. Summary of Findings- FGDs

3.11. Perceptions, Knowledge, and Attitudes Towards Health Insurance

I. General Awareness:

Participants primarily learned about Nepal's free health insurance for people living with HIV/AIDS through ART centers, social media, and peer support. One of the participants mentioned;

"Information about health insurance is provided through ART Centers, Social media, friends/peer, People who have done the health insurance." ***FGD_PLHIV_HI_05***

II. Importance of Health Insurance:

Insurance was considered essential, with several participants noting it significantly reduced

financial strain and offered “lifeline" by covering necessary medications and lab tests. One of the participants mentioned;

"Insurance has become a lifeline for infected people... This has supported their access to health services and reduced their financial burden." ***FGD_PLHIV_HI_05***

III. Perception of Coverage:

While most services were covered, gaps remained in areas such as dental and mental health care, leaving many feelings underserved. One of the participants mentioned;

"The current insurance scheme seems to cover most services. However, it would be beneficial to include dental, skin, and thyroid-related services." ***FGD_PLHIV_HI_03***

3.12 Socioeconomic Barriers to Enrollment

I. Financial Challenges:

Economic hardship limited participants’ ability to access essential health services. Many struggled to afford general medicine, and some reported deaths due to an inability to pay for treatment. One of the participants mentioned;

"Not everyone has a good economic condition. It is difficult to afford even basic medicines, let alone this service." ***FGD_PLHIV_HI_05***

II. Employment Constraints:

Employment barriers impacted affordability and access to insurance services. One of the participants mentioned;

"There would be problems with travel expenses due to lack of employment opportunities." ***FGD_PLHIV_HI_01***

III. Uncovered Health Needs:

Participants cited a lack of coverage for critical health needs like dental and mental health care. One of the participants mentioned;

"There is lack of coverage in teeth, eyes, heart, cancer, high cholesterol, and mental health." ***FGD_PLHIV_HI_02***

3.13 Social Barriers

I. Stigma and Privacy Concerns:

Fear of stigmatization and loss of privacy was common, causing some to avoid health services. One of the participants mentioned;

"Many people did not seek health services due to fear of being identified." ***FGD_PLHIV_HI_05.***

II. Discrimination by Healthcare Providers:

Discriminatory treatment by healthcare providers created additional hurdles, with participants often feeling ostracized. One of the participants mentioned;

"Different behavior from healthcare personnel makes them realize they have committed a serious crime." ***FGD_PLHIV_HI_03***

III. Documentation Issues:

Lack of required documentation, such as birth certificates, often hindered access. One of the participants mentioned;

"Difficulty accessing services due to citizenship or birth certificate issues." ***FGD_PLHIV_HI_05***

3.14 Challenges with Health Insurance Utilization

I. Limited Coverage of Health Conditions:

Specific services, including certain medical treatments and specialized care, were frequently unavailable through insurance. One of the participants mentioned;

"Excluded: diseases related to bones, teeth, throat, eyes, heart, and head." ***FGD_PLHIV_HI_01***

II. Referral and Access Issues:

Challenges with obtaining referral slips and accessing services outside participants' home districts were widely noted. One of the participants mentioned;

"Need to travel away from their home district for services, which is challenging." ***FGD_PLHIV_HI_05***

III. Availability and Timeliness of Services:

Delays in service delivery and inconsistent availability of necessary medications

were significant issues. One of the participants mentioned;

"Delay and inefficiency in service delivery, especially when providing medications." ***FGD_PLHIV_HI_03***

3.15 Impact of Health Insurance on Health and Well-being

I. Improved Health Behavior:

Insurance facilitated regular check-ups and access to necessary treatments, empowering participants to maintain their health. One of the participants mentioned;

"Access to health insurance has encouraged regular medication and reduced the wait times for services." ***FGD_PLHIV_HI_04***

II. Financial Relief and Mental Well-being:

Insurance coverage eased financial pressures, boosting confidence and mental well-being. One of the participants mentioned;

"It has reduced their financial burden and increased self-confidence." ***FGD_PLHIV_HI_05***

3.16. Recommendations for Policy Improvement

I. Increase Coverage Limits and Scope:

Suggestions for policy improvement included increasing the service limit to cover high- cost treatments. One of the participants mentioned;

"Increase the annual service limit to Rs. 100,000 to cover more services, including high- cost treatments." ***FGD_PLHIV_HI_02.***

II. Simplify Access and Expand Service Locations:

Expanding service locations and allo[431]atients to choose preferred ART centers would make access easier. One of the participants mentioned;

"Patients should be allowed to choose their preferred ART Center for treatment." - ***FGD_PLHIV_HI_01***

III. Enhance Awareness and Reduce Stigma:

Participants urged for enhanced confidentiality measures and stigma reduction efforts through awareness campaigns. One of the participants mentioned;

*"Confidentiality should be maintained, and infected persons should not be identified at the ticket counter." – **FGD_PLHIV_HI_02***

4. DISCUSSION

This study highlights significant progress and ongoing challenges in implementing the free health insurance scheme for people living with HIV (PLHIV) in Nepal. The findings reveal notable benefits in terms of financial relief and improved access to health services while exposing limitations such as incomplete coverage, stigma, and logistical barriers.

Comparison with Similar Studies

The results aligned with prior research emphasizing the positive impact of health insurance schemes in reducing economic burdens for marginalized groups. For instance, Alvi et al. (2020) demonstrated that government-led insurance programs could mitigate out-of-pocket expenditures for PLHIV in India, particularly in urban setting. Similarly, Chaumont et al. (2019) reported that community-based insurance reduced financial vulnerability among PLHIV in the Dominican Republic.

However, this study also highlights critical gaps, including limited coverage of essential services such as mental health and chronic diseases. These findings mirror challenges reported in a study by Sharma et al. (2021), which identified dropout rates in Nepal's health insurance programs due to restricted benefits and inadequate service deliver.

Social Barriers

Stigma and privacy concerns, as reported in this study, remain consistent barriers, paralleling observations in South Asia and globally. For example, Malik et al. (2023) noted that fear of discrimination discourages PLHIV from enrolling in health programs, a sentiment echoed in the Kathmandu Valley where confidentiality breaches were reported. Addressing these barriers through targeted education and provider training could improve utilization rates.

Financial and Operational Challenges

The study finds that while the insurance scheme offers financial relief, hidden costs such as transportation and uncovered medications pose challenges. These findings resonate with global trends, where indirect costs remain a hurdle even in well-established insurance systems. As noted in studies from both India and the USA, improving service scope and streamlining operations

could alleviate these burdens.

The findings from both quantitative and qualitative data reveal significant insights into the perceptions, utilization, and barriers to the Nepal Government's free health insurance program for PLHIV. While there is widespread awareness and a generally positive outlook on the program, the data also highlight substantial gaps and challenges that need to be address for improved accessibility and effectiveness.

From the quantitative data, a clear majority of participants were aware of the health insurance program, and almost all were enrolled. This aligns with the qualitative findings, where most participants described gaining information about the program through government sources or social networks, such as ART centres and peer support. As on participant noted, "Insurance has become a lifeline for infected people. This has improved their access to health services and reduced their financial burden" (FGD_PLHIV_HI_05). The majority of respondents also reported the program as crucial, particularly for alleviating the economic burden of essential tests and treatments. However, concerns about the scope of the coverage emerged in both data sets. While the quantitative results show general satisfaction with health insurance reducing economic strain, the qualitative data highlights significant gaps in coverage, particularly for conditions like dental and mental health issues. As on interviewee put it, "The free health insurance program does not cover most health problems of PLHIV like health, liver, cancer, mental health" (IDI_PLHIV_HI_01).

A critical barrier to enrolment and service utilization identified in both the quantitative and qualitative data is financial hardship. Many participants emphasized that while the insurance covered a substantial portion of health-related costs, additional expenses such as transportation and non-covered medications were major obstacles. "It is difficult to afford even basic medicines, let alone this service" (FGD_PLHIV_HI_05), reflected the ongoing financial struggles of many PLHIV. This sentiment was echoed in interviews where participants noted that, "Most of the infected people are financially weak, so it is difficult to pay for health insurance" (IDI_PLHIV_HI_20). Additionally, stigma and fear of social discrimination were significant barriers to enrolment and utilization, as noted in both focus groups and interviews. "Many people did not seek health services due to fear of being identified" (FGD_PLHIV_HI_05) and "Patients are often treated with discrimination and negative attitudes" (IDI)PLHIV_HI_21) indicate that despite the availability of services, fear of exposure prevents many from accessing care.

Furthermore, while majority participants found that the health insurance to be helpful despite, there were still notable barriers related to service delivery. Delays in service provision, referral systems that compromised confidentiality, and issues with availability of medications emerged as recurring problems. As one participant stated, "There is a problem in referral. The referred centre would know about the PLHIV patients, which broke confidentiality"

(IDI_PLHIV_HI_01). These findings suggest that while the free health insurance program has had a positive impact on the physical and mental well-being of PLHIV by facilitating regular check-ups and reducing financial stress, the inefficiencies in service provision diminish its effectiveness.

Triangulating the findings from both data sets, while the free health insurance program has been instrumental in supporting PLHIV, there is a pressing need for policy improvements. Recommendations from participants include expanding the coverage to include mental health and chronic conditions, increasing the insurance limit, simplifying access, and improving the confidentiality of services. These suggestions reflect the core issues identified in the study: financial barriers, insufficient coverage, and stigma. Addressing these concerns could significantly improve the accessibility and quality of healthcare services for PLHIV, ensuring that they benefit from the program to its fullest potential.

5. CONCLUSION AND RECOMMENDATION

5.1 CONCLUSION

The free health insurance scheme for PLHIV in Nepal represents a commendable initiative aimed at reducing healthcare inequities and aligning with the UNAIDS 95-95-95 targets. This study's findings highlight its critical role in alleviating financial burdens and promoting regular health check-ups among PLHIV. Nonetheless, the program's limited- service coverage, logistical barriers, and pervasive stigma restrict its broader impact.

Addressing these shortcomings is essential to ensuring the program's sustainability and effectiveness. Expanding coverage to include mental health services, chronic disease treatments, and family coverage would cater to the comprehensive health needs of PLHIV. Similarly, simplifying the referral process and enhancing service availability through increased ART centers will be an effective commencement to improve access, particularly in remote areas.

This research has provided a comprehensive understanding of the accessibility of health insurance for PLHIV in the Kathmandu Valley, shedding light on various barriers, attitudes and policy gaps. While the free health insurance program introduced by the Nepal Government has had a positive impact on reducing the financial burden of PLHIV, challenges remain that limits its effectiveness.

The study revealed that while awareness of the program is high, significant barriers to enrolment and utilization persist. Financial hardship remains a crucial obstacle, with many PLHIV unable to afford out-of-pocket expenses such as transportation and uncovered treatments. Moreover, social stigma and discrimination continue to discourage many individuals from accessing health services, despite the availability of insurance.

Additionally, the research highlights the limited scope of the insurance coverage particularly in addressing mental health, chronic conditions and specialized treatments. Service delivery inefficiencies, such as delays in care and breaches of confidentiality, further hinder the program's effectiveness. These issues must be addressed to maximize the potential benefits of health insurance for PLHIV.

Policy improvements are essential to overcome these barriers. Expanding the coverage to include more comprehensive healthcare needs, increasing the insurance limit, and enhancing the confidentiality of services are key recommendations that emerged from the study. By addressing these concerns, the health insurance program could become more inclusive and efficient, providing PLHIV with the financial protection and access to care they need to manage their condition and improve their quality of life.

At last, while the free health insurance program has made significant progress in alleviating the financial burdens associated with healthcare, addressing the identified barriers and gaps is crucial to ensuring its full potential. This scheme has proven to be a lifeline for many, reducing out-of-pocket expenses for essential services. However, to enhance its effectiveness, it is imperative to expand the coverage to include more comprehensive healthcare needs, particularly mental health and chronic conditions. Additionally, improving service delivery, confidentiality, and simplifying the enrolment process will further support PLHIV in accessing health care. Strengthening the free health insurance scheme is essential for ensuring that all PLHIV can benefit from better health outcomes, enabling them to manage their condition with dignity and improved quality of life. Continued policy reforms and a focus on inclusivity will be key to creating a robust insurance plan that fully supports the needs of PLHIV in Nepal.

5.2 RECOMMENDATION

5.1 Addressing Socioeconomic Barriers

i. Financial Support: The financial assistance programs should be implemented to support PLHIV cover additional costs associated with healthcare, such as transportation and non-covered medications.

ii. Employment Support: The inclusive employment policies must be promoted and vocational training must be provided to enhance wider employment opportunities for PLHIV.

iii. Reduction of Stigma: Public awareness campaigns must be conducted to reduce stigma and discrimination against PLHIV (especially from health service providers).

5.2 Improving Health Insurance Coverage and Accessibility

i. Expand Coverage: The coverage of the health insurance scheme must be increased to include essential services like mental health care, chronic disease management, and advanced

surgeries. Furthermore, CD4 counting machines should be implemented in greater number of healthcare facilities, as they are currently available in only two facilities across Nepal.

ii. **Make ease in enrollment:** The enrollment process must be made easy providing support to PLHIV in obtaining necessary documentation.

iii. **Strengthened Referral System:** The referral system maintaining confidentiality must be improved to ensure timely access to specialized care, especially in remote areas. Recently these are improved and now there is only referred when the services are not available in the particular center.

5.3 Enhancing Health Insurance Utilization

i. **Patient Education and Counseling:** The comprehensive information and counseling to PLHIV about the benefits of health insurance and how to utilize it effectively should be increased. Moreover, PLHIV should be aware about the services provided by free health insurance. (Not only ART medicine but also the treatment for the other opportunistic diseases) which are covered by Health Insurance.

ii. **Enhance Public Awareness**: Use diverse communication platforms to disseminate information about the free scheme governed by government of Nepal.

Incorporating these measures can better address the unique needs of PLHIV, ensuring the program fulfills its intended objectives and aligns with global HIV response strategies.

iii. **Maintaining Confidentiality:**

Due to the sensitivity of the topic, the confidentiality should be maintained while enrolling PLHIV into Health Insurance, providing enrollment document, service utilization and referring. One of the participants informs that their and their family's identify was displayed as PLHIV in the payment counter while utilizing this service. However, it is important to note that this issue was addressed by the Health Insurance Board during the course of the research.

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6. Annex

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1. Workplan

Particulars	June				July				August				September				October				November			
In Weeks	1																							
Signing of Contract																								
Literature Review																								
Data collection tools and document development and finalization																								
Ethical approval from NHRC																								
Recruitment of team members																								
Preparation for the capacity building of research Team																								
Training and Capacity building of the research Team																								
Preparation for data collection																								
Data Collection																								

Supportive supervision and monitoring																								
Data Cleaning and Analysis																								
Mid-term review																								
Preparation of draft report																								
Sharing of draft report and incorporate feedback																								
Preparation of final draft and sharing																								
Coordination with related stakeholders																								
Dissemination of the result																								

3. Ethical Consideration

Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 312

23 August 2024

Mr. Nanda K. Adhikari
Principal Investigator
Social Development and Promotion Centre
Lalitpur

Ref: Approval of research protocol

Dear Mr. Adhikari,

This is to certify that the following protocol and related documents have been reviewed and granted approval through the expedited review process for its implementation.

Protocol Registration No/ Submitted Date	388_2024 25 July 2024	**Sponsor Protocol No**	NA
Principal Investigator/s	Mr. Nanda K. Adhikari	**Sponsor Institution**	SAARC Tuberculosis and HIV/AIDS Centre (STAC)
Title	Understanding Health Insurance Accessibility for PLHIV Kathmandu Valley: Barriers, Attitudes and Policy recommendations		
Protocol Version No	NA	**Version Date**	NA
Other Documents	1. Data collection tools 2. Informed Consent Form 3. Approval letter from KMC 4. Sponsor agreement letter 5. Conflict of Interest (CoI) 6. Ethics Training Certificate 7. Role and responsibilities 8. Work plan	**Risk Category**	Minimal risk
Co-Investigator/s	1. Regan Ranjit		
Study Site	Kathmandu Valley		
Type of Review	√ **Expedited** ☐ Full Board **Review Date:** 23 August 2024	**Timeline of study** 23 August 2024 to December 2024 **Duration of Approval** 23 August 2024 to 22 August 2025 **This approval will be valid for one year**	**Frequency of continuing review** NA

Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 312

Total budget of research	**NRs 11,55,500.00**
Ethical review processing fee	**NRs 34,665.00**

Investigator Responsibilities

- If you do not start the project within 3 months of this letter, please contact the Ethical Review M & E Section at NHRC
- Any amendments shall be approved from the ERB before implementing them
- Submit progress report every 6 months
- Submit final report after completion of protocol procedures at the study site
- Comply with all relevant international and NHRC guidelines
- Abide by the principles of Good Clinical Practice and ethical conduct of the research

If you have any questions, please contact the Ethical Review M & E Section at NHRC.

Thanking you,

Dr. Pramod Joshi
Member Secretary

Tel: +977 1 5354220,5327460, Ramshah Path, PO Box: 7626, Kathmandu, Nepal
Website: http://www.nhrc.org.np, E-mail: nhrc@nhrc.org.np

4. Approval letter from KMC.

काठमाडौं महानगरपालिका
काठमाडौं महानगरपालिका
नगर कार्यपालिकाको कार्यालय
स्वास्थ्य विभाग
बागमती प्रदेश, नेपाल

पत्र संख्या :०८१।०८२
चलानी नं.: ४१

मिति: २०८१।०४।२३

श्री सामाजिक विकास प्रवर्धन केन्द्र
सानेपा , ललितपुर

विषय: स्वीकृति प्रदान गरिएको सम्बन्धमा ।

उपरोक्त सम्बन्धमा तहाँबाट प्राप्त मिति २०२४ अगस्त २ को चलानी नं ०८१/८२-००२ को पत्रानुसार गर्न लागेको "Understandding Health Insurance Accessibility for People Living with HIV/AIDS in Kathmandu Valley : Barriers , Attitudes and Policy Recommendations" विषयक अध्ययन गर्नको लागि चालु आ.ब.०८१/०८२ सम्ममा लागि प्रत्येक ३/३ महिनामा यस विभागलाई प्रगति प्रतिवेदन उपलब्ध गराउनु पर्ने गरी स्वीकृति प्रदान गरिएको व्यहोरा अनुरोध छ ।

.....
दिपक कुमार के.सी.
विभागीय प्रमुख

बागदरबार, काठमाडौं, नेपाल, फोन नं. +९७७-१-४२३१४८१ फ्याक्स : ९७७-१-४२६८५०९
E-mail: ceo@kathmandu.gov.np, kmcmayor@mos.com.np, website: www.kathmandu.gov.np

5. Information on Health Insurance

स्वास्थ्य बीमा कार्यक्रम

भोलि के पर्छ पर्छ, स्वास्थ्य बीमा आजै गर्नुपर्छ ।

स्वास्थ्य बीमा कार्यक्रम

नेपाल सरकारद्वारा संचालित सामाजिक स्वास्थ्य सुरक्षा कार्यक्रम हो ।

स्वास्थ्य बीमा किन गर्ने ?

स्वास्थ्य उपचारमा लाग्ने अनियोजित खर्च (OOP) न्यूनीकरण गर्न स्वास्थ्य बीमा गर्नु पर्छ ।

स्वास्थ्य बीमाको वार्षिक शुल्क

प्रति परिवार (५ जनासम्मको) रु ३,५००/- पाँच जना भन्दा बढी सदस्य भएमा प्रति थप सदस्य रु ७००/- दरले शुल्क लाग्ने छ ।

स्वास्थ्य बीमा नगरे के हुन्छ ?

स्वास्थ्य सेवा उपयोगको क्रममा हुने सम्पूर्ण खर्च व्यक्ति/परिवार स्वयम् ले व्योहोर्नु पर्ने हुन्छ ।

उपलब्ध सेवा सुबिधाहरु :

- बहिरंग सेवा (OPD Services)
- आकस्मिक (इमरजेन्सी सेवा)
- अन्तरंग सेवा (अस्पताल भर्ना भई लिइने सेवा)
- निदानात्मक सेवा (Lab, X-ray, USG, MRI, CT Scan, etc.)
- सुबिधा थैलीमा उपलब्ध औषधिहरु
- शल्यक्रिया
- तोके बमोजिम मूल्यको चस्मा, श्रवणयन्त्र, सेतो छडी, बैशाखी, आदि ।

नसमेटिने सेवाहरु:

- कस्मेटिक सर्जरी
- आधारभूत स्वास्थ्य सेवा
- महंगा खालका दन्त उपचार
- कृतिम गर्भपतन, कृतिम गर्भाधान सेवा
- निःशुल्क उपलब्ध हुने औषधिहरु

थप जानकारीको लागि:

www.hib.gov.np

टोल फ्री नं: १६००१११२२४

- प्रत्येक वडाहरूमा रहेका स्वास्थ्य बीमा दर्ता सहयोगीमार्फत स्वास्थ्य बीमा कार्यक्रममा आवद्ध हुन सकिनेछ ।
- बीमा नवीकरणको लागि सम्बन्धित दर्ता सहयोगी वा अनलाइनमार्फत आफै (Connect IPS, eSewa, Khalti) पनि गर्न सकिन्छ ।

जर्मन सहयोग DEUTSCHE ZUSAMMENARBEIT

giz Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

MÉDECINS DU MONDE

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