

CHAPTER III

PROPOSAL

A Study of Community Participation to Increase the Cure rates among the TB Patients in Girbari village of Deurali VDC Nepal

3.1 Introduction

Tuberculosis is a major public health problem in the world today, and poses a serious challenge to public health work. So great is the concern about the world-wide magnitude of the modern TB epidemic that in April 1993 the World Health Organization (WHO) declared tuberculosis to be a "global emergency" -- the first declaration of its kind in WHO history.

Someone in the world is newly infected with tuberculosis literally with every tick of the clock -- one person per second. Fully one third of the world's entire population is now infected with the TB bacillus. In the next decade it is estimated that 300 million more people will become infected, that 90 million people will develop the

than AIDS, malaria and tropical diseases combined (World Development Report, 1993).

The need to control TB is essential.. In Nepal about 60 % of the economically active adult population are infected with TB bacillus, with 45-50,000 people developing the disease annually, at least 20,000 of whom have infectious TB. Over 16,000 people die each year from this disease, making it perhaps the single most important cause of death in the adult population in Nepal (National TB Program, Annual Report, 1995).

The control of TB is only possible by treating the TB cases of the community. By treating a TB patient we are cutting the source of infection and thus we break the chain of transmission. This particular patient once cured does not infect anyone else. The only way to treat a TB patient is to give a combination of anti-TB drugs for 8 months (National TB Program Manual, 1997). However, most patients, generally after taking the drugs for few weeks feel much better and do not feel it is necessary to take the drugs. They either stop taking the drugs completely or starts taking them irregularly. This creates low cure rates and multi-drug resistance (MDR-TB), which is very difficult and expensive to treat. The low cure rates can cause suffering, economic loss, and death to the patients. The present cure rates in the NTP (National TB Program) is below 50 % and this is a major concern.

Therefore, the key to controlling the spread of TB lies in the compliance of the patients in adhering to the necessary drug treatment program. This study proposes to

develop and implement a holistic TB treatment protocol that encourages participants which include, not only the patients and their families but also from the communities. The essential strategy that is instrumental in the success of such program is creating a community ownership of this problem and its control.

3.2 Geography and economy of Nepal

The Himalayan Kingdom of Nepal lies sandwiched between the great nations of China and India, and consequently is a melting pot of diverse environments, languages, cultures and religion. Though famous for its mountain and hills, Nepal also has narrow fertile plain-the Terai-running along the southern border of the country, in which nearly 50 % of the 20 million population live. The population structure is typical of developing country, with 52 % of the population under the age 20.

**Table 3.1: A summary of some demographic, health and economic statistics
Comparative general indicators**

Indicator	Nepal	Low income countries
Population	20.6 mill	
Population growth rate (1980-91)	2.6%	2.6%
Urban population (% of total)	10 %	28%
Crude birth rate (per 1000)	38	38
Crude death rate (per 1000)	13	13
Infant death rate (per 1000)	101	91
Female literacy rate	13 %	44%
Life expectancy at birth	53	55
GNP (US \$) GNP	\$ 180	\$350
Growth in GNP	2.1%	1%
Total external debt	\$1,769,000	
External debt as %	53.5%	85.7%

Source: World Bank 1993

According to the World Bank 1993 Report the population of Nepal is 20.6 million, the population growth is 2.6 % and the GNP is 180 US \$. Ninety percent of

people are subsistence farmers (as shown in Table 3.1), living in small villages, but urbanization is increasing rapidly on the *Terai* and around the capital, Katmandu. Communication and travel are limited by the terrain and seasonal rains, and all forms of government infrastructure are poorly developed. Administratively the country is divided into five regions and 75 districts. Each of the districts are further divided into village development committees (VDC) or municipalities, which are the smallest local administrative units.

3. 3 Epidemiology of TB in Nepal.

3.3.1 TB a public health problem

Tuberculosis is an immense problem in Nepal, causing great suffering and death. TB in Nepal does not spare any socio-economic group, although it is most frequent among the least well-off: those with lowest incomes, poorest housing and least schooling. The prevalence of TB is highest among adults, and higher among men than women (TB in Nepal, 1997).

3.3.2 Annual rate of TB infection (ARTI)

Annual rate of TB infection (ARTI) is the crude proportion becoming infected each year. It allows us to estimate the number of people developing the TB disease. Tuberculin surveys are used to calculate the ARTI. In Nepal, the ARTI is estimated to be in between 1-4 % (Annual Report of NTP, 1995), the higher values in urban areas and lower values mountain and hills (as shown in Table 3.2). ARTI of the whole country is assumed to be 2.2 % (Shakya, T. M., 1992). Most patients with TB

are from economically active age group (as shown Fig 3.2) and many are also from the poorest and most disadvantaged sections of the society.

Table 3.2: Summary annual risk of TB infection calculated from tuberculin surveys conducted in Nepal.

Region	WHO/HMG Review(1994)		Onozaki (1992)
	mean	median	
Terai	1.8 %	1.80%	2.5%
Hills	2.3%	1.9%	1.5%
Mountains	?	?	<1%
Urban	4.49%	4.80%	4%
Population adjusted average	2.10%	1.98%	2.2%

Source : National TB programme review 1994
National seminar and workshop 1995

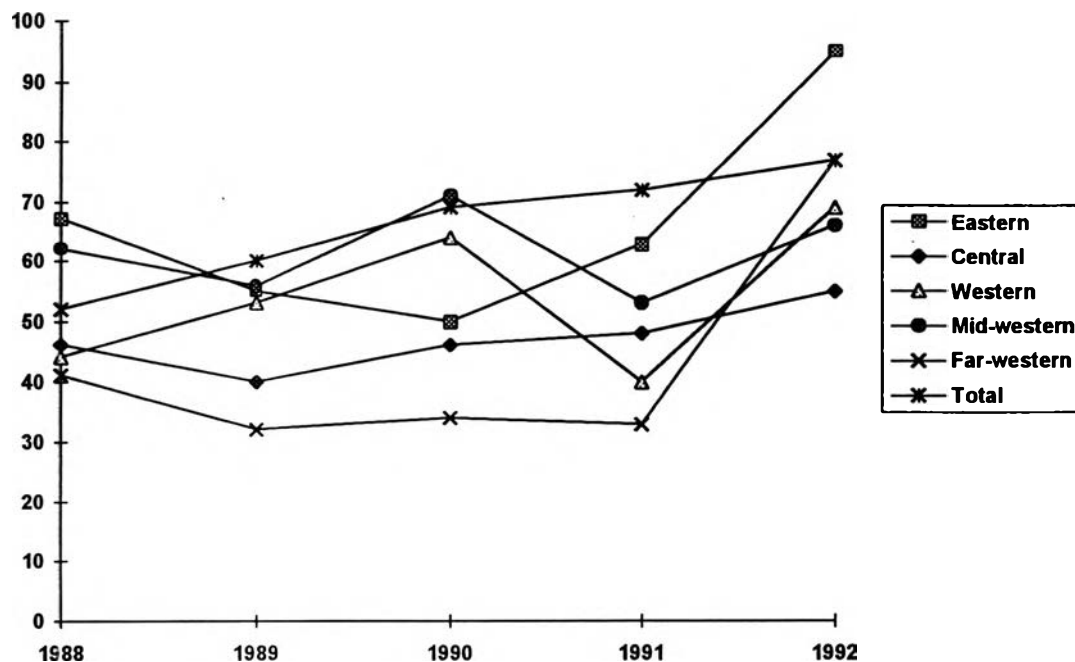
3.3.3 Mortality of TB

TB kills 45 people of young and productive age group per day (16,500 people die annually) in Nepal. In the industrialized countries, TB incidence and mortality rates were higher in young people five decades back. With the decline in the risk of infection in those countries, TB shifted from being the disease of young to a disease of old people. But in Nepal, it is currently the problem of the young and productive age group 15- 49 years (as shown in Fig. 3.2) (National TB Programme, Annual Report, 1995).

3.3.4 Increasing trend of TB incidence

The incidence of sputum-smear positive is 110 per 100,000 or roughly around 20,000 new patients per year. The prevalence is 200-300 sputum-smear positive per 100,000 population (Annual Report NTP, 1995). The number of TB patients reported to the NTP has increased over the last decade. The increasing trend of the disease can be seen from the figure (as shown in Figure 3.1 below). Reporting system is not well developed and well functioning, so under reporting of the cases may have occurred. After integration of all the programs into primary health care in 1988, all the vertical programs including TB had a severe set back because TB program had many trained workers for and after integration these staffs had to leave their job because they were not permanent workers and this contributed in low detection new cases.

Fig 3.1: Notification of incidence new TB cases (+) by region per 100,000
Notification of incidence new TB cases(+) by region per 100,000

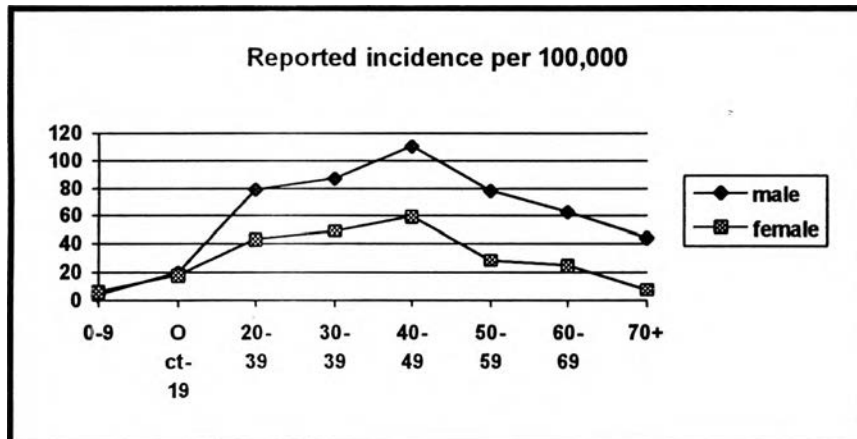


Source: Bam, 1995 (Proceedings of VI th National Seminar on NTP)

3.3.5 Age and Sex Distribution of TB patients

Analysis of age and sex distribution of the cases diagnosed reveals that more men are registered into treatment than women, at all ages. As in many other parts of the world, access to modern medical care for women is limited by many factors, including education, distance, money, social status, stigma, dependency, discrimination, gender of health workers, decision making power, health beliefs, illness behavior, and social roles. TB affects young and productive age groups of 15-49 years (as shown in Fig 3.2).

Fig 3. 2: Reported incidence of TB by age/sex/100,000



Source: NTC (data from 1985-1991: New Sputum positive)

3.3.6 TB and HIV

The strong association between TB and HIV/ AIDS is well established. Both the TB and HIV/AIDS pose a grave public health challenge today. The most important impact of HIV on TB is the increase in incidence of new cases. This is due

to (a) increased breakdown to active TB in those co-infected, and (b) the decrease in time between infection and disease onset in HIV-positive recently infected with tuberculosis bacilli. TB is leading cause of death in person infected with HIV. A study carried out in Abidjan, 1991 showed that 32 % of the deaths in HIV/AIDS was due to TB.

3.3.7 Multi-drug resistance TB (MDR-TB)

MDR-TB occurs when TB patients do not take their medicine as prescribed, the TB bacteria can become resistant to a certain drug and consequently the drug can no longer be used to kill the bacteria. This is called multi-drug resistant TB (MDR-TB) and is an extremely serious problem that is currently treated with other drugs which cause MDR-TB to be very difficult and very expensive to treat. Having MDR-TB is like declaring a death sentence in a developing country.

Patients generally start off by taking their drugs, but lose interest as they gain symptomatic relief and begin to grudge the cost and inconvenience of taking regular treatment. One or more drugs might be omitted as the patient feels increasingly better. Time, work and social commitments may also displace the chore of taking regular treatment.

Once the patient stops taking the medicines without completing their duration of treatment the patient become ill again after some time. This time the same medicines may not be effective in curing him/her and he might die of TB. Before dying

he will infect many more with same strain of bacilli, which has already developed resistance.

3.4 Fate of sputum-positive TB patient in various TB program

A study in South India has shown that if TB is left alone without any treatment 50 % of the cases would die, 30 % would be cured without any treatment and 20% would be still excreting bacilli and infecting others (Grzybowski, 1978). A TB patient (smear positive) will infect 10 to 20 people in a year and a TB patient will survive 2 years without any treatment (Grzybowski, 1978). One could just imagine the number of people being infected.

Under ideal programs, 5 % of the patients die while on treatment, and 93% are cured, 2 % are not cured (Davies, P., 1994). However, Nepal's National TB program achievement of 40-50 % cure rate, which is only about 10-20 % higher than the non treatment cure rate, is very depressing. These poor programs have low death rates but they have large numbers of chronic cases which is again very difficult and costly to treat because these cases develop multi drug resistance. From Fig. in 3.3, one can see that it is better not to have a National TB program (NTP) than to have a poor program (as shown in Fig. 3.3 below).

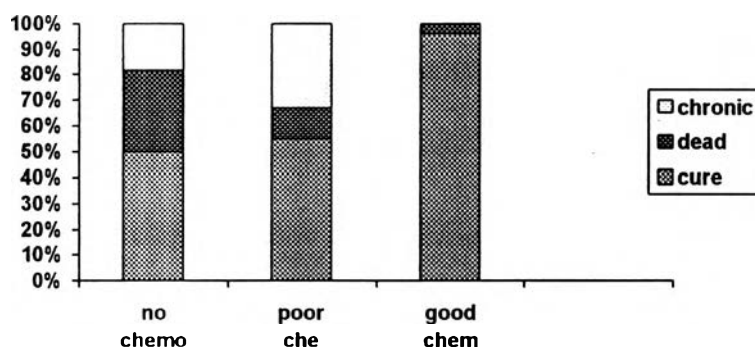
WHO with IUATLD has advocated a strategy called DOTS (Directly Observed Treatment, Short-course). DOTS is observing the patient while taking the treatment.

Thus DOTS is means to ensure that the TB patient, who is enrolled in the treatment, successfully completes the treatment.

3.5. Directly Observed Treatment, Short-Course(DOTS)

DOTS (Directly Observed Treatment, Short-Course) ensures that every dose of treatment is supervised. WHO recommended strategy DOTS is one of the most cost effective strategies available in infectious disease control (World Bank Report, 1993).

Fig 3.3: Fate of sputum positive cases



Source: Grzybowski, 1978

Short-course chemotherapy (SCC) is eight months of treatment, two months of intensive phase with four drugs (Rifampicin, Ethambutol, Pyrazinamide, and Isoniazid) and then six months continuation phase with two drugs (Ethambutol and Isoniazid). Though this SCC regimen is more expensive than the 12 month long standard regimen

(Streptomycin, Isoniazid, and Thiaacetazone for two months followed by Thiaacetazone and Isoniazid for ten months), this regimen has a shorter duration and above all has relatively low side effects compared to the standard regimen.

WHO has recommended that every dose of tuberculosis treatment has to be supervised and WHO has very good reasons to say this. In the past years the cure rates in the developing countries have been below 50 % (TB Epidemics Report, 1997). Low cure rates creates drug resistance (Pathania, 1997). If one is affected with multi-drug resistant tuberculosis bacilli, he/she cannot be cured and he/she will be a source of multi-drug resistant infection. Another threat to the TB program is the increasing of HIV positives. TB and HIV is a deadly combination which multiplies the impact each other causing severity in the disease, if HIV increase so does TB.

Objectives of this study is to increase the cure rates of the TB patients. The length of the treatment and the need to take several drugs is a major challenge in the NTP. Many after few weeks of treatment the patient feels better and does not think necessary to continue the treatment and discontinues or takes the drugs irregularly. Therefore, it is very necessary to supervise the treatment. The treatment can be supervised by a health worker, by a family member, by a friend, by a neighbor, or by the community. Supervision by the health worker is accountable but not accessible to the patients. Supervision by the health worker is when the health worker observes the patient swallowing the TB drugs. It is very difficult for the patient to walk daily to the health facility to swallow the drugs.

Supervision by a family member or a community member like, friend, neighbor or head of the village is accessible for the patients but not accountable for the health services. So there is a need to find a method which is both accountable for the health services and accessible for the patients. Supervision of the treatment supervisor (family member) by the community supervisor through community participation, which I am proposing, is both accessible and accountable.

3.5.1 DOTS by health workers

According to the DOTS strategy, the patients have to come daily and swallow medicine in front of the health workers. However, most of these patients have to earn their living working for others and to feed their dependents. Above all, these patients are mainly farmers, workers and housewives. After a hard days work, it is very difficult to walk all the way to the health post and swallow the drugs . The health workers are not always friendly, cordial and at times he may not available at the health post. These above mentioned factors also contribute to the poor compliance with TB drug regimens.

Health workers also complain that they are overloaded with daily routine work and feeding TB patients with TB drugs daily is an extra burden. This will cause great deal of extra load on these health workers and will naturally increase expenditure of health budget. It is, in fact, very difficult for the patient to walk to the health post and

swallow the medicines in front of the health personnel. But if you ask any patients, who has come for the first at the health facility, he /she will naturally say that he/she will come daily for the medicines but this not practical.

3.5.2 DOTS by family members

Another means of supervising the TB treatment is by the family members. In this method after diagnosis the TB patient is given a month's supply of TB drugs and the patient takes the medicines daily in front of the designated treatment supervisor. The treatment supervisor is the family member who together with the patient, has received extensive health education from the health workers.

The treatment supervisor and patient will also receive health education about the side effects. One of the main reasons for not completing the treatment is because of the side effects (Shakya, 1996). Therefore, patients will have knowledge about the side effects and about it's severity so that the patients can be taken to the health facility. Side effects like nausea, mild vomiting, numbness and flu like symptoms will disappear without any treatment. But severe body rashes and itching have to be attended by a health personnel. The treatment supervisor along with the patient comes to the health center for examination and drug collection. This method also has some drawbacks. If the patient is the head of the family or the father, he does not obey his son/daughter or his wife and does not take the drug but marks that he has taken the drugs (Personal communication during data exercise at Cholburi Zonal TB center).

3.5.3 Alternative of existing methods of DOTS

DOTS by a health worker is difficult to implement because the health workers are overloaded with the daily routine work. And not all the health facilities have all the designated health workers and as a result, usually the PHCs are understaffed. For the patients it is very difficult to come daily and swallow the medicines because most of these patients are farmers or laborers who have to work daily to get bread for them and their family.

So I would like to propose DOTS by treatment supervisors but with community participation. where the community people such as community leaders, women's group activists, ex-TB patients, or someone respectable from the community supervises and monitors these treatment supervisors. These community supervisors will be called community supervisors.

3.5.4 Community participation

In the village almost everybody is aware of tuberculosis and its suffering: everyone can remember someone who has died of TB in their family or in their neighborhood. Community must be aware that TB is a problem for the community and this problem can be solved.

This can be achieved by mobilizing community people and by making them feel it is their problem and by developing trust and ownership. This can be done by creating awareness through various means like arranging talks, street theater, health education.

This health awareness program will create awareness about the TB symptoms and the people with these symptoms like cough for more than three weeks, fever with evening rise, blood in the sputum, loss of weight, and inability to work, will go to PHC for diagnosis. Although the main objective of this proposal is not to increase the coverage, this awareness program will have an impact on the coverage.

3.6 Objectives

3.6.1 Overall Objectives

The overall objective is to increase the cure rates through improved adherence by community participation and thus reduce the morbidity and mortality of TB.

3.6.2 Specific Objectives of the DOTS

The specific objectives are:

1) To implement two intervention programs, one of which is DOTS by treatment supervisors and the other is DOTS by treatment supervisor with community participation in regards to increasing the adherence to treatment.

2) To compare the results of DOTS by treatment supervisors and DOTS by treatment supervisors with community participation in regards to cure rates and adherence to treatment

3) To determine the most effective intervention and recommend to the NTP (National TB program).

3.7 Site of study

The site chosen for this study is Nawalparasi district which is 200 kms away from Katmandu. The reasons for choosing this district are that this district is reasonably accessible from Kathmandu and no studies have been in TB control. Community participation in developmental works have also taken place. Nawalparasi district is in the Western Development Region of Nepal. Village Girbari and village Koliya of Deurali Village Development Committee (VDC) have been chosen for the study. Deurali VDC has a population of 25,000. This is plain fertile land. Most of the people are farmers and farm laborers but few are employees in India. Rice, wheat, oil seed, sugarcane and vegetables are the main crops of this district.

The people of this VDC attend the Koluwa PHC (Primary Health Care Center), which is about one and half hours walk from Village Girbari and Village Koliya. The PHC has a designated medical officer (who is most of the time not there), a health assistant, one staff nurse, three ANM (Auxillary Nurse Mid-wife), two AHWs (Auxiliary Health Worker), and one laboratory assistant.

This district is connected by relatively good transport. Most of the villagers are farmers or farm laborers. This population represents the rural *terai* farmer population of Nepal.

This VDC consists of people of all ethnic origins because this area is a resettlement areas; most of the people have come to this area from the adjoining hilly

districts. The village Girbari and village Koliya consist of almost 5,000 population. These two villages are equally far from the Koluwa PHC. Each village have schools in the village. Both villages are equally developed in terms of development activities like the graveled road constructed by the people and irrigation canals built by the people. Above all due to the encroachment into the forests, people have gathered and decided to have their community forests and replant trees. This shows that both villages have active community participation.

TB is prominent in this district. For this PHC, however, there is no data. The PHC staff have all been trained for DOTS. The logistic supply is fairly good. The laboratory is functioning well and has a binocular microscope. The binocular microscopes can detect the TB cases and the health workers can also use easily. Though this district has fairly well developed infrastructure the compliance of the TB patient is low. As per the annual report 1996 the cure rate is 46 % (Annual Report of NTP, 1995).

3.8 Research Methodology

Village Girbari and village Koliya of Deurali VDC attending the same PHC (Primary Health Care Center) are selected for the study. These two villages consist of approximately the same population, same socio-economic structure, occupation, similar education of the population and same distance to the PHC and community people equally active in community development (drinking water projects, banning alcohol, irrigation canals, etc.).

Koliya village will have DOTS by the treatment supervisors (TS) only. A TS can be any of the family member or a neighbor. The TB patient will choose the treatment supervisor. But for some patients the TS must be of the same gender, age and ethnic group and caste. The TS will supervise the patient daily in taking the drugs and marking it in the treatment card which is called the DOTS card. TS will accompany the patient to the PHC every month and collect the drugs. The DOTS card and the drugs will be kept by the TS. The main function of the treatment supervisor is to supervise the patient (as shown in Fig. 3.4).

DOTS by TS with community participation will be implemented in the other village. Here the community participation is in the form of a TB committee, which will be formed by the forest council. The TB committee with the villagers will decide on method to supervise and monitor the treatment supervisor. The TB committee will choose community supervisors and, with community participation the villagers will decide on how, when and where community supervisor will supervise the treatment.

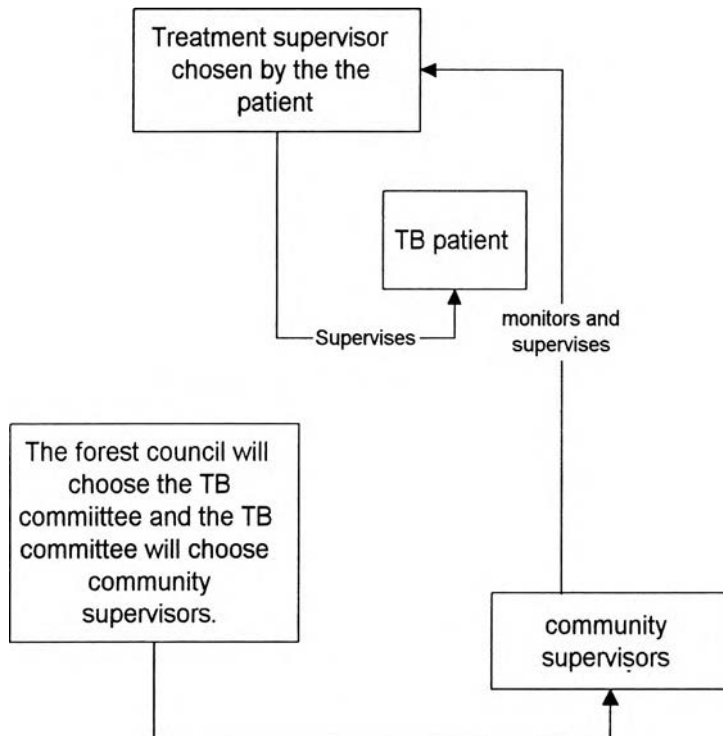
The site of the study, village Girbari, can be divided into 20 such clusters with 12-18 houses (family) and each families having 5-8 members. The village has a population of 2250 people according to the latest census (Statistical Pocket Book, 1996). The community supervisor and the treatment supervisor will decide on how and where will supervision will take place. This process of community participation, choosing community supervisors and forming a committee will take about one month.

The existing forest development council, chosen by people, which has done a very good job for the community by replanting trees which became the community forest. People are not allowed to cut the trees from this community forest but they can gather twigs for firewood and collect leaves for the livestock. This community forest has improved the quality of life for the people, otherwise they had to go very far to collect firewood and cut leaves for their livestock. People have trust on this council. This council consists of seven members but all the villagers choose them by voting. The tenure of this council is five years. I will approach this council on one of their meetings and convince them about the TB problem. Once the council members are convinced, I will persuade them to put TB on their agenda.

The forest council which consists of the village head and other social workers of the village will choose a TB committee amongst the villagers who are interested and dedicated in social works and also have shown dedication in action by working for the community. The TB committee will have seven members, six members will be chosen from the villagers by the forest council and one will be the in charge of the PHC.

The TB committee consisting of seven members will have focus group discussions to develop criteria for choosing the community supervisors and choose and

Fig 3.4: Conceptual framework of Community participation in TB control



to develop strategies and roles of community supervisors. The TB committee will also develop a plan to create awareness to get rid of the stigma, and to educate the villagers. The moderator will be the school head master. The researcher will be note taker and tape recorder will be used. Guideline for focus group discussion will be used (see Appendix A).

The research team will facilitate to give the health education but the TB committee will organize the video shows. Villagers will be encouraged to come and see the video shows. Organizing the shows will increase the popularity of the TB

committee and villagers will have increased faith on this committee. Extensive health education using health education materials like videos, radio programs, leaflets and pamphlets prepared by National Health Education Information and Communication Center (NHEICC) will be used. A week of extensive health education will be given. Video shows will be shown in the evenings and pamphlets and leaflets will be distributed in the school.

Teachers of the local school will be oriented by the research team to teach the children to get rid of the stigma. School children will play in acts which will show that TB is caused by germs and not by a curse or a sinful act (Oakley, 1989). Children will go to their houses and talk about TB and how it is infected, signs and symptom and what has to be done. The school children will also be taken to the known patients houses and will be shown around so that these students will disseminate that TB is a curable disease and nothing to do with wrong doing or sinful act.

After a week of extensive health education this program with video shows will be evaluated at the last video show. There are seven video films made on TB all having the theme of TB is caused by germs and not by sinful act, TB can be cured, and TB can be cured at the PHC. This evaluation will be done before the first show and in the middle of the last show. Around 10 % of the audience of the video show will be interviewed before and after. These people to be interviewed will be chosen by purposive sampling but will include male and female, young (below 20) and old (above 20). Closed ended questionnaire containing only few questions will be used.

Only a small (short) questionnaire will be used because the interview will be in the evening and just before the show, this questionnaire will let us know about the knowledge and the stigma. The following are the questions (see Appendix B). This pre and post survey will let us know the extent of the stigma and how much we have been able to get rid of the stigma.

Focus groups discussions (FGD) after the video shows will be done with six groups to find out what they think about TB patients, the knowledge about TB, and what has to be done to get rid of the stigma and to know the socio-cultural aspect in more detail particularly about the stigmatization. "Focus group discussion can be defined as a discussion in which a small number (usually 7 to 9) of respondents with similar backgrounds under the guidance of a moderator, talk about topics that are believed to be important to the investigation" (Babbie, 1995). Groups must be homogeneous with same characteristics like age and sex. The discussion will be under the interview guideline. The advantages are does not discriminate against people who cannot read and write. FGD can encourage participation from those who are reluctant to be interviewed on their own and can encourage contributions from people who feel they have nothing to say. The focus group discussion can highlight on cultural norms and also come to solution what has to be done.

The six groups of people, each group having seven members, will discuss according to interview guideline. The two groups will be chosen every alternative days after the shows. One group will be male and the other will be female. The school head

master will be the moderator. The researcher will be the note taker and there will an assistant to assist. A tape recorder will be used to record the discussion. The six groups will consist of all groups three males and three females.

There will be focus groups discussions every alternative day after the shows. There will be one male and female groups for every alternative day after the show. The people will be chosen by purposive sampling. The total number of male and female adults watching the show will be counted and seven people will be chosen for each group. While going out from the school, the nth participants will be chosen for the focus group discussion. Guideline for FGD will be used (see Appendix C).

Once the stigma is overcome TB committee will choose the community supervisors who will supervise the treatment supervisor. The TB committee will then decide how to supervise the treatment supervisors. The patient once diagnosed having TB will be sent to the TB committee with his/her treatment supervisor by the PHC. The community supervisor along with treatment supervisor decides when and where the patient will take the drug.

If someone does not come for treatment the community supervisor will go to his house and find out why he did not come. Apart from supervising the treatment the community supervisor will encourage the patients to take the drugs and will discuss other problems that the community has.

3.9 Registering patients for treatment

All patient attending the Koluwa PHC and diagnosed anywhere not only in the PHC and residing within these two villages within September to December 1998 will be registered for this study. The patient will have to come with a member of the family who can supervise the treatment. If he does not have anybody in the family he can even come with a neighbor (see Flow Chart, Fig. 3.5). Unless and until the patient comes with a treatment supervisor, he/will not be enrolled in the treatment. If the patient has come alone and he is diagnosed TB, he will have to come again with someone who can be his treatment supervisor.

3.9.1 Criteria for the patients to be included in study for both groups

Only newly diagnosed patients of both sexes 15 years of age and older with at least two sputum specimen positive will be included in the study. Two smear-sputum positives because one can be false positive. A newly diagnosed case of TB is one who has never been treated for TB for more than four weeks. The patient has to be able to find a treatment supervisor from his family or from the neighborhood. The patient has to sign an informed consent form. However, any diagnosed case of TB who do not fit inclusion criteria will still receive TB treatment.

3.9.3 Exclusion criteria

Exclusion criteria for both groups are those patient who have already been treated for TB or has had reaction with anti-TB drugs. Though TB medicines have no teratogenic effects on the fetus and the mother (Davies, PDO 1994), known Pregnant

women will not be included in the study because pregnant women go to their parent's home for delivery. However, if the women becomes pregnant or finds out that she has become pregnant after she has been included in the study. Then she will continue with study and advised not to go her parents home. People who have other associated diseases like diabetes mellitus, cancer, HIV, etc. will also not be included in the study. However, any diagnosed case of TB who do not fit the inclusion criteria will still receive the TB treatment.

3.9.4 National Regimen

National regimen used in the NTP Nepal SCC (Short-course Chemotherapy) for 8 months and its protocol is illustrated in Figure 3.5. The first two month of the treatment is called intensive phase and the patient is given a combination of 4 drugs (Rifampicin, Pyrazinamide, Ethambutol, and Isoniazid). After two months sputum is examined and if it has converted to negative, the patient continues his treatment for 6 months and this phase is called the continuation phase. In the continuation phase the patient gets a monthly supply of combination of two drugs (Etambutol and Isoniazid). During the period of treatment the patient will have to have his sputum checked at the 2nd, and 5th month, and at the end of the treatment.

In order to be cured the patient has to have his two consecutive negative smears, at least a month apart, the last one being at the end of the treatment. Cure rate is the number of patients cured divided by the number of patients treated (NTP TB Manual, 1996).

If the patient's sputum does not convert after first two months of treatment he will have to continue with the combination of four drugs for one more month and change to combination of two drugs for two months and have his sputum checked at the 5th month. If it is negative he will continue with two drugs for three more months but if it is positive he will reregister and start the retreatment regimen.

Retreatment regimen consist of two months with five drugs (Inj. Streptomycin, Rifampicin, Pyrazinamide, Ethambutol, and Isoniazid); one month with four drugs (Rifampicin, Pyrazinamide, Etambutol, and Pyrazinamide); and continuation phase of five months three drugs (Rifampicin, Etambutol, and Pyrazinamide). Sputum examination will be done at the 3rd, and the 5th month, and at the end of the treatment.

These patients will be given a months supply of drugs and treatment supervisor will be explained how to fill the cells of the DOTS card. DOTS card is divided into 30 cells with date written opposite each cell (see appendix G). After the patient swallows the drugs, the respective cell in the DOTS card is marked. By counting the cells of the DOTS card one can easily say how many days of treatment he has left. The patient with the treatment supervisor has to attend every month and sputum have to be examined every 2nd month, 5th month, and at the end of treatment (as shown in Flow Chart, Fig.3.3).

The patients residing in Village Girbari with the community supervisors, after diagnosis from the health facility with the treatment will be sent to the TB committee for reporting. The patient will be assigned to a community supervisor of the patient's area. The patient and treatment supervisor will be told to attend certain place at certain time.

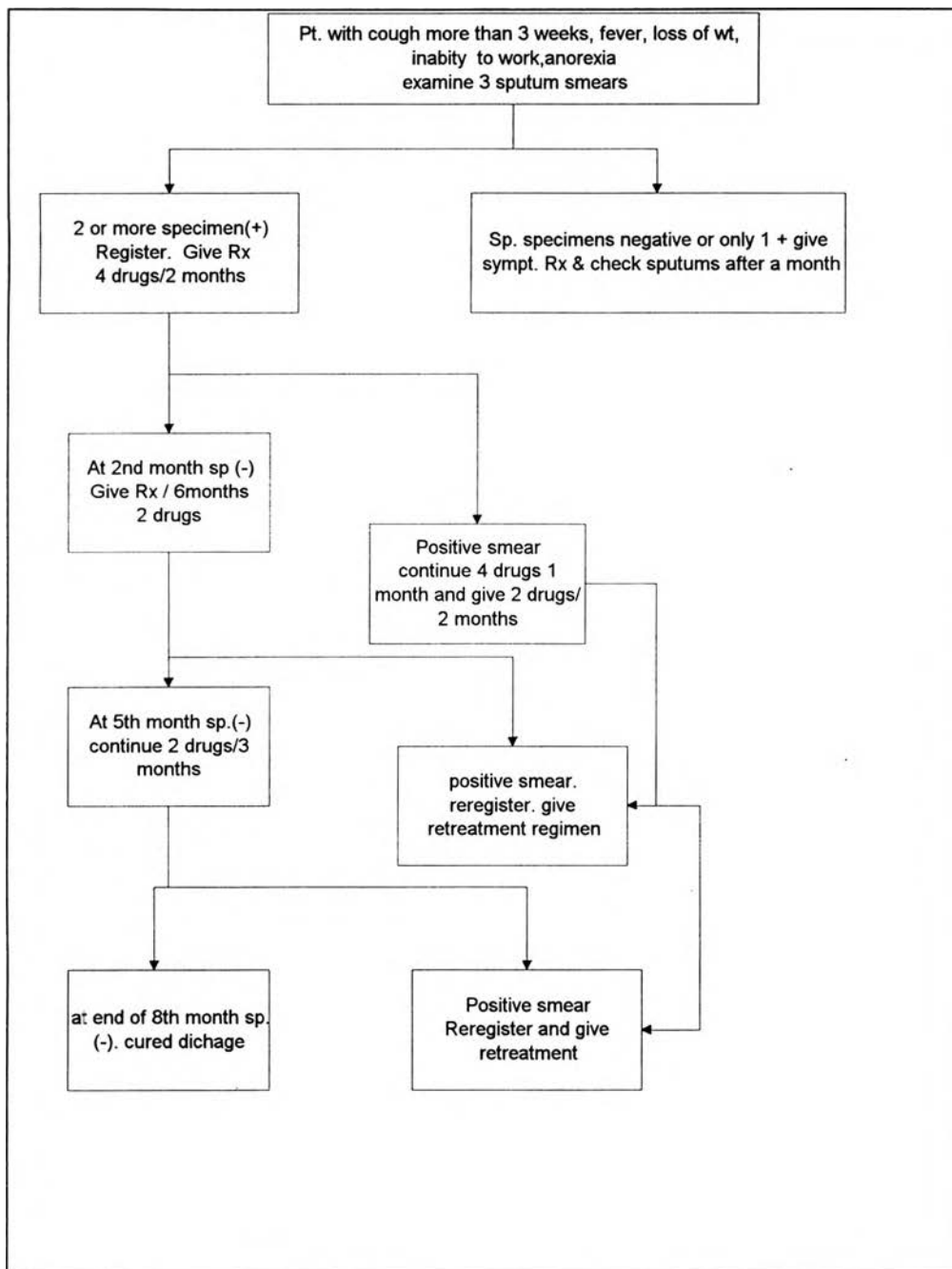
The patients of other village Koliya where treatment is only supervised by treatment supervisor the patients will take the drugs or rather the drug will be given by the treatment supervisor. the patient will swallow the drugs in front of the treatment supervisor and he will make tick mark in the DOTS card.

The patients from both the villages will have to attend the PHC every month with treatment supervisor to collect the drugs and examine the sputum at the 2nd, and 5th month, and 8th month.

3.9.4 Monitoring of Compliance

The compliance of the patient will monitored by the health workers by making surprise visits. Surprise visits will be made once monthly during the first two months and once in two months during the six months. These surprise visits will be randomly

Fig 3.4 : TB Patient's Flow chart



Source: NTP Manual, 1997

assigned so that the patient will not know which day the visit is going to be. During the number of surprise visits the health worker will count the pills. If the patient has taken the drugs for seven days, during the pill count he must have pills left for 23 days.

During these surprise visits health worker can see the color of urine, which becomes pinkish by one of the drugs (Rifampicin). Counting the cells marked in the DOTS card is also another method to monitor the compliance. These DOTS cards are divided into 30 cells, where the treatment supervisor marks after the patient has taken the pills.

Both the groups patients will be followed for 8 months and their outcomes will be measured. The cure rate main indicator to be measured. Cure rate is the patients cured out of the number treated. Cured is the patient who has successfully completed the treatment and has two consecutive sputum smears negative, at least a month apart, the last one being at the end of treatment (NTP TB Manual, 1996). The cure rate of both groups will be compared.

3.9.5 Evaluation

The program is evaluated by the analysis of the cohort. A cohort is group of patients diagnosed with TB and registered during September to December 1998. These patients are followed for 8 months and their outcome, the cure rate, completion rate, death rate, failure rate (see Appendix B for operational definitions) will be measured.

The community participation will be measured by the number of people completing the treatment by the number people enrolled in the treatment.

3.9.6 Study period

The study period will be one year. Organizing community participation will take one month. The patients will be registered during Sept. to Dec. 1998. These patient will followed for 8 months till they an outcome.

3.10 Activity plan, July 1998 -Aug. 1999 :

Table 3.3 : Activity Plan

Activities	July	Aug.	Sept-Dec.	Feb '99	June
Meeting with DG of health services, Director of NTC,	-----				
Forming a research team	-----				
Request funding	-----				
Meeting with community a) forming a TB com. b) creating health awareness		-----			
Meeting with health workers at Koluwa PHC		-----			
Registering TB patient into treatment program			-----		
Evaluation					-----
Data analysis and report					-----

writing					
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Similarly, the focus groups will take 6 days. There are 6 focus groups. So by the end of July 1998 data completion will be completed.

Registration of the cases will begin from September till December 1998. There will be evaluation by cohort analysis at the end of June 1999. The writing and submission of the will be completed by July 1999.

3.11 Budget and manpower requirements :

Necessary budget and manpower required to conduct the study is given below.

These are tentative figures and prepared based on present trend of payment in Nepal :

Table 3. 4: Budget and necessary manpower

Person	Number	Month	Allowance/month	Total
Researcher	1	12	US \$300.00	US\$ 3600.00
Sociologist	1	1	US \$ 300.00	US \$ 300.00
Epidemiologist	1	1	US \$ 300.00	US \$ 300.00
Co-researcher	1	12	US \$ 200.00	US \$ 2400.00
Health assistant	2	12	US \$ 150.00	US \$ 3600.00
Sub-Total	6			US \$ 10,200.00

	10,200.00
Refreshments and gifts for FGD USD	1000.00
Transportation cost @ 5 % of above total USD	510.00
Stationery @ 5 % USD	510.00
Miscellaneous @ 5 % USD	510.00
Contingency @ 5 % USD	510.00
<hr/>	
Total	US \$ 13,240.00

3.12 Ethical issues of study :

This study is aimed to identify an alternative for DOTS by health worker. In this course, the endeavor of research team is to interview and involve the villagers for community participation is for the benefit of these people but not to hurt or harass them or their feelings. Unethical procedures, violation of people's rights and dignity will be avoided. Key informants will not be forced to answer the questions but request will be made with prior information. Any answers received from them will not be exposed, will be kept confidential and will not be used against them at any cost.

In our culture TB still holds stigma. People still think that TB is caused due to the wrong doings, so those who have TB are usually sinful persons. If somebody in the family has TB the people in community will try to treat these patient as untouchables. The patients children might not get married. With extensive health education the stigma for TB will be hopefully be eliminated. During the study health education campaign will be continued. Posters and calendars will be distributed

showing that TB can be treated. Radio programs will also be broadcast once a week. This radio program will be done by NHEICC (National Health Education, Information, and Communication Center). The radio program will broadcast radio drama directed on the stigma and TB is a curable disease. Radio talks will also be broadcasted. Radio spots before the news will also broadcasted.

3.13 Limitations :

The limitation of this study is frequent transfer of the health center's staff. Once the present health staffs build a rapport with the community, it will be very easy to work. But once another set of new staff come it will take sometime for these to staff to get acquainted.

Within this period none of the staffs from the district health office and the primary health care center has to be transferred because they are already trained and part of the research. Not transferring the staff is quite difficult because the staff do not want to stay in a rural village for more than one year. And we cannot provide incentives.

Another constraint, to this study is the migration of the population or rather people go to India for seasonal work and one of the patients goes then the outcome will not be as anticipated. The community participation will try to find a solution so that the young people do not go India. The best possible solution so that these people do not migrate is to have employment opportunities in the community but this is quite

impossible. But the community can organize community banks and give loans so that these youths can be self-employed. This self employment can be in the form of poultry, goats keeping or weaving bamboo furniture.

Another constraint is that private practitioner's and even some of health workers are skeptical about DOTS. It is very difficult to believe that every dose can be observed. The study will prove that they are wrong and these sceptics will become advocates of DOTS.

3.14 Sustainability of community participation in DOTS

This study can be sustainable because the community will develop ownership to the program. This study tries to incorporate the existing community development program like the existing forest council and this council has been functioning and sustaining for quite some years, and this council will also try to sustain the TB committee. Self reliance program is the charm of this community participation and if this works, DOTS program might work. Sustainability of community participation depends of the community development of ownership to the program.

Supervising the treatment supervisors by the community participation can be a sustainable program because this does not need any funding from the government. If the government funding and the manpower is not needed and the program addresses the community needs, such programs can be sustainable. TB committee formed in the village can later turn into problem solving committee because when all the patient in

the village gather in one place designated place to take the drugs, they not only talk of TB but also of the poor harvest or somebody's problem or any problem. They try to find a solution to it.

This committee can also help to raise the social status of the person and with popularity he could even enter politics. Those who are in the committee are privileged people because it is recognition of social status.

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