CHAPTER III
RESEARCH METHODOLOGY

This chapter presents the operational definitions, conceptual framework and methodology adopted to carry out this cost-effectiveness analysis.

3.1 Research Design

This is retrospective and descriptive study and followed cost-effectiveness analysis (CEA) model for economic evaluation of two different management systems working for same health outcomes. The result was expressed in terms of "cost per effectiveness". The effectiveness was measured in natural units. The period of evaluation was the first 8 months of FY 2000/01.

3.2 Operational Definition:

Public DOTS Treatment Center:

Fully government run tuberculosis treatment center from where service was delivered according to the norms of World Health Organization (WHO) DOTS strategy.

Public-Private Mix DOTS Treatment Center:

Government supported (only for drugs, laboratory supplies, and training) private sector Private[1] from where DOTS service for tuberculosis was delivered according to the norms of World Health Organization (WHO) DOTS strategy and National Tuberculosis Program's guidelines.

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1 Private Sector includes both for-profit and not for profit health care providers

DOTS: Directly Observed Treatment, Short-course: most cost-effective and highly successful strategy for tuberculosis control.

Costs: Cost was defined as the value of resources used to produce and deliver tuberculosis treatment services under DOTS strategy.

Capital cost: The cost of any resources input or expenditure whose benefit last more than one year (Philips et al 1993) including building, equipment, long-term training and vehicle used for delivering tuberculosis treatment services value greater than US$ 100.

Recurrent (operational) Cost: The resources that used up in the course of one year were considered as recurrent cost including salary of personnel, material and supply cost, drugs cost, short-term training cost, social mobilization cost, Vehicle/building operation and maintenance cost, utilities (water, electricity, telephone).

Provider' cost: Cost incurred by DOTS center in providing tuberculosis treatment services. In this study two types of providers were taken into account: Public sector provider and private sector provider.

Patient: Patient who came for diagnosis and treatment of TB at DOTS center.

New case: A patient who had never taken anti-TB drugs for more than one month.

Treatment outcomes can be classified according to patient treatment ending and sputum examination results as follows:

Relapse: A TB patient who previously received full course of chemotherapy treatment and was declared cured of any form of TB in the past by the physician, and had once again developed smear positive pulmonary TB.

Treatment failure: A TB patient who, while on treatment, remained smear positive or once more become smear positive at the five month or later during the course of treatment, or was initially smear-negative before starting treatment and become smear-positive after 2 months of treatment.

Default: A patient who completed at least 1-month treatment, and returned after at least 2 month's interruption of treatment, or patient interrupted treatment for 2 consecutive months more.

Cure case: Patient with initially sputum positive and complete treatment, being sputum negative at least twice and sputum negative at the end of treatment.

Cure Rate: The number of new pulmonary smear positive cases cured divided by all registered new pulmonary smear positive cases in a given trimester. It should be at least 85%.

Completion rate: The number of new pulmonary smear-positive cases who completed treatment divided by all registered new pulmonary smear-positive cases for a given trimester.

Treatment Success Rate: It is the sum of cure rate and completion rate. It should be at least 85%.

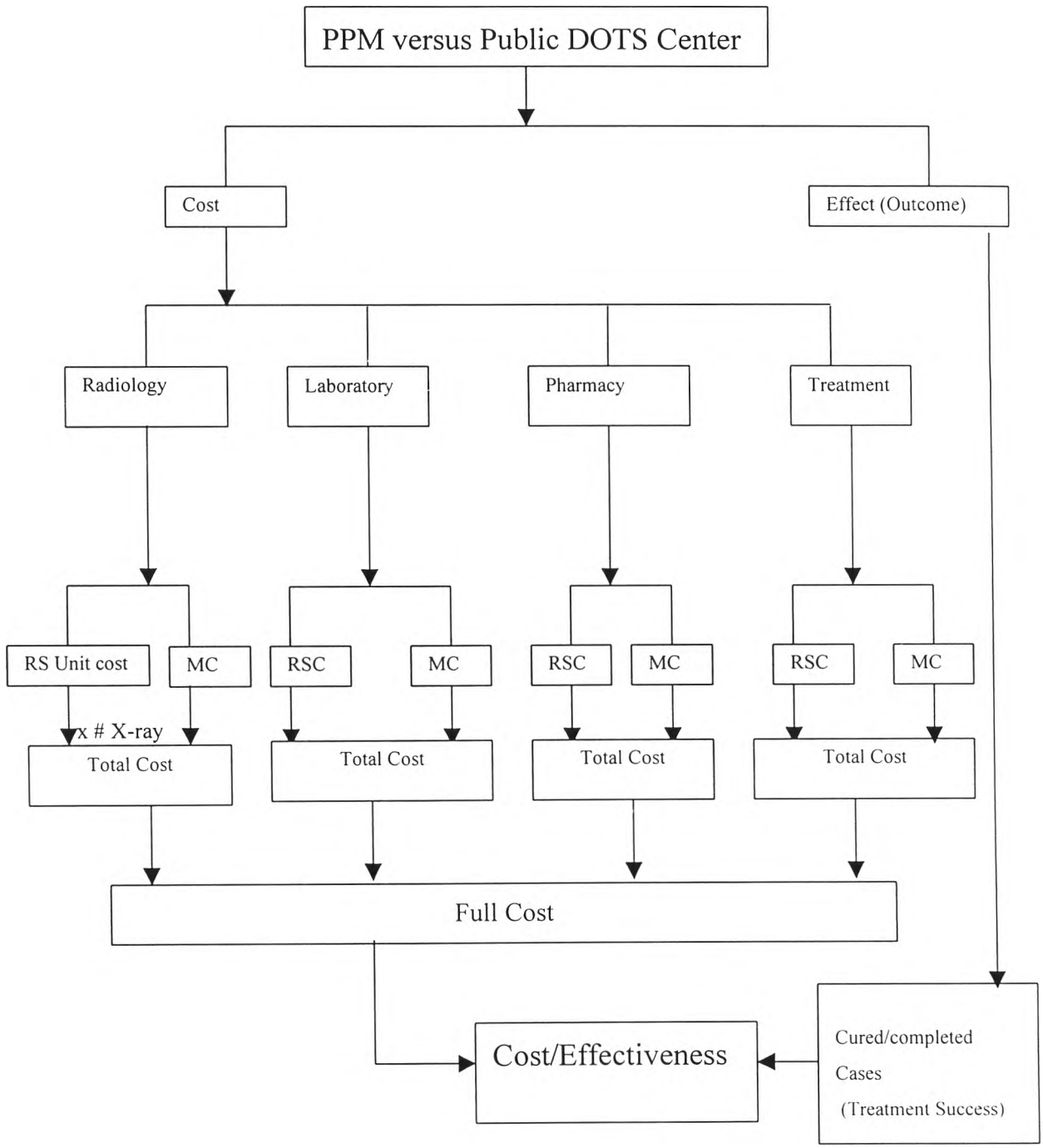
Health outcomes: Cured and complete cases

3.3 Conceptual Framework:

The conceptual framework of this study is shown in figure 3.1. For the treatment of Tuberculosis under DOTS strategy, we did find out four cost centers: namely treatment unit, laboratory unit, radiology unit, and pharmacy unit. First patients visited to treatment unit to have physician's service and referred to laboratory section that provided sputum examination. DOTS strategy follows passive case detection method using microscopy examination of sputum. For per case detection, sputum examination is compulsory. Radiology section provides x-ray service if necessary. Pharmacy unit provided drugs and counseling service to the patients who were diagnosed as TB patients. The cost incurred by TB patients at different units is different. It, therefore, seems to be important to split the cost incurred in each stage. The sum of routine service costs and material costs incurred by each unit gives provider's full cost of treatment. This study compared the cost per effectiveness of different DOTS centers.

During the course of treatment, due to some endogenous and exogenous factors, all cases could not be cured successfully. The consequences would be relapse cases, and treatment failure cases. Provider's cost associated to untreated patients is the wastage of resources. These uncured cases might spread TB to others posing two types of cost for the providers- future treatment cost of uncured cases and treatment cost for new cases born by uncured cases.

Fig 3.1: Conceptual Framework



Where RSC = Routine Service Cost, MC = Material cost

3.4 Study Area:

Since 1997, public–private mix DOTS centers (with not-for-profit organization) have been running in Kathmandu metropolitan city. Since year 2000, two Public-Private (for-profit) Mix DOTS centers have been introduced in this City. There are 11 public DOTS centers and 9 PPM-DOTS centers. Four PPM-DOTS centers among nine have been introduced since the beginning of the F/Y 2001/2002. Total area of this city is 50.67 square kilometer. It has 701,962 population with annual growth rate 6%. The average population density is about 175.7 per hector. The annual rate of tuberculosis infection is about 4% (NTP 1995). The estimate (based on 2001 population) shows the number of new smear positive cases to be 1,404. Table 3.1 presents the estimates of TB cases.

Table 3.1 Estimates of Tuberculosis cases in Kathmandu Metropolis.

	Population, 2001	ARTI	New SP+	Other New TB	Total New TB	Re-treatment Cases	Total Cases
Kathmandu Metropolis	701,962	4	1,404	1,685	3,089	105	3,194

Note: Estimated New Smear Positive Cases = (ARTI)(50/100,000) x Population

3.5 Study Population, Sampling and Inclusion/Exclusion Criteria

Kathmandu Metropolitan City was purposively selected for this study. On the basis of some underlying assumptions, among 11 Public DOTS Centers, two DOTS centers having microscopy facility were selected. Out of 11 public DOTS centers, eight DOTS Centers did not have any microscopy facility. So these eight DOTS centers were excluded from the study. Among nine public-private mix DOTS centers, DOTS service has been implemented in four-health institutions since the beginning of FY 2001/02- therefore, these four were excluded from the study, and among rest five, two were selected for the study purpose. Namely, Ramghat Primary Health Center and

Birendra Police Hospital from public sector and Friends of Shanta Bhawan and Helping Hands Clinic from private sector were included in the study.

Assumptions:

1) Prevalence of TB cases was same for all DOTS centers in the metropolitan city
2) There was no location variation among DOTS centers to get TB services.

3.6 Cost Calculation

Capital Cost:

There are two components of capital cost- opportunity cost of fund tied up in capital assets and depreciation over time of the assets itself. Despite the availability of various economic tools, calculation of " equivalent annual costs" was used in this study as, "this would give both types of the costs" (Drummond et al, 1997). The method of capital cost calculation adopted in this study would reflect the opportunity cost of capital assets.

To calculate the present value of capital investment, 5% discount Rate was used. The logic of setting 5% discount rate was:

1) During FY 2000/2001, the discount rate of treasury bill was 5.5% - 4.93%
2) Commercial Banks' interest rate on saving and lending were 5-6% and 11-14% respectively.
3) General inflation rate was 2-3%

Allocation Criteria

If we allocate resources on the basis of time spent on TB, it might underestimate the cost incurred by that activity. It excludes the leisure/ideal time of physician/health personnel/other staffs. To overcome this drawback, it was assumed that time spent on

TB related cases and other cases were same. In this study the following relation was adopted to calculate allocation proportion:

$(N_{TB} + N_{other}) K = W_H$

Where N_{TB} = Total number of tuberculosis related visits/tests in a year
N_{other} = Total number of other (non-TB cases) visits/tests in a year
W_H = Total working hours in a year
K = Time spent per visits

3.6.1 Cost of Donated Drugs

Since this is economic analysis, it was thought appropriate to take into account the economic cost of donated drugs. It is unrealistic to expect that donors will always be prepared to support the programme. What would happen if the current sources of donated drugs dried up? So, the cost of donated drugs was calculated on the basis of price list provided by National Tuberculosis Center.

3.6.2 Imported Drugs/goods

Drugs/equipments/supplies that were purchased in international market using foreign exchange would not reflect the opportunity cost of the resources (foreign exchange) used for their purchase where countries have over-valued exchange rates and foreign exchange shortages. For Nepal, the variation between the official exchange rate (NRB 2001) and shadow exchange rate (Personal Communication) was not too much. It was about two/three Nepalese rupees per one dollar, therefore, the official exchange rate was supposed to be appropriate to convert dollar value into local currency that could reflect true opportunity cost of the purchase.

3.6.3 Economic Cost of Capital Items

To calculate the economic cost of equipment on an annualized (cost per year) basis, the following approaches (Creese and Parker, 1994) were used:

- Present value: Present value of capital items was estimated using the relation given below. In some cases, capital goods that had already over useful time, the current value of the capital item was estimated according to market price.

Present Value of item, $P_t = P_o (1+ r)^t$

Where P_t = Present Value, Po = Purchase price, r = discount rate,

t = years since purchase

- Useful life: Expected number of years that the item could be used. The useful life was estimated from consensus of different staffs by asking how long these types of furniture and equipment were lasted in the past.
- Discount rate: 5% discount rate was used to annualize capital cost. The supporting indicators were explained section 3.6.
- Annualization of capital outlay: There were several economic tools to calculate economic cost of capital items. Since annualization over the useful life of the asset would automatically incorporate both the depreciation aspect and opportunity cost aspect of the capital cost, this method was adopted here to calculate annual cost of capital items.
- Annualization factors for 5% discount rate and different life years were borrowed from Creese and Parker (1994).
- Annual cost: Annual cost of capital items was calculated dividing Present value of item by annualization factor.

Suppose the current value of a microscope is about US$ 2000 with life time 5 years. The prevailing discount rate let us say 5%. Then, annual economic cost of microscope will be:

US$ 2000/Annualiging factor = 2000/4.329 (Annualizing factor = 4.329, from table)

= US$ 462

The financial cost of that microscope would be: US$ 2000/5 = US$ 400.

Here, we observed the difference between economic cost and financial cost. If we use financial cost, it overlooks a very important fact. If we invest the $ 2000 in this equipment, that money will tied up for the whole period of 5 years. On the other hand, if we are only paying out $ 400 per year, we could be reinvesting the rest $ 1600 in the first and earning interest. After 5 years of paying out $400 a year, we would have some money left over from our accumulated interest. In other words, a $ 2000 initial payment actually means paying out more than $ 400 per year. We, therefore, should consider over this mater while doing economic analysis. In this study, to calculate annual economic cost annualizing factor was used.

3.6.4 Effect of Tax

When tax is imposed, consumer price (P^C) increases than equilibrium price (P). The opposite will happen with subsidy. In this case we can see $P^C > P$ after tax imposed and $P^C < P$ for subsidy.

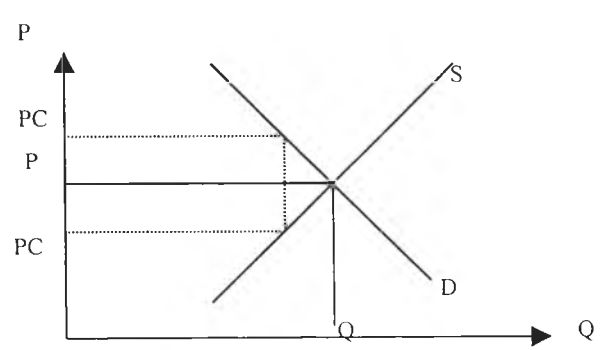


Fig 2: Effect of Tax and subsidy on demand and supply of health care services

The market price of domestic inputs (nontraded items) may incorporate various imperfections because of noncompetitive pricing, external effects, and indirect tax and subsidies. All these factors must be taken into account in adjusting the value of this input. Project costs basically consists of equipment and raw materials that are imported by the country and nontraded items such as labor and land. The costs of the traded items are usually large share of total costs and are expressed directly in border price (CIF or FOB price at the official exchange rate). No further adjustments are required when it is reasonable to assume that the border prices are not affected by the project. When the cost of the traded items is expressed initially in the domestic market prices, these must be converted to border prices by taking out duties and taxes (Ray. 1990).

3.6.5 External Factors Affecting Provider Cost:

The external factors such as geographical setting, and location of treatment center were likely to influence provider's cost. This study was carried out in the same geographical setting by choosing study units (Public and PPM treatment center) from same metropolitan city to avoid the effect of those external factors.

3.6.6 Provider's Future Cost of Treatment:

Due to some endogenous and exogenous factors, all cases could not be cured successfully- the consequences could be relapse cases and treatment failure. These uncured cases might spread TB to others posing two types of cost for the providers- future treatment cost of uncured cases and treatment cost for new cases born by uncured cases. An attempt has been made to estimate the future treatment cost of TB patients who were not cured properly from provider's viewpoint. Chapter V discusses about this in detail.

3.6.7 Necessary Conditions for Successful Treatment:

To minimize the provider's future treatment cost, it was important to assess the necessary conditions of treatment success. Basically, quality of care, monitoring and supervision, recording and reporting, good counseling to patients and late patient chasing were important factors for successful treatment. This study assessed some factors prevailing at Public and Public-Private Mix DOTS centers. Chapter V discusses this in details.

3.6.8 Division of Cost Centers

DOTS center was divided into 4 cost centers categories: treatment unit, laboratory unit, radiology unit and pharmacy unit to identify the provider's total costs. At treatment unit, patients received physician's service. Laboratory and radiology units provided diagnostic services and pharmacy unit delivered DOTS service to the patients. Costs incurred by TB patients at all units thus gave total provider's cost.

Total provider cost was calculated from labor costs, capital costs and material costs at DOTS centers (Public and Public-Private Mix) during the period of 8 months of FY 2000/2001.

The total provider costs of each DOTS center was calculated using following relation:

Total Provider cost = Total labor cost + Total capital cost + Total material cost
Further, it was divided as
Total Provider cost = Total routine service cost + material cost (direct)
Where,
Routine service costs = Total overhead costs – material cost (direct)

Total Overhead Cost = Labor costs + Capital costs + Material costs (Indirect cost)

Total Material (direct) cost = Total sputum examination cost + Total chest X-ray cost + Total drug cost

Total Sputum examination Cost = N x CSE

Where CSE = Cost of each slide examination

N = Number of slide examined

CSE = Cost of (sputum cup + slide + staining)

Chest X-ray cost = N x CCX

Where CCX = Cost of each X-ray test

N = Number of X-ray tested

CCX = Cost of (film + solution)

Total drug cost $= \sum DC_1 + \sum DC_2 + \sum DC_3$

Where DC_1 = Drug cost per patient of category I

DC_2 = Drug cost per patient of category II

DC_3 = Drug cost per patient of category III

3.7 Data collection and Analysis:

Data on providers' costs in both Public and Public-Private Mix DOTS centers were collected from their account records and interview using a structured format. Health outcomes were assessed using TB registered and quarterly progress report maintained at the DOTS centers.

Table 3.2 Summary of Data requirement and their sources:

Data Required	Study instrument	Source
1. Provider costs	Account records/Interview TB Register	Secondary
2. Health Outcomes		Secondary
a) Cured cases	-do-	-do-
b) Completed cases	-do-	-do-

Table 3.3 Identification, measurement and valuation of costs:

Resource Use	How to measure	Basis of Valuation
Health providers' cost		
Staffing (direct)	Time (hours)	Salary/wage
Capital (direct)	Units/amount consumed	Market price (conversion cost) (Annualized)
Consumables (direct)	Units/amounts consumed	Market Price
Overhead (allocated)	Units/amounts consumed	Market Price
	Time (hours)	Wage Rate/ Salary

Source: Adapted from Donaldson and Shackly (1997)

Table 3.4 Criteria for allocation of overhead costs:

Types of Services	Allocation Criteria
Space for clinic and /or office	Square meter (Square meter taken up by program divided by square meter taken by all clinics) x building cost (depreciated) Space (Square meter)
Utility Services (Cleaning, Heating, Lighting, etc)	(Square meter taken up by program divided by square meter taken by all clinics) x Departmental cost
Administration	Number of cases (Number of cases registered to the program divided by total number of cases registered at all clinics) x departmental cost

Source: Adapted from Donaldson and Shackly (1997

Provider's cost was assessed in terms of resource used mainly in the three categories:

- Labor Cost
- Material cost
- Capital Cost

Labor cost: The cost incurred by staff to provide tuberculosis service at public and Public-Private Mix DDTS centers. Data on monthly gross salary of staff were obtained from salary sheet. The gross monthly salary was converted into daily labor cost dividing it by total number of working days in a month. Then, attributable days of salary for 8 months was calculated using following relation:

Attributable days of salary per 8 months for TB = (Time spent on TB in each day x working days in 8 months) divided by working hours in a day. Later, it was converted into 8 months salary attributable to TB.

Material cost:

Material cost of revenue producing center (Radiology, Laboratory and Pharmacy) varied among patients who receive different drug regimens (Kamolratanakul et al, 1992). So, drug cost was calculated separately. Indirect material cost covered all recurrent costs. Direct Material cost covered the cost of sputum examination, chest radiography and TB related stationary. Table 3.6 presents measurement and valuation of Indirect Material cost.

Table 3.5 Material Cost (Indirect):

Resource used	Measurement	Valuation
Building related (maintenances, water and electricity)	Space used	Market price conversion
Vehicles (operation and maintenance)	Time used/distance traveled	Market price conversion
Administration related (telephone, stationary, miscellaneous)	Units/amounts consumed	Market price conversion

Drug costs of different types of TB patients:

In tuberculosis treatment' different strengths and types of regimens were used for the different treatment categories of TB patients. This made the variation of drug costs in treating different types of TB patients. One study conducted by Kamolratnakul et al (1997) showed that the drug cost of smear negative cases and newly smear positive cases were Baht 696.48 and 2482.72 respectively. But for MDR-TB cases, the drug cost was Baht 65,870 that was 95 times as much as smear negative cases. Therefore, drug costs was calculated separately for different types of TB patients. Then total drug costs for different types of TB patients were in the following headings:

1) Total drug costs for new smear positive cases
2) Total drug costs for new smear negative/EP cases
3) Total drug cost for re-treatment cases

Capital Cost:

Costs of resources inputs/expenditure whose benefits last more than one year such as building, vehicles, equipments (X-ray, microscope), furniture, land, etc were calculated in this heading.

Purchase price of capital goods was obtained from office record (account section). In case of non-availability of records, information were obtained by interviewing the senior staff who had been working there for a long time and could tell both year of purchase and price of capital goods. The present values of all capital goods were annualized depending upon the discount rate and useful lifetime. The annual cost so obtained was apportioned to DOTS program by using two allocation bases:

1) Ratio of space used for building and space
2) Ratio of time used for equipment, vehicle

3.8 Effectiveness Measurement:

In this study, two kinds of effectiveness were assessed

- Case cured
- Case completed

Cure case: Patient with initially sputum positive and complete treatment, being sputum negative at least twice and sputum negative at the end of treatment. Data related to cured cases were obtained from TB register available at DOTS centers. This is very important treatment outcome to measure the effectiveness of the program. In this study, all cured pulmonary positive cases were taken as treatment outcomes. Cure rate for new smear positive cases and relapses are the most important treatment outcome indicators. When the cure rates are less than 85% it is useful to examine other treatment outcomes.

Complete cases: The number of new pulmonary smear-positive cases who completed full course of treatment but did not come to have final sputum test. In this study all complete cases of smear positive as well as negative and extra-pulmonary cases were taken as complete cases.

Completion rate**:** The number of new pulmonary smear-positive cases who completed treatment divided by all registered new pulmonary smear-positive cases for a given trimester.

3.9 **Cost-Effectiveness Analysis:**

Cost-effectiveness ratio (C/E) was calculated using costs per effectiveness obtained from two types of DOTS centers (Public and Public-Private Mix).

This result could be used to compare the efficiency of public and public-private mix DOTS centers.

3.10 Sensitivity Analysis:

Given the range of assumptions inherent in most economic evaluation studies it was essential to test sensitivity of the study results to change in these assumptions, otherwise it might suffer from uncertainty. What impact did different valuation of costs has on the result? or different rates of discount? or different timing? Choosing discount rate to annualize the capital costs could affect on total provider cost. To avoid this uncertainty, sensitivity analysis was performed for different discount rates (3%, 5% and 10%).