

CHAPTER 3

RESEARCH METHODOLOGY



3.1 Study Design

This study is an empirical retrospective and prospective study in which how to calculate the costs for each case finding activity, how to determine early case and how to examine cost saved for early diagnosis and treatment will be explored. It is a cross-sectional descriptive study and the primary data have come from the interviewing hypothyroidism patients and some secondary data have come from Chulalongkorn Hospital and Mental retardation foundation. The analysis will present a present value of cost-benefit analysis of two scenarios, base case at Chulalongkorn Hospital and national policy level

3.2 Study Site

The area of this study is a neonatal department at Chulalongkorn Hospital carried out the TSH screening, and another area is a pediatric endocrine clinic, where the pediatric hypothyroidism patients come for follow up their treatment.

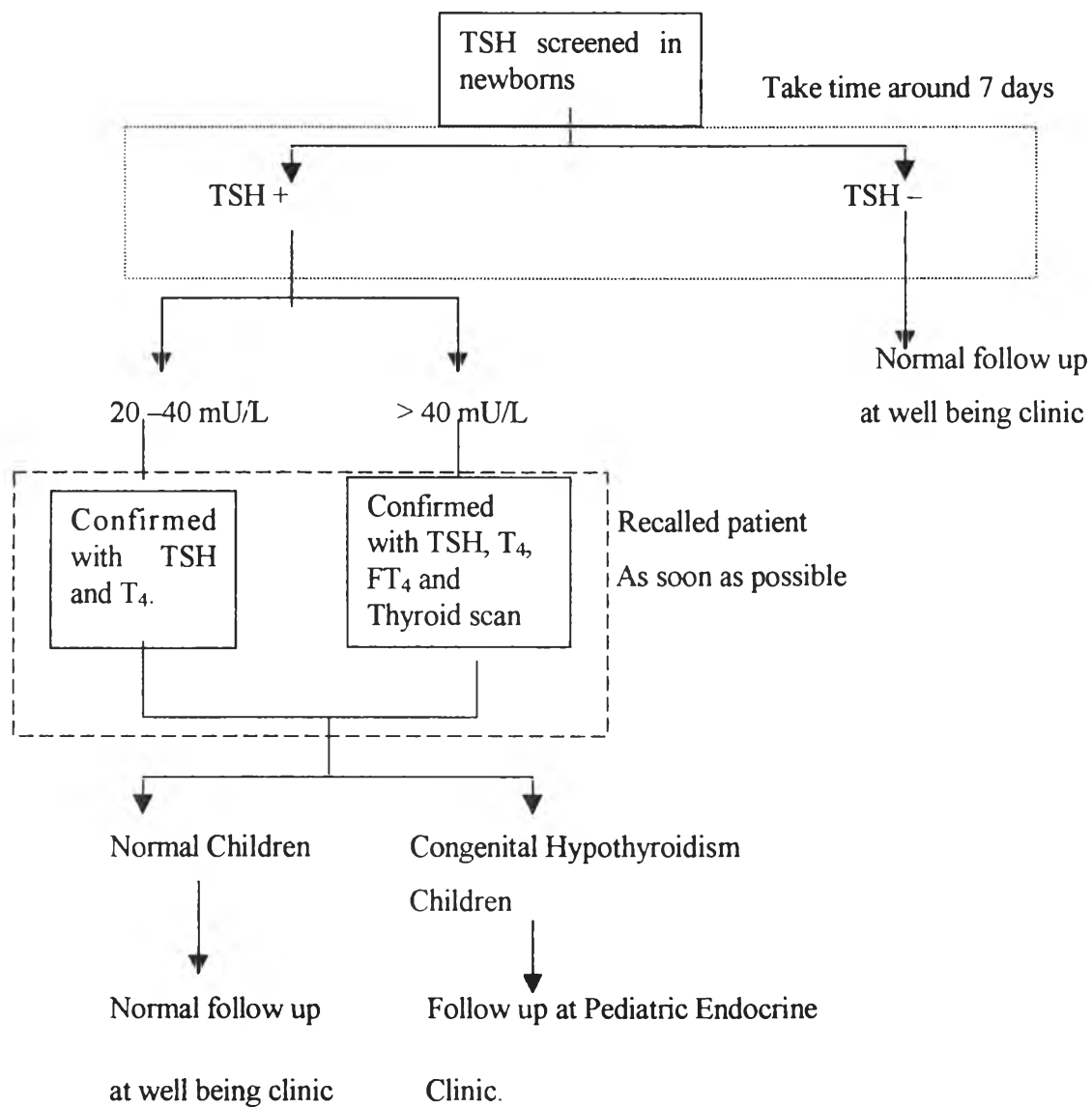
3.3 Study Population

There are two study populations in this study. One is the newborns during 1991 to 1999 at Chulalongkorn Hospital acted as study population for the TSH screening test for the provider cost. Another is the pediatric Congenital Hypothyroidism patients who born at Chulalongkorn Hospital during 1991 to 1999 and attend the pediatric endocrine clinic at Chulalongkorn Hospital. They represent as a study population for patient perspective.

3.4 Sampling Techniques

The empirical study will be carried out on the cases that were detected and treated at Chulalongkorn Hospital. From the recording data, there are 18 Congenital Hypothyroidism patients from 1991 to 1999. All of these are in order to evaluate the patient costs.

Figure 3.1: Step of Procedure that Proposed at Chulalongkorn Hospital.



- **TSH positive:** The result of TSH test is greater than 20 mU/L.
- **TSH negative:** The result of TSH test is less than 20 mU/L
- **T₄ positive:** The result of T₄ test is less than 7 µg/dl.
- **T₄ negative:** The result of T₄ test is greater than 7 µg/dl.

3.5 Definitions

- **The screening program:** The newborns receive the TSH screen at the age after 48 hours from their heel prick and the TSH positive case will confirm with T₄ and start a treatment.
- **Correctly diagnostic case:** It is a case that is a true positive and true negative case.
- **Correctly positive detected case:** It is a case diagnosed as the Congenital Hypothyroidism by TSH and T₄ test and needs a hormone treatment for whole life.
- **The thyroid hormone treatment for whole life:** The patient who needs whole life long supplementary thyroid hormone.
- **Cost:** Cost defines as the value of resources used for Congenital Hypothyroidism screening program.
- **Cost-Benefit Analysis (CBA):** CBA estimates the value of resources used by the program compare with the value of resources the program might save or create.
- **Provider costs:** All of provider cost items incur from providing the Congenital Hypothyroidism screening in newborns and treatment facilities for Congenital Hypothyroidism patient.
- **Patient costs:** All of cost and opportunity cost items incur to patient and family due to receiving the Congenital Hypothyroidism screening program and maintaining the Congenital Hypothyroidism treatment throughout the adult. If there is no Congenital Hypothyroidism screening program, the patient costs will be all of costs burdened to parents and family of mental retarded children, whose cause from Congenital Hypothyroidism, due to taking care them.
- **Society costs:** The total net costs of all of the different components of society, including the patient's lost productivity and the expenses involved in giving and receiving the screening program. In this study means the entire total provider, patient and society costs after adjusting some double costs. In this study will omit the government subsidized costs for the test and the training costs for blood chemistry analysis and specialist doctor.
- **Transportation costs:** All of cost items incur to patient and family due to bringing patient to follow up treatment at the hospital.
- **Time costs:** All of the opportunity worked earning of the parents and family of patient losses due to attending the pediatric endocrine for remaining the treatment.

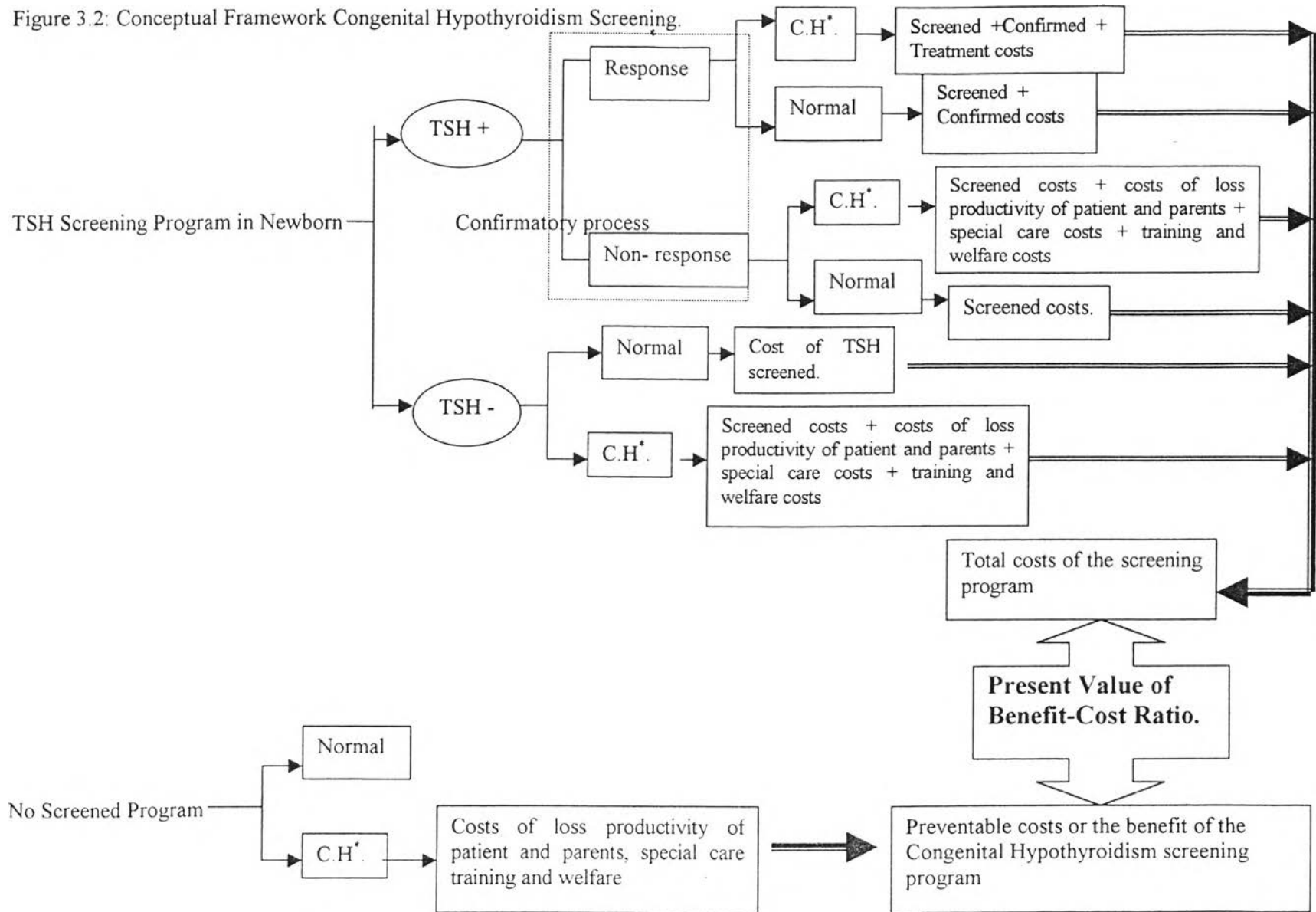
- **Additional treatment costs:** All of extra treatments cost items, which are greater than normal children, occur from health status of mental retarded children.
- **Patient productivity:** It is an opportunity of earning as healthy person.
- **Patient productivity loss:** The loss of opportunity in earning due to mental retardation.
- **Parents' productivity loss:** The potential of mother opportunity earning could earn without taking care of mental retarded children.
- **General supporting:** All of society cost items support for special cares of mental retardation, including researching the mental retarded causes in order to reduce the mental retarded prevalence.
- **Recall rate:** The proportion of the number of confirmatory calling among the total number of screened cases.
- **Responsive recall patient:** The patient that responded to hospital's confirmatory notification for diagnosing the Congenital Hypothyroidism.
- **Compliance rate:** The percentage of patients who complete the treatment process. In this study the compliance rate equals the total completely treatment process patents divides by the total positive cases and times with a hundred.

3.6 Conceptual Framework

This study is carried out by an empirical approach. In this study, there is comparable between cost and benefit of a Congenital Hypothyroidism program screening in Nursery Department of Chulalongkorn Hospital from 1991 until 1999.

The costs of the method will evaluate from provider side, patient side and society side. Benefits express as cost saving for early diagnosis and treatment. If the cases are diagnosed in early stage and given promptly treatment, these cases will not be a social problem and the family burden. Therefore, the costs will save from productivity loss due to mental health problem of family and cost saving for medical expenses. And then, from these cost and benefit, the benefit-cost ratio can be determined from provider, patient and society perspective. The conceptual framework of this study is shown in figure 3.2 in the next page.

Figure 3.2: Conceptual Framework Congenital Hypothyroidism Screening.



* Congenital Hypothyroidism

3.7 Data Collection and Analysis

In this study, costs and benefit of the screening program will be calculated from provider (supplier), patient and family (consumer) and society perspectives. The table for data collection that all of the cost items and the methods of data collection is shown in the table 3.1.

Table 3.1: The Variables and the Methods of Data Collection.

OBJECTIVE	VARIABLE	DATA	SOURCE AND HOW TO OBTAIN INFORMATION	WHO WILL BE MEASURED	REMARKS AND UNIT MEASUREMENT
To identify the number of cases detected	Number of screened babies.	Infants who has the TSH testing result $> 20 \text{ mU/l}$ and $T_4 < 7 \mu\text{g/dl}$	Neonatal Department / Record form	All of newborns who born at Chulalongkorn Hospital during 1991 to 1999	Screened case and positive correctly case / Year.
To determine the total costs of the screening and treatment T S H					
<u>Screening process</u>					
<i>Provider perspective</i>					
- Blood collecting	Operating cost	- Labor cost	Neonatal department / Questionnaire	Blood collecting trainee	Average cost per unit

OBJECTIVE	VARIABLE	DATA	SOURCE AND HOW TO OBTAIN INFORMATION	WHO WILL BE MEASURED	REMARKS AND UNIT MEASUREMENT
- Blood collecting (cont.)		-Material cost	Lab. Room / Record form	TSH kit	Average Cost per Unit.
- Blood transfer	Operating cost	- Labor cost	Lab. room / Questionnaire	Messenger workman	
- Blood Analysis	Capital cost	- Capital cost	Lab. room / Record form	Gamma Counter	
	Operating cost	- Labor cost	Lab. room / Questionnaire	Laboratory technician	
		-Material cost	Lab. room / Record form	Reagents of blood analysis	
<i>Patient perspective</i>	Out of pocket	-Price of TSH test	Ped. Endo. Patient / Questionnaire	Price of TSH test	

OBJECTIVE	VARIABLE	DATA	SOURCE AND HOW TO OBTAIN INFORMATION	WHO WILL BE MEASURED	REMARKS AND UNIT MEASUREMENT	
<u>Confirmatory process with T₄ Provider perspective</u>	- Blood analysis	Operating cost	-Material cost	Lab. Room / Questionnaire	Reagent of blood analysis	} Average Cost per Unit.
			-Labor cost	Lab. Room / Questionnaire	Laboratory technician	
	Capital cost	-Capital cost	Lab. Room / record form	Gamma Counter		
	- Blood analysis	Out of pocket	Price of confirming test	} Ped. Endo. Patient / Questionnaire	Price of confirming test	
		Traveling cost	Average traveling costs			

OBJECTIVE	VARIABLE	DATA	SOURCE AND HOW TO OBTAIN INFORMATION	WHO WILL BE MEASURED	REMARKS AND UNIT MEASUREMENT
<u>Treatment and follow-up process</u>					
<i>Provider perspective</i>	Capital cost	- Capital cost	Ped. OPD / Record form	Space of Ped. OPD	Average Cost per Unit.
	Operating cost	- Labor cost	Ped. OPD / questionnaire	Ped. OPD officer	
<i>Patient perspective</i>	Direct cost	-Hypothyroid treatment cost - Doctor Charge -Transportation cost (pt.+parents)	Ped. Endo OPD / Questionnaire	Ped. Endo. Patient and Parents / Questionnaire	
	Indirect cost	- Time cost (parents)			
<i>Society perspective</i>	Direct Benefit	-Cost saving from supporting			

3.8 Data Analysis

3.8.1 Incidence Rate

The number of correctly detected cases can be defined from two tests. Firstly is the TSH screening and secondly is T₄ testing. The most straight forward method of displaying the comparison of a diagnosis test and the gold standard is with a “two by two” or “four fold” table. The gold standard refers to a definite diagnosis attained by long-term follow up. In this study, all of newborns will be screened with TSH and if the result of TSH is greater than 20 mU/L, which means as “A₁+B₁”, all of these cases will be confirmed by T₄ test. Then, the true positive cases, which can be defined as “A₁” from both tests, are the correctly detected cases of the Congenital Hypothyroidism neonatal screening program. The results of TSH and T₄ screening are shown in the table 3.3

Table 3.2: Four-Fold Table Demonstrating Comparison of a Diagnostic Test with a Gold Standard.

		Gold standard		
		Patient has the disease	Patient does not have the disease	
Test result (conclusion drawn from the result of the test)	Positive: Patient appears to have a disease	True Positive (a)	False positive (b)	(a+b)
	Negative: Patient appears not to have a disease.	False negative (c)	True negative (d)	(c+d)
		(a+c)	(b+d)	(a+b+c+d)

Source: Canadian Medical Association Journal, 1981; 124:704

Table 3.3: Two By Two Table of the TSH and T₄ Screening Test at Chulalongkorn Hospital.

Screening with TSH and T₄

	C.H.	No C.H.
TSH / T₄ + T S H > 20 mU/L T ₄ < 7 μg/dl	A ₁	B ₁
TSH / T₄ - T S H < 20 mU/L T ₄ > 7 μg/dl	C ₁	D ₁

Therefore,

$$\begin{aligned} \text{The incidence rate} &= \text{Total correctly positive cases} / \text{Total screened cases} \\ &= A_1 / (A_1 + B_1 + C_1 + D_1) \end{aligned}$$

Where,

$$\begin{aligned} A_1 &= \text{The true positive cases.} \\ A_1 + B_1 + C_1 + D_1 &= \text{Total screened cases.} \end{aligned}$$

$$\text{The percentage of recall rate} = (\text{Total recalled cases}) * 100 / \text{Total screened cases}$$

The percentage of responsive recall rate

$$= (\text{The number of cases who responded the calling back}) * 100 / (A_1 + B_1)$$

Where, $A_1 + B_1$ = The suspected cases which include with true positive and false positive cases.

3.9 Cost Calculation

The total costs of the early diagnosis and treatment of Congenital Hypothyroidism program divide into two components that are the screening costs and the treatment costs. In the screening process consists of two; TSH and T₄. In this study the total cost will be calculated in three perspectives, provider, patient and society. In provider perspective, the

total costs separate into two components, which are capital and operating costs. For the patient and society perspective consists of direct and indirect costs.

3.9.1 Assumption for Cost Calculation

- After confirming test that is TSH > 20 mU/L and $T_4 < 7 \mu\text{g/dl}$, every detected case has hypothyroidism disease and need whole life long treatment.
- Labor costs and capital costs are calculated from the percentage of total working time in the specific activity.
- Space or building of OPD and labor cost of OPD is based on the unit costs of OPD that was done in 1991 (Vanavek,1991).
- After the sixth years of Congenital Hypothyroidism patient, the estimated direct and indirect costs equal with the average hypothyroidism patient. (Layde, 1979)
- Life expectancy of treated Congenital Hypothyroidism patients equal with the average life expectancy of normal people.
- 3%Inflation rate will be used for the whole calculation.(reference from appendix I)
- Discounting rate is 5%.
- All of the costs will be valued in the year 1999.

Table 3.4: The Ideal Cost Components of the Screening Program.

Perspective	The cost components
Provider	<ol style="list-style-type: none"> 1. Capital costs <ol style="list-style-type: none"> 1.1 Equipment <ul style="list-style-type: none"> • TSH Screen. • T_4 Screen. 1.2 Building <ul style="list-style-type: none"> • Follow up and treatment at Out Patient Department that will be based on the unit cost of OPD 2. Operating costs <ol style="list-style-type: none"> 2.1 Labor costs. <ul style="list-style-type: none"> • Blood collecting for TSH test. • Blood transfer from Neonatal department to Laboratory room.

Table 3.4: The Ideal Cost Components of the Screening Program. (Cont.)

Perspective	The cost components
Provider(cont.)	<p>2.1 Labor cost(cont.)</p> <ul style="list-style-type: none"> • Blood analysis for TSH. • Blood Analysis for T₄ • Follow up and treatment at Out Patient Department. <p>2.2 Material cost</p> <ul style="list-style-type: none"> • Needle for blood collecting. • TSH Kit for TSH test. • Reagent for T₄ test.
Patient	<p>1. Direct cost.</p> <ul style="list-style-type: none"> • Out of pocket for TSH test • Out of pocket for confirmatory process. • Cost of hypothyroidism treatment • Traveling cost for patient and parents or relatives for hypothyroidism treatment. <p>2. Indirect cost.</p> <ul style="list-style-type: none"> • Time costs for parents or relatives for hypothyroidism treatment
Society	<p>1. Direct cost.</p> <ul style="list-style-type: none"> • Government subsidization for screening test and Congenital Hypothyroidism treatment. • Blood chemistry analysis training costs for manufacturing the test kit. • Training costs for specialist doctor • Screening and confirming process (provider side) • Follow up process for provider side

Table 3.4: The Ideal Cost Components of the Screening Program. (Cont.)

Perspective	The cost components
Society (cont.)	1. Direct costs. (cont.) <ul style="list-style-type: none"> • Traveling costs from patient side in the process of confirmatory and follow up process. 2. Indirect cost. <ul style="list-style-type: none"> • Time costs from patient side.

3.9.2 Cost: Provider Perspective

3.9.2.1 Capital Costs

For the capital cost calculation, a special procedure (annualization or depreciation) is required to estimate the annual costs. The general steps are described as follows:

1. Obtained the current value of the capital item.
2. Used the expected years of useful life of the capital item, according to expert judgment or opinion from interviews with staff who use.
3. Derive the annualization factor by consulting the annualization table to calculate or by using the annualization formula.

Annualization formula: $a(r, n) = [r(1+r)^n] / [(1+r)^n - 1]$

Where a = annualization factor

r = discount rate

n = useful life or life time of asset for depreciation

4. Annualizing capital value = Current price of capital aspect / annualization factor

Cost of equipment for diagnosis Congenital Hypothyroidism

$$= (E_1 * e_1) + (E_2 * e_2)$$

Where E_1 = Annual costs of TSH test equipment.

e_1 = Proportion of using time for TSH test

E_2 = Annual costs of T_4 test equipment.

e_2 = Proportion of using time for T_4 test

3.9.2.2 Labor Cost

Firstly, in order to estimate the allocation time spent by health personnel for early diagnosis and treatment of Congenital Hypothyroidism, all health personnel have been interviewed for the empirical study. Then, the next step is to calculate the total personnel cost that can be evaluated by multiplying the total annual income, including fringe benefits, of individual health personnel with the proportion of working load that the opportunities criteria was obtained by interview. From individual personnel cost, total labor cost can be assessed by summing all the individual personnel cost.

3.9.2.3 Material Costs

Material costs can be identified by multiplying unit cost for each material into the number of these materials used for the screening program. For the cost calculation of the pediatric out patient department will base on the adjusted unit cost analysis, which was done by Vanavek *et al.* in 1991, by the health care and personnel services consumer price index into the unit cost in year 1999.

From the above calculations, the following equations can be obtained.

3.9.2.4 The TSH Screening Costs Formula from Provider Perspective

$$TC_{pr.TSH} = TC_{R.TSH} + TC_{K.TSH} \text{ (1)}$$

$TC_{pr.TSH}$ = Total costs, which are a summation of all cost items, incurred by provider side for doing TSH screening.

$TC_{R.TSH}$ = Total costs, which are a summation of all costs items, incurred by operating for TSH screening.

$TC_{K.TSH}$ = Total capital costs for doing TSH activity.

3.9.2.5 The Confirmatory Process With T₄ Cost Formula from Provider Perspective

$$TC_{pr.T4} = TC_{R.T4} + TC_{K.T4} \text{ ----- (2)}$$

$TC_{pr.T4}$ = Total costs, which are a summation of all cost items, incurred by provider side for confirming with T₄ test.

$TC_{R.T4}$ = Total costs, which are a summation of all costs items, incurred by operating for confirming with T₄ test.

$TC_{K.T4}$ = Total capital costs for doing T₄ activity.

3.9.2.6 Screening Cost Per Case from Provider Perspective

$$SC_1 = \frac{TC_{pr.TSH} + TC_{pr.T4}}{(A_1 + B_1 + C_1 + D_1)} \quad (3)$$

Where, SC_1 = Screened cost per screened case.

$A_1 + B_1 + C_1 + D_1$ = Total screened cases.

3.9.2.7 Screening Cost Per Diagnosed Case from Provider Perspective

$$SC_2 = \frac{TC_{pr.TSH} + TC_{pr.T4}}{(A_1 + D_1)} \quad (4)$$

Where, SC_2 = Screened cost per diagnosed case.

$A_1 + D_1$ = Total true positive and true negative cases.

3.9.2.8 Screening Cost Per Positive Case from Provider Perspective

$$SC_3 = \frac{TC_{pr.TSH} + TC_{pr.T4}}{A_1} \quad (5)$$

Where, SC_3 = Screened cost per positive case

A_1 = The number of positive cases.

3.9.2.9 The Average Cost of the TSH Screening Program Including Treatment

$$AC = SC_1 + UC \quad (6)$$

Where, AC = Average cost of the TSH screening program including treatment.

UC = Unit cost of pediatric out patient department per year.

3.9.3 Cost: Patient Perspective

The cost of patient perspective means the out of pocket for each expense item for the Congenital Hypothyroidism screening program at the Chulalongkorn. Assumed that all of patients can not reimburse their spending. For the screening program, the parents of newborns will pay for TSH test. The price of TSH test for ordinary case is 50 Baht per test and the price for special case is 100 Baht per test. The proportion of the special case is about 20% of the total cases, which figure comes from the recording at neonatal department. If the result of neonatal TSH, which finishes in around 7 days, is greater than 20 mU/L but less than 40 mU/L, these patients will be called back to confirm with TSH again. The charge of the TSH confirming is 50 Baht per test. If the result is greater than

40 mU/L, the patients will be called back to confirm with TSH, T₄, FT₄ and Thyroid scan, which the total expenses are 500 Baht, which 300 Baht for laboratory test and 200 Baht for Thyroid scan.

From the interviewing of parents of patient and from an expert opinion, the treatment process is summarized into

- Two days after birth, the newborn are screened with TSH test.
- The result will finish in 7 days after blood collecting. In the cases that have abnormal results, the staff workers at Neonatal Department call these patients to confirm the blood test again.
- After the second blood test result, the Congenital Hypothyroidism children are consulted Pediatric Endocrine Doctors.
- The follow up process is every month until the children 2 years.
- At age 2 to 6 years, the follow up times are every 3 month and after the children 6 years, which children start going to school, the doctor allows to follow up 2 times a year.

Costs for the patient perspective are as following. In this study direct cost means cost incurred by patient for the early diagnosis and treatment of Congenital Hypothyroidism and indirect cost means cost incurred by family and relatives accompanying the patient for treating of Congenital Hypothyroidism. The total costs for patient perspective will be collected from the primary data by patient interviewing.

3.9.3.1 Direct Cost

TSH and T₄ , hormone supplementary, laboratory and doctor charge will be calculated from the charging rate at Chulalongkorn Hospital. TSH costs can be easily evaluated by multiplying the charging with the total number of TSH test as well as the confirmatory process done in a year. Hormone supplementary and laboratory costs will be identified by multiplying the average drug and laboratory charge per visit with the average unit of using per year, which comes from an interviewing parents of the Congenital Hypothyroidism patient. After the age at 6, the hormone supplementary and laboratory are assumed to be the same for the whole life. Doctor charge will be calculated by multiplying the charge with the average number of visit on a year.

The traveling calculation will base on primary data from interviewing parents of patient. From the primary interviewing data, we can be defined the average transportation costs for each visit by summation the total transportation costs from all interviewing and then divided by the total number of interviewing.

3.9.3.2 Indirect Cost

For time costs, will be estimated from the average wage of parents multiplying with the proportion of losing time due to follow up and treatment, when compares with working time. The working time is assumed to be the same as the legal working times that are 40 hours per week and 4 weeks a month.

After the patient age at 6, all of the costs are assumed to fix for whole life because of the expert opinion, which is after the children go to school, the follow up times will be two times a year. Both of the costs, direct and indirect, will increases at rate of inflation 3% per year and all of the future costs will be discounted to be a present value with the discounting rate at 5% annually.

From the above calculations, the following equations can be obtained

3.9.3.3 Screening Costs Per Case from Patient Perspective

$$SC_4 = \frac{(Ch_{ord} * No_{ord}) + (Ch_{spc} * No_{spc}) + (Con_{tsh < 40} * No_{tsh < 40}) + (Con_{TSH > 40} * No_{tsh > 40})}{\text{Total screened cases}} \quad (7)$$

Where, SC_4 = Screened costs per screened case.

Ch_{ord} = TSH charging for the ordinary patient.

No_{ord} = Total number of the ordinary cases.

Ch_{spc} = TSH charging for the special patient.

No_{spc} = Total number of the special cases.

$Con_{tsh < 40}$ = Confirming charging for the case that TSH >20 and <40 mU/L, including transportation cost for bringing the children to confirm.

$No_{tsh < 40}$ = Total number of cases that TSH < 40 mU/L

$Con_{TSH > 40}$ = Confirming charging for the case that TSH >40 mU/L, including transportation cost for bringing the children to confirm.

$No_{tsh > 40}$ = Total number of cases that TSH > 40 mU/L

3.9.3.4 Screening Costs Per Diagnosed Case from Patient Perspective

$$SC_5 = \frac{(Ch_{ord} * No_{ord}) + (Ch_{spc} * No_{spc}) + (Con_{tsh < 40} * No_{tsh < 40}) + (Con_{TSH > 40} * No_{tsh > 40})}{\dots} \dots (8)$$

True positive and true negative cases.

Where, SC_5 = Screened costs per diagnosed case.

3.9.3.5 Screening Costs Per Positive Case from Patient Perspective

$$SC_6 = \frac{(Ch_{ord} * No_{ord}) + (Ch_{spc} * No_{spc}) + (Con_{tsh < 40} * No_{tsh < 40}) + (Con_{TSH > 40} * No_{tsh > 40})}{\dots} \dots (9)$$

True positive cases

Where, SC_6 = Screened costs per positive case.

3.9.3.5 Treatment and Follow Up Process

$$TC_{pt.treat} = \sum TC_{pt.dc} + \sum TC_{pt.ic} \dots (10)$$

Where, $TC_{pt.treat}$ = Total costs, which are a summation of all cost items, incurred by patient and family side for treating Hypothyroidism patient.

$TC_{pt.dc}$ = Total direct costs by patient and family side for the whole life treatment of Hypothyroidism patient, which contain costs of drug, checking laboratory and doctor charge,

$TC_{pt.ic}$ = Total indirect costs by patient and family side for the whole life treatment of Hypothyroidism patient, which contain costs of transportation of parents or relatives and time lost from work of parents or relatives.

3.9.4 Cost: Society Perspective

Society costs in this study mean the total net costs of all of the different components of society, including provider and patient those expenses involved in giving and receiving the TSH screening program. The society costs will divide into two parts, direct and indirect, which details are in the table 3.4. In this study, some society costs: Government subsidization for screening test and Congenital Hypothyroidism treatment, blood chemistry analysis training costs for manufacturing the test kit and training costs for specialist doctor, are excluded from the calculation because in the data recording did not classify in details. So, all of these items might already include in the provider cost.

3.9.5.1 Screening Costs Per Case

$$SC_7 = TC_{dc} + TC_{ic} / \text{Total screened cases} \quad (11)$$

Where, SC_7 = Screened costs per case.

TC_{dc} = Total direct costs due to the TSH screening program.

TC_{ic} = Total indirect costs after adjusting some double counting costs due to the TSH screening program.

3.9.5.2 Screening Costs Per Diagnosed Case

$$SC_8 = TC_{dc} + TC_{ic} / \text{True positive and True negative cases.} \quad (12)$$

Where, SC_8 = Screened costs per diagnosed case.

3.9.5.3 Screening Costs Per Positive Case

$$SC_9 = TC_{dc} + TC_{ic} / \text{True positive cases} \quad (13)$$

Where, SC_9 = Screened costs per positive case.

3.10 Estimation of Benefits

Benefit of this study is in terms of “cost saving” or “preventable cost” from taking care mentally retarded children due to no Congenital Hypothyroidism-screening program. Therefore, the number of positive correctly detection cases are considered first. In this study, it is assumed that if the cases are not diagnosed on time, all these cases will be mentally retardation in the future that will incur costs of taking care, welfare and treating mentally retarded children.

3.10.1 Assumption for Benefit Calculation

- Probably 1% to 2% of mentally retarded patients come from Congenital Hypothyroidism(Layde,1979)
- The severity of mental retardation from Congenital Hypothyroidism in those whom was not detected

Severe retarded (IQ 20-35) 55% of total cases

Moderate retarded (IQ 36-61)
Mildly retarded (IQ 62-67) } 25% of total cases

Suboptimal intelligence (IQ 68-80) 20% of total cases (Dhondt,1991)

- Life expectancy of mental retarded person from Congenital Hypothyroidism in those whom was not detected

Severe retarded 40 years of life expectancy at birth.

Moderate and Mildly retarded 60 years of life expectancy at birth.

Suboptimal intelligence average normal life expectancy(Dhondt, 1991)

- The average productivity is estimated to be at minimum wage.

In severe retarded, only 5 % could find employment at minimum wage

In moderate retarded, 30% could find employment at minimum wage

In mildly retarded, 60% could find employment at minimum wage (Hisashige, 1994)

- The half of their mother earning is foregone by taking care of their children. (Layde,1979)
- The educational cost is an adding cost, which is extra from normal children
- Only 2% of total money are allocated for mental retarded children, which cause comes from Congenital Hypothyroidism.
- The general supported money that will be allocated to mental retarded children until age 21.
- All of the future benefit will increase following the inflation rate at 3 % each year.
- All of the future benefit will discount to be a present value in year 1999 by using the discount rate at 5%.

Cost saving for taking care and treating mentally retarded children from patient and family side is estimated in following way.

Table 3.5: The Total Benefit Components of the Screening Program.

Perspective	The benefit components
Provider	This study assumes no benefit from the provider side because when there is no screening program, the provider still provides the pediatric endocrine services.
Patient.	<ol style="list-style-type: none"> 1. Direct benefit. <ul style="list-style-type: none"> • Cost saving from loss of patient's productivity. • Cost saving from the special education. 2. Indirect benefit. <ul style="list-style-type: none"> • Cost saving from lose of parents' productivity.
Society	<ol style="list-style-type: none"> 1. Direct benefit. <ul style="list-style-type: none"> • Cost saving from general support for mental retarded people.

3.10.2 Cost Saving from Patient and Family Perspective

Direct cost saving of taking care mentally retarded children for patient and family perspective are all additional treated costs that greater than normal children, costs from losing patient productivity due to mentally retarded and costs of special education.

- Cost saving from losing patient productivity is assessed from the opportunity cost of normal people can earn minus the opportunity costs of mental retarded people can earn in their life. In this study, the productivity earning bases on the minimum wage per day. Assumed that the working life starts at age 21 years until the retirement at age 60 years.
- Cost saving from the special education identifies from the additional education costs that are greater than for normal children. The extra educational costs come from the special mental retarded school. From the interviewing an expert opinion at Phanyavuthikorn school, which provides a special education from the kinder garden, primary school and job training class, generally, the study period or training time of mental retarded children is about 15 years. Therefore, the mental retarded child will finish training course at the age around 21. Normally, the tuition fee is free but the parent will pay for food and study materials, which are 3,500 Baht for the first

semester, 3,000 Baht for each semester until graduated the primary class, which takes time 6 years and 3,800 Baht per semester for the job training class.

Indirect cost saving for patient and family perspective will classified as the parents' productivity loss due to taking care mental retarded children.

- Cost saving from reducing parental productivity is calculated by using the opportunity maternal forgone money due to taking care mental retarded child. In this study, the proportion of the foregone money comes from the literature review, which is 50% of maternal earning and the maternal earning bases on the minimum wage per day.

3.10.3 Cost Saving from Societal Perspective

The estimation benefit in societal perspective is the cost saving from general support that is determined from the income of the mental retarded foundation. In this study chooses the Mental Retarded Foundation under Queen Sirikit providing, which was established in 1962 by Queen Sirikit, as a sample of the estimation. The objectives of this foundation are encourage the training course for mental retarded people and study and research about the mental retardation including protecting and rehabilitation. This foundation consists of many parts such as Phanyavuthikorn School, Phapakamphanya mental retarded-trained center and Phanyakarn job trained center. Furthermore, the branches center of this foundation cover others parts of Thailand, for instance, in the northern part at Cheing Mai, in the northeastern part at Udon and in the southern part at Songkha. Since, the objectives of this foundation are for the mental retarded patient so in this study assume that the income of the foundation will be spend on the mental retarded activities. Therefore, the cost saving from general supported will be calculated from the balance sheet of the foundation.

From the above calculations, the following equations can be obtained

$$TC_{mpt} = TC_{mpt.so.} + TC_{mpt.treat.} \text{ ----- (14)}$$

TC_{mpt} = Total costs, which are a summation of all cost items, incurred by patient and family side and societal for taking care mentally retarded person.

$TC_{mpt.treat.}$ = Total costs, which are a summation of all cost items, incurred by patient and family side for treating and taking care of mentally retarded children.

$TC_{\text{mpt.so}}$ = Total costs, which are a summation of all cost items, incurred to society for treating and taking care of mentally retarded children.

3.11 National Policy

Since Chulalongkorn Hospital is a teaching hospital, there are several points that differ from the general public hospital. For instance, the unit costs of out patient department in the general public hospital is lower than in Chulalongkorn Hospital. According to the supplement material from Prof. Pirom Kamol-Ratanakul in clinical Economics, the unit costs of out patient department in the general public hospital, which size is 600 beds, are around 110 Baht per visit in year 1991. Moreover, the treatment guideline at Chulalongkorn Hospital will be more frequency than in the general public hospital. From the Nan Hospital, the treatment guideline of the Congenital Hypothyroidism is every three months in the first year of age, every six months until 4 years old and after that the follow up will be once a year. Thus, the benefit-cost ratio of the national policy will be carried out.

3.11.1 Assumption of the Cost Calculation in National Policy

- The TSH Kit for the screening program will use the Thai manufacturing test, which price is 25 Baht per test.
- The OPD unit costs in the calculation will use the unit cost of OPD in general Public Hospital, which size is 600 beds, that is 110 Baht per visit in 1991 and this figure will be adjusted into year 1999.(Kamol-Ratanakul, 1999)
- The follow up process will be every 3 months in the first year, every 6 months until 4 years old after that every year. (Nan profile, 2000)
- The responsive-recall rate and compliance rates of patient are on the basis of Chulalongkorn Hospital data.
- Transportation costs for each specimen will be 15 Baht that is the minimum charge for EMS post.

3.12 Cost-Benefit Analysis

The benefit-cost ratio will calculate in base case at Chulalongkorn hospital and the national policy. The total costs of the screened program will base on all of the incurring cost items to the provider, patient as well as societal perspective after adjusting some double counting costs. To compare with the all of cost saving items that would be burden to patient and family perspective and societal perspective, if they did not have a screened program. The population of the benefit-cost ratio calculation in the base case will be the actual data from 1991 to 1999 because the population data in 1999 is very small, and for the benefit-cost ratio of national policy calculation, the population of the calculation will assume that there is a million newborns annually. From the above equations (1 to 13), costs for each perspective are calculated and also benefits in term cost saving are calculated from equation 14.

The formula for computing the benefit-cost ratio is following.

Present value of benefit-cost ratio.

$$B / C = \frac{\sum_{t=0}^n B_t}{(1+r)^t} / \frac{\sum_{t=0}^n C_t}{(1+r)^t}$$

Where B_t = Monetary value of benefits incurred at time t
 C_t = Monetary value of costs incurred at time t
 r = Discount rate

3.13 Sensitivity Analysis

Sensitivity analysis will be performed due to some uncertainty variables that will affect the costs and outcomes calculation of the uncertainty are discount rates, the probability of diagnosed cases that need the whole life treatment, the responsive-recall rate and compliance rate of patient.

Discounting rate base on the social opportunity cost of capital that refers to the prevailing real rate of interest. Since health and economic discount rate may in fact differ, the sensitivity analysis will be done at no discount rate and 10% discounting rate keeping the discount rate at 5%. Because, there are some arguments that the health investment is not the same as the wealth investment, as the result, it is not appropriate to take the discount rate.

For the internal factors, the responsive recall rate, the compliance rate of the patient as well as the number of patients who need whole life long treatment have a remarkable impact on the economic evaluation analysis. The base of the responsive recall rate and compliant rate of patient will be used the figure at Chulalongkorn Hospital. For the number of patients who need whole life treatment, there are approximately 80 to 95% of primary congenital hypothyroidism, which causes from thyroid dysgenesis, will essence a whole life long thyroid hormone treatment (Chearsikrew, 1993), so in this study will assumed that in the transient Congenital Hypothyroidism cases will be detected after the patient age 2 years. And for the compliance rate of patient, in this sensitivity analysis assumes that the compliant rate of patient incurs before the children age 2 years, which is effect with the children brain development. Therefore, the sensitivity analysis will be done in the aspects as the following.

- The responsive-recall rate will be 100%
- The compliance rate of patient will be 75 %
- The number of whole life treatment will be 80%

Because of the variety of incidence rate of Congenital Hypothyroidism, the last sensitivity analysis of the national policy will be carried out in a point of incidence. In this part the benefit-cost ratio will be done in two difference of incidence rate. The high incidence rate is 1 per 687 live births that found in Nan province and the low incidence will be 1 per 8,500 live births, which comes from the literature review. Both of these benefit-cost ratio will compare with the base case, that incidence rate is the actual incidence of Chulalongkorn Hospital.