

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Research Design

Retrospective descriptive study.

3.2 Research Methodology

3.2.1 Population and Sample

Pregnant women who came to the Obstetric-Gynecology (OB-GYN) department of BMA Medical College and Vajira Hospital for antenatal care from 1 June - 31 December 2003 were included. These women should meet the criteria as the risk patients for gestational diabetes.

Risk factor 1 (high risk) first visit screening

1. obesity by body mass index as shown in table 1
2. familial history of diabetes mellitus
3. previous gestational diabetes.
4. glucosuria.

Risk factor 2 (average risk) screening during 24-28 weeks of gestational age.

1. age \geq 30 years old.
2. past history of abnormal glucose tolerance test
3. previous birth of big baby (\geq 4,000 grams)
4. previous fetal death in utero or stillbirth

Table 3.1 Obesity by body mass index

Height (cm,)	Weight(kg.)	Height (cm,)	Weight(kg.)	Height (cm,)	Weight(kg.)
135	52.9	151	66.1	167	80.9
136	53.6	152	67.0	168	81.9
137	54.4	153	67.9	169	82.8
138	55.2	154	68.8	170	83.8
139	56.0	155	69.7	171	84.8
140	56.8	156	70.6	172	85.8
141	57.7	157	71.5	173	86.8
142	58.5	158	72.4	174	87.8
143	59.3	159	73.3	175	88.8
144	60.1	160	74.2	176	89.8
145	61.0	161	75.2	177	90.9
146	61.8	162	76.1	178	91.9
147	62.7	163	77.1	179	92.9
148	63.5	164	78.0	180	94.0
149	64.4	165	79.0		
150	65.3	166	79.9		

$$\text{BMI} = \frac{\text{wt. (kg.)}}{[\text{Ht. (m.)}]^2} \quad \text{if BMI} > 29 = \text{obesity}$$

Inclusion criteria

1. The pregnant women should have risk factor 1 or 2 as previous described.
2. The pregnant women should have screening test and / or diagnostic test that according to the guideline(appendix B) at first visit , 24-28 \pm 2 weeks of pregnancy and 32 \pm 2 weeks of pregnancy. At least the important period that should have the result of the screening test and / or diagnostic test were

the results at 24-28 \pm 2 weeks of pregnancy and 32 \pm 2 weeks of pregnancy, except the cases that diagnosed gestational diabetes by the first or 24-28 \pm 2 weeks of pregnancy test because no need to test further.

Exclusion criteria

1. Overt diabetic cases.
2. The pregnant women who had only the result of screening test $\geq 140\text{mg}\%$ and without the result of diagnostic test because these cases were uninterpretable.

3.2.2 Methodology

This is retrospective research, the difference between BMA Medical College and Vajira Hospital Practical Guideline in Diagnosis Gestational Diabetes and American Diabetic Association Recommendation is the American Diabetic Association Recommendation have no test at 32 \pm 2 weeks of pregnancy. The study was conducted as the following:

1. The records of the women that recruited by inclusion and exclusion criteria were collected retrospectively from the medical record department of BMA Medical College and Vajira Hospital as the secondary data source.
2. Define the case that diagnosis of gestational diabetes by the criteria of abnormal of ≥ 2 value of 100 gm. glucose tolerance test and recorded in the recorded form. Then define case that diagnosis of gestational diabetes again but this time without the result of test at 32 weeks of pregnancy, recorded the result in the recorded form similarly. The results of the test in 24-28 \pm 2 weeks of pregnancy and 32 \pm 2 weeks of pregnancy were counted as 24-28 weeks of pregnancy and 32 weeks of pregnancy group respectively.

3. Calculate the cost of the whole process of both groups.

These will include cost of

direct cost indirect cost

future cost in term of cost of undiagnosed cases (kidney disease caused by gestational diabetes).

opportunity cost in term of cost of undiagnosed cases

(macrosomia with hypoglycemia and kidney disease caused by gestational diabetes).

Compare cost per one diagnosis of gestational diabetes in health provider's, and patient's perspective. And without test at 32 weeks of pregnancy (in American Diabetic Association Recommendation) how many cases of gestational diabetes were missed.

4. To analyze the incremental ratio of the additional cost and additional effectiveness between BMA Medical College and Vajira Hospital Practical Guideline in Diagnosis Gestational Diabetes and American Diabetic Association Recommendation in health's provider and patient's perspective similarly.
5. Calculate the cost of kidney disease (health's provider and patient's perspective) and treatment of the most common neonatal morbidity that is macrosomia with hypoglycemia that caused by gestational diabetes by using the incidence of this event in the untreated gestational diabetes reported in literatures and diseases related group cost as the baseline information.
6. Compare additional cost for diagnosis of additional gestational diabetes cases of BMA Medical College and Vajira Hospital Practical Guideline in Diagnosis Gestational Diabetes with the opportunity cost of undiagnosed cases by American Diabetic Association Recommendation (macrosomia with hypoglycemia and kidney disease caused by gestational diabetes).

3.2.3 Cost data

1. Health provider's perspective

1.1 Direct & Indirect cost

Total health provider cost was calculated from labor costs, material costs and capital costs from antenatal care, pharmacy and financial, medical record subunit at OB-GYN department and central laboratory of BMA Medical College and Vajira Hospital, during 1 June – 31 December 2003. The full cost of each unit is the sum of its total direct cost (LC+MC+CC) and its total indirect cost (TIDC) incurred by others unit that the patients did not contact directly such as administrative, general management etc., which were calculated and allocated based on the unit cost data of BMA Medical College and Vajira Hospital in 2001 and modified by the consumer price index to be the cost in 2003. The unit costs of routine service (RSC; overhead costs), antenatal care, medical record, pharmacy and financial unit were calculated by dividing the full costs by number of patients' visits and number of drug lists during the studied period. Similarly, the RSC of central laboratory in reagent was calculated by dividing the full cost by the total number of test requested during the period of studied, then multiply by the unit RSC by the total number of test in studied group. The RSC of Pharmacy and Financial unit in sugar and blood set was the cost of sugar and blood set itself. The total cost received by summing up RSC of GCT and GTT multiply by the number of test in studied group. Upon summing up all these components, we arrived to the total cost. The cost to the provider was the true cost of delivering the service to patients or target populations (Kaewsonthi and Kamolratanakul,1994). This study applied the direct distribution method as a method of cost allocation (American Hospital Association, 1986; Berman and Weeks, 1976). At last, provider cost as full cost determination was received by summing total cost of each cost center as steps showing below.

Steps of cost calculation

Cost center identification & grouping.

1. Non-Revenue Producing Cost Center : NRPCC
2. Revenue Producing Cost Center : RPCC
3. Patient Service : PS

Direct cost determination.

1. labor personal : doctors, nurses, health workers, etc.
 Include salaries and fringe benefits
 Dimension determining cost : Time worked.

2. material cost
 Supplies : Drugs, syringes, small equipment etc.
 Operation & Maintenance : electricity, water, etc.
 Dimension determining cost
 Supplies : Weight / Volume
 Operation & Maintenance : Time used / Space used

3. capital cost (depreciation value) : in this study using " Estimated Useful Lives of Depreciable Hospital Assets" (1978 Edition by The American Hospital Association).

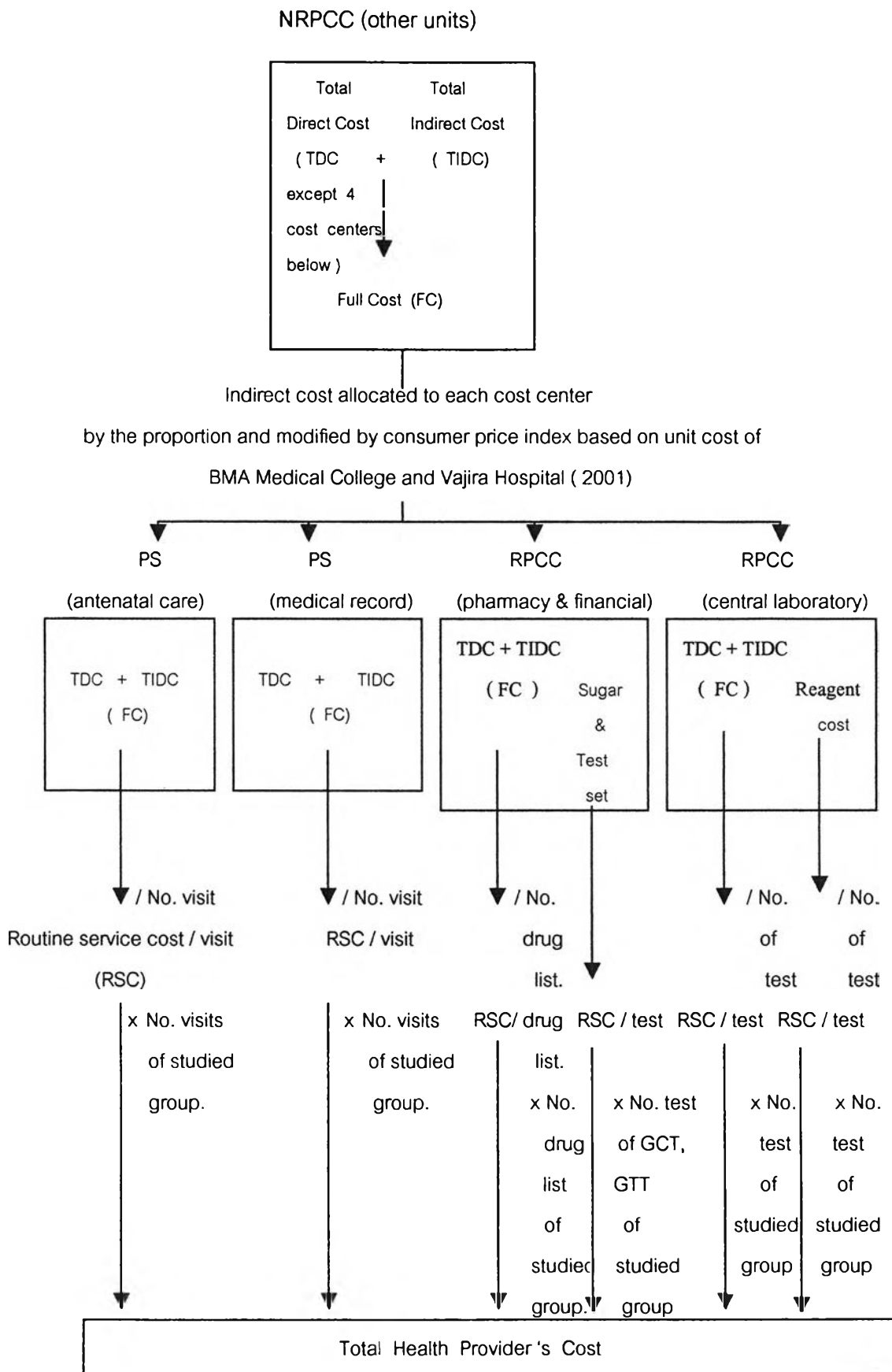
Equipment : laboratory instrument
 Recurrent cost : operation cost
 Dimension determining cost : Time used

Allocation criteria.

Method	direct allocation
Criteria	no. of personals
	no. of patients
	area used
	weight / volume used

Full cost determination.

Figure 3.1 Conceptual framework of total provider cost calculation



1.2 Future cost

There are many long term complications of diabetes mellitus such as cardiovascular, kidney , eye and nervous system complications. One of the way to reduced these complications was the capability in correctly diagnosis with proper management. In this study, the scenario of kidney disease was the only disease that selected to be the example of future cost in health provider's perspective happened by undiagnosed gestational diabetes cases. By using the cost of hemodialysis(in health provider's perspective) for end stage renal disease (ESRD) from King Chulalongkorn Memorial Hospital in 2001(Kamolratanakul P et al, 2001) and incidence rate from Master thesis in health economics in 1998(Sakthong P,1998) as the basic information in calculation the cost.

2. Patient' s perspective

Patients' costs can be classified as direct medical costs usually charged by the health care facilities, direct non medical costs (ie transportation) and indirect costs (productivity loss) (Kamolratanakul et al, 1993b). In this study the first part of patient's cost is the cost for diagnosis and treatment of gestational diabetes and the second part is the opportunity cost for undiagnosed cases of gestational diabetes (in this study will concern only calculation of the cost of treatment of macrosomia with hypoglycemia caused by gestational diabetes which was calculated by using incidence from literature and cost by using diseases related group cost as the fundamental data.) as shown in table below.

Table 3.2 Cost for diagnosis and treatment of gestational diabetes

Cost identification	Method of measurement	Data sources
Direct cost		
Medical		
Diagnosis	charge for GCT and GTT	Pharmacy and financial Central laboratory
Treatment	insulin cost	Pharmacy and financial
Non medical	Transportation fare	Bangkok Mass Transportation
Indirect cost		
Productivity loss	Minimum wage rate	Ministry of Labor

Table 3.3 Opportunity cost (cost for undiagnosed cases of gestational diabetes)

Cost identification	Method of measurement	Data sources
Direct cost		
Medical		
Scenario of kidney Disease	Cost of hemodialysis Cost of drug therapy (ACE inhibitor)	Sakthong P. Master's thesis Pharmacy and financial Bureau of Trade and Economics indices
Macrosomia with hypoglycemia	Cost by DRG version 3 (Thailand)	Ministry of Public Health
Non medical	Transportation fare	Bangkok Mass Transportation
Indirect cost		
Productivity loss	Minimum wage rate	Ministry of Labor

3.2.4 The effectiveness

To reduced long term complications was the capability in correctly diagnosis and proper management of gestational diabetes . So, the numbers of subjects who were correctly diagnosed as gestational diabetes from GTT by criteria of National Diabetes Group (shown in Appendices) in each program were used as an indicator to evaluate the program's effectiveness. In this study, effectiveness(E_B) of BMA Medical College and Vajira Hospital Practical Guideline in diagnosis of gestational diabetes were the number of pregnant women who had been test periodically at first visit and / or 24-28 weeks of pregnancy and 32 weeks of pregnancy by GTT which were found abnormal ≥ 2 values of blood glucose level. The effectiveness (E_A) of American Diabetic Association Recommendation in diagnosis of gestational diabetes were the number of pregnant women who had been test periodically at first visit and / or 24-28 weeks of pregnancy by GTT with the same criteria for abnormality. Those who had abnormal blood glucose ≥ 2 value were defined as the gestational diabetes and will receive proper management for reducing complications especially long term complications. So, the number of gestational diabetes discovered by the program implied the effectiveness of each program.

3.3 Data analysis

The analysis compared the cost-effectiveness in diagnostic program of gestational diabetes between BMA Medical College and Vajira Hospital Practical Guideline in diagnosis gestational diabetes and American Diabetic Association Recommendation in health provider's, patient's perspective. Moreover, incremental cost-effectiveness were also analyzed, that is the ratio of the incremental cost (the net increase in the test cost) to the incremental effectiveness(the net increase in diagnosed cases). The value of incremental cost-effectiveness ratio (ICER) will show how much it

cost for an additional diagnosed case and if the alternative program resulted in less cost and more cases diagnosis the value of ICER would be negative meaning cost savings.

ICER was calculated from the following formula:

$$\text{ICER} = \frac{C_B - C_A}{E_B - E_A} = \frac{\Delta C}{\Delta E}$$

Eventually, comparing the additional cost (cost for additional gestational diabetes cases) of BMA Medical College and Vajira Hospital Practical Guideline in diagnosis gestational diabetes with opportunity cost (cost for undiagnosed cases of gestational diabetes), to see whether it is worthy for investment.

