CHAPTER III

METHODOLOGY

The objectives of this study were to identify the characteristics of the subjects, to ascertain if there was any relationship between anemia in pregnancy and postpartum hemorrhage, and to examine the relationships among the variables in the study. In order to meet these objectives, the following research methodology was used in this study.

A. Research design

A case – control study was used to examine the association between anemia in pregnancy and postpartum hemorrhage. Cases group were those who have a postpartum hemorrhage history (the amount of blood loss more than 500 ml) , and controls group were those who do not have a postpartum hemorrhage history (the amount of blood loss equal or less than 500 ml). Cases and controls were matched by time of delivery in terms of month and year. This study reviewed the medical records of all patients who have delivered in the OBGYN Department, Uthai thani Hospital from January 1998 to December 2002. Based on specific inclusion and exclusion criteria, two groups of patients were selected as study samples. The 1 to 4 proportions was used, so the control group size was four folds as large as the cases.

Figure 2. Flowchart of the Research Design

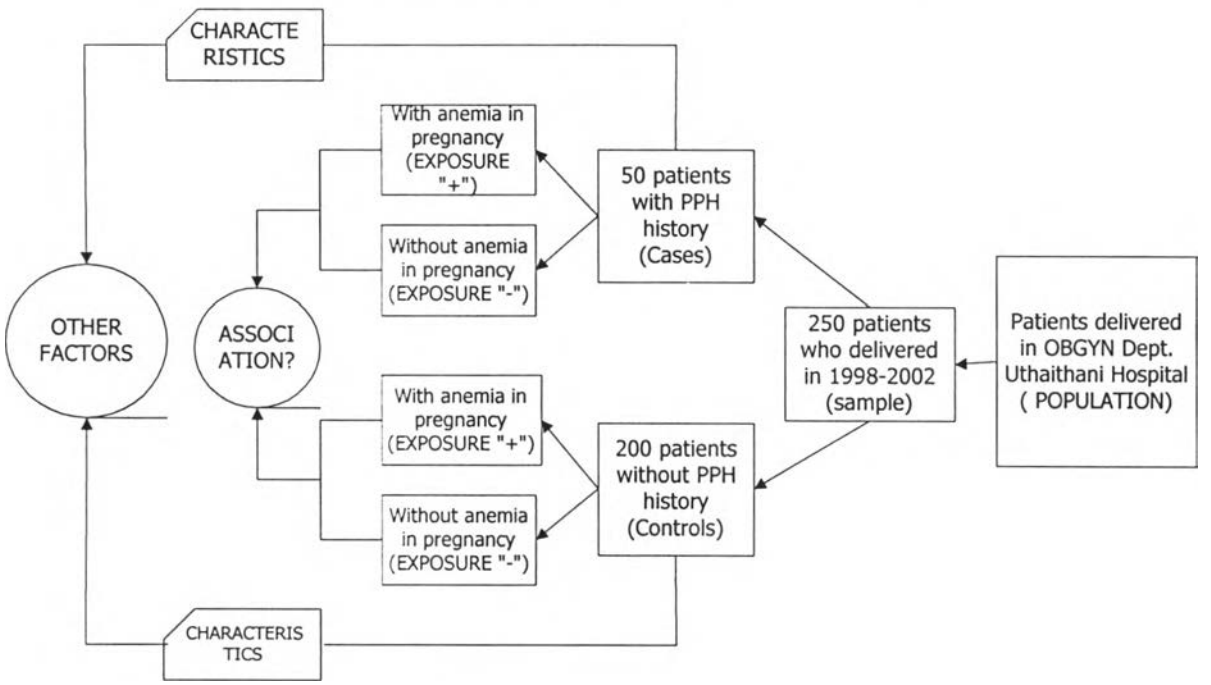

Figure 2 above illustrates the research design in this study. Once the cases and controls have been selected, the research examined the prenatal history to identify whether each subject has anemia in pregnancy (exposure"+") or no anemia in pregnancy (exposure"-"). Statistical analyses were used to determine the association between anemia in pregnancy and postpartum hemorrhage. In addition, other characteristics that may be related to the occurrence of anemia and postpartum hemorrhage have also been examined.

B. **Population and sample of study**

The target population of this study were women who delivered in the Delivery Room of Uthai thani Hospital. The sample population were women who delivery at Uthai thani Hospital from year 1998 to 2002.

Sample size calculation was based on published data by Ministry of Public Health and the researcher's assumption. The prevalence rate of iron deficiency anemia in Thailand in 1999 was 12.9%. The researcher assumed that prevalence rate in the hospital will be higher than the National prevalence rate, and minimum relative risk among the cases will be one and half times as high as among the controls, because three out of four direct causes of postpartum hemorrhage would be associated with anemia.

The calculations started with computing how many cases were appropriate for this study, and then the controls group size was decided by multiplying the cases group size by four. After that, the duration of time to look back can be determined, as well as the population of the study. The sample size calculation using a statistical formula shown below for an unequal case-control study yields a sample size of 50 cases.

$$n = \frac{\left[Z_{\alpha} \sqrt{(1+1/c)\ \bar{p}\ \bar{q}} + Z_{\beta} \sqrt{p1\ q1 + poqo/c} \right]^2}{(p1 - po)^2}$$

n = Sample size

α = 0.05

$Z\alpha$ = 1.96

β = 20%

$Z\beta$ = -0.84

"c" = control size compare with cases size = 4

"po" = rate of exposure among controls = 18% = 0.18

"qo" = 1-po

$$\text{“p1”} = \frac{po(OR)}{1+po(OR-1)}$$

“q1” = 1-p1

OR = Minimum relative risk in exposed among cases = 1.5

$$\bar{p} = \frac{(p1+c.po)}{1+c}$$

$$\bar{q} = 1 - \bar{p}$$

By using 1 to 4 proportions between the case and control groups, the sample sizes were 50 and 200, giving a total of 250 subjects. Information provided by Uthai thani Hospital indicated that the average of live births was about 1800 per year, and the prevalence of postpartum hemorrhage was approximately 1%. Therefore, estimated number of cases will be 18 cases per year. Then, to obtain an inclusive sample of 50 cases required examining medical records retrospectively for 5 years. In other words: *The study population were all pregnant women who delivered at the Ob-gyn Department Uthai thani Hospital from January 1998 to December 2002.*

Inclusion criteria were used to define subjects who can be included in the research. The inclusion criteria were:

- Patients who have undergone delivery in year 1998 to 2002.
- Patients who have a pregnancy history, at least one day before delivery, with record of hemoglobin percentage in the third trimester of pregnancy.
- Patients who have a postpartum history of at least 24 hour after delivery.

In order to control some confounding factors, exclusion criteria and group matches were used. Exclusion criteria were used to define subjects who cannot be included in the study, and the group matches are to make the control group as similar as possible with the case group.

Exclusion criteria:

- Abnormal coagulation problems.
- Multiple gestation
- Polyhydramnions.
- Caesarian section history in previous pregnancy.
- Uterine surgery history
- Placenta previa

Group Matched characteristic:

- Time of delivery: was known by reviewing log book at delivery room, according to month and year.

Regarding data gathering, some steps were followed as described below:

1. Review the log book at delivery room, and identify the patients who have postpartum hemorrhage.
2. Review every medical record of all identified patients.
3. Select cases by using inclusion and exclusion criteria
4. For each case identified, the four patients who delivered in the same month and year according to the log book were selected as controls considering inclusion and exclusion criteria.

Information collected from the medical records included: education, age, occupation, gravidity, parity, place & frequency of ANC, type of delivery, attendant, duration of labor, baby weight, oxytocics administration, and complications/diseases during the ante and intranatal periods, hemoglobin level in the third trimester and amount of blood loss in the first 24 hours after delivery.

C. **Setting and time of the study**

The study was conducted in the Delivery room and Medical Records Office of the Uthai thani Provincial Hospital, Uthai thani Province, Thailand, from December 2002 to January 2003.

D. Measurement Methods

This study used patient's medical records as the data source. In data collection, four nurses were involved as data collectors, and a form that has already been prepared by researcher was used to abstract the necessary information. Double-checking the collected data randomly (± 10%) was performed for the quality control of data. Besides, data entry was performed twice. Therefore no missing data was found. However, there were some outliers based on amount of blood loss, which was later on omitted from the analysis. Two cases were omitted from the analysis, because it was more likely that there were some errors in recording, one with 3200ml and another one with 2800 ml of blood loss.

For data analysis, SPSS 10.00 program was used, and according to the variable of this study, measurements were:

Dependent variable

Name: postpartum hemorrhage

Level: nominal

Values: yes/no.

Independent variable (I)

Name: anemia in pregnancy

Level: nominal

Values: yes/no

Independent variable (II)

Name: characteristics of patients

Level: Nominal (occupation, place of ANC, type of delivery, attendant, oxytoxics administration and complication during ante/intranatal period); Ordinal (education); and Ratio (age, gravidity, parity, duration of labor, baby weight, and frequency of ANC)

Values:

- Occupation: name of occupation
- Place of ANC: name of health facility
- Type of delivery: name of type of delivery
- Attendant: name of attendant
- Oxytocics administration: name, dose, and method of oxytocics drug given in third stage
- Complication/disease during ante and intranatal period: name of complication/disease

- Education: illiterate/elementary/high school/diploma/higher
- Gravidity: 1 / 2-4 / >4
- Parity: 1 / 2-4 / >4
- Age: <20 / 20-35 / 35-45 / >4
- Frequency of visits: 1 / 2 / 3 / 4 / >4
- Duration of labor: <8 / 8-12 / 12-24 / >24 hours
- Baby weight: <2500 / 2500-4000 / >4000 grams

E. Analysis Methods

Data analysis was done by calculating the descriptive statistics, Odds Ratio, chi-square test, T-test, correlation and conditional multiple logistic regression. The following table is about statistical methods used in data analysis:

Table 1. Statistical methods / parameter for data analysis

No	Data analysis purpose	Statistical method / parameter
1	To describe the characteristics of subjects	Mean, SD, Percentage and minimum-maximum
2	To test the unadjusted association between anemia and postpartum hemorrhage	Bivariate Correlation, Chi-square test and T-test
3	To find the strength of adjusted association between anemia/other independent variables and postpartum hemorrhage	Bivariate correlation, conditional multiple logistic regressions, Odds ratio and p value.