CHAPTER IV

POPULATION

This chapter deals with the population and the target population of the study, the selection of the sample and sampling technique.

Population

The study population is an integral part of the research questions. The selection of the population to be studied is important. The eligibility of the population to answer the primary research question of the study is considered and discussed according to the criteria described by Friedman (Friedman, Furburg and DeMets, 1983).

1. Subjects who have the potential to benefit from the intervention are obvious candidates for enrollment into the study.

Bhumipol hospital has campaign for screening of cervical cancer for many years so that the physician can detect about 90 high risk patients who have abnormal pap smear

per years (Bhumipol Hospital, Department of Pathology, 1989). Abnormal Pap smear women need to have the diagnostic procedure that most suitable to them. The diagnostic procedures appropriate for the patients are being considered. Conization is accepted to be the accurate procedure but this procedure cannot be performed in all cases of abnormal Pap smear women because of its serious complications.

Long term follow up by Pap smear or other methods can cause some patients to lose follow up that is very dangerous to them if the disease turns to invasive stage. The colposcopy is one of the candidates to solve the diagnostic problems. The results from the study can show the benefits and the limitations of the colposcopy in the diagnosis of cervical neoplasia in abnormal Pap smear patients, that can guide the physicians to select to the most suitable diagnostic procedure for abnormal Pap smear women.

2. In selecting subjects to be studied, not only does the investigator requires people in whom the intervention might work, he also wants to choose people in whom there is a high likelihood that he can detect the hypothesized result of the investigation.

Pap smear is accepted to be the screening methods for cervical neoplasia on the basis of the patients who have abnormal cell in the Pap smear slides. This procedure will significantly increase the chance for detecting the cervical neoplasia (Papanicolaou, 1943).

For this reason, the abnormal Pap smear patients

should be the target population for this study.

3. The investigator needs to weigh adverse effects against possible benefit when he evaluates the feasibility of doing the study.

The application of the colposcopy to the abnormal Pap smear women is not harmful compared to ordinary diagnostic procedure (diagnostic conization). On the contrary, we introduce a potential useful protocol to protect and maintain safety for the patients. Any patients included in the study will be completely free from additional risk (other medical complications). The exclusion criteria for the patients are preventing them from the adverse effects of the procedure.

4. Subjects at high risk of developing condition which preclude the ascertainment of the outcomes of interest should be excluded from enrollment.

In some conditions, the physicians can diagnose cervical neoplasia easily by simple method (biopsy by naked eye during vaginal examination). Some patients are in more progressive stage of cervical neoplasia. They have typical fungating mass at the cervix or typical cervical lesions that could be clearly seen during vaginal examination. In this condition,it is not necessary to use colposcopy. To prevent from potential confounders to the outcome, frank carcinoma or fungating mass will be excluded. Because the physicians can diagnose the disease or detect the lesion sites by not using colposcopy.

5. Investigators prefer to enroll only subjects who are likely to comply with the protocol.

The colposcopy is much more convenient than Diagnostic Conization or Hysterectomy. The colposcopists can perform it in the outpatient clinic. It is not necessary to use the operating room or any anaesthesia. The patients need not to prepare themselves before the test. It means that if the colposcopy is good enough to be the diagnostic procedure of cervical neoplasia in abnormal Pap smear women, many abnormal Pap smear patients will receive only this test, and thus, will be spared from other more invasive procedures.

Population

All women who attend Gynecology Clinic at Bhumipol Hospital.

Target Population

All women who have abnormal Pap smear examined in the Gynecology Clinic at Bhumipol Hospital.

Population to be Sampled

Women with abnormal Pap smear who satisfy the inclusion and exclusion criteria.

Eligibility Criteria

1. Inclusion Criteria

a) All women whose Pap smear results are abnormal.

b) Patients who are willing to participate in this study.

2. Exclusion Criteria

a) Patients who have definite diagnosis of cervical neoplasia from other center (referred cases).

b) Patients who have serious disease that are contraindicated to conization. (bleeding disorder, severe myocardial infarction)

c) Patients who have fungating mass or frankly typical lesion at the cervix that physician can diagnose by naked eyes during vaginal examination.

Justification of Sample Size

There are 4 factors to determine sample size as follows:

1. Primary Question

This study is designed to answer the primary question if the colposcopic directed biopsy can diagnose cervical neoplasia the women whose Pap smear results are abnormal, with the 93% sensitivity compared with diagnostic conization.

So " p " is = 0.93.

Then " q " is (1 - 0.93) = 0.07.

2. Acceptable Error

According to the literature review, the sensitivity of colposcopy varies from 88% to 99%, the acceptable error of 7% is justified.

So " Δ " is = 0.07.

3. The Type 1 and Type 2 Error

Because this is a descriptive study, it has one sample group, so statistical error is only "α" or "type 1 error" with the confidential level of 95% and this study is designed to determine the sensitivity that is equal or more than 93%.

4. Formula

$$n = (z_{\alpha})^2 \, pq / \Delta^2$$

$z_{\alpha} = 1.96$

$p = 0.93$

$q = 0.07$

$\Delta = 0.07$

$$n = (1.96)^2 \, (0.93) \, (0.07) / (0.07)^2$$

$n = 51.03$

"n" is the number of the patients that have "true disease" (cervical neoplasia or Cervical Intraepithelial

Neoplasia - CIN) from the total number of patients who will undergo **satisfactory (adequate) colposcopic examination.**

In this study we select patients who have **satisfactory colposcopic examination (adequate colposcopic examination)** to be the study cases for finding the sensitivity of colposcopy according to the literature review. The percentage of satisfactory colposcopic examination from **the total cases performed colposcopy,** from literature review, is 85%.

So the **total number of patient** who will undergo colposcopic examination and **have true disease** is

51.03 /0.85 = 60.03.

"N" is equal to number of neoplasia cases in the total number of abnormal Pap smear population. From literature review, false positive of Pap smear is not more than 20%, then true positive is 80% (neoplasia cases). From this data, calculating the total number of abnormal Pap smear patients by dividing 60.03 with 0.8., then the total number of abnormal Pap smear population will be

60.03 / 0.8 = 75.04.

If the percentage of exclusion by exclusion criteria is 10%, then total patients recruited according to inclusion criteria will be

75.04 / 0.9 = 83.38

For conclusion, samples size needed is 84.

In process of collecting data at Bhumipol Hospital, this sample size number can be reached in 8 months.

Sampling Technique

All consecutive cases that "fulfilled" the inclusion and exclusion criteria will be recruited in the study until the number of cases reaches the needed sample size.