CHAPTER IV

THE STUDY POPULATION

This chapter deals with the target population of the study, the selection of the sample and the inference about the generalizibility from the study result.

The Target Population

The study population is an integral part of the research questions. Whether the interventions of an experimental research are effective depends not only on the efficacy of interventions but also the types of the population under study. The selection of the population to be studied is important. The eligibility of the population to answer the primary research question of this 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.

Nosocomial infections involve people who have ill health and are admitted to the hospital for treatment. Thus, they are exposed to various procedures in process of the treatment of their illnesses and also to the hospital environment. Contamination of infectious organisms and cross infections by health personnel who give direct care to patients most likely

occur. These factors are related to the spread of the infections. Hospitalized patients are at risk. The patients who have urinary catheter indwelling are at risk for catheter associated infections. Control behaviors for urinary tract infections in the hospital can prevent the patients from this infection or at least reduce the risk. In conclusion, hospitalized patients, both male and female, who have urinry catheter indwelling will potentially receive the most benefit from this study.

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 intervention.

As mentioned earlier, susceptible patients to nosocomial urinary tract infection are hospitalized patients with urinary catheter indwelling. Nosocomial urinary tract infections occur to patients regardless of whether they have urinary tract instrumentation or whether they are male and female. However, most infections (about 66-90%) occur in patients who have urinary tract instrumentation (Martin and Brookrajian, 1962; Infection Control Committee, Ramathibodi Hospital, 1988). Therefore, the patients who have urinary tract instrumentation have a higher likelihood of possessing the study hypothesized result compared to those who do not.

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

The application of the control guidelines combined with education to ward personnels is not harmful compared to testing of new drugs of uncertain side effects. On the contrary, we introduce a potentially fruitful programme to protect and maintain safety for the patients. Any patient included in the study will be completely free from additional adverse effects. The studied subjects will instead be more protected from the risk to which they are exposed. The exclusion criteria for the subjects of this study are the potential confounders to the outcome and not the adverse effects of the intervention : i.e. the severely ill patients who need special care from other wards were not included in the study.

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

Nosocomial urinary tract infection is an acute illness. Development of the infection does not take as long time as that of chronic diseases such heart disease or hypertension. The infection can be detected in days. Therefore, the issue of expected competing risk is likely to be low. Nevertheless, some patients might have competing events (eg. death shortly after arrival) for detection of infection. We hope that the randomization process will adjust for the imbalance between the experiment and the control groups.

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

The study has been conducted with hospitalized patients. Questions of subjects compliance to this study are unlikely to occur because patients themeselves are not the ones who take actions of practising the control measures. They are recipients to those practices. At the time of admission to the hospital, they are requested to sign the informed consent for curative treatments given by health care personnel during hospitalization. Thus, they are automatically eligible to the study if they possess the required criteria. Since the study deals with not only the hospitalized patients with urinary catheter indwelling but also the nursing personnel who perform urinary catheterization to patients, this personnel are requested to comply to the introduced guidelines and their compliance is the measurement of the study.

The Study Sample

The study sample is patients who are admitted to Chiangmai University Hospital and having urinary catheter indwelling during hospitalization. Chiangmai University Hospital is a teaching hospital with 1100 beds and serves about 1300-1500 hospitalized patients a day. This hospital is a tertiary care facility. Most patients are subjected to many invasive procedures as required by the treatments. These patients are at risk to get nosocomial infections (Soule, 1983; Ayliffe and Taylor, 1984). Health personnel is one of the factors contributing to hospital acquired infections (Soule, 1983). Since this hospital is a big teaching hospital, many health care

personnels both skillful and unskilled (medical students, student nurses, practical nurse students and including newly graduated personnel) render care to the patients either by themselves or under-supervision. Consequently, patients in such a hospital have higher risk of getting hospital associated infections. The nursing personnels are the major group who give care directly to patients. Thus, it is desirable to target our intervention towards this group.

The study sample represents the population of hospitalized patients in a tertiary care facility. The result of this study will be able to be applied to other population with similar characteristics who are looked after by similar types of health care personnels stationed in similar facilities. For example the result can be generalized to patients with urinary tract instrumentation in other general wards of the same hospital.

Sample Justification

The study sample is the hospitalized patients in general medical wards both male and female who have urinary catheter indwelling during their hospitalization. All the nursing personnels who usually perform catheterization to patients and are working in those wards at the time of the study are also the targets. The general background and characteristics such as type of facilities, patients, diseases, disease severity, and the routine work performed by health care personnel among study wards are similar since they are of the same department. Therefore,

all the general medical wards of the Medical Nursing Department are selected for the study. The patients and nursing personnels of the Intensive Care Unit (ICU) and the Coronary Care Unit (CCU) as well as those of the Dialysis Unit have been excluded because these specialized units have different characteristics. Patients in intensive care unit are more severe. Routine responsibility of health care personnel in specialized care units are different from that of the general wards. The generalizibility of this study is aimed at general wards of departments with patients having temporary urinary catheter indwelling during hospitalization. These general wards possess a major share of patients of the hospital.

Inclusion Criteria

Patients have been included if they:

1) are hospitalized in either male for female general medical wards both male and female, and,
2) have urinary catheter indwelling

Exclusion Criteria

Patients have been excluded if they: are in the intensive care unit, coronary care unit or dialysis unit

The Type I and II Error Used in the Calculation.

The Alpha Level

The alpha level is set at 0.05 (one tailed) which

represents the chance we are willing to accept of making a Type I Error. Type I Error occurs when we conclude that the intervention group has a greater reduction in nosocomial infection rate compared to control when if truth truth it is not so.

The Beta Level

The beta level is set at 0.20 which represents the chance we are willing to accept of making a Type II Error, which occurs when the conclusion made from the experiment that there is no difference between groups when in truth there is a difference.

Sample Size Calculation

The study compares two independent groups; the interventional and the control groups. The data has been summarized in proportions. The formula used for sample size calculation is as the following (Sitthi-Amorn, Keuyoo, and Lumpiganon, 1985)

$$n/group = \left[2\left(Z_{\alpha} + Z_{\beta}\right)^2 \bar{\pi}\ (1-\bar{\pi})\right] / \left(\pi_c - \pi_t\right)^2$$

n = The number of subjects

Z_{α} is the standard normal deviate corresponding to the probability

Type I error is set at 5%

Z_{α} = 1.65 (one tailed)

Z_{β} is the standard normal deviate corresponding to the probability

Type II error is set at 20%

Z_{β} = 0.84

π_c = Expected event rate in the control group

= Nosocomial urinary tract infection in the group without the guidelines

= 30% (average UTI rate)

π_t = Expected event rate in the treatment group

= Nosocomial urinary tract infection rate in the group with the guidelines.

= 15% (expecting of a 50% reduction in rate)

$\bar{\pi}$ = $(\pi_c + \pi_t)/2$

= (.30 +.15)/2

= .225

n/group = [2 (1.65 +.84)² .225 (1-.225)]/ (.30 - .15)²

= 96

2 groups = 192 subjects

Thus, to detect a 50% difference in reduction of the incidence of nosocomial urinary tract infection, testing the significance at 5% level and a beta level at 20%, we need a minimum number of subjects of total 192 for the study. Ninety six subjects are for each group either control or experiment.