

## CHAPTER VII

### ANALYSIS RATIONALE

Data summary and analysis depend on the questions being posed and the study design. This chapter deals with the summarization and the analysis of the data to answer the primary and secondary questions.

#### Summarization of Data

#### The Primary Outcome

The primary outcome is the urinary catheter associated infections. This outcome is summarized by using cumulative probability obtained through survival analysis. Survival analysis is an appropriate statistic for the study because time factor is considered in the analysis. The study data are suitable for survival analysis since they have the following characteristics:

1. **A Clear Starting Point for Inclusion of the Subjects into the Study** ; Patients eligible for this study are the ones who have urinary catheter indwelling during hospitalization. For each patient, the starting point is the date of catheter indwelling which is clearly defined.

2. **A Clear Onset of Events** ; The onset of urinary catheter associated infections has been detected at the dates of positive follow up urine cultures.

3. Allowance for Subjects Being Included in the Study at Different Points of Time and for Different Periods of Observations ; The patients are admitted to the hospital at different points of time. Similarly, the times of catheter indwelling vary among patients.

4. Allowance for Subjects Being Withdrawn from the Study before Events Occur ; In this study, the patients may or may not develop a urinary catheter associated infections at the time of the catheter removal or at the time when patients are transferred to other wards or when deaths occur.

All the infection data of each period have been included in the analysis. The duration of observation is considered in term of the numbers of days.

Life table analysis involves the following data.

- The observation periods ( $I_i$ )
- Numbers of subjects included at the beginning of the study ( $N_i$ )
- Numbers of events (infections) occur in each observed time period ( $E_i$ )
- Numbers of subjects withdrawn or censored without an event occurs for each observation period ( $W_i$ )

Table 2 Life table analysis of the infections

Observed time period (Ii) (days)	Numbers of Pts. at beginning (Ni)	Numbers of event occurred (Ei)	Numbers of Pts. withdrawn (Wi)	Survival Prob. (Pi)
<1				
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

### **The Secondary Outcomes**

The secondary outcome is the control behaviors of the nursing personnels. This outcome is measured by multiple methods, including questionnaires and observation with the checklists. Data from the observations and checklists have been used as a gold standard. All control behaviours performed have been recorded for the whole study group (experiment or control). The data of each group before and after the intervention are summarized in proportions, percentage, of practising according to the CDC recommendation.

### **Comparison of Outcomes**

The primary outcome is the urinary catheter associated infections. Differences in rates of infections over a period of urinary catheter indwelling between the two groups have been tested by using Mantel-Haenzel chi-square analysis. Statistical significance is declared when the p-value is below 0.05.

Adjustment for possible differences in some important baseline factors such as sex, age groups or severity of diseases have been carried out using co-variate adjustment (Mantel-Haenzel Chi-square).

### **Secondary Outcomes**

The secondary outcome is the control behaviors of nursing personnel. Before the intervention started, the control behaviors (or control practices) are monitored and subsequently summarized in proportions, percentage, of practising according to

the CDC recommendation. After having implemented for three months, proportions of the control behaviors according to the CDC recommendation will be compared between the control group and the intervention group. Unpaired t - test and paired t - test will be used to test the differences between the two groups and within groups respectively. Subsequently, at the end of the sixth month comparison between the two and within groups will be tested. Statistical significance is declared when the p-value is below 0.05.

Table 3 Summary of the outcome analysis

Research Question	Outcome	Comparison	Data Summary	Statistic Test
Primary Question	Infection Rates	2 independent Groups	Survival analysis	Mantel-Haenzel Chi-Square
Secondary Question (1)	Control behaviors	-	Episodes per person and proportions	-
Secondary Question (2)	Control behaviors	Within Groups	Episodes per Person in each item	Paired t-test
		Between Groups	Proportions of each item	Unpaired t-test Chi-square