CHAPTER IV

RESEARCH METHODOLOGY

This chapter is focused on the research design and design overview, the study setting, population and sampling, instruments and data collection procedures. For the following five studies: 4.1 retrospective study of the medical records of terminally ill patients; 4.2 attitude study in non-critically ill patients; 4.3 non-randomized control study in terminal ill patients; 4.4 focus group discussion with nursing staff; 4.5 self-administered questionnaires for medical staff.

4.1 Retrospective Study of the Medical Records of Terminally Ill Patients

This study was conducted in the Chiang Mai University Hospital. It was aimed at assessing the proportion of CPR performance in terminal ill patients. Since the study did not involve any new intervention or procedure, Institutional Review Board approval for this study was not needed but the confidentiality of patients and clinicians was respected (Polit and Hungler, 1999).

Medical records of terminally ill patients (using the definition of Bayer et al., 1983) who died in this hospital from January 1, 1996 to June 30, 1999 were searched by computer for eight diagnoses:

1) non-small cell lung cancer stage III or IV;
2) multi organ system failure with sepsis;
3) exacerbation of chronic obstructive pulmonary disease;
4) exacerbation of congestive heart failure;
5) non-traumatic and non-diabetic coma;
6) carcinoma of colon with metastasis to the liver;
7) acute respiratory failure;
8) end-stage liver disease.

The charts of patients with one or more of these diagnoses were reviewed using the Utstein Guidelines for in-hospital CPR research to obtain the following information: hospital variables, patient variables, event variables and outcome variables (Cummins et al., 1997).

Hospital variables refers to the location of arrest. Patient variables included: age; gender; arrest witnessed or monitored; ALS intervention in place at time of event; previous cardiopulmonary resuscitation events. The reason and procedure for admission, CPC score or pre-event functional capacity, the major cause of death and comorbid conditions were also included in this part. The major causes of death and comorbid conditions were identified by reviewing the attending physician's documentation on the face sheet of the medical record and in the discharge summary.

Event variables refer to the details of the CPR or NR episode. These were obtained from the concurrent detailed records made by the nurses during resuscitation

and the physician's progress notes and orders. Patient variables, hospital variables, event variables, and the following information was recorded: immediate precipitating cause for CPR; initial resuscitation condition; initial cardiac rhythm; resuscitation attempt; the first provider of CPR. Intervention record included: time collapse noted; time CPR team called; time arrest confirmed; time CPR started; time of achieved intubation; defibrillation and IV medication; time of CPR termination; duration of resuscitation effort.

The outcome variables included: patient survival or non-survival and the sustainability of return of spontaneous circulation.

Descriptive statistics were used to examine the demographic data and the chi square statistic was used to identify the relationships among discrete data (Polit and Hungler, 1999).

4.2 Attitude Study in Non-critically Ill Patients

After approval by the Institutional Review Board of Faculty of Medicine, CMU, we initiated an acceptability study of ADs for CPR. Patients who were admitted to the seven adult medical wards (three female and four male wards) from November 1, 2000 until December 31, 2000 were the study sample. Those, who were at least 18 years of age, alert, oriented, able to communicate in Thai and who agreed to participate by giving an informed consent, were eligible for the study. Patients with at least one of the following, usually terminal diagnoses (as determined by the responsible physician) were excluded: non-small cell lung cancer stages III or IV, non-traumatic and non-

diabetic coma, multi-organ system failure with sepsis, carcinoma of colon with metastasis to liver, end-stage liver disease, exacerbation of congestive heart failure, exacerbation of chronic obstructive pulmonary disease and acute respiratory failure. Patients with HIV/AIDS were also excluded. All of these patients may be sensitive to our questions and may need a specific approach.

According to CMU hospital admission policy, routine admissions are allowed on official days, Monday through Friday (8.00 a.m.- 4.00 p.m.). Only emergency and/or seriously ill patients are admitted during non-official times (4.00 p.m. - 8.00 a.m.) and during the weekend. Therefore, only patients who were routinely admitted to the male and female wards were randomly selected separately by gender; 4-6 cases/day, depending on the number of admissions on that day. When a selected patient's consent could not be obtained, another eligible patient in the same ward was randomly selected. All subjects were interviewed in person by trained interviewers using a structured questionnaire.

The questionnaire was developed based on the literature, which reflect the objective of the study; then, validated by five experts (two adult nursing instructors, one psychiatric nursing instructor, one nursing staff and one physician) and pre-tested with 10 ambulatory patients, who had similar characteristics as our study subjects. The questionnaire inquired about the participants' gender, age, marital status, religion, education, personal income and usual place of residence (rural/urban). The patients were, then, asked about their specific preferences with respect to CPR before and, then, after the presentation of different prognostic scenarios associated with survival chance post- CPR.

The scenarios were 1) if the chance of survival to discharge with CPR between 7-24% (as in acute onset of disease); 2) if survival was 0-5% (as in some specific diseases); and 3) if CPR may be followed by living permanently on mechanical ventilation or by a coma, or both.

The responses to these questions were "Yes CPR", "No CPR", "Up to Physician", and "Up to relative". Finally patients were asked to express their feelings regarding the discussion of ADs for CPR.

During the reliability testing, we found that this questionnaire should not be administered in a single interview; since the patients seemed to be tense. So we changed the interview method (noted below). The inter-rater and intra-rater reliability, assessed using Cohen's Kappa statistic (Munro and Page. 1993), was 0.80 and 0.85, respectively. No changes were required in the questions or in their sequence from that suggested by the experts.

During the data collection phase, the interviews were conducted in person by the primary investigator (s) and three nurses (who had research experience, were trained in the use of the structured questionnaire and were supervised by the primary investigator). The questionnaire was administered over at least two sessions by empathetic nurse-researchers who "paced" the interview according to when the subject seemed ready for next group of questions.

At the first visit, to obtain consent, we introduced ourselves, explained the objective, the process of the study and the method of selection of the subjects. All patients were assured that the confidentiality of their information would be respected. After receiving signed consent, the balance of the initial interview focussed on general information, including the demographic data. The next interview started again with the general topic and, then, moved forward to their CPR preferences and their attitude toward advance planning for CPR.

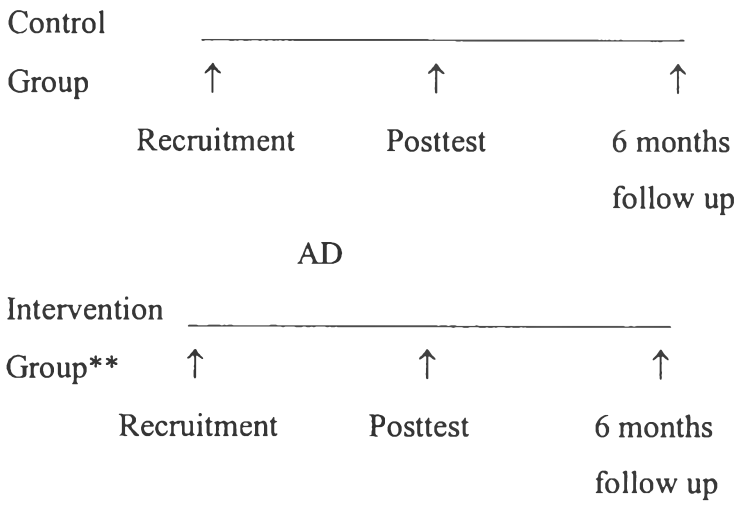
In the analysis, the demographic characteristics of the patients and their other responses were computed using descriptive statistics. Chi-squared statistics were used to test the difference (Polit and Hungler. 1999) in the demographic characteristics by gender. Patients preference for CPR (No-CPR vs. Yes-CPR in different survival scenarios) by; age, marital status, personal income level, place of usual residence and type of illness were computed using Multiple Logistic Regression (Munro. 2001). The odds ratio for each variable was adjusted for possible confounding by all other variables in the table. The statistically significant level was set at $p < 0.05$.

4.3 Non-randomized Control Study in Terminally Ill Patients

4.3.1 Research Design

This study is a quasi-experimental design. It is a non-randomized control study and after-only nonequivalent control group design.(Wood and Haber, 1998). The format of study is presented in figure 4.1

Figure 4.1 : Present an after-only nonequivalent control group design



* Adapted from Wood and Haber, 1998)

** Initiated after completion of the recruitment of the controls

4.3.2 Design Overview

The study was divided into two phases. The first phase was to collect data on the controls who were not questioned about AD or provided with information about AD. The second was designed to test the effectiveness of AD intervention provided to patients with terminal illnesses. This effectiveness was measured by three outcomes; CPR/NR event; discharge (whether by hospital/physicians or self-discharge by patients and/or families); and death (whether while in hospital or post discharge).

4.3.3 Study Setting

4.3.3.1 Organization of the Medical Wards

Since most of terminally ill patients recruited for this study were admitted to the medical wards, an explanation of organization and the physical structure of CMU

Hospital, especially that of the medical wards, may be helpful in understanding the study process used.

There were seven general medical wards (4 Male, 3 Female), three intensive care units (ICU), two sub-intensive care units (Male Sub ICU, Female Sub ICU), a coronary care unit (CCU) and two renal dialysis units. All of the seven wards were equipped with a fixed number of beds. However, the number of patients actually admitted to the wards was generally in excess of available fixed beds. To solve this problem, many temporary beds were employed between fixed beds, or were provided in the hallway and even in front of the elevators. The ICU-M and Sub-ICU offer only a fixed number of permanent beds; generally, no extra beds were provided in these units.

4.3.3.2 Structure of the Study Units

All of the male wards and the Male Sub-ICU were located on the fifth floor of the main building. The female wards and the Female Sub-ICU were located in the eleventh floor. The three ICU-M and two renal dialysis units were on the second floor. The CCU was in a different building and quite far from the others.

Generally, most of the terminally ill patients were admitted to medical wards. All seven medical wards, three ICU-M, and two Sub-ICU excluding the coronary care unit and renal dialysis unit, were our study setting.

4.3.3.3 Characteristics of Patients

The general characteristics of patients in the medical wards were quite similar. The segregation was only by sex. Thus, medical specialists and/or medical residents

may admit patients to any medical ward with general medical problems or any variety of specific problems that require attention.

4.3.3.4 Admission Policy

The admission policies for general medical wards (male or female) were the same. During 8 a.m.-16 p.m. on any official day, newly admitted patients were distributed evenly to the wards. On the other hand, all patients who were admitted between 16 p.m. to 8 a.m. were assigned to only one male (or female) ward according to a block rotation schedule. An exception was the Male IV (a three-day service), which admitted patients with cancer for three days or less for chemotherapy.

4.3.3.5 Admission Policies for the Critical Care Units

Critically ill patients and some terminally ill patients may be admitted directly from the emergency room or the medical out patient departments (OPD-Med), or by transfer from the general wards.

4.3.4 Population and Sample

4.3.4.1 Target Population, Study Sample

In the controls and interventions, the target population and the study sample were defined as follows. The target population was all terminally ill patients who were admitted to the CMU Hospital. The terminally ill patients who were admitted to the Target Units in the CMU Hospital during the study period and fulfilling the eligibility criteria were the study sample.

4.3.5 Eligibility Criteria

4.3.5.1 Inclusion Criteria for the Intervention Group and the Control Group

Patients and/or their Surrogates

1.1 Patients who were admitted to the general medical wards, the Medical-ICU, the Medical-sub-ICU (excluding CCU) in the CMU Hospital with at least one of the following five diagnoses, as determined by the responsible physician: non-small cell lung cancer stages III or IV, multi-organ system failure with sepsis, non-traumatic and non-diabetic coma with Glasgo Coma Score of 3, carcinoma of colon with metastasis to liver, and end-stage liver disease. These patients have previously been reported as terminal illnesses and have a poor outcome after CPR. (described in Chapters I and II)

1.2 Surrogate: the surrogate was a person (relative or non-relative) who was most qualified to make decisions on the patient's behalf. If the patient was competent to be interviewed, he (she) was asked to designate the surrogate. If the patient was incompetent, the selected surrogate was the person identified as being financially responsible for the patient.

1.3 Patients and surrogates who were at least 40 years of age, alert, oriented, able to speak Thai.

1.4 Patients and surrogates who agreed to participate by giving informed consent.

4.3.5.2 Exclusion Criteria for the Intervention and Control Groups

Patients and/or their surrogates who had a severe psychiatric problem or dementia.

4.3.6 Sampling Technique

For both of the control and the intervention groups, all 186 consecutive patients who were admitted in the study units of the CMU Hospital at the time of the study and their surrogates who met the eligibility criteria were the study sample.

4.3.7 Consent

The PI and/or a study nurse were initiated a contact with the patients and surrogates during the observation period. After explaining the objective and the process of the study, patients and surrogates were invited to participate in the study. Written consents were, then, obtained from patients and/or surrogates who met the inclusion criteria. These processes were performed in the ward of admission. For the control group, the consent was to: 1) Obtain the patient's information from the medical record 2) observation and contact with the patient and surrogate in the hospital 3) contact with the patient and surrogate at home. For the intervention group, the consent was for the same purpose as for the controls.

4.3.8 Sample Size Calculation

According to the sample size calculation for two-independent-groups, three main factors affect the sample size. These were type I error (α error), type II error (β error), and the population effect size or gamma (γ). (Polit and Hungler, 1999: 474)

The type I error means that the investigator has rejected the null hypothesis when, in fact, it was true (Polit and Hungler, 1999: 474). For instance, if we concluded that the advance directive intervention was more effective than the control or usual care in facilitating decision making for CPR in terminal ill patients, when in actuality the rate of decision making differences resulted only from sampling fluctuations, then we would have made a Type I error.

The two most frequently use levels of significance (often referred to as α, or alpha) are .05 and .01. By convention, the minimum acceptable level for α generally is .05. (Polit and Hungler, 1999: 474). In this study, an alpha of .05 was used.

Type II error occurs when the investigator accepts the false null hypothesis (Polit and Hungler, 1999: 474), which was the reverse situation from that mentioned previously. If we concluded that the differences rate in decision-making in the advance directive intervention group and the control group were the result of chance, when in fact the intervention did have an effect on decision-making, we would be committing a Type II error by wrongly accepting a false null hypothesis.

A convention standard for $1-\beta$ is 0.80. With power equal to 0.80, there is a 20% risk of committing a Type II error (Polit and Hungler, 1999: 474).

Gamma is a measure of how wrong the null hypothesis is; that is, how strong the effect of the independent variable is on the dependent variable in the population (Polit and Hungler, 1999: 474).

The value of gamma may be arrived at from the literature. Unfortunately, there was no such evidence in Thailand. In preparation for this study, an expected event rates (decision making rate) in the control group and in the intervention group came from our pilot study. For the expected decision making rate for CPR in the control group was obtained from interviewing 20 patients. Of these, 9 of them decided for no-CPR. In the intervention group, AD intervention were performed in 10 patients, of these, 6 decided for no-CPR

$$N / \text{group} = [2(Z\alpha + Z\beta)^2 \pi (1-\pi)] / [\pi c - \pi e]^2$$

πc = expected decision making rate for CPR in control group

$= 9/20 = 0.45$

πe = expected decision making rate for CPR in intervention group

$= 6/10 = 0.6$

$\pi = [\pi c + \pi e] / 2$

$= [\ 0.45 + 0.6\ ] / 2$

$= 0.53$

$N / \text{group} = [2(1.65 + 0.84)^2 0.53 (1-0.53)] / [0.45 - 0.6]^2$

$= [2(2.49)^2 0.53 (0.47)] / [0.15]^2$

$= 155$

At least 155 patients were the study sample in both of the intervention group and control group, with type I error of 5% and type II error of 20%.

For this study, we used 20% more subjects than we actually needed: 10%, as a replacement for patients and surrogates who may refuse permission and another 10%, as a replacement for patients who may withdraw from the study. Accordingly, approximately 186 patients per group were recruited.

From the pilot study, we found that the rate of recruitment was around 25-30 cases per month. Consequently, the time required to collect data for both the control and intervention groups was approximately 12 months.

4.3.9 Ethical Consideration

4.3.9.1 Risk/benefit

In previous studies, it was found that there were more benefits than risks of AD to the study subjects. (Described in Chapters I and II), because the intervention did not hasten or prolong death but rather facilitates patients' decision making for their own care. Patients had the right to choose any kind of treatment they need after being well informed. However, we were aware of risks such as psychological trauma and tried to prevent them.

4.3.9.2 Protection of Human Subject

The implementation of advance directives for CPR or no-CPR in terminally ill patients was a sensitive issue as psychological trauma may occur to patients in the intervention group. We tried to prevent this problem by providing a comprehensive approach and psychological support to the subjects and their families. Research assistants with a good basic knowledge in research, counseling skill and the experience

in caring for patients with terminal illness were selected for the study. They were trained in the use of AD at the beginning of the study and were regularly supervised throughout the study. Approval by the Institutional Review Board of the Faculty of Medicine, Chiang Mai University were sought before starting the study.

4.3.9.3 Withdrawal from the Study

All of our subjects and/or their surrogates were informed before enrolling that they may withdraw from the study at any time without effect to their treatment.

4.3.9.4 Confidentiality

The confidentiality of patients, families and health personnel were respected.

4.3.10 Working Pattern of the Nursing Personnel

The general medical ward, intensive care units and sub-intensive care units were staffed 24 hours a day. Daily work hours were divided into 3 shifts: the day, the evening and the night shifts. While the head nurses work only on the day shift, the other nurses were rotate among the shifts. Therefore, all nursing personnel, with an exception, of course, of the head nurses, in these wards were likely to be randomly distributed. During the evening shift and night shift on the official days and all three shifts on holidays, the most senior nurse on that shift took the responsibility of the nurse in charge of the ward.

4.3.11 Working Pattern of the Physicians

For medical staffs, only faculty staff members were fixed in accordance to their specialties. There was a three-year residency-training program in the Department of

Medicine and all medical residents were rotated every 1-2 month(s) according to the year of training.

4.3.12 Measurement

4.3.12.1 Measurement Tool

The measurement tool used in this study was the data collection tools (as shown in Appendix 4.3.12: NO.1, NO. 2C, NO. 2D, NO.3, NO.4, NO.5, NO.6, NO.7, NO.8, and NO.9). It included: record books for daily list of possible sample; two demographic data collection forms (to obtain data from medical record and interview) (Appendix NO.1, NO.2C); two consent forms (for patient and surrogate)(Appendix NO.8, NO.9); two observational guidelines (to record the clinical condition and terminal event)(Appendix NO.2D, NO.3); three follow up forms (to be used at 1, 3 and 6 months after study entry) (Appendix NO.4, NO.5, NO.6) and the AD intervention tool (Appendix NO.7). The detail of using these tools were presented in Section 4.3.16.2 (data collection).

4.3.12.2 Type of Measurement

There were three kinds of variable to be measured. These were independent, dependent, descriptive variables of population and sample.

4.3.12.2.1 Independent Variables

The independent variable measured in this study were as follows: diagnosis, age and gender.

4.3.12.2.2 Dependent Variables

For the dependent variable, these following variables were measured: clinical condition of patients at the time of enrollment, CPR/NR event; death whether in hospital or at home.

4.3.12.2.3 Descriptive Variable of Population and Study Sample

It was a description of the characteristics of all the patients who were eligible and who were excluded from the study. A total number of the eligible patients and surrogates who signed and did not sign the informed consent. The number of patients and surrogates in the study sample who withdrew from the study.

4.3.13 Composition of Advance Directive Intervention Tool

The AD, as currently envisioned, was outlined below. Importantly, this was confirmed with six experts to ascertain the content validity before the study started .

As described in Chapters I and II, the concept of advance directive was to extend the autonomy of patients, of their treatment decisions with the decisions to be made before the actual event occurs. It was intended to be used when patients were incapable to do so. The AD, as currently envisioned, was outlined below. Importantly, this AD was confirmed with six experts to ascertain the content validity before the study starts.

The AD (see Appendix NO.7) was composed of five parts that were intended to be implemented in a stepwise manner. Part I was composed of questions focusing on

patients' knowledge of their illness and prognosis. Part II addressed the patients' right to obtain the information regarding his/her illness. Part III was focussed on the patients' knowledge of CPR, CPR requiring mechanical ventilation, mechanical ventilator, and intensive care unit practices. Part IV, information was given to explain CPR procedure and the probability of success after CPR. Part V examined each patient's preference for CPR in different situations.

4.3.14 Measurement Outcome

Clinical conditions at the time of enrollment; CPR/NR event in each patient; discharge from hospital (whether at the suggestion of hospital/physicians or self-discharge initiated by patients and/or families); and death were measured.

4.3.15 Assessment of the Quality of the Measurement Tool

Content validity and reliability of the AD intervention tool will be assessed at the beginning of the study.

4.3.15.1 Content Validity

Content validity is concerned with the sampling adequacy of items for the construct that is being measured. (Polit and Hungler, 1999). This tool was developed from materials available in the literature, which reflect the objective of the study. The content of this AD draft were assessed, using their own professional criteria and accumulated experience, by six experts: a medical instructor, a psychiatric nursing instructor, a psychiatric nurse, and three medical-surgical nursing instructors who have extensive experience in caring for terminally ill patients.

To adapt the tool to the culture and beliefs of our subjects, input from 7-10 terminally ill patients was sought by personal discussion with the patients. Following the appropriate adaptation, the same experts were asked to review, to comment and to make suggestions. Their comments and/or suggestions were used in the final adjustment of the tool.

4.3.15.2 Reliability Testing

Reliability of a research instrument is defined as the extent to which the instrument yields the same results on repeated measurement. Reliability is then concerned with consistency, accuracy, stability, and equivalent (Polit and Hungler, 1999; Wood and Haber, 1998). One form of reliability testing, the interrater reliability was performed.

4.3.15.2.1 Interrater Reliability

To assess the consistency, a study was conducted in which two study nurses, the investigator and one of the trained research assistants, used the AD to measure the same set of patients (N=10) at the same time and , then, to record the episode independently. The correlation between the two observers were calculated by Cohen's Kappa (Munro and Page, 1993); a score of 0.7 or greater was considered as achieving adequate reliability (Polit and Hungler, 1999). The interrater reliability of this measurement was 8.5.

4.3.16 Study Process

4.3.16.1 Pilot Study

Before starting the study, a pilot study was performed to test the reliability of measurement tool (as just mentioned) and to assess the feasibility of the study. In addition, we used the pilot study result to estimate the sample size of study subjects.

4.3.16.2 Data Collection

The data was based on retrospective and concurrent medical record reviews, observation, interview, and AD intervention.

4.3.16.2.1 Study in the Control Group

In the first eight months, only the control group was recruited. About 188 consecutive terminally ill patients admitted to CMU Hospital and who satisfy the eligibility criteria were studied. This was done as follows;

4.3.16.2.1.1 Identification of the Study Subjects

Two nurses, the investigator (PI) and one research assistant, were make rounds on each of the study units on every official day. They reviewed all hospital admissions to identify the patients who qualify for the study. The PI and research assistant checked the definite diagnosis, which was made by the attending physician, to identify the patients who may fulfill the eligible criteria. For admissions during the weekend and holidays, the patients were searched in the same manner, on the following official day.

For those considered eligible, the PI and/or research assistant introduced his/herself to the patients, explained the objective of the study and invited them to participate in the study. After obtaining an informed consent from the patients, his/her surrogate was contacted in the same way as above. All patients and surrogates who met the eligibility criteria were included.

For those with consented, demographic data was gathered from the medical record and at the initial interview. The following demographic data were obtained from the patient's chart: name, diagnosis, co-morbidity, date of admission, address and home phone number, age, gender (Appendix NO.1). The following information was verified by interview: age, gender, address and phone number (Appendix NO.2C). In addition, the following information was sought at interview: religion, occupation, marital status and living condition (Appendix NO.2D), and the psychological stage (Appendix NO.10).

4.3.16.2.1.2 Observation

During the study period, the PI and research assistant searched for CPR or NR events in all study wards on a daily basis: to determine whether the event had occurred and, if so, the details of event which were recorded. Death data were also be retrieved from the medical records or the hospital information system when the patient died during hospitalization or during subsequent hospitalization episode(s) at the CMU Hospital.

Patients who were transferred to other hospitals, discharge by hospital or the self-discharge by patients and/or families were interviewed for reasons for the transfer or discharge.

The physicians were observed focusing on his/her action for CPR and NR event in each patient.

4.3.16.2.1.3 Follow Up Studies

For those who were still alive at 6 months, phone/mail were made at 1, 3 and 6 month(s) after study entry. This was aimed at assessing current clinical conditions of the subjects, CPR/NR event and survival of patients after discharge. Finally, the date of death was recorded.

4.3.16.2.2 Study in The Intervention Group

One hundred and eighty-eight consecutive patients who met the eligibility criteria were recruited. The data collection process in which we identified subjects, obtained the demographic data from the medical record and interview, performed the observation and the follow up study was exactly the same as the control group. In this group, the only difference was the provision of AD.

To facilitate the study process, there were five research assistants working as the study nurses. They were responsible for observation, providing AD intervention and collecting data on a daily basis. Each study nurse was assigned for 2-3 wards, as follows:

The first study nurse was responsible for Male I and II; the second: Male III and IV and Female III; the third: Female I and II; the fourth: Male Sub ICU, Female Sub ICU; the fifth: ICU-M I, II, and III.

If any one of the study nurses was not available, the PI or another assistant were available to cover his/her work. The PI were also responsible for the overall management of the study.

4.3.16.2.2.1 AD Intervention by Study Nurses

For subjects in the intervention group, after the patient and surrogate signed the consent, the AD interventions were done using face-to-face interviews. In order to obtain independent data, it was necessary to interview the patient and the surrogate separately.

Study nurses provided the AD intervention to the subjects and family members. This intervention were performed in a stepwise manner in accordance to the AD intervention tool (Appendix NO.7) as follows:

1. Assess the awareness of patient of his/her illness and it's prognosis.
2. Assurance of patient's right to obtain information regarding his/her illness. Encouragement to patients and surrogates to obtain the following information from physicians: diagnosis, prognosis and the likely outcomes of treatment. Study nurses helped to arrange an appointment between patients, family members and physicians, if needed.

After the AD intervention, the study nurses assessed the intention of physician for CPR/NR in terminally ill patient by questionnaire. The actual action, either CPR or NR, provided to each particular patient were measured.

The results obtained from both patients and physicians will be used to measure the correlation between physician intention vs. physician action, physician intention vs. patient decision, physician action vs. patient decision, physician intention vs. patient action.

3. Provision of CPR information. By explaining: in this hospital, we will try on our best to help our patients. For example, if your heart stop beating, we will try to revive it by pumping on your chest but the chance of surviving to discharge depends on several factors. There were: the underlying diseases, its severity, and the actual condition of patient before CPR and the time to start and the duration for CPR. Generally, one out of four patients may survive after this attempted. In contrast, patients with serious illnesses and worse conditions may have much lower chance of survival. In addition, these patients usually need artificial ventilation and admission to ICU after CPR attempted.
4. Determination of patient's perception of disease, prognosis, CPR and the likely outcome after CPR.
5. The final part examines each patient's preference for CPR in different situations.

Importantly, we provided psychological support to patients and families during the whole process of the study. The study nurses assessed the type of patient's coping with illness (mentioned in Chapter II), psychological reaction (just previously mentioned) and provided psychological support accordingly.

In every step, we allowed adequate time for discussion, clarification, and questions as needed. Otherwise, we made an appointment for a return visit. The time for discussion in each step could vary and depended on the perception of individual patient and/or surrogate. The nature and timing to visits must depend on the inclination and energy level of the patient rather than on a fixed schedule of appointments. The agenda was set at least partly by the patient. If an issue arose that the patient clearly did not wish to discuss, this wish was respected.

The surrogate were presented with a questions for CPR in order to determine their CPR choices on behalf of the patient.

Similar clinical outcomes were then observed and recorded. After finishing the study of the control and intervention groups, all data were analyzed.

4.3.16.2.2.2 Stability Study in the Intervention Group

Re-admissions were not uncommon for these groups of patients. If patients were re-admitted during one month following the AD intervention, the follow-up questionnaire, which was identical to the first except for the omission of demographic

information, was administered. This was intended to assess the stability of decision making of the subjects.

4.3.16.2.2.3 Documentation of AD

The pilot study revealed that most subjects were willing to participate in the study and believed that this study was useful. However, none wanted to sign the written advance directive form or any legal document. They were reluctant to commit themselves on record and would prefer to retain more flexible control by giving their wishes in words to the next of kin. The surrogates had to transfer the directive to caregivers by themselves. And the nurses or the physicians who took this word had to communicate to his/her team or the care provider again. In order to respect patient's right, no AD documentation was noted on patients' medical records. We recorded their decisions only in the AD intervention and in an observational guideline, patients were encouraged to transfer their wishes in words to the surrogates and we also followed the outcome.

4.3.16.3 Statistical Analysis

The SPSS statistical package was used to analyze the data. Descriptive statistics were used for all demographic data as well as the nature and extent of decision making of the patients and families with respect to AD. Multiple logistic regression was used to analyze factors affecting the decision making of patients (Streiner and Norman, 1989). The Chi-square was employed to test the differences between the decision making of patients and family members and the actual care provided to them. (Polit and Hungler, 1999) Finally, the 95% CI method were also used to test the differences between the

main outcomes (CPR rate, clinical conditions, and mortality rate) between the intervention and the control groups. (Polit and Hungler, 1999)

4.4 Focus Group Discussion with Nursing Staff

The primary investigator conducted the focus group discussion. The aim of the discussion was to gain a better understanding of traditional practice and beliefs in terminal care and the acceptability of advance directive for terminal care in terminally ill patients. The topic of discussion was also focussed on the information about illness, the attitude towards ADs for CPR and end-of-life care, and ADs in actual practice.

A series of three meetings were organized, one for the head nurses and another two for staff nurses. We divided the nurses into two groups: head nurses and staff nurses. This was done to encourage complete truthfulness and unbiased discussion, which might occur if both head nurses and staff nurses were in same meeting. Because of their valuable experience and possibly high impact on further application of AD, head nurses from all 12 wards were invited and encouraged to participate in the focus group discussion.

One-two staff nurse(s) from each ward was randomly selected. Focus group discussion for staff nurses were performed once for 5 and 7 wards. The ideal numbers of nurses in each group were 7-10 (Krueger, 1988). An average time for discussion in each group was about 45-60 minutes.

After explaining the objectives of the study, nurses who were working and/or caring for terminally ill patients in the general medical wards, the Medical-ICU, the Medical-sub-ICU in the CMU Hospital at the time of study were invited to participate in the study. Consent was also needed from all participants.

The results of the preliminary studies (retrospective study of medical record and attitude study in non-critically ill patients) and including the results of the controls and AD interventions were presented to nurses who agreed to participate in the study. Focus group discussions for the nurses were held during the day shift; recalling that all staff nurses were rotated through each shift.

The discussion were held in an informal and friendly atmosphere with the investigator acting as a moderator. To reduce language and cultural barriers, discussion were conducted using the northern Thai dialect. All information were tape-recorded to ensure completeness. Research assistants who can speak and understand the northern Thai dialect also took notes. After the discussions, tapes were transcribed and summarized by the note-taker, using their notes as a guideline.

4.5 Self-administered Questionnaires for Medical Staff

For physicians, the study using self-administered questionnaire were conducted in one month period, from June 15, 2002 to July 15, 2002. The aim of the study was to gain a better understanding of traditional practice and beliefs in terminal care and the acceptability of advance directive for terminal care in terminally ill patients. The questions were similar to those with nursing staff. It focussed on the information about

illness, the attitude towards ADs for CPR and end-of-life care, and ADs in actual practice. The intention of physician for CPR/NR in terminally ill patient was also questioned.

After explaining the objectives of the study, physicians who were working and/or caring for terminally ill patients in the medical department, in the CMU Hospital at the time of study were invited to participate in the study. Consent was also needed from all participants.

The instruction and the results of the controls and AD interventions including the preliminary studies (retrospective study of medical record and attitude study in non-critically ill patients) were presented on the front sheet of the questionnaire. Self-administered questionnaire was completed by the physicians at their convenience. The telephone number of the primary investigator and research assistant were provided and they were available to answer any question and to pick up the completed questionnaire.