# FACTORS RELATED TO HEALTH STATUS AMONG ISCHEMIC STROKE PATIENS WITH DYSPHAGIA

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Thesis
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ABSTRACT

Dysphagia is associated with poor outcome in ischemic stroke patients. The number dysphagia of ischemic stroke patients admitted in Bach Mai hospital has been rising in recent years. The aimed of this research was to examine the relationships between severity of stroke, levels of dysphagia, nutritional status and health status among ischemic stroke patients with dysphagia (ISPD). Symptom management theory was utilized as a framework of this study. This was a descriptive correlational research was conducted among 115 ISPD (mean age 66 ± 10.4; 60.87% men), who were admitted to the Neurology Department, Bach Mai hospital, Hanoi, Vietnam. Data were collected using the patients' hospital record and interviews. Stroke severity and dysphagia assessment methods using the NIHSS and the GUSS were also used. Spearman's rho was employed to test the relationship among all variables. According to the research findings, 51.30% of the patients suffered from moderate stroke, 66.09% of patients had slight dysphagia, and 88.70% were nutritionally at-risk. The average scores of Physical Component Summary were 35.12±7.25 and Mental Component Summary was 37.27±12.45. Severity of stroke and the levels of dysphagia were negatively correlated with physical health ($r = -0.45$, $p<0.01$; $r = -0.312$, $p<0.01$ respectively) and mental health ($r = -0.54$, $p<0.01$; $r = -0.711$, $p<0.01$ respectively) whereas nutritional status was positively correlated with both physical and mental health ($r = 0.42$, $p<0.01$; $r = 0.23$, $p<0.05$ respectively). The findings of the present study make the following recommendations: nurses should assess and detect the patients' dysphagia symptoms as soon as possible in order to promote their suitable diet, improve the patients' health status. Standard guidelines should be developed and implemented. Further research should be conducted to test the effectiveness of the guidelines.

KEY WORDS: ISCHEMIC STROKE / DYSPHAGIA/ HEALTH STATUS / NUTRITIONAL STATUS / STROKE SEVERITY

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# CHAPTER I
# INTRODUCTION

## 1.1 Background and significance of the study

World Health Organization defined that the rapid development of clinical signs of cerebral function's focal (at times global) disturbance is known as stroke. It extends more than 1 day (24 hours) or even leads to death because of vascular origin (Elkind & Sacco, 2010). Ischemic stroke makes up 87% of all strokes (Go et al., 2013; Mozaffarian et al., 2015). Stroke is a harmful disease which takes negative effects on 15 million individuals in the world annually (Grysiewicz, Thomas, & Pandey, 2008) and following to death record. Sstroke is the second cause worldwide (Basri et al., 2012; Edwardson & Dromerick, 2015; Mackay & Mensah, 2004), accounting for 10% of overall fatalities (Freitas, Bogousslavsky, Bezerra, & Maulaz, 2005). A study of Basri et al. (2012) among Asian countries found that stroke has caused many deaths in ASEAN nations. Particularly, the death rate ranges variously in different countries. In Thailand, 10.9 dies out of 100.000 patients suffering from strokes and this figure is much higher in Singapore with 54.2 people out of 100.000 patients (Basri et al., 2012). According to Vietnam Breaking News published in 2013, there were 200,000 people suffering from stroke in each year, and half of them died.(Vietnam Breaking News, 2013).

The long-lasting negative impacts of stroke have been realized recently and concentration has been formed to take proper measures in order to evaluate people's living standard. Human's life is affected considerably in several aspects namely physicality, mental functions, memory and thinking, communication and role function. It effected on social participation (Sriram, Asokan, & Thomas, 2015). Elkind & Sacco (2010) claimed that stroke is more often disabling than fatal, serious neurologic disability is caused by stroke. Consequently, stroke leads to costly measures for not only in health care sector but also in economics (Elkind & Sacco, 2010). Mackay & Mensah's research (2004) showed that there is 10 percent of stroke survivors

completely recovery. This is followed by the figure for people with some disabilities, at about a quarter. Also, serious disabilities have 40% for patients who need special health care services. 10% for patients need to be stayed in nursing home or other permanent facility, and the rest 15% decreases in a short time after the stroke (Mackay & Mensah, 2004). Follow the estimation of Hudson, Ross, & Taylor (2006) showed that the NHS £2.8 billion annum is the cost of stroke and £4.2 billion is the further cost subjecting to health care service after stroke, productivity and disability loss (Hudson, Ross, & Taylor, 2006).

Dysphagia can be easily found on patients with strokes, but its frequency is reported contradictorily from 19% to 81% (Asadollahpour, Baghban, Asadi, Naderifar, & Dehghani, 2015; Barer, 1989; Meng, Wang, & Lien, 2000; Mourão, Lemos, Almeida, Vicente, & Teixeira, 2016; Suntrup et al., 2012). According to a recent study, dysphagia after stroke is very common in Vietnam (at about 81%) (Tri & Huong, 2011). The more serious dysphagia is, the more popular pulmonary complications are (Marik & Kaplan, 2003; Martino, Martin, & Black, 2012) and even leads to death (Ravi & Christie, 2014).

All ischemic stroke patients with dysphagia may have many complications which have negative impacts on their health status (Ravi & Christie, 2014). According to World Health Organization, it is a person's scale of good or bad health, biological and physiological dysfunction, symptoms. Functional disability can be taken into account. In details, it can also be referred to the manifestation's levels of patient's disease such as functional impairment, symptoms and life's quality which are the discrepancy between desired and actual function (Rumsfeld, 2002). In fact, in order to make patient-centered care better. It is necessary to take advantage of surveys on standardized patients to evaluate all aspects of health status. Ischemic stroke patients' health status deteriorated resulting in their self-care ability. Also, they have to depend on others so excessively that impose a burden on their family. They must seriously cope with psychological problems. Unless patients are concerned with uncertainty of their illness status and therapy results, they will feel stressed and their self-esteem may be reduced, leading to a tremendously negative impact on their living standard. In the literature, many factors effecting health status of ischemic stroke patients have been described.

In particular, stroke is considered as a major cause of increasing people's capacity limit to have daily activities (Bogousslavsky et al., 2006), leading to patients' health status. Stroke can impair several neurological functions and the most popular one is the ability of being paralyzed (Chen, Epstein, & Stern, 2010; Dancause & Nudo, 2011; Hosp & Luft, 2011; Takeuchi & Shin-IchiIzumi, 2012). Higher level of the severity of neurological deficit leads to higher neurological severity of daily activities' deficit thus patients' health status is sharply decreased. Beside the physical disability, there are numerous conditions which undermine a person's health such as the loss of independent ability as well as the employment causing depression. Moreover, other severe diseases which occur on many patients with stroke could take badly effects on their disability (Nguyen, Tran, & Lee, 2013).

The difficult in eating and swallowing is defined as dysphagia. Symptomatic dysphagia is recorded in approximately one fourth to one third of stroke patients. An increased risk for pulmonary complications is connected to the presence of dysphagia (Sura, Madhavan, Carnaby, & Crary, 2012) and even mortality (Altman, 2006; Singh & Hamdy, 2006). Rainbow & Marks (2001) take the levels of dysphagia into consideration, they concluded that different levels can affect patients' health status in term of increasing risks of pressure ulcers, anxiety or depression; otherwise, or even reducing stamina, wound healing and physical recovery (Rainbow & Marks, 2001).

According to Kenneth Wayne Altman, Gou-PeiYu, & Schaefer (2010), functional improvement reduction, prolonged hospital stays and increasing complication rates are connected to impaired nutrition (K. W. Altman, Gou-PeiYu, & Schaefer, 2010). Nutritional status plays a significant role in each person because it is known the balance between two kinds of energy – energy emanating from nutrition intake and the rest which human use for metabolism process. In fact, metabolism process combines with energy storage which is used to do exercises and to improve a person's health status. Strategies to manage dysphagia, food and fluid intakes can be found by estimating nutritional status of stroke patients (Sura et al., 2012). As a result, lower health status could be appeared on patients with high risk of malnutrition.

According to the literature review, the ischemic stroke patients with dysphagia may have many complications which have badly impacts on their health

status (Ravi & Christie, 2014). However, in order to manage the negative ones, nurses should clearly study about the factors relating to patient's health status. Actually, the researches on factors relating to health status among ischemic stroke patients with dysphagia are still rare in Vietnam. In particular, in Neurology Department of Bach Mai Hospital, a scarcity of such a kind of research exists as well. This study aims to find out the factors relating to health status among ischemic stroke patients with dysphagia.

## 1.2 Research questions

What are the factors related to health status among ischemic stroke patients with dysphagia?

## 1.3 Purpose of the study

The specific aims of this research are following:

1) To describe the health status of ischemic stroke patients with dysphagia at The Neurology Department, Bach Mai Hospital in 2016.

2) To identify potential associations amongst levels of dysphagia, nutritional status, and stroke severity with health status in ischemic stroke patients with dysphagia among these patients.

## 1.4 Hypothesis

1) Severity of stroke is negatively correlated with health status in ischemic stroke patients with dysphagia.

2) Levels of dysphagia is negatively correlated with health status in ischemic stroke patients with dysphagia.

3) Nutritional status is positively correlated with health status in ischemic stroke patients with dysphagia.

## 1.5 Conceptual framework

In order to understanding the researched subject and providing a good background, symptom management theory contributes as a major theoretical framework that includes three main concepts such as symptom management strategies, symptom experience, and symptom outcomes (Humphreys et al., 2014). Moreover, these components are viewed in a broader scale of the whole healthcare environment where patients are treated including the environment (social, physical, cultural), person (psychological, demographic, sociological, physiological, developmental) and illness and health (health status, risk factors, disease injury) (Dodd et al., 2001). The symptom experience includes the patient's symptom perception, assessment and the response. Perception of symptoms cites an individual notices a change from the way he or she usually feels or behaves. The judgments which people make about their symptoms namely treatability, cause, symptom severity and the symptoms' effects are evaluation of symptoms. Moreover, according to Larson et al. (1994) and Levine & Shefner. (1981), responses to symptoms contains thoughts, feelings, or behaviors which are secondary to potential health problems or actual (Larson et al., 1994; Levine & Shefner, 1981). All troublesome symptoms are in need of management that is a basic hypothesis in the model. Moreover, not only symptom outcomes but also symptom experience should be controlled and influenced by symptom management. By using biomedical, professional, and self-care strategies, symptom management aims to avert or delay negative outcome. From a patient's perspective, the symptom experience becomes the first assessment of management. Symptom management can include interventions aimed at one or more of the components in the symptom experience to influence one or more desired outcomes. There is undeniable the fact that changes in strategies over time or in response to a patient's acceptance (or lack of acceptance) of the strategy are required by symptom management because it is a dynamic process (Larson et al., 1994). According to Larson et al. (1994), there are 10 multidimensional indicators which conceptualize the association of outcomes with the symptom experience in the model such as financial status, functional status, symptom status, comorbidity, health service utilization, mortality, self-care ability, morbidity, quality of life and emotional status. Moreover, patients' functional status to a level where they can function independently is desired (Larson et al., 1994).

In this research, the association between outcomes and health and illness domain will be used as the theoretical explanations of the relationships among studied variables. All ischemic stroke patients with dysphagia may have many complications which have negative impacts on their health status. In other word, health status refers to symptom outcome. In the model, the illness and health domain comprised of variables unique to the health and illness state of an individual and includes disabilities, risk factors, or injuries (Dodd et al., 2001). Furthermore, dysphagia, nutritional status, and stroke severity are derived from the health and illness domain in the current study. In particular, dysphagia represents injuries in the brain, which particularly influences the functions of the throat. After surviving from stroke, patients have a lot of problems such as reduced dietary intake, and other neurological deficits that might impact on nutrition. The severity of stroke is a complex factor, which present the severity of neurological impairments (Bogousslavsky et al., 2006). Theoretically, Dodd et al. (2001) concluded that illness and health domain could influence outcomes domain (Dodd et al., 2001). Therefore, it could be hypothesized that dysphagia, nutritional status, and severity of stroke are related to health status among stroke patients. The conceptual framework below shows the relationship between independent variables and dependent variable.

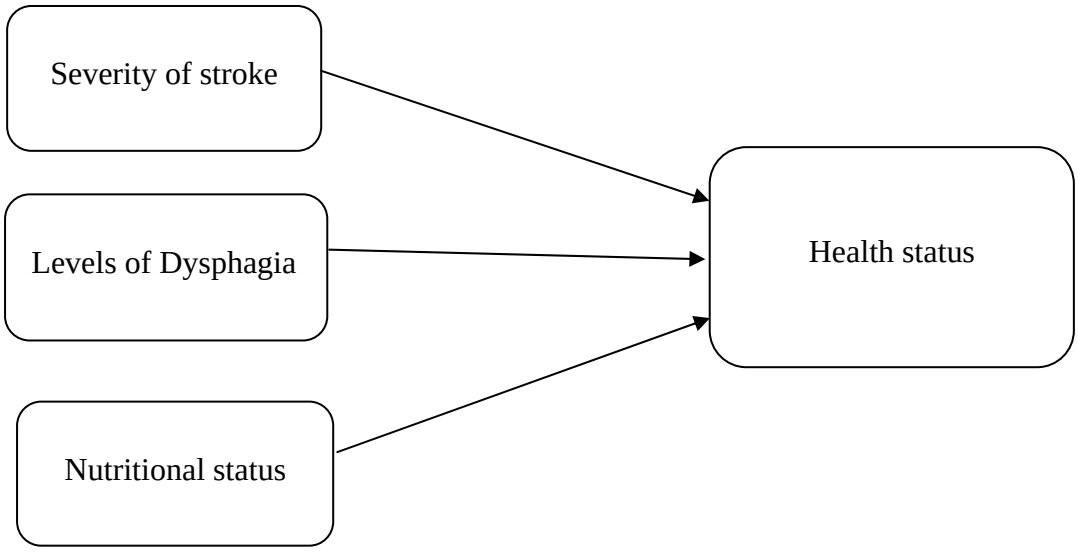


**Figure 1.1** The conceptual framework of health status in ischemic stroke patients with dysphagia modified from health related symptom management theory (Dodd et al., 2001).

## 1.6 Scope of the study

This study aimed to examine its association with nutritional status, stroke severity, and level of dysphagia in ischemic stroke patients with dysphagia. Subjects of this study are Vietnamese adults who suffer from ischemic stroke with any levels of dysphagia. The study is conducted at the Department of Neurology of Bach Mai hospital, Ha Noi, Vietnam.

## 1.7 Expected outcomes and benefits

1) Nurses can use the knowledge gained from this study for dysphagia screening and early detection in order to improve health status in ischemic stroke patients with dysphagia.

2) This study examines the associations between several important factors and health status of patients. Based on the findings healthcare teams can evaluate and develop effective clinical nursing practice guidelines or intervention programs to improve health status of ischemic stroke patients with dysphagia.

3) The knowledge gained from this study can be utilized for the researchers in the other areas of stroke studies. This study provides basic data to conduct future researches to improve health status among ischemic stroke patients with dysphagia.

## 1.8 Definition of terms

1.8.1 The range of manifestation of disease in a given patient is known as health status which functional limitation, including symptoms, and quality of life. Specifically, quality of life is the discrepancy between desired function and actual (Rumsfeld, 2002). Health status will be measured by SF-12v2 scale (Maruish, 2012; Ware, Kosinski, & Keller, 1996). The SF-12v2 scale is 12-item questionnaire that measures eight dimensions of health status: mental health, social functioning, physical functioning, role-physical, bodily pain, role emotional, vitality, and general health. Physical and mental composite scores are calculated from those dimensions. For each

dimension, after being coded, scores are summed and transformed to scale from 0 to 100 in which a higher score denotes better health status (Maruish, 2012).

1.8.2 Severity of stroke in this study will be conceptually defined as degree of neurological deficits observed after the occurrence of an acute stroke (Spilker et al., 1997 ). Severity of stroke will be measured with the NIHSS. The NIHSS is a 15-item instrument dealing the cerebral infarction's severity (Brott et al., 1989; Kasner et al., 1999; Spilker et al., 1997 ). The score illustrated observed levels of wakefulness, language function, sensation, vision, movement, and perception. Total scores can vary from 0 to 42 with higher scores-an indicator of increased severity (Mack, Dusick, Martin, & Gonzalez, 2012; Spilker et al., 1997).

1.8.3 Level of dysphagia is defined as degree of difficulty swallowing observed after the occurrence of an acute stroke (Trapl et al., 2007). Level of dysphagia will be measured with GUSS. The GUSS consists of two parts preliminary investigation / indirect and direct swallowing test, each of which scores a specific ability. The scores in part 1 will be maximum 5 to minimum 0. The scores in part 2 will be maximum 15 to minimum 0. The highest score that one patient can get is 20 while the lowest one should be 0. The lower scores indicated the increasing of dysphagia (Trapl et al., 2007).

1.8.4 The condition of the body in those respects is denoted as nutritional status which influenced by the levels of nutrients in the body, the diet and the ability of those levels to maintain normal metabolic integrity (Kondrup, Allison, Elia, Vellasz, & Plauth, 2003). The nutritional status will be measured by Nutritional Risk Screening 2002 (NRS-2002) scale. There are two screening phases which are caused by the NRS-2002. Four simple questions covering BMI, recent weight loss, reduced intake and the illness severity are consisted in the initial screening phase. The second phrase screening should be done if the "yes" answer existed for any questions. If patients answer "no" for all questions, they should be rescreened on a weekly basis. Nutritional status and disease state are two aspects which the second phase screening entails scoring the patient on. For nutritional status a score is allocated looking at the variable (BMI, dietary intake or recent weight loss) that is the worst off. Based on the illness, the patient is scored for disease state. In order to score the patient, clinical judgment must be used in case the specific illness does not exist in the table. Patients

need for immediate nutritional support because of “at risk of malnutrition” with patients’ scores equal to or more than 3. The specific nutritional support to be followed is not specified. Patients with scores between the ranges of 0-2 should be rescreened on a weekly basis. According to Sorensen, Kondrup et al. (2008), with a kappa value of 0.67 between a nurse, dietician and doctor 0.40 and 0.76 between 28 doctors, the trustworthiness of the NRS-2002 has been reported well. (Sorensen et al., 2008).

# CHAPTER II
# LITERATURE REVIEW

This chapter mentions the literature review of factors related to health status among ischemic stroke patients with dysphagia. The contents enhance the understanding of the phenomena of health status among ischemic stroke patients with dysphagia based on symptom management theory as following 4 issues including the conclusion part:

2.1 Problems among ischemic stroke patients with dysphagia

2.1.1 Incidence of ischemic stroke and dysphagia in ischemic stroke

2.1.2 Pathophysiology of dysphagia after ischemic stroke

2.1.3 Impact of dysphagia after ischemic stroke

2.2 Health status among ischemic stroke patients with dysphagia

2.2.1 The concept of health status

2.2.2 Health status among ischemic stroke patients with dysphagia

2.2.3 Measurement of health status among ischemic stroke patients with dysphagia

2.3 Symptom management theory as a conceptual framework to explain health status among ischemic stroke patients with dysphagia

2.3.1 Symptom management theory

2.3.2 Symptom management theory and the ischemic stroke patients with dysphagia

2.4. Factors associated with health status among ischemic stroke patients with dysphagia

2.4.1 Severity of stroke and its association with health status among ischemic stroke patients with dysphagia

2.4.2 Level of dysphagia and its association with health status among ischemic stroke patients with dysphagia

2.4.3 Nutritional status and its association with health status among ischemic stroke patients with dysphagia

2.5 Conclusion

## 2.1 Problems among ischemic stroke patients with dysphagia

### 2.1.1 Incidence of ischemic stroke and dysphagia in ischemic stroke

In most countries in the world, stroke has been recorded as the third reason leading death and even leading cause of prolonged disability (Caplan, 2009). In America, nearly 800,000 patients undergo a new or recurrent stroke annually. A majority of them (more than 600,000) are first attacks; the share of ischemic stroke makes up 87 % of all strokes (Go et al., 2013; Mozaffarian et al., 2015). In spite of the fact that stroke can take place at any age, the incidence of stroke markedly jumps with age (Brainin, Heiss, & Heiss, 2010), rising twofold for every decade after 55 years old (Brainin et al., 2010; Ovbiagele & Nguyen-Huynh, 2011).

One of the most striking problems recorded amongst patients after stroke is dysphagia. It is defined that dysphagia is the swallowing difficulty and is a side-effect of stroke. According to Rosemary Martino and her partners, for acute patients, the dysphagia rates are told to be from 29 to 67% (Rosemary Martino et al., 2005). Patients with stroke who have dysphagia are twice as likely to die as patients without dysphagia. Several studies have also demonstrated that patients with dysphagia have higher incidence of aspirated pneumonia, longer length of hospital stay, as well as more severe levels of disability years after their stroke (Ravi & Christie, 2014). It is indicated that the risk of pneumonia can be reduced, hospital stay can be shortened and expenses for healthcare can be lessened as long as we can detect and manage the patients' dysphagia (David G. Smithard, Smeeton, & Wolfe, 2007). The timing and method to assess swallowing ability varies. We can identify dysphagia on a patient based on either or both of clinical or radiographic examinations.

Currently, literature review showed that the incidence of dysphagia after stroke was high. The study of Gosney, Martin, & Wright. (2006), in which, 203 acute stroke patients with first-ever stroke from 3 hospitals were evaluated both bedside evaluation and water-swallowing test within 24 hours of symptoms onset. The results indicated that on admission 29% of patients were considered to be dysphagic (Gosney, Martin, & Wright, 2006). A related study on 1,288 patients with first time stroke conducted by David G. Smithard et al., (2007), in which, dysphagia was assessed by clinical examination within 1 week after stroke, and patients were followed up at 3 months and yearly for 5 years. The results indicated that 44% of patients had dysphagia at the point of first assessment (David G. Smithard et al., 2007). A review of 596 ischemic stroke patient charts within 14 days by Remesso et al. (2011) reported that 19.7% of patients suffered with dysphagia, of those, 91.5% of cases were mild dysphagia (Remesso et al., 2011).

Similarly, the results of a clinical swallowing assessments were compared with NIHSS score ≥ 12 of 50 acute stroke patients showed that 16 (32%) patients had dysphagia, in which, 14 patients with dysphagia had NIHSS scores ≥ 12 (Okubo, Fábio, Domenis, & Takayanagui, 2012). A study conducted by Baroni, Fábio, & Dantas. (2012) on 212 stroke patients admitted to the hospital found that 63% of patients presented with dysphagia. Of these, 19% were mild dysphagia, 38% were moderate and 43% were severe; the rate of mortality was higher among patients with any levels of dysphagia at three month after stroke (OR 6.54; 95% CI 2.23 to 19.21) (Baroni, Fábio, & Dantas, 2012).

Lastly, Flowers, Silver, Fang, Rochon, & Martino. (2013) reviewed 221 of acute stroke patients' charts, they explored that 44% of patients had dysphagia with the median time to diagnosis was 2.0 days (ranging between 0 and 26 days) following stroke onset. The odds of experiencing dysphagia were higher for patients with a lower CNS score and lower consciousness level (OR 1.4, 1.3 to 1.6; OR 2.6, 1.03 to 6.50 respectively) (Flowers, Silver, Fang, Rochon, & Martino, 2013).

In some countries, the prevalence of dysphagia is different. In the United States, dysphagia occurs in approximately between 51% and 73% of stroke patients and 75 % of nursing home patients (Perlin, 2006). With respect to other countries, a research conducted by Park TH within 11 stroke centers in Ontario, Canada (2014)

worked out an estimated percentage of post-stroke oropharyngeal dysphagia at 64-68%. Another study by Wiedmann with the sample of over 260,000 patients who had suffered from acute stroke all over Germany showed that the rate of dysphagia was 86.2% (Wiedmann et al., 2014). A similar research in Taiwan carried by Ho revealed the number of patients suffering from dysphagia after stroke accounted for 53.61% (Ho, Liu, & Huang, 2014).

On the other hand, in Vietnam, there have been several recent in-depth researches on dysphagia; however, the separated studies provided different estimations of dysphagia rate. For example, doctoral dissertation by Phan Nhut Tri and Nguyen Thi Huong study on 200 cases of acute cerebral stroke from August 2010 to July 2011 screened dysphagia with the support of GUSS. The result indicates that dysphagia after stroke is very common, at 81% (Tri & Huong, 2011). Other authors, Ma Le Quan and Nguyen The Dung came up with a remarkable lower rate at 57.63% and 64.3% respectively.

In conclusion, the studies above indicated that the incidence of dysphagia among acute stroke patients was quite high ranging from one third to two-thirds of those patients, depending on the sample size and assessment method used.

### 2.1.2 Pathophysiology of dysphagia after ischemic stroke

There are three types of swallowing. Subconscious swallowing occurs approximately once every minute. Eflexive swallowing is an airway-protective mechanism triggered by a sudden stimuli, such as the arrival of refluxate from the stomach or an inadvertent drop of food into the pharynx. Nutritional, or volitional swallowing occurs when eating.

To control volition swallowing, a network in the cerebral cortex that includes the insula, cingulate gyrus, prefrontal gyrus, somatosensory cortex, and precuneus regions is all triggered. In contrast, a reflexive swallow activates only the sensorimotor area. When a person has a stroke, one or more of these areas is usually damaged. Consequently, the swallowing network is disrupted and thus debilitates the command center, causing the swallowing impairment (Barer, 1989). Patients may demonstrate symptoms of dysphagia if a stroke affects the brain stem, such as with lacunar infarcts of the brain stem or a hemorrhage in this region. It is also found that

any neurologic or muscular damage along the deglutitive axes can cause dysphagia. Swallowing abnormalities can develop when these damages result in malfunction, discoordinated function, or lack of function of the neuromuscular apparatus (Ward, 2001). However, brain stem lesions are believed to have association with the presence of dysphagia but the lesions in specific cortical locations have been seen more common in those who have dysphagia or are at risk of aspiration (Galovic et al., 2013; Momosaki, Abo, Kakuda, & Uruma, 2012).

Dysphagia may be manifested by various signs and symptoms. Typically, they are choking on food, coughing during meals, drooling or loss of food from mouth, pocketing on food in cheeks, slow, effortful eating, difficulty swallowing pills, avoiding food or fluids, complaining of food sticking in throat, problems swallowing, reflux or heartburn (David G. Smithard et al., 2007).

There are three types of dysphagia, which are oral-, pharyngeal-, and esophageal dysphagia.

### Oral and Pharyngeal (Oropharyngeal) Dysphagia

Oropharyngeal dysphagia may be caused by many disorders, including neurologic, muscular, structural, infectious, and metabolic causes (Hirano & Kahrilas, 2012). Oral dysphagia leads to poor bolus formation and control. Consequently, food has prolonged retention within the oral cavity and may even seep out of the mouth. Patients with this kind of dysphagia typically demonstrate drooling and difficulty in initiating swallowing. Because of the poor bolus control, food may be spilled into the hypopharynx with resultant aspiration into the trachea or regurgitation into the nasal cavity. In pharyngeal dysphagia, food is retained due to poor tongue or pharyngeal propulsion or obstruction at the upper esophageal sphincter. The presence of concomitant hoarseness or other cranial nerve dysfunctions may be associated with oropharyngeal dysphagia (Hirano & Kahrilas, 2012; Rosemary Martino et al., 2005).

### Esophageal Dysphagia

In adults, the esophagus is 18–26 cm in length, and consists of two parts, which are cervical esophagus and thoracic esophagus. The cervical part extends from the pharyngoesophageal junction to the suprasternal notch and the thoracic part

continues to the diaphragmatic hiatus. When distended, the esophageal lumen has internal dimensions of about 2 cm in the anteroposterior plane and 3 cm in the lateral plane. Solid food dysphagia may occur when the lumen is narrowed to less than 1.3 cm but also can occur with larger diameters in the setting of poorly masticated food or motor dysfunction. It is found that circumferential lesions are more likely to cause dysphagia than are lesions that partially influence the circumference of the esophageal wall. Propulsive disorders leading to esophageal dysphagia result from abnormalities of peristalsis and/or deglutitive inhibition, potentially affecting the cervical or thoracic esophagus. Since striated muscle pathology usually involves both the oropharynx and the cervical esophagus, the clinical manifestations of esophageal dysphagia usually are blurred by oropharyngeal dysphagia (Hirano & Kahrilas, 2012; Palmer, Drennan, & Baba, 2000).

In summary, dysphagia post-stroke is characterized by a delay and reduced function in the pharyngeal phase of swallowing.

### 2.1.3 Impact of dysphagia after ischemic stroke

The impact of different dysphagia's levels on nutritional status was not much researched (Westergren, 2006). Impaired arm movement, lip closure and swallowing are significant predictors of decreased energy intake in stroke patients (McLaren & Dickerson, 2000). Dysphagia following stroke related to increase risk of material being aspirated during swallowing. (Addington, Stephens, & Gilliland, 1999; Aviv et al., 1996; Daniels et al., 1998; Nakajoh et al., 2000), resulting in seven times increasing of aspirated Pneumonia among those patients (DePippo, Holas, Reding, Mandel, & Lesser, 1994; Kidd, Lawson, Nesbitt, & McMahon, 1995; D.G. Smithard et al., 1997). The pneumonia rate with formal dysphagia screen was 2.4% vs 5.4% with no formal screen (Hinchey et al., 2005).

Otherwise, Dehydration is also a common complication of dysphagia and may be a risk factor for aspiration pneumonia as well as immune status depression. It is necessary to maintain hydration through fluid supplementation, or with intravenous fluids in patients who cannot eat or swallow (Sura et al., 2012).

In stroke patients, pneumonia has been associated with an increased cost of US$14,836 per patient (Gordon et al., 1987; Katzan, Cebul, Husak, Dawson, & Baker,

2003; Katzan, Dawson, Thomas, Votruba, & Cebul, 2007) and is strongly associated with poorer outcomes (Davi G. Smithard et al., 1996; Y. Wang et al., 2003; Y. Wang, Lim, Levi, Heller, & Fischer, 2001). The impact of dysphagia on hospital resources was also large. Patients with dysphagia are often at risk of aspirating. The increased mortality risk also increases costs. The researchers estimated the cost of dysphagia at nearly $550 million over two years. (Altman, 2006).

Dysphagia screening programs for stroke patients can significantly decrease the pneumonia risk and should be offered to all (Hinchey et al., 2005). According to Kaye & Brandstarter (2009), more than 40% of patients with vertebrobasilar stroke including an abnormal level of consciousness, as well as hemiparesis or quadriparesis, pupillary abnormalities and oculomotor signs are common, and bulbar manifestations, such as facial weakness, dysphonia, dysarthria, and dysphagia (Langdon, 2012). Patients with brainstem lesions demonstrate the most long recovery course or poorest outcomes. On four patients with strokes involving the brainstem, two patients then died, while the others had swallowing impairment by 25 days post onset and were discharged home (Gordon et al., 1987).

In sum, the impact of dysphagia on patients' health status, morbidity and mortality after ischemic stroke depending on the location, the size of lesion and patients' demographic characteristics. However, the impact of dysphagia places on patients' health status, morbidity and mortality.

## 2.2 Health status among ischemic stroke patients with dysphagia

### 2.2.1 The concept of health status

According to WHO, health status is an individual's level of wellness and illness in presence of biological and physiological dysfunction, symptoms, and functional impairment. Specifically, health status can be defined as the range of manifestation of disease in a patient including symptoms, functional limitation, and quality of life (Rumsfeld, 2002).

Health status may be measured by a physician who performs an examination and rates the individual on several dimensions including life-threatening

illness, risk factors for premature death, severity of disease, and overall health. Individual health status may also be assessed by asking the person to report health perceptions in the domains of interest, such as physical functioning, emotional well-being, pain or discomfort, and overall perception of health. It is attractive to argue that the health measurement should consist of the combination of both individual's objective plus subjective component. Accordingly to order to measure health status, the comprehensive instrument which could cover the wholistic view of health status is strongly recommended.

### 2.2.2 Health status among ischemic stroke patients with dysphagia

There is insufficient evidence on the direct impacts of dysphagia alone on patient's physical health status. However, dysphagia in relation with other disorders and disabilities that occur prior to or as a result of it such as chest infections, pneumonia and negative mental state obviously increases the risks of mortality. The risks vary according to the types of disorder or disability associated with dysphagia.

The swallowing difficulty and losing of appetite caused by dysphagia easily result in malnutrition or undernourishment of patients, affecting the patient's habitus adversely as well as increasing mortality after acute stroke. Those problems will lead to psychological and mental health problems among stroke patients. Ekberg et al. (2002) reported that 41% of patients with dysphagia undergo anxiety during their mealtimes, over a third of patients avoid eating with others because of dysphagia (Ekberg, Hamdy, Woisard, Wuttge–Hannig, & Ortega, 2002). There are many researches support that stroke patients who suffer with dysphagia always avoid themselves from social function, they preferred to stay alone because of the altered body image. These expressions has been demonstrated by Anderson et al (1998) as the early forecasts of post-stroke depression. Its significant predictors include lower levels of social activity, greater severity of stroke and lower levels of function at baseline (Farner et al., 2010 ).

It is difficult for stroke patients to keep the social connection when they are put pressure with physical and communicative difficulties. They are also confronted with a curb on movement and participation in even trivial discussion. It would be hard for stroke patients to stay alone and continue a role as a member of

their community after recovery. Change in personality has been reported by Stone et al. (2004) as frustration, dissatisfaction, patience, and worrying perceived by the caregiver (Stone et al., 2004). Stroke patient describe themselves negatively after their stroke (Ellis-Hill & Horn, 2000). Teasell et al. (2000) reported family conflicts and loss of home, employment, and spouse were common problems among stroke survivors under 50 years old. The rate of unemployment was 80%–90%. (R. W. Teasell et al., 2000). Body image declines after stroke in both gender group who under 40 years old (Keppel & Crowe, 2000). More than half of young survivors have long-term physical and cognitive disabilities and were dissatisfied after stroke. 53% percent were not satisfied with life as a whole, 21% not satisfied with their P-ADL, 48% with their leisure situation, 66% with their vocational situation, 63% with their financial situation, 68% their sexual life, 42% with their partnership relation, 35% with their family life, and 41% with their contact with friends/acquaintances (Röding, Glader, Malm, & Lindström, 2010).

Some research showed rate of depression among this group of patients. Depression is a common psychiatric illness which will be burdensome (due to disability) cause of disability by 2020 (Pfeil, Gray, & Lindsay, 2009). Depressive disorders range from 25% to 79% among people suffering from a stroke and the popularity of post-stroke major depression ranged from 3% to 40% (Bartoli et al., 2013). The depression in stroke patients is related to increased disability and possibly mortality (House, Knapp, Bamford, & Vail, 2001; Salter et al., 2013). And the highest rates of incident depression were reported in the first month after stroke (Bour et al., 2010).

Prevalence of post-stroke depression should not be regarded as static. While there is some improvement in depressive symptomatology over the first year after stroke (Ostir, Berges, Ottenbacher, & Ottenbacher, 2011 ), and incidence rates declines over time (Bour et al., 2010), post-stroke depression may be continue with a significant proportion of individuals (Ayerbe, Ayis, Rudd, Heuschmann, & Wolfe, 2011; Farner et al., 2010 ; Ostir et al., 2011 ). The assessment revealed increased depression in participants; approximately 60% of male and female patients with heavy psychological distress (Gurr, Psych, Psych, Muelenz, & Psych, 2011).

According to Islam et al. (2015), in Bangladesh, more than 70 % patients with stroke had depressive symptoms and 32 % had severe depression and factors significantly associated with depression were living in a joint family. In fact, depression is a significant problem among post-stroke patients in this nation (Islam, Rahman, Aleem, & Islam, 2015)

Psychological distress is a common feature which requires professional attention. Mental health and physical health risks can become more complex (Gurr et al., 2011). Detecting mood symptoms as soon as possible will improve long-term functioning and prevent secondary consequences regarding health and psychological well-being (Gurr et al., 2011).

In summary, patients with swallowing disorders after ischemic stroke will undergo many unexpected physical and mental risks. This has adversely affected their health condition. Screening for early detection and effective management of swallowing disorders is essential to be done to reduce complications, making a significant contribution to the improvement and enhancement the health status of patients.

### 2.2.3 Measurement of health status among ischemic stroke patients with dysphagia

Taking stock of the health status of stroke survivors causes special problems as a result of cognitive impairments that are often a negative impact of stroke. Furthermore, health status, usually gets involved in a subjective component showing stroke survivors' attitudes and beliefs about their well-being and about how well-being has impacts on their activities and attitudes generally.

Health status and quality of life are increasingly considered as outcomes of stroke important to determine (Segal & Schall, 1994). Various generic instruments were identified were utilized to measure health in stroke patients such as Health Utilities Index, Nottingham Health Profile (Fitzpatrick et al., 2006). Edelman et al (1999) suggest that users should choose an appropriate measure in the target population. Three primary factors taken into account in choosing instruments are validity, reliability, and sensitivity, subject satisfaction with the instrument and the

amount of time for measurement completion (Edelman, Williams, Rothman, & Samsa, 1999).

Health status will be measured by SF-12v2 scale (Maruish, 2012; Ware, Kosinski, & Keller, 1996). This questionnaire is a short version of the SF-36, which has been demonstrated to be reliable and valid in clinical and population-based applications in the U.S. and other countries (Ware et al., 1996). The SF-12v2 survey contains categorical questions that assess limitations in role functioning as a result of physical and mental health. Items are rated on 3-points (item 2, 3) or 5-point (other items) Likert scales to assess limitations in physical activity and physical role functioning. The questions are used to ask respondents to rate their health and functioning during the past week. The SF-12v2 scale is 12-item questionnaire that measures eight dimensions of health status: mental health, social functioning, physical functioning, role-physical, bodily pain, role emotional, vitality, and general health. Physical and mental composite scores are calculated from those dimensions. For each dimension, after being coded, scores are summed and transformed to scale from 0 to 100 in which a higher score denotes better health status (Maruish, 2012). Test-retest (2-week) correlations were observed in the general US population for the Physical Component Summary and the Mental Component Summary with 0.89 and 0.76, respectively (Ware et al., 1996).

The SF-12v2 was extensively tested and internationally recognized. Through the International Quality of Life Assessment project, the SF-12v2 has been translated and adapted for use in many countries. In particular among patients with stroke who suffer with dysphagia SF-12v2 is strongly recommended.

## 2.3 Symptom management theory as a conceptual framework to explain health status among ischemic stroke patients with dysphagia

### 2.3.1 Symptom management theory

In order to understanding the researched subject and providing a good background, symptom management theory contributes as a major theoretical framework that includes three main concepts such as symptom management strategies,

symptom experience, and symptom outcomes. Moreover, these components are viewed in a broader scale of the whole healthcare environment where patients are treated including the environment (social, physical, cultural), person (psychological, demographic, sociological, physiological, developmental) and illness and health (health status, risk factors, disease injury) (Dodd et al., 2001). The symptom experience includes the patient's symptom perception, assessment and the response. Perception of symptoms cites an individual notices a change from the way he or she usually feels or behaves. The judgments which people make about their symptoms namely treatability, cause, symptom severity and the symptoms' effects are evaluation of symptoms. Moreover, according to Larson et al. (1994) and Levine & Shefner. (1981), responses to symptoms contains thoughts, feelings, or behaviors which are secondary to potential health problems or actual (Larson et al., 1994; Levine & Shefner, 1981). All troublesome symptoms are in need of management that is a basic hypothesis in the model. Moreover, not only symptom outcomes but also symptom experience should be controlled and influenced by symptom management. By using biomedical, professional, and self-care strategies, symptom management aims to avert or delay negative outcome. From a patient's perspective, the symptom experience becomes the first assessment of management. Symptom management can include interventions aimed at one or more of the components in the symptom experience to influence one or more desired outcomes. There is undeniable the fact that changes in strategies over time or in response to a patient's acceptance (or lack of acceptance) of the strategy are required by symptom management because it is a dynamic process (Larson et al., 1994). According to Larson et al. (1994), there are 10 multidimensional indicators which conceptualize the association of outcomes with the symptom experience in the model such as financial status, functional status, symptom status, comorbidity, health service utilization, mortality, self-care ability, morbidity, quality of life and emotional status. Moreover, patients' functional status to a level where they can function independently is desired (Larson et al., 1994).

### 2.3.2 Symptom management theory and the ischemic stroke patients with dysphagia

In this study, the association between outcomes and health and illness domain will be used as the theoretical explanations of the relationships among studied variables. All ischemic stroke patients with dysphagia may have many complications which have negative impacts on their health status. In other word, health status refers to symptom outcome. In the model, the health and illness domain comprised of variables unique to the health and illness state of an individual and includes risk factors, injuries, or disabilities (Dodd et al., 2001). In the current study, dysphagia, nutritional status, and stroke severity are derived from the health and illness domain. In particular, dysphagia represents injuries in the brain, which particularly influences the functions of the throat. After surviving from stroke, patients have a lot of problems such as reduced dietary intake, and other neurological deficits that could affect their nutrition. The severity of stroke is a complex factor, which present the severity of neurological impairments (Bogousslavsky et al., 2006). Theoretically, health and illness domain could influence outcomes domain (Dodd et al., 2001). Therefore, it could be hypothesized that dysphagia, nutritional status, and severity of stroke are related to health status among stroke patients.

Overall, using symptom management theory as a conceptual base to explain the phenomena of symptom and health status among stroke patients with dysphagia is very applicable. It gives a clear view point of the phenomena of the study interest.

## 2.4. Factors associated with health status among ischemic stroke patients with dysphagia

### 2.4.1 Severity of stroke and its association with health status among ischemic stroke patients with dysphagia

The severity of stroke was a major cause increased limit of capacity to perform activity of daily living (Bogousslavsky et al., 2006), so has effect to health status of patients. The most neurological function impairment following is motor disability contralateral to the stroke lesion side. (Chen et al., 2010; Dancause & Nudo,

2011; Hosp & Luft, 2011;Takeuchi & Shin-IchiIzumi, 2012). Higher level of the severity of neurological deficit leads to higher neurological severity of activity daily living deficit thus decrease health status of patients. Other conditions in addition to physical disability undermine the quality of life for stroke patients. Many stroke patients have other major comorbid diseases, which contributes to their disability (Hudson et al., 2006).

Previous studies have pointed out the association between stroke severity and functional status of stroke patients. In particular, Dong et al**.** (2013) demonstrated that stroke severity (assessed by NIHSS) explained 4.3% variance of functional outcome 3 to 6 months after stroke (Dong et al., 2013). Especially, The accuracy of the NIHSS in predicting outcome is almost unaffected by the timing of assessment in the first 9 days after stroke (Kwakkel et al., 2010). In other study, Gajurel et al (2014) asserted that the health status of patients with more severe stroke condition (4.6 ± 2.2) was significantly lower than that in patients with less severe condition (14.16 ± 7.96) ($p < 0.001$) (Gajurel et al., 2014).

**2.4.2 Level of dysphagia and its association with health status among ischemic stroke patients with dysphagia**

Dysphagia is described as difficulties in eating and swallowing. Symptomatic dysphagia is recorded in approximately one fourth to one third of stroke patients. The higher dysphagia occur, the higher risk of pulmonary complications and even mortality appear (Altman, 2006), which effect to the patients' health status.

Thus, early screening dysphagia is very important in early making clinical decisions, preventing complications caused by dysphagia as well as giving proper nursing plans in feeding patients, controlling complications and recovering. This will result in the improvement of health status and patient outcomes, a reduction in length of hospitalization as well as in treatment costs (Rosemary Martino et al., 2005).

In a related study conducted by Marcel Arnold et al. (2016), which included 118 ischemic stroke patients with dysphagia, in which 30.5% of patients with severe dysphagia were required tube feeding(Arnold et al., 2016). Mohamed Al-Khaled et al. (2016) demonstrated that ISD patients had a likelihood of 3-month disability than ischemic stroke patients without dysphagia (74 vs. 25%, respectively; p

< .001 (OR 2.3; 95% CL 1.8-3.0), and the presence of dysphagia was strongly associated with longer hospitalization (Al-Khaled et al., 2016).

Similarly the findings reported from Marcel Arnold et al. (2016) concluded that dysphagia affected 20.7% ischemic stroke patients and had a negative impact on clinical outcome (Arnold et al., 2016). In other word, the presence of dysphagia during the acute phrase of stroke is associated with poor outcome (Smithard, Smeeton, & Wolfe, 2007).

It can be concluded that, swallowing disorder screening played an important role in caring of stroke patients. It made a significant contribution to preventing risk factors such as aspirated pneumonia, especially silent aspirations as well as malnutrition, event mortality.

The most common tool is bedside screening test, including Gugging Swallowing Screen (GUSS) (John & Berger, 2015; Sørensen et al., 2013;Trapl et al., 2007), the Toronto Bedside Swallowing Screen test (TOR-BSST), Massey Bedside Swallowing Screen (MBSS) and discussion with dysphagia experts. Among these, GUSS is used the most widely because it is reliable, simple and easy-to-use (Trapl et al., 2007). Besides, GUSS is an economical test which can be carried out by any nurses trained in neurology, especially the nurses specialized in taking care of stroke patients. GUSS is demonstrated to have 100% sensitivity and 69 % specificity to foretell aspiration risk (John & Berger, 2015). However, GUSS is impossible to conduct on uncooperative and toothless patients because there will be some obstacles in carrying out all the stages of GUSS.

To be conducted successfully, GUSS requires skilled nurses and practical support from therapists. Therefore, it is necessary for nurses to be trained carefully and methodically before performing the GUSS test on patients.

### 2.4.3 Nutritional status and its association with health status among ischemic stroke patients with dysphagia

Alterations in nutritional status have the potential to affect mortality, morbidity, and quality of life outcomes. Nursing interventions to help maintain optimal nutritional status include careful assessment, identification of patients at risk, and management of problems before the initiation of therapy.

Impaired nutrition is associated with reduced functional improvement, increased complication rates and prolonged hospital stays (Kenneth Wayne Altman et al., 2010). Nutritional status is an important factor of each person which is the balance between energy from nutrition intake and the energy that the human use for metabolism process including energy storage to do activities and promote to good person's health status. Providing management strategies plays an important role in assessing stroke patients' nutritional status in order to manage dysphagia and patients' food and fluid intakes (Sura et al., 2012). Therefore, the patients at high risk of malnutrition would suffer lower level health status.

Some studies suggest that acute stroke patients with malnutrition experienced many complication during their hospital stay. A study conducted by Wang et al., (2014) in China showed that both NRS2002 (34.3%) and MUST (33.8%) can be used to screen for malnutrition risk in patients with stroke (Wang et al., 2014). The nutritional effect of protein intake at 1.6 g/kg is better than 0.9 g/kg and 1.2 g/kg on improving the nutritional status in severe stroke patients (Zhang et al., 2014).

In Vietnam, screening, assessment of nutritional status following acute stroke tools that have not been validated. A study was conducted in 5 years in Scotland with 2995 stroke patients showed that nutritional status early following stroke is not significant independently associated with long-term outcome. Of the 275 undernourished patients, 102 (37%) were dead by final follow-up compared with only 445 (20%) of 2194 patients of normal nutritional status (odds ratio [OR], 2.32; 95% CI, 1.78 to 3.02). The rate of pneumonia, other infections, and gastrointestinal bleeding in undernourished patients were higher than other patients at admission (FOOD Trial Collaboration, 2003).

Overall, under nutrition as a predictor of poor clinical outcomes in acute ischemic stroke patients. Strategic nutrition support in baseline under nutrition patients may improve clinical outcomes (Yoo et al., 2008 ).

## 2.5 Conclusion

Patients with stroke always experience dysphagia which will lead to many complications such as aspirated pneumonia, atelectasis, sepsis or mortal complications. The expected outcomes among these patients are resuming good health status which refers to physical activities and physical role functions. In order to understand this phenomena more clearly, symptom management model is employed to use as a framework that can cover all studied variables. While the health status is conceptually viewed as symptom outcome, dysphagia is viewed as symptom experience, nutritional status; patients' comorbidity and severity of stroke are viewed as individual factors. These reflect the comprehensive view of the study framework. It is expected that the results of this study can be well utilized as a guideline for nurses who work with stroke patients having problem with dysphagia. Moreover, it will emphasize the roles of nurses in assessing, planning, implementation of the plan to enhance nutritional status, reduce or control unpleasant symptoms so that the patients can obtain optimum health status.

# CHAPTER III
# METHODOLOGY

In this chapter, research design, population and sample of the study, studied instruments and their validity and reliability, data collection procedure, human right protection, data analysis and assumption of the statistic used in this study were consecutively presented.

## 3.1 Research design

The study was a descriptive correlational study design aimed to examine the relationship among severity of stroke, levels of dysphagia, nutritional status, and health status in ischemic stroke patients with dysphagia.

## 3.2 Population and sample of the study

### 3.2.1 The population of this study

Population of the study included patients who were 18 years old or above and suffered from ischemic stroke with any levels of dysphagia in both genders. They were admitted to the Department of Neurology of Bach Mai Hospital during the research period.

### 3.2.2 The sample of the study

Sample was selected from the population according to the following criteria:

**Inclusion criteria:**

1) Having ischemic stroke with dysphagia
2) Aged at least 18 years old
3) Understanding Vietnamese
4) Had been admitted in Department of Neurology for at least 1 week
5) Glasgow coma score was 13 points and over

**Exclusion criteria:**

1) Having unstable condition from disease including stuporous, dyspnea, and alternation of hemostasis (blood pressure more than 180/105 mmHg or systolic blood pressure lower than 100 mmHg or Mean Arterial Pressure lower than 70 mmHg).
2) Having tracheostomy/endotracheal tube and/or on ventilator
3) Having co-morbidity such as myocardial infarction, Wernicke's aphasia, dementia.
4) Toothless patients.
5) Having any swallowing disorders at current admission due to other diseases (e.g. myasthenia, previous stroke event)
6) Incomplete fill out questionnaires.

**Termination criteria:** N/A

**Sample size:** The sample size of the study was estimated based on α, β and effect size. Commonly, α, β values are set at 0.05 and 0.2 (Field, 2009; Munro, 2005). Effect size was selected based on evidence from previous studies. Nevertheless, no survey on health status of Vietnamese ischemic stroke patients with dysphagia was found in order to identify potential associations among levels of dysphagia, nutritional status, and stroke severity with health status in ischemic stroke patients with dysphagia.

In the current study, three necessary parameters and another factors required for calculation included 1) the level of significance $\alpha = 0.05$, 2) the power of the statistical test (Power $1 - \beta = 0.8$) and 3) effect size for this study ($f^2 = .099$). The sample size in this study was calculated by using G*power version 3.1.9.2 program to determine the minimum number of participants needed for co-

relational design (Faul, Erdfelder, Buchner, & Lang, 2009). From that, on G*power, sample size should be at least 115 ischemic stroke patients with dysphagia.

## 3.3 Setting

The research was conducted in the Department of Neurology of Bach Mai hospital. Bach Mai hospital has been the biggest general hospital in the North of Vietnam. Indeed, it is the final place for severe patients throughout half of the country coming to treat their diseases. The Department of Neurology of Bach Mai hospital is a center specializing in neuropathy. This 175-bed center is considered the biggest center for neurologic patients in the north of Vietnam. Every day, Neurology Department of Bach Mai hospital admits 10-30 cases, among whom there are about 6 to 8 cases with ischemic stroke of different level of severity. In average, the length of stay of ischemic stroke patients is approximately 11 days. The number of cases met the requirements to be able to conduct GUSS test are about 2 to 3 per day.

## 3.4 Instruments

In this study, the tools used to collect data consisted of five parts as follow:

**Part 1** Demographic data of the patients included the information related to age, gender, weight, height, BMI, occupation, level of education, marital status, length of hospital stay, duration of stroke, history of illness and previous illness.

**Part 2** The 12-item Short Form Survey (SF-12v2): this scale was used to measure health status of the patients (Maruish, 2012; Ware et al., 1996). This questionnaire is a short version of the SF-36, which has been demonstrated to be reliable and valid in clinical and population-based applications in the U.S. and other countries (Maruish, 2012; Ware et al., 1996). The SF-12v2 survey contains categorical questions that assess limitations in role functioning as a result of physical and mental health. Items are rated on 3-points (item 2, 3) or 5-point (other items) Likert scales to assess limitations in physical activity and physical role functioning. The questions are used to ask respondents to rate their health and functioning during the past week. Items of the SF-12v2 generate eight dimensions including: role physical, role

emotional, physical function, social function, mental health, vitality, pain, and general health (Maruish, 2012). The score of each sub-scale ranges 0–100 scale with the higher score indicating less dysfunction or impairment (Ware et al., 1996). Test-retest (2-week) correlations were observed in the general US population for the Physical Component Summary and the Mental Component Summary with 0.89 and 0.76, respectively (Maruish, 2012).

**Part 3** NIH Stroke Scale (NIHSS): this scale is used to measure the severity of stroke. This scale was firstly developed to use in a clinical trials (Brott et al., 1989). The NIHSS is composed of 15 items (Seidel, Gruene, & Borte, 2005). For each item, a score of 0 typically indicates normal function in that specific ability, while a higher score is indicative of some level of impairment (2, 3 or 4). The NIHSS score is the sum score of all items, ranging from 0 to 42 (Kwaha & Diong, 2014). A higher score reflects a more severe stroke condition. Inter-rater reliability (calibrated among 6 raters) of this scale was excellent, with an intra-class correlation coefficient of 0.82. The sensitivity and specificity to diagnose a patients with excellent outcomes (NIHSS score of $\leq 5$) are 0.72 and 0.89, respectively (Kasner et al., 1999).

**Part 4** Nutritional Risk Screening 2002 (NRS-2002) scale: Nutritional status of participants was assessed by this scale (J. Kondrup, Rasmussen, Hamberg, & Stanga, 2003 ). Four simple questions covering BMI, recent weight loss, reduced intake and severity of illness are consisted in the initial screening phase. The second phrase screening should be done if the “yes” answer existed for any questions. If patients answer “no” for all four questions, they should be rescreened on a weekly basis. Nutritional status and disease state are two aspects which the second phase screening entails scoring the patient on. For nutritional status a score is allocated looking at the variable (BMI, dietary intake or recent weight loss) that is the worst off. Based on the illness, the patient is scored for disease state. In order to score the patient, clinical judgment must be used in case the specific illness does not exist in the table. Patients need for immediate nutritional support because of “at risk of malnutrition” with patients’ scores equal to or more than 3. The specific nutritional support to be followed is not specified. Patients with scores between the ranges of 0-2 should be rescreened on a weekly basis. According to Sorensen, Kondrup et al. (2008), with a kappa value of 0.67 between a nurse, dietician and doctor 0.40 and 0.76

between 28 doctors, the trustworthiness of the NRS-2002 has been reported well. (Sorensen et al., 2008).

**Part 5** Gugging Swallowing Screen (GUSS) scale (Trapl et al., 2007): the scale is used to measure the severity of dysphagia. This scale consists of two parts, which are Preliminary Investigation / Indirect Swallowing Test and Direct Swallowing Test. The score of part 1 is varied from 0 to 5, while score of the part 2 ranges from 0 to 15. The total score of the whole scale is from 0 to 20. The higher score indicates a milder swallowing disorder. A study of Trapl found an excellent inter-rater reliability of this scale (2 raters) ($\kappa$=0.84, $P$<0.001) (Trapl et al., 2007).

## 3.5 Instrument Reliability and Validity

### 3.5.1 Instrument Validity

In this study, after getting the permission of author of all scales, those instruments were translated into Vietnamese by back-translation technique using Brislin's Model. According this model, the scale will be translated into the Vietnamese by a bilingual expert at the Language Center, Hanoi Medical University. The translated versions were reviewed by a Vietnamese healthcare provider to identify ambiguous words and to adapt the Vietnamese context and culture. The translated versions were modified following the expert's recommendations. The backward translation from Vietnamese version to English versions were conducted by a bilingual expert at the Language Center, Hanoi Medical University. The original English version and back-translated English versions were compared by a native English speaker. After modifying as expert's recommendations, the final Vietnamese versions were validated the content in terms of equivalence, denotation and suitability of the language in the Vietnamese context by three graduated nurses who work in stroke patient care and are familiar with concept in symptom management theory, one nutritionist and one physician who run along with stroke patients. The experts rated for relevance of each item to concepts in Vietnamese culture by using a 4-point Likert scale. This scale includes "4 = very relevant", "3 = fairly relevant", "2 = little relevant", and "1 = not relevant at all". The content validity index (CVI) was calculated as the percentage of

items that are rated as relevant. It indicated that the content of the Vietnamese version of scale is valid if CVI is at least .80.

### 3.5.2 Instrument Reliability

After obtaining the IRB approval, the Numerical Rating scale, the SF12v2, the Stroke Scale National Institutes of Health (NIHSS), the Nutritional Risk Screening (NRS), the Gugging Swallowing Screen (GUSS) were used in 30 ischemic stroke patients with dysphagia who had characteristic similarly to the sample. The Cronbach's alpha coefficient were employed to test each instrument reliability for 30 patients and for the whole sample (n = 115) (table 3.1).

**Table 3.1** Reliability of scales **(**n= 30 and n=115**)**

| **Scale** | **N of Items** | **Cronbach's Alpha (n = 30)** | **Cronbach's Alpha (n = 115)** |
|---|---|---|---|
| **SF12v2** | 12 | 0.93 | 0.89 |
| **NIHSS** | 15 | 0.62 | 0.69 |
| **NRS** | 3 | 0.74 | 0.76 |
| **GUSS** | 17 | 0.95 | 0.93 |

## 3.6 Data collection

The process of data collection was conducted in the following sequences:

1) Preparing research assistant:

In this study, two research assistants were recruited to support the principal researcher in conducting the study. The selection criteria were having at bachelor level in nursing science, and having five year working experience with stroke patients at the Neurology Department, Bach Mai hospital. The research assistants were supported the principal researcher in inviting potential participants, preparing necessary documents and equipment for conducting tests on patients, cross-checking the data during data entering into the statistical program.

Both research assistants were provided three training sessions (2 hours/session). Researcher trained her/him on objectives, subject selection, data collection procedures, and other details of the project, etc.

2) After getting the approval and receiving the permission to data collection, the researcher met the Director of hospital, Head of Neurology department in order to explain the purposes of data collection. The head of department introduced the researcher and the research assistants to targeted population.

3) The research assistant established a relationship with the patients. Then, the patients were informed the objective of study, data collection procedure and asked for the research participation. In addition, the research assistant asked patients to sign a consent form. If the patients voluntarily participate in the study, the researcher collected some demographic data from medical record form.

4) To collect data, the researcher approached the participants at their beds. After the consent form was finished, the data collection was conducted. For each person, the data collection procedure consisted of two parts. The first part was finished for one questionnaires (the SF-12 scale with 12 items). The second part was finished for one questionnaire (the NRS scale with 6 items) and performed two tests to evaluate stroke severity (NIHSS) and dysphagia severity (GUSS).

In the first part: the questionnaire included 12 items (SF-12v2). To complete all items, it might take about 5 minutes. When patients answered the questionnaires, the researcher was available nearby the patient to support if necessary. After the patient returned the complete questionnaires, the researcher started the second part of the data collection procedure.

In the second part: the researcher conducted physical examination and screening. Firstly, the researcher examined physically for stroke severity with 15 items. This was last about 8 minutes. Secondly, the researcher performed the Nutritional Risk Screening for the patient in 2 minutes. After that, the researcher performed the swallowing test which was the routine procedure for dysphagia evaluation. The result was discussed with the treatment team (physician and clinical nutritionist) in order to recommend the most appropriate diet for the patient. During this test, the researcher observed the patient closely after each time swallowing, the

tests were stopped at any time if one of the four aspiration signs (deglutition, cough, drooling, and voice change) was positive.

The total amount of time used lasts about 30-35 minutes.

## 3.7 Protection of human rights

In this research, the researcher strictly concerned to human rights and ethical issues throughout the research process by:

3.7.1 Proposal of this study was submitted to get approval from the IRB of the Faculty of Nursing, Mahidol University, and IRB of School of Medicine and Pharmacy, Vietnam National University. Data collection was conducted when the approval was granted.

3.7.2 All research objective and data collection process were clearly described to the patients. The participation in this study was voluntary. The patients were informed that they had right to refuse to join in the research process. If patients agreed to join in the research process, they was invited to sign their name in the consent form. During anytime throughout the research process, patients had their own right to withdraw from the research project at any time and it did not affect their treatment or care process.

3.7.3 This research did not cause any risk to the patients' physical health. The participation was voluntary, the respondents were not receive any incentives as the benefit from participating in this study.

3.7.4 All contents were kept confidentially, only the researcher and IRB team were able to get access to the data. Any content related to data that was presented in the thesis or any publication was anonymous. In case of ones who with drawn themselves from the research, all data was deleted from the database and was not used as any part of the research.

## 3.8 Data analysis

The raw materials obtained after carrying out the tests were elaborated and displayed. The data were analyzed using a computer program as follow:

1) The descriptive statistics in terms of frequency, percentages, range, mean, and standard deviation were used to describe the baseline characteristics of the subjects and studied variables.

2) Spearman's rho correlation was used to examine the associations between independent variables (nutritional status, severity of stroke, and severity of dysphagia) and dependent variable (health status) among ischemic stroke patients with dysphagia.

# CHAPTER IV
# RESULTS

The study's results are presented in this chapter. The descriptive statistics for the demographic characteristics and the major study variables are illustrated, which aim to examine various factors relating to health status among ischemic stroke patients with dysphagia. The data analysis's results will be presented as follows:

1 Demographic characteristics and variables of the study.

2 Factors relating to health status among ischemic stroke patients with dysphagia.

**Description of Study Sample**

There were 115 patients who were in the 18-year-old-or-more group in the subjects of the study. Those suffered from ischemic stroke with any levels of dysphagia in both genders. The data analysis showed no missing data for variables. The following data provided the sample's characteristics including demographic information and statistics relating to illness.

## 4.1 Demographic characteristics of the sample

Demographic characteristics of the subject were presented in Table 4.1. Among 115 patients, there were 70 males (accounted for 60.87%) and 45 females (accounted for 39.13 %) who came from several provinces in Viet Nam. In fact, there were 108 people from the North of Viet Nam (accounted for 93.91%), patients are Ha Noi citizens made up 28.7%.The average age of these patient was 66 years old (SD ±10.4), in which the oldest patient was 88 year old and the youngest one was 40 year old. The highest age were individuals who lower than 60 years old, account for 31.30%. The number of 75-year-old-or-more group patients was the lowest, at 20.87%. This was followed by the figures for the ages ranging from 61-68 and 69-75,

at 26.09% and 21.74% respectively. More than 60% of participants gained a secondary education (accounted for 63.48%), College and Bachelor degree constituted at 24.35%, high school education was the lowest segment, at 12.17%. The patients' main occupations were farmers, accounted for 53.04 %. There were 26.08 % of people who retired and the rests were other occupations. There were approximately 39.13% of people who belonged to no-income group. This was followed by the figures for people who had less than 101 USD accounted for 20%, 101-200 USD accounted for 24.35%, 201-300 USD accounted for 13.04 %, and over 300 USD per month accounted for 3.48%. The income's mean was at $87.3 (SE = 8.86), which revealed that most of the participants had low income. Most of the participants were married and lived with their family (accounted for 99.13%). The participants, therefore, received their family's supports (made up 12.17%), health insurance (made up 45.22%) as well as both health insurance and their family's supports (at 42.61%) which helped them to pay hospital fees.

**Table 4.1** Demographic characteristics of the sample

| Characteristics | Number (n = 115) | Percentage (%) |
|---|---|---|
| **Gender** | | |
| Female | 45 | 39.13 |
| Male | 70 | 60.87 |
| **Age (years)** | | |
| Aged <=60 | 36 | 31.30 |
| Aged 61 – 68 | 30 | 26.09 |
| Aged 69 – 75 | 25 | 21.74 |
| Aged > 75 | 24 | 20.87 |
| Minimum: 40 | | |
| Maximum: 88 | | |
| Mean ± SD: 66.1±10.4 | | |

**Table 4.1** Demographic characteristics of the sample (cont)

| Characteristics | Number (n = 115) | Percentage (%) |
|---|---|---|
| **Location of residences** | | |
| North | 108 (33*) | 93.91 (28.7*) |
| Middle | 7 | 6.09 |
| **Marital status** | | |
| Married | 114 | 99.13 |
| Single | 1 | .87 |
| **Religions** | | |
| None | 106 | 92.17 |
| Others (*Buddhism, Catholicism)* | 9 | 7.83 |
| **Educational Level** | | |
| < High school | 73 | 63.48 |
| High school | 14 | 12.17 |
| College school and Bachelor degree | 28 | 24.35 |
| **Occupation** | | |
| Farmer | 61 | 53.04 |
| Housework | 5 | 4.35 |
| Retired | 30 | 26.08 |
| Businessman | 7 | 6.09 |
| Government staff | 8 | 6.96 |
| Industrial worker | 4 | 3.48 |

** Patients came from Ha Noi*

**Table 4.1** Demographic characteristics of the sample (cont)

| Characteristics | Number (n = 115) | Percentage (%) |
|---|---|---|
| **Income per month** | | |
| None | 45 | 39.13 |
| From 1 to 100 USD | 23 | 20.0 |
| From 101 to 200 USD | 28 | 24.35 |
| From 201 to 300 USD | 15 | 13.04 |
| > 300 USD | 4 | 3.48 |
| Minimum: $0 | | |
| Maximum: $439 | | |
| Mean = $87.3 | | |
| SE = 8.86 | | |
| **Payment method** | | |
| Insurance | 52 | 45.22 |
| Family's supports | 14 | 12.17 |
| Insurance and Family's supports | 49 | 42.61 |

## 4.2 Clinical signs and symptoms of patient on admission

Tables 4.2 showed most of the patients were admitted within the first 24 hours after stroke (made up 46.96%). Among them, 13.91% of the patients were admitted within 24 hours to 48 hours after stroke, 10.4% of the patients were received between 48 hours to 72 hours after stroke and 28.7%of the patients were received after the first 3 days. The explanation was that majority of patients came to us from other provinces far from Ha Noi; thus, they were admitted to other provincial hospitals before passing to the Department of Neurology, Bach Mai Hospital. Hemiplegia patients accounted for 97.39%. On clinical examination showed that hemiplegia patients were often accompanied by other focal neurological signs. In fact, the percentage of patients with hemiplegia, who were on the right body and left body were nearly equal (at 40% and 44.34%, respectively).The commonly focal neurological

signs were VII nerve paralysis (at 76.5%), Broca's aphasia (at 8.7%) or communication disorder (at 33%).

Significant comorbidity existed in the sample, there were 29.56% hypertension patients without regular treatment, 26.96% of the patients had a history of hypertension with another diseases (such as Diabetes, Hyperlipidemia, Prior Stroke), 4.35% of them suffered from prior stroke or TIA without consequences, and 26.08 %without Comorbidity. There were 3 patients suffering from pneumonia (made up 2.61%) out of 115 people because of the reason that they were transferred from provincial hospitals and were not given dysphagia screening at the time of hospital admission. The mean length of their stay was 10.97days (SD ±4.1), ranging from 7 to 28 days.

**Table 4.2** Participants' characteristic of illness

| Clinical Information | Number (n = 115) | Percentage (%) |
|---|---|---|
| **Duration since the first symptoms of stroke presented** | | |
| initial 24 hours | 54 | 46.96 |
| > 24 hours to 48 hours | 16 | 13.91 |
| > 48 hours to 72 hours | 12 | 10.43 |
| > 72 hours | 33 | 28.70 |
| **Chief complaint** | | |
| Hemiplegia | 92 | 80.0 |
| Hemiplegia & others | 20 | 17.39 |
| Headache | 3 | 2.61 |

**Table 4.2** Participants' characteristic of illness (cont)

| Clinical Information | Number (n = 115) | Percentage (%) |
|---|---|---|
| **Paralyzed status** | | |
| On the left body | 5 | 4.35 |
| On the left body and other symptoms | 46 | 40.0 |
| On the right body | 6 | 5.22 |
| On the right body and other symptoms | 51 | 44.34 |
| Hemiplegia on both side | 5 | 4.35 |
| Cranial nerve palsy | 1 | .87 |
| None | 1 | .87 |
| **Co-morbidity** | | |
| Hypertension | 34 | 29.56 |
| Hypertension and other disease | 31 | 26.96 |
| Diabetes | 4 | 3.48 |
| Hyperlipidemia | 1 | .87 |
| Prior Stroke/Prior TIA | 5 | 4.35 |
| Other diseases | 10 | 8.70 |
| None | 30 | 26.08 |
| **Complication** | | |
| None | 112 | 97.39 |
| Pneumonia | 3 | 2.61 |
| **Length of hospital stay** | | |
| 7 days | 18 | 15.65 |
| From 8 to 14 days | 78 | 67.83 |
| From 15 to 21 days | 16 | 13.91 |
| > 3 weeks | 3 | 2.61 |
| Minimum: 7 | | |
| Maximum: 28 | | |
| Mean ± SD: 10.9±4.1 | | |

**Description of Study Variables**

Study variables in this study included severity of stroke, nutritional status,levels of dysphagia and health status. This section presents descriptive statistics for health status among subjects followed by other study variables.

## 4.3 Stroke severity

Mean NIHSS was 9.68 (SD ± 5.99) with min equaled to 0 and max equaled to 21. Of this, According to the statistics, there were 59 patients (at 51.30%) who suffered from moderate stroke, 24 patients (at 20.87%) with moderately severe stroke, 24.35% caught minor stroke, severe stroke was at 2.61%, and 1 patient (0.87%) was normal/near normal examination with NIHSS equal to zero (table 4.3).

**Table 4.3** Stroke severity

| Characteristics | Number (n=115) | Percentage (%) |
|---|---|---|
| **Stroke Severity** | | |
| Normal/near normal examination | 1 | .87 |
| Minor stroke (1-4) | 28 | 24.35 |
| Moderate stroke (5-14) | 59 | 51.30 |
| Moderately severe stroke (15-20) | 24 | 20.87 |
| Severe stroke (>20) | 3 | 2.61 |
| Minimum: 0 | | |
| Maximum: 21 | | |
| Mean ± SD: 9.68±5.99 | | |
| Skewness: .305 | | |
| Kurtosis: -1.061 | | |

## 4.4 Nutritional status

Of all patients, the rate of malnutrition prevalence was 88.7%. As a results, a nutritional care plan were initiated.

For BMI, most of the patients had normal BMI ranging from 18.5 to 22.9 (61.74%); the others were overweight 15.65% (BMI from 23-24.9), obesity18.26% (BMI ≥ 25), and Underweight 4.35 (<18.5).

For Albumin, most of the patients (81.74%) had normal Albumin (≥ 3500); the others were Albumin lower 3500 or Protein malnutrition (18.26%)

For Lymphocytes, most of the patients had normal ranging from >=1,500 (68.7%); the others were Lymphocytes lower 1500. (table 4.4).

**Table 4.4** Nutritional status

| Characteristics | Number (n=115) | Percentage (%) |
|---|---|---|
| **Nutrition Risk Screening** | | |
| <3 points: Normal nutritional status | 13 | 11.30 |
| >=3 points: the patient is nutritionally at-risk | 102 | 88.70 |
| Minimum: 0 | | |
| Maximum: 7 | | |
| Mean ± SD: 3.7±1.7 | | |
| Skewness: -.687 | | |
| Kurtosis: .757 | | |

**Table 4.4** Nutritional status (cont)

| Characteristics | Number (n=115) | Percentage (%) |
|---|---|---|
| **Body Mass Index** | | |
| Underweight (<18.5) | 5 | 4.35 |
| Normal weight (18.5-22.9) | 71 | 61.74 |
| Overweight (At Risk) (23-24.9) | 18 | 15.65 |
| Obesity (≥25) | 21 | 18.26 |
| Minimum: 16.37 | | |
| Maximum: 32.65 | | |
| Mean ± SD: 22.25±2.89 | | |
| **Serum Albumin** | | |
| Albumin >=3.500 | 94 | 81.74 |
| Albumin < 3.500 | 21 | 18.26 |
| **Serum Lymphocyte** | | |
| Lymphocyte >=1.500 | 79 | 68.70 |
| Lymphocyte <1.500 | 36 | 31.30 |

## 4.5 Levels of dysphagia

Among the patients, 12 individuals (made up 10.43%) were diagnosed to suffer from severe dysphagia, 27 individuals (made up 23.48%) caught moderate dysphagia and 76 individuals (66.09 percent) had slight dysphagia. Only 18.26% have no tube feeding (table 4.5).

**Table 4.5** Levels of dysphagia

| Characteristics | Number (n = 115) | Percentage (%) |
|---|---|---|
| **Levels of dysphagia** | | |
| Severe dysphagia | 12 | 10.43 |
| Moderate dysphagia | 27 | 23.48 |
| Slight dysphagia | 76 | 66.09 |
| Minimum: 2 | | |
| Maximum: 19 | | |
| Mean ± SD: 16.23±4.24 | | |
| Skewness: -1.787 | | |
| Kurtosis: 2.726 | | |
| **Tube feeding** | | |
| None | 94 | 81.74 |
| Have | 21 | 18.26 |

## 4.6 Patients' health status

Table 4.6 showed Mean of three physical health domain points (PF, RP, GH) fell into the impaired range (<40), while their BP score was at the average range (45.6). Similarly, their score for two of four mental health domains (SF, RE) fell into the impaired range (28.9 and 30.5 respectively), whereas the figures for MH *score* (40.2) and VT *score* (44.8) were in the impairment indicated and the average range respectively. PF, RP, GH, SF, RE had a significant impact on the level of patients' physical and mental health status, at impaired range by the PCS score (35.12) and MCS score (37.27) (SD ± 7.25 vs. 12.45 respectively).

**Table 4.6** Patients' health status (n = 115)

| Health status | Mean | SD |
|---|---|---|
| Physical Functioning (PF) | 31.1 | 7.85 |
| Role-Physical (RP) | 31.4 | 9.61 |
| General Health (GH) | 30.5 | 6.73 |
| Bodily Pain (BP) | 45.6 | 8.24 |
| Vitality (VT) | 44.8 | 10.2 |
| Social Functioning (SF) | 28.9 | 9.80 |
| Role-Emotional (RE) | 30.5 | 14.31 |
| Mental Health (MH) | 40.2 | 12.25 |
| **PCS** | **35.12** | 7.25 |
| **MCS** | **37.27** | 12.45 |

## 4.7 Correlation metric between severity of stroke, levels of dysphagia, nutritional status and health status among ischemic stroke patients with dysphagia

Before using Pearson's Product Moment correlation, the assumption was tested. All variables were cautiously assessed for their normal distribution. The results showed that all variables except for health status (SF12v2-PCS) scores were in the form of normal distribution. Therefore, Spearman's rho was employed to test all variables' correlation with health status.

The result illustrated that severity of stroke took negative low impacts on physical health status (SF12v2 - PCS) at $r = -.452$, $p < .01$ and negative medium correlate on mental health status (SF12v2 - MCS) at $r = -.542$, $p < .01$; nutritional status was positively low in correlation with physical health status (SF12v2 - PCS) at $r = .424$, $p < .01$, and mental health status (SF12v2 - MCS) at $r = .225$, $p < .05$; levels of dysphagia also took negatively low impacts on physical health status (SF12v2 - PCS) at $r = -.312$, $p < .01$, and in negatively high correlation with mental health status (SF12v2 - MCS) at $r = -.711$, $p < .01$ (table 4.7).

**Table 4.7** Correlation between severity of stroke, nutritional status levels of dysphagia, and health status among ischemic stroke patients with dysphagia **(**n= 115**)**

| | | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|---|
| 1. **NIHSS** | | 1.00 | | | | |
| 2. **NRS** | | -.560** | 1.00 | | | |
| 3. **GUSS** | | .756** | -.485** | 1.00 | | |
| **SF-12v2** | 4. **PCS** | -.452** | .424** | -.312** | 1.00 | |
| | 5. **MCS** | -.542** | .225* | -.711** | -.124 | 1.00 |

**. Correlation is significant at the 0.01 level

*. Correlation is significant at the 0.05 level

# CHAPTER V
# DISCUSSION

In this chapter, the researcher presents the discussion of this research findings relevance to the studied objectives.

## 5.1 The health status among ischemic stroke patients with dysphagia

Patients' health status in this study was measured by two components as physical health and mental health. Research results showed that the average scores of 35.12 (SD ± 7.25) and 37.27 (SD ± 12.45) respectively which referred to impaired range on physical and mental health status. More evidences from this finding showed that mean of three physical health domain points (PF, RP, GH) fell into the impaired range (<40), while their BP score was at the average range (45.6). Similarly, their score for two of four mental health domains (SF, RE) fell into the impaired range (28.9 and 30.5 respectively), whereas the figures for MH *score* (40.2) and VT *score* (44.8) were in the impairment indicated and the average range respectively.

The explanation on this finding is that 68.70% of patients over aged 60 and the average age of subjects is 66.1 years old, so that the physical and mental health also declined with aging process. The age of patients in our study is comparable to other studies reported by Marcel Arnold et al. (2016) in Switzerland, Shrestha et al. (2015) in Nepal, Ribeiro et al. (2015) in Brazil, and Tirschwell et al (2012) in Viet Nam, in which mean age were 65.6, 67,68 and 65 years old respectively (Arnold et al., 2016; Ribeiro et al., 2015; Shrestha, Poudel, Khatiwada, & Thapa, 2015; Tirschwell et al., 2012). This means that, stroke occurs mostly in older people. A study among 304 persons with mild stroke in The USA, mean age was approximately 65 years conducted by Duncan et al. (1997) claimed that the consequences of even mild stroke affect all dimensions of health except pain, and the health status of individuals is

below the 50th percentile of a norm-based group of aged 65 to 74 years (Duncan et al., 1997).

In this study, we also found that there were 31.30% of patients under 60 years, this proportion is similar to that reported by the National Statistics (2015), 28 % of stroke patients were under 65 year old (Ngoc, 2016). Our data probably is a warning about the increased risk of stroke in young and middle aged people. Khodabandehlou et al. (2016) demonstrated that young ischemic stroke patients more often suffered from mental health (e.g. anxiety and stress, malaise, solitude, disappointment, and anger) as well physical issues. Therefore, whatever mental health condition weaker odds of ischemic stroke incidence is high (OR = 39.29, CI = 4.93-312.51, p = 0.001) (Khodabandehlou, Mansournia, Mehrpour, & Naieni, 2016).

In terms of comorbidity existed in the sample, 73.92 % of patients reporting comorbidity, in which 56.52% of patients had a history of hypertension, which is lower than the findings of another studies reported from Tirschwell et al (2012), in which the proportion of hypertension patients was 94.5% (Tirschwell et al., 2012) respectively. A study on the relationship between health status and blood pressure in urban African Americans conducted by DeForge et al. (1998) claimed that patients with hypertension reported lower physical functioning (p = 0.003) and poorer general health (p = 0.001) than those without hypertension. In other word, hypertension has a negative impact on health function (DeForge, Stewart, DeVoe-Weston, Graham, & Charleston, 1998). Another study performed in Viet Nam found that the quality of life among hypertensive patients was moderate, except for psychology that was fairly low (mean = 49.4) (Ha, Duy, Le, Khanal, & Moorin, 2014). Thus, most of the cerebral stroke patients had other accompanied diseases, especially hypertension (Nguyen, Tran, & Lee, 2013), causing complicated treatment.

Other factors contributed to impaired range on physical and mental health were the total case of hemiplegia was 98.3% on clinical examination and mean NIHSS was 9.68 ± 5.99 points, which is consistent with the findings of Marcel Arnold et al. (2016) among 118 Switzerland stroke patients with dysphagia, in which, NIHSS was 9.7 ± 7 (Arnold et al., 2016). In general, NIHSS scores for ISPD was higher than those for ischemic stroke patients without dysphagia, leading to poor outcome. Similarly the findings reported from Gajurel et al (2014) asserted that the health status of patients

with more severe stroke condition (mean NIHSS =14.16 ± 7.96) was significantly lower than that in patients with less severe condition (mean NIHSS = 4.6 ± 2.2) ($p < 0.001$). Consistent with our finding, a study performed in Spain among 131 ischemic stroke patients (mean age 70.1 ± 12.5), mean NIHSS score at admission was 7.37 ± 6.2, also found a six month patients' health status were impaired range (the mean score of PCS and MCS were 39.46 ± 9.3 and 34.86 ±10.1, respectively) after ischemic stroke. (Lopez-Espuela et al., 2015).

Overall, ischemic stroke patients with swallowing disorders experienced many unexpected risks on physical and mental health. Most of the patients' daily activities as well as others (individual and social activities) were limited at different levels due to physical disabilities. This will make the patients feel more anxious, fearful, depressed, leading to the impairment of mental health.

## 5.2 Correlation metric between severity of stroke, nutritional status, levels of dysphagia and health status among ischemic stroke patients with dysphagia

### 5.2.1 The relationship between severity of stroke and health status

Our results indicated the correlation between severity of stroke with physical health and mental health were negative low impacts at $r = -.452$, $p < .01$, and negative medium correlate at $r = -.542$, $p < .01$, respectively.

In our study, most of patients suffered from moderate stroke (51.30%), the rests were other levels. Our findings are also similar to result of Gajurel et al. (2014) in Nepal. According to this study, with 200 ischemic stroke patients, the mean NIHSS score was 11.87 ± 8.1, and the majority of patients (47%) was moderate stroke severity (NIHSS 5-14). As a result, according to the NIHSS score, none of the patients with moderately severe and severe strokes had good outcome. The majority of patients (33.5%) who require some help with their activities but able to walk without any assistance, independent patients amounted to 24% (Gajurel et al., 2014). Arnold et al. (2016) indicated that stroke patients with dysphagia had more severe neurological

deficits at baseline (mean NIHSS score 9.7 ± 7 vs. 4.5 ± 5.1; p < .001) and stroke severity was significant determinant for clinical recovery and residency at three months (Arnold et al., 2016). A stroke study done in Nepal by Shrestha et al. (2015) concluded that baseline NIHSS by one unit increase the odds of poor outcome by 1.557 times (p = .001) and severity of stroke might have influenced poor outcome (Shrestha et al., 2015). It can be demonstrated that the more stroke severity, the lower health status.

It was necessary for ischemic stroke patients to predict stroke severity as well as patients' outcome by NIHSS. In Viet Nam, especially in our department, NIHSS is the very instrument that the doctors and nurses working at Neurology Department used to determine severity of disease for ischemic stroke patients.

### 5.2.2 The relationship between nutritional status and health status

Clinical evaluation revealed that nutritional status was positively low in correlation with physical health at r =.424, p <. 01, and mental health at r =.225, p < .05. The results reported that 88.70% of patients were nutritionally at-risk, indicating special diet recommended by dieticians. Malnourished patients were significantly older (p < .001) than well-nourished patients, but the values for BMI (4.35%), serum albumin (18.26). Using different assessment tools, the previous studies identified that the frequency of malnutrition ranged from 6% to 62% (Foley, Salter, Robertson, Teasell, & Woodbury, 2009). Another study conducted by B. J. J. Poels et al. (2006) among 69 stroke patients in Netherland documented, in which 73% of patients were malnourished at admission (n = 50/69 CI: 61 – 82%) (Poels, Brinkman-Zijlker, Dijkstra, & Postema, 2006). A prevalence of 88.7% malnutrition on admittance indicated that establishing a patient's malnutrition status is not always easy because there is no universally accepted definition of malnutrition or a gold standard for malnutrition status assessment (Wang et al., 2014). As Kyle et al. (2006) concluded that the NRS 2002 was a better clinical screening tool than the MUST (Malnutrition Universal Screening Tool) or NRI (Nutritional Risk Index), when compared to the SGA (Subjective Global Assessment) (Kyle, Kossovsky, Karsegard, & Pichard, 2006). The higher specificity of the NRS 2002 may be because it allows for the gradation of

disease effects (scores 1~3). One advantage of the NRS 2002 screening tool is that it depends less on examiner training than do the other nutritional assessment tools (Kyle et al., 2006). The high rate of malnutrition of stroke patients on admission in our research showed that need to have schedule given by physiotherapist, neurologist, occupational therapist, stroke nurses, pharmacist and dietician to manage malnutrition in this population.

Gariballa & Sinclair. (1998) reported that malnutrition is associated with poor outcome in patients with both ischemic and hemorrhagic stroke. Protein and energy malnutrition (PEM) on admission influences the mechanism of ischemic brain injury and impairs recovery. Malnourished patients with stroke experience more intense stress reactions, show higher rates of pressure sores, urinary tract and respiratory infection, have longer duration of hospitalization and higher mortality rates (Gariballa & Sinclair, 1998). Even though for the stroke patients, bed ridden and unable to voice their needs, reduced mobility, limbs weakness, dysphagia, loss of appetite, impaired consciousness, perceptual impairment, delirium or loneliness and social isolation… were all the factors may lead to malnutrition (Shen et al., 2011). The high rate of malnutrition of stroke patients on admission in our research showed that need to have schedule given by physiotherapist, neurologist, occupational therapist, stroke nurses, pharmacist and dietician to manage malnutrition in this population.

### 5.2.3 The relationship between levels of dysphagia and health status

After analyzing the data presented levels of dysphagia took negatively low impacts on physical health at r= -312, p <. 01, and in negatively high correlation with mental health at r = -.711, p <. 01. Of all patients, more than 66.09 % individuals had slight dysphagia. This was followed by the figures for moderate dysphagia and severe dysphagia, at 23.48% and 10.43% respectively. 21 out of 115 studied patients were required to be fed via tubes, including 12 cases of severe dysphagia after stroke and 9 cases of moderate dysphagia. The rests can be fed merely via oral path with soft and thick diet and drinking in small mouthfuls were highly recommended to avoid choking.

In a related study conducted by Marcel Arnold et al. (2016), which included 118 ischemic stroke patients with dysphagia, in which 30.5% of patients with

severe dysphagia were required tube feeding (Arnold et al., 2016). Mohamed Al-Khaled et al. (2016) demonstrated that ischemic stroke patients with dysphagia had a likelihood of 3-month disability than those without dysphagia (74 vs. 25%, respectively; $p < .001$ (OR 2.3; 95% CL 1.8-3.0), and the presence of dysphagia was strongly associated with longer hospitalization (Al-Khaled et al., 2016).

Similarly the findings reported from Marcel Arnold et al. (2016) concluded that dysphagia affected 20.7% ischemic stroke patients and had a negative impact on clinical outcome (Arnold et al., 2016). In other word, the presence of dysphagia during the acute phrase of stroke is associated with poor outcome (Smithard, Smeeton, & Wolfe, 2007).

It can be concluded that, swallowing disorder screening played an important role in caring of stroke patients. It made a significant contribution to preventing risk factors such as aspirated pneumonia, especially silent aspirations as well as malnutrition, event mortality.

In conclusion, it can be demonstrated that the results of this study complied with the concept of Symptom management theory. In the current study, health status refers to symptom outcome; dysphagia, nutritional status, and stroke severity are derived from the health and illness domain. Theoretically, health and illness domain could influence outcomes domain. It is necessary to manage dysphagia, nutritional status, and severity of stroke appropriately in order to improve the health status among ischemic stroke patients.

## 5.3 Conclusion

Our finding showed that were severity of stroke and levels of dysphagia were negatively correlated with physical health ($r = -.452$, $p < .01$; $r = -.31$, $p < .01$ respectively) and mental health ($r = -.542$, $p < .01$; $r = -.711$, $p < .01$ respectively), whereas nutritional status was positively correlated with both physical and mental health ($r = .424$, $p < .01$; $r = .225$, $p < .05$ respectively). Accordingly, in order to improve health status among ischemic stroke patients with dysphagia, nurses should assess and detect patients' dysphagia symptoms as soon as possible to promote their suitable diet as well as patients' nutritional status. By using the scales mentioned

above, the health status of stroke patients with dysphagia can be thoroughly examined and observed. The method of evaluation is also simple and easy to understand to both nurses and patients as well as patient's family. Although there are still a number of limits in this report: clinical interventions or treatment strategies not investigated, the report still provides a good basis for further researches on dysphagia among patients after stroke or for the building of programs for dysphagia patients in the Neurology Department of Bach Mai hospital.

# CHAPTER VI
# CONCLUSION

## 6.1 Conclusion of the study

This descriptive correlational study aimed to examine the relationship between severity of stroke, levels of dysphagia, nutritional status and health status among ischemic stroke patients with dysphagia who aged 40– 88 years old in the Neurology Department from August to October, 2016. Symptom management theory was utilized as a framework of this study. The sample calculation yielded 115 samples. The research setting was the Department of Neurology, a center specializing in Bach Mai Hospital, HaNoi, Viet Nam.

The IRB approval from Institutional Review Board of Nursing faculty, Mahidol University and Institutional of Review Board of SMP, Vietnam National University, Hanoi, Vietnam. The researcher used 5 instruments: the demographic data questionnaire, SF-12v2, NIH Stroke Scale (NIHSS), Nutritional Risk Screening 2002 (NRS-2002) scale and Gugging Swallowing Screen (GUSS) to collect data. All instruments were tested for their validity and reliability as clearly explained in chapter 3. Cronbach's alpha coefficient of SF-12v2, NIH Stroke Scale (NIHSS), Nutritional Risk Screening 2002 (NRS-2002) scale and Gugging Swallowing Screen (GUSS) were .89, .85, .77 and .93 respectively.

The 115 patients were selected according to the inclusion criteria. The researcher collected data by herself from 8.00 am to 5.00 pm every day until the sample reached the essential sample size. For each patient, the researcher spent 30 to 35 minutes on interviewing, clinical examination and collected some data from their patients' records. During data collection, there was no adverse event among the sample. All sample recruited in the study remained throughout the study process with no attrition.

Data analysis was conducted by using computer program. The descriptive statistics were used to describe general information and study variables, including

severity of stroke, levels of dysphagia, nutritional status and health status.The assumption of Pearson' Product Moment Correlation was tested and it was found that all variables were not in normal distribution. Accordingly, Spearman's rho was used to examine correlation between severity of stroke, levels of dysphagia, nutritional status and health status among ischemic stroke patients with dysphagia

**With the results, we conclude that:**

Demographic characteristics of the subject were presented in Table 4.1. Among 115 patients, there were 70 males (accounted for 60.87%) and 45 females (accounted for 39.13 %) who came from several provinces in Viet Nam. In fact, there were 108 people from the North of Viet Nam (accounted for 93.91%), patients are Ha Noi citizens made up 28.7%.The average age of these patient was 66 years old (SD ±10.4), in which the oldest patient was 88 year old and the youngest one was 40 year old. The highest age were individuals who lower than 60 years old, account for 31.30%. The number of 75-year-old-or-more group patients was the lowest, at 20.87%. This was followed by the figures for the ages ranging from 61-68 and 69-75, at 26.09% and 21.74% respectively. More than 60% of participants gained a secondary education (accounted for 63.48%), College and Bachelor degree constituted at 24.35%, high school education was the lowest segment, at 12.17%. The patients' main occupations were farmers, accounted for 53.04 %. There were 26.08 % of people who retired and the rests were other occupations. There were approximately 39.13% of people who belonged to no-income group. This was followed by the figures for people who had less than 101 USD accounted for 20%, 101-200 USD accounted for 24.35%, 201-300 USD accounted for 13.04 %, and over 300 USD per month accounted for 3.48%. The income's mean was at $87.3 (SE = 8.86), which revealed that most of the participants had low income. Most of the participants were married and lived with their family (accounted for 99.13%). The participants, therefore, received their family's supports (made up 12.17%), health insurance (made up 45.22%) as well as both health insurance and their family's supports (at 42.61%) which helped them to pay hospital fees.

1. Among 115 ischemic stroke patients with dysphagia, aged 40 – 88 years old in the Neurology Department of Bach Mai Hospital from August to October, 2016, Hypertension was the most comorbidity disease found (56.52%). Most of patients had hemiplegia (98.2%) and suffered from moderate stroke (51.30%). Average NIHSS score was 9.68 ± 5.99. 66.09% had slight dysphagia. 88.70% of patients were nutritionally at-risk, indicating special diet recommended by dieticians.

2. Level of dysphagia 12 individuals (made up 10.43%) were diagnosed to suffer from severe dysphagia, 27 individuals (made up 23.48%) caught moderate dysphagia and 76 individuals (66.09 ) had slight dysphagia. Only 18.26% have no tube feeding.

3. Regarding health status,

Mean of three physical health domain fell into the impaired range (<40), But BP score was at the average range (45.6). Similarly, their score for two of four mental health domains (SF, RE) fell into the impaired range (28.9 and 30.5 respectively), whereas the figures for MH *score* (40.2) and VT *score* (44.8) were in the impairment indicated and the average range respectively. PF, RP, GH, SF, RE had a significant impact on the level of patients' physical and mental health status, at impaired range by the PCS score (35.12) and MCS score (37.27) (SD ± 7.25 vs. 12.45 respectively).

4. severity of stroke took negative low impacts on physical health status (SF12v2 - PCS) at $r = -.452$, $p < .01$ and negative medium correlate on mental health status (SF12v2 - MCS) at $r = -.542$, $p < .01$; nutritional status was positively low in correlation with physical health status (SF12v2 - PCS) at $r = .424$, $p < .01$, and mental health status (SF12v2 - MCS) at $r = .225$, $p < .05$; levels of dysphagia also took negatively low impacts on physical health status (SF12v2 - PCS) at $r = -.312$, $p < .01$, and negatively high correlation with mental health status (SF12v2 - MCS) at $r = -.711$, $p < .01$.

The results of this study complied with the concept of symptom management theory. In the current study, health status refers to symptom outcome; dysphagia, nutritional status, and stroke severity that are derived from the health and illness domain. Theoretically, health and illness domain could influence outcomes. It is

necessary to manage dysphagia, nutritional status, and severity of stroke appropriately in order to improve the health status among ischemic stroke patients.

## 6.2 Implications of Research Findings

### 6.2.1 Implications for nursing practice

In order to enhance health status in ischemic stroke patients with dysphagia, the following measures have to be performed by nurses:

1) Improving patients' health status by providing them with knowledge about detecting symptoms of dysphagia and preventing the risks affecting their health status such as aspirated pneumonia, especially silent aspirations as well as malnutrition.

2) Assessing and detecting patients' dysphagia symptoms as soon as possible in order to promote their suitable diet and, therefore, improving patients' health status.

3) Developing guidelines related to care ischemic stroke patients with dysphagia. The risks affecting patients' health status will be identified, observed and eliminated more effectively thanks to nurse's thorough understanding and the combination of a variety of tools in diagnosing the risks. With clear analysis on the groups of factors, intervention will also be more efficient with right focus and right time. As a result, the fatality of stroke patients with dysphagia will be reduced and the recovery will be significantly enhanced.

4) Providing routine assessment on ischemic stroke patients with dysphagia for nurses in order to helps nurses to have deeper and more systematic knowledge relating to dysphagia after stroke, facilitating effective approach to treatment and care of dysphagia patients. This will also partly contribute to manage patients' health status.

### 6.2.2 Implications for further study

1). Clinical practice guidelines to improve health status among ischemic stroke patients with dysphagia should be developed and tested for its effectiveness by using quasi experimental research.

2) The GUSS in Vietnamese version should be tested in its psychometric property by using adequate numbers of patients and advanced statistic-factor analysis should be employed to test the psychometric property of GUSS in Vietnamese context.

# REFERENCES

Addington, W. R., Stephens, R. E., & Gilliland, K. A. (1999). Assessing the Laryngeal Cough Reflex and the Risk of Developing Pneumonia After Stroke: An Interhospital Comparison. *Stroke, 30*, 1203-1207.

Al-Khaled, M., Matthis, C., Binder, A., Mudter, J., Schattschneider, J., Pulkowski, U., et al. (2016). Dysphagia in Patients with Acute Ischemic Stroke: Early Dysphagia Screening May Reduce Stroke-Related Pneumonia and Improve Stroke Outcomes. *Cerebrovasc Dis, 42*, 81–89. doi: 10.1159/000445299

Altman. (2006). Dysphagia Found to Increase Length of Hospital Stay AndMortality Risk: The Mount Sinai Hospital / Mount Sinai School of Medicine.

Altman, K. W., Gou-PeiYu, & Schaefer, S. D. (2010). Consequence of Dysphagia in the Hospitalized Patient. Impact on Prognosis and Hospital Resources. *Archives of Otolaryngology-Head and Neck Surgery, 136*(8), 784-789.

Arnold, M., Liesirova, K., Broeg-Morvay, A., Meisterernst, J., Schlager, M., Mono, M.-L., et al. (2016). Dysphagia in Acute Stroke: Incidence, Burden and Impact on Clinical Outcome. *PLOS ONE, 11*(2). doi: 10.1371/journal.pone.0148424

Asadollahpour, F., Baghban, K., Asadi, M., Naderifar, E., & Dehghani, M. (2015). Oropharyngeal Dysphagia in Acute Stroke Patients. *Zahedan Journal of Research in Medical Sciences, 17*(8), e1067. doi: 10.17795/zjrms-1067

Aviv, J. E., Martin, J. H., Sacco, R. L., Zagar, D., Diamond, B., Keen, M. S., & Blitzer, A. (1996). Supraglottic and pharyngeal sensory abnormalities in stroke patients with dysphagia. *Annals of Otology, Rhinology Laryngology, 105*(2), 92-97.

Ayerbe, L., Ayis, S., Rudd, A. G., Heuschmann, P. U., & Wolfe, C. D. A. (2011). Natural History, Predictors, and Associations of Depression 5 Years After Stroke: The South London Stroke Register. *Stroke, 42*(7), 1907-1911. doi: 10.1161/STROKEAHA.110.605808

Barer, D. H. (1989). The natural history and functional consequences of dysphagia after hemispheric stroke. *Journal of Neurology, Neurosurgery, and Psychiatry, 52*(2), 236-241. doi: 10.1136/jnnp.52.2.236

Baroni, A. F. F. B., Fábio, S. R. C., & Dantas, R. O. (2012). Risk factors for swallowing dysfunction in stroke patients. *Arq Gastroenterol, 49*(2).

Bartoli, F., Mantero, V., Lillia, N., Carrà, G., Lax, A., Agostoni, E., et al. (2013). Depression after Stroke and Risk of Mortality: A Systematic Review and Meta-Analysis. *Stroke Research and Treatment*. doi: 10.1155/2013 /862978

Basri, H., Piaw, C. S., Irene, L., Soon, M. C., Muda, M. S., Rafia, H., et al. (2012). *Clinical practice guidelines: Management of ischaemic stroke* (Vol. 2nd Edition). Malaysia.

Bogousslavsky, J., Liu, M., Moncayo, J., Norrving, B., Tsiskaridze, A., Yamaguchi, T., & Yatsu, F. (2006). *Stroke* (Vol. Chapter 3). Switzerland: World Health Organization.

Bour, A., Rasquin, S., Aben, I., Boreas, A., Limburg, M., & Verhey, F. (2010). A one-year follow-up study into the course of depression after stroke. *The journal of nutrition, health and aging, 14*(6), 488-493.

Brainin, M., Heiss, W.D., & Heiss, S. (2010). *Clinical epidemiology and risk factors* (Vol. 2). New York: Cambridge University Press.

Brott, T., Adams, H. P., Olinger, C. P., Marler, J. R., Barsan, W. G., Biller, J., et al. (1989). Measurements of Acute Cerebral Infarction: A Clinical Examination Scale. *Stroke, 20*(7), 864-870.

Caplan, L. R. (2009). *Caplan's stroke: A clinical approach* (Vol. Fourth Edition): Saunders Elsevier

Chen, H., Epstein, J., & Stern, E. (2010). Neural Plasticity After Acquired Brain Injury: Evidence from Functional Neuroimaging. *American Academy of Physical Medicine and Rehabilitation, 2*(12), s306-s312. doi: 10.1016/j.pmrj.2010.10.006

Dancause, N., & Nudo, R. J. (2011). Shaping plasticity to enhance recovery after injury. *Progress in Brain Research, 192,* 273-295. doi: 10.1016/B978-0-444-53355-5.00015-4

Daniels, S. K., Brailey, K., Priestly, D. H., Herrington, L. R., Weisberg, L. A., & Foundas, A. L. (1998). Aspiration in Patients With Acute Stroke. *Arch Phys Med Rehabil, 79*.

DeForge, B. R., Stewart, D. L., DeVoe-Weston, M., Graham, L., & Charleston, J. (1998). The relatioship between health status and blood pressure in urban African Americans. *Journal of th National Medical Association, 90*(11), 658-664.

DePippo, K. L., Holas, M. A., Reding, M. J., Mandel, F. S., & Lesser, M. L. (1994). Dysphagia therapy following stroke: A controlled trial. *Neurology, 44*(9), 1655-6160.

Dodd, M., Janson, S., Facione, N., Faucett, J., Froelicher, E. S., Humphreys, J., et al. (2001). Journal of Advanced Nursing *Nursing theory and concept development or analysis, 33*(5), 668-676.

Dong, Y., Slavin, M. J., Venketasubramanian, N., Crawford, J. D., Collinson, S. L., Chen, C. L.-H., et al. (2013). Cognitive screening improves the predictive value of stroke severity scores for functional outcome 3–6months after mild stroke and transient ischaemic attack: an observational study. *BMJ Open, 3*(e003105), 1-6. doi: 10.1136/bmjopen-2013-003105

Duncan, P. W., Samsa, G. P., Weinberger, M., Goldstein, L. B., Bonito, A., Witter, D. M., et al. (1997). Health Status of Individuals With Mild Stroke. *Stroke, 28*, 740-745.

Edelman, D., Williams, G. R., Rothman, M., & Samsa, G. P. (1999). A Comparison of Three Health Status Measures in Primary Care Outpatients. *JGIM, 14*, 759–762.

Edwardson, M. A., & Dromerick, A. W. (2015). Ischemic stroke prognosis in adults. from www.uptodate.com

Ekberg, O., Hamdy, S., Woisard, V., Wuttge–Hannig, A., & Ortega, P. (2002). Social and psychological burden of dysphagia: its impact on diagnosis and treatment. *Dysphagia, 17*(2), 139-146.

Elkind, M. S. V., & Sacco, R. L. (2010). *Pathogenesis, Classification, and Epidemiology of Cerebrovascular Disease* (L. P. Rowland & T. A. Pedley Eds. Vol. 12th Edition): Lippincott Williams & Wilkins.

Ellis-Hill, C. S., & Horn, S. (2000). Change in identity and self-concept: a new theoretical approach to recovery following a stroke. *Clinical Rehabilitation, 14*(3), 279-287. doi: 10.1191/026921500671231410

Farner, L., Wagle, J., Engedal, K., Flekkøy, K. M., Wyller, T. B., & Fure, B. (2010 ). Depressive symptoms in stroke patients: a 13 month follow-up study of patients referred to a rehabilitation unit. *Journal of Affective Disorders, 127*(1-3), 211-218. doi: 10.1016/j.jad.2010.05.025

Faul, F., Erdfelder, E., Buchner, A., & Lang, A.-G. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behavior Research Methods, 41* (4), 1149-1160. doi: 10.3758/BRM .41.4.1149

Field, A. (2009). *Discovering statistics using SPSS* (Vol. 3rd Edition). Thousand Oaks: Sage.

Fitzpatrick, R., Bowling, A., Gibbons, E., Haywood, K., Jenkinson, C., Mackintosh, A., & Peters, M. (2006). Patient-reported Health Instruments use for people with Stroke *A structured review of patient-reported measures in relation to selected chronic conditions, perceptions of quality of care and carer impact* (Vol. Chapter 9, pp. 300-310).

Flowers, H. L., Silver, F. L., Fang, J., Rochon, E., & Martino, R. (2013). The incidence, co-occurrence, and predictors of dysphagia, dysarthria, and aphasia after first-ever acute ischemic stroke. *Journal of Communication Disorders, 46*(3), 238-248. doi: 10.1016/j.jcomdis.2013.04.001. Epub 2013 Apr 12.

Foley, N. C., Salter, K. L., Robertson, J., Teasell, R. W., & Woodbury, G. (2009). Which Reported Estimate of the Prevalence of Malnutrition After Stroke Is Valid? *Stroke, 40*, 66-74. doi: 10.1161/STROKEAHA.108.518910

FOOD Trial Collaboration. (2003). Poor Nutritional Status on Admission Predicts Poor Outcomes After Stroke: Observational Data From the FOOD Trial. *Stroke, 34*, 1450-1456. doi: 10.1161/01.STR.0000074037.49197.8C

Freitas, B. R. d., Bogousslavsky, J., Bezerra, D. C., & Maulaz, A. B. (2005). Stroke: background, epidemiology, etiology and avoiding recurrence. *Cambridge University Press*.

Gajurel, B. P., Dhungana, K., Parajuli, P., Karn, R., Rajbhandari, R., Kafl, D., & Oli, K. K. (2014). The National Institute of Health Stroke Scale Score and Outcome in a cute Ischemic Stroke. *Journal of Institute of Medicine, 36*(3), 9-13.

Galovic, M., Leisi, N., Müller, M., Weber, J., Abela, E., Kägi, G., & Weder, B. (2013). *Lesion location predicts transient and extended risk of aspiration after supratentorial ischemic stroke* (Vol. 44).

Gariballa, S. E., & Sinclair, A. J. (1998). Assessment and treatment of nutritional status in stroke patients. *Medicine in the elderly, 395-399*, 395-399.

Go, A. S., Mozaffarian, D., Roger, V. L., Benjamin, E. J., Berry, J. D., .Blaha, M. J., et al. (2013). Heart Disease and Stroke Statistics—2014 Update: A Report From the American Heart Association *Circulation* (Vol. 129, pp. e166-e167).

Gordon, C., Hewer, R. L., & Wade, D. T. (1987). Dysphagia in acute stroke. *British Medical Journal, 295*(6595), 411–414.

Gosney, M., Martin, M. V., & Wright, A. E. (2006). The role of selective decontamination of the digestive tract in acute stroke. *Age and Ageing, 35*, 42-47. doi: 10.1093/ageing/afj019

Grysiewicz, R. A., Thomas, K., & Pandey, D. K. (2008). Epidemiology of Ischemic and Hemorrhagic Stroke: Incidence, Prevalence, Mortality, and Risk Factors. *Neurologic clinics, 26*(4), 871–895 doi: 10.1016/j.ncl.2008.07.003

Gurr, B., Psych, D. C., Psych, D., Muelenz, C., & Psych, D. (2011). A Follow-up Study of Psychological Problems After Stroke. *Top Stroke Rehabilitation, 18*(5), 461–469. doi: 10.1310/tsr1805-461

Ha, N. T., Duy, H. T., Le, N. H., Khanal, V., & Moorin, R. (2014). Quality of life among people living with hypertension in a rural Vietnam community. *BioMed Central Neurology, 14*(833), 1471-2458.

Hinchey, J. A., Shephard, T., Furie, K., Smith, D., Wang, D., & Tonn, S. (2005). Formal dysphagia screening protocols prevent pneumonia. *Stroke, 36*, 1972-1976 doi: 10.1161/01.STR.0000177529.86868.8d

Hirano, I., & Kahrilas, P. J. (2012). *Dysphagia* (Vol. Eighteenth Edition): The McGraw-Hill Companies, Inc.

Ho, Y.H., Liu, H.Y., & Huang, S.T. (2014). The prevalence and signs of Dysphagia among stroke patients in rehabilitation units. *Dysphagia of Stroke, 61*(2), 54-62.

Hosp, J. A., & Luft, A. R. (2011). Cortical Plasticity during Motor Learning and Recovery after Ischemic Stroke. *Neural Plasticity*, 1-9. doi: 10.1155/2011/871296

House, A., Knapp, P., Bamford, J., & Vail, A. (2001). Mortality at 12 and 24 Months After Stroke May Be Associated With Depressive Symptoms at 1 Month. *Stroke, 32*, 696-701.

Hudson, J., Ross, C., & Taylor, K. (2006). *The cost of stroke to both the NHS and the wider economy is high with much that could and should be done for those who suffer a stroke*: National Audit Office.

Islam, M. A., Rahman, A., Aleem, M. A., & Islam, S. M. S. (2015). Prevalence and Associated Factors of Depression Among Post-Stroke Patients in Bangladesh. *International Journal Mental Health Addiction*. doi: 10.1007/s11469-015-9582-x

Humphreys, J., Janson, S., Donesky, D., Dracup, K., A.Lee, K., Puntillo, K., et al. (2014). *Theory of Symptom Management* (Vol. Third Edition). New York, NY 10036-8002: Springer.

John, J. S., & Berger, L. (2015). Using the Gugging Swallowing Screen (GUSS) for Dysphagia Screening in Acute Stroke Patients. *Journal of Continuing Education in Nursing, 46*(3), 103-104. doi: 10.3928/00220124-20150220-12

Kasner, S. E., Chalela, J. A., Luciano, J. M., Cucchiara, B. L., Raps, E. C., McGarvey, M. L., et al. (1999). Reliability and Validity of Estimating the NIH Stroke Scale Score from Medical Records. *Stroke, 30*(8), 1534-1537.

Katzan, I. L., Cebul, R. D., Husak, S. H., Dawson, N. V., & Baker, D. W. (2003). The effect of pneumonia on mortality among patients hospitalized for acute stroke. *Neurology, 60*, 620–625.

Katzan, I. L., Dawson, N. V., Thomas, C. L., Votruba, M. E., & Cebul, R. D. (2007). The cost of pneumonia after acute stroke. *Neurology, 68*, 1938-1943.

Keppel, C. C., & Crowe, S. F. (2000). Changes to Body Image and Self-esteem following Stroke in Young Adults. *Neuropsychological Rehabilitation, 10*(1), 15-31. doi: 10.1080/096020100389273

Khodabandehlou, M., Mansournia, M. A., Mehrpour, M., & Naieni, K. H. (2016). Mental health and ischemic stroke in young adults: A case-crossover study in Iran. *Journal Biostat Epidemiol, 2*(1), 9-13.

Kidd, D., Lawson, J., Nesbitt, R., & McMahon, J. (1995). The natural history and clinical consequences of aspiration in acute stroke. *QJM, 88*(6), 409-413. doi: http://dx.doi.org/ 409-413 First published online: 1 June 1995

Kondrup, J., Allison, S. P., Elia, M., Vellasz, B., & Plauth, M. (2003). ESPEN Guidelines for Nutrition Screening 2002. *Clinical Nutrition, 22*(4), 415–421. doi: 10.1016/S0261-5614(03)00098-0

Kondrup, J., Rasmussen, H. H., Hamberg, O., & Stanga, Z. (2003 ). Nutritional risk screening (NRS 2002): a new method based on an analysis of controlled clinical trials. *Clinical Nutrition, 22*(3), 321-336.

Kwaha, L. K., & Diong, J. (2014). National Institutes of Health Stroke Scale (NIHSS). *Journal of Physiotherapy, 60*, 61.

Kwakkel, G., Veerbeek, J. M., Wegen, E. E. H., Nijland, R., Wel, B. C. H., Dippel, D. W. J. (2010). Predictive value of the NIHSS for ADL outcome after ischemic hemispheric stroke: does timing of early assessment matter? *Journal of the Neurological Sciences, 294*, 57-61. doi: 10.1016/j.jns.2010.04.004

Kyle, U. G., Kossovsky, M. P., Karsegard, V. L., & Pichard, C. (2006). Comparison of tools for nutritional assessment and screening at hospital admission: A population study. *Elsevier Ltd and European Society for Clinical Nutrition and Metabolism*, *25*, 409–417. doi: 10.1016/j.clnu.2005.11.001

Langdon, C. (2012). In J. C. G. Rodriguez (Ed.), *Acute Ischemic Stroke : Dysphagia and Respiratory Infections in Acute Ischemic Stroke* (pp. 84-88): InTech.

Larson, P. J., Carrieri-Kohlman, V., Dodd, M., Douglas, M., Faucett, J., Froelicher, E. S., et al. (1994). A Model for Symptom Management *Journal of Nursing Scholarship*, *26*(4), 272–276. doi: 10.1111/j.1547-5069.1994.tb00333.x

Levine, M. W., & Shefner, J. M. (1981). *Levine & Shefner's Fundamentals of Sensation and Perception* (3rd ed). New York, NY: Oxford University

Lopez-Espuela, F., Zamorano, J. D., Ramı´rez-Moreno, J. M., Jimenez-Caballero, P. E., Portilla-Cuenca, J. C., Lavado-Garcı´a, J. M., & Casado-Naranjo, I. (2015). Determinants of Quality of Life in Stroke Survivors After 6 Months, from a Comprehensive Stroke Unit: A Longitudinal Study. *Biological Research for Nursing, 17*(5), 461-468. doi: 10.1177/ 1099800414553658

Mack, W., Dusick, J. R., Martin, N., & Gonzalez, N. (2012). *Principles of Endovascular Therapy* (Vol. Sixth Edition): Philadelphia: Elsevier Saunders.

Mackay, J., & Mensah, G. A. (2004). *Global burden of stroke* (Vol. 15): World Health Organization

Marik, P. E., & Kaplan, D. (2003). Aspiration Pneumonia and Dysphagia in the Elderly. *Chest, 124*, 328–336.

Martino, R., Martin, R. E., & Black, S. (2012). Dysphagia after stroke and its management. *Canadian Medical Association Journal 184*.

Maruish, M. E. (2012). *Concepts, Measures, and Applications* (M. E. Maruish Ed. Vol. Third Edition): Quality Metric Incorporated.

McLaren, S. M. G., & Dickerson, J. W. T. (2000). Measurement of eating disability in an acute stroke population. *Clinical Effectiveness in Nursing, 4*(3), 109-120. doi: 10.1054/cein.2000.0128

Meng, N. H., Wang, T. G., & Lien, I. N. (2000). Dysphagia in Patients with Brainstem Stroke: Incidence and Outcome.*American Journal of Physical Medicine & Rehabilitation, 79*(2), 170-175.

Momosaki, R., Abo, M., Kakuda, W., & Uruma, G. (2012). Which cortical area is related to the development of dysphagia after stroke? A single photon emission computed tomography study using novel analytic methods. *European Neurology, 67*(2 ), 74-80. doi: 10.1159/000333778

Mourão, A. M., Lemos, S. M. A., Almeida, E. O., Vicente, L. C. C., & Teixeira, A. L. (2016). Frequency and factors associated with dysphagia in stroke. *CoDAS, 28*(1), 66-70. doi: 10.1590/2317-1782/20162015072

Mozaffarian, D., Benjamin, E. J., Go, A. S., Arnett, D. K., Blaha, M. J., Cushman, et al. (2015). Heart Disease and Stroke Statistics—2015 Update: A Report From the American Heart Association. *Circulation, 131*, e29-e322. doi: 10 .1161/CIR .0000000000000152

Munro, B. H. (2005). *Statistical Methods for Health Care Research* (Vol. Fifth Edition). Lippincott Williams & Wilkins: Philadelphia.

Nakajoh, K., Nakagawa, T., Sekizawa, K., Matsui, T., Arai, H., & Sasaki, H. (2000). Relation between incidence of pneumonia and protective reflexes in post-stroke patients with oral or tube feeding. *Journal of Internal Medicine, 247*, 39-42.

Ngoc, N. H. (2016). Preventing stroke. *Vietnamese Journal of Neurology, 18*, 107-109.

Nguyen, C. T., Tran, D. V., & Lee, A. H. (2013). Ischemic Stroke Prevention in Vietnam. In V. L. a. B. Somogyi (Ed.), *Ischemic Stroke: Symptoms, Prevention and Recovery* (Vol. Chapter 10): Nova Science Publishers.

Okubo, P. C. M. I., Fábio, S. R. C., Domenis, D. R., & Takayanagui, O. M. (2012). Using the National Institute of Health Stroke Scale to Predict Dysphagia in Acute Ischemic Stroke *Cerebrovascular Disease, 33*, 501–507. doi: 10.1159/000336240

Ostir, G. V., Berges, I.-M., Ottenbacher, A., & Ottenbacher, K. J. (2011 ). Patterns of Change in Depression Post Stroke. *Journal American Geriatrics Society, 59*(2), 314–320. doi: 10.1111/j.1532-5415.2010.03266.x.

Ovbiagele, B., & Nguyen-Huynh, M. N. (2011). Stroke Epidemiology: Advancing Our Understanding of Disease Mechanism and Therapy. *Neurotherapeutics, 8*, 319–329. doi: 10.1007/s13311-011-0053-1

Palmer, J. B., Drennan, J. C., & Baba, M. (2000). Evaluation and Treatment of Swallowing Impairments. *American Family Physician, 61*(8), 2453-2462.

Perlin, J. B. (2006). Management of patients with swallowing (dysphagia) or feeding disorders. *Veterans Health Administration Directive 2006-032.*

Pfeil, M., Gray, R., & Lindsay, B. (2009). Depression and stroke: a common but often unrecognized combination. *British Journal of Nursing, 18*(6), 365-369.

Poels, B. J. J., Brinkman-Zijlker, H. G., Dijkstra, P. U., & Postema, K. (2006). Malnutrition, eating difficulties and feeding dependence in a stroke rehabilitation centre. *Disability and Rehabilitation, 28*(10), 637-643.

Rainbow, D., & Marks, L. (2001). *Working with Dysphagia*: Speechmark.

Ravi, A., & Christie, J. (2014). *Adams and Victor's Principles of Neurology* (Vol. tenth Edition).

Remesso, G. C., Fukujima, M. M., Chiappetta, A. L. d. M. L., Oda, A. L., Aguiar, A. S., Oliveira, A. d. S. B., & Prado, G. F. d. (2011). Swallowing disorders after ischemic stroke. *Arquivos de Neuro-Psiquiatria, 69*(5), 785-789.

Ribeiro, P. W., Cola, P. C., Gatto, A. R., Silva, R. G. d., Luvizutto, G. J., Braga, G. P., et al. (2015). Relationship Between Dysphagia, National Institutes of Health Stroke Scale Score, and Predictors of Pneumonia After Ischemic Stroke. *Journal of Stroke and Cerebrovascular Diseases*, 1-7.

Röding, J., Glader, E. L., Malm, J., & Lindström, B. (2010). Life satisfaction in younger individuals after stroke: different predisposing factors among men and women. *Journal Rehabilitation Medicine, 42*, 155–161. doi: 10.2340/16501977-0497

Rosemary Martino, Foley, N., Bhoga, S., Diamant, N., Speechley, M., & Teasell, R. (2005). Dysphagia After Stroke

Rowland, L. P., & Pedley, T. A. (2010). *Pathogenesis, Classification, and Epidemiology of Cerebrovascular Disease* (Vol. 12th Edition): Lippincott Williams & Wilkins.

Rumsfeld, J. S. (2002). Health Status and Clinical Practice: When Will They Meet? *Circulation, 106*, 5-7. doi: 10.1161/01.CIR.0000020805.31531.48

Salter, K., Mehta, S., Bhogal, S., Teasell, R., Foley, N., & Speechley, M. (2013). Post Stroke Depression *Evidence-Based Review of Stroke Rehabilitation* (pp. 1-104).

Segal, M. E., & Schall, R. R. (1994). Determining Functional/Health Status and Its Relation to Disability in Stroke Survivors. *Stroke, 25*(12), 2391-2397.

Seidel, B. M., Gruene, S., & Borte, M. (2005). *Modified NIH Stroke Scale (NIHSS)* (M. D. Ton, T. V. Luc & N. V. Lieu, Trans. Vol. First Edition): Borm Bruckmeier Publishing.

Shen, H. C., Chen, H. F., Peng, L. N., Lin, M. H., Chen, L. K., Liang, C. K., et al. (2011). Impact of nutritional status on long-term functional outcomes of post-acute stroke patients in Taiwan. *Elsevier*. doi: 10.1016/ j.archger. 2010.08.001

Shrestha, S., Poudel, R. S., Khatiwada, D., & Thapa, L. (2015). stroke subtype, age, and baseline niHss score predict ischemic stroke outcomes at 3 months: a preliminary study from central nepal. *Journal of Multidisciplinary Healthcare, 8*, 443–448.

Singh, S., & Hamdy, S. (2006). Dysphagia in stroke patients. *Postgrad Medical Journal, 82*, 383–391. doi: 10.1136/pgmj.2005.043281

Smithard, D. G., O'Neill, P. A., England, R. E., Park, C. L., Wyatt, R., Martin, D. F., & Morris, J. (1997). The natural history of dysphagia following a stroke. *Dysphagia, 12*(4), 188-193.

Smithard, D. G., O'Neill, P. A., Park, C., Morris, J., Wyatt, R., England, R., & Martin, D. F. (1996). Complications and Outcome After Acute Stroke. Does Dysphagia Matter?. *Stroke, 27*(7), 1200-1204. doi: 10.1161/01.STR. 27.7.1200

Smithard, D. G., Smeeton, N. C., & Wolfe, C. D. A. (2007). Long-term outcome after stroke: does dysphagia matter?. *Age and Ageing, 36*, 90-94. doi: 10.1093/ageing/afl149

Sorensen, J., Kondrup, J., Prokopowicz, J., Schiesser, M., Krähenbühl, L., Meier, R., & Liberda, M. (2008). An international, multicentre study to implement nutritional risk screening and evaluate clinical outcome. *Clinical Nutrition, 27*(3), 340-349.

Sørensen, R. T., Rasmussen, R. S., Overgaard, K., Lerche, A., Johansen, A. M., & Lindhardt, T. (2013). Dysphagia Screening and Intensified Oral Hygiene Reduce Pneumonia After Stroke. *Journal of Neuroscience Nursing, 45*(3), 139-146. doi: 10.1097/JNN.0b013e31828a412c

Spilker, J., Kongable, G., Barch, C., Braimah, J., Brattina, P., Daley, S., et al. (1997 ). Using the NIH Stroke Scale to assess stroke patients. *Journal of Neuroscience Nursing, 29*(6), 384-392.

Sriram, S., Asokan, K., & Thomas, T. S. (2015). Study on the Health Related Quality of Life of Patients with Ischemic stroke *Journal of Pharmacy and Biological Sciences, 10*(1), 45-52.

Stone, J., Townend, E., Kwan, J., K Haga, Dennis, M. S., & Sharpe, M. (2004). Personality change after stroke: some preliminary observations. *Journal of neurology, neurosurgery and psychiatry, 75*, 1708–1713. doi: 10.1136 /jnnp.2004.037887

Suntrup, S., Warnecke, T., Kemmling, A., Teismann, I. K., Hamacher, C., Oelenberg, S., & Dziewas, R. (2012). Dysphagia in patients with acute striatocapsular hemorrhage. *Neurology, 259*(1), 93–99. doi: 10.1007/s00415-011-6129-3

Sura, L., Madhavan, A., Carnaby, G., & Crary, M. A. (2012). Dysphagia in the elderly: management and nutritional considerations. *Clinical Interventions in Aging, 7*, 287-298. doi: http://dx.doi.org/10.2147/CIA.S23404

Takeuchi, N., & Shin-IchiIzumi. (2012). Maladaptive Plasticity for Motor Recovery after Stroke Mechanisms and Approaches. *Neural Plasticity, 2012*, 1-9. doi: 10.1155/2012/359728

Teasell, R. W., McRae, M. P., & Finestone, H. M. (2000). Social Issues in the Rehabilitation of Younger Stroke Patients. *Archives of physical medicine and rehabilitation, 81*(2), 205-209.

Tirschwell, D. L., Ton, T. G. N., Ly, K. A., Ngo, Q. V., Vo, T. T., Pham, C. H., et al. (2012). A prospective cohort study of stroke characteristics, care, and mortality in a hospital stroke registry in Vietnam. *BioMed Central Neurology, 12*, 150.

Trapl, M., Enderle, P., Nowotny, M., Teuschl, Y., Matz, K., Dachenhausen, A., & Brainin, M. (2007). Dysphagia Bedside Screening for Acute-Stroke Patients. The Gugging Swallowing Screen. *Journal of the American Heart Association, 38*. doi: 10.1161/STROKEAHA.107.483933

Tri, P. N., & Huong, N. T. T. (2011). *Study on dysphagia among acute stroke patients in Ca Mau General Hospital in 2010.* (Second Degree Medical Doctor CK 62 72 20 30), Ha Noi Medical University, Vietnam.

Vietnam Breaking News. (2013). 200,000 Vietnamese suffer strokes per year, half die.

Wang, J., Luo, B., Xie, Y., Hu, H. Y., Feng, L., & Li, Z. N. (2014a). Evaluation methods on the nutritional status of stroke patients. *Medical and Pharmacological Sciences, 18*, 3902-3907.

Wang, Y., Lim, L. L. Y., Heller, R. F., Fisher, J., BMaths, & Levi, C. R. (2003). A Prediction Model of 1-Year Mortality for Acute Ischemic Stroke Patients. *Archives Physical Medicine and Rehabilitation, 84*, 1006-1011. doi: 10.1016/S0003-9993(03)00032-7

Wang, Y., Lim, L. L. Y., Levi, C., Heller, R. F., & Fischer, J. (2001). A prognostic index for 30-day mortality after stroke. *Journal of Clinical Epidemiology, 54*, 766-773. doi: http://dx.doi.org/10.1016/S0895-4356(01)00338-9

Ware, J. E., Kosinski, M., & Keller, S. D. (1996). A 12-Item Short-Form Health Survey: Construction of Scales and Preliminary Tests of Reliability and Validity *Medical Care, 34*(3), 220-233.

Westergren, A. (2006). Detection of eating difficulties after stroke: a systematic review. *International Nursing Review, 53*(2), 143-149. doi: 10.1111/j.1466-7657.2006.00460.x

Wiedmann, S., Heuschmann, P. U., Hillmann, S., Busse, O., Wiethölter, H., Walter, G. M., et al. (2014). The quality of acute stroke care- an analysis of evidence-based indicators in 260 000 patients. *Dtsch Arztebl Int 2014, 111*(45), 759-765. doi: 10.3238/arztebl.2014.0759

Yoo, S. H., Kim, J. S., Kwon, S. U., Yun, S. C., Koh, J. Y., & Kang, D. W. (2008 ). Undernutrition as a Predictor of Poor Clinical Outcomes in Acute Ischemic Stroke Patients FREE *Archives of Neurology, 65*(1), 39-43. doi: 10.1001/archneurol.2007.12.

Zhang, L., Li, Z., Luo, B., Li, Z., Lei, M., & Jing, Y. (2014). [Effects of different intakes of protein on nutritional status in severe stroke patients]. *Wei Sheng Yan Jiu, 43*(6), 929-932.

# APPENDICES

# APPENDIX A
# LIST OF THE EXPERTS

**1 Tran Huu Thong MD, PhD**

Head of the 2nd Emergency Unit, Department of Emergency, Bach Mai Hospital, Hanoi, Vietnam.

**2 Vo Hong Khoi MD, PhD**

Vice Head of Department of Neurology, Bach Mai Hospital, Hanoi, Vietnam.

**3 Le Dinh Tung MD, PhD**

Head of Physiology Department, Hanoi Medical University, Hanoi, Vietnam.

**4 Nguyen Trong Hung MD, PhD**

Deputy Chief of Clinical Nutrition and Dietetics Department National Institute of Nutrition, Hanoi, Vietnam.

**5 Dao Thi Thu Hoai RN, MSN, Clinical Nutrition Oriented Bachelor**

Chief of Nutritional Center, Bach Mai Hospital, Hanoi, Vietnam.

# APPENDIX B
# CERTIFICATE OF APPROVAL

MAHIDOL UNIVERSITY
*Since 1888*

The Institutional Review Board
Faculty of Nursing, Mahidol University
Tel 0-2441-5333 Ext 2531-32

Document No. 0517.0510/IRB-NS 145
Date May 3, 2016
Subject Result of research project considerations after the revision
Dear Chair, Master of Nursing Science Program in Adult Nursing (for Vietnamese Nurses)

According to the student named Mrs. Nguyen Thi Thu Hien has submitted the research project entitled Factors related to health status among ischemic stroke patients with dysphagia protocol no. IRB-NS2016/13.0703 at the Institutional Review Board, Faculty of Nursing, Mahidol University on the (date) May 2, 2016 the IRB committee have examined and found the research protocol and all the research documents are revised according to the suggestions of the IRB. The IRB committee have made the decision and the results are as follows:

☒ Approve.
On the date May 2, 2016
Please look at the guideline for the research conduct post approval.
The document is attached together with the COA

Fongcum Tilokskul

(Associate Professor Dr. Fongcum Tilokskulchai)
Chair, Institutional Review Board

Copy to Associate Professor Dr. Wimolrat Puwarawuttipanit
Mrs. Nguyen Thi Thu Hien

**CERTIFICATE OF APPROVAL**
**From**
**Institutional Review Board Faculty of Nursing Mahidol University**

**COA No.IRB-NS2016/338.0205**

| | |
|---|---|
| **Title of Project:** | **FACTORS RELATED TO HEALTH STATUS AMONG ISCHEMIC STROKE PATIENTS WITH DYSPHAGIA** |
| **Project Number:** | **IRB-NS2016/13.0703** |
| **Principle Investigator:** | **Mrs. Nguyen Thi Thu Hien** |
| **Name of Institution:** | **Faculty of Nursing Mahidol University** |
| **Approval includes** | 1) IRB-NS Submission form version received date 2 May 2016<br>2) Participant Information sheet version date 2 May 2016<br>3) Consent form version date 2 May 2016<br>4) Questionnaire version received date 2 May 2016 |

**Institutional Review Board Faculty of Nursing Mahidol University is in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)**

**Date of Approval:** **02 May 2016**

**Date of Expiration:** **01 May 2017**

**Signature of Chair:**

Fongcum Tilokskul

(Associate Professor Dr. Fongcum Tilokskulchai)

Chair

**Signature of Dean, Faculty of Nursing**

Yajai Sitthi

(Associate Professor Dr. Yajai Sitthimongkol)

Dean, Faculty of Nursing

**Office of Institutional Review Board Faculty of Nursing Mahidol University Room 503 Faculty of Nursing, Mahidol University 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170, THAILAND Tel: (662)-441-5333 Ext. 2531, 2532**

**Guideline for the research conduct post approval**

**The Institutional Review Board, Faculty of Nursing, Mahidol University**

1. Use only documents with the stamp from the Institutional Review Board, Faculty of Nursing, Mahidol University (IRB-NS) for conducting the research (e.g., Instruments/ Questionnaires, Informational letter, Informed consent form)

2. If the investigator wishes to make any changes on the research protocol, the "Protocol Amendment Form" and all amended documents are required to submit to the IRB-NS for considerations before continuing the research.

3. If the serious adverse events or the suspected unexpected serious adverse events occur to the research participants, the "Adverse Event Report Form" is required to submit to the IRB-NS for considerations before continuing the research.

4. IF the research project is completed within 1 (one) year, the "Study Closure Form" is required to submit to the IRB-NS. If the project is needed to extend, the "Progress Report Form" is required to submit to the IRB-NS 1 (one) month in advance of the expiry date.

5. If the report for data collection is required, report as follows:

☑ Normal (Report at the renewal of the COA or at the project closure)

☐ Report at 25% of the data collection

☐ Report at 50% of the data collection

**Date May 2, 2016**

**KHOA Y DƯỢC**
HỘI ĐỒNG ĐẠO ĐỨC
TRONG NGHIÊN CỨU Y SINH HỌC

Số: / KYD-HĐĐĐ

**CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM**
**Độc lập - Tự do - Hạnh phúc**

*Hà Nội, ngày 16 tháng 08 năm 2016*

# GIẤY CHỨNG NHẬN
## Chấp thuận của Hội đồng đạo đức trong nghiên cứu y sinh học

Căn cứ Quyết định số 89/QĐ-KYD ngày 22/10/2013 của Khoa Y Dược về việc thành lập Hội đồng đạo đức trong nghiên cứu y sinh học Khoa Y Dược nhiệm kỳ 2013-2018;

Căn cứ Quyết định số 235/QĐ-KYD ngày 23/10/2015 của Khoa Y Dược về việc điều chỉnh, bổ sung thành viên Hội đồng đạo đức trong nghiên cứu y sinh học Khoa Y Dược nhiệm kỳ 2013-2018;

Căn cứ Biên bản họp ngày 02/08/2015 của Hội đồng đạo đức trong nghiên cứu y sinh học Khoa Y Dược nhiệm kỳ 2013-2018;

***Hội đồng đạo đức trong nghiên cứu y sinh học Khoa Y Dược chấp thuận về các khía cạnh đạo đức trong nghiên cứu đối với đề tài sau:***

1. Tên đề tài: **Các yếu tố liên quan đến tình trạng sức khỏe của người bệnh nhồi máu não có rối loạn unốt**
2. Người thực hiện nghiên cứu: **Nguyễn Thị Thu Hiền** (Học viên cao học điều dưỡng ĐH Mahidol)
3. Địa điểm nghiên cứu lâm sàng: **Bệnh viện Bạch Mai**
4. Thời gian nghiên cứu: Từ tháng 08/2016 đến tháng 12/2016

Các tài liệu được chấp thuận bao gồm:

1. Đề cương nghiên cứu (tiếng Anh) phiên bản số 01 ngày 08/08/2016
2. Thông tin dành cho đối tượng nghiên cứu (tiếng Việt) phiên bản số 02 ngày 08/08/2016
3. Bản chấp thuận tham gia nghiên cứu (tiếng Việt) phiên bản số 02 ngày 08/08/2016
4. Bộ câu hỏi nghiên cứu (tiếng Việt)

Ngày chấp thuận: Ngày 16 tháng 08 năm 2016

Nghiên cứu viên chính phải tuân thủ việc báo cáo cho Hội đồng đạo đức trong nghiên cứu y sinh học Khoa Y Dược về các trường hợp có biến cố bất lợi, báo cáo tiến độ theo đúng các hướng dẫn và quy định hiện hành.

***Nơi nhận:***
- Bệnh viện Bạch Mai
- Nghiên cứu viên
- Lưu HĐĐĐ

**CHỦ TỊCH**

**PGS.TS. Lê Thị Luyến**

# APPENDIX C
# PARTICIPANT INFORMATION SHEET
# (ENGLISH VERSION)

IRB-NS Form No. 3.1

- 2 MAY 2016
13.0103

## Participant Information Sheet

*In this document, there may be some statements that you do not understand. Please ask the principal investigator or his/her representative to give you explanations until they are well understood. To help your decision making in participating the research, you may bring this document home to read and consult your relatives, intimates, personal doctor or other doctor.*

**Title of Research Project:**

Factors related to health status among ischemic stroke patients with dysphagia

**Name of Researcher:** NGUYEN THI THU HIEN

**Research Site-Office and its telephone number available for contact both in and out of the office hours:**

Bach Mai hospital, 78 Giai Phong Street, Dong Da District, Hanoi City, Vietnam. Code: 100000, Telephone number: (+84)38686982, Fax: +84-4-38687524

Researcher mobile phone number: (+84)98 599 6888

Email: nursethuhien@yahoo.com

**Source of Fund:** Self- funding

This research project aims to examine the correlation between severity of stroke, levels of dysphagia, nutrition status and health status among ischemic stroke patients with dysphagia, which expects the following benefits:

1) Providing basic data about factors related health status in ischemic stroke patients with dysphagia.

2) In the future, developing program by using this data to promote health status in ischemic stroke patients with dysphagia.

However, in this study, the sample doesn't get any benefit directly but ischemic stroke patients with dysphagia will get benefits in the future.

You are invited to participate in this research project because you are in the 18-year-old-or-more group and suffer from ischemic stroke with dysphagia.

There will be 115 participants, and the research will last for 30-35 minutes for answer questionnaires.

*To participate in this research is completely VOLUNTARY.

**If you decide to participation the research project, you will go through the following procedure.**

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS 016/13.0103
Date of Approval - 2 MAY 2016

# PARTICIPANT INFORMATION SHEET (Vietnamese version)

13.0703

*Thông tin dành cho đối tượng nghiên cứu* *Phiên bản 02 / ngày 08 tháng 08 năm 2016*

## THÔNG TIN DÀNH CHO ĐỐI TƯỢNG NGHIÊN CỨU

*Tài liệu này sẽ có một số vấn đề Ông/bà có thể không hiểu. Hãy hỏi người nghiên cứu hoặc người đại diện của cô ấy để đưa cho Ông/Bà lời giải thích cho đến khi Ông/Bà hiểu rõ ràng vấn đề. Để giúp cho việc quyết định có tham gia vào chương trình nghiên cứu hay không. Ông/Bà có thể mang tài liệu này về nhà để đọc hoặc hỏi ý kiến người thân và các bác sĩ.*

**Tên đề tài nghiên cứu**: Các yếu tố liên quan đến tình trạng sức khỏe của người bệnh nhồi máu não có rối loạn nuốt.

**Người thực hiện nghiên cứu**: Nguyễn Thị Thu Hiền

**Địa chỉ và điện thoại liên hệ trong và ngoài giờ hành chính (Đại diện của người nghiên cứu):** Bệnh viện Bạch Mai: 78 đường Giải Phóng, Quận Đống Đa, Hà Nội, Việt Nam. Mã bưu chính: 100000. Số điện thoại: (+84) 438683731. Fax: (+84). 438691607.

**Nguồn hỗ trợ:** Tự túc.

**Mục đích của nghiên cứu:** Nghiên cứu này nhằm đánh giá các yếu tố liên quan đến tình trạng sức khỏe của người bệnh nhồi máu não có rối loạn nuố, với các lợi ích được kì vọng, bao gồm:

1) Cung cấp dữ liệu cơ bản về các yếu tố liên quan đến tình trạng sức khỏe của người bệnh nhồi máu não có rối loạn nuốt.

2) Phát triển để cải thiện tình trạng sức khỏe của người bệnh nhồi máu não có rối loạn nuốt trong tương lai.

Tuy nhiên, trong nghiên cứu này, người tham gia nghiên cứu có thể không thu được các lợi ích trực tiếp nhưng những người bệnh nhồi máu não có rối loạn nuốt sẽ thu được các lợi ích trong tương lai

Ông/Bà được mời tham gia vào dự án nghiên cứu này bởi vì Ông/Bà đã trên 18 tuổi và được chẩn đoán nhồi máu não có rối loạn nuốt.

Sẽ có khoảng 115 người tham gia, nghiên cứu gồm 2 phần là phỏng vấn và thăm khám lâm sàng, diễn ra trong vòng 30-35 phút.

* Việc tham gia nghiên cứu này của Ông/Bà là hoàn toàn TỰ NGUYỆN.

**Nếu Ông/Bà quyết định tham gia nghiên cứu này, Ông/Bà sẽ trải qua các bước sau::**

1) Người nghiên cứu sẽ yêu cầu Ông/Bà ký tên vào bản chấp thuận tham gia nghiên cứu.

2) Người nghiên cứu sẽ thu thập thông tin của Ông/Bà từ hồ sơ bệnh án.

3) Người nghiên cứu sẽ phỏng vấn, thăm khám và đánh giá khả năng nuốt của Ông/Bà tại giường bệnh. Công cụ thu thập dữ liệu bao gồm 2 phần:

3.1 Phần thứ nhất gồm 12 câu hỏi liên quan đến tình trạng sức khỏe của Ông/Bà, thời gian phỏng vấn khoảng 5 phút. Người nghiên cứu sẽ luôn ở bên cạnh để hỗ trợ Ông/Bà khi cần. Sau khi phỏng vấn kết thúc sẽ chuyển sang nội dung thứ hai.

3.2 Phần thứ hai: gồm 3 nội dung

3.2.1 Trước hết, người nghiên cứu sẽ thăm khám để đánh giá mức độ đột quỵ của Ông/bà. Việc thăm khám này có thể mất 8 phút.

3.2.2 Tiếp theo là 6 câu hỏi liên quan đến tình trạng dinh dưỡng của Ông/Bà (khoảng 2 phút).

3.2.3 Sau đó, người nghiên cứu sẽ đánh khả năng nuốt của Ông/Bà với 3 loại thức ăn (đặc, lỏng và thức ăn rắn). Dựa trên kết quả thu nhận được sau khi làm đánh giá, nghiên cứu viên sẽ thảo luận với bác sĩ điều trị và chuyên viên dinh dưỡng lâm sàng để hướng dẫn chế

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS 816/13.0703
Date of Approval 2 MAY 2016

# APPENDIX D
# INFORMED CONSENT (ENGLISH VERSION)

IRB-NS Form No. 4

- 2 MAY 2016
19.0703

**Consent Form for Informed and Voluntary Participation in Research**

Date...../...../.....

My name is....., aged.....years old, now living at the address: No.....

Road/street..... Sub-district/commune:.....

District/amphur..... ..... Province/ City:.....

Postal code..... Telephone Number:.....

I give my consent to participate as a subject in the research project entitled Factors related to health status among ischemic stroke patients with dysphagia

In so doing, I am informed of the background and purpose of research project; its procedural details to carry out or to be carried out; its expected benefits and risks that may occur to the subjects, including methods to prevent and handle harmful consequences; and payment/ incentives, and expense. I thoroughly read the detailed statements in the information sheet given to the research subjects, I was also given explanations and my questions were answered by the head of the research project.

I consent to participate as a subject in this research project.

On the condition that I have any questions about the research procedures, or on the condition that I suffer from an undesirable side effect from this research, I can contact Mrs. Nguyen Thi Thu Hien via (+84)985996888 or email: nursethuhien@yahoo.com.

On the condition that I am not treated as indicated in the information sheet distributed to the subjects, I can contact the Chair, or the representative of the IRB-NS at the office of IRB-NS room 503 5th floor, Faculty of Nursing, Mahidol University, 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170 Thailand Tel 0066 2 441 5333 ext 2531, 2532 Fax 0066 2 441 5333 ext 2531, Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com

I am aware of my right to further information concerning benefits and risks from the participation in the research project and my right to withdraw or refrain from the participation anytime without any consequence on the service or health care I am

Faculty of Nursing Mahidol University
Project Number IRB-NS 2016/13-0703
Date of Approval 2 MAY 2016

Version 5 date 10 August 2015

# INFORMED CONSENT (Vietnamese version)

*Bản chấp thuận tham gia nghiên cứu* *Phiên bản 02 / ngày 08 tháng 08 năm 2016* 13-0703

## BẢN CHẤP THUẬN THAM GIA NGHIÊN CỨU

Ngày...../...../.....

Tên tôi là ....., tuổi.....,

Mã ID (Người nghiên cứu ghi):.....

Địa chỉ: .....

Mã vùng: .....Số điện thoại: .....

Trước tiên, tôi xin bày tỏ sự đồng ý tham gia vào đề tài nghiên cứu có tên là ***Các yếu tố liên*** quan ***đến tình trạng sức khỏe của người bệnh nhồi máu não có rối loạn nuốt.***

Trước khi tham gia nghiên cứu, tôi đã được thông báo về mục đích của nghiên cứu, chi tiết quá trình thực hiện nghiên cứu, các lợi ích và rủi ro có thể xảy ra đối với người tham gia nghiên cứu, các phương pháp ngăn ngừa và giải quyết các tác dụng không mong muốn có thể xảy ra cho người tham gia nghiên cứu, cả về chi phí tham gia nghiên cứu. Tôi đã đọc kỹ toàn bộ thông tin trong bản thông tin dành cho đối tượng nghiên cứu. Bên cạnh đó, các câu hỏi của tôi cũng đã được giải đáp bởi người thực hiện nghiên cứu.

Tôi đồng ý tham gia vào nghiên cứu này như một đối tượng nghiên cứu.

Trong trường hợp có bất cứ câu hỏi nào hoặc có vấn đề mới phát sinh trong quá trình nghiên cứu, tôi có thể liên hệ với chị Nguyễn Thị Thu Hiền số điện thoại: 0985996888, Email: nursethuhien@yahoo.com (Số điện thoại liên lạc trên được kết nối 24/24 h).

Nếu tôi không được điều trị và chăm sóc như những gì đề cập đến trong bản thông tin dành cho đối tượng nghiên cứu, tôi có thể liên hệ với Hội Đồng đạo đức, Khoa Điều Dưỡng, Đại học Mahidol Thái Lan, đặt văn phòng tại tầng 5 phòng 504, Đại học Mahidol, đường Phuttamonthon 4, Salaya, Nakhon Pathom 73170, Thái Lan. Điện thoại: 66 2 441 5333 số máy lẻ 2531, 2532. Fax 0066 2 441 5333 số máy kẻ 2531, Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com

Tôi cũng có thể liên lạc với Hội đồng Đạo đức trong nghiên cứu Y sinh học, Khoa Y Dược, Đại học Quốc Gia Hà Nội. Địa chỉ: Tòa nhà Y1, số 144 phố Xuân Thủy, quận Cầu Giấy, Hà Nội, Việt Nam; Số điện thoại: 04-37450188; Fax: +84437450146; Email: smp@vnu.edu.vn

Tôi nhận thức được quyền thông tin liên quan tới lợi ích và rủi ro của người tham gia nghiên cứu và quyền được rút khỏi nghiên cứu bất cứ lúc nào mà không gặp vấn đề gì về dịch vụ cũng như việc chăm sóc sức khỏe mà tôi sẽ nhận được trong tương lai. Tôi đồng ý cho bên nghiên cứu sử dụng thông tin cá nhân cho việc nghiên cứu, nhưng không đồng ý việc tiết lộ thông tin cá nhân. Các thông tin phải được trình bày như là một phần của kết quả nghiên cứu.

Tôi hoàn toàn hiểu những nội dung đã nêu trong bản thông tin dành cho đối tượng nghiên cứu và trong phiếu chấp thuận tham gia nghiên cứu này. Qua đó, tôi cung cấp chữ ký của tôi.

Ngày..... tháng..... năm.....

| **Chủ nhiệm đề tài** | **Người tham gia nghiên cứu** |
|---|---|
| *(Ký và ghi rõ họ tên)* | *(Ký và ghi rõ họ tên)* |

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS 2016/13.0703
Date of Approval - 2 MAY 2016

# APPENDIX E
# INSTRUMENTS (ENGLISH VERSION)

- 2 MAY 2016
13-07 03

Code number:.....

## INSTRUMENTS

### 1. General information of the patients (for researcher)

There are 20 questions related to your personal information. Please tick (√) or fill in blanks in the following questions:

1. Age: ..... Years old
2. Gender: ☐ Male ☐ Female
3. Admission date: .....
4. Chief complaint:.....
5. Duration since first symptoms of stroke present:.....
6. Dominant hand: ☐ Right hand ☐Left hand
7. Weight:..... (Kg) Height..... (m) BMI.....(kg/$m^2$)
8. Location of residence: ☐ Hanoi ☐North ☐Middle ☐South
9. Marital status:
   - ☐ Married ☐ Single
   - ☐ Other(please specify).....
10. What is your highest education level?
    - ☐ Primary school ☐Secondary school ☐ High school
    - ☐ College/vocational school ☐ Bachelor degree (University)
    - ☐ Post-graduate
    - ☐ Others (please specify) .....
11. Religious (please specify) .....
12. What is your occupation?
    - ☐ Farmer ☐ Businessman
    - ☐ Housework ☐ Government staff
    - ☐ Retired ☐ Industrial worker
    - ☐ Other jobs (please specify).....
13. How much is your income per month?

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-SN 2016/13.0703
Date of Approval 2 MAY 2016

**2. SF-12 scale**

## Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

**1. In general, would you say your health is:**

| Excellent | Very good | Good | Fair | Poor |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?**

| | | Yes, limited a lot | Yes, limited a little | No, not limited at all |
|---|---|---|---|---|
| | | ☐ 1 | ☐ 2 | ☐ 3 |
| a | <u>Moderate activities</u>, such as moving a table, sweeping the house, swimming, or riding bicycle | ☐ 1 | ☐ 2 | ☐ 3 |
| b | Climbing <u>several</u> flights of stairs | ☐ 1 | ☐ 2 | ☐ 3 |

**3. During the <u>past week</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?**

## 3. NIH Stroke Scale (for researcher)

The NIHSS is composed of 15 items, each of which scores a specific ability between a 0 and 4

| Instructions | Scale definition | Score |
|---|---|---|
| **1a. Level of consciousness:** The investigator must choose a response if a full evaluation is prevented by such obstacles as an endotracheal tube, language barrier, orotracheal trauma/bandages. A 3 is scored only if the patient makes no movement (other than reflexive posturing) in response to noxious stimulation. | 0 = **Alert;** keenly responsive.<br>1 = **Not alert;** but arousable by minor stimulation to obey, answer, or respond.<br>2 = **Not alert;** requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped).<br>3 = Responds only with reflex motor or autonomic effects or totally unresponsive, flaccid, and areflexic. | ____ |
| **1b. LOC questions:** The patient is asked the month and his/her age. The answer must be correct - there is no partial credit for being close. Aphasic and stuporous patients who do not comprehend the questions will score 2. Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, language barrier, or any other problem not secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not "help" the patient with verbal or non-verbal cues. | 0 = **Answers** both questions correctly.<br>1 = **Answers** one question correctly.<br>2 = **Answers** neither question correctly. | ____ |
| **1c. LOC commands:** The patient is asked to open and close the eyes and then to grip and release the non-paretic hand. Substitute another one step command if the hands cannot be used. Credit is given if an unequivocal attempt is made but not completed due to weakness. If the patient does not respond to command, the task should be demonstrated to him or her (pantomime), and the result scored (ie, follows none, one or two commands). Patients with trauma, amputation, or | 0 = **Performs** both tasks correctly.<br>1 = **Performs** one task correctly.<br>2 = **Performs** neither task correctly. | ____ |

**4. Nutritional Risk Screening -2002** *(NRS-2002)* **(scale** for researcher)

**Table 1 Initial screening**

| | | Yes | No |
|---|---|---|---|
| 1 | Is BMI < 20.5? | | |
| 2 | Has the patient lost weight within the last 3 months? | | |
| 3 | Has the patient had a reduced dietary intake in the last week? | | |
| 4 | Is the patient severely ill? (e.g. in intensive therapy) | | |

**Yes:** If the answer is 'Yes' to any question, the screening in Table 2 is performed.
**No:** If the answer is 'No' to all questions, the patient is re-screened at weekly intervals. If the patient e.g. is scheduled for a major operation, a preventive nutritional care plan is considered to avoid the associated risk status.

**Table 2 Final screening**

| **Impaired nutritional status** | | **Severity of disease (≈ increase in requirements)** | |
|---|---|---|---|
| Absent **Score 0** | Normal nutritional status | Absent **Score 0** | Normal nutritional requirements |
| Mild **Score 1** | Wt loss 45% in 3 months or Food intake below 50–75% of normal requirement in preceding week | Mild **Score 1** | Hip fracture* Chronic patients, inparticular with acute complications: cirrhosis*, COPD*. Chronic hemodialysis, diabetes, oncology |
| Moderate **Score 2** | Wt loss 45% in 2 months or BMI 18.5 –20.5 + impaired general condition or Food intake 25–60% of normal requirement in preceding week | Moderate **Score 2** | Major abdominal surgery* Stroke* Severe pneumonia, Hematologic malignancy |
| Severe **Score 3** | Wt loss 45% in 1 month (415% in 3 months) or BMI o18.5 + impaired general condition or Food intake 0-25% of normal requirement in preceding week in preceding week. | Severe **Score 3** | Head injury* Bone marrow transplantation* Intensive care patients (APACHE II>10). |
| **Score:** | + | **Score:** | **= Total score** |
| **Age** | if ≥70 years: add 1 to total score above | **=age-adjusted total score** | |

**Score ≥ 3**: the patient is nutritionally at-risk and a nutritional care plan is initiated
**Score < 3**: weekly rescreening of the patient. If the patient e.g. is scheduled for a major operation, a preventive nutritional care plan is considered to avoid the associated risk status.
* Indicate that a trial directly support the categorization of patients with that diagnosis

## 5. GUGGING SWALLOWING SCREEN (GUSS) scale

**(for researcher)**

This scale consists two parts Preliminary Investigation / Indirect Swallowing Test and Direct Swallowing Test, each of which scores a specific ability.

5.1 Indirect Swallowing: The scores in part 1 will be maximum 5 to minimum 0.

5.2 Direct Swallowing Test: The scores in part 2 will be maximum 15 to minimum 0.

Total maximum possible score for this scale is 20, with the minimum score being 0

**1 Preliminary Investigation / Indirect Swallowing Test**

| No | | YES | NO |
|---|---|---|---|
| 1 | **VIGILANCE**<br>(The patient must be alert for at least 15 minutes) | 1 ☐ | 0 ☐ |
| 2 | **COUGH and/or THROAT CLEARING**<br>(Voluntary cough! Patient should cough or clear his or her throat twice) | 1 ☐ | 0 ☐ |
| 3 | **SALIVA SWALLOW**<br>• **SWALLOWING SUCCESSFUL** | 1 ☐ | 0 ☐ |
| 4 | • **Drooling**<br>(Herausrinnen von Speichelausdem Mund) | 0 ☐ | 1 ☐ |
| 5 | **VOICE CHANGE**<br>(hoarse, gurgely, coated, weak , choke on own saliva) | 0 ☐ | 1 ☐ |
| | **SUM:** | (5) | |
| **1 – 4 = Investigate further**<br>**5 = Continue with "Direct Swallowing Test"** | | | |

## INSTRUMENTS (Vietnamese version)

13.0703

### BỘ CÂU HỎI NGHIÊN CỨU

**Số (No)……..**

**I. Các thông tin chung**

**Số thứ tự: …… Mã bệnh án: ……**

**Mã ID:……**

Dưới đây là 20 câu hỏi liên quan đến thông tin cá nhân của người bệnh và thông tin liên quan đến bệnh tật của người bệnh. Làm ơn hãy sử dấu ✓ để điền vào ô trống:

1. Tuổi:
2. Giới: ☐ Nam ☐ Nữ
3. Ngày vào viện: ……
4. Lý do vào viện: ……
5. Thời gian bị đột quỵ tính từ khi khởi phát bệnh: ……
6. Tay thuận: ☐ Tay phải ☐ Tay trái
7. Cân nặng: …….. (Kg) Chiều cao…… (m) BMI……. (kg/m$^2$)
8. Địa chỉ thường trú: ☐ Hà Nội ☐Miền Bắc ☐Miền Trung ☐ Miền Nam
9. Tình trạng hôn nhân:
   - ☐Đã lập gia đình ☐Độc thân
   - ☐Khác (ghi cụ thể)……
10. Trình độ văn hóa?
    - ☐Tiểu học ☐THCS ☐THPH
    - ☐Cao đẳng ☐Đại học ☐Sau đại học
    - ☐Khác (ghi cụ thể) ……
11. Tôn giáo(ghi cụ thể) ……
12. Nghề nghiệp
    - ☐Nông dân ☐Buôn bán
    - ☐Nội trợ ☐Cán bộ viên chức nhà nước
    - ☐Hưu trí ☐Công nhân
    - ☐Khác (ghi cụ thể)……
13. Thu nhập của Ông/Bà hằng tháng là bao nhiêu?
    Thu nhập của Anh/Chị: ……VNĐ (…… USD)
14. Anh/Chị có bảo hiểm y tế không? ☐Có ☐Không
15. Hình thức chi trả
    - ☐Chính phủ ☐BHYT
    - ☐Tự chi trả ☐Hỗ trợ của gia đình
    - ☐Khác (ghi cụ thể)……
16. Bệnh lý kèm theo:
    - ☐Tăng HA ☐Rối loạn Lipid máu
    - ☐Tiểu đường ☐Rung nhĩ
    - ☐Không ☐Khác (ghi cụ thể)……

# APPENDIX F

# PERMISSION FOR USING INSTRUMENTS


**NON-COMMERCIAL LICENSE AGREEMENT**
**Office of Grants and Scholarly Research (OGSR)**

**License Number:** QM033054

**Licensee Name:** Nguyen Thi Thu Hien, c/o Mahidol University

**Licensee Address:** 19/1 Charun sanit wong Road,Bangprom, Taling chun BANGKOK TH

**Approved Purpose:** Factors related to health status among ischemic stroke patients with dysphagia

**Study Type:** Non-commercial academic research and/or thesis – Unfunded Student
**Data Collection Method:** Paper

**Therapeutic Area:** Wellness & Lifestyle

**Royalty Fee:** None, because this License is granted in support of the non-commercial Approved Purpose

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**B. Appendices:** Capitalized terms used in this Agreement shall have the meanings assigned to them in Appendix A and Appendix B. The appendices attached hereto are incorporated into and made a part of this Agreement for all purposes.

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EXECUTED by the duly authorized representatives as set forth below.

| **OptumInsight Life Sciences, Inc.** | **Nguyen Thi Thu Hien** |
|---|---|
| Signature:_____ | Signature:_____ |
| Name:_____ | Name: _____ |
| Title:_____ | Title:_____ |
| Date:_____ | Date:_____ |

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c. Any waiver of any breach or default under this Agreement must be in writing and shall not be deemed a waiver of any other or subsequent breach or waiver. Failure or delay by either party to enforce compliance with any term or condition of this Agreement shall not constitute a waiver of such term or condition.

d. If any provision in this Agreement is determined to be invalid or unenforceable, the remaining provisions shall not be affected thereby and shall be binding upon the parties hereto, as though the invalid or unenforceable provision were not contained herein.

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h. Any format and/or language changes have the potential to affect the survey data received. Therefore, to maintain the validation and integrity of the SF Health Surveys, **no language or formatting changes** allowed. The format of the survey is scientifically engineered to facilitate accurate and unbiased data, as well as keeping the SF Health Survey in a visual format that is comprehensible to the patient/participant, including those who may be impaired and/or elderly. **Licensee must administer the survey in the exact format Licensed receives it in. The only item Licensee may add is a header with patient identification and / or administration information.** If Licensee wishes to add a header, contact Licensee's Account Representative. Do not use any forms Licensee may have received in the past.

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# LICENSE AGREEMENT - DETAILS

Licensee: Mahidol University
Nguyen Thi Thu Hien
19/1 Charun sanit wong Road
Bangprom, Taling chun, 10170 BANGK

License Number: QM033054
Amendment to: N/A
Study Term: 01/01/16 to 12/31/17

Approved Purpose
Factors related to health status among ischemic stroke patients with dysphagia

**Licensed Surveys (Modes) and Services:**

| Item | Description | Mode of Admin | Quantity |
|---|---|---|---|
| PROJ01 | License Fee | Paper | 1 |
| ADMINS | Administrations | | 200 |
| ES0170 | SF-12v2, Standard Recall | Paper | 1 |
| **Approved Languages:** Vietnam (English) | | | |
| SS075 | Scoring Software v4.5 | | 1 |
| SS079 | SS v4.5 Key: SF-12v2 | | 200 |
| EM126 | SF-12v2 User's Manual 3rd Ed. | | 1 |
| **Approved Languages:** United States (English) | | | |

Please sign at your earliest convenience

**TOTAL FEES:** **0.00 USD**

| | |
|---|---|
| **Subject:** | www.NIHStrokeScale.org - NIH Stroke Scale International Initiative - NIHSS Vietnamese |
| **From:** | Al Pacino (alpacino@healthcarepoint.com) |
| **To:** | nursethuhien@yahoo.com; |
| **Cc:** | shericampbell@healthcarepoint.com; |
| **Date:** | Tuesday, 1 December 2015, 23:07 |

Dear Nguyen,

It was a great pleasure speaking with you today!

As per our conversation, you can use the NIH Stroke Scale for your undergraduate study project accordingly

Also, as per our conversation, we will like you to help us bring the **Standardized NIH Stroke Scale on-line training and certification program to Vietnam** so that all of the healthcare professionals can properly follow the standardized process in order to make sure Vietnam is aligned with the globally / international standardized training and certification process and ultimately helping to improving patient outcomes and inter-rater-reliability between all countries around the world, "Including Vietnam".

The current NIH Stroke Scale International Initiative can be accessed from www.NIHStrokeScale.org

You can see that the standardized program has been created by universities from around the world and we need your help with developing the same for ***the NIH Stroke Scale training and certification process in Vietnamese.***

-

See news release link below

**HealthCarePoint's (HCP) International Electronic Education Network® (IEEN) Reaches 8-year Milestone with the NIH Stroke Scale (NIHSS) International Initiative**

The globally standardized certification methodology is now accepted across healthcare organizations, clinical trial sponsors, CROs and regulatory agencies.

Working closely with global industry leaders – including major universities, governments, private and not-for-profit organizations – we have proven that we can ultimately create globally accepted standards without boundaries, moving our industry to become more efficient by breaking down the silos and non-collaborative models

==========

Below is the simple basic proposal for you to be able to start speaking with your colleagues / professors at your university

***1- Need to have an on-line vehicle to deliver the scale training and certification program in Vietnamese***

a. The NIHSS-Vietnamese Campus will be the responsibility of HealthCarePoint.com

b. Building the campus

c. Maintaining the campus

d. Any other technology maintenance

***2- Need to review, verify and approve the release of the NIHSS in Malaysian by a review panel***

a. Participating Panel

i. NIH – NINDS

ii. Ramesh Sahathevan, MD

iii. Patrick Lyden, MD

iv. Others you may want to consider involving as opinion leaders and interested colleagues in Vietnam

***3- Need to develop the NIH Stroke Scale in Vietnamese***

a. Questions and Items are already in place – Translation into the Vietnamese language

b. Videos to be used are the same as the current videos for the NIHSS in English

c. Videos can be voice over or subtitled in Vietnamese Language

***4- NIH Stroke Scale – Vietnamese project Sustainability***

a. Short term

i. HealthCarePoint will be responsible for any technology and support services to get the project finished

ii. Your organization will be responsible for video translations, either voice over or subtitles into the current NIHSS English videos

b. Long term

i. HealthCarePoint will continue to finance the project in the long term.

ii. You and or your organization will have access to administration tools so that you can use collected user information such as completion certificates and user information who has registered for the NIHSS program for all healthcare professionals in Vietnam to be used for publications into Vietnamese medical and other scientific journals.

Item #3 is what we need help with.

HealthCarePoint will bear the cost of long term maintenance to **provide this *FREE service* to healthcare providers in all of Vietnam!**

Looking forward to speaking with you and answer any questions you may have!

Let's Make a Difference Together! Always at your service!

---

Al O. Pacino

Director / NIH Stroke Scale International Initiative

BlueCloud by HealthCarePoint | Professional Collaborative Networks

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Cell +1 512-260-0000
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WebSite

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P.O. Box 2287
Cedar Park, TX 78630

*BlueCloud® Nominated as one of the Top Innovations of 2015! - PharmaVOICE*



## Attachments

- image003.jpg (5.63 KB)

| | |
|---|---|
| **Subject:** | Antw: Asking permission |
| **From:** | Michael Brainin (Michael.Brainin@donau-uni.ac.at) |
| **To:** | nursethuhien@yahoo.com; |
| **Cc:** | michaela.trapl@aon.at; Bernadette.Firlinger@donau-uni.ac.at; |
| **Date:** | Sunday, 29 November 2015, 22:07 |

Dear Nguyen Thi Thu Hien,
please feel free to use it, as far as I know there already exists a Vietnamese translation, I think at the Bach Mai Hospital. I copy SLT Michaela Trapl, she keeps track and helps you also if needed.
Kind regards
Michael Brainin

>>> Nguyenthithuhien <nursethuhien@yahoo.com> 28.11.2015 00:34 >>>
Dear Prof. Michael Brainin,
My name is Nguyen Thi Thu Hien. I am a Vietnamese Master student at Faculty of Nursing Mahidol University, Thailand.

Currently, I am working on my dissertation entitled "Factors related to health status among ischemic stroke patients with dysphagia".

One of the independent variables in my study is dysphagia. The literature review lets me learn that the Gugging swallowing screen (GUSS) is an instrument, which is perfectly suitable with my study.

Hence, I am writing this letter to ask you to do me a favor and allow me to use the GUSS in my study. I would like to translate the GUSS into Vietnamese and validate it before use in my population. I do believe that your permission is very meaningful to the success of my research.

Thank you very much for making the measurement of dysphagia available, which really enables the subsequent studies like mine. Should you need any more information, please let me know.

I am looking forward to hearing from you,

Sincerely yours,

Nguyen Thi Thu Hien, R.N, Master candidate at Faculty of Nursing
Mahidol University, Bangkok, Thailand
Email: nursethuhien@yahoo.com

NGUYEN THI THU HIEN
Head Nurse of Neurology Department, Bach Mai Hospital.

| | |
|---|---|
| **Subject:** | Re: Asking your permission, |
| **From:** | Stephane,SCHNEIDER@unice,fr (Stephane,SCHNEIDER@unice,fr) |
| **To:** | nursethuhien@yahoo.com; |
| **Date:** | Thursday, 31 December 2015, 19:32 |

Dear Ms. Nguyen,

Thank you for your interest. NRS, that is advised by ESPEN but not owned by us, can, to my knowledge, be used without copyright or imitation.

Best regards

Stéphane Schneider

**Prof. Stéphane M. Schneider, MD, PhD, FEBGH** / Chairman
ECPCommittee@espen.org

**ESPEN's Educational and Clinical Practice Committee**
Office: +33 4 92 03 60 27 / Fax: +33 4 92 03 61 20
Archet Hospital - Nutritional Support Unit - CS 23079 - 06202 Nice Cedex 3 - France
http://www.espen.org

Le 31 déc. 2015 à 13:08, Nguyenthithuhien <nursethuhien@yahoo.com> a écrit :

Dear Sir/Madam,

My name is Nguyen Thi Thu Hien. I am a Vietnamese Master student at Faculty of Nursing Mahidol University, Thailand.

Currently, I am working on my dissertation entitled "Factors related to health status among ischemic

stroke patients with dysphagia".

One of the independent variables in my study is Nutritional status. The literature review lets me learn that the NRS is an instrument, which is perfectly suitable with my study.

Hence, I am writing this letter to ask you to do me a favor and allow me to use the NRS in my study. I would like to translate the NRS into Vietnamese and validate it before use in my population. I do believe that your permission is very meaningful to the success of my research.

Thank you very much for making the measurement of Nutritional status (NRS) available, which really enables the subsequent studies like mine. Should you need any more information, please let me know.

I am looking forward to hearing from you,

Sincerely yours,
Nguyen Thi Thu Hien, R.N, B.N.S, Master candidate at Faculty of Nursing
Mahidol University, Bangkok, Thailand
Email: nursethuhien@yahoo.com

Nguyen Thi Thu Hien, R.N, B.N.S,
Head Nurse of Neurology Department, Bach Mai Hospital.

---

**Attachments**

- ESPEN.jpg (6.68 KB)
- facebook.png (956 B)
- spacer.gif (1.07 KB)

| | |
|---|---|
| **Subject:** | Re: Permission GUSS Provision |
| **From:** | Nguyen Thu Hien (nursethuhien@yahoo.com) |
| **To:** | guss@donau-uni.ac.at; |
| **Date:** | Thursday, 22 December 2016, 19:00 |

Dear Michaela Trapl,
I strongly agree with your idea and you can add the names for being responsible for the translation includes:
1. Professor. Le Van Thinh, M.D., Ph.D.
Head of Neurology Department, Bach Mai Hospital, Ha Noi, Viet Nam.
2. Nguyen Thi Thu Hien, R.N, M.N.S, Head Nurse of Neurology Department, Bach Mai Hospital, Ha Noi, Viet Nam.
3. Tran Huu Thong, M.D., Ph.D.
Emergency Department, Bach Mai Hospital, Ha Noi, Viet Nam.
Thank you very much and I am looking forward to hearing your feedback.

Best regards,
Nguyen Thi Thu Hien
Đã gửi từ iPhone của tôi

Ngày 22 thg 12, 2016, vào lúc 15:29, Guss <guss@donau-uni.ac.at> viết:

Dear Mr. Nguyen

Thank you very much for the Vietnamese version of the GUSS.

We are now ready to provide as much translated versions of the GUSS as possible for professionals and interested persons.

Therefore, we ask for your permission to upload your translated version of the GUSS on our website: http://www.donau-uni.ac.at/en/department/kmp/projekte/id/24436/index.php respectively in our blog: https://gussgroupinternational.wordpress.com/

Can you please let us know the names you want us to add for being responsible for the translation?

We are looking forward to your answer!

Best regards,

Michaela Trapl
and the GUSS Team

Department of Clinical Neurosciences and Preventive Medicine
Danube University Krems

Dr. Karl-Dorrek-Strasse 30
3500 Krems, AUSTRIA
e-Mail: guss@donau-uni.ac.at
http://www.donau-uni.ac.at

Clinical Department of Neurology
University Hospital Tulln

Alter Ziegelweg 10
3430 Tulln an der Donau
http://www.tulln.lknoe.at

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https://gussgroupinternational.wordpress.com

# APPENDIX G
# ADDITIONAL STATISTICAL ANALYSIS

**Tests of Normality**

| | Kolmogorov-Smirnov[a] | | | Shapiro-Wilk | | |
|---|---|---|---|---|---|---|
| | Statistic | df | Sig. | Statistic | df | Sig. |
| PCS | .044 | 115 | .200* | .989 | 115 | .447 |
| MCS | .103 | 115 | .005 | .961 | 115 | .002 |
| NRS Total - Record | .229 | 115 | .000 | .874 | 115 | .000 |
| GUSS Total - record | .306 | 115 | .000 | .696 | 115 | .000 |
| NIHSS Total | .112 | 115 | .001 | .946 | 115 | .000 |

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

# BIOGRAPHY

| | |
|---|---|
| **NAME** | Nguyen Thi Thu Hien |
| **DATE OF BIRTH** | 15 November 1972 |
| **PLACE OF BIRTH** | Hanoi, Vietnam |
| **INSTITUTIONS ATTENDED** | Bach Mai Nursing School, 1993-1996<br>General Nursing<br>Nam Dinh University of Nursing, 2000-2005<br>Diploma of Nursing<br>Nam Dinh University of Nursing, 2007-2008<br>Bachelor of Nursing<br>Mahidol University, 2015-2016<br>Master of Nursing Science (Adult Nursing) |
| **POSITION AND OFFICE** | Head Nurse of Neurology Department, Bach Mai Hospital, Hanoi, Vietnam |
| **EMPLOYMENT ADDRESS** | Department of Neurology, Bach Mai Hospital<br>78 Giai Phong Road, Hanoi, Vietnam.<br>Telephone number: + (84) 43 868 6982<br>Ext. 6582<br>Website: www.bachmai.gov.vn |
| **HOME ADDRESS** | Apartment 512 - E7 Ta Quang Buu Street, Hai Ba Trung District, Hanoi, Vietnam<br>Mobile telephone: + (84) 98 599 6888<br>Email: nursethuhien@yahoo.com |