

**FACTORS RELATED TO DIABETIC FOOT ULCERS SCORES  
IN PATIENTS WITH TYPE 2 DIABETES**



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**A THESES SUBMITTED IN PARTIAL FULFILLMENT  
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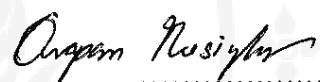
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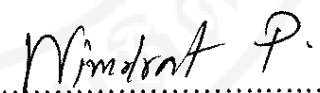
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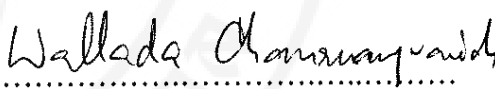
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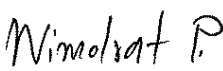
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**FACTORS RELATED TO DIABETIC FOOT ULCERS SCORES  
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THESIS ADVISORY COMMITTEE: ORAPAN THOSINGHA, D.N.S.,  
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The incidence of type 2 diabetes (T2DM) among Vietnamese adults has been increasing in recent years. Many T2DM patients are at risk of occurring foot complications. Screening for patients' foot and understanding factors related to diabetic foot ulcers would prevent foot ulcerations and amputation. This research aimed to study the relationship among age, duration of DM, HbA1C, comorbidity, self-efficacy, and diabetic foot ulcer scores among patients with T2DM. This descriptive correlational research was conducted among 136 patients with T2DM in the outpatient department, at the Bach Mai Hospital, Hanoi, Vietnam. Data were collected using patients' hospital record and a structured questionnaire. The patients' feet were assessed using 60 second Diabetic Foot Screen. Spearman's rho was employed to test the relationship among all variables. Majority of patients were female (60.3%) with mean age of 65.3 years. The majority had experienced T2DM for more than 10 years, hypertension was the most common comorbidity with 89% (n=121), the mean score of self-efficacy was 54.49 (SD=8.34) while the mean score of diabetic foot ulcer was 6.05 (SD=3.14). Age, duration of T2DM and comorbidity positively correlated with the diabetic foot ulcer scores ( $r=0.287$ ,  $p<.01$ ;  $r=0.306$ ,  $p<.01$ ;  $r=0.300$ ,  $p<.01$  respectively) while self -efficacy was negatively correlated with the diabetic foot ulcer scores ( $r=-0.415$ ,  $p<.01$ ). In conclusion, older patients with T2DM had comorbid diseases, long duration of T2DM and low self- efficacy were at risk of having diabetic foot ulcers. They demonstrated poor foot skin integrity and poor behaviors in taking care of their feet. It is recommended that nurses should assess the patients using the 60 second Diabetic Foot Screen, control their co morbidities and promote their self-efficacy. Standard guidelines should be developed and implemented. Further research should be conducted to test the effectiveness of the guidelines.

**KEY WORDS: SELF-EFFICACY/TYPE 2 DIABETES/DIABETIC FOOT  
ULCERS/DURATION OF DM/COMORBIDITY.**

85 pages

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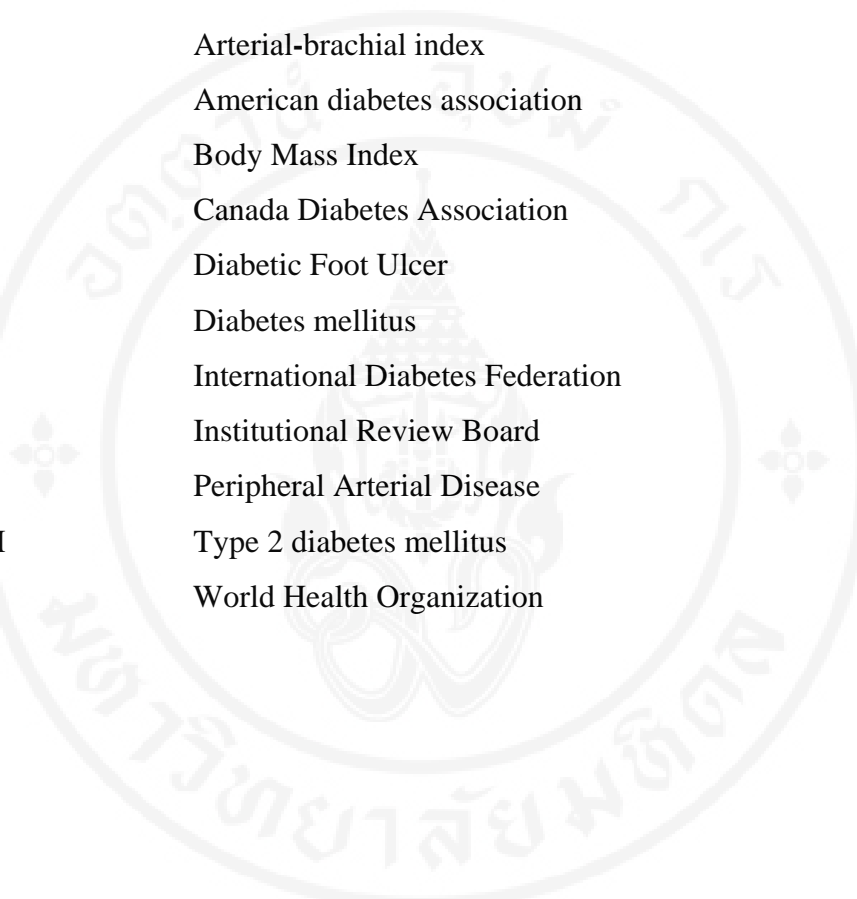
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## LIST OF ABBREVIATIONS



ABI	Arterial-brachial index
ADA	American diabetes association
BMI	Body Mass Index
CDA	Canada Diabetes Association
DFUs	Diabetic Foot Ulcer
DM	Diabetes mellitus
IDF	International Diabetes Federation
IRB	Institutional Review Board
PAD	Peripheral Arterial Disease
T2DM	Type 2 diabetes mellitus
WHO	World Health Organization

## **CHAPTER I**

### **INTRODUCTION**

#### **1.1 Background and significance of the study**

Diabetes Mellitus (DM) is a significant metabolic disease relating with increased level of serum glucose due to disorders in either insulin secretion or insulin action (ADA, 2013). In a global level, DM is a leading cause of death and disability (Lozano et al., 2012; Murray et al., 2012). DM is a global epidemic affecting about 285 million people on the world, which is projected to reach 439 million by the year 2030 (Shaw, Sicree, & Zimmet, 2010). International Diabetes Federation (IDF) estimates that there are 175 million people in global has diabetes and approximately half of them are unaware their disease (IDF, 2013). Type of DM that most frequently found among adults are T2DM. Most of T2DM patients are living in Asia and Eastern Pacific regions. In 2011, there were ninety million or 9% of the population in China having T2DM, followed by India with 61.3 million and Bangladesh with 8.4 million (IDF, 2013). In Vietnam based on current estimates, there are 2.5% of the population with aged over 20 have T2DM which is expected will increase to 3.5% by the year 2025. A new research in 2006 showed that the prevalence of diabetes in whole country is 2.6% (Healthy Ministry of Organization, 2013). World Health Organization (WHO) reported that DM was the seventh cause of death from non-communicable diseases in Vietnam in 2002 (WHO, 2008).

T2DM causes a number of complications that affect health, blood vessels, eyes, kidneys, and nerves (IDF, 2013). A study of Morris et al. shows that 50% of T2DM patients died due to cardiovascular disease. DM reduces blood flow, induces peripheral neuropathy, increases the risk of foot ulcers and infection; and eventually, causes of limb amputation. Retinopathy of diabetes leads to the blindness. Additionally, people with diabetes had two times higher risk of death compared to people without diabetes (Roglic et al., 2005).

There are evidences to support that the most common complication in patients with DM is diabetic foot ulcer (DFUs). The study of Lavery and the others revealed that the foot ulcer rate among diabetic patients ranges from 4% to 10% (Lavery, Armstrong, Wunderlich, Tredwell, & Boulton, 2003b). Furthermore, the prevalence of lower limb amputation in those patients were 10-30 times higher than it is in people without diabetes.

Wounds of DFUs are severe and chronic, affecting physical health and quality of life of patients, and increasing the risk of death among them. Foot ulcerations and subsequent amputation are associated with high diabetes-related hospitalizations, emotional reactions, physical suffering, as well as loss of productivity and quality of life, and huge financial losses both in developed countries and in developing countries (Driver et al., 2010). Patients with DFUs have higher risk of premature, myocardial infarction and fatal stroke than patients without DFUs (Bowering, 2001). A study in 1999, USA, estimated the average cost is \$28,000 USD over a two-year period for an outpatient (Ramsey et al., 1999). Based on a study of Ratur et al., the inpatients cost for DFUs is \$16,580 USD; toe and other distal amputations costs are \$25,241 USD and other major amputations costs are \$31,436 USD (Rathur & Boulton, 2007). So, DFUs is the important problem of the patients that they should concern and take care themselves. However, there are many factors effecting to DFUs such as HbA1C, duration of T2DM, age, comorbidity and self-efficacy.

Dubsky et al. (2013) suggested that the levels of HbA1C were related with the risk of mortality and cardiac events (Dubsky et al., 2013). Literature indicates that the risk of DFUs complications significantly decrease with the decline of HbA1C, and people with HbA1C level under 6.0% have the least risk of diabetes complications (Stratton et al., 2000). In another study found that recurrence was associated with poor glycemic control (Lipscombe&Hux, 2007).

In addition, empirical evidence suggests that duration of disease has a role to develop DFUs. A study of Deribe et al. shows that people suffering diabetes more than 10 years have higher risk of developing DFUs than other people (Deribe, Woldemichael, & Nemera, 2014) The other study shows that long average duration of diabetes increased risk of DFUs occurrence (Shailesh et al., 2012).

In developed countries, most of DM patients are more than 60 years old, while in developing countries, the age is ranged from 40 to 60 (Shaw et al., 2010). However, T2DM can be occurred earlier. Reports show that T2DM in children increase in recent years. Furthermore, people with T2DM may be unaware their disease for a long time because this disease is not detected and no symptoms is presented; and they are diagnosed when they have complications or incidentally have the test for abnormal blood or urine glucose (IDF, 2013).

Comorbidities can have profound effects on patients' ability to take care of themselves. According to study of Bedilu and the others, (Bedilu, Kifle, & Gugsu, 2014), and Lavery, Armstrong, Wunderlich, Tredwell, & Boulton, (2003a) patients with comorbid diseases such as heart disease and hypertension are 7.8 times to have foot ulcers more than those who do not have comorbidity. Moreover, it was found that patients with depression and/or arthritis would have decreased functions in performing self-care and previous work. These cause significant barriers to daily living activity and treatment adherence in patients with T2DM.

Risk of foot ulcer will limit if patients takes care of their feet very well (Diabetes, Article online). Self-efficacy plays an important role to prevent foot damage (Perrin, Swerissen, & Payne, 2009). Self-efficacy is defined as people's beliefs about their abilities to achieve ultimate levels of action that influence over events that affect their lives (Bandura, 1986a; 1986b). Patients with diabetes need to have judgment on their capability to take care of themselves in order to prevent and control DFUs. The self efficacy theory provide the concepts related to the phenomena of the disease process and the behaviors of this group of patients. There are 4 components of self efficacy include enactive attainment, vicarious experience, verbal persuasion and physiological feedback. Each component have associations with others. The theorist belief that person demonstrate any behavior and they do anything if they belief that they has capabilities to perform those behaviors. The theorist belief in cognitive process that will effect on individual behaviors and that the behaviors can be modified by verbal persuasion and outcome expectation. The social cognitive theory uses the concept of self efficacy as predictive of a particular behavior. Self-efficacy is the amount of confidence a person believes he or she has to perform a set of specific activities or behaviors (Bandura, 1977). Bandura stated that self-efficacy is

the most predictive factor in the development and maintenance of a new behavior. He also stated that people who were persuaded that they could succeed were more likely to expend the effort needed to perform the behavior. Several studies showed that higher self-efficacy was equal to concerned about higher self-care and good self-efficacy could prevent foot complications and amputations. It can be concluded that self-efficacy reflects the individual's belief on his or her own successful behaviors to accomplish the certain task (Shi, Ostwald & Wang, 2010; Lorig & Holman, 2003). Accordingly, the study to explore level of self efficacy among patients with T2DM is significance. Moreover, the study of its relationship with the risk of DFUs is also vital because it will lead to strategies on prevention and health promotion among patients with T2DM which is an important role of nurses.

## **1.2 Research question**

What are the factors related to diabetic foot ulcers scores among patients with T2DM?

## **1.3 Purpose of the study**

To study the relationship among age, duration of DM, HbA1C, comorbidity, self-efficacy, and diabetic foot ulcers scores of patients with T2DM.

## **1.4 Hypothesis**

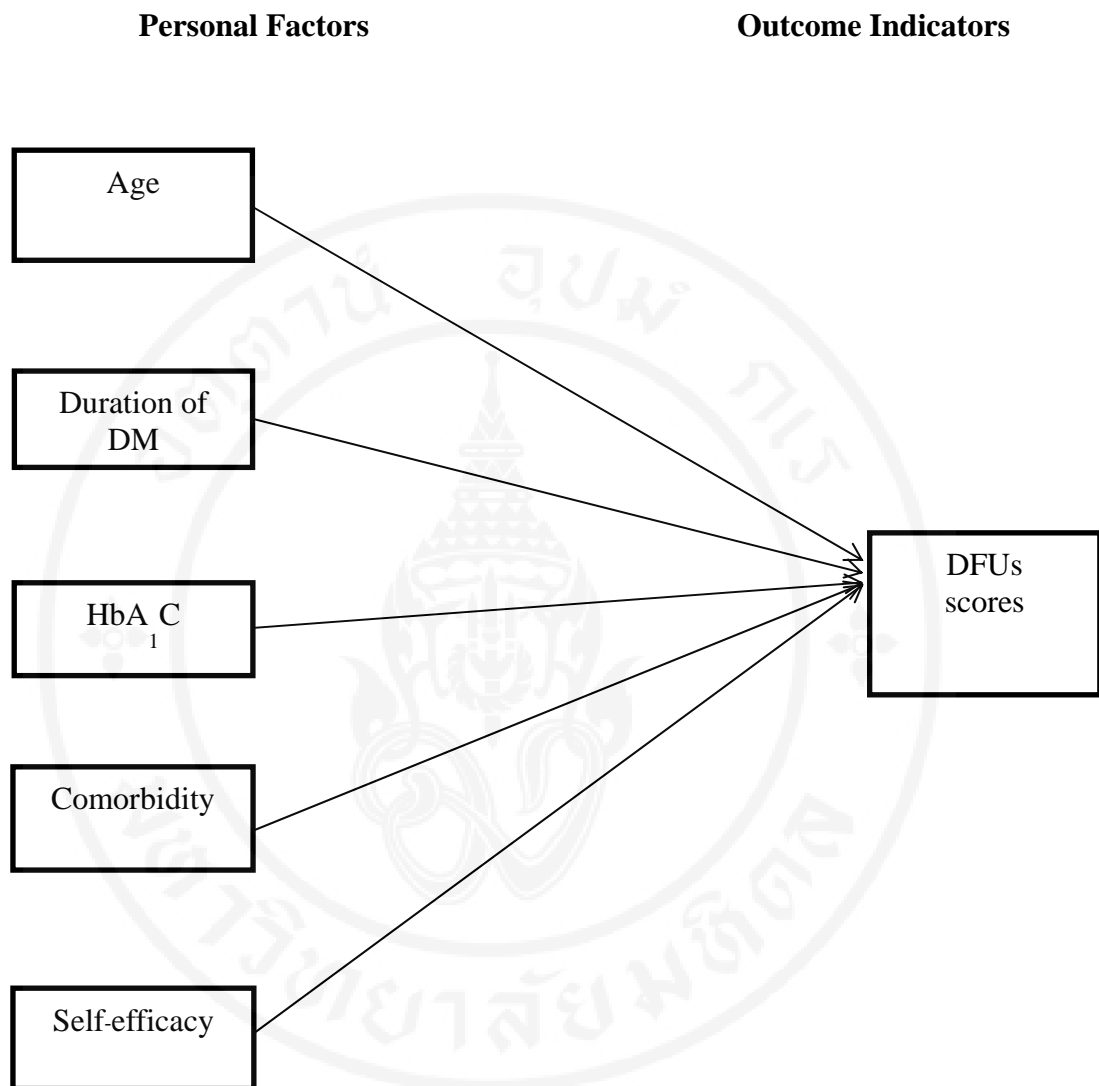
- 1.4.1 Age is positively related to DFUs scores among patients with T2DM.
- 1.4.2 HbA1C is positively related to DFUs scores among patients with T2DM.
- 1.4.3 Self-efficacy is negatively related to DFUs scores among patients with T2DM.
- 1.4.4 Comorbidity is positively related to DFUs scores among patients with T2DM.

1.4.5 Duration of DM is positively related to DFUs scores among patients with T2DM.

## **1.5 Conceptual framework**

Self – efficacy theory (Bandura, 1986) is utilized as a studied framework because it can clearly describe patients behaviors toward diabetes. When patients with DFUs has mastery experience, he or she will have strong belief in his/her own capability with vicarious experience and external verbal persuasion from others (health care team, nurses, family members) so a person will response by any demonstration of the feedback. There are some factors that correlated with the risk of DFUs or the DFUs scores among patients with T2DM. Those include age, self – efficacy, duration of DM, HbA1C, and comorbidity. Patients with high scores on DFUs scale will have high risk of developing DFUs and can eventually lead to disability. When patients have the belief in their ability they can perform successful special task or behaviors to get desirable outcome.

The relationship among independent variable and dependent variable is illustrated in the following conceptual framework (figure 1).



**Figure 1.1:** The relationship between age, duration of DM, HbA1C, comorbidity and self-efficacy with diabetic foot ulcers scores among patients with T2DM.

## 1.6 Scope of the study

This study aims to identify the relationship between age, comorbidity, HbA1C, duration of DM, self-efficacy and diabetic foot ulcers scores among patients with T2DM who came for follow treatment at out-patient department for diabetic patients of Bach Mai Hospital, Hanoi, Vietnam.

## **1.7 Expected outcomes and benefits**

1.7.1 Nurses can use this knowledge to detect, prevent and treat foot ulcers in patients with T2DM.

1.7.2 Health care teams can use this knowledge to develop effective clinical practice guidelines for the management of foot ulcers in patients with T2DM.

1.7.3 This knowledge can be used for the researchers in the other areas of DFUs studies.

## **1.8 Definition of terms**

1.8.1 DFUs scores referred to the scores that reflected the risk of developing DFUs in patients with T2DM. In this study DFUs scores were obtained by using 60-second Diabetic Foot Screen (Orsted, 2009) to assess the patients.

1.8.2 Self-efficacy is a theory that was developed by Albert Bandura, which was the fundamental concept of a social cognitive theory. It mentioned the belief of peoples on their ability to perform a task that successfully and their outcomes were expected. Self-efficacy of individuals and their capabilities could be rose if they received the skill and knowledge that they could gain. The motivation of people could be affected by self-efficacy, which made them do greater effort and maintain the behaviors in the longer duration. Furthermore, the role of self-efficacy was very important in the treatment of chronic disease (Bandura, 1986a, 1986b). In this study, self-efficacy was measured by Self-Efficacy for Diabetes

1.8.3 HbA1c referred to the mean plasma glucose in the last 2-3 months which can be measured by a single test anytime in anywhere without special preparation. It became the gold standard to evaluate glycemic control in people suffering diabetes and the test's result was concerned to measure glucose tolerance in people who were not diagnosed diabetes (WHO, 2006). In this study, HbA1c was collected from the patients' record.

1.8.4 Comorbidity referred to the existence of one or more chronic conditions in a person who already had other diseases. Patients with diabetes regularly had comorbidities such as cardiovascular diseases, retinopathy, nephropathy and DFUs (Beckman, Creager, & Libby, 2002). In this study, comorbidity was measured

by the form developed by the researcher. This form comprised items of common chronic diseases found among adult patients including hypertension, heart disease, renal disease and other chronic diseases. Patients were asked if they had these chronic illness prior to the study. Also, the comorbidity was collected from the patients' profiles.



## **CHAPTER II**

### **LITERATURE REVIEW**

This chapter provides a literature review of factors associated with diabetic foot ulcers scores among patients with type 2 diabetes mellitus (T2DM). The contents enhance the understanding of phenomena of diabetic foot ulcers (DFUs) and risk on the occurrence of DFUs among patients with T2DM based on self-efficacy theory as well as factors related to diabetic foot ulcers scores. Following 3 issues including the conclusion part:

2.1 Review of knowledge related to diabetic foot ulcers scores in patients with T2DM

2.1.1 Incidence of DFUs in patients with T2DM

2.1.2 Pathophysiology of DFUs in patients with T2DM

2.1.3 Impacts of DFUs in patients with T2DM

2.2 Self efficacy theory and its relationship with patients with T2DM

2.2.1 Self efficacy theory

2.2.2 The relationship of self - efficacy theory with patients

with T2DM

2.2.3 Self efficacy and DFUs.

2.3 Factors related to diabetic foot ulcers scores

2.3.1 Age

2.3.2 Duration of DM

2.3.3 Comorbidity

2.3.4 level of HbA1c

2.4 Conclusion

## **2.1 Review of knowledge related to diabetic foot ulcers scores in patients with T2DM**

### **2.1.1 Incidence of DFUs among patients with T2DM.**

Diabetes mellitus (DM) is the significance health problem among global population in the past 2 decades (Shahbazian, Yazdanpanah, & Latifi, 2013). According to the study of Shaw and the others, the number of patients with DM had been dramatically increased every year since the year 1985. Moreover, it was expected to increase to reach 360 million in the year 2030 (Shaw, Sicree, & Zimmet, 2010; Whiting, Guariguata, Weil, & Shaw, 2011). International Diabetes Federation (IDF) estimated that close to a half of patients with DM were not aware of their disease and the majority of them were T2DM (IDF, 2013). Countries in Asia and the eastern Pacific region are facing the similar problem so that if an effective preventive measure is not taken in to consideration at the policy level, the numbers of these patients will gradually increase (Shaw et al., 2010).

In Vietnam, the numbers of patients with T2DM had been increased in 2 decades due to the change of eating habit and life style. Within the past 10 years, T2DM was found among people who live in the city as well as in the rural areas (Binh, Uoc, & Cockram, 2003). According to the Vietnamese Diabetes Education Association (2008) and Vietnamese Ministry of Health (2010), by the year 2025 Vietnam will become one of the top ten Asian countries for T2DM among people with the age range between 20-79 years (Chan et al., 2009).

T2DM leads to both acute and chronic complications (Bellenir, 2008; Holt, Cockram, Flyvbjerg, & Goldstein, 2010). Diabetic ketoacidosis, hyperglycaemic hyperosmolar nonketotic syndrome and hypoglycaemia are 3 major acute complications (Bellenir, 2008; Holt et al., 2010) while neuropathy, micro-vascular and macro-vascular complications are chronic complications (Bellenir, 2008; Holt et al., 2010). Patients with neuropathy are at risk of developing DFUs and limb amputation, while patients with micro-vascular problems are at risk of kidney diseases, visual impairment, and foot ulcers. Patients with macro-vascular problems are at risk of cardiovascular disease, and stroke (Bellenir, 2008; Holt et al., 2010).

DFUs is a common complication of patients with T2DM. The incidence of DFUs is about 15% while 20% of patients with DFUs require hospital admission and more than 80,000 require limb amputation (Boulton, Vileikyte, Ragnarson-Tennvall, & Apelqvist, 2005; Aalaa, Malazy, Sanjari, Peimani, & Mohajeri-Tehrani, 2012; Leone, Pascale, Vitale, & Esposito, 2012). The prevalence of lower limb amputation due to DFUs range from 6 to 78% depending on duration of the disease, level of HbA1C, other comorbid diseases and patients' own ability to perform both self-care and foot care (Monteiro-Soares, Martins-Mendes, Vaz-Carneiro, Sampaio, & Dinis-Ribeiro, 2014). The rate of lower limb amputation is higher in low income countries due to opportunity of patients to get access to medical care (Viswanathan & Kumpatla, 2011; Canadian Institute for Health Information, 2012; IDF, 2013; Hopkins, Burke, Harlock, Jegathisawaran, & Goeree, 2015). Many studies revealed that DFUs not only increased hospital admission rate and medical expense but also affected patients' quality of life and burden of the society (Cook & Simonson, 2012; Sumpio, 2012).

### **2.1.2 Pathophysiology of DFUs in patients with T2DM**

Diabetes has two primary types: type 1 and type 2. The former, accounting for 10-15% of diabetes patients, is insulin-dependent type. It occurs when insulin could not be produced due to the destruction of beta cell in the pancreas. Type 1 diabetes may result in serious complications such as hypo or hyperglycemia. The latter is noninsulin-dependent type, which is the consequence of the combination between deficient insulin production and insulin resistance of the body's cells (Canadian Diabetes Association, 2010). Currently, T2DM is considered clinically metabolic disorder due to the reduction of carbohydrate tolerance. The characteristics of DM include rapid hyperglycemia, atherosclerotic and micro angiopathic vascular disease, and neuropathy. The clinical signs of hyperglycemia are the markers of vascular disease in the longer run.

There are some criteria to diagnose diabetes such as: Fasting plasma glucose levels are from 100 mg/dl (5.6 mmol/l) to 125 mg/dl (6.9mmol/l); or impaired glucose tolerance (IGT) [2-h values in the oral glucose tolerance test (OGTT) of 140 mg/dl (7.8 mmol/l) to 199 mg/dl (11.0 mmol/l)] (ADA, 2013). Besides, HbA1c level is above 6.5% can be used as a threshold to diagnose diabetes patients (Gillett, 2009).

DFUs are the consequence of a number of causes include neuropathy and decreased lower extremity blood flow due to narrow of vascular (Kelkar, 2005; Bowering, 2001). Specifically, the hyperglycemic state rises the actions of the enzymes aldose reductase and sorbitol dehydrogenase, transforming intracellular glucose to sorbitol and fructose which increase vasoconstriction and leads to lower extremity ischemia, nerve dysfunction, cell injury and anatomic foot malformation. As a consequence, the overlying skin of the foot is dried due to the loss of moisturization ability, which leads to increase the vulnerability to tears and eventually develops the infection. The development of ulcerations is exacerbated due to the loss of sensation from peripheral neuropathy. As a result, when patients' foot sustains injury, they cannot identify the damages and therefore the wounds are not noticed and gradually become worsen. Additionally, the influenced area is increasingly exposed to repetitive pressure and shear forces due to moving and weight bearing (Bowering, 2001). With the inappropriate shoes, the wound lesion become worsen.

The occlusion of peripheral arteries is one main cause of DFUs (Huijberts, Schaper, & Schalkwijk, 2008). Persistent hyperglycemic state leads to endothelial cell dysfunction and smooth cell abnormalities (Zochodne, 2008). Consequently, the endothelium-derived vasodilator decline resulting in vasoconstriction, vasospasm and increased platelet aggregation agonist-thromboxane A<sub>2</sub>. Accordingly, plasma hypercoagulability occurs (Paraskevas, Baker, Pompella, & Mikhailidis, 2008). Those aforementioned factors lead to lower limb ischemia and increased chance of DFUs.

The standard care for patients with T2DM therefore emphasize in physical assessment to identify risk factors. Moreover, the standard protocol to assess risk on development of foot ulcers is very vital and can be easily performed by the nurses (Sumpio, 2012). The other significant assessment is peripheral vascular status by palpating all peripheral pulses and assess the appearance and temperature of the patient's lower extremities and also measure the arterial-brachial index (ABI). The arterial-brachial index (ABI) with 0.6 or less indicates peripheral arterial occlusion or arterial insufficiency. Neuropathy sign and symptom which include numbness, paresthesia, and burning sensations should also be assessed (Boulton et al., 2008). Periodic assessment is very importance because the risk will be early detected and risk prevention measures can be effectively implement (Monteiro-Soares, Boyko, Ribeiro,

Ribeiro, & Dinis-Ribeiro, 2012; Iraj, Khorvash, Ebneshahidi, & Askari, 2013; Shahbazian et al., 2013).

### **2.1.3 Impacts of DFUs on patients with T2DM**

DFUs have many impact on patients with T2DM. The impacts cover many dimension of patients' lives (Mohammad , Abida, & Jamal, 2015; Boulton et al., 2005). The details are described below.

#### **Impact on physical health**

Patients with T2DM who have DFUs are at risk for wound infection, sepsis and limb amputation. The wounds inhibit patients to perform their normal activities such as daily living activities, work and travelling (Raspovic, Hobizal, Rosario, & Wukich, 2015). Patients with DFUs would have problems in walking so that many of them would prefer to stay at home and deprive from social function. Some of them feel that they created burden to their families while travelling (Boulton et al., 2005; Valensi, Girod, Baron, Moreau-Defarges, & Guillon, 2005). Eventually, it would affect their quality of life

#### **Impact on psychosocial health**

T2DM patients with DFUs have to face with chronic illnesses so that they have to face with prolong treatment. In some patients who have other comorbid diseases, they have to receive various kinds of medicine. The wound itself needs to get dressing every day until it completely healed which usually take long time. Many studies showed that patients with DFUs demonstrated many psychological and emotional problems such as severe anxiety and depression. Some of them show difficulty in sleep. Some may demonstrate guilty because they feel that their illness brings heavy burden to their family. These eventually lead them to decreased quality of life (Brod, 1998; Adili, Larijani, & Haghghatpanah, 2006; Schram, Baan, & Pouwer, 2009). Depressive symptom is the other psychological problem occurring among T2DM patients with DFUs. Especially, among ones who have advanced foot ulcers with infection or gangrene. They will be very fear of lower limbs amputation

and become more anxious about their health conditions (Bruun, Siersma, Guassora, Holstein, de Fine Olivarius, 2013).

### **Impact on family**

The families of T2DM patients with DFUs have to face with various problems (McCarthy, 2010). They have to deal with patients' treatment expense which become a burden of the household (IDF, 2013). Some of them have to spend their time to accompany the patients every day to receive wound dressing. Some have to change their food type to comply with the patients' health conditions. In patients who are very dependent such as the elderly patients or patients with severe comorbid diseases, the family members have to dedicate their time to providing care for the patients. These are burden of the family and eventually lead them to stress (McCarthy, 2010).

### **Impact on economic**

T2DM is the disease consuming high medical expense (Lipscombe & Hux, 2007). In particular, if patients have DFUs the treatment expense become higher due to the expense for wound dressing, antibiotics, surgical procedures prolonged and increased length of hospital stay (IDF, 2010). T2DM patients with DFUs would have reduced workforce productivity and would also affect the nation economic (Centers for Disease Control and Prevention, 2011; ADA, 2012). Many studies showed that T2DM patients who have DFUs consume more medical expense than patients without DFUs. Moreover, they have to deal with decreased incomes because they could not work at the same pace as they previously performed (Centers for Disease Control and Prevention, 2011; ADA, 2012; Ragnarson Tennvall & Apelqvist, 2004; Van Acker et al., 2000; Canadian Association of Wound Care, 2013; Yazdanpanah, Nasiri, & Adarvishi, 2015; Dhatariya et al., 2012).

According to aforementioned, patients with T2DM should receive foot assessment in order to early detect if they are at risk of developing foot ulcers. The scale "The 60 Second Diabetic Foot Screen" (Orsted, 2009) has been widely used among nurses because of its convenience, effectiveness and can help early detect the risk on DFUs occurrence.

## **2.2 Self efficacy theory and its relationship with patients with T2DM**

### **2.2.1 Self efficacy theory**

Self-efficacy theory is one of the most importance social cognition theory developed by Albert Bandura. Bandura proposed the meaning of self- efficacy “the belief of a person in his or her own capability to perform special successful behaviors to obtain the expected outcomes as he or she intend to achieve” (Bandura,1986a,1986b). After Bandura published his concept of self- efficacy, he had been using this theory in research and practice in many groups of people include healthy individuals, patients with chronic illnesses, patients with non -communicable diseases and people who are at risk of having diseases. Many researchers in health sciences had been using Bandura self -efficacy theory in various groups of patients. Those researches were varied from cross sectional descriptive study to quasi experimental study.

The theory explains that when a person has mastery experience, he or she will have strong belief in his/her own capability with vicarious experience and external verbal persuasion from others (health care team, nurses, family members) so a person will response by any demonstration of the feedback. There are 4 components in self-efficacy theory including enactive mastery experiences, vicarious experience, verbal persuasion and physiological and affective states or physiological feedback (Williams & Rhodes, 2014). Each component has associations with others. Besides, there are some extraneous variables influencing self- efficacy including individual factors and environmental factors. In order to apply self- efficacy theory, nurses have to assess the context and the individual factors to clearly understand the whole phenomena of their interest. Followings are the details of each component in self-efficacy theory;

Enactive mastery experiences or performance accomplishment refers to a person self-belief, confidence in performing an intention behaviors (Iroegbu, 2015). A person can have both direct and indirect experiences which affect his or her belief in his or her own behaviors in performing activities related to health. For example, if a person has been involved in a successful smoking cessation program, he or she will be confidence in smoking cessation activities and will adopt this behavior. Enactive

mastery experiences depend on a person background; knowledge, attitude, experiences, courage and cognition (Williams & Rhodes, 2014).

Vicarious experience refers to the experience of others to whom a person views as an ideal model in the related matter (Iroegbu, 2015). For example, if patients with T2DM would like to control their diet, they would be able to perform the behaviors more successfully by looking at the other patients who were success in diet control. They can learn from others' success and failure and adopt the desirable behaviors to help them success. Providing a patient with good role model or mentoring patients are strategies to increase their vicarious experiences (Williams & Rhodes, 2014).

Verbal persuasion refers to an importance source of self- efficacy in which a person could receive by others. Receiving verbal persuasion will provide a person with more confidence, courage and intention in performing desirable behaviors. Many studies found that patients who received verbal persuasion would put more effort on their healthy behaviors (Shi, Ostwald & Wang, 2010; Gao, Wang, Zheng, Haardorfer, Kegler, Zhu & Fu, 2013; Hussen, 2016). In particular, patients who suffer with chronic disease like T2DM need more effort to comply with prolonged or life time medical regimen, dietary control and exercise. These patients accordingly require verbal persuasion to maintain good health behaviors.

Physiological and affective feedback is an importance source of self- efficacy. It refers to emotional arousal when a person achieves any desirable outcomes. For example, when the patients can control dietary pattern consequently their blood glucose level become within normal limit, they would be satisfy with the health condition. This circumstance will arise the feeling of the patients in a positive way. In turn they will become more confidence to perform the desirable behaviors and willing to maintain the behaviors (Iroegbu, 2015; Williams & Rhodes, 2014).

### **2.2.2 The relationship of self - efficacy theory with patients with T2DM**

Self-efficacy has been described as behavior specific and dynamic, and identifying a person's perception of their capability in a certain setting or with a

certain behavior has often been noted as a preeminent indicator of self-care behavior performance (Shi, Ostwald, & Wang, 2010)

In term of diabetes, behavioral interventions have been successful in developing specific or more general. Self-efficacy beliefs, resulting in improved glycaemic control. Patients with T2DM who possess high level of self- efficacy will be confidence in performing health behaviors to control their diet, regularly exercise, managing emotional stress, taking medications and regularly monitor themselves (Gao, Wang, Zheng, Haardorfer, Kegler, Zhu & Fu, 2013; Hussen, 2016). Accordingly, self efficacy theory is suitable for using to describe the phenomena related to health care behaviors among patients with T2DM as well as to implement as a nursing therapeutic in these patients.

### **2.2.3 Self efficacy and the DFUs**

Patients with DFUs need to have judgment on their capability to take care of themselves in order to prevent and control DFUs. The self-efficacy theory provides the concepts related to the phenomena of the disease process and the behaviors of this group of patients. More over this theory provide the expected outcomes which can be measured by the severity of DFUs. When patients with DFUs have strong belief in their own capacity to perform activities they can to achieve/ pursue desired goals/ aims. In addition, they will be able to control blood glucose level, assess their feet regularly, select the proper shoes and prevent themselves from developing foot ulcers. The study of Vileikyte and the others among patients with T2DM revealed that patients who had confidence were able to take special care of their feet. Consequently, they can prevent DFUs to occur (Vileikyte et al., 2006). Likewise the study of Perrin and the others, they found that patient education about self care and self efficacy played an important role in foot damage prevention (Perrin, Swerissen, & Payne, 2009). Patients who had higher self-efficacy were more likely to perform regular foot self-care behaviors (Driver, Fabbi, Lavery, & Gibbons, 2010) so that they tend to have low risk for DFUs.

## **2.3 Factors related to DFUs**

When the researcher performed extensive literature review, there are researches and articles support that the occurrence of DFUs are depending upon various factors. Some important factors will be described below;

### **2.3.1 Age and its association with DFUs scores among patients with T2DM**

Patients with T2DM are more likely to have DFUs and the occurrence are depending on various factors. One factor that would increase the risk of DFUs is the age of the patients. Previous systematic reviews found that with increasing ages, patients with T2DM were have higher chance to develop DFUs (Monteiro-Soares et al., 2012; Mohammad et al., 2015). Moreover, those reports confirmed that when DFUs occurred, patients were more likely to have many serious complications such as wound infection, delayed wound healing and sepsis. Patients with old age have lower immune function and they may not be able to perform self inspection to their feet. Neuropathy is more frequently found among T2DM patients with older ages so that they would get injured on their feet easily (ADA,2013; Mohammad et al., 2015).

### **2.3.2 Duration of DM and its association with DFUs scores among patients with T2DM**

Patients who have T2DM for longer duration are at risk to have DFUs than ones who have shorter duration of T2DM. The study of Shailesh and the others showed that diabetes patients who have the disease more than 10 years are 8 times to develop DFUs comparing with ones who have diabetes less than 10 years (Shailesh et al., 2012).The longer the patients have the disease the higher risk of various complications due to persistence high level of serum glucose, atherosclerosis and narrowing of peripheral blood vessel. Eventually, decreased blood flow to the lower extremities occurs leading to neuropathy and patients will easily get DFUs (Mohammad et al., 2015).

### **2.3.3 Comorbidity and its association with DFUs among patients with T2DM.**

T2DM patients who have more co morbid diseases are at higher risk to develop DFUs. Many studies support this fact. The study of Shailesh and the others showed that when T2DM patients have retinopathy, nephropathy and hypertension, they are in high risk of having DFUs (Shailesh et al., 2012). The explanation is that these patients have poor sensation in peripheral organs in particular at the lower limbs so that it is easier for them to get injured on their feet without notice. The ulcers would become worse and infected in a short duration. The guidelines of Canadian Diabetes Association recommended that T2DM patients who have hypertension, renal diseases or neuropathy have to receive physical assessment from endocrine physicians more frequently because they have high risk of developing DFUs (Canadian Diabetes Association, 2008).

### **2.3.4 HbA1C and its association with DFUs among patients with T2DM**

Since the past 3 decades, HbA1c has been used to investigate plasma glucose level because it reflects average plasma glucose over the previous 8 to 12 weeks (Nathan, Turgeon, & Regan, 2007). It very well reflects patients' control of their glucose. Croxson stated that patients who can control their level of HbA1c, blood pressure and lipid level would have less chance to develop DFUs (Croxson, 2002). Likewise the recommended from the standard guidelines, controlling level of HbA1c or glycemic control is very significance among patients with T2DM (Canadian Diabetes Association, 2008). Reduction of HbA1c for 1% was associated with a 25% reduction in complications related to micro vascular, heart disease, kidney disease, retinopathy and neuropathy (Croxson, 2002). Accordingly, an aggressive intervention on glycemic control is recommended in patients who have very high level and unstable level of serum glucose because this can prevent patients from various complications (Lu et al., 2012).

## 2.4 Conclusion

According to the literature review it can be concluded that the incidence of diabetes is increasing, and DFUs continues to be a growing challenge for healthcare among patients with T2DM. DFUs has an effect on patients' physical health, physical symptoms, emotional and psychological health. Moreover, DFUs leads to economic burden because it leads to patients' disability due to lower limbs amputation. This group of patients could not effectively work at the same pace comparing with the time prior to the occurrence of the foot ulcers. There are evidences to support that the occurrence of DFUs as well as the risk on developing DFUs are associated with many factors in particular patients' self-efficacy, patients' age, patients' duration of DM, patients' co morbidity and the level of HbA1C. In order to clearly understand these phenomena, the researcher would like to conduct research to confirm the relationship among these variables. It can be expected that knowledge gain from this study can be used to improve the quality of care for patients with T2DM. Finally, these patients can become actively involved in social functions and contribute themselves to the society.

## **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 are consecutively presented.

#### **3.1 Research design**

The study was a descriptive correlational research aimed to investigate the relationship among age, duration of DM, HbA1C, comorbidity, self-efficacy, and diabetic foot ulcers scores of patients with T2DM.

#### **3.2 Population and sample of the study**

##### **3.2.1 The population of this study**

The population of this study included patients who had been diagnosis with T2DM. The sample included the patients who came for follow-up treatment at outpatient department for diabetic patients of Bach Mai Hospital, Hanoi, Vietnam.

##### **3.2.2 The sample of the study**

Sample was selected according to the following criteria:

###### **Inclusion criteria**

- 1) Age was 18 years old or above.
- 2) Be able to verbally communicate with the researcher in Vietnamese

language

**Exclusion criteria**

- 1) Patients had limb amputation

**Termination criteria**

Patients developed instability of vital sign: systolic blood pressure lower than 90mmHg, heart rate lower than 60 beat per minute or higher than 120 beat per minute, respiratory rate lower than 14 per minute, or more than 30 per minute.

**Sample size**

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-relationship design (Faul, Erdfelder, Buchner, & Lang, 2009). The researcher tested the relationship among age, duration of DM, HbA1C, comorbidity, self-efficacy, and diabetic foot ulcer scores of patients with T2DM. The level of significance  $\alpha=0.05$ . the power of the statistical test (power  $1-\beta=0.8$ ). There were five independence variables in this study and effect size for this study ( $f^2 = .099$ ). Base on G\* power, sample size was 136 patients.

**3.3 Setting**

The study was performed at diabetic outpatient examination room in outpatient department of Bach Mai Hospital, Hanoi, Vietnam. Bach Mai Hospital is a biggest general hospital in Hanoi. There was a separate department for endocrine patients. Patients with T2DM came to receive care both in out-patient and in patient department. Patients with very high severity or having instability conditions who required aggressive treatment were admitted to the inpatient department. Those who still required continuous treatment from endocrine physicians came to receive their medication at diabetic out-patient examination room. Each day, there was about 120 patients who came to diabetic outpatient examination room, outpatient department. There were 2 separate rooms for them to receive care from physicians and nurses. The routine care they received composed of general assessment, blood examination, foot assessment and health education. Although there was overcrowded in this out-patient department but the researcher managed to set a private corner for data collection. The

researcher collected the data from patients who met the research inclusion criteria at this setting.

### **3.4 Instruments**

In this study, researcher used four questionnaires to collected data, including: General information of the patients, Information related to illness and treatment method, Self -efficacy for diabetes and the 60 Second Diabetic Foot Screen.

#### **Part 1 General information of the patients**

The general information of patients included: address, occupation, age, gender, weigh, height, BMI, date of admission to hospital, the hospital that patient had treatment before, marry status, education level, payment method, income diagnosis, duration of illness, comorbidity, past and current treatment method, trauma and surgery, habits and metal status.

#### **Part 2 Information related to illness and treatment method**

It included: History of disease, duration of DM, duration of DFUs, diagnosis, comorbidity, blood pressure, body temperature, laboratory, HbA1C, smoking, exercise.

#### **Part 3 Self efficacy for diabetes**

The 8-item self- efficacy for diabetes scale was originally developed and tested for its psychometric property in Spanish. In 2009, it was translated into English by Stanford Patients Education Research Center, USA. The English scale was tested in 186 patients with diabetes and yielded alpha Chronbach of .828 (Lorig, Ritter, Villa & Armas, 2009). The scale comprises 8 items asking about how much confidence the patients with diabetes feel about their self- management on diabetes. These 8 items cover essential activities related to diabetic management. The scale is published and owned by Stanford Patient Education Research Center, USA and is offered for free access without asking for permission to use in practice or research (Lorig, Ritter, Villa & Armas, 2009).

#### **Part 4 The 60 Second Diabetic Foot Screen**

The 60 Second Diabetic Foot Screen was an assessment tool developed by Dr. Inlow, a clinical expert in the field of diabetic foot ulcers in Canada. This tool has been widely used in practice by nurses or other health care professions for screening by performing inspection, palpation, and asking some specific questions related to foot ulcers that would occur in patients with T2DM (Orsted, 2009). The 60 second diabetic foot screen comprises three domains 12 items divided into 1) Look – 20 seconds is 4 items, 2) Touch – 10 seconds is 3 items, 3) Assess – 30 seconds is 5 items. (Cronbach's alpha: Left foot: .93. Right foot: 0,92). This tool is offered for free access online without asking for permission to use in practice or research (Orsted, 2009). The researcher used this scale to detect risk on developing DFUs in patients with T2DM.

### **3.5 Instrument Reliability and Validity**

#### **3.5.1 Instrument Validity**

General information of the patients, Information related to illness and treatment method, The Self efficacy for diabetes, the 60 Second Diabetic Foot were translated into Vietnamese by Vietnamese-English professor and verified by 5 diabetes experts.

#### **3.5.2 Instrument Reliability**

After obtained the IRB approval, the self -efficacy for diabetes scale and the 60 Second Diabetic Foot Screen scale were used in 30 patients with T2DM who had characteristics similarly to the studied sample as aforementioned. Cronbach's alpha coefficient were employed to test each instrument reliability for 30 patients and for the whole studied sample (n = 136) (table 3.1).

**Table 3.1** Reliability of scales (n= 30 and n=136)

Scale	N of Items	Cronbach's	Cronbach's
		Alpha (n = 30)	Alpha (n = 136)
Self-efficacy for diabetes	8	.89	.87
60 second diabetic foot screen	24	.82	.82
Left foot	12	.64	.64
Right foot	12	.63	.63

### 3.6 Data collection

The data collection was conducted in the following sequences:

3.6.1 The researcher collected some information of the patients from the medical record form.

3.6.2 The researcher organized the private room to interview and assess the feet of the patients. The questionnaires for interview include 1) General information of the patients 10 items, 2) Information related to illness and treatment method 9 items, 3) Self-efficacy for diabetes 8 items. The interview was last about 30-40 minutes.

3.6.3 The researcher assessed the feet of the patients using the 60 second Diabetic Foot Screen 12 items which took about 5 minutes.

### 3.7 Protection of human rights

This study was conducted based on the protection of human rights. The participants were asked to participate in the study. The researcher explained the purpose of the study, the research procedure, benefits, risks and type of questionnaire. Length of time for completing questionnaire. And the right to refuse participation in the study anytime. The participants who agreed to participate were informed and assured that the data would be kept confidentially and would be reported only as a group data. Informed consent was signed by all participants.

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

3.7.1 The researcher collected the data after receiving Vietnam National University, Mahidol University and the Ethical Committee of Research with Human Subjects of Endocrine ward.

3.7.2 The researcher self-introduced to the participants at diabetic outpatient examination room, informed the patients about the research objective and all data collection process. The patients were informed that they had right to refused to joined in the research process. During anytime throughout the research process, patients had their own right to withdraw from the research project and it was not influence on their treatment or caring process. If patients agreed to join in the research process, they were invited to sign their name in the consent form.

3.7.3 This research did not cause any risk to the patients physical health. The data collection process might take time about 30 to 45 minutes. Although the patients did not get any benefit from this research, the results were benefit for other patients who had the same health care problem as the sample.

3.7.4 All contents were kept confidential, only the researcher and the research 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.

3.7.5 If the participants had further questions or require more explanation in regard to the research, they informed to feel free to ask the researcher at anytime throughout the research process.

3.7.6 After the participants clearly understood the research process and agreed to join in the research, they were invited to sign their name in the consent form.

### **3.8 Data analysis**

3.8.1 Quantitative data were analyzed using computer programs.

3.8.2 All data were analyzed using descriptive statistic in terms of frequency, percentage, mean and standard deviation and range were used to describe general information and studied variables, including age, comorbidity, HbA1C, duration of DM, self-efficacy and diabetic foot ulcers in patients with T2DM.

3.8.3 The variables were tested for their normal distribution according to the assumption of the Pearson Product-Moment correlation coefficient. All studied variables did not show normal distribution so that Spearman's rho was employed to test correlation among the variables.



## **CHAPTER IV**

### **RESULTS**

The purpose of this research was to study the relationship among age, duration of DM, HbA1C, comorbidity, self-efficacy, and diabetic foot ulcers scores of patients with type 2 diabetes. Data were obtained by interviewing patients and performing foot assessment using the interviewing form and observation sheet as well as the patients record charts. Sample were 136 patients who came for the follow up care at endocrine out patient unit, Bach Mai hospital, Hanoi, Vietnam. The results are presented by tables with narrative explanation in this chapter.

#### **4.1 General characteristics of the sample**

The majority of the sample were female (60.3%) with the mean age of 65.3 years. Most of them were married (79.4%), finished secondary school (27.2%), retired from their work (80.1%) and living in the city (60.3%). All patients had health insurance, more than half of them (57.4%) was paid completely by health insurance. The majority of the patients never smoked (68.4%) (table 4.1).

**Table 4.1** Characteristic of the patients (n = 136)

Characteristics	Number	Percentage
<b>Gender</b>		
Male	54	39.7
Female	82	60.3
<b>Age (years)</b>		
18-39	2	1.5
40-59	26	19.1
>=60	108	79.4
Min: 37		
Max: 83		
Mean $\pm$ SD: 65.3 $\pm$ 8,6		
<b>Marries</b>		
Married	108	79.4
Single	1	.7
Separated	1	.7
Widowed	26	19.1
<b>Educational Level</b>		
Elementary school	7	5.1
Secondary school	37	27.2
High school	29	21.3
Two-year certificate	31	22.8
Bachelor degree	27	19.9
Post graduated	5	3.7
<b>Occupation</b>		
Farmer	13	9.6
House wife	1	.7
Staff government	6	4.4
Retired	109	80.1
Other job	7	5.1
<b>Location of residence</b>		
City (Hanoi)	82	60.3
Rural area	49	36.0
Mountain	5	3.7

**Table 4.1** Characteristic of the patients (n = 136) (cont.)

Characteristics	Number	Percentage
<b>Monthly Income (USD)</b>		
<100	29	21.3
101-200	61	44.9
201-300	36	26.5
>300	10	7.4
Min: 0		
Max: 672.6 USD		
Mean $\pm$ SD: 174.67 $\pm$ 118.26		
<b>Insurance</b>		
Yes	136	100.0
No	0	0
<b>Percentage of insurance coverage</b>		
100%	78	57.4
95%	27	19.9
80%	31	22.8
<b>Number of people live together</b>		
1-5	107	78.7
$\geq 5$	29	21.3
Min: 1		
Max: 10		
Mean $\pm$ SD: 3.8 $\pm$ 1.97		
<b>Smoking</b>		
Never smoking	93	68.4
Current smoker	9	6.6
Former smoker	34	25.0

## 4.2 The sample characteristics of illness

The majority of sample had experienced type 2 diabetes for more than 10 years with the mean duration of 11.93 years (SD  $\pm$  5.92). Only 5.1% patients had history of previous ulcer. Overweight and obese patients accounted for 29.4% and 21.3%, respectively (table 4.2).

**Table 4.2** Characteristic of illness and information about health status (n = 136)

Characteristics	Number	Percentage
<b>Duration of DM(years)</b>		
$\geq 5$	15	11.0
6-10	29	21.3
>10	92	67.6
Min: 1		
Max: 32		
Mean $\pm$ SD: 11.93 $\pm$ 5.92		
<b>History of previous ulcer</b>		
No	129	94.9
Yes	7	5.1
<b>BMI</b>		
<18.5	5	3.7
18.5-22.9	62	45.6
23-24.9	40	29.4
$\geq 25$	29	21.3
Min: 16		
Max: 31.6		
Mean $\pm$ SD: 22.97 $\pm$ 2.63		
<b>HbA1C (mg/dl)</b>		
$\leq 7$	71	52.2
>7	65	47.8
Min: 5.7		
Max: 12.9		
Mean $\pm$ SD: 7.47 $\pm$ 1.47		

**Table 4.2** Characteristic of illness and information about health status (n = 136)

(cont.)

Characteristics	Number	Percentage
<b>ABlleft</b>		
≤ 0.9	5	3.7
>0.9	131	96.3
Min: 0.83		
Max: 2.26		
Mean ± SD: 1.17 ± 0.19		
<b>ABlright</b>		
≤0.9	5	3.7
>0.9	131	96.3
Min: 0.84		
Max: 2.26		
Mean ± SD: 1.18 ± 0.23		
<b>Temperature</b>		
Normal	136	100.0

The mean of glucose was 8.37 (SD=3.13), while the mean of cholesterol and triglyceride were 4.84 (SD=1.42) and 5.29 (SD=23.83), respectively (table 4.3).

**Table 4.3** Range, mean and standard deviation of laboratory values, weight, height and vital signs (n = 136)

clinical characteristics	Minimum scores	Maximum scores	Mean scores	SD
Glucose	3.3	18.9	8.37	3.13
Cholesterol	2.73	12.56	4.84	1.42
Triglyceride	0.56	279	5.29	23.83
Weight (Kg)	38	80	57.26	8.28
Height (cm)	142	175	157.75	7.07
Systolic	100	200	133.12	13.6
Diastolic	60	100	81.82	7.08

Table 4.4 depicts total 22 comorbidities. Hypertension is the most common comorbidity with 89% (n=121), Dyslipidemia disease comes second with 79.4% (n=108) and Peripheral neuropathy comes third with 22.1% (n=30) (table 4.4).

**Table 4.4** Comorbidity of patients with T2DM (n = 136)

Comorbidity	Number	Percentage
Hypertension	121	89.0
Heart disease	9	6.6
Renal disease	24	17.6
Dyslipidemia disease	108	79.4
Peripheral neuropathy	30	22.1
Peripheral artery	5	3.7
Arthritis	3	2.2
Cerebrovascular disease	4	2.9
Gout	5	3.7
COPD	1	.7
Osteoarthritis	4	2.9
Liver disease	2	1.5
Gastritis	1	.7
Urinary tract infections	2	1.5
Hypothyroidism	1	.7
Asthma	1	.7
Hypopituitarism	1	.7
Insomniac	3	2.2
Irritable bowel syndrome	1	.7
Eyes disease	2	1.5
Thalassemia	1	.7
Osteoporosis	1	.7

**Table 4.5.** The number of comorbidity of patients with T2DM (n=136)

Comorbidity	Number	Percentage
0 comorbidity	2	1.5
1 comorbidity	9	6.6
2 comorbidities	74	54.4
3 comorbidities	35	25.7
4 comorbidities	12	8.8
5 comorbidities	4	2.9

### 4.3 Self- efficacy and diabetic foot-score

The mean score of self-efficacy was 54.49 (SD=8.34) while the mean score of diabetic foot screen was 6.05 (SD=3.14). The details of diabetic foot scores as displayed in Table 4.7 showed that the majority of sample had problems with foot skin. About 76% (75.7%) of them had dry foot skin with fungus or light callus, 11 % had heavy callus build up and 5.1% had open foot ulcers or recent history of foot ulcers. Similar to their nails, 71.3% had un-kept and ragged nails while 13.2% had thick, damaged, or infected nails. In regard to foot wear, 84.6% of the sample wore inappropriate foot wear such as slippers or very tight shoes while 3.6% sustained foot trauma due to wearing inappropriate foot wear. More than 30% of sample had limitation of foot movement, they could not perform full range of motion to hallux (33.1% had hallux limitus and 1.5% had hallux rigidus). About 30% showed abnormal sensation on 10 points monofilament test. Dorsalis pedal pulse could not be palpated in only 3.7% of the sample. According to the scores from foot assessment, nearly 40% of the sample required foot screening every 6 months (33.8%) and every 3 months (3.7%) (table 4.8).

**Table 4.6** Mean and Standard Variation of self- efficacy and diabetic foot screen (n = 136)

Variable	Normal	Min	Max	Mean	SD
Self-efficacy	1 –80	36	80	54.49	8.34
Diabetic foot ulcer score	0-25	02	17	6.05	3.14

**Table 4.7** Diabetic foot score in each item (n = 136)

Characteristics	Number of left foot (%)	Number of right foot (%)	Number the highest score of left or right
<b>Skin</b>			
Intact and healthy	13(9.6)	12 (8.8)	11 (8.1)
Dry with fungus or light callus	104 (76.5)	104 (76.5)	103 (75.7)
Heavy callus build up	14 (10.3)	14 (10.3)	15(11)
Open ulceration or history of previous ulcer	5 (3.7)	6 (4.4)	7 (5.1)
<b>Nail</b>			
Well –kept	21(15.4)	21 (15.4)	21 (15.4)
Un-kept and ragged	100 (73.5)	98(87.5)	97 (71.3)
Thick, damaged, or infected	15 (11)	17 (12.5)	18 (13.2)
<b>Deformity</b>			
No deformity	124 (91.2)	124 (91.2)	122 (89.7)
Mild deformity	12 (8.8)	12 (8.8)	14 (10.3)
<b>Footwear</b>			
Appropriate	16 (11.8)	16 (11.8)	16 (11.8)
Inappropriate	115 (84.6)	115 (84.6)	115 (84.6)
Causing trauma	5 (3.7)	5 (3.7)	<b>5( 3.7)</b>

**Table 4.7** Diabetic foot score in each item (n = 136) (cont.)

<b>Characteristics</b>	<b>Number of left foot (%)</b>	<b>Number of right foot (%)</b>	<b>Number the highest score of left or right</b>
<b>Temperature cold</b>			
Foot is not cold	126 (92.6)	126 (92.6)	125 (91.9)
Foot is cold	10 (7.4)	10 (7.4)	11 (8.1)
<b>Temperature hot</b>			
Foot is warm	135 (99.3)	135 (99.3)	135 (99.3)
Foot is hot	1 (0.7)	1 (0.7)	1 (0.7)
<b>Range of motion</b>			
Full range to hallux	89 (65.4)	90 (66.2)	89 (65.4)
Hulluxlimitus	46 (33.8)	44 (32.4)	45 (33.1)
Hallux rigidus	1 (0.7)	2 (1.5)	2 (1.5)
<b>Monofilament</b>			
10 sites detected	96 (70.6)	98 (72.1)	96 (70.6)
7-9 sites detected	25 (18.4)	24 (17.6)	25 (18.4)
0-6 sites detected	15 (11)	14 (10.3)	15 (11)
<b>Sensation ask 4 questions</b>			
No to all questions	35 (25.7)	38 (27.9)	35 (25.7)
Yes to any of the questions	101 (74.3)	98 (72.1)	101 (74.3)
<b>Pedal pulse</b>			
Present	131 (96.3)	131 (96.3)	131 (96.3)
Absent	5 (3.7)	5 (3.7)	5 (3.7)
<b>Dependent rubor</b>			
No	131 (96.3)	131 (96.3)	131 (96.3)
Yes	5 (3.7)	5 (3.7)	5 (3.7)
<b>Erythema</b>			
No	135 (99.3)	135 (99.3)	135 (99.3)
Yes	1 (0.7)	1 (0.7)	1 (0.7)

**Table 4.8** Total scores of samples from foot assessment presented in group according to the risk and or severity of DFUs (n= 136)

<b>Group</b>	<b>Number</b>	<b>Percentage</b>
Group 1; 0-6 (Recommend screening yearly)	85	62.5
Group 2; 7-12(Recommend screening every 6 months)	46	33.8
Group 3; 13-19(Recommend screening every 3 months)	5	3.7
Group 4; 20-25(Recommend screening every 1 to 3 months)	0	0

#### **4.4 Correlation between Age, Duration of DM, HbA<sub>1</sub>C, comorbidity, Self efficacy and Diabetes foot ulcer scores.**

All variables in this study were tested for their normal distribution and the results showed that most of variable did not have normal distribution, except self-efficacy variable. Accordingly, Spearman's rho was employed to test the correlation among variables. Results of table 4.9 indicated that there was not any significant correlation between diabetic foot ulcer and HbA<sub>1</sub>C. Age has positive correlated with Diabetic foot ulcer ( $r=0.287$ ). Duration of DM has positive correlated with Diabetic foot ulcer ( $r=0.306$ ). Comorbidity has positive correlated with Diabetic foot ulcer scores ( $r=0.300$ ) while Self efficacy were negative correlate with diabetic foot ulcer scores ( $r=-0.415$ ) (table 4.9).

**Table 4.9** Correlation between Age, Duration of DM, HbA<sub>1</sub>C, comorbidity, Self-efficacy and Diabetes foot ulcer scores. (n = 136)

	1	2	3	4	5	6
1. Age	1.00					
2. Duration of DM	.331**	1.00				
3. HbA <sub>1</sub> C	.146	.395**	1.00			
4. Comorbidity	.254**	.177*	.096	1.00		
5. Self-efficacy	-.184*	-.122	-.292**	-.127	1.00	
6. Diabetic foot ulcer scores	.287**	.306**	.059	.300**	-.415**	1.00

## **CHAPTER V**

### **DISCUSSION**

In this chapter the researcher will present the discussion on research findings according to research questions and hypothesis. Accordingly, 2 major themes; diabetic foot ulcers scores and the relationship between age, duration of DM, HbA1C, comorbidity, self-efficacy and diabetic foot ulcer scores.

#### **5.1 Diabetic foot ulcers scores of the sample**

The finding of this study showed that the majority of sample had problems with foot skin. About 76% (75.7%) of them had dry foot skin with fungus or light callus, 11 % had heavy callus build up and 5.1% had open foot ulcers or recent history of foot ulcers. Similar to their nails, 71.3% had un-kept and ragged nails while 13.2% had thick, damaged, or infected nails.

Although, the occurrence of diabetic foot ulcers in this study is very low comparing with previous studies (Molvær, Graue, Espehaug, Østbye, Midthjell&Iversen, 2014; Assaad-Khalila, Zakib, Rehima, Megallaaa, Gabera, Gamala&Rohomaa, 2015; Mamo, Yifter, & Lemessa, 2015), majority of sample demonstrated risk on developing diabetic foot ulcers. Their skin integrity was somewhat prone to breakdown because of the dryness with fungal infection or light callus. As stated by Alavi, et al, 2014, the presence of callus on the sole led to decreased protective sensation of the feet from any external forces such as very hot or cold subjects or some traumatic forces. Accordingly, patients with type 2 diabetes who had callus were more likely to develop ulcers (Alavi et al., 2014).

Evidences from this present study also showed that they had many risk of having diabetic foot ulcers. In regard to foot wear, 84.6% of the sample wore inappropriate foot wear such as slippers or very tight shoes while 3.6% sustained foot trauma due to wearing inappropriate foot wear. More than 30% of sample had

limitation of foot movement, they could not perform full range of motion to hallux (33.1% had hallux limitus and 1.5% had hallux rigidus). These patients might have difficulties in walking likewise Alavi et al stated, patients with type 2 diabetes who were in their early stage of foot problems often experienced abnormal foot contour or foot deformity which led to walking difficulty (Alavi, et al, 2014). About 30% showed abnormal sensation on 10 points monofilament test. The loss of sensation in the feet was common in diabetic patients (Borges FA & Cardoso HSG, 2010). Sensory alterations affect the pain sensitivity, the perception of pressure, temperature and proprioception. The loss of protective sensation makes diabetic patients exposure to extrinsic factors, such as insensibility to foreign bodies, precipitated by intrinsic factors. This group of patients required appropriate information about foot care.

The problems related to peripheral arterial occlusion in this studied group was not prominent. Dorsalis pedal pulse could not be palpated in only 3.7% of the sample. The very small number of patients who showed peripheral vascular problem might come from the research setting selected for this study. The researcher collected data in an out-patient endocrine unit which was the follow up clinic for patients with type 2 diabetes who were not severity illness. Those with severity illnesses or have more complications usually were admitted in the hospital. According to the scores from foot assessment, nearly 40% of the sample required foot screening every 6 months (33.8%) and every 3 months (3.7%).

The International Diabetic Association and the American Diabetic Association (IDF, 2013) recommend that all individuals with diabetes should receive an annual foot examination to identify high risk ulceration. It suggests that health care workers should notice to provide the recommendations for type 2 diabetes in order to prevent foot ulcer occurrence. In addition, the instrument named 60-second foot ulcer screening should be used in clinical settings to evaluate the foot status of patients in the short time and increase the performance in preventing foot ulcer.

## **5.2 The relationship between age, duration of DM, HbA1C, comorbidity, self-efficacy and diabetic foot ulcer scores of the sample**

### **5.2.1 The relationship between age and diabetic foot ulcers scores of patients with type 2 diabetes**

The current study found that the mean age of the studied sample was 65.3 years (SD  $\pm$  8.6), and 79.4% of them were age 60 and above. The maximum age was 83 years and the minimum age was 37 years. Type 2 diabetes was more likely to be occurred in patients with age over 40 years, especially those having aged 50 years and older. Previous study showed that in developing countries, most of type 2 diabetes patients were from 45 to 64 years old, while in developed countries, the majority of patients was above 64 years old (Monteiro-Soares et al., 2012; Mohammad et al., 2015). The result also revealed that there was a positive correlation between age and diabetic foot ulcers scores ( $r = .287$ ,  $p < .001$ ). It showed that patients with type 2 diabetes whose ages were older had higher scores. The higher of the scores referred to higher risk or prone to diabetic foot ulcers.

This finding was similar to the study of Molv er and the others in Norwegian population between the year 2006 to 2008 which found that patient with type 2 diabetes whose age were  $\geq 75$  years were more likely to develop diabetic foot ulcers. Moreover, these ulcers required more than 3 weeks to heal and created huge burden to patients and their care givers (Molv er, et al, 2014). The explanation of the relationship between age and the diabetic foot ulcers scores is that patients with old age were more likely to depend on their family. The feet and the foot skin will be the parts that were neglected. The other explanation is when people became older, there is deterioration in body function such as visual ability or some psychomotor skills. These eventually affect their performance in self-care as well as foot care.

### **5.2.2 The relationship between duration of DM and diabetic foot ulcers scores of patients with type 2 diabetes**

The result in this study showed that the mean of duration of DM was 11.93 years (SD  $\pm$  5.92 years). Majority of sample (67.6%) had type 2 diabetes more than 10 years with the minimum of 1 year and the maximum of 32 years. Duration of diabetes

was a significant factor with diabetic foot ulcers in several studies (Shailesh et al., 2012; Alavi, et al, 2014). One study showed that the odds in favor of having diabetic foot ulcer is increased by 8 times higher in those who were diabetic for more than 10 years as compared to those whose duration of diabetes is less than 9 years (Shailesh et al., 2012). Patients who suffered with diabetic for long duration were presumed to be at more risk due to the development of long term diabetic complications such as peripheral vascular disease (PVD), neuropathy, nephropathy and retinopathy which could lead to the occurrence of foot ulcers. There were evidences to support that long duration of diabetes was also significantly associated with diabetic foot ulcers infection, gangrene due to decreased blood flow to the peripheral part and these patients would require lower limb amputation (Mohammad et al., 2015).

This finding showed strong evidence on the risk of diabetic foot ulcers among patients with type 2 diabetes who had the disease more than 10 years. Vascular epithelium changed due to prolonged high blood glucose level is always found in patients type 2 diabetes. Similar to what Shearman & Rawashdeh stated in their review that atherosclerosis was usually found in these patients. In addition, atherosclerotic plaque in the patients' vascular contains more calcium and has increased expression of inflammatory markers leading to more aggressive progression of the disease atherosclerotic plaque in the patients' vascular contains more calcium and has increased expression of inflammatory markers leading to more aggressive progression of the disease (Shearman & Rawashdeh, 2016).

### **5.2.3 The relationship between HbA1C and diabetic foot ulcers scores of patients with type 2 diabetes**

The result showed that nearly half of patients in this study (47.8%) had HbA1C level of greater than 7 with the mean of 7.47 (SD±1.47) but level of HbA1C was not correlated with diabetic foot ulcers scores. The finding of this study was not congruent with those found in previous studies ((Shahbazian, Yazdanpanah, & Latifi, 2013); Gary et al, 2016) in that the level of HbA1C was a predictor of the occurrence of diabetic foot ulcers. The explanation is that patients in this present study had low mean level of HbA1C comparing with those in the previous studies. Gary et al (2016) found that the mean of HbA1C was 8.23% (SD±1.94) moreover in the study of

Shahbazian et al (2013) conducted on 430 patients in Pakistan showed that the mean HbA1C was  $8\pm 1.8\%$ , and there was significant correlation between history of diabetic foot ulcers (OR= 1.49, CI = 1.17- 1.90,  $p<0.001$ ) (Shahbazian et al., 2013).

The other explanation is that in this present study, there was no patients with open diabetic foot ulcers. Some of them demonstrated skin integrity alteration with callus, fungal infection, nail deformity and foot deformity. The scores from diabetic foot ulcers scale obtained from this study therefore represented risk on developing foot ulcers.

#### **5.2.4 The relationship between comorbidity and diabetic foot ulcers scores of patients with type 2 diabetes**

The result in this study showed that 98.5% of the sample had comorbidities. More than half of patients had two comorbidities and 25.7% of sample had 3 comorbidities. The patients had four comorbidities and five comorbidities was 8.8% and 2.9%, respectively. This result indicated that the patients with type 2 diabetes had a number of comorbidity. In 136 patients with type 2 diabetes, 121 patients (89%) had hypertension. In addition, the result revealed that comorbidity has positive correlated with diabetic foot ulcers scores ( $r=0.30$ ,  $p<.01$ ).

This finding was similar in the findings in previous studies. Bruun et al (2013) indicated that peripheral neuropathy, peripheral arterial disease, micro-albuminuria, retinopathy and impaired vision or blindness at diabetes diagnosis were independent predictors of later amputation. (Bruun, Siersma, Guassora, Holstein, & de Fine Olivarius, 2013). Many studies showed that peripheral neuropathy and peripheral arterial disease were significantly associated with both foot ulcers and amputation (Van Battum et al., 2011). Shailesh et al 2012 found that Sensory neuropathy was the prominent risk factor for DFUs as 73 (75.25%) patients reported it. The prevalence of other co-morbidities namely retinopathy, hypertension and nephropathy was also notable, the values being 43 (44.32%), 29 (29.89%) and 14 (14.43%) respectively in different patients. It was nearly the same results in this study, however, in this study we found that the most common comorbidity was hypertension, dyslipidemia disease and peripheral neuropathy. Accordingly, patients with type 2 diabetes who had high

numbers of comorbidity diseases should receive more attention from nurses and other health care providers because they had high risk on developing diabetic foot ulcers.

### **5.2.5 The relationship between self-efficacy and diabetic foot ulcers scores of patients with type 2 diabetes**

The mean score of self-efficacy was 54.49 (SD=8.34) while the mean score of diabetic foot screen was 6.05 (SD=3.14). Self-efficacy is defined as “people's judgment of their capabilities to organize and execute courses of action required to attain designed types of performance and expect the outcomes. It is a pre-requisite of behavior, since is considered as an independent part of basic personal skills. Self-efficacy is an important concept derived from Social Cognitive theory (Bandura, 1977) that refers to people's beliefs and judgments on for executing the duties and responsibilities. Many previous studies supported that patients who had high self-efficacy always had high capability in self-care and were able to manage themselves and deal with their illnesses very well (Hiltunen et al., 2005; Galik et al., 2008).

In this study, the result indicated that self-efficacy had negative correlation with diabetic foot ulcers scores ( $r = -.415$ ,  $p < 0.001$ ) which can be interpreted that patients with type 2 diabetes who had high self-efficacy would showed lower diabetic foot ulcers scores. The finding was similar to what found in previous studies as following. Nazlı Atak et al (2008) reported that increasing self-confidence and self-efficacy can improve people self-care practices, with subsequent positive impacts on their general and feet health status and diabetic control (Nazlı Atak, et al, 2008). Therefore, the implementation of self-efficacy enhancing training programs for those patients is recommended, with the use of the developed illustrated booklet as an educational aid. Other study of McCleary-Jones identified that self-efficacy was associated with foot self-care (McCleary-Jones V, 2011). The study revealed that those with higher self-efficacy also were more likely to perform regular foot self-care behaviors (Driver, Fabbi, Lavery, & Gibbons, 2010) so that they tend to have low risk for DFUs. Gao et al in 2013 (Gao et al., 2013) in China and Walker et al in 2014 in the United States found that the patients with higher self-efficacy had better control of their HbA1c. Moreover, the self-confidence score was positively correlated to the foot care score. This adds to the evidence that increasing diabetic patient's self-confidence

and self-efficacy is of great importance in improving foot complications (Hussen Ali Z, 2016). A study in Taiwan gave evidence of the positive effect of increasing diabetic patients' self-efficacy on their practice of foot care (Chin, Huang, & Hsu, 2013).

### **5.3 Conclusion of the findings**

In conclusion, the findings of this study support self-efficacy theory in that when patients with chronic illness such as T2DM had high level of self-efficacy, they would be able to perform appropriate self-care leading them to achieve positive health outcomes. In this study, it referred to proper foot care to prevent the occurrence of diabetic foot ulcers. Evidences from the study can be summarized that the proper self-care behaviors that should be emphasized included keeping foot skin to be moist, clean and free from infection. If infected nail and skin are detected, the prompt and proper management should be performed. Proper foot wear should also be highlighted. Moreover, the measures to increase self-efficacy should comply with the concepts proposed in Bandura's self-efficacy theory including enactive mastery attainment, vicarious experience, verbal persuasion and physiological feedback. Likewise Bandura's self-efficacy theory, there were others factors related to patients foot care behaviors such as patients' age, comorbidity and duration of T2DM illness.

## CHAPTER VI

### CONCLUSION

#### 6.1 Conclusion of the study

This descriptive correlational study aimed to examine the relationship between age, duration of DM, HbA1C, comorbidity, self – efficacy, and diabetic foot ulcer scores in patients with T2DM who aged 37 – 83 years old at diabetic out- patient examination room, from August to October, 2016. Self- efficacy theory was utilized as a framework of this study. 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. The sample calculation yielded 136 samples. The research setting was out patient department for diabetic patients of Bach Mai Hospital, Hanoi, Vietnam.

After obtained 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 4 instruments; General information of the patients; Information related to illness and treatment method; Self efficacy for diabetes and The 60 Second Diabetic Foot Screen. All instruments were tested for their validity and reliability as clearly explained in chapter 3. Self -efficacy for diabetes was .87; The 60 Second Diabetic Foot Screen Cronbach's alpha: Left foot: .64; Right foot: .63; left and right foot: .82. The 136 patients were selected according to the inclusion criteria. The researcher collected data by herself from 8.00 am to 4.00 pm every day until the sample reached the target of the studied sample size. For each patient, the researcher spent 30 to 45 minutes on interviewing and collected some data from their patients' records. During data collection, there was no adverse event among the patients. All sample recruited in the study remained throughout the study process with no attrition.

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

including age, duration of DM, HbA1C, comorbidity, self – efficacy and diabetic foot ulcers cores. 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 age, duration of DM, HbA1C, comorbidity and diabetic foot ulcer scores in patients with T2DM.

**The findings are summarized as follows:**

Within 136 patients, there were 60.3 % of female 39.7 % of male with the ages ranged from 37 to 83 years. The average age was 65.3 (SD  $\pm$ 8.6 years). Most of them were married (79.4%), finished secondary school (27.2%), retired from their work (80.1%) and living in the city (60.3%). All had health insurance, more than half of them (57.4%) was paid completely by health insurance. The majority of the patients never smoked (68.4%).

The majority of patients had experienced T2DM for more than 10 years with the mean duration of 11.93 years (SD=5.92). Only 5.1% had history of previous ulcer. Overweight and obese patients accounted for 29.4% and 21.3%, respectively. The total 22 comorbidities. Hypertension was the most common comorbidity with 89% (n=121), Dyslipidemia disease came second with 79.4% (n=108) and Peripheral neuropathy came third with 22.1% (n=30). The mean score of self-efficacy was 54.49 (SD=8.34) while the mean score of diabetic foot screen was 6.05 (SD=3.14).

Age was positive correlated with diabetic foot ulcer scores ( $r=0.287$ ). Duration of DM was positive correlated with diabetic foot ulcer scores ( $r=0.306$ ). Comorbidity was positive correlated with diabetic foot ulcer scores ( $r=0.300$ ) while self- efficacy was negative correlated with diabetic foot ulcer scores ( $r=-0.415$ ). Nevertheless, HbA1C had no correlation with diabetic foot ulcer scores ( $p = .105$ ).

The results of this study complied with the concept of self -efficacy theory in that when patients with diabetic foot ulcer perceived in their own self efficacy, they owned the confidence and able to perform desired health behaviors to prevent their risk on developing diabetic foot ulcer. Although the risk might come from various factors, nurses can use scientific knowledge from this research to prevent the risk among these patients by enhancing patients' self-efficacy.

## **6.2 Implications of Research Findings**

### **6.2.1 Implications for nursing practice**

In order to enhance patients with T2DM to prevent DFUs the following measures have to be performed by nurses;

1.Improve patients' self-efficacy by providing them with knowledge to perform foot care and prevention of DFUs. Knowledge and skill about routine foot assessment should be given to patients with T2DM so that they will be confidence to perform preventive behaviors.

2.Improve patients'self-efficacy by encourage them with empowered feedback toward their performance on foot care during their hospital follow up visit. The empowering interaction between nurses and patients will increase patients' self -worth leading to increased self-efficacy.

3.Provide routine foot assessment using 60 second diabetic foot screening tool. Patients whose scores show that they have a risk in developing DFUs, proper management should be immediately conducted.

4.Among patients with older ages, nurses should invite family members to engage in foot assessment and foot care.

5. Patients with T2DM who have co morbid diseases are ones who have more opportunity to develop DFUs. Their co morbid diseases have to be well controlled by multidisciplinary care team.

6.A comprehensive guideline on diabetic foot care should be developed and distributed for nurses and other related health care personnel so that it can be widely used to prevent DFUs among patients with T2DM.

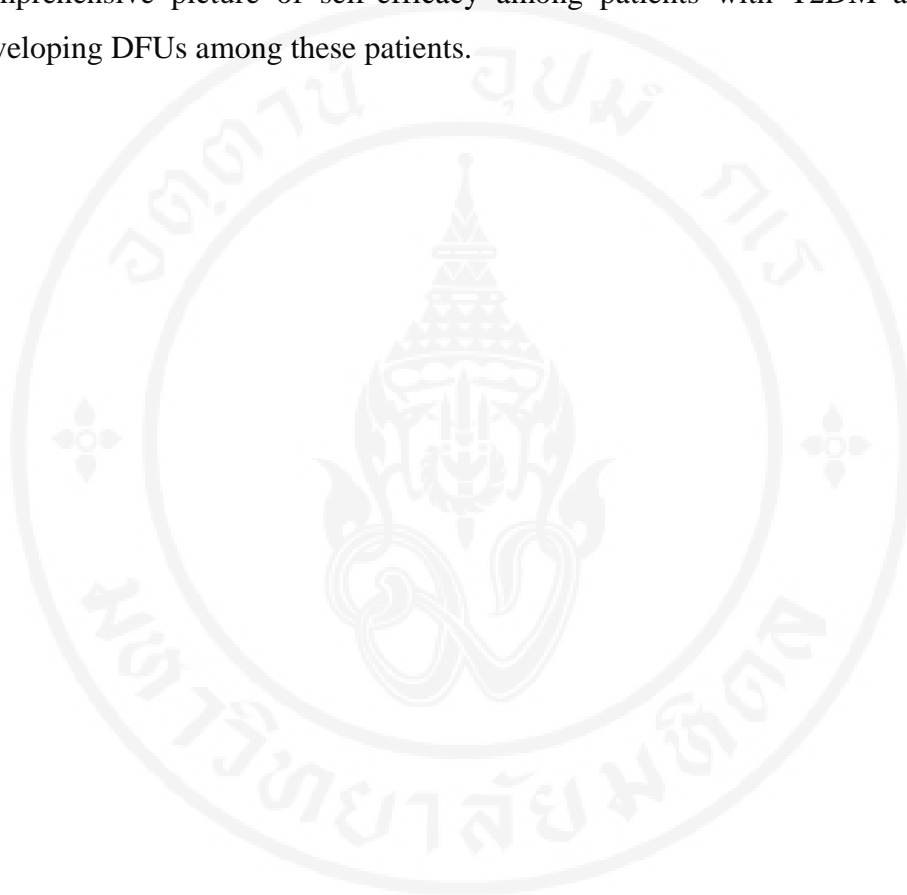
7. A training program on diabetic foot assessment and foot care has to be developed and implemented to equip nurses and other related health care personnel with knowledge and skill to perform comprehensive foot care.

### **6.2.2 Implications for further study**

1.Clinical practice guidelines to preventDFUs among patients with T2DM should be developed and tested for its effectiveness by using quasi experimental research.

2.The 60 second diabetic foot screen in Vietnam version should be used in larger group of patients with T2DM and tested for its psychometric property.

3.Multi sites research should be conducted to illustrate the comprehensive picture of self-efficacy among patients with T2DM and a risk in developing DFUs among these patients.



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**APPENDIX A**  
**LIST OF EXPERTS**

- 1. Dr Vien Van Doan, MD, PhD**  
Dean of Outpatients department- Bach Mai Hospital
- 2. Dr Nguyen Khoa Dieu Van, MD, PhD**  
Dean of endocrine department- Bach Mai Hospital
- 3. Dr Le Ba Ngoc, MD**  
Endocrine department- Bach Mai Hospital
- 4. Dr Ha Luong Yen, MD**  
Endocrine department- Bach Mai Hospital
- 5. Mr Nguyen Tien Hong, RN**  
Head of nursing Endocrine department- Bach Mai Hospital

## APPENDIX B

### CERTIFICATE OF APPROVAL

 <b>CERTIFICATE OF APPROVAL</b> From <b>Institutional Review Board Faculty of Nursing Mahidol University</b>  COA No. IRB-NS2016/337.0205	
<b>Title of Project:</b>	<b>FACTORS RELATED TO THE OCCURRENCE OF DIABETIC FOOT ULCER AMONG PATIENTS WITH TYPE 2 DIABETES</b>
<b>Project Number:</b>	<b>IRB-NS2016/12.0703</b>
<b>Principle Investigator:</b>	<b>Mrs. Tran Thi Bich</b>
<b>Name of Institution:</b>	<b>Faculty of Nursing Mahidol University</b>
<b>Approval includes</b>	1) IRB-NS Submission form version received date 2 May 2016 2) Participant Information sheet version date 2 May 2016 3) Consent form version date 2 May 2016 4) Questionnaire version received date 2 May 2016
<b>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)</b>	
<b>Date of Approval:</b>	<b>02 May 2016</b>
<b>Date of Expiration:</b>	<b>01 May 2017</b>
<b>Signature of Chair:</b>	 (Associate Professor Dr. Fongcum Tiokskulchai)  Chair
<b>Signature of Dean, Faculty of Nursing</b>	 (Associate Professor Dr. Yajai Sitthimongkol)  Dean, Faculty of Nursing
<p>Copyright by Mahidol University</p> <p>Office of Institutional Review Board Faculty of Nursing Mahidol University Room 503 Faculty of Nursing, Mahidol University 999 Phuttamenthon 4 Road, Salaya, Nakhon Pathom 73170, THAILAND Tel: (662)-441-5333 Ext. 2531, 2532</p>	

**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**

## APPENDIX C

### PARTICIPANT INFORMATION SHEET

(English version)

- 2 MAY 2016  
12.C103

IRB-NS Form No. 3.1

#### 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 the occurrence of diabetic foot ulcers among patients with type 2 diabetes

Name of Researcher: Tran Thi Bich

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

National Hospital of Endocrinology, Hanoi, Vietnam. 215 alley- Ngoc Hoi street- Tu Hiep ward- Thanh tri District- Hanoi City

Source of Fund: No research funding

This research project aims to identify the relationship among age, comorbidity, HbA1C, duration of DM, self-efficacy and foot ulcer among patients with type 2 DM, which expects the following benefits:

- 1) Providing basic data about factors related to diabetic foot ulcers
- 2) In the future, developing program by using this data to promote diabetes foot ulcers prevention.

However, in this study you don't get any benefit directly but patients with type 2 diabetes will get benefit in the future.

- 3) You are invited to participate in this research project because you have been diagnosis in type 2 diabetes patients and being age 18 years old or above
- 4) There will be 136 participants, and the research will last for 30- 45 minutes for answer questionnaires

- 5) To participate in this research is completely VOLUNTARY.

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

Participant Information Sheet date 14 June 2016

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS- 0016/18.C103
Date of Approval - 2 MAY 2016

1)The researcher will collect some information of yours from the medical record form.

2)The researcher will organize a private room for interviewing you. The questionnaires for interviewing include 1) General information (10 items), 2) Information related to illness and treatment method (7 items), and 3) Self-efficacy for diabetes (8 items). The interview will last about 30-40 minutes.

3)The researcher will assess your feet using The 60 Second Diabetic Foot Screen (12 items) which will take about 5 minutes.

5) During interviewing or answering questionnaire, if you feel discomfort. You can stop and rest for a while until you feel comfort to continue. If you want to stop participation to this study, you can withdraw from the study at any time.

If you do not participate in this research project, you will receive a standard assessment and treatment.

**If you have any questions about this research please feel free to contact the researcher, Mrs Tran Thi Bich via Telephone: (+84)915251688 or : (+84)965171010**

You do not get any or payment for participating in this research.

If relevant information arises about benefits and risks of the research project, the researcher will inform the participant immediately and without concealment.

Your information will be kept confidential, it will not be subject to an individual disclosure, but will be included in the research report as part of the overall results. Individual information may be examined by a researcher, the ethics committee, etc.

You have the right to withdraw from the project at anytime without prior notice. And the refusal to participate or the withdrawal from the research project will not at all affect the proper service or treatment that you will receive.

This research project is approved by The Institutional Reviews Boards, Faculty of Nursing (IRB-NS) at the office of IRB-NS room 503 5<sup>th</sup> floor, Faculty of Nursing, Mahidol University, 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170

Approved by Institutional Review Board  
2  
Faculty of Nursing Mahidol University  
Project Number IRB-NS 2016/12.0703  
Date of Approval - 2 MAY 2016

IRB-NS Form No. 3.1

Thailand Tel 0066 2 441 5333 ext 2531, 2532 Fax 0066 2 441 5333 ext 2531,  
Email: [nsirbnursing@mahidol.ac.th](mailto:nsirbnursing@mahidol.ac.th), [ns.irbnursing@gmail.com](mailto:ns.irbnursing@gmail.com)

Then submit document and the result to SMP-IRB of VNU

Address of VNU's IRB Office: 144 Xuan Thuy Street, Cau Giay District, Hanoi city, Vietnam. Code: 100000. Phone number of VNU: (+84)437450118, Fax: +84437450146. Phone number of IRB: (+84) 983297654 (Mr. Nguyen Hoang Long). Email: [longvtcc@gmail.com](mailto:longvtcc@gmail.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 contact address presenting above.

I thoroughly read the details in this document.

Signature.....

Participant

(.....)

Date.....

Participant Information Sheet date 14 June 2016

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Faculty of Nursing Mahidol University
Project Number IRB-NS 2016/12-0708
Date of Approval 2 MAY 2016

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## PATICIPANT INFORMATION SHEET (Vietnamese version)

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



### THÔNG TIN GIÀNH CHO ĐỐI TƯỢNG NGHIÊN CỨU

Trong tài liệu này sẽ có một số vấn đề mà ông (bà) có thể không hiểu. Hãy hỏi người nghiên cứu và 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.

**Đề tài nghiên cứu:** Một số yếu tố liên quan đến loét bàn chân của bệnh nhân đái tháo đường tuýp 2.

**Tên người nghiên cứu:** Trần Thị Bích

**Nơi nghiên cứu và số điện thoại liên lạc trong và ngoài giờ hành chính (Đại diện của người nghiên cứu):**

Khoa Y Dược, Đại học Quốc gia Hà Nội, số 144 Xuân Thủy, Cầu Giấy, Hà Nội. Mã: 100000. Số điện thoại: 0438533527

**Nguồn hỗ trợ:** Không có

**Mục đích của nghiên cứu:** Nghiên cứu này nhằm xác định mối liên quan giữa các yếu tố tuổi, HbA1C, bệnh kèm theo, thời gian mắc bệnh đái tháo đường, sự tự tin vào năng lực bản thân của bệnh nhân và loét bàn chân ở bệnh nhân đái tháo đường tuýp 2; với mong muốn đạt được các lợi ích sau:

1) Cung cấp các dữ liệu cơ bản về một số yếu tố liên quan đến loét bàn chân của bệnh nhân đái tháo đường tuýp 2.

2) Sử dụng dữ liệu này để trong tương lai phát triển chương trình cải thiện loét bàn chân ở bệnh nhân đái tháo đường tuýp 2.

Tuy nhiên, trong nghiên cứu này, ông/bà không nhận được các lợi ích trực tiếp mà sẽ mang lại nhiều lợi ích cho những người mắc bệnh tương tự trong tương lai.

3) Ông/bà được mời tham gia chương trình nghiên cứu bởi vì ông/bà đã được chẩn đoán là đái tháo đường tuýp 2 và trên 18 tuổi

4) Sẽ có 136 người tham gia và người nghiên cứu sẽ phỏng vấn khoảng từ 30-45 phút mỗi người để lấy thông tin trả lời các câu hỏi trong bản nghiên cứu.

5) Việc tham gia của ông (bà) vào nghiên cứu này là hoàn toàn TỰ NGUYỆN. Nếu ông/bà quyết định tham gia đề tài 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 một số thông tin của ông/bà từ hồ sơ bệnh án

3) Người nghiên cứu sẽ sắp xếp một phòng riêng để phỏng vấn ông (bà). Sau đó, người nghiên cứu sẽ thu thập số liệu theo bộ câu hỏi gồm 4 phần: 1) thông tin chung với (10 câu hỏi); 2) Thông tin liên quan đến bệnh và phương pháp điều trị với (9 câu hỏi); 3) Thang đánh giá sự tự tin vào năng lực bản thân của bệnh nhân đái tháo đường (8 câu hỏi). Thời gian phỏng vấn cho thu thập số liệu là khoảng 30 – 40 phút.



## APPENDIX D

### INFORMED CONSENT FORM

(English version)

2 MAY 2016  
12.0703

IRB-NS Form No. 4

#### Informed Consent Form

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

My name is....., aged.....years old,

Now living at the address no.....road/street.....

Sub-district/tambon .....District/amphur.....

Province.....Postal code.....Tel.No.....

I give my consent to participate as a subject in the research project entitled Factors related to the occurrence of diabetic foot ulcers among patients with type 2 diabetes.

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. Tran Thi Bich via (+84)915251688 or email: [Tranbich1405@gmail.com](mailto:Tranbich1405@gmail.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 5<sup>th</sup> floor, Faculty of Nursing, Mahidol University, 999 Phuttamonthon 4 Road, Sakaya, Nakhon Pathom 73170 Thailand Tel 0066 2 441 5333 ext 2531, 2532 Fax 0066 2 441 5333 ext 2531, Email: [nsirbnursing@mahidol.ac.th](mailto:nsirbnursing@mahidol.ac.th), [ns.irbnursing@gmail.com](mailto: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

Date 14 June 2016

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IRB-NS Form No. 4

to receive in the future, I consent to the researcher's use of my private information obtained in this research, but do not consent to an individual disclosure of private information. The information must be presented as part of the research results as a whole.

I thoroughly understand the statement in the information sheet for the research subjects and in this consent form. I thereby give my signature.

Signature.....Participants/Proxy/  
(.....) Date.....

Signature.....Person in Charge of Informing and  
Requesting a Consent/Head of (Mrs Tran Thi Bich) Research  
Project/Date.....

In case that the participant is not literate, the reader of all the statements for the participant is (Mr./Mrs./Ms.....), who gives his/her signature as a witness.

Signature.....Witness  
(.....) Date.....

Date 14 June 2016

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Faculty of Nursing Mahidol University
Project Number IRB-NS 2016/12.0103
Date of Approval - 2 MAY 2016

**INFORMED CONSENT FORM (Vietnamese version)***Bản chấp thuận tham gia nghiên cứu**Phiên bản 02 /ngày 08 tháng 08 năm 2016***BẢN CHẤP THUẬN THAM GIA NGHIÊN CỨU**

Ngày...../...../.....

Tên tôi là..... Tuổi: .....

Địa chỉ hiện tại: Số..... Đường/phố.....

Phường/ Xã..... Quận/huyện..... Tỉnh.....

Mã ID: .....

Mã vùng ..... Số điện thoại .....

Trước tiên, tôi xin bày tỏ sự đồng ý tham gia vào đề tài nghiên cứu có tên là **một số yếu tố liên quan đến loét bàn chân của bệnh nhân đái tháo đường typ 2**. 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, những 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 và 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

Nếu có bất cứ câu hỏi nào về nghiên cứu hoặc có vấn đề mới phát sinh trong quá trình nghiên cứu, tôi có thể liên hệ với bà Trần Thị Bích qua số điện thoại 0915.251.688 hoặc email: tranbich1405@gmail.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 lẻ 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; 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 tuyên bố đã nêu trong bản thông tin dành cho đối tượng nghiên cứu và trong phiếu chấp thuận tham gia nghiên cứu này.

Sau đây là chữ ký của tôi.

Ngày..... tháng..... năm.....

CHỦ NHIỆM ĐỀ TÀI NGHIÊN CỨU

NGƯỜI THAM GIA NGHIÊN CỨU

## APPENDIX E INSTRUMENTS

- 2 MAY 2016

12-0703

1

### (English version)

#### INSTRUMENTS

##### Part I General information of the patients

The following questions related to your personal information. Please tick (✓) or fill in blanks in the following questions:

Number:

ID:

1. Gender

Male

Female

2. Age ..... Year

3. Weight(Kg)..... Height(m)..... BMI(kg/m<sup>2</sup>):.....

4. Marital status:

Married

Single

Separated

Divorced

Widowed

5. Education level

Elementary school

Secondary school

High school

two years certificate

Bachelor

Post graduated

6. Occupation

Farmer

House wife

Retired

Staff government

Other Specify.....

7. Location of residence

City

Rural

Mountain

8. Income personal/ family .....

9. Payment method

Government

Insurance

Self-pay

Organization

10. How many people are living with you? .....(in number)

14 June 2016

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**Part II Information related to illness and treatment method**

- 11. Diagnosis .....
- 12. Length of stay in the hospital .....
- 13. Duration of DM.....
- 14. Have you ever diabetes foot ulcer?
- 15. Co-morbidities
  - Hypertension  COPD
  - Heart disease  Peripheral artery disease
  - Renal disease  Other: .....
- 16. Smoking  Yes  No  used to smoke but stopped smoking
- 17. Laboratory: HbA1C..... Cholesterol..... Lipid .....  
Other.....
- 18. ABI: Right.....Left.....
- 19. Vital sign Blood pressure:..... Temperature.....  
Pulse.....Breathing.....

**Part III Self efficacy for diabetes**

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time. The score for each item is the number. Number 1 refers to very low confident while number 10 refers to very high confident. Higher number indicates higher confident in performing that activity.

	1	2	3	4	5	6	7	8	9	10
1. How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?										

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2. How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?										
3. How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)?										
4. How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?										
5. How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?										
6. How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?										
7. How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?										
8. How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?										

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**Part IV The 60 Second Diabetic Foot Screen**

Look-20 seconds	score	
	Left foot	Right foot
<b>1. Skin</b> 0 = intact and healthy 1 = dry with fungus or light callus 2 = heavy callus build up 3 = open ulceration or history of previous ulcer		
<b>2. Nails</b> 0 = well-kept 1 = unkempt and ragged 2 = thick, damaged, or infected		
<b>3. Deformity</b> 0 = no deformity 2 = mild deformity 4 = major deformity		
<b>4. Footwear</b> 0 = appropriate 1 = inappropriate 2 = causing trauma		
<b>Touch – 10 seconds</b>	<b>Left foot</b>	<b>Right foot</b>
<b>5. Temperature – Cold</b> 0 = foot warm 1 = foot is cold		
<b>6. Temperature – Hot</b> 0 = foot is warm 1 = foot is hot		
<b>7. Range of Motion</b> 0 = full range to hallux 1 = hallux limitus 2 = hallux rigidus 3 = hallux amputation		

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Assess – 30 seconds	Left foot	Right foot
<b>8. Sensation – Monofilament Testing</b> 0 = 10 sites detected 2 = 7 to 9 sites detected 4 = 0 to 6 sites detected		
<b>9. Sensation – Ask 4 Questions :</b> i. Are your feet ever numb? ii. Do they ever tingle? iii. Do they ever burn? iv. Do they ever feel like insects are crawling on them? 0 = no to all questions 2 = yes to any of the questions		
<b>10. Pedal Pulses</b> 0 = present 1 = absent		
<b>11. Dependent Rubor</b> 0 = no 1 = yes		
<b>12. Erythema</b> 0 = no 1 = yes		
<b>Score totals =</b>		

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## INSTRUMENTS (Vietnamese version)

ID:

### BỘ CÂU HỎI NGHIÊN CỨU

TÊN ĐỀ TÀI: MỘT SỐ YẾU TỐ ẢNH HƯỞNG ĐẾN LOÉT BÀN CHÂN CỦA  
BỆNH NHÂN ĐÁI THÁO ĐƯỜNG TUYP 2

Xin vui lòng cho biết ý kiến của các anh/ chị bằng cách trả lời các câu hỏi sau:

#### Phần 1: Thông tin chung của người bệnh

Những câu hỏi sau có liên quan đến thông tin cá nhân của bạn. Hãy tích (✓) vào các ô trống theo các câu hỏi sau:

Số bệnh án:.....

#### 1. Giới tính:

Nam  Nữ

2. Tuổi: ..... Năm sinh:.....

3. Cân nặng: ..... (Kg) Chiều cao: ..... (m) BMI (kg/m<sup>2</sup>):.....

#### 4. Tình trạng hôn nhân

Đã lập gia đình  Độc thân  
 Ly hôn  Góa ( chồng hoặc vợ)  
 Ly thân

#### 5. Trình độ học vấn

Cấp 1  Trung cấp, cao đẳng  
 Cấp 2  Cử nhân Đại học  
 Cấp 3  Sau đại học  
 khác(ghi cụ thể): .....

#### 6. Nghề nghiệp

công chức nhà nước  Nông dân  Công nhân  
 Buôn bán  Nội trợ  Nghỉ hưu  
 Công việc khác (ghi cụ thể).....

7. Nơi ở: Thành thị  Nông thôn  Miền núi

#### 8. Thu nhập

- Gia đình lãi bao nhiêu tiền trong một tháng:.....USD

- Thu nhập của bản thân trên một tháng: .....USD

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9. Phương pháp thanh toán

- Chính phủ chi trả                       Bảo hiểm chi trả  
 Tự chi trả                                       Tổ chức chi trả  
 Khác

10. Có bao nhiêu người sống cùng với bạn? .....

**Phần 2: Những thông tin liên quan đến bệnh và điều trị.**

11. Chẩn đoán: .....

12. Số ngày nằm viện:.....

13. Thời gian mắc bệnh ĐTD:.....

14. Thời gian mắc bệnh loét bàn chân do ĐTD:.....

15. Bệnh kèm theo

- Tăng huyết áp                                       COPD  
 Bệnh tim mạch                                       Bệnh động mạch ngoại biên  
 Bệnh thận  
 Bệnh khác: .....

16. Hút thuốc

- Có hút thuốc                                       Không hút thuốc  
 Đã từng hút thuốc nhưng đã dừng

17. Xét nghiệm: HbA1C: .....; Cholesterol:.....; Lipid:.....;

*Khác:* .....

18. ABI: Phải:.....Trái:.....

19. Dấu hiệu sống: Huyết áp: .....; Nhiệt độ cơ thể:.....;

Mạch:.....Nhịp thở:.....

**Phần 3: Thang đo sự tự tin vào năng lực bản thân của bệnh nhân đái tháo đường**

Chúng tôi muốn biết Ông/bà tự tin như thế nào trong một số các hoạt động. Chọn con số phù hợp thể hiện mức độ tự tin của Ông/bà với mỗi câu hỏi bên dưới, thể hiện Ông/bà có thể thực hiện các nhiệm vụ đó hàng ngày ở thời điểm hiện

tại. Số 1 có nghĩa là sự tự tin rất thấp còn số 10 là sự tự tin cao. Số càng cao thì càng tự tin trong việc thực hiện các hoạt động.

Nội dung	1	2	3	4	5	6	7	8	9	10
1.Mức độ tự tin của ông/bà đối với việc duy trì hàng ngày khoảng cách giữa các bữa ăn là 4 đến 5 tiếng, bao gồm cả bữa ăn sáng?										
2.Mức độ tự tin của ông/bà đối với việc tuân thủ chế độ ăn của người bị bệnh tiểu đường ngay cả khi ông bà phải ăn chung với những người khác										
3.Mức độ tự tin của ông/bà đối với việc có thể lựa chọn các loại thức ăn phù hợp với bệnh tật của mình khi ông/bà đói										
4.Mức độ tự tin của ông/bà đối với việc tập thể dục 15 đến 30 phút mỗi lần, 4 đến 5 lần mỗi tuần										
5.Mức độ tự tin của ông/bà đối với việc có thể phòng ngừa hạ đường huyết khi ông/bà tập thể dục.										
6.Mức độ tự tin của ông/bà về khả năng tự đối phó với tình trạng tăng hoặc hạ đường huyết?										
7.Mức độ tự tin của ông/bà đối với việc xác định lúc nào cần đến khám bác sỹ khi tình trạng bệnh của bản thân thay đổi.										
8.Mức độ tự tin của ông/bà trong việc có thể kiểm soát bệnh tiểu đường để nó không ảnh hưởng tới các hoạt động ông/bà muốn tham gia.										

**Phần 4: 60-giây khám sàng lọc bàn chân bệnh nhân tiểu đường**

Nhìn-20 giây	Thang điểm		Khuyến nghị chăm sóc
	Chân trái	Chân Phải	
<b>1. Da</b> 0 = Nguyên vẹn và khỏe mạnh 1 = Khô, nứt, chai sọc 2 = Chai sọc dày lên 3 = Có vết loét mới hoặc có tiền sử loét cũ			
<b>2. Móng</b> 0 = Giữ tốt 1 = Không giữ tốt và không đều 2 = Dày, bị hư hỏng hoặc bị viêm nhiễm			
<b>3. Biến dạng</b> 0 = Không biến dạng 2 = Biến dạng nhẹ 4 = Biến dạng nặng			
<b>4. Dây dóp</b> 0 = Phù hợp 1 = Không phù hợp 2 = Nguyên nhân gây chấn thương			
<b>Chạm – 10 giây</b>			
<b>5. Nhiệt độ – lạnh</b> 0 = Chân ấm 1 = Chân lạnh			
<b>6. Nhiệt độ – ấm</b> 0 = Chân ấm 1 = Chân nóng			
<b>7. Phạm vi của chuyển động</b> 0 = Chuyển động khoảng đủ 1 = Hạn chế 2 = kém 3 = Cắt cụt chi			
<b>Đánh giá – 30 giây</b>			
<b>8. Cảm giác – Monofilament Testing</b> 0 = 10 Vị trí phát hiện 2 = 7 đến 9 vị trí phát hiện 4 = 0 đến 6 vị trí phát hiện			
<b>9. Cảm giác – Hỏi 4 câu hỏi:</b> i. Bạn có từng cảm thấy tê bì không? ii. Bạn có thấy ngứa không? iii. Bạn có từng cảm thấy nóng ran? iv. Bạn có cảm thấy như có côn trùng bò không?			

## APPENDIX F

### PERMISSION FOR USING INSTRUMENTS

from: Zimet, Gregory D <gzimet@iu.edu>  
to: Xuyen Tran <ngocxuyen80@gmail.com>  
date: Fri, Dec 18, 2015 at 11:04 PM  
subject: RE: Ask your permission about using the MSPSS  
Dear Ngoc Xuyen,

You have my permission to use the MSPSS in your research on patients with arthritis. I have attached a copy of the original English language version of the scale (with scoring information on the 2<sup>nd</sup> page) and a document listing several of the articles that have reported on the reliability and validity of the MSPSS.

I hope your research goes well.

Best regards,

Greg Zime

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Gregory D. Zimet, PhD, FSAHM

Professor of Pediatrics & Clinical Psychology

Section of Adolescent Medicine

Indiana University School of Medicine

President-Elect, Society for Adolescent Health & Medicine (SAHM)

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Approved by Institution's Review Board  
Faculty of Nursing, Mahidol University  
Project Number IRB-NS 2016/23 07.03  
Date of Approval - 2 MAY 2016

Fax: +1-317-274-0133

e-mail: [gzimet@iu.edu](mailto:gzimet@iu.edu)

<http://pediatrics.iu.edu/center-hpv-research/about-us/>

<http://pediatrics.iu.edu/sections-and-faculty/adolescent-medicine/our-team/faculty/bio-zimet/>

from: Xuyen Tran <[ngocxuyen80@gmail.com](mailto:ngocxuyen80@gmail.com)>  
to: [gzimet@iu.edu](mailto:gzimet@iu.edu)  
date: Fri, Dec 18, 2015 at 3:31 PM  
subject: Ask your permission about using the MSPSS  
mailed-by: gmail.com

Dear Dr Zimet,

My name is Ngoc Xuyen. I'm working at Rheumatology department in Bach Mai Hospital, Hanoi, Vietnam. I am participating second year Master nursing at Mahidol, Thailan. I'm going to do a study about "factors related to the functional status among patient with rheumatoid arthritis". Social support is one of factors that I want to focus among patient with RA. I just read about your MSPSS scale that measure social support very effectively and I am really exciting its content. So, I want to ask your permission about using this instrument. Please, help me! I promise that I only use it for reference, not for any commercial purposes.

Extremely grateful for your support! Wish you have a happy time!

Best regards,  
Ngoc Xuyen

Approved by Institutional Review Board  
Faculty of Nursing Mahidol University  
Project Number IRB-NS 2016/23.0703  
Date of Approval - 2 MAY 2016

## APPENDIX G

### ADDITIONAL STATISTICAL ANALYSIS

#### Tests of Normality

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Age	.078	136	.041	.968	136	.003
Duration of DM	.180	136	.000	.942	136	.000
HbA1C	.165	136	.000	.871	136	.000
Sumcomorbidity	.306	136	.000	.844	136	.000
SumSE	.052	136	.200*	.991	136	.557
SumDFS	.175	136	.000	.909	136	.000

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

a. Lilliefors Significance Correction

## **BIOGRAPHY**

**NAME** Tran Thi Bich

**DATE OF BIRTH** 14 May 1984

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Bachelor of Nursing Science  
Mahidol University, 2015-2016  
Master of Nursing Science

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