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論文題目

2002 年全民健保險糖尿病患者  
之中醫醫療利用

The utilization patterns of Traditional Chinese medicine among  
patients with Diabetes in Taiwan in 2002

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## 2002 年全民健保糖尿病患者之中醫醫療利用

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在亞洲許多國家已經普遍使用中草藥來治療糖尿病。在台灣，利用替代醫學來治療糖尿病也是相當普遍而且正逐漸增加當中；因此，我們著手進行一個針對台灣地區糖尿病患者使用中醫情形的研究。

一直以來，甚少針對糖尿病患者中醫醫療利用進行大規模的研究，大多不分疾病類別或只有進行小規模的探討。本研究利用台灣全民健保之糖尿病資料庫來分析其中醫門診利用率及其用藥情形。

本研究運用次級資料分析，採用國家衛生研究院提供2002年完整之全民健保資料庫，並限定國際病名碼為250，共774,367名之糖尿病患者為研究對象。首先，分析糖尿病中醫門診利用率的影響因素時，採用二部模型(two-part model)的迴歸分析；接著再針對使用中醫之糖尿病門診處方用藥進行描述性分析，其中包括藥物配伍、使用劑量、天數等。

二部模型複迴歸分析顯示男性、50歲到59歲、投保金額較高，具有腎臟病、慢性皮膚潰瘍、視網膜等併發症及肝膽疾病，居住在中南部高度都市化之市鎮及中醫師資源豐富之地區者，其中醫門診利用率顯著較高。最常使用的複方為六味地黃丸，單味藥為天花粉。

研究結果顯示個人特質、疾病狀態及地區中醫資源均影響糖尿病中醫門診利用率，用藥則以六味地黃丸類方為主。

關鍵詞：中醫、醫療利用、糖尿病、全民健保、台灣

## Chapter 1 Introduction

### 1.1 Background

Diabetes is a predominant public health concern, presently in Taiwan the prevalence in people over 20 years old are 8.0% for hyperglycemia [1]. The disease causes substantial morbidity and mortality. It remains an important risk factor for cardiovascular disease and the leading cause of end-stage renal disease and amputation of the lower extremity in the general population. Diabetes is the 5th leading cause of death in Taiwan in 2008 [2]. Furthermore, diabetes imposes significant financial burden on individuals with the disease. The annual medical costs associated with diabetes is 27.8 billion N.T. dollars in 2003, including direct and indirect medical costs and lost productivity [3].

Traditional Chinese medicine (TCM) is an important category of complementary and alternative medicine (CAM) in Western countries and is one of the types of medical service in Taiwan. In Chinese societies and East Asia, TCM still plays an active role in modern health system [4-7].

In Taiwan, the National Health Insurance (NHI) program was started in 1995 and covers nearly all inhabitants (21,653,555 beneficiaries at the end of 2001) [8, 9]. The use of TCM has been reimbursed by the NHI since 1996. The National Health Insurance Research Database (NHIRD) provided all registration datasets and claim datasets for research.

Alternative medicines or complementary medicines, including herbal drugs, are used by an increasing number of patients worldwide [10]. In the United States, the national surveys demonstrated that alternative medicine has a substantial presence in the U.S. health care system [11, 12]. In addition, national surveys performed outside the United States suggested that

alternative medicine is popular throughout the industrialized world and its use is widespread [10, 13, 14]. The high prevalence rate of alternative medicines or unconventional treatments throughout Europe was also noted [15]. In particular, herbal medicines are gaining in popularity and the herbal market is experiencing unprecedented growth. Chinese medicine (CM), one of the popular alternative medicines, has been practiced in China for more than 2000 years. During the last few decades, traditional Chinese herbal medicines have attracted a great deal of attention and have become increasingly popular. Except for the Western medicines, more and more medical institutions provide CM care service in Taiwan.

Drug utilization studies are important for the optimization of drug therapy and have received a great attention in recent years. Drug utilization has been defined by the WHO as the marketing, distribution, prescription, and use of drugs in a society with a special emphasis on the resulting medical, social, and economic consequences [16]. The studies of drug utilization serve as a tool of investigation for clinical pharmacology and a source of suggestive information for epidemiology. The study of drug utilization or prescribing patterns is a component of medical audit, which seeks monitoring, evaluation, and necessary modifications in the prescribing practices to achieve rational and cost effective pharmacotherapy. Most of the information on drug use patterns has been derived from studies in modern Western medicines; however, the study regarding the utilization pattern of traditional Chinese herbal medicines was not available.

Although previous studies exploring utilization of TCM had been conducted, these findings were without considering disease type [7] or based on small samples [17] [18]. The purpose of this study is to gain a more complete picture of TCM utilization in 2002 using entire DM population in Taiwan.

## 1.2 The aim of this study

The first aim of the present study was to analyze the utilization rate and factors associated with TCM utilization using entire DM population in Taiwan. The second aim was to conduct a large-scale pharmacoepidemiological study and evaluate the frequency and pattern of CHM prescriptions in treating DM. The third aim was to determine the characteristics of TCM physicians prescribing the most common formulae.





## Chapter 2 Literature Review

### 2.1 Definition of Diabetes mellitus

According to World Health Organization, diabetes is a chronic disease that occurs when the pancreas does not produce enough insulin, or alternatively, when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood sugar. Hyperglycemia, or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels.

There are three types of diabetes and they are described as follows:

a. Type 1 diabetes (insulin-dependent or childhood-onset) is characterized by a lack of insulin production. Symptoms include excessive excretion of urine (polyuria), thirst (polydipsia), constant hunger, weight loss, vision changes and fatigue.

b. Type 2 diabetes (formerly called non-insulin-dependent or adult-onset) results from the body's ineffective use of insulin. Type 2 diabetes comprises 90% of people with diabetes around the world, and is largely the result of excess body weight and physical inactivity. Symptoms may be similar to those of type 1 diabetes, but are often less marked.

c. Gestational diabetes is hyperglycemia which is first recognized during pregnancy. Symptoms of gestational diabetes are similar to type 2 diabetes. Gestational diabetes is most often diagnosed through prenatal screening, rather than reported symptoms.

Over time, diabetes can damage the heart, blood vessels, eyes, kidneys, and nerves. Diabetic retinopathy is an important cause of blindness, and occurs as a result of long-term accumulated damage to the small blood vessels in the retina. After 15 years of diabetes, approximately 2% of people

become blind, and about 10% develop severe visual impairment. Diabetic neuropathy is damage to the nerves as a result of diabetes, and affects up to 50% of people with diabetes. Although many different problems can occur as a result of diabetic neuropathy, common symptoms are tingling, pain, numbness, or weakness in the feet and hands. Combined with reduced blood flow, neuropathy in the feet increases the chance of foot ulcers and eventual limb amputation. Diabetes is among the leading causes of kidney failure. 10-20% of people with diabetes die of kidney failure. Diabetes increases the risk of heart disease and stroke. 50% of people with diabetes die of cardiovascular disease (primarily heart disease and stroke). The overall risk of dying among people with diabetes is at least double the risk of their peers without diabetes.

According to its clinical manifestations, diabetes is categorized in TCM as “xiao ke” or “xiao dan”, both of which mean diabetes. It is attributed to yin-deficiency diathesis, improper diet, emotional disorders, overstrain and excessive sexual activities. The main pathogenesis lies in consumption of yin fluid leading to endogenous dryness-heat in the body, with yin deficiency as the principal aspect and dryness-heat as the secondary aspect, and often with the presence of blood stasis and phlegm retention. If prolonged yin deficiency impairs yang, this will result in deficiency of both yin and yang as well as deficiency of both qi and yin.

## 2.2 The prevalence of Traditional Medicine utilization

Global expenditure on traditional medicine is not only significant; it is also increasing rapidly [19]. As a result, its potential public health benefits and costs present increasing controversy. In East Asia there are clear practical reasons concerning cost, access and availability of health resources which explain high utilization rates of TCM. Cultural values also dominate predictors of its use [20]. In Europe and the USA however where modern

allopathic medicine is well established and making further and further advancement, more and more health providers are being confronted with consumer pressure to include more alternatives to modern allopathic medicine as a choice in health service provision [11, 21, 22].

A study of consumer trends in the USA shows 42% used complementary and Traditional forms of medicine at a cost of \$21 billion on average each year. Out of the 425 million visits to practitioners half of this expense was out of pocket. This rate of utilization had increased by 62% over from 1990 - 1997 [12]. In 2004 48% of Australians spent AD\$ 2.3 billion on visits to providers [23]. 70% of Canadians spend US\$ 80 million and in the UK a 40% usage rate results in over US\$ 2300 million expenditure annually [20]. Further, the international market for Traditional pharmacy and complementary products is estimated to have been expanding at more than 15% per year since 1996 at retail level [23].

TCM treatments and products have in the past proven itself to be both effective and affordable. According to a 1993 report of the World Bank, through the concomitant use of TCM and modern Western medicine, China had been able to adequately care for 22% of the world's population with only 1% of the world's health care budget [24]. Emerging evidence of long term cost savings from private insurance companies in USA have also found, fewer hospital admissions for CVD, cancer and mental disorders correlates to premium holders utilizing Traditional or Complementary Medicine [25]. A systematic review of Traditional Medicine by Ernst in 2000 and WHO in 2002 confirms TCM therapies are being used more frequently and increasingly worldwide. Defined populations of patients with rheumatic diseases, cancers, HIV/AIDS and some pediatric patients who seek these treatment options are becoming more quantified as in the studies of acupuncture and Chinese pharmacy above. Of the population at large however more than 50% are not ill but evidently employ such therapies to alleviate chronic conditions and to promote wellbeing [26]. The behavior of

this majority is complex and their reported reasons for visiting practitioners diverse. In conclusion of this review Ernst (2000) and WHO (2002) concur common factors associated with personal health status, attitudes toward health, gender and socio-economic background are related to patterns of higher propensity of utilization [20, 26]. Continued investigation of TCM utilization from the perspective of its users is currently needed because so many doors are being opened by globalization and increased public access to health information, coupled with changing values toward health and health practices. More detailed evidence of influences that make these forms of health care so popular is required as they are becoming an established aspect of public health and health service provision.

### 2.3 Patterns of TCM Utilization in Taiwan

In 1996 Chi et al. conducted a nation wide study of the practice of TCM in Taiwan using National Health Insurance records from the Health Department of all hospitals and clinics providing TCM services and 208 face to face structured interviews with randomly selected licensed Chinese Medicine practitioners. According to the ICD-9-CM classification of diseases made in claims to the insurance system respiratory conditions were the most common reasons for treatment (21.1%) followed by musculoskeletal (15.5%), injuries (15.3%) and digestive complaints (11.4%). The majority of Chinese Medicine practitioners (85%) reported practicing in private clinic settings yet more than half (52.8) of all claims made for TCM services to the NHI are by hospital based out-patient clinics [21]. In a clinic based study of TCM users in 1994 Kang et al. found a 34.7% utilization rate of TCM clinics compared to around 65% attending Modern Western clinics. [8]. More recent research by Chen et al (2006) employing the complete datasets of TCM outpatient reimbursement claims from 1996 to 2001, including the use of Chinese herbal remedies, acupuncture and joint

manipulative therapy, analyzed use frequencies, the characteristics of TCM users, and the disease categories that were treated by TCM in Taiwan. The results of this study show in 2001, 6,142,829 (28.4%) among the 21,653,555 valid beneficiaries of the National Health Insurance in Taiwan had used TCM and 62.5% had used TCM at least once during the whole 6-year period from 1996 to 2001, with a mean of 11.5 visits per user. Chinese herbal remedies (85.9%) were the most common TCM modality used by this population, followed by acupuncture (11%) and joint manipulative therapies (3.1%). TCM clinics provided most of the TCM care (82.6%), followed by TCM hospitals (12%). The top 5 major disease categories for TCM visits were diseases of the respiratory system, musculoskeletal system; symptoms, signs and ill-defined conditions; injury and poisoning; and diseases of the digestive system [22]. Chang et al. also used the NHI 200,432 sample files from 1997 to 2003 by the logistic regression method and found over 90% of CM service was provided by clinics, diseases of the respiratory system was the most frequent primary indication in CM, herbal medication was the most commonly used form of CM (68.4-72.7%) [7]. Further community based research by Kang, Chen & Chou (1998) includes 1085 residents living in Taipei over 30 years old. The response rate to the questionnaire was 47% which asked this population to agree or disagree with 31 statements related to TCM in order to explore knowledge and attitudes toward TCM and asked participants if they had any of 22 common conditions, whether they would use TCM services. There were four most agreed with knowledge and attitude measures or statements contained in this study. First, acupuncture is one of the most common TCM therapies by 84.9% of participants. Second, in case of need TCM will use massage by 81.2%. Third, cupping is one form of TCM by 77.2%. Forth, acupuncture is one type of TCM by 56.3% of participants. There are four most agreed with conditions where TCM would be appropriate treatment, and there are muscular problems (59.9%), bone fractures (35.5%), fatigue and weakness (25.8%) and respiratory conditions

(25%). The overall utilization rate in this study was 29.1% for utilization of both Western and TCM medicine and 2.9% reported only using TCM [23].

## 2.4 Access to healthcare

Healthcare access is defined as the possibility of obtaining healthcare when it is needed. In this term, access is differed into geographical, financial, and social accessibility. Adopting Andersen's definition of access, is the actual use of personal health services and everything that facilitates or impedes the use of personal health services. Other classification mentioned by Anderson & Davidson (1999) typed access, which is described by the following:

### 1. Potential access

It is a situation where the characteristic and resources of health system influence the use of health services. This can be refer in term of the probability that structural indicators such as characteristics of the health care delivery system and enabling resources influence people who need care use the health services.

### 2. Realization access

It is a situation where the availability healthcare services are being used completely. It is also may described as the actual use of health services after the health policy is implemented.

### 3. Equitable access

The distribution of health services is determined by social, economic and demographic characteristics and need. This concept is built on how equity in healthcare if defined and assessed.

### 4. Effective access

The use of healthcare services would improve the health status and satisfaction. Practically, effective access assesses the benefit of medical care as measured by the improvement in health outcomes.

## 5. Efficient access

The healthcare services would minimize the expenses and maximize the health status and satisfaction. In the society, efficiency requires the combination of goods and services with the highest attainable total value, given limited resources and technology can be produced. Healthcare access is concerned to the need, provision and utilization of health service. Aday and Anderson (1981) suggested that access describes both personal and group actual potency entry of a given individual or population group into the health care delivery system. This suggestion involves different aspects of the relationship between the service providers and its clients, which determines the patterns of utilization. The concept of access is emphasized on the process of how the input is entered the system. The access term is commonly used in two ways:

1. Having access theoretically could show the potency to utilization of the needed service. In order to get the service access, the access must be provided and the system could be connected with the health care service.
2. Gaining access is related to the actual procedure of admission into the processes of utilization of the healthcare service. Here, if access has been gained means that the service has been .This definition is refers to the use of and from the healthcare service. Access sometimes identified as one dimension of quality of care.

### 2.5 Anderson model of health service use

Realizing that the access measurement would be differ based on the purpose of the use, we are interested on the process related to access measurement in which the access is eligible to be examined, and this study is try to identify the factors which related to the pattern of health service utilization. Thus, it would be more appropriate using Anderson behavior service utilization model as basic theory of this study.

The model was initially developed in the late 1960s to assist the understanding of family use health services, to define and measure equitable access to healthcare, and to assist in developing policies to promote equitable access, which is shown in Figure 2.1.

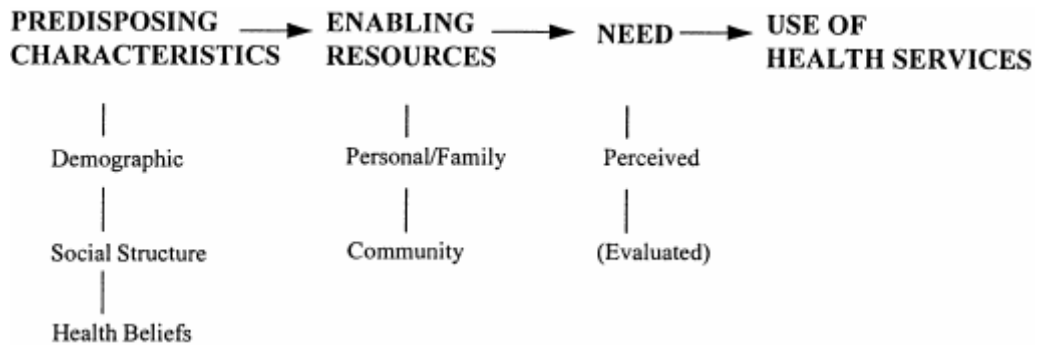


Figure 2.1 1<sup>st</sup> Phase of Anderson model of health service use

There are many predictors come up and impact on the healthcare service utilization. Anderson Model which suggest that the use of the healthcare service is a function of their predisposition to use service, the enabling or impeding use, and their need for care. The behavioral model of the Andersen and its modified version represented one of the holistic attempts to bring together economic, organizational, demographic, geographic, cultural and psychological factors (Andersen, 1995). Regarding to those factors influenced the healthcare service, there still some reason to identify the differences in utilization, consumer satisfaction and its outcomes (Aday, 1993).

Among the predisposing characteristics demographic factors represent biological imperatives suggesting the likelihood that people will need health services. Enabling factors shown that access to healthcare has emphasized the importance having health insurance and regular source of care. And among need factors, shown not only the physical but psychological need



factors are the important predictors of health care utilization (Andersen, 1995 ).

## 2.6 Predisposing Characteristics

Predisposing characteristics are characteristics that make a person inclined i.e. predisposed to health service use which exist in advance of the health service use of interest. Anderson (1995) states measures under the component of predisposing characteristics include demographic characteristics and health attitudes and behavior.

The requirement for the inclusion of these factors is their probable influence of subsequent perceptions of need and use of health services. Age, sex, education, occupation, income, nationality and marital status are well established measures that determine the status of a person in their community and how healthy their personal, work and social environment could be and/or influence utilization of health care. Disease preventative and health maintaining behavior are examples of attitudes and behavior that may be considered as health attitudes and behavior that may influence subsequent perceptions of need and use of health services [27].

### 2.6.1 Demographic characteristics associated with TCM and CAM use

Chen et al. (2006) reported among TCM users, female was higher than male (female: male = 1.13:1), and the age distribution displayed a peak at around the 30s, followed by the 20s and 40s [28]. Chang et al. (2008) also indicated females with age to a peak in the 45-54-year-group are more likely to use CAM [7]. In many countries, those researches of TCM which fall under the broader scope of Complementary and Alternative Medicine (CAM) results suggest age and gender are the most powerful predictors of therapy use followed by education and income. In Canada Kelner & Wellman (1997) found all those who had attended any of 4 therapies including Chinese

pharmacy and acupuncture 75% were female compared to 68% male[29]. In America, Gray (2002) also indicates women (46% v 38% male), those under 45 years old (49% versus 40%), college graduates (46% versus 40%) and those employed (46% versus 35% unemployed) are more likely to use CAM [25]. Australian findings also demonstrate those who have visited CAM practitioners are between 25-44 years of age who were more likely to use CAM (58%) compared to those aged 45-66 (52%) and those aged over 65 years old (37%). Participants on a middle-higher income demonstrated more likely to use than lower income (59% versus 41%). Females were also more associated with practitioner visits than male (58% versus 46%) [30]. In regard to marital status, those who never married had a higher use of CAM for the immune system (23.3% versus 18.2%); and those separated or divorced had a higher use for stress (27.3% versus 13%). MacLennan (2006) found those never married were more frequent users of CAM (55.3%) than those married (53.5%) [13]. Adams (2003) profiled women who consulted CAM practitioners however reported married women had a 17% higher frequency of practitioner visits compared to women who had never married [31].

## 2.7 Theoretical Framework

One of the most frequently used frameworks for analyzing patient utilization of healthcare services is the behavioral model developed by Andersen, Aday, and others. This conceptual framework uses a systems perspective to integrate a range of individual, environmental, and provider-related variables associated with decisions to seek care. Understanding the factors that influence utilization is helpful in identifying reasons for differences in utilization, consumer satisfaction, and outcomes, and for formulating policies and programs that encourage appropriate utilization, discourage inappropriate utilization, and promote cost-effective

care (Aday 1993).

The model of health services use originally focused on the family as the unit of analysis, because the medical care an individual receives is most certainly a function of the demographic social and economic characteristics of the family as a unit. Andersen shifted to the individual as the unit of analysis because of the difficulty of developing measures at the family level that take into account the potential heterogeneity of family members.

Andersen also stressed that the model was initially designed to explain the use of formal personal health services rather than to focus on the important interactions that take place as people receive care or on health outcomes.

The model was initially developed in the late 1960s to assist the understanding of why families use health services, to define and measure equitable access to health care, to assist in developing policies to promote equitable access (Andersen, 1995). The major goal of the behavioral model was to provide measures of access to medical access. The initial behavioral model, described in a 1968 research monograph, included three major categories: (1) predisposing factors (demographic, social structural, and attitudinal-belief variables); (2) enabling factors (family resources and characteristics of the community); and (3) need factors (perceived and evaluated illness) (Andersen 1968). But along the times, this model is already redesigned and revised into 4th phase. The phase 4 of the behavioral model emphasized in the dynamic and recursive nature of the health services use model, which includes health outcomes.

It designed to figure out 4 major components in the behavioral model, such as environmental factors, population characteristics, health behavior and health outcomes. Based on the Andersen behavioral model of the health services use, individual are predisposed to use the services according their demographic and social characteristics. For the enabling factors are bounded that facilitate the use of the services. And the perceived and evaluated needs are the direct stimulus for the use of the health services.

This model portrays the multiple influences on health services use and subsequently on health status. It also includes feedback loops showing that outcome, in turn affects subsequent predisposing factors and perceived need for services as well as health behavior, which is shown in Figure 2.2.

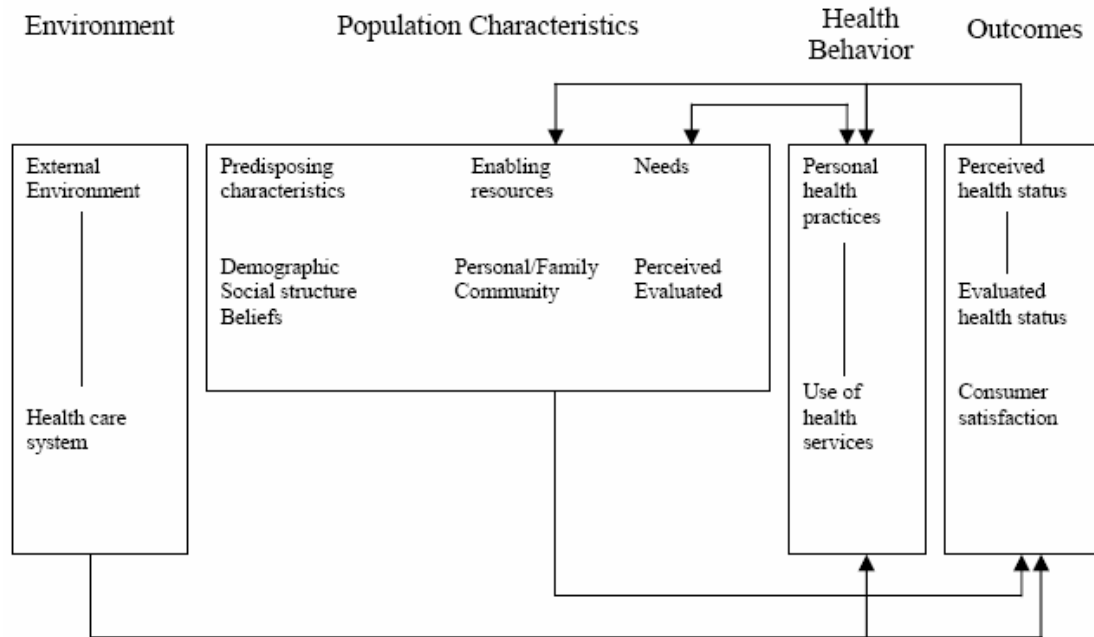


Figure 2.2 4<sup>th</sup> Phase of Anderson model of health service use

## 2.8 Prescription pattern of Traditional Chinese medicine

In 2009 Zhi et al. explored the traditional Chinese medicine (TCM) diagnosis and treatment of type 2 diabetes in Tianjin urban population. A cross-sectional study was conducted on hospital 3,496 patients with type 2 diabetes in TCM hospitals of different levels from 2003 to 2007. In this study, the descending sort proportion of TCM syndrome types of type 2 diabetes was deficiency of both qi and yin, stagnation of phlegm-dampness, exuberant heat due to yin deficiency, deficiency of both yin and yang, and blood stasis and qi stagnation. The most frequently used herbs are Danggui (*Angelica sinensis*), Basishao (*Radix Paeoniae Alba*), Gancào (*Radix*

*Glycyrrhizae*) and Xingren (*Semen Armeniacae*). In the discussion of this paper, they also mentioned that the most frequently used herbs in clinic treatment are Huangqi (*Astragalus mongholicus*), Shanyiao (*Dioscorea opposita*), Dihuang (*Rehmannia glutinosa*), Tianhuafen (*Radix Trichosanthis*), Danshen (*Salvia miltiorrhiza*), Fuling (*Poria*) etc. [18].



## Chapter 3 Materials and Methods

### 3.1 Research Design

The research objectives of this thesis are to (1) Describe the distribution of DM patients and medical expenditures under National Health Insurance in Taiwan, (2) Analyze the utilization rate and factors associated with TCM utilization using entire DM population, (3) Evaluate the frequency and pattern of CHM prescriptions in treating DM.

### 3.2 Data Sources

A cross-sectional retrospective study was conducted using registration and claim datasets of the year 2002 from NHIRD. The datasets contained only the visit files, including dates, time of visit, medical care facilities and specialties, patients' genders, dates of birth, department visited, prescribing physician, dispensing pharmacist and the three major diagnoses coded in the International Classification of Disease, 9<sup>th</sup> Revision, Clinical Modification (ICD-9-CM) format, case type, primary procedure (ex. drug or diagnostic procedure), other procedures. To protect privacy, the data on patient identities, physicians, pharmacists and institutions has been scrambled cryptographically by NHIRD. NHI only covered TCM outpatient services but not inpatient services. Therefore, only TCM ambulatory services were analyzed in this study.

### 3.3 Research Framework

Based on literature review above, we considered the Aday and Andersen behavior service utilization model developed in 1974 as the main research framework, which is shown in Figure 3.1. The dependent variable

in this study is TCM use. The independent variables are patient's predisposing (age, gender), enabling (insured region, insurance premium, urbanization), need factors (complications and comorbidities) and the health care resources factors (physicians of CM, physicians and hospitals per 10,000 population, service providers).

The framework for this research design as follow:

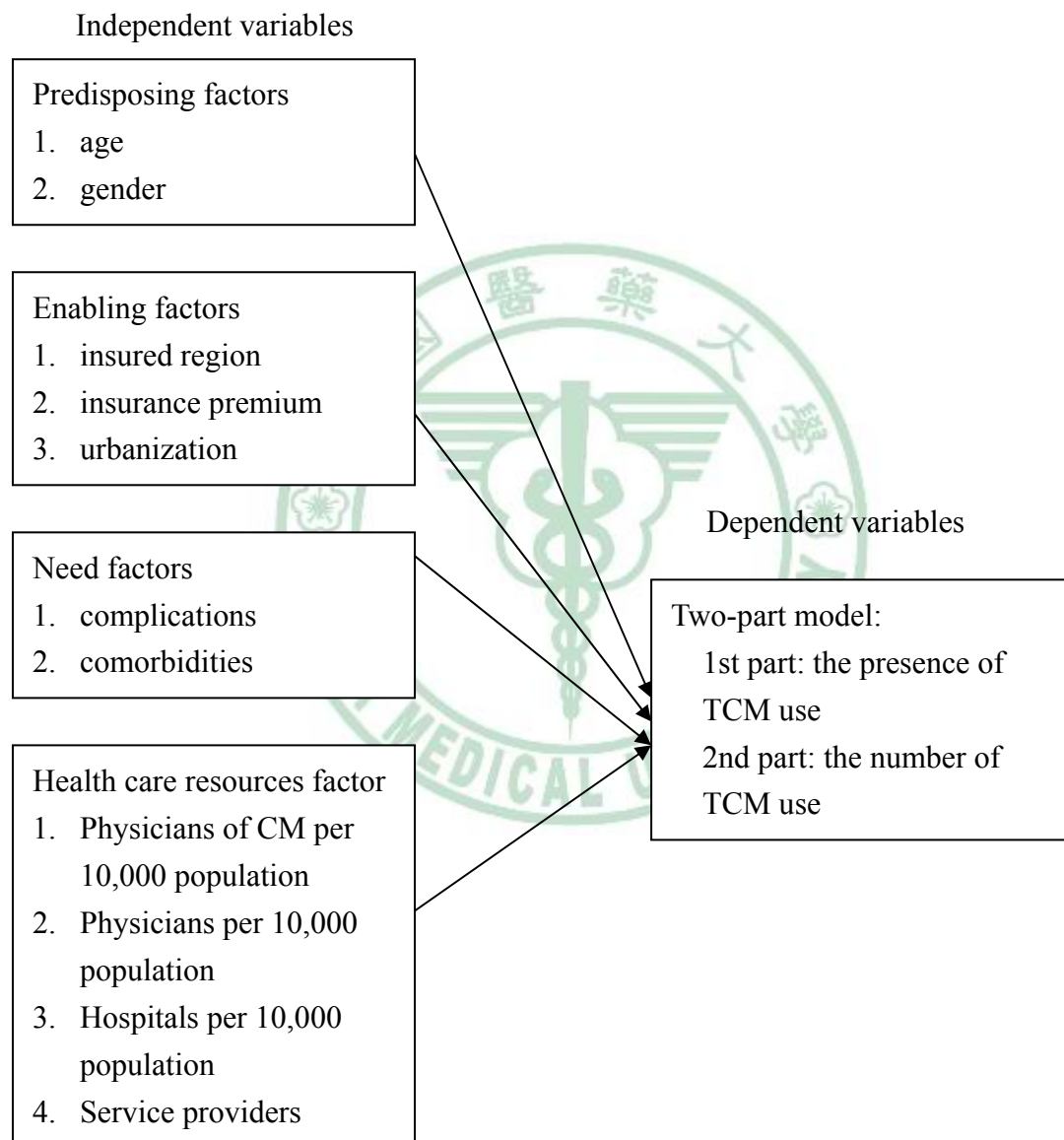


Figure 3.1 Research Framework

### 3.4 Variables Definiton

#### 3.4.1 Predisposing factors

Predisposing factors, including gender and age, were obtained from the BNHI insured's files.

##### a. Gender

Classification of an individual on the basis of anatomic, function, hormonal, and chromosomal characteristic with category as below:

1. Male
2. Female

##### b. Age

The length of time that one has existed, with category:

1. 29 years and younger
2. 30-39 years
3. 40-49 years
4. 50-59 years
5. 60-69 years
6. 70 years and older

#### 3.4.2 Enabling factors

Enabling factors, including insured region, insurance premium, and urbanization, were obtained from the BNHI insured's files.

##### a. Insured region

Geographical regions were:

1. Taipei
2. Northern Taiwan
3. Central Taiwan
4. Southern Taiwan
5. Kaohsiung and Pingtung
6. Eastern Taiwan



b. Insurance premium

Categories of insurance premium were:

1. lower than \$NT15,840
2. \$NT16,500-22,800
3. \$NT24,000-36,300
4. \$NT38,200-57,800
5. \$NT60,800-87,600

e. Urbanization

Urbanicity was divided into I (urban) to VIII (rural) levels.

### 3.4.3 Need factors

Need factors, including complications and comorbidities, were obtained from the BNHI insured's files.

Complications were including stroke, coronary artery disease, nephropathy, skin cellulitis and retinopathy. The diagnostic coding of NHI in Taiwan is according to A-CODE and the International Classification of Disease, 9<sup>th</sup> Revision, clinical Modification (*ICD-9-CM*) diagnostic criteria (Chinese, 2000).

1. Stroke includes *ICD-9-CM* codes 430 through 435, excluding 434, and A-CODE codes A290, A291, A292, and A299, with categories of Yes and No.
2. Coronary artery disease includes *ICD-9-CM* codes 410, 411, 413, 414, excluding 412, and A-CODE codes A270, and A279, with categories of Yes and No.
3. Nephropathy includes *ICD-9-CM* codes 580 through 586, and 590, and A-CODE codes A260, A269, A350, A351, and A585 with categories of Yes and No.
4. Skin cellulitis includes *ICD-9-CM* codes 682, and 686, and A-CODE codes A420 with categories of Yes and No.
5. Retinopathy includes *ICD-9-CM* codes 361, and 362, and A-CODE

codes A239 with categories of Yes and No.

Comorbidities were including hypertension, hyperlipidemia, disease of the respiratory system, liver disease and cancer. The diagnostic coding of NHI in Taiwan is according to A-CODE and the International Classification of Disease, 9<sup>th</sup> Revision, clinical Modification (*ICD-9-CM*) diagnostic criteria (Chinese, 2000).

1. Hypertension includes *ICD-9-CM* codes 401 and 405, and A-CODE codes A269 with categories of Yes and No.
2. Hyperlipidemia includes *ICD-9-CM* codes 272, and A-CODE codes A182 with categories of Yes and No.
3. Disease of the respiratory system includes *ICD-9-CM* codes 491 and 496, and A-CODE codes A323 with categories of Yes and No.
4. Liver disease includes *ICD-9-CM* codes 571 and 574, and A-CODE codes A347 and A348 with categories as below of Yes and No.
5. Cancer includes *ICD-9-CM* codes 14 through 19, and A-CODE codes A08 through A13 with categories of Yes and No.

#### 3.4.4 Health care resources factors

Health care resources included Physicians of CM per 10,000 population, Physicians per 10,000 population, hospitals per 10,000 population, and service providers.

1. Physicians of CM per 10,000 population were classified into one of eight categories: 0, 1, 2, 3, 4, 5, 6, and 7 and more CM physicians.
2. Physicians per 10,000 population were classified into one of seven categories: 9 and less, 10-19, 20-29, 30-39, 40-49, 50-59, and 60 and more physicians.
3. Hospitals per 10,000 population were classified into one of five categories: 0.19 and less, 0.20-0.29, 0.30-0.39, 0.40-0.49, and 0.50 and more hospitals.
4. Service providers were classified into one of four levels: medical

centre, regional hospital, district hospital, and clinic.

### 3.5 Study Sample for type 2 Diabetes

In this study, the subjects were identified from the NHIRD by a principal diagnosis of diabetes (ICD-9-CM codes: 250 and 250.0). In 2002, a total of 774,367, including 378,658 male and 395,709 female, patients with type 2 diabetes and visits were identified from the file of ambulatory care expenditures by visits. These individuals were observed to investigate the retrospective utilization patterns of TCM for type 2 diabetes in 2002.

### 3.6 Urbanization and urban level

Urban level was developed by Liu et al [32], which categorized 365 Taiwan townships into 8 urban levels. The variables used in developing the townships stratification for urbanization level consist of population density (people/km<sup>2</sup>), population ratio of people with college or above educational levels, population ratio of elder people over 65 years old, population ratio of people of agriculture workers and the number of physicians per 100,000 people, etc.

### 3.7 Prescription pattern of Traditional Chinese medicine

All patients with Type2 diabetes under treatment of TCM drugs were included in the studies. The analysis was carried out over a period of 1 year, from January 2002 to December 2002. Core drug use indicators, such as the average number of drugs per prescription, the most common prescribed TCM drugs, the dosing frequency, and duration of TCM prescriptions were evaluated. The diagnosis and the TCM drugs prescribed for were also revealed. We also rank top ten herbal formulae. All data of drug prescriptions were collected prospectively from the NHI database. The data

were analyzed by descriptive statistics.

### 3.8 Statistical analysis

The unit of observation was each individual in the study sample. The frequency of services utilization for TCM were evaluated. The statistical software SAS 9.13 (SAS Institute Inc., Carey, NC) was used for data management and analyses. The distribution and frequency of each category of variables were examined by Chi-square tests. A p-value of less than 0.05 was considered statistically significant. A logistic regression model was used to analyze the data.



## Chapter 4 Results

### 4.1 Prevalence of TCM

#### 4.1.1 Prevalence of TCM according to predisposing factors

Table 4-1 shows the prevalence of Chinese medicine utilization according to subgroups of predisposing factors between Chinese medicine users and non-users. There were a higher prevalence of Chinese medicine utilization in male, individuals aged 40-59.

Table 4-1 Prevalence of Chinese medicine utilization according to subgroups of predisposing factors between Chinese medicine users and non-users

Characteristic	All	CM non-user		CM user		P value
	Total	Total	%	Total	%	
Patient No.	774,367	757,463	97.8	16,904	2.2	
<b>Gender</b>						<0.001
Male	378,658	369,603	97.6	9,055	2.4	
Female	395,709	387,860	98.0	7,849	2.0	
<b>Age(years)</b>						<0.001
≤29	12,247	12,023	98.2	224	1.8	
30-39	30,564	29,920	97.9	644	2.1	
40-49	109,137	106,399	97.5	2,738	2.5	
50-59	187,744	182,875	97.4	4,869	2.6	
60-69	217,639	212,644	97.7	4,995	2.3	
≥70	217,038	213,604	98.4	3,434	1.6	

\*Odds ratio (95% confidence interval)

\*The patients who made more than 2 visits for type 2 diabetes in 2002 were counted as incident cases.

#### 4.1.2 Prevalence of TCM according to enabling factors

Table 4-2 shows the prevalence of Chinese medicine utilization according to subgroups of enabling factors between Chinese medicine users and non-users. There were a higher prevalence of Chinese medicine utilization with insured region in Kaohsiung and Pingtung, insurance premium more than \$NT 24,000, and urban level 2.

Table 4-2 Prevalence of Chinese medicine utilization according to subgroups of enabling factors between Chinese medicine users and non-users

Characteristic	All		CM non-user		CM user		P value
	Total	%	Total	%	Total	%	
Patient No.	774,367		757,463	97.8	16,904	2.2	
<b>Insured region</b>							<0.001
Taipei	315,217		309,028	98.0	6,189	2.0	
Northern Taiwan	95,277		93,859	98.5	1,418	1.5	
Central Taiwan	132,951		129,039	97.1	3,912	2.9	
Southern Taiwan	127,132		123,723	97.3	3,409	2.7	
Kaohsiung and Pingtung	17,882		16,404	91.7	1,478	8.3	
Eastern Taiwan	17,882		17,631	98.6	251	1.4	
<b>Insurance premium (\$NT/month)</b>							<0.001
≤ 15840	170,193		166,657	97.9	3,536	2.1	
16500-22800	385,427		377,408	97.9	8,019	2.1	
24000-36300	86,586		84,490	97.6	2,096	2.4	
38200-57800	92,193		89,904	97.5	2,289	2.5	
60800-87600	39,970		39,006	97.6	964	2.4	

\*Odds ratio (95% confidence interval)

\*The patients who made more than 2 visits for type 2 diabetes in 2002 were counted as incident cases.

Table 4-2 Continued

Characteristic	All	CM non-user		CM user		P value
	Total	Total	%	Total	%	
<b>Urban level</b>						<0.001
I	145,620	142,672	98.0	2,948	2.0	
II	187,728	183,000	97.5	4,728	2.5	
III	121,784	119,003	97.7	2,781	2.3	
IV	67,243	65,880	98.0	1,363	2.0	
V	98,750	96,561	97.8	2,189	2.2	
VI	63,482	62,356	98.2	1,126	1.8	
VII	58,502	57,385	98.1	1,117	1.9	
VIII	24,330	23,829	97.9	501	2.1	

#### 4.1.3 Prevalence of TCM according to need factors

Table 4-3 shows the prevalence of Chinese medicine utilization according to subgroups of need factors between Chinese medicine users and non-users. There were a higher prevalence of Chinese medicine utilization with complications including nephropathy, skin cellulitis, retinopathy, and number of complication more than two and comorbidities including hyperlipidemia, liver disease, and number of comorbidity more than four. There was no significant difference with complications including stroke, coronary artery disease and comorbidities including cancer.

Table 4-3 Prevalence of Chinese medicine utilization according to subgroups of need factors between Chinese medicine users and non-users

Characteristic	All		CM non-user		CM user		P value
	Total		Total	%	Total	%	
Patient No.	774,367		757,463	97.8	16,904	2.2	
<b>Complications</b>							
<b>Stroke</b>							0.710
Yes	10,059		9,834	97.8	225	2.2	
No	764,310		747,631	97.8	16,679	2.2	
<b>Coronary artery disease</b>							0.113
Yes	102,110		99,812	97.7	2,298	2.3	
No	672,259		657,653	97.8	14,606	2.2	
<b>Nephropathy</b>							<0.001
Yes	43,593		42,403	97.3	1,190	2.7	
No	730,776		715,062	97.8	15,714	2.2	
<b>Skin cellulitis</b>							<0.001
Yes	19,529		18,965	97.1	564	2.9	
No	754,840		738,500	97.8	16,340	2.2	
<b>Retinopathy</b>							<0.001
Yes	11,607		11,149	96.1	458	3.9	
No	762,762		746,316	97.8	16,446	2.2	
<b>Number of complication</b>							<0.001
No complication	604,848		592,129	97.9	12,719	2.1	
One complication	153,226		149,549	97.6	3,677	2.4	
Two complications	15,247		14,779	96.9	468	3.1	
Three complications	1,048		1,008	96.2	40	3.8	

\*Odds ratio (95% confidence interval)

\*The patients who made more than 2 visits for type 2 diabetes in 2002 were counted as incident cases.



Table 4-3 Continued

Characteristic	All		CM non-user		CM user		P value
	Total		Total	%	Total	%	
<b>Comorbidity</b>							
<b>Hypertension</b>							
Yes	290,763		284,791	97.9	5,972	2.1	<0.001
No	483,606		472,674	97.7	10,932	2.3	
<b>Hyperlipidemia</b>							
Yes	225,920		220,630	97.7	5,290	2.3	<0.001
No	548,449		536,835	97.9	11,614	2.1	
<b>Diseases of the respiratory system</b>							
Yes	34,542		33,855	98.0	687	2.0	0.012
No	739,827		723,610	97.8	16,217	2.2	
<b>Liver disease</b>							
Yes	105,187		102,556	97.5	2,631	2.5	<0.001
No	669,182		654,909	97.9	14,273	2.1	
<b>Cancer</b>							
Yes	14,735		14,391	97.7	344	2.3	0.203
No	759,634		743,074	97.8	16,560	2.2	
<b>Number of comorbidity</b>							
No comorbidity	274,788		268,720	97.8	6,068	2.2	<0.001
One comorbidity	345,598		338,339	97.9	7,259	2.1	
Two comorbidities	137,156		134,063	97.7	3,093	2.3	
Three comorbidities	16,077		15,620	97.2	457	2.8	
Four more comorbidities	750		723	96.4	27	3.6	

#### 4.1.4 Prevalence of TCM according to health care resources factors

Table 4-4 shows the prevalence of Chinese medicine utilization according to subgroups of health care resources factors between Chinese medicine users and non-users. There were a higher prevalence of Chinese medicine utilization with six physicians of CM per 10,000 population, 40-49 physicians per 10,000 population, less than 0.19 hospital per 10,000 population, and medical centre.

Table 4-4 Prevalence of Chinese medicine utilization according to subgroups of health care resources factors between Chinese medicine users and non-users

Characteristic	All		CM non-user		CM user		P value
	Total	Total	%	Total	%		
<b>Physicians of CM</b>							<0.001
<b>Per 10,000 Population</b>							
0	83,336	81,949	98.3	1,387	1.7		
1	176,525	173,245	98.1	3,280	1.9		
2	209,993	205,655	97.9	4,338	2.1		
3	175,422	171,314	97.7	4,108	2.3		
4	73,984	71,941	97.2	2,043	2.8		
5	15,568	15,038	96.6	530	3.4		
6	9,701	9,327	96.1	374	3.9		
>=7	16,432	15,933	97.0	499	3.0		

\*Odds ratio (95% confidence interval)

\*The patients who made more than 2 visits for type 2 diabetes in 2002 were counted as incident cases.

Table 4-4 Continued

Characteristic	All		CM non-user		CM user		P value
	Total		Total	%	Total	%	
<b>Physicians</b>							<0.001
<b>Per 10,000 Population</b>							
<=9	307,251		301,001	98.0	6,250	2.0	
10-19	232,727		227,650	97.8	5,077	2.2	
20-29	122,434		119,559	97.7	2,875	2.3	
30-39	40,821		39,912	97.8	909	2.2	
40-49	20,330		19,619	96.5	711	3.5	
50-59	11,707		11,414	97.5	293	2.5	
>=60	39,099		38,310	98.0	789	2.0	
<b>Hospitals</b>							<0.001
<b>Per 10,000 Population</b>							
<=0.19	24,716		24,067	97.4	649	2.6	
0.20 - 0.29	328,130		321,900	98.1	6,230	1.9	
0.30 - 0.39	172,624		168,604	97.7	4,020	2.3	
0.40 - 0.49	152,209		148,297	97.4	3,912	2.6	
>=0.50	96,690		94,597	97.8	2,093	2.2	
<b>Service providers</b>							<0.001
medical centre	207,031		202,203	97.7	4,828	2.3	
regional hospital	216,828		211,910	97.7	4,918	2.3	
district hospital	155,237		152,116	98.0	3,121	2.0	
clinic	194,140		190,117	97.9	4,023	2.1	

## 4.2 Factors associated with the utilization of TCM

Table 4-5 shows two-part model analysis for characteristics associated with the utilization of Chinese Medicine. Because of statistical problem, we omit some variables including stroke, coronary artery disease in complications and hyperlipdemia, disease of the respiratory system, and cancer in comorbidities. The first part model estimates the ORs indicating the strength of association between characteristics of patients with type 2 DM and the presence of Chinese Medicine utilization. The odds of using TCM were higher in males (OR = 1.16; 95% CI: 1.13–1.20) and odds of TCM increased with age to a peak in the 50–59-year-group (OR = 1.59; 95% CI: 1.52–1.66). The odds of TCM in the group with household income \$NT 38,200-57,800 were higher than those in the low-income group (OR = 1.11; 95% CI: 1.05–1.17). Patients with DM in Central and Southern areas of Taiwan were more likely to use TCM. The comorbidity diseases that were associated with higher TCM utilization were nephritis, skin abscess, retinal defects and liver disease (OR = 1.25; 95% CI: 1.17–1.33 for nephritis; OR = 1.37; 95% CI: 1.26–1.50 for skin abscess; OR = 1.83; 95% CI: 1.66–2.02 for retinal defects and OR = 1.10; 95% CI: 1.06–1.15 for liver disease). As the degree of urbanization increased, the odds of using TCM increased (OR = 1.39; 95% CI: 1.26–1.52; for level II).

The second part model estimates the mean differences of the number of Chinese medicine uses between various subgroups of patients with type 2 DM who had utilized Chinese Medicine services during the study year. Male patients with DM had a higher mean number of Chinese Medicine uses than female ones (beta = 0.59,  $P < 0.001$ ), Insured region in Central Taiwan had a higher mean number of Chinese Medicine uses than in Eastern Taiwan (beta = 0.72,  $P = 0.06$ ), insurance premium \$NT.16,500~36,300 had a lower mean number of Chinese Medicine uses than insurance premium under \$NT.15,840 (beta = -0.42,  $P < 0.001$  for \$NT.16,500~22,800; beta = -0.46,

$P < 0.01$  for \$NT.24,000~36,300), patients with comorbidity including liver disease had lower mean number of Chinese Medicine uses than ones without comorbidity (beta = -0.40,  $P < 0.001$ ), patients with DM who resided in urban levels of 3 had a higher mean number of Chinese Medicine uses than in urban levels of 6 (beta = 0.56,  $P < 0.05$ ), patients with DM who resided in 40~49 and  $\geq 60$  physicians per 10,000 population had a higher mean number of Chinese Medicine uses than in  $\leq 9$  physicians per 10,000 population (beta = 0.92, and 0.74,  $P < 0.01$  and  $< 0.05$ , respectively), patients with DM who visited in medical centre had a higher mean number of Chinese Medicine uses than in district hospital (beta = 0.64,  $P < 0.001$ ).

The significant factors that were associated with the presence of Chinese Medicine utilization were gender, age, insured region, household income, complication, comorbidity, urbanization, physicians of Chinese medicine per 10,000 population, physicians per 10,000 population, hospitals per 10,000 population and service providers. The significant factors that were associated with the number of Chinese Medicine uses were male, insured region in Central Taiwan, household income \$NT.16,500~36,300 per month, with liver disease, resided in urban levels of 3,  $\geq 60$  physicians and 0.40~0.49 hospitals per 10,000 population, visited in medical centre.

Table 4-5 Two-part model analysis for characteristics associated with the utilization of Chinese medicine (n=774,367)

Characteristics	1st Part Model			2nd Part Model		
	Adjusted ORs	95% CI	p-value	Adjusted Mean	SE	p-value
<b>Gender</b>						
Female	1.00					
Male	1.16	1.13-1.20	<0.001	0.59	0.09	<0.001
<b>Age (years)</b>						
≥ 70	1.00					
≤ 29	1.10	0.95-1.26	0.204	0.24	0.39	0.54
30-39	1.26	1.16-1.38	<0.001	-0.08	0.24	0.73
40-49	1.53	1.45-1.61	<0.001	-0.06	0.15	0.66
50-59	1.59	1.52-1.66	<0.001	-0.03	0.13	0.82
60-69	1.45	1.39-1.52	<0.001	-0.01	0.12	0.93
<b>Insured region</b>						
Eastern Taiwan	1.00					
Taipei	1.14	0.99-1.32	0.077	0.13	0.40	0.75
Northern Taiwan	1.03	0.89-1.19	0.717	-0.46	0.40	0.25
Central Taiwan	1.80	1.56-2.06	<0.001	0.72	0.38	0.06
Southern Taiwan	1.78	1.55-2.04	<0.001	0.56	0.38	0.14
Kaohsiung and Pingtung	1.53	1.32-1.77	<0.001	0.17	0.41	0.68
<b>Household income (\$NT/month)</b>						
≤ 15840	1.00					
16500-22800	0.92	0.88-0.96	<0.001	-0.42	0.12	<0.001
24000-36300	1.04	0.98-1.10	0.230	-0.46	0.16	<0.01
38200-57800	1.11	1.05-1.17	<0.001	-0.15	0.15	0.33
60800-87600	1.11	1.03-1.19	0.008	0.33	0.20	0.11

\*Odds ratio (95% confidence interval)

\*The patients who made more than 2 visits for type 2 diabetes in 2002 were counted as incident cases.

Table 4-5 continued

Characteristics	1st Part Model			2nd Part Model		
	Adjusted ORs	95% CI	p-value	Adjusted Mean	SE	p-value
<b>Complications</b>						
Nephropathy	1.25	1.17-1.33	<0.001	0.02	0.17	0.91
Skin cellulitis	1.37	1.30-1.50	<0.001	-0.27	0.24	0.25
Retinopathy	1.83	1.66-2.02	<0.001	-0.27	0.26	0.31
<b>Comorbidities</b>						
Hypertension	0.97	0.94-1.00	0.046	-0.13	0.09	0.15
Liver disease	1.10	1.06-1.15	<0.001	-0.40	0.12	<0.001
<b>Urbanization</b>						
VI	1.00					
I	1.32	1.18-1.47	<0.001	0.00	0.29	1.00
II	1.39	1.26-1.52	<0.001	0.38	0.26	0.14
III	1.21	1.11-1.32	<0.001	0.56	0.24	<0.05
IV	1.11	1.02-1.21	0.021	0.43	0.24	0.08
V	1.08	1.00-1.17	0.059	0.42	0.22	0.05
VII	1.06	0.97-1.16	0.172	0.35	0.24	0.14
VIII	1.18	1.04-1.33	0.010	0.32	0.34	0.35
<b>Physicians of Chinese medicine Per 10,000 Population</b>						
0	1.00					
1	1.23	1.14-1.33	<0.001	-0.08	0.20	0.71
2	1.26	1.16-1.37	<0.001	-0.22	0.23	0.34
3	1.45	1.32-1.59	<0.001	-0.26	0.26	0.31
4	1.60	1.42-1.81	<0.001	-0.43	0.33	0.19
5	1.57	1.36-1.82	<0.001	-0.45	0.40	0.26
6	1.88	1.58-2.24	<0.001	-0.02	0.47	0.96
≥7	1.76	1.46-2.06	<0.001	-0.51	0.44	0.25

Table 4-5 Continued

Characteristics	1st Part Model			2nd Part Model		
	Adjusted ORs	95% CI	p-value	Adjusted Mean	SE	p-value
<b>Physicians Per 10,000 Population</b>						
<=9	1.00					
10-19	0.91	0.87-0.96	<0.001	0.02	0.13	0.91
20-29	0.89	0.83-0.96	0.001	0.16	0.19	0.40
30-39	0.84	0.76-0.92	<0.001	-0.42	0.25	0.10
40-49	1.00	0.90-1.11	0.997	0.92	0.30	<0.01
50-59	0.92	0.81-1.05	0.213	-0.09	0.36	0.80
≥60	0.79	0.70-0.89	<0.001	0.74	0.32	<0.05
<b>Hospitals Per 10,000 Population</b>						
0.20 - 0.29	1.00					
≤0.19	1.31	1.17-1.46	<0.001	-0.41	0.30	0.17
0.30 - 0.39	1.15	1.08-1.22	<0.001	-0.13	0.17	0.45
0.40 - 0.49	0.89	0.82-0.96	0.004	0.12	0.21	0.59
≥0.50	1.03	0.96-1.11	0.430	0.10	0.20	0.63
<b>Service providers</b>						
district hospital	1.00					
medical centre	1.13	1.08-1.18	<0.001	0.64	0.13	<0.001
regional hospital	1.09	1.04-1.14	<0.001	0.15	0.13	0.24
clinic	1.00	0.95-1.05	0.975	0.03	0.13	0.80



### 4.3 Prescription pattern of TCM

A total of 16,904 TCM using patients, representing 735,411 TCM drugs uses, were screened during the study period.

The most frequently prescribed Chinese herbal formula was Liu-Wei-Di-Huang-Wan (9.26%), followed by Bai-Hu-Jia-Ren-Shen-Tang (6.22%), Zhi-Bo-Di-Huang-Wan (5.31%), Qi-Ju-Di-Huang-Wan (4.06%), and Yu-Quan-Wan (3.75%) (Table 4-6). The most frequently prescribed single Chinese herb was Gwa-Low-Gen (5.71%), followed by Huang-Qi (4.76%), Dan-Shen (4.66%), Shan-Yiao (4.18%), and Xuan-Shan (2.78%) (Table 4-7). Table 4-8 presents the most common herbal formulae prescribed in the TCM visits. According to the association rule, the most common combination of two formulae for DM was Liu-Wei-Di-Huang-Wan plus Bai-Hu-Jia-Ren-Shen-Tang (Table 4-9), and the most common combination of formulae and drug was Liu-Wei-Di-Huang-Wan plus Gwa-Low-Gen (Table 4-10).

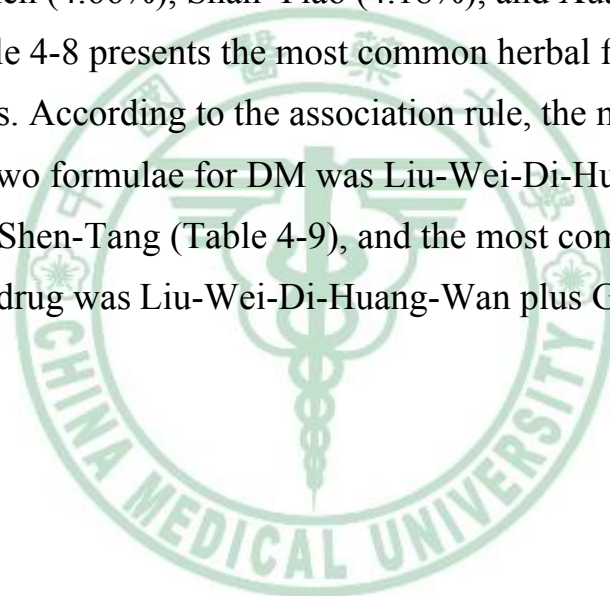


Table 4-6 Top ten Chinese herbal formulae for DM in Taiwan (total prescription numbers, n=141,103)

Chinese herbal formulae	Ingredients	n (%)
Liu-Wei-Di-Huang-Wan extract granules	<i>Rhizoma Rehmanniae Praeparatae, Fructus Corni, Rhizarna Dioscoreae, Rhizonia Alismatis, Cortex Moutan Radicis, Poria.</i>	46,016 (9.26)
Bai-Hu-Jia-Ren-Shen-Tang extract granules	<i>Gypsum Fibrosum, Rhizoma Anemarrhenae, Radix Glycyrrhizae Praeparatae, Semen Oryzae Sativae, Radix Ginseng.</i>	30,875 (6.22)
Zhi-Bo-Di-Huang-Wan extract granules	<i>Rhizoma Anemarrhenae, Cortex Phellodendri, Rhizoma Rehmanniae Praeparatae, Fructus Corni, Rhizarna Dioscoreae, Rhizonia Alismatis, etc.</i>	26,395 (5.31)
Qi-Ju-Di-Huang-Wan extract granules	<i>Flos Chrysanthemi, Fructus Lycii, Rhizoma Rehmanniae Praeparatae, Fructus Corni, Rhizarna Dioscoreae, Rhizonia Alismatis, etc.</i>	20,187 (4.06)
Yu-Quan-Wan extract granules	<i>Radix Trichosanthis, Radix Puerariae, Radix Ophiopogonis, Radix Ginseng, Poria, Radix Astragali, Radix Glycyrrhizae Praeparatae, etc.</i>	18,615 (3.75)
Ji-Sheng-Shen-Qi-Wan extract granules	<i>Semen Plantaginis, Radix Achyranthis Bidentatae, Ramulus Cinnamomi, Radix Aconiti, Rhizoma Rehmanniae Praeparatae, Fructus Corni, etc.</i>	17,858 (3.60)
Ba-Wei-Di-Huang-Wan extract granules	<i>Ramulus Cinnamomi, Radix Aconiti, Rhizoma Rehmanniae Praeparatae, Fructus Corni, Rhizarna Dioscoreae, Rhizonia Alismatis, etc.</i>	14,999 (3.02)
Bai-Hu-Tang extract granules	<i>Gypsum Fibrosum, Rhizoma Anemarrhenae, Radix Glycyrrhizae Praeparatae, Semen Oryzae Sativae.</i>	12,865 (2.59)
Zu-Ye-Shi-Gao-Tang extract granules	<i>Gypsum Fibrosum, Semen Oryzae Sativae, Radix Ophiopogonis, Radix Glycyrrhizae Praeparatae, Pinellia ternata, Radix Ginseng, etc.</i>	12,123 (2.44)
Gan-Lu-Yin extract granules	<i>Radix Rehmanniae, Radix Ophiopogonis, Radix Glycyrrhizae Praeparatae, Herba Dendrobii, Radix Asparagi, etc.</i>	11,873 (2.39)

Table 4-7 Top ten single Chinese herbs prescribed for DM in Taiwan (total prescription numbers, n=141,103)

Single Chinese herbs (Chinese name)	Generic name	n (%)
Tian-Hua-Fen extract powder	<i>Radix Trichosanthis</i>	42,013 (5.71)
Huang-Qi extract powder	<i>Astragalus mongholicus</i>	35,025 (4.76)
Dan-Shen extract powder	<i>Salvia miltiorrhiza</i>	34,287 (4.66)
Shan-Yiao extract powder	<i>Dioscorea opposita</i>	30,769 (4.18)
Xuan-Shan extract powder	<i>Scrophularia ningpoensis Hemsl</i>	20,421 (2.78)
Mai-Men-Dong extract powder	<i>Dphiopogon japonicus</i>	19,744 (2.68)
Ge-Gen extract powder	<i>Pueraria lobata</i>	17,641 (2.40)
Cang-Zhu extract powder	<i>Atractylodes lancea (Thunb.) DC.</i>	12,803 (1.74)
Shi-Hu extract powder	<i>Dendrobium nobile</i>	12,749 (1.73)
Di-Huang extract powder	<i>Rehmannia glutinosa</i>	10,948 (1.49)

Table 4-8 Top ten herbal formulae prescribed by TCM physicians for DM in Taiwan (total prescription numbers, n=141,103)

Herbal formulae	Frequency of prescriptions n (%)	Average daily dose (g)	Average duration for prescriptions (days)
Liu-Wei-Di-Huang-Wan extract granules	46,016 (9.26)	4.2	14.0
Bai-Hu-Jia-Ren-Shen-Tang extract granules	30,875 (6.22)	3.3	15.2
Zhi-Bo-Di-Huang-Wan extract granules	26,395 (5.31)	3.4	17.1
Qi-Ju-Di-Huang-Wan extract granules	20,187 (4.06)	4.8	13.1
Yu-Quan-Wan extract granules	18,615 (3.75)	3.5	16.2
Ji-Sheng-Shen-Qi-Wan extract granules	17,858 (3.60)	3.4	15.9
Ba-Wei-Di-Huang-Wan extract granules	14,999 (3.02)	4.4	12.6
Bai-Hu-Tang extract granules	12,865 (2.59)	3.5	12.9
Zu-Ye-Shi-Gao-Tang extract granules	12,123 (2.44)	2.4	20.7
Gan-Lu-Yin extract granules	11,873 (2.39)	4.1	10.5

Table 4-9 The most common two-formulae combination of TCM in a single prescription for DM in Taiwan (total prescription numbers, n=141,103)

Chinese herbal formulae	Support (%)	Prescription number
Liu-Wei-Di-Huang-Wan and Bai-Hu-Jia-Ren-Shen-Tang	1.93	2,723
Zhi-Bo-Di-Huang-Wan and Bai-Hu-Jia-Ren-Shen-Tang	1.54	2,167
Liu-Wei-Di-Huang-Wan and Yu-Quan-Wan	1.09	1,536
Ji-Sheng-Shen-Qi-Wan and Bai-Hu-Jia-Ren-Shen-Tang	1.02	1,442
Liu-Wei-Di-Huang-Wan and Bai-Hu-Tang	0.90	1,272
Qi-Ju-Di-Huang-Wan and Bai-Hu-Jia-Ren-Shen-Tang	0.89	1,250
Zhi-Bo-Di-Huang-Wan and Bai-Hu-Tang	0.84	1,185
Liu-Wei-Di-Huang-Wan and Xue-Fu-Zhu-Yu-Tang	0.77	1,083
Zhi-Bo-Di-Huang-Wan and Gan-Lu-Yin	0.70	994
Liu-Wei-Di-Huang-Wan and Gan-Lu-Yin	0.69	967

Table 4-10 The most common formulae-drug combination of TCM in a single prescription for DM in Taiwan (total prescription numbers, n=141,103)

Chinese herbal formulae	Support (%)	Prescription number
Liu-Wei-Di-Huang-Wan and Tian-Hua-Fen	3.53	4,982
Liu-Wei-Di-Huang-Wan and Huang-Qi	2.86	4,041
Bai-Hu-Jia-Ren-Shen-Tang and Tian-Hua-Fen	2.56	3,619
Zhi-Bo-Di-Huang-Wan and Tian-Hua-Fen	2.44	3,443
Liu-Wei-Di-Huang-Wan and Dan-Shen	2.39	3,369
Liu-Wei-Di-Huang-Wan and Shan-Yiao	2.17	3,061
Zhi-Bo-Di-Huang-Wan and Dan-Shen	2.02	2,857
Bai-Hu-Jia-Ren-Shen-Tang and Shan-Yiao	1.90	2,684
Zhi-Bo-Di-Huang-Wan and Huang-Qi	1.76	2,477
Bai-Hu-Jia-Ren-Shen-Tang and Huang-Qi	1.72	2,434

## Chapter 5 Discussion

### 5.1 TCM utilization in patients with DM

The utilization of CAM has rapidly increased in many countries, for example, the United States, Canada....., during the last two decades [12, 13]. CAM is rarely covered in national health systems. In Taiwan, the NHI Program is a comprehensive and universal health insurance program. This program not only covers conventional WM services, but also TCM services. Moreover, TCM is popular and more than 60% of all beneficiaries of this health insurance system had used TCM at least once a year [33].

In this study, the two-part models were used to identify patient characteristics associated with the utilization patterns of TCM over time. We found that : (1) males used health care services more than females, (2) the age distribution of TCM utilization peaked at 50-59 years, (3)the utilization of TCM was higher in the high insurance premium group than the low insurance premium group, (4) the adjusted odds ratios of patients visiting TCM practitioners decreased with the level of urbanization, (5) living at areas with more sufficient health care resources in Chinese medicine, (6) CM service was provided by medical centre and regional hospital.

The utilization of TCM among patient with type 2 diabetes in males with age to a peak in the 50-59-year-group, living in high-urban areas, and service provided by medical centre is different in the previous studies that in female with age to a peak in the 45-54-year-group, living in sub-urban areas, and service provided by clinics [7, 17]. Moreover, the age distribution of TCM utilization is similar to those reported previously [34]. The result shows that the utilization of TCM was in higher insurance premium group than the low one is similar to the previous findings that CAM users are those with higher education and in the middle to upper socioeconomic status [11,

35, 36]. In a previous study, 62.5% of the valid beneficiaries in the NHI Program have been reported to use TCM at least once from 1996 to 2001 [33].

To the best of our knowledge, no prior study has ever explored the relationship between CAM usage and the level of urbanization of the community in which the patients reside, although one study in Taiwan, undertaken by Wu et al. [37] did find that almost half of rural families and two-thirds of urban families had, at some time, used CAM. One possible reason for the lower incidences of visits to TCM practitioners in rural areas may simply be the barriers to accessibility, given the low density of TCM practitioners in such areas; indeed, there is a significant geographical imbalance in the distribution of TCM clinics in Taiwan, since they are more likely to be concentrated in metropolitan and suburban areas than rural areas. Therefore, those residing in the lower urbanization levels simply have fewer opportunities to visit TCM clinics.

This study is the first population-based investigation to determine the utilization patterns of TCM in Taiwan under the NHI Program. The large sample size and the comprehensive datasets allow us to study a wide array of factors in the DM population. This manipulation of the data may lead to some selection bias. Since we used the NHI database, we are able to determine the utilization of TCM services covered by the NHI program. Therefore, the utilization of TCM in Taiwan might be not underestimated.

## 5.2 Prescription pattern of Traditional Chinese medicine

Liu-Wei-Di-Huang-Wan was the most commonly used herbal formula for patients with type 2 diabetes, as shown in Table 4.5. According to a TCM book, Liu-Wei-Di-Huang-Wan can nourish yin and invigorate the kidney [38]. It is applicable to chronic nephritis, hypertension, diabetes, tuberculosis, renal tuberculosis, hyperthyroidism, central retinitis,



anovulatory dysfunctional uterine bleeding, menopausal syndrome and other diseases, which pertain to the syndromes of kidney-yin deficiency. In case of hyperactivity of fire due to yin deficiency, add Zhi-Mu (*Rhizoma Anemarrhenae*) and Huang-bo (*Cortex Phellodendri*) to enhance the action of clearing away heat, which constitute another recipe entitled Zhi-Bo-Di-Huang-Wan. If concomitant with deficiency of the liver-yin manifesting blurring of vision, add Gou-Qi-Zi (*Fructus Lycii*) and Ju-Hua (*Flos Chrysanthemi*) to nourish the liver, forming another recipe entitled Qi-Ju-Di-Huang-Wan. In case of deficiency of kidney-yang, add Gui-Zhi (*Ramulus Cinnamomi*) and Fu-Zi (*Radix Aconiti*) to enhance the action of warming and invigorating kidney-yang. Gui-Zhi (*Ramulus Cinnamomi*) may be replaced with Rou-Gui (*Cortex Cinnamomi*), aiming to enhance the effect of warming yang, in case of severe edema, adding Che-Qian-Zi (*Semen Plantaginis*) and Niu-Xi (*Radix Achyranthis Bidentatae*) to promote diuresis and relieve edema, forming another recipe entitled Ji-Sheng-Shen-Qi-Wan. Despite the previous researches showed that Liu-Wei-Di-Huang-Wan was a obvious effect for type 2 diabetes [39, 40], there has not yet been any clinical trial to demonstrate its efficacy and safety.

Bai-Hu-Jia-Ren-Shen-Tang was the second most commonly uses herbal formula for patients with type 2 diabetes; it forms from another recipe entitled Bai-Hu-Tang, which can clear away heat and promote the production of body fluid. In case of impairment of qi and body fluid due to excessive heat marked by full large but weak pulse, thirst not quenched with drink, add Ren-Shen (*Radix Ginseng*) to replenish qi and promote the production of body fluid. Generally, the previous results suggested that the application of Bai-Hu-Tang and Bai-Hu-Jia-Ren-Shen-Tang can extend to many acute illnesses and injuries, which commonly cause hyperglycemia [41].

Tian-Hua-Fen was the most commonly used Chinese herb for patients with type 2 diabetes, as shown in Table 4.6. According to a TCM book [38],

Tain-Hua-Fen can clear away heat and promote the production of body fluids, resolve swelling and drain pus, it is used for febrile disease with thirst, diabetes and frequent drinking, since it is sweet, cold but moistening in properties, and can clear away heat and promote production of the body fluids.

Huang-Qi was the second most commonly used Chinese herb for patients with type 2 diabetes, it can replenish qi to invigorate yang; benefit the lung to strengthen the body; promote diuresis and relieve edema; relieve skin infection and promote tissue regeneration. In addition, it is also used for treating diabetes in combination with Sheng-Di-Huang (*Radix Rehmannia*), Mai-Men-Dong (*Radix Ophiopogonis*), Tian-Hua-Fen (*Radix Trichosanthis*), and Shan-Yao (*Rhizoma Dioscoreae*), etc. The single Chinese herbs prescribed for DM in Taiwan is different in the previous study but similar to the clinical usage [18].

Table 4.8 shows that Liu-Wei-Di-Huang-Wan and Bai-Hu-Jia-Ren-Shen-Tang were the most common two-formulae combination of TCM in a single prescription for patients with type 2 diabetes, we also found that almost the top ten two-formulae combination of TCM were derived from Liu-Wei-Di-Huang-Wan plus Bai-Huang-Tang. Co-prescriptions of two herbal formulae have not been recommended in ancient Chinese medicine textbooks, which raises concern for both their safety and effectiveness.

Table 4.9 shows that Liu-Wei-Di-Huang-Wan and Tian-Hua-Fen were the most common formulae-drug combination of TCM in a single prescription for patients with type 2 diabetes, we also found that almost the top ten formulae-drug combination of TCM were derived from Liu-Wei-Di-Huang-Wan plus Tian-Hua-Fen.

Finished herbal products (FHP) was invented about 40 years ago and has been utilized since then. When physicians of Chinese medicine prescribe FHP, they can either add a single herb or several herbs into the core formula.

But they can not subtract any herb or change the proportions of herbs in the finished products, because they are completely mixed together and extracted in the manufacturing process. Thus, physicians of Chinese medicine only can either add single herb(s) or combine other formula(e) that are manufactured into FHP to treat a patient. Because the NHI in Taiwan only reimburses FHP and not decoction, the above new prescription pattern of FHP has evolved to become a typical practice pattern of physicians of Chinese medicine in Taiwan [42]. Thus, more outcome research is needed to test the effectiveness and safety of new prescription patterns of FHP.

### 5.3 Limitation

Using insurance data had many advantages, including a large available number for the sample and the saving of time and money needed to perform metabolic assessments. Our study used entire DM population in Taiwan to prevent selection bias. However, we faced some limitations, such as the reliability and validity of the secondary data, and the incorrect classification, diagnosis and coding of the type of diabetes may have implications for patient management and limit our ability to measure quality [43]. Also, we could not imply some variables in Anderson's model, such as Education level, Occupation, Marital status and so on. We therefore adopted some rules to manage these problems, but there were still some difficulties left to be overcome.

The only reimbursement of FHP is of limited use in predicting their usage, which is not included decoction and Chinese herbal remedies purchased directly from pharmacies of traditional Chinese medicine, nor did we include health food containing herbs. Thus, the frequency of TCM utilization might be underestimated. However, since all FHPs prescribed by physicians of Chinese medicine were fully reimbursed by the NHI of Taiwan, the under-estimation might be of small magnitude.

Besides, we can not come to any conclusion about the relationship between the severity of diabetes and TCM utilization for lack of actual clinical data which is constrained by the following factors: lack of trials that tested the same herbal medicine, lack of details on co-interventions, unclear methods of randomisation, poor reporting and other risks of bias [44].



## Chapter 6 Conclusions and Suggestions

First, our results show that Chinese medical services utilization rates varies significantly according to patient characteristics, attributes of diseases, geographical regions and adequacy of Chinese medical resources. To determine the adequacy of Chinese medical services for patients with type 2 diabetes, attention must be paid not only to DM education, prevention, and treatment but also to their general health care. In the future, we hope to analyze and discuss the longitudinal NHI data of Chinese medicine utilization and costs, to provide us with evidence-based implications for future policy making.

Second, this is the first extensive survey examining the drug utilization patterns of Chinese herbal medicines in the treatment of type 2 diabetes. Although the data were generated in Taiwan, the herbs and practices identified are likely to be widely generalizable wherever Chinese herbal remedies are used for type 2 diabetes. Tian-Hua-Fen and Liu-Wei-Di-Huang-Wan family were commonly used. The baseline data generated should be of use in informing subsequent studies, including those aimed at a thorough evaluation of the herbs' effectiveness. Safety issues and drug-herb interactions should be a priority for future research and more clinical trials and outcome research are needed to assess the effectiveness of new prescription patterns in utilization of TCM.

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# **The utilization patterns of Traditional Chinese medicine among patients with Diabetes in Taiwan in 2002**

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Traditional Chinese medicines (TCM) utilization in patients with Diabetes Mellitus (DM) by large-scale study is limited, only by a small-scale survey. This study analyzes utilization rate and factors associated with TCM utilization using entire DM population in Taiwan.

Besides, Chinese herbal medicine (CHM) has been commonly used in treating diabetes in Asian countries. Interest in the use of alternative treatments for diabetes is increasing exponentially and is fairly common in Taiwan. We undertook a survey to define the drug utilization patterns of Chinese herbal medicines (CM) for diabetes in Taiwan.

This study used the National Health Insurance (NHI) complete datasets in 2002. The diagnosis of DM was extracted with ICD-9 Code of 250. In the first part, the two-part model logistic regression method was employed to estimate the odds ratios (ORs) for yearly utilization of TCM. A significance level of  $\alpha = 0.05$  was selected. In the second part, outpatients with primary diabetes and being treated with CM were studied. Core drug-use indicators were the dosing frequency and duration of CM prescriptions, the most common prescribed CM herbs and CM formulae used.

In the one side, the first part model estimates the odds of using TCM were higher in males (OR = 1.16; 95% CI: 1.13–1.20) and that of TCM increased with age to a peak in the 50–59-year-group (OR = 1.59; 95% CI: 1.52–1.66). The odds of TCM in the group with household income \$NT 38,200–57,800 were higher than those in the low-income group (OR = 1.11;

95% CI: 1.05–1.17). Patients with DM in Central and Southern areas of Taiwan were more likely to use TCM. The comorbidity diseases that were associated with higher TCM utilization were nephritis, skin abscess, retinal defects and liver disease (OR = 1.25; 95% CI: 1.17–1.33 for nephritis; OR = 1.37; 95% CI: 1.26–1.50 for skin abscess; OR = 1.83; 95% CI: 1.66–2.02 for retinal defects and OR = 1.10; 95% CI: 1.06–1.15 for liver disease). As the degree of urbanization increased, the odds of using TCM increased (OR = 1.39; 95% CI: 1.26–1.52; for level II).

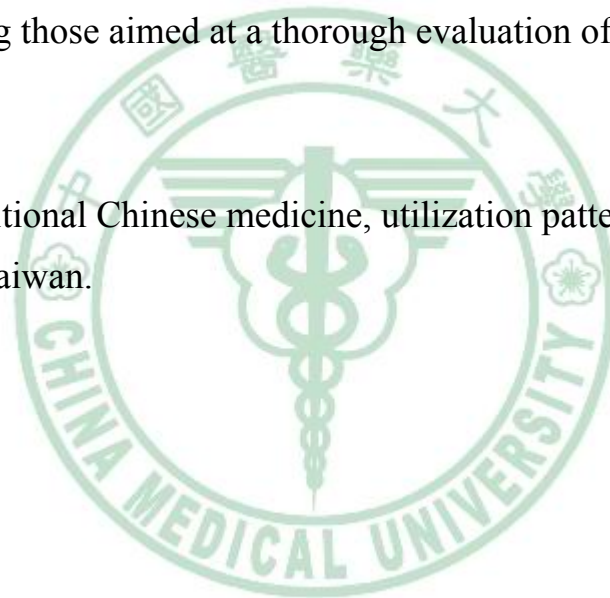
The second part model estimates the mean differences of the number of Chinese medicine uses were higher in males (beta = 0.59,  $P < 0.001$ ). Patients in Central Taiwan had a higher mean number of Chinese Medicine uses than in Eastern Taiwan (beta = 0.72,  $P = 0.06$ ), household income \$NT.16,500~36,300 had a lower mean number of Chinese Medicine uses than household income under \$NT.15,840 (beta = -0.42,  $P < 0.001$  for \$NT.16,500~22,800; beta = -0.46,  $P < 0.01$  for \$NT.24,000~36,300), patients with comorbidity including liver disease had lower mean number of Chinese Medicine uses than ones without comorbidity (beta = -0.40,  $P < 0.001$ ), patients with DM who resided in urban levels of 3 had a higher mean number of Chinese Medicine uses than in urban levels of 6 (beta = 0.56,  $P < 0.05$ ), patients with DM who resided in 40~49 and  $\geq 60$  physicians per 10,000 population had a higher mean number of Chinese Medicine uses than in  $\leq 9$  physicians per 10,000 population (beta = 0.92, and 0.74,  $P < 0.01$  and  $< 0.05$ , respectively), patients with DM who visited in medical centre had a higher mean number of Chinese Medicine uses than in district hospital (beta = 0.64,  $P < 0.001$ ).

In the other side, sixteen thousand nine hundred and four patients, using 735,411 CM herb items, were screened during the study period. The most often prescribed Chinese herbal products were Tian-Hua-Fen (*Radix Trichosanthis*) and Liu-Wei-Di-Huang-Wan, which includes *Rhizoma Rehmanniae Praeparatae*, *Fructus Corni*, *Rhizoma Dioscoreae*, *Rhizonia*

*Alismatis, Cortex Moutan Radicis, Poria.*

Not only Our results show that Chinese medical services utilization rates varies significantly according to patient characteristics, attributes of diseases, geographical regions and adequacy of Chinese medical resources. But also this is the first extensive survey examining the drug utilization patterns of Chinese herbal medicines in the treatment of diabetes. Although the data were generated in Taiwan, the herbs and practices identified are likely to be widely generalizable wherever Chinese herbal remedies are used for diabetes. Multiple herbs and complex formulae were commonly used. The baseline data generated should be of use in informing subsequent studies, including those aimed at a thorough evaluation of the herbs' effectiveness.

Keywords: Traditional Chinese medicine, utilization pattern, diabetes mellitus, NHI, Taiwan.



## 誌謝

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