A STUDY OF HERBAL DRUGS UTILIZATION AMONG PREGNANT WOMEN, HEALTH CARE PROFESSIONALS, ACADEMICIANS AND STUDENTS IN BEDONG AND SUNGAI PETANI

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by

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LIST OF ABBREVIATIONS

AD	After Death of Jesus Christ
AIMST	Asian Institute of Medical Sciences and Technology
CAM	Complementary Medicine
COPD	Chronic Obstructive Pulmonary Disease
DA	Darul Aman
DR	Darul Ridzuan
FDM	Food drug market
GIT	Gastro-intestinal tract
HR	Human Resource
NSAID	Non- steroidal anti-inflammatory drugs
OTC	Over the counter
SAH	Sultan Abdul Halim
NCCAM	National Centre for complementary and alternative Medicine
SPM	Sijil Pelajaran Malaysia
SPSS	Statistical Package for Social Sciences
UKMI	United Kingdom Medicine Information
WHO	World Health Organization

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KAJIAN KE ATAS PENGGUNAAN UBAT-UBATAN HERBA DALAM KALANGAN WANITA MENGANDUNG, PENJAGAAN KESIHATAN PROFESIONAL, AHLI AKADEMIK DAN PELAJAR DI BEDONG DAN SUNGAI PETANI

ABSTRAK

Kajian ini dijalankan bertujuan untuk mengkaji dan menganalisis nilai sebenar ubat-ubatan herba dalam aspek penggunaan terhadap kalangan wanita mengandung, penjagaan kesihatan profesional, ahli akademik dan pelajar dalam institusi pendidikan khas dan hospital di Sungai Petani, Kedah Darul Aman, Malaysia. Data analisis dijalankan dengan menggunakan "Statistical Pacakage of Social Sciences (SPSS)", versi 20. Sejumlah 1018 responden terlibat dalam kajian ini membabitkan tiga kumpulan iaitu, wanita mengandung 450, penjagaan kesihatan profesional melibatkan (doktor/ ahli akademik) 168 dan pelajar 400. Kajian keratan rentas telah dijalankan dan teknik persampelan rawak dipratikkan untuk memilih responden bagi kajian ini. Seramai 934 (91.7%) responden daripada 1018 dilaporkan aktif dalam penggunaan ubat-ubatan herba berbanding yang tidak menggunakannya. Dalam kajian tersebut, seramai 84 (8.3%) adalah berbangsa Melayu (n=352, 37.7%), Cina Malaysia (n=282, 30.2%), India Malaysia (n=262, 28.1%) dan juga responden dari warganegara lain (n=38, 4.1%) telah dilaporkan menggunakan ubat-ubatan herba bagi kajian ini. Pengumpulan data telah bermula pada bulan November 2010 dan tamat pada bulan Januari 2015 (lebih kurang 25 bulan) selepas tinjauan pustaka dijalankan. Berdasarkan pengumpulan data dari tiga kumpulan tersebut, wanita mengandung adalah sebanyak 450, 386 responden iaitu 41.3% menggunakan ubat-ubatan herba, manakala dalam kalangan penjagaan kesihatan profesional (doktor/ ahli akademik) 168, menunjukkan 150 responden bersamaan dengan 16.1% menggunakan ubat-ubatan herba dan seramai 398 dari kalangan pelajar 400 sebagai responden dalam kajian ini menunjukkan mereka aktif dalam mengamalkan ubat-ubatan

herba iaitu bersamaaan dengan 42.6%. Berdasarkan pengumpulan data dari tiga kumpula-tersebut, situasi ini dapat disimpulkan bahawa wanita mengamalkan ubat-ubatan herba 79.9% berbanding dengan responden lelaki 20.7%. Corak penggunaan ubat-ubatan herba dalam kalangan tiga kumpulan responden didapati adalah paling tinggi bagi responden yang mempunyai lulusan sekurang-kurangnya Sijil Pelajaran Malaysia (SPM) iaitu seramai 592 orang berbanding paling kurang bagi yang mempunyai lulusan Ijazah Kedoktoran (Ph.D). Selain itu, penggunaan ubat-ubatan herba ini juga sangat tinggi bagi wanita mengandung ke atas salah satu jenis penyakit dan ianya adalah sangat tinggi dalam kalangan pelajar bagi lima jenis penyakit seperti yang dinyatakan. Penggunaan ubat-ubatan herba ini sangat dominan bagi bangsa Melayu (n=352, 37.7%), diikuti oleh Cina Malaysia (n=282, 30.2%) dan India Malaysia seramai n=262, 28.1%. Tambahan pula, tiada masalah yang didapati oleh para responden bagi penggunaan ubat-ubatan herba itu. Bagi golongan wanita mengandung, Melayu sebanyak 82.1% adalah dari kumpulan kelulusan minimum iaitu 49.7%. Sebanyak 56.2% responden mengamalkan ubat-ubatan herba adalah dari kalangan wanita mengandung yang bekerja berdanding yang tidak bekerja. Penggunaan ubat-ubatan herba dalam kalangan pesakit yang juga merupakan responden bagi kajian ini mencatatkan peratus sebanyak 51.3%. Responden-responden dari Hospital Sultan Abdul Halim Sungai Petani, lebih cenderung menggunakan ubat-ubatan herba iaitu sebanyak 73.1% berbanding responden dari Hospital Swasta Pantai, Sungai Petani yang mencatatkan sebanyak 26.2%. Bagi golongan wanita mengandung, mereka lazimnya mengamalkan ubat-ubatan herba bagi melegakan sakit kepala, sakit otot, sakit membabitkan telinga dan juga gastrik. Selain itu, responden dari kumpulan penjagaan kesihatan profesional membuktikan golongan lelaki yang mengamalkan ubat-ubatan herba adalah lebih ramai berbanding golongan wanita iaitu sebanyak 56.7%. Kebanyakan responden dari kumpulan ini terdiri daripada kaum India responden.

Fakulti Perubatan menggunakan 45.3% ubat-ubatan herba berbanding pelajar dari fakulti-fakulti lain. Penggunaaan ubat-ubatan herba dalam kalangan penjagaan kesihatan profesional, jelas menunjukkan penggunaan bahan tersebut adalah bagi tujuan melegakan batuk, demam biasa, sakit kepala, sakit otot, sakit telinga dan gastrik. Manakala bagi responden dari kumpulan pelajar, responden wanita mencatatkan penggunaaan ubat-ubatan herba sebanayak 72.9% lebih dari responden lelaki. Dalam kalangan kumpulan pelajar. Sebanyak 64.1% dari kaum Cina mengamalkan lebih ubat-ubatan herba berbanding biasa. Pelajar dari Fakulti Farmasi mencatatkan penggunaan sebanyak 37.2% berbanding dari fakulti-fakulti lain. Sementara itu, responden yang menetap di dalam kampus mencatakan penggunaan sebanyak 73.1% lebih tinggi dari responden yang menetap di luar kampus ataupun secara persendirian. Kebanyakan responden dari kumpulan pelajar mengamalkan ubat-ubatan herba bagi melegakan semua jenis penyakit, masalah pernafasan, demam dan reaksi alergik.

A STUDY OF HERBAL DRUGS UTILIZATION AMONG PREGNANT WOMEN, HEALTH CARE PROFESSIONALS, ACADEMICIANS AND STUDENTS IN BEDONG AND SUNGAI PETANI

ABSTRACT

This research work attempted to analyze and to evaluate the real values of herbal drugs in aspect of their utilization in pregnant women, health care professionals (physicians)/academicians, and students in specific educational institutions and hospitals in Sungai Petani, Kedah Darul Aman, in Malaysia. Data analysis was performed using Statistical Package of Social Sciences (SPSS), version 20. Total of 1018 respondents were involved in this study consisting of three groups, pregnant women (450), health care professionals (physicians/academicians) (168) and students (400). The cross-sectional survey was conducted and random sampling technique was used for respondent selection. Out of 1018 respondents surveyed, 934 respondents (91.7%) reported the utilization of herbal drugs as compared to non-users 84 (8.3%). Malays (n=352, 37.7%), Malaysian Chinese (n=282, 30.2%), Malaysian Indians (n=262, 28.1%) and respondents from other nationalities also reported the utilization of herbal drugs for this study (n=38, 4.1%). The data collection was started in November 2010 and was completed in January 2013 (about 25 months) after the literature review. From the data collection of all three groups, 386 pregnant women respondents utilized herbal drugs 41.3%, health care professionals (physicians/academicians), 150 respondents utilized herbal drugs was 16.1% and 398 student respondents utilization of herbal drugs was 42.6%. Among all three groups, utilization of herbal drugs by female respondents was 79.3% as compared to male respondents 20.7%. The trend of herbal drugs utilization was highest among Sijil Pajalaran Malaysia (SPM) qualified 592 while it was lowest at Ph.D. level in all three groups.

The herbal drugs utilization was highest in pregnant women in one illness while it was highest among students in five illnesses. The practice of herbal drugs utilization was dominant in Malays (n=352, 37.7%), Malaysian Chinese (n=282, 30.2%) and in Malaysian Indians was (n=262, 28.1%). Possible problem was not observed by respondents regarding utilization of herbal drugs. Among pregnant women, Malay respondents utilization of herbal drug was 82.1% with low qualification 49.7%. Working pregnant women respondents utilized herbal drugs, 56.2% as compared to non-working. In-patient respondents, herbal drugs utilization was 51.3%. Respondents from Sultan Abdul Halim (S.A.H.) (general) Hospital, Sungai Petani, were more likely to utilize herbal drugs, 73.1% than the respondents from Pantai (private) Hospital 26.2%, Sungai Petani. Pregnant women usually utilized more herbal drugs for headache, muscular, ear and gastric pains. In the group of health care professional respondents, males utilized 56.7% herbal drugs more as compared to females. Mostly health care professional respondents were of Indian Nationals. The Faculty of Medicine respondents utilized 45.3% herbal drugs as compared to the respondents of other Faculties. Herbal drugs utilization was common in cough, common flu, chills than headache, muscular, ear and gastric pains. In the group of student respondents, female respondents utilized 72.9% more as compared to male respondents. Malaysian Chinese student respondents utilized 64.1% more herbal drugs. The student respondents from Faculty of Pharmacy utilized 37.2% more than the other Faculties. In-campus respondents utilized 73.1% more than private living respondents. All student respondents utilized herbal drugs in pains, respiratory indications, fever and allergic reaction.

CHAPTER 1

GENERAL INTRODUCTION

1.1 Definition of herbs and herbal drugs

The botanical definition of the term 'herb' was specific for certain leafy plants without woody stems. However, the term "*herbal preparation*" often includes non-herb plant materials, even animal and mineral products. Thus, in a broad sense, the term herb includes any "natural" or "traditional" remedy. Although such products often are also called *medications,* this terminology may be inaccurate and misleading (Vickers *et al*., 1993). Many herbal preparations were purportedly used for their nonspecific "adoptogenic" properties by permitting the body return to a normal state by resisting stress but they lack any specific medicinal effects. Because many herbal drug users / herbalists consider herbal preparations as medications (Barnes *et al.*, 2004).

1.2 Medicinal herbs

Some plants contain phytochemicals that have effects on the body when consumed in the small quantity and toxic in larger quantities. For instance, some types of herbal extract such as St. John's wort (*Hypericum perforatum*) or kava (*Piper methysticum*) can be used for medical purposes to relieve depression and stress. However, large amounts of these herbs may lead to toxic overload that might involve complications of serious nature (Hazlitt *et al.,* 1905).

Medicinal herbs had long been used as the basis of traditional Chinese herbal drugs with usage dating as far back as the first century A.D. and far before. In India, the ayurvedic medicinal system is based on herbs. Medicinal usage of herbs in

Western cultures had its roots in the Hippocratic Elemental Healing System. Some herbs were used not only for culinary and medicinal purposes but also for psychoactive and / or recreational purposes, one such herb was cannabis (Hazlitt *et al.,* 1905).

There are many herbs considered to be sacred in different societies. In anglo-Saxon Panism **(**people who inhabited The Great Britain including Germanic tribes in the 5th century), the following nine herbs were considered to be very sacred; *Mucgwyrt* (Mugwort), *Attorlaoe* (CockspurGrass) , *Stune* (Lamb's-Cress), *Wegbrade* (Plantain), *Moegoe* (Mayweed or Matricaria (Chamomile), *Stioe* (Nettle), *Wergulu* (Crab-apple), *Fille* (Thyme), and *Finule* (Fennel) **(**Hazlitt *et al*., 1905). In some places Neem (*Azadirachta indica*) leaves, basil or *Tulsi* (*Ocimum tenuiflorum*), Turmeric or "Haldi" (*Curcuma longa*) is also thought to be holy and sacred. In Hiduism and many Rastafarians people (an Abrahamic religion which developed in Jamica), consider cannabis (marijuana) to be a holy plant. Shamans (Siberian Spirituality) also used herbs for spiritual purposes **(**Hazlitt *et al*., 1905). Some plants are used as both herbs and spices such as dill weed and dill seed or coriander leaves and seeds. Also, there were some herbs such as those in the mint family, which were used for both culinary and medicinal purposes (Robson *et al.,* 2009).

1.3 Herbal drugs (Herbalism)

Herbal drugs had been defined in many ways. According to (Kamboj, 2000), "herbal drugs constitute only those traditional medicines where medicinal plant preparations were used primarily". Another definition (Lucas, 2010) defines herbal drugs as "the use of plant products to treat or prevent a disease". It was suggested by (Nsowah-Nuamah *et al.,* 2004) that the treatment of herbal practitioners usually "took the form

of herbs or plant preparations. The World Health Organization (WHO) defined herbal drugs as "a plant-derived material or preparation with therapeutic or other human health benefits, which contains either raw or processed ingredients from one or more plants [(WHO, 1998), (WHO, 2000a)]. But the WHO Regional Office for Africa (2004) used the term "traditional medicine" as a synonym for herbal drugs and defines it as "the use of indigenous medicinal and aromatic plants, animal parts, or organic and inorganic materials for preventive and therapeutic purposes (WHO Regional Office for Africa (2004).

Traditional and herbal drugs are presently defined as complementary and alternative medicine (CAM) (Aziz and Tey, 2009). On the other hand, the University of Maryland Medical Centre (2010) gave a definition of herbal drugs as a plant seeds, berries, roots, leaves, bark, or flowers for medicinal purposes. Herbs that were used for medicinal purposes come in a variety of forms. Active parts of a plant might include leaves, flowers, stems, roots, seeds, and berries (Woolf, 2003). They might be taken internally as pills or powders, dissolved into tinctures or syrups or brewed in teas and concoctions.

Herbalism (herbal drugs) is a use of plants or plant parts for medicinal and study purposes. Plants had been the basis for medical treatments through much of human history and such traditional drugs are still widely practiced. Modern medication recognized herbalism as a form of alternative treatment because the practice of herbalism was not strictly based on evidence that gathered using the scientific method. Modern medicine did, however, made use of many plant-derived compounds as the basis for evidence-tested pharmaceutical drugs.

The Western world had also changed the concept of knowing herbal drugs (Sue, 2008). The scope of herbal drugs is sometime extended to include fungal and bee products, minerals, shells and certain animal parts (Anderson *et al*., 1982), (Blunt *et al.*, 1980), (Culpeper, 1995), (Dwivedi *et al.*, 2007), (Greene, 1981), (Grieve, 1984), (Hong-Yen, 1980). Herbalism is also known as botanical medicine, medical herbalism, herbal medicine, herbology, herbal drug, phyto-therapy and herbal drugs along with surgery (Barnes *et al.*, 1998), (Barnes *et al.*, 2004), (Barnes *et al.*, 2009), (Bright Adjei 2013), (Edmund, 2005), (Hazlitt *et al.*, 1905), (Lee *et al.*, 2007), (National Center, 2005), Nissen *et al.*, 2013), (Prasad *et al.*, 2004).

1.4. Malaysian herbal drugs review

Home to some of the world's heavy rainforests, Malaysians boosted remarkable biodiversity with a great range of plant species (Bodeker, 2009). The Malaysian herbal product market is experiencing a tremendous growth (Abas Hj Hussin, 2001), (Ong and Nordiana, 1999), (Siti *et al.*, 2009) due to intense public interest in the use of crude plant-based products as medications. More people are turning to herbal products as an alternative to the conventional therapeutic medicine. Malaysians consume approximately RM1.2 billion worth of imported herbal products annually (Ibrahim, 2006). According to recent estimate by the World Health Organization (WHO), more than 3.5 billion people in the developing countries including Malaysia are relying on plants to treat various ailments (Samad, 2005). The retail sales of herbal products were estimated to be slightly over U.S. 4 $ billion in 2000 (WHO, 2003). More than 90% of the raw material used in the manufacture of herbal products in Malaysia is imported, mainly from Indonesia, China and India (Kelly *et al.*, 2005). The Statistics Department Government of Malaysia in 1996 reported that a total import of medicinal plants amounting to RM 93.4 million in 1986, gradually

increased to RM 264.8 million in 1996. For the period from January to November, 2003, the Malaysian Pharmaceutical market was estimated to be about RM 1.84 Billion (U.S. $ 484 million), registering a growth of 5.5 % over the corresponding period of 2003. The market for herbal remedies was estimated to be above RM 2 billion (U.S. 530 million $). The local interest in traditional/herbal medicine is reflected in the large number of products available. It is estimated that about 2700 products are registered by Drug Control Authority, with more than 10,000 traditional / herbal products. Malaysian rain forest support more than 12,000 plant species out of which 2000 species have been reported for medicinal value. With this diversity of mega sorces, it is expected that Malaysia may take a leading position as producer of herbal drugs in the region (South–south trading promotion programme Malaysia, International trade centre, March 2008). The traditional medicine presented in pharmaceutical form will require registration to National Pharmaceutical Control Bereau and today about 17,000 products have been registered (South–south trading promotion programme Malaysia, International trade centre, March 2008). In Malaysia, total import of pharmaceutical and natural products was RM 2712 million and export was RM 496 million (Department of Statistics, Malaysia, 2006).

To reduce cash outflow, the authority encouraged the propagation of home-grown herbs which were underutilized and the production of home-made herbal products. Attempts have been made by several public and private sectors to cultivate medicinal plants such as *Eurycoma longifolia* (Tongkat Ali), *Labisia pumila* (Kacip Fatimah) and *Cinnamomomum verum* (Kayu manis) on a commercial scale (Azizol, 1998), (Ibrahim *et al.*, 1996).

Despite the paucity of knowledge of pharmacological efficacies of herbals, sales of partially tested or untested preparations was very high either manufactured locally or imported in Malaysia (Hussin, 2001), (Normiadillah and Noriah, 2012), (Shahzad *et al.*, 2009), (Siti *et al.*, 2009), (Hassan, 2005). However, the herbal industry now produces herbal products containing isolated chemicals or extracts of single plants in different dosage forms (Hussin, 2001).

In the year 1997, Malaysians spent about RM 2.0 billion on herbal medicines. This amounts to about RM 45.00 spent on herbals / herbal drugs per person per year in the United States compared to about RM 91.00 per person per year in Malaysia taking into account populations of 273 million and 22 million respectively (Hussin, 2001). About 17.1% of Malaysians used herb drugs to treat their health problems while 29.6% consumed for their health maintenance. Herbal drugs are the most frequently used (49.4%) by adult patients in Malaysia (Chan *et al.*, 2003). In 1999, more than 8000 herbal products were registered with the Ministry of Health, Malaysia. This illustrated the potential of the herbal market in Malaysia (Hussin, 2001). Moreover the general public was also accessed in connection with the utilization of herbal drugs (David *et al.*, 2009), (Hasali Hasali *et al.*, 2012), (Muneer *et al.*, 2012), (Siti *et al*. 2009), (Zhari, 2001).

1.5 Herbal drug preparations and products

There are many forms in which herbs can be administered, the most common of which is in the form of oral solids or liquids. Whole herbal drug consumption is also practiced either fresh or in dried form (Anderson, 1982), (Blunt *et al.*, 1980), (Breakspear, 2006), (Culpeper, 1995), (Dwivedi *et al*., 2007), (Greene, 1981), (Grieve, 1984), (Hong-Yen, 1980). Herbal drugs are often promoted as natural and safe. Since

ancient times and perhaps prehistoric times, people from all cultures had used herbal drugs / preparations to treat disease and promote health (Awodele *et al*., 2012), (Vadamrita and Fawzi, 2012). For example, a 60,000 year old Iraqi burial site contained 8 different medicinal plants, suggesting very early historical usage. Second example was the early surviving written account of medicinal plants in Egypt as "Ebers papyrus, circa 1500 B.C. ", which listed dozens of medicinal plants and their intended use (Awodele *et al*., 2012), (Vadamrita and Fawzi, 2012).

In India, the *Vedas*, epic poems written in about 1500 B.C., contained references to herbal drugs / preparations of that time. In China, the Divine Husbandman's Classic, written in the 1st century A.D., listed about 252 herbal preparations.

In ancient Europe, herbal drugs were used in healing and in 1st century, Greek physicians wrote one of the first European Herbal Book, "*De Materia Medica*" which listed 600 herbals which were translated into many languages. Shamans and folk healers from the America, Africa, Australia and Asia continued to include herbals for spiritual and medicinal purposes, based on traditions passed from generation to generation (Ackerknecht, 1982), (Awodele *et al*., 2012), (Chen, 1999), (Fabricant *et al.,* (2001), (Hong, 2004), (Nunn, 2002), (Robson *et al.,* 2009), (Unschuld, 2003), (Vadamrita and Fawzi, 2012).

Herbalists tend to use extracts from parts of the plants, such as roots, leaves etc., but not isolating particular phytochemicals (Eisenberg *et al.,* 1995), (Hirani, 2012) (Vickers, 1999). Herbalist often rejected the notion of a single active ingredient, arguing that the different phytochemicals present in many herbs would interact to enhance the therapeutic activity of the herbs and dilute toxicity (Challem, 1999). Herbalists also deny that herbal synergism could be duplicated with synthetic

chemicals (Challem, 1999). They further argue that phytochemical interactions and trace components may alter the drug response in ways that could not currently be replicated with a combination of a few active ingredients (Challem, 1999), (Williamson, 2001). Pharmaceutical researchers noted that clinical trials might be used to investigate the efficacy of a particular herbal drug / herbal preparation / herbal product, provided the formulation of the herb is consistent (Goldman, 2001). The herbalist's content that historical medical records and herbals are underutilized resources (Slikkerveer, 2006). The efficacy of a particular herbal drug / herbal preparation / herbal products favoured the use of convergent information in assessing the medical value of plants (Riddle, 2002). Some researchers trained in both Western and traditional Chinese medicines had attempted to deconstruct ancient medical texts in the light of modern science Boxin *et al.*, 2003), (Lio *et al.*, 2008). It has been mentioned that the factors for resurgence of herbal drugs utilization included the low cost, ease of purchase; consumer empowerment; dissatisfaction with conventional therapies and perception that herbs were better and safe being natural (Ernst, 1998), (Edgar, 2002).

1.6 Herbals / herbal drugs Utilization

The use of herbal drugs/traditional products in Malaysia is highly appreciated by large number of Malaysians (Euromonitor International Consumer Health, 2015). Trend in Malaysia also indicated more herbal drugs/herbals/traditional ingredients being incorporated into newly launched consumer health products. For example, "milk thistle" and "dandelion" were relatively new herbals / traditional products in 2014 with the products traditionally used as a liver tonic. This is partly because consumers in Malaysia are familiar with herbal/traditional ingredients, which made

them convinced about the use of herbals/ traditional ingredients. Cerebos topped herbals/traditional products in Malaysia by owing 16% value share throughout 2014. Over the forecast period, herbals/traditional products are expected to record CAGR (Compound annual growth rate) of 3% in constant sale terms. The effects of consuming herbals/traditional products which are scientifically prove to have helped in stimulating greater sales. For instance, many ophthalmic related supplements those were launched in 2014, contains "bilberry" and "wolfberry", used traditionally (Euromonitor International Consumer Health, 2015).

In Malaysia, the herbal drugs are very frequently utilized starting from small ailments to chronic diseases irrespective of age, status and even in pregnancy (Pinn *et al.*, 2002). In fact, claims on the use of herbs as sex aids such as *Eurycoma longifolia* (Tongkat Ali) has been the most popular and widely publicized. The plant *Sarcolobus globosus* has been used as herbal medication for treatment of rheumatism, dengue fever (Hussin, 2001), (Hooi, 2004), (Li *et al.*, 2009), (Maryam *et al*., 2012), (Ong and Norzalina, 1999), (Turnheim, 1998).

Herbals / traditional products established national popularity in 2014. The increase tendency towards herbals/traditional products was seen in 2014 because to their consideration of healthy being natural ingredients. Due to aggressive marketing efforts, consumers have better information which supports the growth of herbals / traditional products (Euromonitor International Consumer Health 2015). Two brands "Tolak Angin" and "Antangin" are products very commonly used remedies in Indonesia for the disease called "masuk angin". These two products continue to have strong brand awareness by the consumers in Indonesia. The other popular brands are "Kuat Lelaki" (strong man), "Kuku Bima" (Nail of God) and super "Biul Erection

Oil". With the increase of well-informed consumers, herbals/traditional products have become more popular. By this way consumers have become more educated regarding natural herbal drugs. Based upon the facts, many new products are on the way to be launched to accelerate growth of herbals/traditional products (Euromonitor International Consumer Health 2015). Many Indonesians believe in the effectiveness of *jamu* drink as health tonic while men take it to increase stamina and sexual power (Ian, 2012). Jamu has also been used to treat cancer. By combining the *benala* leaves with tea and a strict soya bean diet, the patient has said to make a full recovery in 18 months (Susan, 1990). The sour sop tree leaves are used to relieve gout and arthritis while fruit inhibit the growth of human breast cancer. Jamu is also used in post natal care and suppressing appetite.

Herbals/traditional products growth was decreased in year 2014 as compared to year 2013. Manufactures, especially Cerebos Thailand, are continued to market the benefits of herbals / natural traditional products for their holistic treatment capabilities, which made it superior to standard Western modern products with 55% increase in 2014. Along-side the various food safety issues, consumers increasingly preferred herbals/traditional products in 2014 (Euromonitor International Consumer Health 2015). The herbals / traditional products category is expected to register positive constant value growth over the forecast period. The consumer's interest in herbals / traditional products will soon continue to grow, given the natural offering and perceived less harmful effects to the body as compared with over the counter drugs (Euromonitor International Consumer Health 2015), (Ong *et al.* 1999), (Muneer *et al.*, 2012), (Siti *et al*. 2009), (Shahid *et al.* 2013), (Jamia *et al.* 2011), (Maryam *et al.* 2012).

Today herbal preparations and products continued to be dominant form of healing in the developing world because of high cost of Western medical treatment and the scarcity of Western-trained medical personnel. In India, Ayurvedic medicine has quite complex formulas with 30 or more ingredients, chosen to balance Vata, Pitta or Kappa (Kala Chandra, 2006). In Ladakh (India), over 337 species of medicinal plants are documented (Kala Chandra, 2003), (Kala Chandra, 2005). In Tamil Nadu, they have their own medicinal systems called as Sidah Medicine. It contains about 300,000 verses covering diverse aspects of herbal drugs (Theivaththin) (Kala Chandra, 2003), (Kala Chandra, 2005). Countries like Malaysia, China, India and Sri Lanka has achieved tremendous success in developing their herbal drug sector (WHO, 2003a).

In 1999, sales of herbal drugs in the United States (U.S.) was estimated to be approximately $4 billion, with an annual growth rate of 18% per year (Eisenberg, 1993, (Hirani, 2012), (Vickers, 1999), (WHO, 1993). In 1998, several U.S. pharmaceutical companies launched a line of herbal products. However, increase in demand was in 1990. Market growth (food, drug and mass market retailers (FDM) dropped by 1% in 2000, 21% in 2001, and 14% in 2002. The drop in sales was attributed to negative publicity concerning the dangers associated with some popular herbal preparations. By 2005, the U.S. herbal market appeared to have stabilized, and more recently in 2007, total estimated U.S. herbal sales increased by 7.6%. Total U.S. herbal dietary supplement sales were estimated at $4.79 billion in 2007 from mass market retailers (Committee on use of CAM, 2005), (Eisenberg, 1993), (Hirani, 2012), (Vickers, 1999), (WHO, 1993). Although they often were used by consumers in the hope of preventing or treating medical illness.

Rural areas of Mississippi and South-western West Virginia reported that 71% and 73% of respondents, used herbal drugs in the past year, respectively. Among Chinese Americans in New York City and Hispanic Americans in West Texas, herbal drugs use was reported to be 43% and 50%, respectively (Barnes, 2006), (James, 2002), (National center, 2004).

Utilization of herbal drugs appeared to be higher among people with chronic illness such as AIDS, rheumatoid arthritis and cancer. In the U.S., increased likelihood of herbal drugs utilization was associated with multiple factors including concurrent illness and diverse socio-economic and cultural influences. In 1998, U.S. Congress established a National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health, to stimulate, develop, and support research in complementary and alternative medicines. Countries like China, India and Sri Lanka had achieved tremendous success in developing their herbal sector. In these countries, herbal drugs were highly developed (WHO, 2003a), well documented and practised at the family, community, primary health care levels and in hospitals where they were providing secondary and tertiary care (WHO, 2003a). The herbal drugs were the first line of treatment for more than 60% of children with high fever resulting from malaria (WHO, 2003a) in some of the Central African States. Indeed, various researchers had found that herbal drugs were effective, affordable, culturaly acceptable and was consistently being argued as an easily accessible health care system (Heggenhougen, 1980), (WHO, 1998), (WHO, 2000a).

1.7 Evidence based approach on herbal drugs

In Malaysia, adverse effects of herbal drugs were reported to the Malaysian Adverse Drug Reaction Advisory Committee (MADRAC), National Pharmaceutical Control

Bureau (NPCB) and Ministry of Health (MOH). However, most utilizers of herbal drugs were not aware of the potential adverse effects of the particular herbs (Hussin, 2001), (Ang, 2008). The list of some herbal drugs involved in adverse effects has been placed in appendices as Table 1.1.

As an overall view, the herbal drugs are part of the culture and belief for maintenance of health in Malaysian culture. The herbal drugs are also considered to be relatively cheap and hence easily affordable to the low income group **(**Abas Hj Hussin, 2001). Moreover, there is an impression that herbal drugs are safer as being natural. It is also stated that among Malay, Chinese and Indian communities, Chinese people are utilizing more herbal drugs as compared to other races in Malaysia **(**Hussin, 2001),(Jamia *et al.,* 2011),(Shahid *et al.,* 2013),(Maryam *et al.* 2012).

That concept of Ramuan referes to a blend of herb or herbal parts of plants which are selected and mixed to create pleasing or healthful effects in the preparation of food or the creation of herbal drugs. The concept of ramuan is considered most significant in its application to holistic herbal health and beauty preparations. Malaysians boosted remarkable biodiversity with a great range of plant species (Bodeker, 2009), (Shahezwan *et al.,* 2014.

1.8 Problems of herbal drugs by pregnant women in Malaysia

The pregnant women in Malaysia utilized herbal drugs in different trimesters of their pregnancy (Azriani *et al.,* 2008), (Jamia *et al.,* 2006), (Saw *et al*., 2006). Cases are reported where the herbal drugs were also used in post-delivery. These herbal drugs were utilized usually in the form of oral or local use. Most of them were utilized in the oral form (Hussin, 2001), (Azriani *et al.,* 2008), (Born *et al.,* 2005), (Badhisatta *et al.,*

2011), (Gimlette *et al.*, 2007), (Hassan, 2006), (Jamia *et al.* 2006), (Kelly *et al.*, 1999), (Nording *et al.*, 2005), (Saw *et al*., 2006). The herbal drugs / herbals commonly used by Malaysian pregnant women are listed in appendices as Table 1.2. The incidence of use by expectant mothers was unconfirmed and had been quoted as varying between 7.0% -55.0% (Tiran *et al.*, 2003), (Hussin, 2001), (Jamia, 2006), (Jamia *et al.*, 2011), (Yasser *et al.*, 2014). Some herbal drugs were also utilized for post natal care (Jamia *et al.*, 2011), (J. J. Dugoua, (2010), (Lone *et al.* 2011). Herbal drugs have played a significant role in health care delivery.

The World Health Organization (WHO) estimated that about 80% of the population of some of the Asian/African countries are dependent on herbal drugs for some aspects of primary health care (WHO, 2003a). Herbal drugs were grown from seeds or gathered from nature for little or no cost (James, 2000), (Kala *et al.*, 2007). At least 7000 medical compounds in the modern Pharmacopeias were derived from plants (James, 2000), (Kala *et al.*, 2007). The herbal drugs are the first line of treatment for more than 60% of children with high fever resulting from malaria (WHO, 2003a) in some of the Central African States. Indeed, various researchers had found that herbal drugs are effective, affordable and culturally acceptable (Heggenhougen, 1980), (WHO, 1998), (WHO, 2000a), (Eisenberg, 1993), (Hirani, 2012), (Vickers, 1999), (WHO, 1993), (Committee on use of CAM, 2005), (WHO, 1993).

Herbal drugs are also being utilized increasingly as dietary supplements to fight or prevent common maladies like cancer, heart disease and depression (Cohen *et al.*, 2000). Some of the popular herbal supplements commonly used in males are: Seville orange *(Trifoliate orange);* Enzyte (C*affeine and Ginseng*); Piascledine (S*oyabean and Avocado*); Airborne (Herbal extract); Cayenne pepper (*Capsicum annum*); Mega

garlic plus and Rasa Shastra (where metals are combined with herbs) (Jae, 2005), (Chan *et al.,* 2007), (Breenlee *et al.,* 2007), (Eisenberg *et al.,* 1995), (Goldman, 2001), (Golden *et al.,* 2009), (Heiss *et al.,* 2007), (Hirani, 2012), (Huffman, 2003), (Qi LW. *et al.,* 2011), (Wittkowsky, 2001), (Wills *et al.,* 2009).

Females utilized Triple Berry Complex, Kacip Fatima and Tong Kuei plus tablets as energy supplements mentioned (Breenlee *et al.,* 2007), (Chan *et al.,* 2007), (Eisenberg *et al.,* 1995), (Goldman, 2001), (Golden *et al.,* 2009), (Heiss *et al.,* 2007), (Hirani, 2012), (Huffman, 2003), (Qi LW *et al.,* 2011), (Wittkowsky, 2001), (Wills *et al.,* 2009). Herbal remedies could also be dangerously contaminated without established efficacy (Nortier *et al.,* 2000), (Spolarich *et al.,* 2007). Certain herbs sometimes interfere with cytochrome P450, an enzyme more suitable for drug metabolism (Nekvindova *et al.,* 2007), (Budzinski *et al.,* 2000). Medicinal herbs contain powerful, pharmacologically active compounds. Herbal drugs should be used with caution (Hussin, 2001). The current health care system which is predominantly founded on the allopathic approach, is struggling to meet the basic health needs of the people especially for ailments like diarrhoea, fever, chills, cough and cold, ulcer, diabetes mellitus, skin and fungal allergies, ease in labour, gastro-intestinal diseases and even serious problems like cancer and AIDS etc., (WHO, 2010). Moreover, general public has comparatively lower educational status and they trust to treat their illnesses by herbal drugs at affordable cost (WHO, 2010). Health care providers (physicians/academicians) were also involved in this study to evaluate the utilization and cure of herbal drugs in different diseases.

1.9 Herb / drug interaction

As herbal remedies grow in popularity it became increasingly important that users and health care practitioners knew about the potential interactions between herbs and pharmaceutical drugs (Hussin, 2001), (Ernst, 2007), (Vikers, 2007). Many herbs have powerful effects which might be increased or counteracted by pharmaceutical drugs and vice versa (Jun *et al.,* 2006). Among main findings the (Lucinda, 1998) example was Echinacea, if used for more than eight consecutive weeks could cause liver toxicity. Garlic, ginger, ginseng and ginkgo biloba, all affect bleeding time and should not be taken by patients along with warfarin. Another finding was that St. John's Wart should not be taken with monoamine oxidase inhibitors (Lucinda, 1998).

Liquorice, plantain, hawthorn and ginseng might interfere with digoxin therapy and valerian root should not be taken when barbiturates are used. Evening primrose oil is contraindicated in patients taking anticonvulsants and liquorice could offset the pharmacological effect of the potassium-sparing diuretic “spironolactone”. Immuno-stimulants such as Echinacea and zinc should not be given with immuno-suppressants such as corticosteroids (prednisone) and cyclosporine which are contraindicated in patients suffering from rheumatoid arthritis and systemic lupus erythematosus (Lucinda, 1998).

A number of herbal drugs may cause some unwanted effects (Barnes *et al.,* 1980), (Pin *et al.,* 2002), (Tiran, 2003). Furthermore adulteration, inappropriate formulation or lack of understanding of plant and drug interactions has led to adverse reactions that are sometimes life threatening or lethal (Ansari *et al.,* 2008). Proper double-blind clinical trials are needed to determine the safety and efficacy of each plant before they could be recommended for medical use (Caey *et al.,* 2007). Although many

consumers believed that herbal drugs are safe because they are of natural origin (Lichterman, 2004). It is undeniable fact that plants have an important role in the development of modern medicines. More than 60-70% of modern medicines in the global market are directly or indirectly derived from plant products. In the past few years, research has uncovered interesting and beneficial chemicals in herbs (Hussin, 2001).

1.10 Herbal - herbal interactions

Herbal-Herbal interactions are common phenomenon occurring with herbal drugs usage (Bailey *et al.,* 2004), (Chaudhary *et al.,* 2006), (Saunjoo *et al.,* 2006), (Solberg *et al.,* 2004). The interactions could be pharmacological, chemical and biochemical in nature. In most cases the induction of cytochrome P450 enzyme and the high molecular weight bioactive compounds present in herbal drugs are probable reasons for these interactions (Guengerich, 2008). In Africa, some herbal drugs are contaminated with orthodox drugs in a view to enhance the efficacy of such preparations. This factor could be averted by monitoring, evaluation and regulating agencies, by ensuring that detailed quality assurance systems were put in place (Saunjoo *et al.,* 2006).

1.11 Advantages / disadvantages of herbal drugs utilization

The herbal drugs utilization had some advantages which were as low / minimum cost, potency and efficacy, more privacy, easy accessibility and well tolerated with lower side effects. While the possible disadvantages of herbal drugs might be considered as, not able to cure rapid sickness and accidents, risk with self- dosage, complexity and standardizations (Barnes *et al.,* 1998).

1.12 Utilization of the herbal drugs during pregnancy

Herbal drugs are often promoted as natural and safe (Chen, 1999). These claims attract the pregnant women who are often concerned about their unborn child's well-being. Some studies has assessed the use of herbal drugs in pregnancy and the factors related to their utilization **(**Bailey *et al.,* 2004), (Boivin *et al.,* 2009), (Chaudhary *et al.,* 2006), (Eisenberg *et al.,* 1993), (Hedvig *et al.,* 2005), (WHO, 1993), (Riddle, 1992), (Rod Flower *et al.,* 2007), **(**Solberg *et al.,* 2004), (Saunjoo *et al.,* 2006), (Yasser *et al.,* 2014). Some of the herbals and herbal drugs, women avoid during pregnancy and lactation (Rebecca *et al.* 1992), (Rod Flower *et al.* 2007), (Kulier *et al.* 2004), (John, 2005), (Jamia *et al.,* 2011), (Yasser *et al.* 2014), (Jamia, 2006), (Jamia *et al.,* 2011), (Yasser *et al.,* 2014) and is placed under appendices as Table 1.3.

Some of the other herbal drugs/herbs are usually avoided by women during pregnancy in fear of miscarriage (Fergusson *et al.,* 2002), (John, 2005), (Kulier *et al.,* 2004), (Rebecca *et al.,* 1992), (Riddle, 1992), (Rod Flower *et al.,* 2007), (Jamia *et al.,* 2011), (Yasser *et al.,* 2014). The list is mentioned in appendices as Table 1.4.

1.13 Research questions

The research questions were structured to evaluate the utilization of herbal drugs among pregnant women, healthcare professionals (physicians / academicians) and students in Sungai Petani, Bedong, Kedah D.A; secondly the socio - demographic effects on the utilization of herbal drugs. The utilization of herbal drugs against certain indications/illness was also evaluated (Yasser *et al.,* 2014), (Muneer *et al.,* 2012), (Shahezwan *et al.,* 2014).

1.14 Justification and Inspiration for the Present Study

In Malaysia, a little research work has been carried out on the utilization of herbal drugs in pregnant women, health care professionals (physicians/academicians) and students separately (Heggenhougen, 1980). All these groups has been evaluated separately in different publications (Yasser *et al.,* 2014), (Muneer *et al*., 2012), (Shahezwan *et al.,* 2014). The inspiration of present study was to gather all these above mentioned three groups in one study. This was the major factor for inspiration and adoptation of the present study. Present study would indicate the utilization of herbal drugs towards various indications/illnesses in Malaysian pregnant women, health care professionals (physicians/academicians) and students regarding thier gender, qualification, ethnicity and status. Number of indications/illnesses mentioned in the questionnaire form were from 1-15 and are shown in appendices as appendix BM.2, BM.3, BM4 (in Bahasa Malaysia) and E.2, E.3, E.4 (in English language).

1.15 Limitations of the present study

There was difficulty faced in getting data from the pregnant women of Chinese community on the rate of background characteristics regarding utilization of herbal drugs in Pantai Hospital (private), Sungai Petani (George June, Consultant O&G Pantai Hospital, personal communication). Even these respondents were assured that the information they gave would be treated confidential as mentioned in the appendices as appendix BM.1 (consent form in Bahasa Malaysia) and appendix E.1 (consent form in English). The interviews/distribution of questionnaires was carried out in the morning time till 2.00 p.m. in the respective hospitals. One of the limitation was that pregnant women respondents stayed maximum three days in hospitals while at the University, health care professional/students were busy in other own social

activities apart from academics. Questions were in English language but translated for easiness of respondents in a National language (Bahasa Malaysia) as well. These limitations, measures and strategies did not effect on the results of the present study.

1.16 Scope of the present study

Current study will provide the understanding about the utilization and efficacy of herbal drugs among pregnant women, health care professionals (physicians/academicians) and students in Malaysia. Furthermore, pregnancy is a sensitive area where pregnant women are using herbal drugs with limited pharmacological information. So it might be fruitful to understand their concept and practices.

1.17 Objectives of the study

1.17.1 General objectives

The objective of this study was to evaluate the herbal drugs utilization by pregnant women, health care professionals (physicians/academicians) and students from hospitals and university in the State of Kedah Darul Aman, respectively.

1.17.2 Specific objectives

1.17.2.1 The utilization of herbal drugs, through valid and reliable questionnaire among pregnant women, health care professionals (physicians/academicians) and students.

1.17.2.2 To determine the effect of respondent socio-demographic characteristics on utilization of herbal drugs.

1.17.2.3 To examine the utilization of herbal drugs against various indications/illness among all groups of respondents.

1.17.2.4 The association between herbal drugs utilization/hospitals among pregnant women respondents.

1.17.2.5 The most common reasons for herbal drugs utilized among the student respondents over the campus.

1.18 Ethical approval

The joint committee of School of Pharmaceutical Sciences, USM, Penang – Lam Wah Ee Hospital, Penang on clinical studies approved the protocol of this study with reference letter No. USM-HLWE/IEC/2011 (0016) on 30.06.2012 as shown in appendices as appendix info.1.

The study was also registered with National Medical Research Registry (NMRR) and was approved by Medical Research & Ethics Committee (MREC), National Medical Research Register Malaysia (NMRR Reference I.D. 10124 (Nabila Perveen C/O Azmi Sarriff) on 14.10.2011 as shown in appendices as appendix info. 2 and appendix info. 3.

1.19 Expected outcomes of the study

The aim of present study is to find out herbal drug utilization in pregnant women, health care professionals (physicians/academicians) and students in Malaysia. The study would also help to understand how herbal drugs are being used by making estimates of number to particular herbal drugs; against number of indications/illness;

herbal drugs prescribed or self-prescribed; the extent of the herbal drugs used and the problems observed during utilization of herbal drugs.

CHAPTER 2

LITERATURE REVIEW

2.1 Literature review

2.1.1 Importance

A literature survey or review is a text written to consider the critical points of current knowledge including substantive findings as well as theoretical and methodological contributions to a particular topic (Creswell, 2007), (Cooper, 1998), (Dellinger, 2005), (Galvan, 2009), (Lamb, 2013), (Rudestam *et al.*, 2007).

2.1.2 General literature review

In the present study, the literature survey was considered adequate to start since 2000–2014 because recent research work will help to reflect on utilization trends of herbal drugs but some of the olr refrences are also added for precise review.

The literature survey was reviewed using the following: MEDLINE or MEDLARS Online (U.S. National Library of Medicine); PubMed (National Institute of Health); (PubMed Central and UK PubMed Central); Go PubMed; Bioline International; UKESSAYS.com; Internet Scientific Publications (ISPUB.com); Biological procedures online; Pub Med. Gov, Google Scholar.

Papers published (Abas Hj Hussin, 2001), (Ernst, 2007) had described the utilization and the side effects of herbal drugs in Malaysia. It mentioned that herbals should be used wisely though these drugs have a place to control certain ailments and diseases. From above results, findings by many researchers had reinforced the idea that the use of herbal drugs might not be without risk. Health care professionals should remain vigilant for potential interactions and prescription medicines (Hussin, 2001), (Ernst, 2007). Health care providers (physicians/academicians) were also involved in this

study to evaluate the utilization of herbal drugs in different diseases. It was noted that herbal drugs are safe and had no risk regarding their utilization.

Ibrahim (2006), discussed the scientific study on values of Malaysian herbal products in detail. The study concluded the real value of herbal products as medicinal agents dependent upon how much they comply with the standards set for efficacy, safety and quality. The requirements were difficult to be fulfilled by many local herbal manufacturers. The standards of quality and safety set were amended and made less stringent to ensure that local herbal manufacturers could comply with the requirements. The consumer should be made aware of the real value of herbal products and the exploitation and threat of quackery.

Bodeker (2009) and Hassan (2006) published about the health and beauty of women in Malaysia. Outer beauty is a reflection on inner health, was a notion that had passed through many generations among Malay women. In addition, men are concerned with their health and well-being throughout life. Ramuan is unique Malaysian concept, referring to a blend of plants which are selected or mixed to create pleasing or healthful effects in the preparation of food or the creation of herbal drugs (Bodeker, 2009), (Hassan, 2006). The belief in inner and outer wellness as a totality was eminent in the Malaysian culture. Many herbals were responsible for the skin care, facial complexion and many other indications. But this had to be regulated after their positive process of safety. The complete investigations for men's health and beautification in females with herbal drugs utilization must be checked on scientific bases.

Jamia Azdina Jamal (2006) stated in a published article about the Malay traditional medicine and suggested that in promoting the use of herbal medicinal products, a comprehensive programme of research and development, cultivation, production,