EVALUATION OF EDUCATION AND ECONOMIC BARRIERS IN IMPLEMENTING ESSENTIAL MEDICINES CONCEPT IN MALAYSIA

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by

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DEDICATION

I dedicate this work to my husband Bakri Elamein Yousif, my mother Amal Elimam, my father, my sons Mohammad and Omer, and my brothers Osman and Omer

Thank you for the love and sacrifices

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ABBREVIATION

DM type II	Diabetes Mellitus type II
EM	Essential Medicines
EMC	Essential Medicines Concept
EML	Essential Medicines List
FDA	Food and Drug Administration
G	Generic
IB	Innovator Brand
IPP	Intellectual Property Protection
MOH	Ministry of Health
NDP	National Drug Policy
NEML	National Essential Medicines List
NGOs	Nongovernmental Organizations
RM	Malaysian Ringgit
TNC	Transnational company
TRIPS	Trade-Related Aspect of Intellectual Property Rights
WHO	World Health Organization
WTO	World Trade Organization
WIPO	World Intellectual Property Organization

PENILAIAN KEKANGAN PENDIDIKAN DAN EKONOMI TERHADAP PELAKSANAAN KONSEP UBAT PERLU DI MALAYSIA

ABSTRAK

Walaupun senarai Ubat Perlu Kebangsaan (NEML) di Malaysia telah dilancarkan pada tahun 2000, tidak terdapat sebarang kajian yang telah dijalankan untuk mengukur tahap kesedaran terhadap konsep ubat perlu di kalangan pengamal perubatan, ahli farmasi dan pelajar-pelajar perubatan dan farmasi, atau untuk mengukur tahap keupayaan membeli ubat untuk rawatan penyakit kronik. Kajian ini mengandungi tiga bahagian. Bahagian pertama mengenal pasti pengetahuan, tingkah laku dan praktis pengamal perubatan dan ahli farmasi masing-masing di klinik dan hospital kerajaan. Dua soal selidik yang berasingan telah digunakan. Soal selidik telah dipos ke 113 klinik dan 60 hospital di Semenanjung Malaysia. Daripada bilangan tersebut, 186 pengamal perubatan (65 klinik) dan 277 ahli farmasi (44 hospital) telah memberikan respons kepada soal selidik tersebut. Nilai median pengetahuan adalah 5 bagi kedua-dua kumpulan daripada 8 poin; nilai skor median bagi tingkah laku adalah 17 dan 18 daripada 25 poin, manakala nilai skor median bagi praktis adalah 8 dan 6 daripada jumlah total 10 bagi kedua-dua pengamal perubatan dan ahli farmasi, masing-masing. Bahagian kedua telah dijalankan untuk mengukur pengetahuan dan tingkah laku pelajar-pelajar perubatan dan farmasi di universiti-universiti kerajaan di Malaysia terhadap ubat perlu dan untuk menilai kurikulum universiti jika konsep ubat perlu diajar kepada pelajar-pelajar prasiswazah. Soal selidik untuk pelajar dan kurikulum telah dipos ke 5 universiti.

Sejumlah 250 pelajar perubatan dan 314 pelajar farmasi telah melengkapkan soal selidik dengan memberikan kadar respons 60% dan 100% bagi fakulti perubatan dan farmasi setiap satu. Nilai skor median bagi pengetahuan adalah 3 dan 4 daripada 8 poin, manakala skor median bagi tingkah laku adalah 8 bagi kedua-dua kumpulan daripada 10 poin bagi pelajar perubatan dan farmasi setiap satu. Bahagian ketiga telah dilaksanakan untuk menilai tahap keupayaan membeli ubat perlu bagi rawatan penyakit hipertensi, diabetes mellitus jenis II, asma dan kombinasi penyakit-penyakit kronik tersebut. Kajian kes telah dijalankan untuk menilai kandungan preskripsi yang diperolehi daripada borang tuntutan klinik panel USM bagi tahun 2006. Tahap keupayaan membeli ubat yang digunakan telah diukur menggunakan harga ubat daripada kedai farmasi. Tahap keupayaan membeli dinilai sebagai bilangan hari gaji yang diperlukan untuk membiayai rawatan untuk tempoh satu bulan oleh staf USM yang berpendapatan paling rendah. Tahap keupayaan membeli didapati rendah bagi kebanyakan produk-produk berjenama, bagi kebanyakan rawatan kombinasi dan rawatan bagi kes-kes penyakit berganda. Justeru itu, usaha diperlukan di Malaysia untuk memfokus bagi meningkatkan kesedaran di kalangan profesional kesihatan terhadap konsep ubat perlu. Komitmen kerajaan juga diperlukan untuk memenuhi keperluan rakyat yang mengalami penyakit kronik.

EVALUATION OF EDUCATION AND ECONOMIC BARRIERS IN IMPLEMENTATING ESSENTIAL MEDICINES CONCEPT IN MALAYSIA

ABSTRACT

Although the National Essential Medicines List (NEML) in Malaysia was launched in 2000, there were no studies conducted to measure prescribers, pharmacists and medical and pharmacy students' awareness on essential medicines concept, or to measure affordability of actual prescriptions used for treatment of chronic conditions. This study consists of three parts. The first part determined knowledge, attitude and practice of prescribers and pharmacists among government clinics and hospitals, respectively. Two separate survey questionnaires were used. Questionnaires were mailed to 113 clinics and 60 hospitals in west Malaysia. Out of 65 clinics (186 prescribers) and 44 hospitals (277 pharmacists) responded to the survey. Knowledge median scores were 5 for both groups; out of 8 points, attitude median scores were 17 and 18, out of 25 points, while practice median scores were 8 and 6 out of 10 points for prescribers and pharmacists, respectively. The second part was conducted to measure knowledge and attitude of medical and pharmacy students on essential medicines in Malaysian government universities and to check university curricula if essential medicines concept is taught to undergraduate students. The survey questionnaires for students' and the curriculum survey were mailed to 5 universities. A total of 250 medical students and 314 pharmacy students completed questionnaire for a valid response rate of 60% and 100% for medicine and pharmacy schools, respectively. Knowledge median scores were 3 and 4 out of 8 points, while

attitude median scores were 8 of the two groups out of 10 points for medical and pharmacy students, respectively. The third part was conducted to evaluate affordability of essential medicines used in treatment of hypertension, diabetes type II, asthma and multiple chronic conditions of the previous diseases in Malaysia. A case study measured prescriptions contents of USM panel clinics' claim forms for year 2006. Affordability of medicines used was calculated using private retail pharmacies prices. Affordability was expressed as number of days' salary required by a USM lowest wage workers to pay for one month treatment. Low affordability was noted for most brands products, most combined treatments and all multiple chronic cases treatments. Therefore, efforts are required in Malaysia to focus on increasing the awareness of health professionals on essential medicines concept. A commitment by the government is also required to meet the needs of citizens who suffer from chronic diseases.

CHAPTER 1

INTRODUCTION

1.1 Background

1.1.1 Definition and general principles of essential medicines

The principal idea of essential medicines list (EML) is that certain medicines have more importance than others in terms of priority for treating some diseases conditions (Chirac, 2003). The essential medicines concept could lead to better access to health care through enhanced medicine management and the use of efficient financial resources. Essential medicines are one of the key primary health care elements (Quick, 2003).

According to the World Health Organization (WHO) "Essential medicines are those that satisfy the priority health care needs of the majority of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety and comparative cost-effectiveness. Essential medicines (EM) are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility" (WHO, 2004).

Essential medicines list is one of the key features of the national medicine policy and essential medicines program (Ratanawijitrasin *et al.*, 2001). Key components of a national medicine policy contains many plans include; selection of essential medicines, affordability, medicine financing, supply system, medicine regulation, rational use of medicines, research, human resources development and

finally monitoring and evaluation. All components work together for better health care for the population (WHO, 2001a).

WHO first formulated the concept of essential medicines in 1970, with definition of essential medicines (EM) in 1975 and publication of the first WHO model of essential medicines list in 1977 (WHO, 2004). The list contained 208 generic medicines, which was easily adopted by any country based on the local situations and needs. The aim was to improve quality of health and make medicines affordable, available and improve their use (Dunne, 1996). WHO works with all countries to implement medicine policies and EML, and as a result over 150 countries have an essential medicine list, three quarters of which were recently updated (Quick, 2003; WHO, 2004). Reidenberg and Walley (2004), mentioned that many rich countries applied the EML in order to improve health care and manage the cost of medicines, as EML maintains medicine affordability in the selection of EM.

1.1.2 Essential medicines concept

The reasons for implementing the concept of essential medicines are due to the following reason: (WHO, 2001a)

- Essential medicines which are selected on the basis of safe and cost-effective clinical guidelines lead to more rational prescribing, and therefore lead to higher quality of health care and better value for money;
- Training of health workers and medicine information in general can be more focused;
- Prescribers gain more experience with fewer medicines and more easily recognize medicine interactions and adverse reactions;

- Quality assurance, procurement, storage, distribution and dispensing are all easier with a few number of medicines;
- The procurement of fewer items in larger quantities results in more price competition and economies of scale**.**

All these are even more important in resource-poor situation where the availability of medicines in the public sector is often not on regular basis. Under such circumstances, measures which ensure supply of essential medicines would result in real health gains and in increased confidence in health services (WHO, 2003b).

1.1.2 (a) Practical implications of essential medicines concept

National essential medicines lists and national medicine formularies, together with clinical guidelines should serve as the basis for formal education and in-service training of healthcare professionals. In addition, they should also be used in public education about medicine use and serve as the main basis for public sector medicine procurement, distribution, as well as for medicine donations (Quick *et al.*, 1997).

Health insurance schemes often use a limited list of medicines, the cost of which they will reimburse. This is one of the most common applications of the principles of medicine selection in developed countries (Quick *et al.*, 1997). In developing countries, health insurance is less widespread, but coverage is growing and schemes are generally based on reimbursement for essential medicines. In view of the rapidly rising costs of medicines in most countries, it can be safely stated that all forms of health insurance scheme would ultimately need one process of medicine selection or another. Essential medicines lists and teaching about the benefits of medicine selection could also be used to influence practices in the private sector,

through the basic training of medical students, and programmes of continuing medical education with universities and professional associations (WHO, 2001a).

1.1.2 (b) Challenges facing essential medicines concept

There may be opposition to the use of the essential medicines list. Prescribers may see it as placing some restrictions on their clinical freedom, while pharmacists may be worried about the financial implications. Manufacturers may have fears of their market being eroded, and consumers may think they are being offered second-rate, cheap medicines. If these concerns are not addressed, the concept of selection and the use of an essential medicines list may not be accepted. This is the reason why medicine selection process should be consultative and also justifies why informing and educating those affected is important (Quick *et al.,* 1997).

1.1.2 (c) Barriers to implementing essential medicines concept

According to Tetteh (2007), access to essential medicines reduces disease burden. However, lack of access to EM is still a wide spread problem worldwide (Laing *et al.*, 2003). Many factors affect access to essential medicines and hinder the implementation of the essential medicines list (EML) and essential medicines concept (EMC) in many countries; these factors thus act as barriers to medicines reaching the public. These barriers are:

i. Medicine availability

Many people throughout the world cannot obtain the medicines they need because the medicines are not available (WHO, 2001a). In a book authored by Zafrullah Chowdhury (1995), developing countries' population which account for

about 75% of the world population consume only about 14% of the medicine supply for the whole world, which indicates low availability. In addition, Chowdhury (1995), further mentioned that irrational medicine use is common due to the promotion of many brands even though in the developing countries the largest numbers of brands are found due to lack of developed regulatory systems and quality control mechanisms**.** Medicine availability is one of the main barriers preventing essential medicines from reaching the public in the poor countries (Pécoul *et al.*, 1999). Moreover, the major barrier in poor countries is the prevention of availability of the essential new medicines needed for treating diseases such as TB, multidrug resistant malaria, etc (Ruxin *et al.*, 2005).

ii. Economic barriers

Lee *et al.*, (2002), define affordability as free access to good and services without economic barriers. Therefore, high costs of medicines make medicines poorly accessible to the public even for important treatments in rich countries (Lopert *et al.*, 2002), because high costs lead to affordability barrier to medicines (Tetteh, 2007). In the United States there is no regulatory mechanism to medicine prices, therefore one in every four elderly patients limit their medicine use because of high prices (Ellner, 2003). Economic barriers due to costs of treatment and fees for services make health care unaffordable to individuals. Medicine affordability affects all social groups in all countries, but the poor are the most affected (Shalev, 2004).

Transnational companies (TNCs) market their medicines all over the world; some of the medicines may be of doubtful efficacy. However, TNCs have little or no concern regarding the usefulness of these medicines or about the serious adverse reaction they cause as they do about obtaining high profits, thus resulting in high

medicine prices (Chowdhury, 1995). Research and development (R&D) is an additional reason for high cost of medicines, although few therapeutic gains may be recorded especially in third world countries where there is poor medicine regulatory machinery (Chowdhury, 1995; Pécoul *et al.*, 1999). In low income countries combined effects of taxes, duties, distribution costs and retail margins result in a final medicine price that is commonly more than double and sometimes 35 times the producer or importer prices (Quick, 2003). WHO (2001a) is concerned with this phenomena because this result in many people all over the world not being able to obtain the medicines they need because it becomes unaffordable.

The problem of increasing medicine costs is not restricted to developing countries. As most of the cost increases may be due to the introduction of new medicines, medicines selection becomes important even for rich countries. Therefore, the concept of essential medicines is not that of the developing countries alone (Hogerzeil, 2004).

iii. Education barriers

Doctors see medicines as means of stopping illness and are often bothered that pharmaceutical industries' concern is mainly for profits because of:

- the economics of medicine production;
- health care marketing strategies of medicine industries; and
- high medicine costs and affordability.

These are usually not apart of the medical education curriculum in many developed and third world countries. Therefore, this lack of knowledge can make doctors easily convinced by the marketing promotion of pharmaceutical companies about new medicines and by any hints regarding their clinical freedom restriction.

Eventually, the patients are the apparent purchaser of medicine of choice of their medicine as prescribed by the doctors. Therefore, doctors must have knowledge and be aware of the pharmaceutical situation and essential medicines concepts (EMC) which allows them to prescribe medicines as a matter of priority (Chowdhury, 1995).

According to Laing *et al.*, (2001), in most developing countries, regular education of healthcare professionals is minimal, with little incentives for participation in continuous education programmes for promotions rather than to improve the quality of health care. Therefore, the production of printed bulletins and pharmaceutical newsletters can help to increase healthcare professionals' awareness of EMC. In addition, Ruxin *et al.*, (2005), stated that human resources inadequacies such as decline in number of pharmacists and technicians are one of the major barriers for access to essential medicines. On the other hand, Quick (2003) mentioned that presently, at least 88 countries have introduced the essential medicines concept into the curricula of medical and pharmaceutical students. Many people all over the world cannot obtain the medicines they need because there are no trained personnel to prescribe (WHO, 2001a).

Many countries frequently lack adequate supplies of medicines. The reason behind medicine shortages may indicate attitude and behavior of the government, prescribers and dispensers (WHO, 1988). Organized physicians have opposed EMC in many developing countries (Kanji and Hardon, 1992). Educational programs and strategies must be applied for health students, physicians, nurses and pharmacists to improve their attitudes and behaviors towards EMC (WHO, 1988). Knowledge and attitude of healthcare professionals are important factors for implementing specific concepts. Health professionals were prevented access to some medical use of medicines due to their attitudes and knowledge toward that medicine. An effort is

made to educate physicians and nurses about the principle of palliative care (Rajagopal and Joranson, 2007).

Healthcare professionals (prescriber and dispenser) should provide essential medicines (EM) as a matter of priority, to help people to select their medicines between the thousands of promoted medicines. This improves the essential medicines list (EML) implementation by bridging the gap between the theory of essential medicines list document and the actual implementation in the field.

iv. Patent regulations

Patent is a property right granted by a sovereign state to a product that has not been previously disclosed else where in the world. Patent gives the owner the right to prevent others from making, using, offering for sale or selling the product for a period of 20 years (Lehman, 2003).

Although developments in Intellectual Propriety law in the wake of WTO's Doha Declaration affirmed the priority of public health over the protection of patents, it agreed that the 50 least developed member country are not obliged to implement the patent law for pharmaceuticals until January 1, 2016 (Lehman, 2003). The Doha declaration acknowledged the short sightedness of the TRIPS agreement rule mandating that member countries could break patent only in public health endogenously, in order to produce generic medicine for local markets. Therefore, developing countries without local industries producing medicines will limit access to essential medicines (Westerhaus and Castro, 2006), but access to patent generic medicine from other countries remain restricted.

Patent is controlled by World Intellectual Property Organization (WIPO) and World Trade Organization (WTO). In case of WTO patent regulation are contained

in the agreement of Trade-Related Aspect of Intellectual Property Rights (TRIPS). Under the present intellectual property regulation a patent may protect the sale of medicines for as long as 35 years, putting those medicines out of reach of poor people because of high prices (WHO, 2006). Moreover, according to Chowdhury (1995), patents enable pharmaceutical industries to adopt high prices. A third of the world's population' lack of access to quality medicines is due to patent protection of many essential medicines. Stronger protection of patents through introduction of patent protection stronger than required under WTO rules, strong intellectual property protection (IPP) and strengthened global rules under TRIPS make medicines unavailable and not affordable to the public (Bale, 2004). WTO rules on TRIPS encourage pharmaceutical industries to put patents as priority over public health care concerns (McDonald, 2007).

Furthermore, to increase access of patients to essential medicines, the medicines should be made affordable because high prices of medicines put them beyond reach of the public even in rich countries. In addition, patents maintain medicines prices high, which far exceed their cost of innovation (Henry and Lexchin, 2002). This means that TRIPS Agreement standards are a factor that limits access to medicines because it does not allow the availability of affordable medicines, due to reducing generic competition in the pharmaceutical market. Therefore, patent of pharmaceutical products does not only limit access to medicines but also elevates medicines prices (Cohen, 2006). In addition, Quick (2003), noted that appropriate use of TRIPS by any country makes cost of new medicines more affordable by patients.

v. Technical barriers

One of the barriers to access to essential medicines is technical barriers. These barriers include counterfeit medicines (Anonymous, 2002; Pécoul *et al.*, 1999), also, John Bell, President of the Commonwealth Pharmaceutical Association, mentioned other factors contributed as a technical barriers to access essential medicines such as in-effective distribution system, non-existent or corrupt regulatory procedures, absence of rational medicine use strategies and lack of pharmacovigilance (Anonymous, 2002).

vi. Political barriers

According to Ellner (2003), political resistances are mainly from pharmaceutical companies which worry or limit their incentives to innovation. In addition, patients may think that essential medicine list (EML) prevents them from access to new medicines and their unique needs for medicines. Kanji and Hardon, (1992), noted that pharmaceutical industries oppose EMC in many developing countries. Limited or no manufacturing to pharmaceutical products by a country is a barrier to access medicines to the population (Cohen, 2006). Many countries have frequently lacked adequate supplies of medicines. Reason behind medicine shortage may indicate attitude and behavior of consumers and the medicine industries (WHO, 1988).

There is great need for political commitment to make implementation of EMC a reality. Therefore, evaluation of these barriers helps to put all hands on check to understand the strengths as well as weaknesses. However, evaluation of these barriers help in updating EML in an evidence based approach rather than experience based.

The study focused only on education and economic barriers because they are major barriers, and there are problems reported about the two barriers. In addition medicines availability was investigated by two researchers in all different sectors all over the country (Saleh and Ibrahim, 2005; Babar *et al*., 2007). Also the three other barriers are relatively minor barriers.

1.1.3 Promoting the essential medicines concept

There have been lots of benefits recorded with the use of essential medicines list in the public sector. However, in most low- and middle-income countries, the majority of the people are treated with medicines from the private sector, paid for out-of-pocket. Often, these consumers are prescribed or dispensed as high-priced medicines, often in small quantities, rather than as therapeutic amounts of essential medicines. Promotion of non-essential medicines often results in over-treatment of mild illness, inadequate treatment of serious illnesses and overuse of antibiotics. Widespread prescription and sale of non-essential medicines means that households, especially poor households, are not getting the best health care value for their money and may ultimately not receive the treatment they need (WHO, 2001a).

WHO vision that people all over the world should have access to essential medicines (EM) which they need medicines that are safe, effective, and of good quality and that the medicines are prescribed and used rationally. Access to EM especially for HIV/AIDS, tuberculosis (TB) and malaria are critical to global efforts by WHO to prevent millions of death each year, reduce peoples' suffering and help reduce the diseases treatment cost on the poorest families. WHO estimates that over 10.5 million lives per year could be saved by 2015, also boosting economic growth and social development by expanding access to existing interventions for infectious

diseases, maternal and child health, and no eradicating communicable diseases. Medicines' cost is the second highest expenditure after staff salaries in many developing countries. It is also the second highest household expenditure after food (WHO, 2004). Health is fundamental human rights. Highest access to health care, which include access to EM is a prerequisite for realizing those rights. This means that essential medicines are a human right i.e. a part of the right to health (Hogerzeil *et al.*, 2006).

WHO goal is to help save lives and improve health by ensuring medicines quality, efficacy, safety and rational use of medicines including traditional medicines, and by promoting equitable and sustainable access to EM, particularly for the poor. EM save lives, reduces sufferings and improves health situations, but only if they are of good quality and safe, available at low prices and properly used. WHO (2004) further stated that in many countries today not all these conditions are being met.

Essential medicines (EM) have a huge economic impact on countries and household in developing countries. Due to high prices, medicines account for 25% - 70% of all health care expenditure, compared to less than 15% in most high income countries. For governments and NGOs providing primary health care, medicines are the largest expense after personnel costs. For households in low income countries, medicines represent 50% - 90% of out of pocket spending on health, yet in some countries less than half of people living in poor households receive all the medicines they need for curing illnesses, with one third receiving none of the medicines they need (WHO, 2004).

The reasons behind higher access to essential medicines and those efforts that are needed to close the gap to access is attributable to fundamental economic, social and educational factors that directly affect the health sector (Quick, 2003).

The main projects to improve the use of medicines is to establish procedures for developing and revising an essential medicine list (or hospital formulary) based on treatments of choice, and to encourage targeted, problem-based in-service educational programs by professional societies, universities and the Ministry of Health, and request for regular continuing education for the licensure of healthcare professionals (Laing *et al.*, 2001).

1.1.4 Advantages of essential medicines list

Essential medicines play a crucial role in many aspects of health care. Limited list of essential medicines lead to easy procurement; efficient storage and distribution due to low stocks, and this may minimize medicines wastages; and assured quality and easy dispensing (WHO, 2003a). In addition, it is also helpful for prescribers in focusing on few medicines, which result in more experience, better recognition of adverse medicine reaction, more rational use as in case of Mexican EML, where the list is used as a good instrument for rationalization of medicine therapy (Kravzov and Altagracia, 1994). Also it focuses education efforts of patients to reduce confusion and increase adherence to treatment (Quick *et al.*, 1997).

Moreover, EML is an aid to the following:

- Procurement, due to the bulk purchase of generic medicines which is often of lower cost than the brand;
- It makes for competition between generic suppliers and leads to lowering of prices;

- Choice of specific medicines helps in possibility of lower medicines waste (Redenberg, 1996); and
- EML also is used in medicine distribution and procurement and for the development of national formulary (NF) (Laing *et al.*, 2001);

Furthermore, EM enables health authorities and policy makers to ensure those medicines are available on all health care system levels; it helps people to choose their treatments between large numbers of promoted medicines; it also helps healthcare professionals to know medicines that must be prescribed and dispensed as a matter of priority (Chirac, 2003). As in the case of Mali where NDP aimed to make medicines more available while improving appropriate uses by rational prescribing (Maïga *et al.*, 2003). The national essential medicine list shows public health priorities which help policy makers to know the country's national priorities for public procurement and reimbursement and for training and educating healthcare professionals (Smith and Tickel, 2003). The most important is EM are those that are aimed at reducing morbidity and mortality in the developing countries (Pécoul *et al.*, 1999).

1.1.5 Selection of essential medicines

Essential medicines (EM) are one of the main basic principles of a national medicine policy because it helps to set all requirements of the pharmaceutical system (WHO, 1988). Medicine selection, preferably linked to national clinical guidelines is a crucial step in ensuring access to essential medicines and in promoting rational medicine use, because no public sector or health insurance system can afford to supply or reimburse all medicines that are available in the market (Hogerzeil, 2003).

The selection of essential medicines is a two-step process. Market approval of a pharmaceutical product is usually granted on the basis of efficacy, safety and quality and rarely in the comparison with other products already in the market or based on cost. The regulatory decision defines the availability of a medicine in the market. In addition to this, most public medicine procurement and insurance schemes have mechanisms to limit procurement or reimbursement of medicine costs. For these decisions, an evaluation process is necessary, based on a comparison between various medicine products and in considerations of value for money. This second step leads to a list of essential medicines.

1.1.5 (a) Selection criteria

The treatment recommended and the medicines selected depend on many factors such as; the pattern of diseases prevalence, treatment facilities, the training and experience of available personnel, financial resources and genetics, demographic and environmental factors. The type and number of essential medicines selected depends on the circumstances in which the medicines are to be used, but the selection should be based on the EMC and in particular, on the following criteria which are used by the WHO expert committee on the use of essential medicines, that only medicines for which sound and adequate evidence of efficacy and safety in a variety of settings is available should be selected. Relative cost-effectiveness is a major consideration in the choice of medicines. In comparing between medicines, the total cost of treatment - not only the unit cost of the medicine – must be considered. Also, it should be taken into account the treatment in relation to the savings (i.e. surgery and hospitalization) and be compared with its efficacy; in some cases, the choice may also be influenced by other factors such as pharmaco-kinetic properties or by

local considerations such as the availability of facilities for manufacturing or storage. Different rates of success of treatment are achieved as a result of improved patients' compliance. Reduction of loss or wastage achieved by using more stable products; selection of pharmaceutical products and dosage form which provide the most favorable benefit / risk ratio; each medicine selected must be available in a form in which adequate quality, including bioavailability can be ensured; its stability under the expected condition of storage must be determined (WHO, 2001a; Quick *et al.*, 1997; WHO, 1988).

Most essential medicines should be formulated as single compounds. Fixed-ratio combination products are acceptable only when the dosage of each ingredient meets the requirements of a defined population group, and when the combination has a proven advantage over single compounds administered separately, in terms of therapeutic effect, safety or patient adherence to treatment (WHO, 2001a; Quick *et al.*, 1997; WHO, 1988).

Selection must be by medicines international nonproprietary (generic) name. If necessary, a cross-index of nonproprietary and proprietary names should be supplied to prescribers and dispensers (WHO, 1988). According to Loff (2003), the benefits of the use and selection of the few numbers of medicines is to improve medicine supply, more rational prescribing and medicines affordability by decreasing medicine prices through bulk purchase of generic medicines. The cost-benefit ratio is the major concern in selecting some medicines to be in the essential medicines list. In other words, selection of EM should be based on the list of pathogenic conditions and complaints and the treatment of choice for these conditions as in the standard treatment guidelines. Therefore, EML is the next step after forming standard treatment guidelines by any country. Manufactures should not be involved in the

decision making process of defining an EML to prevent conflicts of interest (Laing *et al.*, 2001).

1.1.5 (b) Committee for selection of essential medicines

Committee for selection of the essential medicines includes a wide range of geographical and professional backgrounds, including clinical pharmacology, clinical medicine, international public health, guideline development methodology, systematic literature search methods, risk-assessment and cost-effectiveness analysis. Patient advocacy groups and representatives of the health care industry are invited to comment on the applications and draft recommendations, but are not invited to attend decision-making meetings of the Expert Committee (WHO, 2001b).

1.1.6 Updating essential medicines list

Essential medicines list (EML) update should be done by an expert advisory committee that consists of clinical pharmacologist and physicians. Updating takes into account new information on medicine efficacy, safety, risk-benefit and data about cost-effectiveness. In other words, updating is due to adapting changes in new medicines, new indications, new diseases, discovered adverse effects and development of resistance. The list of essential medicines should have to be updated every two years (Chirac and Laing, 2001; Chirac, 2003)

1.1.7 Essential medicines for special cases

1.1.7 (a) Essential medicines for children

Essential medicines for children are those medicines for use by pediatric only. In the past FDA criteria for selection EM for children was that medicine

content used in therapy of neonates has therapeutic value document, data for dosage recommendation, therapeutic indication and toxicity; finally, current labeling for neonatal use must exist, then frequency of use, low therapeutics index, reports of serious toxicity of the medicine (Kauffman, 1999). According to Hogerzeil (2006), WHO is boosting EM for children which aims firstly for the prequalification of pediatric medicines for treating AIDS, TB and Malaria and secondly, ensures suitable pharmaceutical formulation for children for all childhood disease in the EML to help fill up the gap to access EM. For this purpose, UNICEF and WHO hope to make access to EM for children because many pharmaceutical industries do not want a progress to EM for children, so that there are no pediatrics formulation withdrawal of many pharmaceutical preparations for children from markets and no registration of these products in many countries. Moreover, many medicines are not in suitable formulations and there is no funding for children (Anonymous, 2006).

1.1.7 (b) Essential medicines for rare diseases

Orphan medicines are medicines for rare diseases or low prevalence disorder. Some developed countries developed this policy for individual patients with rare disorders, although WHO has not boosted the rare essential medicines yet, but it is in use in the United State of America and European Union (Stolk *et al.*, 2006). Reidenberg (2006) noted that the orphan medicine is not an absolute essential medicine unless identified as “essential”.

1.1.8 Implementation of Malaysian essential medicines list

The initial idea for implementing national essential medicines list (NEML) in Malaysia was in 1996. The idea came from the fact that, there must be some

measures to obtain health care cost of medicines especially in the private health sectors in order to maintain this sector at an affordable level. Also one of the aims of implementing NEML was to maintain medicines prices (MOH, 2006a).

The Malaysian national essential medicines list was launched on January 27, 2000; the list was developed in four years. Table 1.1 shows a chronology of major events before implementing the national essential medicine list.

Table 1.1: Chronology of major events before implementing the national essential medicine list in Malaysia

Date	**Event**
January 31st, 2000	Editorial Voice : Status Quo in medicine use
January 30th, 2000	Essential medicines and telehealth
January 27th, 2000	Launching Ceremony – National Medicine List
December 5th, 1999	Profit takes priority over care
August, 1999	Excerpt of MMA-PhAMA Dialogue Report on NEML
March 22nd, 1999	National Essential Medicine List Seminar in Kuala Lumpur
February 11st, 1999	6thMeeting of National Essential Medicine List in Kuala Lumpur
July 4th, 1998	Internal Circulation of Draft National Essential Medicine List
July 2nd, 1998	5thMeeting of National Essential Medicine List in Kuala Lumpur
June 25th, 1998	Going Generic and Bringing Health to All
September 5th, 1997	Seminar on Essential Medicines Concept – An International Perspective
June 23rd, 1997	4thMeeting of National Essential Medicine List in Kuala Lumpur
October 25th, 1996	3thMeeting of National Essential Medicine List in Kuala Lumpur
September 3rd, 1996	2thMeeting of National Essential Medicine List in Kuala Lumpur
April 22nd, 1996	Malaysian Pharmaceutical Society rejected a proposal supporting National Essential Medicines Lists at its 29th AGM held in Kuala Lumpur

"Table 1.1 Continued"

Date	Event
March 21st, 1996	Inaugural meeting on National Essential Medicines List in Kuala Lumpur
March 2nd, 1996	National Essential medicines List hailed
February 17th, 1996	Announcement by the Health Minister in the local press
February 16th, 1996	Press Release : Medicine Prices in Malaysia (Excerpt of Proposal)

Source: USM Poison Centre Archive

The list was developed by the Ministry of Health together with the Malaysian Pharmaceutical Society, the Federation of Private Medical Practitioners, the Malaysian Medical Association, the Pharmaceutical Association of Malaysia, The Malaysian Organization of Pharmaceutical Industries, Universiti Kebangsaan and Universiti Sains Malaysia (Ritikos, 2000).

The NEML was formulated using the Ministry of Health's (MOH) Medicines List as a basis. The MOH Medicines List which was introduced in 1983 serves as the essential medicines list for the public healthcare sector. Every medicine in the list was classified according to the category of medical officer or healthcare provider allowed to prescribe it. The list is dynamic and is reviewed every 4 months by a panel consisting of specialists from the main disciplines and pharmacists (MOH, 2006a).

The committee for creating the National Essential Medicines List decided that the List shall consist of two parts. The first part called the Essential Medicines List contains all preparations needed for primary and secondary healthcare treatment commonly used by medical officers and paramedics in primary healthcare facilities. Several preparations used in tertiary care are included in order to be consistent with

WHO's model of Essential Medicines List. This part contains 358 chemical entities and 605 preparations (MOH, 2006a).

The second part called the supplementary List consists of medicines used by specialists for tertiary level treatment. This part contains 257 chemical entities and 391 preparations. While government's hospitals have used a list of 680 generic medicines since 1983, this is the first time such a list has been extended for private sector use. The Malaysian Health Minister Datuk Chua Jui Meng said "the formation of the list expects to bring down the cost of medicines as well as the healthcare, because the prescription of generic medicines brought down the cost by 50 to 70 per cent as mentioned in WHO report" (Azhar, 2000).

Committee for selection of NEML included representatives from various sectors such as relevant government agencies, professional bodies, universities and the pharmaceutical industry. Sub committees were set up to help in various aspects of the list (MOH, 2006a):

- medicines list contents
- medicines prices
- medicine information
- logistics

Prices for all the medicines are provided in a separate book (Abdul Razak, 2000).

1.2 Problem statement

1.2.1 Health professional awareness on essential medicines in the Western Pacific Region

WHO reported that in the Western Pacific Region, health workers have misconceptions about the essential medicines concept. They think that essential medicines have low efficacy and quality, cheap and may not satisfy patients' need. Moreover, healthcare professionals think that their clinical freedom may be restricted by adhering to the list of essential medicines (WHO, 2005). This misconception may be due to the fact that there is no education for professionals as well as students for the medicine policy and the concept of essential medicines; or could be due to their negative attitude toward essential medicines. Low awareness and acceptance of essential medicines concept can act as a barrier to implementing this concept in the country.

1.2.2 Medicines affordability in Malaysia

It is a fact that in Malaysia, there is no regulatory system for medicines prices. This justifies why many essential medicines used in treatments of many chronic diseases are not affordable. Furthermore, Malaysia depends on imports of medicines, although the essential medicines list enables the country to focus on becoming self-reliant where the generic equivalence of essential medicines can be manufactured and popularized to meet health needs for the majority of the people (Ibrahim and Bahri, 2003). According to Azhar (2006) in Malaysia imported medicines prices have rise by up to 28 per cent annually in the last 10 years, especially daily used medicines. In addition, Chowdhury (1995), reported that most medicines prices range from 10-293% higher than in Australia and the UK. In

addition, prices are not stable, which increases annually by 20.7% when the rate of inflation was 7%.

A survey on these prices was done by (Babar *et al.,* 2007), which showed median prices ratios for some medicines for innovator brand (IB), the most sold generic (MSG), and the lowest priced generic (LPG) for government procurement prices, private retail pharmacy, and dispensing doctor sector as shown below (Table 1.2).

Table 1.2: Medicines prices in different sectors comparing with international reference price

Sectors	IB	MSG	LPG
Government purchase price	2.4 X	1.56 X	1.09 X
Private retail pharmacies	16 X	6.89 X	6.57 X
Dispensing doctor	15 X	7.5 X	7.5 X

X=Times the international reference price

In addition, the study finding shows that most medicines in private sector have higher prices than the public sector and international reference prices; those medicines include off-patent one's.

High medicine prices justify why some medicines of chronic diseases are not affordable. Chronic diseases need treatment for a life time. Therefore, if patient cannot afford medicines, this could lead to more serious illnesses and complications.

1.3 Rationale of the study

In Malaysia national EML was launched in January 2000, and there is no study has been conducted to look into this issues recorded to the implementation of the EMC. This study, as the first of its kind in Malaysia, it considered as an important contribution, especially because it provides baseline evidence to monitor changes regarding transitions toward essential medicines concept' awareness among practitioner as well as future healthcare professionals. In addition, problems of medicines affordability are still reported after the launched of EMC, although the two studies were using hypothetical methodology regarding treatments.

In the absence of data regarding to what extent practitioners and future health professionals know about the essential medicines concept, a survey based study is the most suitable methodological approach in our setting. Health workers included are prescribers, pharmacists, and the future health professionals such as medical students and pharmacy students, to ensure that students know about the concept of essential medicines before graduation, because there might be no time for them to know or to consider issues such as the concept of essential medicines after graduation.

Awareness of practitioners and future health workers on the essential medicines concept is important because they help consumers to select their medicines between the thousands of promoted medicines and improve the implementation of the essential medicines concept by filling the gap between the theory of essential medicines and the actual implementation of the list. Their misconceptions act as a barrier to implement the concept of essential medicines.

Although medicines are free of charge in the public sectors, but when it is not available, or prescription does not include all medicines for a month's therapy to treat chronic diseases, patient would have to buy their medications from the private