CHAPTER 1

INTRODUCTION

Situation and Problems of Drug System Management

Drug System Management (DSM) is directly related to a country's ability to address health concerns. Many drug systems and programs run into difficulty of achieving their goals because they have not addressed how the drugs, essential for live saving and health improving, will be managed. DSM is a set of practices aimed at ensuring the timely availability and appropriate use of safe, effective, quality and services in any health care setting. These activities are organized according to functional components of a system. Activities in the DSM are related to the selection of drugs which are circulated in the drug system. The procurement, storage and distribution, and use of drugs are also involved. DSM is also affected by a political, legal, and regulatory. The capacity to carry out these activities is mediated by the level of management support that is available. Management support includes information systems, human resource capacity, and financial resources (WHO, 2007).

In many countries, WHO guideline had been used to develop DSM for a better health care system. Especially in developing countries, they faced severe problems including procedures in selection, quality control, economically procurement, etc. These problems had been documented in numerous reports and publications (MSH, 1981; Quick and Foreman, 1989; Rankin and Korn, 1991; and WHO, 1992). World Health Organization (WHO) which is an agency of the United Nations (UN), plays an important role involved with the DSM in developing of an assessment tool for the developing countries to solve their problems.

Many international organizations involved the DSM by establishing of various assessment tools. As for the international organizations, WHO published the World Drug Situation in 1988 which presented an impressive amount of useful information in indicator format. Another group is the International Network for

Rational Use of Drugs (INRUD), a network promoting rational drug use in developing country. It is coordinated by Management Sciences for Health (MSH) with technical support provided by the Harvard Drug Policy Research Group. The INRUD developed drug use indicators which subsequently have been adopted by WHO to be used as the Manual of "How to Investigate Drug Use in Health Facilities" (WHO, 1993). The WHO action programme on essential drugs established model indicators for monitoring of the national drug policies in 1994. These model indicators were intended to be used for developing countries to assess their drug systems. In 1995, WHO worked with research groups including the Harvard School of Public Health and the Centre de Researches et d'Etudes pour le Developpement de la Sante (CREDES – Paris, France) to develop the indicators for field testing in health facilities. Finally, WHO developed the using indicators to measure the country pharmaceutical situations in 2006 and created an operational package for assessing, monitoring, and evaluation of the country pharmaceutical situations in 2007.

The most of developed countries published their own set of indicators related to DSM as follows. Firstly, United Kingdom (UK) created drug purchasing & supply and drug prescription indicators by the Prescribing Indicators National Group (PING) in 2002 and National Health Service (NHS) in 2009. Secondly, in the United States of America (USA), the rapid pharmaceutical management assessment by Management Science for Health (MSH) in 1995 and the pharmaceutical benefit management were developed by Health Care Financing Administration (HCFA) (Chawla et al, 2001), the health plan employer data and information was set by National Committee for Quality Assurance (NCQA) in 2001, the pharmacy information system indicators were created in 2001 by Qualidigm, and the hospital accreditation programe was developed by the Joint Commission on Accreditation of Health Care Organization (JCAHO) in 2010. Thirdly, Canada developed drug utilization indicators by Prescription Drug Utilization Standards and Reporting System (PDUSRS) project of the Canadian Institute for Health Information (CIHI) in 2002 and created pharmacy practice in hospital and pharmaceutical economic indicators by Health Canada in 2003. Finally, Australia created management of drug system, drug use in hospital, pharmaceutical care in hospital, and drug and therapeutics committees (DTCs) by Therapeutic Assessment Group (TAG) in 1998,

pharmaceutical benefit scheme in 2004 by Department of Health an Aging, prescription medicines in 2005 by Therapeutic Goods Administration (TGA).

All of the set of quality indicators (QIs) have been used for years in developed countries to assess the aspects of DSM. From the experiences of many countries using the different tools focused on the success of achieving the objectives of DSM, many countries often have similar problems of irrational drug use, drug unavailability, etc. Different intervention strategies had been implemented to address these problems. Their successes depended on many factors, including the availability of trained human resources, infrastructure, cultural factors and the socio-economic situation. Solutions that were effective for one country might be not necessarily effective in another.

In Thailand, there were many organizations affiliated with Ministry of Public Health (MOPH) using QIs of international organizations for assessing the DSM in Thailand. They were as follows; (1) Office of the Permanent Secretary under MOPH published "The Improving Efficiency on DSM" in 1998 and "The Measure of Efficiency Improvement on DSM" in 1999 with criterion for assessing the DSM of hospitals under MOPH (Office of the Permanent Secretary under MOPH, 1998; 1999); (2) The Drugs and Medical Supplies Information Center (DMSIC) developed the drug information (DMSIC, 2011) ; (3) Bureau of Inspection and Evaluation created QIs for monitoring and evaluation of DSM at the community hospitals (Bureau of Inspection and Evaluation of the MOPH, 2010); (4) the Healthcare Accreditation Institute developed a set of medication safety indicators (HA Institute, 2011); and (5) National Health Security Office (NHSO) created indicators of drug information and drug use to assess the medication safety in the hospitals, both of public and private sectors (NHSO, 2011). Furthermore, some academic institutions such as Pharmaceutical System Research and Intelligence Center (PSyRIC) and Thai Drug Watch also involved in developing of the QIs.

In the present, the performance of Drug System Management of the hospitals showed that drug expenditure increase from 32.88% of overall health expenditure in 1997 to 46.39% in 2008. The drug expenditure of 46.39%, or nearly half of overall health expenditure in 2008, was mostly on curative care (Wibulpolpresert, 2010). It was agreed with the allocation of 60% to 66% of the

government budget for hospital-based services (National Statistical Office Thailand, 2010). Furthermore, the DMSIC under MOPH reported that the drug expenditures had increased from 17,485 million baht in 2006 to 25,549 million baht in 2009 (DMSIC, 2009). Data of the over drug expenditure indicated that, somehow, DSM in Thailand was unsuccessful or inefficient.

Because of the inefficiency of the DSM, community hospitals faced up with two main problems. The first problem was about the performance of DSM at the community hospitals such as severe increase of drug expenditure and drug budget (Aunsanun, 1999; Wibulpolprasert, 2010; DMSIC, 2009; Bureau of Inspection and Evaluation, 2009); expired drugs (DMSIC, 2009; Bureau of Inspection and Evaluation, 2009); increase of drug items in hospital formulary (Aunsanun, 1999; Sripairoj, 2006); low quality of drugs (Supasirivitaya, 2006; Tongpue, 2007; DMSIC, 2009; Bureau of Inspection and Evaluation, 2009); irrational use of drugs (Ningsanon and Ratanavijitrasin, 2008; Prapanwattana, 2010); inappropriate drug availability; breach of procurement regulation; inefficient regulatory and monitoring of DSM especially in regard to drug storage, drug distribution, and drug utilization; inadequacy of health personnel, inappropriate use of resource (Sripairoj, 2006); limitation of drug information (DMSIC, 2009); and uncovered monitoring and evaluation of DSM. The second problem was about the QIs (PSyRIC, 2007; Thai Drug Watch, 2009; Phianchana and Amrumpai, 2010) such as unclear definition of indicators by executive or policy-makers; complex indicators of many organizations; complication of some indicators with different criteria, measurable only some issues of DSM; incomparable the results of DSM between the hospitals; and unrepresented to the overall DSM performance.

All problems mentioned above were involved the 10 key issues of DSM. Therefore, it has been questioned that "Do the QIs used for monitoring and evaluation of DSM obviously have evaluation potential QIs covering all the 10 key issues of DSM?" Consequently, this study was focused on development of potential QIs for assessing DSM at the community hospitals. If the QIs can reflect the performance by covering all 10 key issues of DSM, it is believed that DSM should be in success and the goal of National Drug Policy (NDP) will be achieved.

Research Questions

What are the potential QIs that obviously represent the efficiency of DSM performance in community hospitals?

General objective

To develop a set of potential QIs for assessing DSM performance of the community hospitals.

Specific objectives

1. To gather the QIs from international organizations and organizations in Thailand following the key issues of DSM.

2. To select the QIs that have potential to represent the efficiency of the success of DSM performance.

3. To test ability of the set of potential QIs for assessing the DSM performance.

Education/application advantages

1. The set of potential QIs will be obtained for assessing the DSM performance at the community hospitals.

2. The results of this study would be useful for administrators and policy makers of MOPH to plan and develop the monitoring and evaluation processes to maximize efficiency of DSM performance.

Definitions

1. **Drug System Management (DSM)** refers to the management that reflects the performance of the DSM at the hospitals under MOPH to achieve NDP's goals. DSM composes of 10 key issues as follows.

1.1 Drug policy and regulation refers to the QIs which effectively measure the guideline of policies and regulations related to DSM.

1.2 Financing and budgeting refers to the QIs which measure the participation in allocating of the financing and budgeting with equity, accountability,

cost effectiveness, and self-reliance and to measure the appropriateness and worthiness of drug expenditure.

1.3 <u>Knowledge management</u> refers to the QIs which measure the development and support of knowledge to the medical professions in the same direction and consistency with the current situation.

1.4 <u>Human resource</u> refers to the QIs which measure the role of pharmacy and therapeutic committees (PTCs) in management of the drug system at the community hospitals continuously.

1.5 <u>Drug selection</u> refers to the QIs which measure the use of drug items according to patterns of drug use and standard treatment guidelines.

1.6 <u>Drug procurement</u> refers to the QIs which measure the procurement of drugs which good quality and sufficient supplying for saving of drug expenditure.

1.7 <u>Drug storage and distribution</u> refers to the QIs which measure the administration on quality and quantity of drugs distributed in drug system, and drugs should be safe from robbery and not cause any public hazard.

1.8 <u>Drug use</u> refers to the QIs which measure the use of generic name, promotion of rational use of drugs, and development of drug surveillance system for patients safety..

1.9 <u>Accessibility</u> refers to the QIs which measure the equity of drug accessibility of population in health insurance system following universal coverage scheme, social security scheme, and civil servant medical benefit scheme.

1.10 <u>Rational use of drugs</u> refers to the QIs which measure the results of the RUD patterns with a focus on drug knowledge of patients and patient safety.

2. **Quality indicators** (QIs) refer to the indicators which are used to evaluate the quality of DSM performance following the 10 key issues.

3. **Potential quality indicators** refer to the selected quality indicators which have potential to represent DSM performance of community hospitals.

Characteristics of potential QIs are

3.1 <u>Importance</u> which refers to the quality of being important of each QI on evaluation of DSM performance.

3.2 <u>Validity</u> which refers to the quality of being valid and rigorous of each QI on evaluation of DSM performance.

3.3 <u>Appropriateness</u> which refers to the quality of being especially suitable of each QI on evaluation of DSM performance.

3.4 <u>Congruence</u> which refers to the quality of being agreement of each QI on evaluation of DSM performance.

3.5 <u>Feasibility</u> which refers to the quality of being usable of each QI on evaluation of DSM performance.

3.6 <u>Realiability</u> which refers to the quality of being dependable or reliable of each QI on evaluation of DSM performance.