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A Systematic Review: Quality Indicators for Assessing Drug System Management

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Abstract A National Drug Policy (NDP) was implemented in 2011 affecting the Drug System Management (DSM) performance. An essential tool for assessing the DSM performance is quality indicators (QIs). The purpose of this study was to review QIs recommended by Thai and international organizations relating to the DSM. The QIs were gathered following 10 key issues of DSM based on the World Health Organization (WHO) guideline and presented as the function of DSM following a logic model. Overall, 253 QIs were found to be recommended by 21 institutions. 52 QIs were excluded and 201 QIs were selected following the purposes of 10 key issues of DSM. The three DSM issues which have the highest number of recommended QIs were drug use (75 QIs, 37.5%), drug procurement (25 QIs, 12.4%), and drug storage and distribution (24 QIs, 11.9%). These QIs of 3 key issues were the major tools of WHO and international organizations in developing, testing, and assessing DSM in developing countries. However, the lowest number of recommended QIs were found to be 3 QIs of accessibility of drugs (1.5%) and 2 QIs of rational use of drugs (RUDs) (1.0%). In these 5 QIs, 2 key issues were beneficial tools for assessing the effectiveness of DSM. The next step of this study, 201 QIs will be evaluated from DSM specialists in Thailand by using delphi technique. Therefore, the new set of QIs will be beneficial to policy makers, health personnel and stakeholders in improving the DSM performance in Thailand.

Key words: **systematic review, quality indicators, drug system management**

Introduction

DSM is the management of pharmaceuticals to address public health concerns. The concerns include how the medicines, essential to save lives and improve health, will be managed, supplied, and used.[1] In many countries, the guideline of the World Health Organization (WHO) has been used to develop DSM for a better health care system, especially in developing countries. They faced severe problems including ineffective procedures in selection, poor quality

control, inefficient economic procurement, etc. These problems have been documented in numerous reports and publications.[2-4]

In Thailand, based on several srudies, the problems of DSM performance in government hospitals were identified to be as follows: (1) increasing of drug expenditure and drug budget.[5-8] In 1997, drug expenditure rose from 32.88 percent of the overall health expenditure to 46.39 percent in 2008. In line with drug expenditure, the government budget increased from 60 percent to 66 percent of the budget allocated for government hospitals in 2008. Drug expenditure of government hospitals increased from 17,485 million baht in 2006 to 25,549 million baht in 2009. Data of the overall drug expenditure indicated that, somehow, DSM was inefficient and not successful, (2) increasing drug items,[5,9] (3) decreasing drug quality (4) significant amount of expired drugs,[7-8,10] (5) irrational use of drugs,[11-13] (6) inappropriate use of resources, (7) inadequacy of health personnel,[9] (8) limited drug information,[8] and (9) incomprehensive of DSM evaluation.[14-15]

All of these problems are related to the 10 key issues of DSM recommended by WHO[1] which compose of policy and regulation, financing and budgeting, knowledge management, human resource, drug selection, drug procurement, drug storage and distribution, drug use, accessibility of drugs, and rational use of drugs. Therefore, the DSM in Thailand can be considered as being improperly operated as well as in other developing countries. Quality indicators (QIs), as an assessment tool, were recommended by many organizations at the international and local levels to assess DSM performance. Good DSM performance should be shown by the success of each key issue. Therefore, such key issues should be evaluated by the suitable QIs which would have the potential to explore the success of the DSM operation. Unfortunately, even there are many QIs available from many organizations, it was found that those QIs have not been evaluated for their potentials to explore the success of DSM. In addition, the success of DSM operation also depends on the context used in each country; therefore, those available QIs may not be appropriate for all countries. To solve the problems in Thailand, a set of potential QIs should be developed.

The purpose of this study was to gather the available QIs from international and local data sources by a systematic review and verify them following the 10 key issues of DSM. The gathered QIs should be grouped following logic model[16] to present the most effective system among the resources, activities, output, and outcome components. This is the first step of development of potential QIs. In further studies, the gathered QIs will be judged on analysis of their suitabilities for evaluation of DSM performance at community hospitals in Thailand.

Methods

A systematic review was used for identifying the key issues and QIs related on DSM. Literature reviews were conducted by searching directly from Thai and international organizations. The QIs were collected from January 2010 to August 2011. Firstly, the key issues and the purpose of each key issue relevant to DSM were stipulated based on WHO concept and the DSM of Ministry of Public Health (MOPH). As shown in Table 1.

Secondly, the QIs were searched from 14 international databases. In Thailand, QIs were searched from databases and websites of 7 organizations related to DSM. The QIs were directly gathered ac-

cording to ten key issues from websites of international organizations: WHO, the Management Science for Health (MSH), the Pan American Health Organization (PAHO), the International Network for the Rational Use of Drugs (INRUD), the EURO-MED-STAT Group (EURO-MED-STAT), the Organization for Economic Cooperation and Development (OECD), United Kingdom (UK): Prescribing Indicator National Group (PING) and National Health Service (NHS), US: Health Care Financing Administration (HCFA) and Qualidigm, Australia: the New South Wales Therapeutic Assessment Group (the NSW TAG) and National Prescribing Service Limited (NPS), Canada: Health Canada and Canadian Institute for Health Information (CIHI). Organizations in Thailand included Ministry of Public Health (MOPH), the Drug and Medical Supply Information Center (DMSIC), Bureau of Inspection & Evaluation, the Healthcare Accreditation Institute (HA), National Health Security Office (NHSO), Pharmaceutical System Research & Intelligence Center (PSyRIC), and Thai Drug Watch (Table 2).

Thirdly, the gathered QIs were verified following 10 key issues of DSM. Finally, repeated or similar

Table 1 Purposes of 10 key issues related to drug system management

10 Key issues	Purposes
[1] Policy and regulation	To effectively measure the guideline of policies and regulations related to DSM.
[2] Financing and budgeting	To measure the participation in allocating of the budgeting and financing with equity, accountability, cost effectiveness, and self-reliance and to measure the appropriateness and worthiness of drug expenditure.
[3] Knowledge management	To measure the development and support of knowledge to the medical professions in the same direction and consistency with the current situation
[4] Human resource	To measure the role of pharmacy and therapeutic committees (PTCs) in management of the drug system at the community hospitals continuously.
[5] Drug selection	To measure the use of drug items according to patterns of drug use and standard treatment guidelines.
[6] Drug procurement	To measure the procurement of drugs which good quality and sufficient supplying for saving of drug expenditure.
[7] Drug storage and distribution	To 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.
[8] Drug use	To measure the use of generic name, promotion of rational use of drugs, and development of drug surveillance system for patients safety.
[9] Accessibility of drugs	To 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.
[10] Rational use of drugs (RUDs)	To measure the results of the RUD patterns with a focus on drug knowledge of patients and patient safety.

QIs were removed. Gathered QIs were examined for their appropriateness and correctness following the purposes of the 10 key issues of DSM by three reviewers. The QIs were analyzed to identify those QIs that represent the purpose of the 10 key issues and were presented following logic model: resource, activity, output, and outcome components.

Results

WHO and partners focused on the DSM by trying

Table 2 Key issues and data sources of quality indicators

Organizations	Key issues									
	Policy & regulation	Financing & budgeting	Knowledge management	Human resource	Drug selection	Drug procurement	Drug storage & distribution	Drug use	Accessibility of drugs	Rational use of drugs
International organizations										
WHO	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
MSH	✔	✔	✔	–	✔	✔	✔	✔	–	–
PAHO	✔	✔	✔	–	✔	✔	✔	✔	–	–
INRUD	–	–	–	–	–	–	–	✔	✔	✔
EURO-MED-STAT	–	✔	–	–	–	–	–	✔	–	–
OECD	–	–	–	–	–	–	–	✔	–	–
PING (UK)	–	–	–	–	–	–	–	✔	–	–
NHS (UK)	–	–	–	–	–	–	–	✔	–	–
HCFA (USA)	–	–	–	–	✔	–	–	✔	–	–
Qualidigm (USA)	–	–	✔	–	–	–	–	✔	–	–
The NSW TAG (Australia)	–	–	–	✔	–	–	–	✔	–	–
NPS (Australia)	–	–	–	–	–	–	–	✔	–	–
Health Canada (Canada)	–	–	✔	–	–	–	–	✔	–	–
CIHI (Canada)	–	–	–	–	–	–	–	✔	–	–
Organizations in Thailand										
MOPH	✔	–	–	✔	✔	✔	✔	✔	–	–
DMSIC	✔	–	–	✔	✔	✔	✔	–	–	–
Bureau of Inspection & Evaluation	✔	–	–	✔	✔	✔	✔	–	–	–
HA	–	–	–	–	–	–	–	✔	–	✔
NHSO	–	–	–	–	–	–	–	✔	–	✔
PSyRIC	–	–	–	–	–	–	–	✔	–	✔
Thai Drug Watch	–	–	–	–	–	–	–	–	✔	✔

to set up an assessment tool which is useful to diagnose DSM problems in health care settings. Most organizations namely: WHO, MSH, INRUD, PAHO, etc. are well known organizations which have created and developed QIs or manuals for monitoring and evaluation of drug system in many countries. From the systematic review, a total of 253 QIs were collected based on the 10 key issues of DSM (Table 3). From the data, it was found that most organizations were primarily interested in the drug use issue (83 QIs, 32.8%) and only WHO developed QIs covering all 10 key issues, much more than other organizations in developed countries and Thailand.

Three reviewers verified 253 QIs to examine the appropriateness and correctness of each QI according to the purposes of the 10 key issues. Repeated or similar QIs were also identified and subsequently, excluded. As a result, 52 QIs were excluded and the remaining 201 QIs were explored and were concluded to covering the 10 key issues of DSM. (Tables 3, 4)

The results showed the coverage of the 201 QIs on all key issues of DSM and all components of the Logic model (Table 4). Fifteen QIs of policy and regulation key issue were mostly followed the concept of NDP. The strategies of NDP in Thailand are defined to guarantee the availability of drugs, rational use of drugs, self-reliance on drugs, safety of drugs for the population, and to ensure that drugs are properly used. Therefore, QIs were developed in many organizations relating to activities of NDP[4]. A drug policy should be followed by the enactment of appropriate regulations to provide a legal basis for the policy and make it enforceable. These QIs will be reflected on the related policies and regulations for evaluating the effectiveness of NDP and other regulations of the authorities established by policy-makers. They will be beneficial for self-assessment to identify any weakness. Nine QIs of the financing key issue were concerning financial sustainability. In community hospitals, their budgets are received from NHSO, other health security schemes, and patient

Table 3 Number and percentage of quality indicator s following 10 key issues of drug system management

10 Key issues of DSM	Gathering QIs		Repeated QIs		Selected QIs	
	No. of QIs	%	No. of QIs	%	No. of QIs	%
Policy and regulation	18	7.1	3	5.8	15	7.5
Financing and budgeting	14	5.5	5	9.6	9	4.5
Knowledge management	16	6.3	2	3.8	14	7.0
Human resource	20	7.9	1	1.9	19	9.5
Drug selection	21	8.3	6	11.5	15	7.5
Drug procurement	40	15.8	15	28.8	25	12.4
Drug storage and distribution	33	13.0	9	17.3	24	11.9
Drug use	83	32.8	8	15.4	75	37.3
Accessibility of drugs	4	1.6	1	1.9	3	1.5
Rational use of drugs	4	1.6	2	3.8	2	1.0
Total	253	100.0	52	100.0	201	100.0

out-of-pocket expense, etc. These hospitals have been recognized as being able to balance the resources with a basic quality of care[3]. The main points of the QIs represented the operation and verification of the usage of budgeting and financing. In this key issue, QIs are needed for measuring the capacity of managing budget and finance for improving efficiency, reducing demand, increasing financial resources, and accepting a decline in quality of care. Fourteen QIs of knowledge management key issue were classified. This key issue was organized to develop and support knowledge for the providers, receivers, and patients or population. The QIs have been applied to assess the operations of reporting formats, data entry screens, and feedback reports. Sufficient training for health personnel is needed in the knowledge management, which may include design and development of data collection, computerized data, processing, and use of data[1]. Nineteen QIs of human resource key issue measured the role of Pharmacy and Therapeutics Committees (PTCs) in management of the DSM at community hospitals[9]. The key issue is an important and challenging task for PTCs. All QIs ensure the effectiveness of the performance of PTCs and patients are provided with the best possible cost-effective and quality of care.

Fifteen QIs of drug selection were focused on:

1. national list of essential medicine (NLEM); whose purpose is to promote the use of generic name (GN) and to select a limited number of essential drugs (EDs).

2. Standard treatment guidelines (STGs) are needed for practitioners and prescribers who are responsible for the drug prescribing and dispensing of drugs following RUDs to ensure that patients receive safe drugs.

3. Hospital formulary is an important tool for hospitals to guide drug items for common health problems in the community. The hospital formulary is used for representing therapeutic effective and economic efficient prescribing.

Twenty-five QIs of drug procurement are classi-

Table 4 201 quality indicators following 10 key issues of drug system management and 4 components of Logic model

4 components of Logic model	10 Key issues of DSM	No. of QIs
Resource	Policy and regulation	15 QIs
	Financing and budgeting	9 QIs
	Knowledge management	14 QIs
	Human resource	19 QIs
Activity & Output	Drug selection	11 QIs & 4QIs
	Drug procurement	18 QIs & 7QIs
	Drug storage and distribution	18 QIs & 6QIs
	Drug use	12 QIs & 63QIs
Outcome	Accessibility of drugs	3 QIs
	Rational use of drugs	2 QIs
Total		201 QIs

fied to assess the operation related on quantified drug requirement and drug quality assurance.[1,3] Twenty-four QIs of drug storage and distribution were selected. The QIs can be classified in two main points as follows (1) drug inventory[1,3,5,10,14] and (2) distribution process[1,3,5]. All QIs represent the assessment of the operation of drug storage and distribution, while maintaining of drug supply, keeping of drugs in good condition, minimizing of drug losses caused by drug spoilage and expiry.

All seventy five QIs of drug use were gathered and classified in 8 main points as follows. (1) Measurement of drug use,[1,3] (2) monitoring of drug use,[17] (3) drug prescribing,[1,3] (4) patient care,[3] (5) health facility,[3] (6) drug utilization,[1,3] (7) drug expenditure,[14] and (8) medication errors.[14] These QIs represent their capacities in investigation of the drug use process for achieving the promotion-rational prescribing, ensuring good dispensing practices, and encouraging appropriate use of drugs, etc.

The outcomes of the review are presented as the results of effectiveness of DSM which considered the accessibility of drugs and RUDs. Accessibility of drugs related to the population in the health insurance system following universal coverage scheme, social security scheme, and civil servant medical benefit scheme should be available with equity.[1,4] RUDs is focused on patient knowledge and patient safety.[1,3,14] Both of the key issues are benefitial for representing the operation of DSM on patient safety from drug use in the provider's perspective.

Conclusion

This research identified QIs for assessing DSM. Overall 201 QIs relate to the purpose of 10 key issues of DSM are presented by 4 components of logic model. The model will have to be designed or refined in order to fit into the DSM of community hospitals. A logic model can be useful in planning, implementation, analysis, and evaluation of DSM. Therefore, this model will be useful in moving towards developing QIs of DSM by using Delphi technique for selecting the potential of QIs. However, this part of the study is limited on the searching of papers published because QIs from some studies may be suitable only for some specific areas. Many countries or settings have their own situations which are relevant and different from each other. The QIs could be used for monitoring and evaluating DSM policies/ programs following the NDP goal in Thailand. The findings of this study could be used for further development of a valid and practical set of QIs to facilitate the improvement of DSM in Thailand.

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บทคัดย่อ: การทบทวนอย่างเป็นระบบของตัวชี้วัดคุณภาพเพื่อประเมินการจัดการระบบยา

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คณะเภสัชศาสตร์ มหาวิทยาลัยเชียงใหม่

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นโยบายแห่งชาติด้านยาที่เริ่มใน พ.ศ. 2554 มีผลโดยตรงกับผลการดำเนินงานในการจัดการระบบยา โดยมีตัวชี้วัดคุณภาพเป็นเครื่องมือที่สำคัญเพื่อใช้ในการประเมินผลการดำเนินงานของการจัดการระบบยา วัตถุประสงค์ของการศึกษานี้เพื่อทบทวนตัวชี้วัดคุณภาพที่พัฒนาโดยสถาบันในองค์กรระหว่างประเทศและในประเทศที่เกี่ยวข้องกับการจัดการระบบยา ตัวชี้วัดคุณภาพจะถูกรวบรวมตาม 10 ประเด็นสำคัญของการจัดการระบบยาตามแนวทางขององค์การอนามัยโลกและนำเสนอตัวชี้วัดคุณภาพตามหน้าที่ของการจัดการระบบยาโดยใช้โลจิกโมเดล จากการศึกษาพบตัวชี้วัดคุณภาพทั้งหมด 253 ตัว ที่ได้รับการเสนอแนะจากองค์กร 21 แห่ง ตัวชี้วัดคุณภาพ 52 ตัวถูกคัดออก และ 201 ตัวที่ได้รับการคัดเลือกตามวัตถุประสงค์ตามประเด็นสำคัญ 10 ประการของการจัดการระบบยา ทั้งนี้พบว่า ประเด็นสำคัญ 3 ประเด็นแรกที่มีจำนวนตัวชี้วัดคุณภาพมากที่สุดประกอบด้วยการใช้ยา 75 ตัว (ร้อยละ 37.5) การจัดซื้อจัดหายา 25 ตัว (ร้อยละ 12.4) และการสำรองและการกระจายยา 24 ตัว (ร้อยละ 11.9) ซึ่งตัวชี้วัดใน 3 ประเด็นสำคัญนี้ เป็นเครื่องมือสำคัญขององค์การอนามัยโลกและองค์กรระหว่างประเทศเพื่อนำไปพัฒนา ทดสอบและประเมินการจัดการระบบยาในประเทศกำลังพัฒนา สำหรับประเด็นสำคัญที่มีตัวชี้วัดคุณภาพจำนวนน้อยที่สุดคือ ความสามารถในการเข้าถึงยา 3 ตัว (ร้อยละ 1.5) และการใช้ยา อย่างสมเหตุผล 2 ตัว (ร้อยละ 1.0) เนื่องจากตัวชี้วัดใน 2 ประเด็นสำคัญเป็นเครื่องมือที่เป็นประโยชน์ในการประเมินประสิทธิผลของการจัดการระบบยา ในการศึกษาขั้นต่อไป 201 ตัวชี้วัดคุณภาพควรจะถูกนำไปประเมินจากผู้เชี่ยวชาญในระบบยาของประเทศไทยโดยใช้เดลไฟเทคนิค ดังนั้นการพัฒนาชุดตัวชี้วัดคุณภาพจึงเป็นประโยชน์ต่อผู้วางนโยบาย บุคลากรด้านสุขภาพ และผู้เกี่ยวข้องในการประเมินผลการดำเนินงานระบบยาต่อไป

คำสำคัญ: **การทบทวนอย่างเป็นระบบ, ตัวชี้วัดคุณภาพ, การจัดการระบบยา**