Chapter I
Introduction

Rationale and Statement of the Problem

The very rapid growth of pharmaceutical expenditure is the major problem in many countries. In Member States of the European Union (EU), the continuous rise in the cost of pharmaceuticals has caused increasing concern to governments since the 1970s. Expenditure on pharmaceuticals has risen faster than GDP in the past 15 years and currently accounts for between 10% - 20% of the total cost of health care. Rising in drug cost has been fuelled by several factors, foremost among which are changing demographic patterns with increase in elderly population and patients with chronic diseases, and the introduction of expensive new medicines (Mossialos, 1998). In Thailand it was found that the proportion of drug expenditure in 1998 accounted for 29 % of total health expenditure (Kulsomboon, Tearngpitak, and Thanaviriyakul, 2002). Drug expenditure in Thailand still increase every year. IMS reported the wholesale drug price value in the drug market in 2005 (63.5 billion baht) was almost 2 times of its value in 2001 (35.6 billion baht). It highly increases in hospital market.

High cost drugs define as modest acquisition cost but use in high volume or very high cost medication, which even limited used might create budgetary pressure (Macintyre, Sindusake, and Rubin, 2001). High cost drug is one of the most important factor affecting the increasing of pharmaceutical expenditure in many countries such as USA, Australia, Canada, etc. In USA, it was reported that an increase of drug expenditure was resulted from new drug spending 65% (The National Institute for Health Care Management Research and Educational Foundation, 1999 cited in Kulsomboon, Tearngpitak, and Thanaviriyakul, 2002). In Australia, it was found that the proportion of high cost drug expenditure on Individual Patient Use (IPU) increased significantly (p<0.001) from 1.6% in 1999 to 3.6% in 2001 (Gallego, Metocco, Taylor et al., 2004). Besides, high cost drugs were mainly use in patients who enrolled in fee for service (FFS) payment mechanism with irrational trend. In Canada, Manitoba study reported that some patients mainly in FFS payment schemes, were prescribed these drugs without clear clinical reasons (Kozyrskyj, Lix, Dahl et al., 2005).

In Thailand, like other countries, the increasing of high cost drug use especially in the hospital channel effected the highly increased of drug expenditure. Most of top ten drug items in a hospital channel in 2006 were high cost drugs, for example, Atorvastatin, Clopidogrel, Celecoxib, etc (IMS Health 2Q2006). Recent study of top ten essential high cost drug use in subclass 4 in a regional hospital accounted for 18-20% of overall pharmaceutical expenditure per year. Sixty four percent of top ten high cost drug expenditure was in Civil Servant Medical Benefit Scheme (CSMBS) which payment mechanism was fee for service. Regarding the rate of some high cost drugs use such as atorvastatin, and clopidogrel per 1000 patients in aging group in CMBS were 20.8 and 6.47 respectively. In UC, they were only 0.05 and 1.45 respectively (Munkratok, Kulsomboon, and Sirisinsuk., 2006). In addition, the study in three hospitals in Thailand showed that the rate of outpatients with the same disease diagnosed in CSMBS and Social security scheme (SSS) received Erythropoietin, high cost essential drug, was much higher than the patients in Low income card in all hospitals (Limwattananon and Pannarunotai, 2003). Consistent with this result, CSMBS had chance to be prescribed Rosiglitazone higher than other schemes (Kanchanapiboon, 2006). Concerning the quality of treatment, there were many documents indicated that CSMBS were prescribed high cost drugs inappropriately. Overuse were commonly found in CSMBS outpatients for chronic diseases treatments, such as using Atorvastatin as a first line drug instead of generic Simvastatin (Medical audit, 2006) These lead to the increasing of the pharmaceutical expenditure in CSMBS patients.

The CGD reported that medical spending in CSMBS increased every year from 680 million baht in 1980 to 37,004 million baht in 2006. Drug spending accounted for 32% of total medication in CSMBS patients in 2003-2005. Concerning the growth rate of medication spending in CSMBS patients during 2000-2006, it was found that this growth rates in outpatient (with 16% in 2001 to 29% in 2006) were much higher than its growth rate in inpatients (with 10% in 2001 to 21% in 2006) For outpatients, drug spending was the main medication expenditure.

Because of limited resources and high cost drug expenditure in CSMBS was continue increased with irrational used. It might effect not only the cost containment but also an inequity to access the quality of care. After economic crisis, cost effectiveness of drug use was concerned by government. The new regulation of Ministry of Finance regarding to the CSMBS outpatient reimbursement for pharmaceutical had been set up

in 2002. These were some criteria for the reimbursement. Essential drugs in National Essential Drug List can be reimbursed. For non-essential drug, reimbursement was controlled by medical committee. Direct reimbursement was another measure currently used. Medical audit was introduced. However, these regulations were failed to control outpatient drug use spending because of the weakness of control measures.

Strong policy at national level is an important strategy to solve those problems related to high cost drug spending control in CSMBS. Preauthorization has been already used for 6 high cost non-essential cancer drugs, Imatinib, Rituximab, Gefitinib, Erlotinib, Transtuzumab, and Bivacizumab. For outpatients, the CGD will implement the policy of controlling of pharmaceutical expenditure in CSMBS soon. Improving drug list for CSMBS and set up criteria for reimbursement have been in the process. External drug use evaluation for reimbursement purpose will be done after policy implementation.

External drug use evaluation was planned to use to strengthen the effectiveness of policy implementation to monitor and control high cost drug use for outpatient in many countries. State electronic database systems were very useful and had been used in developed countries for drug use monitoring by payers. But Thailand still lack of efficient national database system about patient drug prescriptions. Since conventional drug use evaluation (DUE) used patient records as data sources, it consumed much times and resources. Moreover, there were not many drug items can be evaluated in a short period of time. The scare of human resources was also the main problem. Thus, it might be not appropriate for external drug use evaluation in nation- wide. Although, national database of drug use was absence, many regional hospitals have been used soft ware programs in current health care services such as dispensing, laboratory, International Statistical Classification of Diseases and Related Health Problems Tenth Revision (ICD-10). These databases should be applied for drug use evaluation. In Thailand, there were some studies about drug use evaluation using computerized databases. Drug spending, the quantity of drug use, the number of patient who were prescribed studied drug were measured. However, there was no study about retrospective rational drug utilization using computer database in Thailand. Therefore, computer adaptive assessment tool for monitoring high cost drug use in CSMBS by using current hospital database for both the expenditure and the appropriateness should

be developed in order to use this tool for external drug use evaluation with efficient resource use.

Concerning high cost drug use in outpatients for this study, two high cost drugs, Atorvastatin and Rosiglitazone, were selected because of their very high expenditure (IMS 2005) and trend to have inappropriate use.

Objectives

The objectives of this study were

(1) To develop computer adaptive assessment tool (CAAT) for monitoring the use of high cost drugs in Civil Servant Medical Benefit Scheme (CSMBS)

(2) To validate the assessment tool with the conventional drug use evaluation

(3) To evaluate the use of high cost drugs in CSMBS concerning pharmaceutical spending and rational utilization

Expected Benefits:

The advantages expected from this study were

(1) The results of this study will provide assessment tool to monitor high cost drug use.

(2) The Comptroller General's Department can introduce this tool for external drug use evaluation to improve efficiency of health care resource.

(3) Hospital pharmacists can apply the assessment tool for monitoring the change of high cost drug use in their institutes.

Operational definitions

High cost drug(s) [HCD(s)] defines as two selected high cost drugs for this study, Atorvastatin and Rosiglitazone.

Rational utilization of HCDs defines as CSMBS outpatients were firstly prescribed HCDs followed CAAT during the studied period.

Conventional DUE defines as patients were prescribed HCDs evaluated from patient records according to HCD use guideline.

Sensitivity defines as the proportion of all rational HCD use evaluated by using CAAT that are correctly classified as rational HCD use evaluated by using Conventional DUE.

Specificity defines as the proportion of all irrational HCD use evaluated by using CATT that are correctly classified as irrational drug use evaluated by using Conventional DUE.

Accuracy defines as the proportion of HCD use evaluated by using CATT that are correctly classified as HCD use evaluated by using Conventional DUE.

Pattern analysis defines as the aspect of drug use evaluation which using sequential analysis of first line drugs' date, laboratory check date, and first use of HCDs date in CSMBS outpatients

Scope of the study

This study will be conducted in outpatient, only in CSMBS.

Conceptual framework
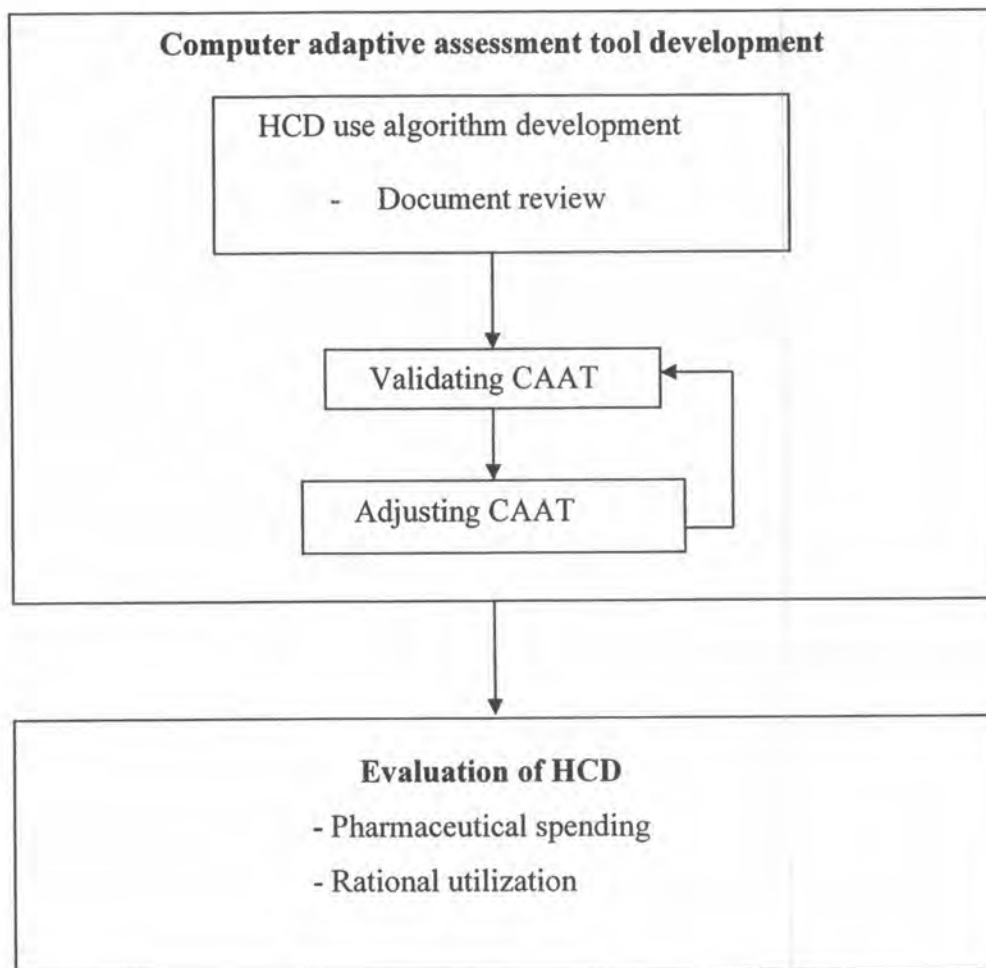
Figure 1.1. Conceptual framework