Chapter III
Research Methodology

This study consisted of three main objectives. The methods used for a particular objective were described separately.

Computer adaptive assessment tool (CAAT) development and validation

For the policy maker, rapid assessment results especially in the first period were needed. Although, conventional drug use evaluation was mostly done by the hospitals to monitor the appropriateness of drug use. It could not serve the policy's purposes enough because it was time consumed time and high resources used. Moreover, many HCDs were not done DUE in the hospitals. Therefore, the new assessment tool should be developed. Their characteristics must be fast and easily retrieved, analyzed, and reported about the target HCD drug use spending and their rational utilization. CAAT with high validity was developed for monitoring HCD use in CSMBS..

To develop CAAT, three procedures should be considered.

I : Development of CAAT guideline of HCD use

Study design

Qualitative research was used for CAAT guidelines of HCD use development. Documentation review methods use for this process. This process was conducted from March – April 2007

Study samples

For document review, standard treatment or clinical practice guidelines and research articles related to studied HCDs were reviewed from electronic online data base, text and journals. Studied samples were from four main resources including NICE guidelines, related articles, 2004 National Essential Drug List, and the CGD's guideline for external HCD use evaluation and monitoring. For Atorvastatin, NCEP ATPIII guideline was added. For the CAAT guidelines, the appropriateness criteria and indicators for evaluation and the cut-point of indicators each studied HCD were revealed

Data collection

To gain an appropriate HCD use guidelines for CAAT, data collection was conducted. Details of the method used in this study was describe as follows.

Documentation review

This technique was use to obtain varieties of data from different sources. Documents were revealed by the researcher and all these drug use criteria were collected. They were included main indications, dose, duration, precaution or their adverse drug reactions, main drug use indicators and their cut points. These data will be used for CAAT guideline development.

Data analysis

With a qualitative nature of the data, this part of study will undertake a systematic, formalized and comparative way of analysis to achieve valid finding The data were analyzed using both qualitative and quantitative techniques. Data analysis will be performed in each type of method as follows.

Essential documentations were analyzed to give fundamental and theoretical information to facilitate CAAT development. Thus content analysis was performed for these textual data by categorizing particular items in documentation. With this technique, reliability and validity of the finding through precise counts of words was established. Information of HCD drug use guidelines were used to initiate the CAAT guidelines.

Since CAAT was developed based on current available database in the hospitals, the guideline for CATT must meet all these criteria

1. The indicators or outcome measures in the guideline use for CAAT must be commonly available in computerized database.

For this study, three main computerized data sources were needed. These were Dispensing database, ICD-10 database, and Laboratory database. These database were available in most regional hospitals. However, there were some differences among hospitals for software program of these three database. HCD use were monitored by using CATT based on this situation. It was necessary to check the availability of necessary data for the drug use evaluation in these data sources.

For Dispensing database, necessary data should be available in this database which included patient hospital identification number (HN), patient name, age, sex, drug allergic history, prescribing of studied HCDs , drug strength, dose, drug quantity, dispensing date, health insurance scheme. These data were used to assess the rational use of HCDs by linking to other database. Spending value of studied HCDs and the spending value of other drugs in the same group were the other necessary data must be

available in this database. These data were used to evaluate the impact of government policy on HCDs expenditure.

About ICD-10 database, necessary data including HN, date, and diagnosis code must be available.

Regarding Laboratory database, patients' data at least HN, laboratory testing date, laboratory testing of level of the indicators use in the guideline of CAAT must be available.

2. Indicators of studied HCDs must be related to the specific indications

3. Criteria or cut- point for those indicators use for CAAT should be clear, and provide advantages to major population.

4. Since the cut- point value depends on several factors that were not available in the database such as smoking behavior, family history of cerebro-vascular diseases, the cut-point indicated in the CAAT guidelines had to be adjusted for these risk factors.

The developed CAAT guidelines were used to evaluate the rational use of HCDs. The patients who were prescribed studied HCDs followed the CAAT guidelines were decided as rational use. In contrast, patients who were prescribed those HCDs but did not follow the CAAT were decided as irrational use.

Because the objective of this study was to evaluate the rational use of HCDs in CSMBS patients. Therefore, starting from studied drugs were better than start from the rational drug use indicators use in the CAAT guidelines. If starting with the rational drug use indicators, the data of studied HCD prescribed were underestimate because many of HCDs were prescribed without the indications or laboratory testing. Thus, it might not achieve the study objective.

For the process of rational drug use evaluation by using CAAT, it was started with dispensing database. The data of CSMBS patients who were prescribed HCDs during the studied time from dispensing database were retrieved. Then, linking to other databases such as laboratory database for Atorvastatin by using HN, dispensing date to the indicators use for those HCDs. Then, the evaluation of HCD use were interpreted by the computers

II : Validating CAAT

This process aims to validate the use of CAAT for monitoring HCD use by comparing with conventional DUE according developed guidelines

Study design

Retrospective study was conducted in one regional hospital in North-eastern region, Thailand during November, 2006 – April, 2007.

Study sample

Studied samples for this part were new CSMBS outpatients who were prescribed studied HCDs during a study period from dispensing database.

Sample sizes

From $n = \frac{Z^2 \alpha/2\ PQ}{e^2}$

n = Number of sample

$Z\alpha/2$ = Z score of $\alpha/2$

P = Proportion of population

Q = 1-P

e = Error of proportion approximation

Sample sizes for Atorvastatin

According to literature review, it was found that less than 10% of the patients who will need Atorvastatin for lowering LDL level.

P = 0.1

Q = 1-0.1 = 0.9

At 95% Confident interval, $\alpha = 0.05$, $Z\alpha/2 = Z_{0.05/2} = 1.96$

e = 0.05

Therefore $n = \frac{Z^2 \alpha/2\ PQ}{e^2}$

$= \frac{(1.96)^2 * 0.1 * 0.9}{(0.05)^2}$

= 138 .29patients

= 139 patients.

Thus, sample size for atorvastatin will be 140 patients.

Sample sizes for rosiglitazone

According to the literature review, it was found that around 10% of diabetes patients were potentially suitable for Rosiglitazone treatment. Like Atorvastatin, sample size for Rosiglitazone were 140 patients

The researcher used simple random sampling technique to obtain the studied samples for data collection process.

Data collection

For data collection process, the researcher was ask for a permission of patient data collection from the hospital director.

Data collection procedure was shown in Figure 3.1. The process was described as follows:

1. HN of CSMBS outpatients who were prescribed studied HCDs during studied period were searched by computerized dispensing database. To select the patients, computerized simple random sampling were used.

2. Specific data of patients and studied HCD use were collected or retrieved depending on DUE method as followed.

For **conventional DUE**, data collection forms were used to obtain patients' data related to developed guideline from outpatient records.

For **CAAT DUE**, some specific patient data related to HCD use from dispensing database were extracted. Then, linking to the HCD use guideline indicators in databases (laboratory database or ICD-10 database) by HN, and dispensing date.

3. Comparing the actual value of patient data with the cut-point of guideline indicators.

4. Rational drug use was evaluated. If HCD use followed the guidelines, they were assessed as rational use. If not, they were evaluated as irrational use.

5. If there were problems based on data collected, the researcher would follow these criteria

- For conventional DUE, if there was no data related to the developed guidelines for studied HCD use appearing in outpatient records , the researcher assumed that the patients do not have indication to use HCDs.

- For CATT DUE, if there was no data related to the CATT guideline for HCDs use appearing in the computerized database, the researcher assumed that the patients do not have indication to use HCDs.

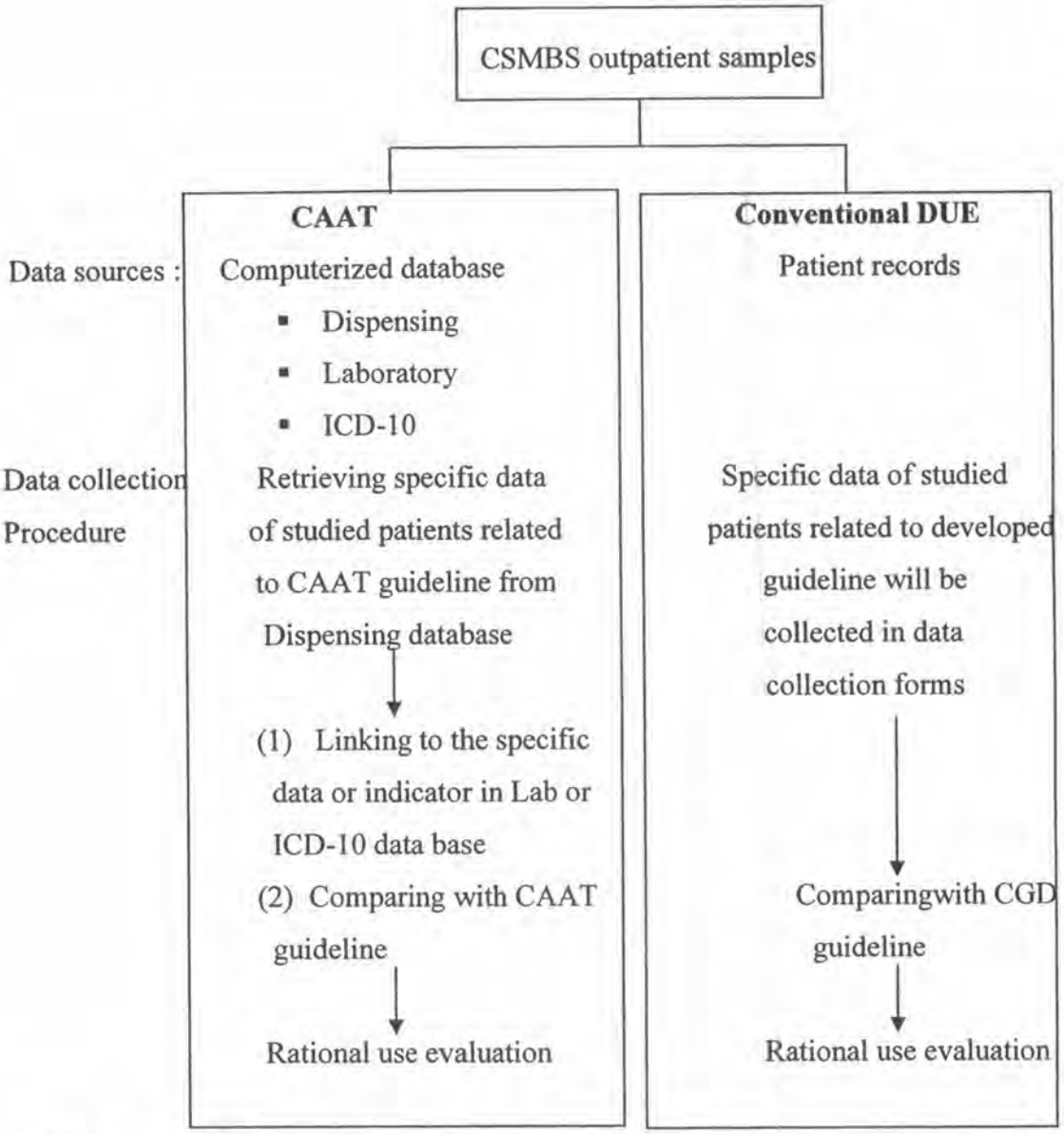

Figure 3.1: Flow of data collection procedure

Data analysis

Microsoft Access 2003 and Microsoft Exel 2003 were used for data management in CAAT development. SPSS was used for data analysis. Descriptive statistics, such as frequency, proportion were used for the rational use of studied HCD analysis of each DUE method.

To validate the CAAT for monitoring HCD use in CSMBS, its results compared with conventional DUE results which were used as standard. Sensitivity, specificity, and accuracy analysis were used to validate the CAAT.

Sensitivity of CAAT was equal to the percentage of all rational HCD use evaluated by using CAAT that were classified as rational use evaluated by using Conventional DUE method divided by all rational HCD use evaluated by using Conventional method as following formula.

Sensitivity = (All rational HCD use evaluated by using CAAT that were classified as rational use evaluated by using Conventional method * 100) / All rational HCD used evaluated by Conventional method

Specificity of CAAT was equal to the percentage of all irrational HCD use evaluated by using CAAT that were classified as irrational use evaluated by using Conventional method divided by all irrational HCD use evaluated by using Conventional method as following formula.

Specificity = (All irrational HCD use evaluated by using CAAT that were classified as irrational use evaluated by using CAAT * 100) / All irrational HCD used evaluated by Conventional method

Accuracy of CAAT was equal to the percentage of all rational and irrational HCD use evaluated by using CAAT that were classified as rational and irrational use evaluated by using Conventional method divided by all rational and irrational HCD used evaluated by Conventional method as following formula

Accuracy = (All rational and irrational HCD use evaluated by using CAAT that were classified as rational and irrational use evaluated by using CAAT * 100) / All rational and irrational HCD used evaluated by Conventional method.

III: Adjusting the CAAT

According to the literature review, there was no developed tool or test has 100% sensitivity and/or specificity. Since using CAAT aimed to efficient available resource use for monitoring the use of HCDs and the characteristics of the CAAT indicators had some limitation. Therefore, acceptable sensitivity and specificity of CAAT in this study should be 80% up.

Adjusting the CAAT guideline would be revised if the sensitivity, specificity, and accuracy of CAAT were not achieved the acceptable value.

Evaluating HCD use in CSMBS concerning pharmaceutical spending and rational utilization

Developed CAAT for monitoring the rational use o f HCDs were used to evaluate the use of Atorvastatin and Rosiglitazone in the studied regionals hospitals. Besides, the pharmaceutical spending of these two drugs and their alternatives were assessed.

Study design :

Retrospective study were conducted in 4 regional hospitals between November 2006 and April 2007. Since patients' data were collected for this study, asking for the hospital director permission for access to patient data had been done.

Population:

Studied population of this study were depended on the aspect of drug use evaluation.

For **pharmaceutical spending evaluation**, CSMBS outpatients who initiating the use of studied HCDs and their alternatives during study periods were recruited in the study.

Atorvastatin and its alternative drugs including Simvastatin, Rosuvastatin and other anti-lipemic drugs (Gemfibrozil, Nicotinic acid, Cholestyramine, Fenofibrate, Bile acid, Clofibrate) were evaluated.

Rosiglitazone and its alternative drugs including sulfonylurea, Metformin, insulin, non-sulfonylurea were evaluated

For **rational drug utilization,** CSMBS outpatients initiating the use of Atorvastatin and Rosiglitazone during study periods were recruited in the study.

Data Sources

For **pharmaceutical spending evaluation**, studied HCDs and their alternative drugs' spending used in new CSMBS outpatients during the study period were obtained from hospitals' dispensing database.

For **rational utilization**, data related to the CAAT guidelines and data processing were obtained from hospital dispensing database, laboratory database, and ICD-10 database.

Data collection

For **pharmaceutical spending evaluation**, data of these variables including HN, generic drug dispensed, drug strength, quantity of drug dispensed, value of drug dispensed were retrieved from the computerized dispensing database.

For **rational utilization**, patient data related to HCD use and data processing were extracted from computerized dispensing database. Then, linking to the HCD use guideline indicators in other databases (laboratory database or ICD-10 database) by HN, and dispensing date. Comparing the actual outcome indicators of studied HCD use with the CAAT guidelines. Initiating use of Atorvastatin and Rosiglitazone followed the CATT guidelines were rational evaluated.

If there are problems based on data collected by using CAAT, such as there was no data related to the CATT guideline in the database, the research assumed that the patients do not have indications to use HCDs.

Data analysis

Microsoft Access 2003, Microsoft Exel 2003 and SPSS version were used for data processing and analysis..

For **pharmaceutical spending,** descriptive statistics such as frequency were used to analyze the number of patients initiating the use dispensed studied HCDs and their alternative drugs. All spending of studied drug prescribed during studied time were calculated.

For **rational utilization**, descriptive statistic were used to analyze patient data related to CAAT guidelines for Atorvastatin and Rosiglitazone evaluation. Excess spending of irrational use of Atorvastatin was calculated.