CHAPTER 1





1.1 Problem and Its Significance

1.1.1 Rationale

The majority of all acute respiratory infections (ARI) occur in developing countries where poverty and inadequate medical care contribute to high mortality rates (World Health Organization [WHO], 2000). In view of the magnitude of the problem, WHO developed practical guideline for the management of ARI in children for use by doctors working in small district hospitals with limited X-ray and bacteriological facilities, and stresses, in particular, the need for rational use of antimicrobial drugs (WHO, 1988). Due to the growing need to have more comprehensive and up-to-date guideline, WHO published case management in small hospitals in developing countries, "A manual for doctors and other senior health workers" and the management of acute respiratory infections in children, "practical guidelines for outpatient care" in 1994 and 1995 respectively (WHO, 1994 and 1995).

ARI in children is one of the most important health problems in Thailand. The Ministry of Public Health (MOPH) in Thailand launched a program for the control of ARI in children (ARIC) in 1990 to provide appropriate health care. However, since the launching of ARIC program, it has been observed that doctors are reluctant to accept the WHO classification of ARI (MOPH, 1999). Why doctors are reluctant and to what extent their practices vary from the the guideline for the treatment of children with AURI is a special area of concern.

According to the MOPH report, two-thirds of Thai people use medication advised by health professionals (doctors, pharmacists and other health personnels) and about one-third use treatments suggested by relatives, friends or advertisements (MOPH, 2000). On the other hand, self-medication has been noted as one of the problems related to ARI, though the use of drugs with health professional's advice is increasing. The problem of self medication could be partially attributed to the current Drug Act. According to the latest Drug Act of Thailand (1987), drugs are classified into two major groups: modern and traditional drugs. Modern drugs are further devided into four categories, namely household remedies (sale require no license), readily-packed drugs (sold in stores by nurses or other medical professionals), dangerous drugs (which can be bought without a prescription but must be dispensed by the pharmacist), and specially controlled drugs (drug which may possess potentially harmful effects to health if misused, thus sale requires a prescription) (MOPH, 2000). The Drug Act, except for those drugs categorized under controlled drugs, does not strictly require a pharmacist to demand a prescription, hence dispensing over the counter and self-medication is widespread. Parents usually prefer to go to the nearest pharmacy or clinic when their children get sick. Dispensing drugs over the counter and parents treating their children with drugs before visiting health facilities and examined by doctors has become a problem. No matter who provides advise on drug use, irrational consumption is found at all levels particularly the use of antibiotics, analgesics, and cold-relieving drugs (MOPH, 2000). This problem, in addition to affecting the drug expenditure, has resulted in drug toxicity and allergies.

Apart from issues of drug safety and efficacy, high and increasing drug costs are of ongoing concern. Mounting drug bills for taxpayers compound the challenge to provide equity of access to medicines. Most countries have some form of subsidy for high cost of pharmaceuticals, whether through Government or private insurance or both. Who pays and for what, are inevitably political questions and political controvercy is evident now as government try to alter the mix (Mant, 1999).

It is evident that the consequences of unnecessary use of drugs particularly antibiotics for AURI firstly increases the cost of medical care and secondly contributes for the emergence of resistant strains of pathogenic microorganisms. From public health and economic points of view, assessing the compliance of treatments provided by doctors to children with AURI is given emphasis in this research.

A number of important activities have been undertaken by MOPH to address some of these problems including improving the rational use of drugs at all levels of health care through effective implementation of the National Essential Drug List (NEDL), therapeutic guidelines and training of health personnel on Standard Case Management (SCM), integration of SCM into the medical school curricula, surveillance of antimicrobial resistance, revision of cough and cold formula, and evaluation of some of the activities of the ARI programs (MOPH, 1999).

Following the revision of the national drug policy in 1993, activities in support of the rational use of drugs (RUD) have been extensively strengthened (Kornkasem et al., 1996) e.g. development of standard treatment guidelines (STG), prescriber's journal, drug information center, adverse drug reaction monitoring system, and formation of Pharmacy and Therapeutic Committees (PTC) in hospitals. The government of Thailand through National Drug Policy Committee emphasizes on ensuring rational utilization of quality drugs, such that losses, wastages, shortages and over-consumption of drugs are minimized (MOPH, 1993). Expenditure on pharmaceuticals represents a large share of the national health expenditure in most developing countries. In Thailand, the national health spending had risen significantly during the past decades from 25,315 million Baht in 1980 to 283,576 million Baht in 1998. The per capita health spending had increased nearly 9 fold (current price) from 545 Baht to 4,663 Baht during the same period, a real increase of 9.1 % per annum. The rate of increase is quite high, much higher than the per capita GDP growth (MOPH,

2000). The total national drug expenditure for example in 1998 is estimated at 46,400 million Baht (wholesale price) or 83,516 million Baht (retail price) and represent 29.5 % of the overall national health expenditure (MOPH, 2000).

The share of the total drug expenditure out of the total health spending is significant, and it is important especially from societal perspective to reduce avoidable cost and foster cost-saving mechanisms mainly in hospitals where about 62 - 66 % (MOPH, 2000) of the government health budget is allocated for curative care. In Comparison with other Asian countries (Table 1.1), the Thai government has not given a high priority to health care as the people still bear a larger share in health spending for self-care. Thai people's household health spending is as high as 65.2 % of all health spending, which is higher than those in other countries, while the public sector shares in developed countries range from 50 to 90 % (MOPH, 2000).

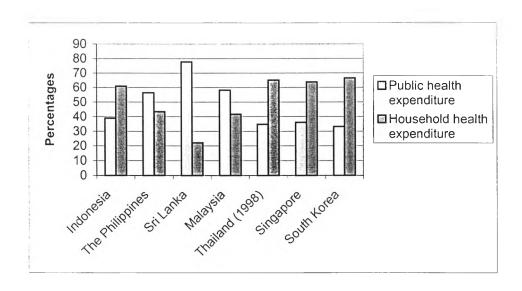
<u>Table 1.1</u> Comparison of Health Expenditures among Some Asian Countries

Country	Per capita health expenditure (US\$)	Percentage in relation to GDP	Percentage share of public health expenditure	Percentage share of household health expenditure
Indonesia	76	1.8	39	61
The Philippines	60	2.3	56.5	43.5
Sri Lanka	61	1.8	77.8	22.2
Malaysia	220	2.4	58.3	41.7
Thailand (1998)	126	6.21	34.8	65.2
Singapore	845	3.6	36.1	63.9
South Korea	518	5.4	33.3	66.7

Note: For 1998, the exchange rate of 37 baht to a US\$ was used, MOPH, 2000, page 204

Source: MOPH, 2000, citing the World Bank 1998, data for (1990-1995)

Figure 1.1 Percentage Share of Public and Household Expenditures among Some Asian Countries



Source: Table 1.1

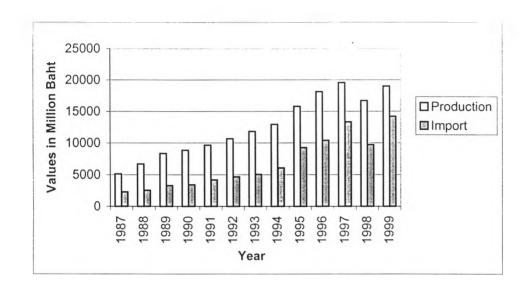
Table 1.2 provides basic information that the value of modern medicines for human use both produced locally and imported from abroad is at an increasing rate. In Thailand, traditional medicines are used for treating common ailments, however, information provided under Table 1.2 is limited only to modern drugs.

<u>Table 1.2</u>: Value of Locally Produced and Imported Modern Medicines for Human Use in Thailand, 1987 –1999 (Million Baht)

Year	Production	Import	Total	% Import to
				Production
1987	5145.75	2325.43	7471.18	45.19
1988	6708.85	2570.98	9279.83	38.32
1989	8372.85	3307.60	11680.45	39.50
1990	8886.02	3449.08	12335.1	38.81
1991	9657.54	4216.41	13873.95	43.66
1992	10696.54	4682.61	15379.15	43.78
1993	11831.03	5075.31	16906.34	42.90
1994	12969.68	6086.63	19056.31	46.93
1995	15820.87	9276.47	25097.34	58.63
1996	18174.43	10435.34	28609.77	57.42
1997	19591.55	13375.57	32967.12	68.27
1998	16726.12	9739.08	26465.2	58.23
1999	19033.94	14232.33	33266.27	74.77

Source: MOPH, Thailand Drug Control Division, data as at 06/11/00 (Value at factory price / importer)

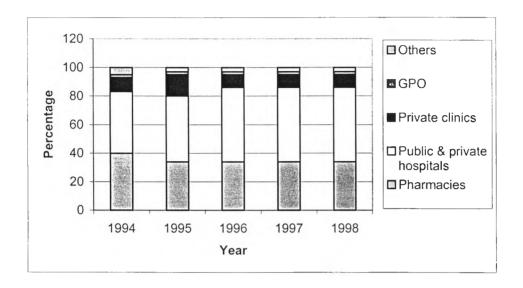
Figure 1.2 Value of Locally Produced and Imported Modern Medicines for Human Use in Thailand, 1987-1999



Source: MOPH, 2000

Imported and locally produced pharmaceutical products are distributed through the Government Pharmaceutical Organization (GPO), pharmacies (drug stores), public and private hospitals, and private clinics. Higher percentages of drugs, in value terms, are distributed through public and private hospitals (Figure 1.3).

Figure 1.3: Percentage of Drug's Values Distributed through Drug Outlets in Thailand, 1994-1998



Source: MOPH, 2000

Pharmaceuticals in Thailand consume significant amount (29.5%) of the national health budget. As the cost of health care continues to rise significantly, there is a growing concern of the government to reduce cost without compromising the quality of health care. Based on the WHO practical guidelines developed for ARI, in 1996 the working group on standard treatment of acute respiratory tract infection assigned by the Thai Food and Drugs Administration (FDA) produced a recommendation of ARI management both in children and adults, and ARIC working group, TB division, Department of Communicable Diseases Control (CDC), MOPH also produced national guideline for the management of ARI in children below five years of age. Experienced medical practitioners and specialists were involved in the process of development of the guideline and later it was published and disseminated for use in public health institutions. Two sets of guidelines were produced, one for primary level health care workers and the other for doctors at hospitals, both intended to standardize

medical practices, ensure safe and cost-effective patient care. The guideline for doctors practicing at a hospital level is the one referred in this study, this guideline contains detailed instructions on clinical diagnosis of acute upper and lower respiratory infections, selection of appropriate treatment, referral system and care at home.

However, there was no direct study done in King Chulalongkorn Memorial Hospital and evidence indicating the extent of utilization of the national guideline and its impact on standardizing medical practices, ensuring safe and cost-effective patient care in hospitals. Informal discussions with senior staff of the medical faculty and the hospital management indicated the prevalence of prescribing many drugs to children with AURI, and their concern to develop and implement a new clinical guideline for ARI in particular enhanced the selection of this hospital for the study.

According to Singkaew and Songyot (1998) although some mechanisms for health care supervision and monitoring in public health facilities are implemented, there is a lack of continuous, formal appraisal of quality and appropriateness of care in public and private health facilities in Thailand. For effective implementation of the guideline for the management of ARI at all levels, and to achieve expected clinical and economic outcomes, health policy makers need to be supported with evidence and this study aims at this point using King Chulalongkorn Memorial Hospital as a case study.

1.1.2 Background

King Chulalongkorn Memorial Hospital is implementing quality improvement activities as a part of the hospital accreditation system in Thailand. Quality improvement activities and the publication of a guide to the hospital, clinical practice guidelines and care map have been prepared in collaboration with personnel of the hospital and the Faculty of Medicine (King Chulalongkorn

Memorial Hospital Report, 2000). Beside the national guideline on treating ARI in children, a new clinical practice guideline has been developed, (almost at its final stage) by the hospital and University staff and is expected to be implemented in the near future. Quality improvement activities currently undertaken by the hospital include improving quality of clinical care in which drugs are an integral part.

Prescribed medicines both for inpatients, outpatients and staff of the Thai Red Cross are provided by the Pharmacy Department of King Chulalongkorn Memorial Hospital. The latter also provides information on medicines for physicians and the general public (King Chulalongkorn Memorial Hospital Report, 2000). Regarding procurement of drugs, like many public hospitals in Thailand, the hospital pharmacy procures its own supplies through bidding by outside suppliers guided by the hospital formulary approved by the PTC. As shown in Table 1.3, the total annual drug expenditure of King Chulalongkorn Memorial Hospital for the fiscal year 2000 amount 645.68 million Baht and antibiotics constituted 23.33 % of the total expenditure on drugs and rank first among others (Department of Pharmacy Report, King Chulalongkorn Memorial Hospital, 2000). Guided by the government procurement policy, public hospitals in Thailand purchase their own requirement and there is an incentive for costsavings. A study made at Ramathibodi hospital, one of the teaching hospitals in Bangkok, (1988 – 1991) revealed that an increase in antibiotics use by about four million baht annually (MOPH, 2000), particularly for new generation antibiotics. But after implementation of the rational antibiotic use program, coupled with a special reporting system, in 1992, the spending on antibiotics dropped by four million Baht (rather than increasing by four million baht, resulting in a net saving of eight million baht). Such interventions should therefore be replicated in other hospitals to contain increasing cost due to over use of antibiotics.

<u>Table1.3</u>: King Chulalongkorn Memorial Hospital Annual Drug Expenditure by
Therapeutic Class for Fiscal Year 2000

No.	Therapeutic Class	No. of drugs	Drug expenditure (million Baht)	Percentage
1	Systemic anti-infectives	237	150.65	23.33
2	Cardio-Vascular drugs	164	121.72	18.85
3	Anti-neoplastics	97	94.33	14.61
4	Neuromuscular drugs	276	66.44	10.29
5	Hormones and synthetic substitutes	148	48.8	7.56
6	Blood formation and coagulation	59	37.35	5.78
7	Gastro intestinal drugs	108	24.62	3.81
8	Nutritional agents and vitamins	95	18.37	2.85
9	Electrolytes and water balance	70	17.98	2.78
10	Blood derivatives	5	14.51	2.25
11	Eye ear nose throat preparations	98	13.65	2.11
12	Serum toxoid and vaccines	40	12.3	1.91
13	Drugs used for respiratory tracts	79	7.76	1.2
14	Unclassified therapeutic agents	46	6.69	1.04
15	Skin and mucous membrane agents	61	4.15	0.64
16	Antihistamines	29	3.75	0.58
17	Anesthetics	14	1.4	0.22
18	Heavy metals and antagonists	1	0.6	0.09
19	Diagnostic agents	4	0.3	0.05
20	Oxytocics	1	0.2	0.03
21	Disinfectants	6	0.11	0.02
	Total	1,638	645.68	100.00

<u>Source</u>: Department of Pharmacy Report, King Chulalongkorn Memorial Hospital, 2000 (Unpublished).

The type, quality and number of drug products available in the hospital formulary is more likely to influence the choice of drugs, prescribing decisions of doctors and thereby drug expenditure, therefore proper selection of essential drugs considering quality, safety, efficacy and cost should be emphasised. Currently, drugs included in the hospital formulary are approved by the PTC. The Head of the hospital pharmacy work as a secretary to the committee. Hospital pharmacists play an important role in ensuring the proper selection, procurement, management of essential drugs and dispensing prescribed medicines with appropriate information to the patient that are integral parts of rational drug use. Although there is no official drug prescribing policy in King Chulalongkorn Memorial Hospital, selected (expensive) drugs both at the outpatient (OPD) and inpatient departments can only be prescribed with the approval of senior infectious diseases specialists. Implementing prescribing policies coupled with the hospital formulary and treatment guideline is an essential element to promote rational use of drugs in the hospital. A number of other intervention mechanisms are mentioned later in this study.

The purpose of reviewing prescriptions in accordance with treatment guidelines is to assess the extent of drug/prescription guideline compliance for some health conditions where clear pharmaceutical standards of treatment exist locally (WHO, 1993). There have been some studies in King Chulalongkorn Memorial Hospital on the general prescribing pattern of drugs for adults and elderly at OPD, but no study has yet been done with respect to the compliance with the guideline and its cost implications in treating children with AURI.

Generally, this research investigates the extent of treatment variations or compliance with the guideline for treating children with AURI and estimates the potential cost-savings if the guidelines are adhered. The research findings could be used for experts and policy makers to design appropriate strategies and ensure that the guideline for AURI could be accepted and implemented effectively so

that treatments are provided according the guideline and clinical as well as economic efficiency can be attained in treating children with AURI.

1.2 Research Questions

1.2.1 Primary question

1.2.1.1 Is there any variation from the guideline in treating children with AURI at King Chulalongkorn Memorial Hospital? If so, what is the associated cost?

1.2.2 Secondary questions

- 1.2.2.1 How are children with AURI treated?
- 1.2.2.2 How is the compliance of antibiotic prescribing with the guideline for children with AURI?
- 1.2.2.3 How much would be the cost-savings if children with AURI are treated according to the guideline?

1.3 Research Objectives

The overall objective of the research is to explore whether or not treatment variations exist between actual practice and the guideline for the management of children with AURI and thereby to estimate associated costs. Specifically, the study attempts to:

- 1. Assess the level of variations of treatment of children with AURI vis-a-vis the guideline.
- 2. Determine the degree of compliance of drug prescribing for children with AURI.
- 3. Estimate the potential cost-saving if the guideline is properly followed for treating children with AURI.

1.4 Scope of the Study

Areas covered in this study can be categorized into two, clinical and pharmaceutical. Secondary data collected from medical records (clinical) and prescriptions (pharmaceutical) were reviewed against the guideline for the management of AURI in children in order to assess if variations (noncompliance) exist between practice and guideline. Children that were less than 15 years old were included in the study.

The associated cost of noncompliance to the guideline was estimated and compared to prescriptions that complied with the guideline. The cost of noncompliance with the guideline is confined to the charges paid for prescribed drugs only. For the purpose of this study, it is assumed that there are no complications or side effects after treatment of children with AURI and patients are only seen once and not followed up thereafter.

1.5 Organization of the Report

There are five chapters in this study. Chapter one is the introduction presenting the significance of the problem, the objectives and scope of the study. Chapter two presents the general theoretical framework and review of related literatures. Chapter three presents the conceptual framework and methodology employed for data collection and analysis. Chapter four presents description of the data used and the empirical results, analysis, discussion and conclusion. Finally, the last chapter provides summary points and recommendations.