CHAPTER 3

RESEARCH METHODOLOGY

3.1 Definition of Terms:

Compliance/Non-compliance: In this study, prescribing of antibiotic for children with AURI in line with the concise criteria (contained in Appendix B) which is based on the recommendations of the guideline for the management of AURI is termed as "compliance" and any deviation from guideline recommendations is termed as "non-compliance".

The following definitions are taken from WHO (1995).

ARI: An acute infection of the ear, nose, throat, epiglottis, larynx, trachea, bronchi, bronchioles, or lung

AURI: An acute infection of the nose, pharynx (throat) or middle ear.

Cold: An acute viral infection of the upper respiratory tract.

Antibiotic: A drug that kills bacteria or inhibit their growth. The term antibiotic in this study refers to those ones recommended for treating bacterial AURI.

3.2 Research Design

The treatment variations from the guideline recommendations and estimation of associated costs in treating children with AURI are described through analysis of data from medical records and prescriptions collected

prospectively in general pediatric outpatient department of King Chulalongkorn Memorial Hospital.
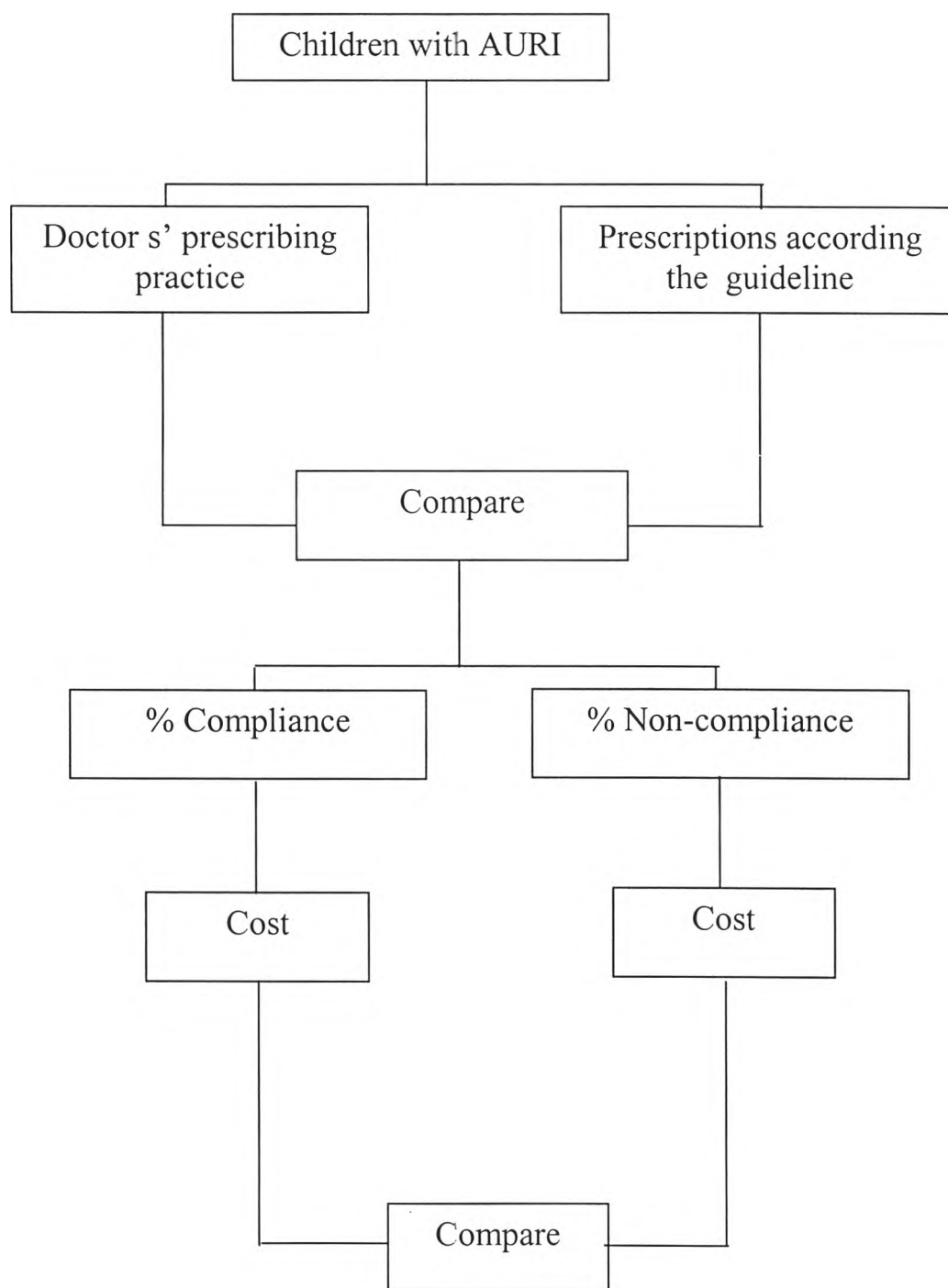
Variables used to explain characteristics of the patient (age; body weight, sex and diagnosis) were collected from medical records. Cases were classified as bacterial or viral AURI guided by the criteria developed particularly for this purpose. Based on the criteria, it was possible to check the need for antibiotic treatment and overall assess the treatment variations. Some of the variables used to describe status of doctors (staff, fellow, resident, and extern) were collected along with the clinical data. An attempt was made to collect other characteristics such as age, gender, clinical experience, specialty, participation in teaching activities and additional training provided to doctors, but data were not readily available.

The compliance to the guideline for treating children with AURI was assessed using the criteria that was developed based on the guideline. When drugs are not prescribed in accordance with guidelines that are based on scientific evidence to ensure safe, effective and economic use (Quick et al., 1997), it is referred as inappropriate prescribing which is a manifestation of irrational drug use behavior. Appropriateness of care is where the expected health benefits exceed the expected negative consequences by sufficient margin that the care is worth providing (Marlyn et al., 1992). For the sake of clarity and consistency, appropriateness in this study is represented throughout this document by the degree of compliance with the guideline (Appendix A).

3.3 Conceptual Framework

Figure 3.1 shows the conceptual framework of the study. Once children come to the outpatient department to see a doctor, the doctor examines, diagnoses and prescribes drug(s).

Figure 3.1:   Conceptual Framework of the Study


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                    ┌──────────────────────┐
                    │  Children with AURI   │
                    └──────────────────────┘
          ┌──────────────────┴──────────────────┐
┌──────────────────────┐            ┌──────────────────────┐
│  Doctor s' prescribing │            │ Prescriptions according│
│       practice         │            │     the  guideline     │
└──────────────────────┘            └──────────────────────┘
          │         ┌──────────────┐           │
          └─────────│   Compare    │───────────┘
                    └──────────────┘
          ┌─────────────┴─────────────┐
┌──────────────────────┐    ┌──────────────────────┐
│     % Compliance      │    │    % Non-compliance   │
└──────────────────────┘    └──────────────────────┘
          │                            │
┌──────────────────────┐    ┌──────────────────────┐
│         Cost          │    │         Cost          │
└──────────────────────┘    └──────────────────────┘
          │      ┌──────────────┐      │
          └──────│   Compare    │──────┘
                 └──────────────┘
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The standard treatment guideline developed by MOPH (1996) for doctors to standardize medical treatment of AURI in young children, improve the quality of medical care and rationalize the use of drugs was basically used as a yardstick to distinguish treatments into compliance and non compliance groups. Based on the guideline, a more concise criteria was further developed to facilitate ease of categorizing treatments provided in the two groups. The study also tried to estimate the possible cost-savings if the guideline could have been properly followed and drugs were prescribed accordingly.

Information concerning the type of drugs, number of drugs, quantity, selling prices of prescribed and dispensed drugs was collected from medical records, prescriptions and computer database and financial costs associated with non-compliance with the guideline was estimated.

Based on the quantitative data collected on medicines prescribed and dispensed, the total charge paid for antibiotic treatment was calculated for the compliance and non-compliance groups. The mean total prices of antibiotics in the two groups were calculated and compared to see the difference between actual practice and guideline recommendations. The observed variation was used to describe the cost-savings that could be made if the guideline is followed and treatment could have been compliant with guideline recommendations. Results of the study are demonstrated and discussed in Chapter 4.

3.4 Inclusion and Exclusion Criteria

Inclusion Criteria

a) Children below 15 years of age seeking medical care for AURI at general pediatric OPD King Chulalongkorn Memorial Hospital were eligible for the study.

b) Cases with complete medical history and specific diagnoses (acute nasopharyngitis or common cold, streptococcal sore throat, acute otitis media or acute sinusitis) or unspecified URI.

c) Patients who bought prescribed medicines from the hospital pharmacy.

Exclusion Criteria

a) Cases with incomplete medical records

b) Consumable medical supplies such as syringes prescribed for administration of liquid preparations and vaccines for immunization of children were excluded from calculation of price paid for the treatment.

c) Patients with co-morbidity other than AURI, or under supervision or treatment for underlying diseases were excluded from the study as the treatment varies accordingly.

d) Patients who did not buy their medication from the hospital pharmacy were excluded.

3.5 Tools Used for Data Collection

The criteria contained in the data collection form 1 (Appendix B) used to categorize patients into bacterial or non-bacterial AURI was based on the guidelines produced by FDA and ARIC working group of the CDC department, MOPH and it was approved by all the staff of the respiratory unit of King Chulalongkorn Memorial Hospital. The other tool used was the data collection form (Appendix C) for collecting prescribing information and prices from the hospital pharmacy.

3.5.1 Measuring non compliance of treatment with the guideline

Measuring the extent of treatment variations, noncompliance with guideline is the core of this study. Clear working definition of "compliance", evidence based treatment guideline and criteria to clearly distinguish bacterial AURI from viral AURI are pivotal.

All drugs prescribed for each AURI case with relevant prescribing information were collected from patient record cards and prescriptions with corresponding prices from a computer database.

Treatments actually provided to children were compared with what is recommended in the guideline for AURI and classified as compliance and non-compliance with the guideline and diagnostic criteria. Cases mainly of viral etiology and minor infections whose history and clinical findings did not suggest the need for antibiotic therapy but antibiotics prescribed were considered noncompliance. Besides cases with history and physical examination confirming the diagnosis of bacterial AURI, but antibiotics not prescribed were considered as non-compliance.

The level of variation or degree of noncompliance to guideline was reviewed considering if diagnosis of bacterial AURI match with the criteria, extent of prescribing of cough and cold preparations for symptomatic releif, prescribing of antibiotic for non bacterial AUR. Generally compliance of antibiotic prescribing with guideline recommendations is the focus with respect to the objectives of the study.

3.5.2 Measuring cost implications of non compliance

The whole issue of treatment variations among medical practitioners can be attributed to different approaches towards differentiating bacterial infections from viral etiology. The cause of URTI is almost invariably viral (usually

rhinoviruses, sometimes respiratory syncytial viruses, Para-influenza and influenza virus). Most symptoms will subside in a few days although cough may persist for up to two weeks. Antibiotics are not indicated. If symptoms are significant, paracetamol (antipyretic) make the patient more comfortable. There is no evidence to suggest that antibiotics can prevent bacterial complications such as otitis media. (Victorian Medical Post Graduate Foundation (VMPF), 1996). Prescribing drugs such as cough and cold remedies, antihistamines and antibiotics when not therapeutically justified or prescribing newer and expensive drugs when relatively comparable, established safety and efficacy and less expensive drugs are available lead to unnecessary cost to the service provider, the patient and to the society at large.

The economic effects of a medical care treatment may be viewed as the sum of its costs and benefits. The costs include (1) the cost of the treatment itself (2) the cost of treating adverse effects and (3) the medical costs incurred during extended life-years (if mortality is postponed). These are direct costs of treatment. Two other costs may also be involved (4) expense incurred for non-medical services and (5) earnings lost by the patient or family members as a result of receiving the treatment. The benefits of the treatment relate to its impact on the costs of illness. The items are similar conceptually to those above and included the medical costs, non-medical expenses and lost earnings associated with the illness that are avoided or saved because of the treatment (Bootman, Townsend and McGhan, 1999).

As it has been explianed in Chapter 2, the use of stanadrd treatement guidelines help in minimizing costs associated with non-compliance. The economic costs of medical treatment in general are wide-ranging, but in this study, only the total charge of antibiotic drugs prescribed as a result of deviation from what was recommended in the guideline for the management of AURI in children is addressed. Unit price (charge) of each prescribed drug and total charge paid by the patient for the prescribed drugs was collected from a

computer database using the data collection form designed for this purpose. For the purpose of comparison, the price of antibiotic treatment of correctly diagnosed cases that are in line with the criteria and considered treated compliant with the guideline was calculated. Using the same method, total price of prescribed antibiotic considered non-compliant with the guideline for treating AURI was calculated accordingly and used to estimate the amount of financial resources that could have been saved if the guideline was followed.

3.6 Data Collection

3.6.1 Study population and sample

The target population for the study was children below 15 years of age with AURI and treated at the general pediatric outpatient department of King Chulalongkorn Memorial Hospital.

3.6.2 Sample size calculation

Avaiable data suggests that 35.6 % to 63% of children with URI are treated with antibiotics (MOPH, 2000). However, there has been no direct study done in King Chulalongkorn Memorial Hospital to estimate particularly drug prescribing compliance with guideline among children with AURI. A study done on general drug prescribing pattern at King Chulalongkorn Memorial Hospital revealed that approximately 10 % of drugs prescribed for three major diseases including the respiratory system were considered inappropriate and another 10 % were found questionable. In order to have an approximate idea of the order of frequency of non-compliance expected, about 20 % was taken for the purpose of calculating the sample size required for this study. The level of precision usually for such type of studies is specified to be 2.5 %, this would

imply that in 95 % of samples of this size the actual result would be within about 5 % (+/- 2.5 standard error) of the population value.

In calculating the sample size the below formulae by Barker and Rose (1990) is used:

$$\text{s.e.} = \frac{\sqrt{p(100 - p)}}{n}$$

thus $\quad n \quad = \quad \dfrac{p\,(100\text{-}p)}{(\text{s.e.})^2}$

$$= \quad \frac{20(\,100\text{-}20)}{(2.5)^2}$$

$$= \quad 256$$

where:

n   =   required sample size

p   =   expected percentage of prevalence rate (non compliance)

s.e   =   standard error of the prevalence rate

However, only 200 complete medical records and prescriptions were available for the review during the study period. Given the seasonal occurrence of acute upper respiratory tract infections and that some cases could also be treated at primary health care facility level, additional data was not avaiable

prospectively. Efforts were made to collect data retrospectively, however, it was found rather difficult as most of the formats used for recording data in the computer database were in the local language, Thai, which needed more manipulation of the medical record database system.

3.6.3 Type of data collected

Secondary data was collected purposively and prospectively for the study over one month period (from 6 February to 13 March 2001) at the general pediatric OPD of King Chulalongkorn Memorial Hospital.

Two types of data were collected, clinical and pharmaceutical. Clinical data included history, findings of physical examination, and diagnosis by the doctor. Pharmaceutical data included name, strength, dosage form, dose, interval between doses, duration of treatment, quantity, and prices of medicines. Variables such as age, body weight, gender of the patient, diagnosis and status of examining physicians (staff, fellow, residents and extern) were collected along with the clinical data.

Some of the difficulties encountered during the data collection process included unavailability of sufficient number of AURI cases prospectively during the study period, incomplete medical records, language limitations which hindered direct observations, and lack of information on profile of individual prescribing doctors. Details of the data collection steps are described below.

3.6.4 Collection of clinical data from medical records

Parents with a sick child report to the OPD medical record unit of the hospital. Date and time the patient reported to the hospital, hospital number, name, age, and department where the patient needs to consult, and name of the

doctor (if patient has an appointment) is recorded in a computer and a blank prescription is given for each patient at the reception counter. This blank prescription containing columns indicating the name of the medicine, dose, quantity and price was attached with the medical record and sent to the respective examining doctor through nursing staff. After examination, the doctor diagnoses, prescribes drugs, writes his code number, signs and issues the prescription to the patient. Doctors are provided with the hospital formulary that contains some information on the drugs (except prices) available in the hospital.

Doctors have to complete patient medical records including patient characteristics, diagnosis and treatment prescribed for each patient. Completed medical records are sent to support staff for data entry to the computer system. Recording of data to the computer system is done following the standard hospital format, which is mainly based on International Classification of Diseases (ICD9). All cases diagnosed as AURI were collected on daily basis during working days for the study period.

A medical doctor completed the clinical data collection (Appendix B) form developed in consultation with head of the respiratory unit and senior experienced pediatricians in the hospital. The form contained information regarding individual hospital number, date of examination, body weight, gender, age, payment scheme and address of the patient, details of the history, physical findings, diagnosis and status of the prescribers. Based on the predefined criteria, the doctor who assisted in data collection mark "yes" or "no" on each criterion, which at the end the diagnosis was summarized into bacterial and viral AURI as has been observed from history and physical findings, by the examining doctor. To quantify the data, the yes or no attributes were assigned values 1 and 2 for bacterial and viral AURI respectively. All records were marked whether or not antibiotics were prescribed for each case. At the end, examining doctors were categorized as staff (S), fellow (F), resident (R) and extern (E).

3.6.5 Collection of prescribing information and drug charges

Corresponding prescriptions were then checked to obtain prescribing information including type, strength and form, dosage, quantity and price of medicines. Patients were free to buy the prescribed medicines either from the hospital pharmacies or from other pharmacies outside the hospital. However, it was noted that most patients bought their medicines from the hospital pharmacy. Sometimes doctors do not specify strengths of drugs they prescribe or the strengths they prescribe are not available, sometimes they prescribe non-formulary drugs and doses are not clearly and correctly written. When these types of problems are encountered, the hospital pharmacist makes a reference to the code numbers on the prescription and sends it back to the concerned doctor and get them corrected. Dispensing prescribed medication from the hospital has an added advantage in that such prescribing errors can be corrected immediately which otherwise would have caused serious implication on patient care. As the pharmacist checks all the incoming prescriptions before recording information into the system and dispensing, no major prescription errors were observed in prescriptions reviewed particularly for antibiotics.

Each prescription received daily by the hospital pharmacy is linked to the hospital number of the patient and information about each patient including examination date, name, strength and form of medicine dispensed, dose, interval between doses, duration of treatment, quantity, payment scheme and prices charged for medicines are recorded. All these information are searchable using the hospital number. All pharmacies in the hospital have a computer network and it is possible to trace each case provided prescribed medicines are dispensed from the hospital.

Understanding how the system operates and how it can be used to retrieve drug prices was a challenge. Except names of medicines and prices, all other information was recorded in Thai language. Therefore, extracting price information from the database required significant portion of staff time that assisted in data collection. Within the time limit, 200 searches were achieved which were considered as complete ones. Thus analysis is based on these cases.