



CHAPTER III

METHODOLOGY

This chapter gives details of the study methodology, which included study design, population and sample, steps and instruments used in two study phases, data analysis, and ethical considerations.

STUDY DESIGN

This study was a descriptive study in one sample group.

POPULATION AND SAMPLE

1. Study Population

The study population or target group of this study was the residents of a slum community in Bangkok, Thailand.

1.1 Study Community

Slum communities in two districts of Bangkok, Klong Toey district and Dindang district, were selected as the study communities. Klong Toey slum, the largest slum community in Bangkok, consisted of a population of 111,790 people living in 18,786 households on land measuring 1.66 square kilometers in Klong Toey district (Klong Toey District Office, Bangkok Metropolitan Administration, 2000). The area is well known for its illicit drug problems as well as drug addiction, substandard housing, poor sanitation, unemployment and low income, high incidence of HIV/AIDS, MDRTB, and sexually transmitted diseases. The congested community in Dindang

district included 12,782 individuals in 3,277 households on 0.25 square kilometers of land. In this study, there were totally about 124,600 individuals living in 22,063 households on two square kilometers of the slum area.

Many community organizations, including non-government organizations (NGOs), are located in the study area. They have strong cooperation with the local people and support the community in many different areas, such as education, health, environment, and social support.

Several health care services are available in the community. This include the Bangkok Metropolitan Administrative (BMA) Health Center, BMA Sub-Health Centers, private hospitals, private clinics, and private pharmacies or drug stores. The BMA health centers belong to the Health Office of the BMA, Ministry of Interior. Physicians together with the dentists, pharmacists, and nurses provide primary care and also some special care for people in their service area. There are about 53 drug stores for modern pharmacy (Type 1-drug stores) in the area. This type of drug store needs pharmacist to be on duty and they are able to dispense some dangerous drugs, narcotic drugs and also most oral antibiotics. For non-dangerous drug stores (Type 2-drug stores), a staff with 3-months training is needed to sell only ready-packed drugs, without dangerous drugs and narcotic drugs.

1.2 Study Population

Three main groups of the study population were included in this study with the intent of getting the most complete information on the practices of every possible major actor in drug use system, and to involve them in development of the guidelines. The first group of the study population was adults over 18 years of age. The second group was physicians and the third was drug sellers. The two latter groups were health providers who influenced drug use behavior in various ways.

The physicians at the health centers included full-time government officers, part-time physicians (retired physicians or full-time physicians from other health centers working as a part-time physician), and interns or residents who were in their training programs. All of these physicians in 13 clinics of the health centers that related

to URIs treatment were included in the second group of the study population. With limitations on approaching physicians in the private sector, physicians in private clinics and private hospitals were not included in the study target group. Drug store personnel, either pharmacists or non-pharmacists, who were responsible for interaction with their customers, were viewed as the third group of study population.

In addition to the health provider group, existing community organizations were invited to support and join the local guideline development. These included the staff of NGOs, community leaders and community committee members, Housewives or Women's Group, Youth Group, community health volunteers (CHV), schoolteachers, the Elderly Group, Community Volunteer Group, Co-Op Group, Anti-drug Group, and Environmental Group.

2. Sampling Procedure

Phase I study

Different sampling procedures were applied to select each target population for Phase I data collection.

2.1 Community members

Multistage sampling was used in the household survey of adults in slum community (Figure 2). First, two districts out of 50 districts of Bangkok and the congested communities around the health centers and community organizations in that district were purposively sampled to be the study area. Second, systematic random sampling was used in household selection. Third, the inclusion and exclusion criteria for adult URIs patients eligible for a 2-week recall interview were applied for case selection in each visited household.

The inclusion criterion for eligible adult URIs patient were as following.

- Adults (age ≥ 18) living in household.
- Adults had/have at least one of these signs and symptoms for 2 days or more during the past 2 weeks, with or without fever (≥ 38.6 C°): sneezing, cough, sore

throat, tonsillar abscess, sputum, ear pain (otalgia), nasal congestion, watery nasal discharge, enlarged cervical lymph nodes with tenderness

- Adults who could give verbal informed consent and able to give information

Forth, the exclusion criteria used to exclude adults who had the following characteristic or diseases: tuberculosis or other lower respiratory tract infections, severe asthma, congestive heart failure, chronic obstructive pulmonary disease, immunosuppression, illicit drug dependency, acute or severe physical or mental illness, and adults who stayed in the community less than 5 days per week. In case there was more than one adult URIs eligible for the interview, adults who could give complete information or those who had the highest education, were selected.

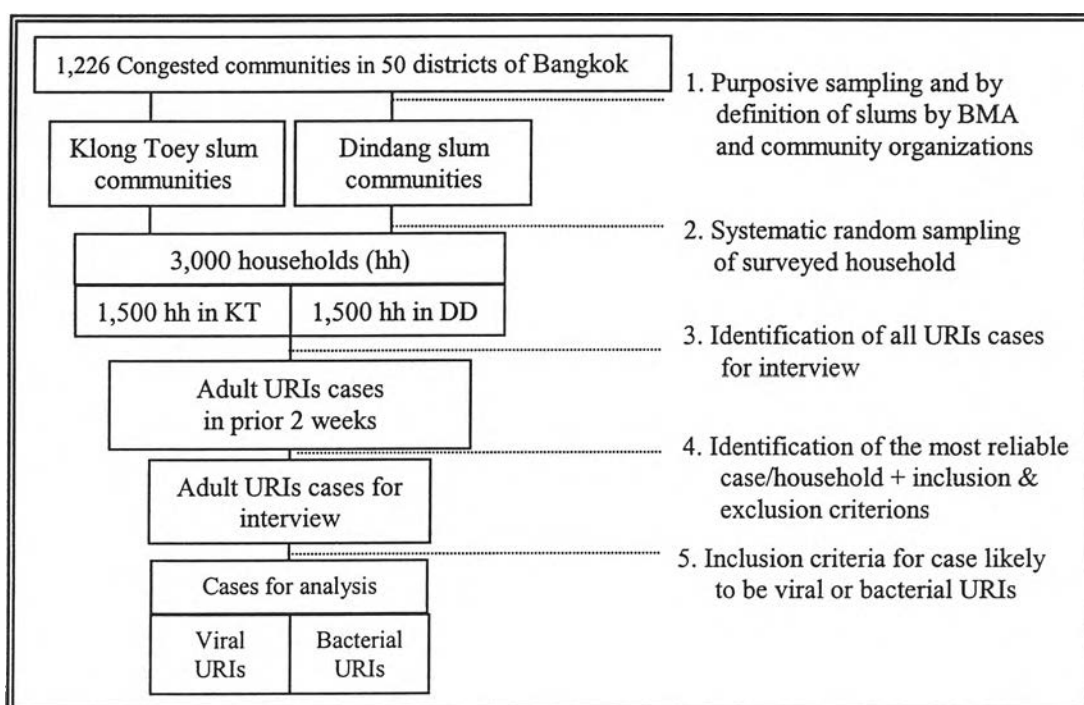


Figure 2. Sampling method for household survey

Criteria for viral and bacterial URIs classification was adapted from the clinical score for group A streptococcus (GAS) sore throat (McIsaac et al., 1998b) and the number of symptoms and signs for sinusitis (William & Simel, 1993). This criterion was later used as a recommendation for case differential in the URIs management guidelines developed by the stakeholders of the civil society. To determine the GAS score, one point was assigned for each of the following characteristics: high fever

(temperature greater than or equal to 38°C), absence of cough, and tonsillar swelling (as patient reported 'severe sore throat'). If the patient's age was 45 or over, one point was subtracted. A total score of less than 2 ruled out the GAS infection, while a total score of 2 or 3 indicated a high likelihood of GAS infection.

For sinusitis, symptoms of maxillary toothache, purulent secretion, and poor response to decongestant were counted. A total number of symptoms less than 2 ruled out sinusitis. If the number of symptoms was 2 or 3, the likelihood of having bacterial sinusitis was high. If there was any GAS score, a likelihood of having sinusitis, or a case diagnosis from a physician suggested bacterial infection, the person was classified as 'likely to have bacterial URIs', otherwise, the case was classified as 'likely to be viral URIs'.

2.2 Physicians at the health centers

All physicians in the 13 clinics of the health centers who treated adult patients (age 18 or over) with a diagnosis of URI, cough and cold symptoms, pharyngitis, tonsillitis, otitis media, or sinusitis in year 2001 were included in the study to review their prescribing pattern.

2.3 Drug sellers at drug stores

All drug sellers at modern pharmacies and non-dangerous drug stores around the study area were eligible for data collection in Phase I.

Phase II study

In Phase II study, the involvement of civil society was critical in the process of guideline development. Establishing the civil society organization and carrying out the activities requires extraordinary energy, available infrastructures, as well as trust from the community. Regarding the long-term relationship of the College of Public Health with the community organizations and the Health Center in Klong Toey through previous researches done in this area, only the Klong Toey community was purposively selected for Phase II study.

The staff members at the NGO in Klong Toey community helped in identifying and contacting possible community groups or key persons who might become the core-working group of the civil society organization. Thus, it was a purposive sampling and also based on their interest and willingness to join the research project. The health provider group, physicians, pharmacist, and nurses at Klong Toey Health Center and all drug store owners and personnel were invited to participate in the guideline development process. Their involvement in the research project was totally based on their concern of the selected drug use problem and their willingness to join.

3. Sample and Sample Size

3.1 Community members

In total 3,973 households were visited and 779 adults with URIs symptoms in the preceding 2 weeks were interviewed. As this dissertation is under the umbrella of the 'Involvement of civil society in a strategy to reduce the use of antibiotics in the treatment for adults with upper respiratory infections (URIs) from viral origins at the household and community level project, the assumptions and sample size calculation for household survey were based on the research design of the project (Appendix I).

3.2 Health center physicians

All registration books from January 2001 to December 2001 and 4,512 prescriptions (1,889 at Klong Toey Health Center and 2,623 at Dindang Health Center) from patients diagnosed as having URIs during the year 2001 were reviewed. These prescriptions were prescribed by 19 physicians, 9 at Klong Toey and 10 at Dindang. Three physicians at Klong Toey Health Center were interviewed.

3.3 Drug personnel at drug stores

All 53 drug stores around the study area, 33 in Klong Toey slum and 20 in Dindang community, were visited by simulated clients for data collection for dispensing patterns in drug store.

PHASE I: KNOWING PATTERNS OF DRUG USE IN COMMUNITY

There were 2 phases in this study. The first phase was getting to know the community, the pattern of drug use and its contributing factors for URIs treatment in community. Knowledge gained from this phase provided input for Phase II, which is the guideline development process with the involvement of the civil society organizations. Figure 3 shows the intervention framework of this study. Phase I study included two main activities, both qualitative and quantitative methodology: I.1) Formative study and I.2) Preliminary survey of the target behaviors. These activities together gave different types of information and could be seen as triangulation to increase validity of the study.

TARGET GROUPS	PHASE I		PHASE II		
	FORMATIVE STUDY February 2001-May 2002	PRELIMINARY SURVEY May – October 2002	GUIDELINE DEVELOPMENT October 2002 – February 2004		
Community members	Semi-structured interview <ul style="list-style-type: none"> • Knowledge & Attitude • Health seeking behavior • Antibiotic use • Self-care practice • Feasibility of the study 	Household survey: 2-week recall interview (8-21 Oct. 2002) <ul style="list-style-type: none"> • Knowledge & Attitude • Health seeking behavior • Antibiotic use • Self-care practice 	Forming of civil society organization Guideline development	URI management guideline for community members	Planning for guideline implementation
Physicians	Prescription analysis (yr.2000) <ul style="list-style-type: none"> • URIs incidence • Antibiotics prescribed • Quality of ABT prescribed Semi-structured interview <ul style="list-style-type: none"> • Knowledge & Attitude • Feasibility of the study 	Prescription analysis (yr. 2001) (May, Oct. 2002) <ul style="list-style-type: none"> • URI incidence • Antibiotic prescribed • Quality of ABT prescribed 	Forming of working team Guideline development	URI practice guideline for the Health Center	Planning for guideline implementation
Drug sellers	Community mapping Semi-structured interview <ul style="list-style-type: none"> • QAT • Antibiotic dispensing • Patient's behavior • Feasibility of the study 	Simulated Client Method (SCM) 1 visit/drug store (August 31, 2002) <ul style="list-style-type: none"> • Question asked • Antibiotics dispensing • Quality of ABT dispensed 	Guideline development	URI management guideline for drug stores	Planning for guideline implementation
Participation observation <ul style="list-style-type: none"> • Role of each partner, activity, obstacles, enabling factors, recommendations 					
PROCESS EVALUATION					

Figure 3. Activities in the study

I.1 Formative Study

The formative study was necessary since there is no previous research about URIs and drug use behavior of the target group in the study area. This step gave clues of the patients' and health providers' knowledge, belief, their possible range of behavior, and factors with respect to antibiotics use, which may direct the development of intervention to reduce inappropriate use or antibiotics in the second phase (Palmer & Bauchner, 1997). In addition, the formative study also helped in designing data collection forms for the preliminary survey and answered questions about the feasibility of conducting research in the study area. Before the formative research was started, a review of literature was undertaken, which allowed the author to gain concrete knowledge and scientific evidence-based information that was useful for the field study and input for guideline development in Phase II. The review included both published information sources and available unpublished information. The level of information ranged from community level through national and international levels.

Three strategies used in the formative study were community mapping, semi-structured interviews and review of prescriptions at the health centers.

I.1.1 Community mapping

Community mapping gave a picture of community characteristics, such as location and the distribution of households, community organizations and health facilities; its environment and interaction of people in the community; as well as available sources of drug and health information in community (Figure 9 and 10 in Appendix II). It was also useful for the sampling and planning of locations for the research activities. In addition, community mapping also gave some understanding of the communication network and relationships of people in the study area. To map out the community, lists of the community, community information and some community maps were obtained from the BMA District Offices and community organizations. The community leaders or NGO staffs were asked to help introduce their community and key persons of the organizations to the author, and then the author made additional observations and surveys in the community with some help from those key actors.

I.1.2 Semi-structured interview

Semi-structured interviews were done during November and December 2000 with adult consumers, physicians, drug sellers, and key persons or representatives of different community organizations in order to learn about their knowledge, attitude, decision making and usual practices related to URI treatment and antibiotic use. Their concern regarding problems of antibiotic use and the feasibility to establish a local URI guideline and campaign activity in community were assessed.

The interview guideline for the interviewer, developed from literature review, included objectives of the interview and chronological steps starting from the preparation for interview, interview questions, and things to do before leaving the field. The interview questions had 4 parts: i) situation of URIs in community perceived by the interviewee, ii) practice or behavior regarding URI treatment, iii) knowledge and attitude towards URIs and antibiotic use, and iv) their concern with problems as well as the perceived feasibility of the study. Most of the questions were open-ended questions. The interview started with an introduction of the interviewer and an explanation of the objectives of the interview. The interviewee was asked for verbal consent to answer the question and give permission to use a tape recorder during the interview. The interviewers interviewed and documented answers on a questionnaire, reviewed and wrapped up, checked and labeled tape recordings before leaving, and thanked the interviewee with a small honoraria gift.

The interviewers directly contacted and made an appointment with the health providers. The key persons from each community organization group were identified with the help of NGO staff and later interviewed by the interviewers. Numbers of interviewees in each group were thoroughly sampled to redundancy, usually about 3 per group. Each interview in the following groups took about 30-45 minutes: 12 community members of which 3 had HIV/AIDS, 3 representative from a Women's Group, 5 NGOs staff, 3 from a Youth Group, 4 community health volunteers (CHVs), 3 community leaders, 4 from a Community Elderly Group, and 3 teachers. In April and May 2002, 1 full-time and 2 part-time Health Center physicians, 1 nurse at a private clinic and 9 drug sellers were interviewed.

The results from the semi-structured interview with community members and key actors of the community organizations suggested that people in slum community usually start treatment with self-care at home, then go to a drug store or health setting later on. Most of them had taken physician or drug seller prescribed antibiotics during their illness. Misconceptions about URIs, appropriate symptomatic treatment, and indications of antibiotic use were commonly found. The terms ‘antibiotic’, ‘virus and bacteria’, ‘drug resistance’, ‘unnecessary drug use’ were new for some people and those who have heard them seem to have a wrong definition for these terms. In addition, people usually do not know the name and indication of the drug that they were taking. Regarding the question about feasibility of the study, there were answers on both positive and negative sides. The interviewees also suggested possible interventions for the community and their role as well.

On the other hand, physicians had certain levels of knowledge about diagnosis of viral and bacterial URIs. Although all said that they do not have problems in making decisions to prescribe antibiotics for their patient, they reported the criteria for prescribing antibiotics and type of antibiotic treatment for URIs varied among physicians. Physicians agreed that it is necessary to have treatment guidelines and intervention for their patient in order to promote rational drug use, even though they felt that the changing behavior of their colleagues and patients makes this difficult. In the drug sellers group, none were found to be pharmacists.

Most drug sellers sold drugs upon request from their customers without asking a question. In the cases where patients requested suggestions, there was a variation in practice that was dependant upon the way the seller asked questions in order to assess the customer, drug dispensing and recommendation given. Criteria for antibiotic dispensing were not clear among interviewed drug sellers. They dispensed what ever the patient requested or what they preferred, rather than basing their decision on assessment questions and patient symptoms. Thus, the qualification of drug sellers and their knowledge about URIs, drug use for URI treatment, and antibiotics were questionable.

These results helped to understand the possible response categories, which was helpful in framing and developing a preliminary survey questionnaire. The results also had a critical role as raw material for the next phase of guideline development.

I.1.3 Prescription review at the health centers

The objective of the review of registration books and prescriptions at the health center in the formative study was to identify the diagnosed URIs case, to know the rate of adult URI patients at the health centers, and to know the pattern of drugs prescribed by physicians, all of which provided useful information in developing a data collection form for the preliminary survey.

From 19 February to 21 May 2001, registration books of year 2000, of both usual service time (8 a.m.– 4 p.m.) and the extended OPD (4-8 p.m.), were screened to measure the rate of adults (18 years or over) with URIs and to identify cases for prescription review. Cases with diagnoses of URI, cough and cold symptoms, pharyngitis, tonsillitis, otitis media, or sinusitis were included. Information about patients' age, gender, and diagnoses was collected from registration books. Type, amount, and cost of prescribed drugs, type of payment for drugs, and physician name, were collected from copies of the prescriptions maintained in the clinic pharmacies. Additional information about physician characteristics (age, gender, full-time or part-time employment status, specialty, and number of years practicing) was gathered directly from the physicians and from Health Center administrators.

In the year 2000, 4,798 adult URIs patients (34.1% of URI patients, 19.3% of the total patients) visited health centers. There was no seasonal change in the rate of URI cases visited. A review of prescription from January to July of the same year included 1,099 valid prescriptions, 54.3% of which were filled with antibiotics, mostly amoxicillin. Most of the cases (86.4%) had only URI/cold and 61.4% of this group had viral-like symptoms, but the patients received antibiotics. Most URI patients were female, in their middle age, and on a self-payment program for drug costs. Average drug cost was 55 baht with nearly 45 baht difference between the cases prescribed with and those without antibiotics. This formative information was presented to and used in discussions with the physicians and health teams to create feedback about their prescribing practices and whether they should work together to decide what action might be taken to bring down the percentage of antibiotic prescribing for viral URIs at the health center level.

I.2 Preliminary Survey: The Measurement of KAP

The results from the formative study suggested that there were problems with drug use in the treatment of adult URIs in all target groups, and there was room for improvement. A preliminary survey was carried out on a larger scale with a more quantitative sense after the formative study was completed. The preliminary survey consisted of a household survey, simulated client methods (SCM) in drug stores, and prescription analysis of year 2001 at the health centers.

I.2.1 Variables

Variables for the drug use pattern study are grouped under different construct regarding to the Social Cognitive Theory (SCT). These constructs help explain how people acquire and maintain certain behavior patterns and also provides the basis for intervention strategies (Glanz, Lewis and Rimer, eds, 1997:153). Variables in the preliminary survey included demographic; target behaviors; knowledge, expectation, attitude and belief towards antibiotic use; environment; reinforcement; and incidence of URIs in community (Table 4). Some variables that were available from the formative study with the same construct are also included in this table.

Table 4. Variables, operational definition, data source and data collection

Variables	Operational definition	Data source ¹	Data collection ²
Construct: Demographic characteristics			
Age	Age (year) of respondent at the time of survey	All	HHS Intv. Obsv.
Gender	Gender of respondent		
Education	Highest education level of respondent		
Address	Community's name, drug store's name, Health Center's name		
Income	Approximately income per month	Pt.	HHS
Specialty	Professional specialty or training	MD., Rx.	Intv.
Experience	Year of experience in the current job		
Construct: Expectation, Attitude, Belief			
Towards different treatment approaches, antibiotic use for URI, and health locus of control	Mean score of attitude towards different treatment approaches	Pt.	HHS, Intv.
	Mean score of preference for health related information		
	Mean score of preference for behavioral involvement in care		
	Mean score of attitude towards internal health locus of control		
	Mean score of attitude towards chance health locus of control		
	Mean score of attitude towards powerful others health locus of control		
Construct: Knowledge			
Knowledge	% respondent with correct answer regarding knowledge about URIs, treatment and antibiotics	Pt.	HHS, Intv.
		MD.,Rx.	Intv.

Table 4. Variables, operational definition, data source and data collection (cont.)

Variables	Operational definition	Data source ¹	Data collection ²
Construct: Behavior			
Health seeking behavior	Action, place to visit and drug taken of respondent in his/her last URIs within the prior 2 weeks	Pt.	HHS
Pattern of URI treatment	Name of drug, strength, dose, and drug administration usually taken, prescribed or dispensed to calculate:	Pt.	HHS
	% of URI respondent who takes antibiotics for last URIs illness during 2 weeks prior the interview	MD. Prescp.	PR., Intv
	% of URIs respondent who did self-care (non-medication)		
	% of URIs respondent who took symptomatic treatment for their last URIs illness	Rx.	SCM, Intv., Obsv.
Question asked and advice for URIs patient	% of URIs respondent who did both self-care and symptomatic treatment for their last URI illness		
	% of prescription for URIs patient prescribed with antibiotics		
	% of simulated encounter in which antibiotic was dispensed		
Question asked and advice for URIs patient	% of prescription for URIs patient prescribed with symptomatic treatment drug		
	% of encounters in which symptomatic treatment drug was dispensed		
	% of encounters in which question for patient assessment was asked to distinguish bacterial and viral infection	Rx.	SCM
Question asked and advice for URIs patient	% of encounters in which information about symptomatic drug for URI treatment was given		
	% of encounters in which information about dangers of antibiotics for URI treatment was given		
	% of encounters in which information about dangers of antibiotics for URI treatment was given		
Construct: Environment			
Drug available	Name of drug available in household or Health Center and drug store	Pt.	HHS
		MD. Prescp.	Intv., PR
		Rx.	Intv.,SCM, Obsv.
Community network	Name of all existing community organizations and their interaction (role) to communicate the guideline to community	All	Intv.
Construct: Incidence of URIs			
True incidence	% of URI case in the population occurring during the period of study time	Pt.	HHS
Rate of health care utilization	% of adult URIs case to total adult patient at the Health Center	Prescp.	PR
Construct: Reinforcement			
Cost of treatment	Average expense for URI treatment per case - total price of drug for patient - average antibiotic cost/ prescription	Pt.	HHS, Intv.
		Prescp.	PR
		Rx.	SCM

¹ All = community member, physicians, drug sellers;
MD. = physician; Prescp. = Prescription; Pt.= community member; Rx. = drug seller

² HHS = household survey; Intv. = semi-structured interview; Obsv. = observation;
PR = prescription review; SCM = simulated client method

I.2.2 Instruments

Five instruments for data collection and two accompany tools were used in the preliminary survey: i) URI case screening form; ii) a structured interview questionnaire for 2-week recall period for household survey, iii) a Disease card with exclusion criteria for household survey; iv) a Drug card; v) a data collection form for URI incidence at health centers; vi) a data collection form for prescription analysis at health center; and vii) data collection form for SCM in drug store.

i) URI case screening form

The objective of the two-sided page of the URI case screening form was to measure URI incidence in community and to screen cases of adults with URIs within the prior 2 weeks of the interview. The form included a brief introduction about the research project, information about the interviewer, date of interview, name of community, household number and landmark, number of household members, their gender, age, existence of URIs within 2 preceding weeks, and existence of diseases or characteristics as listed in the exclusion criteria.

ii) 2-week recall interview questionnaire for household survey

The household survey interview questionnaire aimed to assess symptoms and health seeking behavior (including self-care practices) for the previous URIs of adult patients, sources of care and the sequence in which these were accessed, type and amount of medicines received and taken from different sources, and expenses for direct drug cost. Possible chronic conditions, days of having URIs symptoms, education level, income, and type of health insurance were assessed as well as knowledge about URIs, self-care, and drug use, and attitude toward those issues. This 4-page structured interview questionnaire, consisting of 6 subsections with 74 questions based on results found in the formative study and information from literature review (Appendix III.1).

The part of the question that related to health seeking and drug use behavior was constructed from Andersen's Behavioral Model of Health Services Utilization (Aday and Awe. In Gochman, ed., 1997) and most of the questions were close-ended questions. Questions about knowledge of care seeking and antibiotic use had 24 items

with Yes-No-Not sure answer. Questions about attitudes toward different treatment approaches and health locus of control were adapted based on the 16-item Krantz Health Opinion Survey (KHOS) (Krantz, Baum and Wideman, cited in Naowarat Charupatanapong, et al., 1996: 104, 108) and the 18-item Multi-dimensional Health Locus of Control (MHLC) (Wallston, Wallston and De Vellis, cited in Nawarat Charupatanapong, et al., 1996: 104, 108) respectively. The reason behind the choice to include these two concepts was because the study intended to promote more involvement of consumer's decisions and their ability to take care of their own health.

Questions of attitudes toward different treatment approaches included 4 items for information subscale and 3 items for behavior involvement subscale. The answer was 5-likert scale (1 = strongly disagree, 3= don't know, 5 = strongly agree). The questions measuring beliefs regarding one's ability to exert control over health included 3 items for belief that one's health outcomes are the direct results of one's behavior (internal health locus of control, IHLC); 2 items for belief that health professionals control one's health (powerful others, PHLC) and 2 items for belief that one's health is under the control of luck or fate (chance health locus of control, CHLC). The answer was 5-likert scale (1 = strongly disagree, 3= don't know, 5 = strongly agree). The questionnaire was reviewed by the experts and has been tested in the field before use.

iii) Disease card

Disease card, a one-page size A4 card, is a list of disease or symptoms regarding the exclusion criteria for selection of adult URIs case in community.

iv) Drug card

Drug card, a 2-sided half size A4 card, consisted of pictures of pills received during the simulated client visit to the local pharmacies and drug group. The objective of the Drug card was to help the respondent in identifying possible tablets that they took, thus increasing the reliability of information gained as well.

v) URI incidence data collection form for health centers

Total number of patients visiting the health center each day, number of adult patients (age ≥ 18 years), number of URI patients, and number of adult URI patients counted from the registration books at the health center were noted on this data collection form in order to calculate URIs incidence at the health center (Appendix III.2).

vi) Prescription analysis form

A data collection form for prescription review at the health center in year 2001 was developed from the former version used in formative study. The form included areas to fill out the patient ID, date of visit, patient's name, age and gender, diagnosis, type of health insurance, and name of prescribing physician. This form was also used to collect type, amount, and cost of prescribed drugs for URI symptoms, and whether antibiotics and injection were prescribed (Appendix III.3).

vii) SCM form for data collection in drug stores

Simulated Client Method (SCM) was designed to measure actual case management or drug dispensing practice of drug sellers for adult URIs patient. The SCM form was adapted from the Good Pharmacy Practice Project (Saowakon Ratanawijitrasin et al., 2001) and consisted of 6 parts. Most of the items were close-ended question in order to save the fill out time for the simulated client. The first part of the form was for the demographic data of the drug store and drug seller, summary of drug received from the visit, and drug cost. The type of questions asked by the drug sellers was in the second part and advice given on self-care was in the third part. The forth part included information of drugs dispensed while verbal and written advice related to drug administration was in the fifth and sixth part respectively (Appendix III.4).

I.2.3 Validity and reliability of instruments

i) Validity

Questionnaires in this study were developed from materials available in the literature or previous research reports and were assessed by experts to assure its content validity. The household survey questionnaire was developed based on existing behavioral model (Aday & Awe, cited in Gochman, ed., 1997; Krantz, Baum & Wideman; Wallston, Wallston & De Vellis, cited in Nawarat Charupatanapong, et al., 1996) and additional literature review of potential determinant of antibiotic use. Experts in behavioral science (1), social and administrative pharmacy (3), clinical pharmacy (1), rational drug use (1), and a medical doctor (1) reviewed and gave comment on framework, constructs and variables of the questionnaire before the revision of the draft questionnaire. A Data collection form for prescription review and a SCM data collection form were also developed based on literature review, but were reviewed by experts in social and administrative pharmacy (1), rational drug use (1), and medical doctor (1).

ii) Reliability

The household survey questionnaire was tested for reliability of the questions related to attitude and belief by 33 community members in a non-study slum community during 27 to 28 July 2002. Cronbach's alpha of the test was 0.7438, which is greater than the accepted reliability coefficient of 0.7. Some words and order of question were changed regarding the feedback from the respondents.

Any interviewers' bias was reduced by using a structured questionnaire with interview guidelines, carefulness in recruiting and training of pharmacy students to be data collectors, supervising during the interviewing and data entry. During the interview, a drug card was used to assure the most reliable drug information from the respondents. Samples of drugs were collected. Recheck and examination of the consistency of the outcome were also done.

I.2.4 Data Collection

i) Household survey

Before starting the household survey, 21 pharmacy students (3rd-5th year students from Chulalongkorn University) were recruited and trained to be interviewers. The one-day training on October 5, 2002 included a lecture session in the morning and a field work at the real community setting in the afternoon. In October 2002, these trained interviewers visited 3,973 households in the study communities, with some help from community leaders or NGOs in the area that were contacted before the survey began. At each household, a household representative was asked for number of household members, their age and gender, and whether any member had experienced an URIs in the past 2 weeks. Patients were interviewed if they were at least 18 years old, had experienced at least 1 URI symptom (sore throat, cough, sneezing, tonsillar abscess, sputum, ear ache, nasal congestion, rhinitis, enlarged lymph nodes with tenderness, with or without fever) for more than 2 days during the past 2 weeks, and were able and willing to provide information. Persons with exclusion criteria as listed on the disease card shown to them were excluded.

The interview took about 15-30 minutes, mostly dependent on the number of the interviewees health seeking visits and number of drug taken. To be assured of medicines names, the interviewers asked URI patients to show their medicine and drug package, if available, and also asked for their permission to take back a sample of any unidentified tablet for later identification. In cases where there was no medicine left (either the patient completed the treatment or lost it), interviewers showed pictures of pills (Drug card) for interviewees to recognize. After finishing the interview, interviewer checked the completeness of the answers, wrapped, up the interview, and gave a small bottle of camphor or a tiny pack of aromatic incense as an honoraria to the respondent before leaving for next sampled household. At the mid and the end of each day, interviewers checked and returned the filled questionnaires back to the supervisor.

ii) Prescription review at health centers

In May 2002, 12 pharmacy students (3rd and 5th year students from Chulalongkorn University) were trained to be data collectors for prescription review of year 2001. Steps in abstracting the prescription were the same as in the formative study. Data collectors first had to review the registration book to document the number of patients, adult patients, URI patients, and adult URI patients on the data collection form for incidence of URIs. Only patients diagnosed as having URI, cough and cold symptoms, pharyngitis, tonsillitis, otitis media, or sinusitis were included in the study. Then the data collectors listed the name, age and gender of adult URIs patients and their diagnoses, found in the registration, to the data collection form for prescription review.

All prescriptions of each month, which usually came in 2-separate packs for patients under the universal coverage plan or patient with self-payment, were reviewed by the data collectors. Once the prescriptions of listed adult URIs patient were found, type, amount, and cost of prescribed drugs, and physician name were collected and noted down on the data collection form for prescription review. Additional information of all 19 prescribing physician characteristics (age, gender, full-time or part-time employment status, specialty, and number of years practicing) was gathered directly from the physicians and from the health center administrators.

iii) Simulated Client Method (SCM)

On 25 August 2002, five pharmacy students were trained to be simulated clients with an assigned scenario to interact with the drug sellers. The training included a lecture and field practice in a real drug store out of the study area (about 2 practicing drug store per simulated client). Regarding the GAS score, antibiotics should not be dispensed for the developed uncomplicated URIs scenario. The scenario was designed to request suggestions from drug seller instead of requesting antibiotics directly, because the semi-structured interview in drug sellers suggested that most drug sellers dispensed whatever their customer requested and we may have missed the opportunity to measure their logic in patient assessment, decision to dispense antibiotics or other drugs, and their advice given to the patient.

The scenario for the simulated client was 'May I buy a drug for a cold please', with no other information given to the drug seller. If drug seller asked for more information, the story was that the client's cousin age 20-40 who has symptoms for 2-3 days asked the simulated client to buy medicine for his/her symptoms. The patient has a mild sore throat (no swollen or redness in throat), some coughing all day, clear runny nose and some sneezing, felt tired sometimes, and had a low grade fever. The patient has not taken any drug or seen a doctor, does not smoke, and does not know if he/she is allergic to any medicine. The simulated clients bought all drugs dispensed by the drug sellers and remembered to write down all question asked and advice given by the drug sellers after they left the drug stores.

Data collection was done on only one visit per drug store on August 31, and December 7, 14, 2002. The latest two SCM round were a revisit to 3 drug stores in order to identify some unknown drugs received earlier. It was done by a research assistant who is a young pharmacist and more familiar with drug package/ bottles than the pharmacy students.

PHASE II. INVOLVEMENT OF CIVIL SOCIETY IN GUIDELINE DEVELOPMENT

The findings in Phase I suggested that each target group had **practiced deviation** from what the evidence-based had recommended for URI treatment. There was also a **redundancy** in the role of drug sellers and physicians who both gave antibiotics to their patient and a **fragmentation** in their work as they usually concentrated only on their part with no cooperation with other sectors. In addition, a **gap** in the role and practice of each actor in treatment cycle still exists, such as while the patient lacked knowledge, their health providers failed to educate or communicate essential messages for URI treatment to them. Moreover, the deviation in practices of both community members and health providers can affect the community as a whole. Unnecessary costs of office visit and antibiotics dispensing, and a rise in antibiotic resistance are no longer an individual problem, but a complex public problem that needs the cooperation of all stakeholders in changing their treatment behavior.

Phase I results called for a need of a local URI management guideline to address the best practice that each target group should follow in order to achieve the goal of rational drug use. This guideline is a tool to help make informed decisions for individual patients, providers, and organizations by making clear the benefits and harms of different treatment options (NZGG, 2002). In addition, to reducing the problem of redundancy, gap, and fragmentation in the role and practice of each target group, cooperation of community members and health providers as a civil society organization was essential in the guideline development. However, as there was a big gap in the knowledge and trust of community members and health providers, the norm of the civic community, as well as the structure of civil society and the network of public communication of all three target groups could not be established. Although there was some links in activities between groups, an attempt to involve all of them together in the same process of guideline development and making a consensus of community for best practice of URI treatment was not successful in the current situation of this study. Therefore, the involvement of civil society in guideline development in the Phase II study was a separate process for each target group in Klong Toey slum as follows.

II.1 Involvement of Community Members in URI Guideline Development

The steps in the development of URI management guideline for community members consisted of six steps as shows in Figure 4 and details of each step were as following.

Step 1. Selecting the guideline topic

The guideline for URI treatment was chosen by the researcher with the reasons that i) URIs is a major source of morbidity in among adult community member and antibiotic use for URIs is irrational and commonly found; ii) the problem is fixable; iii) the availability of adequate literature to make an evidence-based decision about appropriate practice for URI treatment; and iv) alternative treatments (symptomatic drug and self-care) and resource are available if the guideline is implemented (NZGG, 2002). The review of the literature in step 3 was based on this chosen guideline topic. The civil society were not directly involved in this step, however, they were informed and participated in discussion about this topic in the next step.

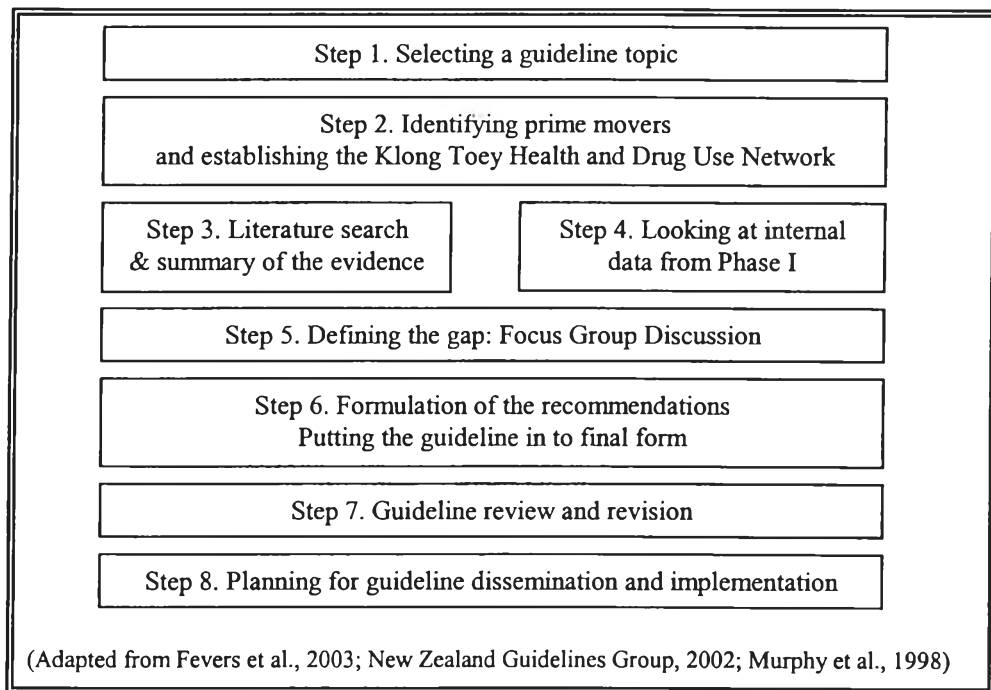


Figure 4. Steps in guideline development

Step 2. Identifying prime movers and establishing the Klong Toey Health and Drug Use Network

The role of existing formal and informal groups in the community was identified with help from the NGO staff at Duang Prateep Foundation (DPF). Knowing the roles of the community groups was important in identifying the prime movers or the key actors to carry on further activities in their community, possible type of intervention, and also the sustainability of the community activity. As the study community was exposed to many research projects for more than two decades, building trust and acceptance among the community was also the first and very important step to overcome. The study group was aware of the usual problem of community's negative attitude towards research projects, which frequently came to gain what they wanted, but did not contribute benefits to the community.

Focus group discussions, an introductory meeting of the research project to the community, and several subsequent meetings were held in community for nearly a year, starting in January 2003. The objectives of these meetings were to identify the prime

movers, to introduce the research project, to raise civic consciousness of the people on issue of health as a public problem, and to discuss the potential of civil society in solving the community problems of irrational drug use. The research team presented the results of the preliminary study and discussed the possible types of intervention to promote rational drug use for URI treatment in the community. After several meetings of the research team with the community, the '**Klong Toey Health and Drug Use Network**' was established. The Network aimed to promote rational drug use (including antibiotics) in community, by focusing on URI treatment for adult patients first. The Network consisted of active individuals, existing community groups, or even an ad hoc group that was concerned about health and drug use problems, had a commitment to help and had an ability to take on the task, and could clearly define their responsibility in the Network. The person or organizations that join the Network should be able to analyze an issue, judge its effects on community, and present an argument rationally and convincingly (NZGG, 2002). This group of people could be named the 'civil society' as the individual became a partner in guideline development, which is a job not for themselves but for community. The research team worked as the secretary and coordinator of this Network.

Step 3. Evaluating the medical literature

A systematic approach, such as meta-analysis and evidence grading is great for a strong evidence-based guideline. However, the process will take too much time and it requires a lot of skill, which could be barrier for the participation of laymen who were not familiar with medical and technical terminology, or even the health providers who are busy or lack continuing education. Therefore, the research team took responsibility for this step by focusing on the adaptation of existing guidelines and took advantage of critical appraisals and evidence summaries done by others using systematic process. The resulting information was summarized and a simple presentation was prepared to inform the civic group of how appropriate practice for treating URIs should be, so they can define the gap between their practice and the recommended practice. Copies of easy reading articles and some news cutting from the newspaper that talk about URIs, symptomatic treatment, or danger of antibiotics were prepared for distribution and discussion of the research team and the civic group.

Step 4. Looking at internal data & Step 5. Defining the Gap

Data from Phase I was translated to become information on knowledge and usual practices of people treating URIs, and then presented it in ways that may be easily understood in order to gain more meaningful participation of people. Drug use patterns, problems of misconception and misbehavior of people in treating URIs, and economic losses incurred from unnecessary physician visit and antibiotic use gleaned from the household survey were summarized in to a sheet. This sheet was to give a clear picture of how critical a health problem that they are facing and why the community should be concerned about it. The presentation first took place in a **focus group discussion (FGD)** on January 23, 2003 held at DPF.

The Focus Group Discussion (FGD) is ‘a carefully planned series of discussions designed to obtain perceptions on a defined area of interest in a permissive environment. Group member influence each other by responding to the ideas and comments of others’ (Krueger and Casey, 2000: 5). It is useful for a study that wishes to ‘empower’ research participants so the participants can become an active part of the process of analysis (Kitzinger, cited in Mays and Pope, eds, 2000). Thus, it fitted with the purpose of involving civil society in the study.

FGD was used to i) share the internal data from Phase I and look for the range of ideas that target groups used on their practice for URI treatment; ii) understand differences in perspectives between groups of people; iii) explore factors influencing opinions and behavior of antibiotic use or self-care; and iv) pilot test idea of developing the local guideline by people from their own group (Krueger and Casey, 2000:24). Steps in conducting a FGD were as follows.

i) Plan the entire FGD study

ii) Decide type of group: Participant in our FGD consisted of 15 identified prime movers, including 5 community members, 3 community leaders, 3 NGO staff, 1 school teacher, 1 Community Health Volunteer. Two community members who frequently got URIs in the past year, identified from the preliminary survey at the Health Center, were also invited. The research team initially contacted participants by

personal contact and through the NGO staff and provided prospective participants with general descriptive information of the study.

iii) Select moderator and field team: The research team was the modulator of the FGD. The research assistant was the recorder who observed, took notes, and recorded discussions and observed non-verbal expressions.

iv) Develop moderator's guide and format for recording response

v) Conduct the FGD: On the day of the discussion, the research team was at the DPF early to prepare the discussion and welcome participants with snacks and drinks to make them comfortable. The discussion session started with introductions by the moderator, a warm-up with self-introduction by participants followed by the actual discussion of the study topic and finally a wrap-up summary. The whole process took 2 hours.

The moderator explained that the aim of the focus group is to encourage them to talk to each other rather than present themselves to moderator (Kitzinger, cited in Mays and Pope, eds., 2000: 41). During the discussion, medical literature evidence (from Step 3) and internal data were presented to the group to encourage general discussion, e.g., the issues that they want to explore more, or share experience with others, and how to translate the results that were just presented to them. Then the moderator lead the a more specific discussion on their ideas of the importance of irrational drug use in community, whether they should take any action to control or solve the situation of drug use, and what they thought about developing a local URI guideline for community members. In addition, possible types of intervention, responsible persons and role of participation organization, budget needed and payment for working group were also discussed before the moderator wrapped up the discussion. Data obtained from FGD by tape recorder and field notes were summarized before starting the introduction meeting of the research project and community organizations, and before the formulation of the guideline recommendations.

Step 6. Formulation of the recommendations

The research team presented and shared the internal data in several meetings to promote the research project to the community and to enhance the guideline credibility by having the ideas and involvement of the group of people who, as the users of the guideline practice, will be affected by the guideline. The meetings were conducted by the research team. Other existing regular meetings were held by community organizations at DPF, community library, district office, community sub-office, school, or day care center, depended on the participants in each meeting. The meetings were held in January 2003 to November 2003 and each meeting lasted from 2 to 3 hours. A list of meetings of the research team and the community members/organizations follows.

January 2003

27th Presentation of baseline study and introduction of research project to Community leaders, District administrators, and District officers at the monthly meeting of Klong Toey District Office

February 2003

6th, 21st Discussion on the outline of URI management guideline draft at DPF

June 2003

15th Meeting and brainstorming with community members at Wat Klong Toey Nai School

September 2003

7th Training of core groups from 5 communities

21st Meeting with civic group

23rd Training of core groups from 3 communities

October 2003

5th Training of core groups from 4 communities and Youth groups

November 2003

16th Meeting with school teachers

27th Meeting and discussion with Klong Toey well known people about the intervention

Two formal meetings focusing on guideline development were held on February 6 and 21, 2003. The guideline panel changed in each meeting but some participants were involved in every meeting. In these first meetings, participants were asked to read,

extract the main idea and discuss the outline and content of the local URI management guideline as drafted by the research team. The drafted guideline attempted to make clear the responsibility of the community members in care delivery focused on the differential diagnosis of viral and bacterial URIs, symptomatic treatment, and self-care at home. Since the guideline is a decision tool, the heart of it is the information that is organized to allow all users to be involved in decision making in a meaningful way. Therefore, all participants in the meeting were asked to express and contribute ideas that improve the final product guideline. Participants were also asked to bring back the draft of the guideline to read and discuss with their family members, friends, as well as other members of the Network who did not participate in these two meetings. Those who missed the meeting for guideline development could pass their comments to the core-working group of the Network, and then it would be discussed in the next meeting of the Network.

Step 7. Guideline review and revision

The local URI management guideline was distributed to the members of the Network for review and it was also brought to the meeting of the Health Center physicians for professional review. This was meant to test the validity of the guideline, and it was also another way to promote the community guidelines to people out of the community group as well as to gain their acceptance. Feedback comments from the responding core groups were obtained from 4 community members, 1 teacher, 2 members of Youth Group, and 4 NGO staff. The revision of the guidelines for community member included some rearrangement of the guideline section, changes in wordings, adding of cartoon pictures and more pictures of drug tablet, and adding of more sample or explanation in some issues.

Step 8. Planning for guideline dissemination and implementation

The complete local URI management guideline will be a tool for each target group to make decision whenever they face a problem of care for URIs and drug use. To let the whole community have the ability for appropriate decision making, which will finally lead to the reduction of antibiotic use, the guideline should be distributed to the final user. Therefore, the Network together with the research team had several

meetings during June 2003 to February 2004 to plan for guideline dissemination to reach the community members as much as possible. Because only dissemination does not ensure that people will use or adhere to the guideline, plan for other campaign activities or materials to promote the concept and key message of the guideline to the target group, and plan for monitoring and evaluation the use of guideline were also discussed. One concern on planning further intervention was that the plan should be relevant to the existing role of each group and cause no additional burden to the group. In the long run, the Network must think about time to update their guideline because drug and standard practice may change overtime.

This dissertation was finished after this stage, however, the research project still continues because use of guideline without the monitoring system has no effects. Therefore, dissemination of the guideline and campaign materials, implementation of other community interventions, continuous evaluation and review of the utilization of the guideline, adherence to the guideline, and a change of people's behavior are the main activities for the ongoing research project (Siritree Suttajit et al., 2003; Ruangthip Tantipidoke et al., 2004).

II.2 Involvement of Physicians, Pharmacist and Nurses at Health Center in URI Guideline Development

Step 1. Selecting a guideline topic: This step was done with the same reason as in the group of community member.

Step 2. Identifying prime movers

The Director of the Health Center was directly contacted and asked for his help in identifying staff that may be able to serve as key persons to carry out the activity. One young staff member, a full-time physician, the head of pharmacy department, and the head of nurses were identified as the key persons responsible for drafting the practice guidelines and coordinating process.

Step 3. Literature search and summary of the evidence

The scientific papers regarding the standard treatment for adult URI treatment and other related information were reviewed and prepared. Copies of URI treatment guidelines from the Ministry of Public Health of Thailand and Singapore, campaign materials that promote rational use of antibiotics from National Prescribing Service (NPS), CDC, and REACH Mass (Reducing Antibiotics for Children) Project (Department of Ambulatory Care and Prevention, Harvard Medical School) were prepared.

Step 4. Looking at internal data from Phase I & Step 5. Defining the gap

Preliminary survey results of prescription reviews from the Health Center were summarized and presented to 4 physicians, 1 pharmacist, 15 nurses, and other Health Center personnel on January 17, 2003 at the Health Center. The objectives of the presentation were to introduce the research project and to get feedback from the health team on the prescribing pattern of physicians so as to determine whether any intervention is needed to promote a rational use of drug for URIs treatment at the health center level. This meeting took 2.5 hours with open discussion on the principles and personal experiences of physician in URI diagnosis and treatment.

Step 6. Formulation of the recommendations

After the first meeting, the Health Center held a meeting among their personnel and decided to join the research project. The responsible physician drafted the URI treatment guidelines for the Health Center based on the reviewed documents given by the research team at the first meeting. Then, the second and third meeting of the research team and physicians was held on July 31 and August 14, 2003 at the Health Center to discuss more on prescribing patterns, comments and revision on the first draft of the guideline.

Step 7. Planning for guideline implementation

Subsequent monthly meetings were held on September 8, 24 and October 8, 29, and November 12, 2003 at the Health Center. During these meetings, the research

team, physicians, pharmacist, and nurses discussed and revised the treatment guideline and guideline implementation plan as well as other interventions for their patients.

II.3 Involvement of Drug Sellers in URI Guideline Development

Plans for the involvement of drug sellers in URI guideline development were the same as in the community member group and physician group. However, as the cooperation of drug sellers was very low, there was no group setting and output from a group of drug sellers. Only one meeting with drug store owners and one visitation for an interview about drug dispensing patterns was done in this group

The meeting with drug store owners was held at DPF on February 4, 2003. All personnel from 19 drug stores were invited by a letter from the research project to join the meeting of drug sellers. Only 2 owners participated. A brief introduction of the research project was given. The issue of antibiotic overuse and the important role of drug sellers in promoting rational drug use in community were clarified. Participants also discussed selecting drugs to dispense for URI patients, barriers for participating in community activity, and how to overcome the barriers and encourage other drug sellers to join the activity.

Regarding the low participation rate and concern of drug sellers on time limitation and high competition among them, the strategy was changed to face-to-face visiting at their drug store instead of inviting them together for the guideline development. Fourteen drug stores were visited during November 10-11 and December 1-6, 2003. The visitations were to introduce the research project to drug sellers who missed the previous meeting, discuss their health services for adult URI patients, and evaluate the possibility of drug sellers to join the research project. From the 14 drug stores visited, 2 strongly resisted to the research project for unknown reasons.

Materials developed from the Klong Toey Health and Drug Use Network and the Health Center were later distributed to drug stores in the study area as there was no group forming and no further activity in this group.

II.4 Monitoring and Evaluation of Guideline Development Process

During the process of guideline development in each target group, the date, time and place of study, role of each participant, and output from each step of guideline development were observed and documented. In addition, the research team also observed the acceptability among group members who did not participate in guideline development and obstacles that make difficulty to the guideline development. Field notes, both structured and unstructured observation forms, tape recordings and photography were used together to collect these data. At the end of each session, data were rechecked and completed the data and notes, checked the tape recorder and labeled it.

The outcome of the guideline development was an agreement among group members on criteria to differentiate viral and bacterial URIs patient, appropriate treatment of viral URIs and appropriate antibiotic use in bacterial URIs documented in the local URI management guideline.

DATA ANALYSIS

This study was a descriptive study with no comparison group. The methodology combined both qualitative and quantitative methods. Quantitative data were checked, coded and then entered in to SPSS program for Window or Excel program (for URI incidence at the health center). The data before the analysis were checked and corrected.

Classification of Case Likely to be Viral or Bacterial URIs

Criteria for viral and bacterial URIs classification for URIs cases found in household survey was adapted from the clinical score of group A streptococcus (GAS) sore throat (McIsaac et al., 1998b) and number of symptoms and signs for sinusitis (Willian and Simel, 1993). Physician's diagnosis, as reported by the patient, if available, was also considered. To determine the GAS score, one point was assigned for each of the following characteristics: high fever (temperature greater than or equal to 38

°C), absence of cough, and tonsillar swelling (as patient reported 'severe sore throat'). If the patient's age was 45 or over, one point was subtracted. Total score less than 2 ruled out the GAS infection, while total score of 2 or 3 indicates high likelihood of GAS infection. Based on a study done on empirical validation of guidelines (McIsaac et al., 2004), sensitivity of the adapted GAS score might be around 77% and 44% specificity

For sinusitis, symptoms of maxillary toothache, purulent secretion, and poor response to decongestant were count. The total number of symptoms less than 2 ruled out sinusitis. If the number of symptoms was 2 or 3, likelihood of having bacterial sinusitis is high. If any of GAS score or likelihood of having sinusitis or diagnosis from physician suggested bacterial infection, we classified that person as 'likely to be a bacterial URIs' case, and antibiotic treatment is appropriate.

At the Health Center, patients were classified by the diagnosis as URI or common cold, unspecified URI, or symptoms like cough, rhinitis or headache as having 'likely viral' URIs. Patients diagnosed with pharyngitis or sore throat, tonsillitis, acute otitis media, or sinusitis were classified as having 'likely bacterial' URIs. Patients with more than one URI diagnosis were classified according to the most severe diagnosis.

Knowledge of the Adult URIs Cases

One score was given to the correct answer of patient's knowledge in the household survey questionnaire. The answer of 'not sure/ don't know' was classified as a wrong answer. Summing up the total knowledge score on health seeking behavior included knowledge about etiology and prevention of URIs and selection of appropriate source of care for each symptom. Total knowledge score on antibiotic use referred to the score of knowledge about antibiotic use, danger of antibiotics, and effectiveness of antibiotics. A higher knowledge score was more preferred. Data were presented as a percentage of the patients correct answers to each specific knowledge question.

Attitude towards Different Treatment Approaches

Scores in negative questions were reversed and the score was summed for the information subscale (IF) and behavior involvement subscale (BI) separately before

summing them together to total score for attitudes toward different treatment approaches. The higher IF score means that respondent was more likely to have more favorable attitudes towards receiving health care information. At the same time, the higher BI score indicated that the respondent was more likely to be actively involved in their health care. Thus, a higher score of IF, BI and KHOS were preferred.

Belief Regarding One's Ability to Control over Health

Regarding the suggestion from the developer of the Multi-dimensional Health Locus of Control (MHLC) (Wallston, Wallston and De Vellis, 1978), instead of using 3 for the middle choice of the 5-likert scale, score of 3.5 was suggested so it could be comparable to other study that use 6-likert scale as in the original model. The calculation of the total score and mean score of each dimension were done separately without reverse of the score.

Drug Group

The medicines reported by adult URIs cases and medicines received from SCM in drug stores were grouped into antibiotics, analgesics/antipyretics, nasal preparations (antihistamines, decongestants, and combinations with or without analgesics/antipyretics), and cough remedies (including antitussives, mucolytics and expectorants).

Location of Treatment and Point of Care

Location of treatment was classified as treatment at home, drug store with and without request for advice (self-prescribing at drug stores), and clinical setting (including government and private hospitals, private clinics, and BMA Health Center). The point of care for adult URIs cases was classified as first and subsequent point of care.

Descriptive Analysis and Test of Association

The missing information of age and income of respondents in the household survey and the prescription review were replaced with their median values. Cases were

excluded in each particular analysis if other categorical data were missing. To describe the characteristics or patterns of treatment, percentage, proportion, mean, or median were reported where appropriate, such as percentage of antibiotic use in the course of URIs in the community setting, percentage of antibiotic prescriptions of all prescriptions for eligible Health Center patients, and mean cost associated with inappropriate antibiotic use. To measure the unadjusted association between predictor variables (characteristics of the patients, type of drug use, pattern and cost of treatment by possible type of URI infection) and antibiotic use for URIs, chi-square test or Fisher's exact test for categorical variables and Student's t-test for continuous variables was performed. A two-sided P-value of less than 0.05 was considered statistically significant.

Cost Associated with Antibiotic Use

In analyzing treatment cost for each particular patient, either in the household survey or at the health setting, only the direct cost of the drug received was analyzed. Other direct costs not associated with URI treatment or other indirect medical cost (e.g. travel cost and lost of workdays) were not included in the study. The cost of drugs taken at home by the patient was not collected as the study assumed that the patient used left over medicine available at home, thus the average cost of self-prescribing (with or without antibiotics) at drug store was assigned for self-prescribing at home in order to compare the direct medical cost at each setting.

Predictors and Models

Logistic regression was used to examine independent predictors of antibiotics dispensing by drug sellers in drug stores. Results were presented as odd ratio (OR) with 95% confidence intervals (CI).

Two multilevel models (or hierarchical models or generalized linear mixed models) (Guo and Zhao, 2000) were developed to adjust for clustering by the provider, while examining predictors of antibiotic prescribing at the health centers. Numerical variables were recoded to categorical variables for univariate and logistic regression analyses. The factors associated with appropriate treatment in both viral and bacterial

URI were identified using two logistic regression models, one for viral URIs and one for bacterial URIs. Variables that were statistically significantly (P -value <0.1) associated with antibiotic prescribing in univariate analyses were included in the initial logistic regression model and removed sequentially if they did not change odds ratios of the remaining predictors by at least 20%. Odds ratios and 95% CI were calculated from the final models. We replaced missing age values ($n=6$, 0.13%) with median age and seven cases (0.16%) with missing payment status (a dichotomous variable) were excluded from the logistic regression analysis. Data were managed and analyzed using the Statistical Package for the Social Sciences (SPSS) for Windows 12.0.0. (SPSS Inc., 2004) and Statistical Analysis Software (SAS) 8.02 (SAS Institute Inc., 1999). **Qualitative data**

Qualitative data were collected with data collection form, field note, tape recorder, and photography from the semi-structured interview, FGD, and participation observation in guideline development process. Notes from each meeting or focus group discussion were compared for accuracy with tapes and then summarized. Framework of the step in guideline development was used to evaluate the process of guideline development.

ETHICAL CONSIDERATION

The study was approved by i) the Human Research Ethical Committee at the Faculty of Medicine of Chulalongkorn University, ii) the Ethical Review Committee for Research in Human Subjects, Ministry of Public Health, Thailand, and iii) the Boston University Medical Center Institutional Review Board.

Inform consents and information sheets were established and distributed to each target group. Written consent was obtained from local NGOs to any project activity in the area and community member approval to participate in the activities of civil society was automatically sought previously at each activity. Verbal inform consent was obtained from cases at each household before the semi-structured interview and household survey. All information of the study cases was kept confidential in order to

protect human rights. The individual was free to refuse to participate and free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled.

For the health provider, inform consent was obtained from the head of medical officers at the health centers at the beginning of the study. The information sheet was given to the physicians and verbal inform consent was obtained from each individual physician before the semi-structured interview begin. The drug sellers received an information sheet and gave verbal informed consent before the semi-structured interview. Their information sheet also stated that once they were in the study, their practice could be observed by a simulated client at any time.