CHAPTER 8

RESEARCH METHODOLOGY OF STUDY 2

Four male and four female SCs were carefully trained in asking for treatment of uncomplicated URI from pharmacists in 32 drugstores.

1. Study setting

This study was conducted in 2005 in a city in the south of Thailand with a population of about 160,000. The study was confined to type I drugstores, where a pharmacist is available at opening hours. By Thai law, the pharmacist is allowed to dispense antibiotics without prescription.

There were 189 type I drugstores in the study area. Name list of drugstores in the study area was obtained from the Provincial Public Health Office. Twenty-five drugstores were excluded because their practising pharmacists worked as staff members in the Faculty of Pharmaceutical Sciences where the first author (SW) was a graduate student and therefore some of the staff members might be aware of this research.

Thailand experiences a similar problem as many other developing countries, such as India and Peru (Goel, et al., 1996). That is the problem of "officially employed but physically absent pharmacists", resulting in many drugstores staffed with minimally trained or untrained persons. Our study focused on the behaviors of pharmacists. However, it is possible that pharmacists are not available on duty during our data collection. Consequently, our research assistants surveyed every drugstore in order to identify the drugstores with practicing pharmacists. The survey was conducted during 5-9 p.m. because pharmacists are more likely to be available during this time of day. Many drugstores hire part-time pharmacists, who normally start working after 5 p.m. In addition, drugstores are usually busy during the evening. Pharmacists are more likely to practice at that time, even though they are not physically present at the drugstore during the day.

In order to identify pharmacists, two research assistants entered the drugstore and asked for a pharmacist. If someone presented him/herself as a pharmacist, one of the research assistants would ask him/her on one of two fictitious drug related problems. In the first drug related problem, the research assistant showed containers of tetracycline and ferrous fumarate to the drugstore personnel without the names of drugs on containers. The assistant stated that his/her brother had taken these drugs to manage acne for five days, but his cheeks were still red and rough because of acne. The assistant asked them about the effectiveness of these drugs for management of acne. The other drug related problems used for identifying practising pharmacists was adverse drug reaction from erythromycin. The research assistant showed erythromycin in a container labeled with only the dose and administration (take one tablet, four times a day before meals and at bedtime), without the drug's name. The assistant said that he/she had nausea every time after taking this drug and asked the drugstore personnel about the cause and how to handle the problem.

It was assumed that the pharmacist should be able to recognize rather simple drug related problems in these fictitious cases. The drugstore staff who correctly told the research assistants on cause and solution of such problems was identified as the pharmacist for later data collection. The research assistants described the characteristics of the pharmacist in detail (such as gender, age, height, appearance) in the record form immediately after leaving the drugstore. The characteristic of the pharmacist in each drugstore was verified immediately. If the research assistants could not find the pharmacist, they would visit the same drugstore again one week later. Any drugstore in which a pharmacist could not be identified in both surveys would be excluded from this study. Information on the pharmacist characteristics was used by the SCs during secret shopping.

2. Sample

The current study identified 60 drugstores with the presence of pharmacists. Of these, 32 drugstores were randomly selected. The sample size of drugstores was calculated using the formula based on the randomized block factorial design (Kirk, 1995).

The formula for computing the sample size is

$$f^* = f/\sqrt{1-\rho}$$

where

f^* is effect size that is used in table produced by Foster (1993) in order to estimate the sample size in that table.

f is effect size in the study.

(f = 0.10 is a small effect size; f= 0.25 is a medium effect size and f> 0.40 is a large effect size). Three effect sizes were chosen 0.20, 0.30 and 0.40 representing small to moderate effects.

ρ is the population correlation among the *pq* treatment combinations.

ρ was considered to be close to 0.30 due to data being collected from the same person. On visiting a drugstore, each shopper had to dress as having moderate and low SES appearance.

Steps to calculate the sample size

1) Specify f = 0.20 and ρ = 0.30 into the above formula.

$$f^* = f/\sqrt{1-\rho}$$
$$= 0.20/\sqrt{1-0.30}$$
$$= 0.24$$

2) Determine the values of level of significance (α=0.05) and power (1-β = 0.80)

3) Compute degrees of freedom (ν_1 and ν_2) from $\nu_1 = p - 1$ and $\nu_2 = (pq - 1)(n-1)$

where p = levels of the treatment A (gender) = 2 (male and female)

q = levels of the treatment B (SES) = 2 (moderate and poor SES)

n is the number of blocks.

$\nu_1 = p - 1$
$= 2-1$
$= 1$

$\nu_2 = (pq - 1)(n-1)$
$= (2*2 - 1)(n-1)$
$= 3(n-1)$

4) Enter f^*, α, 1-β, ν_1 and ν_2 into the sample size table of Foster (1993). The value of f^* = 0.24 was between the columns headed by f^*= 0.204 and f^*= 0.250 in the row labeled 1-β = 0.80. The f^* was close to f^*= 0.250. Then, the required number of blocks was 32.

5) Repeat step 1) to 4) again with f = 0.30, 0.40. The number of blocks was 15 and 10, respectively.

Thus, 32 drugstores were required in the SCM study.

Each shop was visited by one male SC twice (with different dressing) and one female SC twice (with different dressing). The number of total visits was 32x2x2=128.

3. Scenario presentation

All SCs were instructed to ask the pharmacists a simple question, "What do you recommend for a sore throat?" Additional information was given by the SC only if the pharmacist asked for it. The full scenario was: since yesterday the SC has had a mild sore throat, clear rhinorrhea, sometimes sneezing and congestion during the daytime and nighttime. The SC symptoms occur once or twice per year. He/she had no cough, no fever, no chronic illnesses, is not taking any medications at present and has no history of drug allergy. SCs would leave all decisions to pharmacists.

4. Data collection forms

Data collection forms included only checkboxes with dichotomous yes/no responses. Items in the checkboxes were based on the guideline and the case scenario in this study. The checkboxes consisted of items on history taking (11 items for male and 12 items for female). Female clients included an extra item for pregnancy/breast feeding status. Other items of the checklists included antibiotic dispensing (1 item), advice giving (2 items) and drug cost (1 item). Each item was assigned 1 point for a correct answer and 0 for an incorrect answer (Table 18). The correct answer was defined as appropriate history taking, advice giving and antibiotic dispensing according to the guidelines of URI management.

Core checklist items to be observed and subsequently recorded by SCs were adapted from guidelines for URI management by Ministry of Public Health in Thailand (Thai Ministry of Public Health, 1988) and American Pharmaceutical Association (Tietze, 2004). The items were reviewed by two clinical pharmacy specialists with 10 years of experiences in

pharmacy practice and an otolaryngologist. The data collection form was pretested in pilot secret shopping in four drugstores.

The pharmacists were expected to ask all questions in accordance with the guideline.

Table 18 Items listed in the URI treatment guideline for community pharmacy practice scoring system

Item	Score
History taking: (maximum score = 11 for male, 12 for female)	
Age of patient (child or adult)	1
Duration of disease (or onset of disease)	1
Symptoms of disease:	
Fever (yes/no)	1
Sneezing (yes/no)	1
Nasal congestion (yes/no)	1
Rhinorrhea	1
-Yes/No (0.25 point)	
-Color (0.25 point)	
-Thickness (0.25 point)	
-Chronicity (0.25 point)	
Sore throat	
-Severity (or dysphagia)	1
Cough (yes/no)	1

Table 18 (continued)

Item	Score
History taking: (continued)	
(maximum score = 11 for male, 12 for female)	
Chronic diseases / previous history (yes/no)	1
Medication currently taking (yes/no)	1
History of drug allergy (yes/no)	1
Being pregnant or breast-feeding for female only (yes/no)	1
Advice giving:	
Rest	1
Maintaining adequate fluid intake	1
Antibiotic dispensing: Do not dispense antibiotics.	

5. The simulated clients and training

Eight SCs (4 males and 4 females) were carefully selected in this study. All were fifth-year pharmacy students aged 21-23, whose hometowns were not in the study site. The SCs received the manual of secret shopping that informed them how to shop, present the symptoms, answer the questions when asked by pharmacists and complete the data collection forms. The manual detailed a standardized data collection process in order to reduce observation bias and variations between SCs. The researchers gave a three-hour lecture on the tasks of SCs, such as how to present themselves to the pharmacist and ask for service, employing the proposed scenario, memorize the key response of the pharmacist in accordance with the checklist aforementioned, purchase the drugs, depart and complete the data record form as soon as he/she was out of sight of the drugstore personnel.

All SCs also went through extensive training in data collection as detailed in the following section.

5.1 Training simulated clients in laboratory

Every SC was well-trained on how to present themselves in drugstores and how to answer the questions. They were trained to present symptoms according to the case scenario (i.e., URI). Steps of training SCs in laboratory were:

1) One of the SCs conducted secret shopping from a trainer (acting as a pharmacist), while the other trainees observed and listened.
2) After the role play, every SC, including the shopper, independently completed the data collection forms.
3) The trainer gave feedback to the practising SCs on how well he/she interacted in the secret shopping scenario and compared the data collection forms from all SCs. Then, the trainer discussed and clarified each point of disagreements.
4) The participants took turns to be the SC and the training was repeated until all SCs performed well in secret shopping and recorded the data in the same way.
5) Each SC had at least three rounds of practice in the laboratory.

Each SC was further evaluated by having them perform two more secret shopping role plays, one with dressing as having moderate SES and the other with dressing as having low SES. The researcher videotaped the secret shopping of each SC. Two community pharmacists viewed each videotape and rated how realistic the SCs were on acting as patient, presenting the symptoms, answering the questions and dressing in moderate and low SES attires.

Manipulation of SES by dressing – We believe that patients from high SES group would preferably seek care from hospitals or physician clinics rather than drugstores. Thus, the current study focused on comparing patients with moderate SES and those with poor SES. The SCs were trained in dressing and presenting themselves as having moderate SES or low SES. The study standardized the dress. In moderate SES, SCs dressed in typical office work attire: blue shirt, black slacks, belt and loafers for males; blue shirt, black suit, short black skirt, black handbag and high heels for females. For low SES, both gender groups wore an old T-shirt, old long pants and sandals. They were asked to dress in the same way at each time of secret shopping. The

researcher examined each SC appearance before conducting secret shopping. Manipulation check was conducted by having two raters (not pharmacists in the study) evaluated each SC's appearance, on a 5-point scale ranging from not realistic at all (1) to very realistic (5). Table 19 displays the rating of SES of SCs by the raters. There was an interaction between rating in dressing of SCs and the raters. The Bonferroni test was used for multiple comparison tests. The mean scores from the first rater on rating of moderate and low SES were 5.00±0.13 and 1.00±0.13, respectively. The results found that the difference in SCs' SES rated by the first rater was significantly different ($P < 0.001$). The rating from another rater for moderate and low SES realistic appearance was 4.75±0.13 and 1.38±0.13, respectively. The rating in SES difference were also significantly different ($P < 0.001$).

Table 19 The measures of dressing in different SES of simulated clients by two raters

Variable	df	Mean square	F	Sig.
Subject	7	0.103	0.812	0.588
Dressing	1	108.781	860.012	0.000
Rater	1	0.031	0.247	0.624
Dressing*rater	1	0.781	6.176	**0.021**

After SCs passed the training in the laboratory, they were given another course of training in an actual drugstore.

5.2 Training simulated clients in a real drugstore

The trainer was a community pharmacist contacted by the researcher. The researcher and the trainer agreed on how the trainer would ask about symptoms, disease management and advice giving. The trainer maintained the same style of interaction with all SCs. For the assessments of the SCs in a real drugstore, conversations were recorded on audiotapes with permission from the pharmacist. Subsequently, the data collected by the SC were examined against information in the audiotape. If the data recorded by the SC differed by more than 5%

(2/41 items) from what really happened in the training drugstore, they were retrained until their data were accurate.

6. Simulated client survey

Secret shopping was conducted by eight trained SCs in 32 drugstores, as shown in Table 20. Each SC visited eight drugstores twice one month apart, one with moderate SES appearance and the other with low SES appearance. The sequence of low or moderate SES appearance and drugstores to be shopped were randomly chosen for each client.

The timing of the visit was late afternoon or early evening, after official working hours when the pharmacist was more likely to be on duty in each drugstore. All visits in a particular drugstore (four times) were planned to interact with the same pharmacist.

7. Drug identifications

Since drugstore personnel typically do not label the names of medications, drug identifications were performed as follows. Firstly, the SCs tried read and remembered the drugs' names on the label of the containers, while the pharmacists were dispensing the medications during each encounter. Secondly, the main researcher and another community pharmacist identified the drugs dispensed independently. Their identifications of drugs were compared for agreement. Finally, if pharmacist and researcher disagreed on drug identification, a research assistant would go back to drugstore and purchase the unidentified drugs. The research assistant had to remember the name listed on the label and then asked the pharmacist to write the name of drugs for him/her.

Table 20 Diagram of the study design to investigate the effects of gender and SES appearance of clients on dispensing behaviors of pharmacists using SCM study

Drugstore	Simulated client characteristics															
	Male								Female							
	Moderate SES				Low SES				Moderate SES				Low SES			
	S1*	S2*	S3*	S4*	S1*	S2*	S3*	S4*	S5*	S6*	S7*	S8*	S5*	S6*	S7*	S8*
1	✓				✓				✓				✓			
2	✓				✓				✓				✓			
3	✓				✓					✓				✓		
4	✓				✓					✓				✓		
5	✓				✓						✓				✓	
6	✓				✓						✓				✓	
7	✓				✓							✓				✓
8	✓				✓							✓				✓
9		✓				✓			✓				✓			
10		✓				✓			✓				✓			
11		✓				✓				✓				✓		
12		✓				✓				✓				✓		
13		✓				✓					✓				✓	
14		✓				✓					✓				✓	
15		✓				✓						✓				✓
16		✓				✓						✓				✓
17			✓				✓		✓				✓			
18			✓				✓		✓				✓			
19			✓				✓			✓				✓		
20			✓				✓			✓				✓		
21			✓				✓				✓				✓	
22			✓				✓				✓				✓	
23			✓				✓					✓				✓
24			✓				✓					✓				✓
25				✓				✓	✓				✓			
26				✓				✓	✓				✓			
27				✓				✓		✓				✓		
28				✓				✓		✓				✓		
29				✓				✓			✓				✓	
30				✓				✓			✓				✓	
31				✓				✓				✓				✓
32				✓				✓				✓				✓

S1*- S4* reflects male SCs numbered 1 to 4.

S5*- S8* denotes female SCs number 1 to 4.

8. Statistical analysis

In addition to routine descriptive statistics, mean±SD of scores were calculated for each subgroup of combinations between SC gender and SES appearance and between gender of pharmacists and of SCs. These allowed clear comparisons among the combinations.

Dependent variables included scores (continuous variable) on history taking, advice giving and drug cost and binary outcome of dispensing/not dispensing antibiotics. Since the observations were carried out separately nested on both the same SCs and drugstores, mixed effects modeling under 'lme4' (Bates and Sarkar, 2006) of R software version 2.4.0 was used (R Development Core Team, 2006). Fixed effects included the gender and SES appearance of clients and gender of pharmacists. Interaction terms, both between client gender and pharmacist gender and between client SES and pharmacist gender, were also tested as fixed effects and retained in the model if significant. SCs and drugstores were treated as random effects, which means that each drugstore and each SC had their own baseline estimated scores or probability of having antibiotics dispensed, which were assumed to be random variables (without any coefficient). The 95% confidence limits for continuous variables were achieved using Markov Chain Monte Carlo sample from the posterior distribution of the parameter estimates and the Highest Posterior Density Interval (HPDinterval) function from the 'coda' package (Plummer, et al., 2006). For binary outcomes, odds ratios and 95% confidence intervals were directly calculated from the coefficients and standard errors based on the Z distribution assumption.

9. Ethical approval

The study was approved from the Ethics Committee, Faculty of Pharmaceutical Sciences, Prince of Songkla University. Informed consent from the pharmacists was not obtained, because the consent process may influence their behaviors.