

## **CHAPTER IV**

### **Data exercise**

#### **The prevalence and risk ratio of patients suspected of leptospirosis**

##### **4.1 Introduction**

This chapter presents the results of a data exercise to test the questionnaire designed for the study. The questionnaire is developed on the basis of WHO standard guideline for leptospirosis diagnosis. However, the specific risk factors from Tangkanakul et al. and Lepto-dipstick assay are used to adapt the questionnaire in Part B and Part C of WHO guideline for leptospirosis diagnosis.

##### **4.2 Objectives of data exercise**

- 4.2.1 To implement the pretest of the questionnaire.
- 4.2.2 To achieve the skill and familiarity with data analysis
- 4.2.3 To achieve the skill on research management.

##### **4.3 Questionnaire and Lepto-dipstick assay**

The checklist includes demographic information of the patient, case history associated to specific risk factors, lepto-dipstick assay's result.

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#### **4.4 Field activities**

Patients over ten years of age who presented to the hospital with clinical symptoms that matched to the inclusion criteria (Fever and at least one of myalgia or headache) and screening test to rule out common disease were negative, were included in the study. Recruitment of patients was performed at Yupparadsawangdandin Hospital, Sakon Nakhon province during June to August, 2000, from both the Out-Patient Department (OPD) and the In-Patient Department (IPD).

Selected patients were asked to answer a questionnaire that included their demographic information, history of present illness, and participation in certain risk factors. Patients were then separated into risk positive and risk negative patients based on their responses to the specific risk factors questions. The risk positive patients were defined as patients who had participated in any of the following activities for at least 6 hours a day: plowing, pulling out sprouts, fertilizing and caring, and walking through water. The remaining patients were defined as the risk negative patients. A blood sample was then obtained and sent to the laboratory on the date of admission. Serum was collected and tested specific for leptospirosis by using Lepto-dipstick assay. Patients in the study were asked to return for a follow-up visit one week later for taking the second serum. Paired serum samples were needed to reliable make a negative diagnosis. However, due to low levels of compliance among the patients,

some of them either returned over a week later or did not return at all. In the latter case, an effort was made to visit them in the community to obtain a follow-up sample. As a result, paired serum samples were obtained anywhere from one to three weeks after initial presentation of the illness. However, this still fell within the optimal period for the Lepto-dipstick tests used in this study.

On-site testing was conducted with the Lepto Dipstick test on the paired samples obtained from each patient. Assay results was independently read by 3 separate readers to try to eliminate reader bias. The range of values for the test bands are -, 1+, 2+, 3+, and 4+. Serum from patients with results graded 2+ or higher were considered positive for recent leptospirosis infection. Readings conducted at the hospital were provided by the collaborating Internist, the chief of the laboratory, and the research nurse of this study. The responsibility people and function were as Table 4.1.

**Table 4.1 Responsibility people and function**

Responsibility person	Function
1. OPD Nurse	<ul style="list-style-type: none"> <li>- Interview and enter history into chart</li> <li>- If inclusion criteria match, send to researcher</li> <li>- Make entry into admission logbook</li> </ul>
2. Physician	<ul style="list-style-type: none"> <li>- Physical examination and order for screening test to rule out common disease, cases that were tested negative, were enrolled to the study.</li> <li>- Order Leptospirosis Ab</li> </ul>

	- Optional logbook.
3. Researcher	- Filled in the questionnaires based on admission logbook - Check all logbooks and lab results - Take second serum if patient did not return.
4. Laboratory	- Test for leptospiral IgM antibody by using lepto-dipstick assay and the other blood tests - Divided serum into 3 quantities and stored in freezer for MAT testing. - Log samples and patient numbers in laboratory logbook.
5. Ward and OPD Nurse	- Make appointment for second serum test in 1 week (appointment logbook).

## 4.5 Findings

### 4.5.1 Finding of demographic data of risk positive and risk negative patients

The filled form of demographic data checklist was as follows

	Risk positive patient ( )	Risk negative patient ( )
	No.....	
<b>1. Identify part</b>		
Hospital..... H.N. ....A.N.....		
Date of admission.....Departure date.....		
Result of treatment ( )cure ( ) dead ( ) refer		
Type of patient ( ) outpatient ( ) inpatient Hospital ward.....		

## 2. Demographic data

Name-surmane ..... age .....

gender ( ) male ( ) female occupation .....

Hometown No..... village..... Tambon.....

Amphur.....

Province.....

Ill place No..... Village..... Tambon.....

Amphur.....

Province.....

(at least stay in the location more than for 14 days)

During the study period, a total of 113 patients were interviewed with the questionnaires, 65 were defined as the risk positive patients and 48 were defined as the risk negative patients. However, due to various factors, 12 patients were excluded from the risk positive patients and 1 patient was excluded from the risk negative patients. This left a final sample size of 100 patients, 53 risk positive patients and 47 risk negative patients. The male to female ratios was 1.7: 1 (33:20) for the risk positive patients and 1.4: 1 (27:20) for the risk negative patients. The median age among the risk positive patients was 32 (range 13-65) while risk negative patients averaged 42.0 (range 10-79). A significant difference existed in the occupation distributions between the two groups. Ninety one percent of the patients who had risk factors were farmers while only 53% of the patients who did not have risk factors were farmers.

Other occupations represented in the risk negative patients were student, housewife, monk, government service, and teacher.

#### 4.5.2 Finding of epidemiological factors of risk positive and risk negative patients.

The filled form of epidemiological factors checklist was as follows

3. Epidemiological Factors Engage to these factors in the past 15 days before admission		
<input type="checkbox"/> had risk factors <input type="checkbox"/> did not have risk factors		
Epidemiological factors	Did	Did not
• Water Contact		
1. Plowing more than 6 hours per day		
2. Plowing .....hours a day		
3. Pulling out sprout more than 6 hours per day		
4. Pulling out sprout .....hours a day		
5. Fertilizer and caring more than 6 hours per day		
6. Fertilizer and caring ..... hours a day		
7. Walking through water or mud more than 6 hours per day		
8. Walking through water or mud .....hours a day		
9. swimming or fishing more than 6 hours per day		
10. swimming or fishing ..... hours a day		
11. Cleaning the sewage system more than 6 hours per day		

12. Cleaning the sewage system ..... hours a day		
13. Wound which contact to mud or water		
14. Feeding animals		
15. Butchering		
16. Working with the animals		
17. Direct contact with animal		
18. Drinking water in the river		
19. Eating remnant food		
20. Drinking unboiled water		

All of risk negative patients did not have rice activities or walking through water more than 6 hours. Risk positive patients reported eating remnant food and drinking unboiled water more than risk negative patients. Percentage of all participants, who related to animals, was few. (Table 4.2).

**Table 4.2 Results of epidemiological factors among risk positive and risk negative patients.**

<b>Epidemiological factors</b>	<b>Risk positive patients (%), N=53</b>	<b>Risk negative patients (%), N = 47</b>
1. Plowing more than 6 hours per day	54.7	0
2. Plowing .....hours a day	0	0
3. Pulling out sprout more than 6 hours per day	100	0
4. Pulling out sprout .....hours a day	0	0
5. Fertilizer and caring more than 6 hours per day	3.7	0
6. Fertilizer and caring ..... hours a day	0	2.1
7. Walking through water or mud more than 6 hours per day	1.8	0
8. Walking through water or mud .....hours a day	0	4.2
9. swimming or fishing more than 6 hours per day	1.8	0
10. swimming or fishing ..... hours a day	0	6.3
11. Cleaning the sewage system more than 6 hours per day	0	0
12. Cleaning the sewage system ..... hours a day	0	0
13. Wound which contact to mud or water	0	0
14. Feeding animals	0	0



15. Butchering	1.8	0
16. Working with the animals	0	0
17. Direct contact with animal	1.8	0
18. Drinking water in the river	1.8	2.1
19. Eating remnant food	98.1	78.7
20. Drinking unboiled water	100	85.1

#### 4.5.3 Results of Lepto-dipstick assay

The filled form of Lepto-dipstick assay was as follows

#### 4.Laboratory

1. Date blood drawn for lepto Dipstrip 1st..... titer .....
2. Date blood drawn for lepto Dipstrip 1st..... titer .....

Initial results of the Lepto Dipstick assay performed on the first serum sample, as shown in Table 4.3, revealed 19 positive cases among the 53 risk positive patients. In the risk negative patients, 5 cases were positive among the 47 risk negative patients. This indicated a prevalence of 35.8% among the risk positive patients and 10.6% among risk negative patients. Subsequent testing on the second serum samples produced an increase in every category. Positive tests in the risk positive patients increased by 10 to 29 cases, or 54.7% of the risk positive patients, while positive results increased by 5 to 8 cases, or 17%, within the risk negative patients. The overall prevalence of leptospirosis within our respondents based on these figures was 37%.

**Table 4.3. Results of Lepto Dipstick assay performed on first and second serum samples.**

<b>Sample</b>	<b>Results</b>	<b>Risk positive patients N = 53 (%)</b>	<b>Risk negative patients N = 47 (%)</b>	<b>Total N=100</b>
<b>First Serum</b>	<b>Positive</b>	19 (35.8 %)	5 (10.6 %)	24
	<b>Negative</b>	34 (64.2 %)	42 (89.4 %)	76
<b>Second Serum</b>	<b>Positive</b>	29 (54.7 %)	8 (17.0 %)	37
	<b>Negative</b>	24 (45.3 %)	39 (83.0 %)	63

#### **4.5.4 Results of prevalence ratio (risk ratio) and the prevalence differences (risk differences)**

The results indicated that the overall prevalence of leptospirosis among the patients was 37%. Among the risk positive and risk negative patients, the prevalence rates were 54.7% and 17.0% (CI), respectively. The prevalence ratio (risk ratio) between these two groups was 3.21 (1.63 <RR<6.33).

**Table 4.4. Analysis of Risks Associated with Risk Factor Exposure**

Risk Factors	Diagnosis	
	Positive	Negative
Risk positive patients	29	22
Risk negative patients	8	39
Attributable Risk	37.7% (54.7%-17%)	
Risk Ratio	3.22	

#### 4.6 Discussion

Data exercise was done primarily to fulfill the objectives of making trial of questionnaire. The result also meant to make revision and modification of the contents, structure and format of the questionnaire. The other objective was to get some extent of acquaintance with data analysis.

The data exercise has been shown that almost all of the farmers did plowing, pulling out sprouts and fertilizing more than 6 hours per day and no respondents did cleaning the sewage system. The result also showed that the important of univariate analysis and multiple logistic regression to identify the independent risk factors because most of the risk positive patients also drinking unboiled water and eating remnant food. In this data exercise, prevalence ratio and prevalence differences were calculated by using the combination of four specific risk factors from Tangkanakul et al. study. However, it should divide and calculate for each specific risk factor in the complete study.

The duration of the study has also shown the bias on data collection. This study was conducted during the period of pulling of sprout, so that the percentage of this activity was higher than the other rice activities. For the next study, we have to collect the information for the whole period of rice activities.

#### **4.7 Lesson learnt from data exercise**

From data exercise, it was found that OPD cases had various problems encountered during the course of the study especially collecting the second serum that might be taken into account when analyzing the results. Although efforts were made to obtain a complete sample of patients who presented with symptoms, which matched the inclusion criteria. However in OPD cases, it was not possible to collect questionnaires or sera from all patients who were seen in the OPD. To achieve complete information on taking the second serum, it was emphasized to collect only inpatient cases.

## References

1. Tangkanakul, W, Tharmaphornpil, P, Plikaylis, BD, Poonsuksombat, D, Choomkasian, P, Kingnate, D, Ashford, DA. Risk factors associated with leptospirosis infection in northeastern Thailand, 1998. (inpress).
2. Patumanond J. 1998. **Medical Epidemiology**. First printing. Bangkok: Suksopa press;