CHAPTER V

Presentation

In this chapter the slide presented in the examination are described according to sequence shown to examination committee.

The prevalence and risk ratio of patients suspected of having Leptospirosis

Waraluk Tangkanakul

Problems

- A large epidemic of leptospirosis in Thailand.

- Large proportion of undetected cases.

- Differences in diagnosis between physicians.

- Differences in clinical manifestation of the disease.

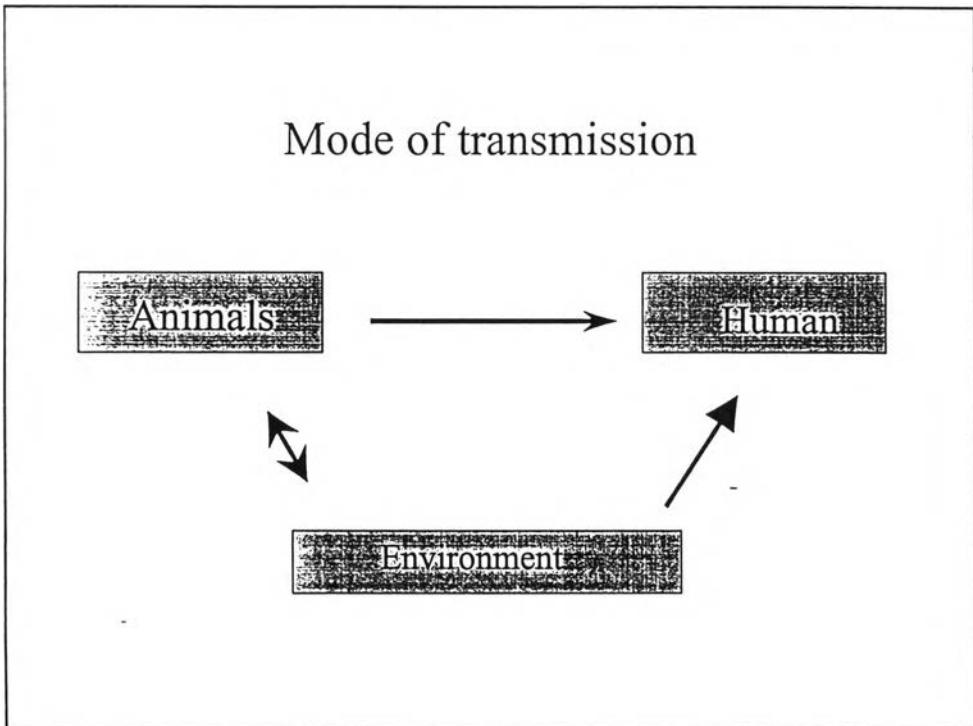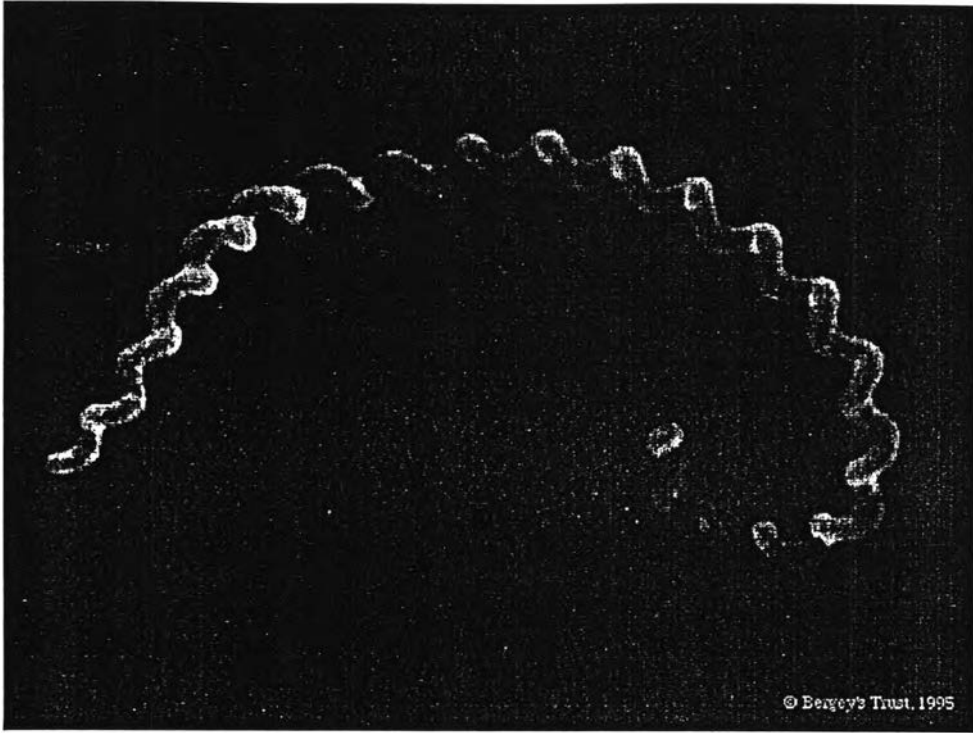- Differences in availability of laboratory services throughout country.

Reported Cases of Leptospirosis and case ratio (Per 100,000 Population) by Year, Thailand, 1995-2000

%

No. of Cases — Morbidity
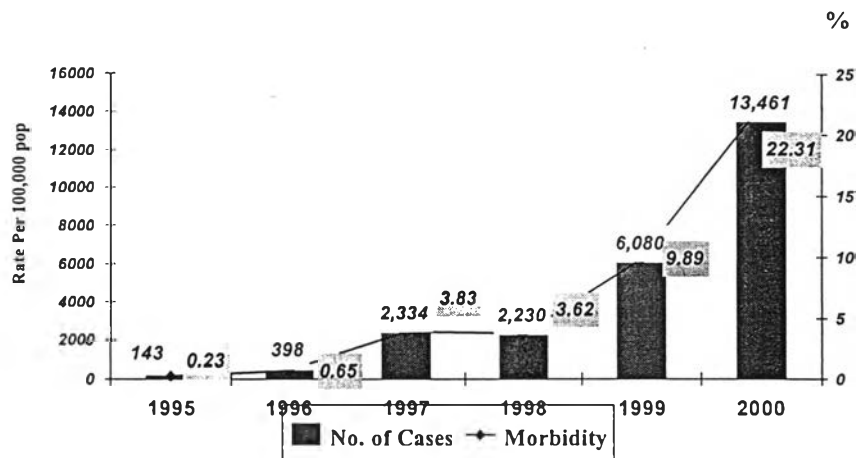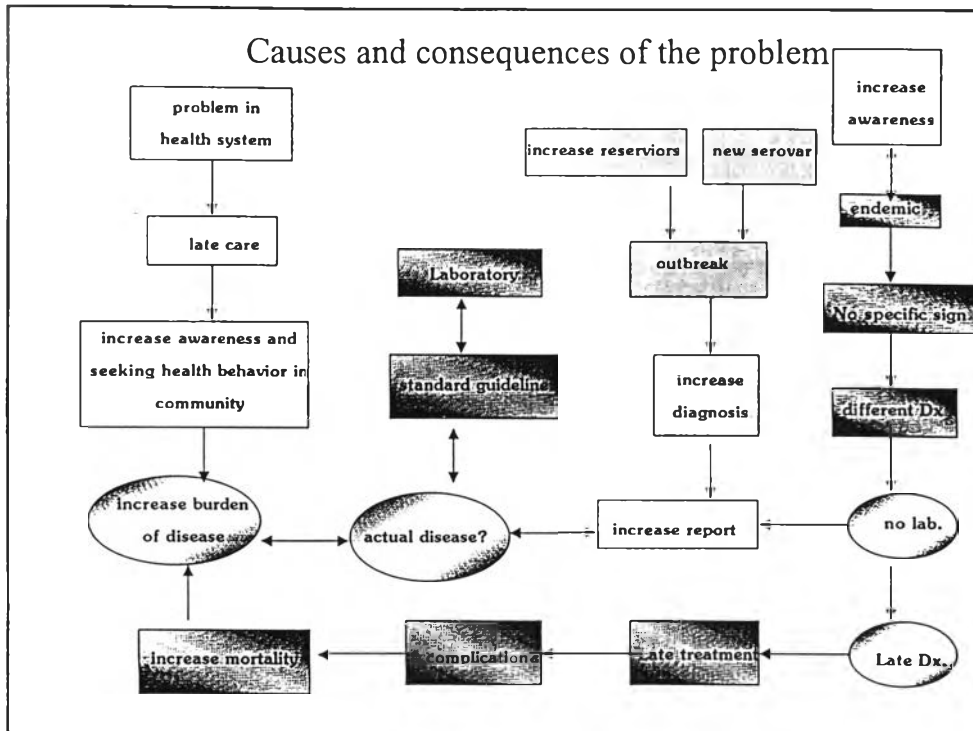
Source: 31 Dec. 2000, 506 Disease Notification Report, Leptospirosis Control Office

Background

- Reservoirs: Feral and domestic animal species

- Transmission: the urine of infected animals or a urine-contaminated environment

- Spreading: a humid subtropical or tropical climate. seasonally, certain occupations.

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Mode of transmission

Animals → Human

Environment

Causes and consequences of the problem

```
[problem in              [increase reserviors] [new serovar]        increase
 health system]                                                     awareness
       |                                                                |
       v                                                                v
   [late care]                [Laboratory]      [outbreak]          [endemic]
       |                          |                 |                   |
       v                          v                 v                   v
[increase awareness and    [standard guideline] [increase       [No specific sign]
 seeking health behavior in                       diagnosis]           |
 community]                       ^                  |                  v
       |                          |                  |            [different Dx]
       v                          v                  v                  |
  (increase burden  <-->  (actual disease?) <-- [increase report] <-  (no lab.)
   of disease)                                                          |
       ^                                                                v
       |                                                          (Late Dx.)
  [increase mortality] <- [complications] <- [late treatment] <--
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WHO standard guideline for Leptospirosis diagnosis

- Part A Clinical manifestation

- Part B Risk factors associated with leptospirosis infection

- Part C The standard test results (Microscopic Agglutination Test, MAT)

Specific Risk Factors (Tangkanakul et al, 1998.)

- Walking through water

- applying fertilizer in wet fields for more than 6 hours a day

- plowing in wet fields for more than 6 hours a day

- pulling out rice plant sprouts in wet fields for more than 6 hours a day

- *All risk factors were statistically significant on both univariate and multivariate analysis.*

Laboratory Tests

- Gold Standard

1. Culture : not available in Thailand.

2. MAT : limits in reference laboratory and epidemiological study.

3. IgM ELISA : not practical.

Lepto-dipstick assay

- Detection of *Leptospira*-specific IgM antibodies

- Sensitivity (86.8%- 98%) and specificity (92.7%-100%) as IgM ELISA.

- Practical in clinical diagnosis.

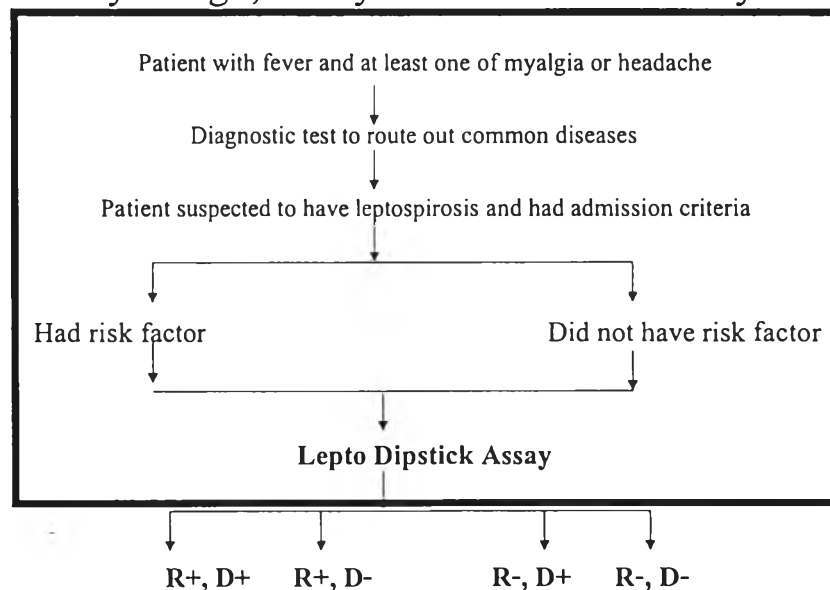- Individual test.

- Stored at room temperature (20°C-25°C).

Hypothesis

Prevalence of leptospirosis in patients suspected leptospirosis who had risk factors are > who did not have risk factors

Objectives

- General objective: To identify and measure the effects of specific risk factors for leptospirosis diagnosis among patient suspected leptospirosis.

- Specific objectives:

- To test an association between leptospirosis and specific risk factors.

- To conduct a field test of the Lepto-dipstick assay in a rural endemic tropical region.
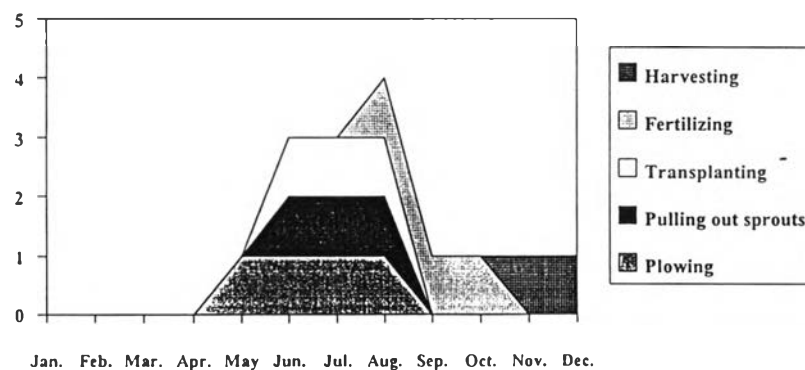
Study design; Analytic crossectional study

Patient with fever and at least one of myalgia or headache

↓

Diagnostic test to route out common diseases

↓

Patient suspected to have leptospirosis and had admission criteria

↓

Had risk factor   Did not have risk factor

↓

Lepto Dipstick Assay

R+, D+   R+, D-   R-, D+   R-, D-

Sample size

- $N1 = (Zalpha + Zbeta)^2 \times PQ \times (r+1) / (P_1 - P_0)^2$

- $P = P1 + r P_0 / 1 + r$ and $r = n_{t}/n_{t}$

- P = proportion of average outcome among two group, Q=1-P

- P1= proportion of exposed that has outcome

- P0 = proportion of non exposed that has outcome

- Prevalence of lepto in FUO = 5%, OR from Tangkanakul et al. = 4

- $N = [(1.96 + 1.28)^2 \times 0.22 \times 0.78 \times (0.66+1) / (.15)^2$

- where zalpha is 1.96 (95% CI), Zbeta is 1.28 (90% power)

- $P = 0.2 + (0.66 \times 0.05 / 1 + 0.66) = 0.22$

- **Total Sample Size = 222**

Study period

Legend:
- Harvesting
- Fertilizing
- Transplanting
- Pulling out sprouts
- Plowing

Jan. Feb. Mar. Apr. May Jun. Jul. Aug. Sep. Oct. Nov. Dec.

Outcome measures

- Prevalence of leptospirosis in participants

- Prevalence ratio or risk ratio among risk positive and risk negative patients.

- Prevalence difference or risk difference among risk positive and risk negative patients.

. Odd ratio

Method of data collection

- Standardized questionnaire

- Results from Lepto-dipstick assay

Analysis of data

- After data collection, data entry will done with Epi Info software (version 6.02, CDC, Atlanta, GA)

- Prevalence ratio and prevalence difference will been calculated.

- Logistic regression to identify independent risk factor

Utilization of the study

- The study will determine whether the prevalence of positive leptospirosis serum tests were higher in patients who expose to the risk factors versus the patient who did not expose to the risk factor.

- The benefit of identifies the prevalence ratio and prevalence difference among these patients will help to improve the guideline to diagnose leptospirosis.

Budget

- Data collection expenses   230,900 bahts

- Equipment and Lepto-dipstick assay   80,000 bahts

- Transportation cost   87,500   bahts

- General   10,000   bahts

- Grand total cost   408,400   bahts

- In US dollar (1 dollar = 44 baht)   9,281 dollars

Data exercise

The prevalence and risk ratio of patients suspected of Leptospirosis

Objectives

- To implement the pretest of the questionnaire

- To achieve the skill and familiarity with the data
  analysis

- To achieve the skill on research management

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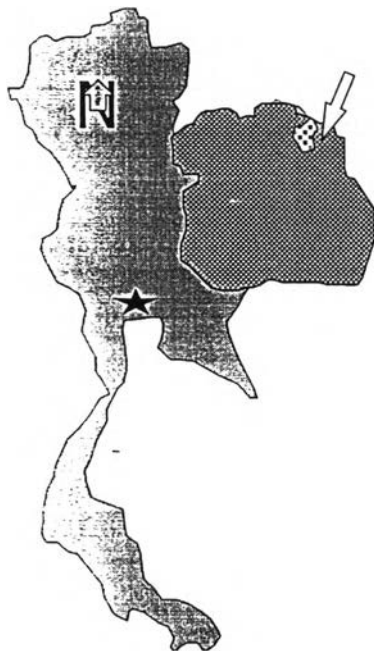
- **Study area**

- Sakhon Nakorn province

- population of 946,957 (1998 data)

- area of 9,605.8 km^2

- population density of 98.58
  person/km^2.

- Yuparadsawangdandin hospital in the
  Sawangdanin district. These patients
  will primarily come from the district's
  local population of 119,672.

Demographic data of risk +ve and risk -ve patients

	Risk +ve patient (n=53)	Risk -ve patient (n= 47)
M : F	1.7 : 1	1.4: 1
Age (range)	32 (13 - 65)	32 (10 - 79)
Farmers	91%	53%
Admit in first week	88.6% (3 -	82.6%)
IPD : OPD	1.7:1	0.96:1

Epidemiological factors among risk +ve and risk -ve patients
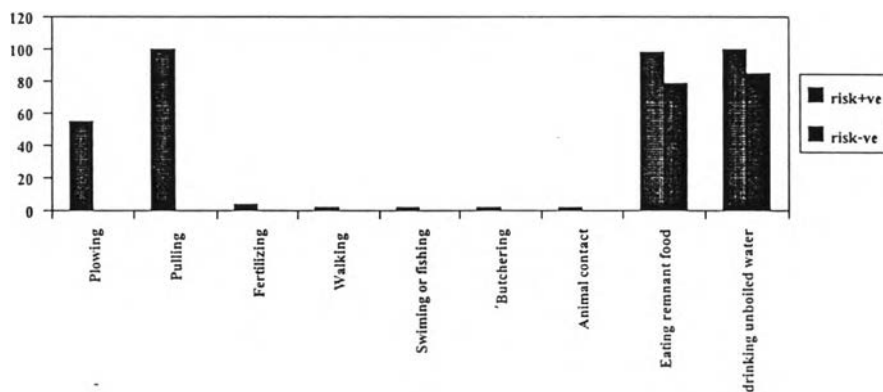
Results of Lepto dipstick assay performed on first
and second serum samples

- First serum
- Risk+ve (N=53)
- Risk -ve (N=47)

	Risk+ve (N=53)	Risk -ve (N=47)
positive	19 (4 convert from + to -)	5 (2 convert + to -)
Negative	34	42
Second serum		
positive	25 (+10)	6 (+3)
negative	28	41
Total +	29 (54.7%)	8 (17%)

Analysis of risk associated with risk factor exposure

- Risk+ve patients   positive 29 (54.7%)
- Risk -ve patients   positive 8 (17%)
- Attributable risk   54.7%-17% = 37.7%
- Risk ratio   54.7%/17% = 3.2
- 95% CI   (1.6 <RR< 6.3)