

CHAPTER V

PRESENTATION

This chapter deals with a thesis summary, which will be presented to the thesis examination committee. The presentation is divided into two main parts: part (1) is proposal and part (2) is data exercise.

In the first part (proposal), I will present about background and rationale, methodology, activity plan and budget estimation need for conducting the study of comparison of Cost-effectiveness between 9-month Isoniazid and 2-month Rifampicin plus Pyrazinamide for prevention to active tuberculosis among people living with HIV in Chiang Rai province, Thailand

In the second part (data exercise), I will present about objectives, methodology, findings, recommendation and limitation from data exercise.

Microsoft Power Point will be used for my presentation show. The contents of the slides are shown as following:

Comparison of Cost-effectiveness between 9-month Isoniazid and 2- month Rifampicin plus Pyrazinamide for prevention to active tuberculosis among people living with HIV in Chiang Rai province, Thailand

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Definition

Latent tuberculosis infection(LTBI): tubercle bacilli are in the body but the immune system is keeping them under control.

Active tuberculosis: TB disease develops when the immune system cannot keep the tubercle bacilli under control and the bacilli begin to multiply rapidly in the body

Tuberculin skin test(TST): a test used to detect LTBI

Treatment of LTBI: is the use of medication one or more anti-tuberculous drug given to people who have *Mycobacterium tuberculosis* infection in order to prevent the progression to active TB. [WHO/UNAIDS, 1999]

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Operational definition

Effectiveness: Achieving 1 case with completing treatment . Complete treatment explain as patient who has successfully complete treatment regimen.

Day Care Center(DCC): a hospital-based facility provides physical, psychological and social services to people living with HIV/AIDS).

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Background/Rational

- Chiang Rai was one of the first 10 provinces with highest number of cases of AIDS in Thailand.
- Increase incidence rate of new TB patients. (63/100.000 in 1990 to 140/100.000 in 1999)
- Implementation of preventive therapy for tuberculosis among HIV-infected individual is needed . [WHO, 2002]

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The efficacy of difference regimen of tuberculosis preventive therapy

Setting	Regimen	TB incidence
Pape/Haiti (1993)	INH OD x 12 m	2.2 per 100 py
	Placebo	7.5 per 100 py
Zambia (Mwinga 1986)	INH biw x 6m	4.94 per 100 py
	RFP-PZA biw x 3m	4.65 per 100 py
	Placebo	8.06 per 100 py

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Comparison of two regimen in term of complete treatment of TB preventive therapy

	INH	RFP+PZA
Gordin 2000	69%	80%
Zambia 98	63%	68%
Thailand 97	69.4 (Chiang Rai hospital)	-
Regional 10	39%, 34%, 32%	-
Thailand 2000		

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Cost

Drug cost per regimen

- RFP+PZA(2month) 260.8 Baht
- INH(9month) 162.0 Baht

How about other direct costs, indirect costs in different durations of treatments?

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Research question

Which regimens, between 9-month INH and 2-month RFP plus PZA is more cost-effective to HIV-infected person with LTBI?

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Objectives (1)

- To measure the *costs* of implementing treatment of LTBI two regimens: 9-month INH and 2-month RFP plus PZA to HIV-infected person from the perspective of provider (hospital) and patient.

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Objectives (2)

- To measure the *effectiveness in term of completed treatment* of LTBI two regimens: 9-month INH and 2-month RFP plus PZA to HIV-infected person.

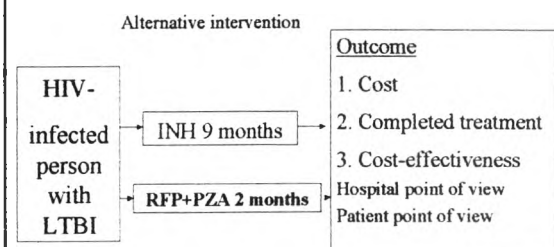
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Objectives (3)

- To compare the *cost-effectiveness* of LTBI two regimens : 9-month INH and 2-month RFP plus PZA to HIV-infected person from the perspective of hospital and patients.

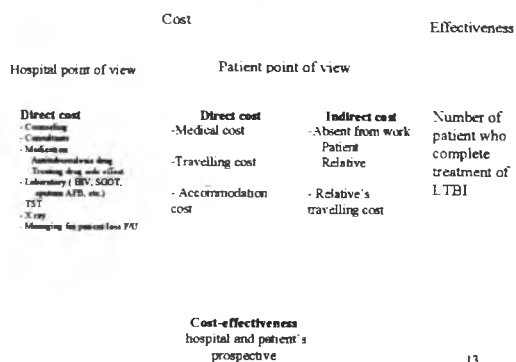
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Conceptual Framework(1)



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Conceptual frame work (2)



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Study design

Multi-center randomized, two-arm, open-label controlled clinical trial.

Study population

The HIV-infected person in Chiang Rai province

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Inclusion criteria

1. HIV positive
2. PPD skin test positive ≥ 5 mm
3. Signed consent form

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Exclusion criteria

1. Current active tuberculosis
2. Patients with a history of active TB
3. HIV infected person who had ever taken INH preventive therapy.
4. Pregnancy women
5. Age ≤ 18 and ≥ 50 years

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Exclusion criteria

6. Weighing ≤ 30 kg and ≥ 75 kg
7. Laboratory:
Aspartate aminotransaminase (SGOT) ≥ 122 U/L, total bilirubin ≥ 2
8. Karnofsky performance status ≤ 60

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Sample size

1. Completion rate of INH = 70.0 %
2. Expected difference completion rate to RFP + PZA = 10%
3. Type I error = 0.05(two-side)
4. Type II error = 0.2
5. Ra

$$n = 634,$$

$$\text{INH} = 317, \text{RFP} + \text{PZA} = 317$$

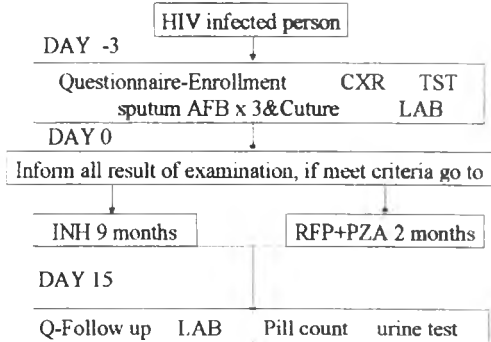
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Study site

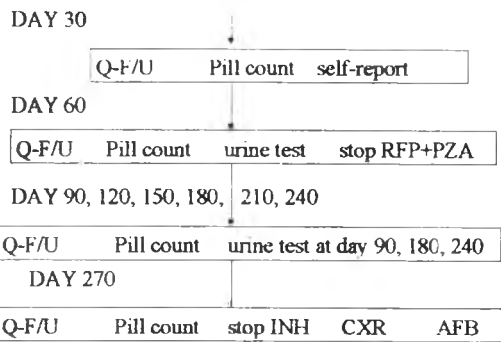
Day care centers in 10 hospitals, Chiang Rai.

Hospital	HIV+	Death	Alive	not yet IPT
1.Phan	1086	258	828	37
2.Mae Chan	970	307	663	230
3.Wiang Papao	503	93	410	347
4.Khuntan	323	32	291	213
5.Chiang Khong	308	69	239	29
6.Chiang Sean	300	58	242	230
7.Mae Sai	238	54	184	88
8.Wiang Kan	183	20	163	142
9.Padad	154	39	115	98
10.Wiang ChiangRung	116	9	107	59
Total	4181	939	3242	1479¹⁹

Method and follow up (1)



Method and follow up (2)



Data analysis

$$\text{Cost-effectiveness ratio} = \frac{\text{cost}}{\text{effectiveness}}$$

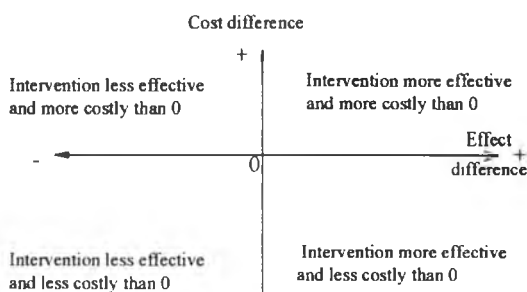
$$= \frac{\text{Total cost of implementing treatment of LTBI}}{\text{Number of patient who completed treatment}}$$

$$\text{Incremental analysis} = \frac{\text{Additional cost}}{\text{Additional effect}}$$

$$= \frac{\text{Cost of RFP+PZA} - \text{Cost of INH}}{\text{Effectiveness of RFP+PZA} - \text{Effectiveness of INH}}$$

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The cost-effectiveness plane



Ethical considerations

Benefits/Risks, Refusal to participate, Informed consent, Confidentiality, Ethical approval

Action plan
January- December year 2003

Budgets
1,820,310 baht

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Expected outcome

The cost effectiveness based on research findings will be made to facilitate decision making for health care policy.

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Data exercise

Treatment outcome of 9-month INH preventive therapy (IPT) and factors affecting to complete and non-complete treatment in four hospital Chiang Rai province, Thailand

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General objective

Develop skill and gain experience in conducting analysis and qualitative method in order to apply the information for prospective clinical trial of treatment of LTBI.

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Specific objective

1. To assess the effectiveness of IPT in term of the treatment outcomes of 9-month INH among HIV infected persons in 4 hospitals, Chiang Rai province.
2. To identify factors affecting to follow up status of IPT in 4 hospitals, Chiang Rai province.

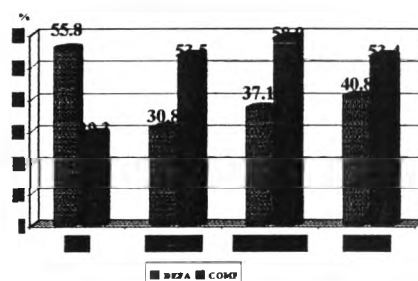
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Methodology

- **Study site:** Phan, Mae Chan, Chiang Khong and Mae Sai hospitals
- **Study population:** HIV infected persons who received INH preventive therapy
- Review of secondary data
- Semi-structure interview : using four probing questionnaire

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Default and completion rate of IPT program in 4 hospital Chiang Rai, Thailand 1995-2001

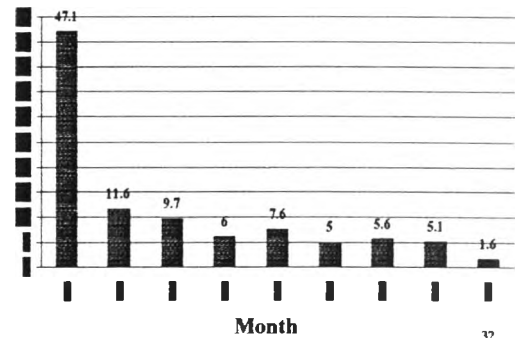


Default - failure to take medication on for 60 consecutive days without a known reason 30

Factor affecting follow up status of INH preventive therapy in four hospital, Chiang Rai

- Year at enrollment; Mae chan hospital
- Gender
 - Chiang Khong:
Male: relative risk to be default 1.48 (1.03 <RR < 2.12)
 - Mae Chan:
Missing: Relative risk to be default 3.95 (3.19 <RR < 4.90)
- Day Care membership
 - Mae Sai:
No DCC: Relative risk to be default 1.73 (1.11 <RR < 2.70)
 - Mae Chan:
No DCC: Relative risk to be default 2.35 (1.81 <RR < 3.06)

The percentage of default stratify by monthly of INH preventive therapy in four hospital, Chiang Rai 1995-2001



Semi-structure interview

- No well-established system to active follow up.
- Turn-over of staff, workload
- Insufficient trained health staff.
- Lack of supervision and monitoring.
- Some symptomatic HIV were include.
- Prescribed anonymously.
- Affecting from Anti-retrovirus.
- PLWA himself, no symptomatic, out-migration in search of work.

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Lessons learned and recommendation

- Hospital site preparing: lack of supervision, turn-over, insufficient training
- IPT should be responsible by AIDS unit: Mae Chan
- DCC function: DCC may improve complete rate.

These factor have to be assessed and support before implementation clinical trial.

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Thank you
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