フィリピン国公衆衛生プロジェクト
短期専門家報告書集
(平成6年度)

国際協力事業団
医療協力部

フィリピン国公衆衛生プロジェクト
短期専門家報告書集
(平成６年度)

国際協力事業団
医 療 協 力 部

目　次

平成６年度

平成６年度

１．藤木明子専門家

（指導科目）結核菌検査
（派遣期間）94/04/24～94/05/21

平成　6年　5月27日

業務報告書

（平成6年4月24日－5月21日）

国際協力事業団

総裁殿

第　　号

氏　　名	藤木明子
プロジェクト名	フィリピン公衆衛生プロジェクト
指導科目	結核菌検査
現住所	東京都清瀬市松山２－12- 14-101
連絡先	財団法人結核予防会結核研究所国際協力部 東京都清瀬市松山３丁目１番24号

Ⅰ．はじめに

1994年４月24日（日）～５月21日（土）までフィリピン共和国における「フィリピン公衆衛生プロジェクト」において、以下の結核菌検査に関わる指導を行ないましたのでご報告致します。

1)塗抹検査の現状と問題点の把握
2)塗抹検査用マニュアル作成についての検討
3)レファレンスラボラトリーに関わる機材の配置計画および活動計画策定の指導

Ⅱ．塗抹検査の現状と問題点の把握

塗抹検査の精度の向上は、これまでもWHO の報告書などで指摘されていた。塗抹検査の現状と問題点の把握のために、Argao RHU, Oslob RHU, Alcantra RHUから１ケ月分全ての塗抹標本を集め、それら標本の評価を行なった。

1)評価に用いた塗抹標本数

標本は1994年３月に集められたもので、内訳は次の通り。

Argao RHU	計 73	（陽性 4枚、陰性69枚）
Oslob RHU	計 53	（〃 1枚、〃 52枚）
Alcantra RHU	計 11	（〃 0枚、〃 11枚）

2)塗抹標本作成および染色技術（Fig.１～３）

Argao RHU ― 78%は薄い塗抹で、肉眼的には唾液様の塗抹に見受けられる。しかし、鏡検下の観察では、喀痰が塗抹されている事が、全標本に確認された。また塗抹の仕方は89%が不均等に塗抹されているものであった。塗抹のサイズは、わずか11%が適切な大きさであったにすぎず、不適切な塗抹のうち70%がサイズが小さいものであった。染色状態はほとんど(95%) は適切に染色、脱色されていた。ただし沈澱物によって汚れているものが71%を占めた。

Oslob RHU ― Alcantra RHU切な検体が塗抹されていたが、塗抹の仕方は、94%が薄く、89%が不均等であった。全標本に染色液の沈澱物による汚れが見られた。また、後染色後の水洗いが不十分で、メチレン青の脱色不足が見られた。

Alcantra RHU―90%は適切な検体であったが、塗抹は薄く不均等であった。

3)鏡検技術 (Table 1)

Argao RHU ― 計73標本のうち、68標本(93%) は鏡検結果が一致した。不一致のうち5 枚の標本は、全て強陽性（一横線以内で110 以上のAFB を確認）を陰性とする偽陰性であった。

Oslob RHU ― 計53標本のうち52標本は鏡検結果が一致した。残りの一枚は偽陽性すなわち陰性を(++)veと読んだものであった。

Alcantra RHU―計11標本の全ては鏡検が一致した。

4)Argao RHU およびOslob RHU の現状

偽陰性と偽陽性の結果を出したArgao RHU, Oslob RHUの現場を視察した。

	Argao RHU	Oslob RHU
・TB検査技師の経験	5 年	10年
・塗抹検査の訓練	なし、大学の経験のみ	1984年2 週間セブの TB Pavillionで
・フクシン染色時間	10 - 15 分	30分
・後染色時間	30秒	15分
・脱色時間	充分	水洗不十分
・鏡検報告法	Table 3 参照	Table 3 参照
・試薬	既製試薬 MEDIC 社(1ℓ)	既製試薬 MEDIC 社(½ℓ)
・試薬供給	3ヶ月に1ｾｯﾄ	6ヶ月に1ｾｯﾄ
・試薬有効期限	May 1995	Sep. 1994

5)Argao RHU 及びOslob RHU における指導・助言

Oslob RHU における染色液の沈澱物は、染色液の容器の底に蓄積したものが標本を汚しているものと思われた。また後染色の水洗脱色不充分のため、全体的に脱色不充分の標本になっている。フクシン液による染色及びメチレン青後染色も異常に長い。

染色液の沈澱物除去には、1)染色液を他の容器に移し替えることなく、染色びんから直接標本スライドへ満載するか、2)移し替える容器を新しいものに変え、常に沈澱物の蓄積を除いてから試薬を移し替えるなど工夫をするよう助言を与えた。また染色時間の修正をArgao RHU 及びOslob RHU に行なった。

Argao RHU における偽陰性と判定されたケースの処置については、須知専門家によって、至急再検する事をRHU の医師に伝えられた。また、Oslob RHU における偽陽性一例については、調査の結果、治療は行なわれていなかったため、検査技師に人工産物のチェックの仕方の指導するにとどめた。

III. VALIDATION システム

1986年以来、塗抹検査の精度管理のために、バリデーションシステムが確立されている。結核対策のナショナルスタンダードマニュアルによると、方法の概略は、各RHU は毎月全陽性標本と無作為に集めた20%の陰性標本が、TBコーディネーターによってチェックする検査室へ運ばれる。運ばれた標本はバリデーターによってブラインドリーディングされ、結果がTBコーディネーターによってRHU に知らされ、照合される。

しかし、実際には、プロビンスに所属するバリデーター（検査技師）が出向いて標本の再チ

ェックを行なっている。Cebuプロビンスはカバーする地域を４分割し、４人のバリデーター達により、一人一地域を受け持つ。毎週月曜はPHO で会合し、火～金までが現場に出掛けバリデーションを行なう。一部のRHU (Katomon, Sogod, Borton, Tabgon)は District 病院の検査室へ再読を依頼。PHO のバリデーターがそれらを再チェックする事はない。

現在のバリデーターの役割は、標本を現場でチェックするだけである。バリデーションの結果がどこも毎月一致率100 %である事をみると、実施方法に問題があると思われる。またわざわざ現場へ出向いてスライドチェックをする必要性の意味を見いだす事は難しい。実際の活動を一度、行動を共にして観る必要があろう。

IV．塗抹検査用マニュアル作成の重要性

結核対策のナショナルスタンダードマニュアルは、1986年に作られて以来、改訂する事なく今日まで来た。結核対策の一部見直し、改正に当たり、マニュアルの内容も一部改訂される事になった。それに伴って検査部分においても見直し、検討を行なった。

既に述べたように、RHU 間で技術の統一化がなされていない事の大きな原因に、混乱を来す表現や、不明瞭な部分があるためと思われる。塗抹検査だけに的を絞った実際的で、明解なマニュアル作りが急がれる。技術の統一化にはマニュアルは絶対に不可欠なものである。この件については本省のTBCPのDr.N.Cruz と何度か検討を重ね、理解を得ている。

V．今後の課題

1)塗抹標本の作り方や鏡検の精度の向上・強化のために塗抹検査に関するトレーニングを検査技師及び助産婦達に行なう事が重要である。
2)実際的な塗抹検査のマニュアル作成。
3)塗抹検査のモニターやスーパーバイジョンの強化のために現在いるバリデーター達をもっと有効に活用する事が望まれる。また、塗抹検査の精度を上げるための評価の仕方についての訓練をバリデーター対象に行なう必要があろう。
4)染色液沈澱物除去のための改善を行なう。そのために既製染色液の質のチェックを時々行なう事が必要と思われる。必ずしも質の良い染色液が供給されているわけではないようである。
5)試薬、器具の供給システムの強化。
6)レファレンスラボラトリー要員の確保は大至急望まれる。現在レファレンスラボラトリー要員はCebu Chest Center のラボにいる一人の技師のみであり、彼一人だけでは仕事量に限界がある。十分な人員が揃わないうちは、仕事内容を拡大することなく、塗抹検査に的を絞るべきであろう。

業務日誌

1994年 4月24日～ 5月21日
藤木　明子

4月
24日（日）：14:55　PR 433便にて成田発
18:50　Cebu着。(Cebu Mid Town 泊)
25日（月）：8:00 - 17:00 地方衛生局(RHO) 表敬。州衛生局(PHO) 表敬
スケジュール打ち合わせ、Project 活動概況説明
26日（火）：8:00 - 16:00 Catmon RHU視察
27日（水）：8:00 - 17:20 Catmon RHU, Tabili Barangay Station 視察、結核患者家庭訪問
28日（木）：8:00 - 17:00 ３回連続検痰に関する集計について討議
検査台帳の記録法について検討
29日（金）：8:00 - 17:00 塗抹標本の評価。３回連続検痰に関する調査（データ入力）
30日（土）：資料整理
5月
1日（日）：資料整理
2日（月）：8:00 - 17:00 Region 7の試薬倉庫にて試薬保存状況の視察
３回連続検痰に関する調査
3日（火）：8:00 - 17:00 州庁内検査室の視察及びバリデーションシステムについての
インタビュー
4日（水）：8:00 - 17:00 NTP 新政策のガイドライン説明講習会にオブザーバーとして参加
5日（木）：8:00 - 17:00 塗抹標本の評価
6日（金）：8:00 - 17:00 塗抹標本の評価
7日（土）：顕微鏡をホテルへ持込み塗抹標本の評価
8日（日）：　同上
9日（月）：バランガイ選挙日のため休日
顕微鏡をホテルへ持込み塗抹標本の評価
10日（火）：7:30 - 17:00 Ronaldwood Reprosy Institute　視察
塗抹標本の評価
11日（水）：8:00 - 17:00 塗抹標本の評価
12日（木）：7:30 - 10:30 Mandaue LaboratoryにてJICA用撮影
11:30　マニラDOH へ行くため空港へ移動
飛行機遅れ4:30発 (Inter-Con.泊)
13日（金）：8:00 - 17:00 DOH にて検査用マニュアル改訂会議
14日（土）：10:30 - 17:00 ホテルにて検査用マニュアル改訂検討
15日（日）：8:00 - 11:10 Cebuへ移動 (Cebu Mid Town 泊)
16日（月）：8:00 - 17:00 塗抹標本の評価
塗抹検査における問題点について検討会議
17日（火）：8:00 - 17:00 機材配置打ち合わせ
塗抹標本の評価

18日（水）： 8:00 - 17:00 Oslob RHU, Argao RHUの検査室視察
19日（木）： 8:00 - 17:00 塗抹標本の評価
検査台帳記録法に関する検討会議
20日（金）： 8:00 - 10:30 活動報告会議
12:10 Cebu発
14:00 - 16:00 DOH にて活動報告及び今後の課題について打ち合わせ
17:00 JICAへ活動報告
21日（土）：14:30 JL 742便にてマニラ発、19:30 東京着

SUMMARY REPORT ON TB LABORATORY ACTIVITIES FOR SHORT TERM ASSIGNMENT CONCERNING THE DOH-JICA HEALTH DEVELOPMENT PROJECT

AKIKO FUJIKI
JICA Short Term Consultant on TB Laboratory Work
24th April – 21st May 1994

1. Objectives and Activities:

JICA TB Laboratory work specialist has mainly concentrated on following activities during her stay with the Project,

1) To check the quality of smear slides for situation analysis of direct smear examination.
2) To discuss and study on manual preparation of smear examination for new NTP Policy.
3) To give advice on TB Reference Laboratory set up.
4) To collect information and to make recommendations to the Project activities.

Here in this report, the situation and problems of direct smear examination in project areas will be summarized.

2. Evaluation of smear examination:

Stained smear slides were collected for one month in March from Argao RHU, Oslob RHU and Alcantara RHU. The evaluation of smear examination was made with these smear slides according to the following points;

1) smear area size
2) thickness of smear
3) evenness of smear
4) decolourizing condition
5) smear cleanness
6) sputum quality
7) smear reading accuracy

Specimen Collected:

Institution	No. of Specimen	No. of Positive	No. of Negative
Argao RHU	73 (100)	4 (5)	69 (95)
Oslob RHU	53 (100)	1 (2)	52 (98)
Alcantara RHU	11 (100)	0	11 (100)

Smear preparation and staining techniques: (Fig. 1-3)

Argao RHU – All sputum specimen collected were of good quality with more than 10 leucocytes per field but almost 80% of the sputum smears were too thin and almost 90% of the smears had an uneven distribution of leucocytes. Concerning staining techniques, most of the smear slides were properly stained.

Oslob RHU – 83% of sputum specimens collected were of good quality of sputum but majority (94%) of smears were too thin smear and had an uneven distribution of leucocytes (89%). All smear slides were contaminated with many precipitants. All of them were under decolourized.

Alcantara RHU – More than 90% of sputum specimens collected were of good quality of sputum. 72 % of the smears were uneven smeared slides and 64% were thin smeared slides.

Smear slide reading techniques: (Table 1)

Argao RHU – 93% (68/73) of slides were read correctly. Out of 5 incorrectly read slides, all of them were false negative or read (++++)ve slide as negative. Sensitivity and specificity were 44% (4/9) and 100% (64/64) respectively.

Oslob RHU – Out of 53 slides, 52 smears were read correctly but 1 slide was false positive or read (–)ve slide as (++)ve.

Alcantara RHU – All of the slides were read correctly.

3. **Overall Comments and Recommendations:**

1) Good quality of smear preparation should be stressed to laboratory workers to make a reliable smear examination. Most of the smears examined were poorly prepared in size, thickness and evenness. Proper sputum specimens have been submitted by TB suspects/patients as it is shown in Fig 1–3.

2) The reporting scale of smear examination results should be standardized among medical technologists. The interpretation of national standard scale for smear reading varies among RHUs (Table 2).

3) Some improvement should be considered to eliminate the precipitants in the solution. Majority of smear slides collected in 3 institutions were contaminated with many precipitants. Improvements can be expected by filtrating carbol fuchsin solution and checking the quality of ready made staining solution.

4) Refresher training of TB microscopy should be urgently conducted for midwives, medical technologists and those who work for TB smear examination. Practical guideline/manual for TB microscopy at RHU level should be made.

5) Monitoring/supervision should be strengthened for quality control of direct smear examination. Existing validators should be more properly utilized for this purpose. Refresher training on quality control of smear examination is needed for them.

6) A logistics supply of reagents and equipments should be strengthened.

7) Cebu Chest Center Reference Laboratory, which is under construction, is expected to do the following tasks: 1) sputum smear examination, 2) reagent supply to microscopy centers, 3) training, 4) validation of smear examination, 5) culture and sensitivity test.

   Manpower (at present only one) is insufficient to carry out all the task at the moment. Two or three more technical personnels are needed and accumulation of technical experience for the laboratory is necessary.

   The activity of the reference laboratory should not be expanded unless enough manpower in quantity and quality is provided. It should be concentrated at present on sputum examination and training activities.

Table 1. COMPARISON OF REPORTED AND ASSESSED SMEAR RESULTS

Result by	Reported in Argao			Reported in Oslob			Reported in Alcantara		
Assessor	+	–	Total	+	–	Total	+	–	Total
+	4	5	9	0	0	0	0	0	0
–	0	64	64	1	52	53	0	11	11
Total	4	69	73	1	52	53	0	11	11

Agreement rate:	93%	(68/73)	98%	(52/53)	100%	(11/11)
Sensitivity :	44%	(4/9)	–		–	
Specificity:	100%	(64/64)	98%	(52/53)	100%	(11/11)

Table 2 PROPORTION OF EVELUATION RESULT FOR STAINED SMEARS

ARGAO RHU

	Good (%)	Poor (%)	Total (%)
Specimen Quality	73 (100.0)	0 (0.0)	73 (100.0)
Size	8 (11.0)	65 (89.0)	73 (100.0)
Thickness	16 (21.9)	57 (78.1)	73 (100.0)
Evenness	8 (11.0)	65 (89.0)	73 (100.0)
Staining	69 (94.5)	4 (5.5)	73 (100.0)
Cleanness	21 (28.8)	52 (71.2)	73 (100.0)

ALCANTARA RHU

	Good (%)	Poor (%)	Total (%)
Specimen Quality	10 (90.9)	1 (9.1)	11 (100.0)
Size	4 (36.4)	7 (63.6)	11 (100.0)
Thickness	4 (36.4)	7 (63.6)	11 (100.0)
Evenness	3 (27.3)	8 (72.7)	11 (100.0)
Staining	6 (54.5)	5 (45.5)	11 (100.0)
Cleanness	10 (90.9)	1 (9.1)	11 (100.0)

OSLOB RHU

	Good (%)	Poor (%)	Total (%)
Specimen Quality	44 (83.0)	9 (17.0)	53 (100.0)
Size	3 (5.7)	50 (94.3)	53 (100.0)
Thickness	3 (5.7)	50 (94.3)	53 (100.0)
Evenness	6 (11.3)	47 (88.7)	53 (100.0)
Staining	0 (0.0)	53 (100.0)	53 (100.0)
Cleanness	0 (0.0)	53 (100.0)	53 (100.0)

Table 3 REPORTING SCALE USED FOR SMEAR EXAMINATION BY RHUS

	National Standard	Catmon RHU	Argao RHU	Oslob RHU
(–)	No AFB found / whole* smear	No AFB in 5 horizontal lines	No AFB in 4 vertical lines	No AFB/whole# smear
(+)	1–5 AFB/whole smear	1–5 AFB in 5 horizontal lines	1–5 AFB in 4 vertical lines	1–5 AFB/VF
(++)	6–24 AFB/whole smear	6–13 AFB in 5 horizontal lines	6–10 AFB in 4 vertical lines	6–24 AFB/VF
(+++)	25 AFB and more in most fields	14 AFB and more in 5 horizontal lines	11–20 AFB in 4 vertical lines	25 AFB and more/VF
(++++)	Numerous in most fields	----	20 AFB and more in 4 vertical lines	Numerous AFB/VF

* whole smear:
3 horizontal lines &
2 vertical lines

whole smear:
entire smear

Fig. 1 Proportion of Evaluation Result for Stained Smears in Argao RHU

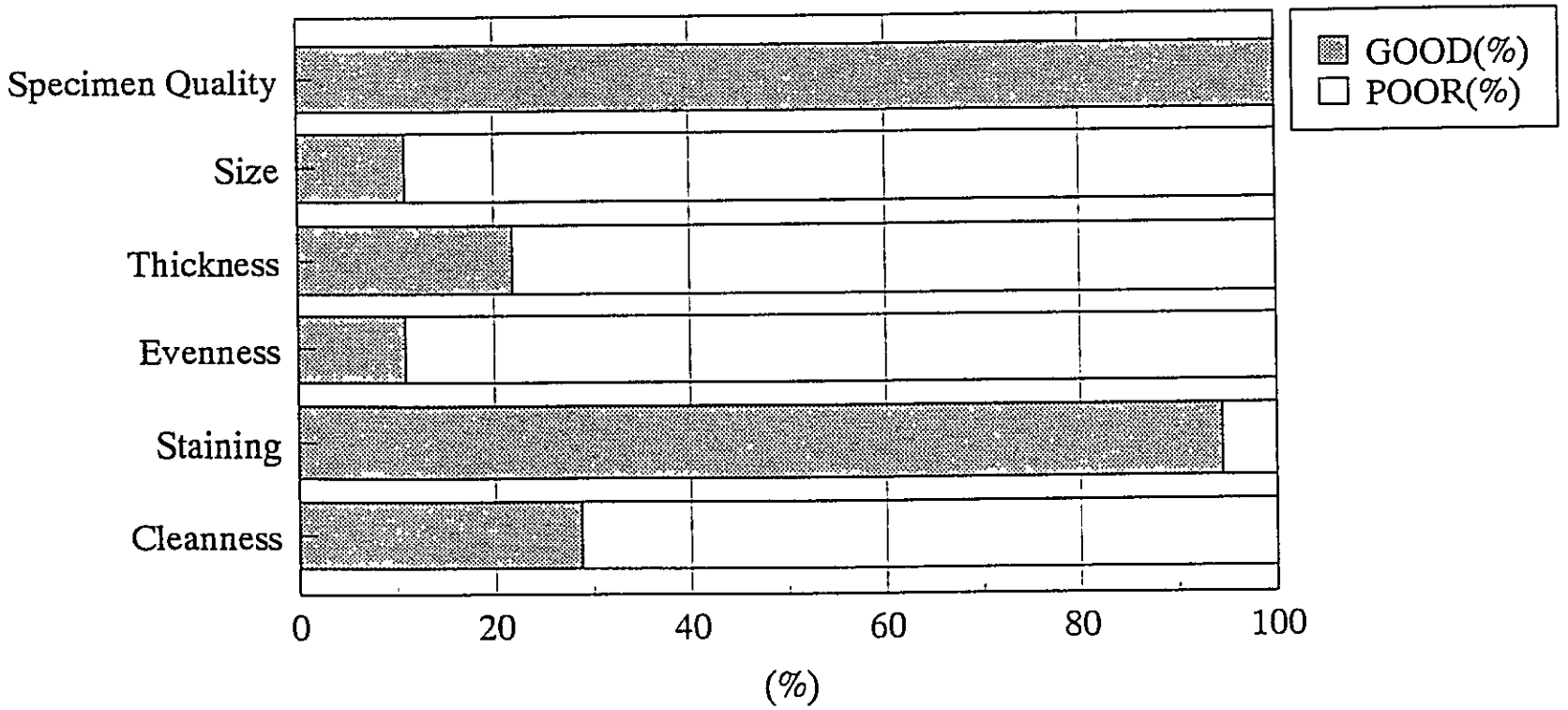


Fig. 2 Proportion of Evaluation Result for Stained Smears in Oslob RHU

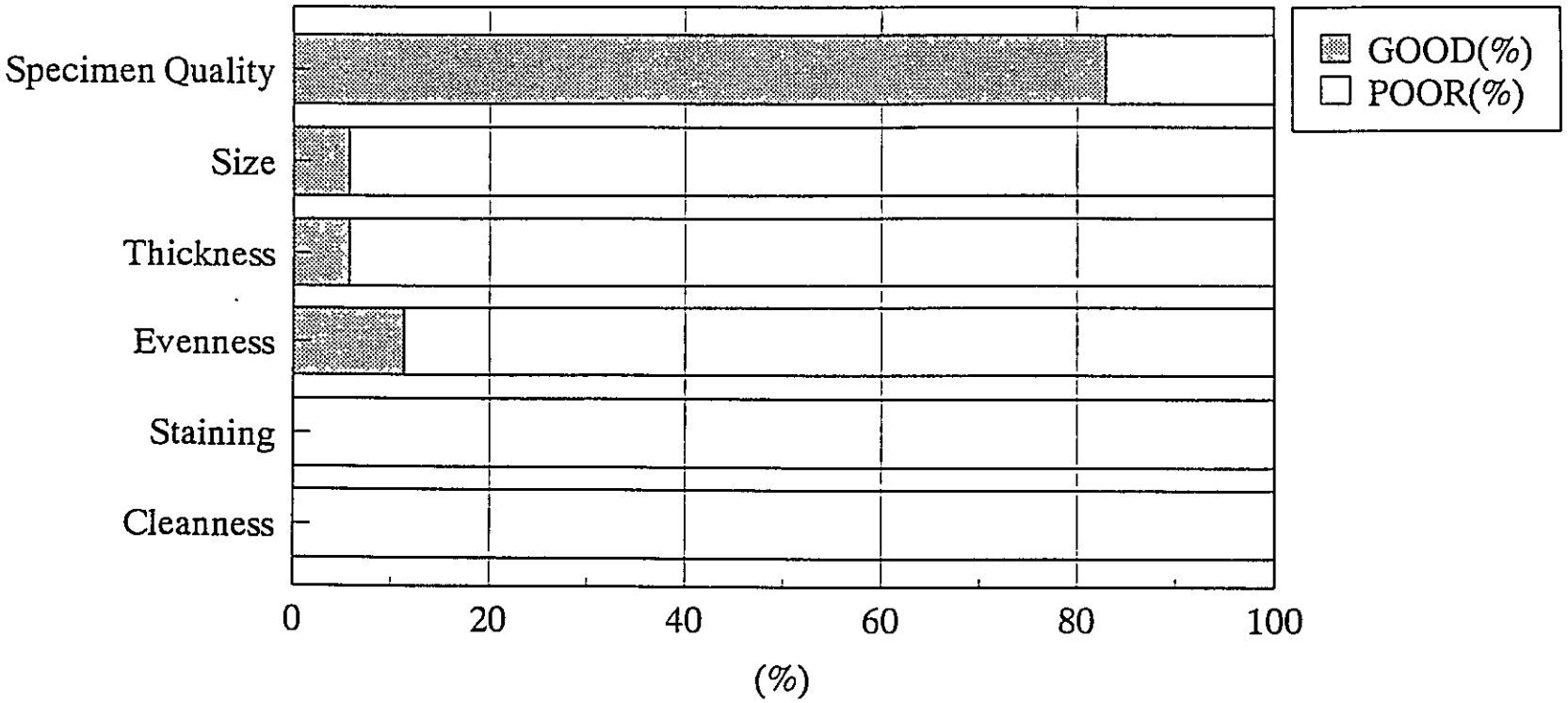
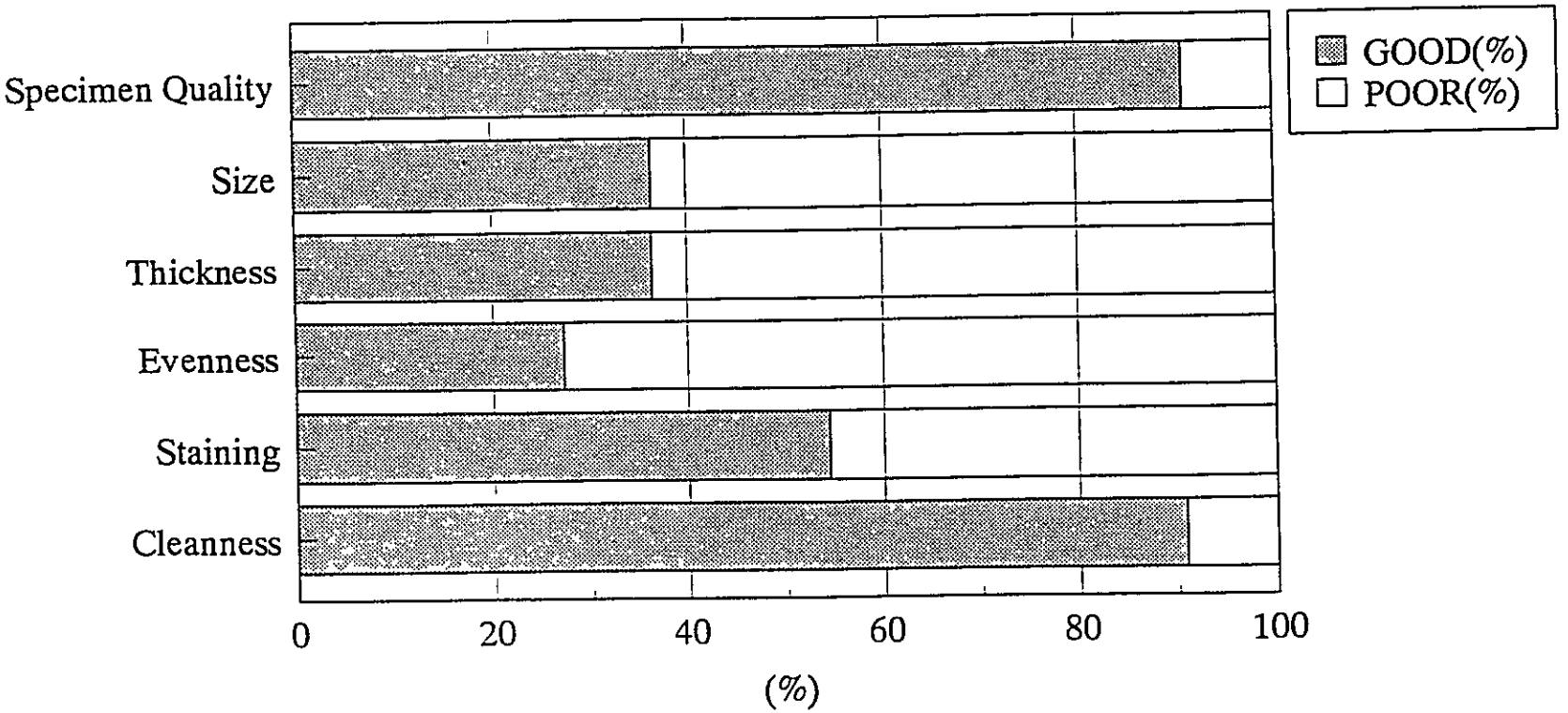
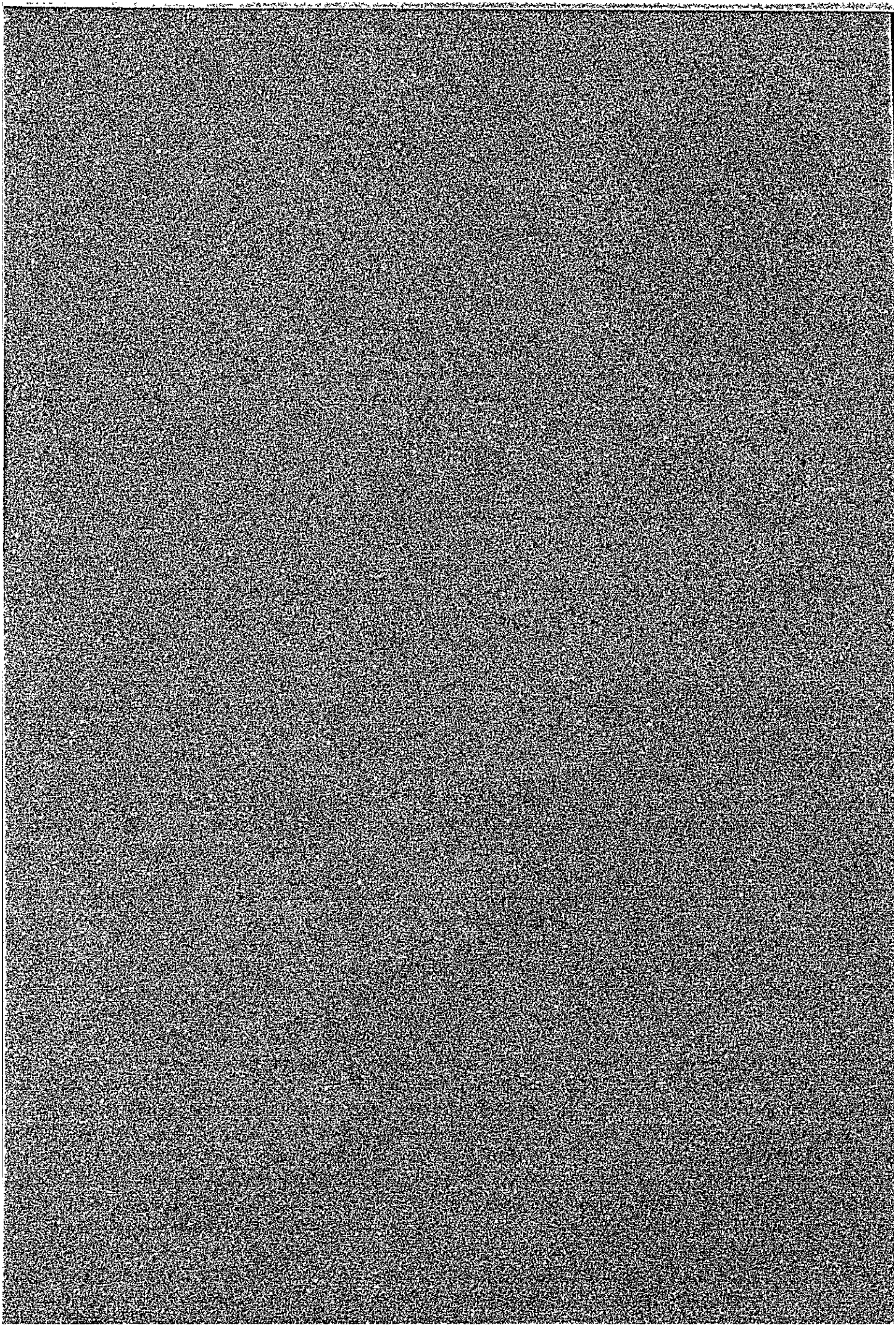


Fig. 3 Proportion of Evaluation Result for Stained Smears in Alcantara RHU



２．清田明宏専門家

（指導科目）結核菌検査室ネットワーク
（派遣期間）94/04/24～94/05/07



平成　6年　5月10日

業務報告書

(平成6年4月24日－5月7日)

国際協力事業団

総裁殿

第　　号

氏　　名　　清田明宏

プロジェクト名　　フィリピン公衆衛生プロジェクト

指導科目　　結核菌検査室ネットワーク及びロジスティックス・システム

連絡先　　財団法人結核予防会結核研究所国際協力部

東京都清瀬市松山3丁目1番24号

1．はじめに

今回の派遣の目的はフィリピン国の結核対策におけるロジスティックスの評価、現在フィリピンの国家結核対策（ＮＴＰ）が導入しようとしている新しい結核対策指針の評価、喀痰塗抹検査システムの評価等であった。２週間という短い訪問期間であったが、上記目標は概ね達成できた。筆者にとっては初めてのフィリピン公衆衛生プロジェクト訪問であり、関係各者には多大なお世話になった。とくにプロジェクトの須知専門家及び寺崎調整員には公私にわたりめんどうをみて頂き、心からの感謝を表したい。また、同行した結核研究所の藤木短期専門家にもお世話になった。

今回の報告書は最初に簡単な日本語の要約を記し、本文、特にロジスティックスの評価は英文とした。これは筆者が現在開発中の結核対策のロジスティックス評価マニュアル（英文）を使用した為であり、又、現地側の理解の助けになるためである。

2．結核対策の新指針

今回の主目的であるロジスティックスの評価を述べる前に現在フィリピン国で導入されつつある結核対策の新指針について簡単に述べる。

この新指針は世界保健機関（ＷＨＯ）が推奨している結核対策の方法に準じたものであり、現在のフィリピンの結核対策の方針がかなり変更されている。フィリピン側のこの試みは高く評価されるものであろう。新指針の詳しい内容については公衆衛生プロジェクト側から報告されると思うのでここは簡単に記す。

第１に結核対策の目標が患者発見から患者の治癒に変わった点である。今までは過去の調査から推定される患者数が活動の目標とされており、そのために様々な弊害が生じていたが、その点が改善されるであろう。

次に、患者発見及び治療の評価としての喀痰塗抹検査が重視されたことである。今までは患者発見時には喀痰検査は実質１回しか行っておらず、治療中及び治療終了時の喀痰検査は実質的には行われていなかった。喀痰検査はフィリピンの結核対策の最大の問題の一つと思われるので、その改善が期待される。

治療方式も今までは塗抹陽性患者だけに短期治療が適用されていたが、塗抹陰性患者にも４カ月の短期治療（2HRZ+2HR）が適用され、再治療方式もＷＨＯ方式が適用された。従来の12カ月の標準治療はなくなる予定である。

また、登録用紙及び報告書が改訂された。今まではかなり複雑な登録・報告様式であったが、ＷＨＯの形式に基づき必要最小限に簡素化されている。

薬剤配布に関しても、今までは標準化された配布申請書がなかったが、ＷＨＯの形式に基づいた配布量の計算方式を含んだ申請書が導入されている。

現在結核対策課が公衆衛生プロジェクトと共同で新方式の導入に関するパイロットスタディをセブ島の２地域で開始した。筆者もその２地域の一つであるマ

ンダウエでの研修会に参加したが、現場の医師、保健婦及び助産婦（Barangay Midwife）の質の高さ、動機付けの高さが非常に印象に残った。現場のスタッフの質から考えると新方式の導入はかなり円滑に行われると思われるが、最後に述べるフィリピンの特性（？）を考えると、結核対策課及び公衆衛生プロジェクト側の定期的な監視（supervision）および現地での研修（on the job training）が必要であると思われる。

新指針に関する筆者のメモを付記する。このメモは結核対策課に対して書かれたものである。技術的な点に関する指摘が多いが、セブ島でのパイロット研究で、様々な点が議論され改修されていくことが期待される。

3．ロジスティックス

今回の訪問時には中央の結核対策課、中央の薬剤倉庫、Regionの結核対策コーディネーター、Regionの薬剤倉庫、Provinceの結核対策コーディネーター、Provinceの薬剤倉庫、Municipalityの保健所（ＲＨＵ）、バランガイの保健所（ＢＨＳ）を訪問できた。ロジスティックスに関するすべての点が観察・評価できたのではないが、様々な評価すべき点及び問題点の観察ができた。報告書は英文で作成した。ここではその要点を記す。

フィリピンでは塗抹陽性患者に用いる短期治療用（2HRZ+4HR）の抗結核剤はブリスターパックになっており、それが中央政府（保健省結核対策課）から配布されている。塗抹陰性患者に用いる12カ月の標準治療用薬剤は各市町村（Municipality）が購入、配布することになっている。すなわち、抗結核剤の配布には２つのチャンネルが存在することになっている。しかし現実的には市町村での薬剤購入は余り行われず、１２カ月用の薬剤に関しても中央政府（一部Region）が補助的に購入したものが使用されているようである。市町村レベルでは予算が潤沢にあるわけではないこと、保健問題（その中でも特に結核）の位置づけが必ずしも高いわけではないこと等がその理由であろう。少量の薬剤を購入すればその価格は比較的高価になる点や、ロジスティックスの管理にはチャンネルは一つの方がよいことなどを考え合わせれば、将来的には１２カ月の治療方式が４カ月の短期治療に置き換えられる際にすべての抗結核剤の購入配布を中央から行うことにする事が望ましい。

６カ月の短期化学治療用の薬剤（blister pack）は現在潤沢に存在する。中央・中間・末端の施設を見たが、昨年・今年と薬剤の枯渇は発生していない。このblister packはフィリピンの結核対策上の特徴の一つであり、国際的にみても廉価である（国際平均価格の88%）同blister packの使用は患者側の簡便さもあり、高く評価されるであろう。しかし、ロジスティックス全体でみた場合様々な問題点が存在する。先ず第１に保健省の方針として、薬剤の使用期間が製品化後２年間と

定められていることである。抗結核剤は薬理学上最低３年は使用可能だが、フィリピンでは２年間である。これがロジスティックスの確立上の大きな障害となっている。その他の問題点を以下にロジスティックスの流れに沿って簡単に記す。

３．１　薬剤の選択（selection）

購入する抗結核剤の選択は、国のDrug Formularyに基づき結核対策課が行っている。blister packの内容に関しては結核対策課が作成した様式書に詳細に記載されている。このblister packは１週間分の薬剤をまとめたもので、１日分の薬剤量は以下の通りである。

初期強化期間	ＲＦＰ４５０ｍｇ	１錠
	ＩＮＨ３００ｍｇ	１錠
	ＰＺＡ５００ｍｇ	２錠（計１０００ｍｇ）
継続期間	ＲＦＰ４５０ｍｇ	１錠
	ＩＮＨ３００ｍｇ	１錠

blister packの内容に関しては、ＰＺＡの量及び低体重の場合の管理が問題であろう。ＰＺＡ1000mgは成人男性（４０から５０ｋｇ）では少量だと思われる。特に初期期間に３剤しか使用していない現状では、1200mgが望ましい。ＰＺＡ400mg３錠で解決できるであろう。また、結核対策課では異なる容量（mg）のＲＦＰ、ＩＮＨを購入しておらず、それでは低体重患者に関しての管理が不十分となる。ＩＮＨやＲＦＰのシロップで管理しているとの話もあったが、同製品は高価であることや使用上の不便さを考えると、RFP150mgやINH100mgの追加購入が望まれる。

３．２　薬剤の購入（Procurement）

薬剤の購入は保健省のLPS（Logistics and Procurement Service）が行っている。同部は年に一度国内での入札を行い、入札上位３社からblister pack等を購入している。その購入価格は国際的な平均価格よりも10%以上安く、平均で国際価格の88%である。これはblister pack化した後の価格であり、高く評価される点であろう。blister packを用いた場合の短期治療１回分の薬剤価格は１８米ドルとなる。

購入薬剤量は結核対策課が計算している。購入量は基本的には推定結核患者数から算出しているが、中央薬剤庫の在庫量は考慮されていない。よって必要以上の薬剤量を購入する可能性がある。

薬剤の注文から受取までは約４カ月（１２０日）かかる。又、受取後国の機関（Bureau of Food and Drug）で品質管理があり、それに約１カ月かかる。上述したように薬剤の使用期間が２年しかないため、この期間は薬剤配布に影響を及ぼしている。

3．3　薬剤の配布（distribution）

中央では薬剤は薬剤中央倉庫に保管される。在庫管理は同倉庫が行っているが、結核対策課にも薬剤管理の職員がいる。各薬剤別の記入用紙（leders）があるが、全在庫量を示す台帳は倉庫にはない。

中央からregionへの配布は結核対策課の指示によりおこわなれている。その配布量の計算は各regionの推定患者数に基づいているが、各regionの在庫量は考慮されていない。配布は他の薬剤と一緒に行われる。

各regionではregionの薬剤倉庫に抗結核剤は保管される。筆者が訪問したregionの薬剤倉庫はその在庫管理上問題があった。先ず薬剤がまとまって保管されていないことである。抗結核剤も複数の場所に別々に置いてあった。在庫管理台帳が不備であった。在庫量を記載する台帳がなかった。

RegionからProvinceへの配布はRegionのコーディネーターの指示で行われる。しかしその用紙は統一されておらず、又配布量の計算方法も統一されていない。Provinceの在庫量も計算上考慮されていない。

筆者の訪問したProvinceの倉庫はProvinceのコーディネーターにより管理されていたが、在庫量は正確に記載されており、薬剤も整理して保管されていた。Provinceから各市町村への配布はこのコーディネーターが指示している。その配布量は各市町村の患者数から算出されている。その際には各市町村の在庫量は考慮されていない。

筆者の訪問したＲＨＵでは短期治療用の薬剤は必要量あったが、標準治療用の薬剤はあと１－２カ月で期限が切れるＥＢやＩＮＨが消費可能量以上にあった。上記配布方式による結果だと思われる。

上述のように、フィリピンのロジスティックスではこの配布・在庫管理上に問題がある。在庫管理を効果的にするには在庫量の正確な把握が不可欠であるが、その在庫を記入する統一した台帳がない。結核対策だけでそのような台帳を設置する事は議論があるであろうが、結核対策側がその在庫量を把握する事は必要である。配布量の計算も統一されていない。基本的には末端の患者数からの計算であるが、計算方法を示す申請書はなく、又末端の在庫量も考慮されていない。そのため、末端で必要以上の在庫を抱える事が危惧される。　　現在、結核対策課ではＷＨＯ方式の薬剤配布方法の導入を検討しており、配布申請書も作成されている。同申請書には若干の問題はあるが、基本的には必要な事項である。

3．4　薬剤の使用（ｕｓｅ）

今回薬剤の使用に関しては充分な資料を収集できなかった。blister packを使用しているので、塗抹陽性患者に関しては薬剤使用上のばらつきはないと思われる。１２カ月の標準治療に関しては、現在既に４カ月の短期治療を使用している場所もあり、多少の混乱がみられた。

3．5　Private Sector

フィリピンでは一般の薬局・開業医での抗結核剤の使用に関する規制はない。ほぼすべての抗結核剤が薬局で購入可能である。本来は処方箋がなければ購入不可能のはずであるが、おそらく処方箋がなくても抗結核剤の購入は可能と思われる。薬剤にはＲＦＰとＩＮＨの合剤もあれば、１日分がblister packになったものもある。その価格はフィリピンの一般市民に取っては高価とおもわれ、結核患者が多く脱落している事が危惧される。この状態が続けば治療が非常に困難となるＲＦＰo及びＩＮHの耐性患者が増加する事が危惧される。非常に困難だと思われるが、何らかの処置・介入が必要であろう。

4．喀痰塗抹検査の評価

喀痰検査の技術的な問題点は結核研究所の藤木専門家により報告されているので、ここではシステム上の問題点を簡単に記す。

今までは診断時の喀痰塗抹検査は実質１回しか行われて折らず、治療中及び治療終了時の喀痰検査も充分には実施されていなかった。今回結核対策課が導入する新指針では上記の点は明確に改善されているため、今後はこの指針がどの様に実現可能かを結核対策課及び公衆衛生プロジェクト側が注意深く観察・指導する事が必要であろう。

今回の訪問時に様々な塗抹標本を観察したが、その精度は様々であり、藤木専門家の報告書にもあるがその判定基準も統一されていない。検査技師に対しては再度塗抹検査の研修を実施する事が必要であろう。それ以上に結核対策課・プロジェクト側が塗抹検査の実施方法・精度管理に取り組む事が必要である。現在の精度管理方法は必ずしも効果的とは言えず、抜本的な見直しが必要である。基本的には、地方視察をより頻回にしOn the job trainingを強化する事、塗抹検査のvalidatorの役割を再検討する事（validityが100%という事は全体に何かがおかしい事を再認識する事）、現在の精度管理の方法の改善（例えば登録患者の塗抹標本のみを再検討する事など）があると思われるが、一番重要な事は結核対策側が塗抹検査を検査室・検査技師にまかせず、積極的に関わっていく事であろう。

5．最後に

フィリピンの結核対策は現在大きな変革点を迎えている。今までの方式からＷＨＯ方式への転換であるが、その成功のためには現在開始されたセブ島の２カ所のpilot地区での成果が重要な点である。結核対策課・Region及びProvinceのコーディネーター・公衆衛生プロジェクトによる頻回の巡回指導が当初は必要であろ

う。筆者の今までの経験からみると、フィリピン側関係者の質はかなり高いと思われ、今後の成果が期待される。しかし、フィリピン側の特性かも知れないが、問題点を表面的に取り繕っている部分もあり、多少の困難が生じる事も考えられる。基本は巡回指導であろう。勿論、巡回指導とは関係者のencouragement・motivationであり、punishmentでないことは以前に訪問された遠藤専門家の報告書に記載されたとうりである。

フィリピン訪問日程表

4月

24日（日）

14:55　定刻通りフィリピン航空433便で成田発セブへ向かう

18:30　定刻通りセブ空港到着。外気温摂氏３２度。暑い。
須知チーフアドバイザー、寺崎調整員の出迎えを受ける。
携行機材１１箱を含め全部無事通関ありがとうございます。

17:30　須知専門家宅にてお茶付けを頂きながら日程打ち合わせ

21:00　セブミッドタウンホテルにチェックイン。部屋で荷物整理。

25日（月）

08:00　ホテル発、地方医務局（Integrated Regional Field Office, IRFO）に向かう。５分で到着、近い。プロジェクトの部屋へ。

08:30　IRFOの副局長（Assistant Regional Director）Dr Jose Rodriguesを表敬訪問。

09:00　州衛生部を訪問。衛生部のビルはまだ建設中。そこを事務所としている。困難と思われる状況で仕事をしている職員に敬意を表したい。衛生部長は不在のためIRFOに帰る。

09:30　IRFOの敷地内のReference Laboratoryを訪問。現地側専門家及び藤木専門家の今までの努力に敬意を表したい。
続いてセブ胸部センターを訪問。Dr Sancho所長、Mr Benny検査技師の案内で所内視察。
以後プロジェクトの部屋で須知専門家らからフィリピンの状況の説明を受ける。

12:00　昼食。日本料理店へ。美味。

13:00　プロジェクト事務所でフィリピンの結核対策の状況、プロジェクトの状況の説明を受ける。多くの資料を頂く。だんだん分かってくる。

17:30　IRFOを出、ホテル経由買い出しへ。日用品を購入。

18:30　プロジェクト側、藤木専門家らと韓国料理屋で夕食をしながら意見交換。

20:00　ホテルへ戻る。風呂に入った後仕事をす。

26日（火）

08:00　ホテル出発、IRFOに。
08:15　IRFO出発。Catmon保健所（Rural Health Unit, RHU）に向かう。
10:00　Catmon保健所到着。Jillgo所長以下の出迎えを受ける。
　　所内を見学。意見交換。
12:00　昼食。近くのレストランでフィリピン料理。美味。
13:00　市長（Mayor）表敬訪問。
　　以後保健所に戻り意見交換を続ける。
14:30　保健所出発、IRFOに戻る。
16:00　IRFO到着。以後本日の訪問に関して意見交換。
17:30　IRFO出発。日本料理屋'ふじやま'に。プロジェクトの人と
　　意見交換。
20:00　ホテルに戻る。仕事をし、風呂に入り、仕事をする。

27日（水）

08:00　ホテル出発、IRFOへ。
08:30　IRFO出発。Catmonへ向かう。
10:00　CatmonRHU到着。すぐにTabili Barangay Health Station (BHS)に。
10:30　山道を越えTabiliBHSへ到着。Midwife等と意見交換。
12:00　昼食。海産物（蟹、海老、魚、イカ等）を頂く。美味。
13:00　CatmonRHUに戻り少し意見交換した後、患者訪問に向かう。
13:30　患者訪問。色々話を聞く。
14:30　CatmonRHUに再度戻り、意見交換。帰路に付く。
17:00　途中Sogot District Hospitalによった後IRFOに到着。
　　以後寺崎調整員宅によばれ、夕食を頂きながら意見交換。
21:30　ホテルに戻る。入浴後仕事をする。

28日（木）

05:10　起床。マニラ行きの飛行機に乗るため空港へ。
07:30　３０分遅れの飛行機でマニラへ。
08:30　マニラ空港到着。JICA雇用のタクシーで保健省へ。
09:30　保健省結核対策課到着。Teoxon課長、Vivian医師と意見交換。
12:00　保健省を出、世界保健機関西太平洋事務局へ向かう。
12:30　同事務局到着。Dr Blancと昼食を共にし意見交換。
15:00　Mandarin Oriental Hotelチェックイン。余りの立派さに驚愕。
17:00　Manila Midtown Hotelに行き、フィリピン大学のClinical Epide-
　　miology Unit (CEU) の学長・社会学者等と会い意見交換。
19:00　Mandarin Hotelに戻り、夕食。羽田新首相の記者会見を見る。

29日（金）

09:00　ホテル出発。保健省結核対策課の職員と共に国の中央薬剤倉庫に行く。同倉庫の職員と共に意見交換。

12:00　同倉庫出発。National Book Centerでフィリピンの社会学の本など関係図書を購入。

14:00　昼食。

14:30　空港近くのMercury Pharmacyで抗結核剤購入。簡単であった。

15:30　予定より１便早い飛行機でセブに戻る。満席。乗客の半分は日本からのリゾート客であった。

16:30　セブ到着。ホテルで着替えた後須知専門家の家で報告・夕食。

21:00　ホテル到着。そのままベッドへ。

30日（土）

09:15　ホテル出発。ﾏｸﾀﾝ島のリゾートへ行く。
終日須知・寺崎両専門家の家族と共に海遊び、水遊び。

20:00　夕食を終えホテルに戻る。

５月１日（日）

終日ホテルでのんびり。
途中、National book Centerで文具を購入。

５月２日（月）

08:00　IRFOへ

09:00　Regional Warehouse訪問

10:30　IPHOの倉庫訪問。

12:00　午後は終日資料整理。

５月３日（火）

08:00　IRFOへ

09:00　Cebu Chest Center訪問。Dr Sancho等と意見交換。

12:00　昼食
午後は終日資料整理。

５月４日（水）

08:00　IRFOへ。すぐにMandaue市でのセミナー出席のため移動。

08:30　Mandaue市到着。以後終日セミナー。

５月５日（木）

07:15　IRFOへ。すぐにMandaue市でのセミナー出席のため移動。

08:00　Mandaue市到着。以後終日セミナー。

5月6日（金）

08:00　IRFOへ。
10:30　プロジェクト専門家らと最終の意見交換。
12:30　昼食終えセブ空港へ。
14:20　須知専門家と共にセブ出発、マニラへ。
15:20　マニラ到着。
16:00　フィリピン大学医学部臨床疫学課訪問。
17:00　JICAフィリピン事務所表敬訪問。
18:30　JICA母子保健・家族計画プロジェクトの井上・田中両専門家と夕食を共にしながら意見交換。
23:00　ホテル着。須知専門家と意見交換。

5月7日（土）

07:00　ホテル出発、マニラ空港へ。
09:40　ノースウエスト2便で成田へ向け出発。
14:00　定刻通り成田到着。混雑は全く無かった。

Logistics in Tuberculosis Control in the Philippines

June 11, 1994

Akihiro SEITA M.D.
International Cooperation Department
Research Institute of Tuberculosis, Japan

1. Preface

The logistics system of anti-tuberculosis drugs in the Philippines was reviewed by the author from April 25 to May 6, 1994, based on the request from the Public Health Development Project of Japan International Cooperation Agency (JICA). The author would like to appreciate team members of this Project and also the concerned staff of Tuberculosis Control Services of Department of Health and other related staff in provinces and municipalities.

"Rapid Assessment Manual on Tuberculosis Drug Management in National Tuberculosis Control Programme (NTP)" (the Manual) was used for this review. This Manual was developed by the author and other related researchers. This Manual has indicators which describe the anti-TB drug management activities. Although this is still on the stage of draft, the author found that this Manual is useful to evaluate the logistics in tuberculosis (TB) control.

This Manual reviews the drug management activities according to the following logistics cycle.

1. General Economics
   Public Health sector and NTP Sector budget and finance
2. Drug Policy Issue
3. Selection of anti-Tuberculosis Drugs
4. Procurement of anti-Tuberculosis Drugs
5. Distribution of anti-Tuberculosis Drugs
6. Use of anti-Tuberculosis Drugs
7. Private Sector

This report will firstly describe the executive summary and recommendations and then the review of Philippine's anti-TB drug management. Discussions and recommendations will follow. This review represents the analysis done by the author and does not represents those of the Project nor JICA.

At first, the administrative structure in the public sector in this country will be briefly mentioned.

Administratively, nation is divided into Regions, then Provinces and then Municipalities in this country. Some large cities are considered as Provinces.

Department of Health (DOH) is covering the whole nation. Region has its DOH office called Integrated Regional Field Office (IRFO). Province has its own health office called Integrated Provincial Health Office (IPHO) and Municipality has Rural Health Units (RHUs). The peripheral unit in the community is called Barangay and it has a Barangay Health Station (BHS).

Tuberculosis Control Services (TBCS) in DOH is in charge of TB control in this country.

This office has more than 30 staff. Each region has usually two regional TB coordinators. One is a medical officer and the other is a nurse. IPHO also has two TB coordinators. At RHU and BHS, TB control services are integrated into general health services.

Regarding to this administrative structure, two issues should be added. One is the devolution (decentralization). It started in October 1992. Before devolution, all the health offices and staff in public sector belonged to DOH. After the devolution, IRFO is belonging to DOH, but IPHO belongs to Province and RHU and BHS belong to Municipality. This devolution changed several aspects in health activities including the logistics system. It seems to the author that there is still slight confusion in the field.

The other issue is the on-going revision of NTP by TBCS. This revision was based on the TB control policy package developed by World Health Organization (WHO). The field tests of this revised NTP are about to start. Some of the issues discussed in this report are already taken into TBCS's consideration and modified in this on-going revision.

2. Executive Summary and Recommendations

2.1 Executive Summary

In the Philippines, there are two standardized chemotherapeutic regimens. One is 6 months regimen called Short Course Chemotherapy (SCC) and the other is 12 months regimen called Standard Regimen (SR). Tuberculosis Control Service (TBCS) of Department of Health is in charge of the management of anti-TB drug for SCC. Drugs for SR is under the responsibility of Municipalities. However, this 12 months SR will probably replaced with 4 months SCC because the NTP policy is under the revision now and they will be supplied by Tuberculosis Control Service. So, this report will focus on the management of anti-TB drugs for SCC.

There is a written National Tuberculosis Control Programme drug policy document titled NTP DRUGS LOGISTICS AND IEC (modification specifications). This document describes the specifications of drugs for SCC. NTP manual also describes the Drug Distribution Scheme. DOH also has the National Drug Formulary which describes all drugs in the Philippines. Anti-TB drugs are listed in this Formulary.

Anti-TB drugs are selected by TBCS from National Drug Formulary. In this Formulary there are six entities of anti-TB drugs such as Rifampicin (RFP), Isoniazid (INH), Pyrazinamide (PZA), Ethambutol (EB), Streptomycin (SM) and Kanamycin in the National Drug Formulary. In the NTP DRUGS AND IEC, three drugs for SCC such as RFP, INH and PZA. It is a TBCS's policy to use the blister packed anti-TB drugs for SCC. There are two types of blisters. One is for initial phase of SCC which contains RFP, INH and PZA. The other is for continuation phase which contains RFP and INH. Both blisters are prepared for one week drug intake. One day quantity is one tablet of RFP 450mg, one tablet of INH 300mg and two tablets of PZA 500mg.

Procurement of anti-TB drugs are done by Procurement and Logistics Service of DOH. TBCS computes the quantity of each drugs to be procured. This procurement is done through a domestic public bid. In 1993, totally 166 million Philippine Peso (6.3 million US Dollars) were spent for drug procurement. This means 0.1 US dollars were spent for anti-TB drugs per capita in the Philippines. All of these budget is from DOH. The average price paid in this procurement

was 88% of international average price, which was computed by Management Sciences for Health. One SCC costs 19 US dollars. Average lead time between the order of drugs and arrival of these drugs to Central Warehouse is 120 days. One issue should be mentioned here is the term of validity for all anti-TB drugs. All of them are expired 2 years after the manufacture in this country.

Distribution of anti-TB drugs is divided into three steps. One is from central to Region. Next is from Region to Province. The last one is from Province to Municipality (Rural Health Unit, RHU). TBCS is in charge of the first step. Second step is done by Regional TB Coordinator and the third step is by Provincial TB Coordinator. Each level has its Warehouse. These supply channels and warehouses are integrated into general services, not TB specific. However some Provincial TB coordinator have storage for anti-TB drugs. The inventory control is done by tally, ledger and stock-cards at Central Warehouse, by ledger and stock cards at Regional warehouse and by stock cards at provincial warehouse. However, at Central Warehouse and one Regional Warehouse which author visited there are no stock-records of reports which describe the stock-level of anti-TB drugs. Drugs are not well-arranged in that Regional Warehouse.

The quantity of drugs to be distributed is computed by the TBCS, Regional TB Coordinator and Provincial TB Coordinator primarily based on the expected number of TB cases. From Province to Municipality (RHU), the quantity is calculated based on the number of TB cases started the treatment during the last certain period, usually three months. In this calculation, the stock-level of the warehouse for the distribution is not taken into consideration. There is no standardized anti-TB drug request form at this moment.

At this moment anti-TB drugs for SCC are available for all over the country. Moreover, there have been no stock-outs of these drugs in 1993 and 1994, so far.

The use of anti-TB drugs are surveyed in a limited number of health facilities. As drugs for SCC are prepared in blister packages, all the patients for SCC are treated according to the NTP policy. However, some patients for SR are treated with 4 months of SCC which NTP is now planning to implement. Only two points were interviewed for drug use. They all have the correct knowledge of dispensed anti-TB drugs.

Regarding to the private pharmacies, there is no governmental regulations to control anti-TB drugs. Almost all kinds anti-TB drugs are available. It seems that anti-TB drugs can be bought at private pharmacy without any difficulties. The average price of several important anti-TB drugs compared to the international average price is 528%. It means the price of anti-TB drugs are six times more expensive than those paid by the DOH.

2.2 Recommendations

The current TBCS's policy on the use of blister packed anti-TB drugs for SCC is a strong support to the management of anti-TB drugs in this country. It should be mentioned that DOH is providing all the budget for the anti-TB drugs procurement and the price paid by DOH in the last procurement is almost 10% cheaper than the international average price. It is amazing that even after the preparation for blister packages, the price of anti-TB drugs are 10% cheaper than the average. The commitment and effort done by TBCS and DOH to maintain these activities should be highly appreciated. Blister packs are available at each level. To secure the drug supply is one of the key component for effective TB control.

The author would like to mention several issues concerning the current logistics system. One is the strengthening the NTP commitment particularly at region level. Logistics system for SCC and SR should be unified and TBCS should take the responsibility for both. It may be better to visit warehouse more often to have an idea on the storage system and stock-out level of each drugs. Second is the standardization and establishment of recording and reporting forms which are necessary for the logistics management. Standardized drug request form is needed. TBCS is now implementing this forms. NTP side also needed to set a standardized stock record which describe the stock-level and in and out of each anti-TB drugs. Third is the control of anti-TB drugs at private sectors. This issue seems to be quite difficult, however if the current situation continues, it is anticipated that the drug resistant TB cases may increase in number.

The followings are the discussions and recommendations concerning these issues such as procurement of SR drugs, terms of validity of drugs, inventory control measures, calculation of the drug quantity to be distributed and the regulation of anti-TB drugs in private sectors.

Drugs for SR are supposed to be procured by Municipality Government. However, as the number of TB cases at Municipality level is relatively small, it is not economic to continue to procure anti-TB drugs at this level. It may lead the shortage of drugs. It is needed to change its policy to put all the logistics management under the responsibility of TBCS. As NTP policy is being revised currently, it is a good opportunity to modify this policy now.

All anti-TB drugs expire two years after the manufacture according to the regulation by Bureau of Food and Drugs. It is too short. Anti-TB are valid at least in three years after the manufacture. TBCS is now proposing to extend this term to three years. This proposal is quite reasonable because this short term makes the distribution management particularly buffer stock setting difficult. This short term of validity need to be changed.

Inventory control of anti-TB drugs is done by general warehouse. It seems that this general warehouse need more improvement in inventory control. Drugs in warehouse need more arrangement. Anti-TB drugs should be kept in one place to count the stock level more easily. Warehouse needs to make a stock record or a report to have information on stock level. To assure this activity, NTP offices of each level need to visit the warehouse more often and regularly. It is needed to check the stock level. NTP officer should have the up-to-date stock-level of its warehouse.

At this moment, quantity of drugs to be distributed are computed based on the expected number of TB cases. It is not based on the number of TB cases detected (morbidity) nor the consumption of anti-TB drugs. Stock-level of anti-TB drugs at the warehouse is not considered in this calculation. TBCS is now planning to introduce the morbidity based calculation method and request form. This kind of logical way of calculation need to be implemented. However, it is anticipated that unless the term of validity extends to three years, it may be difficult to set buffer stock at each level.

It seems that there is no regulation on anti-TB drug use in private sector. Almost all kind of anti-TB drugs are available in the private pharmacies including at least five types of blister packages prepared for daily intakes. To control this situation seems to be very difficult at this moment, however the awareness among policy makers and DOH officers needs to be increased. More frequent and tight communication between private and public sectors are also needed.

3. Review of anti-TB Drug management in the Philippines

As described previously, anti-TB drug management in this country are reviewed by utilizing the indicators in the Manual. The full data concerning these indicators are attached in the Annex.

3.1 General Economics, Public Sector and NTP Sector budget and finance

The total population of the Philippines was 60,703,206 in 1990 (1992 Philippine Year Book). Per capita Gross National Product (GNP) was 730 US dollars in 1991.

The budget utilized for the NTP was around 229 million Philippine peso. Of them, 4.3 million Philippine peso was for the distribution of NTP diagnostic supplies for TB suspects, 12.7 million peso was for the procurement of NTP diagnostic supplies and IEC materials and 189 million peso was for the procurement of anti-TB drugs.

According to the NTP Annual Report of 1992 by TBCS, in 1992, 110,576 smear positive cases were detected. This figure gives the incidence rate as 173 per 100,000. The number of TB cases who initiated to the Short Course Chemotherapy (see below) during 1992 was 146,047. And, 88,475 cases initiated to the Standard Regimen (see below) in 1992.
The latest cure rate of TB cases was % in 19 . Based on the limited scaled tuberculin survey in the region V, VIII and X in 1992, the annual risk of infection was computed as 1.5%.

3.2 Drug Policy Issue

Existence of a written NTP drug policy is the key indicator in the Manual. Standardized chemotherapeutic regimen for TB cases is also the important indicator. In terms of essential drugs, existence of a national drug policy and its list are also the indicators.

In the Philippines, DOH has a National Drug Formulary. The latest revision of this formulary was done in 1993. Anti-TB drugs are included in this formulary (Annex).

TBCS has a written document on anti-TB drugs titled NTP DRUGS LOGISTICS AND IEC (modification specifications). This document was developed in 1993 and it describes the details of each anti-TB drugs. For example, the size, length, thickness, diameter and color of each drug are mentioned.

TBCS has its NTP manual which was developed in 1988. This manual describes standardized three treatment regimens such as so-called Short Course Chemotherapy (SCC), Standard Regimen (SR) and re-treatment regimen. Followings are the details of these regimens described in this manual. To simplify the explanation, in this report the following abbreviation of anti-TB drugs are used.

INH;	Isoniazid	RFP;	Rifampicin
PZA;	Pyrazinamide	EB;	Ethambutol
SM;	Streptomycin		

For new smear positive cases or smear negative cavitary cases;

6 months Short Course Chemotherapy (SCC)

2 months of daily INH, RFP, PZA and 4 months of daily INH and RFP

For new smear negative cases;

12 months Standard Regimen (SR)

daily INH supplemented by SM daily for one month and twice weekly for another eleven months.

For re-treatment cases;

There is no one standardized re-treatment regimen. One regimen is mentioned in the NTP manual is 2 months of SM, INH, EB and PZA and followed by SM, EB and INH daily for 4 to 7 months.

This manual also describes the logistics of SCC drugs in one chapter titled Drug Distribution Scheme (page 38). This chapter mentions the basic policy on procurement and distribution of SCC drugs, and their monitoring and reporting.
In this country, TBCS is responsible for the logistics of SCC drugs. However, logistics of SR drugs is Municipality's responsibility. This issue will be discussed later.

It is also the national policy to use the blister packed anti-TB drugs for SCC. The specifications of the blister package described in the NTP DRUGS, LOGISTICS AND IEC will be explained in the next chapter.

3.3 Selection of Anti-TB Drugs

Number of anti-TB drugs on NTP drug list is a key indicator in the Manual. Person in charge of drug selection is also the indicator.

In the Philippines, as mentioned previously, selection and procurement of SCC drugs are TBCS's responsibility and those of SR drugs are Municipality's. In this report, the author reviewed only TBCS's drug selection and procurement. Municipality's activities are not mentioned in this report because of the following reasons. Firstly, as far as the author observed and discussed, not all municipalities are selecting and procuring the SR drugs. It varies Municipality by Municipality. Secondly, TBCS is also selecting and procuring SR drugs and distributing them to the IRFO. Many of the SR drugs used at the RHU level seems to be the drugs procured by TBCS. Thirdly, 4 months SCC including RFP will probably be applied for smear negative cases when the revised NTP policy is accepted. In this case, blister packages for SCC can be used for smear negative cases. This means there may be no need for Municipality to procure the current SR drugs.

Regarding the selection of anti-TB drugs at national level, six kinds of anti-TB drugs such as EB, INH, PZA, RFP, SM and Kanamycin (KM) are listed in the National Drug Formulary. Following table shows the pharmaceutical forms and strengths of these anti-TB drug listed in the Formulary.

Drug		Pharmaceutical forms and strengths
EB	oral	200mg and 400mg tablets
INH	oral	100mg, 300mg, 400mg tablets
		100mg/5ml. 60ml and 120ml syrup
PZA	oral	500mg tablets and capsules
RFP	oral	150mg, 300mg, 450mg, 600mg tablets and capsules
		100mg/5ml, 30ml, 60ml syrup / suspension
SM	inj	1g vial
KM	inj	1g vial

From this list, TBCS selects the drugs for the procurement. NTP DRUGS, LOGISTICS AND IEC describe the specifications of four anti-TB drugs such as RFP 450mg capsule, INH 300mg tablet, Pyrazinamide 500mg tablet and EB 400mg tablet.

This document also describes the specifications of blister packages for SCC. There are two types. One is for the initial phase and the other is for the continuation phase. The former is called as Type 1 blister pack and the latter is called as Type 2 blister pack. The followings are the contents of each blister package.

Type 1; 7 days quantity for initial phase, such as

RFP 450mg capsule x 7 capsules	(1 capsule a day)
INH 300mg tablet x 7 tablets	(1 tablet a day)
PZA 500mg tablet x 14 tablets	(2 tablets a day)

Type 2; 7 days quantity for continuation phase, such as

RFP 450mg capsule x 7 capsules	(1 capsule a day)
INH 300mg tablet x 7 tablets	(1 tablet a day)

3.4 Procurement of Anti-TB Drugs

Procurement activities were evaluated according to its cycle such as calculation of quantities, methods of procurement, total cost for procurement, monitoring of procurement and lead time between the order to arrival of drugs are evaluated. The Manual selects three key indicators in this part such as per capita spending on anti-TB drugs, average price paid for anti-TB drugs compared to international price list and average lead time for drug procurement.

In the Philippines, Procurement and Logistics Service (PLS) of DOH is in charge of procurement of all drugs including those for TB.

LPS conducts a domestic public bid once a year. Six domestic private suppliers were nominated by Government according to their blister pack productivity and the importation source of row materials. Through tender, three suppliers are designated such as supplier bid the lowest price (supplier A), bid second to the lowest (supplier B), and bid third to the lowest (supplier C).

The price of drugs for this order are set at the lowest bid price. These three suppliers share the order. Supplier A will receive 50% of total quantity, supplier B will receive 30% of total, and supplier C will receive 20% of total.

TBCS determine the quantities of SCC drugs, namely blister pack type 1 and 2, for the procurement according to the expected number of TB cases. For example, in 1993, it was determined at first to procure blister packs for 150,000 SCCs. This number was computed by multiplying the whole population of the Philippines and prevalence (0.36%) of smear positive TB and the achievement (60%) of NTP. Some quantity are added as a reserve. As the unit price of blister packs decreased, the quantity was increased to 298,106 for type 1 packs and 237,328 for type 2 packs. In this calculation, the constant reserve stock at central, region, province and peripherals is not taken into consideration.

The quantities of non-blistered drugs such as INH tablets, EB tablets, INH syrup and RFP syrup was set to assist the regional hospitals and offices because these drugs are primarily supposed to be procured by Municipalities.

The names of selected anti-TB drugs for the procurement, their quantities, unit price and total cost in the 1993's drug purchase is shown in the following tables.

Drug	Unit Cost Peso	Quantity	Total cost Peso	US dollars**
Type 1*	29.50	2,064,712	60,909,004.00	2,298,452.98
	32.80	332,968	10,921,350.40	412,126.43
Type 2*	16.33	2,950,608	48,183,428.00	1,818,242.59
	20.85	649,936	13,551,165.60	511,364.74
EB 400mg	65.54/100	362,000	23,725,480.00	895,301.13
INH 300mg	32.00/100	146,000	4,672,000.00	176,301.89
SM 1g	7.25	2,000	14,500.00	547.17
INH 100mg/tsp 120ml. bot.	3.86	320,000	1,235,200.00	46,611.32
RFP 100mg/tsp 60ml. bot.	9.95	280,000	2,786,000.00	105,132.08
		TOTAL COST	165,998,128.64	6,264,080.33

The total cost of anti-TB drugs in the procurement of 1993 was around 166 million

Pesos. DOH provided all the budget for this procurement. There is no foreign donation in this year. TBCS used to receive donation from the Italian Cooperation, however it was terminated. This total cost is equivalent to around 6.3 million US dollars (consider one US dollar is 26.5 Philippine Peso). As the Philippines population was 60.7 million in the year 1990, per capita spending on anti-TB drugs was 0.10 US dollars, namely ten cents, in 1993.

The unit price of each anti-TB drug is compared to the international price. Following table shows the % average international price paid for the procurement in 1993. The average international price in the International Drug Price Indicator Guide 1993-94 developed by Management Sciences for Health (MSH), USA was referred. The author do not have the average international price of INH syrup and RFP syrup, so the columns for them are kept blank.

% average international price paid for last procurement and its average in 1993 procurement in the Philippines

Drug	Unit Price Peso	US$ (A)	(Per Drug US$ (B)*	MSH Price US$ (C)	% (B)/(C)*100
Type 1**	29.50	1.1132	0.1590	0.2146	74.1%
	32.80	1.2377	0.1768		82.4%
RFP 450mg***				0.1473	
INH 300mg				0.0153	
PZA 1000mg****				0.0520	
Type 2**	16.33	0.6162	0.0880	0.1626	54.1%
	20.85	0.7868	0.1124		69.1%
RFP 450mg***				0.1473	
INH 300mg				0.0153	
INH 300mg	0.32	0.0121	0.0121	0.0153	78.9%
SM 1g	7.25	0.2736	0.2736	0.1692	161.7%
EB 400mg	0.66	0.0247	0.0247	0.0257	96.2%
INH liq. 100mg/ts 120mg/bottle	3.86	0.1457	0.1457		
RFP liq. 100mg/ts 60ml/bottle	9.95	0.3755	0.3755		
				Average	88.1%

N.B.
1US$ = 26.5 Philippine Peso

Unit Price (B)* ; Type 1 and type 2 blister packs contain one week (7 days) quantity of each anti−TB drugs

Type 1**, Type 2** The MSH Unit Price of Type 1 and 2 blister packs were calucalated from the summation of MSH unit price of each contained anti−TB drugs

RFP 450mg*** ; The MSH Unit price of RFP 450mg was calculated from the summation of MSH Unit Price of RFP 300mg and RFP 150mg.

PZA 1000mg**** ; The MSH Unit Price of PZA 1000mg is equivalent of the two tablets cost of PZA 500mg tablet.

When seeing this table, it is remarkable that even with the blister pack preparation, the combination of RFP 450mg, INH 300mg and PZA 1000mg (Type 1) is 20% to 25% cheaper than the average international price. Type 2 combination, namely RFP 450mg and INH 300mg, is also 30% to 45% cheaper than the average international price. As a whole the average % of the average international price paid for the 1993's procurement is 88.1%.

According to the price of type 1 and 2 blisters, one treatment regimen costs around 480 Peso. It is equivalent to 18.8 US dollars. Even when EB 800mg will be added during the intensive phase, the total cost is 21.6 US dollars. Referring the average international price by MSH, the WHO standard 6 months SCC (2 months of daily INH 300mg, RFP 450mg, PZA 1500mg, EB 800mg, and 4 months of thrice weekly INH 600mg, RFP 450mg) will cost around 17.1 US dollars. However, this WHO regimen contains intermittent (three times a week) drug intake during the continuation phase. If INH 300mg and RFP 450mg will taken daily during the continuation phase like Philippine's SCC, the total drug cost for one WHO SCC is 27.5 US dollars. These comparisons indicate the TBCS and PLS are procuring anti-TB drugs at reasonable unit price.

PLS monitors the procurement process. All the drugs are primarily delivered to the Central Warehouse from the suppliers. The average lead time between the order and arrival of these drugs to the Central Warehouse is around 120 days. These drugs are then sent for quality assurance to the Bureau of Food and Drug (BFAD). It will take one month in average to complete this quality assurance. So, as a whole it will take around 150 days, namely 5 months, after ordering the drugs and before being able to distribute the drugs.

3.5 Distribution of anti-TB Drugs

In the Manual, port clearance, inventory control and distribution system to peripheral facilities are evaluated. However, in the Philippines, all anti-TB drugs are delivered directly to Central Warehouse from domestic supplier and there are no port clearance. So this section starts with inventory control.

3.5.1 Inventory Control

Inventory control system including the existence of stock records and reports, availability of anti-TB drugs and experiences of stock-outs are the indicators in this section.

3.5.1.1 At Central Level (Central Warehouse)

Central Warehouse is a place to keep all drugs at central level. This Warehouse is under the jurisdiction of PLS and it is located around one-hour driving distance from DOH. Central Warehouse is a gymnasium-like one-floor building. Drugs are kept in carton boxes as they were delivered. In this warehouse, there is a separate dark and cool room in a corner. Anti-TB drugs are kept in this room. The carton boxes of each anti-TB drugs or blister packs are piled on the floor separately, but there are no shells.

Inventory control in this Warehouse is done manually, not by computers. Tally system is used at TBCS and Ledger system and stock cards are used to monitor the stock-level and distribution.

Tally is kept by TBCS. TBCS also has a stock-record which shows the stock-level of each anti-TB drugs at Central Warehouse.

Ledgers are kept at the office in this Warehouse. Ledgers are kept by the officers of Warehouse. One ledger card starts when there is a new delivery from supplier. So, ledger is different from delivery to delivery. For example, type 1 blister packages are delivered from three suppliers, and one supplier sometimes delivered type 1 blisters in two times. In such case, ledger is different from supplier to supplier and also different from delivery to delivery even from the same supplier. There is no general stock record which shows the total stock-level of each anti-TB drugs in this Warehouse. So, one have to compute the stock-level by summing the balance in relevant ledgers.

Stock cards are kept and recorded by the stock-keepers. These cards are put with the carton boxes of drugs.

Physical check-ups of the stock level is done every month. However, it seems that there is no reporting system of inventory level at Central Warehouse to TBCS. It was explained that TBCS is keeping the inventory record which describe the latest stock level of each anti-TB drugs or blister packs. According to the ledgers reviewed by the author, the following quantities are the stock level of each anti-TB drugs at this warehouse.

Blister Type 1;	8,608 packs
Blister Type 2;	63,189 packs
INH 300mg;	146,000 bottles (100 tablets/bottle)
EB 400mg;	66,480 bottles (100 tablets/bottle)
Streptomycin 1g;	935,000 vials
RFP syrup;	35,775 bottles (100mg/tsp, 120ml)
INH syrup;	1,536 bottles (100mg/tsp, 120ml)

As author might miss some ledgers and all the distribution might not be registered in this ledgers, the real stock level may be different.

3.5.1.2 Regional Level (Regional Warehouse)

Regional Field Office (IRFO) of DOH has its own warehouse. It is a general warehouse for all drugs and equipment. Author visited one regional warehouse. Same ledger and stock card system is implemented, but it seems that supplies and distributions are not fully recorded in them. The Bill of Landing and Requisition and Issue Voucher are also kept in this warehouse. The former describes the supply from the central to region and the latter records the distribution to the provinces or rural health unit from region. However, the stock-level of each anti-TB drugs are not recorded in these documents.

This Regional Warehouse is also gymnasium-like one floor building, however there are small rooms in the second floor. Cartons of each anti-TB drugs are piled on the floor here and there without well-arrangement. Some of the blister pack cartons are placed on the first floor and some of them are placed on the second floor. So, it was not easy for the author to check the current stock-level. The followings are the stock level of each anti-TB drugs except SM checked

by the author.

Blister Type 1;	19,500+ packs
Blister type 2;	17,000+ packs
EB 400mg;	14,900 tablets
INH 300mg;	29,700 tablets
RFP syrup;	432 bottles (100mg/5ml susp. 120ml)

For blister pack type 1 and 2, one carton is already opened and some of them are already distributed. So, the exact number of each blisters could not be counted.

3.5.1.3 Provincial Level (Provincial Storage)

Provincial Health Office has its own warehouse or stock-room. One provincial stock-room of a Provincial Health Office (IPHO) is visited. Stock cards of anti-TB drugs are kept by the provincial TB coordinator. One stock card is used to record in, out and balance of one type of anti-TB drug. For example, blister pack type 1 has one stock card. These stock-cards clearly describe the balance of each anti-TB drugs. According to these stock cards, the followings are the quantity of the current stock level.

Blister type 1;	1,088 packs
Blister type 2;	484 packs
EB 400mg;	98,500 tablets (985 bottles)
INH 300mg;	39,200 tablets (392 bottles)
RFP syrup;	555 bottles (100mg/tsp, 120ml)
INH syrup;	365 bottles (100mg/tsp, 120ml)

3.5.1.4 Rural Health Unit (RHU)

Author paid a visit to one Rural Health Unit. This Unit has 7 type 1 blister packs, 65 type 2 blister packs, 1,800 tablets of EB 400mg, and 500 tablets of INH 300mg. There is no stock cards nor inventory record.

3.5.2 Availability of anti-TB drugs and experience of stock-out

All the anti-TB drugs selected by the TBCS such as blister pack type 1 and 2, INH 300mg tablet, EB 400mg tablet, INH syrup, RFP syrup are available at central, regional and provincial warehouse when author paid visits. At one RHU which the author has visited, all of above drugs except INH syrup and RFP syrup are available.

It was reported that there has been no stock-out experience of type 1 and 2 blister packs at all level in 1993 and 1994.

3.5.3 Distribution system

The distribution channel of anti-TB drugs is integrated into general one. It starts from Central Warehouse, Region Warehouse, Province storage and then to Municipality, namely Rural Health Unit. Before the devolution, there were District Hospitals in between Province and

Municipality, however this level has been omitted.

TBCS supervise the distribution from Central to Region, Regional TB Coordinator supervise from Region to Province. Provincial TB Coordinator supervise from Province to Municipality, namely Rural Health Unit.

The NTP manual describes the Drug Distribution Scheme on page 38. It says that from Region to Province, six months supply will be sent. From Province to District, four months supply will be sent. Then, from District to RHU, two months of supply will be sent. However, because of omission of District and other following reasons, this scheme is changed at this moment.

3.5.3.1 From Central to Region

TBCS is supervising the distribution from Central Warehouse to Regional Warehouse. TBCS computes the quantity of anti-TB drugs to be distributed to each region. At first, 10 % of the drugs are taken to the TBCS because it has an Out-patient clinic in DOH. Remaining 90% are divided to each region according to its expected number of TB cases. The stock-level at Regional Warehouse is not taken into consideration. Actually, stock-level at regions is not reported to TBCS.

This distribution is supposed to be done three times a year, namely every four month. However, due to the following two reasons it is done four to six times a year.

One is the term of drug validity. All anti-TB drugs will expire two years after the manufacture in the Philippines. This is because of the regulation of the Bureau of Food and Drug (BFAD). As mentioned previously, it takes around 120 days to receive drugs after an order and another one month to complete the quality assurance. So when drugs are ready for distribution at Central Warehouse, these drugs are valid one year and 8 months more. It makes TBCS to distribute them as soon as possible.

The second is the different delivery time from suppliers. There are three suppliers for each drug. They deliver drugs in a different time. Even from the same supplier, drugs are not always delivered at the same time. This will also make TBCS more difficult to establish a regular distribution period.

These drugs are transported to the regions by trucks. These trucks are private ones and hired by DOH. They carry all the drugs and equipment, not only TB drugs and they will not leave Central Warehouse until they are fully loaded. So, there will be another delay.

3.5.3.2 From Region to Province

Anti-TB drugs are kept at the Regional Warehouse and then distributed to provinces by the order of Regional TB Coordinator. This distribution quantity is computed according to the requests from provinces or the expected number of TB cases in province calculated by Regional TB Coordinator. It seems that there is no standardized request forms from provinces to region or order forms from Regional TB Coordinator to Regional Warehouse. It also seems that there is no standardized method to calculate the quantity of drugs to be distributed. Same as Central level, stock-level at Province is not considered in this calculation.

As mentioned previously, when region receives the anti-TB drugs, their terms of validity

are around one and a half year. The following table shows the date of expiry and terms of validity of anti-TB drugs stored at one Regional Warehouse. It is understandable that Regional TB Coordinator needs to distribute them without any delay.

Name of drugs	Date of Expiry	Terms of validity
Type 1	March/95	1 months
	August/95	15 months
Type 2	March/95	10 months
	August/95	15 months
EB 400mg	April/95	11 months
INH300mg	April/95	11 months
RFP syrup	April/95	11 months

The distribution of these anti-TB drugs are integrated into that of general drugs and equipment. It is explained at one Regional Warehouse that warehouse officers bring the all the drugs and equipment to province by Regions truck. In other occasions, province officers come to regional warehouse to collect the drugs.

3.5.3.3 From Province to Municipality (RHU)

Author visited one storage room of IPHO where all anti-TB drugs are kept under the supervision of Provincial TB Coordinator. He controls the inventory and distribute them to RHUs according to their requests.

Distribution is done every one to three months to the RHUs. The quantity of drugs to be distributed is calculated by the provincial TB coordinator. RHU reports the number of cases started treatment during the past certain period and Provincial TB Coordinator compute the quantity. There is no standardized request form. The stock-level at RHU is not primarily taken into consideration.

In terms of calculation methods for the quantity, the following method was explained to the author. Suppose RHU had 20 new SCC cases, 10 SR cases and 2 cases for RFP and INH syrup during last three months;

* For SCC;
  Blister pack Type 1: 20 x 4 wks/mo x 2 mo = 160 packs
  Blister pack Type 2: 20 x 4 wks/mo x 4 mo = 320 packs
* For SR;
  10 x 1 bottle of INH 300mg (100 tablets) = 10 bottles
  10 x 1 bottle of EB 400mg (100 tablets) = 10 bottles
* For Syrup;
  2 x 1 bottle of INH syrup (100mg/5cc, 120ml) = 2 bottles
  2 x 1 bottle of RFP syrup (100mg/5cc, 120ml) = 2 bottles

For the transportation of these drugs, one of the RHU staff who is in charge of this issue

usually comes to the IPHO. This person submits the request form and collect the drugs. After the devolution, anti-TB drugs such as blister pack type 1 and 2 are to be distributed from Central however other essential drugs such as anti-pyretics or anti-biotics are supposed to be purchased by Municipalities. So, the distribution of anti-TB drugs are independent from general distribution channel.

3.6 Use of anti-TB drugs

In the Manual, % of patients treated accurately according to NTP policy, % of patients with correct knowledge of dispensed anti-TB drugs and patient's satisfaction on the service provided are the indicators for the use of anti-TB drugs. These information are obtained by visiting the health facilities and interviewing TB patients. Author could visit only one RHU, two BHSs and one Chest Center. The information obtained there was limited because TB patients do not attend clinic every day.

Twenty-one treatment cards of TB patients who initiated treatment during 1993 were evaluated. Of them, 13 were smear positive and put under SCC, one patient was smear negative but serious and put under SCC. Seven patients were smear negative and put under SR.

SCC drugs are prepared in blister packages, so drug combinations of SCC are accurate. The duration of treatment was also accurate. However for SR drugs, there was sort of confusion because it is a transitional period to change SR regimen to RFP included four months SCC. Some medical officers have already started this RFP included regimen for smear negative cases.

Regarding to the weight of TB patients, all of these 21 cases were weighed at the beginning of treatment. The dosage of drugs in blister packs are fixed, it is explained that patients weigh less than 40 Kg are treated with RFP syrup, INH syrup and EB 400mg tablets. However, the RHU which was visited has no RFP syrup and INH syrup. It seems that the adult patients weigh less than 40 Kg are given the same blister packs, not modifying the dosages.

In terms of patients interview, only two patients were asked their knowledge of dispensed drugs and satisfaction with the services provided at RHU. There was difficulties in interview. One is the language problem and the other is the prejudice on TB in the community. It seems that patients are not always willing to reply the questions regarding to TB. Even when patient replied that he does not know, it does not always mean it. This can be that he does not willing to tell it to us. However, taking these difficulties into consideration, patients seems to have correct knowledge of drugs and satisfied the service provided.

One of these patients looks weigh apparently less than 40kg, however this patient told the author that he is taking the full dose of blister packs and he develops epigastric discomfort after taking the drugs.

3.7 Private Sector

Existence of government regulation on anti-TB drugs in private pharmacy, availability

of anti-TB drugs and their prices are the indicators in this section.

In the Philippines, there is no government regulation on anti-TB drugs in private sector. Author visited couple of private pharmacies and found that all anti-TB drugs except NTP's blister packages are available at there. For example, the following 11 types of RFP are available at one pharmacy.

RFP 150mg tablets and capsules
RFP 300mg tablets and capsules
RFP 450mg tablets and capsules
RFP 600mg tablets and capsules
RFP syrup 100mg/5cc
RFP syrup 100mg/30cc
RFP suspension 100mg/60cc

Even for the same preparation of RFP, there are different prices because of different manufactures. For example, there are two unit prices of RFP 300mg. One is 22.30 Pesos and other is 17.12 Pesos. There are four different unit prices in PZA 500mg.

The following table shows the unit prices of these anti-TB drugs at private pharmacy. When there are more than one price, the average unit price was calculated and used.

Drug	Unit Price (peso)	(US$) [A]	MSH average (US$) [B]	% [A]/[B]
RFP 300mg	19.71	0.744	0.0927	802.3
INH 100mg	0.31	0.012	0.0041	285.3
INH 300mg	0.75	0.028	0.0153	185.0
PZA 500mg	3.43	0.129	0.0266	999.6
SM 1g	11.00	0.415	0.1692	245.3
EB 400mg	4.45	0.168	0.0257	653.4
			Average %	528.5

As discussed previously, % average international price paid by DOH in the last procurement is 88.1%. So at the private pharmacy, the drugs cost around 6 times higher than the DOH price (528.5/88.1).

It should also be mentioned that blister packed anti-TB drugs are available at private pharmacy. These blisters are not prepared for one week intake like NTP's blisters but for one day intake. At one pharmacy there are five kinds of blister packs available. Following table shows the combination of drugs and cost of these blister packs.

	Cost per blister (peso)	(US$)
M-O-P Compliance Pack RFP450mg; 1 capsule INH400mg; 1 tablet PZA500mg; 3 tablets	25.25	1.05
Combi Pack RFP225mg+INH200mg; 2 capsules PZA500mg; 3 tablets	29.67	1.12
ECONOPACK INH400mg; 1 tablet RFP450mg; 1 tablet PZA500mg; 3 tablets	23.35	0.88
QUADPACK Pyrina Capsule; 3 capsules RFP150mg+PZA500mg+INH150mg EB 400mg; 3 tablets	28.65	1.08
SCC Kit EMB Forte tablet; 2 tablets EB 500mg+INH200mg RFP450mg; 1 tablet PZA500mg; 3 tablets	39.00	1.47

These drugs can be dispensed only with preparation. The author prepared prescription by himself and purchased them with this prescription by himself. There were no difficulties in purchasing these drugs. However, it seems that even without any prescription these anti-TB drugs can be bought at private pharmacy.

It is deadly needed to establish regulation to control this free market of anti-TB drugs. The emergence of drug resistant cases are strongly suspected if this kind of situation continues.

4. Discussions and Recommendations

Anti-TB drugs management of the Philippines are reviewed by utilizing the Manual. At this moment, DOH is procuring the anti-TB drugs with its own budget. NTP has enough stock of anti-TB drugs particularly Type 1 and 2 blister packages. Anti-TB drugs are available at region, province and municipality level. It is a remarkable achievement of the country whose GNP per capita is 730 US dollars. To sustain this activities, several issues need to be discussed and modified. NTP is now revising its policy according to the current WHO TB control policy. Some of the following issues discussed here are already included in the NTP policy revisions.

4.1 Drug Policy Issues

Philippine has its National Drug Formulary and NTP has its written NTP drug policy document. Treatment regimens for smear positive cases and smear negative cases are written clearly in the NTP manual. Blister pack preparation of anti-TB drugs for smear positive cases, namely SCC, is an NTP policy. These issues regarding to drug policy are highly appreciated. This blister pack formation, particularly, is contributing the effectiveness of TB control activities in this country. However, several issues are needed to be discussed.

One is the term of validity of anti-TB drugs. According to the policy made by BFAD, all anti-TB drugs expire two years after the manufacture. This short term of validity is affecting the effectiveness of logistics system in NTP. As described above chapters, this makes the logical distribution system very difficult. In the IUATLD's TUBERCULOSIS GUIDE, the following years are mentioned as the duration of time after the manufacturing date that drugs may be used safely (on condition that they are kept in proper conditions).

INH; 5 years
RFP; 3 years
PZA; 3 years
SM; 3 years
EB; 5 years

The term of validity of these drugs can be three years after the manufacture in this country although these drugs are prepared in the blister packages. TBCS is now putting its effort on this issue.

Second issue is the logistics of anti-TB drugs for smear negative cases, namely SR. At this moment, drugs for SR are supposed to be procured and provided by Municipalities. It is worried that this policy may affect the security of drugs and therefore the effectiveness of TB control activities because of the following reasons. One is the price of anti-TB drugs in this procurement. The number of TB cases for SR is small at Municipality level. When procuring the small quantity of anti-TB drugs, the prices are usually more expensive. It is not economic to procure anti-TB drugs by Municipality. One medical office in RHU told the author that he faced the difficulty to have Municipality procure these drugs because the priority of TB control is not so high in the Municipality.

As TBCS is planning to replace this SR with four month regimen including RFP. In this new regimen, the same blister packed anti-TB drugs can be used, so it will be a good opportunity to simplify the logistics system into one channel.

Third issue is the treatment regimen. To establish an effective logistics system, standardization of treatment regimens are needed. TBCS is now planning to change the regimens for smear negative cases and re-treatment cases according to the current WHO recommendation. This effort is highly appreciated.

4.2 Selection of Anti-TB Drugs

TBCS is in charge of the selection of anti-TB drugs. At this moment, the following drugs are selected for procurement by TBCS.

RFP 450mg tablet
INH 300mg tablet
PZA 500mg tablet
SM 1g vial for injection
EB 400mg tablet
INH 100mg/tsp 120ml bottle
RFP 100mg/tsp 60ml bottle

As described previously, drugs for SCC are prepared in blister packs. The one day dosage of this blister packs are RFP 450mg, INH 300mg and PZA 1000mg (2 tablets of PZA 500mg) for initial phase and RFP 450mg and INH300mg for continuation phase of SCC. Concerning the selection of these dosages, two issues need discussions.

First one is the dosage of PZA. One gram (1g) of PZA is not enough for the adult patients weigh around kg (probably the average weight of TB patients in the Philippines). For these patients, 1200 mg is desirable. This issue can be managed by changing the dosage of PZA tablet to 400mg (3 tablets a day) or 600mg (2 tablets a day).

Second issue is the dosage of RFP and INH. These drugs are selected for blister pack preparation. However, only one dosage is selected for each drug, namely 450mg for RFP and 300mg for INH. To modify the dosages of these drugs according to the weight of the patients, another dosages of these drugs are necessary. It would be better to introduce RFP 150mg tablets and INH 100mg tablets. These problems can be managed by providing the INH and RFP syrups, however, these drugs are quite expensive compared with the tablets.

4.3 Procurement of anti-TB drugs

Procurement and Logistics Services of DOH is in charge of procurement. This office is procuring anti-Tb drugs through domestic public bid. It should be mentioned that the price paid by PLS for this bid is 88.1% of the international average price. The effort made by PLS and others to procure these drugs at these low prices should be highly appreciated. The price of anti-TB drugs for one SCC is US$ 18.8 which is one of the cheapest price in the world although the dosage of PZA is 1000 mg not 1200 mg nor 1500 mg and EB is not included in this SCC. The Bureau of Food and Drug is conducting the quality assurance of these drugs. It seems that the procurement system is well-established.

The quantity of these drugs for the procurement is calculated by TBCS. This calculation is a morbidity method. However in this calculation the stock-level of central warehouse and the regional warehouses are not taken into consideration. It may cause the over-procurement of anti-TB drugs. This is due to the lack of stock-level monitoring and reporting system. The short term of validity of drugs as discussed above is also one of the contributing factors. This issue will be discussed later in the chapter of Drug Use.

The average lead time between order of drugs and arrival of the drugs at the central warehouse is 120 days. Taking into consideration that all the drugs are manufactured from the imported raw materials in the Philippines, it is expected that this period can be reduced. At this moment the term of validity of these drugs are only two years, it is needed to reduce this period to establish the effective distribution system.

4.4 Distribution of anti-TB drugs

Drugs for SCC is distributed from central to regions, provinces and then RHUs. These drugs are kept at the general medical store at each level. The quantity of drugs to be distributed is calculated by TBCS at central level, Regional TB coordinator at regional level and Provincial TB coordinator at provincial level based on the morbidity data of TB cases. At this moment anti-TB drugs particularly the blister packages are available at each level.

Inventory control of these drugs are done by general medical store at each level. Ledger and tally system is introduced. However, the stock-level of each anti-TB drugs are not always available. At Central Warehouse, there is no general stock record which describe the stock-out level of each anti-TB drugs although tally system is introduced. At the visited Regional Warehouse, drugs are not stored in an arranged manner and there is no stock records. At the provincial storage, anti-TB drugs are well arranged and there are stock records which describe the stock-level. To establish a effective logistics system, the ongoing data on stock-level of each anti-TB drugs is badly needed. NTP is needed to put more consciousness on this matter. To visit the warehouse more often and to set a stock record of these drugs at NTP side can be helpful.

The calculation of quantity of drugs to be distributed is based on the morbidity data of TB cases. However there is no standardized national request form for this distribution, and the stock-level of drugs is not taken into consideration. It may cause the mal-distribution of drugs. Actually at one RHU where the author visited, there were 1800 tablets of EB 400mg and 500 tablets of INH 300mg which will expire within couple of months. According to the morbidity data at this RHU, it seems that these drugs will not be fully used before the expiry date. TBCS is now planning to implement the drug request form which is basically similar to WHO's recommended form. This effort is highly appreciated.

Buffer stock at each level is not set although it is written in the NTP manual. This issue, however, is somehow understandable because the term of validity of anti-TB drug is only two years. What is practically needed at each level is to distribute these drugs before the expiry dates. To establish an effective buffer system like six months at central, three months at regional and three months at provincial, the terms of validity needs to be extended to three years.

4.5 and 4.6 Use of Drugs and Private sectors

As these issues were discussed in each respective chapters above, this part is omitted here.

5. Acknowledgement

The author would like to extend its sincere appreciation to the members of the DOH-JICA Public Healht Project, Staff of TBCS, Staff of Central Warehouse, Regional VII TB Coordinators, Staff of Region VII Warehouse, Cebu Province TB Coordinators, Staff of Catmon Rural Health Unit and other relevant staff for their tremendous support to my visit to the Philippines. Particularly the support by the Dr Masashi Suchi, Chief Advisor of DOH-JICA Project, Dra Corazon Teoxon, Officer In Charge of TBCS and Dra Elaine Teleron, Region VII TB Coordinator was of great help.