SERVICES FOR THE TREATMENT OF PATIENTS WITH TUBERCULOSIS IN HONG KONG

An audit of information obtained from the medical records of a cohort of patients and its use to support the future planning and evaluation of services

A collaborative study between the Department of Community Medicine, The University of Hong Kong, The Department of Health and The Hospital Authority

sponsored by

The Hong Kong Tuberculosis Chest and Heart Diseases Association

and

The Hong Kong Health Services Research Committee

Final report to the project steering group

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GLOSSARY

Adherence: extent to which patient takes anti-tuberculosis therapy as recommended and instructed by health care workers.

Ambulatory care: includes out-patient clinics, Accident and Emergency Departments, chest clinics, private practitioners providing primary care services, ward follow-up appointments.

Case-mix: groups of patients with similar clinical need.

Cohort*: a designated group of persons who are followed or traced over a period of time.

Complication of tuberculosis: pathology resulting from tuberculosis eg pleural effusion, haemoptysis.

Complication of treatment: pathology resulting from anti-tuberculosis therapy eg hepatitis. Sometimes referred to as "side-effects"

Culture: a diagnostic tool which relies on culture methods specific to mycobacteria (eg Lowenstein-Jensen media) – can be used for sputum or other samples.

Error: A false or mistaken result. Several kinds of error are recognised in epidemiology including *bias* due to inclusion or exclusion of ineligible or eligible patients; *random error* is the proportion of variation with no apparent connection to other measurements or variables; *systematic error* often has a recognizable source such as faulty technique.

Date of first symptoms: date that patient first complained of symptoms which could be attributed to their tuberculosis cough.

Date of first presentation: date patient first presented to medical care for symptoms which could be attributed to tuberculosis.

Directly observed therapy: anti-tuberculosis therapy which is given to the patient in the presence of a health care worker, who also observes that the patient actually swallows the tablets.

Economic evaluation: An evaluation which relates inputs of a programme to outputs.

Efficiency: Maximising the benefit to cost ratio of a programme. When comparing between programmes, the more efficient is the one which produces most benefit per dollar or which costs least per unit of benefit produced.

Epidemiology*: study of the distribution and determinants of health-related events or states in specified populations, and the application of this study to control of health problems.

Episode of care: a unit of health care: includes an in-patient admission to hospital (episode starts on day of admission and ends on day of discharge or transfer); day case management or ward follow-up; out-patient attendance (episode starts on day of first out-patient appointment with doctor and ends on day of last out-patient appointment with doctor). An admission to hospital terminates an episode of ambulatory care.

Episode – start: First clinic visit or at admission to hospital.

Episode – end: Last clinic visit or at discharge from hospital.

Episode – during: At any time in an episode other than start or end.

Inequality in health: The virtually universal variation in health (incidence rates, complications, losses to follow-up, mortality) associated with socio-economic status.

Information system and clinical information system: A combination of vital and health statistical data from multiple sources used to derive information about health needs, health resources, costs, use of health services, and outcomes of use. It may be used to issue automatic/semi-automatic pre-programmed reports, prompts and warnings. In the case of clinical records it may be used for record linkage and active patient care.

Loss to follow-up: patient fails to attend for scheduled follow-up appointment or admission and no record of subsequent attendance can be found.

Model (mathematical): A representation of a system or relationship in which equations are used to simulate the behaviour of the system.

Mycobacteria: A group of rod-shaped bacilli. Generally slow growing and cause chronic diseases such as leprosy and tuberculosis.

Notification: a statutory reporting system for certain communicable diseases including tuberculosis, using a specific form which requests core data for each patient and which should be signed by the notifying clinician.

Objective: The *precisely* stated end to which efforts are directed, specifying the *population outcome* and the variables to be measured to assess this.

Odds ratio: the ratio of two odds eg the exposure odds ratio is the ratio of the odds in favour of exposure among the cases to the odds in favour of exposure among the non-cases.

Pulmonary disease: disease affecting the lungs.

Respiratory disease: includes disease within the thorax: the lungs, pleura and intrathoracic lymph nodes.

Sensitivity analysis: A method to determine the robustness of an assessment by examining the extent to which results are affected by changes in methods, values of variables, or assumptions.

Sensitivity and specificity: Sensitivity is the proportion of true cases in the screened population who are identified by a screening; the probability that you will *correctly* identify a case using this method. Specificity is the proportion of truly negative (non-diseased) subjects who are identified by the screening test.

Smear: a diagnostic tool which relies on direct microscopy of a smear of sputum or other sample which has been appropriately stained (for example with Ziehl-Neilson or auramine).

Surveillance: the collection, analysis, interpretation and dissemination of data.

Tuberculosis disease: disease arising from infection with *Mycobacterium tuberculosis* or *M bovis*.

Tuberculosis infection: exposure to *Mycobacterium tuberculosis* resulting in a (cell-mediated) immune response. In many individuals this may result in containment of the tissue infection without progression to the full blown clinical disease picture.

* definitions taken from: Last JM. A Dictionary of Epidemiology. Second edition. New York: Oxford University Press, 1988.

FIRST PREFACE TO THE REPORT

The idea for this survey and audit was originally generated in the Health Services Research Group of the Department of Community Medicine, The University of Hong Kong. Applications for funds to support the work were submitted to the Hong Kong Tuberculosis, Chest and Heart Diseases Association and the Hong Kong Health Services Research Committee.

Following local and international peer review and several modifications to the protocols the work was begun in December 1995. The data collection was completed on schedule in late 1997. The completion of the final report has been delayed by illness and subsequent departure from Hong Kong of one principal member of the team.

The study is overseen by a multisector Steering Group representing all divisions and levels of the public sector services which contribute to the management of TB. The final report will have been processed through a number of reviews by members of the steering group and the content and conclusions will reflect their view points, critical appraisal and recommendations. The intention and hope is that the report will be seen as the first step in a new phase of service based monitoring and evaluation of care for tuberculosis. To achieve this it would be essential for a new working group to be set up and tasked with overseeing the implementation of the report's recommendations.

The plan is to incorporate corrections and amendments into the text of the report and add, with attribution to the various sources, additional information which is regarded as a particular view point or opinion. In this way the report will become a comprehensive document which represents all shades of interpretation, acceptance or possibly disagreement with the survey findings and conclusions.

Inevitably the settings, in which the care of the patients described in this study took place, will have been changing in various ways since the inception of the study but the majority of the findings are likely to be valid indicators of the way in which current services for tuberculosis operate.

The study is unique in that it examines both the processes of care and its outcomes in a representative cohort of patients in a defined period of time. In most instances, because of the generalizability of findings, the outcome measures in the study sample can indicate what is happening in the whole population of new cases of tuberculosis presenting each year (approximately 6500) to the chest service and other medical care facilities in Hong Kong.

The need for a strong well funded and fully integrated service for the management of tuberculosis will continue to be an essential feature of health care in Hong Kong for several decades at least. The current incidence rate of about 100 per 100,000 population together with future population growth of up to 2 million by 2010 are compelling reasons for a thorough review of the provision and management of services for tuberculosis. The development of state-of-the-art information systems to support TB services should be regarded as a very high priority.

A J Hedley
Chairman
Tuberculosis Audit Project Steering Group

February 1999

SECOND PREFACE TO THE REPORT

Since the first draft was distributed to members of the Steering Group in February 1999 a large number of comments have been received, both verbally and in writing.

In general there has been wide acceptance of the findings, conclusions and recommendations of the report. A long list of amendments and corrections suggested by several readers has been addressed and the changes incorporated in the text. Section 1 has been rewritten and brought up to date. Some further analyses have been completed and incorporated in sections 4, 6 and 8 and a new section 9 has been added.

The report writers have drawn together a summary set of recommendations based on the survey findings and comments of the steering group.

At a time when several reforms in health care are being considered it is clear that tuberculosis, with an estimated average population rate of over 100 per 100,000, and potential serious consequences for both the individual patients and the general population, should be the target of the highest quality services achievable.

The issue of tuberculosis control and treatment has continued to feature prominently in the media since the beginning of the consultation stage of the first draft report. Headlines such as "TB infection rate reaches highest level in 12 years" (*South China Morning Post* March 25 1999) and "Tuberculosis epidemic 'kills one every six minutes'" (*South China Morning Post* Aug 17 1999) are indications that the issues of health care policy, provision and evaluation of services will continue to attract attention and scrutiny in the public domain.

We believe that the general public can be reassured by the findings of this report. The survey showed that the provision of tuberculosis services was mostly based on a sound public health approach, high standards of clinical care and associated with concerted efforts to monitor the process of care as closely as possible given the resources available.

Inevitably the high degree of scrutiny and attention to detail in this clinical audit revealed several areas where performance could be improved and where methods of working should be changed to prevent failures in delivery of care. The application of these methods to *any* clinical service in *all* health care systems would reveal important problems which require resolution. However it is clear that, over time, there are marked and unacceptable variations in certain aspects of service delivery in different sectors or units providing services for tuberculosis. We believe that these shortfalls and gaps in service provision should be addressed urgently and effective action taken.

The clinical audit approach used here, albeit based on implicit rather than explicitly stated service objectives and targets, has revealed many opportunities for improvement in the system for providing care. Many of these are fundamentally concerned with information and its use and transfer between different providers. One of the biggest obstacles to completing the surveys in this report was the lack of certain types of information or difficulty and cost of obtaining it. Quality assurance of care in Hong Kong's complex tuberculosis services, as in all other medical services, needs to be information driven. The principal investments needed, to develop a more robust framework for delivering care and population control for tuberculosis, are in appropriate information technology and information systems as well as time and commitment of health care professionals.

The clinical audit approach used here to examine the functioning of services could form the basis of a new approach to quality assurance in the provision of care for tuberculosis based on the definition:

> *Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.*

This project has always been characterised by a high level of collaboration and support, to the principal investigators, from the clinicians providing services. Their contributions have been invaluable and always very perceptive and constructive. We are very grateful for their participation in the Steering Group and sincerely hope that in return the report will have some lasting value in guiding the next step in the development of Hong Kong's services for tuberculosis.

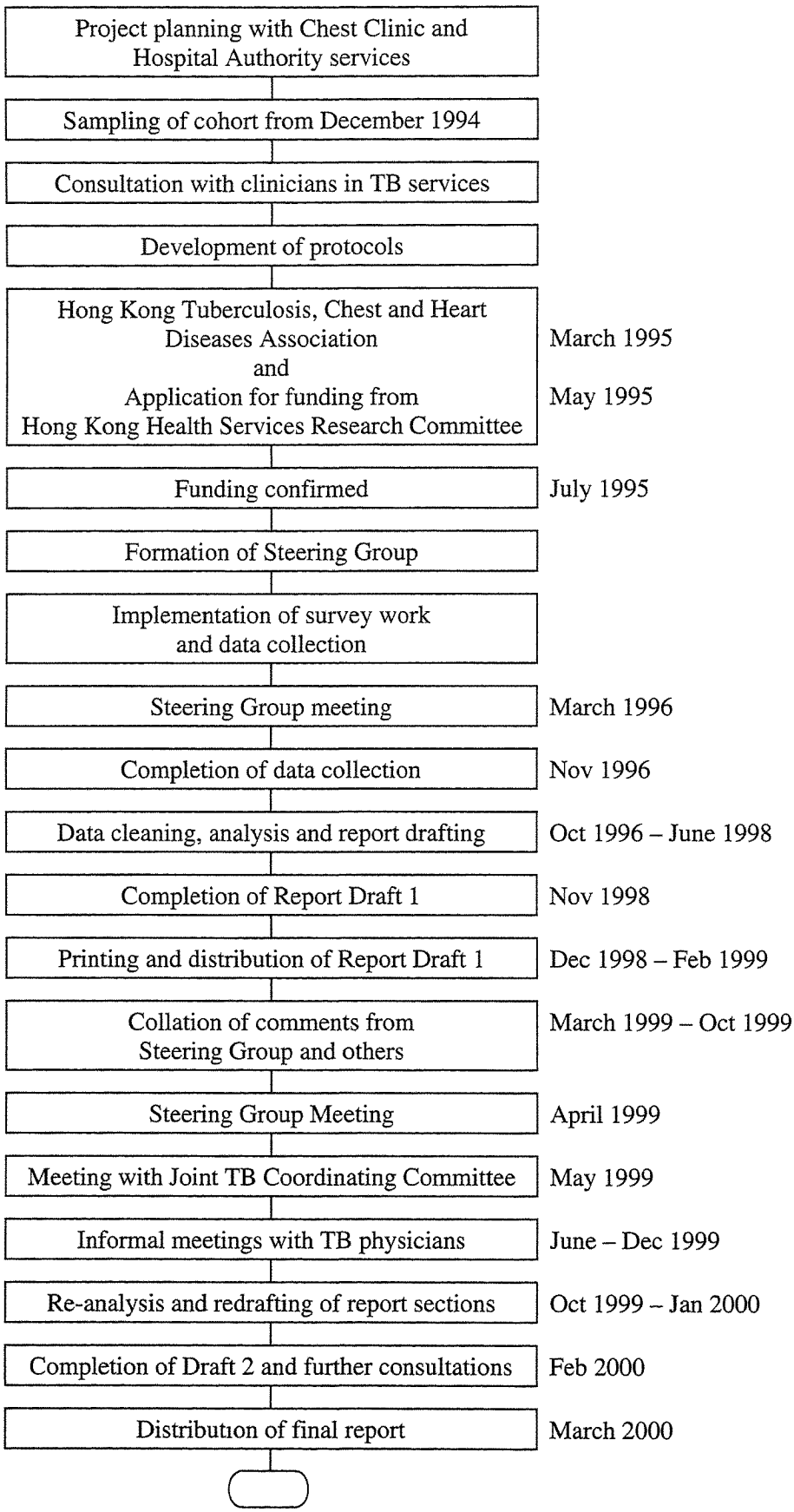
A new phase of the review of services for tuberculosis should now begin. We suggest that this could be based on the formation of a task force to undertake detailed assessment of problems identified in the report, draw up specific action plans, follow these through their implementation and measure the outcomes. This iterative audit cycle should be come an integral feature of the management of tuberculosis services and resources should be provided to support it. The ultimate aim is to develop a regional framework for tuberculosis services.

A J Hedley
Chairman
Tuberculosis Audit Project Steering Group

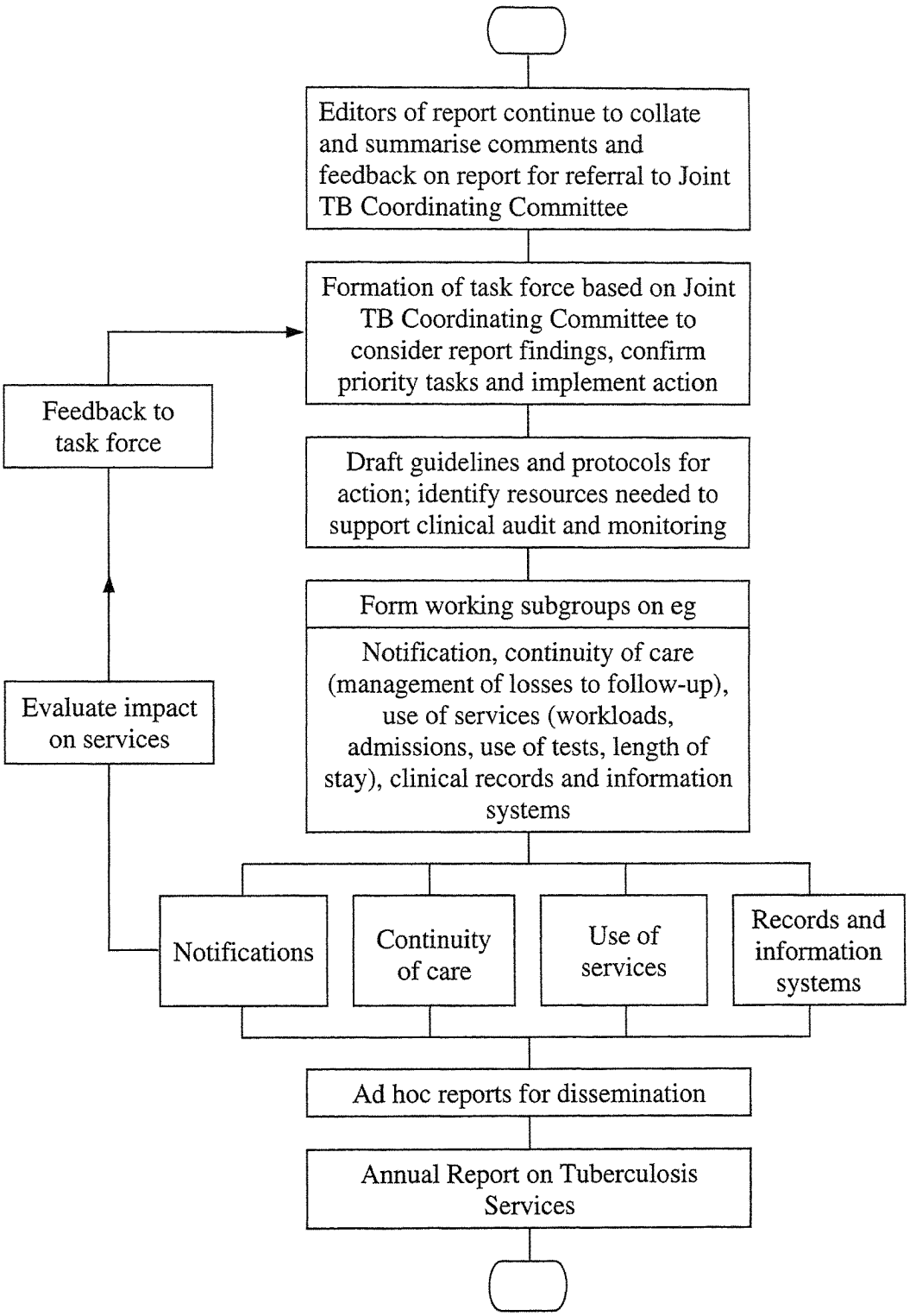
March 2000

Chronology of the survey and future developments

Flow chart: Clinical audit and patient cohort evaluation of services for the treatment of tuberculosis in Hong Kong



Proposed further developments in audit and monitoring of services for tuberculosis



RECOMMENDATIONS

Population at risk of tuberculosis	Develop, implement and monitor new guidelines for all health care personnel on the recognition and early investigation of possible cases of tuberculosis, with special emphasis on the elderly; maintain coverage of newborns with BCG vaccination; improve strategies for tobacco control and smoking prevention
Interface between private sector, and specialist services for tuberculosis	Develop mutually agreed standards and protocols with private sector for investigation and referral of patients who may have tuberculosis
Notification of tuberculosis	Review, upgrade and monitor all steps in the procedure for notification of patients; develop a full systems approach to capture of notification information, linking all sources, and with feedback to users of the system; develop standardised computer-based real time standard system for SAR-wide coverage
Clinical records and need for an integrated clinical information system	Review the design and function of all records for TB; adopt standardised record system across all units (DH and HA) providing services; develop computer-based linked record system to support clinical care and audit; implement continuous audit using outputs of the system; involve patients in transfer, updating and audit of records
Guidelines, protocols and goals for clinical care	Establish explicit standards for care, including protocols for: *early management of patients* suspected to have tuberculosis, to reduce variation (and avoid long delays) in initiation of treatment *continuity of care* to ensure that clinical management procedures are not interrupted and that records are not lost between referrals or within the same facility; a priority is avoidance of losses to follow-up at all stages of management *matching individual patient needs to type of care provided* (referrals, investigations, treatment regimen) with special reference to hospital admissions, use of tests, site and level of ambulatory care and coverage by DOTS *routine audit* covering all aspects of clinical management and administration of tuberculosis services
Needs assessment, manpower and resources	Establish continuing appraisal of needs for health care facilities recruitment, training and professional development of health personnel and medical workloads predicted by population trends in tuberculosis
Framework for Tuberculosis Services	Establish a *Framework for Tuberculosis Care* linking *patients*, *stages of disease*, *interventions* and all aspects of the process of care with *performance indicators* and *outcomes*

IMPLEMENTATION OF CHANGES, TIMING AND IMMEDIATE PRIORITIES

The suggested programme of change is clearly ambitious and all of it cannot be implemented immediately. There are a number of recommendations which will affect all parts of the services for tuberculosis. The achievement of some of these may require additional facilities or staff. In the case of developing and implementing new records systems for notifications and clinical care this may take up to four years. However we suggest that practical difficulties in one area should not stop recommendations being implemented in all those areas in which progress is possible. For this reason a number of interventions have been identified in which progress can be made within existing policies and resources. There are a number of immediate priorities in which rapid progress should be made.

Immediate priorities and goals within the first year

• Notifications	To develop guideline, protocols, audit procedures to support reliable notification procedures
• Explicit standards for care	To develop guidelines, protocols, audit procedures to support early management of patients and continuity of care
• Standardisation of clinical records	To review and improve the format, content and completion of records to support high quality databases and communication for the managed patient population

Intermediate priorities and goals within the second year

• Interface with private sector	To improve the early management, referral and continuity of care of patients who may have TB
• Population at risk	To improve early recognition and investigation of possible cases, especially in the elderly To improve smoking cessation facilities at the population level and in TB patients
• Development of performance indicators and the *Framework for Tuberculosis Care*	To establish a regional standard for tuberculosis in the form of a *Framework for Tuberculosis Care* which links different categories of patients and their needs, with all stages and sites of clinical management and other forms of care, using performance indicators and measures of outcome

Intermediate priorities and goals within the third year

• Implementation of a standardised SAR-wide computer-based clinical information system for tuberculosis for patient management and population surveillance	To adopt appropriate state-of-the-art information technology to support the development and use of standardised records and record linkage

Longer term priorities and goals within the fourth year

• Matching individual patient needs to type of care.	Will be achievable, given the infrastructure of protocols; information systems and the availability of high quality information.
• Needs assessment, manpower and resources	

BRIEF EXECUTIVE SUMMARY BY REPORT SECTIONS

Section 1: Background and Introduction

- Hong Kong's tuberculosis incidence rates are less favourable than other advanced post-industrial communities in the Asia Pacific.
- Good quality information (valid, accurate, reliable, complete, available) is an essential feature of competent TB services worldwide. However it is usually deficient in one or more of these key criteria.
- Better current evidence of efficacy of clinical practices and regimens is constantly needed from randomized controlled trials Routine clinical settings should support this approach.
- The decline in the reported incidence of tuberculosis has slowed in recent years. The reasons for this need to be examined further. They may be a composite function of demographic change (aging population), migrant patterns and improved notification.
- The need and demand for tuberculosis services will remain high well into the next millenium.
- Tuberculosis services need increased resources to support information systems, audit and clinical and operational research.

Section 2: Services for the Management of Tuberculosis in Hong Kong

- Patients with tuberculosis may receive care, at some stage, from six different sectors or levels in the public health care system; from two levels in the private sector and from the traditional or informal system. Most patients are seen by specialists in the public system and the aim is to promote the delivery of care to all patients from this sector.
- All sectors and sites in the public sector have potential advantages and limitations. An improvement in the general understanding of the service would be gained if these characteristics and potential problems of different services and the interfaces between services were recognized, disseminated, discussed and kept under review.
- The involvement of private sector services is reviewed in Section 3 and provides the first objective appraisal on this issue since 1979.

Section 3: Aims and Objectives of the Survey

- The aims and objectives of the report are stated explicitly and include assessments of
    * quality and utility of information available from records
    * notifications of patients with tuberculosis
    * the interface between different sectors and levels of services
    * patterns and types of care
    * outcomes of care
    * resource use in relation to need
    * information needed for evaluation, planning, and the development of an information system

Section 4: Notification of Tuberculosis

- Notification of tuberculosis is a critically important public health action.
- The audit shows that it has a relatively low priority in some sectors of the service.
- Under-reporting affects 1 in 4 patients in the general hospital sector and 1 in 30 in Chest Clinics.
- The best estimate of both under and over-reporting suggest that the annual true figure (1994) for new cases of tuberculosis is higher by 0.7% (lower estimate) to 16% (higher estimate). In 1994 this would involve 44 up to 1236 patients.

Section 5: Observational Study of Chest Clinic

- Chest clinics provide convenience with walk-in services.
- Performance pledges in terms of access and throughout are achieved for 99% of patients. The survey confirmed these outcomes for medical consultations and supervised therapy.
- Proportions of TB patients in individual chest clinic sessions varied widely, from 7% to 37%. This is likely to influence the provision of care to individual patients.
- Clinic operations are similar to other public sector ambulatory care services in that consultations are short, while waiting times are long.
- At some sessions 25% of patients spent less than 2 minutes with a doctor and less than 45 seconds with a nurse.
- The survey findings suggest some opportunities to revise clinic operations to avoid low need medical and nursing contacts.

Section 6: Evaluation of Treatment of a Cohort of Patients

- The levels of need, provision of care and outcomes were assessed in a cohort of 454 patients identified from the notification system. The findings (in section 4) that notification is incomplete may have led to some bias in the sample selection process.
- Most patients (68%) were male; about 1 in 5 had evidence of previous TB; most (93%) had respiratory TB.
- Patterns of care across the SAR are complex with care being provided at a total of 87 up to 140 different sites or units, depending on how they are defined.
- A total of 2012 episodes of care were identified for the 454 patients. Records for 201 (10%) episodes could not be found or could not be used for other reasons.
- Most care, 64% of episodes, was provided in ambulatory settings but most patients (62%) experienced at least one hospital admission. The median length of stay (9 days; range 4 to 18 days) indicates that some admissions may be avoidable.
- Department of Health chest clinics notified the majority of patients but 28% were notified from HA chest hospitals and five other categories of services.

- Clinical evidence to support the diagnosis was available from chest X-rays (97%) positive smears (27%) and cultures (55%) but no results were found in records for 1 in 10 patients.
- Drug resistance on initial testing was found mainly for streptomycin (10%), isoniazid (5%) and rifampicin (2%). A past history of TB was associated with drug resistance.
- Records for 90 (4.4%) of the 2012 episodes could either not be found or accessed.
- Most patients received directly observed therapy but 29% were treated with other forms of supervision.
- Long delays occurred, for some patients, from presentation to diagnosis, to treatment, and to notification
- There was a high rate of referral between different sources of care. In 1523 referrals, for the 454 patients, 83% were to a different source of care.

Section 7: Survey of Private Practitioners

- The regulation and maintenance of good practice in the management and referral of tuberculosis patients, in the private sector is an important element in community control of tuberculosis.
- In Hong Kong private practice (PP) is the principal source of first contact primary care, so it is expected that a proportion of patients with symptomatic TB will first present to PP.
- A 1977 (reported 1979) survey of Chest Clinic attendees found that 53% had *first attended* a private practitioner. Over 80% of those with a definite diagnosis received anti-tuberculosis treatment from PP, amounting to 24% of all patients.
- In 1979, a further survey of a group who had first attended a private practitioner showed that the proportion receiving treatment from PP had fallen to 12%. In the present survey this proportion had fallen to 2%.
- In this survey contact was made with 87 PP who had managed patients at any stage of the disease. The response rate was 72%, higher in NT (94%) than HKI (61%) or Kowloon (68%).
- Most patients (75%) were followed for less than two weeks before referral to a Chest Clinic, public hospital or in a few cases private hospital. However 25% were followed for longer periods, up to 6 months in one case
- A large number of investigations were carried out but few (23%) had sputum examinations; 85% of those who were smear positive at the clinic/hospital had not had a smear examination in PP. The proportion of smear tests compares with 5% in 1977 and 18% in 1979.
- If the sample from this cohort is representative then it indicates that, in each year, newly notified cases of tuberculosis are associated with at least 1218 PP doctor-patient pairings generating about 1358 episodes of care.
- The findings of the survey suggest that further integration and improvement of services for tuberculosis patients would be achieved through an intensive collaborative programme of professional education on the early management and referral of patients who may have tuberculosis.

Section 8: Medical Work and Resource Implications: An Economic Evaluation

- The three approaches taken in this study range from simple and arbitrary methods of scoring *need* to more complex attempts to grade and weight need according to different types and severity of clinical conditions and their complications.

- Three principal indicators of increased need for medical care were common in the cohort, including TB complications (51%), treatment complications (79%) and co-morbidity (67%). Twenty-eight percent of patients had none or only one of the need indicators; 42% had two and 29% had three.

- At the first level, using a simple score, hospital admissions and length of stay were respectively zero or very low in those with the lowest need score (0 or 1) but rose steeply in those scored 2 or 3.

- At the second level, the use of chest X-rays, liver function tests and smear examinations *during treatment* was examined using need criteria based on complications of tuberculosis and treatment and the presence of co-morbidities.

  There was no association between need status and the use of any (that is ≥1) test; the *proportions* of patients in both lower and higher risk groups who received tests were similar. However need status was strongly associated with the *number* of tests; the median number of tests in the higher risk group was the 87th centile (chest X-ray) or higher (98th centile for LFT's; 94th centile for smear tests) of the number of tests in the lower risk group.

- At the third level, a more elaborate need score, adjusted for perceived severity and the likelihood of co-morbidities affecting the management of TB, was used to identify possible areas of practice where need and utilisation were not well matched.

  Each additional TB complication or co-morbidity mitigated against successful completion of treatment and follow-up. The opposite was true for treatment complications alone, although the chance of a good outcome was higher with minor rather than severe complications.

- Higher levels of need, that is number and severity of TB complications and co-morbidities, were associated with a higher level of care in specialist units, but not the severity of treatment complications.

  Levels of need, assessed in this way, are seen to be drivers of care utilization. They are associated with use of higher specialist outpatient and inpatient units, frequency of ambulatory care attendance and duration of treatment. One salient finding is that whereas TB and treatment complications are associated with admission to a chest hospital, co-morbidities (even minor ones) are strongly associated with admission to general hospitals.

- In the low need group, starting treatment outside of the chest service was associated with higher utilisation.

- The need indicators appear to be valid and can be used to identify sub-groups or individuals with apparently higher need and low utilisation, or vice versa, as an additional approach to evaluating the efficiency of services.

1.0

BACKGROUND AND INTRODUCTION TO THE STUDY

1.0 BACKGROUND AND INTRODUCTION

1.1 BACKGROUND

This survey was prompted by many factors and view points. These include the recognition that the rapidly changing demography of Hong Kong, increased immigration of mainlanders to SAR, greater mobility of populations in the Asia Pacific rim and the relatively high prevalence of HIV/AIDS in this hemisphere are all potential mechanisms which may complicate and obstruct control of tuberculosis.

Several reviews of the population control and clinical management of tuberculosis have been conducted in Hong Kong (see section 1.8).

This study is different in style and content from the other reports in that it is based on primary data captured from a cohort of patients and a detailed examination of the medical work carried out for a defined and representative sample of patients presenting with tuberculosis. It also estimates the appropriateness of the care provided in relation to measures of medical need. Finally it studies the outcomes of care for this cohort and draws inferences about the efficacy of the services provided and the implications for future developments of services for tuberculosis monitoring, audit and evaluation.

The report begins with a review of some topical and important global issues in tuberculosis epidemiology, control and treatment and highlights those which are important for Hong Kong. The current health services provided for tuberculosis in Hong Kong are described in summary form and an attempt is made to reiterate key findings and recommendations from the previous reports on the service and to raise questions as to whether the necessary actions were taken and if not whether there are outstanding unresolved issues from these previous reports.

1.2 SURVEILLANCE OF TUBERCULOSIS

1.2.1 Incidence and prevalence: The current estimates of the global problem, in terms of both morbidity and mortality of tuberculosis, have been based on a range of clinical and microbiological measures of tuberculosis infection. The principal epidemiological variables used to describe the magnitude, trends and impact of tuberculosis are:

- incidence (including incidence of smear positive cases)
- prevalence (including prevalence of smear positivity in all cases)
- predicted incidence (including use of skin tests)
- notification rates
- mortality (including case fatality in smear positive and other cases)

1.2.2 Surveillance and information quality: In many countries, especially those with the highest risks, surveillance and information systems cannot provide information of adequate quality for community diagnoses and monitoring.

Assessment of the emergent problem depends on the availability of comprehensive, accurate, and continuous information on the incidence and mortality. The development and maintenance of surveillance systems is a vital component of any strategy for tuberculosis control and treatment which in itself is a cost-effective approach to population health.

Tuberculosis is a notifiable disease in most countries but routine audit of the notification of cases is usually lacking, and both accuracy and reliability are uncertain. Surveys based on case detection and notification have been condemned as notoriously unreliable (Zumla and Grange 1999). When audit is carried out under-notification is usually identified and improvement occurs when notification procedures are revised and reinforced (Brown *et al.* 1995). Effective notification systems require record linkage between clinical units, pathology laboratories and pharmacies and possibly other sources of health care information.

The current failure of control programmes in many countries can be attributed to complacency and a failure to conduct adequate monitoring of infection rates, notify cases, provide adequate care, record completion of therapy, and measure and assess outcomes of treatment and overall trends in high risk communities. Beilin (1994) points to the need for action registries and information systems. The tasks associated with this approach should be clearly defined and conducted along strict guidelines. They should be acknowledged to be labour intensive at least in their early stages and resources should be provided to meet this need; the information captured should be accurate, reliable and comprehensive; processing and analysis should be timely and feedback should identify gaps in reporting and problems with clinical management and follow-up. The application of new information technology could provide approaches to improve the quality of information and professional responsibility for reporting should be enhanced and subject to sanctions if physicians default, ultimately incurring suspension of the medical licence to practice. Separation of responsibility for surveillance from that of providing direct health care is at the root of this problem. The capture and use of epidemiological and clinical information must be part of the job description of all personnel providing tuberculosis services. Only the integration of surveillance with health care and patient management together with research on longer term outcomes will achieve the type and quality of intelligence required to control tuberculosis in populations. We urgently need a fundamental change of attitudes towards information management for surveillance. There are issues here which should be considered by all health care policy makers, chiefs of services, managers and all clinicians.

The problem of linking information management with clinical practice requires systems analysis and continuing operations research directed at the chosen solutions. The WHO global tuberculosis programme has started the global tuberculosis research initiative (GRTI) (M^{c}Connell 1998). The aim is to promote operations research and develop the skills and funding to support it. Operations research is needed to achieve improvements in surveillance and epidemiology. New approaches are required worldwide for the achievement of these goals in mixed medical economies and between different levels and sectors of health care systems, often complicated by the politics of relationships between government, non-governmental organizations and health professionals. The first problem to be addressed in tuberculosis control is the quality of information and that is as true in Hong Kong as elsewhere.

1.3 THE CHANGING GLOBAL SITUATION OF TUBERCULOSIS

1.3.1 Mortality: In 1993 WHO declared tuberculosis to be a global emergency. Tuberculosis is the most frequent cause of death from any infectious agent. About one third of the world's population is infected, with about 8 million new cases a year occurring in the mid 1990's, associated with 3 million deaths. Tuberculosis is a leading cause of death in the age group 15 to 44 especially in women in whom it causes 10 per cent of the deaths (Murray and Lopez 1997*b*). Tuberculosis kills about one third of all patients who die from AIDS in

Africa. The estimated mortality for HIV negative individuals in 1998 was 1.49 million with a range of 1.1 to 2.2 million deaths. An additional 365,000 HIV positive individuals are estimated to have died from tuberculosis in 1998. Eighty three percent of these deaths occurred in Africa, with approximately equal numbers of males and females. Low and middle income groups in the Americas and South East Asia, including India contributed 49,000 deaths compared with 9,000 from Europe and the whole Western Pacific. In Hong Kong there were 252 deaths (including "late effects of tuberculosis") of which 188 (75%) were in males and 24% were aged under 65 years.

1.3.2 Notifications: The largest numbers of new cases of tuberculosis arise in South East Asia (2.9 million), China (1.4 million) and Africa (1.05 million). Forty nine percent of African cases are HIV positive. The estimated burden of the disease, expressed as disability adjusted days, is greatest in South East Asia, Africa, China and Eastern Mediterranean regions. However in the Asia Pacific there is marked variation in reported notifications between both high income and low income countries (Table 1.1) (SEAMIC 1998).

Some of these data appear implausible. For example it seems highly unlikely that a country such as Thailand, with a very high prevalence of HIV infection, would have a tuberculosis notification rate which is less than half of that in Hong Kong where the risk of HIV is still relatively low. On the other hand in three high income post-industrialised countries or regions, Japan, Singapore and Hong Kong there is a three fold variation between the highest and lowest notification rates. Given that the information systems supporting notification are relatively well developed these differences are unlikely to be due to under reporting in Japan and Singapore.

Many data sources are incomplete, for example in Indonesia and Malaysia for certification of tuberculosis in deaths, and this raises questions about the validity of the notification data.

1.4 IDENTIFYING PROBLEMS IN GLOBAL CONTROL OF TUBERCULOSIS

1.4.1 The U-shaped curve: In the 1980s and 1990s the reverse in the previously established decline of tuberculosis led the World Health Organization to declare the global emergency. The earlier fall in tuberculosis incidence in the nineteenth and twentieth centuries was attributed to improvements in socio-economic conditions and the isolation of infected cases. However, the pattern of disease control this century now describes a U-shaped curve in which the seriousness and complexity of disease is much greater in the second limb of the U (Reichman 1991).

1.4.2 The WHO strategy: In 1991 The World Health Assembly proposed an effective tuberculosis control strategy with two goals, to be achieved by 2000: successful treatment of 85 per cent of cases and detection of 70 per cent. The features of the WHO Directly Observed Therapy Short course (DOTS) strategy were:

- government commitment to tuberculosis control
- case detection focussing on patients with symptoms who self-report to health services
- use of sputum smear microscopy
- standardised administration of the short course treatment
- direct observation of the chemotherapy for at least two months
- adequate supplies of treatments
- good records and information systems to allow evaluation of treatment results

Table 1.1: *Tuberculosis notifications and mortality in Asia Pacific countries*

Country		Population (000)	TB incidence all forms	Rate / 100,000	Deaths from Tuberculosis											
					Respiratory TB			Rate/100,000			Other tuberculosis			Rate/100,000		
					T	M	F	T	M	F	T	M	F	T	M	F
Brunei[1]	1996	305,000	140	45.9	3	2	1	1.0	1.2	0.7	3	-	3	1.0	-	2.1
Indonesia[1]	1996	196,263	394,551	201.0	77*	50	27	3.0			3*	2	1			
Hong Kong[2]	1998	6,690	7,673	114.7	235	169	66	3.5	2.5	0.98	35	21	14	0.52	0.31	0.21
Japan[1]	1996	124,709	42,715	34.2	2,639	1,948	691	2.1	3.2	1.1	219	116	103	0.2	0.2	0.2
Malaysia[1]	1996	21,169	13,539	63.9	430**	329	101	2.0	3.0	1.0	143**	77	66	0.7	0.7	0.6
Philippines[1]	1994	69,946	118,951	170.1	26,208	17,354	8,854	38.2	50.3	26.1	1,049	626	423	1.5	1.8	1.2
Singapore[1]	1997	3,044	2,772	89.3	103	81	22	3.2	5.1	1.3	12	9	3	0.3	0.4	0.1
Thailand[1]	1997	59,788	26,787	44.8	2,494	1,873	621	4.1	6.2	2.4	1,265	934	331	2.1	3.1	1.1
Vietnam[1]	1996	75,355	70,349	93.4	1,146***						83***					

* Based on 10 day sample of discharges from hospital for each quarter
** Medically certified deaths only which comprise 44% of all deaths
*** Hospital based figures only
[1] Adapted from SEAMIC Health Statistics 1998; South East Asian Medical Information Center, International Medical Foundation of Japan
[2] Hong Kong Government Chest Clinic Report 1998

WHO set up a surveillance and monitoring project in 1995 to assess national tuberculosis programmes and to compare regions which had adopted the WHO strategy (DOTS) and those which had not. Raviglione *et al.* (1997) estimated that within those countries which adopted the strategy only 23 per cent of the world population was covered.

Improved delivery of care must focus on early diagnosis and reliable delivery of effective treatments, but in 1998 WHO identified 22 countries, which accounted for 80 per cent of tuberculosis cases worldwide, of which 16 countries were not making satisfactory progress in control of the disease. Half of those with a poor performance were middle income countries which had the resources but not the political will to tackle the problem (Wise 1998).

The failure of tuberculosis controls is exemplified by the problem in the Philippines which has been estimated to have the highest numbers of cases of tuberculosis per capita in South East Asia and is fourth ranked in the world. No progress has been made in two decades and the situation is complicated by low utilisation of services by people with symptoms, high levels of drug resistance (60 per cent for isoniazid), the social stigma attached to the disease and inability to pay for a full course (US$75) (Easton 1998).

Tuberculosis is associated with war, famine, social disruption and poverty, including homelessness, unemployment, imprisonment and alcoholism. In Russia the incidence and mortality has increased steadily since 1990 with rates of 67.5 and 17.0/100000 respectively since 1996 (Wares and Clowes 1997).

Prospects for the future, in projections of mortality and disability by cause for 1990 to 2020 as part of the Global Burden of Disease Study (Murray and Lopez, 1997*c*), indicate that tuberculosis ranked seventh as a cause of death in 1990 and its rank is not predicted to change throughout the thirty year period. The total number of DALYs attributed to tuberculosis worldwide (1990 data) is 42.5 million, of which 42.4 million arise in developing regions.

These current trends are complicated throughout the world by the growing problem of double infection by tuberculosis and HIV. The warm-climate developing countries will experience the sharpest rises in incidence and this is directly related to the incidence of tuberculosis in the emerging HIV epidemics in Africa, India, and Asia Pacific countries. It will dictate the need for a marked change in priorities and a reallocation of resources from both within and outside of existing services, but the public health priorities are the alleviation of poverty and provision of good quality services to which all those in need have unhindered access. All of these issues have direct relevance to the emerging demographic and social changes in the Hong Kong SAR.

Cornwall (1997), with a perspective from Cambodia, argues that it is not knowledge which is lacking in the fight against tuberculosis but the will to use it appropriately and the need for greater focus on the point of contact between patient and health worker.

Many predictions for tuberculosis are pessimistic but others argue that the tools to implement cost-effective programmes are available. One year of healthy life can be gained for not more than US$3 making it one of the most cost-effective interventions in health care (Kochi *et al.* 1997).

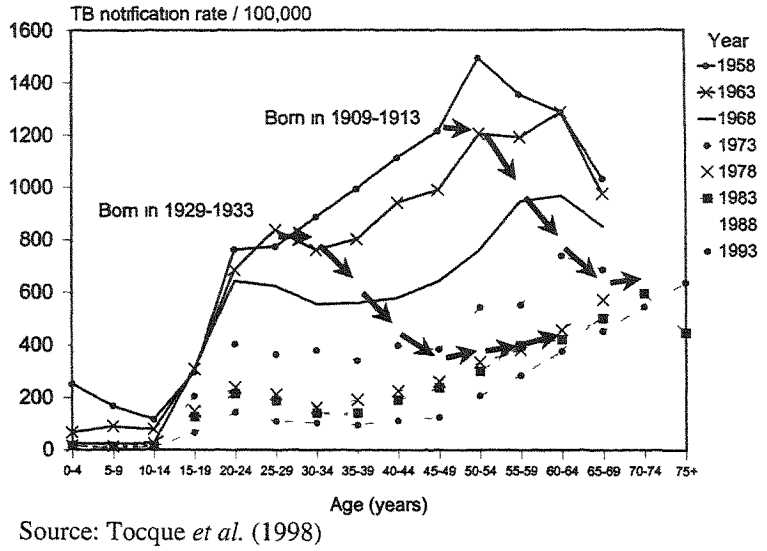
1.5 FACTORS INFLUENCING GLOBAL TRENDS IN TUBERCULOSIS

1.5.1 Ageing communities: Several authors have reported on the rising age of tuberculosis patients in developed countries and a slowing down in the decline of notification rates overall.

In Hong Kong the notification rates in 1980 were 211/100 000 for males and 103/100 000 for females. A steady decline followed with these rates falling to 135 and 66, respectively, by 1995. These improvements followed, albeit relatively slowly, behind many other improvements in health indices including low infant mortality and low age specific mortality rates from most causes. Since 1995 then there has been a sharp up-turn in tuberculosis rates attributable mainly to the continuing high rates in the elderly and growth in their numbers in the population. Modelling based on these trends in notifications and population projections for the next two decades indicate that notification rates will continue to rise well into the new millenium (see section 1.8.6).

To examine past long term trends in tuberculosis in Hong Kong and the UK, Tocque *et al.* (1998) used a birth cohort analysis approach. They calculated age-specific rates of disease, by different age groups for different birth cohorts, for England and Wales and Hong Kong. In Hong Kong each birth cohort showed a similar pattern of disease by age with rates peaking in the 29 to 39 year age groups and then gradually declining (Figure 1.1). Since 1978, regardless of age at that time, all age cohorts showed an increase in tuberculosis rates with increasing age, particularly in females. A similar pattern was seen in England and Wales but the peak occurred at an earlier age (less than 25 years) and the pattern of decline with age did not cease until 1984. Life expectancy is increasing steadily, particularly in countries with high or increasing per capita incomes. In the Asia Pacific region this includes the post-industralised countries or regions of Japan, Taiwan, Singapore and Hong Kong but the numbers of elderly are also increasing across many other developing nations. The aging of communities therefore is becoming an important potential factor in the deterioration in control of tuberculosis.

Figure 1.1: *Age incidence curves for male tuberculosis cases in Hong Kong from 1958 to 1993. The arrows indicate how rates were calculated for two individual birth cohorts as examples of how data were derived to compare age-cohort data between Hong Kong and England and Wales*



Source: Tocque *et al.* (1998)

1.5.2 Tobacco: In addition to its contribution to the burden of cancer, heart and respiratory disease smoking is an importance influence on the risk of tuberculosis mortality.

In China the smoker to non-smoker tuberculosis mortality ratio for men is 1.17 (rural) and 1.42 (urban) and in women 1.25 and 1.56 respectively (Liu *et al.* 1998) and smoking was estimated to account for 12 per cent of all tuberculosis deaths. A lung which is damaged by smoking may offer a propitious environment for the tuberculosis bacillus (WHO 1999*a*). Because of the high prevalence of smoking in men, in excess of 60 per cent in many Asian countries, tobacco will continue to make an important contribution to the burden of tuberculosis in the 21st century. Tobacco smoking is the biggest single preventable environmental or behavioural risk factor for tuberculosis in Hong Kong. A recent study of over 20,000 registered deaths in Hong Kong in a mega case-control study, found a relative risk of 2.54 for smoking and mortality from respiratory TB in males aged 35-69, indicating an excess risk of 154% (Lam et al 2000). The control and prevention of tuberculosis in Hong Kong will require a two pronged approach on both improvement of services and resources and effective tobacco control measures.

1.5.3 Role of BCG in prevention: BCG vaccine is a recommended component of the WHO Extended Programme on Immunisation for infants and is used by the majority of countries worldwide. In Hong Kong coverage of new borns by BCG vaccination has been maintained at over 98% since 1981, a commendable achievement, although it is always necessary to reflect that risk is usually inherently greater in those who do not receive preventive medicine and so the unprotected margins are relatively more important than the rest.

The efficacy of BCG vaccine has been reported as ranging from being nil or possibly having adverse effects to conferring a high level of benefit up to 88% in the case of deaths from TB. Reviews have pointed to several areas of uncertainty including overall effectiveness, variation in efficacy with age at vaccination, duration of protection and variation in efficacy with different BCG strains. A meta-analysis of 13 trials, including those with random allocation (7), systematic allocation (4) and alternate allocation (2) yielded an overall protective effect of 51% (RR 0.49; 95CL 0.34-0.70) and 71% (RR 0.29; 95CL 0.16-0.53) against a tuberculous death (Colditz et al 1994).

Data combined from case-control studies using a random effects model gave estimates for protective effects similar to the trials. The protection in eight studies based on vaccinated infants was 55% (OR 0.45; 95CL 0.34-0.59). In ten studies, with predominantly pulmonary TB cases, protection was 50% and the overall protection in case-control studies was 50% (OR 0.50; 95CL 0.39-0.64). Protection for tuberculosis meningitis in vaccinated infants was 64%; and for all forms of TB following vaccination in infancy 83% (OR 0.17; 95CL 0.07-0.42); protection for disseminated TB was 78% (OR 0.22; 95CL 0.12-0.42). Factors which were associated with protection, estimated as the observed variance explained in prospective trials, included the assessed scientific validity of the study (data validity explained 30%) and geographic latitude (41%), with efficacy increasing with distance from the equator. These effects were more important in the model than age at vaccination which only explained 6% of the variance and study designs (<1%). However opportunities to study age specific groups at vaccination was limited. Findings related to BCG strains were not consistent and apparently genetically identical strains gave different results in different populations. Rigorous sensitivity analyses including the use of additional hypothetical data supported the original

findings. On this basis it seems reasonable to assume that BCG vaccination has made a significant contribution to TB prevention and control in Hong Kong particularly in infants and children.

The use of meta analyses to examine the impact of BCG on health outcomes is an important contribution to understanding of the efficacy and benefits. It provides information for health care planners which can guide current policy without the need to resort to long term trials in different health care environments or the disadvantages of other direct measures such as tuberculin reactions in vaccinated and unvaccinated groups.

1.5.4 Human Immune Virus infection: Any consideration of future trends of TB in Hong Kong must take account of trends in HIV/AIDS both locally and in the surrounding region. A new epidemic wave of tuberculosis around the world is following the global increase in HIV with six million cases of both HIV and tuberculosis. Seventy five percent are estimated to be in Africa (WHO 1994).

In the mid 1990's the prevalence of combined infection with HIV and tuberculosis was about 6 million and HIV was estimated to cause up to half a million new cases of tuberculosis per year (WHO 1996). Information from African countries with reliable information systems, Burundi, Malawi, Tanzania and Zambia, indicates the impact on their health care systems from the HIV related rise in incidence of tuberculosis (WHO 1996). The harm to maternal and child health is particularly serious (Chintu and Zumla 1995); in Zambia where 25 per cent or more pregnant women are HIV positive, tuberculosis is the principal cause of death in pregnancy (Fylkesnes *et al.* 1997).

In the United States tuberculosis cases have steadily increased in number since 1985. Most of this is attributed to the HIV epidemic (Styblo 1991). Whereas the lifetime risk in HIV-negative tuberculin positive subjects is estimated as 1 in 10 the annual risk in those who are HIV positive is 1 in 10 to 1 in 14. In 1995 in New York the rate of 40.9 per 100 000 was four times the national average.

Tuberculosis is now a major problem in patients with HIV infection in large metropolitan areas. For example in the United States with an incidence of up to 9000 new cases per year (Markowitz *et al.* 1997). In New York the notification rate of tuberculosis (40.9/100,000) is four times the national average and associated with nosocomial spread and multi-drug resistant tuberculosis (MDRTB). In London tuberculosis rates have increased by 35 per cent compared to 15 per cent in England and Wales but the extent of HIV associated tuberculosis is uncertain because notification of tuberculosis in HIV is reported to be unreliable (Pym *et al.* 1995). Patients with drug sensitive tuberculosis infection respond similarly to HIV negative patients with a standard six month course of therapy but have a higher relapse rate. This may be prevented by 9 or 12 months of chemotherapy and DOT improves the outcome (Alwood *et al.* 1994; Jones *et al.* 1994, Hopewell 1997).

Prophylactic drug therapy may help to prevent tuberculosis in HIV positive individuals (Msamanga and Fawzi 1997). Six months treatment with isoniazid in tuberculosis positive HIV subjects reduced the risk of tuberculosis by 70 per cent (Whalen *et al.* 1997). Similar findings were made in Haiti and Zambia but not in Kenya.

Cost, access to anti-retrovirus drugs and adherence to treatment are major obstacles which should be priorities in aid programmes to Africa and in health care for HIV positive immigrants to western countries. HIV related tuberculosis is a barometer for tuberculosis control and highlights weaknesses in its prevention and treatment (Coker and Miller 1997). The prevalence of HIV infection in Hong Kong is still relatively low but it is increasing, as is the rate of increase. There are clear indications that perceptions of the risk of contracting HIV among cross-border travellers are low (Abdullah *et al.* 1999) and the trend of increasing incidence is now well-established. It would be surprising if this does not have a significant impact on endemic patterns of tuberculosis in Hong Kong.

Prisons: Prisons have been identified as important reservoirs of tuberculosis in Asia and elsewhere, particularly drug resistant strains, in both western industrialised and developing countries. Surveys of prisons in New York City, Russia, Azerbaijan, Malawi and Ethiopa have demonstrated a strong association between tuberculosis and HIV infection in prisoners and both the opportunities for and problems of achieving solutions in these neglected settings (Nyangulu *et al.* 1997; Reyes and Coninx 1997; Coninx *et al.* 1998). The major epidemic of HIV in Thailand began with the concessionary release of large numbers of HIV positive prisoners.

1.5.5 Multiple drug resistant tuberculosis (MDRTB): Poor clinical practice, inadequate supervision and resources, unethical commercial sales of inappropriate anti tuberculosis drugs and combinations have all combined to create the problem of drug resistance. The risk of MDRTB, described as the "Third Epidemic" may become the dominant pattern of tuberculosis spread on several continents, fanning out from countries such as Peru, northern India, Sierra Leone, the Baltic States and Russia. Outbreaks of drug resistant tuberculosis, once rare, are now common place and many involve HIV positive patients. Early outbreaks were associated with high mortality because of failure of recognition and appropriate action. Several outbreaks of MDRTB have occurred in Europe including nosocomial infections in London and Madrid.

The WHO-International Union Against Lung and Tuberculosis Disease (IUALTD) Global project on Anti-Tuberculosis Drug Resistance and Surveillance 1994 to 1997 in thirty five countries found evidence of resistance in all of them, in patients with no previous treatment the prevalence was 9.9 per cent (range 2 to 41 per cent). *M. tuberculosis* strains were resistant to one or more drug. Among those with a history of treatment the prevalence of resistance to any of four drugs (isoniazid, streptomycin, rifampicin and ethambutol) was 36 per cent (range 5.3 to 100 per cent). High prevalences were found in the former Soviet Union, Asia, Dominican Republic and Argentina (Pablos-Mendez *et al.* 1998).

Many outbreaks occur in hospitals, prisons and institutions with infection of both patients or residents and staff (Snider and Castro 1998). Mathematical models project a 50 year surge in multi-drug resistant tuberculosis. Empirical use of DOTS will not solve the problem of MDRTB especially when it is already established and may in fact amplify first line drug resistance (Blower *et al.* 1996) and HIV co-infection will accelerate the progression of tuberculosis epidemics. The solution is universal access to adequate tuberculosis control programmes but this requires much greater aid, from the developed world, than is currently offered.

Multidrug resistant tuberculosis is relatively uncommon in Hong Kong. However, given the high levels of tuberculosis and poor standards of care in many of Hong Kong's neighbours, global and regional trends in tuberculosis will be relevant to, and a major challenge to, Hong Kong's public health system for many decades to come.

1.6 PROVISION OF CARE FOR TUBERCULOSIS AND COMPLIANCE WITH TREATMENT

1.6.1 Diagnosis: It is estimated that less than half of those with tuberculosis who need medical care are in contact with treatment services. Continuity of care for tuberculosis often breaks down and this represents an additional hazard for community spread of the disease. Diagnosis has always presented problems. The protean manifestations, mimicry of other conditions, validity of tests including lack of sensitivity (eg sputum microscopy) or specificity (chest radiology) and slow procedures (culture) all contribute to the problem.

Nucleic acid technology (polymerase chain reaction and ligase chain reaction) are evolving as potentially useful diagnostic tools. Sequencing of the *M. tuberculosis* genome should also allow development of rapid tests but the availability of new technology to those countries which need it most urgently will be limited for many years (Zumla and Grange 1999). Near-patient (as opposed to central laboratory) testing could yield important public health benefits, such as rapid initiation of contact tracing. However the validity and reliability of such tools in the field will determine their cost-effectiveness. There may also be negative effects on the capture of epidemiological information from central diagnostic facilities, compounding the existing shortfalls in record keeping and notification. So implementation of these techniques will require their integration with new information technology, for example to enable automatic storage and transmission of results from multiple geographically separate sites (Borriello 1999).

1.6.2 Short course multiple drug regimens: A wide range of short-course regimens are employed in different countries. Choices are based on past experience and established practice, cost and availability of drugs and evidence for effectiveness in trials. In Hong Kong (Hong Kong Chest Service 1984 *a, b*) randomized trials of different drug combinations and durations of treatment showed that four-drug regimens were more effective than a three-drug regimen without streptomycin, at preventing relapse at 30 months. Four-drug regimens will contribute to population control of the disease by preventing the development of drug resistance and primary resistance in contacts.

1.6.3 Directly observed therapy: The aim of all treatment regimens must be to ensure high levels of compliance in the intensive phase. Short-intensive and continuation courses facilitate this but the allocation of resources for recruitment, training and supervision of community health workers is an essential part of any strategy.

Measures adopted to improve compliance in both urban and rural health care settings range from electronic pill dispensing devices to directly observed treatment programmes. Despite the evidence from trials generated by British researchers in Africa, Asia and London in the 1940's and 1950's, self administration remained the standard in the US. DOT was considered to be too costly despite its demonstrated cost-effectiveness (Weis et al 1994). When it was applied in the US, where non-adherence is identified as the principal reason for drug resistance, directly observed therapy (DOT) was associated with reductions in primary drug resistance (13-6.7%), acquired resistance (14-2.1%), uncomplicated relapses (20-5.5%)

and those with multiple drug resistance (25-5%). The programme operated in an environment with high levels of homelessness, intravenous drug abuse and increasing incidence of tuberculosis. Annual losses to follow-up were relatively low. Better evidence, from randomized controlled trials, may be needed before the most cost-effective options are identified (Morse 1996). Eventually the compelling evidence of clinical economics was accepted with recognition that the cost of treating one case of multidrug resistance could fund DOT for 700 patients.

Directly Observed Therapy (DOT) or Directly Observed Treatment Short Course (DOTS) has been strongly promoted in the 1990's as the key to the control of tuberculosis in both developing and developed countries. Iseman *et al.* (1993) argued that we cannot afford not to do it and in 1997 the World Bank and WHO contended that DOT is the most cost-effective of all health interventions. This revelation, implying a breakthrough in therapeutic management, caused some concern and was followed by strong arguments that good evidence on the best approaches to implementation of supervised therapy and rigorous evaluation were lacking (Grange and Zumla 1997).

There are clearly mixed views on many aspects of this strategy and recently there has been renewed questioning and interest about DOT, or "supervised swallowing" in terms of what makes it work (Garner 1998). The idea of DOT was prompted by the need to tackle non-adherence to treatment and prevent the disastrous consequences of it. It was developed in settings typically characterised by poverty (Bayer and Wilkinson 1995). Now, because of enormous escalation of the scale of tuberculosis in populations, for example from 5000 to 19000 in Malawi between 1985 and 1995 (Malawi National Tuberculosis Programme), high costs and unavailability of hospital care, DOT is seen to be a potentially important contribution to new global tuberculosis control strategies such as short course drug regimens (Squire and Wilkinson 1997).

In South Africa, Zululand, a DOT twice weekly six months course of a four-drug regimen achieved an 80 per cent completion rate (Wilkinson 1994). Between 50 and 60 percent of the patients were supervised by unpaid non-health workers most of whom were storekeepers. There was no difference in failed treatments between this group and that supervised by health personnel in wards, clinics or community. A comparison of community based DOT and conventional treatment was the basis for an economic evaluation of this approach (Floyd *et al.* 1997). DOT was 2.8 times cheaper than conventional care and 2.4 to 4.2 times more cost-effective and allowed a year's case load to be managed with 47 beds compared with a notional 160 required (but unavailable) for conventional care.

In China the adoption of WHO-DOTS was associated with a cure rate of nearly 90 per cent in new cases and a fall in the treatment failure rate in previously treated cases from 17.6 to 6.2 per cent. Supervision of treatment was provided by village doctors with financial incentives and careful supervision (China Tuberculosis Control Collaboration 1996).

However, in contrast, a randomised controlled trial of DOT compared with self-supervised patients showed equivalence of the two approaches with a trend for better outcomes in the self-supervised group (Zwarenstein *et al.* 1998). The investigators concluded that DOT is authoritarian, reduces self-reliance, and alienates patients. They even suggested it may do harm by interfering with patient autonomy. Flexibility of approach taking into account local conditions is necessary as demonstrated by the success of other approaches in rural Nepal (Jochem *et al.* 1997). Where programmes provide easily accessible, affordable and culturally

acceptable care and can be shown to achieve adherence targets and good treatment outcomes, health care planners can confidently continue to take an eclectic approach. On the other hand it is clear that the future of tuberculosis control and treatment programmes in many different settings should ideally be based on randomised controlled trials. There is scope to consider whether new trials would provide information on how best to improve care in Hong Kong. There also needs to be more emphasis on operational studies, qualitative research and the patient's viewpoint. The trial of Zwarenstein, which included a relatively small number of eligible patients with high treatment interruption rates, was prompted by the high workload imposed by a DOT programme and its report led to many cautionary statements about advocacy of any one method without adequate testing of its individual components.

It does appear that DOTS can provide high cure rates for patients who are covered by such a programme and WHO projects that the annual number of cases could be halved in the next decade with adequate treatment and supervision. But we have been lulled into a false sense of security about tuberculosis. Globally, only 5 to 10 per cent of cases are reached by DOTS now, and this report shows that the proportion of Hong Kong patients receiving DOT is lower than might be expected for a variety of different reasons. Ironically some patients cannot participate in routine DOT programme because they are suffering from complications of tuberculosis or its treatment which dictate that they undergo different forms of management. Drug resistant strains are increasing while low research activity has resulted in no new drugs for tuberculosis for 30 years and no new vaccines for nearly 80 years (Bloom *et al.* 1997).

A mathematical model (Dye *et al.* 1998) which assumed WHO targets of 70 per cent case detection and enrollment in DOTS programmes, with cure rates of 85 per cent of patients who would otherwise receive inferior treatment, predicted a fall in incidence of 11 per cent and deaths by 12 per cent per year. Achievement of WHO targets by 2010 would prevent 23 per cent or 48 million cases by 2020. These predictions are considered to be optimistic because they do not take account of patient preference for private practitioner care where case detection is low and DOTS is generally not available (Sandiford 1998). This report includes a survey of Hong Kong private practitioners who first managed patients who were eventually notified with TB. The study indicates several problems in accessing information in private practice and reinforces WHO concerns about the gap between private practice and the responsible public health authorities in the management of TB.

Volmink and Garner (1997*a*) argued that it is necessary to develop more reliable reviews of DOT to support organisations such as WHO and World Bank. Without this, rhetoric about DOT may lead to currently effective programmes being discarded without a thorough evaluation of all the options available. A systematic review of five randomised or pseudo randomised controlled trials of other preventive or curative strategies for tuberculosis showed that all six interventions tested were effective (Volmink and Garner 1997*b*). The interventions tested which did not include the "supervised swallowing" procedures of DOT, were component reminder letters, monetary incentives to patients, health education, intensive supervision of staff and two combinations of these strategies. As all the interventions were effective the findings may indicate a form of *Hawthorne effect* in which increased overall commitment and intensity and comprehensiveness of interventions yield the desired clinical and public health results. Such an effect can obviously be exploited for benefit although the precise elements of any one strategy which are responsible for its success may remain unidentified.

Finally, at the present time, most high epidemic countries have low DOTS coverage and only 12 per cent or less of patients are receiving DOTS. The development and application of DOTS must not detract from the need for much greater investment in research for new vaccines and therapeutic agents for which DOTS or its variants must be the vehicle.

1.7 THE NEED FOR A PUBLIC HEALTH APPROACH

Few tuberculosis treatment programmes achieve the aim of 85 per cent adherence and completion of the drug regimen. Inadequate adherence to treatment is very common. This is one of the most serious problems in tuberculosis management and has profound public health implications. Factors which are associated with or predict non-adherence have been identified from case-studies rather than randomised trials (Table 1.2). In addition to DOT and other approaches mentioned previously it is essential that we improve the approach of services to delivering patient communication and education (Table 1.3). This approach is low cost and extremely effective and in any case should be a mandatory feature of good quality, that is ethical, medical care. It is estimated that 15 to 20 minutes of patient education yields two months of regular attendance for care without default. This supports the argument of Zwarenstein *et al.* for better patient-carer relationships. The aim should be to improve patient confidence and autonomy. Information systems and new technology must be adopted to facilitate methods to improve compliance, particularly in supporting the development of new records, for both carers and patients, and improving the quality and flow of information. This is particularly important in mixed medical economies or any other settings where patients may be seen at different times by health personnel from several different sectors of a health care system and at different levels between primary and specialist care. Records created by these encounters should be patient-held and patient-driven to ensure continuity of both information and care. It should be noted that the information we have about factors which are associated with, or predict, non-compliance are generally drawn from case studies and not randomised controlled trials. We need better evidence and epidemiology and decision analysis can make a major contribution to the future of care for tuberculosis.

Table 1.2: *Factors associated with non-adherence in the treatment of tuberculosis*

Problem area
Principal problems
Subjective responses of patients, including feeling better and side-effects
Difficult access to health care facilities
Additional contributing problems
Delay between referrals and appointments
Clinic environments, comfort, cleanliness, refreshments
Duration of treatment
Communication between health professionals and patients
Number of drugs
Side-effects
Cost
Social support

Source: adapted from Cuneo and Snider (1989).

Table 1.3: Steps to improve adherence and overall effectiveness of programmes

Need for patient orientated measures to improve compliance	Health care system response
Education at diagnosis	Provide supervised therapy
One to one counselling and communication adjusted to levels of educational attainment and literacy	Use trained outreach workers to provide direct supervision for disadvantaged patients who do not attend clinics
Explanation of changes in treatment regimens	Provide adequate training programmes for health care workers
Services convenient for patients including care at the workplace	Develop services for patients in remote areas
Access to care, including adequate transportation	Recruit volunteers and other non-health personnel to support tuberculosis care
Incentives tailored to patients' personal circumstances	Audit all procedures
High quality appointments systems, reminders, and failsafe follow-up methods	Evaluate the cost-effectiveness and acceptability of different programmes
Improve patient autonomy and promote self monitoring and belief in their own actions	
Ensure patients have access to and ownership of information from medical records and other sources	

Source: adapted from Cuneo and Snider (1989).

The lessons learned from the New York city tuberculosis epidemic demonstrate that even in the West tuberculosis is as much a political and fiscal issue as a medical management problem and *therefore* so are the solutions (Coker 1998). In New York, funding for tuberculosis was severely cut in the 1970's. To this was added the internal management problems in tuberculosis services and the growth of overcrowding, inequalities and HIV in high risk neighbourhoods. Treatment rates dropped to an average of 60 per cent. The response to the crisis cost US$1 billion but through effective public health action led to a halving of case-loads and an eighty five percent reduction in multi-drug resistance.

The authors of this report hope that the audit of services in Hong Kong will lead to a new phase of close monitoring and evaluation of service performance as a means of guiding policy and resource allocation to tuberculosis.

Coker recalls the New York City Board of Health 1915 slogan "The city can have as much reduction of preventable disease as it wishes to pay for. Public health is purchasable; within natural limitations a city can determine its own death rate".

1.8 PREVIOUS REVIEWS OF TUBERCULOSIS SERVICES IN HONG KONG AND THEIR RECOMMENDATIONS 1975-90

1.8.1 Need for continuing review: The planners and the providers of services for tuberculosis had the benefit of several earlier reviews of services for tuberculosis. They include

> Report on tuberculosis services in Hong Kong and their future development
> FRG Heaf, W Fox 1962
>
> Tuberculosis in Hong Kong: Present position and future planning of methods of control and treatment
> JG Scadding, W Fox 1975
>
> The present status of tuberculosis and its management in Hong Kong and the future development of the tuberculosis and chest services
> W Fox, GS Kilpatrick 1990
>
> Report of the working group to examine the Fox/Kilpatrick report
> (Chairman M Gabriel) 1990

Many observations, questions and recommendations are raised by these enquiries and although the reports cannot be analysed and discussed in their entirety, we suggest that the reports could usefully be revisited and the salient issues should be addressed. A preliminary discussion follows, to illustrate some important points.

1.8.2 Incidence of tuberculosis: The Scadding and Fox and Fox and Kilpatrick reports both took the view that TB incidence and therefore future medical work was declining rapidly in Hong Kong. Scadding and Fox suggested that in 1975 although the trends such as those in immigration, aging and intensive case finding would lead to a delay in the decline of new cases, we would eventually be rewarded with a more rapid rate of decline. They predicted that incidence would fall from about 180/100,000 in the mid 1970's to about 100/100,000 in 1985.

In fact by 1985 the incidence estimated from notification was 138/100,000 and in 1996, 11 years later, had only fallen to 103/100,000. It should be remembered that these figures from routine notifications are probably under-estimates by an order of 10% or more.

It is now possible to use a modelling approach, under varying assumptions, to examine projections of tuberculosis notifications and from that estimate medical work and the resources needed to support it. An illustration is given in section 1.8.6.

1.8.3 Need for an integrated service: Earlier reports discuss the problem of creating a truly integrated service. Scadding and Fox (1975) suggested that departments of respiratory medicine would increasingly eventually take over the management of tuberculosis, with physicians with special training and experience in tuberculosis and respiratory medicine. Later, at the time of the Fox Kilpatrick (1990) report, there was a strong view held among some that new proposals for a truly integrated service should be put forward. Fox and Kilpatrick recommended that the important functions related to the control of tuberculosis "should remain the responsibility of a single individual, the senior physician in charge of the

Government anti-tuberculosis and respiratory disease service". They went on to say that "this arrangement should not be disturbed to any appreciable extent by reorganisation currently envisaged or planned in the future. It is now clear that this is not the case; services for tuberculosis are handicapped by the split across the two public sectors of care provided by the Department of Health and the Hospital Authority.

This present report on the audit of the tuberculosis services should be considered in the light of the recommendations made by Fox and Kilpatrick (1990). In fact today it would seem to be totally implausible that a physician working in the chest service could have control over the medical work and decision-making which is going on in HA sites, including the many dozens of interfaces between different sectors and levels of the services.

In the final discussion and conclusions drawn from the survey findings the report will attempt to address these issues, including, for example, the monitoring and management problem resulting from the split in health care services concerns the potential referral chain between Government Chest Clinic services and HA specialist outpatient and inpatient units.

Since the separation of services which are now provided by the Department of Health and the Hospital Authority, many patients have been retained for continuing review at Specialist Outpatient Departments, and not referred to (or back to) the Chest Clinics. The rationale and justification for this is not entirely clear. The reasons are probably those common to referral problems in all specialist facilities, including a legitimate interest in the natural history of the disease, training experience of junior staff, and clinical research. However the policy for either retaining patients or using the referral chain between DH Chest Clinics and HA facilities has not been formally clarified and for several years there was no clear policy despite discussions on the issue between clinicians in the two sectors. Recently the practice of retaining patients at clinics has drifted in favour of referring patients back to Chest Clinics, probably because it was recognised that the lack of any facilities for directly observed therapy was a serious hazard for compliance, completeness of treatment and the risk of drug resistance.

Attendance at SOPD's will of course be required for many patients with co-morbidities and extensive disease, complications or side effects of treatment. But there should be agreed case-mix criteria which allow the network between different ambulatory care facilities, different sectors, and in-patient facilities to be used efficiently.

The Fox and Kilpatrick (1990) report referred to Scadding and Fox (1975) and reiterated that its main recommendation was the "continuity of management" from outpatient care, to inpatient care when indicated, and then to outpatient again, at all stages under the same team. This survey undertaken five years later describes to what extent this does or does not happen. The fact is that there is no mechanism which provides fail-safe seamless care, which is the clear intention of the Fox and Kilpatrick (1990) report. For example Fox and Kilpatrick states "It is our strong conviction... that any division between the Hospital Authority and the Health Department must be avoided at all cost". Unfortunately this schism was not avoided. Apart from clinical management such a division would disrupt the public health function of services for TB patients.

At least part of the perception of the feasibility of seamless care, by Fox and Kilpatrick (1990) is based on the assumption that care was moving away from inpatient management to community care. "This approach minimises hospital stay and this is not only cost saving but

ensures patients are not removed from their usual home and working environment for any longer than necessary". This may be true but in Hong Kong many patients with TB have high social dependency levels. It is often likely that the work and home environments are the very reasons why patients have to be admitted for management of particular problems. In fact readers of this report will see in section 6.0 that this present survey demonstrates that, in the late 1990's, admission to hospital is a prominent feature of the care provided for the majority of TB patients in Hong Kong.

The reasons for the high admission rate can be explored further using the survey database along the lines suggested by Fox and Kilpatrick (1990). This task could be undertaken by, or through, the Tuberculosis Control Coordinating Committee, but it will require appropriate types and sources of information to monitor this in the future. A clinical information system, providing record linkage across all TB services would be able to support such an approach. The data in other sections of this report could be used to draft the initial proposals for management of the referral chain. Another important reason for such an approach is the need for efficient and complete notification of patients. The present system splits notification between two sectors as well as many clinical and pathology units.

The expectations, recorded in (Scadding and Fox 1975), that TB services would contract *and* become a fully integrated part of public sector specialist services for respiratory disease have not materialised. The views of the research team which carried out this study need to be highlighted.

Physicians working in the Chest Service have not benefited from the split in services in terms of their roles, responsibility and continuing professional development. Patients are disadvantaged by the following:

- Chest physicians have a different (less advantageous) working environment and terms of service from other respiratory specialists
- Specialist training in Chest Clinics is a continuing problem. Despite the acquisition of intermediate higher qualifications (eg MRCP) the road to specialist status is long and uncertain. Given the present epidemiological indicators, it is clear that Hong Kong will need to continue to attract high quality recruits to tuberculosis services, for most of this century. There should be no disincentives for potential recruits and the administration should examine career tracks to ensure they offer terms and opportunities comparable to other specialities.
- Supervision of many clinics is the responsibility of only a few senior experienced chest physicians and some of the clinicians providing services in the chest service are honorary visiting physicians.
- The management (referral) of patients between the HA and DH Chest Clinic sectors has been and probably still is an arbitrary process. To ensure that all staff, particularly juniors carry out appropriate procedures there should be detailed, mutually agreed, protocols.
- The whole process of admission (HA) and discharge (to SOPD and/or DH Chest Clinics) should also be subject to rigorous protocols. This should include the quality and content of communication and information between all doctors (especially juniors) and patients in relation to drug therapy and continuity of care. There should be special fail-safe procedures to ensure that patients attend for DOT, that appropriate referrals are made and that notifications are completed without delay.

1.8.4 Estimation of bed needs for tuberculosis: Scadding and Fox (1975) states that it is difficult to forecast precisely the future requirements for beds. Both Scadding and Fox (1975) and Fox and Kilpatrick (1990) refer to difficulties in projecting trends and determining the likely optimal number of beds required.

These reports allude to the problems of both accurate and reliable data, and other need and demand factors. By 1990 Fox and Kilpatrick commented that the implementation of Scadding and Fox (1975) made the estimation of beds required for the treatment of tuberculosis irrelevant. The implication being that beds for all respiratory complaints can be considered collectively. The rationale for this is not clear. This report describes the current utilisation of beds for TB patients, including overall admissions and length of stay and those specifically for treatment of TB, management of TB complications and for management of co-morbidities.

The Fox and Kilpatrick (1990) report recommended that

> "(the) aim in future is to know the reason for bed occupancy in detail, the number of patient days per annum (that) beds are occupied by patients who have tuberculosis, the type of disease and the bacteriological status and a detailed classification of the varieties of episode requiring hospitalisation."

No mechanism is yet available for achieving this on a routine basis. The Hospital Authority IPAS/MRAS system would provide an index to these patients but a fully fledged clinical information system is needed to support analyses of reasons for admission and levels of medical dependency.

Four factors will influence the demand for beds. First, medical need among the patient population; second social need which would hinder management without access to beds, and third the volume of patients, including new and existing cases, which will be influenced by demographic trends as well as environmental risk. The fourth factor will be clinical and management decision making among the physicians caring for these patients.

The database generated from this survey will provide exactly the type of data which is suggested by the Fox and Kilpatrick report. In the future, the source of such intelligence should be a purpose-designed clinical information system. Several references are made to the need for such an approach in this report.

1.8.5 Research: In Scadding and Fox (1975) the authors referred to the collaborative research between Hong Kong and the British Medical Research Council. In 1975 it was estimated that $45000 was being allocated against actual costs of about $100K to $150K. How much is being spent on TB research in Hong Kong now? The need for both clinical and operational studies in TB services is much higher than both current activity and available resources. A substantive investment in health care research for tuberculosis is needed in Hong Kong.

In Fox and Kilpatrick (1990) there is a detailed catalogue of clinical research and enquiries. Among them is reference to the 1979 survey of TB investigation and treatment by private practitioners. It was suggested that a further survey was carried out in 1989 to assess changes in practice. The present report provides data on the medical work done by private

practitioners particularly in the early stages of presentation of TB. This can be assessed and compared with previous information on this topic.

All information systems require a continuous cycle of audit and evaluation if they are to be accurate, reliable and efficient. Notification is a good example of the need for a high quality information system.

The Fox and Kilpatrick report made special reference to notification of tuberculosis, but only in relation to private practitioners and clinicians who were not working in respiratory diseases. In this report we describe a detailed audit of notification procedures within TB services and derive a best estimate of both under- and over-reporting.

A new health services research programme for tuberculosis, including questions generated from this report, would be professionally stimulating and provide a valuable focus for service development, evaluation and training for junior staff working in the services.

1.8.6 Current and future incidence of TB in Hong Kong

On the basis of the secular trends in TB notifications in the 1950's and 1960's, in the 1970's it was predicted that TB care would begin to wind down, necessitating the redeployment of staff from tuberculosis services to involvement in other responsibilities.

Today it is clearly necessary to take several discrete factors into account in projecting TB incidence and the supply of services to manage it. These factors include:

- age specific rates for TB and their trends
- demographic change in the Hong Kong population structure and numbers
- reliability of the notification system

Hong Kong's future trends in TB notification will be driven particularly by the already high, stable or increasing trends in age specific rates in the elderly, the increasing numbers of older people in the community and the probable increase in the size of the "infective pool" from mainland immigration.

There is a more than two fold difference in the population rates for both deaths and notifications between males and females (Table 1.4). In 1975 there were 8192 cases notified giving rates of 257 for males and 112 for females per 100,000 population. The trend since then led to the lowest observed rate so far, in 1995, of 135/100,000 for men and, in 1996, 65/100,000 for women.

Since 1995, male rates have increased through 140 in 1996 to 144 in 1997. Female rates rose from 65 to 72 in 1997. Inspection of annual figures over the last 20 years shows that considerable fluctuation may be expected from year to year and perturbations in the data now appearing as an increase may not be sustained. It should also be noted from Section 4.0 in this report that all of these year on year variations in rates are well within our estimated uncertainty attached to the reported notification rate. However inspection of the age specific notification rates (Figure 1.2) suggests that elderly rates are increasing in both males and females and that an impact on the population rate is both plausible and likely. There is no obvious reason why under-reporting should be selectively associated with the over 65 age group.

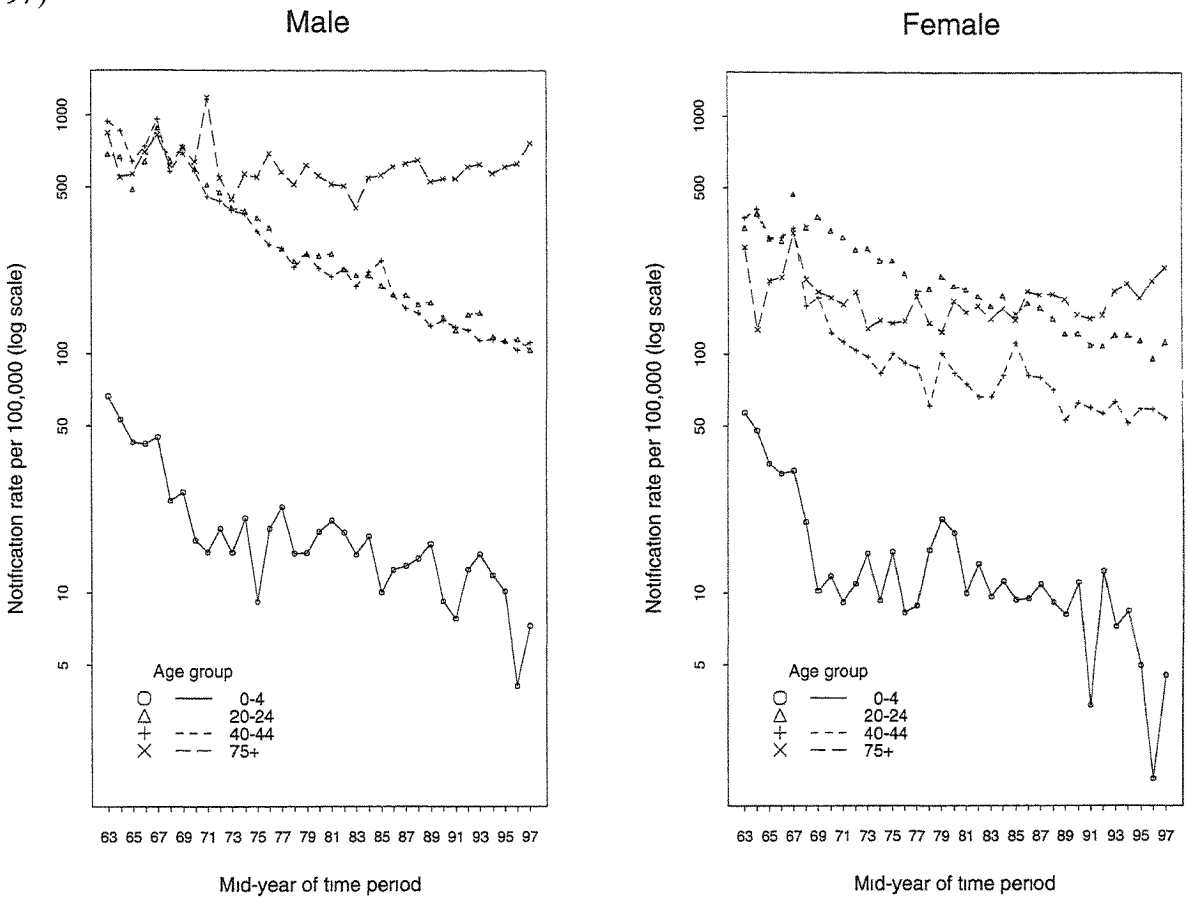
Table 1.4: *Annual number and rate (per 100,000) of TB deaths and notification by gender (1963-1997)*

	Death				Notification			
	Male		Female		Male		Female	
Year	N	Rate	N	Rate	N	Rate	N	Rate
1963	1226	70.86	536	31.70	9013	520.95	4018	237.64
1964	1060	59.91	381	21.95	8293	468.74	4264	245.71
1965	885	48.68	393	22.08	6571	361.44	3356	188.55
1966	1091	59.98	424	23.41	7990	439.30	3437	189.77
1967	1080	57.65	413	22.33	10783	575.58	4470	241.70
1968	1110	57.88	373	19.79	7207	375.80	2585	137.14
1969	1098	56.41	370	19.31	8117	416.98	2955	154.18
1970	1102	54.93	334	17.10	7462	371.93	2615	133.92
1971	949	46.13	301	15.14	6654	323.45	2441	122.78
1972	1032	49.26	280	13.86	6190	295.49	2230	110.35
1973	922	42.97	232	11.23	5749	267.92	2403	116.27
1974	769	34.98	205	9.66	5979	271.96	2341	110.37
1975	498	22.18	148	6.88	5775	257.19	2417	112.41
1976	444	19.53	124	5.71	5665	249.16	2263	104.27
1977	399	17.29	133	6.04	5117	221.76	2074	94.17
1978	323	13.73	97	4.32	4572	194.31	2051	91.40
1979	407	16.14	116	4.92	5503	218.18	2404	102.02
1980	438	16.68	113	4.68	5561	211.72	2497	103.52
1981	370	13.74	119	4.84	5397	200.39	2332	94.77
1982	348	12.76	106	4.23	5125	187.96	2402	95.84
1983	350	12.67	96	3.76	5005	181.15	2296	90.03
1984	325	11.64	95	3.65	5383	192.82	2460	94.39
1985	321	11.40	88	3.33	5196	184.54	2349	88.96
1986	314	11.04	93	3.47	5006	175.96	2426	90.53
1987	319	11.11	86	3.17	4855	169.11	2414	89.09
1988	290	10.03	98	3.58	4772	165.01	2249	82.21
1989	301	10.32	102	3.68	4696	161.04	2008	72.49
1990	295	10.10	87	3.13	4522	154.75	1988	71.45
1991	322	10.96	87	3.09	4352	148.12	1931	68.65
1992	314	10.65	96	3.36	4496	152.56	2038	71.42
1993	350	11.73	96	3.29	4402	147.55	2135	73.15
1994	309	10.17	100	3.34	4297	141.37	2022	67.49
1995	319	10.34	99	3.22	4174	135.33	2038	66.35
1996	213	6.74	79	2.51	4441	140.59	2060	65.35
1997	188	5.75	64	1.98	4731	144.62	2341	72.46

Sources: Annual Reports from Chest Service of the Department of Health

Monitoring of the rate of change in notification rates will provide an important indicator of future demand for care but another over-riding influence is the dramatic projection of population increase by 2010 and beyond.

Figure 1.2: *Hong Kong TB notification rates by age group and by gender per 100,000 (1993-97)*



The average annual rate of decline in notifications has fallen from around 17/100,000 in the 1960's to less that 1/100,000 in the 1990's. If we double this estimate then, by 2010, the whole population rate would be 77/100,000. The population is estimated to increase to 8 million by that point so, even if we experience a marked decline in TB incidence, the expected numbers would still be in excess of 6,100 compared with around 6,400 in 1996.

The present downward trend in incidence has slowed and suggests that, at best, rates may become stable or only decline very slowly. If the true rate declines to only 90/100,000 by 2010 then the expected numbers will be 7,200 for a population of 8 million and 9,000 for a population of 10 million. These figures should be adjusted upwards to take account of probable current and past under-reporting.

Inspection of trends in age-specific notification rates (Figure 1.2) raises additional points for consideration, the development of hypotheses and research questions about susceptibility to, and transmission of, tuberculosis in different age and gender subgroups.

Whereas the male rates for young and middle life adults track closely together those for females show marked dissociation, with much higher rates in young women (20-24).

The current trends are difficult to interpret, given that there is considerable short-term fluctuation in previous years. Several approaches to interpreting and predicting trends could now be used on a continuing basis to obtain information for planning. One such approach is illustrated here.

Data sources: The number of TB deaths and notifications by age group and sex were extracted from the annual reports from the Chest Service of the Department of Health, (1967-97). [TB data for period 1963-66 can also be included from the early years of these annual reports in future analyses]

The Hong Kong mid-year populations for 1963 to 1997, by age group and sex, were supplied by the Census and Statistics Department. The mid-year population projections for 1988 to 2012, by age group and sex were extracted from Hong Kong Population Projections 1997-2016, published by the Census and Statistics Department.

Methods: For males and females separately, the number of TB deaths and person-years at risk were stratified by 5-year age groups (0-4; 5-9; ...; 70-74; 75+) and 5-year calendar periods (1963-67; 1968-72; ...; 88-92; 93-97). In addition, birth cohorts were defined by these age groups and calendar periods. Person-years at risk were calculated using mid-year population estimates. The TB notifications were obtained from the Chest Service annual reports.

For TB projections, an age, period and cohort (APC) model was employed in which the mortality (or notifications) was summarised using the above-mentioned three sets of parameter values. The observed mortality rates were fitted using a Poisson regression, estimated by the maximum likelihood method.

The specifications of the APC model were defined as:

Log (no. deaths) = offset (log (person years)) + [Sex, Age, Period and/or Cohort effects]

where [Sex, Age, Period and/or Cohort effects] are different combinations of these parameters including their main effects and the interaction terms among them.

In order to avoid the, so-called non-identifiability problem, the age, period and cohort parameters were never included together into the same model.

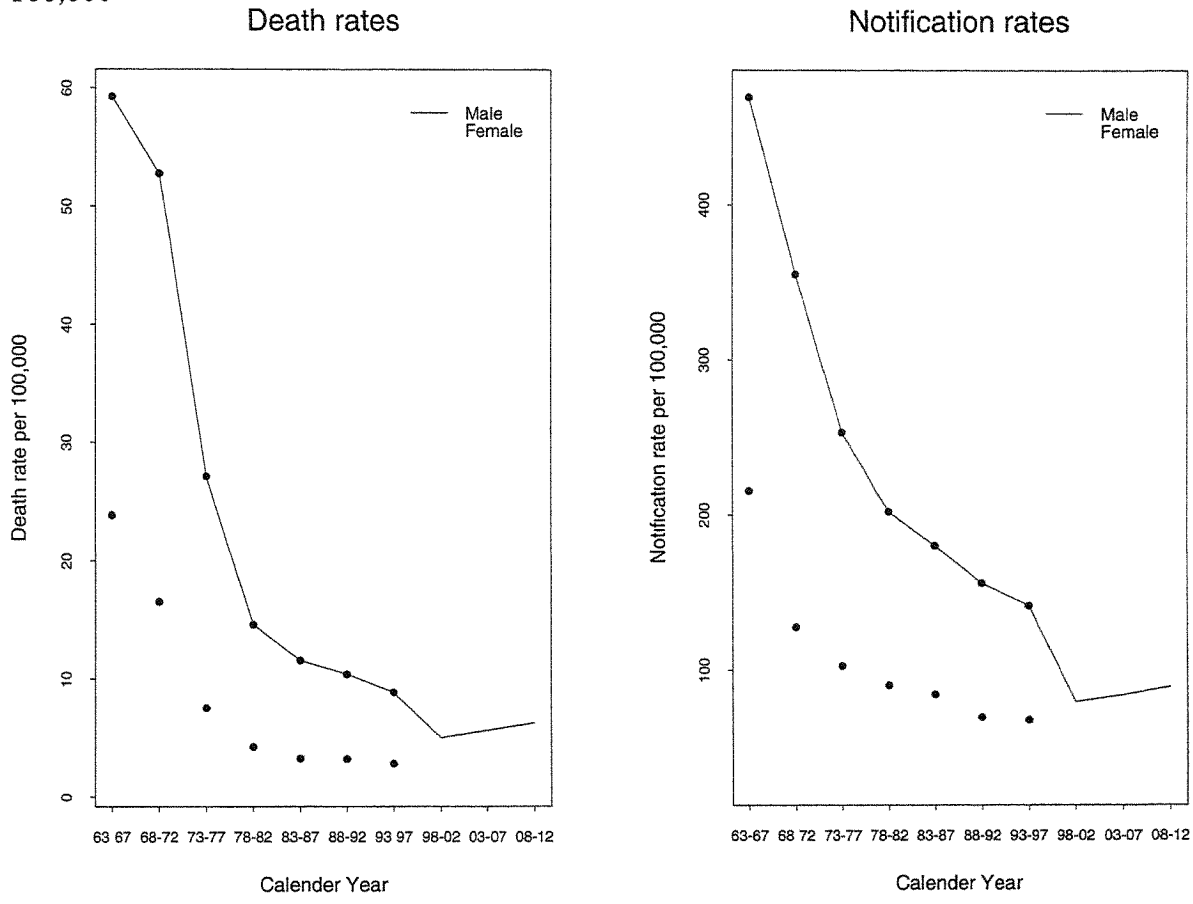
The log-likelihood ratio statistics (deviance) were used to assess the goodness-of-fit of the models. The final selected model had the lowest residual deviance.

The model employed does not include any factor for variations in under-notification. The predictions of TB deaths and notifications in 1998-2012 are based on the final selected model obtained from the above. The age and period patterns of TB risk were assumed to be constant into this projection period. The mid-year population projections for 1998-2012 were applied to the final model to obtain the number of TB deaths and notifications.

Table 1.5: *Five year estimates for deaths and notifications: observed (1963-1997) and predicted (1998-2012) TB numbers by gender in Hong Kong*

	Deaths		Notifications		
	Male	Female	Male	Female	M/F Ratio
63-67	5341.00	2147.00	42299.00	19419.00	2.17
68-72	5289.00	1658.00	35621.00	12821.00	2.77
73-77	3029.00	842.00	28283.00	11496.00	2.46
78-82	1885.00	552.00	26151.00	11682.00	2.23
83-87	1629.00	460.00	25408.00	11927.00	2.13
88-92	1520.00	471.00	22820.00	10210.00	2.23
93-97	1376.00	442.00	22020.00	10582.00	2.08
98-2002	1714.39	517.15	27378.43	10541.29	2.59
2003-2007	2054.70	610.25	30739.11	11546.43	2.66
2008-2012	2415.85	689.72	34552.51	12484.93	2.76

Figure 1.3: *Observed (1963-1997) and predicted (1998-2012) TB rates by calender year per 100,000*



Findings: The models show a sharp upturn in the predicted numbers of deaths and notifications (Figure 1.3). The strongest driver of this trend is the ageing population and the high incidence rates in the elderly. On this basis the recently observed increase in notifications appears to be confirmed. The predicted trends in notifications appear to be entirely plausible, based on the increased rate recorded in 1998. Deaths on the other hand are higher by about 40% compared with a simple arithmetic estimate based on the 1998 figure. This is due in part to the sharp fall in deaths, from an average of 414 in 1995/96 to 272 in

1997/98. This may be a random fluctuation (numbers vary considerably year on year) or it may reflect improvements in detection, treatment and general management.

The model predicts a total of 37919 notifications in 1998-2002 with a male/female ratio of about 2.6. The five year totals are predicted to increase to 42285 and 47036 in 2003-2007 and 2008-2012 respectively. Further sensitivity analyses should be carried out to examine the possible patterns of future trends.

1.8.7 Conclusions

In the 21st century tuberculosis will remain a major, and indeed increasing, challenge to the Hong Kong health care system.

In view of the assessments made by previous reviews and the reorganisation of the public sector services which have taken place since, there is a urgent need for a full review of the structure, management, operations and outcomes of services for tuberculosis. The present surveys and audit will provide much of the information which would be needed for such a review. However it should be emphasised that this needs to be a continuous process and not simply a series of *ad hoc* periodic reviews.

In many neighbouring, developing Asia Pacific countries the problems of TB have been described as being beyond control, despite early optimism derived from the early successes in developed countries when BCG and chemotherapy were introduced. There is however no room for complacency in any country or region and Hong Kong will have to work hard to achieve, by 2020, comparable improvements to those which were realised in the past twenty-five years.

Both clinicians and public health professionals have an important role to play in the future management of TB services. First, there is a responsibility to identify trends reliably and measure the effects of both hazards and interventions. Second, policy makers must be supported with high quality information on risks and benefits which can be gained from public health and clinical measures to control TB. Effective communication of information is needed together with advocacy for prevention and control. The avoidable costs of failures in clinical management and TB control overall should be given greater attention. Clinical and public health audit procedures should be accepted as indivisible components of routine care. Much of this can be built in to services as self audit, but we would also argue for the benefits of independent (but fully collaborative) evaluations such as the one attempted in this survey.

Services for tuberculosis in Hong Kong should be seen not simply as part of clinical services but as a key public health function. In the past, standards of care have directly benefitted form research conducted in routine service settings, such as the randomised trials of short course regimens. The potential for such benefits to be realised still exists and is, in fact, as great as it ever was. There are new opportunities and an urgent need for audit, evaluation and research on clinical management to become a truly integral part of the services for tuberculosis.

Public services for the population control of tuberculosis and clinical management of patients should be unified across all sectors of Hong Kong's health care, and within the TB services there should be a review of staff recruitment and terms of service, training and promotion opportunities. There should also be a detailed review of the areas where reorganisation and

increased resources would lead to improved continuity and quality of care and contribute to population control of the disease.

Key messages and action points

- Hong Kong has one of the highest tuberculosis notification rates in the developed post-industrialised world.

- Tuberculosis rates and numbers of cases will continue to rise in Hong Kong because of the ageing population and increasing size of the population from immigration. Immigration will contribute to maintaining the size of the infective pool.

  The incidence of tuberculosis in the elderly as indicated by the notification rate, has remained stable or shows an increasing trend during the last decade. This is the main factor contributing to the slower rate of decline in overall notification rates in the last decade, and most recently to the apparent increase.

- The SAR is surrounded by other countries and regions in which tuberculosis is predictably high but reported rates are often low.

  Many neigbouring regions have high and increasing rates of HIV infection. High levels of cross border movement and regional travel, low perceptions of the risk of acquiring HIV infection through unsafe sex and increasing HIV prevalence generally in southern China must be regarded as a real and growing threat to tuberculosis control.

- The World Health Organisation recognizes tobacco smoking as a major risk factor associated with tuberculosis morbidity and mortality. Effective tobacco control and the prevention of smoking in children in Hong Kong would make a very important contribution to the control of tuberculosis in Hong Kong.

- Surveillance of tuberculosis should be accorded the highest possible priority in any public health information system, in terms of expertise and other resources, routine audit and quality assurance.

- Previous reviews of tuberculosis services in Hong Kong have not been based on a primary audit. As such they could not develop insights to the workings of the service at patient care level. However these reviews in 1962, 1975 and 1990 did raise important issues and make several specific recommendations. Many of these have not been acted on at a strategic level.

- Previous expectations that tuberculosis services would gradually wind down, because of declining incidence, and be fully integrated in a unified respiratory medicine service, have not come to pass. Now there is a clear need for a strengthened TB service with increased capacity well into the foreseeable future. Full integration with other respiratory medicine units and services may not be the best option but there is no clear policy for the management of TB patients across different units, levels of care and sectors of public health care services. Some trends (eg management of increasing numbers in non-chest hospital SOPD's) have been partially reversed but there is considerable fragmentation of services. The problems arising from the division of tuberculosis care between the

Department of Health and the Hospital Authority should be formally addressed and resolved.

- In Hong Kong many innovations in care, such as short course directly observed therapy, have undoubtedly had a major impact on clinical management and population control of tuberculosis. However there are many other essential elements in a successful tuberculosis control programme. A systematic review of all aspects of Hong Kong's tuberculosis programme is now needed to identify areas where changes are needed to strengthen and integrate all components of the service. The audit reported here provides the basis for such a review to begin.

2.0

SERVICES FOR THE MANAGEMENT OF TUBERCULOSIS IN HONG KONG

2.0 SERVICES FOR THE MANAGEMENT OF TUBERCULOSIS IN HONG KONG

2.1 INTRODUCTION

This section aims to provide a brief summary of services for tuberculosis in Hong Kong. The health services in Hong Kong are distributed in both public and private sectors with specialist care being largely public and primary care largely private.

The principal sources of care in the public sector for patients with potential or confirmed tuberculosis include:

Chest clinics	Specialist OP departments
General OP clinics	Chest hospitals
Accident and emergency departments	General hospitals

Many patients will also receive initial investigations or other items of care from:

Private practitioners	Herbalists
Private hospitals	Other traditional practitioners

The provision of services can also be described in terms of levels of care. The following are available:

Ambulatory	Primary
Inpatient	Secondary
	Tertiary

Diagnoses and treatments may be extremely heterogeneous because of the large number of gateways to care which are available to new patients who develop respiratory symptoms — the majority who are diagnosed eventually to have tuberculosis.

Anecdotally, delays in diagnosis and treatment typically occur because a patient attends a traditional practitioner or private general practitioner. If the diagnosis of tuberculosis is not considered at the outset and a chest radiograph obtained then, a variable delay of several weeks or months will ensue.

If, on the other hand, the patient attends a chest clinic as a walk -in self-referral then such delays are likely to be avoided.

2.2 PUBLIC SECTOR

2.2.1 Ambulatory care

Chest clinics: There are 18 chest clinics throughout Hong Kong managed by the Department of Health (Ref DoH report 1997/98). Total attendance at chest clinics was 914,951 in 1997. Active TB cases make up 10.2%, and inactive TB 11.5%, of the cases seen.

Chest clinics are usually open all day during the week and on Saturday mornings and offer a walk-in service. Any person may self-refer to a chest clinic if they suspect they may have TB or another respiratory problem. These clinics are free to users.

General outpatient clinics: In 1997, there were 63 general outpatient clinics (GOPC) providing primary medical care throughout Hong Kong. In some clinics, evening, Sunday and public holiday sessions are offered. In remote areas and the islands, there are mobile dispensaries, floating clinics and helicopters.

Total attendance at GOPCs in 1997 was 5.3 million of which 32.3% were for acute respiratory infections (DoH 1999). Services are available to all-comers on payment of a small fee; there may, however, be a wait before being seen.

Hospital Authority accident and emergency services: Accident and emergency (A&E) services are available in 15 Hospital Authority (HA) institutions throughout Hong Kong principally at major general hospitals. In 1996/7, there were 2,080,006 attendances at A&E (HA 1999). These are open 24 hours a day and provide open access and self-referral. The A&E service may be the first place that a TB patient is seen.

Hospital Authority specialist outpatient departments: There are 46 specialist outpatient departments (SOPDs) throughout Hong Kong. These clinics provide specialist consultation and follow-up services and are available on referral from a general practitioner. In 1996/7, there were 6,121,160 attendances at SOPDs and 754,572 at the attached general outpatient clinics (HA 1998). Consultation and medicines are provided for a small fee.

Advantages of public sector ambulatory care:

- Patients can self-refer to chest clinics, GOPCs and A&E providing good access.
- Geographical accessibility to chest clinics, GOPC and A&E is good and opening hours, particularly of chest clinics and A&E, are extensive.
- Geographic access to SOPD is poorer than for the other services. The need to travel a long distance may act as a selection factor for attendance at SOPD.
- Services are either free or only a small fee is charged.
- Facilities and expertise are particularly good in chest clinics and SOPDs. Chest clinics provide a wide range of complementary services including radiology, routine pathology, social work, health education and contact tracing.
- Chest clinics offer supervised directly-observed therapy (DOT), semi-supervised and unsupervised options for treatment.
- Chest clinics provide a system for follow-up of defaulters.
- SOPDs have access to a wide range of inpatient and outpatient diagnostic services.
- Booking system in SOPDs should result in shorter waiting times than, for example, in chest clinics.
- Patients can move, for example, between chest clinics without losing continuity of care.

Disadvantages of public sector ambulatory care:

- If clinics are busy, there may be long waiting times where there is no booking system.
- There may be a stigma attached to attendance at a chest clinic.
- Staff in chest clinics may not be expert in managing co-morbidities such as diabetes.
- Staff in GOPCs and A&E are generalists and patients suspected to have TB are referred on, usually to chest clinics, or are admitted (from A&E).
- Waiting times for results of investigations is longer in chest clinics than in other services.
- A&E services are only really appropriate for the new patients with urgent complications, for example, haemoptysis, shortness of breath.
- DOT therapy is not available at SOPDs. Referral on to chest clinics for DOT may result in dual follow-up and other failures of co-ordination.
- Referral is required for SOPD and waiting lists may result in delay in attendance.

2.2.2 Inpatient care

Chest hospital: There are 5 chest hospitals and other several general hospitals (including 2 teaching hospitals) with respiratory medicine units. These are concentrated in Kowloon and Hong Kong Island. In 1995, there were around 831 beds designated for TB and chest diseases. Services are provided at a nominal fee to users.

General hospitals: HA hospitals are distributed throughout Hong Kong with concentrations on Hong Kong Island and Kowloon. Thirteen are classed as *major* hospitals and these had 660,901 inpatient discharges and deaths in 1997/98 (HA Statistical Report 1997/98). These are organised, mainly geographically, into 8 hospital clusters. In 1995, there were around 6,095 internal medicine beds available throughout Hong Kong to which TB patients could be admitted. Again there is only a nominal charge made to patients.

Advantages of public sector inpatient care:

- There is a high level of expertise and range of services available in chest hospitals but a wider range of services in general hospitals who may be better placed to handle co-morbidities.
- There is a wide distribution of general hospital beds throughout Hong Kong.
- Communication links are good between chest hospitals and chest clinics. Records are transferred with the patient when the patient is referred to a chest hospital. This referral chain is well established and used.

Disadvantages of public sector inpatient care:

- Communication links between general hospitals and chest clinics are not so well established as for chest hospitals.
- Expertise in chest medicine/management of TB will predictably vary in general hospitals.
- Only 5 chest hospitals exist so geographic access is limited; there are none in the New Territories so patients may be a long way from home.
- Care in chest hospitals is only appropriate for a proportion of TB patients.

2.3 PRIVATE SECTOR

2.3.1 Ambulatory care

Private practitioners: There are several thousand private practitioners (PP) in Hong Kong, many of whom practice first contact medicine while a proportion offer specialist services. Around 85% of first contact consultations are with a PP. From previous studies, 53% of chest clinic attendees first attended a PP and over 80% received treatment for TB. In our study, as reported in section 6.3.4.2, 97 episodes of care (4.8%) were with a PP. Ten patients (2.2%) started treatment with a PP although only 1 (0.2%) was notified by the PP (section 6.3.4.3); 5 were later notified by a chest clinic and 1 by a chest hospital. PPs charge patients direct for each consultation and associated medicines and tests (typically several hundred dollars).

Advantages of private sector ambulatory care:

- Owing to the number of PPs throughout Hong Kong, geographic access is good.
- There is a generally high utilisation rate for PP services so there are no apparent obstacles or stigma in using the service.
- Many PPs have booking systems which reduce waiting times.
- If PPs are skilled in early recognition of possible TB and take appropriate action, their intervention can make a major contribution to TB control.

Disadvantages of private sector ambulatory care:

- For a new episode of TB, there is frequently a delay in diagnosis and treatment.
- Lack of PP expertise and high cost would be an obstacle to full treatment from a PP.
- DOT is unlikely to be available at a PP's office.
- PPs are not equipped to deal with complications of management, defaulters, contact tracing or health education.
- Charging for care in private practice is the antithesis of the approach to TB management adopted in the public sector.

2.3.2 Inpatient care

Private hospitals: There are several private hospitals in Hong Kong who would admit TB patients. Their charge would be much higher than in the public sector.

Advantages of private sector inpatient care:

- Patient comfort and convenience.

Disadvantages of private sector inpatient care:

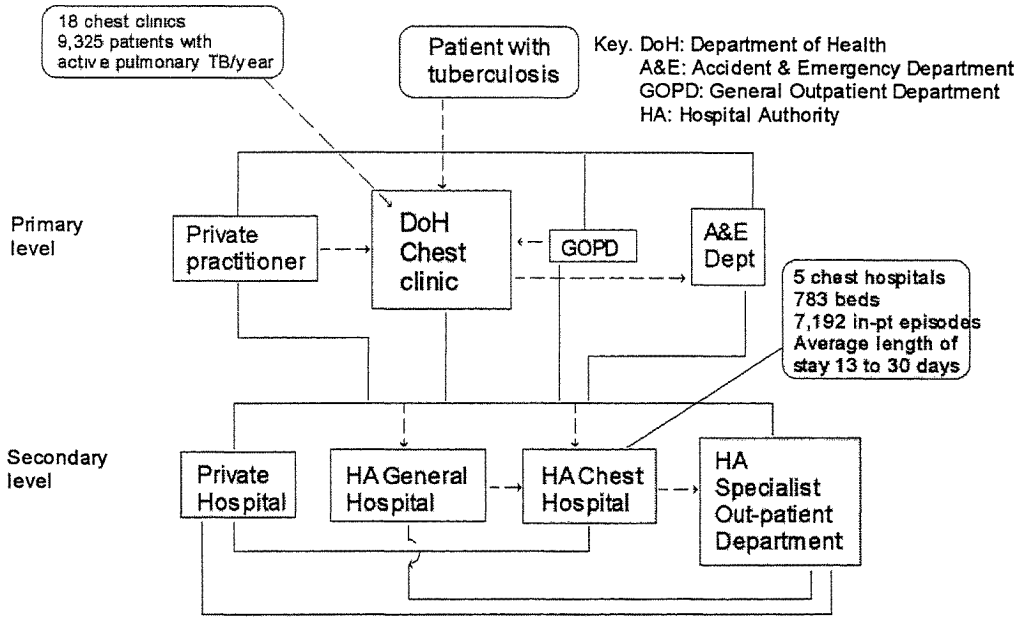
- Lack of expertise or experience because of a low volume of TB in the patient population
- Limited range of services, for example, no contact tracing
- High costs resulting from fees for all items of service

2.4 Overall assessment of services for tuberculosis in Hong Kong

Hong Kong has a comprehensive system for TB care available, if appropriately accessed, and a wide choice of services is available in theory. Figure 2.1 gives an overview of the services available and the potential referral pathways. However, problems include:

- Complex array of service locations and levels
- Opportunities for "doctor shopping" (moving from one practitioner to another within the same episode of care)
- Allocation of patients to different sectors/institutions may be determined by a doctor's preference rather than medical need
- Lack of coordination in such a complex system may hinder communication between sectors eg lost medical records; late or absent discharge summaries or referral letters; repetition of investigations and duplication of medical work; possible duplication of care (eg follow-up); failure of anyone to assume full responsibility for the patient and outcome of care; unnecessary use of resources by both health service providers and patients.

Figure 2.1: *Services available to patients with tuberculosis in Hong Kong, and potential referral patterns*



3.0

AIMS AND OBJECTIVES OF THE SURVEY, STRUCTURE OF THE CLINICAL AUDIT STUDY AND STRUCTURE OF THE REPORT

3.0 AIMS AND OBJECTIVES OF THE SURVEY

3.1 AIM

The aim was to document and analyse, from all of the sources of information available, the cumulative health care experience of a defined group of patients. The analysis extends from the earliest record of their first presentation to the health care system through to completion of treatment and the clinical outcome, or at least the end of the available documentation. The information will be made available for service development at clinical, administrative and strategic levels.

3.2 OBJECTIVES

1. To examine and assess the quality and utility of information available for an audit of tuberculosis services, including the notification system.
2. To examine the interface between and within primary and secondary care levels and sites.
3. To determine the pattern and type of care provided to a representative cohort of patients.
4. To analyse the outcomes of care provided to patients by their demographic and clinical characteristics.
5. To examine patterns of resource use in the management of tuberculosis.
6. To provide basic information which can be used to facilitate the development of a clinical information system and universal medical record for tuberculosis patients with the aim of improving communication and co-ordination between care sites.
7. To provide relevant information for the planning of service development at a strategic level.

3.3 STRUCTURE OF THE STUDY

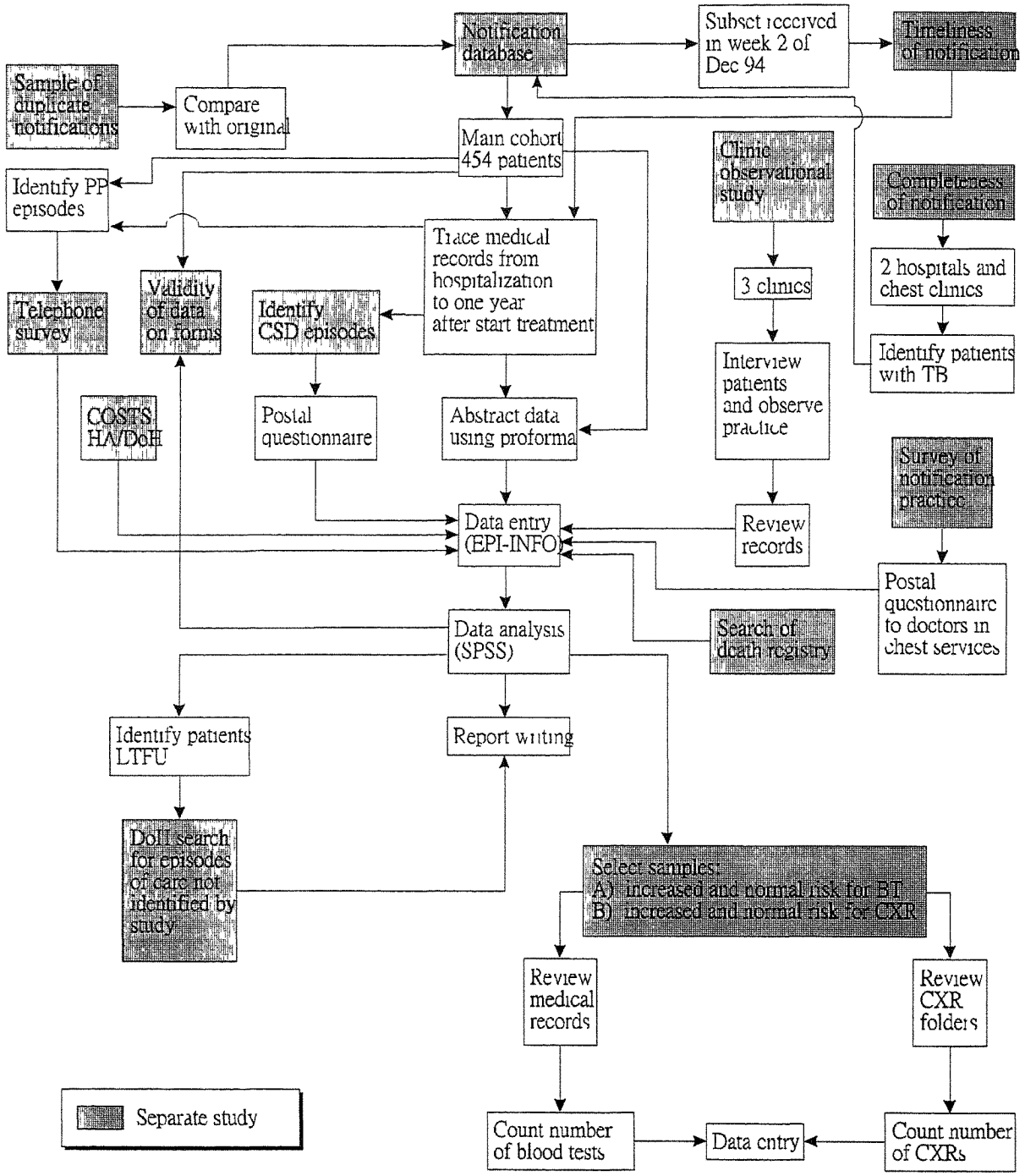
The approach taken was to carry out a detailed evaluation of the care given to a representative cohort of notified patients and to supplement this with *ad-hoc* studies, as required. The data was then examined to determine as far as possible the effectiveness of the current system, its efficiency in the provision of effective care and how well information needs were being met. The main cohort study and separate studies are shown in the flowchart (Figure 3.1).

The principal working procedures are detailed below:

Main cohort: steps in establishing the study data base

1. Sample selection of 454 patients
2. Obtaining data from notification database
3. Tracing medical records
   a) start with episode where patient was notified
   b) abstract data
   c) identify preceding/subsequent episodes
   d) collate data – list of medical records required from each site
   e) write to site requesting records
   f) visit site to review records
   g) repeat steps b) → f) until no further episodes identified (required contacting some sites many times)

Figure 3.1: Overall approach to methods



4 Abstracting data
- two different forms, one patient-specific, one episode specific, each to be completed/ updated in each cycle
- if more than 1 episode at same site, separate episode form for each
- very labour intensive (10-30 minutes for each episode)

5 Data entry
- relational database

6. Data analysis
   - transfer to SPSS – need to aggregate variables in EPISODE files and analysis using PERSON files

Blood test/chest X-ray/sputum study

1. Sample selection using data from cohort study to categorise patients into increased and normal risk groups
2. a) (i) identify relevant episodes
      (ii) review medical records
         - prospectively with cohort
         - retrospectively for relevant episodes where medical record already received for cohort study
      (iii) abstract data for blood tests/sputum smear and culture
   b) (i) identify relevant episodes
      (ii) write to site requesting X-ray folders
      (iii) visit site
      (iv) review folders and count films, record view and date

Clinic observational study

1. Select clinics using data on attendance figures/geographic locations
2. Obtain permission to visit clinics
3. Arrange 2/3 days for each clinic
4. 2-3 observers, at least one Cantonese speaker, visit clinic between 8.30 am and 5.30 pm
   - observe and record times
   - interview patients
   - review records
5. Set up databases
6. Data entry on EPI-INFO
7. Data analysis

Completeness of notification

<u>Hospital</u>

1. Obtain permission – 3 hospitals (1 pilot, 2 main study)
2. Review list of discharge codes
3. Request records
4. Visit site, abstract data, exclude patients
5. Enter data
6. Review list of microbiology/histology
7. Cross check for patients already identified
8. Request records (often inadequate information)
9. Visit site, abstract data, exclude patients
10. Enter data
11. Obtain notification database
12. Search for notification
13. Enter notified/not
14. Review duplicate notifications for patients not notified with past history of TB (manual)

Chest clinic

1. Obtain permission
1. Obtain list of all patients starting treatment at chest clinic
2. Select random sample and proportional sample
3. Abstract data from list
4. Obtain notification database
5. Search for notification
6. Enter notified/not
7. Review duplicate notifications for patients not notified with past history of TB (manual)

Survey of private practitioners (PP)

1. Identify PP episodes from cohort study
2. Letter to PPs informing them of study
3. Follow up with telephone questionnaire
4. Trace those difficult to contact

Survey of notification practice

1. Pilot study methods in one hospital
2. Send questionnaire to Chiefs of Service/members of Steering Group at chest hospitals/chest clinics/general hospitals
3. Ask to distribute to members of staff
4. Receive questionnaires in batches from each source (except clinics)
5. Follow up non-responding units
6. Data entry etc.

Validity of data items

1. Identify items for comparison
2. Using whole cohort of items, determine correspondence (this required re-classification of site of disease)
3. Estimate impact of incorrect age etc.

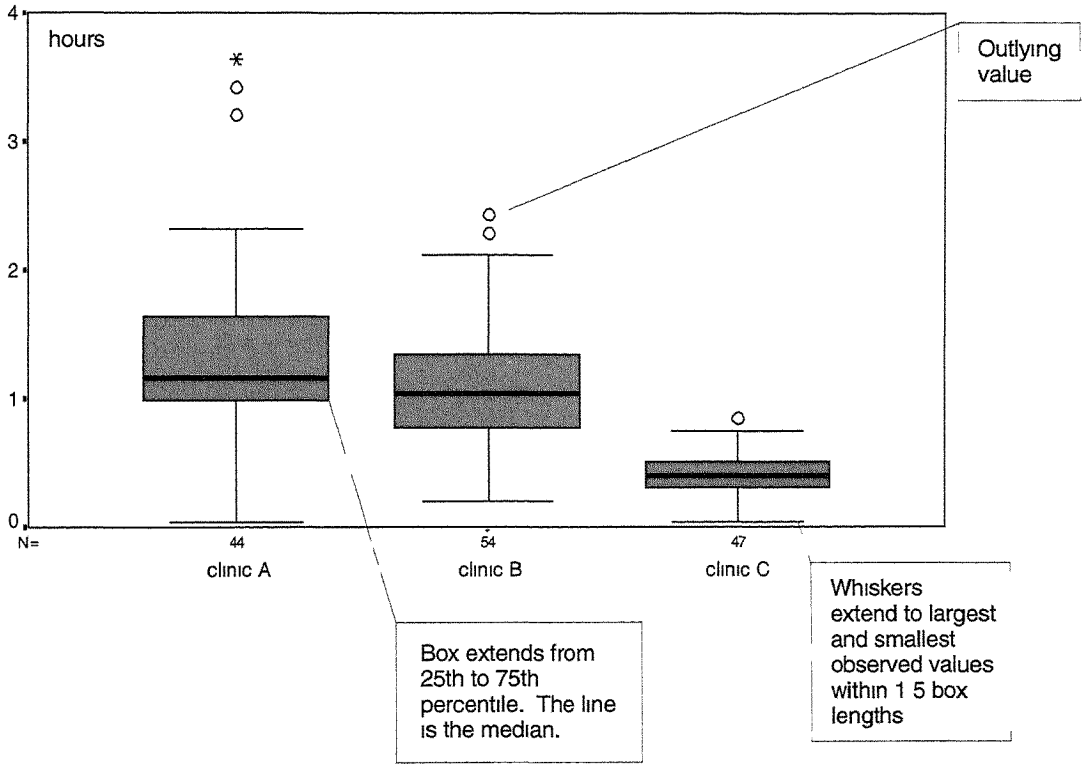
3.4 STRUCTURE OF THE REPORT

Section 4 reports on the audit of the notification system and variation in completeness of notifications between Department of Health Chest Clinics and HA Chest and General Hospitals. The procedure for setting up the audit of the notification system, the patterns of notifications and failure to notify for different reasons from different sources of care are described. This section highlights the strengths and weaknesses of current procedures and highlights the need and the opportunities to develop a new integrated clinical information system for notifications (objectives 1 and 6). A best estimate of the true number of notifications per year is derived, based on the probability of both under- and over-notification.

Section 5 describes the results of operational studies of Chest Clinics including registration, medical and nursing consultations. Clinic throughputs, waiting and consultation times and comparison of observations with service pledges are examined and described. The potential value of further operational studies and possible changes to some organizational aspects are discussed.

Interpretation of boxplots: Here, and in subsequent chapters, boxplots are used to summarise numerical data. They help the reader to visualize the distribution of a variable. The example below is from Section 5 and is an interval from registration to seeing a doctor for different chest clinics.

Boxplot of interval from registration at clinic to consultation with a doctor



The lower boundary of the box represents the 25th percentile. The upper boundary represents the 75th percentile. (The percentile values known as Tukey's hinges are used to construct the box.) The vertical length of the box represents the interquartile range. Fifty percent of all cases have values within the box. The line inside the box represents the median. Note that the only meaningful scale in the boxplot is the vertical scale. All values are plotted on this scale. The width of a box doesn't represent anything (MJ Marusis. SPSS 8.0 Guide to data analysis. Prentice Hall: New Jersey, 1998).

Section 6 reports on the sampling of notifications to identify a cohort (approximately 15% of all notifications in a year) and the analysis of patterns of diagnosis, treatment, referrals, utilisation of care at different levels, the responses of the health care system in terms of diagnosis and treatment (timeliness, completeness), follow-up and outcomes.

Section 7 describes a survey of private practitioners with whom patients, who were subsequently diagnosed and notified with tuberculosis, made their first contact. The survey complements and updates two previous surveys in 1977 and 1979. It provides information on several aspects of the patterns of medical care for these patients in the private sector before referral. The report discusses the implications for educational and administrative interventions at the interface between primary care and specialist services for tuberculosis.

Section 8 draws on the data from Section 6 to examine the relationship between various potential measures of medical need and patterns of care and resource use. The aim is to explore potential areas of over-provision or unmet need. Three different approaches are taken to scoring need and then examining how these relate to the observed use of medical resources.

Section 9 brings the focus back to the main purpose of this report which is to examine how clinical audit, embracing all aspects of the provision of care for a defined group of patients, can be used as a tool in quality assurance. Another section describes the need for high quality clinical records and their integration across all sectors of the service for tuberculosis. The urgent need for application of state-of-the-art information technology is discussion.

4.0

NOTIFICATION OF TUBERCULOSIS

4.0 NOTIFICATION OF TUBERCULOSIS IN HONG KONG

SUMMARY

Need for high quality notification systems

- Notification of TB is a statutory requirement and notification databases are important public health resources for monitoring and control of TB.

- Quality assurance and completeness of information is a world wide problem in tuberculosis services. Audit and evaluation of information and information systems should be a priority in the public health approach to tuberculosis control.

A multisector approach to audit

- An audit of notification in Hong Kong was based on a sample of 111 patients drawn from two hospitals (A: n=76) and B: n=35), 133 patients starting treatment in 11 chest clinics (Jan-Mar 1995). The representatives of these samples was compared with 989 patients *notified* by chest clinics (Jan-Mar 1995).

- Patients were included if they had

    * *A discharge diagnosis* (ICD-9) coded 010-018 between 1 Jan 1995 and 31 March 1995

    and/or

    * *Microbiology report* (1 Nov 1994 to 31 May 1995) with positive microscopy or culture

    and/or

    * *Histopathology report* (1 Nov 1994 to 30 April 1995) with positive findings of granuloma AFB, caseating necrosis or other indicators of tuberculosis.

- The hospital and clinic records were used to search notification databases (Nov 1994 to Jan 1996) for a match. For patients who could not be matched a search was made of the previous 5 years records to identify possible duplicate notifications.

- Of the 79 patients from hospital A, 72 (91%) were initially identified by discharge codes for the primary diagnosis, an additional 7 by microbiology and none exclusively by histology. In hospital B the corresponding figures were 78%, 0% and 22%, but the order in which the different identification methods were used varied between the two hospitals. (Hospital A: Discharge codes, microbiology, histology; Hospital B: Discharge codes, histology, microbiology)

- In 11 chest clinics, sampling was based on lists of all patients starting treatment 1 Jan 1995 to 31 March 1995. Matching was based on name, ID number, age and gender.

Operational problems in notification

- Substantial delays have been identified between start of treatment and completion of the notification form and between completion of the form and its receipt by the DoH Statistics Unit.

- The estimated proportions of patients who were not notified were 3.0% (95% CI 0.8-7.5) for chest clinic patients and 28.3% (95% CI 20.2-37.6) for hospital patients. In 1994, 4631 patients were notified from chest clinics; the estimated numbers of patients not notified ranges from 37 to 375. In 1994, 1597 patients were notified from HA hospitals leading to estimates of numbers not notified, from this source, of 404 to 962.

Estimated under- and over-reporting

- The overall estimated percentage (95% CI) of patients not notified is 5.7-20.6%. Applying this estimate, the number who should have been notified in 1994 is 6761-7711 compared with the actual number of notifications of 6319.

- Over-reporting (after deletion of known duplicates) is estimated at 2% to 5%.

- The best estimate of the true number of notifiable patients (BEN) with tuberculosis applying both estimates for under- and over-reporting is 6363 to 7493 compared with the actual 1994 figure of 6319.

- The limitations of the survey include lack of access to private sector records. The audit procedure is very resource intensive but would be facilitated by development of the information systems needed to support it.

- A survey of clinicians working in tuberculosis services suggests that many of them are not very familiar with notification procedures. The notification of patients should be presented as a systems approach with clear guidelines, protocols and criteria.

- There should be stronger emphasis on accurate and reliable notification as an obligatory clinical responsibility.

- The notification process, its standard forms and supporting documentation should be reviewed on the basis of these findings. Under- and over-reporting should be reduced from the present relatively high levels in some sectors of the service.

- A purpose designed clinical information system should be developed as a matter of high priority, and operated using modern information management methods.

- The problems associated with notification procedures which were identified in this part of the survey have implications for the sampling of the cohort described in Section 6.0. In particular patients who should have been notified from hospitals are likely to be under represented.

4.1 ESTIMATION OF THE COMPLETENESS AND TIMELINESS OF NOTIFICATION OF TUBERCULOSIS IN HONG KONG

4.1.1 Introduction

Notification of tuberculosis is a statutory requirement and is important for epidemiology, initiation of contact tracing and monitoring and planning of health services It is therefore important that they are valid and interpreted with care Reports from elsewhere indicate that notification, registration or reporting of cases of tuberculosis is incomplete (Sheldon, 1992 (UK), Driver, 1996 (USA), Beyers, 1994 (S Africa), Nationwide Survey, 1990 (China)), but an examination of this issue had not previously been performed in Hong Kong This study was set up to examine the completeness and the timeliness of notification in Hong Kong A separate estimate of over-notification was obtained from the cohort study (see Section 6 0) Since completeness of notification was expected to vary according to the source of care, separate enquiries were planned for patients who were diagnosed or who started treatment in Department of Health chest clinics and those who were in-patients at Hospital Authority hospitals Notification is a critically important public health instrument in the control of tuberculosis and incomplete notification is a world wide problem

4.1.2 Aims and objectives

Aims: To estimate the completeness and timeliness of notification of patients with tuberculosis in Hong Kong and identify factors which could be modified to improve notification procedures

Objectives:

1 To obtain a representative sample of in-patients in whom the treatment of tuberculosis was initiated or the diagnosis of tuberculosis was made during admission
2 To obtain a representative sample of chest clinic patients starting treatment for tuberculosis
3 To determine the proportion of treated patients who were notified
4 To calculate the interval between initiation of treatment and notification
5 To compare the source where the diagnosis was made or treatment started and the source of notification
6 To identify factors associated with failure to notify or delays in notification
7 To discuss the implications of under-notification and delays in notification, for the prevention and control of tuberculosis in Hong Kong
8 To generate information necessary to represent the variations in procedures and outcomes in algorithmic form as an aid to decision analysis and problem solving in the future.

It is important to recognize that there is currently no case-definition to guide notification in Hong Kong For the purpose of this study, the following definitions were used

hospital patients:
- patients in whom a definitive diagnosis* of tuberculosis is made, or
- patients who are started on anti-tuberculous therapy

* the definition of a diagnosis of tuberculosis for the purposes of this survey, is set out in section 4.1.3.1.

chest clinic patients:

- patients who are started on anti-tuberculous therapy

4.1.3 Study on notification of hospital patients

4.1.3.1 Methods

Setting: A pilot study was carried out in one hospital. The main study was performed at two other hospitals called, in this report, Hospital A (chest hospital) and Hospital B (non-chest hospital).

Sample size calculation: A sample size of 78 was calculated to be required in order to provide an estimate of under-notification with 95% confidence, where the expected proportion was 30% and the degree of precision required was 10%.

Sampling procedure: Initially, patients were identified using the following methods:

1. *Discharge diagnosis:* Patients with a discharge diagnosis coded with ICD-9 codes 010-018 who were discharged between 1 January 1995 and 31 March 1995 inclusive.
2. *Microbiology reports:* Samples received from 1 November 1994 to 31 May 1995 inclusive with reports stating either positive microscopy for acid alcohol fast bacilli or positive cultures for mycobacteria of the tuberculosis complex.
3. *Histopathology reports:* Samples received from 1 November 1994 to 30 April 1995 inclusive with reports stating one or more of the following:
   granuloma,
   acid alcohol fast bacilli on microscopy,
   caseating necrosis,
   other features suggesting diagnosis of tuberculosis.

Tracing records: Once the patients had been identified using one or more of the above methods, their medical records were traced and reviewed. Where possible, medical records were requested using the patient's ID number and hospital number. Microbiology and histopathology reports did not always include this data, and records had to be traced using name alone or name and ID number.

Inclusion criteria: After review of the record, the patient was included in the study if he or she met the following criteria:

- discharged from 1 January to 31 March 1995 inclusive, and
- a definitive diagnosis of tuberculosis was made, or treatment started on an empirical basis during that admission.

A definitive diagnosis was made if the patient had a positive microbiological or histological diagnosis and/or was diagnosed to have TB on empirical grounds using clinical or radiographic criteria*. If a patient had more than one admission that fulfilled these criteria, only the first admission was included.

* For reference the US CDC definition of tuberculosis disease is shown in Appendix 1.

Abstraction of data: If a patient was included in the study, the following data items were abstracted using a standard proforma:

- patient name, ID number, medical record number, hospital number
- age, gender
- site of disease
- sputum smear and culture status
- definitive diagnosis (positive microscopy, culture or histology result before, during or after admission)
- date of admission
- date of discharge
- date of diagnosis
- date of initiation of treatment
- date of notification if known
- speciality at time of starting treatment
- past history of tuberculosis and year of most recent previous treatment
- other active medical or surgical conditions

To determine the proportion of patients notified:

1. ***Notification databases:*** Notification databases for the months November 1994 to January 1996 were searched. These databases were stored using the database package EPI-6. The initial search was performed using the patient's name, and then the patient's ID number if the name search was negative.

2. ***Successful matches:*** If a match was found, it was confirmed by checking that the age and gender for the patient on the notification database matched that for the study patient. The date and source of notification were recorded from the notification database. If the date was missing from the notification database, it was assumed to be the same as the subsequent dated notification in the database (notifications are entered by week of receipt).

3. ***Failure to match:*** If no match could be found and the patient had either a definite past history of tuberculosis or the history in the last five years was unknown, attempts were made to determine whether the patient had been notified in the five years prior to the study period. If the patient had been notified in the previous five years, a repeat notification in the study period would have been defined as a duplicate notification* and excluded from the notification database. These patients should not be considered as new notifications and included in incidence data but their identification details are required for contact tracing. (A new notification information system should automatically screen out these records.)
   - a list was compiled of those who had a history of tuberculosis, in the previous five years, noted in the medical record. Those with no mention of previous tuberculosis (past history unknown) were also included in the list.
   - the notification database for the years from 1989 to July 1996 was searched using name and ID match
   - for those who had been notified in the previous five years, a manual search of the duplicate notification forms received from November 1994 to June 1995 was carried out to determine whether the patients had been notified again for the episode relating to the study period.

* Duplicate notification: a duplicate notification is one made within 5 years of the original. These are excluded from the main notification database and excluded from the chest clinic annual report analyses.

To determine the factors affecting notification: After review of the literature (Sheldon, 1992) and assessment of data available in medical records, the following variables were considered to be potential factors in determining whether or not a patient was notified:

patient related factors
- gender
- age (0-60 and over 60 years)
- site of disease (pulmonary and extra-pulmonary)
- sputum smear and culture status (positive versus negative or unknown)
- definitive diagnosis (yes versus no or unknown)
- past tuberculosis (yes versus no or unknown)
- co-morbidity (present or absent)

health care related factors
- source of care
- length of stay (0-14 and over 14 days)
- speciality of care (chest medicine versus other)

The relationship between each of these independent variables and whether or not a patient was notified was explored initially using chi-square tests, and then the overall relationship was analysed using logistic regression analysis. An audit of the notification system depends on the ability to achieve accurate and reliable record linkage. Missing information was an obstacle.

4.1.3.2 Results

Method for identification of patients

Pilot study: Eighteen patients were initially identified and included in the study. After the notification database match, three were not notified: one had no previous history of tuberculosis, one had a possible past history and one had a definite past history. Search of the notification databases from 1989 to 1996 revealed that neither of the latter two patients had previously been notified. All 18 patients were therefore confirmed for inclusion; of these 15 (83.3%) were notified (95% CI, 58.6 to 96.4).

Main study: Using the three methods of *discharge codes*, *microbiology* and *histology reports*, 79 patients were identified at Hospital A and 36 at Hospital B. The sequence of use of the three methods differed: at both hospitals discharge codes were used first; at Hospital A microbiology reports and at Hospital B histology reports were then used. At both hospitals most patients were identified using discharge codes. The number of patients identified using each method and reasons for exclusion of patients from the study are outlined in Table 4.1.

Yield: The yield for un-notified patients from each method has been defined as (Driver, 1996):

(number of un-notified cases identified) /
(number of potential cases - number of notified cases identified)

The yield was calculated for each method. Results are shown in Table 4.2.

Table 4.1: Patients identified according to method used and reason for exclusion

Hospital A

Method of identification (sequence of use)	discharge codes (primary diagnosis) (1)		microbiology reports (2)		histology reports (3)	
Number of episodes / samples identified	164		435		62	
Number (%) of patients identified	138	(100.0)	202	(100.0)	58	(100.0)
Number (%) of patients already identified by previous method(s)	0		93	(46.0)	12	(20.7)
Number (%) of patients excluded	66	(47.8)	102	(50.5)	46	(79.3)
Reason for exclusion:						
• started treatment before episode	52	(37.7)	16	(7.9)	6	(10.3)
• episode not due to tuberculosis	1	(0.7)	5	(2.5)	2	(3.4)
• episode possibly due to tuberculosis, but no treatment given or diagnosis confirmed	9	(6.5)	8	(4.0)	4	(6.9)
• inactive tuberculosis	1	(0.7)	0		0	
• medical record not found	3	(2.2)	13	(6.4)	4	(6.9)
• date of discharge outside study period	0		38	(18.8)	26	(44.8)
• diagnosis after discharge of patient	0		14	(6.9)	1	(1.7)
• out-patient record only	0		8	(4.0)	3	(5.2)
Number (%) of patients included	72	(52.2)	7	(3.5)	0	(0)

Hospital B

Method of identification (sequence of use)	discharge codes (any diagnosis) (1)		microbiology reports (3)		histology reports (2)	
Number of episodes / samples identified	168		75		291	
Number (%) of patients identified	94	(100.0)	48	(100.0)	183	(100.0)
Number (%) of patients already identified by previous method(s)	0		5	(10.4)	12	(6.6)
Number (%) of patients excluded	66	(70.2)	43	(89.6)	163	(89.1)
Reason for exclusion:						
• started treatment before episode	25	(26.6)	0		16	(8.7)
• episode not due to tuberculosis	3	(3.2)	1	(2.1)	31	(16.9)
• episode possibly due to tuberculosis, but no treatment given or diagnosis confirmed	21	(22.3)	14	(29.2)	22	(12.0)
• inactive tuberculosis	9	(9.6)	0		1	(0.5)
• medical record not found	8	(8.5)	3	(6.2)	30	(16.4)
• date of discharge outside study period	0		25	(52.1)	45	(24.6)
• diagnosis after discharge of patient	0		0		0	
• out-patient record only	0		0		18	(9.8)
Number (%) of patients included	28	(29.8)*	0	(0)	8	(4.4)

** 24 identified using the primary discharge diagnosis)*

Of the 72 patients identified by discharge codes in Hospital A, 52 had been notified and 20 had not. Of the additional 7 identified using microbiology reports, 4 were notified and 3 were not. Including similar data for Hospital B gives us the data to calculate the yield of un-notified patients using each method in each hospital (Table 4.2).

Table 4.2: *The yield of patients not notified for each method of identifying patients*

Method	Hospital A	Hospital B	Total
discharge codes	20/(138-52) = 23.3	10/(94-18) = 13.2	30/162 = 18.5
microbiology	3/(138-4) = 2.9	0	3/134 = 2.9
histology	0	1/(171-7) = 0.6	1/164 = 0.6

Predictive value: The predictive value has been defined as (Driver, 1996; Rosenblum, 1993):

(the total number of cases of tuberculosis identified) / (the potential number of cases of tuberculosis).

The predictive value of the three methods (discharge codes, microbiology, histology) used in this study (Table 4.3) and the proportion of patients found by each method (sensitivity) (Table 4.4) were calculated.

Table 4.3: *Predictive value (%) of the three methods of identifying TB patients in hospital*

Method	Hospital A	Hospital B	Total
Discharge codes	72/138 = 52.2	28/94 = 29.8	100/232 = 43.1
Microbiology	7/109 = 6.4	0/43 = 0	7/152 = 4.6
Histology	0/46 = 0	8/171 = 4.7	8/217 = 3.7

Table 4.4: *Proportion (%) of patients found by each method*

Method	Hospital A	Hospital B	Total
Discharge codes	72/79 (91.1)	28/36 (77.8)	100/115 (87.0)
Microbiology/histology	7/79 (8.9)	8/36 (22.2)	15/115 (13.0)

Details of the included patients

Based on the inclusion criteria, 115 patients were initially included in the study. After the notification database match, 15 patients who were identified as not being notified had a possible history of tuberculosis in the previous five years; nine with a definite history, and six with an unknown past history. Search of the notification databases from 1989 to 1996 revealed that one patient was in fact notified in June 1996, and four patients in the five years prior to the study. The remaining 10 patients had not previously been notified.

Of the four patients who had been notified in the previous five years, two were notified again around the time of the study period and these notifications were defined as duplicates. There was no evidence for repeat notification of the remaining two patients who had been notified in the previous five years. All four of these patients were subsequently excluded from the study since they should not have been notified again.

In summary, of the 15 patients who were initially thought not to have been notified, but who had a possible history of past tuberculosis:

- 10 were confirmed as not being notified
- 1 was subsequently notified over a year after the study ended
- 4 were previously notified: 2 were notified again around the time of they study and counted as duplicates

The final sample therefore consisted of 111 patients.

Patient characteristics

Age and gender: Of the 111 patients included in the study, 82 (74%) were male and 29 (26%) female. The median age was 50 years. The patients' characteristics were compared with those of patients notified by Hospital Authority hospitals from January to March 1995 (Table 4.5).

Table 4.5: *Characteristics of the study sample and all public hospital-based notifications over 3 months*

	study sample (n=111)	notified patients (n=288)
no (%) male	82 (74%)	188 (65%)
Age: median, interquartile range	50 (31 to 70)	61 (36 to 74)

Site of disease: Most patients had pulmonary tuberculosis, although over 10% had pleural involvement (Table 4.6). In the sample of notified patients, 93.4% were notified as having disease of the respiratory system. As respiratory disease includes both pulmonary and pleural disease, 106 (93.8%) of study patients had tuberculous disease of the respiratory system.

Table 4.6: *Site of disease among patients identified*

Site of disease	number	percentage
pulmonary	90	81.1
pleural	14	12.6
extrathoracic lymphatic	1	0.9
spine	1	0.9
bone/joint other than spine	1	0.9
genito-urinary	1	0.9
peritoneal/digestive tract	1	0.9
skin	1	0.9
disseminated	1	0.9
total	111	100.0

Sputum status: The sputum status of the study patients is shown in Table 4.7. Nearly half (47%) of the sputum examinations were negative and 32% positive. Fourteen percent of the cultures were negative and 36% positive. The usefulness of this data was compromised because the results of 21% of sputum examinations and 54% of cultures could not be found. Note that these categories are not mutually exclusive.

Table 4.7: Sputum status of the study patients

Sputum test	Smear (%)	Culture (%)
negative	52 (46.8)	16 (14.4)
positive	36 (32.4)	35 (31.5)
unknown	23 (20.7)	60 (54.1)
total	111 (100)	111 (100)

Definitive diagnosis: Seventy eight patients (70.3%) had a definitive diagnosis of tuberculosis (defined as smear or culture positive, or histologically proven) during the study admission episode.

Previous tuberculosis: In 93 patients a record of whether or not they had previous tuberculosis was made: 21 (18.9%) had had previous tuberculosis, 71 (64.0%) had not. In 19 patients (17.1%), this fact was not recorded.

Year of previous treatment: Of the 21 patients who had had previous tuberculosis, 11 had had treatment recorded in 1989 or before (Table 4.8).

Table 4.8: Time since previous treatment

year of previous treatment	number	% of total with previous history
over 5 years previously (1989 or before)	11	52.4
5 years previously or less (after 1989)	6	28.6
unknown	4	19.0
total	21	100.0

Co-morbidity: Forty seven patients (42.3%) had one or more co-morbidities at the time of starting treatment or diagnosis of tuberculosis.

Case-definition: Of the 111 patients, 105 (94.6%) fulfilled the second case-definition, that is, they started treatment for tuberculosis during their admission, and six (5.4%) fulfilled only the first case-definition, that is, a definitive diagnosis was made during the admission, but no treatment was started.

Health care characteristics

Length of stay: The median length of stay in Hospital A was 14.5 days, interquartile range 9 to 28.5. The median length of stay was slightly shorter at Hospital B (Table 4.9).

Table 4.9: Length of stay in hospital

source of care	median length of stay (days)	interquartile range
Hospital A	14.5	9 to 28.5
Hospital B	10.0	5 to 23

Speciality of care: Nearly two thirds of patients were being managed by chest physicians at the time of diagnosis or starting treatment (Table 4.10).

Table 4.10: Speciality of physicians managing patients

Speciality	number	proportion
chest medicine	72	65
general medicine	22	20
other medical specialities (paediatrics, geriatrics, intensive care, radiotherapy)	7	6
thoracic surgery	8	7
other surgical specialities (orthopaedics, general surgery)	2	2
Total	111	100

Notification

Proportion notified: Overall, 79/111 (71.2%) of patients were notified. This proportion was very similar at both hospitals (Table 4.11).

Table 4.11: Proportion of patients notified

source of care	number of patients identified	no (%) notified	95% CI for proportion
Hospital A	76	55 (72)	64 to 80
Hospital B	35	24 (69)	54 to 84
Total	111	79 (71)	62 to 80

Source of notification: Fewer than 10% of the patients at Hospital B were notified by Hospital B and nearly 20% by other hospitals (Table 4.12). In contrast, nearly 40% of patients at Hospital A were notified by Hospital A and only one patient was notified by another hospital. Approximately 40% of patients from both hospitals were notified by chest clinics rather than the hospital.

Table 4.12: Source of notification for patients at Hospital A or Hospital B

	number (%) of patients notified by:				
source of starting treatment / diagnosis	same as source of starting treatment / diagnosis	other hospital	chest clinic	none	total
Hospital A	26 (34.2)	1 (1.3)	28 (36.8)	21 (27.6)	76 (100.0)
Hospital B	3 (8.6)	7 (20.0)	14 (40.0)	11 (31.4)	35 (100.0)
Total	29 (26.1)	8 (7.2)	42 (37.8)	32 (28.8)	111 (100.0)

Timeliness of notification

Interval between starting treatment and notification: The timeliness of notification was assessed by calculating the interval between start of treatment and date of notification which was taken as the date on the notification form. The median value was 15 days and was identical for both hospitals (Table 4.13). The minimum value was -31, for a patient who was notified one month before starting treatment, and the maximum value was 478 days, for a patient notified in June 1996 by a chest clinic.

Table 4.13: *Interval between starting treatment and notification*

source of care	median interval (days)	interquartile range
Hospital A	15.0	2.0 to 35.0
Hospital B	15.0	11.0 to 61.5
Total	15.0	5.0 to 36.0

Factors associated with notification

The only variable to show an association with being notified, was sputum smear status: smear positive patients were more likely to be notified (Table 4.14).

Table 4.14: *Probability of notification*

Independent variable	χ^2 value	p value
Male	0.29	0.59
age category (0-60, >60)	0.91	0.34
Pulmonary disease	0.06	0.81
sputum smear positive	*4.77*	*0.03*
sputum culture positive	2.62	0.11
definitive diagnosis	3.34	0.07
past tuberculosis	0.60	0.44
co-morbidity	0.00	1.00
source of care	0.03	0.85
length of stay (0-14, >14 days)	0.87	0.35
chest medicine specialty	0.30	0.58

The logistic regression model consisted of all independent variables in Table 4.14 and an interaction term consisting of sputum smear status and length of stay. The result is shown in Table 4.15. If the patient was admitted for over 14 days, he or she had a reduced probability of being notified (OR=0.23, p=0.021). *However, if the patient was smear positive and had a longer admission, the odds of notification were about 8 times that of other patients although it was marginally insignificant (OR=8.11, p=0.092).*

Table 4.15: *Logistic regression model of notification*

Variable	Odds ratio	p value	95% CI
Length of stay	0.23	0.02	0.65-0.80
Smear status	1.18	0.86	0.19-7.38
Length of stay & smear status	8.11	0.09	0.71-92.77
Male	1.81	0.29	0.61-5.38
Age category	2.37	0.13	0.77-7.31
Pulmonary disease	0.78	0.69	0.23-2.66
Sputum culture positive	1.26	0.75	0.31-5.18
Definitive diagnosis	2.02	0.23	0.64-6.43
Past TB	1.00	1.00	0.29-3.44
Comorbidity	1.82	0.31	0.58-5.73
Source of care	2.06	0.60	0.14-30.16
Chest medicine specialty	2.24	0.55	0.16-30.94

4.1.3.3 Discussion

Methods of identifying patients: The predictive values for each method of identifying patients at the two hospitals cannot be directly compared because the sequence of use of the methods determines its predictive value. The methods used first identify patients most likely to be included in the study, and exclude them from being identified by subsequent methods. In both hospitals, the discharge code method was used first and had the highest predictive value. At Hospital A, microbiology was applied second and had a higher predictive value than histology, and vice-versa for Hospital B.

Just under half of patients identified by discharge codes were included in the study. The most common reason for exclusion was that the patient had already started treatment before their admission and did not fulfil the criteria for the case-definition. This reflects the referral pattern for patients with tuberculosis who often start treatment at one source of care and are subsequently referred elsewhere.

The predictive value was highest at Hospital A where the discharge codes included only those patients where tuberculosis was coded as the primary diagnosis. At Hospital B the list consisted of patients where tuberculosis was coded as primary, secondary or other diagnosis. The more specific criterion at Hospital A did not apparently lead to failure to identify patients as the discharge coding identified a higher proportion of the total number of identified patients at Hospital A than Hospital B.

The overall predictive value of microbiology or histology reports, when used after discharge codes, was low. Most patients were excluded because their date of discharge fell outside the study period. This reflects the wide margins chosen for obtaining laboratory samples. The long time periods for pathology reports were specified because of the need to identify patients with prolonged admissions. Such patients could have had specimens sent to the laboratory in November 1994 and been discharged in January 1995 or later. The end date was specified as 30 April for histology and 31 May for microbiology samples. This was to ensure that any patients whose samples were sent just prior to discharge at the end of March 1995 were identified. In fact these end dates could have been brought forward to the first week of April as the samples are dated according to the date of receipt rather than the date of report. In the final outcome, unnecessarily prolonged time periods for pathology reports artificially lowered the yield of these methods.

In some cases the information required to trace records from laboratory reports was incorrect or inadequate, and either the wrong record or no record was retrieved.

The yield of each method, in terms of its ability to identify patients who were not notified, was greatest for discharge codes at Hospital A. The overall yield for discharge codes was just under 20%. That is, of discharge code identified patients who were not notified, one fifth met the inclusion criteria for the study. The yields for microbiology and histology were very low.

Ambiguities in discharge coding: Overall, 15 patients identified using histology and microbiology reports fulfilled the study case-definitions. In theory these 15 patients should have been coded as having tuberculosis on discharge. As tuberculosis could be coded as either a primary or secondary diagnosis, it is only possible to examine the sensitivity of discharge coding at Hospital B where any discharge diagnosis of tuberculosis was requested. At Hospital B, 8/36

(22%) of patients with tuberculosis were identified using histology and microbiology reports but not through the discharge code method.

In addition, overall, 4/232 (1.7%) of patients were identified by the discharge code method who did not in fact have tuberculosis.

Furthermore discharge coding did not apparently distinguish between active and inactive tuberculosis. If correctly coded, whether the TB is active or inactive should be clear. At Hospital A, 1/138 (0.7%) of patients had inactive disease whereas at Hospital B, 9/94 (10%) had inactive disease. The lower proportion at Hospital A probably reflects the fact that only patients with a primary diagnosis were considered, and inactive disease is more likely to be coded as a secondary diagnosis.

Medical records: Medical records could not be traced for 61 patients. In the case of microbiology and histology identified patients, this largely reflected the fact that the information on laboratory reports was inadequate to link them to medical records: for example ID numbers and hospital numbers were often missing.

The possibility of bias arising from missing records was considered. It is possible that patients for whom the record could not be found were also less likely to be notified. If it is assumed that cases identified by discharge codes, whose records could not be found, all fulfilled the study case-definition and were not notified, then the effect this would have on the rate of under-notification can be calculated:

- number of patients identified by discharge codes and no medical records reviewed = 11
- assume 11 additional cases satisfied the case definition and were included in study all of whom were not notified

The revised estimate for the proportion of cases notified would be:

number of patients identified = 124
number of patients notified = 81
proportion of cases notified = 65.3%

This is approximately 6% lower than the estimate obtained from the study.

The effect of missing records for patients identified by other methods is assumed to be minimal as a much lower proportion of these patients fulfilled the study case-definition.

Methods for matching patients with notification database: The initial match was performed using name and ID number. In order to minimise the risk that matches failed because of incorrect spelling of names or errors in ID numbers, searches were performed using only the first name, and then only the letter and first four digits of the ID number. Further steps were then taken to ensure that if an initial match was not made, the patient had not in fact been notified by performing additional searches for patients who may have been notified for a past episode of tuberculosis in the previous five years.

Characteristics of patients included in the study: Nearly 70% of patients had a definitive diagnosis either during the admission or subsequently, and nearly 95% started treatment during the admission. Despite the wide ranging opinions over who should be notified in the survey of notification practice (Section 4.2), it seems likely that there would be consensus among doctors that these patients should have been notified.

Notification: The proportion of patients notified in the pilot study was higher than in the main study. However, this figure should be interpreted with care because:

- the sample size was small, and 95% CI are wide
- the sample is not representative because only patients from one department were included, and many records could not be retrieved.

In both hospitals, approximately 70% of patients were notified. The overall proportion was 71.7% (95% confidence interval 62.4% to 79.8%). The corresponding range for the proportion not notified is 20.2% to 37.6%. Applying this range of estimates to annual notification figures it is possible to estimate how many patients are not notified each year. Incomplete identification information and failure to retrieve records creates uncertainty about the validity of the outcome of any audit.

Although 70% are *ultimately* notified, the proportion of patients notified by the same source of care where treatment was started, or a diagnosis was made, is less than 10% for Hospital B and less than 40% for Hospital A. Subsequent sources of care notify the majority of patients: at both hospitals, nearly 40% of patients are referred to and notified by chest clinics. At Hospital B, another 20% are referred to and notified by another hospital (in all cases except one this was one particular chest hospital which reflects the current referral system).

The referral of patients after diagnosis or treatment, but failure to notify, has two important consequences:

1. *Notification delay:* The median interval between starting treatment and notification was over two weeks, and for 25% of patients it was over one month.
2. *Failure to notify:* Subsequent sources of care may be unclear whether or not the referring source has notified the patient. They may assume incorrectly that the patient has already been notified and fail to notify the patient.

Factors associated with notification: Results from the logistic model suggest that the two most important factors in determining notification are sputum smear status and length of stay:

- A length of stay of two weeks or less was associated with an increased probability of notification. This might reflect the practice of some doctors to wait until discharge to notify the patient. If a patient starts treatment at an early stage of a long admission, doctors may be less likely to notify on discharge, particularly if the patient has co-morbidities which caused the prolonged admission. The mean length of stay of patients increases from 13.1 days to 31.7 days for patients with at least one co-morbidity (p=0.001).
- Patients who were admitted for over two weeks and who were sputum smear positive had a much higher probability of being notified. This group of patients may consist of patients with more serious forms of tuberculosis rather than patients whose co-morbidities are the main diagnosis. Doctors may therefore be more likely to notify these patients than either:
    - smear positive patients with short admissions who get referred elsewhere for management and may not be notified prior to referral
    - smear negative patients with short or longer admissions. A positive sputum smear result is an indication of infectivity as well as providing evidence for the disease. Doctors may be reminded to notify the patient because of the public health implications of a positive smear result, or they may consider smear positivity to be the most important criterion for notification (refer to notification practice survey).

Additional independent variables such as gender and age may be important determinants of the probability of notification, but the sample size may not have been large enough to identify such relationships.

4.1.4 Study on notification of chest clinic patients

4.1.4.1 Methods

Setting: All 11 Department of Health full-time chest clinics.

Sample size calculation: A sample size of 120 was calculated to be required in order to provide an estimate of under-notification with 95% confidence, where the expected proportion was 3% and the degree of precision required was 3%.

Sampling procedure: The nursing officer at each clinic prepared a list of all patients who started treatment between 1 January 1995 and 31 March 1995. Two sampling techniques were applied to these patient lists:

1. *Proportional sampling:* the number of patients included in the sample was in direct proportion to the number of patients starting treatment at that clinic.
2. *Additional sampling:* from clinics treating small numbers of patients to ensure that at least 10 patients were included from each clinic.

Once the number of patients to be sampled from each clinic had been calculated, patients were sampled at set intervals from the clinic list.

Inclusion criteria: In some clinics, the nursing officer stated whether or not the patient was a new case or a relapse. Relapsed cases were excluded from the study, and the next new case on the list was selected instead.

Data abstraction: Records were not traced for this study. The following data items were available from the clinic lists:

- patient name and ID number
- age, gender

All other methods were identical to those in the study of hospital patients except that item 3, under procedures to determine the proportion of patients notified (page 3), is replaced by the following:

3. ***Failure to match:*** If no match could be found, the medical records were reviewed to determine whether the patient was a new case or was a relapse, and whether notification had been noted in the medical record

4.1.4.2 Results

Identification of patients

Sixteen patients could not initially be matched with data on the notification databases. The records of these patients were reviewed: 10 were defined as relapses and 2 were patients on prophylactic treatment for the purpose of emigration. These 12 patients were subsequently excluded from the study.

Three samples of patients were analysed:
From the list of patients starting treatment in clinics from January to March 1995:

- **sample 1:** obtained using proportional sampling method (n=85)
- **sample 2:** sample 1 plus an additional 48 patients (n=133)

From the notification database:

- **sample 3:** all patients notified by chest clinics from January to March 1995 (n=989)

Patient characteristics

Age and gender: The age and gender of patients in each of the three samples was compared (Table 4.16).

Table 4.16: *Characteristics of the patients in each study sample*

	sample 1 (n=85)	sample 2 (n=133)	sample 3 (n=989)
mean age (years)	44.5	43.6	46.1
no (%) male	52 (61.2)	87 (65.4)	662 (66.9)

Source of starting treatment and source of notification: The number and proportion of patients in each sample starting treatment at or being notified by each source is shown (Table 4.17).

Table 4.17: *Distribution of patients by source within each sample*

source of care	% notified by each source	number (%) starting treatment at each source			
	sample 3	**sample 1**		**sample 2**	
A	6.2	3	(3.5)	10	(7.5)
B	15.1	21	(24.7)	21	(15.8)
C	4.1	1	(1.2)	7	(5.3)
D	4.4	1	(1.2)	10	(7.5)
E	17.4	15	(17.6)	15	(11.3)
F	6.9	5	(5.9)	9	(6.8)
G	4.9	3	(3.5)	10	(7.5)
H	17.1	17	(20.0)	17	(12.8)
I	12.5	15	(17.6)	15	(11.3)
J	5.4	3	(3.5)	8	(6.0)
K	6.1	1	(1.2)	11	(8.3)
L	NA	NA	-	NA	-
M	NA	NA	-	NA	-
total	100.0	85	(100.0)	133	(100.0)

Extent of under-notification

Two patients were not notified in sample 1 and four in sample 2 (Table 4.18).

Table 4.18: *Number (%) of patients not notified*

	no (%) not notified	95% CI for proportion (exact binomial)
sample 1	2/85 (2.4%)	0.29 - 8.24
sample 2	4/133 (3.0%)	0.83 - 7.52

Of the four patients not notified:

- two were recorded as being notified by the clinic in the medical record but notification forms were not received by the Department of Health Statistics Unit (one in sample 1 and one in sample 2).
- one had started anti-tuberculous treatment empirically for radiological tuberculosis but defaulted after one month: on return to the clinic after one year, there was no evidence of active tuberculosis (sample 1).
- one was notified by a chest hospital and the fact that the patient had been notified was noted on the discharge summary which was sent to the chest clinic: the clinic therefore did not notify the patient again, but the notification form from the chest hospital was never received by the statistics unit (sample 2).

As the estimate for under-notification was very similar for samples 1 and 2, subsequent analyses are only described for sample 2.

The number and proportion of patients starting treatment at and notified by each chest clinic is shown below (Table 4.19)

Table 4.19: *Number of patients starting treatment at and notified by each source of care*

source of care	no. starting treatment	no. notified
A	10	10
B	21	20
C	7	6
D	10	9
E	15	14
F	9	10
G	10	10
H	17	14
I	15	15
J	8	7
K	11	10
L	-	3
M	-	1
total	133	129

Some clinics notified fewer patients than started treatment, others notified more than started treatment. This pattern results from the transfer of patients between chest clinics, or from clinics to chest hospitals, in the interval between starting treatment and notification, and also from failure to notify.

Transfers of notification forms are unsuccessful for about 1 in 50 patients who are notified.

Timeliness of notification

Over 95% (127/133) of notifications were dated within the study period, two before and one after (Table 4.20). Of the four patients whose notifications were delayed, all were notified by the same clinic that started treatment.

Table 4.20: *Timeliness of clinic notifications*

date of notification	sample 2 (%)
Within study period	127 (95.5)
Notified prior to January 1995	2 (1.5)
Notified > 1 week after end of March 1995:	4 (3.0):
dates of notification	16/05/95
	22/07/95
	05/09/95
	16/01/96

Source of notification

Over 90% of patients were notified by the same clinic that started treatment, and just under 5% by a different clinic or hospital (Table 4.21).

Table 4.21: *Source of care notifying patients*

Source of notification	sample 2 (%)
Same source	123 (92.5)
Different clinic	3 (2.3)
Hospital	3 (2.3)
Not notified	4 (3.0)
Total	133 (100.0)

4.1.4.3 Discussion

The age and sex distributions of patients in the samples obtained for this study are similar to those of all patients notified in the same time period. This is expected given the overall low rate of under-notification.

The proportional sampling technique (sample 1) was used to provide an estimate of under-notification which could be applied to all clinic notifications in order to estimate the numbers of clinic patients which are not notified each year. The assumption underlying this technique was that the proportion of patients starting treatment for the first time in each clinic was approximately equal to the proportion of patients being notified by each clinic. Comparison of the proportions in sample 3 notified by each clinic with the proportions in sample 1

starting treatment at each clinic indicates that for most clinics this was a valid assumption. Clinic B, however, may be over-represented in sample 1 because the proportion in sample 3 was much smaller than the proportion in sample 1.

Sample 2 was created to increase the sample size and validate the point estimate of under-notification obtained from sample 1. It was intended that sample 2 should include at least 10 patients from each clinic, but some of these patients were subsequently excluded which meant that three clinics had fewer than 10 patients in the sample. The lowest number of patients from any clinic was seven. The estimates of under-notification obtained from the two samples were very similar which suggests that failure to notify a patient is not strongly associated with any one clinic. Indeed, given the small under-notification rate, a very large sample size would be required to provide evidence for any such association.

The proportion of patients treated, by chest clinics, which is not notified has been estimated to range from 0.8% to 7.5% (using larger sample). Applying this range of estimates to annual notification figures, it is possible to calculate the numbers of patients who are not notified each year.

The principal reason for a patient not being notified was that notification forms did not arrive at the statistics unit at the Department of Health: of the four patients who were not notified, two forms from chest clinics and one from a chest hospital did not arrive. Notification forms are usually sent by internal messenger within the Department of Health and by ordinary mail from other sources.

Between 2% and 3% of notifications were delayed for over one month. The basis for this deduction is that notifications occurred over a period of several months following the entry of information in the record which substantiated the diagnosis of TB (see Table 4.20). The reasons for this were not established in this study, although it appears that the delays are not caused by patients being transferred between clinics as three of the four patients whose notifications were delayed were ultimately notified by the same clinic as started treatment.

Over 90% of patients were notified by the same clinic which started treatment. The remainder were either not notified, or notified by a different clinic or hospital. This is a very different pattern of notification to that seen for patients starting treatment in hospitals.

Overall, completion of notification procedures is high for patients attending chest clinics, but small proportions of under-notified patients may amount to relatively large absolute numbers in the whole population of patients with tuberculosis.

4.1.5 Calculation of the under-notification rates

4.1.5.1 Calculation of the under notification rate for hospitals

Let:

- **x** = true number of patients who should be notified by HA hospitals each year
- **a** = proportion of patients not notified
- **y** = actual number of notifications by HA hospitals each year

$$y = x - ax$$
$$\therefore y = x(1 - a)$$
$$x = y / (1 - a)$$

In the first three months of 1995, 22.3% of notifications were made by HA hospitals. Applying this proportion to the total number of notifications in 1994 (6319), **y** = 1409. The actual number of notifications from HA hospitals in 1994 was 1597. The estimate of 1409 for that year is within 190 of the actual number. The following calculations use the actual number of 1597 for **y**. Applying the range of estimates for **a** of 0.202 to 0.376, **x** ranges from 2001 to2559. The estimated number of patients who started treatment in the HA hospitals but who were not notified in 1994 therefore ranges from 404 to 962.

4.1.5.2 Calculation of the under-notification rate for chest clinics

Let:

- **x** = true number of notifications by chest clinics each year
- **a** = proportion of patients not notified
- **y** = actual number of notifications by chest clinics each year

$$y = x - ax$$
$$y = x(1 - a)$$
$$x = y / (1 - a)$$

In 1994, **y** = 4631. Applying the range of estimates for **a** of 0.008 to 0.075, **x** can be calculated to range from 4668 to 5006. The estimated number of patients who started treatment in the chest clinics but who were not notified in 1994 therefore ranges from 37 to 376.

The formulae used for this calculation are the same as in the previous two cases:

$$y = x - ax,$$
$$y = x(1-a),$$
$$x = y/(1-a)$$

The results of the calculations are shown in Table 4.21 below.

Table 4.21: *Calculation of the under-notification rate for all patients*

		hospital patients	chest clinic patients	other *	total #
% of notifications (1994/5)		22.3	73.3	4.4	100.0
(y)	actual number of notifications (1994)	1597	4631	91	6319
(a)	estimated % not notified (95% CI)	28.3 (20.2-37.6)	3.0 (0.8-7.5)	unknown	(5.9 - 18.0)
(1-a)	estimated % notified (95% CI)	71.7 (62.4-79.8)	97.0 (92.5-99.2)	unknown	(82.0 - 94.1)
(x)	estimated true number of patients who should have been notified (range of estimates)	2227 (2001 - 2559)	4774 (4668 - 5006)	apply estimated range (92 – 146)	(6761 - 7711)
(x-y)	estimated true number who were not notified (range of estimates)	630 (404 - 962)	143 (37 - 375)	(1 - 55)	(442 - 1392)

** "other" includes patients managed by private practitioners, hospitals and other institutions such as prison hospitals and mortuaries. The range of estimates for the true number of notifiable patients (x) in the 'other' column (280-446) was derived by using the full range of estimates for "a" (0.8% to 37.6%) in the calculation x=y/(1-a).*

 # the total column estimated range for a, (1-a), x and (x-y) were obtained by summing the minimum and maximum estimates for x and using this figure in the calculation a=1-(y/x).

With several sources of care involved, notification is an uncertain process; it is often *delayed*, *omitted* or *duplicated*.

4.1.6 Adjustment of notification rates for under and over-reporting

Over-reporting exists when the number of cases notified is greater than the actual number of cases. Over-reporting is identified from the notification register from those cases which have been notified within a specified period of time. Those cases which are duplicates or are subsequently discovered not to have tuberculosis are defined as the over-reported cases. The over-reporting ratio or rate has the total number of reports as the denominator and the over-notified cases as the numerator. In theory this measure is error free because it uses the whole population of notified cases. Even if a sample was used, the error would be small because of the large denominator. The proportion of duplicates is normally around 15% (refer to section examining duplicate notification in more detail). Duplicates are normally removed from the notification database before the total number of notifications is reported. The number of patients with revised diagnoses and doubtful diagnoses in the cohort study is 2% and 3% respectively (section 6.3.7); these cases are not removed from the database so they contribute to over-reporting.

Under-reporting exists when cases who should have been notified are not. It must be estimated by using independent sources of information such as discharge diagnoses, laboratory reports, social welfare registers, prescriptions. Samples drawn from these sources can then be linked to the notification register in a specified time period. The result is an estimate, with confidence intervals, of under-reporting based on a sample from an unknown denominator.

The under and over-reporting ratios can theoretically be used to adjust the observed notification rate. The best estimate of the true number (BEN) can be calculated as follows:

The actual number of notifications in 1994/95 was 6319 (O).
The over-reporting ratio was estimated to be 2 to 5% (ORR).
The under-reporting ratio was estimated in our study to be between 5.7% and 20.6% (i.e. 442/7711 to 1392/6761) URR.

we can adjust the observed number upwards by the under-reported ratio and down by the over-reported ratio

BEN	=	O*(1-ORR)*(1+URR)		
	=	6319*0.95*1.06	to	6319*0.98*1.21
	=	6363	to	7493

So the lower bound for BEN is 6363 and the upper bound 7493. That is, the true number of cases eligible for notification may exceed the number notified each year by around 44 to 1174 cases.

4.1.7 Conclusions and recommendations

This study was restricted to the public sector. It would, however, be very useful to include the private sector in a similar audit review.

The estimated under-notification rate of approximately 3% for patients starting treatment in clinics, and approximately 30% for patients starting treatment in hospitals, means that between 370 and 1263 patients for whom there is good evidence of active tuberculosis are not being notified each year. This has important implications for public health in Hong Kong including the facts that these patients:

- are not being referred to the public health unit for contact tracing (except for chest clinic patients for whom contact tracing is initiated irrespective of notification)
- are not being included in official statistics used to monitor the epidemiology of tuberculosis in Hong Kong

The management of patients across several different sources of care is an important factor contributing to under-notification. In hospitals, only a quarter of patients are notified by the source of care where they start treatment or receive a definitive diagnosis, less than half were notified by their new source of care and the rest were not notified. Failure to notify at the time of starting treatment appears to be associated with a greater risk that the patient will never be notified or that notification will be delayed.

In chest clinics, over 90% of patients were notified by the same clinic which started the treatment and delays were much smaller than those for hospital patients. This reflects the system which exists at clinics for automatic notification once a patient starts treatment. The main reason for patients not being notified was due to forms apparently being lost between the clinic or hospital and the Department of Health Statistics Unit. These procedures should be evaluated further and modified if necessary to ensure that the process has fail-safe checks built in.

In order to increase completeness of notification, it should be automatically linked to one or more components of patient care. The chest clinic system is one way of doing this and the possibility of extending it to hospitals should be explored. In other countries other methods have been suggested or are in use. For example:

- in Singapore, information on positive cultures is used to identify patients who have not been notified (Snodgrass, 1995). This has also been recommended in the UK (Grange, 1993).
- in one London hospital, doctors, pharmacists, pathologists, radiologists and microbiologists send information on possible tuberculosis patients to a consultant in communicable disease control who sends notification reminders to the relevant physicians (Brown, 1995). This is likely to have contributed to an increase in the proportion notified from 73% to 93%.
- information from pharmacists proved to be a useful method for identifying patients in Saudi Arabia (Shanks, 1984) and Italy (Maggini, 1991) and has been recommended in the US (MMWR, 1992).

Measures such as these, to increase the completeness of notification, carry with them potential hazards. These include an increased risk of duplicate notification, and notification of patients whose diagnosis is subsequently revised (over-notification). In association with such a system to identify those patients who should be notified, it would therefore be important to ensure that:

- duplicate notifications are easily identified and eliminated
- a system for de-notification is introduced to adjust incorrect notifications

Completeness of notification is related to ease of notification, and this should be taken into account when considering case-definitions for notification.

It would be inappropriate and too resource intensive to repeat an *adhoc* study such as this at regular intervals. However, using experience gained from this study, the methods could be simplified. For example, hospital patients with newly diagnosed tuberculosis could be identified using discharge coding alone (as the yield is greatest for this method). A method of linking the Hospital Authority Integrated Patient Administration System (IPAS) should be developed as one method of quality assurance for information on tuberculosis patients.
The findings from this study have implications for the representativeness of the cohort of 454 patients identified from the notification database in the main survey (see also Section 6). Hospital patients in particular are under-represented. These patients are likely to be greater resource users than patients starting treatment in ambulatory care.

The notification system for tuberculosis now merits the application of information management and new technology to provide a new purpose-designed fail safe clinical information system. The system should be on-line, interactive and provide record linkage together with both notification and denotification procedures with clear protocols for its operation. It would allow routine audit to be carried out on a continuous basis. This would be a cost-effective intervention with direct benefits to patient care and public health in Hong Kong. (See also Section 9.4 for further discussion of information technology developments to support tuberculosis services.)

4.2 TUBERCULOSIS NOTIFICATION PROCEDURES: A SURVEY OF CURRENT PRACTICE

In order to identify possible reasons for delayed and missing notifications, a questionnaire survey of chest physicians and others involved in the notification of tuberculosis was carried out in November 1995.

4.2.1 Aim and objectives

The aim of the survey was to determine the current practice underlying the notification of patients with tuberculosis. The specific objectives were:

1. To determine which patients were likely to be notified.
2. To determine whether individual departments had an agreed definition of those patients who should be notified and any written guidelines for notification.
3. To determine procedures for re-notifying patients who had previously been notified.
4. To determine procedures for the storage, completion and submission of notification forms.

The results from this survey would be used to:

1. Help to interpret results from the audit of notification practice
2. Guide recommendations for the improvement of notification practice, particularly in relation to timeliness, completeness, validity (case-definition) and consistency (duplicates).
3. Guide standard setting for the continuation of the audit cycle.

4.2.2 Methods

A questionnaire was developed and sent to members of the Steering Group for their comments which were incorporated into the revised questionnaire.

The revised questionnaire was piloted in January 1996 at Queen Elizabeth Hospital by distribution to 27 doctors in the departments of respiratory medicine, general medicine and cardio-thoracic surgery. After analysis of responses to the pilot survey, the questionnaire was again modified. A report of the findings from the pilot survey was sent to Queen Elizabeth Hospital.

On 16 February 1996, questionnaires were sent to the Chiefs of Service at each of the five chest hospitals, to Queen Mary Hospital and to the consultant in charge of the chest clinics. The questionnaires were then distributed within each of these units to all senior and junior

medical staff involved in the treatment of patients with tuberculosis. Doctors were asked to complete and return questionnaires by 22 March 1996. The Chiefs of Service at units which had not responded by this date were telephoned with a reminder and a request to respond.

4.2.3 Results

4.2.3.1 Characteristics of sample

Units included in the survey: 69 completed questionnaires were received by 30 April 1996. Questionnaires were received from the following units:

Unit	No. of questionnaires received
Chest hospitals	41
Queen Mary hospital	11
Chest clinics	17
Total	69

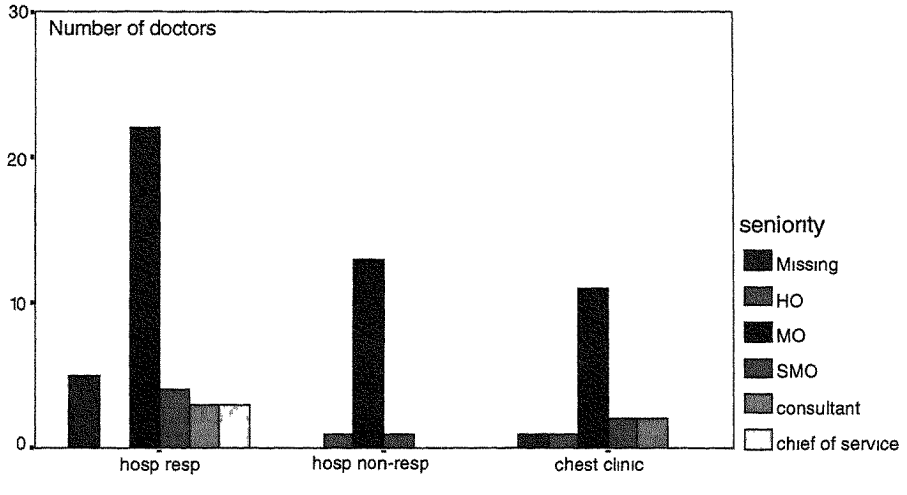
In the 52 questionnaires received from hospital doctors, 15 defined their unit as acute and 37 non-acute. Of the 52 hospital doctors, 37 worked in respiratory medicine, 11 in general medicine and one each in renal medicine, geriatric medicine and haematology.

Grade of doctors who responded and their clinical experience of tuberculosis: Doctors were asked to state their grade of employment. Results are in Table 4.23. The distribution of grade by specialty is presented in Figure 4.1

Table 4.23: Grades of responders to the survey

Grade	Number	%
House officer	2	3
Medical officer	46	67
Senior medical officer	7	10
Consultant	5	7
Chief of service	3	4
Not stated	6	9

Figure 4.1: Distribution of medical grades between sources of care responding to the survey



Source of care: Respiratory and non-respiratory hospitals and chest clinics

Doctors were asked if they ever notify patients with tuberculosis. Of the 57 (83%) that replied yes, 41 made between 1 and 6 notifications, and 11 made over 9 per month (Table 4.24).

Table 4.24: *Average number of notifications made per month*

average number of notifications per month	number of doctors	proportion of doctors who ever notify (%)
< 1	2	4
1-3	28	49
4-6	13	23
7-9	3	5
>9	11	19
total	57	100

Chest clinic doctors were more likely to notify 7 or more patients each month (p=0.00001) than hospital doctors. There was no difference in the average number of patients notified by junior and senior doctors (p=0.47).

4.2.3.2 Which patients are notified?

Doctors were asked which patients they notified as having tuberculosis, according to certain diagnostic categories. The response was classified in terms of the probability of notifying patients in that category. Five fixed probabilities were allowed in each response: 100%, 75%, 50%, 25%, 0%. The categories and responses are in Table 4.25.

Table 4.25: *Probability of notification of patients in each diagnostic category*

Diagnostic category (n=number of doctors completing item)	**% of doctors stating probability of notification of patient in diagnostic category**				
	100%	75%	50%	25%	0%
Acid fast bacilli on microscopy only (n=64)	81	3	3	0	13
Mycobacterium tuberculosis on culture only (n=63)	86	3	3	3	5
Histological evidence only (n=61)	80	5	7	2	7
Chest X-ray evidence only (n=64)	52	8	16	5	20
No positive diagnostic tests but diagnosis made empirically (e.g. response to trial of therapy) (n=63)	52	6	13	10	19
Patient receiving chemoprophylaxis only (n=61)	10	2	3	0	85
Any patient started on treatment (n=64)	64	3	11	3	19
Suspected tuberculosis only, treatment not started (n=60)	0	2	2	3	93

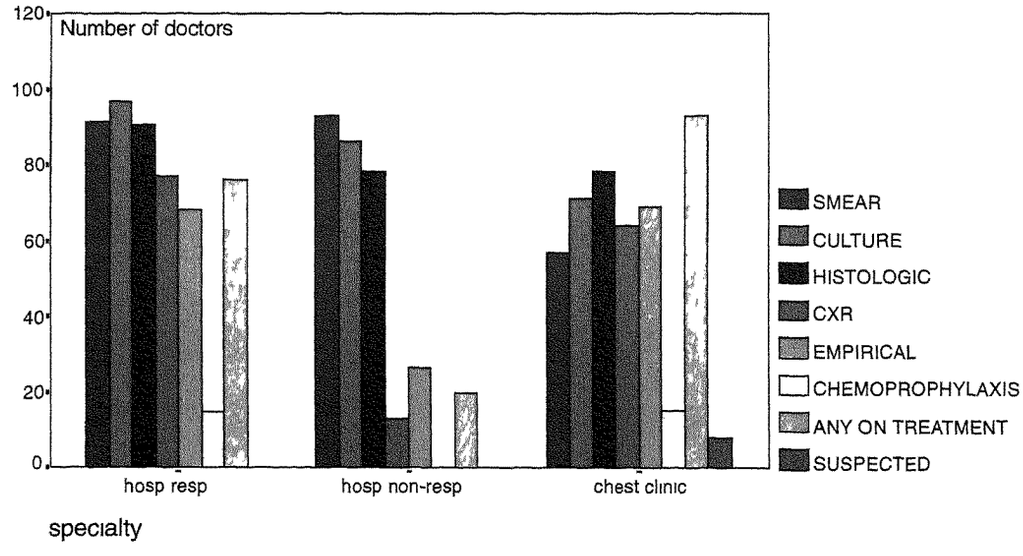
The maximum level of agreement on the probability of notification on any of the eight criteria is 86%. There is wide variation in declared intentions to notify different groups of patient between chest clinic and hospital doctors.

Four doctors commented that a small proportion of patients are started on treatment but not notified: these are patients who have small solitary lung nodules who decline invasive investigations to determine exact cause, and who are given a trial of anti-tuberculous therapy. One doctor commented that the diagnostic categories were inappropriate as a combination of clinical features was used to make the diagnosis.

The probability of notification of patients in different diagnostic categories was examined separately for doctors in chest clinics and hospitals (respiratory and other specialties were also analysed separately) (Figure 4.2).

"Likely" to notify means that the doctor stated that the probability of notification was 75% or 100%. A lower proportion of doctors from chest clinics were likely to notify patients on the basis of smear status or culture status alone. Hospital doctors working in non-respiratory specialties were much less likely to notify on the basis of CXR evidence alone than other doctors. Nearly all chest clinic doctors and hospital respiratory doctors were likely to notify any patient started on treatment, whereas only 20% of hospital doctors working in non-respiratory specialties would. Less than 20% of doctors in each setting were likely to notify patients on chemoprophylaxis. Very few clinic doctors and no hospital doctors would notify patients with suspected tuberculosis only.

Figure 4.2: *Perceptions of doctors: Probability of notification being carried out by different clinical categories of evidence for tuberculosis*



Case-definition

Current situation: 29 doctors (43%) stated that their unit or department had an agreed definition of which patients should be notified, 18 (27%) stated that they did not, and 21 (31%) were not sure. There was no difference between the clinic and hospital doctors response (p=0.49).

Of those that did have an agreed definition, 12 referred to the above diagnostic categories, 12 stated that "any patient started on TB treatment" would be notified , one stated "active" tuberculosis, one "proven" tuberculosis, and one a combination of microscopy, culture, radiology, histology and clinical evidence.

One reviewer comments that *"there is an intrinsic difficulty with the survey [of notification practice by doctors] as the decision whether or not to notify a case as TB will depend on the whole clinical picture, rather than on the results of an individual investigation"*. We agree with this view in general but this is the problem which needs to be addressed in the formulation of specific guidelines and protocols.

Most doctors responsible for notifications are not working to agreed case-definitions. The majority believe that such criteria should be introduced.

Recommendations: Of the 69 responses, 53 (79%) thought that a case-definition should be introduced, 2 (3%) thought not, and 12 (18%) were not sure.

The most frequently suggested case-definitions were as follows (number of responses):

- any patient started on treatment (9)
- diagnostic categories used above (8)
- histological/pathological proof (4)
- active tuberculosis (4)

Other doctors suggested that the notification of each patient should be evaluated at the end of their treatment, that there should be a mechanism for de-notification, and that case-definitions used by other countries should be considered.

4.2.3.3. Reasons for not notifying a patient

Doctors were asked which of the following were reasons for **not** notifying a patient with tuberculosis (Table 4.26).

Table 4.26: Doctors agreeing with reason for not notifying patient

Reason	number of responses	proportion of total number of responses (69)
Patient referred elsewhere to start treatment	10	15%
Empirical diagnosis only	19	28%
Tuberculosis only suspected	54	78%
Patient known to have received treatment before in previous 5 years	13	19%
Notification forms not available	2	3%

4.2.3.4 Previous notification

Doctors were asked if it was possible to find out if a patient had previously been notified for the same episode of illness. Twenty four (35%) replied yes, 11 (16%) replied no and 33 (49%) were unsure. There was no difference in response between clinic and hospital doctors (p=0.39). Of those that replied yes, the most common mechanisms cited were:

- medical record (9), specifically chest clinic record (6)
- Department of Health statistics unit (5)
- discharge summary (3)
- previous source of treatment (2)

They were then asked if this information would be useful. Fifty four (79%) replied yes, 5 (7%) no, and 9 (13%) were unsure. There was no difference between hospital and clinic doctors (p=1.00). Of those that replied yes, the most common uses were:

- to avoid duplication (19)
- to reduce effort/clerical work (5)
- for epidemiological statistics (4)
- to guide the patient's treatment (3)

Most doctors are unsure about the workings of the present notification system.

Re-notification

Doctors were asked about the probability of notifying again a patient that they knew had previously been notified. Results are in Table 4.27. There was a wide spread of responses across all the selected prior probabilities.

Table 4.27: *Probability of notifying again if previously been notified*

	probability of notifying again				
	100%	75%	50%	25%	0%
% of responders (n=66)	18.3%	3.3%	25.0%	11.7%	41.7%

Six (9%) doctors stated that they would re-notify patients on an individual basis. There was no difference between hospital and clinic doctors (p=0.16).

Time interval between episodes of illness: Forty doctors (65%) stated that their decision would depend on the time interval between the previous notification and the current episode of illness, 14 (23%) that it would not, and 8 (13%) were not sure. Of those that would make their decision based on the time interval, there was some variation in the cut-off for the time interval (Table 4.28).

Table 4.28: *Re-notification practice according to time interval between episodes*

time interval	yes (%)	no (%)	not sure (%)
< 1 year before	18 (45)	12 (30)	10 (25)
1-2 years before	28 (65)	4 (9)	11 (26)
2-5 years before	30 (75)	5 (13)	5 (13)
> 5 years before	37 (84)	4 (9)	3 (7)

Four doctors (6%) stated that their decision would depend on the severity of the disease. One reason given was that increased severity of disease may indicate re-infection which needs re-notification.

General comments were that a patient would not be re-notified for the same episode of illness (5), but that relapse of disease would be re-notified (4). In addition, completion of treatment in the initial episode was stated as a determining factor by one doctor, and another stated that a "failed" case would not be re-notified.

Half of the doctors would create duplicate notifications in the present system. A redefined set of notification categories reflecting clinical status is needed to create a logical and appropriate database.

4.2.3.5 The notification form

Storage: Doctors were asked where notification forms were currently stored. Results are in Table 4.29.

Table 4.29: *Storage of notification forms: number (%) of responses*

area for storage	yes (%)	no (%)	not sure (%)
ward - clinic doctors excluded (n=47)	37 (79)	6 (13)	4 (9)
doctor's office (n=55)	32 (58)	19 (35)	4 (7)
medical records department (n=46)	17 (37)	11 (24)	18 (39)
other (n=31)	3 (10)	9 (13)	19 (61)

The other areas mentioned were: out-patient department, supplies department, general office. More clinic doctors (12/12 (100%)) than hospital doctors (5/16 (31%)) stated that notifications were stored in the medical records department (p=0.0002).

Completion of the notification form

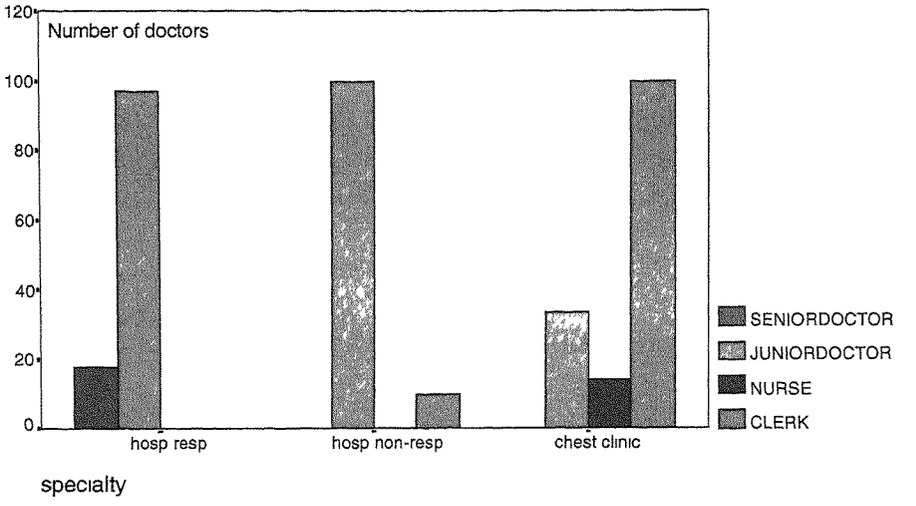
Doctors were asked who completed notification forms. Results are in Table 4.30.

Table 4.30: *Probability of particular members of staff completing notification forms*

staff member (n=number of doctors completing item)		**% of doctors stating probability of staff member completing form**				
		100%	*75%*	*50%*	*25%*	*0%*
senior doctor	(n=42)	12	0	5	36	48
junior doctor	(n=59)	63	25	5	0	7
nurse	(n=42)	2	0	5	0	93
clerk	(n=48)	27	2	0	0	71

Differences were found in the staff members stated likely (probability of 75% or 100%) to be completing forms in hospitals and clinics (Figure 4.3). In the clinic there was consensus that clerks were likely to complete forms, over a third of doctors named junior doctors, and over 10% stated that nurses were likely to complete forms. In hospitals in both respiratory and non-respiratory specialties, nearly all thought that junior doctors were likely to complete forms, nearly 20% nominated senior doctors in respiratory specialties, and 10% named clerks in non-respiratory specialties None stated that nurses were likely to complete them.

Figure 4.3: *Perceptions of doctors: Personnel considered most likely to complete notification forms, by specialty*



Doctors were asked when notification forms were completed. Results are in Table 4.31 and Figure 4.4.

Figure 4.4: *Perceptions of doctors: Probability of notification being made at different stages of treatment*

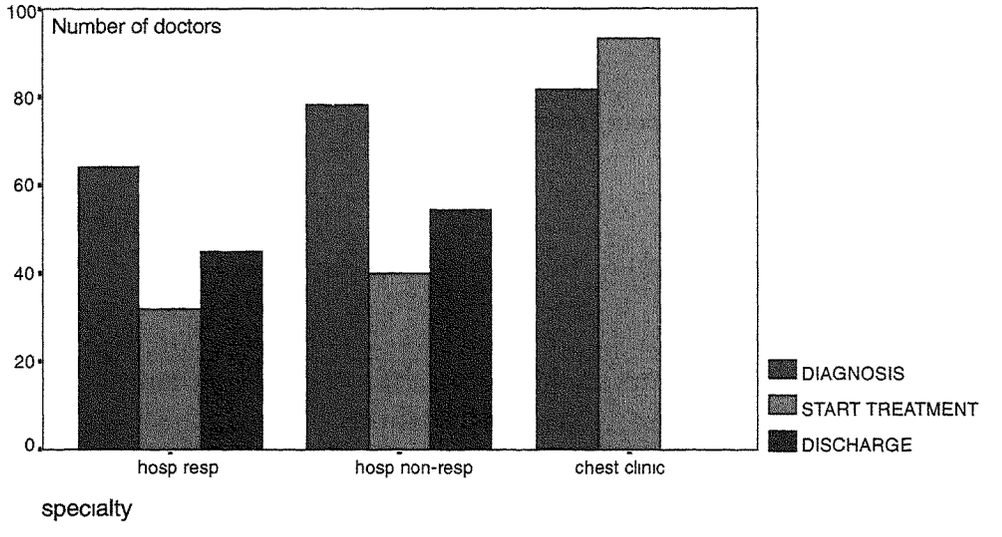


Table 4.31: *Probability of stage of completion of notification forms*

stage of disease (n=number of doctors completing item)	**% of doctors stating probability of form being completed at this stage**				
	100%	*75%*	*50%*	*25%*	*0%*
at time of diagnosis (n=53)	36	36	6	8	15
at time of starting treatment (n=53)	43	8	4	26	19
at time of discharge - excludes chest clinic doctors (n=42)	36	12	7	10	36

In the clinic, nearly all doctors stated that notification forms were completed at the start of treatment, and over 80% also agreed that forms were completed at diagnosis. In hospitals, there was more variation with between 60 and 80% of doctors stating that forms were likely to be completed at diagnosis, less than 40% at the start of treatment and between 40% and 60% at discharge.

Doctors were asked about the probability of forms being completed in the presence of the patient. Results are in Table 4.32.

Table 4.32: *Probability of completing notification form in presence of patient*

	probability of completing form with patient				
	100%	*75%*	*50%*	*25%*	*0%*
no (% of responders	11 (16)	6 (9)	7 (35)	4 (6)	40 (59)

There was no difference in the probability of completing the form in the presence of the patient between clinic and hospital doctors (p=0.53)

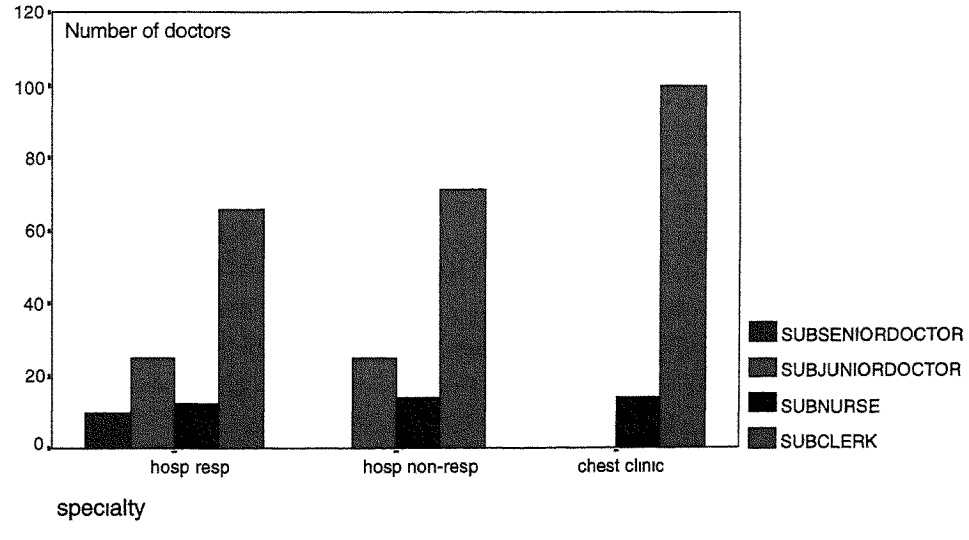
4.2.3.6 Submission of notification forms to Department of Health

Doctors were asked which members of staff submitted the notification forms to the Department of Health. Results are in Table 4.33 and Figure 4.5.

Table 4.33: *Probability of particular staff members sending form*

staff member (n=number of doctors completing item)		**% of doctors stating probability of staff member sending form**				
		100%	*75%*	*50%*	*25%*	*0%*
senior doctor	(n=23)	4	0	0	4	91
junior doctor	(n=26)	19	0	4	0	77
nurse	(n=38)	13	0	34	3	50
clerk	(n=64)	73	2	20	0	5

Figure 4.5: *Perceptions of doctors: Probability of different staff members sending the form to Department of Health*



In the clinic, all doctors agreed that clerks were likely to submit notification forms, and a few thought that the nurse was likely to be involved. In contrast, hospital doctors thought that all members of staff were likely to be involved, although most doctors thought that clerks were likely to be involved, and very few thought that senior doctors submitted forms.

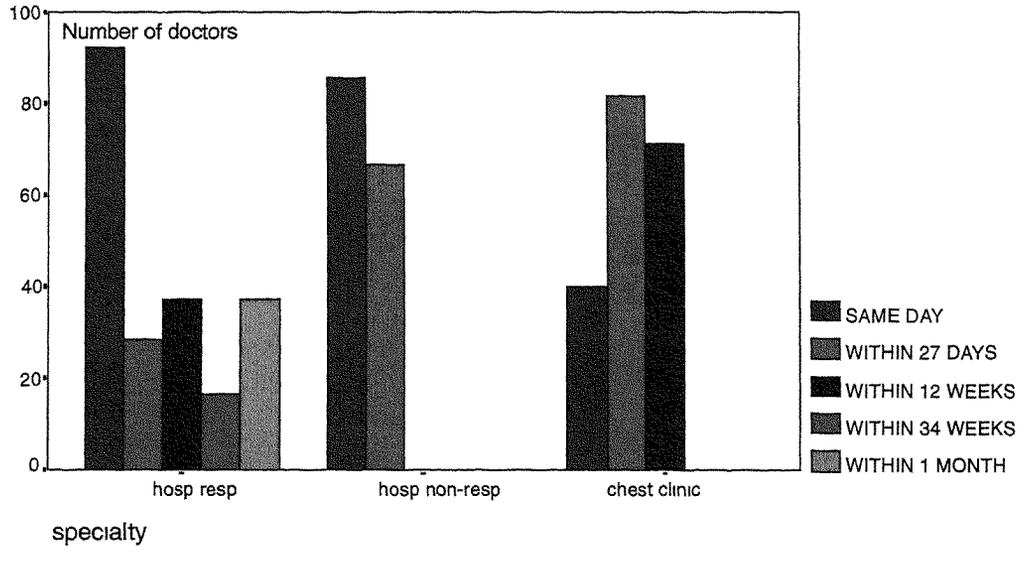
Doctors were asked how frequently forms were sent to the Department of Health. Results are in Table 4.34 and Figure 4.6.

Table 4.34: *Probability of frequency of form being sent to the Department of Health*

frequency of sending forms (n=number of doctors completing item)	**% of doctors stating probability of sending forms in this way**				
	100%	*75%*	*50%*	*25%*	*0%*
on day of completion (n=39)	77	8	0	3	13
in batches every 2 days to 1 week (n=24)	50	13	4	8	25
in batches every 1-2 weeks (n=18)	39	6	11	6	39
in batches every 3-4 weeks (n=13)	0	8	0	15	77
in batches every 1 month or more (n=15)	13	7	0	0	80

All of the clinic and non-respiratory hospital doctors thought that forms would be submitted at least every two weeks, whereas nearly 20% of the hospital respiratory doctors thought it was likely that forms were submitted in batches every 3 to 4 weeks and nearly 40% thought it was in batches of 1 month or more. However a very high proportion of hospital doctors in all specialties also thought that forms were likely to be submitted on the same day that they were completed.

Figure 4.6: *Perceptions of doctors: Frequency of submitting forms to Department of Health*



4.2.3.7 Written guidelines for notification

Of the 69 responses, no doctor stated that there were written guidelines for the notification of patients with tuberculosis, 52 (77.6%) stated that there were none, and 15 (22.4%) were not sure.

4.2.3.8 Other comments

The most frequent comments were:

- doctors need incentives to notify (especially those in private sector and in general hospitals) (7)
- guidelines are inadequate and there are no standard procedures for notification (6)
- notification should be simplified (2)

Others included:

- notification should be computerised (1)
- there is no mechanism for de-notification (1)
- it is difficult to obtain forms (1)
- current system is excellent (1)
- current system is OK except for duplicate notification (1)
- doctors need positive re-inforcement for notifying (1)
- there is insufficient publicity (1)
- need to explain to ward clerk and nurses the significance of and procedures for notification (1)
- need to know what the Department of Health wants (1)

Doctors current perceptions of the notification system, its functions and their responsibility for it, provide a basis for evaluating new criteria and guidelines for notification of tuberculosis.

4.2.4 Discussion

The survey was distributed to those doctors most likely to be diagnosing, treating and notifying patients with tuberculosis in Hong Kong. Rather than determining what should be done in terms of notification practice, the aim was to determine what was being done, and in particular to identify any variation in practice which could form the basis for discussion for development of notification procedures.

Characteristics of notifiers verus non-notifiers: Non-notifiers were left in the study group. Of the 12 who did not notify any patients, 11 were definitely employed in positions where they were likely to come across patients with TB and therefore should be prepared to notify them (ie, 6 worked in chest clinics and five in chest hospitals). The remaining doctor worked at a general hospital and the specialty was unstated. We therefore felt that it was appropriate to include non-notifiers in the analysis.

Response rate: It is not possible to determine the response rate to the survey as the denominator is unknown. However, each Chief of Service and the chest clinic consultant were actively involved in ensuring that relevant members of staff completed the questionnaires, and at least four completed questionnaires were received from each hospital. The ratio of junior to senior doctors was as expected.

The individual item response rate was good although it declined towards the end of the questionnaire.

Format of questionnaire: The response format for five items required respondents to indicate the probability for each of several sub-items. The probability for each sub-item ranged from 100% to 0%. In four of the items, the sub-items were mutually exclusive and in theory, the sum of the probabilities for each of the sub-items should have been 100%. However, it is clear that doctors did not complete the questionnaire with this in mind, for example, they may have marked 75% for two sub-items and 25% for a third, resulting in a summed probability of 175%. This does not, however, adversely affect interpretation of responses which have been used only to provide an estimate of likelihood. For the analysis of differences in response between hospital and clinic doctors, 100% and 75% probabilities have been combined into a "likely" probability category.

Experience of respondents: Although junior doctors were more likely to complete forms than senior doctors in both settings, senior and junior doctors did not report a difference in the average number of notifications made per month.

Which patients are notified: Responses were most consistent for patients with microbiological and histological evidence (likely to be notified), and those with suspected tuberculosis only (unlikely to be notified). This might reflect a degree of agreement among physicians, although there appeared to be greater agreement among hospital doctors for all four categories. More hospital than clinic doctors were likely to notify patients on the basis of microbiological or histological evidence alone.

There was most variation in response among doctors for patients with radiological evidence only or an empirical diagnosis, and this variation persisted once clinic and hospital doctors were analysed separately. In contrast, the range in responses to "any patient started on treatment" was largely due to variation in response of hospital doctors: nearly all clinic doctors stated that they were likely to notify such patients. This is consistent with chest clinic policy where notification occurs automatically once the patient starts treatment.

Patients receiving chemoprophylaxis should not be notified under the present system. However, approximately 10% of doctors in clinics and hospitals said that they were likely to notify such patients. Reasons for this should be ascertained.

Two respondents replied that they had difficulty answering this item because they did not have access to statistical data: they had mis-interpreted the question as asking what proportion of the patients that they notified fell into these diagnostic categories. If other doctors also interpreted the question in this way, the responses may not be an accurate reflection of the probability of notification of patients in each category. However, if doctors have reported the percentage of notified patients falling into these categories, the results are likely to parallel the probability of notification of patients in each category.

Case-definition: There was general agreement that a case-definition should be introduced. One of the main disadvantages of introducing a case-definition is that, unless it is very simple, it may increase the time it takes to decide whether a patient should be notified and may therefore reduce the likelihood that the patient will be notified. Overall however clear criteria and guidelines are needed and case-definitions should be part of this.

Simple versus complex: There was no consensus on which case-definition should be introduced. A simple case-definition such as "any patient on treatment" is sensitive but non-specific. It would be relatively easy for doctors to decide whether to notify a patient, but it would be more important to have a mechanism for de-notification. A more complicated case-definition such as that used by the United States in their "Report of a Verified Case of Tuberculosis" system (MMWR, 1997) is more specific but less sensitive, and it would be time-consuming for doctors to decide whether or not to notify. Any case definition should be appropriate for both the clinic and hospital setting: for example, it should not rely on results from complex diagnostic procedures which are not readily available in some care settings. Any system which is chosen initially should be continuously evaluated. This would be professionally instructive and rewarding procedure and would lead to progressive improvements in the system.

De-notification: If there is a case-definition for notification, it becomes more straightforward to decide who should not be notified. If patients are notified on the basis of empirical evidence, a proportion will subsequently have their diagnosis revised. If a mechanism for de-notification was introduced, any patient in whom the diagnosis was subsequently revised would be de-notified, and removed from the official statistics. This would result in additional workload for Department of Health staff but it would be cost-effective as a means of improving the quality of this important notification data base.
In the cohort study up to 5% of patients fulfilled the criteria for de-notification.

Reliability of questionnaire: The agreement between reasons offered for not notifying patients and probability of notifying patients in particular diagnostic categories was examined:

- *empirical diagnosis:* in 67% of questionnaires respondents both agreed that this was a reason not to notify and were less likely to notify (less than or equal to 50% probability).
- *suspected tuberculosis:* in 98% of questionnaires, doctors agreed that this was a reason not to notify and were less likely to notify (less than or equal to 50% probability).

Although there is some concordance between these two variables this is clearly not very high and appears to reflect uncertainty on the part of the respondents.

Timeliness of notification: Only 14.5% of respondents agreed that if the patient was referred elsewhere to start treatment, this was a valid reason not to notify the patient.

If doctors agree that patients who have a confirmed diagnosis and who are referred elsewhere to start treatment should be notified prior to referral, then this should be included in the guidelines.

Duplicate notification: Only a third of doctors said that it was possible to find out if patients had previously been notified. This is a reflection of the short comings of the present information system for patients with tuberculosis and doctors knowledge of it. Notification is not routinely recorded in hospital medical records and although there is a space for it to be noted on discharge summaries, anecdotal evidence suggests that this is incomplete. In some units, records are stamped when the patient is notified and the notification date is recorded. However, even if notification is recorded in one unit, this information may not be passed on to the subsequent source of care. If a doctor is unsure whether or not a patient has previously been notified, he or she is more likely to re-notify the patient. In 1994, 15% of notifications were duplicates.

Although only a third of doctors were able to find out if a patient had previously been notified, 80% agreed that the information would be useful, mainly to avoid duplication, but also to guide the patient's treatment.

The official definition for duplicate notification is any notification made within five years of the original. Only 19% of doctors agreed that if the patient was known to have received treatment in the previous five years, this was a valid reason for not notifying the patient, that is, 81% would notify the patient. This is likely to reflect the uncertainty that doctors face in not knowing whether a patient has previously been notified. In some cases, doctors may disagree with or be unaware of the definition of duplicate notification. In any event all doctors who notify patients need rapid and reliable access to the notification database.

There was a considerable range in the recorded probabilities that a patient who had previously been notified would be re-notified, and this reflects the many possible factors which may lie behind such a decision. These factors include the time interval between episodes of illness, the clinical features of the case, and the outcome of treatment for the original notification.

Although the official guidelines for when to re-notify rely exclusively on the time interval between the original notification and the current episode of illness, only two thirds of respondents stated that their decision would depend on the time interval. There was, in addition, considerable variation in the cut-off time for re-notification. As expected, as the time interval increased, the proportion stating that they would re-notify increased, and the proportion who would not re-notify, or who were unsure, decreased. However at an interval of over five years, 16% of respondents still stated that they would not re-notify or were unsure. This may reflect a lack of awareness of the official definition of duplicate notification. In addition, although the official definition is five years, 75% stated that they would re-notify patients whose previous episode was less than 5 years previously.

There was no consensus reached on other factors which are important for deciding whether to re-notify.

Storage of the notification form: Many respondents stated that they were unsure whether notification forms were stored in particular places, and this has been cited as a problem in another survey elsewhere (Harvey, 1991). Only 3% of respondents agreed that if notification forms were not available this was a valid reason not to notify a patient, but in reality the practical problem of finding a form will reduce the likelihood of the patient being notified. In order to increase the completeness of notification, notification forms should be widely available. Flexibility in terms of methods for sending the information (facsimiles, telephone, email) should be considered. Ultimately, notification should be possible using a fully integrated linked computer-based information system.

Staff members responsible for completing the forms: In clinics, there was consensus that clerks should complete the forms, although junior doctors and nurses appear to be involved in some cases. The clinic policy is for nurses to complete "Form A" when a patient starts treatment and for clinic clerks to complete the notification form using information from "Form A" and the medical records. They may then ask doctors to complete or check the form. The doctor has to sign the form.

This contrasts with the current situation in the hospitals where there is no automatic notification linked to starting treatment, and most responsibility appears to lie with junior doctors.

Stage of completion of form: In clinics, forms are likely to be completed at diagnosis and treatment. This is consistent with clinic policy and may also reflect the fact that as soon as a patient is diagnosed, he or she begins treatment. In hospitals many forms are completed when the patient is discharged; if the patient has a prolonged length of stay, this might delay notification. The variation in procedure may also reduce the completeness of notification; the doctor responsible for discharging the patient may assume incorrectly that the patient has already been notified.

Completion in presence of patient: Notification forms are unlikely to be completed in the presence of the patient. This means that certain items are less likely to be completed accurately as they may not have been noted in the patient's record. These items are: place of work/school attended; telephone number of place of work/school; status of residence in Hong Kong (permanent resident/new immigrant/tourist etc.).

None of these items are entered onto the computerised notification database, and their completeness cannot therefore be estimated. Such details are required for contact tracing, and nursing personnel currently collect and use them. In any new modified notification system responsibility for completing different sections in the data base would be allocated to different personnel, including clerical, medical and nursing staff.

Submission of forms: The broad range of staff involved in submitting forms from hospitals may result in failure to submit forms, particularly if one person assumes that it is another's responsibility. Although most hospital doctors stated that forms were submitted on the same day or at up to two week intervals, over 20% said that it was likely to be every month or more. This batching of notification forms results in difficulty in the interpretation of monthly notification figures and may reduce the likelihood of forms being submitted.

General comments: A number of doctors said that greater incentives were required for doctors to notify, particularly in the private sector and general hospitals. Incentives could take the form of money, feedback of analyses, or other types of information. It can be noted however that an increase in fees paid to doctors for notification did not change practice in a UK based study (McCormick, 1987). An alternative view would be that notification is a clear contractual responsibility of any medical practitioner and failure to do this amounts to negligence.

4.2.5 Conclusions and recommendations

1. There is no consensus between doctors over which patients should be notified. If the validity of notification data is to be increased, a case-definition should be introduced. The experience of other countries should be considered in the development of the criteria for case-definition.
2. A proportion of doctors appear to be notifying patients who are receiving chemoprophylaxis. The current policy is not to notify such patients and doctors should be given clear advice on this. If such information is judged to be useful then a separate reporting system should be introduced for these patients.

3. There is considerable variation in notification practice, both in terms of who does it and when the forms are completed and submitted. Variation has been reduced in the chest clinics by an automatic system of notification. Guidelines should be developed for a universal system of notification for both hospitals and clinics to reduce variation and increase both sensitivity and specificity. Ultimately, notification should form part of a computer-based information system with appropriate record linkage covering all tuberculosis services. In the meantime, the process of notification should be facilitated by increasing the availability of forms and increasing the number of methods by which notifications can be sent. The revision and monitoring of the procedures, with clear representations in flow charts, together with regular audit procedures is likely to have an immediate beneficial effect.
4. Certain items on the notification form can only be accurately completed after direct questioning of the patient. As forms are rarely completed in the presence of the patient, consideration should be given to either omitting these items from a revised form and devising a complementary system whereby demographic information can be captured and checked with patients.
5. Consideration should be given to whether to revise the current definition for duplicate notifications. If the current definition is not going to be revised, it should be made more widely known. There should be standardised data fields, in the records used for all TB patients, for recording actions taken on notification. Accurate routine recording of notification in the medical records and on discharge summaries will reduce the risk of duplicate notification. Ultimately, however, a computer-based information system with on-line facilities will allow doctors to find out if and when patients have previously been notified which will reduce duplicate notifications and guide clinical management.
6. These proposals should be discussed by a working group. In particular the working group should discuss:
   - the pros and cons of various case-definitions
   - guidelines for a universal notification system
   - the definition of duplicate notification
   - the drafting of explicit standard procedures for notifications.

4.3 VALIDITY OF DATA ON THE NOTIFICATION FORMS

4.3.1 Introduction

Comparison of data on notification forms and that obtained from other sources was made for a sample of patients in order to determine the validity of the data in the notification database. The data examined was patient age, site of disease, sputum smear and culture status, past history of tuberculosis and year of previous treatment. In each of the following validity studies, the classifications and methods used are briefly described followed by the findings.

4.3.2 Validity studies

4.3.2.1 Age of the patient

The age of the patient given on the notification form was compared with the age calculated from the date of birth of the patient abstracted from medical records and the date of notification. The difference between these two ages was calculated in this way for 440 patients. It could not be calculated for the remaining 14 patients either because either the date of birth was not obtained or the age of the patient was not completed on the notification form.

Of the 440 patients, the difference was greater than + or - 2 years for 13 patients (3.0%). The values of the age differences for these patients are presented (Table 4.35).

Table 4.35: *Difference in age recorded on notification form and that calculated from year of birth given in medical record*

Patient	age on notification form	Calculated age (rounded)	age difference	year of birth from medical record
1	62	34	-28.2	1961
2	46	26	-20.1	1969
3	61	69	8.0	1926
4	55	62	7.0	1933
5	52	59	6.8	1936
6	19	25	6.2	1969
7	61	67	6.0	1928
8	46	41	-5.3	1954
9	60	55	-4.8	1939
10	34	38	4.2	1956
11	75	79	3.6	1916
12	54	57	3.0	1938
13	38	40	2.4	1954

The mean age difference for the 4 patients where the calculated age was younger than the notification age was 14.6 years. The mean difference for the 9 patients where the calculated age was older than the notification age was 5.2 years.

4.3.2.2 Site of disease

Classification systems: On both old and new notification forms, "Site of TB" is categorised as: *Respiratory system, Meninges, Bone & joint, Other(s).*

The system adopted by the IUATLD for European surveillance uses:

Pulmonary,
Pleural,
Lymphatic, intrathoracic,
Lymphatic, extrathoracic,
Spine, Bone/joint other than spine,
Meningitis,
CNS other than meningitis,
Genito-urinary,
Peritoneal/digestive tract,
Other,
Disseminated.

This classification was used in the validity study. In the main survey, up to two sites were coded but pulmonary disease was always coded as the major site and the second site as the minor site.

The results of the validity study (Table 4.36) show that the principal distinction between the two systems is the use of respiratory versus pulmonary disease. *Respiratory* includes any disease occurring in the thorax

pleural,
pulmonary,
intrathoracic lymphadenopathy

whereas *pulmonary* refers only to disease occurring in the lungs.

4.3.2.3 Sputum smear and culture status

Classification system: On both old and new forms, doctors were given the following options for sputum status at the time of notification: *Positive, Negative, Unknown.* On the old forms, no distinction was made between sputum smear and culture status whereas on the new forms, the two investigations were presented separately.

For the validity study the smear and culture status were defined as results of sputum examinations performed within one month of the patient starting treatment. Patients who did not start treatment were classified as such and their sputum status was not recorded.

The results of the validity study show that it is not possible to examine agreement on sputum status between the old forms and the data forms in this survey because the old forms did not distinguish between sputum smear and culture status. Sputum smear (Table 4.37) and culture status (Table 4.38) can be compared for those patients notified using the new forms although the data on notification forms relates to the *time of notification* whereas that in the survey relates to the *time around the start of treatment.* Notification usually occurs after the patient starts treatment and can be delayed by a few weeks or even months: the median interval estimated from the survey data was 6 days (interquartile range 1 to 20 days, minimum minus 134 days, maximum 310 days) and in 16% of patients, the interval was greater than a month. As sputum status may change over time this delay may confound a comparison of survey data with notification data.

Among the patients whose sputum status was inconsistent with that recorded on the notification form, a proportion may in fact be explained by a change in sputum status over time:

- Of the 11 patients who were classified as smear or culture negative in the survey (start of treatment) but were smear or culture positive at notification, two (18%) were notified over a month after starting treatment and their sputum status could have changed in that time. The remainder were notified less than two weeks after starting treatment and their sputum status should not therefore have changed.

- Of the seven patients who were smear or culture positive in the survey but classified as negative at notification, two (29%) were notified over a month after starting treatment.

Table 4.36: *Validity study: comparison of site of disease classified on notification form and in the main survey*

notification form site (no of patients)	number consistent with major site recorded in the survey	sites classified in survey for patients inconsistent with major site on notification form:		number (%) of patients where form consistent with:	
		major site	minor site	major site	major or minor site
respiratory system (421)	402 pulmonary 17 pleural 1 intrathoracic lymphatic total: 420	1 extrathoracic lymphatic	none	420 (99.8)	420 (99.8)
meninges and CNS (1)	1 meningitis total: 1			1 (100)	1 (100)
peritoneum, intestines, mesenteric (1)	0 total: 0	1 pulmonary	1 peritoneal/ digestive tract	0	1 (100)
bone/joint (6)	1 spine 4 bone/joint (not spine) total: 5	1 pulmonary	1 bone-joint (not spine)	5 (83.3)	6 (100)
genito-urinary (2)	2 genito-urinary total: 2			2 (100)	2 (100)
lymph node (18)	1 intrathoracic lymphatic 13 extrathoracic lymphatic total: 14	4 pulmonary	3 extrathoracic lymphatic 1 none	14 (77.8)	17 (94.4)
neck abscess (2)	1 extrathoracic lymphatic total: 1	1 meningitis	1 extrathoracic lymphatic	1 (50)	2 (100)
TB abscess (1) (ischio-rectal abscess - not stated on form)	0	1 pulmonary	1 peritoneal/ digestive tract	0	1 (100)
pleural (1)	1 pleural total: 1			1 (100)	1 (100)
endometrium (1)	1 genito-urinary total: 1			1 (100)	1 (100)
Total (454)	**445**			**445 (98.0)**	**452 (99.6)**

- Of the 31 patients whose smear or culture status was unknown at notification, 22 had a definite result recorded in the survey. Of these 22, two (9%) were notified over a month after starting treatment.

- Patients who were categorised in the survey as not starting treatment may have been sputum smear or culture positive or negative at the time of notification.

The degree of consistency calculated for each group of patients is therefore a minimum estimate as it assumes that all inconsistencies are due to errors in the recording of sputum status on notification forms rather than change in sputum status over time.

Forty patients were classified as smear or culture positive on the notification form but their smear or culture status was unknown in the survey. For the purpose of the survey, all medical records were reviewed to determine sputum investigation results. The survey smear or culture status was classified as unknown because within the period of one month before and after starting treatment either medical records could not be traced, or sputum investigations were not requested

Table 4.37: *Comparison of sputum smear status classified on the notification form and in the validity study*

notification form sputum smear status (no of patients)	number consistent with sputum smear status in study	study smear status for patients inconsistent with study smear status	% of patients where notification form consistent with study
positive (72)	64	5 negative 1 did not start treatment 2 unknown	88.9
negative (211)	174	5 positive 2 did not start treatment 30 unknown	82.5
unknown (9)	3	2 positive 3 negative 1 did not start treatment	33.3
not done (4)	3 (unknown)	1 negative	75.0
total (296)	**244**		**82.4**

Table 4.38: *Comparison of sputum culture status classified on notification form and in study*

notification form sputum culture status (no of patients)	number consistent with sputum culture status in study	study culture status for patients inconsistent with study culture status	% of patients where notification form consistent with study
positive (49)	35	6 negative 2 did not start treatment 6 unknown	71.4
negative (17)	13	2 positive 2 unknown	76.5
unknown (22)	4	8 positive 9 negative 1 did not start treatment	18.2
total (88)	**52**		**59.1**

4.3.2.4 Past history of tuberculosis

Classification system: On the notification forms, doctors are asked "Does patient have a history of past treatment for tuberculosis?", and are given the options "yes" and "no". They may either get this information from the medical record, or from the patient directly. If the item is not completed, the response is assumed to be negative.

For the validity study, patients were classified as having past tuberculosis if it was noted in the medical record. A distinction was made between patients with a definite past history and those who only had evidence of past tuberculosis on chest X-rays.

The results showed that, at the time of notification, 27 doctors stated that the patient did not have past tuberculosis, but there was definite evidence for this in the patients' medical records. This could have occurred if:

- the patient did not recall previous disease at the time of notification
- the doctor did not refer to the medical record
- the doctor failed to complete the item on the notification form

One patient was notified as having a previous episode of tuberculosis at the time of notification but the medical record stated that there was no previous history of tuberculosis. The patient had started treatment earlier in the year at a private practitioner and after defaulting had been referred to a chest clinic where he was notified. The earlier treatment by the private practitioner may have been considered as a previous episode of tuberculosis although it could be argued that it was the same episode of illness interrupted by the patient's default.

Table 4.39: *Comparison of past history of tuberculosis classified on the notification form and in the validity study*

notification form: "past tuberculosis"	number consistent with study data	study data for patients inconsistent with study response	% consistency
no (405)	339 no 39 unknown	27 yes	93.3
yes (49)	48 yes	1 no	98.0
total (454)	**426**		**93.8**

4.3.2.5 Year of previous treatment

Classification system: On the notification forms, a record "Year of first treatment" is requested for notified patients.

In the validity study, the year that the last previous treatment was initiated was determined. These data are not therefore directly comparable for patients who have received more than one course of treatment in the past.

The results of the validity study show that two patients were stated on the notification form to have received treatment in the previous five years, but there was no evidence for this in the medical records (Table 4.40). This discrepancy cannot be explained by the difference in classification systems between the survey and the notification forms as the survey data refers to the most recent previous treatment. For the remainder of patients, where year of previous treatment was noted on the forms, there was agreement with the study data.

Table 4.40: *Comparison of treatment in previous five years recorded on the notification form and in the validity study*

notification form "tuberculosis in last 5 years"	number consistent with survey data	survey category for patients inconsistent with study category	% consistency
yes (6)	4	2 (no)	66.7
no (37)	37	nil	100.0
total (43)	**41**	**2**	**95.3**

4.3.3 Discussion

Age of patient: The age of notified patients is one of the key variables for epidemiological analyses. In this sample, there were more patients for whom the notification age under-represented their true age than vice-versa, but the mean age difference was greater for patients where the notification age was higher than the true age. The total number of years by which each subgroup was discrepant was greater for the subgroup where the notification age was older (58.4 years versus 46.8 years).

Applying these findings to the age-specific notification rates in Hong Kong would mean that:

- age-specific rates for 20 to 40 year old patients may be slightly under-represented as two younger patients are falsely categorised into age groups 10 to 20 years older.
- age-specific rates for older patients are more accurate because any discrepancies only result in patients moving up or down one 10 year age band at most.

However, the sub-sample of patients with discrepant ages is very small, and it may not be appropriate to make such generalisations.

Site of disease: Overall the consistency was high. The audit does, however, highlight some potential problems in the coding system for notifications.

One of the objectives of notification is to identify trends in patterns of disease. One sub-group of patients of particular interest are the group of patients with infectious disease, that is *sputum smear positive pulmonary disease*. The current classification system does not allow these patients to be identified as a separate and exclusive group because patients with pleural disease and intrathoracic lymphadenopathy are included in the category "respiratory".

Other patients were coded as having disease of "lymph node" or "abscess" which gives no indication of the site of disease.

Sputum smear and culture status: The system of including sputum smear and culture classification on the new forms is an improvement.

The greatest discrepancy was found for patients where sputum status was unknown at notification, but classified as positive or negative within a month of starting treatment. This may reflect the notification practice of doctors who notify patients before the results of sputum investigations are known.

Excluding these patients and those where sputum examinations were "not done", the minimum estimates for consistency range from 71.4% for culture positive patients to 88.9% for smear positive patients. The overall consistency rate for smear or culture negative or positive patients is 286/349 (81.9%). Of the 63 inconsistent patients:

- 5 did not start treatment in the survey
- 40 had unknown sputum status in the survey
- 18 had different sputum smear or culture results between the notification and survey data bases.
    - of these 18, 4 could be explained by changes in sputum status over time (notification occurred over one month after starting treatment)

Only 14 patients therefore had definitely inconsistent records. The maximum estimate for consistency can therefore be estimated at (349-14)/349 = 96.0%.

Past history of tuberculosis: The consistency was high. There was evidence for possible confusion over what constitutes a separate episode of tuberculosis and should therefore be reported as such on a notification form. The objectives of collecting data on past tuberculosis need to be clarified. Such data may be collected in order to:

- estimate the proportion of patients with past tuberculosis treated in the last five years, in order to determine what proportion should have been notified previously
- estimate the proportion of patients which can be defined as relapses

Should data be collected and labelled for the year of *first treatment* or year of *last previous treatment*?

4.3.4 Conclusions and recommendations

1. Age is well documented but the importance of accuracy in calculating age-specific notification rates should be emphasised, and date of birth might be requested in addition to age as a check on accuracy.

2. Site of disease is well documented on notification forms but:
    - the classification system should be modified to enable patients with pulmonary disease to be identified
    - the classification system should require doctors to state the *site of disease* as well as the *type of pathology* (e.g. abscess, lymph node)

3. Sputum smear and culture status are relatively well documented on notification forms but:
    - there is a relatively high proportion of unknowns because notification is performed before results of sputum investigations, particularly culture are available. This

problem could be overcome if new procedures for updating and completing notification records were introduced. Record linkage between the notification data base and other types and sources of information should be a high priority in the next phase of development of the notification system.

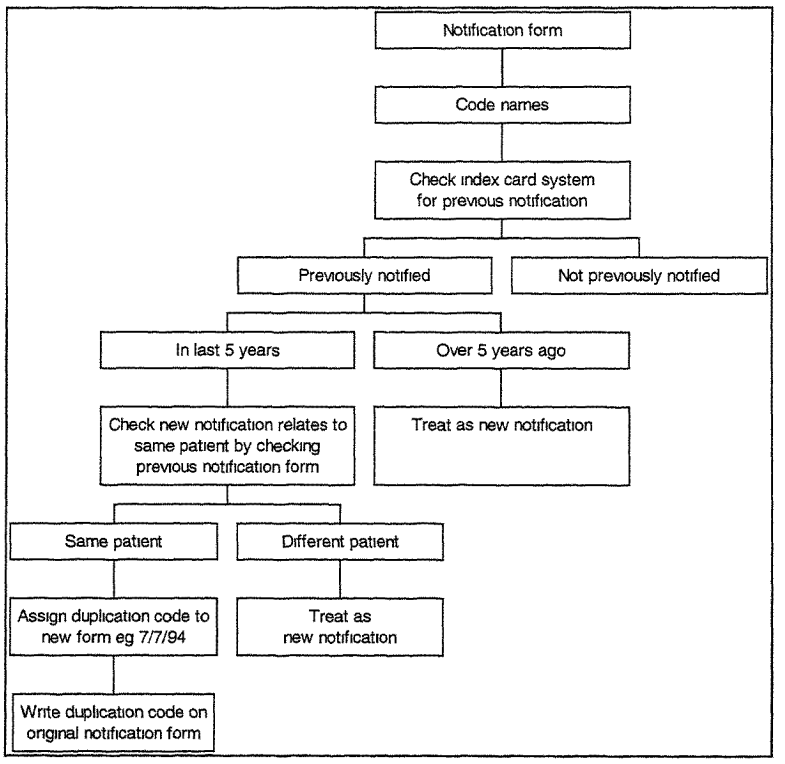
4. Past history and year of previous treatment are well documented but:
   - the definition of a past history of tuberculosis should be clarified
   - the objectives of collecting such data should be discussed and agreed
   - the pros and cons of collecting the year of first treatment or year of last previous treatment should be discussed.

4.4 DUPLICATE NOTIFICATIONS

4.4.1 Introduction

Notification of the same patient more than once has the potential to result in inaccurate data for epidemiological analyses, and may result in unnecessary duplication of contact tracing if it occurs soon after the earlier notification. For these reasons, a system to identify patients notified more than once has been established for over 20 years in Hong Kong (Figure 4.7). Duplicate notifications are defined as those relating to a patient previously notified in the preceding five years. Such notifications are excluded from further epidemiological analyses. However, when the interval from the previous notification is greater than one year, the case will be referred to the chest clinics for contact tracing. In 1994, of 7403 notifications, 1084 (15%) were defined as duplicates.

Figure 4.7: *System for identifying duplicate notification in Hong Kong*



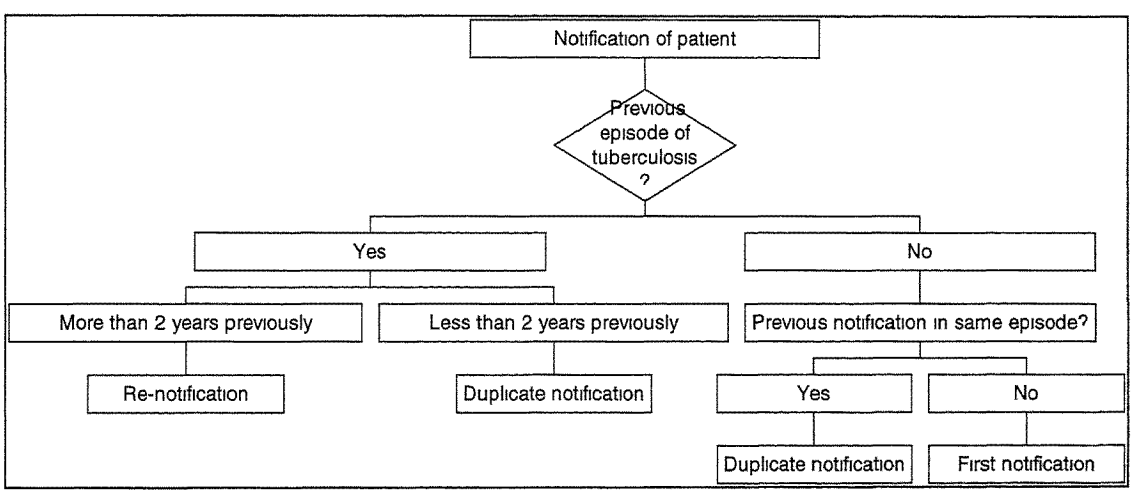
In the United Kingdom, although there is no on-going national system for identification of those patients notified more than once, *ad hoc* surveys of notifications have provided estimates of the size of the problem. Two types of repeat notifications were identified (Davies *et al.* 1981):

a) ***"duplicate notifications":*** repeat notification of a patient during the same episode of illness, estimated at 2% of total notifications.
b) ***"re-notification":*** notification of a patient for a second episode of illness, irrespective of whether the first episode of illness was notified, provided that the first episode was more than two years previously, estimated at 10% of total notifications.

In this survey, notifications of patients previously treated for tuberculosis, but less than two years before, were defined as duplicates (Figure 4.8). In order to clarify the situation, the Joint Tuberculosis Committee made the following recommendations for previously treated patients (Joint Tuberculosis Committee of the British Thoracic Association 1982):

a) the clinician *should* re-notify if a *new episode of illness* has occurred, regardless of the interval between episodes;
b) the Medical Officer for Environmental Health (now known as the Consultant in Communicable Disease Control), responsible for collating notification data, should treat the re-notifications as a new notification if the patient is experiencing a new episode of tuberculosis. If there is any doubt whether the notification should be treated as a duplicate or a re-notification, the clinician should be contacted.

Figure 4.8: *Algorithm to distinguish duplicate notifications and re-notifications in United Kingdom based on definitions used in notification survey*



Although in Hong Kong it is known that approximately 15% of notifications are repeat notifications, it was not known what proportion of repeat notifications refer to the same episode of illness, and are therefore could appropriately be labelled as duplicates, and what proportion in fact refer to different episode of illness.

The aim of this part of the study on notifications was to determine the interval between original and repeat notifications, and thus assess the appropriateness of the current policy of excluding repeat notifications from further analysis and contact tracing. In addition, the study would explore potential reasons for repeat notification.

4.4.2 Methods

Once identified, duplicate notifications are allocated a sequential code indicating the order in which they are received in any given year. For example, the first 10 duplicate notifications received in 1994 were given the codes 01/94 to 10/94. The last 100 duplicate notifications received in 1994 were selected for this study. The duplicate notification forms were examined and key data items were abstracted and entered onto a computerised database using EPI-INFO software. The unique serial number of the original notification is written on the duplicate notification forms. This allowed the original notification forms to be traced and further data were abstracted from them (including the exact date of original notification, and the existence of any additional notifications for the same patient). Data were analysed using EPI-INFO. The study period was December 1994.

A second sample of 473 patients notified for the first time during December 1994 was selected for comparison with the first sample of patients notified more than once.

4.4.3 Results

The 100 duplicate notifications related to 97 patients (three of them related to only one patient, and two to one other patient: both these patients were originally notified in the preceding month). The three repeat duplicates were excluded from further analysis.

Nine of the remaining patients in the sample had also been notified again more than once but outside the study period. In six, there was one more duplicate, and in three there were two more. For seven of the study patients, the repeat duplicates occurred in the time period between the original notification and the study period, and for two the repeats occurred in the four months after the study period. In summary, 209 notifications for the 97 patients included in the study (Table 4.41).

Table 4.41: *Timing of duplicate and original notifications for 97 patients in sample*

	Before study period	During study period	After study period
Duplicate notifications	9 (7 patients)	100 (97 patients)	2 (2 patients)
Original notifications	68	29	-

Interval between original and duplicate notifications

Of the 97 duplicate notifications made at the end of 1994, 90 (93%) were originally notified in 1994 (Figure 4.10). The original notifications were made in November and December 1994 for 34 and 29 patients respectively. The remaining seven patients were originally notified in 1993 (5), 1992 (1) and 1989 (1).

Most duplicates occur soon after the original notification.

Source of notifications: The source of notification was provided on both original and duplicate forms in 96/97 patients (Table 4.42).

Table 4.42: Source of original and duplicate notifications

		Duplicate notification	
		Chest clinic	Hospital
Original notification	Chest clinic	7	51
	Hospital	26	12

The majority of patients (51/96 (53%)) were originally notified by a chest clinic, and then notified again by a hospital.

Of the 12 patients notified on both occasions by hospitals, five were notified by different hospitals. Of the 7 patients notified on both occasions by chest clinics, six were notified by different chest clinics.

In summary, 88/96 (92%) of the patients were notified for the second time from a different source.

Duplications typically arise because of multiple sources of care and a lack of record linkage.

Gender: 76/97 (78%) of patients were male compared with 324/473 (68%) of those notified for the first time in December 1994 (p=0.05).

Age: There were no significant difference in the mean age of patients notified more than once and those notified for the first time (55.7 and 49.8, p=0.14). However, comparing the mean age of men and women separately revealed that men notified more than once tended to be older (57.8, 51.1, p=0.06), whereas the difference between women was not significant (48.3, 46.9, p=0.8).

Site of disease: 96/97 (99%) of patients had respiratory disease, compared with 439/473 (93%) of those notified for the first time (p=0.02).

Sputum smear status: The smear status of patients in the two samples is shown in Table 4.43.

Table 4.43: Sputum smear status for those patients where it was provided on both the original and duplicate notifications

		Duplicate notification	
		Smear positive	Smear negative
Original notification	Smear positive	6	8
	Smear negative	1*	23

* The smear status converted from negative to positive in only one patient. The interval between notifications for this patients was one month.

Past treatment: In 17/97 (18%) of duplicate notifications, it was stated that patients had received treatment for tuberculosis in the past. The duration from previous treatment to duplicate notification ranged from a few months to 40 years, but in 13/17 (76%) of patients, the interval was greater than five years. A smaller proportion of patients notified for the first time in December 1994 had previously received treatment (48/473 (10%), p=0.02).

4.4.4 Discussion

In Hong Kong, two thirds of duplicate notifications occur within two months of the original notification, and over 90% within the subsequent 12 months. Nearly all duplicate notifications came from a source other than that of the original notification. The majority of repeat notifications in Hong Kong would also be classified as duplicates in the United Kingdom because they appear to be made within the same episode of illness. A much higher proportion of notifications appear to be duplicates in Hong Kong compared with the United Kingdom.

These features of duplicate notifications in Hong Kong are likely to reflect the complexity of services provided for patients with tuberculosis which are delivered from different sectors and sites. Services are provided by both the public and private sector at both primary and secondary care levels. Patients frequently attend more than one source of care for an episode of illness, and may be referred between sources by health care professionals.

It appears that older male patients with respiratory disease who have previously received treatment for tuberculosis are more likely to be notified twice. This may reflect heightened awareness of the importance of tracing contacts of such patients because of the increased risk of patients being infectious and of having a drug resistant strain. It may also reflect the referral system: if such patients are more likely to be referred between sources of care, they are also more likely to be notified from more than one source. Many duplicates of chest clinic notifications came from hospitals, where the patients admitted tend to be older and male.

Which criterion should be used to determine whether a patient should be notified again? Ideally, this decision should be taken on clinical grounds: if a doctor considers that the patient is suffering from a new episode of illness, the patient should be notified again, and that notification should be treated as a new notification for contact tracing and epidemiological purposes. In the current system, however, it is very difficult for a doctor to know whether the patient has already been notified either for that episode or a previous episode, particularly if the notification came from a different health care source. As notification is a statutory requirement, doctors may be more likely to err on the side of caution.

Alternatively, as is currently the case in Hong Kong, the decision could be based on the time interval between notifications. In Hong Kong, this interval is currently set at five years: repeat notifications less than five years after the original are classified as duplicates and excluded from further analysis although contact tracing takes place if the interval is greater than one year. Although reliance on time interval does have the advantage of being objective, consistent and easily measured, the disadvantage is that for some patients, it may be more appropriate to treat the repeat notifications as new notifications: they may indeed be suffering from a discrete episode of illness, and should be appropriately included in epidemiological statistics. This is particularly the case for patients with complex health care needs due to drug resistance and chronic disease complications.

The time interval could be reduced further:

- data from this study suggest that if the interval were set at two years, only 2% of current duplicates (or 21 each year) would be reclassified as new notifications
- if it were one year, 7% of current duplicates (or 75 each year) would be re-classified as new notifications.

- if the interval were six months, the proportion would increase to approximately 10% (or 100 each year).

The current system for dealing with duplicate notifications in Hong Kong is appropriate for the majority of patients as most duplicate notifications appear to relate to the same episode of illness. However, for the patients re-notified more than one or two years after the original notification, the current system may not be appropriate, and consideration should be given to reducing the interval for classification of duplicates from five years .

However, an ideal solution would be to have greater control over the clinical information being entered into the notification system, for example, through a screen based notification system. A decision on each case could be made using clinical judgement based on relevant information. There should be greater ownership for clinicians in the system to encourage and allow them to decide whether or not a patient should be defined as a new notification or a duplicate. This would clearly be greatly facilitated by the availability of a clinical information system but should not be dependent on its introduction. If necessary, medical records should be retrieved to inform decision making.

4.5 TIMELINESS OF NOTIFICATION

4.5.1 Aim

The aim of this study was to assess the timeliness of notification.

4.5.2 Methods

The medical records of 128 patients whose notifications were received in the week 4-10 December 1994 were traced. The following data items were abstracted:

- date of starting treatment
- source of care where treatment was started
- source of care where notification form was completed

The date that the form was completed was abstracted from the notification database held at the DoH Statistics Unit. The following intervals were calculated:

- *interval 1:* the interval between date of starting treatment and date of completion of notification form
- *interval 2:* the interval between date of completion of form and date that it was received by the DoH Statistics Unit. This was taken as 10 December 1994.

The monthly notification databases were analysed to determine the total number of notifications received from each source, and the number of forms for which the interval between completion and receipt was greater than 4 weeks.

4.5.3 Results and discussion

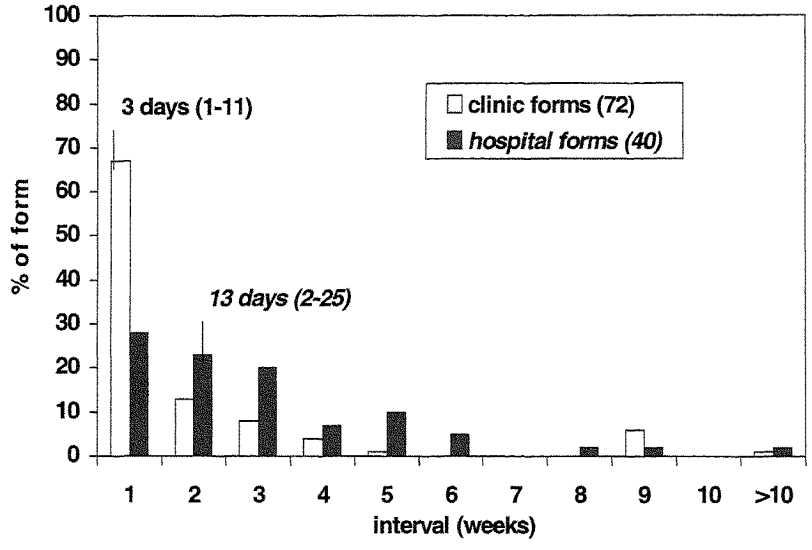
In 8 notification forms (6.3%) the date of completion of the form was not available.

Interval 1

For 8 forms (6.3%), the date of starting treatment was not available because the medical records could not be traced or permission had not been granted.

Of the 112 patients for whom "interval 1" could be calculated, 72 were notified by clinics and 40 by hospitals. Overall, the interval between starting treatment and completion of the notification form tended to be shorter for clinic patients than hospital patients (median interval 3 days (interquartile range 1-11), compared to 13 days (2-25)) (Figure 4.9).

Figure 4.9: *Distribution of values for interval 1*



A possible reason for the interval being shorter for clinic patients is

- *Automation of clinic notification system.* When a patient starts treatment in the clinic, the nursing staff complete "form A" which is then sent to clerical staff who proceed to complete a notification form. Individual hospitals are likely to employ different notification procedures.

Possible reasons for delays in notifying patients are:

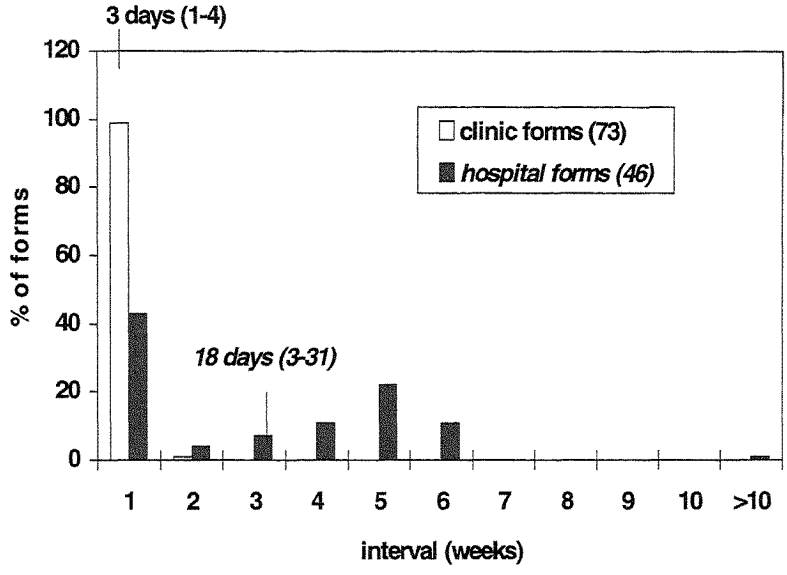
- *Transfer to another source of care.* Eleven of the 112 patients (9.8%) started treatment in one clinic or hospital but were transferred before notification and notified by another source of care. Of these 11, seven were notified by a clinic having started treatment in a hospital. The median interval for this group of 11 patients was 19.5 days.

- *Doctor waits to notify patient until patient is discharged or definitive diagnosis is made.* Doctors may wait to notify patients until they write the discharge summary, or until they receive the results of diagnostic tests.

Interval 2

Of the 119 patients for whom "interval 2" could be calculated, 73 were notified by clinics and 46 by hospitals. 72/73 (99%) of clinic forms were received within one week of being completed (median interval 3 days, interquartile range 1-4) (Figure 4.10). In comparison, the distribution for forms received from hospitals showed a biphasic pattern with a longer median interval of 18 days (range 3-31).

Figure 4.10: *Distribution of values for interval 2*



A possible reason for the shorter clinic interval is:

- Clinic forms are submitted directly to the DoH Statistics Unit at Wanchai Chest Clinic via an internal messenger system. Other forms have to be posted first to Wu Chung House, which then re-directs them to Wanchai Chest Clinic.

A possible reason for the biphasic distribution of hospital form return is:

- There is substantial variation between hospitals in the time taken to send in a form once it has been completed. Some hospitals appear to send forms in batches every few weeks. This may reflect administrative procedures at those hospitals. This is more clearly demonstrated by comparison of the proportion of forms which are delayed by more than four weeks at two hospitals, Hospital A and Hospital B.

There is considerably more variation in the total number of forms received each month from Hospital B (Figures 4.11 and 4.12). In addition, a greater proportion of forms are delayed by over 4 weeks from date of completion, and this proportion varies substantially from month to month. The variation in proportion of forms which are delayed accounts *in part* for the variation in the total number of forms received. However, there are clearly other factors behind this monthly variation. The low number of forms received in February might reflect the fact that this was Chinese New Year and many staff were taking annual leave!

Figure 4.11: Notification forms received from Hospital A by month of receipt

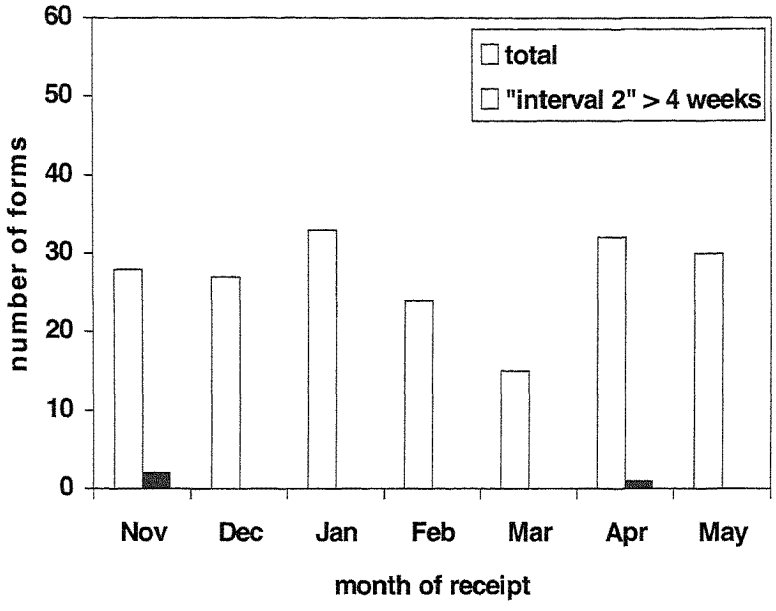
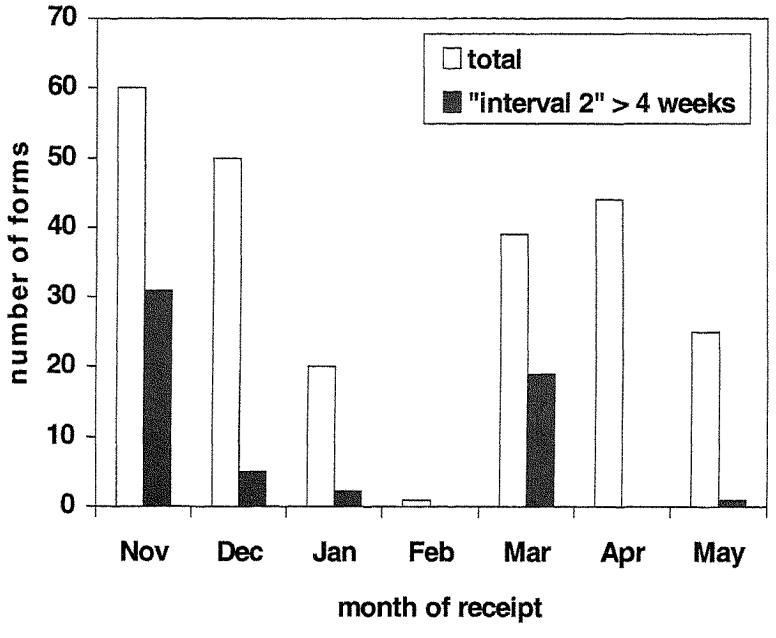


Figure 4.12: Notification forms received from Hospital B by month of receipt



Notifications are analysed according to month of receipt. Substantial delays have been identified between start of treatment and completion of notification form, and completion of form and receipt of the form. These delays tend to be greater for patients notified by hospitals.

The implications of these delays are two-fold:

- Monthly notification databases should not be assumed to reflect seasonal variation in notifications. For example, they would probably not reliably indicate the impact of a change in referral system between hospitals which might be expected to result in changes in the number of notifications received each month from particular sources.

- There will be delays in initiation of contact tracing for patients in whom notification is delayed.

Conclusions and recommendations

The enquiry conducted into the notification system demonstrates what would be expected; namely that all information systems are subject to error. In the case of the tuberculosis notification system the information which is to be registered is coming from multiple sources in many different sectors and levels. There are, collectively, a very large number of decision points where information may not be captured, develop errors or be delayed.

All information systems should be subjected to continuous audit to identify and correct sources of error. In the notification of tuberculosis the managers of the system should develop and routinely apply validation procedures of the type used in this enquiry. It would be feasible and justifiable to develop a state-of-the-art system which linked pharmacy dispensing, microbiological and histopathological investigations, hospital discharges and chest clinic records directly to the TB notification system. There are several approaches which could be taken at different levels of sophistication. See section 9.4 for some suggestions on the development of a system.

The information resulting from this audit should be disseminated to hospitals and clinics responsible for notifying patients. In the short term the approach could focus on the two critical intervals (Interval 1 and Interval 2) which are described in this report.

For Interval *1*, hospitals should evaluate their current notification procedures. A "system approach" to notification should be designed whereby notification procedures are automatically linked to treatment procedures (for example, the pharmacy department could send automatic reminders to doctors initiating anti-tuberculosis therapy) and implemented where appropriate. Quality assurance mechanisms for notification should be incorporated into this systems approach.

For *Interval 2*, the Department of Health Statistics Unit should adopt a continuous monitoring function for the interval between date of completion of form and date of receipt. This would be facilitated in a purpose-designed information system. Clinics and hospitals where delays were occurring could be identified quickly. Administrative procedures should be evaluated at these sources of care, explicitly documented and simplified if necessary.

The notification system does not function at present as an *action register* in that it does not routinely use all available sources of data (eg admission, clinic attendance, laboratory reports), in a *continuous* process of identification of under-notification. Routine feedback of such information to all clinicians would heighten awareness of errors, omissions and drift in the handling of notification information. This whole process should have the same status as any other task in clinical management.

Hong Kong should move rapidly to ensure that its notification system becomes the most reliable instrument which can be developed to indicate the population risk of developing tuberculosis. At present the best estimate of the true number of new cases may be under reported by up to 19%. Variation of this magnitude would have major implications for

accurate matching of resources to need. It also has an important bearing on information available to trigger contact tracing for audit of care and evaluation of overall outcomes.

The problem of under-reporting may have affected the reliability of the clinical audit reported in section 6 and other sections. If so then it would be prudent to assume that those not notified had a worse outcome on average than those who were notified.

This survey of notifications was by necessity confined to the public sector but a full and proper overview of tuberculosis care in Hong Kong should now include all aspects of private sector work carried out for patients with tuberculosis.

Key messages and action points

- Quality assurance in the notification of tuberculosis is a vital part of the contribution which clinical services must make to the public health function.

- Notification data in Hong Kong is probably unreliable in that all the evidence points to a significant degree of under-notification. At the highest estimate correction of under-notification could increase current annual estimates by 10%.

- Under-notification was lowest (~3%) in Chest Clinics and highest in Hospitals (~28%). Chest Hospitals may be marginally better than other General Hospitals

- A full review of all aspects of the notification system should be undertaken. Notification should be supported by a continuing process of advice and feedback to clinicians. The review should eventually lead to a comprehensive fail-safe system covering all TB care providers and interfaces between them.

- Urgent priorities include revision and dissemination of guidelines and protocols to all staff. The mandatory nature of notification as part of job descriptions should be emphasised.

- Information technology offers new opportunities to develop a true *systems approach* to notification supported by record linkage between different types and sources of information and continuous feedback to the users.

5.0

OBSERVATIONAL STUDY OF CHEST CLINICS

5.0 OBSERVATIONAL STUDY OF CHEST CLINICS

SUMMARY

Operations of Hong Kong Chest Clinics

- Observational studies of clinic operations were made in three clinics.
- Clinics operate on a walk-in basis with a chit system to determine order in the queue.
- Medical consultations are offered on a morning and afternoon sessional basis 5.5 days per week.
- Referral to a nursing consultation is automatic after the medical consultation for advice and guidance on medication use, side effects and sputum sampling.
- Supervised therapy is offered on an open-door walk-in basis.

Factors associated with variation in provision of services

- The findings of the survey include
    * just under half the patients were seen before the allotted chit time
    * there was considerable variation between clinics
    * the median value for registration time to consultation was about 1 hour. The maximum wait ranged from 2.5 up to 4 hours.
- The median time of medical consultations was 3.95 minutes (interquartile range (IQ) 2.5-6.0; range (R) up to 18.9); nursing consultation 1.5 minutes (IQ 2.1-5.3; R up to 83.2).
- Consultation times did not vary greatly between clinics although some clinics had a wider range. There was consistent and systematic variation between doctors amounting to doubling of consultation times.
- At some sessions 35% of patients spent less than 2 minutes with a doctor and less than 45 seconds with a nurse.
- Nursing consultations included very short encounters (to retrieve the treatment card) to long sessions for patients starting treatment.

Utilization of clinic services

- Over twenty percent of patients attended from work; the proportions varied by clinic and session.
- The proportion of patients with tuberculosis in a Chest Clinic session varied from 7% to 37%.

Performance compared with pledges

- The Department of Health publishes achievements of performance pledges for (1) medical consultations (same day), (2) chest X-rays (within 30 minutes for 90% of patients) and (3) waiting times for supervised therapy (<15 minutes for 90%) are in excess of 99% (Jan 1999).

  This survey confirmed that (1) and (3) are achieved but does not include data on (2).

Conclusions and recommendations

- Clinic operations are an important component of overall acceptability of services to patients. The findings create some opportunities to review and possibly modify working practices in clinics. Factors affecting clinic performance include

  * *number of doctors per session:* the ideal would be to allocate doctors to match the size of sessions but this is likely to be infeasible. A reviewer comments that "tuning between a walk in policy for all patients and a shorter waiting time for individual patients is difficult". However operational studies could continue to be used to examine the impact of different methods of working. Patients scheduled for a visit should have some priority. This may be achievable if walk in services were separate.

  * *registration of patients:* there are both advantages and disadvantages to the present walk-in system; a telephone booking system for same day or next day attendance would provide a planned time of arrival and chit time without unnecessary queuing. The walk-in facility could be retained as this may facilitate compliance for some patients. One reviewer was of the opinion that "a telephone booking and scheduled appointment for treatment follow-up will definitely spread the workload and give better predicted waiting time, while allowing a walk in policy for new cases and treatment complications."

  * *clerks estimates of patients:* the estimates of the number of patients seen per hour should be reviewed and checked.

  * *duration of consultations:* the appropriateness of short consultation times should be reviewed; alternative methods of follow-up should be considered for some patients.

  * sources of variation in practice arising from individual doctors should be identified, discussed and resolved in confidence.

- Variation in incidence between districts could account for some of the variation in proportions of TB patients in different clinics and for the busyness of clinics. The following could be considered as potential interventions to modify workloads and improve care in clinics:

* a short medical consultation might be replaced by a nurse consultation but arguments against include patient expectations and any positive effect of seeing a doctor on adherence to treatment.

* longer intervals between appointments would create scope for longer planned consultations. An arbitrary proportional increase (say 15%) in the length of all follow-up intervals would probably be clinically acceptable and would release clinic time and other resources for the improvement of consultations (Jones and Hedley 1986). This approach could be studied further and evaluated.

* Patient preferences for Mon/Wed/Fri for DOT thrice weekly could be considered as possibly modifiable or working practices changed to accommodate them.

- Operational studies of clinics can provide information on performance to complement clinical audit of patient management.

5.1 INTRODUCTION

In order to estimate the resource use, both direct and indirect, associated with treating patients for tuberculosis, it is necessary to have some indication of the time spent by clinical staff in treating patients, and the time patients spend travelling and attending the clinic. Clinic staff provided estimates for some of these variables, but in order to increase the validity of the estimates, an observational study was performed on a representative group of patients.

5.1.1 Background:

5.1.1.1 Organisation of chest clinics

Chit system: There is no fixed appointment system at chest clinics. Patients are seen on a walk-in basis. In August 1995, a chit system was introduced in all clinics except mobile clinics. On registration patients are given a chit (a small piece of paper) specifying the hour (eg 10 to 11, 2 to 3) within which they can expect to be seen by the doctor. Chits are issued on a first come, first served basis. Clerks estimate the approximate number of patients that can be seen by the doctor each hour to decide how many chits to distribute. After receiving the chit, the patient may require a chest X-ray. Patients can decide whether to remain at the clinic or to return at the beginning of the hour specified on the chit. Most patients decide to stay and, if other patients are seen more quickly than anticipated, they may be seen earlier than the chit time. There is no telephone booking system, except for a few patients from old-age homes.

A modified version of the chit system is used by at least one clinic (clinic C in this study). Patients are given a chit time of exactly one hour after they have registered.

Registration system: As an example, the registration desk at one clinic is open from 8.30am to 12.45pm and 1.45pm to 4.45pm. The period from 8.30 to 9.00am is for patients who may need a chest X-ray because the first doctor's appointment is not until 9.00am.

Medical consultations: At the same clinic, these run from 9am to 1pm and 2 to 5pm on Monday to Friday and from 9am-1pm on Saturday. Patients receiving treatment for tuberculosis are asked to come back for routine visits at monthly intervals during treatment. They are not, however, given a specified date. Because there are no fixed appointments, there may be considerable variation in the number of patients seen per session. For example, a large number of patients usually attend on the first day after a public holiday. Clinics tend to be busier in the mornings than the afternoons, and on Mondays and Fridays. If there are more doctors working in a particular session, a greater number of patients attend.

Nursing consultations: Patients with tuberculosis are automatically referred to the public health nurse after the medical consultation. At their first visit, the side-effects of treatment and treatment card system are explained, they are observed after taking their first dose of medication and taught how to produce sputum samples. Patients are also seen throughout treatment, for example if treatment is modified.

Supervised therapy: There is no appointment system, and patients can just walk in to the clinic to receive supervised therapy.

Performance pledges: The Department of Health publicises a number of performance pledges relating to the TB & Chest Service. The results for January 1996 are:

• 90% of patients seeking medical consultation to be seen on the day of registration	99.6 %
• chest X-ray to be taken within 30 minutes after registration for 90% of patients in government full-time chest x-ray units	99.1%
• waiting time for taking supervised anti-tuberculosis treatment in full-time clinics to be under 15 minutes for 90% of patients	100%

5.1.2 Aim and objectives

Aims: To estimate staff time and patient time involved in treatment of patients with tuberculosis, and identify variation in practice and possible factors explaining that variation. The objectives were:

1. To estimate total waiting time of patients attending with tuberculosis, and identify components of the waiting time, and factors associated with variation in waiting time.
2. To estimate medical and nursing consultation times for patients receiving treatment for tuberculosis, and identify factors associated with variation in duration of consultation.
3. To estimate time spent by patients receiving directly supervised therapy.
4. To estimate proportions of patients attending from work and from home, and for patients attending from work, distance between work and clinic.

5.2 METHODS

5.2.1 Sampling of clinics

There are 11 full-time chest clinics distributed throughout the SAR. These were stratified according to the number of patients seen per doctor session. Three strata were formed: highest, intermediate and lowest tertiles (Table 5.1). One chest clinic was then selected from each stratum, resulting in three chest clinics in the sample, one from each region.

Table 5.1: Stratification of chest clinics according to mean number of patients seen per doctor session

clinic	region	patients/dr session Nov 1995 to Jan 1996
1		37
2		32
3 (Clinic A)	**Hong Kong Island**	**31**
4		31
5		30
6		30
7 (Clinic B)	**Kowloon**	**29**
8		29
9		28
10 (Clinic C)	**New Territories**	**26**
11		23

5.2.2 Sampling of patients attending clinics:

A minimum of two observers attended each of the three clinics on one busy day, one quiet day and, for Clinic C only, Saturday. Busy and quiet days were defined by clinic staff according to the expected number of patients which was, in turn related to the number of doctors working at the clinic. The two observers from the survey team arrived prior to 8.30am and stayed until the last patient left in the afternoon.

5.2.2.1 Waiting times: sample 1

On registration, the patient was given a chit (a small piece of paper) which had marked on it the time that the patient was expected to see the doctor, referred to subsequently as the *chit time*. The patient's *registration time* was also recorded on the chit by the registration clerk. The time that the patient actually saw the doctor was then marked on the chit by the nurse (*actual doctor time*). The chits were then attached to the front of the medical record.

At the end of the day, the medical records of all patients attending the clinic were reviewed by the observers to identify patients receiving treatment for tuberculosis. The *chit times*, *registration times* and *actual doctor times* for these patients were recorded.

5.2.2.2 Consultation times: sample 2

The two observers sat in the waiting room of the chest clinic. One observer noted the duration of all medical consultations. *Start time* was recorded as the time that patients entered the consultation room, and *end time* as the time that patients left the room.

Simultaneously, the second observer interviewed all patients as they came out of the medical consultation room, in Cantonese or English as appropriate. After introduction and explanation, patients were asked questions to determine whether or not they should be included in the study. To be included, they had to be receiving treatment for tuberculosis (patients who had temporarily stopped taking their drugs were included). If patients were included they were asked whether they had come to the clinic from work or home, and if from work which district of Hong Kong they worked in. Finally, study patients were asked if they were going to see the nurse.

For these patients, the duration of their consultation with the nurse and, if appropriate, time taken for supervision of treatment were noted. These were recorded by observing times that the patient entered and left the relevant room. The order of staff contact in the clinic was almost invariably: doctor, nurse then supervised treatment.

5.3 RESULTS

5.3.1 Waiting times: sample 1

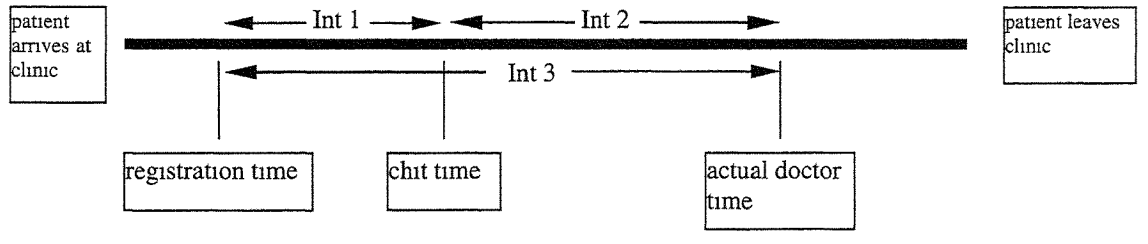
Waiting times were recorded for a total of 150 patients receiving treatment for tuberculosis at three clinics for two whole days at each clinic and one half day at clinic B (Saturday). The number of patients included from each session is shown in Table 5.2.

Table 5.2: *Number of patients included in study from each clinic session*

session	clinic A	clinic B	clinic C	total
busy morning	17	22	27	66
busy afternoon	10	12	11	33
quiet morning	15	6	7	28
quiet afternoon	3	0	2	5
Saturday morning	NA	18	NA	18
total	45	58	47	150

The following intervals were calculated from "registration time", "chit time", and "actual doctor time":

- interval 1 from registration time to chit time (Int 1)
- interval 2 from chit time to actual doctor time (Int 2)
- interval 3 from registration time to actual doctor time (Int 3)



The following values (in decimalised hours) were obtained for these intervals:

interval	median	interquartile range	full range
interval 1	1.00	0.77 to 1.13	-1.47 to 2.98
interval 2	0.05	-0.51 to 0.42	-0.88 to 1.78
interval 3	0.94	0.50 to 1.28	0.04 to 3.65

The negative minimum value for interval 1 reflects a patient who was given a chit for the hour prior to registration. The negative 25% centile value for interval 2 reflects the fact that just under half of patients were seen before their allotted chit time.

5.3.2 Variation between clinics

Interval 1: There was little variation between clinics for interval 1. Interval 1 is fixed at one hour by the registration clerk for clinic C, and as expected, there was least variation at this clinic (Figure 5.1).

Interval 2: Clinic C had a substantially shorter median value for interval 2, the median value actually being negative, reflecting the fact that all patients were seen before their allotted chit time, that is, less than one hour after registration. At clinics A and B, all patients should have been seen within one hour of their chit time, and only four patients at clinic B were not. At these two clinics, 25% were seen before the allotted chit time (Figure 5.2).

Interval 3: The median value for interval 3 for clinics A and B was approximately one hour, but was slightly longer at clinic A. At clinic A, approximately 50% of patients waited between one and two hours from registration, the maximum wait being nearly four hours. At clinic B, most patients were seen in just over one hour and the maximum wait was approximately 2.5 hours. At clinic C, the median value was approximately half an hour and all patients were seen within one hour of registration (Figure 5.3).

Interval 3: variation between busy days and quiet days, and between morning and afternoon sessions

On busy days, at clinics A and B the wait to see a doctor was longer in the afternoon, whereas on quiet days, the afternoon wait was shorter (clinic A only) (Figures 5.4 and 5.5). At clinic C, however, the afternoon waits were shorter on both days (Figure 5.6). In all three clinics there was not much variation in morning waits between quiet and busy days.

The wait at clinic C was shorter than at the other clinics for all types of session.

Interval 3: variation according to hour of registration

Registration times were analysed according to the hour of registration, for example, if a patient registered at any time from 8.00am to 8.59am, the registration hour was recorded as 8.00. At clinic A, there was considerable variation in the waiting time to see the doctor according to the hour in which the patient registered with the longest waits for patients registering late morning (Figure 5.7). At clinic B, waiting times were shorter but peaked in the early morning and early afternoon. This may reflect the larger number of people waiting to register in the early morning. At clinic C there was very little variation throughout the day.

5.3.3 Consultation times: sample 2

A total of 763 interviews were performed. Of these, 168 patients (22.0%) were receiving treatment for tuberculosis. The number of interviews performed at each session, and proportion of patients with tuberculosis is shown (Table 5.3).

Figure 5.1: *Interval from registration to chit*

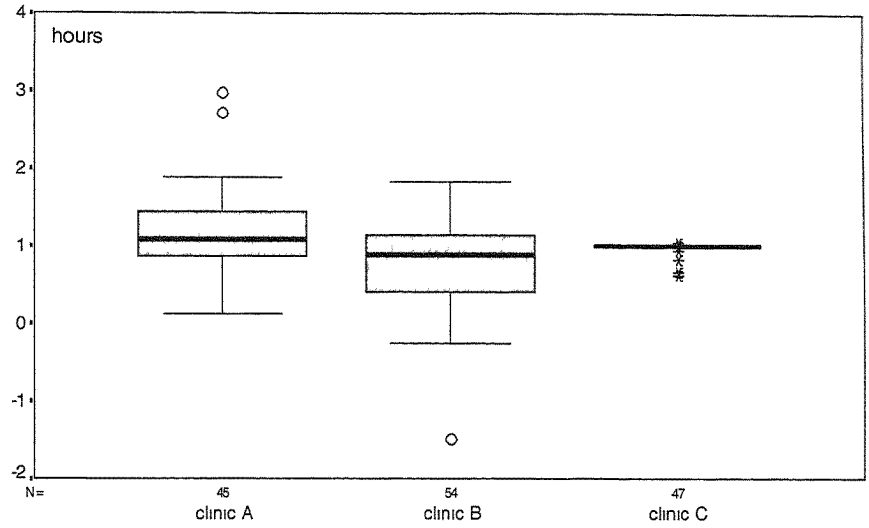


Figure 5.2: *Interval from chit to seeing doctor*

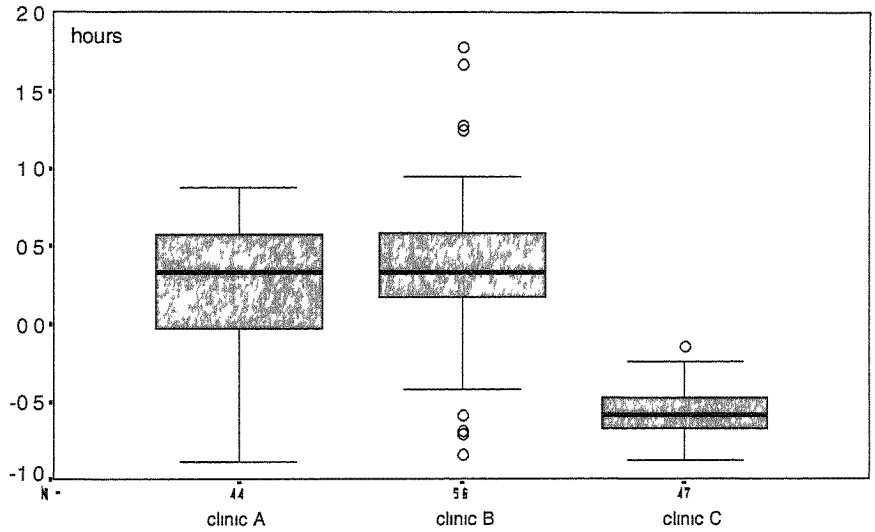


Figure 5.3: *Interval from registration to seeing doctor*

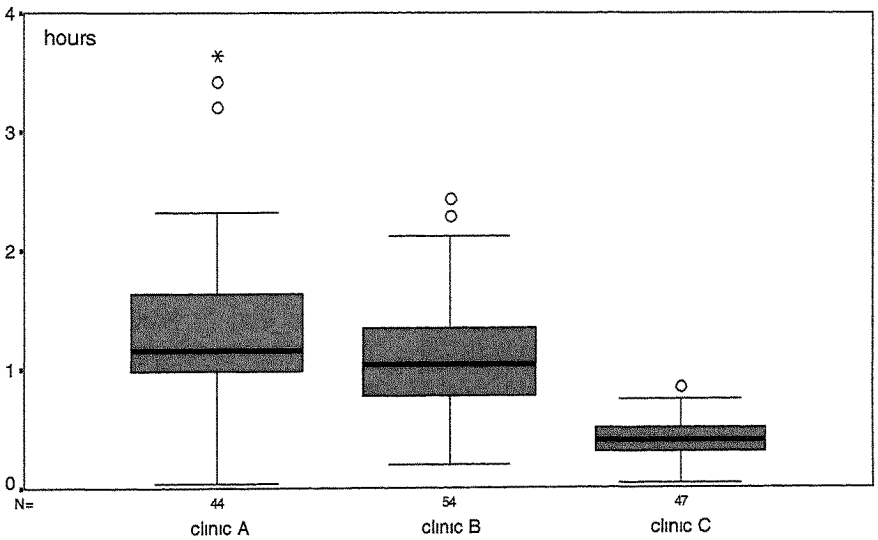


Figure 5.4: *Interval from registration to seeing doctor for Clinic A*

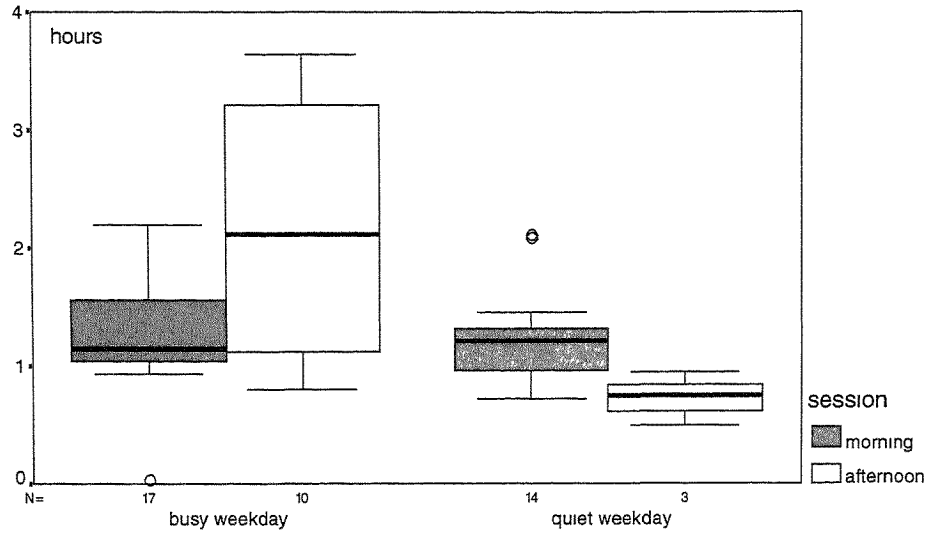


Figure 5.5: *Interval from registration to seeing doctor for Clinic B*

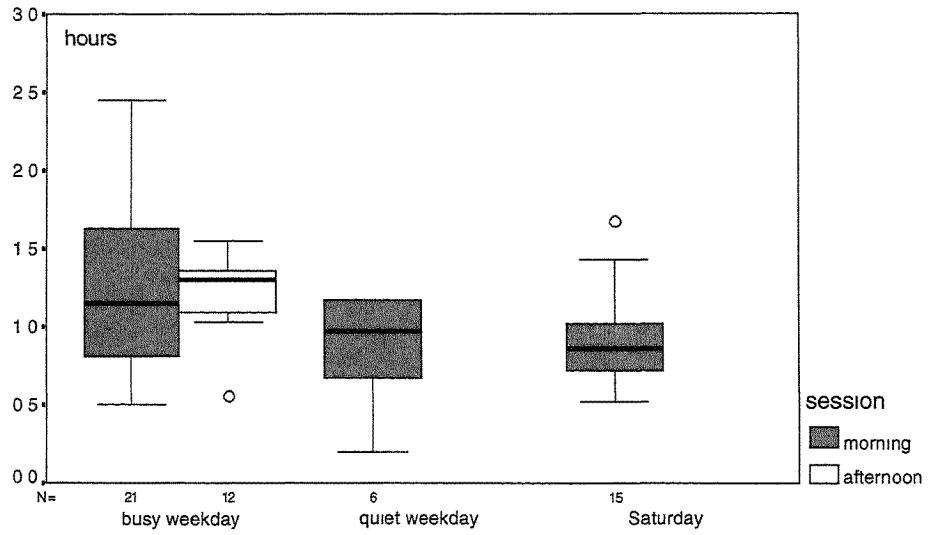


Figure 5.6: *Interval from registration to seeing doctor for Clinic C*

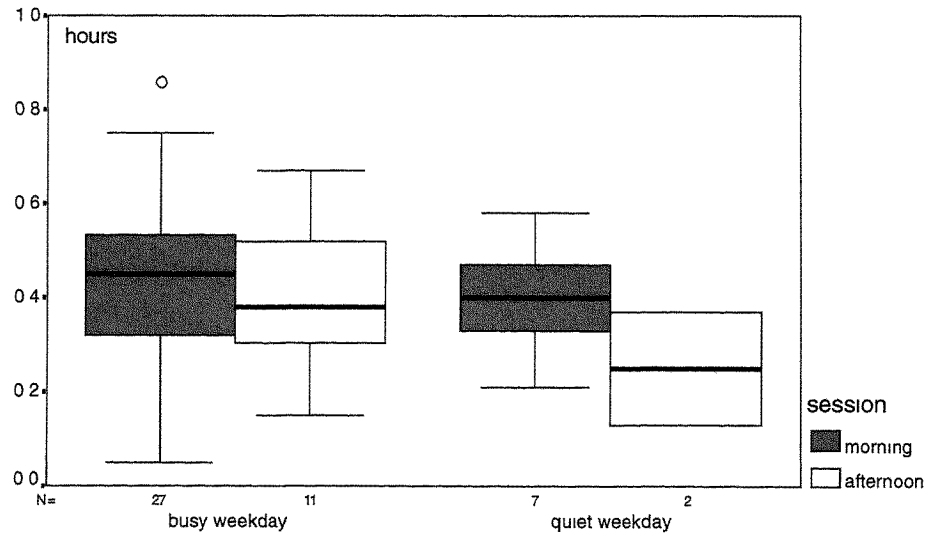


Figure 5.7: *Interval from registration to seeing doctor*

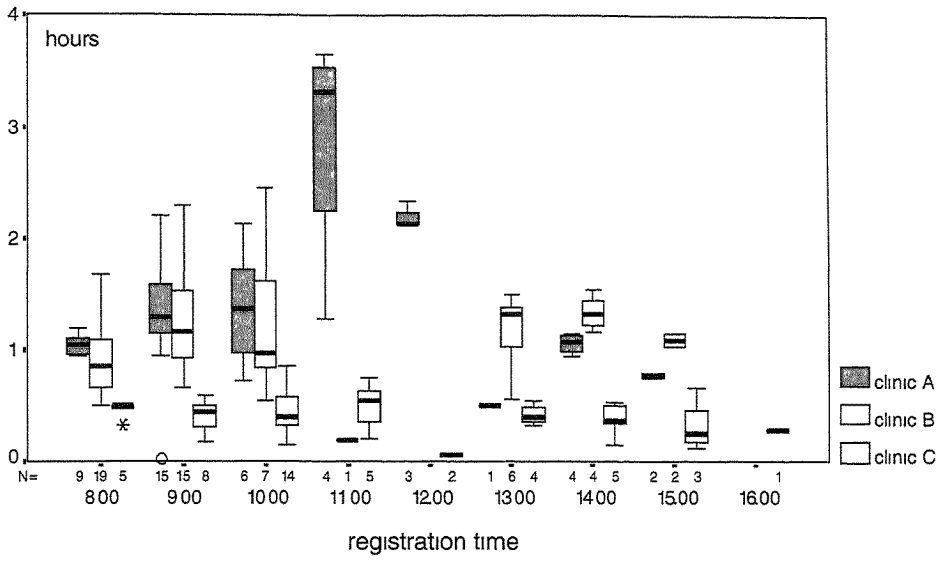


Table 5.3: *Number of patients interviewed (% with tuberculosis)*

session	clinic A	clinic B	clinic C	total
busy morning	75	120	76	271
	(21.3)	(17.5)	(36.8)	(24.0)
busy afternoon	50	61	35	146
	(26.0)	(24.6)	(37.1)	(28.1)
quiet morning	70	80	30	180
	(25.7)	(7.5)	(23.3)	(17.2)
quiet afternoon	24	44	19	87
	(20.8)	(11.4)	(15.8)	(14.9)
Saturday morning	NA	79	NA	79
		(22.8)		(22.8)
total	219	384	160	763
	(23.7)	(16.9)	(31.9)	(22.0)

Consultation times were recorded for 167 of these patients. The number of patients included from each session is shown (Table 5.4).

Table 5.4: *Number of patients included in study from each clinic session*

session	clinic A	clinic B	clinic C	total
busy morning	16	20	28	64
busy afternoon	13	15	13	41
quiet morning	18	6	7	31
quiet afternoon	5	5	3	13
Saturday morning	NA	18	NA	18
total	52	64	51	167

Clinics A and C had similar numbers of patients with tuberculosis, but the proportion of tuberculosis patients at clinic C was greater.

Of the 167 patients, 114 (68.3%) were men, and 140 (83.8%) were asked to see the nurse after the medical consultation. The following values were obtained for the duration of patient contacts with clinical staff (Table 5.5).

Table 5.5: Median values (interquartile range) for patient contact times (decimal minutes)

type of contact	median	interquartile range	full range
medical consultation	3.95	2.54 to 6.06	0.33 to 18.92
nursing consultation	1.50	0.71 to 4.10	0.03 to 89.00
treatment supervision	3.13	2.10 to 5.29	0.03 to 83.20

5.3.3.1 Duration of medical consultation

The duration of medical consultations was normally distributed except for a few patients with very long consultations (Figure 5.8).

Variation between clinics: Medical consultation times did not vary greatly between clinics, although there was a wider range at clinics B and C (Figure 5.9).

Variation between doctors within a clinic session: There was evidence for consistent variation between doctors at each clinic. This was examined by analysing medical consultation times for a specific session by room number: for example, at clinic C, on the busy day, the doctor in room 2 spent longer than the doctor in room 1 in both the morning and afternoon sessions. The difference in the median values were approximately 3 and 5 minutes respectively (Figure 5.10).

Variation between sessions: Overall, patients spent shorter times with the doctor in the morning compared to the afternoon, but there was little difference between quiet days and busy days. A similar pattern was observed at each clinic (Figure 5.11).

Figure 5.8: Duration of medical consultation

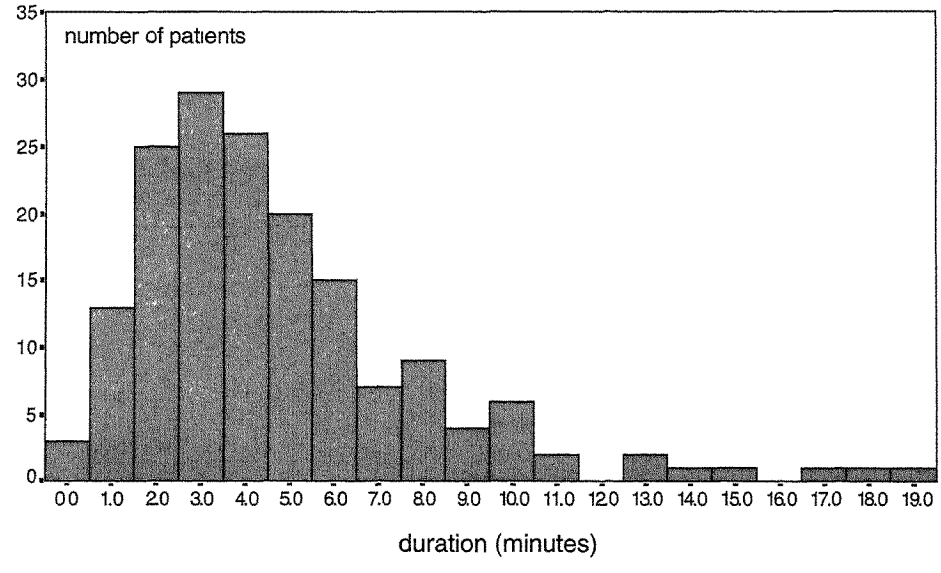


Figure 5.9: *Duration of medical consultation*

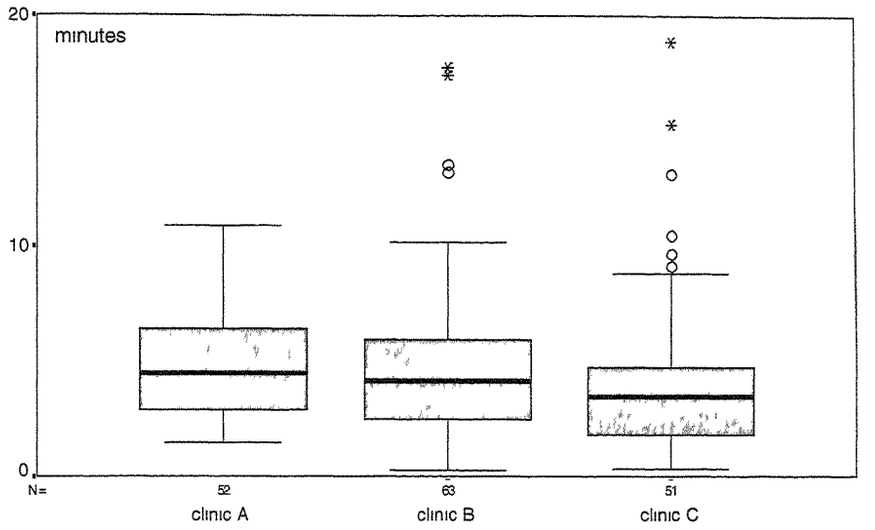


Figure 5.10: *Duration of medical consultation on busy day at clinic C*

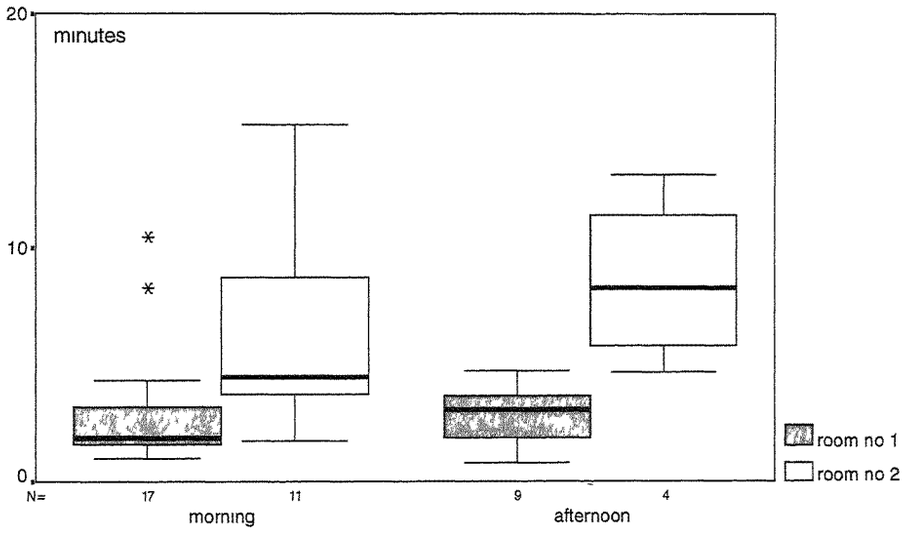
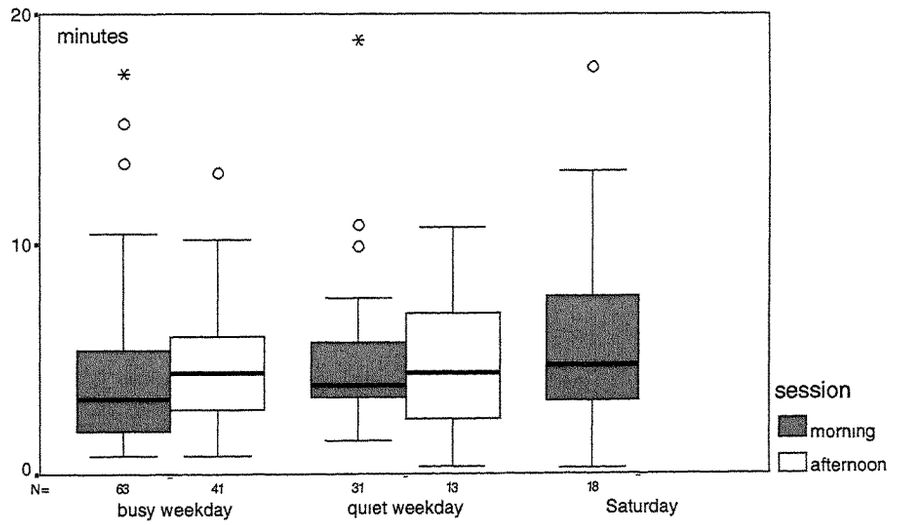


Figure 5.11: *Duration of medical consultation, all clinics*



Variation between men and women: There was no difference between the sexes apart from at clinic C, where women spent longer with the doctor than men (Figure 5.12).

5.3.3.2 Duration of nursing consultation

The majority of patients had very short consultations (less than 2 minutes) with the nurse. Observers noted that the reason for these short consultations was usually simply to retrieve the patient's treatment card.

A few patients had much longer sessions with the nurse. These were largely accounted for by patients who were starting their treatment that day, who had to have the treatment explained to them, their visual acuity checked, details for contact tracing noted and receive health education (Figure 5.13).

Variation between clinics: There was little difference in the median value between the clinics, although in clinic B values were slightly higher and there was more variation (Figure 5.14).

5.3.3.3 Duration of treatment supervision

For the majority of patients, supervision of treatment took five minutes or less, but for a few patients it took between 10 and 20 minutes, and for one, over an hour (Figure 5.15).

Variation between clinics: There was little difference in the median value between the clinics, although in clinic B a greater proportion of patients took longer to receive their treatment.

Figure 5.12: Duration of medical consultation

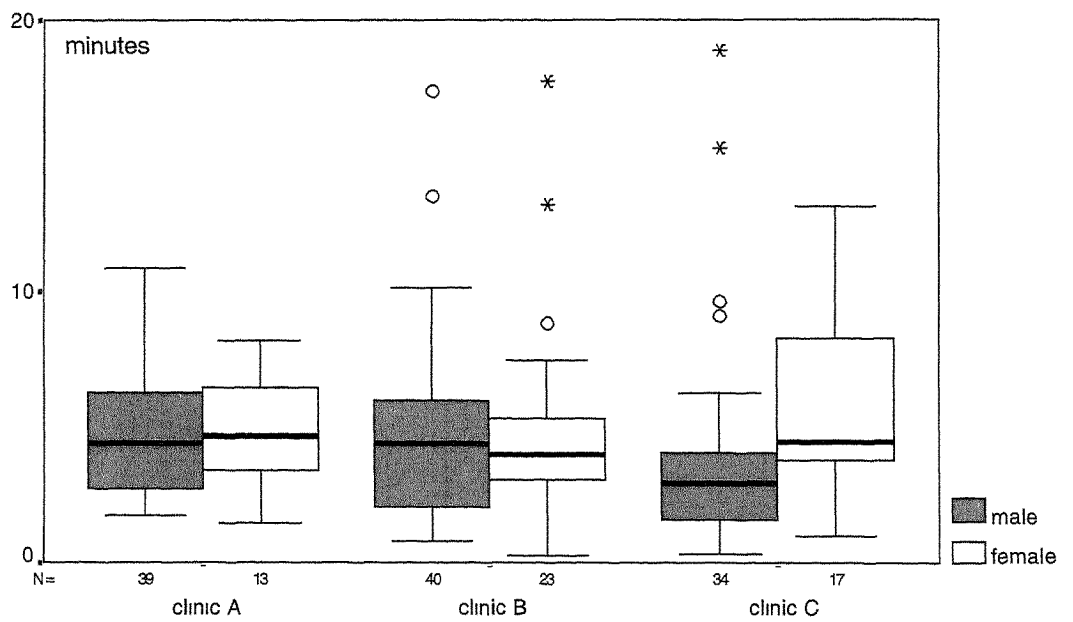


Figure 5.13: *Duration of nurse consultation*

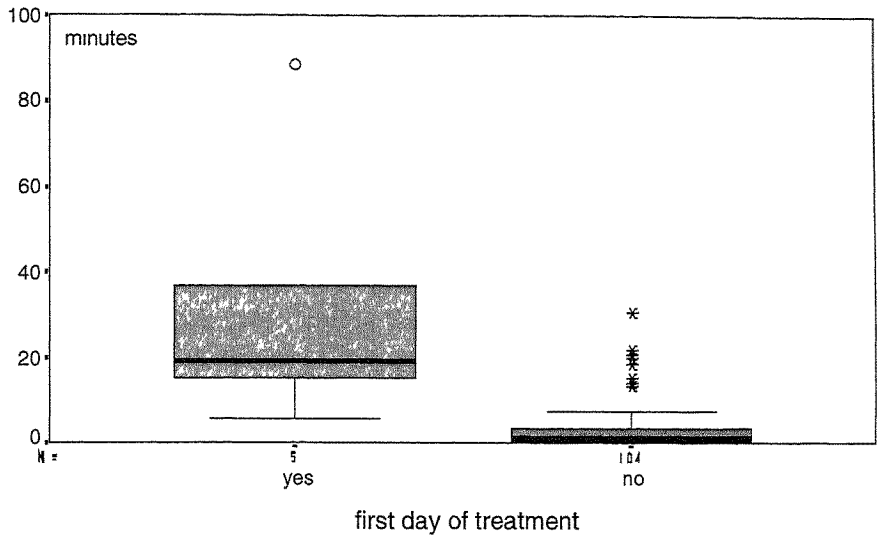


Figure 5.14: *Duration of nurse consultation*

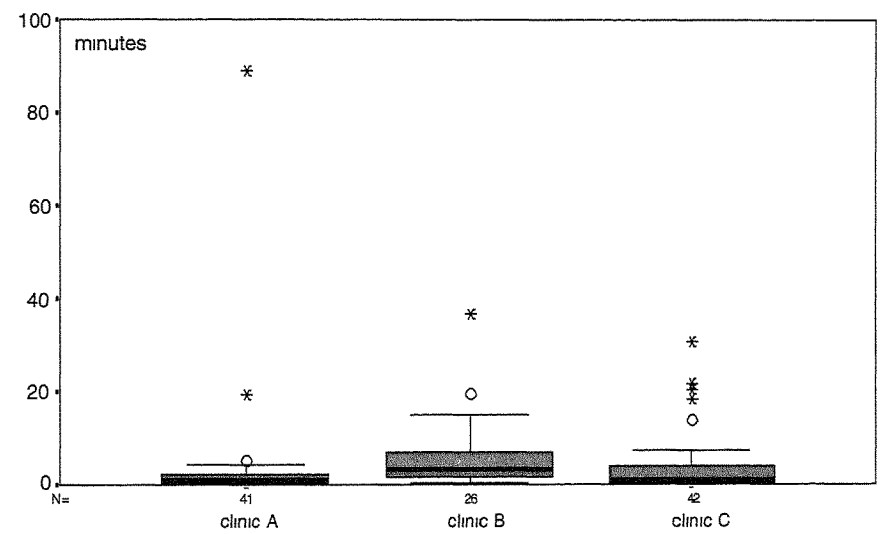
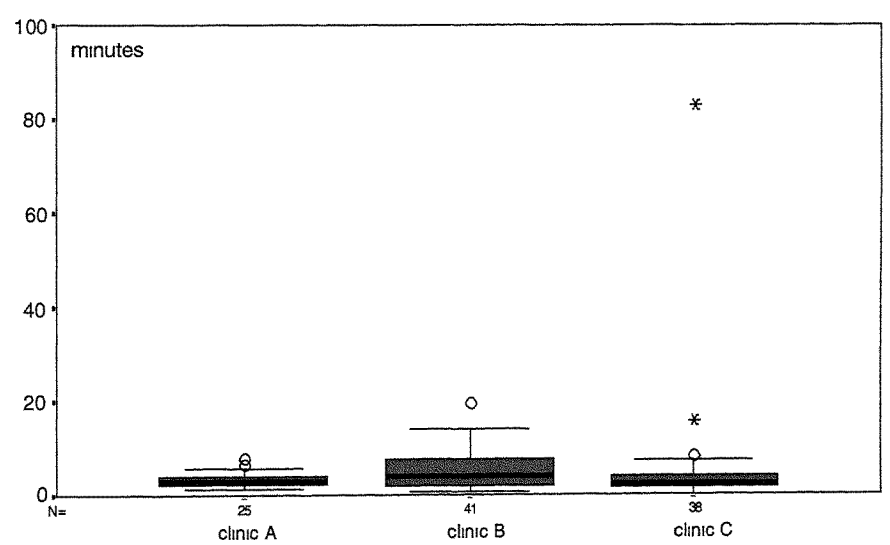


Figure 5.15: *Duration of supervised treatment*



5.3.4 Proportion attending clinic from work and home

Of the 168 patients interviewed who were on treatment, 36 (21.4%) were attending the clinic from work. The proportion varied between clinics and sessions.

Table 5.6: *Number (%) of patients with tuberculosis attending the clinic from work*

session	clinic A	clinic B	clinic C	total
busy morning	2	3	3	8
	(12.5)	(14.3)	(10.7)	(12.3)
busy afternoon	6	8	5	19
	(46.2)	(53.3)	(38.5)	(46.3)
quiet morning	3	0	2	5
	(16.7)		(28.6)	(16.1)
quiet afternoon	1	1	1	3
	(20.0)	(20.0)	(33.3)	23.1)
Saturday morning	NA	1	NA	1
		(5.6)		(5.6)
total	12	13	11	36
	(16.9)	(20.0)	(21.6)	(21.4)

5.4 DISCUSSION

Two samples of patients were identified for the two components of this study using different sampling techniques. In theory, the two should have been identical, but in practice, 17 fewer patients were identified for sample 1 than sample 2. This is most likely to be due to the fact that not all of the medical records were available for review, especially those belonging to afternoon patients. However, it is also possible that some patients in sample 2 responded incorrectly to the question about tuberculosis treatment, either because they did not understand, or because they did not want to discuss their illness in the waiting room. The risk of the former was minimised by careful phrasing of questions (which were designed to confirm previous responses) and because patients were also asked if they had a pink treatment card which is unique to patients with tuberculosis. The risk of the latter cannot be accurately estimated, but nearly all patients seemed willing to answer the questions, and in addition, if this were the case, it would have had the opposite effect of making sample 2 smaller than sample 1. It is also possible that a few patients who should have been included in sample 2 were missed because the interviewer was busy talking to another patient. However, very few patients were missed in this way.

The proportion of patients interviewed who were on treatment for tuberculosis varied greatly from 7.5% to 37.1%, both between clinics, and between busy and quiet days and morning and afternoon sessions. Most patients on thrice-weekly DOT prefer to come to the clinic on Mon/Wed/Fri rather than Tues/Thurs/Sat since the Saturday clinic ends at lunchtime rather than 7 pm. This may explain some of the variation between busy and quiet days. Patients may also prefer to see particular doctors. Some clinics might see patients with a wider range of conditions, perhaps because their services are more widely publicised.

The proportion of patients in sample 2 who were men (68.7%) was almost identical to that for annual notifications in 1994 (68.0%). This provides evidence that the sample was representative of the clinic population receiving treatment for tuberculosis.

5.4.1 Waiting times

Variation in practice between clinics: The most consistent difference between clinics was that the interval between chit time and actual doctor time was considerably reduced for clinic C, and that all patients were seen before the allotted chit time. Clinic C had a slightly modified version of the chit system, in that patients were automatically given a chit time for an hour after registration. Staff did report that if too many patients had registered at the same time, they would have had to revise the chit time to two hours, although this did not happen on the days of observation. Clinic C had the fewest patients (160 over 2 days compared with 219 for clinic A and 305 for clinic B) which means that there was less pressure on the queuing system for patients which may explain the shorter waiting times.

At clinic A, long waits between registering and being seen by a doctor were observed for patients registering in the late morning. This was caused by the morning clinic being full, and the patients being asked to return to the afternoon clinic. In contrast, the variation in waits at clinic B appeared to be caused by the increased number of patients registering in the early morning and afternoon. The clinic capacity was reached, and these patients had to wait longer to see the doctor. By late morning and afternoon the doctors had managed to clear the backlog, and the waiting times reduced.

Some of the longer waits might be explained by patients failing to return to the clinic at the allotted time, and not being there when they were called to see the doctor.

5.4.2 Consultation times

These were calculated from the entrance and exit times. However, these might not reflect the actual time the doctor or nurse spent managing the patient, although they were with the patient at all times. In some cases, the patient's consultation was split into two or more periods: in these cases the final consultation time was calculated as the sum of the individual consultations.

Although the doctor in charge of the clinic and the chief nursing officer were fully informed, remaining doctors and nurses were not told anything about the study in an attempt to minimise behaviour change.

5.4.3 Medical consultation times

Wide variation in the medical consultation times was observed. Potential reasons for this variation include:

- doctor-related factors: differences between individual doctors in level of experience and personality.
- number of patients waiting, which is in turn related to:
    - size of clinic population and number of doctor sessions
    - external factors such as public holidays and the weather
    - accuracy of prediction of chit system
- patient-related factors: stage of treatment and presence of co-morbidity, side-effects of treatment or complications of tuberculosis. Patients may attend simply to request drugs to take away whilst traveling, and this may require only a very short consultation. Women appeared to have longer consultations at one of the clinics.

There is no gold standard for medical consultation times: shorter and longer consultations are appropriate for different patients. Patients, in general, tend to prefer longer consultations. The data obtained from this study do, however, indicate areas where current practice might be reviewed. For example, at some sessions, 25% of patients spent less than two minutes with the doctor. The reasons for these very short consultations were not identified. It may, however, be possible to replace some of these appointments with other forms of care, for example, a nurse triage system or telephone follow-up.

It appears that a considerable part of the variation in medical consultation times can be attributed to the doctors themselves. At any one clinic session there are likely to be doctors with differing experience and personalities. Variation in consultation times resulting from these personal characteristics will always exist.

Medical consultation times tended to be longer in the afternoon when there were fewer patients and perhaps less pressure on the doctors. An individual appointment or block booking system might help to spread the load of patients throughout the day, and allow doctors greater flexibility in the time they give to each patient.

5.4.4 Nursing consultation times

A quarter of patients spent less than 45 seconds with the nurse. Anecdotally, it appears these patients were seeing the nurse only to receive their patient-held treatment card, which had been attached to the medical record after they had seen the doctor. It may be that the nurse reviews the card before seeing the patient in order to evaluate their compliance.

5.4.5 Supervised treatment

The duration for supervised treatment was not observed for all patients in the study. For some, it was not possible to observe them whilst observing other patients. For others, they did not receive supervised therapy, either because they were receiving it from another clinic, or their treatment was semi-supervised or unsupervised.

5.4.6 Proportion of patients coming from work

Overall, approximately 20% of patients attended the clinics from work. The proportion was similar for each clinic, but was highest for each clinic on the busy afternoons, and higher in the afternoon than the morning for all sessions.

If 20% of patients with tuberculosis are attending the clinic from work, the travel time, waiting time and staff-contact time represent substantial patient-related costs in terms of time away from work and potentially in lost wages. In addition, for many of those attending from home, there may be hidden costs such as child care.

5.4.7 Comparison with service pledges

It is not possible to compare the data from this study directly with that obtained for monitoring the Department of Health service pledges. However, the study did not identify any patient who was not seen on the day of registration, and from informal observation it seems very likely that 100% of patients received their supervised treatment within 15 minutes.

5.4.8 Variables not identified

Waiting time and contact time for chest X-rays and blood tests were not observed. However, it appears that most patients receive their chest X-ray examination after registering and before seeing the doctor, although a few will require additional X-rays after seeing the doctor. Blood tests are performed in the same room as the supervision of treatment, and may account for some of the longer supervised treatment times.

5.5 CONCLUSIONS AND RECOMMENDATIONS

1. The various factors which influence the two components of the total waiting time are summarised in Table 5.7.

Table 5.7: Factors affecting intervals 1 and 2

factor affecting interval	interval 1 (fixed for clinic C)	Interval 2
number of patients registering per unit time	yes varies by session and throughout session can be predicted for each session (busy versus quiet) ? possible to predict throughout session	? no does not affect interval if clerks accurately estimate number of patients each doctor will see per hour
number of doctors per session	yes fixed for each session	no taken into account when estimating chit times
medical consultation times	yes clerks use advance prediction to estimate how many patients can be seen in one hour	yes if actual medical consultation time differs from predicted, then interval 2 will increase or decrease
patient-related factors	no	yes for example, if patients fail to return to the clinic at their allotted time

Interval 1 may not be considered as a component of the waiting time by the clinic, because the patient is given the option of leaving the clinic. From the patient's perspective, however, it is an important component. It is dependent on factors which are fixed (number of doctors per session), outside the control of the clinic (the number of patients registering per unit time) or dependent on previous experience (the medical consultation prediction). However, these factors can influence the size of interval 1. For example if many patients

arrive at the same time or if clerks under or over-estimate the number of patients which can be seen per hour.

Interval 2 is, by contrast, more directly dependent on human factors which are amenable to change. It depends largely on the ability of the clerk to accurately estimate the number of patients which can be seen per hour, and the duration of the medical consultation which is largely determined by the doctor.

2. There is a complex relationship between the number of patients attending the clinic, the range of time over which they register, and the working practices of the individual doctors. If a lot of patients register at any one time, waiting times will increase, and doctors may shorten consultations times slightly to compensate. If medical consultations are not shortened, waiting times may remain high for the rest of the session, and this may result in patients being referred to subsequent sessions, as occurred in clinic A.

3. The opportunities to modify the working practices in the clinics can be considered in the following terms:
   - *number of doctors per session:* the number of doctors is limited and the current distribution is sensitive to the needs of each clinic. It may be difficult to allocate doctors exactly according to the size of the clinic population.
   - *number of patients registering per unit time:* the advantages and disadvantages of a walk-in system such as this should be compared with a block booking or appointment system. The current system can result in variation in patient load, but does give the patient more flexibility in deciding when to attend the clinic. Alternative systems might reduce variation, but equally, patients might be more likely not to attend their scheduled appointments. A compromise might be to allow telephone booking for clinics on the same day. This telephone booking would be the equivalent of registration, but patients would not need to attend the clinic until the specified chit time.
   - *accuracy of clerks' estimates of number of patients seen per hour:* this should be reviewed.
   - *duration of medical consultations:* the appropriateness of shorter consultations should be reviewed, and alternative methods of follow-up considered.

Key messages and action points

- A review, such as that carried out here, provides a basis for considering improvements to procedures in clinics.

- There was considerable variation between clinics in the delivery of care, some of which may be attributable to local population factors but sources of variation arising from individual doctors should be identified and resolved in confidence.

- Performance in delivering care met the Department of Health pledges for medical consultations and waiting times for supervised therapy.

6.0

EVALUATION OF TREATMENT OF A COHORT OF PATIENTS

6.0 EVALUATION OF TREATMENT OF A COHORT OF NOTIFIED PATIENTS

SUMMARY

Identification of the cohort

- The statutory notifications database was used to sample a set of 454 consecutive notifications of patients with tuberculosis dated between 1st Dec 1994 and 31st Dec 1994 or undated but received during that period.

- The sample size was determined on the basis that the expected proportion, among those requiring admission, in each of four case-mix categories was 10%; then 443 patients would be required to estimate a proportion of this order with absolute precision of 2.7% and 95% confidence.

Characteristics of the sample

- The sample, which is considered to be representative (but may be biased in terms of all TB patients if notification is incomplete), had a majority of males (68%), younger people (64% <59 years), Kowloon and New Territories residents (77%). Forty two percent lived in public housing and most of these (79%) in Group A housing.

- The majority were notified from chest clinics (72%) or chest hospitals (23%), but at least five other categories of services notified patients.

- Most patients (93%) had tuberculosis of the respiratory system.

- Eighty percent were symptomatic at the start of treatment, 18% were not and 1.5% did not start treatment.

- 396 (88%) had an initial chest x ray consistent with tuberculosis; 27% had a positive smear and 55% had a positive culture. No results were available for 10%.

- Drug resistance on initial testing was found for Streptomycin (10%), Isoniazid (5%), Rifampicin (2%), Ethambutol (0.4%) and Pyrazinamide (1 case); 13/240 (5.3%) were resistant to 2 or more drugs. A past history of TB was associated with resistance to one or more drugs.

Outcomes of treatment

- Full adherence to the treatment was recorded for 67%; 13% defaulted intermittently, 6.5% for varying periods and 6% were completely lost to follow-up for a variety of reasons.

- At one year 69% had a record of complete treatment and follow-up. Other outcomes included revised diagnosis, migration, still on treatment, follow-up ceased (lost to follow-up), and death.

- In terms of IUATLD outcomes, 109/409 (27%) patients had initial smear positive pulmonary disease. Of these, 67% became smear negative; 0% remained positive and the outcome is unknown in 8% and the remainder did not complete treatment; 271/396 (68%) of initially abnormal X-rays had improved on completion of treatment; 10% showed no change and 1% had deteriorated.

Records and provision of care

- A total of 2012 episodes of care were identified for the 454 patients. Records for 90 (4.4%) episodes could not be accessed because records were not found, were not complete or maintained, or permission was not granted.

- Most (64%) care was provided in an ambulatory setting (1293 episodes) and the remainder in hospitals (718 episodes). However most patients (62%) were admitted to hospital at some stage of their management. A continuing review of current and future bed care needs for TB patients is indicated.

- The median length of stay as an inpatient was 9 days (interquartile range 4-18 days); 90% of values were below 30 days, indicating that many admissions may be avoidable.

- Out of 2012 identified episodes pre-treatment, treatment and post-treatment, pre-treatment amounted to 627 (31%) and treatment to 1328 (66%).

- Studies on the process of care identified delays in the period of

*	first presentation to laboratory diagnosis	median : 33 days	Range 0 - 322
*	laboratory diagnosis to start of treatment	median : 20 days	Range -179 to 147
*	start of treatment and notification	median : 6 days	Range -134 to 215

- Smear positive patients who presented to a PP or GOPD experienced longer delays in treatment.

- The majority (66%) received chest clinic supervised directly observed therapy (DOT) but a substantial proportion received other regimens including semi-supervised (19%) and other supervised (10%). The need to increase DOT should be examined further.

- The recorded duration of treatment showed wide variation from 11 to 550 days with a median of 6.5 months (interquartile range 6.1-9.2). The distribution was bimodal with peaks at 6 and 9 months; 7/9 patients with treatment less than 120 days had a revised diagnosis.

- Medical work was characterised by a high level of referral between sources of care at all stages of patient management. In a total of 1523 referrals 1258 (83%) were referrals to a different source of care, 122 (8%) were between chest clinics and 143 (9%) patients were self-referrals. Most referrals (85%) were for tuberculosis management and 14% for another condition.

- Complications were identified in 534 (27%) episodes. The most frequent complications were haemoptysis (49%) and pleural effusion (32%).

Conclusions and recommendations

- The audit revealed the dominant clinical procedures and patterns of care associated with them; it also identified at-risk groups and the possible or probable numbers at risk from delays in treatment, losses to follow-up and other poor outcomes.

- The findings suggest that, once treatment begins, the quality of service provided to most individual patients who stay in the system is good.

- Potential problems in the management of a population of patients with tuberculosis may arise because of

    * multiple levels and sites of care between two sectors and three providers of health care in Hong Kong
    * frequent referrals between sites, levels and sectors of care
    * lack of explicit agreed criteria, guidelines and protocols for different aspects of management
    * lack of an integrated clinical information system based on protocols to support notification, patient management and audit.

  The principal shortfalls in management are related to

    * lack of availability and completeness of information for an audit such as this one.
    * delays in starting treatment which may be associated with preventable transmission of TB to others in the population
    * inefficient procedures for notification, information exchange and record linkage
    * incomplete follow-up and adherence to treatment for a large minority of patients

- Future planning and development of services should focus on problems which arise in important marginal groups of patients. In addition to harm to the individual patients, discontinuity in their care of some of these patients may be responsible for further spread of TB in the community.

- The information needed to construct a complete record of a patient's career in the health care system is, for many of them, distributed between a large number of different sources. This means that an audit such as this one cannot be carried out without a major labour intensive survey. An additional problem is that 1 in 25 records could not be found. Tuberculosis treatment services need a fully integrated record system which will ensure that comprehensive and complete patient careers can be retrieved and audited routinely.

6.1 INTRODUCTION

This section reports on the evaluation of treatment of a cohort of patients identified through the notification database.

6.2 METHODS

6.2.1 Defining the cohort of patients with tuberculosis for the study

6.2.1.1 Sampling frame

Statutory notifications of patients with tuberculosis were used as the sampling frame. This provided a cohort of recently diagnosed patients which should be representative of the reference population of all newly diagnosed cases of tuberculosis (use of medical records as the sampling frame would result in over-representation of patients with chronic disease and would not provide an overview of the service). All notifications were collated and analysed centrally. A survey of notifications performed in October 1994 revealed high levels of completeness of data items required to identify patients and link notification forms with records (English name (98%), age (100%), sex (100%), ID number (98%), address (100%)). However, there was no estimate of the extent of under-notification. A pilot study was therefore performed which estimated the extent of under-notification of patients (see Chapter 4).

6.2.1.2 Sample size calculation

It was initially estimated that approximately 15% of newly notified patients are admitted to hospital. One of the most important outcomes of interest is the proportion of patients admitted who fall into different case-mix categories. There are thought to be three main categories of reasons for admission: the proportion of newly notified patients in each category can therefore be estimated at 0.15 * 0.25 = 0.0375 = 3.75% (Table 6.1). A sample size of 1,000 would enable this proportion to be estimated with an absolute precision of 1.2% with 95% confidence. The study initially therefore intended to aim for a sample size of 1,000 notifications.

Table 6.1: *Estimated proportion of patients requiring admission by case-mix category*

Proportion requiring admission	*proportion of those requiring admission in each case-mix category*	*proportion of all patients in each case-mix category*
15%	25%	3.75%

However, based on preliminary analyses from the first phase sample of 102 patients, the original estimate for the proportion of patients requiring admission was too low. Applying the proportions of patients notified from chest clinics and hospitals who require admission obtained from the first phase sample to the sample of patients whose notifications were dated December or undated but received in December (December cohort) results in an overall estimate of 39% of all newly notified patients who are expected to require at least one admission (Table 6.2).

Table 6.2: Derivation of overall estimate of 39% expected to require at least one admission

Source of notification	*proportion in December cohort*[a]	*proportion expected to require admission*[b]	*number requiring admission in sample of 100*[a×b]
chest clinics	72%	20%	14.4
hospitals	28%	88%	24.6
total	100%	39%	39.0

If the original estimate is therefore revised from 15% to 39%, the expected proportion in each case-mix category is approximately 10% (Table 6.3).

Table 6.3: Revised estimated proportion of patients requiring admission by case-mix category

Proportion requiring admission	*proportion of those requiring admission in each case-mix category*	*proportion of all patients in each case-mix category*
39%	25%	10%

The required sample size was therefore re-calculated based on this revised proportion. With a greater expected proportion of 10%, the desired precision was modified to 2.7% rather than 1.2%. In order to obtain an estimate for this proportion with an absolute precision of 2.7% and 95% confidence, the required sample size is 443.

6.2.1.3 Sampling method

All notifications dated 1 to 31 December 1994 or undated but received by the Statistics Unit of the Department of Health in the same time period were included in the sample. The sample therefore included patients whose notifications were dated December 1994 but not received until, at the latest, March 1995. A pilot study (see Section 4.5) performed prior to the main study examined the notification process and the time distribution of notifications: substantial delays were identified between date of completion of form and date of receipt in the Statistics Unit and there was evidence of batching of forms from some hospitals prior to submission to the Unit. If date of receipt rather than date of notification had been chosen as the sampling method, the resulting selection bias is likely to have been greater.

6.2.2 Classification of data

6.2.2.1 Development of a case-mix classification system

A patient classification system was developed based on the advice of clinicians on the Steering Group, data from the reviews of medical records and relevant work performed elsewhere. Consideration was given to the minimum data which are routinely and consistently available, and reflect differences in severity of disease and clinical dependence for investigation and treatment.

The principal classification was based on *complications of TB*, *complications of treatment* and *co-morbidities*. Variables reflecting these conditions were tested for their association with outcomes and for their ability to predict utilisation of medical care services. Details are provided in Section 8.

6.2.2.2 Classifying outcomes

Clinical outcomes of treatment were classified using the IUATLD classification of outcomes. The WHO and IUATLD defined outcomes for the following groups of patients:

- smear or culture positive **and**
- pulmonary disease **and**
- never been previously treated for tuberculosis.

The outcomes are as follows:

1. **smear/culture negative**
   negative smear/culture within one month of completion of treatment (date treatment stopped) and on at least one previous occasion
2. **smear/culture not done**
   completed full course of treatment but without sputum smear/culture examinations as noted above
3. **smear/culture positive**
   smear/culture positive 5 months or more after the commencement of treatment
4. **died/migrated**
   migration or death before, during or after treatment
5. **defaulted**
   missed treatment for two consecutive months or more after the diagnosis or still on treatment 15 months after the diagnosis (assumed default)
6. **transferred**
   transferred formally to the care of another institution and the results of treatment are unknown

In this survey the first of any of the six events which occurred in an individual patient was recorded as the treatment outcome. For the study data, the first three outcomes took precedence over the remaining outcomes; for example if a patient was on treatment over 15 months and was smear negative, the outcome was coded as smear negative rather than default. Where a patient fulfilled the criteria above, the WHO/IUATLD outcome was recorded.

In addition, survey outcomes one year after the start of treatment were defined and recorded for every patient. The main outcomes of interest were:

1. successful completion of treatment and follow-up
2. lost to follow-up before, during or after treatment
3. still on treatment
4. migration or death during study
5. revised diagnosis

6.2.3 Data collection

6.2.3.1 Linking records: notifications to medical records, and medical records to other medical records

Key patient identifiers (see sampling frame Section 6.2.1.1 p.132) were abstracted from the sample of notifications to allow linkage to medical records in the various clinical settings. In a proportion of notification forms, the unit to which the patient has been referred (24%), and the hospital or chest clinic number (40%) are included: this facilitated linkage to records. Medical records were obtained for the duration of each patient's treatment programme. These records were held at 63 sites; 11 chest clinics, five dedicated hospital chest units 19 general and 28 clinics (see Appendix 4). Linking records between care sites for the duration of the treatment programme was facilitated by the use of Hong Kong ID numbers on all records.

6.2.3.2 Abstraction of data from records

Proformas were developed to standardize the abstraction of a minimum dataset from hospital and clinic records (Appendix 1). These were piloted and amended before the main survey. The minimum dataset included data for case-mix categorisation, information relevant to clinical decision-making and data which establishes the referral pattern. In pilot studies of hospital and clinic medical records, the quality of recorded data was found to be adequate for the study. Validation of the quality of data abstraction by the research assistant was performed at regular intervals by independent review of a random sample of records by one of the principal investigators (RMH).

Record linkage is dependent on identifiers which are unique, universally used and available. Further developments in information systems and audit should consider the inclusion of a mandatory and comprehensive set of identification information for all TB records, including investigation reports.

6.2.4 Data processing and analysis

6.2.4.1 Data entry

Data was abstracted from medical records and entered manually onto 2 paper abstraction forms: a patient-specific form which recorded data which did not vary between episodes, eg. demographic data, treatment start date, sputum smear status and an episode-specific form which recorded data specific to each episode, eg. source of care, start and end dates, complications of treatment occurring etc. The data from each of these forms was entered onto a relational database in Epi-Info where each patient has a "PERSON" file (for patient-specific data) linked to one or more "EPISODE" files (for episode-specific data) using a unique identifier (the AENO on the notification form).

6.2.4.2 Validation of data entry

Aim
The aim was to determine the extent of errors for data entry during the survey.

Methods
A random 10% sample of 45 patients was selected from the cohort of 454 patients for repeat entry of both person and episode form data. The patients were selected by generating a random list of 45 patients from the main database using SPSS. The data were entered into new person and episode files.

The person and episode files were then compared using the "validate" programme in EPI-6. This compares each field of each record for the two person files and the two episode files and produces a report of differences between fields.

Results
Person files: n=45
No differences were detected.
Error rate = 0%

Episode files: n=195
8 errors were detected in the original database.
There are 120 variables in each episode file.
Error rate = 8 / (195 x 120) x 100 = 0.03%

Conclusion
These error rates are well within the bounds of acceptability and can be considered to be negligible.

6.2.4.3 Data analysis

Patients were allocated to a case-mix category for each stage of their treatment programme. Criteria for exclusion of patients from subsequent analysis were kept to a minimum and are clearly described at the beginning of each set of results. The data set was analysed using SPSS software. An algorithm representing the referral pattern was prepared from presentation to primary and secondary care levels, with decision nodes and chance nodes with probability estimates. In this way, the most common pathways were established and highlighted. The algorithm could be constructed for case-mix categories. It could be used to model the impact of changes in case-mix on the service, to assess the extent to which needs are met, to determine the pattern of resource use and estimate the impact of changes in services on the extent to which needs are met.

The pattern of service provision experienced by this cohort of patients can also be compared with the referral pattern indicated by existing protocols or guidelines and a consensus statement on the ideal referral pattern drawn up in consultation with clinicians.

In addition to analysing the *process* of care, outcomes of care were analysed to establish factors associated with them.

6.3 RESULTS

6.3.1 Identified patient sample

6.3.1.1 Inclusion and exclusion criteria for survey patients

All 454 patients whose notifications were dated in December 1994, or undated but received in December 1994, were included in the main study. No patients meeting these criteria were excluded from the study.

6.3.1.2 Representativeness of patients included in the study

The 454 patients were compared with all notifications made in 1994 to determine the representativeness of the sample (Tables 6.4 to 6.7). Chi-square tests were used to compare the characteristics of study sample with the whole 1994 notified population. 1994 data was abstracted from the 1994 Chest Service Annual Report.

Gender: The gender ratio of the study sample was similar to that in the 6319 patients notified in 1994 (Table 6.4). There was a slight deficit of males.

Table 6.4: *Gender distribution of sample and 1994 cohort*

Gender	Study sample		1994 cohort	
Male	302	(66.5)	4297	(68.0)
Female	152	(33.5)	2022	(32.0)
Total	454	(100.0)	6319	(100.0)

chi squared = 0.36, p=0 55

Two thirds of patients treated for TB in Hong Kong are male.

Age: The age specific prevalence ratios are similar throughout, but a relative deficit of survey subjects in the 10-19 years age group was noted (Table 6.5).

Table 6.5: *Age distribution of sample and 1994 cohort*

Age (years)	Study sample		1994 cohort		p value
0-9	4	(0.9)	56	(0.9)	NA
10-19	13	(2.9)	320	(5.1)	0.03
20-29	73	(16.1)	1052	(16.6)	0.77
30-39	86	(18.9)	1065	(16.9)	0.26
40-49	53	(11.7)	737	(11.7)	NA
50-59	67	(14.8)	802	(12.7)	0.21
60-69	76	(16.7)	1121	(17.7)	0.61
70-79	62	(13.7)	824	(13.0)	0.68
80 or above	20	(4.4)	338	(5.3)	0.41
Unknown	0		4	(0.1)	
Total	454	(100.0)	6319	(100.0)	

Patients receiving tuberculosis services are relatively young; 40% are aged 39 years or less and only 26% are over 60 years.

Place of residence: The distribution of place of residence across the SAR was similar and there were no significant variations between the administrative regions (Table 6.6).

Table 6.6: Region of residence of the sample and 1994 cohort

Region	Study sample		1994 cohort		p value for comparison
Hong Kong Island	91	(20.0)	1217	(19.3)	0.7
Kowloon	190	(41.9)	2411	(38.2)	0.12
New Territories East	71	(15.6)	1092	(17.3)	0.36
New Territories West	84	(18.5)	1359	(21.5)	0.13
Other	18	(4.0)	240	(3.8)	0.86
Total	454	(100.0)	6319	(100.0)	

About forty percent of TB patients live in Kowloon and a further 40% between New Territories East and West.

Source of notification: Eight groups of different sources of notifications were defined. For the three main groups, chest clinics, chest hospitals and general HA hospitals, the proportions in the study were entirely similar to the main group (Table 6.7).

Table 6.7: Source of notifications of the sample and 1994 cohort

Source	Study sample		1994 cohort		P value for comparison
Chest clinic	327	(72.0)	4631	(73.3)	0.55
Chest hospital	102	(22.5)	1270	(20.1)	0.23
General HA hospital	18	(4.0)	327	(5.2)	0.25
Private hospital	1	(0.2)	20	(0.3)	0.87
SOPD	1	(0.2)	NA		
Private practitioner	1	(0.2)	53	(0.8)	0.26
Public mortuary	1	(0.2)	NA		
Other	3	(0.7)	18	(0.2)	
Total	454	(100.0)	6319	(100.0)	

Most patients are notified from chest clinics (72%) and about one quarter from chest or general hospitals (27%).

Site of disease: The majority (93%) were pulmonary cases (Table 6.8). Among the extra-pulmonary cases there was a slight excess of diagnoses for bone and joint disease. The site of disease categories used here are those stated on the notification form, rather than those used later in the study.

Table 6.8: Site of disease of the sample and 1994 cohort

Site of disease	Study sample		1994 cohort		p value for comparison
Respiratory	421	(92.7)	5852	(92.6)	0.91
Meninges	1	(0.2)	16	(0.3)	0.87
Bones and joints	6	(1.3)	33	(0.5)	0.05
Others	26	(5.7)	418	(6.6)	
Total	454	(100.0)	6319	(100.0)	

In summary, the only significant variations, in age and site of disease, involved less than 3% of the sample in each instance.

6.3.2 Demographic characteristics of the sample

Age: The age of patients in the study had a bimodal distribution with two peaks occurring in the 20 to 40 year age group and the 60 to 70 year age group (Figure 6.1). The median age was 48.0 years (interquartile range 32.0 to 66.0). Fewer than 1% of patients were aged under 10, and fewer than 4% under 20 (Table 6.5). The younger age peak is more pronounced for females than males who experience a correspondingly larger older age peak (Figure 6.2).

Figure 6.1: *Age distribution*

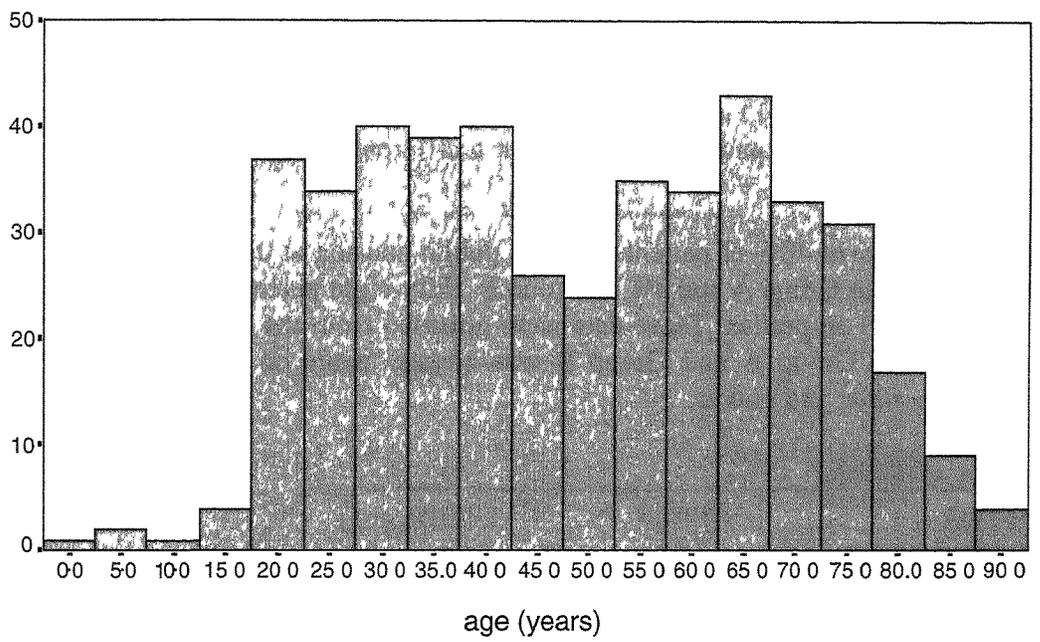
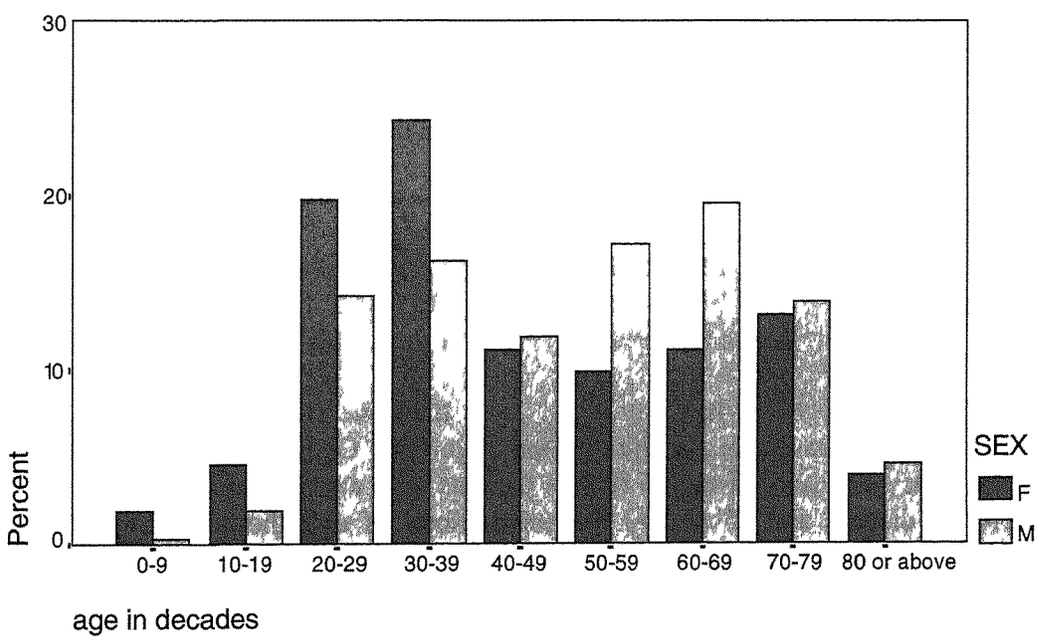


Figure 6.2: *Age groups by gender*



Gender: Of the 454 patients, 302 (66.5%) were male and 152 (33.5%) female. The median age of males was greater than females (Figure 6.3).

Region of residence: At the time of notification, over 40% of patients lived in Kowloon with lower proportions from Hong Kong Island, and New Territories East and West (Table 6.6). Eighteen patients (4%) lived in refugee centres (Whitehead, Tai A Chau, High Island and New Horizons). The proportion of all notifications from each district in 1995 was as follows: Hong Kong Island 21%, Kowloon 36%, New Territories East 17%, New Territories West 24% and others, principally refugees, 3%.

Patients in refugee centres were younger than Hong Kong SAR residents. Hong Kong residents living in the New Territories East tended to be younger than other residents. The age distribution varied between patients living in different regions: among patients living in Kowloon, the first age peak is associated with the 20-29 year age group in contrast to the 30-39 year age group for the other three regions (Figure 6.4).

Mobility: Thirty patients (6.6%) moved residence at some point during the period of follow-up in the survey. Of these 30 patients, 25 moved to a different district, and 22 to a different region.

Public housing: Just over 40% of patients lived in public housing at the time of notification (Table 6.9) with 33% in Group A and 8% in Group B. Fifty-eight percent lived in non-public (mainly private sector) properties. These data were obtained from the notification form and the classification into Group A and Group B was already made on the form. Group B housing tends to be older and poorer.

Table 6.9: Type of housing

Type of housing	number	Proportion
Group A public housing	149	32.8
Group B public housing	38	8.4
Temporary housing	2	0.4
Not public housing	265	58.4
Total	454	100.0

Patients living in public housing tended to be older than others (Figure 6.5).

Forty one percent of patients live in public housing; the majority of young patients live in Kowloon and are less likely to be in public housing.

6.3.3 Clinical features of the study patients

Clinical features were obtained from the medical records at the health care sites.

Major site of disease: If patients had disease of more than one site including pulmonary disease then pulmonary disease was classified as the major site. Over 90% of patients in the sample had pulmonary disease. Of the 45 (9.9%) patients with extra-pulmonary disease, 18 (4.0%) had pleural disease and 15 (3.3%) had tuberculosis of extrathoracic lymph nodes (Table 6.10).

Figure 6.3: *Age by gender*

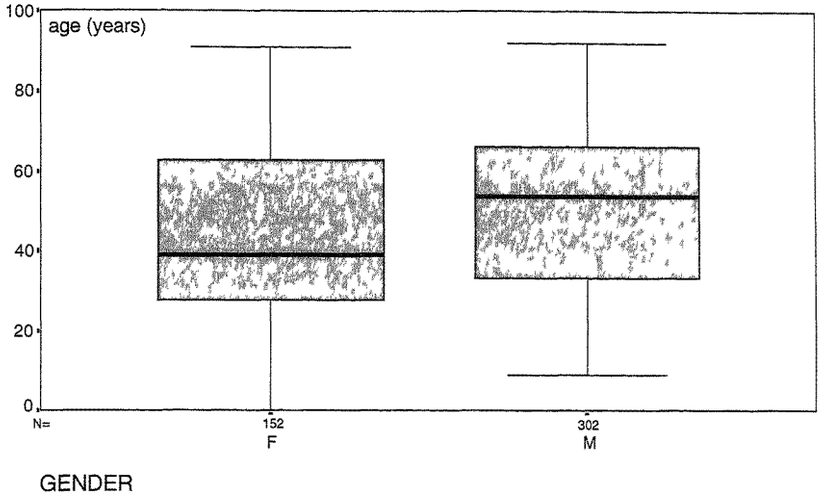


Figure 6.4: *Age distribution by region*

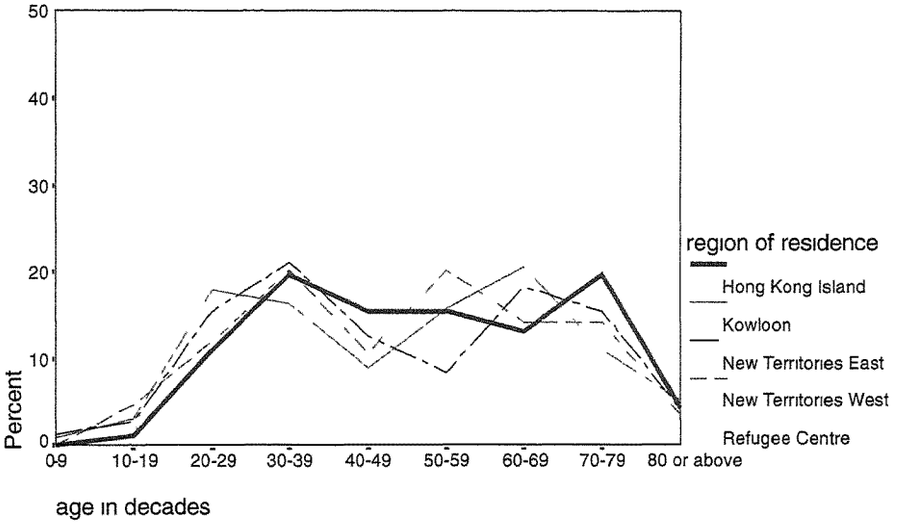


Figure 6.5: *Age of patients according to type of housing*

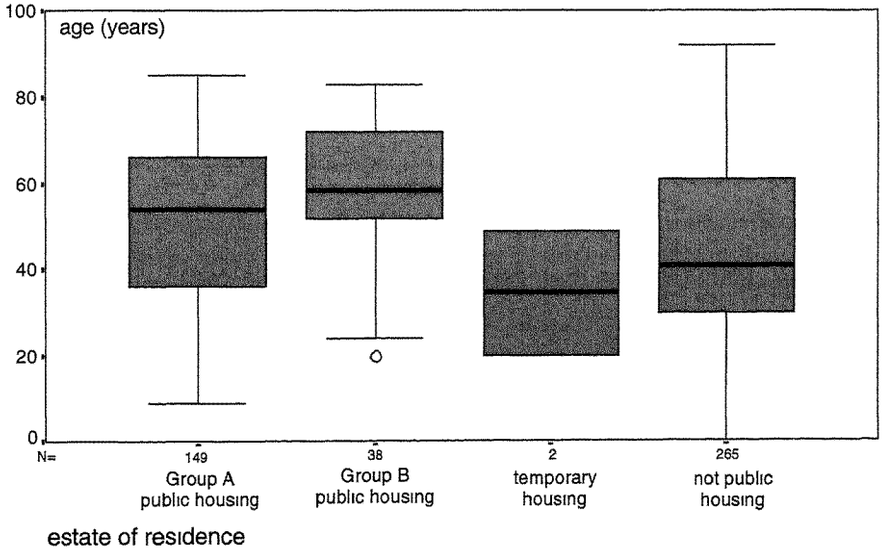


Table 6.10: *Major site of disease*

Major site	Number	%
Pulmonary	409	90.1
Pleural	18	4.0
Lymphatic, intrathoracic	2	0.4
Lymphatic, extrathoracic	15	3.3
Spine	1	0.2
Bone/joint, not spine	4	0.9
Meningitis	2	0.4
Genito-urinary	3	0.7
Total	454	100.0

Forty four patients had disease of more than one site. The most common combinations of sites were pulmonary disease with pleural involvement (n=23) and pulmonary disease with extrathoracic involvement (n=10) (Table 6.11).

Table 6.11: *Minor site of disease for patients with more than one site*

Minor site	Major site: pulmonary	Major site: extrapulmonary	Total: number (%)
Pleural	23	0	23 (52.3)
Lymphatic, extrathoracic	10	2 (lymphatic, extrathoracic; meningitis)	12 (27.3)
Spine	1	0	1 (2.3)
Bone/joint, not spine	1	0	1 (2.3)
Genito-urinary	1	0	1 (2.3)
Peritoneal/digestive tract	3	0	3 (6.8)
Skin	0	1 (pleural)	1 (2.3)
Disseminated	2	0	2 (4.5)
Total	41	3	44 (100.0)

Symptoms: Over 80% of patients had symptoms attributable to their tuberculosis at the start of treatment but more than one in six were apparently symptomless (Table 6.12). Eight patients in the study sample (1.5%) did not start treatment for various reasons.

Table 6.12: *Patients' symptoms at the start of treatment*

Symptoms	Number	%
Yes	365	80.4
No	80	17.6
Did not start treatment	8	1.5
Unknown	2	0.4
Total	454	100.0

Of those without symptoms attributable to their tuberculosis, only 29 (36%) were identified through screening programmes, and a further 7 (9%) self-referred themselves to a clinic. Of patients with symptoms, 1% were identified through screening programmes, and 35% self-referred to a health care source.

Past tuberculosis: Seventy five patients (16.5%) had a definite history of past tuberculosis noted in the medical records, and an additional 14 (3.1%) had evidence of previous tuberculosis on chest X-ray examination noted in their medical record. Of the 75 with a definite past history, the year of last previous treatment was noted in the record. This ranged from 1944 to 1994. Ten patients (2.2%) had received treatment in the previous five years (from 1990 to 1994 inclusive).

Most patients (80%) had symptoms attributable to tuberculosis and 20% had a past history or radiological evidence of TB.

Sputum status: Using information available from medical records, both sputum smear and culture status were determined for patients at the start and end of treatment. The periods for which smear and culture status were determined were defined as including the month before or month after starting or completing treatment. For smears, only specimens *obtained* from patients in these time periods were included. For cultures, because of the 6-8 week delay in obtaining results, specimens *obtained* or specimen *reports* available in these time periods were included. For example:

- if a culture was taken three weeks after starting treatment but the result was not available until 10 weeks after starting treatment and was positive, the patient was classified as culture positive
- if a culture report within one month of starting treatment was negative but a specimen taken within one month was positive, the patient was classified as being culture positive
- if a culture report within one month of starting treatment was positive but a specimen taken within one month was negative, the patient was classified as being culture positive

Of the 409 patients with pulmonary disease, 109 (26.7%) were smear positive and 224 (54.8%) were culture positive at the start of treatment (Table 6.13). Results for smear and culture tests were not available from records of nearly 10% of patients.

Table 6.13: *Sputum smear and culture status of patients at start of treatment (pulmonary disease only)*

Culture / Smear	Positive	Negative	Did not start treatment	No result available	Total (%)	
Positive	97	6		6	109	(26.1)
Negative	116	130		7	253	(61.9)
Did not start treatment			7		7	(1.7)
No result available	11	3		26	40	(9.8)
Total (%)	224 (54.8)	139 (34.0)	7 (1.7)	39 (9.5)	409	(100.0)

The sputum status of patients was also determined at the end of treatment (Table 6.14). One smear negative patient had became smear positive by the end of treatment, and two culture positive patients remained so. In nine (8.3%) of smear positive patients and 21 (9.4%) of culture positive patients, their smear and culture status respectively was not recorded at the end of treatment. One quarter of smear positive and 17.4% of culture positive patients did not complete treatment.

At the time of diagnosis a total of 27% were smear positive and 55% culture positive. Results were missing from records for 1 in 10 of the cohort.

One reviewer comments that *"the proportion of patients with negative bacteriology is much higher than other countries. The chest service here must be giving treatment to a substantial number with inactive disease ... in fact giving these individuals prophylaxis. It is possible that some may have positive bacteriology if bronchoscopy was carried out and BAL sent for smear and culture."* The question is raised as to whether a review of chest X-rays in this population of patients shows improvement during treatment.

Another reviewer responds that because of the high prevalence of TB in Hong Kong *"the value of chest X-ray for diagnosing TB (in contribution with other clinical information) is quite high"* unlike that in some other western countries. When the positive predictive value is low it may be justifiable to do other investigations like bronchoscopy.

There are 6 (1.4%) out of 409 patients who are smear positive and culture negative, raising the question whether the smear results were correct and possibly the result of contamination with non-tuberculous mycobacteria. 130 patients were smear negative/culture negative; of these:

26 (20%) had a definitive diagnosis made using another diagnostic test.

104 with no further diagnostic test, all had a chest X-ray at the start of treatment which was abnormal and consistent with TB. Seventy one (68%) of these had improved by the end of treatment.

Table 6.14: *Sputum smear status by sputum culture status at start of treatment with pulmonary disease*

Culture	Sputum status at completion				Total (%)
Smear	Positive	Negative	Did not start treatment	Unknown (no result)	
Positive	97	6		6	109 (26.1)
Negative	116	130		7	253 (61.9)
Did not start treatment			7		7 (1.7)
Unknown (no result)	11	3		26	40 (9.8)
Total (%)	224 (54.8)	139 (34.0)	7 (1.7)	39 (9.5)	409 (100.0)

Chest X-ray findings: Information about chest X-ray findings at the start and end of treatment were abstracted from medical records. The objective of obtaining this information was to present additional evidence for the diagnosis of tuberculosis, particularly in patients without positive microbiological or histological evidence, and to evaluate patients' responses to treatment. Radiology is an important monitoring as well as diagnostic tool for chest physicians in Hong Kong.

Of 409 patients with pulmonary disease, at the start of treatment, 397 (97%) patients had an abnormal chest X-ray examination which was consistent with tuberculosis. Of these 397, 271 (68.3%) had improved at the completion of treatment. In 39 (9.8%) the radiological pattern had not changed in response to treatment and three (0.8%) had deteriorated (Table 6.15). Seven patients with pulmonary disease did not start treatment.

Table 6.15: *Chest X-ray findings for patients with pulmonary disease*

Chest X-ray at start of treatment	chest X-ray at end of treatment						
	Improved	no change	worse	treatment not completed	unknown	Other findings	total
Abnormal, consistent with tuberculosis	271 (68.3)	39 (9.8)	3 (0.8%)	72 (18.4%)	6 (1.5%)	5 (1.3%)	396 (100.0)
Abnormal inconsistent with tuberculosis	0	2	0	0	1	0	3
Unknown	0	0	0	2	1	0	3
Total	271	41	3	74	8	5	402

* Irrelevant to treatment of TB

Most (97%) of patients with pulmonary disease had an abnormal chest X-Ray of whom nearly 70% improved on completion of treatment.

Definitive diagnosis: Of the 454 patients, 320 (70.5%) had some form of definitive diagnosis. A definitive diagnosis was defined as a positive microbiological or histological diagnosis. Patients may have had more than one positive diagnostic test. Up to three diagnostic tests were recorded. The first available diagnostic test was identified. In nearly 75% of patients the first test available was a sputum smear or culture result (Table 6.16).

Table 6.16: *First diagnostic test available for patients with definitive diagnosis*

Source of sample	Smear	Culture	Histology	Cytology	Total no (%)
Sputum	105	129	0	0	234 (73.1)
Pleural biopsy/aspirate	0	1	27	0	28 (8.7)
Bronchial aspirate	3	3	0	0	6 (1.9)
Bronchial biopsy	0	0	2	0	2 (0.6)
Lung aspirate	0	0	0	3	3 (0.9)
Lung biopsy	0	1	10	0	11 (3.4)
Gastric lavage	0	1	0	0	1 (0.3)
Lymph node aspirate	0	0	0	11	11 (3.4)
Lymph node biopsy	0	0	12	0	12 (3.8)
Rectal biopsy	0	0	1	0	1 (0.3)
Spinal biopsy	0	0	1	0	1 (0.3)
Endometrial curettage	0	1	2	0	3 (0.9)
Nasopharyngeal biopsy	0	0	2	0	2 (0.6)
Peritoneal fluid	0	1	0	0	1 (0.3)
Bone/joint biopsy	0	0	1	3	4 (1.2)
Total	108	137	58	17	320 (100.0)

120 patients had one further diagnostic test and 16 had two further diagnostic tests so that 152 additional tests were identified. The most frequently ordered additional test was a sputum culture (Table 6.17).

Of the 320 patients who had some form of definitive diagnosis, 153 had one diagnostic test for sputum and 97 had two. The second most frequently occurring source was pleural fluid aspirate or membrane biopsy (Table 6.18).

A question has been raised by the reviewers as to whether the biopsy samples were sent for culture and sensitivity or whether they were simply placed in fixative. Cultures are important if TB is suspected because of increasing drug resistance.

Table 6.17: *Additional diagnostic tests for patients with a definitive diagnosis*

Source of sample	Smear	Culture	Histology	Cytology	Total no (%)
Sputum	4	109	0	0	113 (74.3)
Pleural biopsy	0	2	3	0	5 (3.3)
Pleural aspirate	0	6	0	0	6 (3.9)
Bronchial aspirate	2	4	0	0	6 (3.9)
Lung biopsy	0	1	5	1	7 (4.6)
Lymph node aspirate	0	3	0	4	7 (4.6)
Lymph node biopsy	1	1	0	0	2 (1.3)
Bone biopsy	0	2	1	0	3 (2.0)
Other	2	0	1	0	3 (2.0)
Total	9	128	10	5	152 (100.0)

Table 6.18: *Frequency of diagnosis from different sources*

Source of test	Number of patients with one diagnostic test from source	Number of patients with two or more diagnostic tests from source	Total from source
Sputum	153	97	250
Pleural aspirate or biopsy	27	6	33
Lung aspirate or biopsy (open or percutaneous)	15	3	18
Bronchial aspirate or biopsy (at bronchoscopy)	10	2	12
Lymph node aspirate or biopsy	19	5	24
Other	13	3	337

At diagnosis four different tests (smear, culture, histology, cytology) were performed on material from 15 different sources. Most tests (73%) were on sputum.

Most diagnoses were made on sputum (74%) with another 19% from pleural or lung aspirates and biopsies.

Drug sensitivity: Sensitivity tests were available for 240 (93.4%) of the 257 patients with at least one positive culture (for example, sputum, pleural aspirate, lymph node) (Table 6.19). Sensitivity tests were not performed for seven patients (2.7%) and results were not noted in the medical record for ten (3.9%) patients.

Table 6.19: *Initial sensitivity results for individual drugs (240 patients)*

Drug	Number sensitive	Number resistant	Number unknown	% resistant
Streptomycin (S)	214	25	1	10.4
Rifampicin (R)	234	5	1	2.1
Isoniazid (H)	228	12	0	5.0
Ethambutol (M)	232	1	7	0.4
Pyrazinamide (Z)	41	1	198	NA

Of the 240 patients, 5 (2.1%) were classified as multi-drug resistant, that is resistant to at least isoniazid and rifampicin, either on examination of the initial specimen or the later one.

Analysis of sensitivity patterns for individual patients revealed that 31 patients (12.9%) were resistant to at least one drug. The maximum number of drugs that any patient was resistant to was four (Table 6.20).

Table 6.20: *Sensitivity patterns for first specimen (n=240)*

Number of resistant drugs	Number of patients	% of total
1 or more	31	12.9
2 or more	9	3.7
3 or more	3	1.2
4 or more	1	0.4
5 or more	0	0

Of the 240 patients with at least one sensitivity test result, a further different sensitivity pattern was identified at a later stage in the treatment of 12 patients (Table 6.21).

Table 6.21: *Second sensitivity results for individual drugs (12 patients)*

Drug	Number sensitive	Number resistant	Number unknown	% resistant
Streptomycin	9	3	0	25.0
Rifampicin	10	2	0	16.7
Isoniazid	9	3	0	25.0
Ethambutol	10	1	1	8.3
Pyrazinamide	3	1	6	NA

Acquired drug resistance: Four patients (1.7%) acquired drug resistance during their treatment. Two developed resistance to one drug (one to streptomycin and one to isoniazid). One changed from SH resistant to SHR resistant, and one from SRM resistant to SHRMZ resistant.

All four of these patients were male and had pulmonary disease; three were smear positive and all four were culture positive. Their ages were 21, 63, 66 and 69 years. Their acquired resistance profile is as follows:

- one acquired resistance to rifampicin (at start of treatment also resistant to isoniazid and streptomycin; received 511 days treatment due to multiple drug resistance and drug intolerance)
- one acquired resistance to isoniazid and pyrazinamide (at start of treatment also resistant to ethambutol, rifampicin and streptomycin)
- one acquired resistance to isoniazid (and died of unknown cause)
- one acquired resistance to streptomycin (defaulted treatment and follow-up for five months.

At one year after starting therapy, two were still on therapy, one had been lost to follow-up during therapy and one had died, with the cause possibly related to tuberculosis.

A past history of tuberculosis was categorised as definite or not, and then a subcategory of patients treated in the last five years was defined. In both categories, patients with a past history of tuberculosis, however recent, were more likely to have a mycobacterial strain resistant to at least one of the first line drugs but, if treated in the last five years, the proportion resistant to one or more drugs rose to 80% (95% CI: 45%-100%) (Table 6.22).

Table 6.22: *Pattern of drug resistant patients according to past history of tuberculosis*

	Category of past TB			
	definite past TB		TB treated in last five years	
	yes	no	yes	no
No. of patients	41	199	5	235
No. resistant to at least one drug	10	21	4	27
% resistant to at least one drug	24%	11%	80%	11%

Table 6.23: *Resistance pattern of patients according to certainty of past history of tuberculosis*

Past history of tuberculosis	Yes no. resistant/no. sensitive (% resistant)	No/unknown No. resistant/no. sensitive (% resistant)	p value
Possible	12/50 (24.0)	19/190 (10.0)	0.01
Definite	10/41 (24.4)	21/199 (10.6)	0.02
Treated in last 5 years	4/5 (80.0)	27/235 (11.5)	-

In the cohort, at initial presentation, 13% were resistant to at least one drug, 2% to two or more (H, R, plus others). Four out of 5 patients treated previously within 5 years were drug resistant.

Smear outcome: Of the 454 patients, 87 patients had smear positive pulmonary disease with no history of previous tuberculosis treatment. The outcomes for these 87 patients showed that 64% were smear negative, 5% were smear positive and in 13% there was no record. Information on a further 16% was lost because of death (6%) or default from medical care (10%).

Table 6.24: Smear outcome on completion of treatment (IUATLD classification)

Outcome	Number	%
Smear negative	56	64.4
Smear not done	11	12.6
Smear positive	4	4.6
Died	5	5.7
Defaulted	9	10.3
	(5 lost to FU; 4 "still on treatment")	
Transferred	0	0
Revised diagnosis	2	2.3
Total	87	100.0

Culture outcome: Of the 454 patients, 186 patients had culture positive pulmonary disease with no history of previous tuberculosis treatment. The outcomes for these 186 patients are shown in Table 6.25.

Table 6.25: Culture outcome on completion of treatment (IUATLD classification)

Outcome	Number	%
Culture negative	115	61.8
Culture not done/not recorded	36	19.4
Culture positive	6	3.2
Died	9	4.8
Defaulted	20	10.8
	(10 lost to FU; 10 still on treatment)	
Transferred	0	0
revised diagnosis	0	0
Total	186	100.0

6.3.4 Patterns of care in the study sample

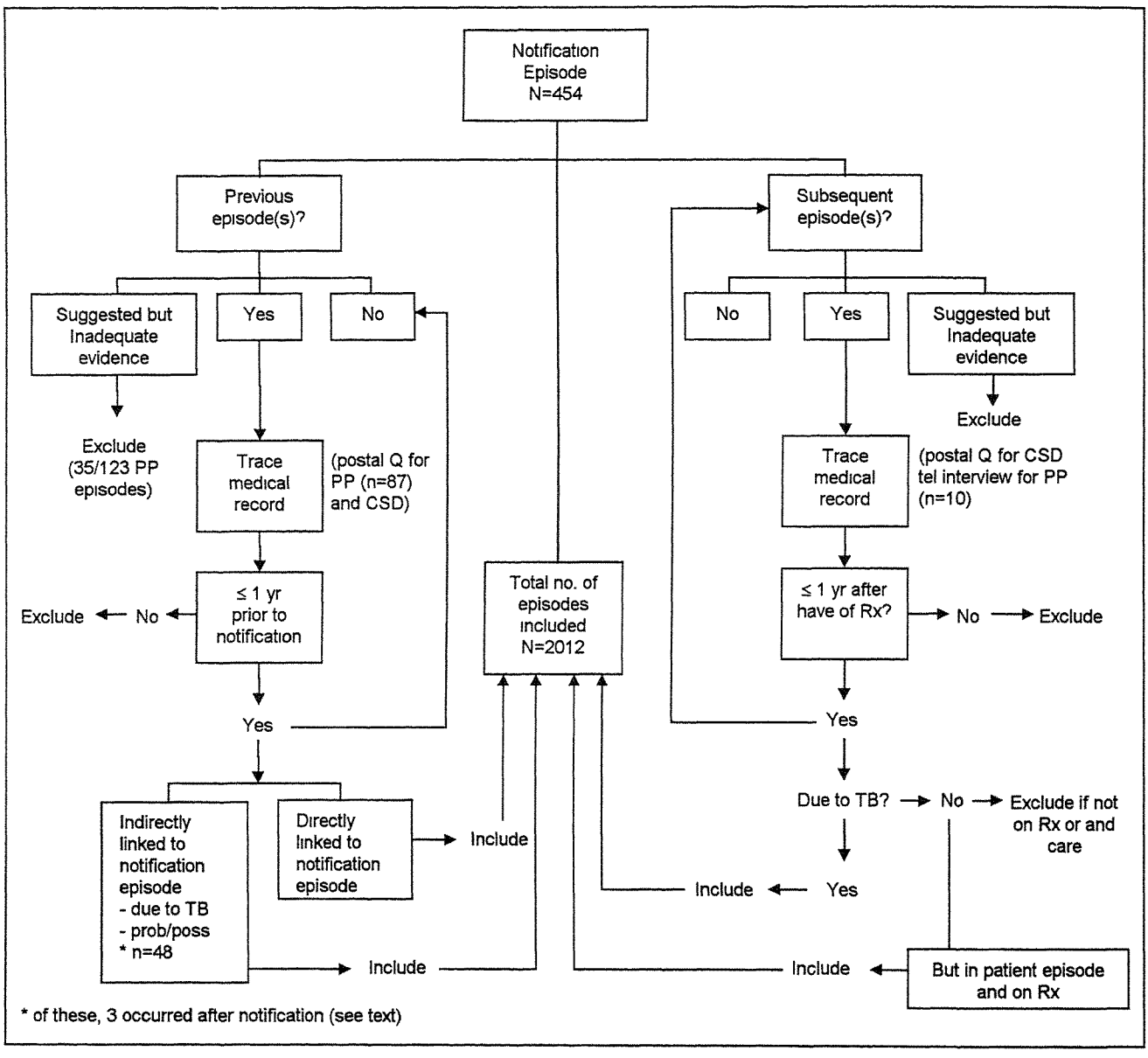
6.3.4.1 Episodes of care

An episode of care in this study is defined as care from one source between admission and discharge for in-patients and between first visit and last visit for ambulatory care patients. Ambulatory care episodes were defined to end if the patient was admitted to inpatient care but continued if they were referred to another source of ambulatory care.

Ninety (4.4%) of the episodes of care for the study cohort could not be found in medical records.

For the 454 patients in the study, 2012 episodes of care were identified in 140 different sites or units (Figure 6.6). Refer to section 6.3.4.8 for information on duration of episodes. Of these 2012 episodes, data for 1811 (90.0%) were abstracted directly from the medical records. The remaining 201 records were not reviewed either because alternative methods were used to abstract data (97 from private practitioners, 14 from correctional service department) or because the records were not available (90) (Table 6.26).

Figure 6.6: *Flow diagram for identification and documentation of episodes*



Key: PP : private practitioner
Q : questionnaire
Rx : treatment for TB

Table 6.26: Reasons for non availability of medical record (IUATLD classification)

Reason	number of episodes	% of episodes
Source of care could not be identified (unknown GOPD, chest clinic, HA hospital, OPD)	**12**	**13.3**
cannot find record (subtotal)	**38**	**42.2**
medical record not available because given to another source of care and not returned	*7*	*7.8*
record cannot be found after a minimum of two searches	*16 #*	*17.8*
records not computerised and very difficult to trace	*3 (computerised since early 1995)*	*3.3*
record lost or burnt or given to patient on repatriation	*7*	*7.8*
information given to MRO to trace record was inadequate	*5 **	*5.6*
incomplete information available (subtotal)	**15**	**16.7**
evidence for patient's attendance but incomplete record (eg only laboratory results or discharge summaries, or record relating to another episode)	*9*	*10.0*
no formal medical record created because only investigation or minor procedure performed	*6*	*6.7*
permission refused (subtotal)	**7**	**7.8**
permission refused by clinician	*2*	*2.2*
permission refused by patient	*5*	*5.6*
no individual records are maintained	**6**	**6.7**
not documented	**12**	**13.3**
Total	*90*	*100.0*

Principal groups are listed in bold font, subgroups are in italics

Data available to trace record may be inadequate because of lack of information in preceding or subsequent record.

* There were many more records where the information was inadequate but records were found through the efforts of the research assistant and MRO staff.

Definition of episodes of care:

- Classified as ambulatory care (A&E, chest clinics, SOPDs, GOPDs, PPs, refugee centres) and in-patient care (admissions, day care in hospital setting, ward follow-up).
- A&E episode followed by admission to hospital counted as two separate episodes
- In-patient episodes start on day of admission and end on day of discharge/transfer/default
- Ambulatory care episodes start on day of review by doctor where attendance related to TB and end on last day of review by doctor prior to discharge/referral to another source of care/default. If patient attends two sources of ambulatory care simultaneously, both episodes continue (eg chest clinic and SOPD).

Inclusion criteria: The survey included episodes occurring:

- Up to one year prior to date of notification (includes episodes starting more than one year before notification, but ending within one year of notification)
- Up to one year after start of treatment (or notification if treatment is not started)

We included all episodes which could have been related to TB prior to notification episode. In these episodes either the patient had symptoms which could have been due to TB, or results of investigations suggested TB in the differential diagnosis. Episodes occurring prior to notification were recorded as "directly" or "indirectly" linked to notification episode. "Directly" linked episodes were those in which the patient was referred from that episode to the notification episode (although there may have been intervening episodes).

"Indirectly" linked episodes were categorised as:

- Due to TB (recorded as such)
- Probably related to TB (symptoms were compatible with TB but diagnosis of TB was not confirmed. There were no comorbidities recorded which could account for those symptoms)
- Possibly related to TB (symptoms were compatible with TB but diagnosis of TB was not confirmed and there were comorbidities recorded which could account for those symptoms)

There was very limited information available for some of the first episodes identified, eg "saw PP" or "went to GOPD" is noted in medical record. Only those episodes where there was further information were included, eg dates of episode, reason for attendance:

- Notification episodes: all included
- All episodes due to TB after notification episode
- In-patient episodes after the notification episode where the patient was receiving treatment for TB but was admitted principally for the management of a comorbidity (these were coded as such)
- Episodes where diagnosis remained uncertain if diagnosis was revised after notification episode to "not TB".

Private practitioner episodes: A total of 123 episodes under the care of a private practitioner were identified before notification occurred (Figure 6.7). Of these, 35 were excluded because the only identifying information was "PP" (no clinical or administrative information was provided). The remaining 88 episodes were reviewed using a postal questionnaire survey. One further episode was excluded because the doctor was a radiologist and had not managed the patient's treatment. Eighty seven episodes were therefore included.

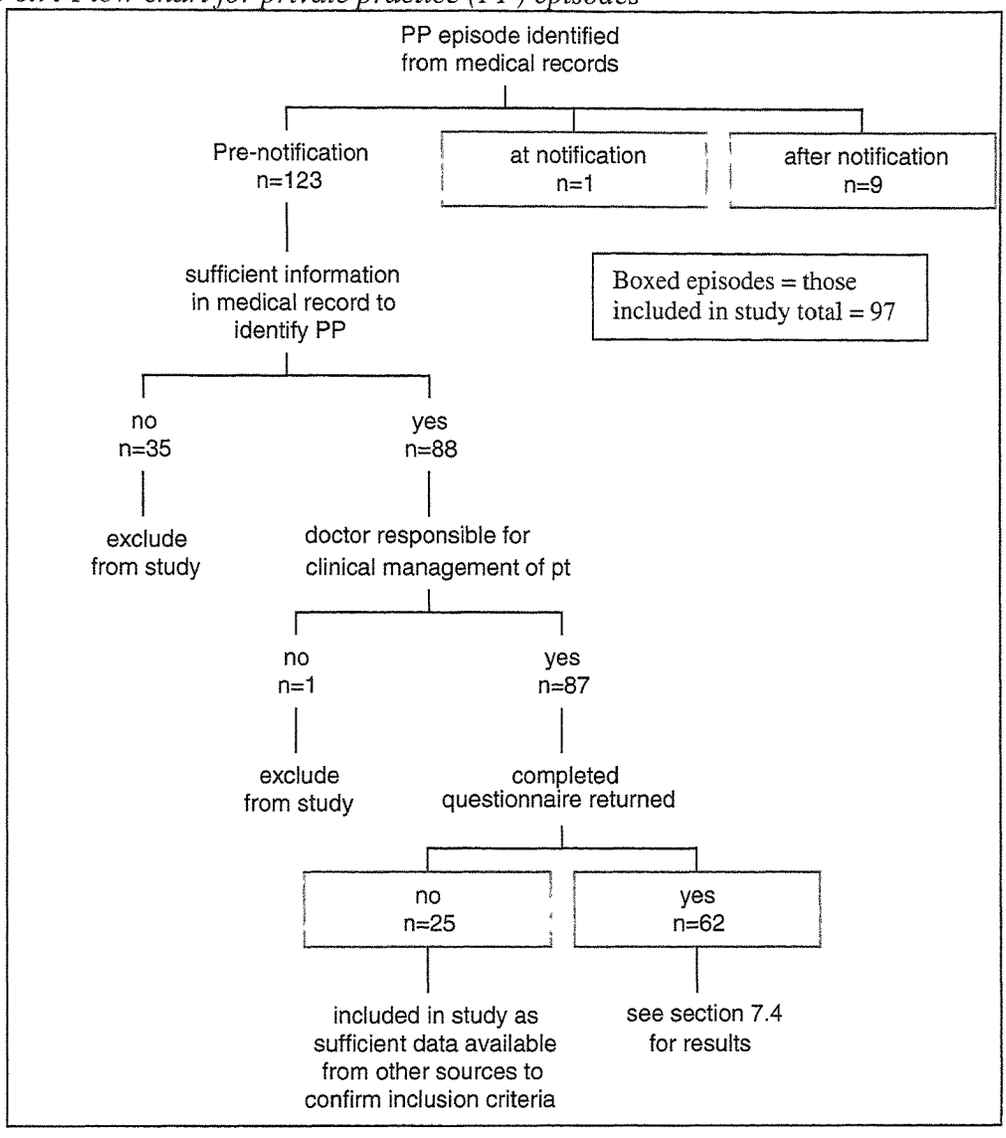
Completed questionnaires were received for 62 (71%) of the 87 episodes. For the remaining 25 episodes:

no response was received (11)	medical records could not be found (4)
the doctor had moved premises (5)	doctor refused permission (1)
medical records were not kept (3)	patient refused permission (1)

A further 10 episodes were identified which occurred at or after notification. These practitioners were interviewed by telephone.

Hence, a total of 97 PP episodes were included in the study. Results of this survey are presented in Section 7.4

Figure 6.7: Flow chart for private practice (PP) episodes



Correctional Services Department (CSD) episodes: A total of 14 episodes took place in hospitals and clinics managed by the CSD. The medical records relating to these episodes were not reviewed directly: a questionnaire was sent to medical staff. All 14 were returned completed.

Remaining episodes: Excluding PP and CSD episodes, there were 1901 episodes of care where the medical record was requested. Of these, data were not abstracted directly from the medical record for 90 episodes (4.7%). The reasons were documented for 78 episodes (Table 6.26). The most common reason was that the medical record could not be found.

There are several obstacles facing a full audit, including multiple sites of care, records in the private sector, missing records and refused access.

Episodes of care for another condition: Of the 2012 episodes, 118 (6%) episodes of care were principally for a co-morbidity rather than tuberculosis. Episodes were classified in this way if the co-morbidity was stated to be the main reason for referral or admission either by the preceding (referring) source or by the source of care itself. Episodes for co-morbidities occurring before or after tuberculosis treatment episodes were excluded from the study unless they were relevant to the management of tuberculosis; for example, an admission for cataract operation where the tuberculosis was identified through pre-operative chest X-Ray (CXR) screening would be included. Of the 118 episodes, 114 occurred during treatment and 4 before treatment started.

Of the 118 episodes of care for other conditions 89 (75.4%) were in general hospitals of the Hospital Authority (HA), 15 (12.7%) in chest hospitals, and the remaining 14 (11.9%) in a variety of ambulatory care settings.

The episodes of care for co-morbidities were for a wide range of conditions. The most frequent co-morbidities were diseases of the circulatory system and neoplasms other than lung.

Fifty seven patients had one or more episode where a co-morbidity was the principal diagnosis. Of these 57, 32 (56.1%) had only one episode for another condition, but 1 patient had 15 (co-morbidity multiple myeloma) (Table 6.27).

Table 6.27: *Number of episodes of care for co-morbidities*

Number of episodes	Number of patients	% of patients experiencing at least one episode for another condition
1	32	56.1
2	13	22.8
3	5	8.8
4	4	7.0
5	2	3.5
15	1	1.8
Total	57	100.0

Comorbidity is common in patients with tuberculosis and more than 1 in 20 episodes of care were specifically for the comorbidity.

Episodes only indirectly linked to notification episode: Of the 2012 episodes, 48 (2%) were only indirectly linked to the notification episode, that is, there was no direct referral between that episode of care and the episode in which notification took place. These episodes were identified because they were referred to in the medical records at other sources of care.

Forty five (94%) of the 48 episodes occurred before the patient started treatment and three (for the same patient) when the patient was on treatment. (The latter patient started treatment but was not notified, and then defaulted for several months, re-started treatment and was notified.)

Of the 48 episodes:

- 5 (10%) were definitely due to TB
- 23 (48%) may have been due to TB (ie symptoms compatible with TB but the exact cause of symptoms not determined)
- 20 (42%) were possibly due to another condition (ie symptoms compatible with TB but another known condition could have caused them)

These episodes may be an indicator of a clinical management process which failed to identify tuberculosis when it was at a stage which was potentially diagnosable. A clinical information system which could routinely identify episodes of care which were effectively false negative tests for TB, would enhance and complement other approaches to the audit of TB services.

Routine audit should be able to reliably detect episodes of care in which the diagnosis of TB was missed.

Medical work during the episode: Of the 2012 episodes nearly two thirds occurred during the treatment of patients, nearly a third of those identified occurred before treatment started and only 47 (2.3%) occurred after treatment was completed (Table 6.28).

Table 6.28: *Type of medical work during the episode*

Nature of episode	Number of episodes	% of episodes
Pre-treatment	627	31.2
During treatment	1338	66.5
Post-treatment	47	2.3
Total	2012	100.0

If a patient started or completed treatment during an episode, the whole of that episode was categorised as a treatment episode. The low number of post-treatment episodes is due to the fact that most patients continued to be followed up during the same episode of care where treatment was completed and a new episode did not occur before the end of the one year follow-up. The 47 post-treatment episodes that were identified resulted from the patient being referred to another source of care after the completion of treatment. These episodes were experienced by 29 patients of whom 18 had only one, 7 had two, 2 had three, one had four and one had five. Most of these episodes were in chest clinics with 47% of the episodes immediately following treatment and 63% of the final episodes in a chest clinic. Those with post-treatment episodes are more likely to be female χ^2 =5.71, df=1, p=0.017.

Type of care: Approximately two thirds of episodes were in ambulatory settings and one third hospital in-patient care (Table 6.29).

Ambulatory care episodes were defined as those taking place in:

- chest clinics
- SOPDs
- ward follow-up
- A&E departments
- refugee detention centre clinics
- private practitioners

- private OPDs
- correctional services department clinics (prisons, addiction centres)

In-patient episodes were defined as those where the patient was admitted to:
- chest hospitals
- general HA hospitals
- private hospitals
- military hospitals
- correctional services department hospitals

One episode for one patient, which was notified by a coroner, was located in a public mortuary and was unclassified.

Table 6.29: *Type of care provided by episodes identified in study*

Type of care	Number of episodes	% of total
Ambulatory	1293	64.3
In-patient	718	35.7
Other	1	0.0
Total	2012	100.0

Total number of episodes: The distribution of the number of episodes experienced by each patient is bi-modal. The median value is 4 episodes (interquartile range 2 to 6) (Table 6.30).

Table 6.30: *Number of episodes per patient*

No of episodes	No of patients	% of patients
1	65	14.3
2	86	18.9
3	56	12.3
4	84	18.5
5	45	9.9
6	32	7.0
7	20	4.4
8	16	3.5
9	13	2.9
10	12	2.6
11	5	1.1
12	7	1.5
13	3	0.7
14	2	0.4
15 or over	8	1.7
Total	454	100

Total number of in-patient episodes: A majority of patients were admitted to hospital. Of the 454 patients, 171 (37.7%) were not admitted to hospital at any stage of their care. Of those that were admitted, most experienced one or two admissions, but 37 (8%) had more than 4 admissions and one patient was admitted 11 times (Table 6.31).

The range of the number of episodes extended from 1 to 15 or more. 30% of patients had more than 4 episodes of care.

Table 6.31: *Number of in-patient episodes*

No of episodes	No of patients	% of patients
0	171	37.7
1	95	20.9
2	96	21.1
3	41	9.0
4	14	3.1
5	9	2.0
6	12	2.6
7	5	1.1
8	4	0.9
9	3	0.7
10	3	0.7
11	1	0.2
Total	454	100.0

Total number of ambulatory care episodes: Six patients (1.3%) did not experience any ambulatory care episodes at any stage of the study. Over two thirds of patients experienced between one and three, 102 (22%) had between 4 and 6 episodes and one patient experienced 13 ambulatory care episodes (Table 6.32).

Table 6.32: *Number of ambulatory care episodes*

No of episodes	No of patients	% of patients
0	6	1.3
1	96	21.1
2	121	26.7
3	111	24.4
4	57	12.6
5	26	5.7
6	19	4.2
7	8	1.8
8	5	1.1
9	2	0.4
11	1	0.2
12	1	0.2
13	1	0.2
Total	454	100.0

Total number of treatment episodes: The total number of treatment episodes experienced ranges from 1 to 22. The median value was 2 episodes (interquartile range 1 to 4).

Patients who only experience ambulatory care (never admitted): 171 patients only experienced ambulatory care episodes during the three phases of the study (pre-treatment, treatment and post-treatment phases). Of the 171, most experienced one or two episodes, 32 (19%) experienced between 3 and 4 and one patient experienced seven (Table 6.33).

Table 6.33: *Number of ambulatory care episodes experienced by patients who were never admitted to hospital*

Number of ambulatory episodes	No of patients	% of patients
0	1	0.6
1	63	36.8
2	70	40.9
3	21	12.3
4	11	6.4
5	4	2.3
7	1	0.6
Total	171	100.0

Pre-treatment episodes: 316 (67%) patients, out of the total of 454, had at least one pre-treatment episode; 163 (35%) had one, 131 (29%) had between 2 and 4 and 22 (5%) had more than 5 (Table 6.34).

Table 6.34: *Total pre-treatment episodes*

Number of episodes	No. of patients	% of patients in group	% of all patients
1	163	51.6	36
2	152	24.1	17
3	144	12.0	8
4	68	5.4	4
5	50	3.2	2
6	42	2.2	1.5
7	28	1.3	0.8
10	10	0.3	0.2
Total	627	100.0	

279 patients experienced at least one pre-treatment ambulatory care episode; most of these had only one (Table 6.35). The median value was 1 episode, interquartile range was 1 to 2 episodes.

Table 6.35: *Pre-treatment ambulatory care episodes*

Number of episodes per patient	Number of patients	% of total
1	168	60.2
2	79	28.3
3	26	9.3
4	5	1.8
6	1	0.4
Total	279	100.0

124 (27%) patients experienced at least one in-patient episode before treatment started, the maximum number experienced by any one patient being 6 (Table 6.36). The median value was 1 episode, interquartile range, 1 to 2 episodes.

Most of the medical work in the identified episodes of care was concerned with treatment (67%) and most of this care was in ambulatory care (64%).

On the other hand hospital care forms a substantial part of services for tuberculosis; 62% of all patients had at least one admission at some stage of their care.

Table 6.36: *Pre-treatment in-patient care episodes*

Number of episodes per patient	Number of patients	% of total
1	81	65.3
2	27	21.8
3	8	6.5
4	4	3.2
5	3	2.4
6	1	0.8
Total	124	100.0

Treatment episodes: 446 patients experienced at least one treatment episode (8 patients did not start treatment) (Table 6.37). The modal number was 1 episode (35%) but just under half, 47%, had between 2 and 4 treatment episodes. The median value was 2, interquartile range, 1 to 4 episodes.

Table 6.37: *Treatment episodes*

No of episodes	No of patients	% of patients
1	158	35.4
2	200	22.4
3	161	12.8
4	204	11.4
5	135	6.1
6	102	3.8
7	62	1.3
8	64	1.8
9	72	1.8
10	40	0.9
11	22	0.4
13	39	0.7
14	28	0.4
18	18	0.2
21	21	0.2
22	22	0.2
Total	1328	100.0

Post treatment episodes: 29 (6%) patients experienced post-treatment episodes. Of these 18 had only one episode but 1 patient had five (Table 6.38). The median value was 1 episode, interquartile range 1 to 2 days.

Table 6.38: *Post treatment episodes*

No of episodes	No of patients	% of patients
1	18	62.1
2	14	24.1
3	6	6.9
4	4	3.4
5	5	3.4
Total	47	100.0

Types of episodes of care: The types of episodes of care experienced by patients during treatment were identified and classified into three groups:

- ambulatory care episodes related to tuberculosis
- in-patient episodes principally attributable to tuberculosis
- in-patient episodes where the main reason for admission was for a co-morbidity but the patient continued to receive treatment for tuberculosis (non-TB episodes)

The most frequently experienced type of episode was ambulatory care and 95% of patients experienced at least one ambulatory care episode (Table 6.39).

Table 6.39: *Types of treatment episodes experienced by patients*

Type of episode	Total number of episodes	Number of patients experiencing at least one of this type of episode
Ambulatory care related to tuberculosis	814	431 (94.9%)
In-patient care for tuberculosis	395	225 (49.6%)
In-patient care for co-morbidity	112	61 (13.4%)
Total	1321	446 (98.2%)

For each treatment episode type, most patients experienced only one episode, although one patient experienced 12 ambulatory care treatment episodes (Figure 6.8). In-patient TB episodes (Figure 6.9) and non-TB episodes (Figure 6.10) ranged from one to nine per patient. The maximum total number of episodes experienced was 22 (Figure 6.11) and the maximum number of TB treatment episodes was 19 (Figure 6.12).

Reviewers commented that because of *"(i) the high hospitalization rate; (ii) the ageing population and (iii) the relatively high prevalence of TB complications and comorbidities it may be worthwhile to re-examine the overall hospital care (and bed) requirements for TB patients,"* and *"analysis of the subgroup of chest clinic admissions to chest hospital would be rewarding as this group is homogeneous and shared-care practice could be controlled."*

One in 5 of the inpatient episodes were for management of a co-morbidity. In-patient episodes ranged from 1 to 9 per patient.

Figure 6.8: *Number of ambulatory care treatment episodes experienced*

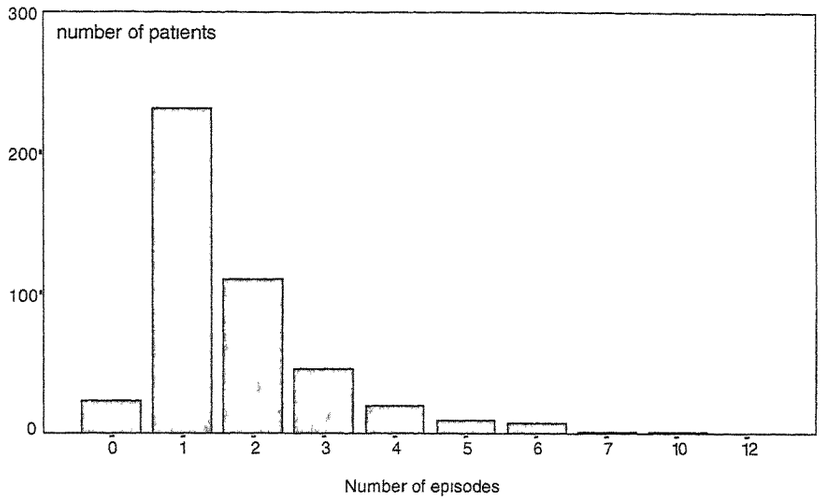


Figure 6.9: *Number of in-patient care treatment episodes experienced*

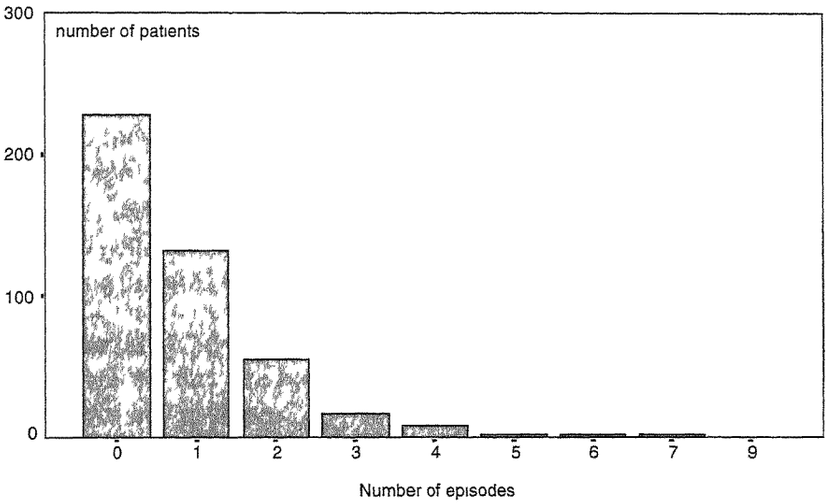


Figure 6.10: *Number of non-TB in-patient care treatment episodes*

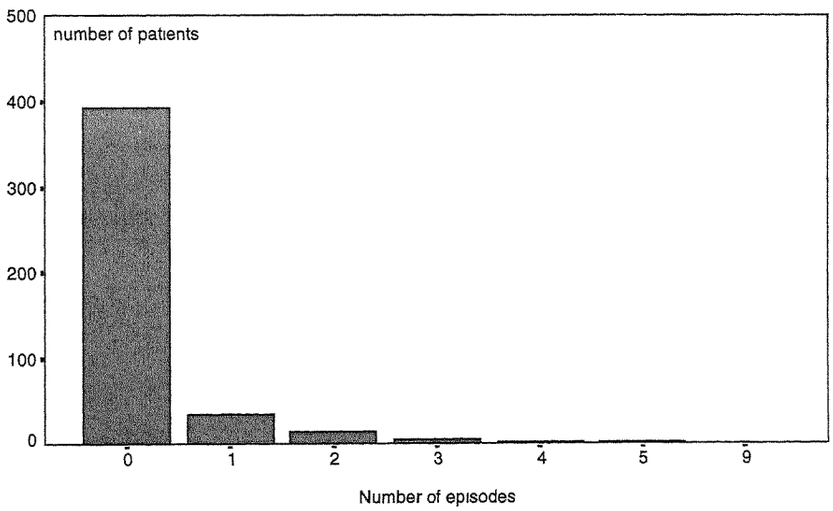


Figure 6.11: Sum of all treatment episodes

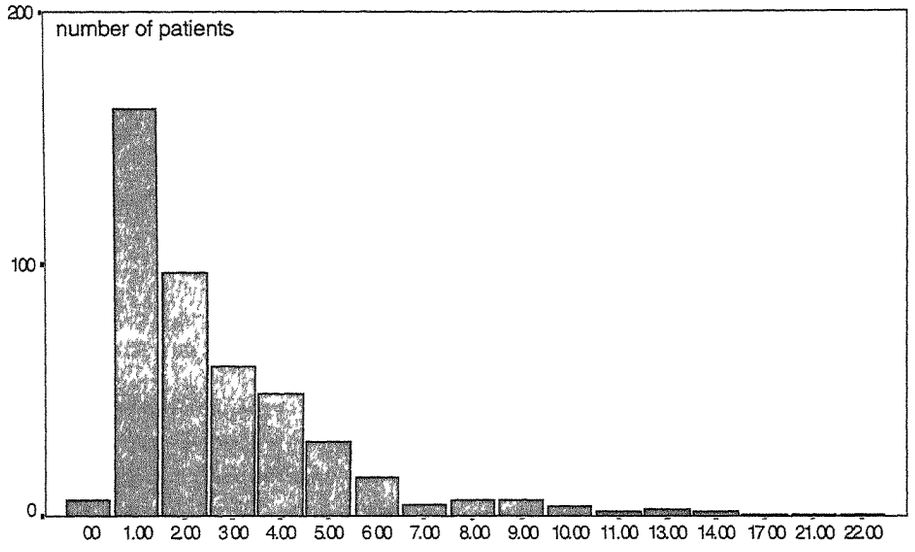
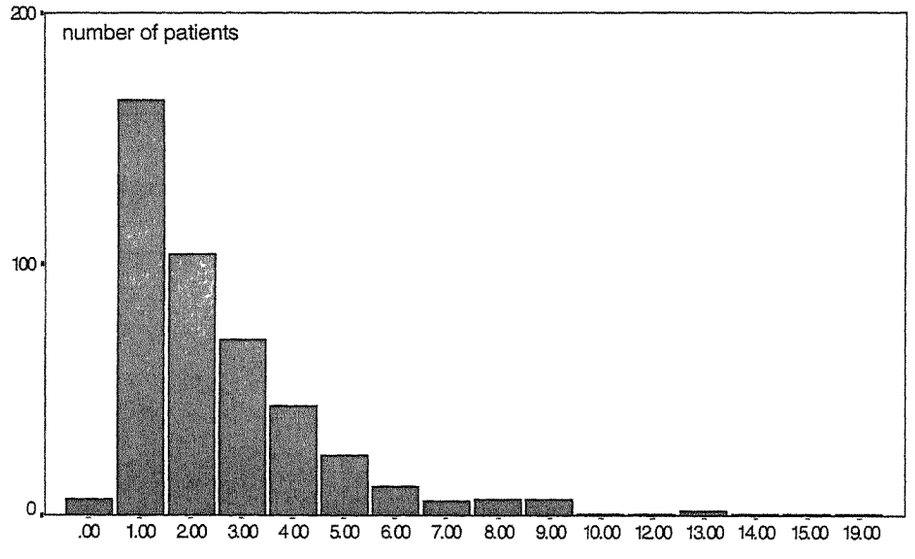


Figure 6.12: Sum of TB treatment episodes



6.3.4.2 Sources of care

Source of episode: Over 40% of episodes were in chest clinics, and nearly 20% each in chest hospitals and general hospitals. The remainder of episodes took place in a wide range of ambulatory and in-patient care settings (Table 6.40).

Table 6.40: Source of care

Source	No of separate sources	No of episodes	% of episodes
Chest clinic	11	828	41.2
General HA hospital	19	364	18.1
Chest hospital	5	334	16.6
SOPD - general hospital	17	132	6.6
Private practitioner	97	97	4.8
A&E department	13	92	4.6
GOPD	28	46	2.3
SOPD - chest hospital	4	38	1.9
Refugee detention centre	5	20	1.0
Correctional institution	7	14	0.7
Ward follow-up - general hospital	6	14	0.7
Private hospital	8	13	0.6
Ward follow-up - chest hospital	4	12	0.6
Private OPD	3	4	0.2
Public mortuary	1	1	0.0
Other	1	3	0.1
Total	229	2012	100.0

Preceding source of care: Most referrals took place:

- from chest hospitals to chest clinics (224) and vice-versa (173)
- between chest clinics (180)
- from A&E departments to general HA hospitals (207).
- from general HA hospitals to chest clinics (112)
- from general HA hospitals to chest hospitals (85)

Self-referral: There may be no preceding source of care if the patient(s) had referred themselves to this present source of care. 198 (44%) of the 454 patients had referred themselves and of these

- 25 went to a chest clinic
- 28 went to a GOPD
- 76 went to A&E
- 11 went to a PP

Other source of referral: 33 were referred after identification during a screening procedure for migrants, employment or other reason. Six patients were referred after contact tracing. In 140 episodes the source of referral was unknown.

The management of tuberculosis took place in 15 different categories of care facility at 229 different sites.

Figure 6.13: Pathway of care for those who start treatment in a chest clinic

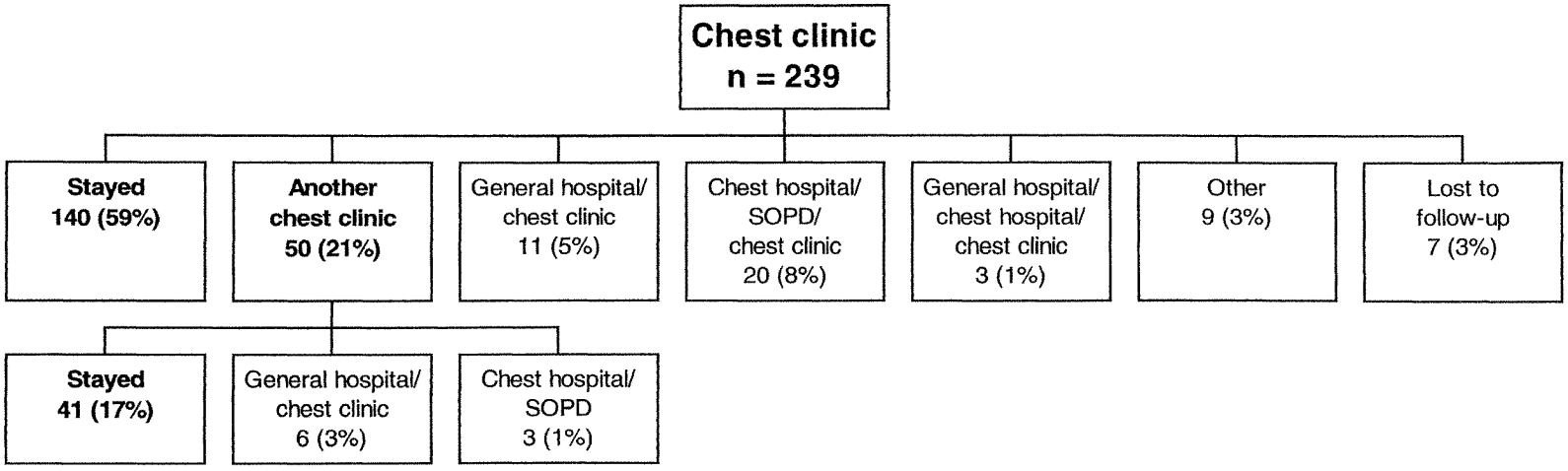


Figure 6.14: Pathway of care for those who start treatment in a chest hospital

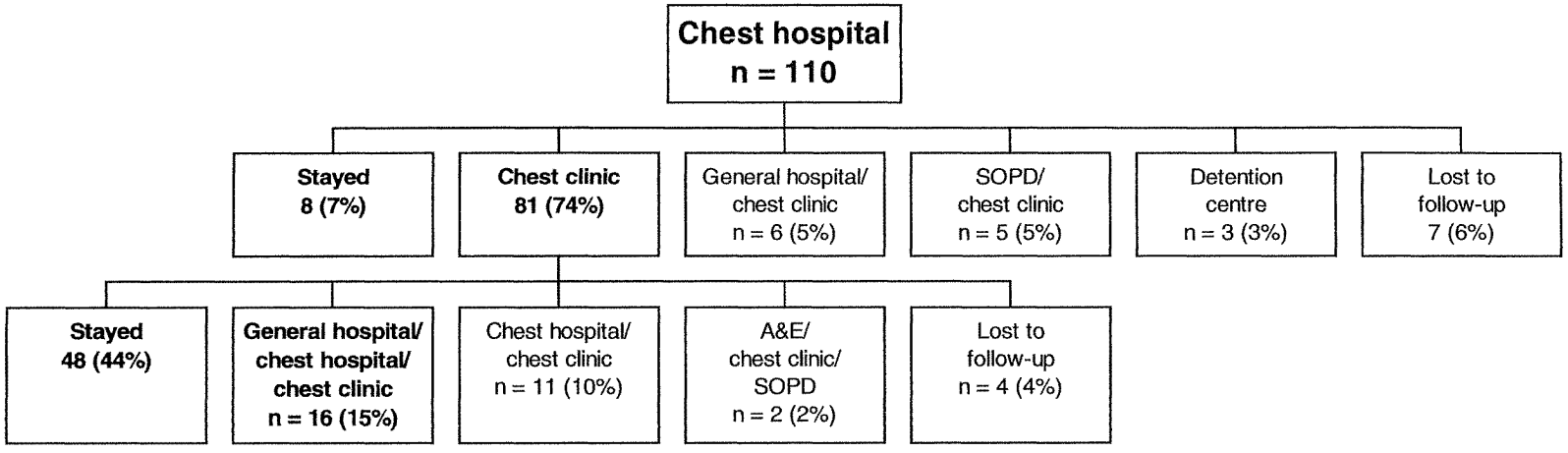
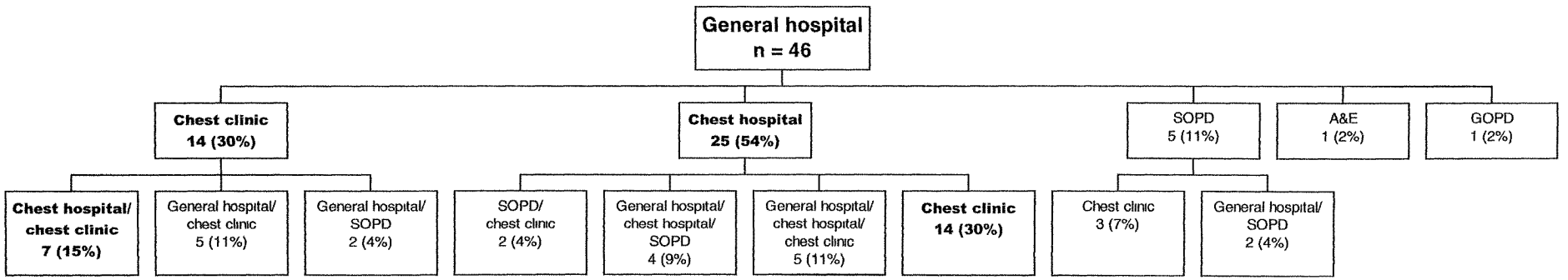


Figure 6.15: *Pathway of care for those who start treatment in a general hospital*



Subsequent source of care: A total of 1514 referrals to a subsequent source of care took place. The 5 most frequent types of referral are shown in Table 6.41.

Table 6.41: Referrals to subsequent sources of care

Type of referral	Number of referrals	% of total
chest hospitals and chest clinics	217	14.3
chest clinics and chest hospitals	194	12.8
one chest clinic to another	131	8.7
general HA hospital to chest clinic	90	5.9
general HA hospital to chest hospital	89	5.9
other	793	52.4
Total	1514	100.0

There were 14 instances where patients were referred to two different sources of care. In 11 of these instances, patients referred themselves to one of the sources and were referred to the other by the current source.

In 108 instances, the subsequent source of care for planned readmissions or reviews was the same as the current source. In 88/108 the source was a chest or general HA hospital and these were planned readmissions (Table 6.42).

Pathways of care: The data on site of care during each episode was used to identify the paths that each patient took through the health care system. These are summarised in Figures 6.13, 6.14 and 6.15 for those patients who had between 1 and 10 episodes and started treatment in a chest clinic, a chest hospital or a general hospital. The principal paths (ie followed by most patients) are shown in bold.

Table 6.42: Type of source of care for planned readmissions or reviews

Type of source	Number of readmissions/reviews	% of total
Chest hospital	52	48.1
General hospital	36	33.3
Chest clinic	2	1.9
SOPD (general)	10	9.3
SOPD (chest)	3	2.8
Ward FU (general)	3	2.8
A&E	1	0.9
Private practitioner	1	0.9
Total	108	100.0

6.3.4.3 Source of notification

Source of notification, starting treatment and completing treatment: At all three stages, most patients were being managed by a chest clinic. However, the proportion of patients notified by a chest clinic was higher than the proportion starting treatment there. For all other sources of care the opposite trend was seen. Of the 379 patients who completed treatment, chest clinics were managing over 90% at completion (Table 6.43). Only 2 patients were notified from the private sector.

Ninety six patients (23.1%) were not notified by the same source of care that started treatment (Table 6.44). Of these, 74 (77.1%) were notified by chest clinics including 5 patients who started treatment in one chest clinic but were notified by another. The most frequent pattern was for patients to start treatment in chest hospitals and be notified by chest clinics.

Table 6.43: *Source of care at notification, start and completion of treatment*

Source of care	Notification	Starting treatment	Completing treatment
Chest clinic	327 (72.0)	245 (54.9)	346 (91.3)
Chest hospital	102 (22.5)	113 (25.3)	5 (1.3)
Hospital - general HA	18 (4.0)	57 (12.8)	3 (0.8)
SOPD - chest HA	0	4 (0.9)	13 (3.4)
SOPD - general HA	1 (0.2)	3 (0.7)	6 (1.6)
Private practitioner	1 (0.2)	10 (2.2)	2 (0.5)
Private hospital	1 (0.2)	4 (0.9)	0
Public mortuary	1 (0.2)	0	0
Detention centre	0	1 (0.2)	1 (0.3)
Ward follow-up – chest HA	0	0	1 (0.3)
OPD - private	0	0	1 (0.3)
Other country	0	8 (1.8)	0
Other	3 (0.7)	1 (0.2)	0
Total	454 (100.0)	446 (100.0)[a]	379 (100.0)[b]

a. 8 did not start treatment
b. 67 of the 446 who started treatment did not complete treatment

Table 6.44: *Source of starting treatment and notification for patients not notified by the source where they started treatment*

	source of notification				
Source starting treatment	chest clinic	chest hospital	general hospital	other	total
Chest clinic	5	3	-	-	8
Chest hospital	31	-	-	1	32
General hospital	28	14	-	-	42
Private practitioner	5	1	-	-	6
Private hospital	5	-	1	-	3
Chest hospital SOPD	1	2	-	-	3
General hospital SOPD	2	-	-	-	2
Total	74	20	1	1	96

Notification of patients in this sample was mainly shared between chest clinics (72%) and chest hospitals (23%) but more than 1 in 20 were receiving treatment at other sites at notification.

6.3.4.4 Intervals between stages of care

Interval from first probable presentation to first definite presentation: The first probable presentation was defined as the first presentation to medical care prior to the first definite date where:

- the reason for presentation was noted in the medical record, and
- the reason for presentation could be attributed to tuberculosis (if symptoms could have been due to another known pathology (eg if the patient presented with haemoptysis but was also known to have bronchiectasis), then the episode was excluded), and
- the episode was not directly linked to the first definite episode.

If only the month of first probable presentation was known, the last day of the month was recorded.

A first probable presentation was identified for 73 (16.1%) patients. For 29/73, the episode relating to the first probable presentation was not included in the study for one of the following reasons:

- there was insufficient information in the record to trace the record which related to the previous probable presentation. For example, the doctor may have recorded: "attended hospital two months ago with haemoptysis". This occurred in medical records at all categories of source of care (n=22).
- the first probable presentation was for screening purposes (n=5).
- the first probable presentation was over one year before the patient started treatment (n=4)

For the remaining 44 patients, the first episode included in the study related to the first probable presentation.

The first definite presentation to medical care was defined as the first presentation where:

- the reason for presentation was noted in the medical record, and
- the reason for presentation could be attributed to tuberculosis, and
- the episode of care was directly linked (the patient is referred from one source to another) to the episode where the patient was diagnosed with tuberculosis, was notified, or started treatment.

If the exact start date of this first definite episode was not known, the earliest date that the patient was known to have been seen for assessment was used.

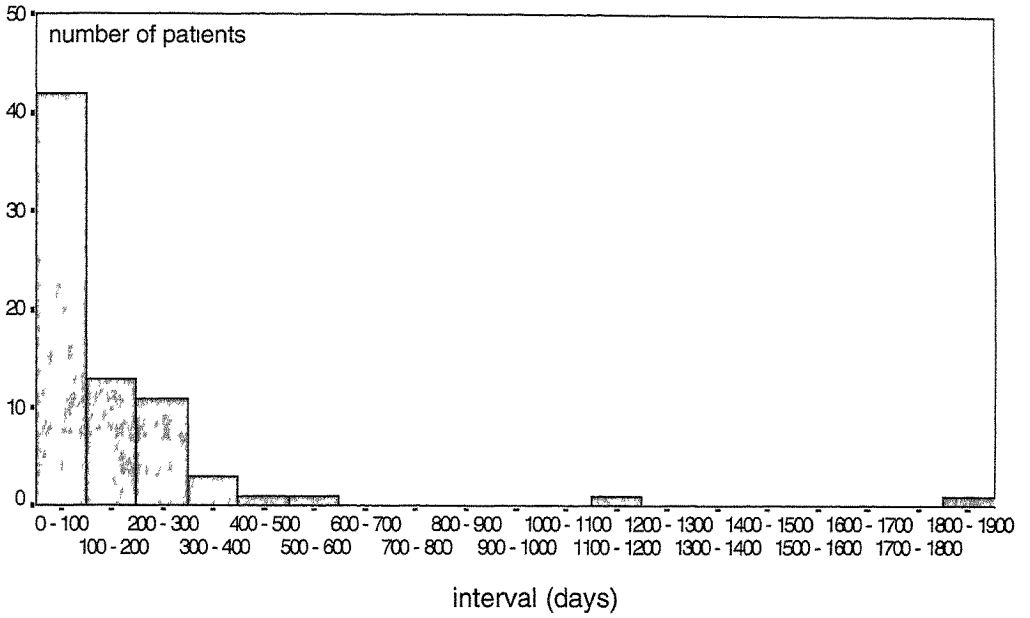
> ***Example:*** *Patient first presented to a private practitioner who referred the patient to a chest clinic. No definite start date is available for the private practitioner episode, but it is known that a chest X-ray was performed on 1 November 1994 which demonstrated a cavitatory lesion. The date 1 November 1994 is used as the first definite date of presentation.*

The median value for the interval between first probable and first definite presentation was 69 days (interquartile range 22 to 197). Whilst the majority of patients presented again within a few months of their first probable presentation, two patients had an interval of over 3 years (Figure 6.16):

- patient A (interval 3 years) first presented in 1991 with a lesion which was suspected to be a TB granuloma. The lesion was monitored and the patient started treatment once it developed into a cavitating mass in 1994.

- patient B (interval 5 years) first presented in 1989 with symptoms leading to a biopsy of a lesion which was "highly suggestive of TB". The patient was lost to follow-up and presented with disease in two different sites of the body in 1994.

Figure 6.16: Interval between probable and definite first presentation



Interval from first definite presentation to first definitive diagnosis: First definitive diagnosis was defined as the date of the first laboratory report of a positive microbiological or histological diagnosis of tuberculosis.

This interval was calculated for 291 patients. The remaining patients were not included for one or more of the following reasons:

- they started treatment in another country (n=41, 9%)
- they had no definitive diagnosis (n=134, 30%)
- they did not start treatment (n=8, 2%)

The median value was 33.0 days (interquartile range 7 to 58 days) (Figure 6.17). The distribution was bimodal with the first larger peak occurring between zero and ten days, and the second between 45 and 60 days.

The interval varied according to the sputum smear status of the patient at the start of treatment, with smear positive patients experiencing the shortest intervals (Figure 6.18). However, some smear positive patients also experienced delays in definitive diagnosis of over three weeks.

For the 25% of patients whose delay in definitive diagnosis was over two months after first presentation, nearly 40% started treatment *before* a definitive diagnosis was made (that is, for 40%, although diagnosis was delayed, treatment was not).

Records systems for TB services should ensure reliable capture and recording of information about the initial presentation and the subsequent milestones in management.

Figure 6.17: *Interval from first definite presentation to definitive diagnosis*

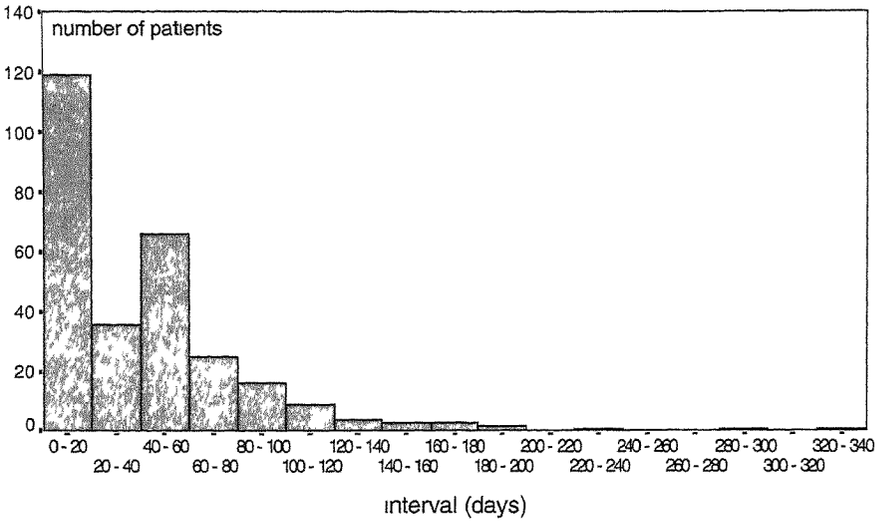


Figure 6.18: *Interval from first definite presentation to first laboratory report*

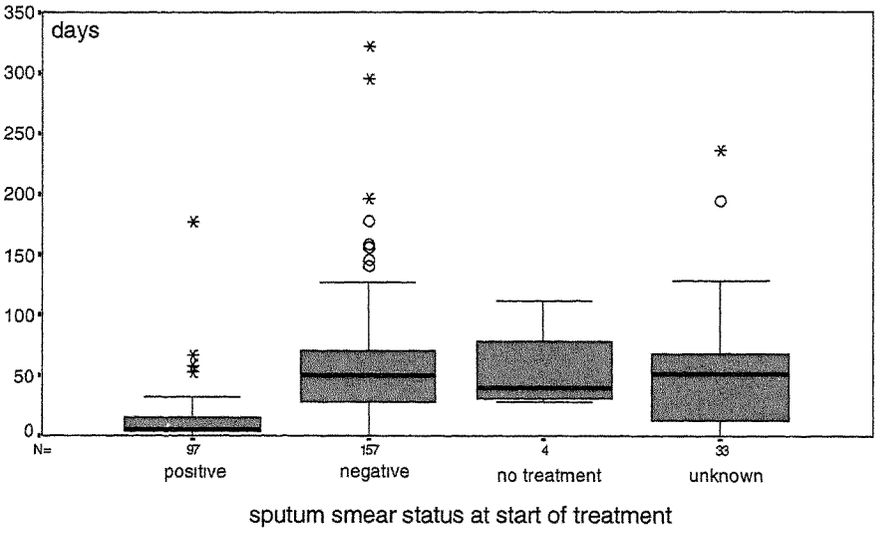
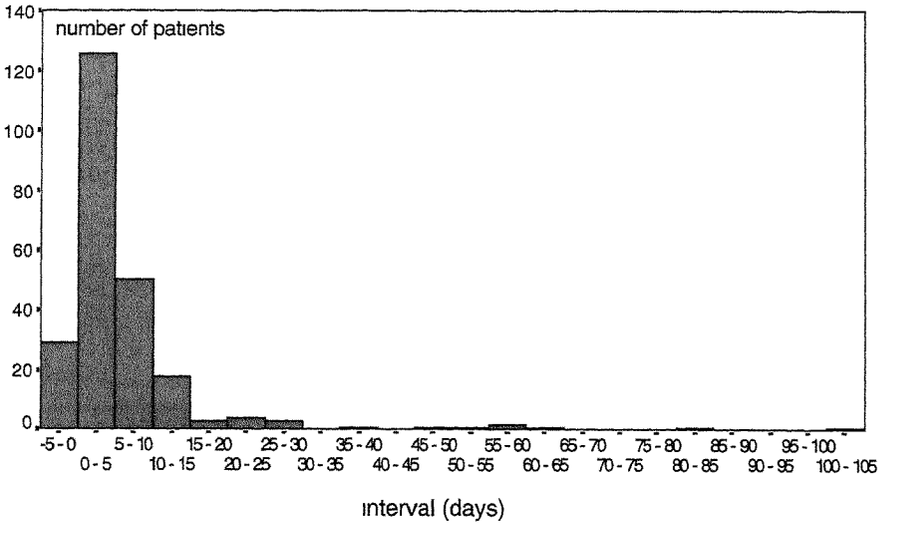


Figure 6.19: *Interval from laboratory report to diagnosis noted in record*

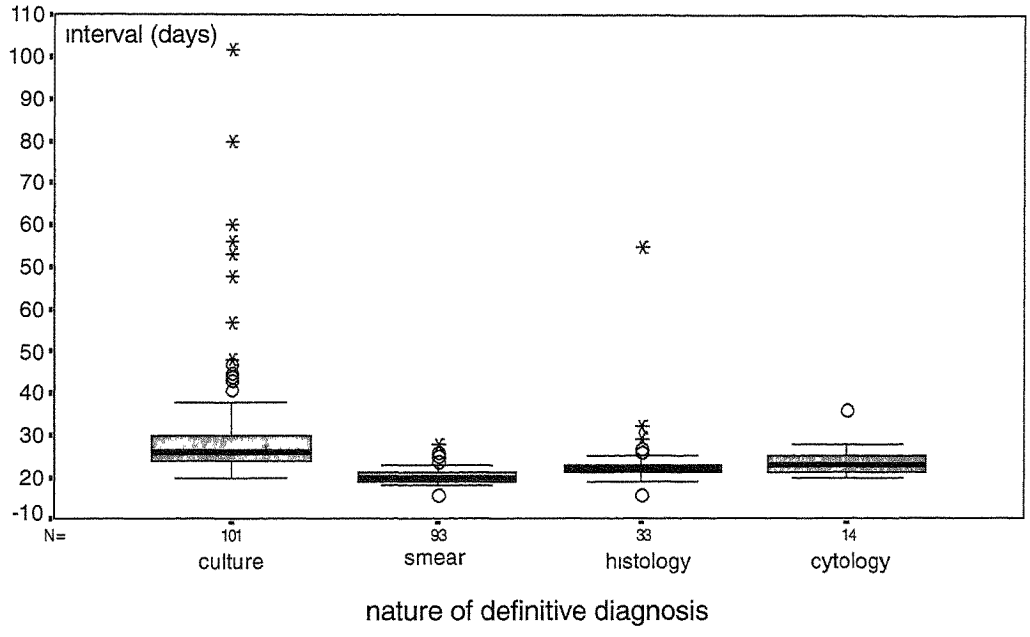


Interval from first laboratory report to first entry in medical record: For first definitive diagnosis, the interval between the date of the laboratory report and the date the same result was first noted in the medical record was calculated for 241 patients. In over 75% of patients, this interval was less than a week (Figure 6.19). The median value was 3 days (interquartile range 0-6 days). For 29 patients the result was noted in the medical record in the week *before* the laboratory report was dated. These results related to 26 sputum smears, 1 bronchial aspirate smear, 1 lung biopsy histology and 1 bone/joint biopsy histology.

For eight patients the result was noted over a month *after* the date of the laboratory report. In one patient where the delay was 55 days, the delay appeared to result in a delay in treatment as treatment was started on the same day that the result was noted in the record. In the remaining seven patients, treatment was started between 15 and 45 days before the date of the laboratory result, presumably on an empirical basis or because of information through other lines of communication.

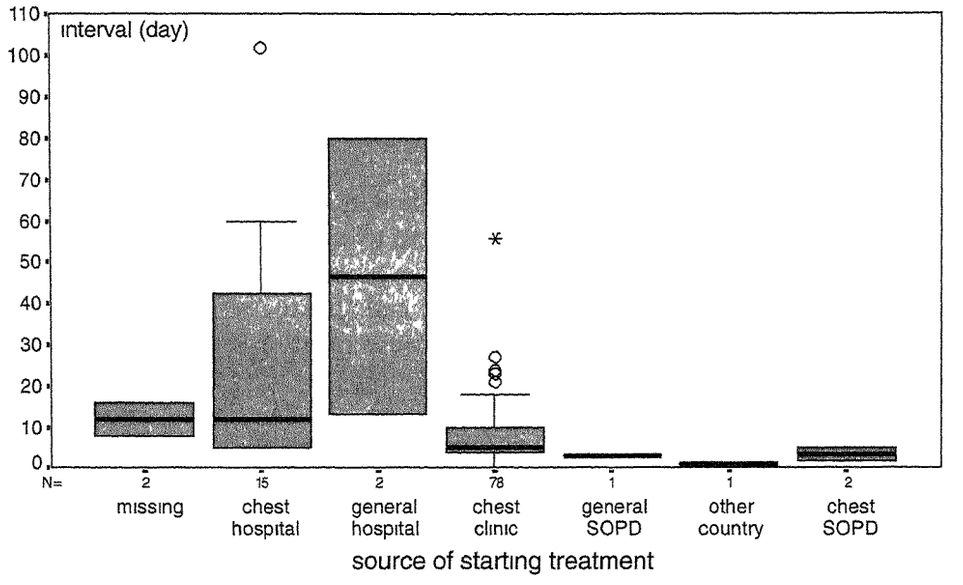
Most of the delays in recording positive reports in the record occurred for positive culture results rather than positive smear, histology or cytology results (Figure 6.20). Using the source of starting treatment as a proxy for the source of diagnosis, most delays in noting positive culture results occurred in chest hospitals and general hospitals, although some delays occurred in chest clinics (Figure 6.21).

Figure 6.20: *Interval from date of first laboratory report to result noted in record*



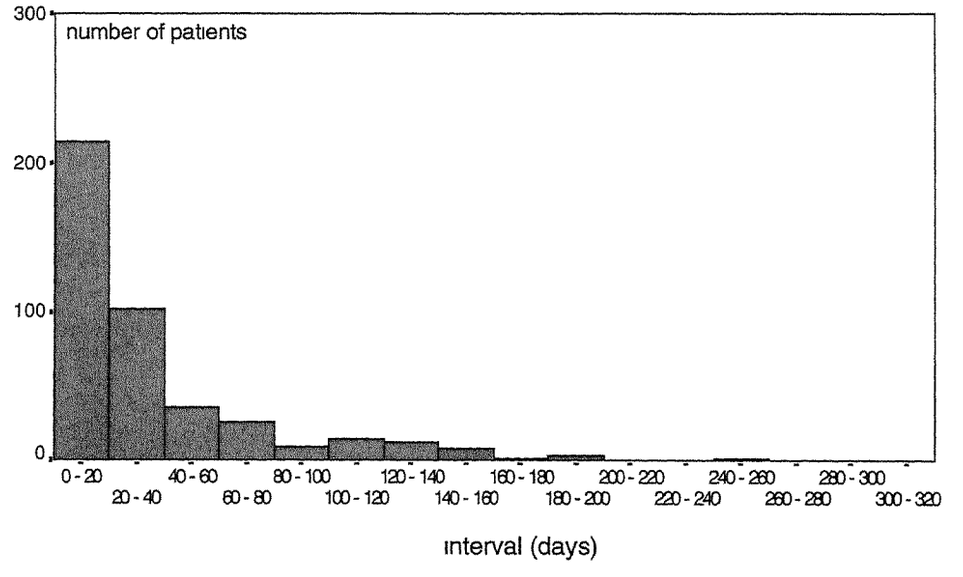
There were delays in noting positive culture results in medical records in all of the main treatment facilities.

Figure 6.21: *Interval from first laboratory report to date of result noted in record (positive culture reports)*



Interval from first *definite* presentation to start of treatment: This interval was calculated for 436/454 patients. Of the 18 patients for whom it could not be calculated, 8 did not start treatment, 2 started treatment at a private practitioner and the date of starting treatment could not be established, and 8 started treatment in another country. The median value was 20 days, interquartile range 7 to 44 days (Figure 6.22).

Figure 6.22: *Interval from first definite presentation to starting treatment*



This data was analysed using interval as a continuous variable to maximise use of the data. The relationship between the interval and the following variables was examined using boxplots:

Patient characteristics:

- smear status at start of treatment: positive, negative/unknown
- age: under 60, 60 or above
- gender: male, female
- region of residence:
- definitive diagnosis:
- definite past TB
- site of disease: pulmonary, extrapulmonary
- presence of any TB complication during treatment

Health care characteristics:

- source of first presentation (excludes patients with a date of probable first presentation, because the source of care for first presentation would not relate to source of definite presentation): category of care
- source of starting treatment: category of care

Outcomes:

- IUATLD outcome for smear positive patients
- Operational study outcome for all patients

Results: Smear positive patients tended to start treatment earlier than smear negative or unknown (Figure 6.24). For smear positive patients, the interval between presentation and treatment had a median value of 8 days, interquartile range 4 to 19, while patients whose smear status was unknown at the start of treatment had the longest interval (median = 35 days, interquartile range 6 to 92 days) (Figure 6.23).

A considerable number of smear positive patients were however delayed in starting treatment, and these may pose a risk of transmission to the community.

One smear positive patient is estimated to infect 10 people each year (Rouillon 1976). Delayed treatment of smear positive patients increases the risk of transmission. This risk to the community can be estimated using the data from this study as follows:

Number of additional infections attributable to delays in treatment: In the study, 38 smear positive patients had an interval from first definite presentation to start of treatment of greater than 2 weeks. The median value of this interval for these patients was 27.5 days (range 15-180). Using this data:

Estimated number of smear positive patients per year with treatment delayed over two weeks = 38/454 x 6500 = 544

If 10 people are infected by one smear positive patient each year,

Estimated number of people infected = 544 x 13.5/365 x 10 = 201
(estimated range as a result of this delay in treatment is: 15-2474)

Older patients were more likely to experience delays in receiving treatment (Figure 6.24).

There was a slight tendency for female patients to experience longer delays than males (Figure 6.25).

Figure 6.23: *Interval from first definite presentation to date of starting treatment, by smear status*

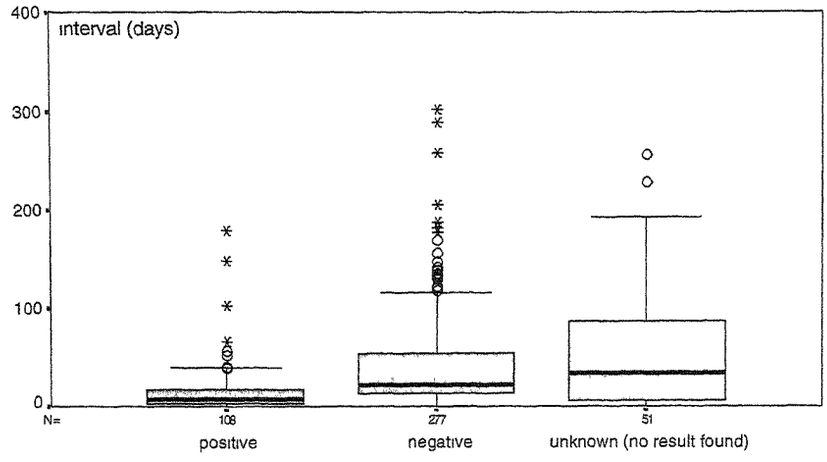


Figure 6.24: *Variation in interval from first definite presentation to date of starting treatment, by age*

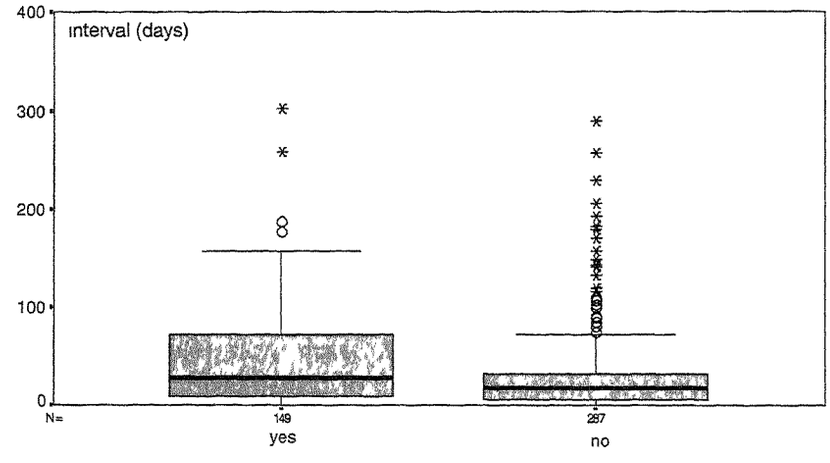
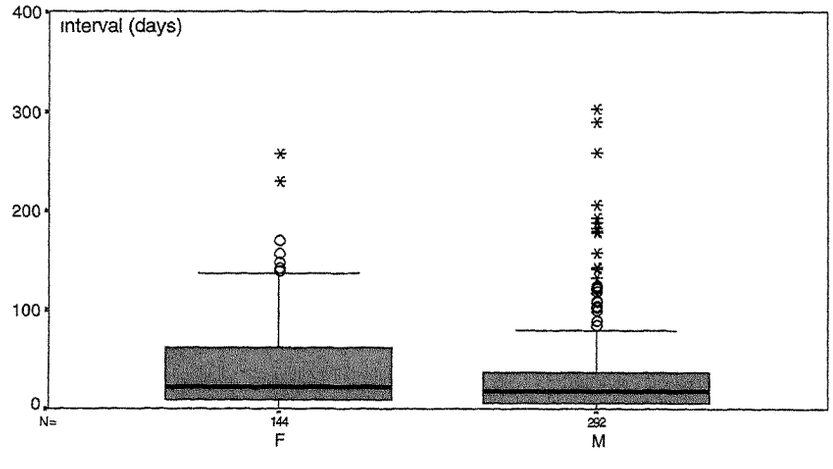
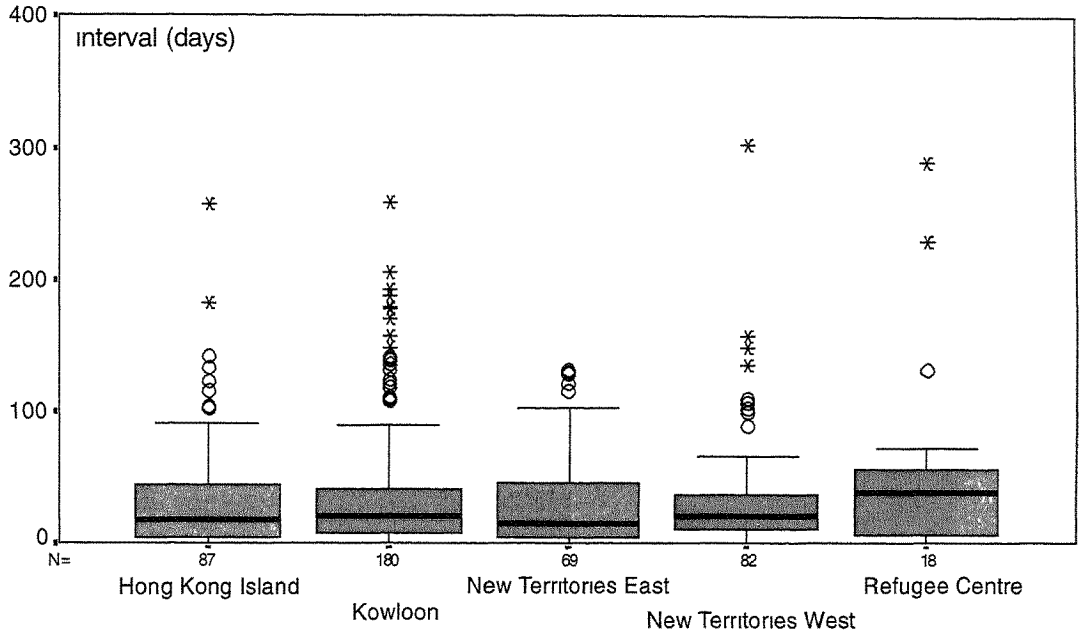


Figure 6.25: *Variation in interval from first definite presentation to date of starting treatment, by gender*



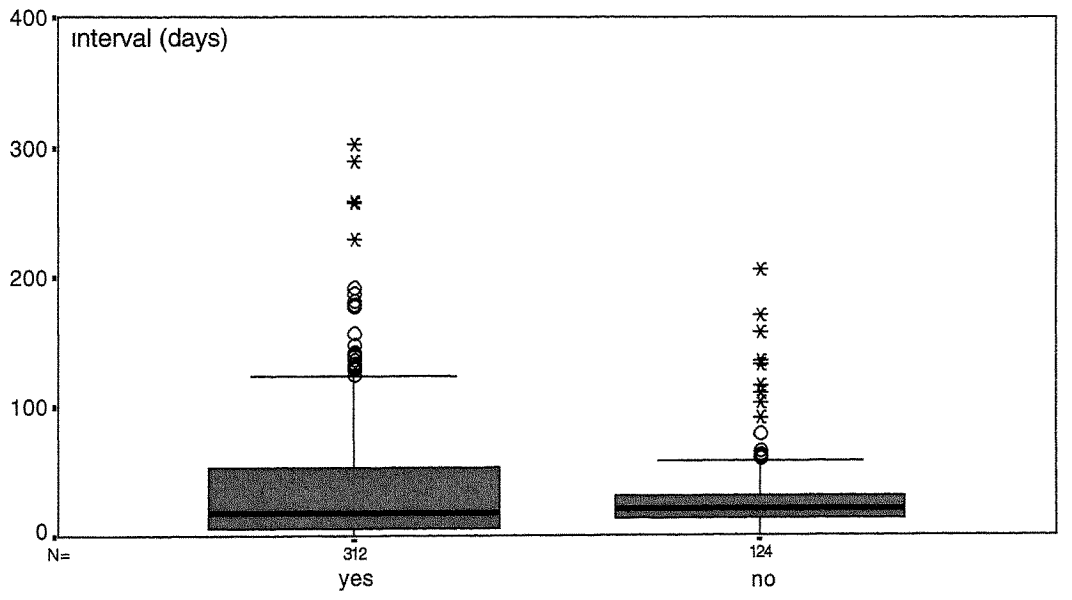
There was no obvious differences between region of residence, although patients living in refugee centres tended to experience longer delays (Figure 6.26).

Figure 6.26: *Variation in interval from first definite presentation to date of starting treatment, by region of residence*



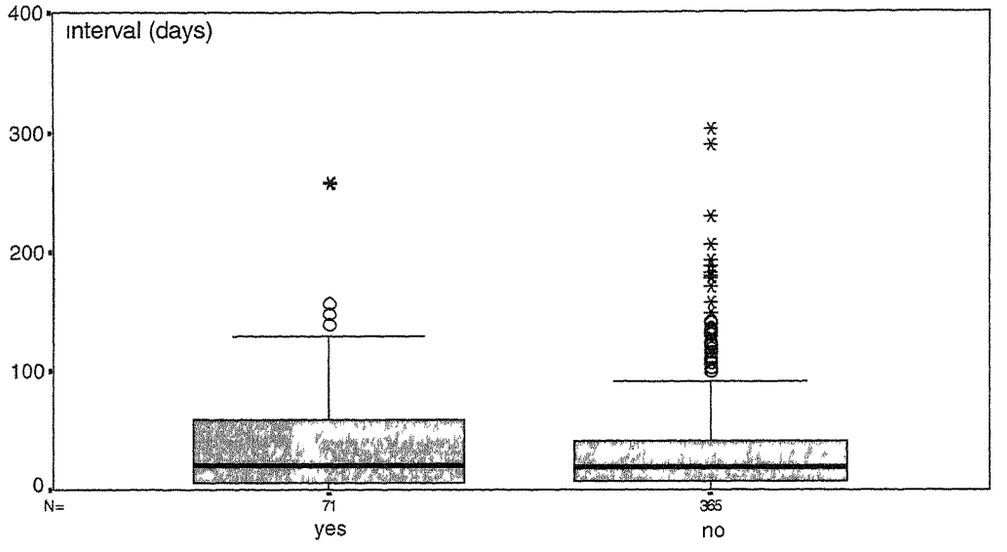
The range of values was greater for patients with a definitive diagnosis, suggesting that treatment may be delayed in such patients until a diagnosis is made (Figure 6.27).

Figure 6.27: *Variation in interval from first definite presentation to date of starting treatment, by label of definite diagnosis*



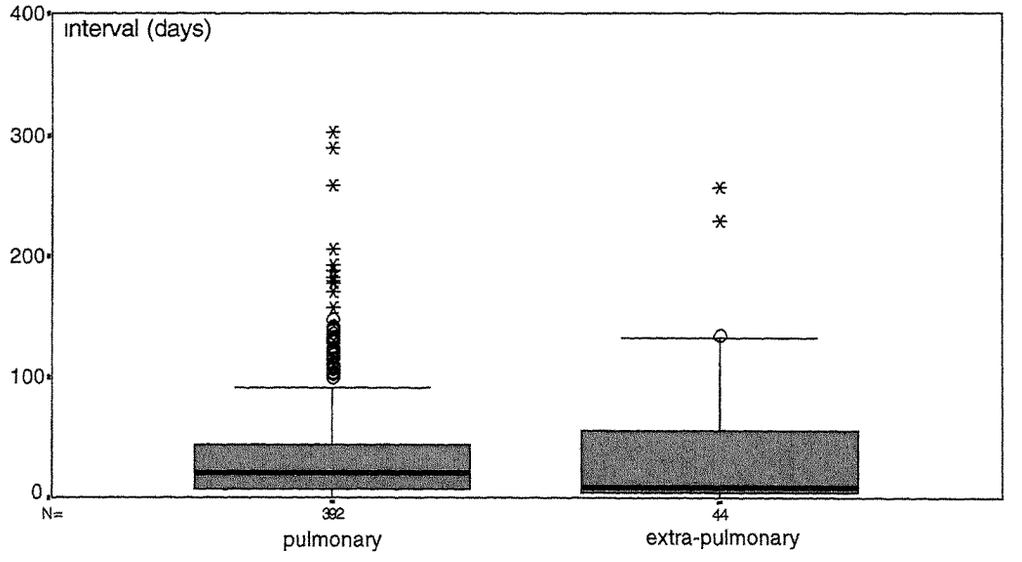
The median values were similar for patients with and without a definite past history of TB: a past history of TB is not associated with any reduction in the delay in starting treatment (Figure 6.28).

Figure 6.28: *Variation in interval from first definite presentation to date of starting treatment, by past history of TB*



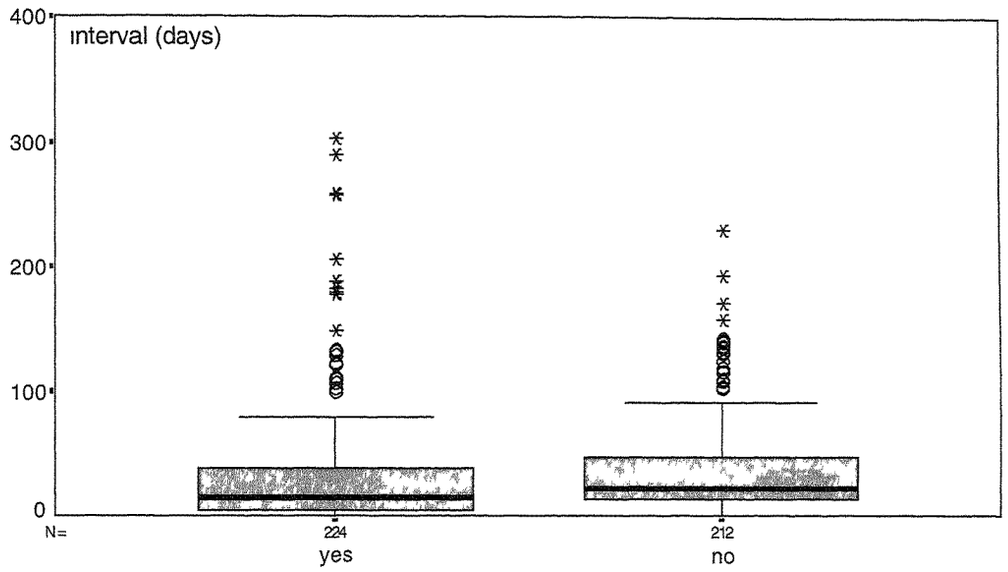
Patients with pulmonary disease have a slightly longer median delay than those with extra-pulmonary disease (Figure 6.29).

Figure 6.29: *Variation in interval from first definite presentation to date of starting treatment, by site of disease*



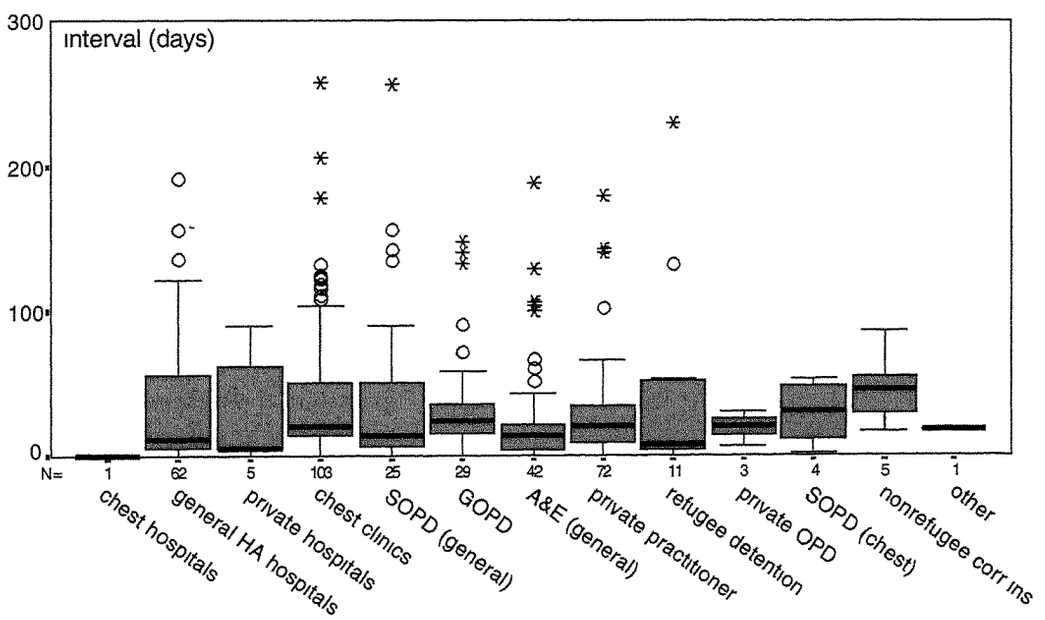
Delays in treatment do not appear to predict the occurrence of complications of the disease (Figure 6.30).

Figure 6.30: *Variation in interval from first definite presentation to date of starting treatment and occurrence of complications*



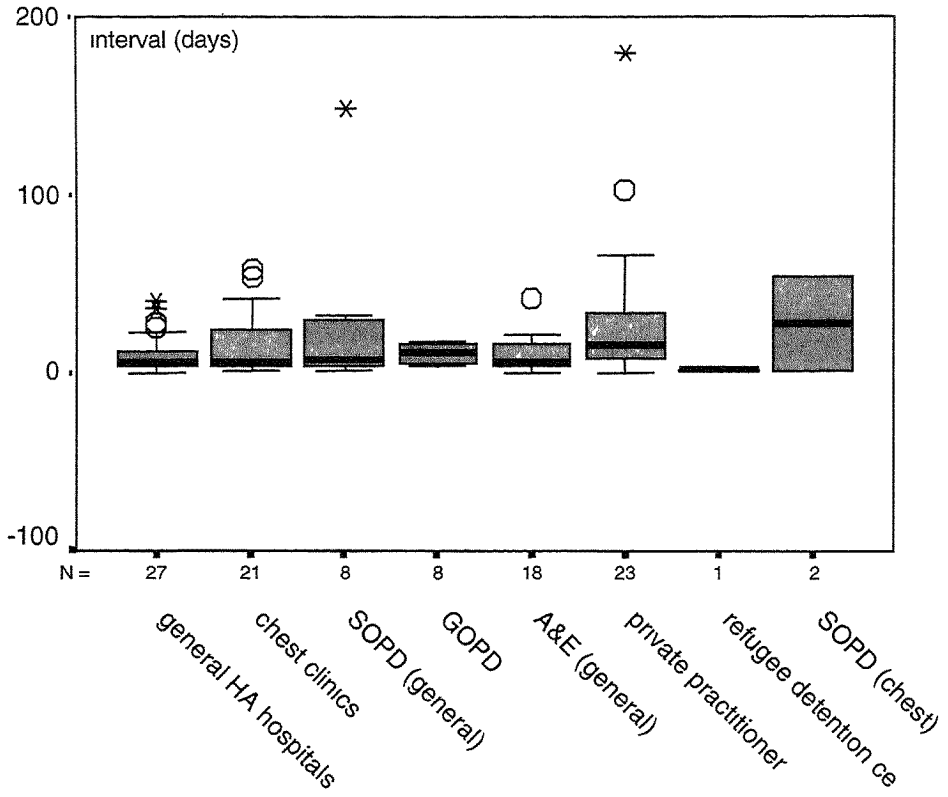
There was considerable variation according to the category of first source of presentation. Patients attending a hospital or A&E department experienced the least variation and shortest delay to the start of treatment, whilst those attending SOPDs, GOPDs and correctional institutions as the first health care site experienced the longest median length of time between presentation and treatment (Figure 6.31). Patients presenting first to chest clinics, SOPDs at general hospitals, refugee detention centres and general hospitals experienced the greatest overall range of delays.

Figure 6.31: *Variation in interval from first definite presentation to date of starting treatment, by first episode source of care*



When only those patients who are smear positive at the start of treatment are examined, those with the highest median length of time between presentation and start of treatment are those who presented to a chest SOPD (only 2 cases), a private practitioner or a GOPD.

Figure 6.32: *Variation in interval from first definite presentation to date of starting treatment by first episode source of care for smear positive cases only*



There was similar variation according to the category of care where treatment was started. Of those with sufficient numbers of patients for analysis, patients starting treatment at chest clinics had experienced the longest delays, followed by chest hospitals (Figure 6.33).

These health care relationships must be interpreted cautiously taking into account likely case-mix and problems of diagnosis and management.

Smear positive patients with failed treatment regimens appear to have experienced slightly longer delays to starting treatment than others, although the numbers are very small (Figure 6.34).

Figure 6.33: *Variation in interval from first definite presentation to date of starting treatment, by source of care starting treatment*

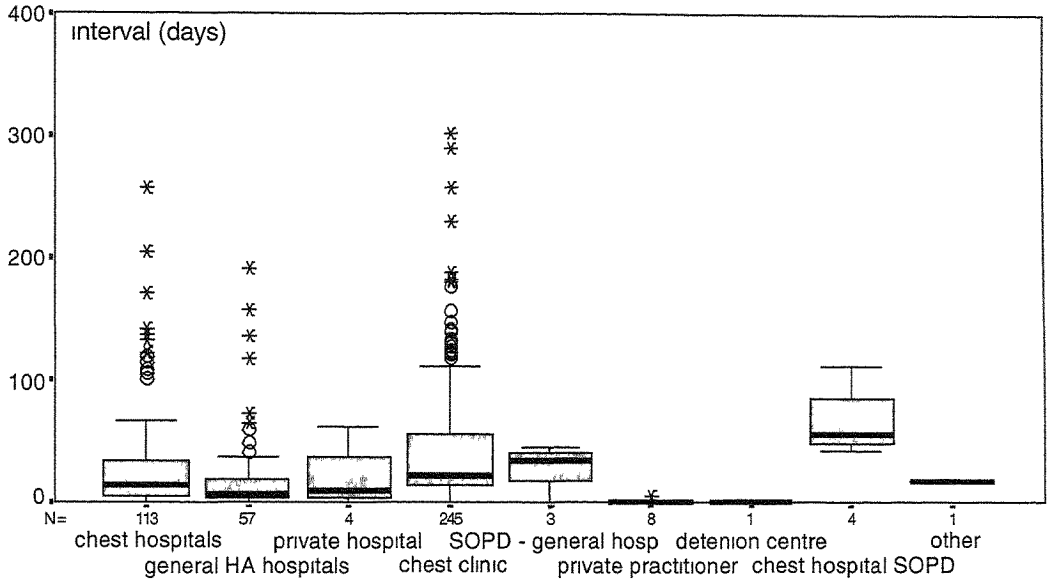
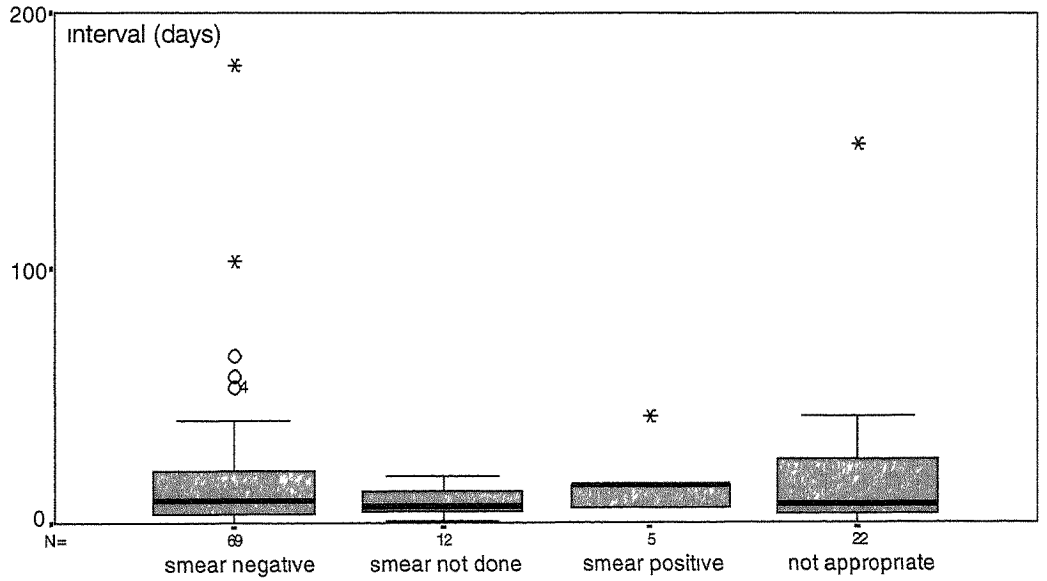
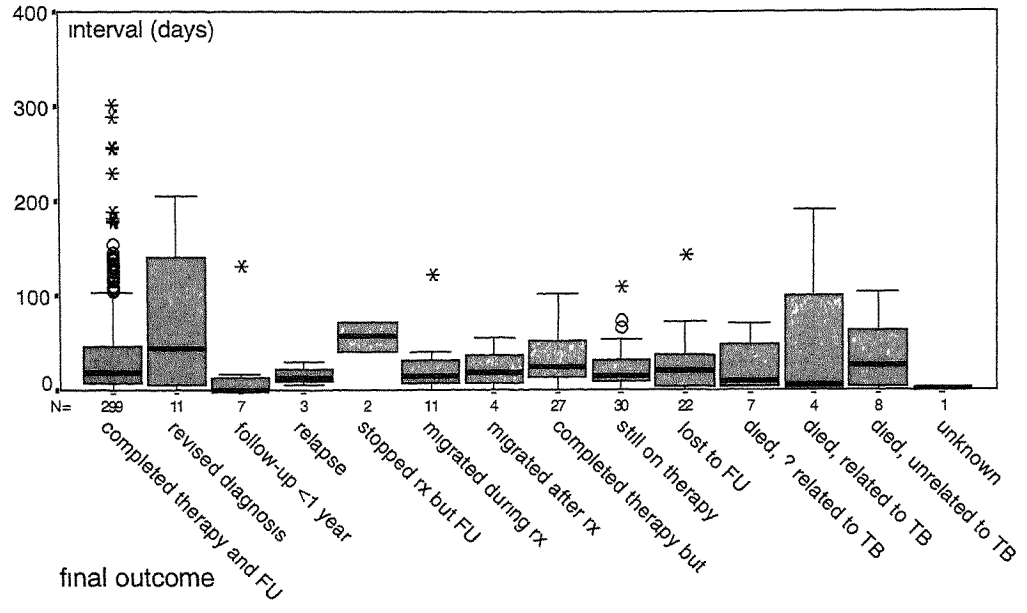


Figure 6.34: *Variation in interval from first definite presentation to date of starting treatment, by IUATLD outcome*



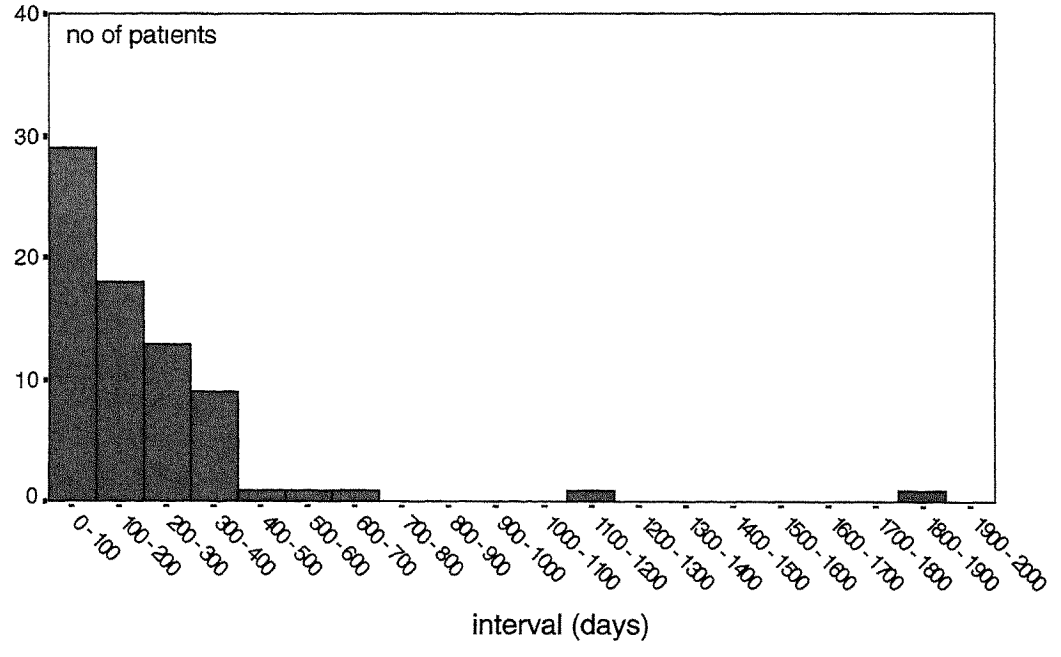
Patients successfully completing treatment and follow-up in the study had a low median delay in starting treatment but there were a considerable number of patients in this category who experienced very long delays. The biggest median value was experienced by patients whose diagnosis was subsequently revised, suggesting that initiation of treatment was delayed because of doubts over the diagnosis (Figure 6.35).

Figure 6.35: *Variation in interval from first definite presentation to date of starting treatment, by final outcome*



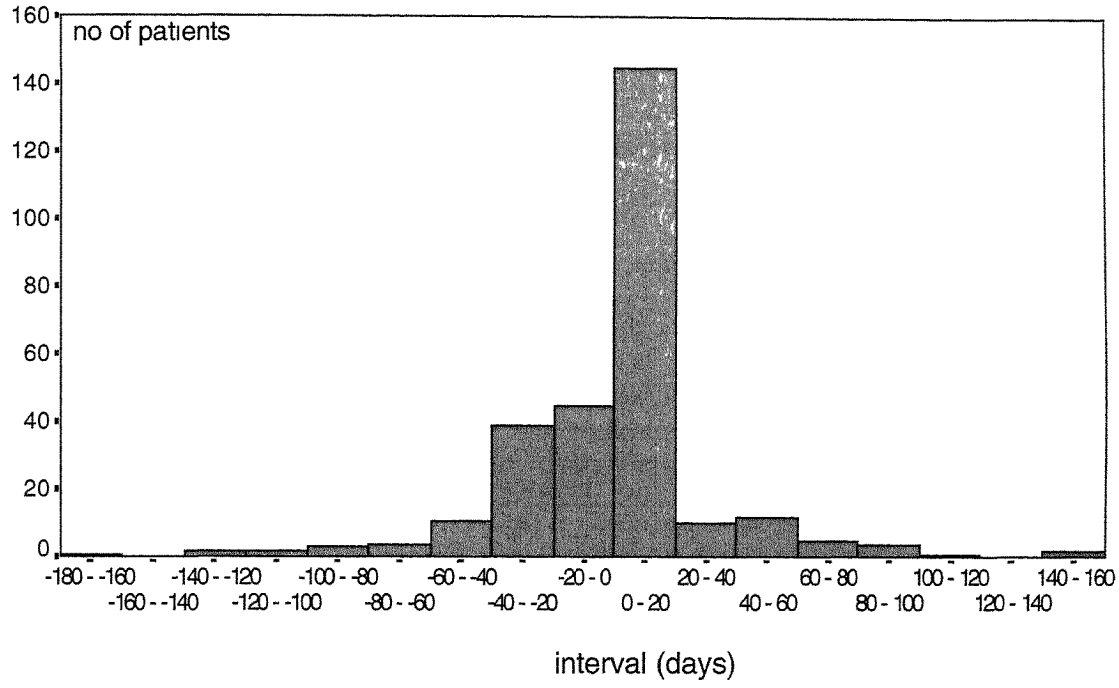
Interval between first *probable* presentation to health care and start of treatment: This interval was calculated for 74 patients. The median value was 133 days (interquartile range 58 to 255 days) (Figure 6.36). Patients starting treatment in another country were excluded from this calculation.

Figure 6.36: *Interval from first probable presentation to starting treatment*



Interval from first laboratory report to start of treatment: This interval was distributed around zero (Figure 6.37). The median was 1 day (interquartile range -14 to +6 days).

Figure 6.37: Interval from confirmatory laboratory report to starting treatment



Proportion of the delay in starting treatment attributable to each component: Table 6.45 summarises the contribution of the various intervals to delays in starting treatment.

Table 6.45: Summary of components of interval

Description	Code for interval component	Number of patients with calculated interval	Median (days)	Interquartile range
Probable first presentation to definite first presentation	A	73	69	22 to 197
Definite first presentation to first laboratory report	B*	291	33	7 to 58
first laboratory report to first entry in medical record	C	241	3	0 to 6
first laboratory report to start of treatment	C+D	286	1	-14 to 6
first definite presentation to start of treatment	**B+C+D***	**436**	**20**	**7 to 44**
first probable presentation to start of treatment	**A+B+C+D***	**74**	**133**	**58 to 255**

** excludes patients starting treatment in another country*

Total time to treatment: The total time to treatment was calculated by summing individual components of the interval. The components which were used differed according to whether the patient had a definitive diagnosis or not, and if they did, whether the date of the first laboratory report was available (Table 6.46).

Table 6.46: Method for calculating total time to treatment

Category of patient	Components used to calculate total time to treatment
No definitive diagnosis	total time to treatment = A+(B+C+D)
Definitive diagnosis and a date for the first laboratory report	total time to treatment = A+B+(C+D)
Definitive diagnosis but no date for the first laboratory report	total time to treatment = A+(B+C+D)

The median and range of total time to treatment for each category of patient is shown in Table 6.47.

Table 6.47: Total time to treatment

Category of patient	No of patients in category	Median (days)	Inter-quartile range
No definitive diagnosis	124	22	15 to 50
Definitive diagnosis and a date for the first laboratory report	286	23	8 to 75
Definitive diagnosis but no date for the first laboratory report	27	24	5 to 54

Proportion of total time to treatment attributable to individual components: The proportion of total time to treatment due to various components was calculated for each patient by dividing the value of the component by the total time to treatment. For example, for patients with no definitive diagnosis, the proportion of total time elapsed to start of treatment due to interval A was equal to A/(A+(B+C+D)) (Figure 6.38).

The distribution of proportions of the total time due to the various intervals varied according to the interval and the category of patient (Table 6.48).

Many factors potentially contribute to the total time elapsed to treatment. Delays in starting treatment represent a population health risk for TB. Efficient and reliable information systems can help to identify and resolve avoidable delays.

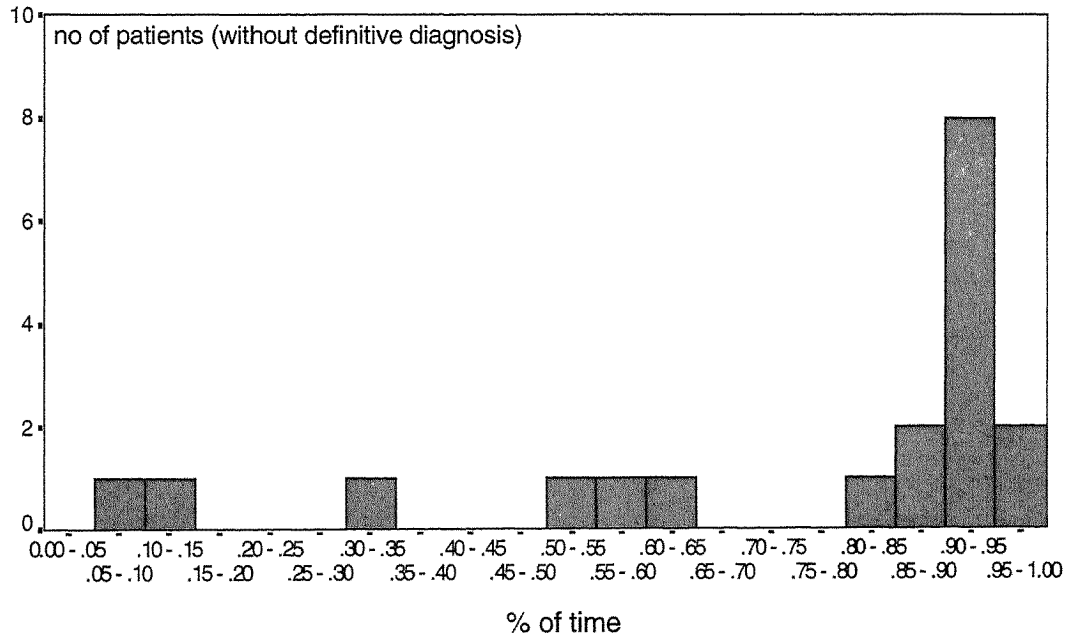
Table 6.48: Distribution of proportions of the total time due to intervals

Category of patient:	Proportion of total time due to interval	
	Median	Interquartile range
No definitive diagnosis:		
Interval A	0.91	0.55 to 0.97
Interval (B+C+D)	1.00	1.00 to 1.00
Definitive diagnosis and a date for the first laboratory report:		
Interval A	0.70	0.43 to 0.91
Interval B *	0.91	0.60 to 1.39
Interval (C+D) #	0.03	-0.50 to 0.20
Definitive diagnosis but no date for the first laboratory report:		
Interval A	0.56	0.40 to 0.85
Interval (B+C+D)	1.00	1.00 to 1.00

** proportion of total time due to B is larger than 1.00 in many patients because the patient started treatment before the definitive diagnosis laboratory report was available. In other words, the interval from first definite presentation to date of laboratory report was greater than the time from first definite presentation to starting treatment*

 # the proportion of total time due to (C+D) is negative for many patients because the patient started treatment before the date of the laboratory report. For many of these patients the proportion was greater than -1.00 because the interval from starting treatment to date of laboratory report was greater than the total time to start treatment

Figure 6.38: Proportion of pre-treatment time due to interval A



Interval between starting treatment and notification: This interval was calculated for 426 patients. Patients starting treatment in another country were excluded from this calculation. The median value was 6.0 days (interquartile range 1 to 19 days). Of the 426 patients, 39 (8.9%) were notified on the day of starting treatment, 377 (88.5%) were notified after starting treatment, and 10 (2.3%) prior to starting treatment.

Patients notified before starting treatment: Of these 10, three patients were notified over a week before starting treatment:

- patient A (29 days before) was notified by a chest clinic but was last seen at the chest clinic over a month previously. At the time of notification the patient was being managed by a chest hospital SOPD team who were not aware of the positive culture result obtained by the clinic until one month after notification when they recalled the patient to start treatment.
- patient B (87 days before) refused treatment until after the delivery of her baby
- patient C (134 days before) discharged himself against medical advice after the diagnosis was made. He presented 6 months later to an A&E department and died 2 days after admission.

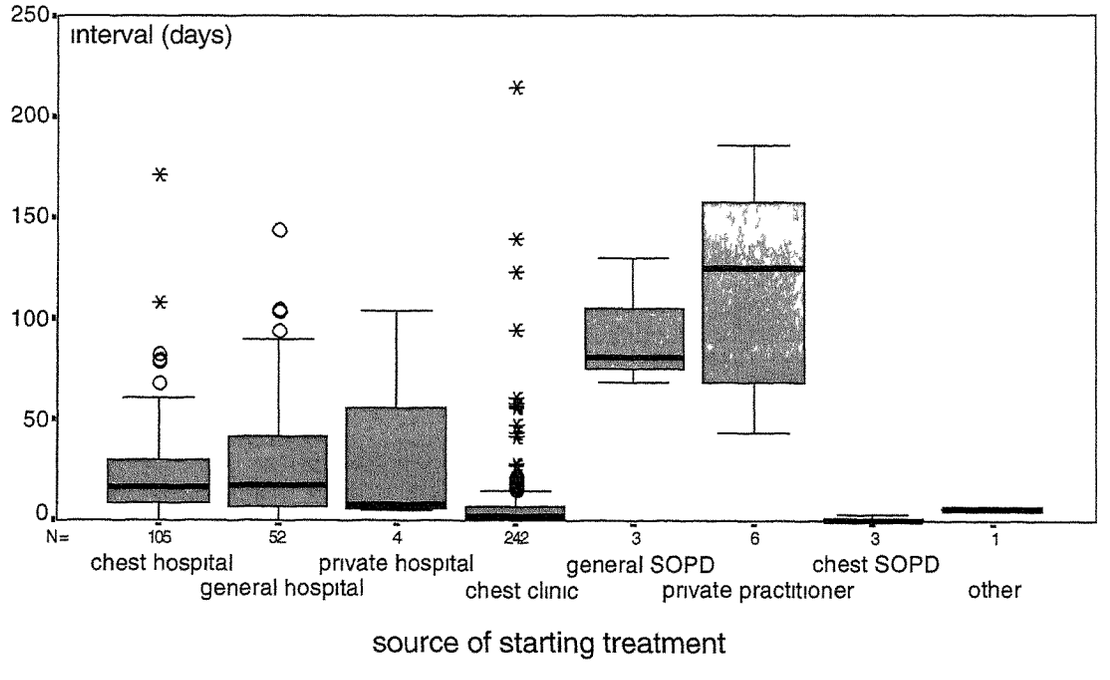
Patients notified on same day or after starting treatment: 416 patients fell into this category. The possible reasons for delayed notification were explored.

Patients starting treatment in a chest clinic were likely to be notified earlier than patients starting treatment in chest or general HA hospitals (Table 6.49) (Figure 6.39).

Table 6.49: *Delay from starting treatment to notification according to source of starting treatment*

Source of starting treatment	Number in study	Median delay (days)	Interquartile range
Chest clinic	242	2	1 to 7
Chest hospital	105	17	8 to 30
General hospital	52	17	7 to 42

Figure 6.39: *Interval between starting treatment and notification*

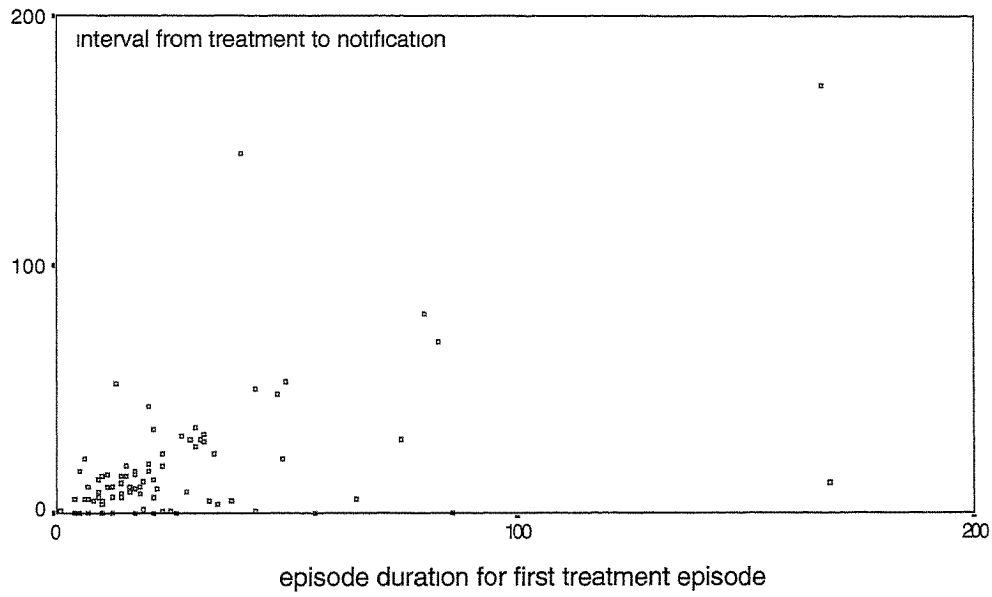


Notification of 58 (25%) patients starting treatment in chest clinics was delayed for over a week after starting treatment. Six of these patients (10.3%) were notified by a different source, three by a different chest clinic and three by a chest hospital. The reason for failure by the chest clinic to notify the patient is not recorded. For the remaining 52 patients notified by the same chest clinic which started the treatment, notification was delayed by two months or more in five of them:

- patient A (delay=124 days): received treatment for only one week and then discharged himself against medical advice
- patient B (delay=95 days): treated for six months, completed follow-up
- patient C (delay=215 days): identified by migrant screening, previous four month treatment from private practitioner completed 2 months prior to screening, received a further 4 months treatment from chest clinic, discharged with no follow-up by chest clinic at end of treatment
- patient D (delay = 140 days): identified by migrant screening, treated for 6 months by chest clinic, discharged with no follow-up by chest clinic at end of treatment
- patient E (delay=61 days): treated for six months by chest clinic and completed follow-up

Patients notified by a source other than that where they started treatment experienced greater delays in notification (median 24 days, interquartile range 13 to 44) than patients notified by the same source (median 4 days, interquartile range 1 to 12).

Figure 6.40: *Interval from starting treatment to notification for patients starting treatment and notified in same hospital*



Eighty three patients started treatment and were notified by the same chest or general hospital. In order to assess the possibility that some in-patients were not notified until discharge rather than immediately after starting treatment, the relationship between length of stay (for the episode where treatment was started) and interval from starting treatment to notification was examined (Figure 6.40). The scatter plot illustrates that there was some correlation between the two variables with very few patients being delayed for longer than their length of stay. The median delay for these patients was 11 days (interquartile range 5 to 24).

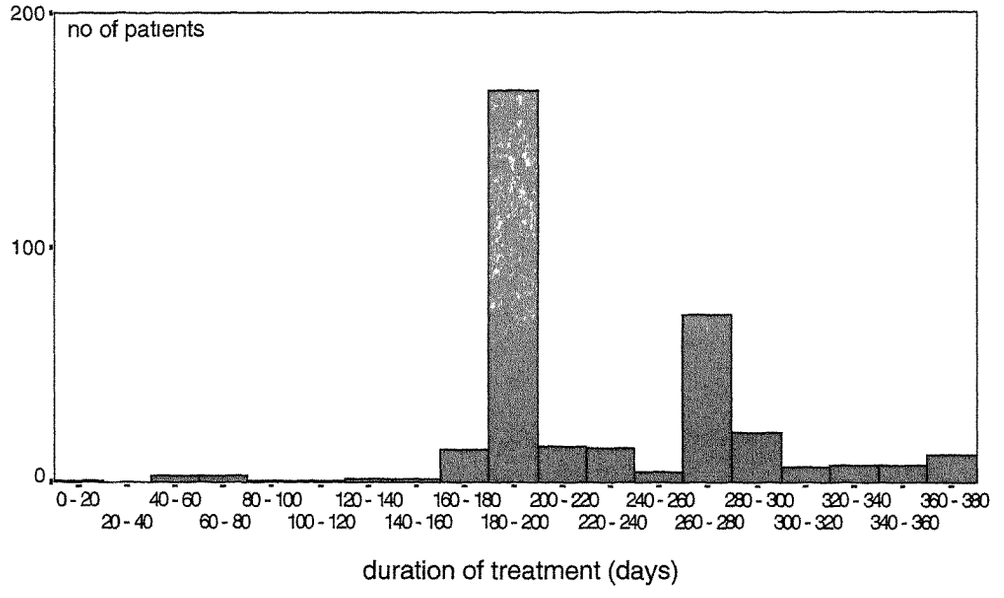
Interval between starting and completing treatment: The duration of treatment was calculated for 377 patients. The remaining 77 patients either did not start treatment, did not complete treatment, or the start or completion dates were not available from medical records.

Data were only abstracted for the study up to a year after start of treatment. However, in many cases, records were reviewed up to 18 months after the start of treatment. If treatment was continued after the official end point of the study, but the treatment completion date was identified in these records, it was recorded. Of the 31 patients still on treatment after one year, the exact duration was recorded for 18. The remaining 13 patients were still on treatment at the last medical record review.

The recorded treatment duration ranged from 11 days to 550 days. The median value was 197 days (approximately 6.5 months) (interquartile range 182 to 276 days (6.1 to 9.2 months)). The distribution of values was bimodal, with the highest peak at 6 months and the second peak at 9 months (Figure 6.41).

Of 9 patients with a treatment duration of less than 120 days (4 months):
- 7 had a definite revised diagnosis
- 1 had a possible revised diagnosis
- 1 had already received 4 months treatment from a private practitioner starting 1 year previously, and received a further 119 days treatment from a chest clinic.

Figure 6.41: *Treatment duration (one year or less)*



Extended treatment duration: In 403 patients it was known whether the treatment duration was 7 months or over. Of these, 194 (48.1%) had a treatment duration of 7 months and over. The reasons for extended treatment were documented for 150/194 (77.3%) patients (Table 6.50). Drug intolerance was the commonest single reason for extended treatment (17%) followed by comorbidities (11%), relapse (11%), extensive disease (10%), poor response to therapy (10%) and poor compliance (7%).

The median duration of treatment and range of values varies according to the documented reason for extension. The least variation and shortest median values are seen for patients with extra-pulmonary disease or other conditions. The longest median value is for patients with poor compliance. The greatest variation is for patients with drug resistant tuberculosis (Figure 6.42).

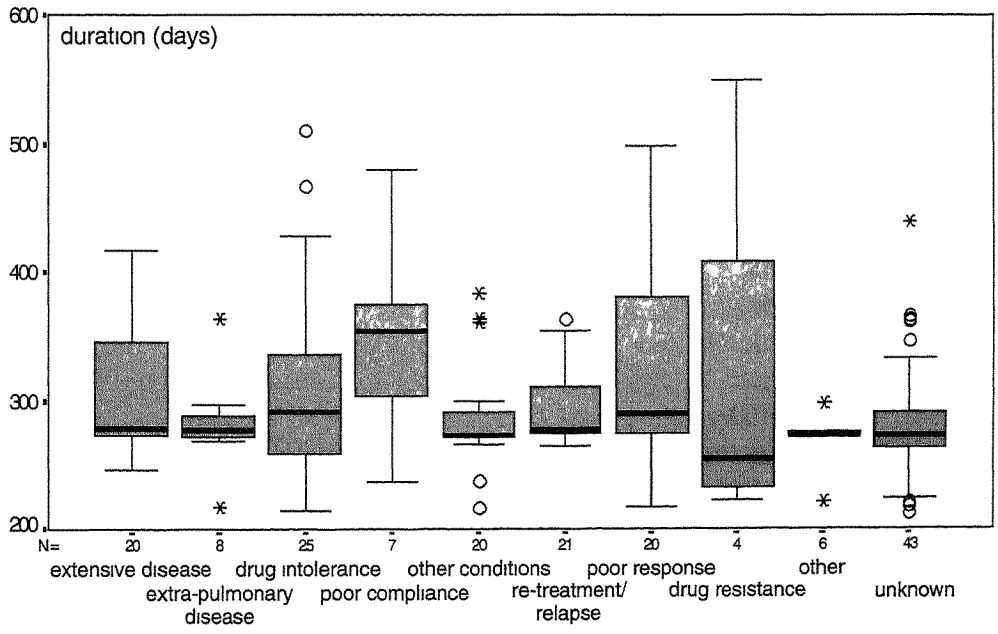
Table 6.50: *Reason for extended treatment*

Reason	Number	%
Extensive disease	20	10.3
Drug intolerance	32	16.5
Poor compliance	14	7.2
Co-morbidities	21	10.8
Relapse	22	11.3
Poor response to therapy	20	10.3
Drug resistance	6	3.1
Extrapulmonary disease	8	4.1
Other	7	3.6
Unknown	44	22.7
Total	194	100.0

One reviewer comments that it is *"a surprise that 48% of patients experienced extended treatment, particularly for drug intolerance; 6 months is generally sufficient for patients with extensive disease."*

Operational studies of the intervals elapsed between presentation, diagnosis, treatment and notification can help to identify areas for improvement of overall management of tuberculosis services.

Figure 6.42: *Duration of treatment by reason for extended treatment*



6.3.4.5 Referral patterns

Referral from last pre-treatment episode to first treatment episode: These referrals were analysed for 308 patients. For the remaining patients, treatment was either started in the first episode, or treatment was not started at all.

The most frequent referral patterns, involving 108 patients, were from chest clinics to chest hospitals (23%) and private practitioners to chest clinics (12%) but many other variations were found (Table 6.51). In the remaining 200, 94 (48%) involved referrals to the chest clinics from other sources.

Table 6.51: *Most frequently occurring referrals from last pre-treatment episode to first treatment episode*

Referred from	Referred to	Number of referrals	% of patients with such referrals
Chest clinic	Chest hospital	70	22.7
Private practitioner	Chest clinic	38	12.3
General HA hospital	Chest hospital	26	8.4
A&E department	Chest clinic	22	7.1
General SOPD	Chest clinic	22	7.1
GOPD	Chest clinic	16	5.2
General HA hospital	General HA hospital	15	4.9
General HA hospital	Chest clinic	14	4.5
Chest clinic	Chest clinic	13	4.2
A&E department	Chest hospital	8	2.6
Other	Other	64	20.8
Total		308	100.0

Referrals between first and last treatment episodes (for patients with two treatment episodes): 100 patients had two treatment episodes. The referral pattern between these episodes is largely made up of referrals from chest hospitals to chest clinics and between chest clinics (Table 6.52).

Table 6.52: *Referrals between treatment sources for patients with two treatment sources*

Referral from	Referral to	No of referrals	% of patients with two treatment episodes
Chest hospital	Chest clinic	44	44.0
Chest clinic	Chest clinic	21	21.0
General HA hospital	Chest clinic	4	4.0
General SOPD	Chest clinic	3	3.0
GOPD	Chest clinic	3	3.0
Chest hospital	Chest SOPD	3	3.0
Chest clinic	Private practitioner	3	3.0
Other	Other	19	19.0
Total		100	100.0

Referral from last treatment source to first post-treatment source: This referral pattern was analysed for only 29 (6%) out of 454 patients. In the remainder of patients, either treatment was completed in the last survey episode, and there were no post-treatment episodes, or treatment was not started.

Of the 29 patients, 10 referrals were between chest clinics and four from chest clinics to chest hospitals (Table 6.53).

Table 6.53: *Referrals between last treatment source and first post-treatment source*

Referred from	Referred to	No of referrals	% of patients
Chest clinic	Chest clinic	10	34.5
Chest clinic	Chest hospital	4	13.8
Chest clinic	GOPD	2	6.9
Other	Other	13	44.8
Total		29	100.0

6.3.4.6 Treatment patterns

Type of treatment regimen: Patients were receiving treatment for 1338 (66.5%) out of the total of 2012 episodes captured by the survey. Patients could receive either standard or non-standard treatment regimens: standard regimens consist of any combination of the five first line drugs streptomycin, rifampicin, isoniazid, pyrazinamide and ethambutol. Of the 1338 treatment episodes, the standard regimen was used in 1159 (86.6%) and non-standard in 163 (12.2%). A record of the regimen used was not available for 16 episodes (1.2%).

The non-standard regimen is indicated if patients have drug resistant tuberculosis or develop complications of treatment, such as hepatitis, with the first line drugs.

The remainder of this section examines only treatment delivered in the chest clinic. The survey demonstrated that in the chest clinic, patients may receive treatment in a variety of ways: the mode of supervision can vary; the frequency of treatment can range from daily to three times a week. The type of treatment (mode of supervision and frequency) may change during the episode. Up to three different periods of treatment of different types were recorded for each episode. The duration of each period of treatment was recorded.

One treatment period was recorded for 528/671 episodes (78.7%), two were recorded for 110 (16.4%), and three periods for 33 episodes (4.9%).

Mode of supervision: The mode of supervision of patients during treatment at a chest clinic ranges from directly observed therapy (DOT) to completely unsupervised. The mode can change during an episode, for example, at the start of treatment the patient may be fully supervised and receive DOT, but change to semi-supervised at a later stage in the treatment. For example, in one episode, a patient may experience one period of treatment which is DOT and two periods of treatment which were semi-supervised. Some patients are 'supervised elsewhere' meaning that they are supervised outside the clinic setting usually be another health care professional eg by the community nursing service, in an old people home, in a long stay psychiatric hospital. The most frequently occurring mode of supervision was directly observed therapy (Table 6.54).

Table 6.54: *Mode of supervision*

Mode of supervision	No of periods of treatment	% of total
Directly observed	559	66.0
Semi-supervised	161	19.0
Supervised elsewhere	85	10.0
Unsupervised	7	0.8
Other	2	0.2
Unknown	13	1.5
Treatment not provided by chest clinic	20	2.4
Total	847	100.0

We reviewed Zwarenstein et al's (1998) report on the first randomised control trial of treatment strategies for tuberculosis. They found no difference in outcomes between patients who received DOT and those who received other treatment regimens. The findings are interesting but of limited generalisability because of the low proportion of eligible patients who were actually analysed (216/1177 (18%)). The exclusions included many patients with characteristics which are present in actual practice. The present observational study in Hong Kong reflects some of these realities and illustrates the complex nature of tuberculosis health care. It can be used to put the Zwarenstein report in context.

Of the 2012 episodes (discrete hospital admissions or uninterrupted periods of ambulatory care), 1337 (66%) occurred whilst patients were receiving treatment, 671 (50%) of which were at one of the government chest clinics.

Hong Kong's treatment guidelines state that "all antituberculosis drugs should be administered as far as possible by directly observed treatment (DOT) to ensure patient compliance" (Tuberculosis Coordinating Committee and Tuberculosis Sub-committee in Internal Medicine 1996). To maximise accessibility, clinic service hours for DOT extend beyond normal office hours and patients can attend any one of 18 clinics throughout Hong Kong. Health care workers are trained not to be authoritarian in their approach and use flexible approaches to help patients overcome any difficulties they have in continuing with DOT.

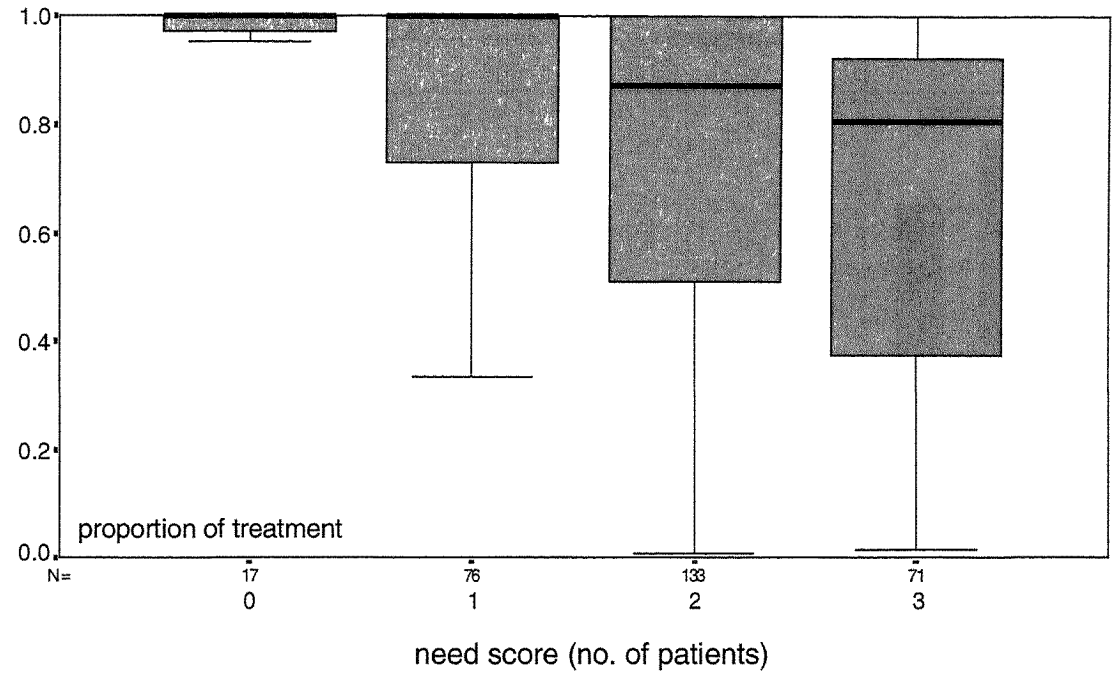
Despite these measures, this study shows that there was widespread use of both intermittent supervision by chest clinics and supervision outside the clinic setting. 411 (91%) patients received treatment at some time from a chest clinic. Of these, 334 (81%) received DOT from chest clinics for a median total period of 181 days (interquartile range 103 to 194), and 158 (38%) received treatment using alternative methods of supervision for a median of 148 days (interquartile range 69 to 193). Eighty five (21%) patients received both. The median proportion of treatment time during which DOT was received, for those patients receiving DOT at any time (either alone or in combination with alternative supervision), was 89% (interquartile range 54% to 100%). For any patients receiving alternative supervision, with or without DOT, the proportion of time for which alternative supervision was received was 69% (interquartile range 34 to 92%).

A reviewer comments that *"for DOT, the figure of 66% could perhaps be higher and (1) agree entirely with the sentiment that health care workers are trained not to be authoritarian in their approach and use flexible approaches to help patients overcome any difficulties that they have in continuing with DOT. Relationship is the key here, and a conversation after swallowing tablets is not only good for the soul but also prevents concealment!"*

Clinical, social and administrative factors are likely to determine the choice of mode of supervision of patients with tuberculosis. In Section 8.0 we describe the construction and use of need scores to evaluate the relationship between medical need and provision of care. Here they are used to examine the use of DOT. Need scores were calculated for all 454 patients based on the presence or absence of comorbidities, complications of tuberculosis and complications of treatment. The higher the score, the greater the need, as defined by these criteria. There is an inverse linear relationship between need and proportion of time spent receiving DOT: patients with greater need received DOT for smaller proportions of total treatment time (Figure 6.43).

There is clearly a requirement for more evidence on the effectiveness of various forms of tuberculosis treatment administration. However, it is important to remember that outside the trial setting, factors which are sometimes unchangeable play an important part in determining the process of care, including the use of DOT.

Figure 6.43: *Proportion of treatment as DOT by need score during care (median, interquartile range and overall range). N=number of patients in need score group.*



DOT appears to achieve at least *equivalence* in terms of completeness of care, compared to unsupervised drug therapy. In a setting such as Hong Kong DOT should probably be retained as an important adjunct to treatment, control and prevention until the factors influencing outcome are better documented and understood. There is scope to consider randomized controlled trials of different management regimens for selected groups of patients.

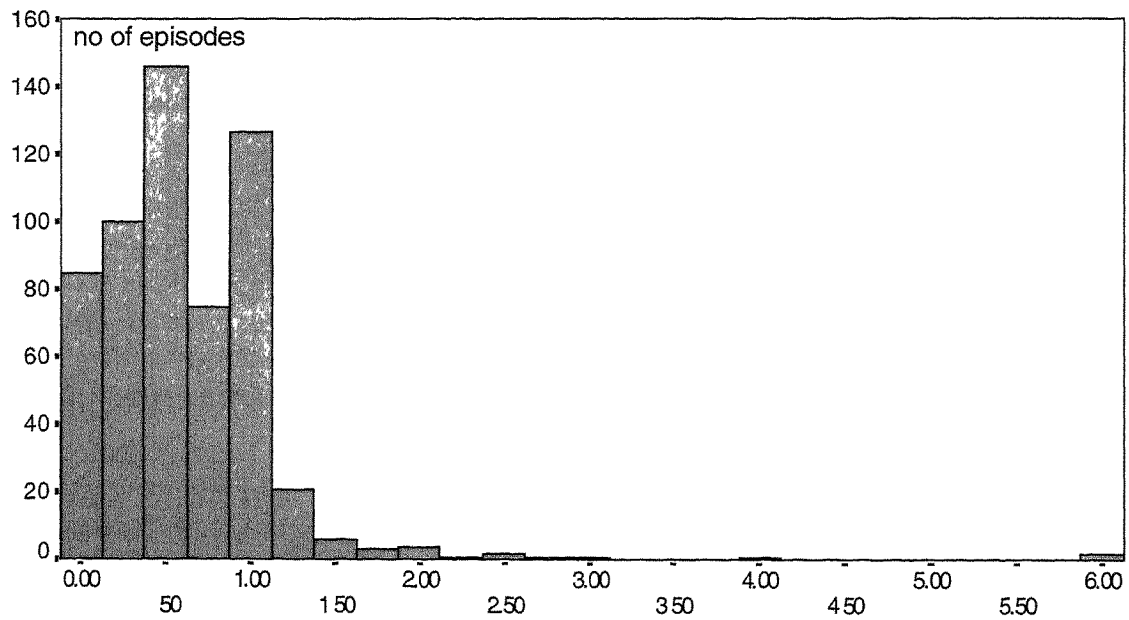
Frequency of treatment: Treatment may be given three times a week or daily. Daily treatment was more common than thrice weekly treatment (Table 6.55).

Table 6.55: Frequency of treatment

Frequency	No of periods of treatment	% of total
Daily	489	57.7
Thrice weekly	306	36.1
Other	17	2.0
Unknown	15	17.7
Treatment not provided by chest clinic	20	2.4
Total	847	100.0

Duration of treatment: The duration of each period of treatment was divided by the episode duration to obtain the proportion of the episode during which the patient was receiving that type of treatment. For most treatment periods the proportion was less than 1.0, but in a few periods, the proportion was greater than 1.0 because the treatment extended beyond the duration of the episode as defined by follow-up by one specific doctor. For example, in one episode, the treatment duration was six times the episode duration because the episode duration was two days, and the treatment was received for a further 10 days from the same chest clinic (Figure 6.44).

Figure 6.44: Duration of treatment types



In addition to the majority of patients receiving DOT, these treatment periods accounted for substantial proportions of the episode duration, although the median value was higher for semi-supervised therapy (Figures 6.45-6.47). A set of three figures is presented because some patients had more than one treatment period; eg DOT for two weeks then semi-supervised for two weeks gives two treatment periods. The three figures therefore need to be viewed together.

Figure 6.45: *Duration of mode of treatment – first treatment period*

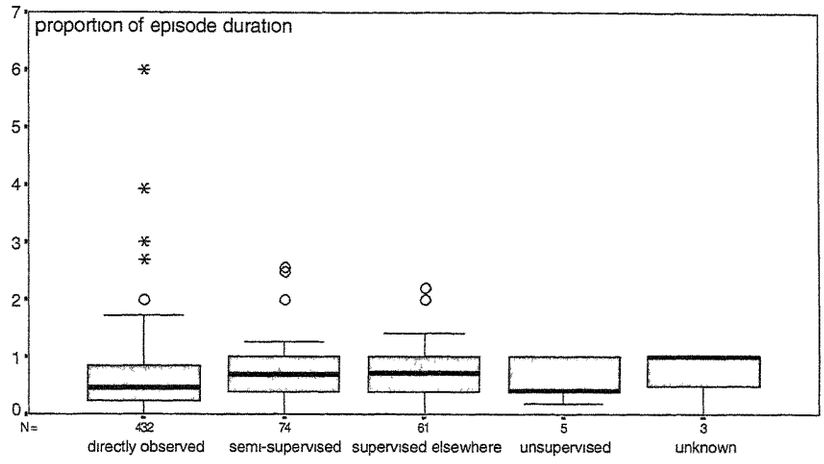


Figure 6.46: *Duration of mode of treatment – second treatment period*

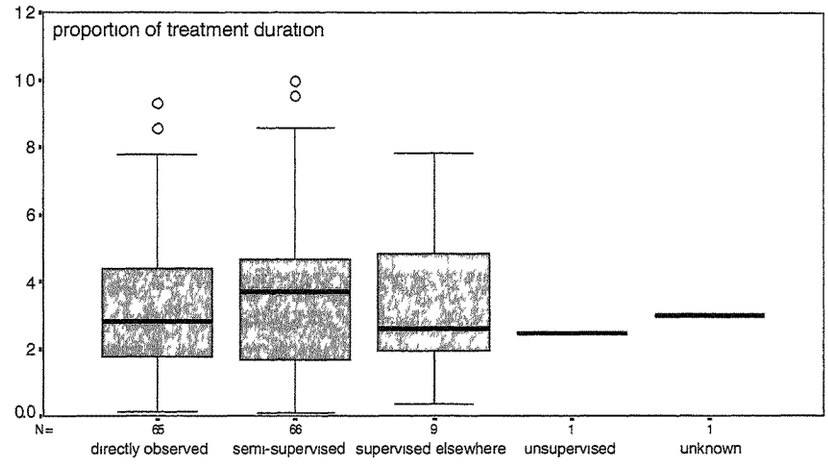
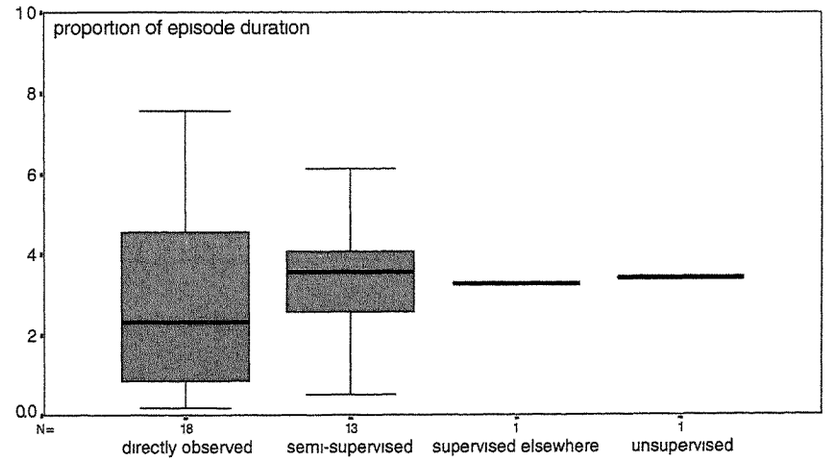


Figure 6.47: *Duration of mode of treatment – third treatment period*



The mean values for the proportions of the episode duration are presented in Table 6.56.

Table 6.56: *Comparison of mean values for proportions of episode for different treatment types (first treatment period)*

Treatment type	Number of episodes	Mean treatment duration as proportion of episode duration	Standard deviation
Directly observed	432	0.58	0.57
Semi-supervised	74	0.72	0.50
Supervised elsewhere	61	0.73	0.48
Unsupervised	5	0.61	0.37
Unknown	3	0.67	0.58
Total	671	0.62	0.55

DOT was given in equal numbers of periods on a thrice weekly and daily basis. In contrast, semi-supervised treatment was given largely on a daily basis (Table 6.57).

Table 6.57: *Frequency of treatment for different modes of supervision*

Mode	Thrice weekly	Daily	Other	Unknown	Total
Directly observed	251	292	14	2	559
Semi-supervised	27	134	0	0	161
Supervised elsewhere	28	54	3	0	85
Unsupervised	0	7	0	0	7
Other	0	2	0	0	2
Unknown	0	0	0	13	13
Total	306	489	17	15	827

Additional investigations: At least one additional investigation was performed in 486/2012 episodes (24.2%). This information was not available in 75 episodes (3.7%). The most frequently performed investigations were sputum cytology, lung function tests, bronchoscopy and pleural aspiration and biopsy (Table 6.58). Many investigations were performed to exclude lung cancer from the differential diagnosis or to obtain a definitive diagnosis of tuberculosis.

Non-medical procedures: Non-medical (i.e. surgical) procedures were performed in 28 episodes (1.4%). The information was not available for 78 episodes (3.9%) and in the remaining 1906 episodes (94.7%), none were recorded. Of the 78 episodes where the information was not available, 60 (76.9%) were in ambulatory care and it is therefore unlikely that any non-medical procedures were performed.

In 10 of the 28 episodes (35.7%) the procedures were orthopaedic in nature (Table 6.59) and included:

- wrist splint (1)
- examination under anaesthesia and arthrodesis (1)
- rehabilitation (1)
- debridement (1)
- knight brace (2)
- hydrotherapy and hip spica (1)
- exploration and debridement (2)
- external fixation and joint destruction (1)

Table 6.58: *Investigations performed*

Investigation	Charge ($) on private ward†	Frequency of use	% of investigation performed
Sputum cytology		306	37.7
Lung function tests		128	15.8
Bronchoscopy	*2940-7520	88	10.9
CT scan chest	2750-4350	70	8.6
Magnetic resonance imaging scan	4710-10480	2	0.2
Fine needle aspiration of lung lesion		7	0.9
Open lung biopsy		5	0.6
Percutaneous transthoracic needle biopsy of lung lesion		5	0.6
Pleural aspiration and biopsy	*2940-7520	71	8.8
Fine needle aspiration cytology of lymph node	*2940-7520	23	2.8
Excision biopsy of lymph node	*2940-7520	11	1.4
Lumbar puncture		10	1.2
Skin biopsy	*2940-7520	1	0.1
Bone biopsy	*2940-7520	4	0.5
Gastric aspirate		2	0.2
Spinal biopsy	*2940-7520	1	0.1
Bone marrow biopsy	*2940-7520	1	0.1
Bone scan		2	0.2
Early morning urine		23	2.8
Other		51	6.3
Total		811#	100.0

These investigations could be stratified according to their resource implications
** minor operation: also need to include cost of anaesthesia where appropriate (range $1050-2640)*
 # HA Gazette No. 16/1995
† does not total 486 because more than one investigation was performed in some episodes

Table 6.59: *Non-medical procedures performed*

Procedure	No of episodes	% of episodes
Pleuradesis	4	14.3%
Lung resection	4	14.3%
Thorascopic decortication	2	7.1%
Therapeutic lumbar puncture	1	3.6%
Tracheotomy	1	3.6%
Incision and drainage of abscess	4	14.3%
Ventriculo-peritoneal shunt	2	7.1%
Orthopaedic	10	35.7%
Total	28	100.0%

6.3.4.7 HIV testing

For 454 patients, 228 (50.2%) there was a record that they were offered an HIV antibody test at some point in the study period. Of these 228, 180 (40% of the total) accepted and 47 declined. Of the 180 who accepted, 171 were HIV negative and for nine the result was not noted in the medical record.

Of the 228 patients who were offered a test, 218 (95.6%) were being managed by a chest clinic at the time that the test was offered. The remaining 10 patients were offered tests by chest hospitals (5 patients at 2 hospitals), general HA hospitals (4 patients at 4 hospitals) and one by a private practitioner (Table 6.60).

Table 6.60: *Source offering HIV tests*

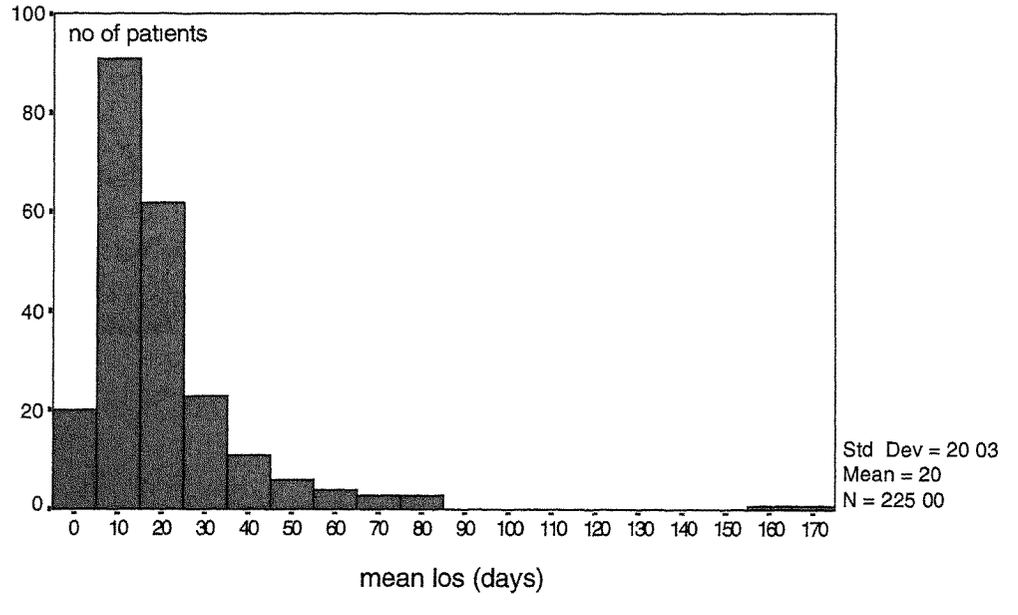
Source	Number of patients	Proportion of patients offered HIV test	Number (%) at each source accepting test
Chest clinic	218	95.6	170 (78.0)
Chest hospital	5	2.2	5 (100.0)
General HA hospital	4	1.8	4 (100.0)
Private practitioner	1	0.4	1 (100.0)
Total	228	100.0	180 (78.9)

6.3.4.8 Duration and frequency of treatment and follow-up

In-patients

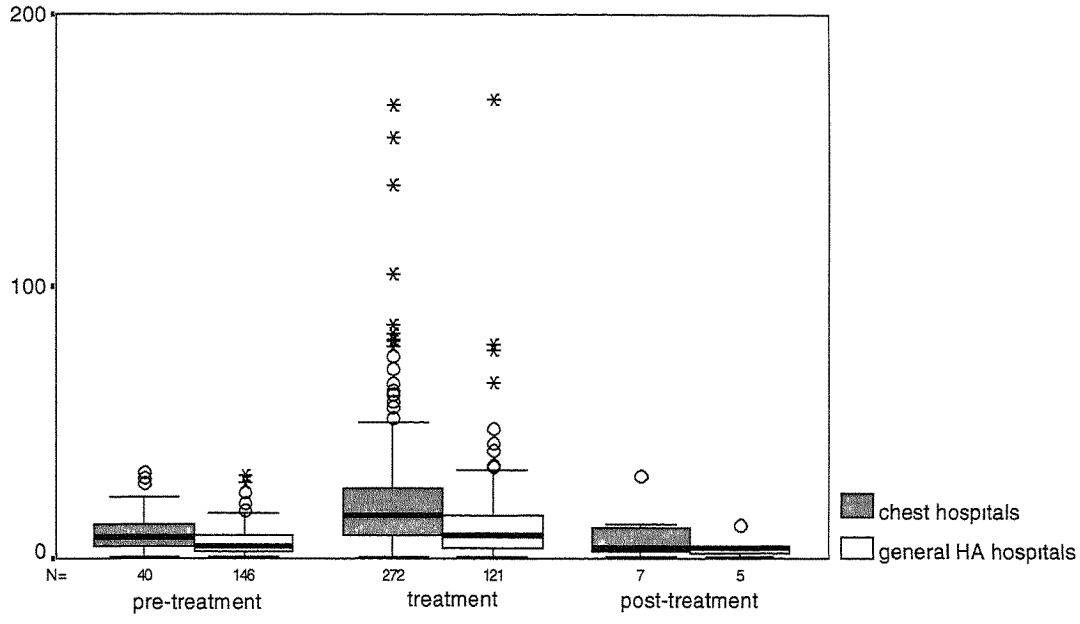
Duration of in-patient episodes: The median value for in-patient episodes length of stay was 9 days (interquartile range 4-18 days). The distribution of values was extremely skewed with 90% of values below 30 days but with two values over 350 (Figure 6.48). These higher values were found for episodes where the patient was a long term in-patient for psychiatric co-morbidities.

Figure 6.48: *Mean LOS for TB in-patient episodes*



The length of stay varies between the treatment phase of the patient (ie pre-treatment, treatment, post-treatment) and the type of hospital. Treatment admissions were longest and for treatment phase admissions, patients were admitted to chest hospitals for longer periods than general HA hospitals (Figure 6.49).

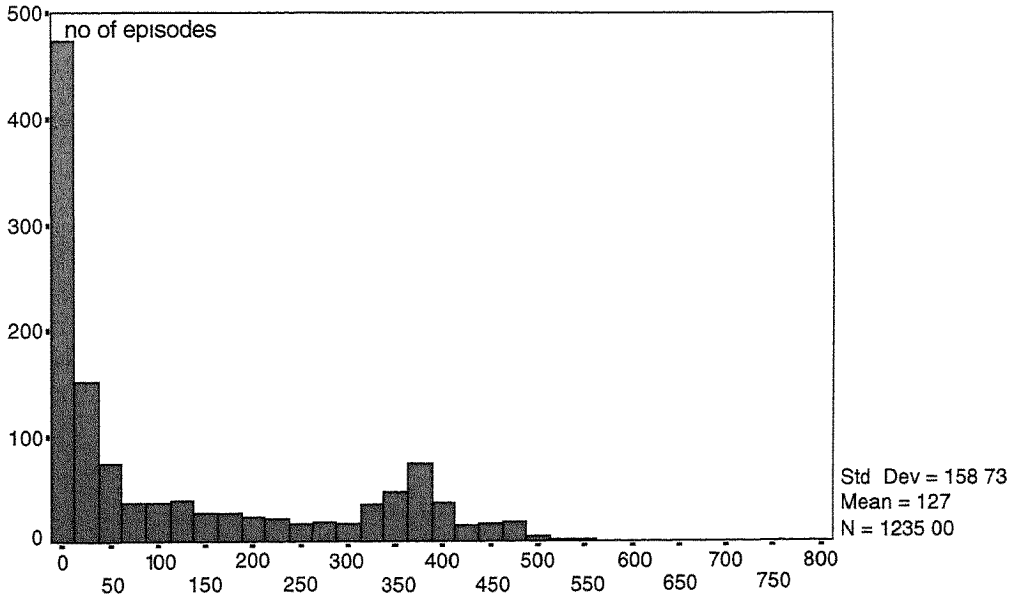
Figure 6.49: *LOS (days) TB episodes only*



Ambulatory care

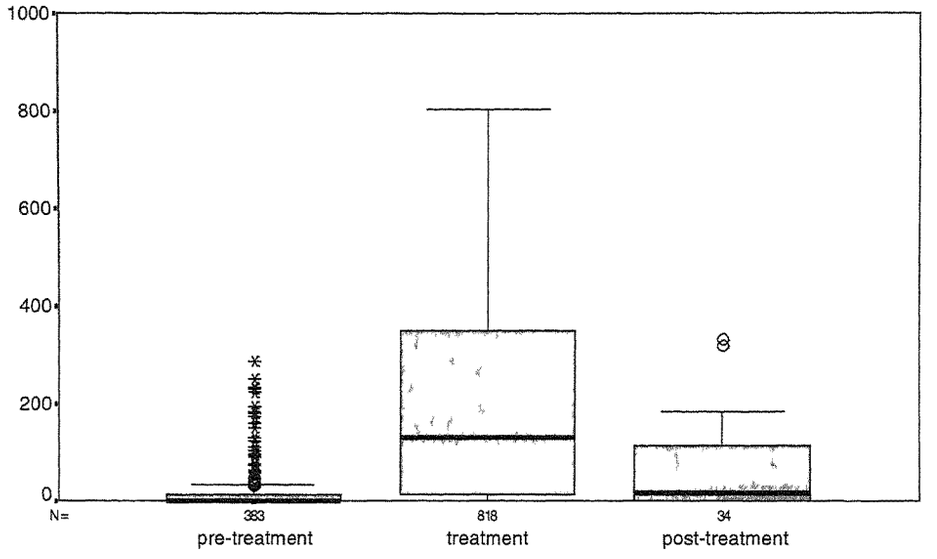
Duration of ambulatory care: The median value for the duration of all ambulatory care episodes was 38 days (interquartile range 1 to 260 days). The distribution of episode duration was bimodal with the major peak occurring in the 0-20 day range and a second peak occurring at around one year (Figure 6.50).

Figure 6.50: *Ambulatory care duration (days)*



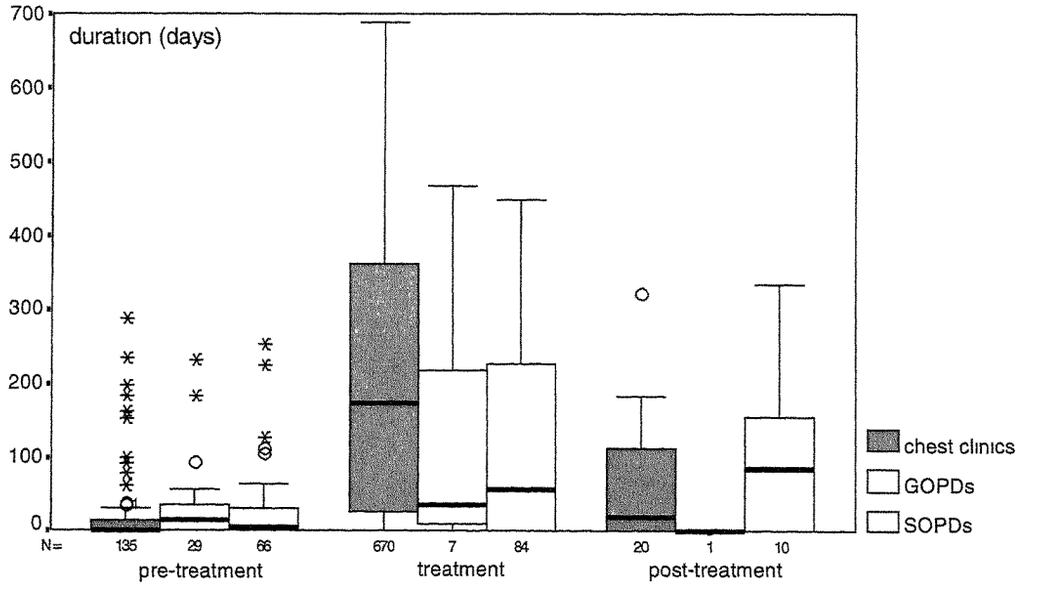
There was substantial variation in episode duration according to the treatment phase of the patient: treatment episodes were the longest and varied the most, followed by post treatment and then pre-treatment phase episodes (Figure 6.51).

Figure 6.51: *Duration of ambulatory care episodes (days)*



The longest episodes were those in chest clinics in the treatment phase; GOPD and SOPD episodes were substantially shorter. In the pre-treatment phase, chest clinic episodes were shorter but there were many episodes with extreme values (up to 300 days). There were only 31 post-treatment episodes, and of these the SOPD episodes were the longest (Figure 6.52).

Figure 6.52: *Duration of ambulatory care episodes (days)*



Frequency of follow-up: Patients are followed-up at ambulatory care sources at intervals ranging from one day to one year, depending on their clinical need and routine practice.

In chest clinics and SOPDs during the treatment phase, patients are usually reviewed routinely every one month. However, many patients attend more frequently than this for a wide range of reasons. In the survey the following variables were collected:

- total number of visits including first and last visit
- non-routine visits for side-effects of treatment
- non-routine visits for the purpose of obtaining a drug supply if the patient cannot attend the clinic for any reason (eg leaving Hong Kong).
- non-routine visits for any other reason

If a patient attended for more than one reason, the reasons were categorised in the following order;

1. routine visit
2. non-routine visit for side-effect
3. non-routine visit for drug supply
4. non-routine visit for any other reason (within these visits, a visit for with a complaint of cough was most common)

A visit was classified as routine if it occurred approximately one month after the previous scheduled visit whilst the patient was on treatment unless it was clearly for a non-routine reason. Additional visits made around the same time were classified according to the reason given in the medical record.
Additional variables were derived from these:

- the *frequency of follow up* (FFU) was calculated by dividing the episode duration in days by the total number of visits
- the *frequency of visits for side-effects* was calculated by dividing the episode duration in days by the number of non-routine visits for side-effects
- the *frequency of visits for drugs to take away* was calculated by dividing the episode duration in days by the number of non-routine visits for drugs supply
- the *number and frequency of routine visits* were calculated for patients in whom no visits for "other" reasons were made by subtracting the side-effect and drug supply visits from the total number of visits

Interpretation of frequency of follow-up: In many episodes, the duration is one day as the patient only attends the clinic once. The frequency of follow-up would also be one. Reasons for this include:

- patient was immediately referred to another source of care (eg another chest clinic or admitted to hospital)
- patient failed to attend follow-up appointment

If an episode lasts 10 days and the patient is seen once at the start and once at the end, the frequency of follow-up would be five, that is the patient would be seen on average every five days.

Chest clinic and SOPD episodes may span pre-treatment, treatment and follow-up phases. The frequency of follow-up in these three phases is likely to vary, but if one episode spans all three phases (and is therefore classified as a treatment phase episode), the frequency of follow-up would be an average of the frequency of follow-up in all three phases. We therefore examined the visits made to chest clinics only for the period when the patient was actually receiving treatment.

Frequency of follow-up for chest clinics

Frequency of total number of visits: This variable was derived by dividing the episode duration in days by the total number of visits. The median value was 15.2 days (interquartile range 4.9 to 21 days, range 1 to 123 days) (Figure 6.53).

The total number of visits was available for 671 episodes in chest clinics when the patient was on treatment. The median number of visits per episode was 6 (interquartile range 2 to 10, range 1 to 36) (Figure 6.54).

Non-routine visits: Of the 671 episodes, non-routine visits were made in 252 (37.6%). The reasons for these visits are shown in Table 6.61.

The number of additional visits made per episode for each of these reasons ranged from one to six, except for the first two.

In the 303 episodes which included one or more visits for side-effects, the number of such visits ranged from 1 to 23 (Figure 6.55).

In the 152 episodes which included one or more visits for the supply of drugs, the number of such visits ranged from 1 to 9 (Figure 6.56).

Figure 6.53: *Frequency of follow-up in chest clinic whilst on treatment*

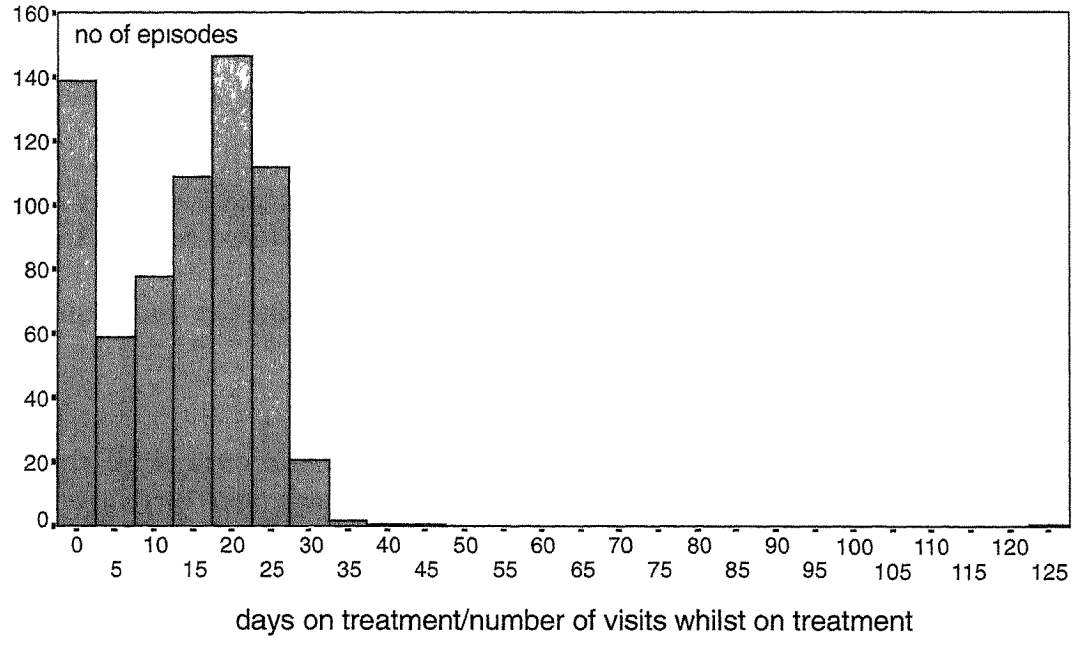


Figure 6.54: *Number of chest clinic visits per episode when on treatment phase*

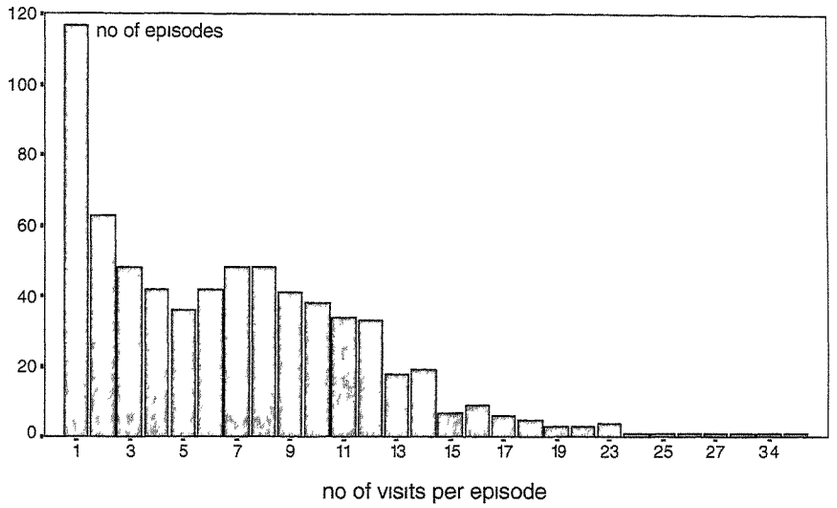


Figure 6.55: *Number of visits to a chest clinic for side effects*

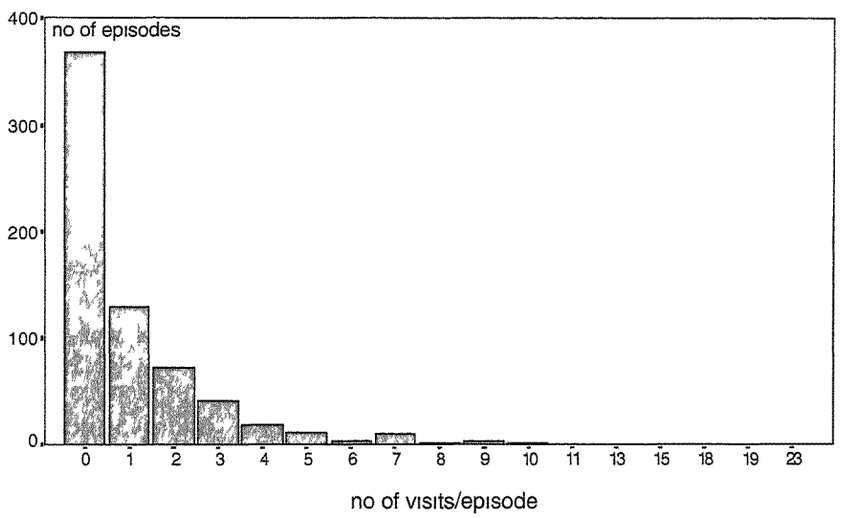


Figure 6.56: *Number of visits to a chest clinic for medicines only*

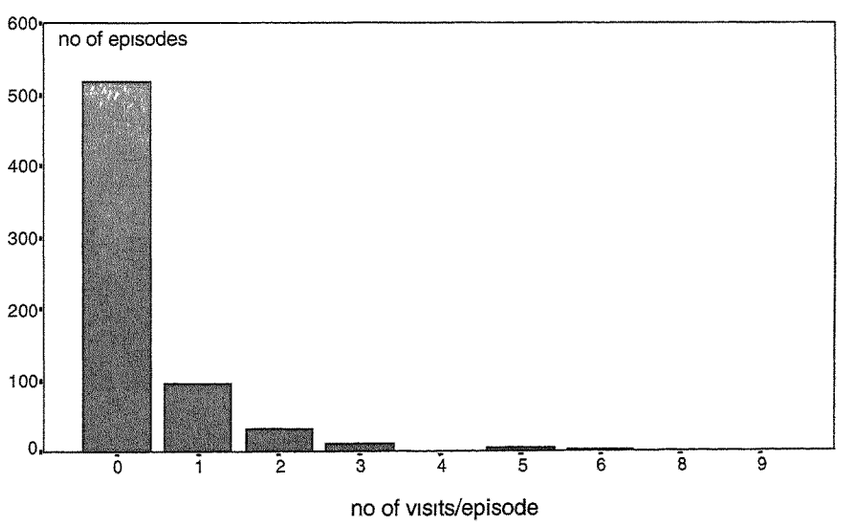
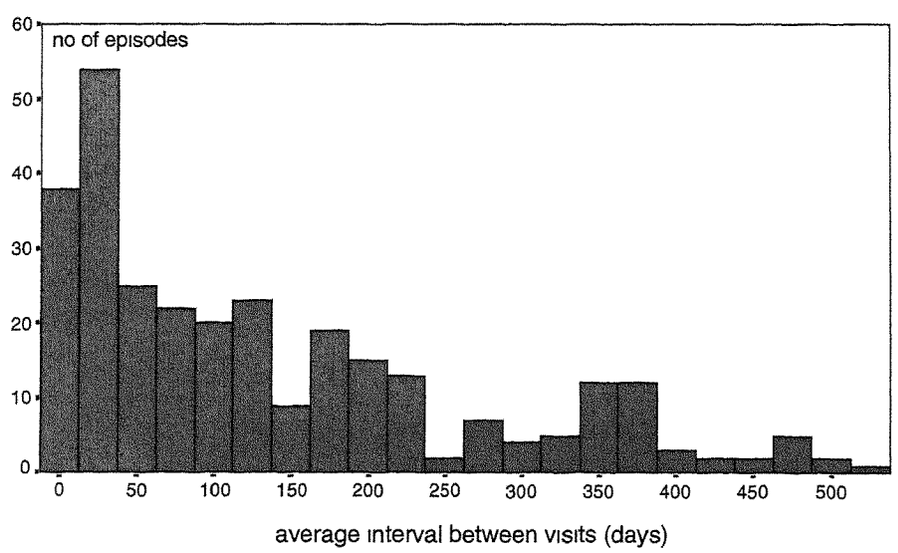


Table 6.61: Reasons for non-routine visits

Reason for visit	Number of episodes
Side-effects	303
Drug supply	152
Cough	69
Shortness of breath	10
Hoarse	2
Chest pain	14
Fever	2
Cyanosis	1
Lymph node swelling	3
Malaise	4
Haemoptysis	16
URTI	23
Other	2
Medical social worker	22
Other condition	57
By mistake	11
Default	10
Results or record not previously available	10
Health education	5
For medical report or sick certificate	16
Tuberculosis complications	11
Research	7
To plan admission	10
Lost pink treatment card	7
Others	15

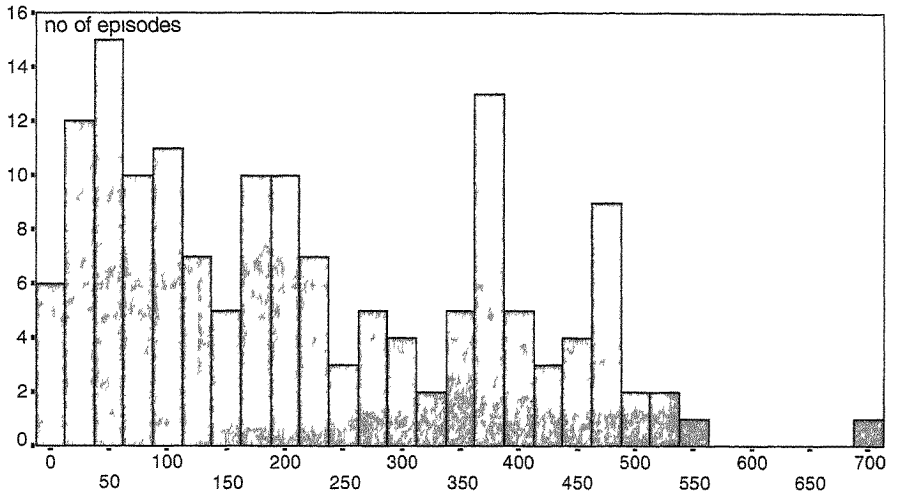
Frequency of visits for side-effects: This variable was derived by dividing the episode duration in days by the number of non-routine visits for side-effects (excluding episodes where no visits for side-effects were made). The median value was 92.5 days (interquartile range 25.1 to 200 days, range 0.3 to 530 days) (Figure 6.57). Patients in the lowest quartile were receiving additional care because of side-effects.

Figure 6.57: Frequency of visits for side effects



Frequency of visits for drug supply: This variable was derived by dividing the episode duration in days by the number of non-routine visits for drug supply (excluding episodes where no visits for drugs supply were made). The median value was 188.7 days (interquartile range 71.2 to 367.5 days, range 1.0 to 690 days) (Figure 6.58). Patients in the lowest quartile were receiving additional care because of demand for drug supplies.

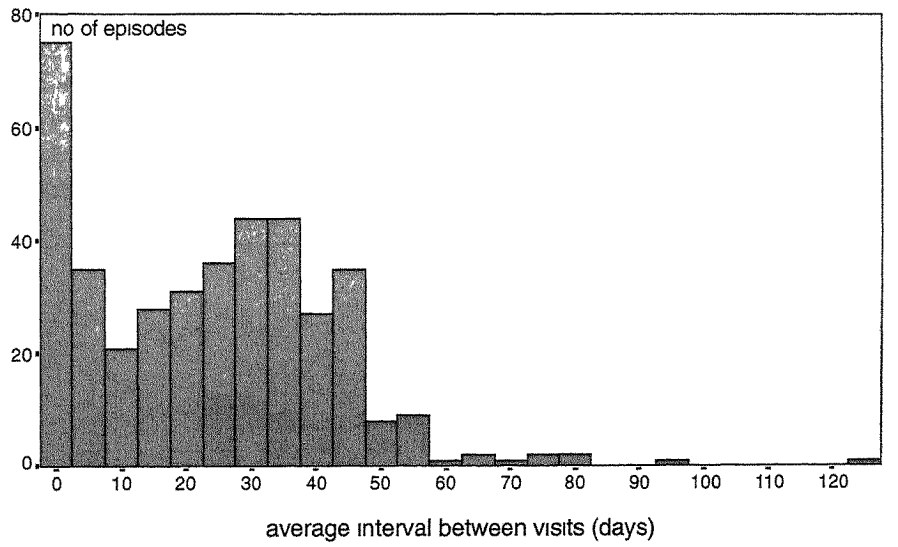
Figure 6.58: *Frequency of visits to obtain medicines only*



Number of routine visits: This was calculated for episodes where the only non-routine visits made were for side-effects or drug supply. The number ranged from zero to 15.

Frequency of routine visits: This was calculated for episodes where the only non-routine visits were made for side-effects or drugs supply by dividing the episode duration by the number of routine visits. The median value was 24.7 days (interquartile range 7.3 to 36.4 days, range 1.0 to 123 days) (Figure 6.59).

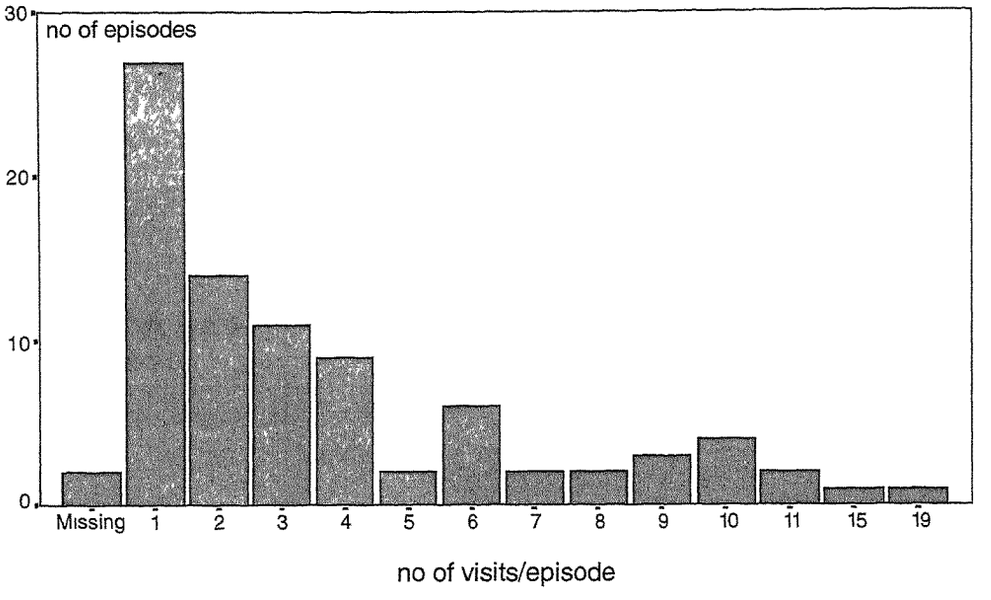
Figure 6.59: *Frequency of routine visits*



Follow-up at Specialist Out-patient Departments (SOPDs)

Frequency of follow-up for SOPDs: Data on the total number of visits was available for 84 episodes in SOPDs. The value ranged from 1 to 19 (Figure 6.60).

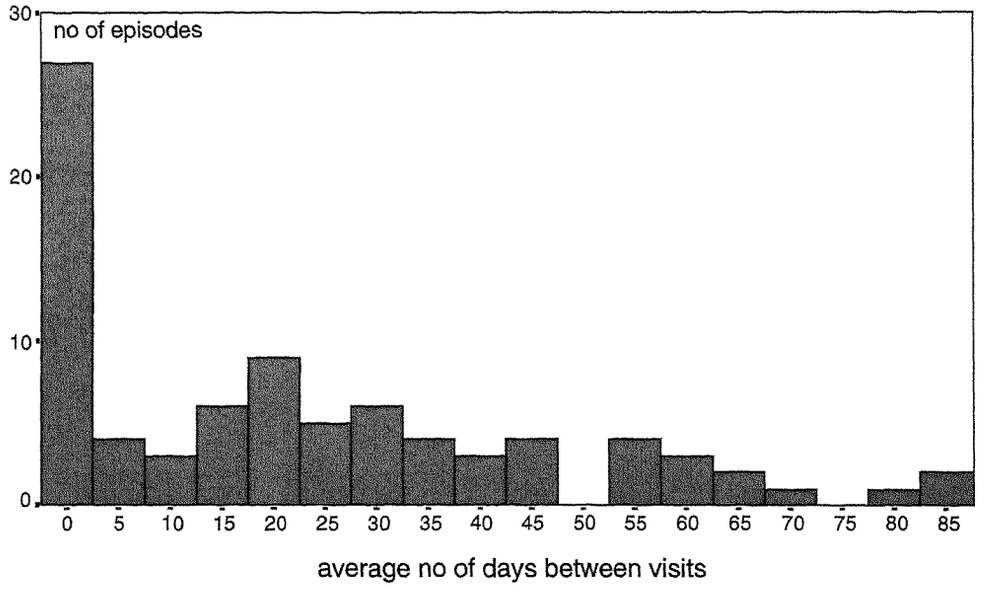
Figure 6.60: *Number of visits to a specialist clinic*



Frequency of total number of visits: This variable was derived by dividing the episode duration in days by the total number of visits. The median value was 19.1days (interquartile range 1.0 to 36.0 days, range 1.0 to 84.3 days) (Figure 6.61).

Reasons for visits were not obtained for SOPDs.

Figure 6.61: *Frequency of visits to specialist clinics*



6.3.5 Complications

6.3.5.1 Complications of tuberculosis

In 537/2012 (26.7%) episodes the patient was reported to have developed one or more complications of tuberculosis. In 51 (2.5%) episodes this information was not available. The most frequent complications were haemoptysis and pleural effusion (Table 6.62). In any one episode a patient could experience more than one complication. The sum of the number of episodes where each specific complication was experienced (593) is therefore greater than the number of episodes where at least one complication was experienced (537).

The complications of tuberculosis could occur at any stage of the episode: these were categorised into those developing or present at the start of the episode, those developing during the episode and those developing at the end of the episode. Most complications were present at the start of the episode, although many also developed during the episode (Table 6.63).

Table 6.62: *Complications of tuberculosis*

Complication	Number of episodes where this specific complication experienced	% of total number of complications (593)
Haemoptysis	281	47.4
Pleural effusion	118	30.0
Empyema	2	0.3
Drug resistance	20	3.4
Lymph node abscess/wound	8	1.3
Endobronchitis	14	2.4
Lobar collapse	15	2.5
Bronchiectasis	10	1.7
Extensive disease	20	3.4
Pneumothorax	11	1.9
Other	34	5.7
Total	593	100.0

Table 6.63: *Onset of complications of tuberculosis*

Onset of complication	Number of episodes	% of total number of complications (593)
At start	457	77.1
During	126	21.2
At end	8	1.3
Unknown	2	0.3
Total	593	100.0

The action in response to each complication was recorded as a proxy for the level of severity of each complication. The actions were classified into categories ranging from "nil" to "permanent surgical treatment". The most frequent response to a complication was to perform additional investigations, such as pleural aspiration or bronchoscopy, or simply request sputum cytology to investigate haemoptysis (Table 6.64).

Table 6.64: *Specific action taken (ie recorded) in response to complication of tuberculosis*

Action	Number of episodes	% of total number of complications (593)
Nil (no action recorded)	56	9.4
Monitor (eg with repeat CXRs)	56	9.4
Symptomatic treatment (eg transamine for haemoptysis)	125	21.1
Additional investigations (eg pleural aspiration)	142	23.9
Modify treatment (eg increase duration, add steroids)	35	5.9
Refer to ambulatory care	56	9.4
Admit to hospital	92	15.5
Surgical symptomatic treatment (eg chest drain)	11	1.9
Surgical permanent treatment (eg pleuradesis)	9	1.5
Other	6	1.0
Unknown	5	0.8
Total	593	100.0

6.3.5.2 Complications of treatment

Patients were reported to have developed complications of treatment or investigations in 1294 episodes.

Up to five complications were recorded for each episode. The complications ranged in nature from dizziness to hepatitis. The most frequent complications were nausea and vomiting, skin rashes, hepatitis (and abnormal liver enzymes) and dizziness (Table 6.65).

The onset of these complications ranged from those present at the start of the episode, those which developed during the episode to those occurring at the end. Most complications arose during the episode (Table 6.66).

Action in response to treatment complications was used as a proxy for their severity. If a patient developed a complication which required progressively more serious action, the most serious action was coded. Final action ranged from "nil" to "admission". The most frequent final response was symptomatic treatment (Table 6.67).

Table 6.65: *Complications attributed to treatment*

Complication	Number of episodes	% of total number of complications (1294)
Dizzy	120	9.3
Skin rash	126	9.7
Itchy skin	86	6.6
Tinnitus	22	1.7
Abdominal discomfort	65	5.0
Belching	3	0.2
Ear discomfort	6	0.5
Peri-oral numbness	1	0.1
Fever	27	2.1
Impaired vision	49	3.8
Bone/joint pain or increased urate	50	3.9
Headache	29	2.2
'flu-like	11	0.9
Pneumothorax post pleural aspiration	3	0.2
Hepatitis	55	4.3
Gout	2	0.1
Hearing loss	7	0.5
Thrombocytopaenia	9	0.7
Facial flushing	11	0.9
Surgical emphysema post thoracotomy	1	0.1
Appetite loss	53	4.1
Malaise	40	3.1
Nausea/vomiting	196	15.1
Diarrhoea	31	2.4
Abnormal liver enzymes	116	9.0
Jaundice	10	0.8
Other	41	3.2
Impaired renal function	13	1.0
Parasthesiae	7	0.5
Poor compliance	68	5.3
Poor response	36	2.8
Total	1294	100.0

Table 6.66: *Onset of complications of treatment*

Onset	Number of episodes	% of total number of complications (1294)
Start	296	22.9
During	887	68.5
End	9	0.7
Unknown	102	7.9
Total	1294	100.0

Table 6.67: Action in response to treatment complication

Action	Number of episodes	% of total number of complications (1294)
Nil (no action recorded)	85	6.6
Symptomatic treatment	423	32.7
Investigate/monitor	184	14.2
Modify treatment (eg stop one drug)	158	12.2
Interrupt treatment	132	10.2
Desensitise	57	4.4
Refer to ambulatory care (eg ophthalmology OPD)	35	2.7
Admit	94	7.3
Other	7	0.5
Unknown	119	9.2
Total	1294	100.0

6.3.5.3 Co-morbidities

Table 6.68: Frequency of recording of comorbidities according to ICD10 class

ICD10 class	Number of episodes where comorbidity in this class was an active ongoing problem	% of total comorbidities recorded
Circulatory	256	14.2
Diabetes	275	15.3
Other endocrine/metabolic	26	1.4
Chronic obstructive airways disease	201	11.2
Lower respiratory infection	61	3.4
Upper respiratory infection	12	0.7
Atypical mycobacterial infection	11	0.6
Other infection	12	0.7
Lung neoplasms	133	7.4
Other neoplasms	130	7.2
Gastro-intestinal (excluding hepato-biliary)	82	4.6
Liver pathology	92	5.1
Renal impairment	19	1.1
Other genito-urinary	72	4.0
Nervous system	76	4.2
Mental and behavioural	130	7.2
Musculo-skeletal	61	3.4
Ear pathology	20	1.1
Eye pathology	77	4.3
Skin	13	0.7
Pregnancy related	18	1.0
Fractures and assaults	17	0.9
Other	8	0.4
Total	1802 #	100.0

 # sum is greater than 1120 because more than one comorbidity was recorded in many episodes

In 1120 (55.7%) episodes, a patient was reported to have a co-morbidity which was an active ongoing problem. This information was not available for 67 episodes and in 825 episodes (41.0%) there were no co-morbidities. Of the 1120 episodes where a co-morbidity was recorded, co-morbidity directly affected the management of the patient's tuberculosis in 579 (51.7%) episodes. In total there were 118 different co-morbidities identified. These were classified into ICD10 disease categories. The frequency of occurrence of each ICD10 class of comorbidity is shown in Table 6.68. The most frequently recorded comorbidites were diabetes (mainly non-insulin dependent), diseases of the circulatory system (mainly related to coronary artery disease) and lower respiratory disorders (infections including those due to atypical mycobacteria, neoplasms and chronic obstructive airways disease). Other neoplasms and mental and behavioural disorders also accounted for considerable morbidity. In many pre-treatment episodes, lower respiratory disorders were recorded as part of the differential diagnosis and subsequently excluded by appropriate investigations. 157 of the 356 episodes (44.1%) where a lower respiratory disorder was recorded occurred in the pre-treatment phase, compared with 151/764 (19.8%) of episodes with non-lower respiratory disorders (chi-square 72.5, $p<0.000001$).

Psychosocial problems: In 117/2012 episodes (5.8%) the patient had a psychosocial problem. These problems were mainly financial or housing related (Table 6.69).

Table 6.69: *Nature of psychosocial problems*

Psychosocial problem	Number of episodes	%
Housing related	13	11.1
Financial	45	38.5
Health education required	2	1.7
Nutrition	7	6.0
Physical disability	1	0.9
Home-help required	3	2.6
Poor family support	1	0.9
CNS required	4	3.4
Works in another country	2	1.7
Needs interpreter	2	1.7
Other	4	3.4
Unknown	33	28.2
Total	117	100.0

6.3.6 Adherence to treatment

Level of adherence was recorded for 432 patients. Of these, 287 (66.4%) were fully adherent (up to two doses missed during therapy), and the adherence of 33 (7.6%) was unknown because medical records could not be traced or adherence was not recorded. The remaining 112 patients had varying levels of non-adherence ranging from intermittent default (13%) to complete loss to follow-up (6%) (Table 6.70).

Table 6.70: Levels of adherence

Adherence level	Number	%
Full adherence	287	66.4
Intermittent default (more than two doses missed)	54	12.5
Continuous default, 1 week to 1 month	17	3.9
Continuous default, 1 to 2 months	5	1.2
Continuous default, over 2 months	6	1.4
Complete loss to follow-up	25	5.8
Other	5	1.2
Unknown	33	7.6
Total	432	100.0

The action in response to impaired adherence was recorded for 112 patients (Table 6.71). There was a trend for more significant action to be taken in response to patients with worse levels of adherence.

Table 6.71: Action in response to impaired adherence n (%)

Level of adherence	No action recorded	Follow-up, health education	Increase supervision of therapy	Admit	Prolong treatment	Other	Un-known	Total
Intermittent	40 (74)	8 (15)			1 (2)	1 (2)	4 (7)	54 (100)
Continuous 1 week to 1 month	6 (35)	4 (23)	1 (6)	1 (6)	2 (12)		3 (18)	17 (100)
Continuous 1 to 2 months		2 (40)	1 (20)		1 (20)		1 (20)	5 (100)
Continuous Over 2 months	1 (17)	2 (33)		1 (17)	1 (17)		1 (17)	6 (100)
Loss to follow-up	4 (16)	11 (44)		1 (4)			9 (36)	25 (100)
Other	1 (20)	1 (20)					3 (60)	5 (100)
Total	52 (46)	28 (25)	2 (2%)	3 (3)	5 (4)	1 (1)	21 (19)	112 (100)

6.3.7 Outcomes

6.3.7.1 Outcome at one year after starting treatment

Patients' status was classified at one year after the start of treatment, or at the first clinic attendance after one year.

At one year after starting treatment, 311 patients (68.5%) had completed treatment and follow-up. A further 27 (5.9%) had completed treatment but subsequently been lost to follow-up and 22 (4.8%) were lost to follow-up during treatment. Twenty three patients (5.1%) died during the study period and 19 (4.1%) migrated from Hong Kong (Table 6.72).

Table 6.72: Outcome at one year

Outcome	Number	%
Completed treatment and follow-up	311	68.5
Lost to follow-up during treatment	22	4.8
Completed treatment but subsequently lost to follow-up	27	5.9
Still on treatment	27	5.9
Revised diagnosis #	11	2.4
Died, possibly related to tuberculosis	10	2.2
Died, related to tuberculosis	5	1.1
Died, unrelated to tuberculosis	8	1.8
Follow-up stopped at less than one year	7	1.5
Loss to follow-up before starting treatment	1	0.2
Relapse (1 discontinued treatment but continued follow-up)	3	0.7
Patient discontinued treatment but continued follow-up	2	0.4
Migrated before starting treatment	2	0.4
Migrated during treatment	12	2.6
Migrated after completion of treatment	5	1.1
Unknown	1	0.2
Total	454	100.0

 # One patient had a possible revised diagnosis. treatment was stopped after 4 months No definite revised diagnosis was made and the SOPD responsible for follow-up thought that the patient was still on treatment

Revised diagnoses: There were 12 patients in total with revised diagnoses, seven men and five women. Their ages ranged from 18 to 78 years. The diagnosis of TB was revised to atypical mycobacterial infection (4 cases); lung cancer (3 cases, 2 primary lung cancer, one secondary to cancer of the stomach); septic knee, replacement (1 case); no alternative diagnosis (4 cases one of which, a 37 year old male, was lost to follow-up in April 1995 and subsequently died in December 1995, cause of death stated as pulmonary TB). Treatment received prior to revision of diagnosis was none (3 cases) and from 11 days to 275 days for the others.

What predicts a successful outcome?: Patients were classified into 'successful' if they were in the first category in Table 6.72 (completed treatment and follow-up) and 'not successful treatment' otherwise. Logistic regression analysis was used to identify the variables associated with a successful treatment and follow-up programme. The results are in Table 6.73.

The following variables were also tested but were not found to be associated with a successful outcome: severity of complications, duration of treatment, number of episodes, region of habitation, presence of symptoms, result of first smear or culture test, extra-pulmonary disease, past TB, acquired drug resistance, source of notification, source of starting and source of finishing treatment.

The association between living in public housing and successful follow-up was further examined. Public housing was classed into two types: A which is newer and B which is older, often with shared facilities and lower rents. Those who live in Group A public housing had an OR for successful treatment of 2.84 (95% CI (1.54-4.00, p=0.0002). Table 6.74 shows the differing outcomes of those in Group A, Group B and private housing.

Table 6.73: *Association of variables with completion of treatment and follow-up*

Variable		OR	p	95% CI
Age	25-39	0.74	0.465	0.32-1.68
	40-59	0.63	0.280	0.27-1.46
	≥60	0.63	0.283	0.27-1.46
(baseline is 0 to 24)				
Male gender		1.00	0.994	0.64-1.57
(baseline is female)				
Live in public housing		2.05	0.002	1.31-3.20
(baseline do not live in public housing)				
Severity of comorbidity*				
	Minor	0.86	0.660	0.44-1.69
	Moderate	0.62	0.106	0.35-1.11
	Severe	0.36	0.002	0.19-0.68
(baseline is no comorbidity)				

* Severity of co-morbidity is defined in section 8.1.

Table 6.74: *Characteristics of those in different types of housing*

	Group A	Group B	Private
% who died	4.1%	10.5%	0
%who migrated	0.7%	5.3%	14.9%
% LFU	8.8%	18.4%	4.4%

The percentage of the treatment period for which a patient was receiving directly-observed therapy (DOT) was examined to determine whether it predicted completion of treatment and follow-up. A logistic regression model was used in which the percentage of time on DOT was included as an independent variable along with age, gender and type of housing and successful treatment and follow-up was the dependent variable. Table 6.75 shows that those who spent no time on DOT were significantly less likely (OR<1) to have a successful outcome than those who spent 100% of their treatment time on DOT. However, this is a preliminary analysis only; there may be other confounding variables which have not been accounted for in this model.

Table 6.75: *Association of time spent on DOT with completion of treatment and follow-up*

Variable		OR	p	95% CI
Age	25-39	0.58	0.436	0.15-2.26
	40-59	0.40	0.193	0.10-1.58
	≥60	0.41	0.192	0.11-1.57
(baseline is 0 to 24)				
Male gender		1.09	0.718	0.69-1.70
(baseline is female)				
Live in public housing		1.82	0.008	1.17-2.82
(baseline do not live in public housing)				
Percentage of time on DOT				
	Some time, but less than 100%	0.73	0.269	0.42-1.27
	Zero time on DOT	0.27	<0.0001	0.15-0.49
(baseline is 100%)				

6.3.7.2 Loss to follow-up

A patient was classified as being lost to follow-up if:

- there was no record of attendance at scheduled follow-up, and no record of referral to another health care source
- the patient was recorded as being referred (either by that source or a self-referral) to a source which could not be identified (eg self referral to "private practitioner").

A proportion of patients classified as lost to follow-up are likely to have attended another health care source and completed follow-up or treatment, but there was no way of identifying these patients in this study.

If a patient defaulted from scheduled follow-up but re-attended at a later date the patient was classified as completing follow-up. Medical records of such patients were reviewed up to 6 months after the end of treatment in order to identify re-attendance.

Characteristics of those lost to follow-up: The following categories of final outcome were classified as *lost to follow-up* and grouped together.

- lost to follow-up during treatment (n=22)
- completed treatment but lost to follow-up (n=27)
- follow-up less than 1 year (n=7)
- lost to follow-up before treatment started (n=1)

A logistic regression model was then derived to determine what characteristics predicted loss to follow-up. As Table 6.76 shows, being notified from a source other than the chest service was significantly associated with being lost to follow-up. No significant association was found between loss to follow-up and the following variables: age, gender, living in public housing, severity of complications, duration of treatment, number of episodes, region of habitation, presence of symptoms, result of first smear or culture test, extra-pulmonary disease, past TB, acquired drug resistance, site of starting or finishing treatment.

Table 6.76: *Association of variables with loss to follow-up*

Variable		OR	p	95% CI
Age	25-39	2.71	0.624	0.53-1.83
	40-59	2.86	0.350	0.33-22.02
	≥60	2.00	0.332	0.34-23.75
(baseline is 0 to 24)				
Male gender		0.99	0.963	0.53-1.83
(baseline is female)				
Live in public housing		0.71	0.262	0.39-1.30
(baseline do not live in public housing)				
Notified from				
	chest hospital	1.45	0.286	0.73-2.86
	non-chest service	3.75	0.015	1.29-10.90
(baseline is chest clinic)				

An additional study to identify further sources of care in patients lost to follow-up in this survey was subsequently performed and is described below.

6.3.7.3 Additional study to identify further sources of care in patients lost to follow-up in this study

Methods: The Department of Health was provided with a list of patients (n=50) who were classified as lost to follow-up before, during or after treatment. The list included patient's names, ID numbers, sex, age, date of birth, source of care for last known episode, outcome of last episode, source of care referred to from last known episode, chest clinic or hospital number at notification, last date of contact with treatment services any relevant additional information abstracted from the medical record.

They tried to identify any contact with health services after the last date of contact.

Results: Five of the 50 patients were traced.

Table 6.77: Tracing of patients lost to follow-up during the study period

Lost to follow-up in study	Number lost to follow-up	Traced by Department of Health
Before treatment started	1	1
During treatment	22	3
After treatment completed	27	1
Total	50	5

A summary of the key features of these five patients' care is presented in Table 6.78.

Of the five patients:

- Two appear to have complied with their discharge referral from chest hospitals to chest clinics. For some reason their attendance at the relevant chest clinics was not identified in the study. The most likely reason for this is that they did not attend the specific chest clinic that they were scheduled to attend. Because there is no centralised record system for chest clinic records it can be difficult to trace patients if the chest clinic they attended is not known
- One failed to attend the 3 month follow-up after completion of therapy but did eventually attend seven months after completing therapy
- One appears to have lost all contact with health services for over a year and re-presented with haemoptysis
- One appears to have lost contact with the chest clinic service but self-referred to a private practitioner for continued management and then re-presented to a chest clinic with haemoptysis. Without review of the private practitioner's management, it is not possible to give the reasons for this. The possible reasons include: inadequate therapy prescribed by private practitioner; poor compliance by patient, failure of therapy for some other reason.

Table 6.78: *Summary of key features in five patients' care*

Final outcome currently recorded in study	Date lost to follow-up during study	Duration of treatment prior to loss to follow-up in study (days)	Date of first contact identified by DoH	Duration of apparent loss of contact with health services (days)	Source of care for first contact identified	comments
LTFU before treatment	22-11-94	None	23-01-96	427	A&E	Presented with haemoptysis
LTFU during treatment	29-11-94	66	13-12-94	14	Chest clinic	Attended chest clinic after discharge from WTSH
LTFU during treatment	08-04-95	135	02-12-96	604	Chest clinic	DoH states date LTFU in study should be 08-03-95. Patient received anti-TB Rx from GP from 08-03-95. Returned to chest clinic with harmoptysis
LTFU during treatment	06-12-94	21	09-12-94	3	Chest clinic	Attended chest clinic after discharge from Hospital
LTFU after treatment	12-10-95	Completed	13-05-96	214	Chest clinic	Did not attend schedulted FU Jan 96

In summary therefore, there are.

- Two patients who were not in fact lost to follow-up
- One patient who missed a scheduled follow-up appointment after completion of treatment. This is true for quite a number of patients in the study but, for these patients, the subsequent attendance after the scheduled appointment was identified during the study period, and they were not coded as lost to follow-up This patient does not therefore differ from many of the patients coded as completing therapy and follow-up.
- Two patients for whom loss to follow-up had public health implications in terms of prolonged duration of disease. For one of these patients the extent of loss to follow-up is not clear.

Summary: Of the 50 patients recorded in the study as being lost to follow-up, two are known to have experienced continued care in the public sector and one self-referred to the private sector. Some of the remaining 47 patients may have experienced episodes which were not traced, particularly in the Hospital Authority and private sector.

Sensitivity analysis:

3 were not in fact LTFU (subsequently referred to as "**false positives**")
2 were confirmed LTFU (subsequently referred to as "**confirmed LTFU**")
45 had no evidence of further episodes identified (subsequently referred to as "**apparent LTFU**")

a) best case scenario

If we assume that the five in whom further data were found in fact represent the 45 "still apparent LTFU", applying the ratio of 3.2 false positive confirmed LTFU to the 50 "apparent LTFU", gives

30 false positives (ie not in fact LTFU)
20 confirmed LTFU

b) worst case scenario

If we assume that the 45 "still apparent LTFU" were in fact confirmed as LTFU, the 50 "apparent LTFU" would comprise:

3 false positives (ie not in fact LTFU)
47 confirmed LTFU

a) best case

20/454 x 6500 = 286 cases confirmed LTFU per year

b) worst case

47/454 x 6500 = 673 cases confirmed LTFU per year

A reviewer comments that *"there is a system of home visits to trace defaulting patients by community nurses. Probably these patients were in the high risk default group of drug addicts/street sleepers or migrant workers. Even so, the figure (for loss to follow-up) of between 286-673 is high, at the worst case this is 10% of all notifications."*

6.3.7.4 Duration of treatment in those who did not complete it

Duration of treatment prior to death: Of the 19 patients who died during treatment (4 died prior to the start of treatment), the duration of treatment prior to death ranged from 1 day to 359 days. The median value was 70 days (interquartile range 32 to 145 days).

Three patients died within three days of starting treatment and four patients died prior to the start of treatment. Of these seven patients two died of causes directly related to tuberculosis, and five died of causes possibly related to tuberculosis (Table 6.79).

Table 6.79: Cause of death in patients dying before or just after starting treatment

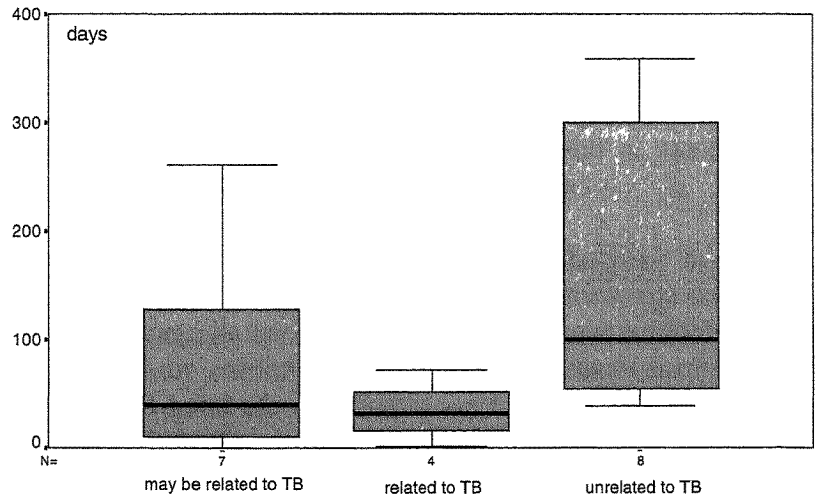
Treatment status	Death directly related to TB	Death possibly related to TB
Not started	1	3
Started less than three days	1	2

The duration of treatment prior to death is shortest for patients who died of causes directly related to TB and longest for patients dying of causes unrelated to TB (Figure 6.62).

Duration of treatment prior to loss to follow-up: The 23 patients who were lost to follow-up during treatment received treatment for periods ranging from 7 days to 330 days. The median value was 134 days (interquartile range 21 to 222 days).

Duration of treatment prior to migration: The 11 patients who migrated during treatment received treatment for periods ranging from 7 days to 213 days. The median value was 72 days (interquartile range 21 to 158 days).

Figure 6.62: Duration of treatment prior to death



6.3.7.5 Identification of deaths occurring after follow-up

Aim: To identify deaths occurring in the study population after the last date of follow-up

Methods: A list of patients to be included in the search was sent to the Department of Health. The search was performed with the assistance of the Immigration Department. The following patients were excluded from the search:

- patients known to have migrated during the study (n=19)
- patients known to have died during the study (n=23)

The death registry was computerised in December 1995. Two separate lists were prepared:

- patients who were lost to follow-up before December 1995. Both manual and computerised death registries were searched for these patients (n=57).
- patients who were still being followed up or with a revised diagnosis in December 1995 or whose diagnosis had been revised during the study. Only the computerised registry was searched for these patients (n=355).

The name, ID number, age and sex of each patient was provided for the search.

Results: Twenty one of the 412 patients (5.1%) were identified in the death registry. Six of the 57 (10.5%) lost to follow-up before December 1995 were found to have died, compared to 15/355 (4.2%) still followed up or with a revised diagnosis at the end of the study.

Patients lost to follow-up during study: No further episodes of care were identified after the study by the Department of Health for any of the six patients lost to follow-up during the study and found to have died. The last date of follow-up and date of death are listed below (Table 6.80).

Table 6.80: *Date and cause of death of patients lost to follow-up during study*

Patient lost to follow-up	last date of follow-up	date of death	cause of death
during treatment	26-04-95	21-08-96	carcinoma of lung
during treatment	28-11-94	22-01-95	carcinoma of larynx
during treatment	25-12-94	06-12-95	chronic obstructive airway disease
after treatment	01-08-95	15-08-95	carcinoma of lung
after treatment	21-07-95	01-09-96	carcinoma of colon
after treatment	29-08-95	05-10-95	respiratory failure

Patients still followed up one year after starting treatment or with revised diagnosis: The outcome at one year for the 15 patients in this category whose deaths were identified is recorded below (Table 6.81).

One of the two patients with outcome of "revised diagnosis" was also lost to follow-up before the end of the study period. Treatment was started for this 37 year old man on the basis of a positive sputum smear in December 1994 but stopped in April 1995 when all sputum cultures were negative. No alternative diagnosis was made, but he was known to suffer from bronchiectasis. He was last seen in June 1995 and did not attend for scheduled follow-up in October 1995. Pulmonary tuberculosis was stated to be one of three causes of death.

The second patient with a revised diagnosis was followed up to the end of the study period. Treatment for tuberculosis was started in December 1994, but stopped in February 1995 when a revised diagnosis of carcinoma of the lung was made. Carcinoma of the lung was given as the cause of death.

Table 6.81: *Outcome at one year, date and cause of death for patients still followed up one year after starting treatment or with revised diagnosis*

outcome at one year	date of death	cause(s) of death
completed treatment and follow-up	05-03-96	• pneumonia • chronic obstructive lung disease
completed treatment and follow-up	04-03-96	• chronic obstructive airway disease
completed treatment and follow-up	14-05-96	• carcinoma of prostate with metastasis
completed treatment and follow-up	30-03-96	• carcinoma of lung
completed treatment and follow-up	14-01-96	• carcinoma of lung • hepatic failure • sepsis
completed treatment and follow-up	20-04-96	• chronic obstructive airway disease
completed treatment and follow-up	03-05-96	• multiple injuries • suicide • self-inflicted injury by jumping from high place
completed treatment and follow-up	01-02-96	• respiratory failure • chronic obstructive airway disease
still on treatment	22-04-96	• malignant cachexia hepatocellular carcinoma
still on treatment	18-09-96	• pneumonia • liver cirrhosis • diabetes mellitus
still on treatment	19-03-96	• hepatocellular carcinoma • cirrhosis of liver
revised diagnosis	27-09-96	• carcinoma of lung
revised diagnosis	28-12-95	• chronic obstructive airway disease • bronchiectasis • pulmonary tuberculosis
relapse	05-05-96	• bronchopneumonia
stopped treatment, continued follow-up	07-10-96	• carcinoma of lung

Discussion: In order to minimise work for the Immigration Department, the number of patients for whom a manual search had to be performed was kept to a minimum by selecting patients lost to follow-up before December 1995. Patients with alternative outcomes at one year (e.g. completed treatment and follow-up) were listed separately and a search of only the computerised database from December 1995 onwards was made.

Of the six patients known to have died who were lost to follow-up during the study, three died within two months of being LTFU. The remaining three died a year or more later. For the former group of patients, it could be that the morbidity associated with their terminal illness contributed to their LTFU by the tuberculosis services, but this seems to be an unlikely explanation for the latter group.

Of the 15 deaths in patients who were still being followed up at one year or who had a revised diagnosis during the study, one was attributed in part to pulmonary tuberculosis. This patient did not attend for his scheduled follow-up two months prior to his death, but his diagnosis had been revised and treatment stopped eight months prior to his death. Without review of his medical records, we do not know whether or not this patient's death could be attributed in part or in whole to his tuberculosis

6.4 PRACTICAL ISSUES IDENTIFIED DURING THE SURVEY

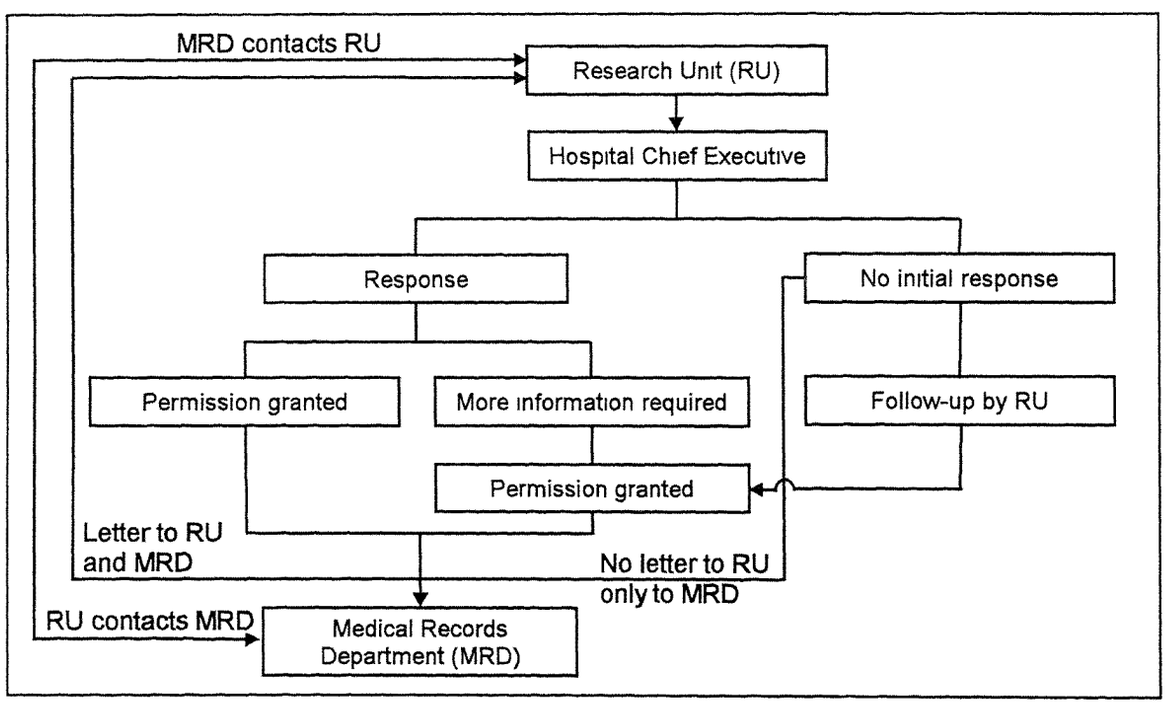
6.4.1 Problems obtaining information from records

6.4.1.1 Requesting records

Chest hospitals: In the chest hospitals, the Chief of Service was contacted directly prior to the study. No problems in requesting records were encountered apart from some clarification on the privacy of information bill being required (See Section 6.4.1.3).

Other hospitals: The procedure used was that one of the principal investigators wrote directly to the Hospital Chief Executive (HCE) enclosing a covering letter and a list of patients whom we wished to include in the survey Some units requested the protocol, as offered; some phoned to discuss the project in more detail; some were concerned about the privacy bill; some gave no response. Figure 6.63 shows the process for requesting records.

Figure 6.63: *Process for requesting of medical records*



When the permission of the HCE was obtained, the researcher contacted the Medical Records Department (MRD) and asked if they would obtain the records for us. If there had been no response from the HCE, a follow-up phone call was made. Some HCEs requested another copy of the letter (in one situation, the previous HCE had been replaced). Some HCEs had advised the MRD to get records for us, but the MRD had not contacted us.

The list of patients was sent again to the MRD if the HCE's office had not forwarded the list originally sent by the survey team. The MRD either contacted the researchers after receiving the list or they had to follow-up the request. A time was arranged to review the records; occasionally this had to be done in the presence of a staff member.

For the next round of data abstraction when further episodes had been identified from the medical records which had been reviewed in earlier rounds (there was up to a few months interval between data collection rounds and this was indicated in the initial letter to HCEs), the researchers initially contacted the MRD. Some MRDs asked the researchers to write to the HCE again while others immediately granted permission.

Identifying the responsible person in hospital: To obtain permission to review a record in one hospital, the researchers wrote to the HCE who asked them to apply to the research committee. The research committee then asked the chief of service of the respiratory department to approve the project. His approval was then followed by the HCE's consent. The researchers then approached the MRD, but there were many records in different departments. They had to then approach the Chief of Service (COS) in each department who allocated responsibility to team heads.

Identifying the responsible person in clinics: In some clinics it was unclear whether they were Department of Health (DOH) clinics or Hospital Authority (HA) clinics. The researchers initially wrote to the DOH who said that HA was responsible. They then wrote to the HA who advised them that the clinic was under the control of a HA hospital. They therefore wrote to the HCE of this hospital. In one polyclinic, some clinics were managed by the DOH (general out-patient department clinics (OPDs)), and specialist clinics were run by the HA. From the data in the records, it was not usually clear whether a patient attended a GOPD or specialist clinic.

6.4.1.2 Tracing the records once permission granted

At one chest hospital, there was a manual system of record storage filed under medical record number. If the medical record number was missing from the notification form, the records had to be traced using only the patient's name in a small card filing system.

At chest clinics, records were filed under clinic number. If clinic number was not known, a manual search of an alphabetically ordered name list had to be done to find the clinic number. If the clinic of attendance was not known, this would have entailed searching through every name list for each clinic. The ID number was not used for filing.

Each HA episode is normally assigned an IPAS number (Integrated Patient Administration System) which is unique to that episode and patient. IPAS numbers start with year of admission and then run in sequential order throughout the year, e.g. HN94000124 would refer to the 124th patient admitted in 1994. Each patient can therefore collect multiple different IPAS numbers. The only numbers which are constant for each patient are:

- HK ID number (people who do not have an ID card are assigned a new hospital ID number each time they visit e.g. refugees/illegal immigrants, visitors)
- medical record number (only used at some hospitals)

In one general HA hospital, the records were not all held in the MRD, but some were in individual departments. (The MRO helped the researchers to trace the records, whereas in another hospital, they had to go to the individual departments themselves.) Some records were filed in the MRD but others were in departments. For example, for surgery, in 1994, the department was split into two sections (which are now integrated). Records were filed according to the team caring for the patient and there were approximately 10 teams. Once approval of the HCE, COS for surgery and the department head had been obtained, the researchers had to go to the team specific for that patient to get the record.

6.4.1.3 Personal Data (Privacy) Ordinance

HCEs, private practitioners, GOPDs, HA clinics and private hospitals all expressed concern about meeting the requirement of this Ordinance. They were reassured that no individual patient would be identified in any report and that the ethics committee had advised that individual patient's consent was not required. Despite this, some private hospitals contacted patients to obtain their consent, and all patients contacted in this way refused.

6.4.1.4 Issues relating to specific institutions

British Military Hospital: No longer exists: records were stored elsewhere and had to be traced.

Refugee Detention Centres: The researchers initially wrote directly to the Senior Medical Officer (SMO) at each Centre. It then became apparent that the SMO for one was also responsible for another. DOH was then involved in obtaining the necessary consent to participate in the study.

Correctional Services Division: The researchers originally wrote to individual prisons/detention centres. Permission was not granted for the survey team to review medical records directly, but after discussion, the CSD agreed to provide data which they had abstracted from the records themselves onto questionnaires designed by the study team.

Coroners: One Public Mortuary granted permission to review the record immediately. Another asked the survey team to first get permission from the Coroner.

6.4.1.5 Abstracting data from medical records

Episode identification: Information for individual episodes was sometimes not filed separately for each episode but mixed up in one folder; for example all the investigations for two episodes were filed together, but progress sheets were filed separately.

A new patient record was sometimes created for a new episode resulting in sequential episodes being filed in different folders: this resulted in each folder being incomplete e.g. laboratory results filed in one folder and progress sheets in another. Folders for the same patient were sometimes filed separately and not all were retrieved.

Laboratory results: Laboratory forms were sometimes incomplete, e.g. with no record of date or type of specimen. Laboratory results were sometimes not filed or filed in the wrong episode or folder. Sometimes, even though they were not filed in the hospital medical record,

copies of laboratory reports were found in the chest clinic record. In-patient laboratory results were sometimes filed in the out-patient records. Laboratory reports were sometimes glued to pieces of card or used paper and filed randomly.

Data about referrals made: The previous and subsequent sources of care were not always clearly recorded, e.g. recorded as "cc" (chest clinic, not specified) or GOPD or OPD, or sometimes inconsistent with information obtained from other sources. The date of referral to subsequent sources of care was not always recorded.

Discharge summaries: Discharge summaries were not prepared for each episode, e.g. if a patient had two admissions in a short space of time, one discharge summary may have been written to cover both admissions. Discharge summaries were sometimes incomplete.

Ward follow-up: Ward follow-up was frequently not clearly recorded. Occasionally it was recorded in the progress sheet, but sometimes the only evidence about the patient's attendance was a laboratory result.

Out-patient records: Out-patient records were sometimes filed separately from the in-patient records, or some hospitals had a central filing system where the out-patient record was filed with the in-patient record. In one of these hospitals the out-patient record was a smaller booklet slotted in the front cover of the in-patient folder with a different booklet for each out-patient clinic. In another, there was a separate section in the in-patient folder for out-patient records.

If a patient was admitted as a day case (e.g. for bronchoscopy), the details were sometimes filed in the SOPD file rather than the in-patient medical record.

Structure of record: Progress sheets and investigations were frequently not in date order. Sheets from other patients' records were sometimes misfiled in study patients' records (e.g. laboratory results). Custom made problem sheets or summary sheets were (a) sometimes not completed at all, (b) were incomplete or (c) were used as plain paper (ie columns and headings ignored). Doctors sometimes wrote medical progress on both progress sheets and treatment sheets, which were supposed to be used for summarising drugs and investigations.

Chest X-rays: In one hospital, chest X-ray folders were filed according to X-ray number. The same or a new X-ray number might be assigned to a patient the next time he/she had an X-ray (depending on whether the patient could remember the previous X-ray or not). The only way to retrieve an X-ray from the filing system was to find a radiology report in the medical record and retrieve the X-ray number from the radiology report. There were, however, very few radiology reports filed. X-rays from some chest hospitals were filed in chest clinic records, as a means of communicating the results.

Some other general problems encountered in data abstraction: Illegible handwriting, cryptic notes, minimal or no information recorded for some clinic visits or in-patient days.

Chest clinic only: Correspondence, laboratory results and treatment cards were usually stored in a back pocket of the file and were difficult to review because they were not in chronological order.

6.4.2 Interface between sources of care

Data relating to the interface between sources of care were abstracted from medical records. From one set of medical records at one source of care, data were abstracted relating to the interface between the preceding source and the current source, and the current source and the subsequent source of care. These data are similar but not the same because of data taken from episodes at the beginning and end of the study period.

6.4.2.1 Data referring to interface between current source and preceding source of care

Referrals from hospital to chest clinic: A total of 336 referrals from chest hospitals or general hospitals to chest clinics took place. Of these 336 referrals, a discharge summary or referral letter was filed in the chest clinic medical record in 275 (81.8%) instances. The proportion of referrals where a discharge summary or referral letter was filed was higher for referrals from chest hospitals (Table 6.82).

Of the 275 discharge summaries which were filed, "drugs on discharge" were listed on 250 (92.6%) of the 270 occasions where appropriate. The results of investigations performed whilst an in-patient, was recorded in 260/272 (95.6%) instances where it was appropriate. Doctors working in chest hospitals were more likely to include drugs and investigation results on the discharge summary.

Table 6.82: *Content of discharge summaries for patients referred from HA hospitals to chest clinics*

Discharge summary:	Chest hospital		General hospital		Total	
Filed in chest clinic	Yes	:212 (94.6%)	Yes	: 63 (56.2%)	Yes	:275 (81.8%)
	No	: 4 (1.8%)	No	: 38 (33.9%)	No	: 42 (12.5%)
	Unknown	: 8 (3.6%)	Unknown	: 11 (9.8%)	Unknown	: 19 (5.7%)
Drugs listed	Yes	:208 (98.1%)	Yes	: 42 (66.7%)	Yes	:250 (90.9%)
	No	: 2 (0.9%)	No	: 18 (28.6%)	No	: 20 (7.3%)
	NA	: 2 (0.9%)	NA	: 3 (4.8%)	NA	: 5 (1.8%)
Investigation results noted	Yes	:207 (97.6%)	Yes	: 53 (84.1%)	Yes	:260 (94.5%)
	No	: 3 (1.4%)	No	: 9 (14.3%)	No	: 12 (4.4%)
	NA	: 2 (0.9%)	NA	: 1 (1.6%)	NA	: 3 (1.1%)

NA=Not appropriate

The interval between the date of the discharge summary and the planned start date of the next episode of care was calculated. Ideally, this interval should be sufficient to allow the discharge summary to reach the subsequent source of care before the patient attends.

The interval was calculated for 130/275 (47.3%) referrals. The median value for the interval was 13 days (interquartile range 10 to 14 days). On three (1.1%) occasions the interval was negative, that is the discharge summary was dated between 3 and 27 days after the planned start date of the subsequent episode. On a further 11 (4.0%) occasions the discharge summary was dated less than a week before the planned start date.

This interval could only be calculated for 1/63 (1.6%) discharge summaries from general hospital to chest clinic: either the discharge summary date or planned start date or both was missing from the discharge summary. It was calculated for 129/212 (60.8%) discharge summaries from chest hospitals.

The interval between the referral date and the discharge summary was calculated for 109/275 (39.6%) discharge summaries (62 from chest and 47 from general hospitals). The median value was 0 days (that is the discharge summary was written on the same day as discharge) (interquartile range 0 to 1.5 days). In five instances the discharge summary was dated up to 16 days prior to discharge. The remainder were dated up to 8 days after discharge with one exception of a 27 day delay.

Chest hospitals had slightly higher values for this interval than general hospitals (Table 6.83).

Table 6.83: *Interval between referral date and discharge summary date*

Hospital	Median	Interquartile range	Range
Chest	1 day	0 to 3.25 days	-14 to 27 days
General	0 days	0 to 0 days	-16 to 5 days

Referrals between hospitals: Twenty referrals were identified from chest hospitals to either general HA or other chest hospitals, excluding planned readmissions. Of these, a discharge summary was filed at the subsequent source of care in only 7 (35.0%) instances.

99 referrals were identified from general hospitals to other general hospitals or chest hospitals, excluding planned readmissions. Of these, a discharge summary was filed at the subsequent source of care in 57 (58%) instances.

The content of the discharge summaries is summarised in Table 6.84.

Table 6.84: *Content of discharge summaries for patients referred between HA hospitals*

Discharge summary:	Chest hospital	General hospital	Total
Filed in referral hospital	Yes :7 (35.0%)	Yes :57 (57.6%)	Yes :64 (53.8%)
	No :4 (20.0%)	No :21 (21.2%)	No :25 (21.0%)
	Unknown :9 (45.0%)	Unknown:21 (21.2%)	Unknown:30 (25.2%)
Drugs listed	Yes :5 (71.4%)	Yes :37 (64.9%)	Yes :42 (65.6%)
	No :0	No :12 (21.1%)	No :12 (18.7%)
	NA :0	NA: 1 (1.8%)	NA :1 (1.6%)
	Unknown :2 (28.6%)	Unknown:7 (12.3%)	Unknown:9 (14.1%)
Investigation results noted	Yes :4 (57.1%)	Yes :48 (84.2%)	Yes :52 (81.2%)
	No :1 (14.3%)	No :3 (5.3%)	No :4 (6.2%)
	NA :0	NA :0	NA :0
	Unknown :2	Unknown:6	Unknown:8
Overall proportion	(28.6%)	(10.5%)	(12.5%)

NA=not appropriate

The interval between the date of the discharge summary and the planned start date of the next episode of care was calculated for 4/7 discharge summaries from chest hospitals. It was 0 days for all four, that is the planned start date was the same as the discharge summary date.

This interval was calculated for 12/57 discharge summaries from general hospitals. The median value was 0 days (interquartile range 0 to 1.75 days)

The interval between the referral date and the discharge summary was calculated for 5/7 discharge summaries from chest hospitals. The median value was 0 days (interquartile range 0 to 1 days).

This interval was calculated for 24/57 discharge summaries from general hospitals. The median value was 0 days (interquartile range 0 to 0 days).

Interval between planned start date and actual start date: The interval between the start date as planned by the preceding source and the actual start date of the subsequent source of care was calculated for 727 referrals. The median value was 0 days (IQ range 0 to 0 days). Values for the interval ranged from -79 days to 244 days. Negative values indicate that patients start the next episode earlier than scheduled (for example, after discharge from hospital they go to a chest clinic earlier than their scheduled appointment.

Positive values indicate that the patient did not attend the scheduled appointment, but delayed follow-up, by a period varying its status was up to 244 days (over 8 months). In the latter case the patient defaulted on treatment for this period.

For referrals from chest hospitals to chest clinics, if the patient was originally referred to the chest hospital from the chest clinic, the clinic record is sent in with the patient. The chest clinic medical record is then returned to the clinic on discharge. The planned start date is usually two weeks after discharge. If the patient attends the clinic earlier than scheduled, the medical record might not be available. The interval between planned and actual start dates was calculated for 155 patients. The median value was smaller for patients for whom the medical record was not available (- 10 days) compared with those whose medical record was available (0 days) (see Section 6.4.2.8).

Type of referral from chest clinic to chest hospital: Of 173 such referrals, the referral was recorded as being elective in 15 instances (8.7%), urgent in 55 (31.8%) and its status was not recorded in 103 (59.5%).

6.4.2.2 Data referring to interface between current source and subsequent source of care

Outcome of episodes: Up to two outcomes of each episode were recorded. The most frequent outcome was referral by the current source of care to another source. The second most common outcome was that the patient was still being followed-up, this was recorded at the end of the study period if further appointments were scheduled. The third most frequent outcome was that of self-referral by the patient to another source (Table 6.85).

Table 6.85: Outcome of episode

Outcome	Number of episodes	% of episodes
Referred	1258	61.4
Transferred to another chest clinic	122	6.0
Lost to follow-up	56	2.7
Discharged against medical advice	20	0.9
Self-referred elsewhere	143	7.0
Died	21	1.0
Migrated	17	0.8
Discharged with no further follow-up	45	2.2
Still followed-up	356	17.4
Other	2	0.1
Unknown	10	0.5
Total	2050*	100.0

** In 38 episodes there were two outcomes. In each instance the most important outcome was recorded as the first outcome*

Of the 1523 referrals (either referred, transferred between clinics or self-referred), 1296 (85.1%) were recorded as being for tuberculosis and 208 (13.7%) for another condition. The reason for referral was not recorded for the remaining 19 referrals.

Of the 193 referrals from a chest clinic to a chest hospital, 15 (7.8%) were recorded as being elective, 70 (36.3%) were recorded as being urgent, and in 108 instances (56.0%) the type of referral was unknown.

Interval between end of episode and date of referral: This interval was calculated for 1132 referrals. The median value was 0 days (IQ range 0 to 0 days). In 914/1132 (80.7%) referrals the interval was zero. The values ranged from -518 days to 86 days.

Interval between referral and discharge summary: This interval was calculated for 271 referrals. The median value was -1 days (IQ range -5 to 0 days). The values ranged from -215 days to 9 days.

Interval between referral and planned start date of subsequent episode: This interval was calculated for 591 referrals. The median value was 10 days (IQ range 1 to 15 days). The values ranged from 0 days to 183 days.

Availability of medical record at chest clinics: In 224 referrals from chest hospitals to chest clinics, the medical record was available at the first clinic visit in 102 instances. However, in 41 referrals it was not appropriate for this to be reviewed as the chest clinic had not originally referred the patient to the chest hospital and the medical record was still in the clinic's possession. Excluding these referrals means that the record was available in 102/183 (55.7%) of instances, not available in 77/183 (42.1%) and availability unknown in 4/183 (2.2%).

6.5 DISCUSSION

The survey and retrieval of records required for this audit began with definition of terms (such as episode of care) needed to examine the medical work carried out for these patients. These proved to be extremely complex and heterogeneous. Future development of information systems for tuberculosis services will require a robust classification of events to chart a TB patient's career. However standard protocols for care would probably reduce heterogeneity in patterns of care and facilitate audits.

Tracing records was difficult and time-consuming. Even within a particular treatment site records may lie either in a medical records department, a clinical unit or with a particular team. To perform the critical monitoring, which is needed to assess the care of TB patients, records must be unified so that practitioners use the same record for an individual patient. The standard of some records needs to be improved. The findings of illegible hand writing, cryptic notes and minimal or no information are not by any means unique to TB records but they are a major obstacle to the evaluation of care. In section 9 we emphasise the need for an informatics approach to the development of a modern records system. This is needed for all health care but is nowhere more urgent than in TB services.

Most episodes of care (64%) took place in ambulatory settings but most patients (62%) experienced at least one episode as an inpatient. This finding of a high admission rate has surprised most clinicians working with the research team among whom personal guesstimates ranged down to as low as 20%. It is possible that the sample is biased, but very unlikely given the comparability of its other characteristics with the parent cohort. TB patients receive care from a very wide and heterogeneous spectrum of different sources. Many sources will see relatively few patients and many contact will be with relatively junior staff (eg in HA facilities). Although we believe that the Joint TB Coordinating Committee has discussed this issue we suggest that further consideration is given to rationalising sites and levels of care.

Co-morbidity levels are very high in TB patients, particularly cardiovascular and respiratory problems and diabetes and this is an important factor determining dependency and costs of care. Another is the presence of psychosocial problems, mainly finance and housing, and affecting more than 1 in 20 patients.

Whereas there is no suggestion that many patients are unnecessarily admitted to hospital, one receiver of the first draft reported pointed out that the overall median length of stay (LOS) (9 days) was relatively short, suggesting that at least patients with a very short LOS might be managed differently. There should be a review of the criteria for admission and of possible alternative approaches to care, especially if the reasons for admission are only for gathering information for diagnosis. We need to be able to audit reasons for admission. In this study we were unable to do this because reliable and complete data on reasons for admission was not available.

Several reports in the international literature describe delays in starting treatment. In this cohort, 25% of patients waited for 20 to 40 days and substantial numbers for over 80 days. Although the smear positive patients started treatment earlier (median 8 days) than smear negatives (median 35 days) some were markedly delayed. This problem could be addressed urgently through a review of the criteria for starting treatment, the use of protocols and audit to identify problems and overcome inertia where it exists. The gender differences in delays should be explained.

Complications of tuberculosis (involving 27% of patient-episodes) and side effects of treatment (involving 64%) are important factors increasing the demand for care.

The assessment of outcomes points to an important marginal group of patients, amounting to 1 in 10 of the sample who were lost to follow-up mainly either during or after treatment. Some of these patients were probably receiving care elsewhere but we could only find additional information for 5 out of 50 who were lost. These patients were more likely to be from lower socioeconomic groups or otherwise disadvantaged in their living conditions. The service should be better geared to identifying such high risk patients and testing different approaches to reduce the proportions who are lost. The loss of only a small proportion of the treated population may, in public health terms, negate many of the benefits gained by those who complete the programme.

Future work on clinical audit of TB services would be aided by the development and use of performance indicators. These should be linked to

> *population health improvement; access to and effective delivery of appropriate care; efficiency of services; patient experience of services; medical outcomes.*

These indicators should be applied to the whole range of clients and patients eligible for preventive and curative services, including

> *well populations* (all new borns, adolescents, the elderly); *patients at first presentation; patients undergoing DOTS or other regimens; post-treatment patients under follow-up and review.*

One approach to the long term monitoring of performance is based on the *combination* of different types and sources of records in a *health care matrix* (NHS 2000). The combination of groups of clients or patients with groups of interventions, can combined in a *Healthcare Framework* "in which the conditions of groups of people can be mapped to the interventions that they have (or should have) received and linked to appropriate indicators of performance", as shown in the table.

Characteristics of a model Healthcare Framework for tuberculosis

	Prevention & Health Promotion	Investigation & Diagnosis	Clinical Management	Continuing Care	*Outcome indicators*
At risk	Matrix 1				
Presentation		Matrix 2			
Confirmed disease			Matrix 3		
Continued consequences of disease				Matrix 4	
Structure & process indicators					

(Modified from NHS 2000: National Service Framework for Coronary Heart Disease p79)

The aims of the Healthcare Framework for tuberculosis in Hong Kong would be to:

- identify all management interventions for tuberculosis which are effective in local settings.
- develop methods of care across the SAR which can reliably deliver effective interventions.
- provide a mechanism for making rapid adjustments to service delivery in response to problems identified from audit and other evaluation procedures.
- develop audit tools and performance indicators to ensure consistent and uniform standards
- set milestones and clear targets to monitor progress in quality improvement.

The overall intended effect is to achieve continuing quality improvement and reduce unacceptable variations in service delivery.

Finally, because this audit was necessarily only based on the retrieval of information from records we do not have any assessment of patients' subjective health, their perceptions of the quality and acceptability of care, and the impact of TB and its management on quality of life. Future service based audit and research should give a high priority to these areas and examine their relationship to clinical outcomes, including adherence to treatment and continuity of care.

Key messages and action points

- A reliable records system, supported by state-of-the-art information technology, is needed to facilitate continuity of care and clinical audit.

- Patients receive care from multiple sources at different levels and in different administrative sectors of the health care system. A review of the referral system and utilisation patterns is recommended to assess how provision of care could be rationalised and made 'seamless'.

- Further consideration should be given to the appropriateness of having a large heterogeneous mix of different sources of care.

- Socially disadvantaged patients are likely to have a worse outcome. Treatment programmes could identify these patients and take pro-active measures to prevent events such as loss to follow-up.

- Many patients experience long delays before starting treatment. Some of these are clearly related to continuing efforts to make a diagnosis. Others may be associated with avoidable factors.

- Delays in treatment and losses to follow-up during or after treatment are likely to be causes of further transmission of infection. A review of current management procedures should be followed by interventions to test the feasibility of reducing these critical events.

- Comorbidities, complications of tuberculosis and treatment side effects are associated with much higher levels of need and are the most important cost drivers in this service. More work on the diagnosis related group of TB is indicated.

- Utilization of in-patient care, with extended periods of stay for some patients, is higher than expected. Criteria for admission, in-patient management and length of stay should be reviewed. Audit should be carried out routinely to monitor use of hospital resources.

- Operational studies of the principal pathways of care will assist future planning and resource allocation in TB services. A relatively small number of episodes of care are distributed across a large number of different facilities with resulting fragmentation of services.

- Patients' subjective health, perceptions of quality of care and related measures should be given a high priority in future evaluation of services.

- Further reviews of the services for TB should develop a standard set of mutually agreed *performance indicators*. Ideally these should span all aspects of tuberculosis control and treatment in Hong Kong. A simple set of robust indicators could be developed now and gradually refined and adjusted, along with the longer term development of more sophisticated indicators.

7.0

SURVEY OF PRIVATE PRACTITIONERS

7.0 SURVEY OF PRIVATE PRACTITIONERS

SUMMARY

Role of private practice

- In Hong Kong private practice (PP) is the principal source of first contact primary care, so it is expected that a proportion of patients with symptomatic TB will first present to PP.
- A 1977 (reported 1979) survey of Chest Clinic attendees found that 53% had first attended PP. Over 80% of those with a definite diagnosis of TB received anti-tuberculosis treatment from PP.
- In 1979 a further survey showed that the proportion receiving treatment from PP had fallen to 12%.
- In this survey contact was made with 87 PP who had managed patients at any stage of the disease. The response rate was 72%, higher in NT (94%) than HKI (61%) or Kowloon (68%).

Referrals from private practitioners

- 96 stated reasons for referral of patients included definite or possible TB (38%), abnormal chest X-Ray (52%), symptoms (38%) and others (compliance, chest clinic expertise, patient preference, financial constraints).
- Most patients (75%) were followed for less than two weeks before referral to a Chest Clinic, public hospital or in a few cases private hospital. However 25% were followed for longer periods, up to 6 months in one case.

Investigations in private practice

- A large number of investigations were carried out but few (23%) had sputum examinations; 85% of those who were smear positive at the clinic/hospital had not had a smear examination in PP. The proportion of smear tests compares with 5% in 1977 and 18% in 1979.
- More patients (84%) received chest X-rays, compared with 50% in 1977 and 76% in 1979. (The different studies may not be comparable in that identification, sampling and enquiry methods were different).

Implications

- Apparently fewer patients are receiving anti-tuberculosis therapy before referral but the status of those referred on to other private units cannot be ascertained.
- If the sample from this cohort is representative then it indicates that, in each year, newly notified cases of tuberculosis are associated with at least 1218 PP doctor-patient pairings generating about 1358 episodes of care. The sample may not be representative if there is incomplete referral of patients from PP and under-notification.
- The findings of the survey suggest that further integration and improvement of services for tuberculosis patients would be achieved through an intensive collaborative programme of professional education on the early management and referral of patients who may have tuberculosis.

7.1 INTRODUCTION

Interest in the role of private practitioners in the control of tuberculosis is growing. The World Health Organisation Tuberculosis Operational Research Unit identified this as one of its main priorities and held a workshop on the subject in Bombay in September 1994. The aim of the workshop was to encourage research to assess management of tuberculosis in the private sector, and to examine possible ways to integrate public and private sectors in the control of tuberculosis.

Following the revitalisation of National Tuberculosis Programmes in many high prevalence countries, there is growing awareness that private practitioners need to be fully involved if cure rate targets are to be met. Even if public services achieve 100% cure rates for patients under their care, this would have minimal influence on the control of tuberculosis if 50% of patients were being treated ineffectively in the private sector. Principal concerns about the private sector are that inappropriate regimes are prescribed for incorrect durations and compliance is not being monitored; these can potentially lead to high treatment failure rates, increased levels of drug resistance and continuing transmission.

In 1989, a survey of 102 private practitioners in Bombay found that 80 different regimens were used to treat tuberculosis, most of which were inappropriate and expensive (Uplekar, 1991). If patients were referred to the public sector it was mostly for financial reasons, and 10% of doctors said they would never refer to the public sector (Uplekar 1993). Most doctors relied on chest X-rays rather than sputum examination to make the diagnosis of tuberculosis. Over 90% of doctors estimated that treatment completion rates were 50% or less and no doctors had a mechanism for follow-up of defaulters. None of the doctors ever notified a patient with tuberculosis.

A survey of private doctors has not been previously performed in Hong Kong. However, in 1977 a survey of patients with tuberculosis attending Hong Kong's chest clinics found that 53% of patients with symptoms had first attended a private practitioner (Allan, 1979). Of these, 50% had a chest X-ray performed, and 5% had their sputum examined. Fifteen percent were referred directly without treatment to a chest clinic for further management. Twenty four percent of symptomatic patients (44/183) received anti-tuberculous treatment. Thirty seven percent had an initial diagnosis by the private practitioner of definite or suspected tuberculosis. Of the patients with a definite diagnosis of tuberculosis, 44/54 (81%) received anti-tuberculous treatment from the private practitioner.

A repeat survey in 1979 of patients attending chest clinics who had already attended a private practitioner found that 76% had had a chest X-ray, and 18% their sputum examined (HKCS/BMRC, 1984). Eleven percent were referred without delay to a chest clinic. The interval between first attendance at the private practitioner and first attendance at the chest clinic was one month or less for 60%, two weeks or less for 40% and more than six months for 6%. Twelve percent of all patients received anti-tuberculous therapy from the private practitioner.

There has been no study of the management of patients with tuberculosis by private practitioners since 1979. However, other studies have focused on the behaviour of patients in seeking health care. A phenomenon of "doctor shopping" has been described where patients seek the opinion of many doctors for the same complaint (Lo, 1994). "Doctor shopping"

crosses the public-private interface, as well as being performed within each sector. Doctors may be consulted sequentially or in parallel and this can have serious implications for the outcome of treatment, as well as being an extremely inefficient use of resources.

There is a paucity of routine information available about private practitioners in Hong Kong. The Hong Kong Medical Council stated that in October 1996 there were 7,632 doctors registered on the resident list. This includes private practitioners in primary and secondary care and doctors working the public sector. The proportion working in the private sector in primary care is unknown.

A survey of doctor consultations performed in 1992 as part of the General Household Survey (GHS, 1992) found that 68% of consultations in the two weeks prior to the interview had been with private practitioners. The remainder had been with government doctors in clinics (13%), herbalists, acupuncture specialists and bone setters (9%) and out-patient doctors in the Hospital Authority (7%). The overall consultation rate in the last 14 days was 103 per 1,000 population.

The fee for consultations varied, but in 1992, 26% of respondents paid less than $100, 53% paid between $100 and $200 and 10% paid over $200.

7.2 AIM AND OBJECTIVES

To evaluate the management of patients with tuberculosis in Hong Kong by private practitioners

1. To estimate duration and frequency of follow-up of patients in private sector
2. To determine reasons for referral of patients
3. To determine range of investigations performed
4. To determine spectrum of drugs prescribed

7.3 METHODS

7.3.1 Sample

Patients who had been managed by private practitioners were identified in the main cohort study by examination of medical records. One private practitioner was identified because he notified the patient under his care: this doctor was excluded from this study sample. The remainder were identified either from referral letters filed in the record or from the records themselves. The final sample therefore consisted of any private practitioner who had managed a patient at any stage of his or her disease, but not notified the patient.

For each patient, the first episode with each private practitioner was included and subsequent episodes with the same doctor were excluded.

7.3.2 Questionnaire

A questionnaire (Appendix 3) was developed which was divided into two sections. The first section was already completed and gave the patient's details to facilitate record retrieval. The second section asked for reasons for referral to the subsequent source of care, the date the patient first presented with symptoms leading to referral, number of times that the patient was seen before referral, investigations performed and treatment given. The response format was open, although doctors were given numbered spaces in which to write their replies. This was designed to encourage them to think of more than one response. The second section was personalised as far as possible by including the name of the subsequent source of care.

The questionnaire was posted with a covering letter explaining the nature of the study. A stamped addressed envelope was included. In some instances the full postal address of the doctor was not included in the medical record; the address was obtained from the telephone directory.

If no reply was received after two weeks, the private practitioner was followed-up with a telephone call. If appropriate, another questionnaire was sent. Occasionally the questionnaire was completed by a telephone interview. If the practitioner refused to cooperate, reasons were noted where possible.

7.3.3 Data management

The data was entered using EPI-INFO software and analysed using SPSS statistical software. The database was merged with certain variables from the main cohort study database (for example, smear status at start of treatment).

7.4 RESULTS

123 first attendance private practitioner episodes were identified from the records. Four subsequent episodes at the same doctor were excluded relating to three patients. Of the 123 episodes, 35 were excluded because there was no way to trace the private practitioner, for example, all that was written in the record was "referred by PP".

7.4.1 Response rate

Eighty eight questionnaires were sent over the period of the study. Sixty three completed questionnaires were received, a response rate of 71.6%. One of these was excluded because the practitioner was a radiologist and had not been consulted directly by the patient.

Of the 25 non-completed questionnaires:

- no response was received from 11
- five questionnaires were returned unopened because the address was incorrect or the doctor had left the practice
- three did not keep patients' records
- four could not find the patients' records
- one refused to cooperate

- one was concerned about confidentiality and had asked the patient's permission which had been refused.

For the remaining 62 completed questionnaires, each questionnaire referred to the management of one patient. Each doctor treated only one patient.

7.4.2 Geographical location of private practitioners

Nearly 50% of doctors worked in Kowloon and equal proportions in Hong Kong Island and the New Territories (Table 7.1).

Table 7.1: Region of work

region	responders		non-responders		total	
	no	%	no	%	no	%
Hong Kong Island	17	27.4	11	44.0	28	32.2
Kowloon	28	45.2	13	52.0	41	47.1
New Territories	17	27.4	1	4.0	18	20.7
Total	62	100.0	25	100.0	87	100.0

The response rate for doctors from the New Territories was 17/18 (94.4%), higher than that for doctors from Hong Kong Island (17/28 (60.7%)) or Kowloon (28/41 (68.3%)).

7.4.3 Management of TB

Stage of management: After review of the responses and finalised data from the cohort study, 57 (91.9%) of the questionnaires related to the first episode of care identified for that patient. Five related to subsequent episodes; in three of these the patient had not yet started anti-tuberculous therapy but in two the patient had started treatment in previous episodes. The management of these two patients was evaluated separately. The following results relate to the 60 patients who had not started anti-tuberculous treatment before attending the private practitioner.

Duration of follow-up: The median duration of follow-up was 7.5 days (interquartile range 2 to 14 days). Most patients were referred on the same day that they first attended the doctor (mode = 1 days). The maximum duration was 175 days (nearly 6 months) (Figure: 7.1).

Duration of follow-up in relation to subsequent smear status: The median duration of follow-up was similar for patients who were smear positive and smear negative at the start of treatment, although there was a greater range of values for smear positive patients. Two smear positive patients were followed up by private practitioners for over two months prior to referral without examination of their sputum (Figure 7.2).

Figure 7.1: Duration of follow-up

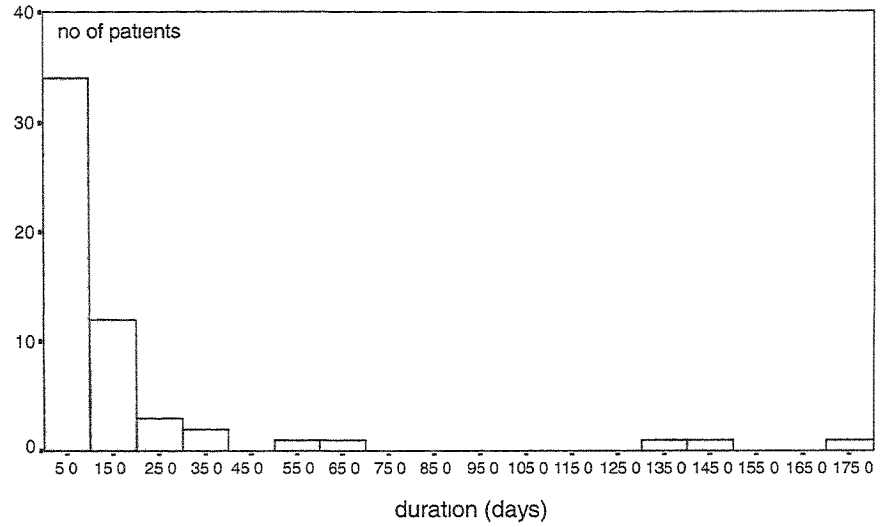
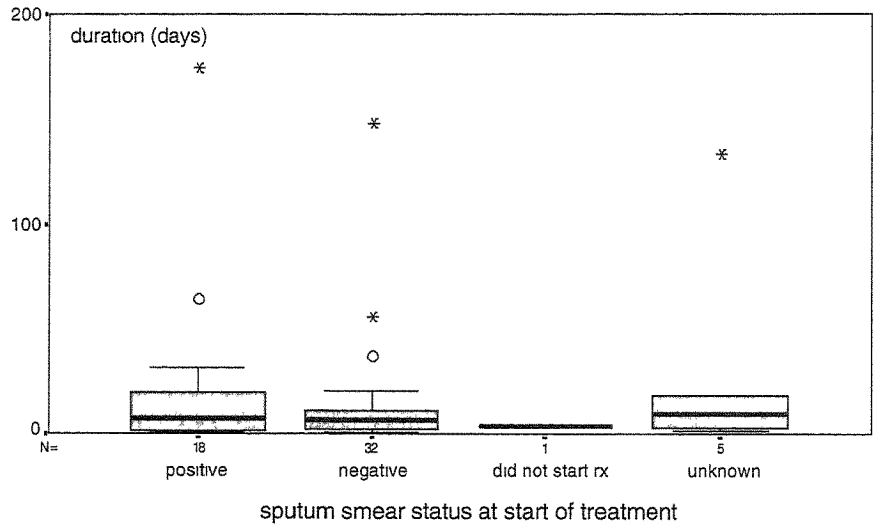


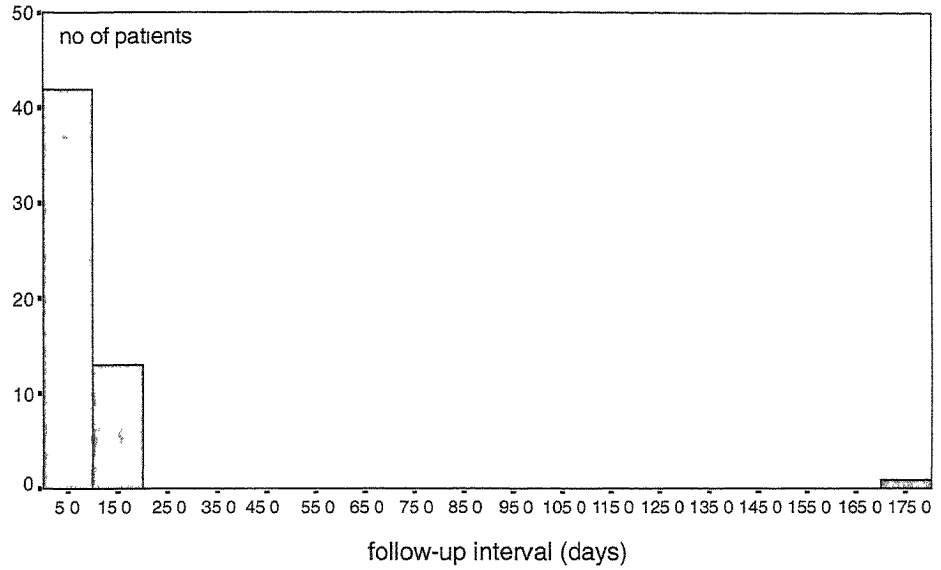
Figure 7.2: Duration according to smear status



Follow-up interval: The follow-up interval was calculated as "duration divided by (number of visits minus one)". The value obtained was the average number of days between follow-up visits to the doctor. The median value was 3.9 days/visit (interquartile range 0 to 9.7 days/visit). For most patients the value of this derived variable was zero as most patients were seen only once. The maximum interval between visits was 175 days[1] (Figure 7.3).

[1] The patient who was seen twice at an interval of 175 days was referred to a chest clinic at the second visit because of an abnormal chest X-ray and symptoms and signs compatible with tuberculosis. His sputum had not been examined. The chest X-ray was the only investigation performed and he had had no drug therapy. Anti-tuberculous treatment was started 6 days after referral to the chest clinic when he was found to be sputum smear positive.

Figure 7.3: Follow-up interval



Subsequent source of care: Forty five doctors (75%) referred patients to chest clinics for further management, 20% to public hospitals and 5% to private hospitals (Table 7.2).

Table 7.2: Subsequent source of care for patients attending private practitioners

subsequent source of care	number of different units	number of patients	% of patients
chest clinic	9	46	75.0
public hospital	6	12 [2]	20.0
private hospital	2	3	5.0
total	16	60	100.0

Reasons for referral: Ninety six reasons for referral were stated. Thirty one doctors gave two reasons, and six gave three. The most common reason given by 31 (51.7%) doctors was that the patient had an abnormal chest X-ray. The reasons were mainly clinically related, but financial and other factors were also given (Table 7.3).

Investigations: Fifty two doctors (86.7%) performed one or more investigations whilst managing the patient. Twenty two performed two investigations, 12 performed three, seven performed four, three performed five and two performed six. Over three quarters of patients had chest X-ray examinations and over a third had blood tests. Eight (13.3%) had sputum smear examinations and six (10.0%) sputum cultures (Table 7.4).

[2] One patient was not referred by the private practitioner, but the next source of care identified was a public hospital. The patient was originally referred to the private practitioner for screening prior to migration. She next presented to Tuen Mun Hospital and was referred on to a chest clinic where she started anti-tuberculous treatment. However, she referred herself back to the private practitioner whilst continuing follow-up at the chest clinic because she wanted to stop treatment and the private doctor told her he thought the disease was inactive. She was lost to follow-up by the chest clinic three weeks after notification, and discharged by the private practitioner prior to this.

Table 7.3: Reasons given by doctors for referring patient

reason	number	% of patients
patient may have tuberculosis	9	15.0
patient has tuberculosis	14	23.3
patient has abnormal chest X-ray	31	51.7
symptoms eg persistent cough, haemoptysis, shortness of breath, fever, weight loss	23	38.3
to ensure compliance	1	1.7
factors associated with chest clinics (expertise, centralised management, tradition)	5	8.3
patient's convenience/request	4	6.7
patient's financial constraints	4	6.7
other (old age, control of diabetes, patient wanted referral to private hospital, patient is civil servant, prolonged treatment by GP)	5	8.3

Table 7.4: Investigations performed

Investigation	number	% of patients
sputum smear	8	13.3
sputum culture	6	10.0
chest X-ray	48	80.0
CT scan of chest	3	5.0
lumbar puncture	1	1.7
examination of CSF	2	3.4
chemical pathology tests	5	8.3
complete blood count	7	11.7
ESR	5	8.3
fasting blood sugar	3	5.0
triglyceride	1	1.7
Hepatitis B surface antigen	1	1.7
lymph node biopsy	1	1.7
lymph node aspiration	1	1.7
urinalysis	1	1.7
barium meal	1	1.7
ECG	1	1.7
tuberculin skin test	1	1.7
joint aspiration	1	1.7
cold agglutinins	1	1.7
total	98	

Investigations in relation to duration of follow-up: Six patients had prolonged follow-up but no sputum smear or culture tests performed. However, the median duration of follow-up was similar for patients with and without examination of their sputum (Figure 7.4). No patients had prolonged follow-up without at least one chest X-ray being performed (Figure 7.5).

Investigations in relation to subsequent method of diagnosis: Of 20 patients ultimately diagnosed first by sputum smear examination, three (15.0%) had their sputum examined by

the private practitioner. Of these three, one was followed up by the private practitioner for less than 10 days, one more than 10 days, and for one the episode duration was unknown.

Patients in whom a definitive diagnosis could not ultimately be made were not followed up for longer than patients in whom the diagnosis of tuberculosis could subsequently be confirmed (Figure 7.6).

Figure 7.4: *Duration of episode according to investigations performed*

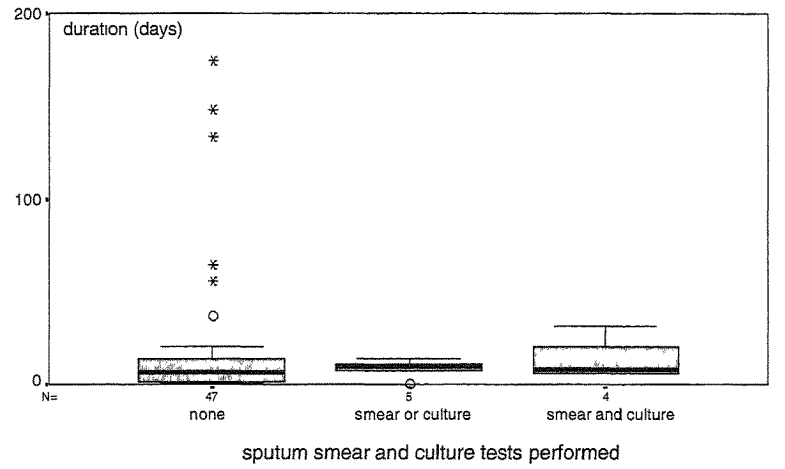


Figure 7.5: *Duration of episode by investigations performed*

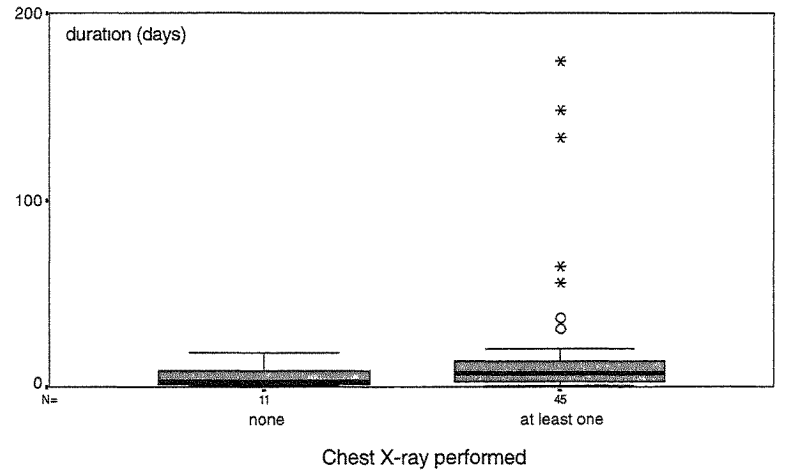
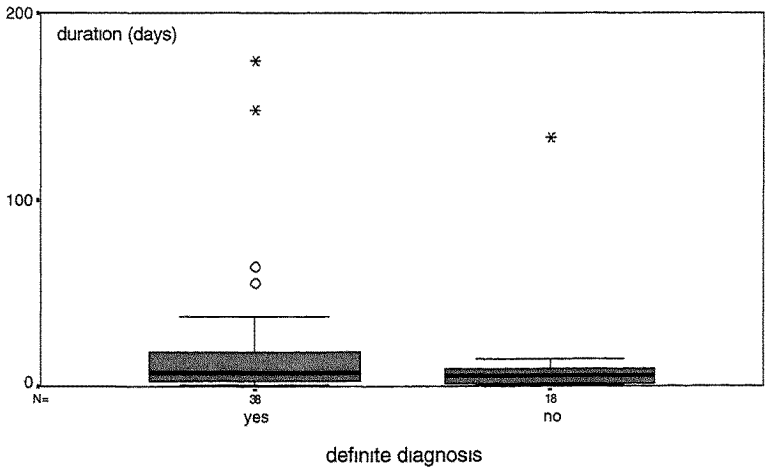


Figure 7.6: *Duration by certainty of diagnosis*



Potentially avoidable medical work: CT scans were performed in three patients who were followed up for periods of two, seven and thirteen days. Although two of these patients also had chest X-ray examinations, none apparently had sputum smear or culture tests. Ultimately, two patients were diagnosed by sputum culture and one by lymph node biopsy. All three had abnormal chest X-rays consistent with tuberculosis (two pulmonary, one intra-thoracic lymphatic). Reasons given for referral were the abnormal chest X-ray findings and symptoms and signs compatible with tuberculosis.

Comparison of investigations performed in patients presenting first to chest clinics and private practitioners: Using data collected in the main cohort study, investigations performed in the first episode of care were compared for patients whose first point of presentation was chest clinics and private practitioners. Eighty three patients first presented to private practitioners, and 129 to chest clinics. More patients were included in the main cohort analysis than in the private practitioner survey analysis because the cohort data includes episodes where the private practitioner did not respond to the questionnaire or could not be identified from the record but some data was available from other sources.

The median age of patients presenting to chest clinics was slightly higher but the range and distribution of ages was very similar (Figure 7.7). Comparing the most common investigations recorded in the main cohort study in ambulatory care episodes revealed that neither chest clinics or private practitioners performed lung function tests, but that private practitioners were more likely to request a CT scan (p=0.01) whereas chest clinics were more likely to request sputum cytology examination (p=0.05) (Table 7.5).

Figure 7.7: *Age of patients according to first presentation*

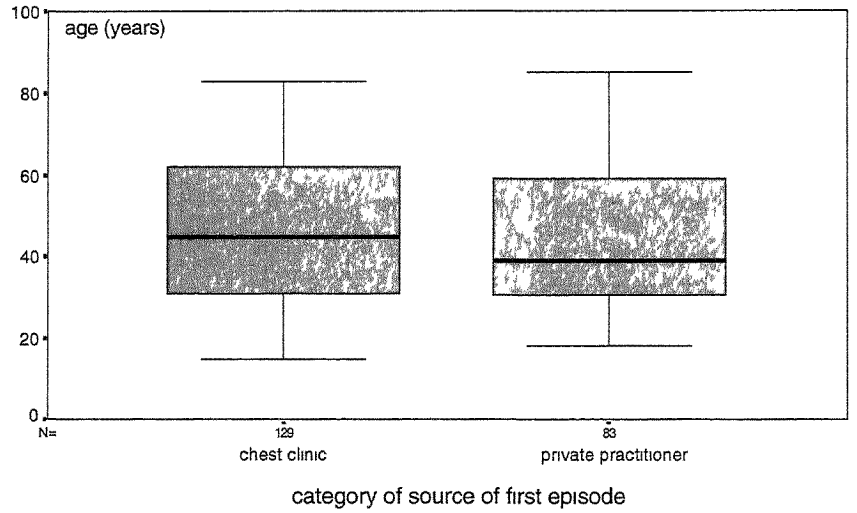


Table 7.5: *Number of patients for whom investigations requested by source of care*

	CT scan	cytology
chest clinic (n=129)	0	6
private practitioner (n=83)	5	0

Drugs prescribed: The drugs written down by the doctor on the questionnaire were categorised according to the main mode of action, eg antibiotics, anti-pyretics. If the drug's name could not be deciphered, it was coded as unknown.

Thirty doctors (50%) prescribed one or more drugs. Twenty two doctors prescribed two drugs, 13 prescribed three, four prescribed four and one prescribed five. Two patients received anti-tuberculous treatment. The most frequently prescribed drugs were antibiotics, given to 20 patients and cough suppressants to 17 (Table 7.6).

Table 7.6: Drugs prescribed by doctors

drug category	number of times prescribed	% of patients
anti-tuberculous therapy	2	3.3
cough suppressant	17	28.3
antibiotics	20	33.3
bronchodilator	6	10.0
analgesic	7	11.7
anti-histamine	1	1.7
anti-pyretic	2	3.3
other (transamine, treatment for diabetes ischaemic heart disease and hypertension, vitamins)	9	13.4
unknown	6	10.0

Both patients who received anti-tuberculous therapy were prescribed standard regimens.

- one was referred on to a private hospital on the same day of presentation to the private practitioner; the patient had a chest X-ray and sputum smear examination and was referred because of an abnormal chest X-ray and symptoms and signs compatible with tuberculosis.
- one was treated for just over 4 months before being referred to a chest clinic; the patient was seen on average at intervals of just over one week throughout this period, and had a chest X-ray examination and blood tests but no sputum examinations. The patient was referred because of haemoptysis and for management of diabetes.

The median duration of episode was slightly longer for patients prescribed one or more drugs than for patients with none. Three patients who experienced prolonged care by the private practitioner without any drugs being prescribed (Figure 7.8). Patients prescribed antibiotics or cough suppressants had slightly shorter episodes than those without (Figures 7.9-7.10). No patient had an episode lasting over a week without any investigations or treatment (Figure 7.11).

Management of two patients attending private practitioner after starting treatment elsewhere: One patient referred himself to a private practitioner from a chest clinic and was followed up for two months without further investigations. After two months he was prescribed seven weeks more anti-tuberculous treatment and did not attend for further follow-up.

The second patient also referred himself to a private practitioner from a chest clinic but was only followed up for one day before referral to a private hospital. The patient had pleural disease and the private practitioner performed a pleural aspiration and biopsy. The reason

given by the doctor for referral to a private hospital was that the patient was "dissatisfied with the government service because of a lack of communication".

Figure 7.8: *Duration of the episode by drugs prescribed*

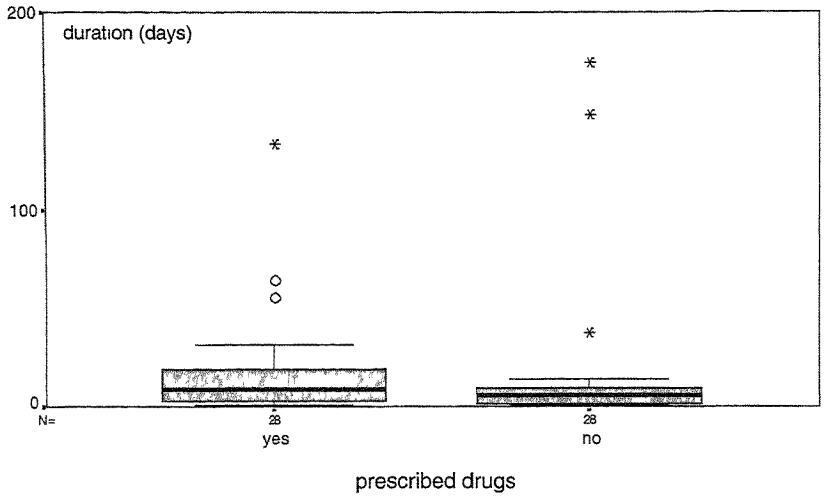


Figure 7.9: *Duration of episode by drugs prescribed*

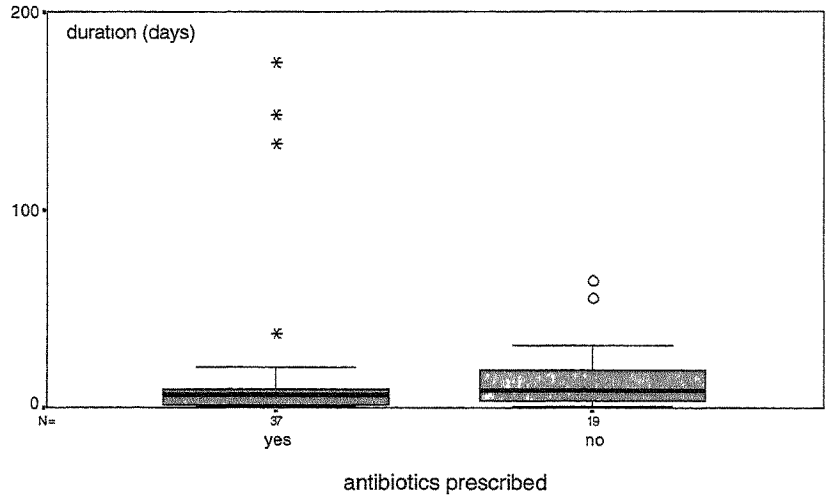


Figure 7.10: *Duration of episode by drugs prescribed*

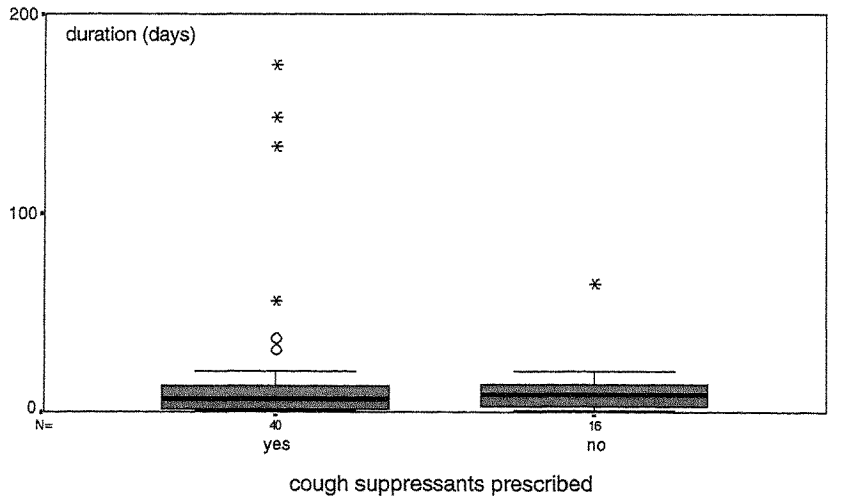
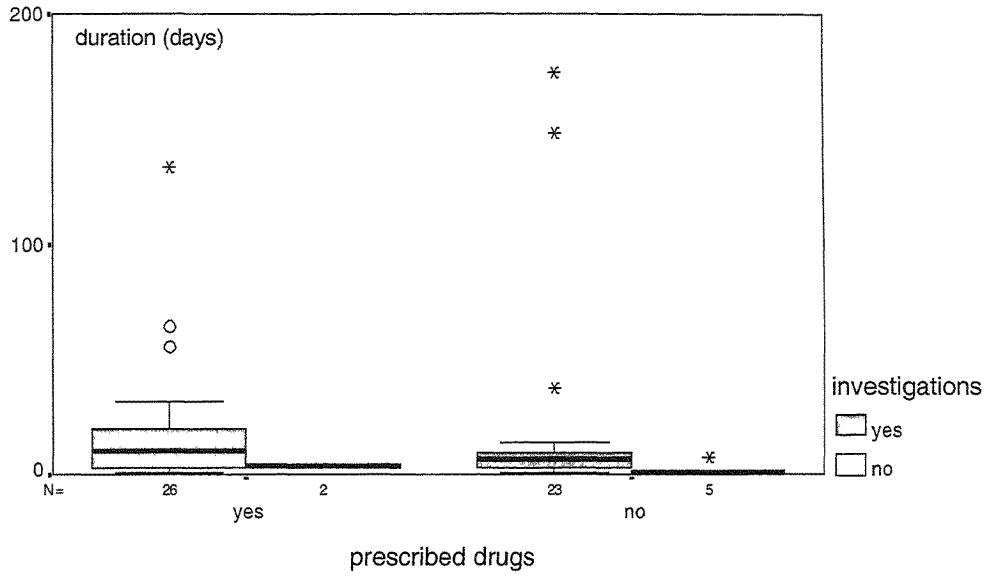


Figure 7.11: Duration of episode by management

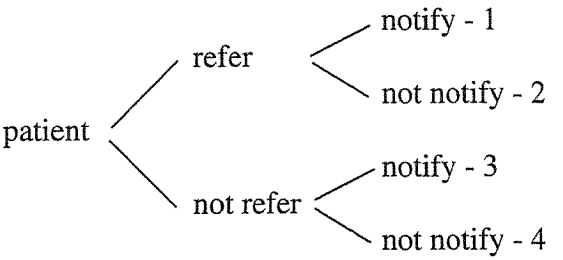


7.5 DISCUSSION

7.5.1 Types of private practitioner episode: representativeness of sample

There are four possible scenarios for the management of patients with tuberculosis by private practitioners (Figure 7.12).

Figure 7.12: Possible pathways for management of TB



Scenario 1 (patient referred to another source of care and notified by that source of care): this is the group from whom private practitioners included in this survey are sampled. However, over a quarter of private practitioner episodes falling into this category could not be identified from the subsequent source of care in the cohort study either because of inadequate medical records, or a failure of the private practitioner to write a referral letter. The sample of private practitioners included in this survey is therefore a potentially biased sample.

Scenario 2 (patient referred but not notified by subsequent source of care): private practitioners falling into this category would not be included in this survey. This might occur if, for example, patients were referred to the private sector or to a general public sector source.

Scenario 3 (patient managed solely by private practitioner and notified): one private practitioner was identified in the main cohort study as falling into this category. The management of this patient is presented separately and not included in this survey.

Scenario 4 (patient managed solely by private practitioner and not notified): these private practitioners were not identified for this survey.

In summary, the group of private practitioners included in this survey may be unrepresentative of private practitioners managing tuberculosis in Hong Kong. Private practitioners who refer patients with tuberculosis may differ in their clinical skills from private practitioners who decide to manage the patient themselves.

7.5.2 Validity of study

The patients included in this survey were, of course, only those notified. This may be a potential source of bias in that patients who are referred to TB services may be different from those who are not. In particular they are likely to be poorer, have more complications and possibly have worse outcomes overall. For the patients identified, a good response rate of over 70% was obtained from their GP's, although the regional distribution of response rates was not equal; doctors from the New Territories were over-represented in the sample. Only one doctor stated explicitly that he did not want to cooperate with the study, although some of the remaining non-responders might have been equally unwilling to respond if we had spoken to them. Doctors were assured of the confidentiality of patients and that they would not be identified. In a few cases, doctors stated their interest in the project and sent very detailed information including copies of laboratory reports.

The response rate was enhanced because the questionnaire was short; it was less than one side of A4 paper. The open format of responses was useful in obtaining a wide spectrum of reasons for referral. However, coding would have been more straightforward if responses to investigations and treatment had been split into categories on the questionnaire.

Sources of care prior to the private practitioner were not identified in this survey. This means that for some patients additional private practitioner episodes may have been excluded from the survey. In the 1979 survey, 79% of patients attended only one private practitioner before attending the chest clinic, 16% attended two, 4% attended three, and less than 1% attended four or five different doctors (Hong Kong Chest Service/British Medical Research Council, 1984). Applying these figures to this study, if private practitioners had been asked about previous episodes of care, an additional 17 private practitioner episodes might have been identified. Information about previous sources of care would not necessarily have been available for this survey, either because the private practitioner had not asked the patient, or it had not been noted in the medical record.

7.5.3 Management of TB

Stage of management: Nearly all the patients in this survey (60/62 (97%)) attended a private practitioner prior to the start of their treatment. Only 2/62 (3%) went to a private practitioner after starting treatment elsewhere. As most of the care provided to patients in the cohort during treatment was provided by the public sector, this suggests that most people in the

public health service do not "doctor shop" in the private sector once they have started treatment. However, there may be additional private practitioner episodes which were not identified because no record was made of them in the public sector medical records.

Duration of episode: Three quarters of patients were followed up by private practitioners for less than two weeks. The general pattern appeared to be that patients presented to private practitioners with symptoms suggestive of chest disease, and after a short period of symptomatic treatment and simple investigations, they were referred to the chest clinic. This pattern of care contrasts sharply with that identified in India (Uplekar, 1993) where private practitioners were reluctant to refer patients to the public sector. However, it may simply reflect the sampling procedure used for this survey.

Given the relatively short duration of follow-up in the private sector of patients in this sample, the potential impact of the private sector on the care received by patients with tuberculosis may be minimal. However, 25% of patients were followed up for over two weeks, and one patient was managed for six months without treatment prior to referral to the chest clinic where sputum smear examination was positive (no previous smear examination had been performed). Case studies such as these indicate the potential dangers of inappropriate management of patients with tuberculosis.

Frequency of follow-up: The general picture was one of visits every few days for one to two weeks, followed by referral to the chest clinic. At the first visit, patients may have received symptomatic treatment and if their symptoms had not improved after a few days, a chest X-ray examination might have been requested which if abnormal, spurred the private practitioner to refer the patient elsewhere.

Subsequent source of care: Three quarters of patients were referred to chest clinics, 20% to public hospitals, and very few to private hospitals. This may, however, simply reflect the sampling method, for example, patients referred to private hospitals may be less likely to be notified and would not therefore be identified in the cohort.

Reasons for referral: It is difficult to interpret the response to this question. The reasoning behind a decision to refer a patient is likely to involve a complex mixture of factors relating to the patients' clinical condition and attitude towards alternative care, the experience of the doctor and his or her perception of the service provided elsewhere.

Half of doctors cited an abnormal chest X-ray as a reason for referral of the patient which reflects the widespread use of radiology as a first line investigation by private practitioners. Over a third cited the patients' symptoms and another third were concerned that the patient had definite or suspected tuberculosis. This latter figure may have been artificially raised because doctors were told that the patient was subsequently confirmed to have tuberculosis. Only one doctor said that the referral was to ensure compliance of the patient during therapy. Compliance is an important issue, however, in private practice where treatment is largely unsupervised.

These doctors were identified *because* they referred patients on for management of tuberculosis. They therefore differ from their colleagues who opt not to refer patients with suspected or confirmed tuberculosis. The reasons for referral appear to mainly clinical, that is if the doctor suspects that the patient has tuberculosis, he or she refers the patient to

specialist care. This differs markedly from the Indian survey which asked: "Do you refer your TB patients to municipal or government clinics? When?". In this survey, for those that did refer, the two most common reasons were that patients could not afford the private sector, or wanted to use the public health service.

Investigations: The most frequently performed investigation was chest X-ray examination and relatively few patients had sputum examinations. This pattern is similar to the findings of the survey in India. Uplekar et al (1991 and 1993) speculate that private doctors in Bombay are more likely to perform chest X-rays because the revenue is much greater than for a sputum examination. However, it could also be because chest X-ray examinations are less specific to tuberculosis and easier to justify if the patient is complaining of non-specific chest symptoms. A previous study recommended that private practitioners should perform more sputum examinations of patients with suspected tuberculosis (HKCS/BMRC, 1984).

One reviewer comments that *"it is not surprising that private doctors do chest X-ray examinations for a higher proportion of patients with chest symptoms rather than sputum examinations for AFB. Chest X-ray is a more sensitive test to detect TB lesions and provides information (on) other lesions eg pneumonia and lung carcinoma."*

Another reviewer of the first draft report commented that *"despite the limitations of the sample, it is obvious that sputum examination is under utilized in the private sector. While TB culture may require a long time and be expensive, smear examination should be relatively easy and cheap. Smear status also reflects infectiousness and prompt treatment of smear-positive TB cases is of paramount importance in TB control. Therefore, a practical approach will be to promote the use of sputum smear examination for patients with symptoms suggestive of TB in the private sector. Smear-positive patients should be either promptly assessed for treatment by the doctor concerned or immediately referred to TB and Chest Service or other appropriate sources of care."*

The paucity of sputum smear or culture examinations is highlighted by the fact that 17/20 patients who were smear positive at the time of starting treatment did not have their sputum examined by the private practitioner.

Over a third of doctors perform blood tests ranging from complete blood counts to liver function tests or Hepatitis B markers. The indications for these investigations are not clear from this survey.

Potentially avoidable medical work was identified in the survey. This was difficult to quantify, but it seems to be inappropriate to perform a CT scan before considering sputum examination, or to omit sputum examination altogether.

Treatment given: Approximately a third of patients were given cough suppressants and a third, antibiotics. These prescribing patterns reflect the symptoms of patients when they present, usually with a cough. Private practitioners may appropriately decide to prescribe a trial of antibiotics prior to chest X-ray examination and referral to the chest clinic. Very few patients received treatment for tuberculosis. This may, however, reflect the sampling method, for example, patients treated by private practitioners and never referred to the public sector may be less likely to be notified.

7.5.4 Changes over time

The 1977 and 1979 survey results cannot be directly compared with the current study (Table 7.7) because:

- the study subjects differed: in previous studies, patients were interviewed to determine investigations and treatment whereas in this study, doctors themselves were approached
- the sampling method differed: in previous studies, patients newly diagnosed at chest clinics were included, whereas in this study, newly notified patients managed at some stage by private practitioners (but not notified by them) were included.

Despite these differences, trends over time can be examined for three variables if patients are selected in the present study who were referred to the chest clinic by a private practitioner:

Table 7.7: Comparison over time (approximate %)

variable	1977 survey	1979 survey	current survey[3]
% of patients having chest X-ray examination	50%	76%	84%
% of patients having sputum examination	5%	18%	smear: 13% culture: 9% one examination: 9% two examinations: 7%
% of patients on anti-tuberculous treatment prior to referral to chest clinic	24%	12%	2%

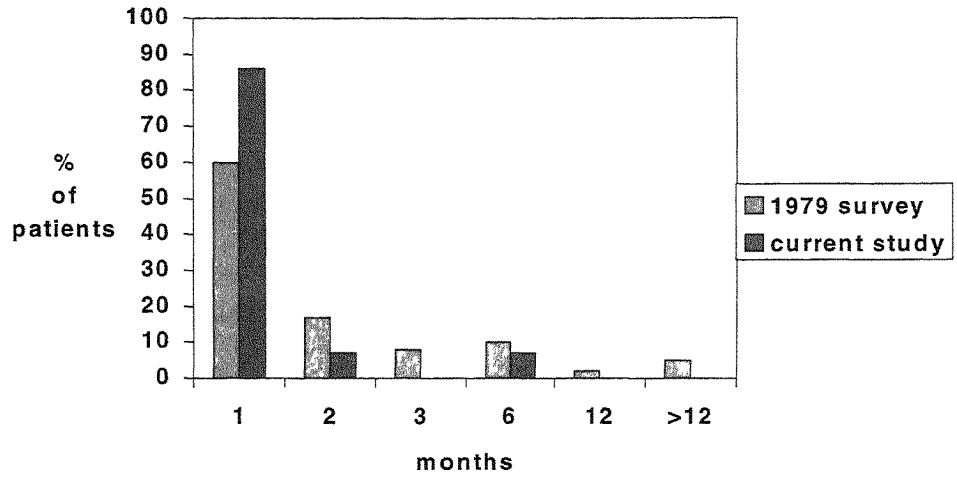
The main trends are:

- fewer patients are receiving anti-tuberculous treatment prior to referral. This trend may be real or apparent; a smaller proportion of private practitioners may be treating patients with tuberculosis, or the doctors who are treating patients may be less likely to refer patients to the public sector.
- more patients are having chest X-ray examinations but similar proportions are having smear and/or culture examinations. This is despite the fact that the authors of the 1979 survey recommended that private doctors should perform more sputum examinations.

It is also possible to compare the duration of follow-up by private practitioners before referral to chest clinics. Selecting only those 45 patients (75%) who were referred on to chest clinics rather than other sources of care, the episode duration for patients in the current survey was compared with that for patients interviewed in the 1979 survey. The episode duration was available for 41/45 (91.1%) patients (in three the start date was unknown, and in one the referral date was unknown). It was recoded into the same intervals used in the 1979 survey. A greater proportion (85% versus 60%) of patients in the current survey were referred to chest clinics within a month of presenting (Figure 7.13). In the 1979 survey, smear positive patients were more likely to be followed up for over 6 months prior to referral whereas there was no significant difference in the management of smear positive and smear negative patients in the current survey.

[3] these data refer to the 45/60 (75%) of patients referred to chest clinics

Figure 7.13: Comparison of interval before referral to chest clinic



7.5.5 Conclusion

The actions of private practitioners in managing patients who have, or may have, tuberculosis could have an important impact on both quality of care for individual patients and the population control of tuberculosis. Patients with TB frequently present first to the private sector. This study includes only a proportion of private practitioners treating patients with tuberculosis in Hong Kong. Despite these deficiencies, the study has provided some new information about referral patterns, reasons for referral and management of patients in the private sector.

Comparison with previous studies suggests that patients are being referred to chest clinics more quickly and are less likely to have started treatment with anti-tuberculous drugs. Compared with previous surveys a higher proportion have been investigated using chest X-rays, but very few have their sputum examined. This bias can be seen to have some merit in that chest X-rays are a more sensitive test for pulmonary tuberculosis.

Some patients were followed for long periods without treatment or investigations. Given this variation, guidelines should be developed to help doctors decide which investigations are most appropriate and at what stage patients should be referred to specialist care. It is essential that the private sector is closely involved in development of these guidelines. An example of the guidelines which should be provided would be the management of patients with a cough lasting over a month.

The response rate of 70% was acceptable in terms of drawing preliminary conclusions, but future plans for audit of the interface between private first contact medicine and TB services should aim for a yield closer to 100%. Those who do not respond to surveys of this type may have different characteristics from those who do. There are strong grounds for an SAR wide approach to all doctors providing first contact medicine.

Involvement of a representative group of private practitioners, perhaps through the Hong Kong Medical Association and the College of Family Physicians, in the development of guidelines and in considering other ways to improve coordination between public and private sectors, could help to disseminate examples of good practice throughout the private sector. The group of doctors who responded to this questionnaire may constitute a good starting point for further collaborative work.

Two proposals from the WHO Bombay workshop (WHO/World Bank, 1994) can be considered in a Hong Kong context. These are:

1. provision of free sputum smear examinations through the official diagnostic services to private practitioners
2. integration of private practitioners into the public programme by provision of free diagnostic services, free drugs and monitoring and evaluation of outcomes, in return for private doctors supervising treatment according to certain standards.

The first of these might contribute to, and enhance, early detection and referral rates for TB patients. The second is somewhat contrary to the present approach being adopted in Hong Kong. This is to conduct all TB clinical management in a specialist service, open to all and free at the time of use.

Without fuller involvement and better agreed working arrangements between TB services and the private sector in prevention, treatment and control strategies, it will be impossible to comprehensively evaluate their effectiveness.

Key messages and action points

- It is recognized world wide that there are problems in achieving uniform standards of organized care for tuberculosis in mixed medical economies where the private sector provides a high proportion of first contact medicine.

- The care of many patients with tuberculosis could be improved and expedited through appropriate referral with the use of agreed management protocols by private practitioners.

- The apparent trends between surveys in 1977, 1979 and 1995 suggest that the management and referral of these patients has improved considerably.

- A new consensus statement on first contact management of patients who may have TB should be developed, disseminated and evaluated.

- The interface between primary care, other sectors of the health services and tuberculosis services should be continuously and intensively monitored.

8.0

MEDICAL WORK AND RESOURCE IMPLICATIONS: AN ECONOMIC EVALUATION

8.0 MEDICAL WORK AND RESOURCE IMPLICATIONS: AN ECONOMIC EVALUATION

SUMMARY

Indicators of need

- This section describes three approaches to the examination of resource use in the care of patients with tuberculosis.

- The three approaches taken range from simple and arbitrary methods of scoring *need* to more complex attempts to grade and weight need according to different types and severity of clinical conditions and their complications. These models have limitations which are acknowledged.

  The method used to categorize need may be regarded as crude and its potential shortcomings must be acknowledged. However it does illustrate the possible which could be taken to examine the efficiency with which resources are used in tuberculosis services.

Levels of need in the cohort

- Three principal indicators of increased need for medical care were common in the cohort, including TB complications (51%), treatment complications (79%) and co-morbidity (67%). Twenty-eight percent of patients had none or only one of the need indicators; 42% had two and 29% had three.

  With a total annual incidence of 6500 this pattern reflects that about 2000 patients per year are added to the highest need group.

Relationship between need score and use of services

- At the first level, using a simple score, admissions and length of stay were zero or very low in those with the lowest need score (0 or 1) but rose steeply in those scored 2 or 3.

- At the second level, a more elaborate need score, based on the use of chest X-rays, liver function tests and smear examinations *during treatment* was examined using need criteria based on complications of tuberculosis and treatment and the presence of co-morbidities.

  There was no association between need status and the use of any (that is ≥1) test; the *proportions* of patients in both lower and higher risk groups who received tests were similar. However need status was strongly associated with the *number* of tests; the median number of tests in the higher risk group was the 87^{th} centile (chest X-ray) or higher (98^{th} centile for LFT's; 94^{th} centile for smear tests) in the lower risk group.

- At the third level, a more elaborate need score, adjusted for perceived severity and the likelihood of co-morbidities affecting the management of TB, was used to identify possible areas of practice where need and utilisation were not well matched.

Each additional TB complication or co-morbidity mitigated against successful completion of treatment and follow-up. The opposite was true for treatment complications alone, although the chance of a good outcome was higher with minor rather than severe complications.

- Higher levels of need, that is number and severity of TB complications and co-morbidities, were associated with a higher level of care in specialist units, but not the severity of treatment complications.

  Levels of need, assessed in this way, are clearly seen to be drivers of care utilization. They are associated with use of higher specialist outpatient and inpatient units, frequency of ambulatory care attendance and duration of treatment. One salient finding is that whereas TB and treatment complications are associated with admission to a chest hospital, co-morbidities (even minor ones) are strongly associated with admission to general hospitals.

- When the high need indicators are used to examine geographical variations in levels of care, it is found that patients in New Territories East were less likely to be admitted than those from other regions.

Conclusions and recommendations

- In the low need group, starting treatment outside of the chest service was associated with higher utilisation.

- Further development of need scores would be a useful clinical, management and educational tool for tuberculosis services. This process would be a greatly facilitated with the support of a clinical information system in which the data fields required to construct the need score were complete and reliable.

- The need indicators appear to be valid and can be used to identify sub-groups or individuals with apparently higher need and low utilisation, or vice versa, as an additional approach to evaluating the efficiency of services.

8.1 AIMS AND OBJECTIVES

The aim of this part of the survey were to determine whether services provided to individual patients were matched to needs and to identify factors associated with variation in resource use by patients. This section of the report covers objectives 1, 3, 4 and 6 listed in Section 3. There were three studies made of the available data. The objectives of each are given in the individual sections.

8.2 STUDY 1: A SIMPLE APPROACH TO ESTIMATING PROVISION OF CARE IN RELATION TO NEED

8.2.1 Introduction

8.2.1.1 Aim

To identify groups of patients with a similar need for health care

8.2.1.2 General considerations

This was a very simple approach to determining need and examining its association with some utilisation measures. It is accepted that the classification of need is oversimplified in this study but it has some face validity. It is also believed that even a simple approach may raise some important questions.

8.2.2 Methods

8.2.2.1 Steps in the methods

Step 1: Define need as presence or absence of one or more of the following three variables at any stage of the study (pre-treatment, treatment or post-treatment):

1. complication of tuberculosis
2. complication of treatment
3. co-morbidity requiring health care

Step 2: Develop a scoring system. A simple scoring system, or need score, was developed using the following schema. Reference should be made to Sections 8.2.2.2 – 8.2.2.4 for the classification of variables relating to complications of tuberculosis and treatment, and comorbidities.

Table 8.1: Need score

need score	Definition
0	none of variables recorded
1	one of variables recorded
2	two of variables recorded
3	three of variables recorded

Step 3: Assign patients to *need* score groups

Step 4: Examine relationship between need care groups and variables reflecting process of care.

8.2.2.2 Complications of tuberculosis (reflecting natural history of disease or clinical pathology):

pleural effusion *	adrenal disease
endobronchitis	synovitis
haemoptysis *	erythema nodosum
lobar collapse	neurological (eg hydrocephalus, epilepsy, SIADH)
bronchiectasis	impaired renal function
pneumothorax	dysfunctional uterine bleeding
empyema	orthopaedic (eg limb shortening)
abscess or discharging wound	epistaxis
extensive disease	hoarse voice
drug resistance	lung abscess

*Notes: * accounts for majority of patients*

8.2.2.3 Complications of treatment:

poor response	peri-oral numbness
poor compliance	parasthesiae
dizzy	fever
headache	flu like illness
loss of appetite	facial flushing
malaise	impaired vision
nausea/vomiting	arthralgia/bone pain/gout
diarrhoea	hepatitis
epigastric/abdominal pain/discomfort	oedema
belching	abnormal liver enzymes
jaundice	impaired renal function
skin rash	increased urate
itchy skin	thrombocytopaenia
tinnitus	anaemia
ear discomfort	pneumothorax post pleural aspiration
hearing loss	surgical emphysema post thoracotomy

8.2.2.4 Comorbidities:

pulmonary disease caused by atypical mycobacterial infection	other infections
benign or malignant lung neoplasm	other neoplasms and blood disorders
pneumonia	upper respiratory
chronic obstructive lung disease	
liver pathology	non-liver digestive system
diabetes	other endocrine and metabolic disorders
mental and behavioural problems	nervous system pathology
visual pathology	circulatory
hearing impairment	skin
renal failure	non-kidney genito-urinary
pregnancy	musculo-skeletal

8.2.3 Results

The majority of patients had at least one of the three characteristics which were defined as indicators of increased need. Fifty one percent had at least one complication of tuberculosis, and 79% had a complication of treatment. The generally high level of dependency among TB patients is emphasised by the prevalence of co-morbidities at 67%. In the total annual incident group of new notifications this indicates that over 4000 TB patients a year require additional medical resources and skills for the management of other conditions (Table 8.2).

Table 8.2: Number of patients with each need variable

need variable	yes	no
TB complication	230 (51%)	224
treatment complication	358 (79%)	96
comorbidity	304 (67%)	150

About one quarter (28%) had lower need scores of 0-1, 29% were in the highest score group. Again this indicates that about 1800 new cases per year are in the high need group (Table 8.3).

Table 8.3: Number of patients with each need score

need score	number (%)
0	20 (4%)
1	109 (24%)
2	192 (42%)
3	133 (29%)

The simple need score appears to have at least face validity in that it shows a strong association with length of stay for patients admitted to hospital. There is a clear dichotomy between need score group 0-1 and 2-3.

Table 8.4: Cumulative LOS (all episodes)

need score	median cumulative LOS (days)	IQ range
0	0	0 to 0
1	0	0 to 6
2	10	0 to 31
3	24	9 to 54

8.3 STUDY 2: THE FREQUENCY OF INVESTIGATIONS USED DURING THE MANAGEMENT OF TUBERCULOSIS

8.3.1 Introduction

8.3.1.1 Aim

To identify variation in the use of investigations in relation to estimated need. This study attempted to examine the association between specific investigations (Chest X-ray (CXR) and blood tests) and need for these tests. In this study, need was defined as increased risk of needing the particular investigation and criteria were developed for the study using data on recorded complications and co-morbidities. This study used only a sub-sample of the patients and collected extra details on CXR and blood tests carried out.

8.3.1.2 Objectives

1. To identify groups of patients at increased risk of requiring a chest X-ray (CXR) and/or blood tests at some stage in the treatment phase of their tuberculosis management
2. To estimate the frequency of CXRs, blood tests and sputum smear and culture investigations in these patients
3. To identify any relationship between *identified need* and *supply of medical care*
4. To identify variation in supply which appears to be unrelated to need

8.3.2 Methods

8.3.2.1 Identification of groups of patients

The following criteria were used to select patients for the increased risk categories. If a patient experienced one or more of these criteria at any stage of his or her treatment, they were assigned to the increased risk category. Patients experiencing none of these criteria were assigned to the normal risk category.

Criteria for patients at increased risk of needing a CXR

1. complications of tuberculosis
   - haemoptysis
   - pleural effusion
   - endobronchitis
   - lobar collapse
   - empyema
   - pneumothorax
   - bronchiectasis
2. co-morbidities
   - asthma
   - bronchiectasis
   - pneumonia
   - carcinoma of lung
   - heart failure
   - chronic obstructive airways disease
   - pneumothorax

Criteria for patients at increased risk of needing a blood test

1. complications of treatment
   - abnormal liver enzymes
   - jaundice
   - impaired renal function
   - hepatitis
2. co-morbidities
   - hepatitis
   - cirrhosis
   - hepatic failure
   - hepatocellular carcinoma
   - renal failure
   - nephrotic syndrome
   - proteinuria

Patients for this study were selected from the main study sample by using a sequential sampling technique: the patients were ordered by AENO and the first 50 patients meeting the criteria for being at increased risk of needing a chest X-ray and the first 50 meeting the criteria for being at increased risk of needing a blood test were selected. Similarly the first 50 patients not meeting the criteria for these 2 groups were selected to be in the two "normal risk" category groups for comparison. There was some overlap between the CXR and blood test samples: 71 patients were included in both and were either in the increased risk category for one and normal risk for the other or in the same risk category for both (Table 8.5).

Table 8.5: Distribution of risk categories for patients in the main study (n=454)

		CXR category			Total
		increased risk	normal risk	excluded from CXR sample	
Blood test category	increased risk	**16**	**6**	28	50
	normal risk	**21**	**28**	1	50
	excluded from blood test sample	13	16	325	354
Total		50	50	354	454

8.3.2.2 Estimation of frequency of CXRs

The X-ray folders of patients included in the CXR sample were requested for all the episodes taking place during the treatment of the patient. In the main study, it had been noted that X-ray reports were rarely filed in medical records, and identification of CXRs using medical records would therefore have resulted in a gross under-estimate of the number taken. However, folders contained only completed X-ray films and not X-ray request forms: there was therefore no method for identifying CXRs which had been taken but were not filed which again would also result in an under-estimate of the number taken. The contents of the X-ray folders were reviewed and the type of X-ray and date were noted for each episode. Each chest X-ray was counted as one, whichever view (eg posterior-anterior or lateral) had been taken.

If the X-ray folder was not available this was coded as such. It was not possible to review the X-ray folders of patients managed by one hospital because folders were filed according to X-ray number but X-ray numbers were not recorded in medical records.

8.3.2.3 Estimation of frequency of blood tests

The medical records of patients included in the blood test sample were requested for all the episodes taking place during the treatment of the patient. The number of filed blood test reports were counted: inadequate filing would therefore result in an under-estimate of the number of tests performed. The following blood tests were identified:

- liver function tests (LFTs) (bilirubin, alkaline phosphatase, alanine transaminase, aspartate transferase etc): total protein and albumin were not counted separately if performed as part of the LFT.
- renal function tests (RFTs) (sodium, potassium, urea, creatinine etc): calcium, phosphate, chloride were not counted separately if performed as part of the RFT.

- complete blood counts (CBCs) (haemoglobin, white cell count, platelets etc)
- erythrocyte sedimentation rate (ESR)
- Hepatitis A: antibody tests
- Hepatitis B: tests for antibody and antigen were counted separately
- urate/uric acid: if performed separately from LFT/RFT
- glucose
- clotting studies (eg APTT, PT, PTT, INR)
- arterial blood gases
- other: specified

8.3.2.4 Estimation of sputum smear and culture tests

The medical records of all patients included in the CXR sample were also reviewed to determine the number of sputum smears and culture tests performed. These were identified according to the number of laboratory reports filed in the record, and may therefore have under-estimated the true figure. Smear and culture tests performed on non-sputum specimens were excluded.

8.3.2.5 Identification of relationship between identified need and supply

Chest X-rays: The rate of chest X-ray (CXR) examination was calculated by dividing the number carried out during that episode by the episode duration in days. For both the numerator and denominator only the data relating to the period when the patient was actually receiving treatment was included. For example if the patient started treatment half way through the episode, the number of CXRs was the number performed after treatment was started and the episode duration was the duration of the second half of the episode when the patient was on treatment. The mean CXR rate (CXRs per treatment day) was calculated for each patient by dividing the sum of CXRs by the sum of episode duration whilst the patient was receiving treatment. The distribution of values was examined for patients classified to be at normal or increased risk of requiring a CXR.

Blood tests: The rate of blood testing was calculated for each episode by dividing the number of each type of blood test by the episode duration in days. Data were only included for the period when the patient was actually receiving treatment. The number of different types of blood test performed in each episode was calculated. The total number of each type of blood test was calculated for each patient and the mean and median number of tests for patients in the normal and at risk categories were compared. The mean blood test rate for the frequently used tests was calculated for each patient by dividing the total number of each test by the sum of episode duration whilst the patient was receiving treatment.

Sputum tests: The risk categories were defined by smear and culture status at the start of treatment for smear and culture tests respectively. These were smear or culture positive, negative and unknown. The rate of sputum smear and culture examination was calculated for each episode by dividing the number of sputum smears or cultures by the episode duration in days. Data were only collected for the period when the patient was receiving treatment. The total numbers of smear and culture tests were calculated for each patient and the distribution of tests for patients in three risk categories were compared. The mean sputum smear and culture rates were calculated for each patient by dividing the total number of each test by the sum of episode duration whilst the patient was receiving treatment.

8.3.3 Results

8.3.3.1 Chest X-Rays

100 patients were included in the CXR sample, 50 at *increased risk* of needing a CXR and 50 at *normal* risk, during the treatment phase of TB management.

Episodes: 268 treatment episodes were identified for these 100 patients, 86 for patients at normal risk and 182 for patients at increased risk. The mean episode duration was shorter for patients in the increased risk category (100 days compared with 153 days, p=0.001).

Seventeen of the 268 episodes (6.3%) were in-patient episodes where the patient had been admitted principally for the management of a co-morbidity but was still being treated for tuberculosis. The proportions of these in-patient episodes were similar for patients in the normal and increased risk categories (5/86 (5.8%) and 12/182 (6.6%) respectively).

X-ray folders were not available for 29 episodes (10.8%). The non-availability of X-ray folders is summarized below (Table 8.6).

Table 8.6: *Sources of care where X-ray folder not available*

Source	number of episodes where X-ray folder not available		% of total episodes
	normal risk	increased risk	at that source
A	0	5	50.0
B	0	1	6.7
C	0	4	57.1
D	1	0	12.5
E	1	4	100.0
F	0	2	100.0
G	0	1	100.0
H	0	1	100.0
I	0	1	100.0
J	1	0	33.3
K	0	7	38.9
total	**3**	**26**	**10.9**

Patients: The number of episodes for which data was not available was determined for each patient. CXRs were not available for one or more episodes for 12/100 patients (12.0%). For 11 of these patients CXRs were not available for between 1 and 3 episodes, but for one patient CXRs were not available for all 14 of his treatment episodes (Table 8.7). This patient was in the increased risk category because of haemoptysis, requiring blood transfusion, and suspected carcinoma of the lung. His X-ray folders were not available at five different sources of care.

Table 8.7: Number of episodes for which X-ray folder not available

number of episodes X-ray folder not available	number of patients		% of total patients with at least one episode where X-ray folder not available
	normal risk	increased risk	
1	3	5	66.7
2	0	2	16.7
3	0	1	8.3
14	0	1	8.3
total	**3**	**9**	**100.0**

Number of CXRs per episode: The number of CXRs was counted for the 239 (89.2%) episodes where data was available. The number of CXRs performed in each episode ranged from zero to 11. The median value was lower and interquartile range narrower for patients in the increased risk category. In this sample there was an apparent increased frequency of testing in the normal risk group, as indicated by a higher proportion receiving at total of 3, 4 or 5 X-Rays (Table 8.8) (Figure 8.1).

Table 8.8: Distribution of number of CXRs performed per episode

number of CXRs per episode	normal risk		increased risk	
	number	%	number	%
0	21	25.3	45	28.8
1	14	16.9	34	21.8
2	8	9.6	30	19.2
3	16	19.3	20	7.5
4	14	16.9	12	7.7
5	6	7.2	7	4.5
6	2	2.4	5	3.2
7	2	2.4	1	0.6
8	0	0	1	0.6
11	0	0	1	0.6
total	**83**	**100.0**	**156**	**100.0**
median	**2**		**1**	
interquartile range	**0-4**		**0-3**	

Sum of CXRs performed during treatment for each patient: For both risk categories, the distribution of values for the total number of CXRs performed during treatment was approximately normal. Patients in the increased risk category had a higher median value, the interquartile range was wider and the distribution was positively skewed (Table 8.9) (Figures 8.2 and 8.3).

Figure 8.1: *Number of CXRs performed in each episode*

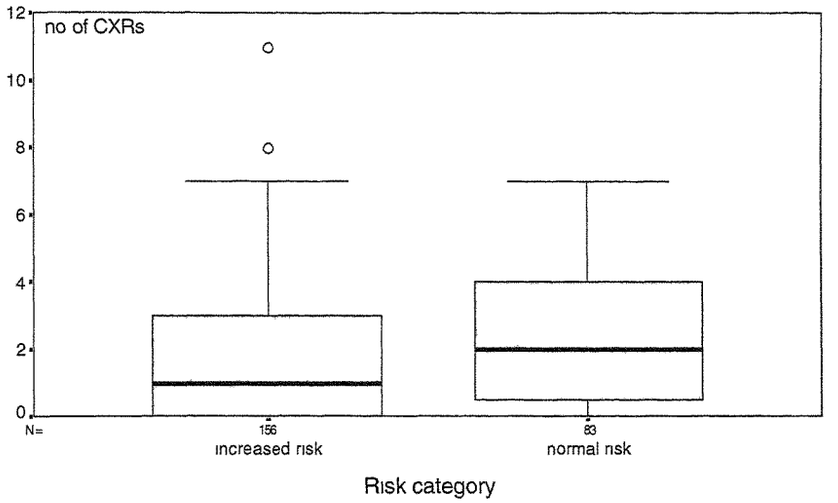


Table 8.9: *Distribution of number of CXRs performed per patient*

sum of CXRs during treatment	normal risk		increased risk	
	number	% of patients	number	% of patients
0	2	4.0	3	6.4
1	1	2.0	0	0
2	5	10.0	1	2.1
3	15	30.0	4	8.5
4	14	28.0	10	21.3
5	7	14.0	6	12.8
6	1	2.0	5	10.6
7	4	8.0	4	8.5
8	0	0	6	12.8
9	1	2.0	2	4.3
11	0	0	1	2.1
12	0	0	1	2.1
13	0	0	1	2.1
15	0	0	2	4.3
19	0	0	1	2.1
median	4		5	
interquartile range	3-5		4-8	
no. of patients for whom CXR folders available for some/all episodes	50	(100%)	47	(94%)

The overall pattern for increased risk patients is one of multiple discrete episodes of care, with slightly lower testing rate per episode but higher total resource use for testing.

Figure 8.2: Sum of CXRs performed during treatment

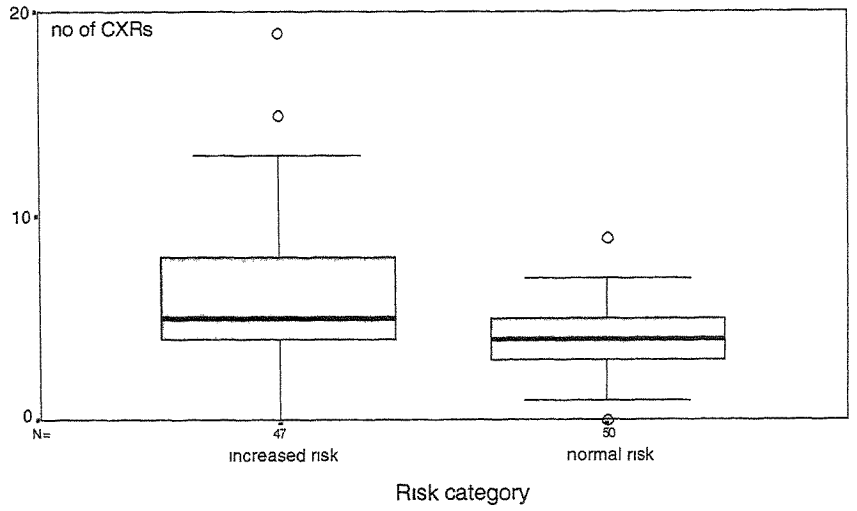
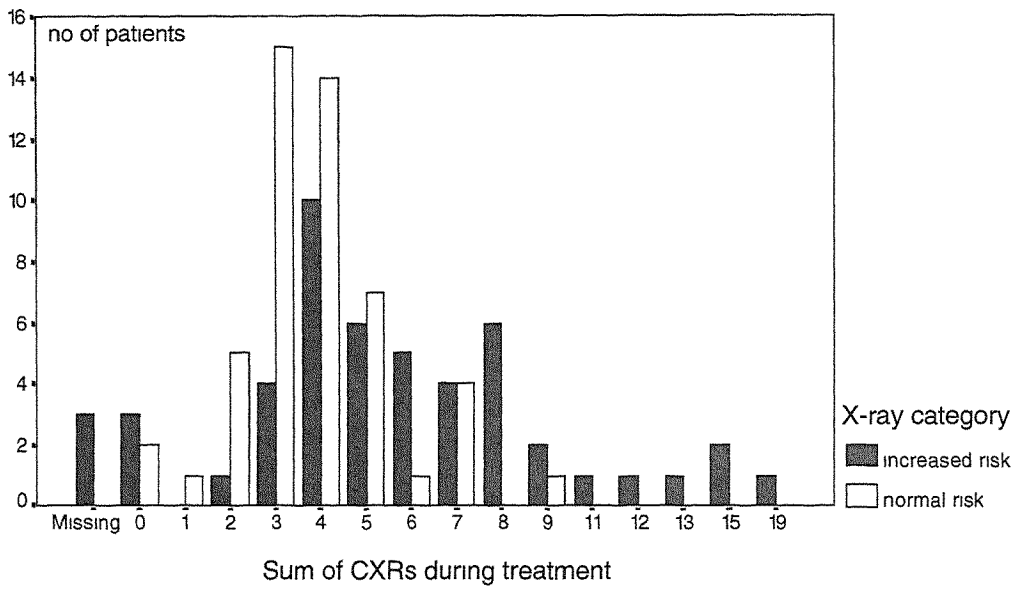


Figure 8.3: Sum of CXRs during treatment

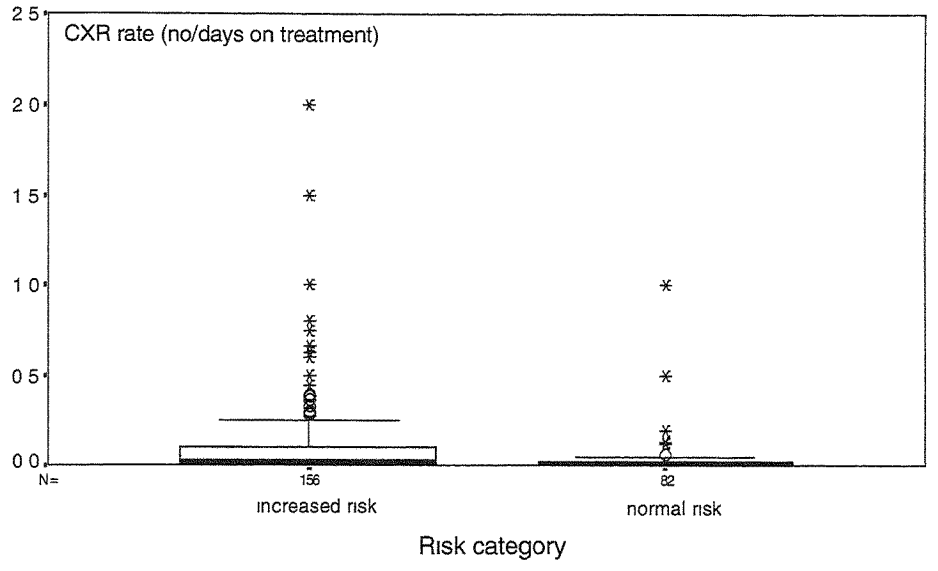


Episode CXR rate: The episode CXR rate takes into account the effect of the episode duration on the number of CXRs performed. The median value and inter-quartile range was greater for episodes relating to patients in the increased risk category (Table 8.10) (Figure 8.4).

Table 8.10: *Distribution of values for episode CXR rate for episodes relating to patients in the two categories (number of CXRs per day on treatment)*

Episode CXR rate	normal risk	increased risk
Median	0.016	0.023
Interquartile range	0.000 - 0.026	0.000 - 0.108

Figure 8.4: CXR rate for each episode

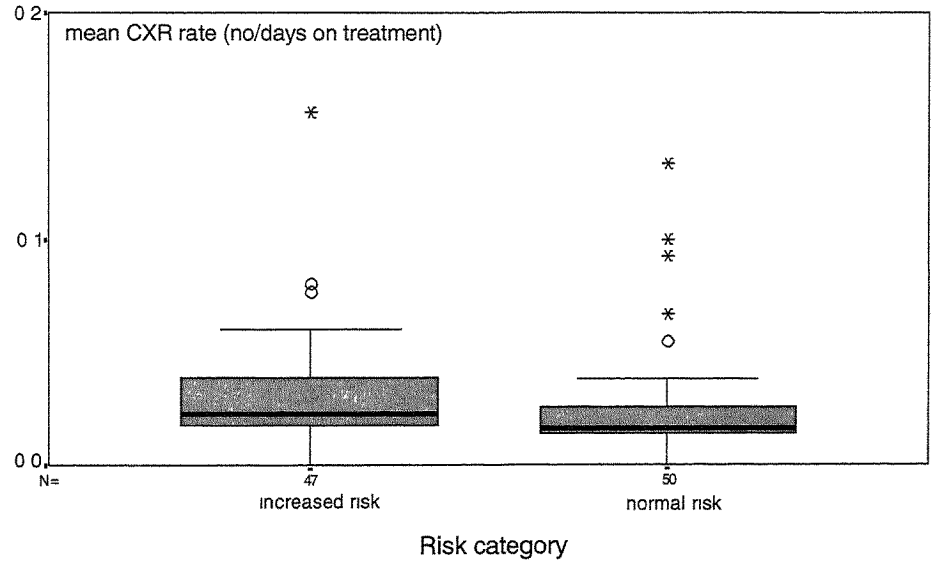


Patient-specific CXR rate: The mean patient-specific CXR rate was calculated for each patient by summing each episode CXR rate for that patient and dividing by the number of episodes. The median value and interquartile range of this mean patient-specific CXR rate was greater for patients in the increased risk category (Table 8.11) (Figure 8.5).

Table 8.11: Distribution of values for mean patient-specific CXR rate during treatment for patients in the two categories

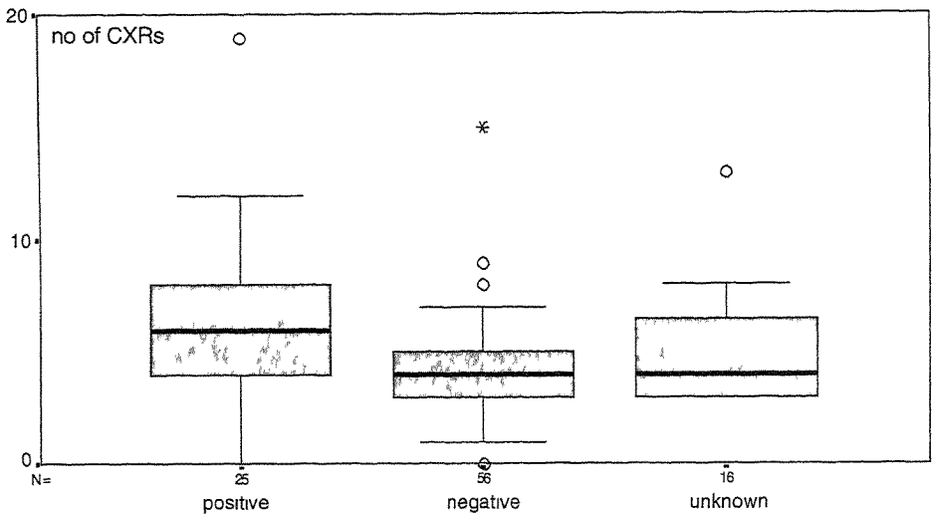
mean patient-specific CXR rate during treatment	normal risk	increased risk
Median	0.016 - 0.017	0.052 - 0.023
Interquartile range	0.011 - 0.027	0.020 - 0.161

Figure 8.5: Mean rate of CXRs performed by CXR category



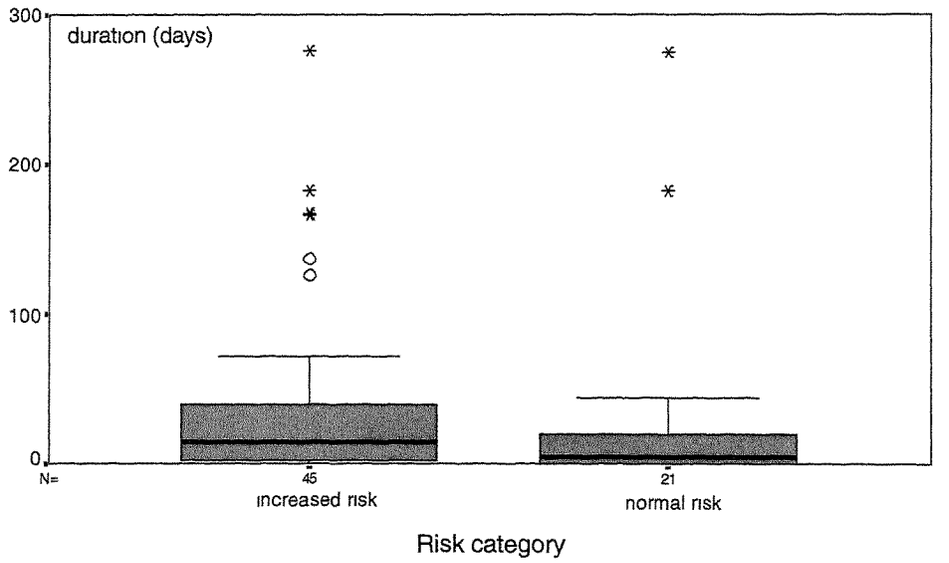
CXR numbers and sputum smear status: The distribution of the sum of CXRs also varied according to sputum smear status at the start of treatment. The median value and the interquartile range were greatest for patients who were smear positive at the start of treatment (Figure 8.6).

Figure 8.6: *Sum of CXRs by smear status*



Evidence for under-supply of CXR examination: Episodes where no CXRs were identified (CXRs may have been performed but not identified) were examined in further detail. Episodes relating to patients in the increased risk category tended to be longer (Figure 8.7). Episodes relating to patients in the normal risk category took place largely in chest clinics (14/21) whereas for patients in the increased risk category, 17 took place in chest clinics and 12 in chest hospitals.

Figure 8.7: *Duration of episodes when no CXRs identified*



Twenty three (46.0%) patients in the increased risk category experienced at least one episode during treatment where no CXRs were identified after review of X-ray folders. These 23 patients experienced a total of 45 episodes of all types where no CXRs were identified. Review of the episode duration and episode-specific co-morbidities and complications of tuberculosis revealed that in 4/45 episodes (8.9%) there was a suggestion that CXR examination would have been appropriate (Table 8.12). Discussion of the case-histories of the four patients with possible unmet need might help in the development of guidelines for CXR examination. This uncertainty about the use (or availability) of CXR in 8.9% of the high risk group could reflect involvement of about 400 patients per year.

In the remaining episodes, absence of CXR examination appeared to be appropriate for one or more of the following reasons:

- the episode was short (one week or less)
- there was no current reason for the patient to be at increased risk (eg no haemoptysis in that episode)
- the comorbidity which resulted in the patient being in the increased risk category was a chronic condition (eg chronic obstructive airways disease)
- the patient had had a CXR examination before starting treatment or after completing treatment in the episode

Increased use of Chest X-ray (CXR) examination is associated with 7 complications of tuberculosis, 7 co-morbidities, and smear positive status at start of treatment. There is uncertainty about CXR use in 9% of the increased risk group, possibly either because of under use of CXR or non-availability of films or reports.

Table 8.12: *Summary of episodes relating to patients in increased risk category where no CXRs were identified*

patient	episode duration (days)	episode source	stage of treatment	reason for increased risk	comments
A	183	chest clinic	started treatment in chest clinic 1 month after starting episode	haemoptysis	one CXR pre-treatment
B	307	chest clinic	started treatment in chest clinic 4 months after starting episode	haemoptysis	no CXRs identified
C	16	chest hospital	started treatment 2 months previously	haemoptysis	no CXRs identified, had 3 CXRs in chest clinic after discharge
D	138	chest hospital	started treatment 2 months before start of episode	pleural effusion	no CXRs identified, one CXR in chest clinic day prior to admission, one in chest clinic week after discharge; very unlikely this patient had no CXRs during admission

8.3.3.2 Use of blood tests by risk category of patient

100 patients were selected for the blood test sample, 50 at increased risk and 50 at normal risk.

Episodes: 310 treatment episodes were identified for these 100 patients, 112 for patients at normal risk and 198 for patients at increased risk. There was no significant difference in mean episode duration for patients in the increased risk category compared to those at normal risk (106 days versus 125, p=0.3). Twenty two of the 310 episodes (7.1%) were in-patient episodes where the patient had been admitted principally for the management of a co-morbidity but was still being treated for tuberculosis. The proportion of these episodes was lower for patients in the normal compared to the increased risk category (4/108 (3.7%) compared to 18/180 (10.0%). Medical records were not available for eight episodes (2.6%). The unavailability of medical records is summarised below (Table 8.13).

Table 8.13: Sources of care where medical record not available (% of episodes at that source)

source	number of episodes medical record not available		% of total episodes at that source
	normal risk	increased risk	
L	0	1	9.1
M	0	3	75.0
N	0	1	100.0
D	1	0	12.5
O	1	0	100.0
J	1	0	33.3
Total	**3**	**5**	**2.6**

Patients: The medical record was not available for one or more episodes for six of the 100 patients (6.0%). For four of these patients, it was not available for one episode, and for two patients it was not available for two episodes. There were three patients in each risk category (Table 8.14).

Table 8.14: Number of episodes for which medical record data not available

number of episodes medical record not available	number of patients		% of total patients with at least one episode where medical record not available
	normal risk	increased risk	
1	3	1	66.7
2	0	2	33.3
Total	**3**	**3**	**100.0**

Number of blood tests performed in each episode: The number of blood tests performed in each episode varied greatly between episodes and according to the type of blood test being performed. The most frequently performed tests were liver function tests (LFT), followed by renal function tests (RFT) and haematology tests. The number of tests performed in each episode varied considerably.

Episodes relating to patients in the normal risk category were more likely to have no LFTs, haematology or hepatitis B tests compared to episodes of care for increased risk patient

episodes. The interquartile range for number of tests performed was wider for episodes relating to patients in the increased risk category for LFTs and RFTs but there were no differences in the median or interquartile range for the remaining blood tests (Table 8.15) (Figures 8.8, 8.9 and 8.10).

Number of different blood tests performed in each episode: Considering each of the above tests as different blood tests, the number of different blood tests performed in each episode was determined. For example, if a patient only had LFTs, then he or she only had one type of blood test regardless of how many LFTs were performed. The median number of different types of test was 2 for both risk categories (interquartile range 0-4 for normal risk, 1-5 for increased risk). The distribution of episodes was bimodal for both risk categories with the first peak occurring for no blood tests and the second occurring for two blood tests (Figure 8.11).

Figure 8.8: *Total number of LFTs per episode*

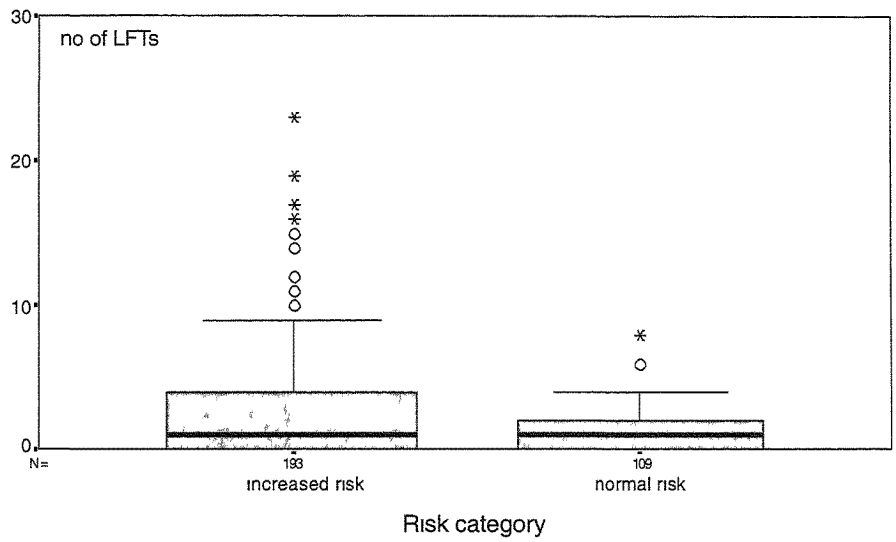
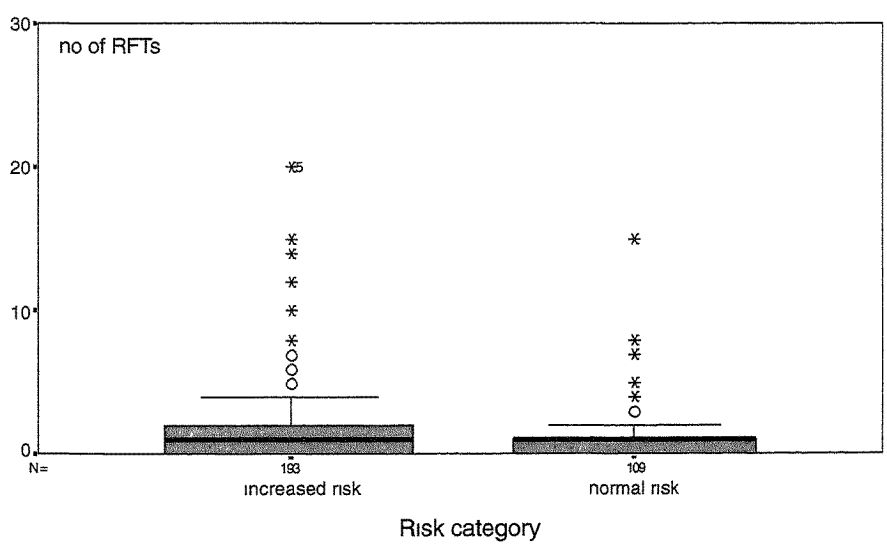


Figure 8.9: *Total number of RFTs per episode*



For both LFT's and RFT's the median and interquartile range are lower in the normal risk group. However there is a tail to the distribution pattern which suggests that there is scope or developing guidelines on the rational use of tests.

Table 8.15: *Distribution of blood tests in episodes relating to two risk categories of patients*

test	normal risk				increased risk			
	no (%) of episodes with no tests	range of number of tests performed per episode	median	inter-quartile range	no (%) of episodes with no tests	range of number of tests performed per episode	median	inter-quartile range
LFTs	38 (34.9)	0-8	1	0-2	49 (25.4)	0-23	1	0-4
RFTs	41 (37.6)	0-15	1	0-1	71 (36.8)	0-20	1	0-2
haematology	73 (67.0)	0-6	0	0-1	105 (54.4)	0-16	0	0-1
ESR	88 (80.7)	0-6	0	0-0	150 (77.7)	0-6	0	0-0
clotting	100 (91.7)	0-8	0	0-0	165 (85.5)	0-8	0	0-0
glucose	92 (84.4)	0-15	0	0-0	146 (75.6)	0-9	0	0-0
hepatitis A	109 (100.0)	-	-	-	188 (97.4)	0-2	0	0-0
hepatitis B	99 (90.8)	0-2	0	0-0	162 (83.9)	0-4	0	0-0
urate	109 (100.0)	-	-	-	193 (100.0)	-	-	-
ABGs	88 (80.7)	0-12	0	0-0	159 (82.4)	0-9	0	0-0
other blood tests	102 (93.6)	NA	-	-	169 (87.6)	NA	-	-

Figure 8.10: Total number of complete blood counts per episode

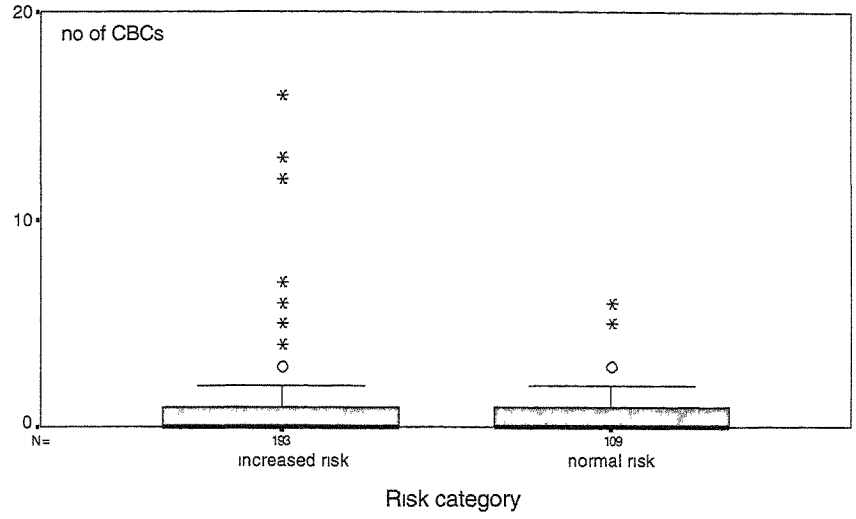
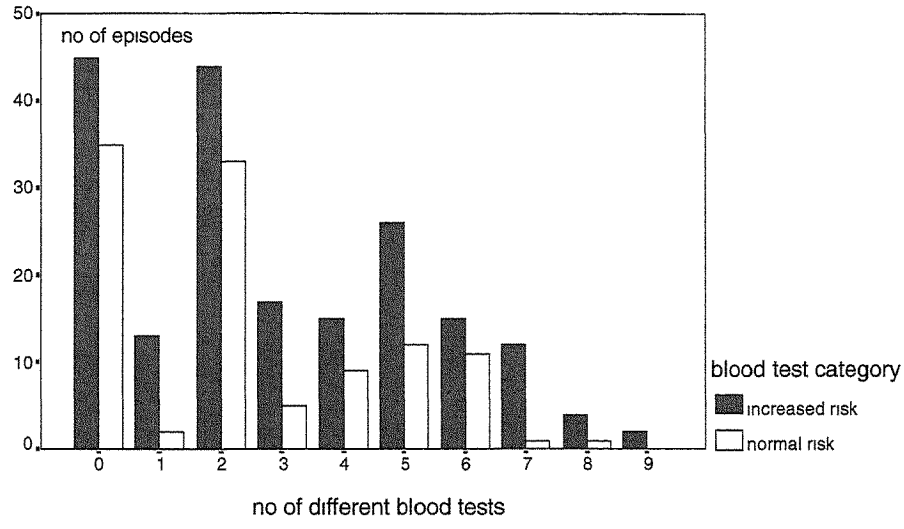


Figure 8.11: Number of different blood tests per episode



Evidence for under-supply of blood tests: No blood tests were performed in 45 episodes relating to patients in the increased risk category. In 11 of these the episode lasted over one month and these were reviewed in more detail. In nine of the episodes the patient either had no active problem to assign them to the increased risk category, or that problem was being managed at another source of care. In two episodes, the patient had abnormal liver function tests recorded as a complication of treatment. In one the ALT level was 1-2 times and in the second it was over 10 times the upper limit of normal. Given that the ALT level was recorded during these episodes, liver function tests must have been performed. In these two episodes at least, blood tests were performed but the results were not filed in the medical record.

Blood tests performed for each patient during treatment: The proportion of patients who had at least one of each type of blood test varied according to the test and the risk category of the patient. Nearly 100% of patients in both categories had LFTs whereas no patient in either category had any urate tests during treatment (Table 8.16). Patients in the increased risk category were more likely to have at least one of each type of test except RFTs and urate. The median number of tests and/or interquartile range were greater for patients in the

increased risk category for all tests. Over 20 tests were performed during the treatment of seven (LFTs), five (RFTs) and one (haematology) increased risk patients. No normal risk patients had more than 17 of any test. (Figures 8.12, 8.13 and 8.14).

Excess risk of having one or more tests for patients in increased risk category: Patients in the increased risk category were more likely to have one or more complete blood counts, ESR, and hepatitis B tests (Table 8.17).

Appropriateness of blood test investigations: The 22/50 increased risk patients experiencing fewer than the median value of eight LFTs during treatment were selected for more detailed review. Five patients had renal risk factors rather than liver-related. The remainder had at least one recorded liver complication of treatment or liver co-morbidity. To explore this further, the number of times a liver complication or comorbidity was recorded during treatment was summed and plotted against the sum of the LFTs performed during treatment (Figure 8.15). There was a strong correlation between the two variables ($r=0.7$, $p<0.001$), but also evidence of repeated screening in the absence of any clinical record of liver pathology.

Figure 8.12: *Sum of LFTs throughout treatment*

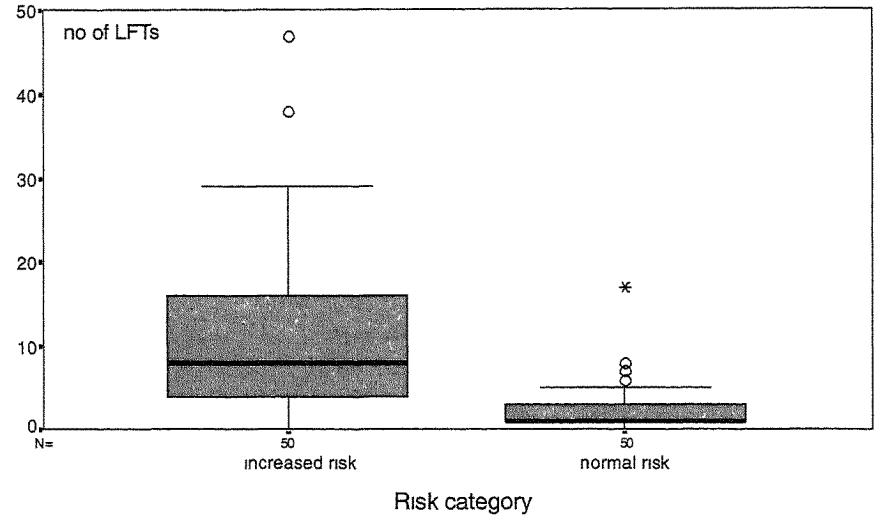


Figure 8.13: *Sum of RFTs throughout treatment*

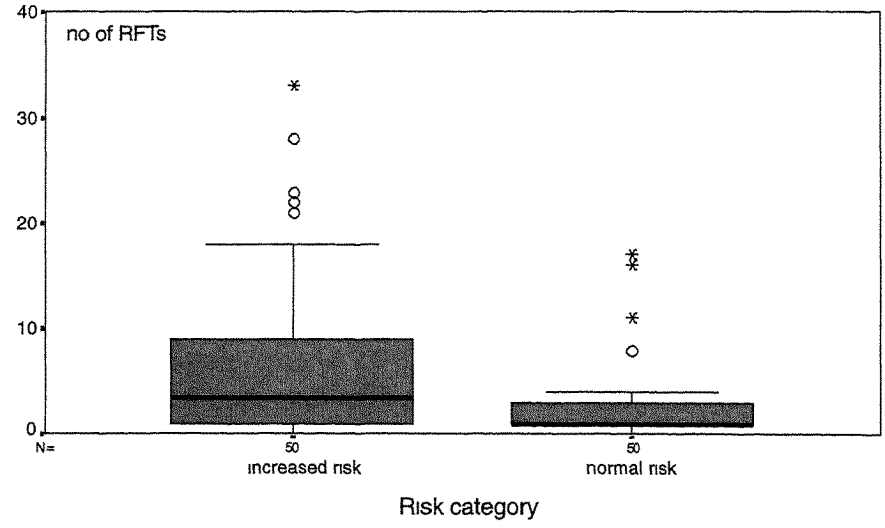


Table 8.16: *Distribution of sum of blood tests during treatment in two risk categories of patients*

test	normal risk number (%) of patients with no tests	range of number of tests performed per patient	median	inter-quartile range	increased risk number (%) of patients with no tests	range of number of tests performed per patient	median	inter-quartile range
LFTs	1 (2.0)	0-17	1	1-3	1 (2.0)	0-47	8	4-16
RFTs	3 (6.0)	0-17	1	1-3	8 (16.0)	0-33	3	1-9
haematology	27 (54.0)	0-14	0	0-1	13 (26.0)	0-27	2	0-5
ESR	36 (72.0)	0-17	0	0-1	22 (44.0)	0-9	1	0-2
clotting	42 (84.0)	0-8	0	0-0	33 (66.0)	0-9	0	0-1
glucose	34 (68.0)	0-15	0	0-1	24 (48.0)	0-12	2	0-2
hepatitis A	50 (100.0)	-	-	-	45 (90.0)	0-2	0	0-0
hepatitis B	42 (84.0)	0-2	0	0-0	24 (48.0)	0-6	1	0-2
urate	50 (100.0)	-	-	-	50 (100.0)	-	-	-
ABGs	34 (68.0)	0-12	0	0-1	31 (62.0)	0-11	0	0-2

Table 8.17: *Odds ratio for having one or more of each test for patients in increased risk category compared to normal risk category*

test	odds ratio (95% CI)
LFTs	1.0
RFTs	0.3 (0.1-1.5)
haematology	3.3 (1.3-8.5)
ESR	3.3 (1.3-8.2)
clotting	2.7 (0.9-7.9)
glucose	2.3 (0.9-5.6)
hepatitis A	NA
hepatitis B	5.7 (2.0-16.3)
urate	NA
ABGs	1.3 (0.5-3.2)

Figure 8.14: Sum of haematology tests during treatment

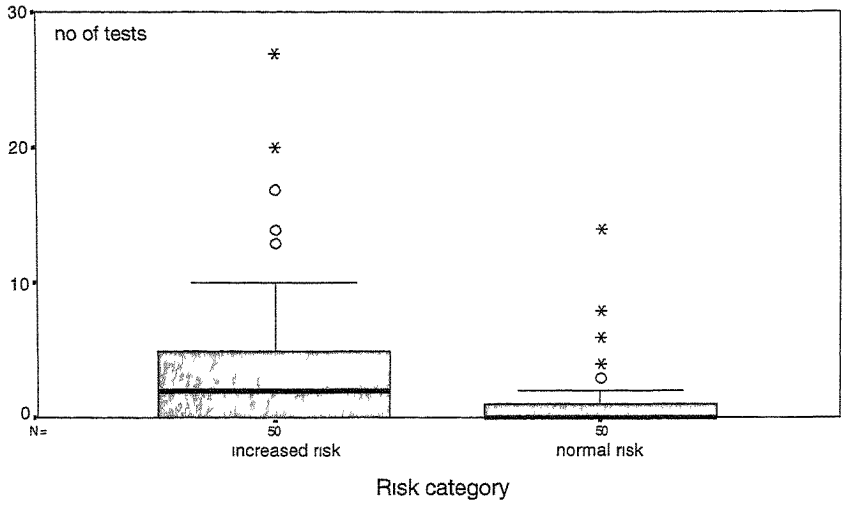
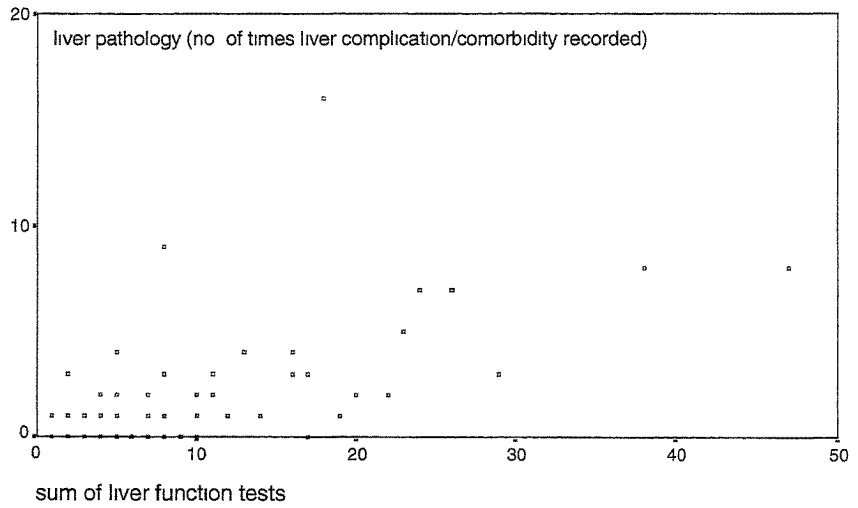


Figure 8.15: Scatter plot of need against supply



Mean rate of testing: The mean of episode-specific rates of testing was calculated for each patient by dividing the total number of tests by the number of days on treatment. The median value was higher for patients in the increased risk category for LFTs and RFTs (Figures 8.16 and 8.17). The outlying value of 1.0 in the normal risk category for LFTs and RFTs was caused by a patient who migrated after one day's treatment having had an LFT and RFT on that day. The extreme normal risk outlier in the RFT chart was a patient who died after 2 day's treatment. A scatter plot of sum of recorded liver complications/ comorbidities against mean rate of LFTs showed no association (Figure 8.18) (r=0.1, p=0.26). The mean rate of LFTs is independent of the number of treatment episodes experienced (p=0.5).

Figure 8.16: *Mean LFT rate (tests per treatment day)*

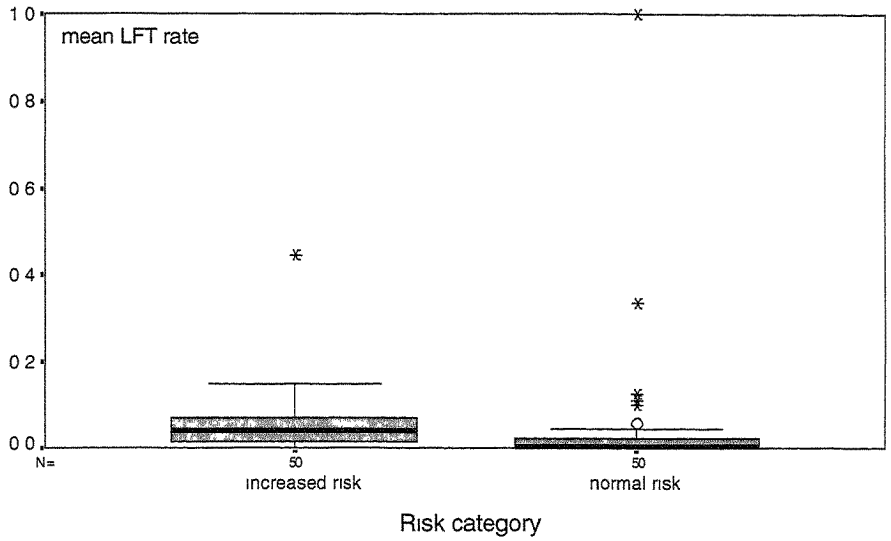


Figure 8.17: *Mean RFT rate (tests per treatment day)*

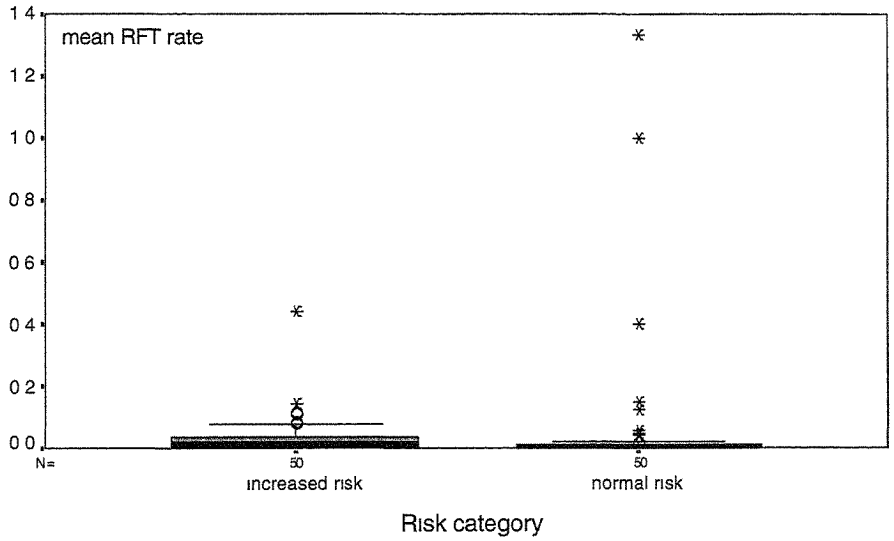
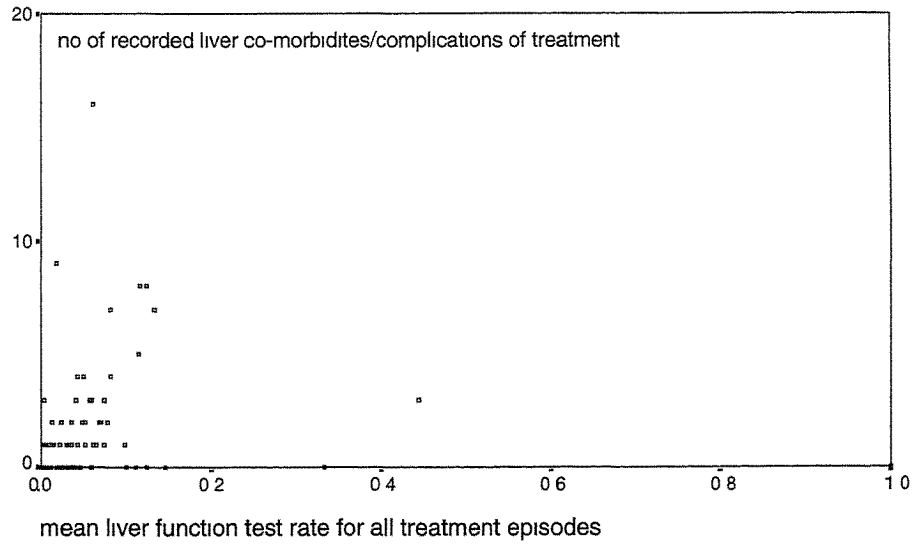


Figure 8.18: *Scatter of need and supply*



Overall, biochemical tests show a pattern which is strongly associated with estimated risk status. However as expected there are marginal patterns which suggest avoidable excess use of testing.

8.3.3.3 Sputum smear and culture

The number of sputum smears and culture examinations performed during treatment was abstracted for the same sample of patients included in the Blood Test study. The information was therefore available for 100 patients, 50 at "increased" risk and 50 at "normal" risk of needing a blood test. An estimation of the *need* for these investigations would be based on the smear and culture status of the patient at the start of treatment. Of these 100 patients, 25 were smear positive, and 55 were culture positive at the start of treatment (Table 8.18).

Table 8.18: *Smear and culture status of 100 patients at start of treatment*

	positive	negative	unknown
smear status	25	58	17
culture status	55	34	11

Number of tests per episode: 268 episodes were identified for the 100 patients in the sample. Sputum smear and culture reports were not available for one of these episodes (0.4%). There was no significant difference in the mean episode duration for smear positive and smear negative patients (123 versus 121 days) or for culture positive and culture negative patients (126 versus 120 days).

Approximately equal numbers of smear and culture examinations were performed in each episode. There was wide variation in the number of smears or cultures performed per episode, ranging from 0 to 15 smear tests and 0-18 culture tests. The distribution for smear tests was similar for episodes relating to patients who were smear positive, smear negative or smear unknown (Figure 8.19) with peaks at zero, two and four tests per episode, progressively declining in size. A similar pattern was seen for culture test distribution (Figure 8.20). Although the overall distributions were similar, approximately 50% of episodes relating to *smear negative* or *smear unknown* patients had no smear tests recorded, whereas less than a third of episodes relating to *smear positive* patients had none recorded.

Figure 8.19: *Number of sputum smear tests per episode*

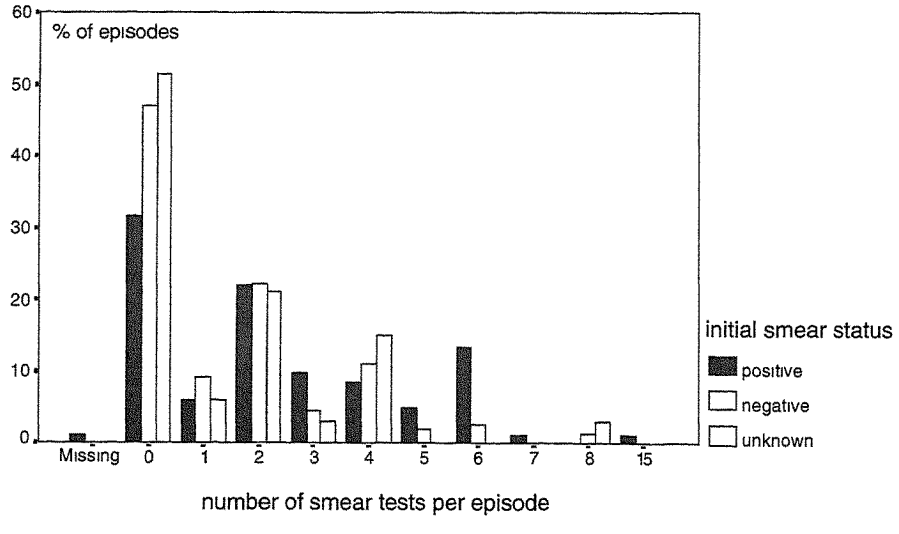
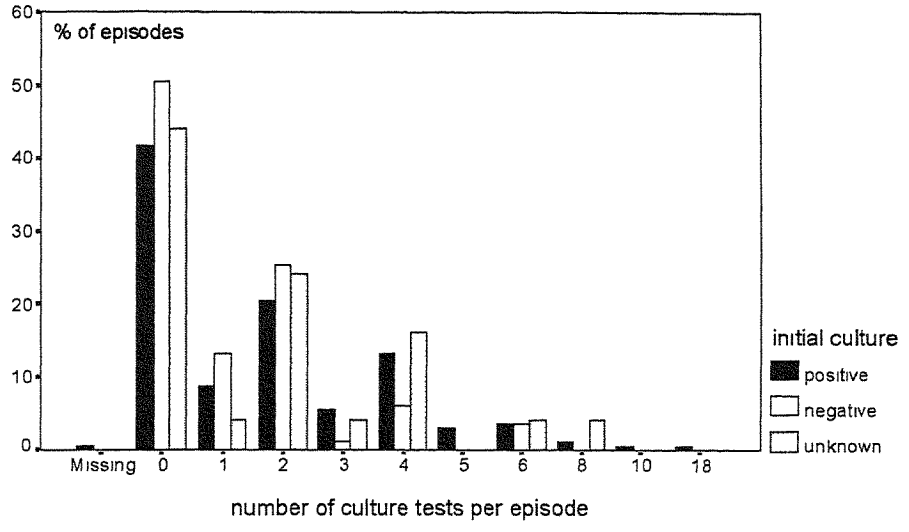


Figure 8.20: Number of sputum culture tests per episode



Number of tests per patient: Sputum smear positive patients had more sputum smear tests performed during treatment. The number ranged from 2 to 27 (median 6, interquartile range 3-11) (Figure 8.21). The difference was less marked for culture tests: culture negative patients had fewer tests but the median value was the same for culture positive patients and culture unknown patients (Table 8.19) (Figure 8.22).

Figure 8.21: Sum of sputum smear tests during treatment

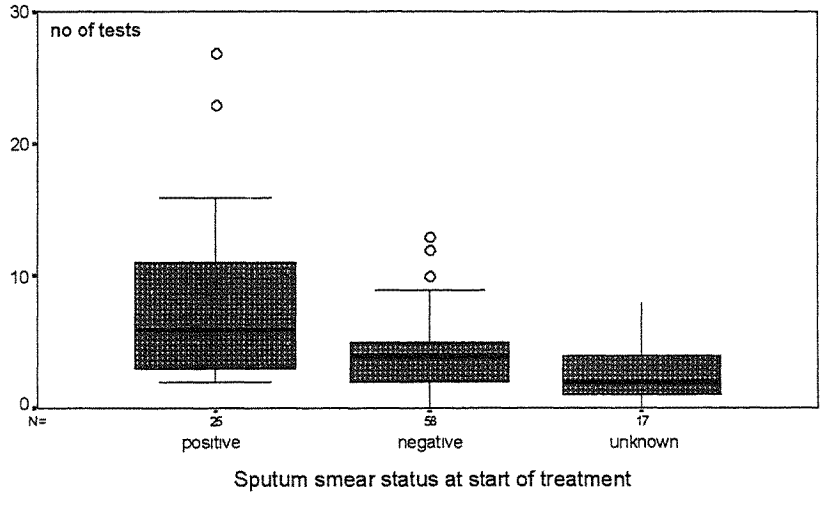


Table 8.19: Distribution of sputum tests performed during treatment

	sum of sputum smear tests performed		
	full range	median	interquartile range
smear positive	2-27	6	3-11
smear negative	0-13	4	2-5
smear unknown	0-8	2	1-4
	sum of sputum culture tests performed		
culture positive	0-20	4	3-6
culture negative	0-9	2	2-4
culture unknown	0-8	4	2-8

Episode-specific smear and culture rates: Rates of smear testing (number of smear tests divided by the episode duration in days) varied widely. Rates were higher for episodes relating to sputum smear positive patients (Table 8.20) (Figure 8.23).

Rates of culture testing did not vary so much according to culture status, although episodes relating to culture positive patients had a wider range (Figure 8.24).

Table 8.20: *Distribution of episode-specific smear rates*

	episode-specific smear rate		
	full range	median	Interquartile range
smear positive	0-2.00	0.02	0-0.11
smear negative	0-2.50	0.01	0-0.03
smear unknown	0-0.67	0	0-0.02
	episode-specific culture rate		
culture positive	0-4.00	0.01	0-0.05
culture negative	0-0.67	0	0-0.02
culture unknown	0-0.67	0.01	0-0.03

Figure 8.22: *Sum of sputum culture tests during treatment*

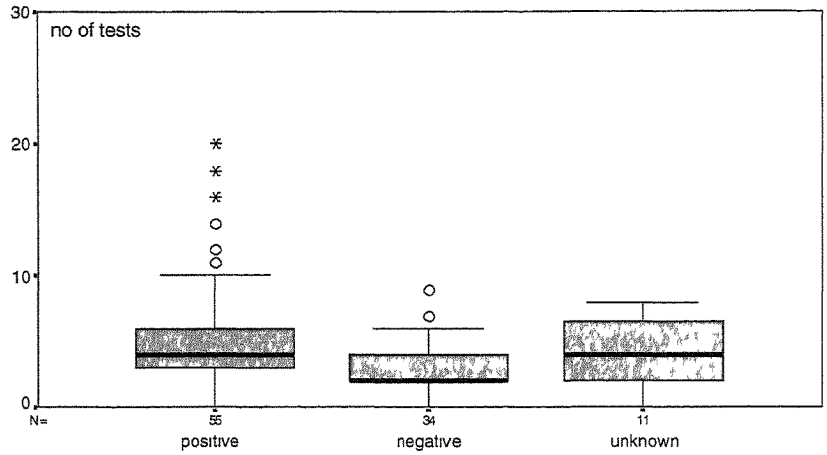


Figure 8.23: *Episode-specific sputum smear rate*

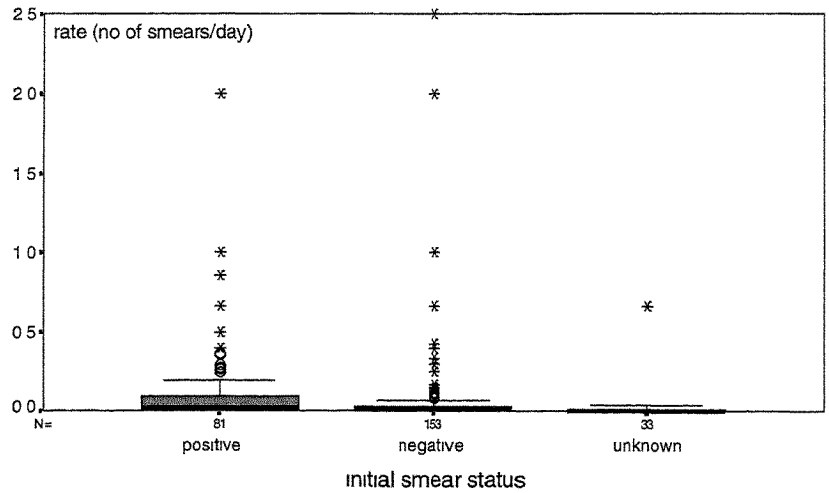
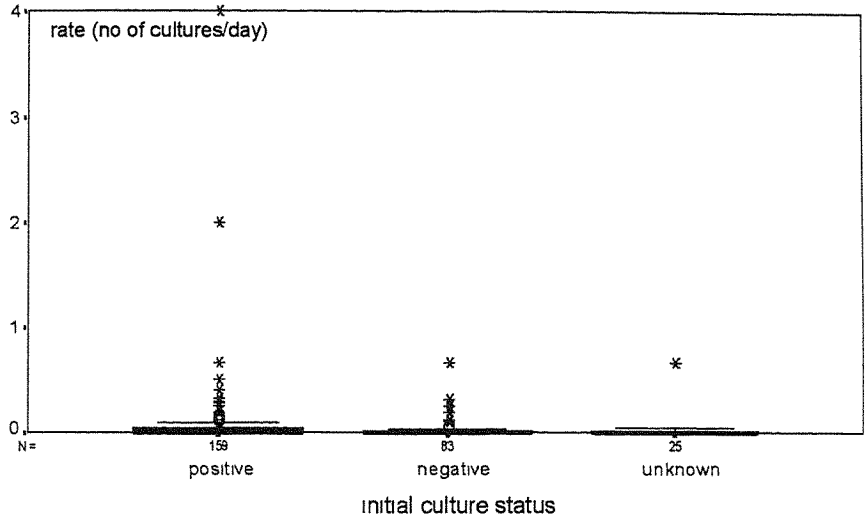
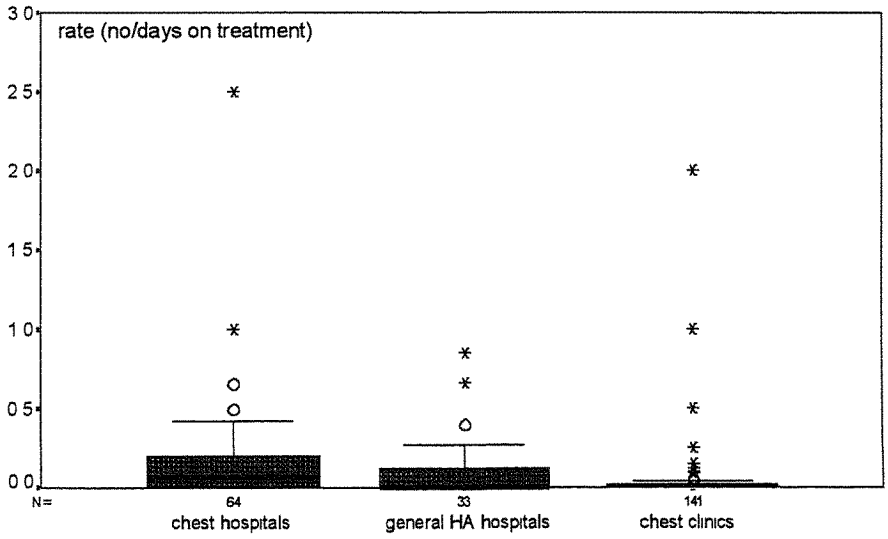


Figure 8.24: Episode-specific sputum culture rate



Episode-specific smear and culture rates also varied according to the source of care managing the patient Rates tended to be higher at chest hospitals than at general hospitals or chest clinics for both smear and culture testing (Figure 8 25 and 8 26) There was some variation in smear rate between chest hospitals, although the median values were similar at all five hospitals (Figure 8 27) Further examination of smear rate for chest hospital episodes reveals that within each hospital the rate varies by smear status, although numbers of episodes become too small for valid comparison at this level of analysis (Figure 8 28)

Figure 8.25: Rate of smear testing between clinics and hospitals



Smear and culture testing varies between types and sources of care as well as by individual risk status.

Figure 8.26: *Rate of sputum culture testing between clinics and hospitals*

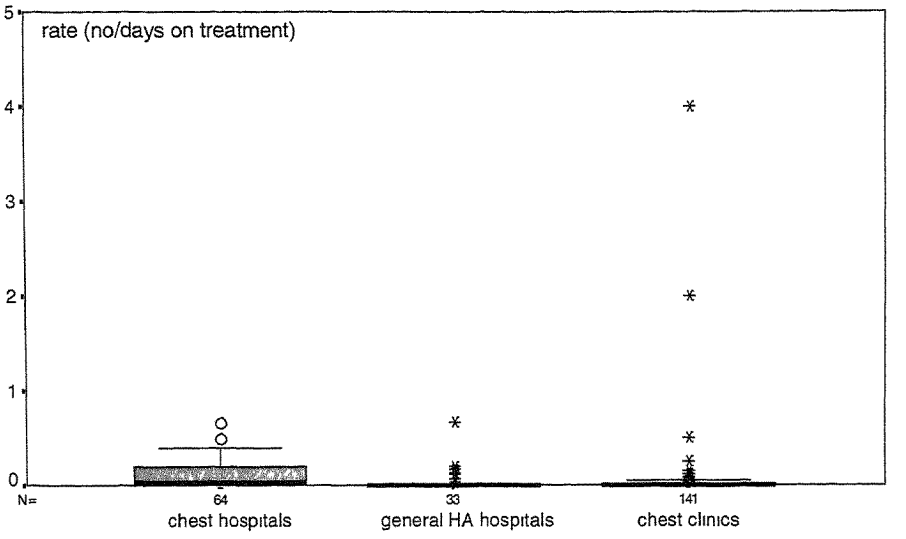


Figure 8.27: *Rate of sputum smear testing between chest hospitals*

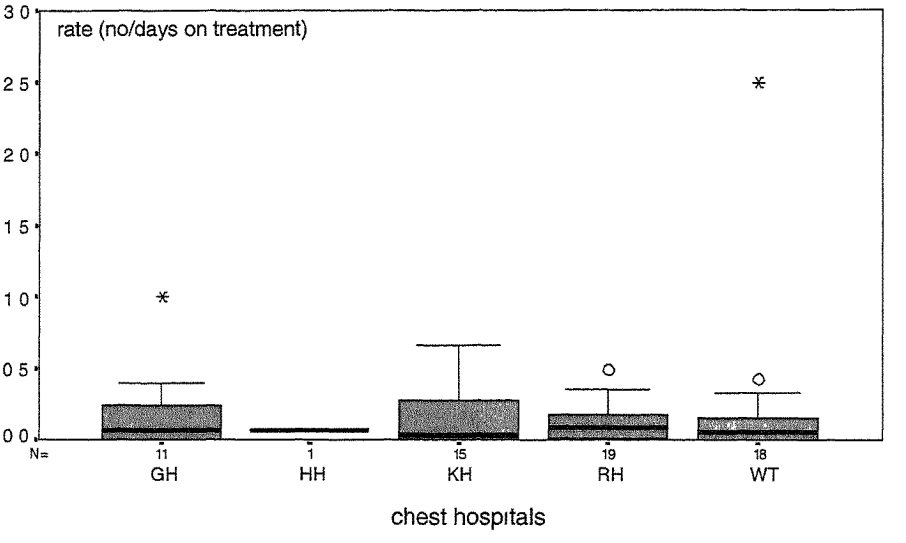
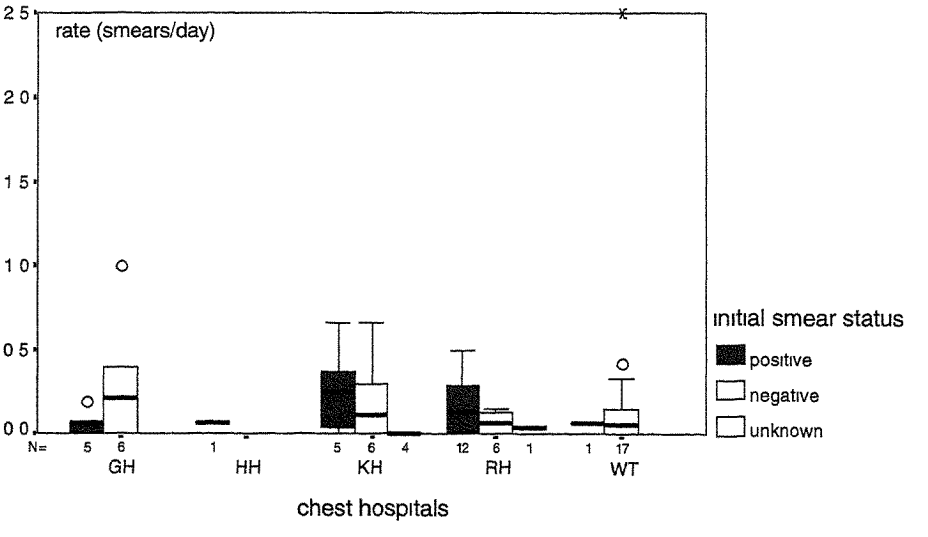


Figure 8.28: *Episode-specific sputum smear rate*

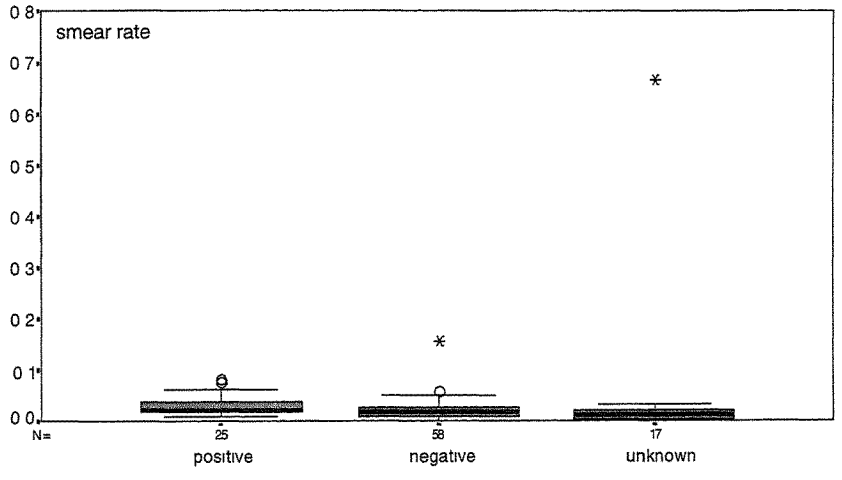


Mean smear and culture rate: Mean smear and culture rates for all episodes were calculated for each patient by dividing the sum of smear and culture examinations by the number of days on treatment. Median rates were higher for smear and culture positive patients (Table 8.21) (Figures 8.29 and 8.30).

Table 8.21: *Distribution of mean smear and culture rates*

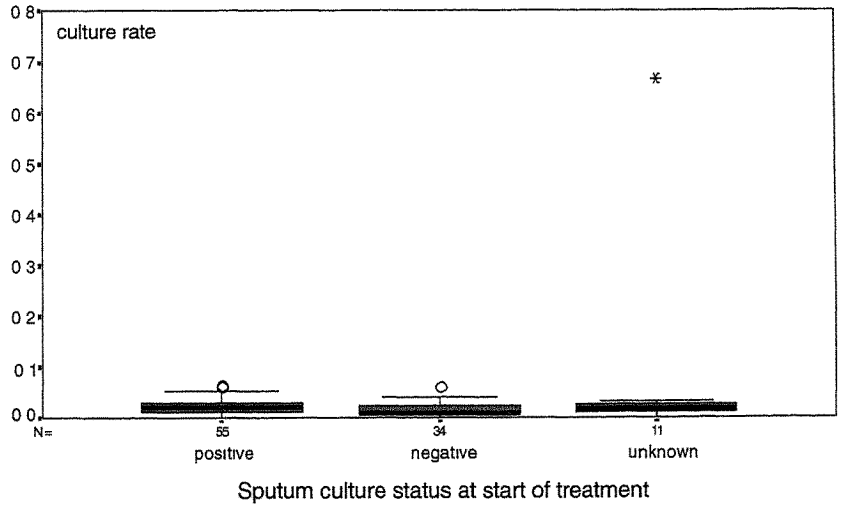
	mean smear rate		
	full range	median	interquartile range
smear positive	0.0-0.08	0.023	0.017-0.045
smear negative	0-0.156	0.019	0.011-0.028
smear unknown	0-0.667	0.015	0-003.021
	mean culture rate		
culture positive	0-0.067	0.021	0.013-0.032
culture negative	0-0.063	0.011	0.009-0.025
culture unknown	0-0.667	0.019	0.011-0.032

Figure 8.29: *Sputum smear rate (smears per treatment)*



Sputum smear status at start of treatment

Figure 8.30: *Sputum culture rate (smears per treatment)*



Sputum culture status at start of treatment

8.3.4 Discussion

Data collection period: Data were only collected for the period of the study whilst patients were receiving treatment for tuberculosis. This was to increase the comparability and generalisability of results. There are, however, considerable resources used for the investigation of patients outside this period, particularly before treatment starts.

8.3.4.1 Risk categories reflecting need for investigations

Mismatch of need and supply: Patients were assigned to risk categories according to the presence or absence of criteria which were felt to reflect need for investigations. These need criteria may have been present for only part of the patient's treatment, but data reflecting the supply of investigations was collected for the whole of the patient's treatment. Some of the apparent mismatch between need and supply identified in this analysis may reflect this difference. For example, if a patient had only one occurrence of haemoptysis at the beginning of treatment, additional CXRs may not have been clinically indicated for the remainder of that patient's treatment.

Use of data: All patients in the main cohort survey can be assigned to the same risk categories and risk category-specific supply rates can be applied in order to estimate resource use.

Appropriateness of need criteria: A balance needs to be achieved between:
- a practical way of assigning patients to risk categories and
- an accurate reflection of need

The system used in this study could be criticised for being too simplistic: for example, patients with haemoptysis could have widely ranging needs for CXR examinations depending on the severity of haemoptysis, and a patient with chronic obstructive airways disease may have no indication for additional CXR examination if the condition is stable. However, the need categories used in this study have been shown to be associated with supply which is evidence for the validity of this approach. It would, however, be possible to increase the number of categories to reflect need more accurately.

The number of treatment episodes identified was at least twice as large for patients in the increased risk category for CXRs and blood tests, providing further evidence that the risk categories, as defined, were a valid reflection of need.

Estimates of workload and potential bias: Data collected in this study under-estimate rather than over-estimate the actual number of investigations performed during a patient's treatment because only those data filed in medical records or in X-ray folders are included. Patients for whom X-ray folders or medical records were not available for all treatment episodes were not excluded from the study and there are likely to be additional investigations which were not filed or where medical records or X-ray folders were not available. This is clearly demonstrated by the patients who were recorded as having abnormal LFTs in two episodes, but for whom no LFT results were filed. Patients in the increased risk category for CXRs were more likely to have missing X-ray folders and this may have resulted in a bias towards under-estimating the excess medical workload in these patients. The reasons for missing information in high risk patients should be examined further. They may be related to an increased number of transfers of information or to the fact that these patients are likely to

be of greater clinical and scientific interest. It is ironical that their records are not available for audit.

Data relating to episodes primarily concerned with co-morbidities were included in the study. Whilst this may be a more accurate reflection of the total workload, a proportion of the investigations performed in these episodes were likely to be related mainly to the patient's comorbidity rather than to tuberculosis. In the CXR sample, a similar proportion of episodes relating to increased and normal risk patients were mainly for comorbidities. Any bias is therefore likely to have a similar effect on both groups of patients. However, in the blood test study, fewer patients in the normal risk category experienced episodes for comorbidities and inclusion of these episodes may therefore have resulted in an over-estimate of work-load attributable to tuberculosis in the increased risk category.

8.3.4.2 Chest X-rays

Use of X-ray folders in study: It was necessary to obtain data on CXRs by examination of the contents of X-ray folders rather than relying on reports in medical records because reports are rarely filed in medical records. This may in turn either reflect:

- a failure to report on CXR findings or
- a failure to file CXR reports in the medical record

In either situation, a doctor has to rely on access to the CXR or a description of the CXR in the medical record. This may not be a problem when the patient is currently being managed by that source of care, but it is likely to be a difficult and uncertain process to review management retrospectively.

Transfer of information between sources of care: Information about CXRs is transferred between sources of care in the form of:

- a CXR film
- a CXR report
- a description of the CXR in the medical record or discharge summary

Failure to communicate results may result in unnecessary duplication of CXR examination with associated resource and health implications. In practice, CXR films are transferred between chest clinics and chest hospitals, but referrals between other sources of care are likely to result in inadequate exchange of information.

X-ray folders unavailable: It is possible that X-ray folders were not available because no CXRs were performed but, in most cases, the episodes where X-ray folders were unavailable related to patients in the increased risk category and it is unlikely that no CXRs were performed. It was particularly difficult to get access to X-ray folders at certain sources of care. At one hospital the filing system did not allow access to folders unless the X-ray number of the patient was known, but this was not recorded in the medical record. At another hospital X-ray folders were not available for all seven of the episodes experienced by one patient. Indeed for this patient, no CXRs were available for all 14 of his treatment episodes, but the severity of his complications suggest that it is extremely unlikely that no chest X-rays had been taken.

Number of chest X-rays: Paradoxically, patients in the increased risk category experienced fewer CXRs per episode. This reflects the greater number of episodes of shorter duration experienced by these patients during their treatment. When compared with the low risk group they had a greater number of shorter episodes, with only one or two CXRs, but more episodes with over five CXRs than the lower risk patients. This interpretation is supported by analysis of the total number of CXRs performed during treatment: patients in the increased risk category had more X-rays taken overall.

Most patients had between four and eight CXRs during their treatment, but one patient had 19. This large number could reflect increased need or may reflect unnecessary duplication because of poor communication between sources of care.

Chest X-ray examination: As expected, episode specific CXR rates were slightly greater for episodes relating to patients at increased risk. A similar pattern emerged for the mean CXR rate with patients at increased risk having CXRs at an average rate of one every 43 days compared with one every 59 days for normal risk patients.

Evidence for under-supply: Although some increased risk patients apparently experienced episodes with no CXRs, this could reflect:

- failure to file CXRs in the X-ray folder
- the criteria assigning patients to the increased risk category were not severe enough to justify CXR examination (e.g. blood stained sputum)

However, one patient (patient D in Table 8.12) had a pleural effusion which would almost certainly have justified CXR examination, but no CXRs were filed in that episode. In addition, no CXRs relating to that episode were found filed in the subsequent chest clinic episode.

8.3.4.3 Blood tests

Inclusion criteria for blood tests were clearly defined to maximise consistency of data collection.

Unavailable medical records: The proportion of episodes for which data were not available was smaller for blood tests than for CXRs. This may reflect a better filing system for medical records than for X-ray folders. Three of the unavailable medical records were for episodes at private practitioners where records were not requested. Data were unavailable for equal numbers of episodes relating to patients at increased and normal risk.

Variation between blood tests performed: Two comparisons were made:

- whether or not a particular blood test was performed in an episode
- if it was performed, the number of tests performed.

In both risk categories, most episodes had at least one LFT and RFT, between a third and a half had haematology tests, and less than a fifth had the remaining tests.

There are many indications for doing blood tests. For patients with tuberculosis, tests may be done to:

- establish a base-line before initiation of a potentially toxic drug
- monitor side-effects of drugs
- investigate signs or symptoms which may be attributable to tuberculosis, drug therapy or co-morbidities

LFTs are expected to be the most frequently performed blood test because the most frequent potentially serious side-effects of anti-tuberculous drugs are related to the liver, and liver co-morbidities such as chronic liver disease related to hepatitis B infection require close monitoring for toxicity. In 25% of episodes relating to increased risk patients, more than four LFTs were performed. The maximum number performed was 23 in one episode.

Variation between risk groups: Episodes relating to increased risk patients were more likely to have at least one LFT, haematology or hepatitis B test. There was no such relationship for RFTs. This is probably because most of the patients in the increased risk category had complications of treatment or co-morbidities related to the liver rather than the kidney.

Number of different blood tests: The bimodal distribution, with most episodes having either none or two different blood tests, may indicate that requests for both LFTs and RFTs are made when LFTs alone might be indicated. It is, however, very difficult to draw conclusions from these data without knowing more about the clinical picture.

Appropriateness of blood tests: There was no evidence of inappropriately low use of blood tests, but there were at least two patients in whom LFTs must have been performed but for whom results were not filed.

There was a strong correlation between the number of LFTs performed and the number of times a liver complication or co-morbidity was recorded during treatment. However, these two variables are both dependent on the number of treatment episodes the patient experienced which may explain the relationship. Indeed, there is no such correlation between the mean LFT rate (which is independent of the number of episodes) and the number of recorded liver complications and comorbidities. Lack of correlation between these two variables may reflect:

- that mean LFT rate is not a valid representation of supply
- that the number of recorded liver complications or comorbidities is not a valid representation of need
- that there is no strong relationship between need and supply *within the increased risk group*

Variation between patients in risk groups: Very few patients in either risk category had no LFTs or RFTs during their treatment. The differences between risk categories were more marked when data for the whole of the patient's treatment were examined rather than episode-specific data. Increased risk patients were more likely to experience each blood test except RFTs and urate, and were more likely to have a greater number of each test. Some patients had very high numbers of certain tests. For example, 25% of increased risk patients had more than 16 LFTs during their treatment. In some cases, high numbers of tests could reflect inadequate communication of results and unnecessary duplication.

8.3.4.4 Sputum examination

Unavailable data: Data about sputum examination were not available in only one episode in which the medical records could not be retrieved.

Categories of need: The three risk categories used to reflect need for sputum smear and culture tests related, respectively, to smear and culture status of the patient at the start of treatment. The three categories were smear or culture positive, negative and unknown.

Patients who were smear positive at the start of treatment would be expected to require the most subsequent smear examinations to monitor their response to treatment. Smear negative patients *may* have additional smear examinations to confirm their negative status or in conjunction with subsequent sputum culture tests taken to establish the diagnosis. If smear status is unknown at the start of treatment, subsequent sputum smears may be obtained in order to establish the patient's smear status.

Culture positive, negative and unknown patients are likely to follow a similar pattern to smear positive, negative and unknown patients respectively.

Numbers of sputum tests: It is expected that equal numbers of sputum smear and culture results should be reported as it is usual practice to request both for the same specimen. However, anecdotal reports suggest that slightly fewer culture results are filed because of the time interval between requesting the test and obtaining the report. This was confirmed in this study where 474 smear tests were filed for 100 patients, but only 436 culture tests, 38 fewer. Assuming smear and culture tests were requested on each occasion then 38/474 (8%) of requested culture tests were not recorded.

In some episodes, over five sputum smears or cultures were requested and in one episode relating to one smear and culture positive patient 15 smears and 18 culture tests were recorded. Examining the total number of smears during treatment, 25% of smear positive patients had more than 11 smear examinations and one patient had 27. Without examining the full clinical details of each patient, it is difficult to interpret these results. However, there is almost certainly some unnecessary duplication of investigations due to failure to communicate results between sources of care.

A common standard clinical information system would ensure communication of test results between sources of care and reduce the cost of duplicate investigations.

Rates of sputum tests:

Episode-specific rates

Episode-specific rates of smear and culture tests varied according to smear and culture status as expected. The median rate for smear positive patients was twice that for smear negative. However, some variation in rates was also explained by the source of care managing the patient, with smear and culture rates being higher at chest hospitals. This might be explained by the difference in case-mix of patients managed by chest hospitals compared to general hospitals or chest clinics, and also the stage of treatment during their admission. For example, smear positive patients responding poorly to treatment might be admitted to a chest hospital for management and require several smear tests to monitor their response. It is difficult to further analyse the relative effect of patient-specific and source-specific factors on smear and culture rates because of the small numbers of episodes in each subcategory.

Patient-specific rates
The median of the mean smear rate was 0.023 smears/day or one every 43 days for smear positive patients and 0.019 (one every 53 days) for smear negative. The median of the mean culture rate was 0.021 (one in every 48 days) for culture positive and 0.011 (one in every 91 days) for culture negative patients. This compares with the intervals of 43 and 59 days for CXRs for increased and normal risk patients.

Comparison with other countries: The IUATLD recommends that sputum smear and culture tests are used at the end of therapy to confirm cure. In Hong Kong, however, the Department of Health chest clinic service, which is responsible for managing the majority of patients at the completion of treatment, prefers to rely principally on radiological response as an indicator of cure with sputum tests used to provide further evidence.

8.3.4.5 Development of guidelines

These data could be used as the basis for discussion about development of guidelines for:

- need for investigations
- transfer of information between sources of care.

8.3.5 Development of decision analysis tree

The data collected was used to develop a decision analysis tree for the patients in the main cohort.

8.3.5.1 Methods

All 454 patients in the main survey were assigned to the same risk categories for CXR and blood tests as those in this study:

1. Treatment episodes were categorised into increased risk or normal risk according to the presence or absence of:

For CXRs

- complications of tuberculosis: haemoptysis; pleural effusion; endobronchitis; lobar collapse; empyema; pneumothorax; bronchiectasis
- complications of treatment: pneumothorax
- comorbidity in categories: circulatory system; lower respiratory system; neoplasms of respiratory system

For liver related blood tests

- complications of treatment: abnormal liver enzymes; jaundice; hepatitis
- comorbidity in category: liver-related (includes neoplasms, cirrhosis, hepatitis)

renal related blood tests

- complications of treatment: impaired renal function
- comorbidity in category: renal related (includes renal failure, nephrotic syndrome, proteinuria, contracted kidney, kidney calculus)

2. Patients were then categorised according to the number of episodes with at least one of these criteria. Patients with no episodes with these criteria were *normal risk* patients, patients with one or more were *increased risk* patients.

8.3.5.2 Results

Episodes: Of the 2012 episodes identified in the main survey, 675 were non-treatment episodes. Of the remaining 1337, 525 (39.3%) were increased risk for CXRs, 222 (16.6%) were increased risk for liver-related blood tests and 48 (3.6%) were increased risk for renal-related blood tests (Table 8.22).

Table 8.22: Distribution of risk for investigations during treatment episodes

	increased risk	normal risk
CXR	525 (39.3%)	812 (60.7%)
liver-related	222 (16.6%)	1115 (83.4%)
renal-related	48 (3.6%)	1289 (96.4%)

Patients: Of the 454 patients in the main survey, 247 (54.4%) had one or more treatment episodes which fulfilled one or more of the criteria for increased risk of CXR. Fewer patients had one or more increased risk episodes for liver-related blood tests and fewer still for renal-related blood tests (Table 8.23).

Table 8.23: Distribution of patients according to risk categories

	increased risk	normal risk
CXR	247 (54.4%)	207 (45.6%)
liver-related	100 (22.0%)	354 (78.0%)
renal-related	25 (5.5%)	429 (94.5%)
liver or renal-related	116 (25.6%)	338 (74.4%)

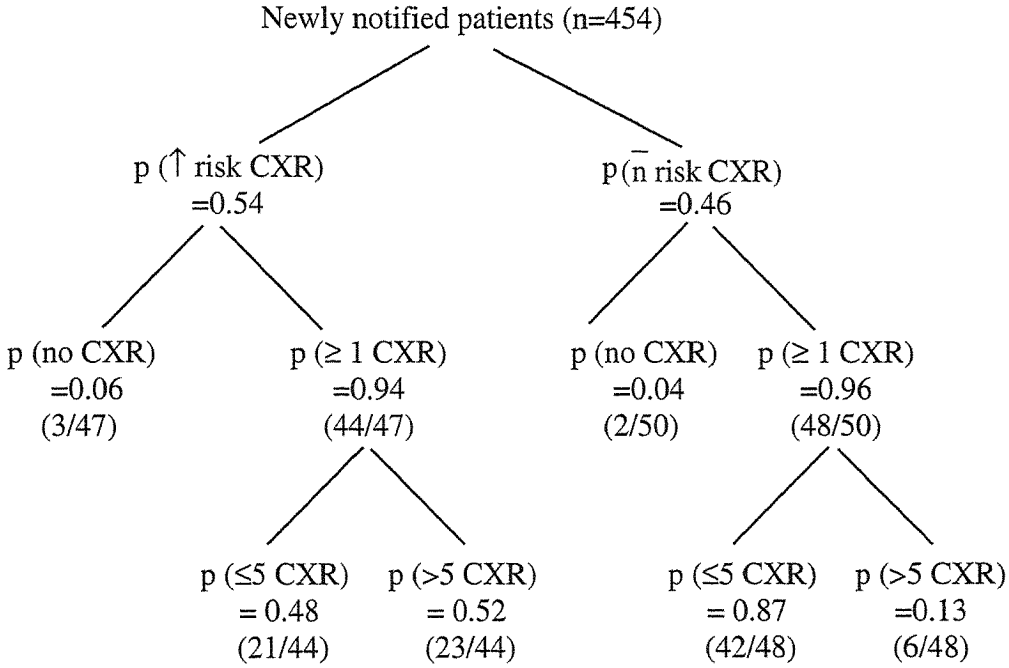
The number of increased risk episodes ranged from 1 to 13 for CXRs, 1 to 11 for liver blood tests and 1 to 9 for renal blood tests (Table 8.24).

Table 8.24: Range of increased risk episodes for patients with at least one

no of increased risk treatment episodes per patient	**CXR**	**liver-related**	**renal-related**
1	130	53	18
2	53	20	3
3	27	11	1
4	14	6	1
5	7	1	0
6	9	4	0
7	3	2	0
8	0	1	1
9	1	0	1
10	2	1	0
11	0	1	0
12	0	0	0
13	1	0	0
total	**247**	**100**	**25**

Approximately half (54%) of all newly notified patients are estimated to be at increased risk of requiring radiograph monitoring during the active treatment (Figure 8.31). Of these the majority (94%) have one or more CXRs taken and recorded. The residual 6% may be accounted for by either a mismatch between predicted need and clinical decision making, or simply by missing films and reports. The group at normal risk show an entirely similar pattern in that 96% had at least one CXR during treatment episodes. However the risk grading does predict a higher utilisation among the higher risk group; 52% had more than 5 CXRs compared with only 13% in the low risk group. The cut-off point of 5 CXRs is the median for the high-risk group and was selected, at this stage, only for illustrative purposes. This cut-off point could be varied if it is considered to be too high or too low.

Figure 8.31: *Algorithm for probability of chest X-ray examinations during treatment episodes*



p (↑ risk CXR) = probability that a patient has an increased risk of chest X-ray.
p (n̄ risk CXR) = probability of no increased risk (ie normal risk) of chest X-ray.

CXR's are costly items of care and overall clinical radiation protection guidelines strongly advocate reduction of unnecessary exposures. Small marginal reductions, of a few percentage points, would lead to large savings in radiograph examinations. The question which needs to be posed is whether there is scope from a clinical viewpoint for a management guideline in which CXRs are strictly linked to criteria of need and likely utility. How often does an CXR in the normal risk group actually influence and change management rather than simply confirm clinical status? The value of repeated chest radiography during treatment should be questioned.

It would be possible to design a test exercise in which anonymised records and films were used in blind assessments by clinicians in order to assess the value of routine CXRs in normal risk patients. The same approach could be taken for the high risk patients in terms of the multiple (>5) CXRs ordered for 52% of the population.

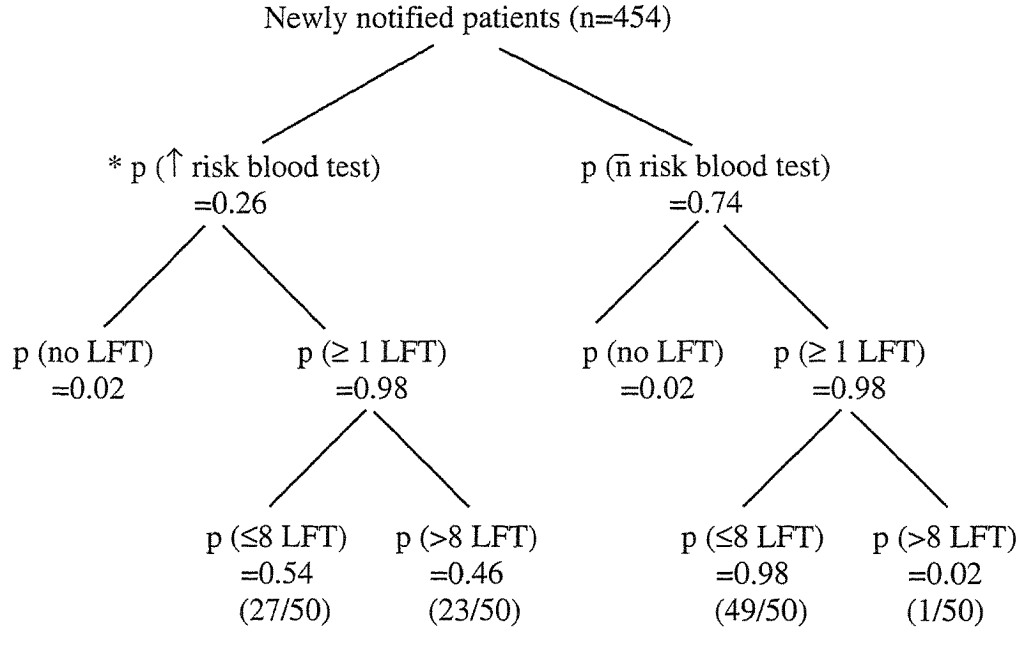
In 1983 the findings of the chest radiograph panel in the US FDA included the view that

> "There was no indication to repeat chest radiography during treatment."

This aspect of clinical management should be a priority for review of usual practices and the development of guidelines designed to promote cost-effectiveness in TB management.

Use of liver function tests: The proportion of increased risk patients amounted to 26% (Figure 8.32). The proportions of increased and normal risk patients who had one or more tests were identical (98%). However a different pattern emerges for multiple testing. The prior probability than a increased risk patient will have more than 8 tests is 46% compared with 2% for the normal risk group.

Figure 8.32: *Algorithm for probability of liver function tests during treatment episodes*

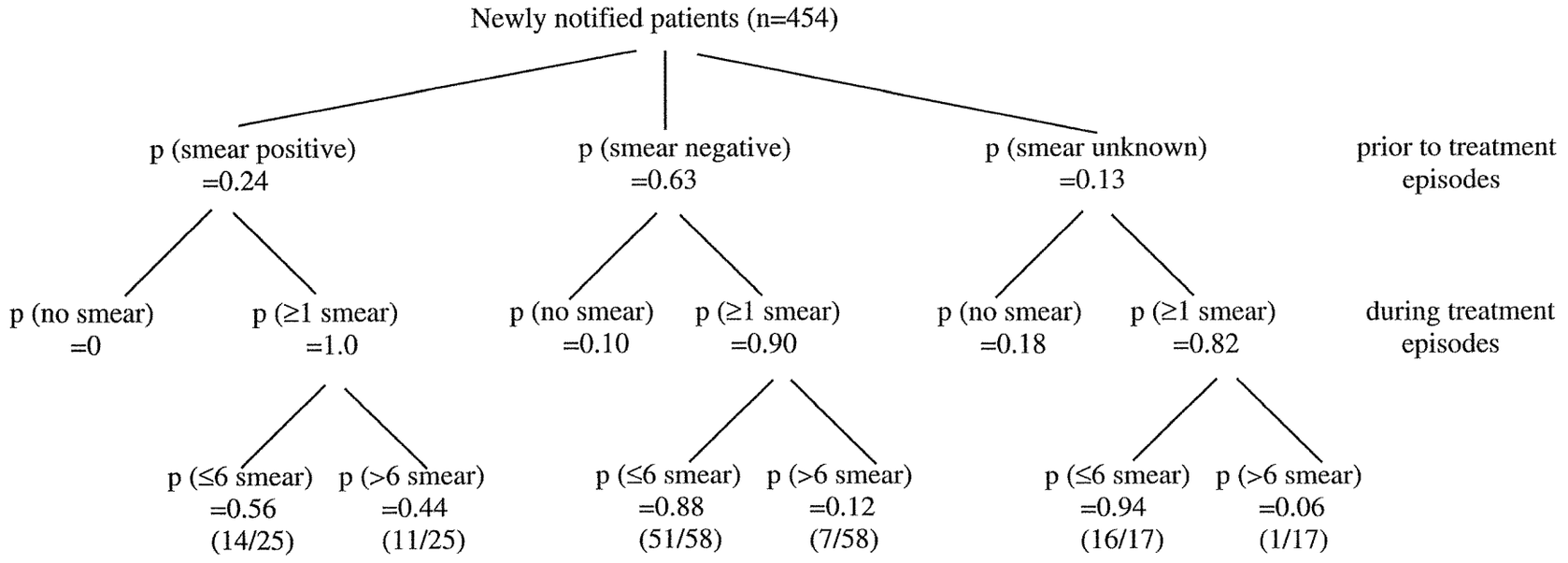


NB * *Increased risk category for blood test includes some patients whose criteria for being included are related to renal problems rather than liver problems.*

As in the case of repeated chest radiographs a decision analysis approach could be applied to the use of liver function tests. Questions related to this include, whether multiple testing is in part related to lack of communication of test results between different sources of care; arbitrary routine testing or other undocumented reasons.

Smear tests during treatment episodes: Only a minority of new patients (24%) were smear positive, 63% were negative and 13% unknown. All smear positive patients underwent smear testing during treatment compared with 90% for smear negative and 82% for the unknowns. The clinical utility of routine testing in the smear negative group could be further explored by examining the outcome of the smear tests and influence on management.

Figure 8.33: *Algorithm for probability of smear tests during treatment episodes*



As with chest X-rays and liver function tests the median number of tests is in the range of 5-8. About 44% had more than 6 smears in the increased risk group compared with 12% in the negative group and 6% in the unknown. This pattern obviously reflects perceived need on the part of clinicians but also points to the potential value of a further evaluation of the utility of the tests in the three groups as a step towards developing evidence-based guidelines.

Overall the probabilities derived from these decision trees provide a means of routinely monitoring changes in case-mix, the effect of case-mix patterns on investigation use and identify areas where further audit and evaluation can help to estimate the utility of testing in different subgroups of patients.

8.4 STUDY THREE: A MORE DETAILED INVESTIGATION OF NEED AND UTILISATION

8.4.1 Introduction

8.4.1.1 Approach of Study 3

This study was carried out in a similar manner to Study 1 but using more detailed need scores, adjusted for perceived severity of the complications recorded and/or the likelihood of comorbidities affecting the management of TB. Several need variables were examined along with several utilisation variables. Those need and utilisation variables which appeared to show consistent associations were selected and used to identify any specific areas of practice where need and utilisation may not be well matched.

In this study, only the treatment period was investigated.

8.4.1.2 Aims

The aim of this part of the study was to determine whether services were matched to needs and to identify factors associated with variation in resource use by patients.

8.4.1.3 Objectives

The objectives were:

1. To determine categories of need for treatment based on more detailed versions of the case-mix indicators previously described (Section 6 and Section 7 Study 1).

2. To validate the indicators of need against outcomes and resource use.

3. To assess the correspondence between estimated need and indicators of utilization and hence resource use in this group of patients and to identify any discrepancies.

4. To make recommendations to promote better matching between need and utilization/ resource use.

8.4.2 Methods

8.4.2.1 Overview of the investigation

The first part of the investigation involved classifying the *complications of TB*, *complications of treatment* and *co-morbidities,* which were already identified for each patient, into discrete categories according to their likely indication of need for care. This was achieved by:

1) categorizing the complications into severe, moderate and minor groups according to the most likely degree of severity of that complication (acknowledging, however, that most of these complications have a range of severities
2) identifying those co-morbidities which are likely to affect the management of TB and those which are not and categorizing them as severe, moderate and minor.

Several *need indicators* were then derived for each patient. These were:

1) the total number of *different* complications or co-morbidities that an individual experienced at any point in their treatment
2) the level of severity (according to the classification) of their most severe TB complication, treatment complication and co-morbidity
3) whether or not a co-morbidity was likely to affect the management of TB. Those which were likely to affect the management of TB were further classified as severe or moderate; those which were not likely to affect management were classed as minor.

These *need indicators* were then tested for their association with the outcome of care and with several *utilisation indicators* which were created from the data on the utilisation experience of that individual such as: the type of service used, length of stay in hospital, frequency of visits to clinics, length of treatment period.

We then examined the characteristics of those patients who, by these indicators, had either high need and low utilisation or conversely low need and high utilisation.

8.4.2.2 Determination of need during treatment

The severity of the three types of problems (TB complications, treatment complications and co-morbidities) was estimated *a priori* according to the following categorisation where *moderate* describes those problems which are either between severe and minor or those which could have a spread of severities and are therefore difficult to classify:

Complications of TB

Severe	**Moderate**
Endobronchitis	Pleural effusion
Lobar collapse	Haemoptysis
Bronchiectasis	Drug resistance
Pneumothorax	
Empyema	
Lymph node abscess	

Complications of treatment

Severe	Moderate	Minor
Hearing loss	Nausea/vomiting	Dizziness
Thrombocytopaenia	Abnormal liver enzymes	Headache
Blurred/impaired vision	Jaundice	Loss of appetite
Tinnitus	Impaired renal function	Malaise
	Skin rash	Diarrhoea
	Fever	Itchy skin
	Flu-like illness	Abdominal pain
	Increased urate	Belching
	Pneumothorax after aspiration	Ear discomfort
	Hepatitis	Peri-oral numbness
	Gout	Facial flushing
	Surgical emphysema after thoracotomy	
	Poor response to treatment	
	Poor compliance	

Comorbidities

Severe	Moderate	Minor
Atypical mycobacteria	Liver pathology	Other infection
Lung neoplasm	Diabetes	Other neoplasms
COAD	Mental/behavioural problem	Endocrine problem
- these are considered to affect the management of TB	Eye disorder	Neural problem
	Lower respiratory infection	Ear disorder
	Renal pathology	Circulation problem
	Pregnancy-related problem	Urinary infection
	- these are considered to affect the management of TB	Non-liver GI problem
		Skin problem
		Muscular problem
		Non-kidney GU problem
		Fracture/assault

Coding: A complication/co-morbidity in the severe group was assigned a score of 3, moderate group was 2, minor group was 1.

The following variables were created to indicate the need for care of an individual patient:

- total number of distinct complications plus co-morbidities during treatment; the number of specific TB complications, the number of specific treatment complications and the number of specific co-morbidities.
- the level of severity rating (1, 2 or 3) of the most severe TB complication, treatment complication and co-morbidity during treatment.

8.4.2.3 Determination of utilisation

Several variables were considered to best reflect utilisation and were all chosen because of their resource implications (where resource means all types of resource such as use of facilities, staff time as well as monetary cost ie anything which could have an alternative use). These variables were, *level of care, length of stay in hospital, frequency of visits to a*

clinic (for those on ambulatory care) and *duration of treatment.* The following sections describe how these variables were created.

Level of care during treatment: The level of care at which treatment was given was classified into four categories:

1. Primary care only (private practitioner or GOPD),
2. Chest clinic
3. Specialist clinic (chest outpatient clinic or general specialist outpatient clinic)
4. General hospital or chest hospital inpatient

Variables reflecting these levels of care were:

- *Ambulatory care*: that is, the patient had care at levels 1 to 3 only during treatment.
- *Hospital/specialist care*: that is care at levels 3 to 4 at some time during treatment.
- *General inpatient:* care in general hospital only.
- *Chest hospital:* care in a chest hospital.
- *Inpatient care:* inpatient care at either general or chest hospital.
- *Level of care index:* a weighted score, which was created by assigning a value to each level and calculating each patient's index as: (length of time at that level) x (the value/weight of the level) and summing these for the whole treatment period. Weights used were 0.5 for primary care only, 1 for chest clinic, 2 for specialist clinic and 3 for in-patient. The rationale for weighting primary care as only 0.5 is that it could be considered less than appropriate care since attendance at a chest clinic would generally be recommended for all TB patients.

Length of stay in hospital: This was calculated from the dates of admission and discharge recorded in the medical record.

Frequency of clinic visits: This was calculated by dividing the total ambulatory care treatment period by the number of visits made to a clinic; each ambulatory patient had at least one visit.

Duration of treatment: This was calculated from the dates of starting treatment and completing treatment given in the medical record.

8.4.3 Results

8.4.3.1 Determination of need

The number of patients suffering co-morbidities and complications is shown in Table 8.25 below.

Table 8.25: *Number of patients suffering each number of distinct complications and/or co-morbidities*

Number of problems	**Total number of complications or co-morbidities n (%)**	**Number of TB complications n(%)**	**Number of treatment complications n(%)**	**Number of co-morbidities n(%)**
0	22 (4.8)	254 (55.9)	88 (19.4)	166 (36.6)
1	67 (14.8)	167 (36.8)	103 (22.7)	130 (28.6)
2	68 (15.0)	23 (5.1)	93 (20.5)	80 (17.6)
3	73 (16.1)	1 (0.2)	62 (13.7)	41 (9.0)
4	55 (12.1)	1 (0.2)	39 (8.6)	14 (3.1)
5	49 (10.8)	-	35 (7.7)	9 (2.0)
6	36 (7.9)	-	9 (2.0)	4 (0.9)
7	35 (7.7)	-	9 (2.0)	2 (0.4)
8	14 (3.1)	-	3 (0.7)	-
9-16	27 (5.9)	-	5 (2.4)	-
Missing*	8 (1.8)	8 (1.8)	8 (1.8)	8 (1.8)
Total	454 (100)	454 (100)	454 (100)	454 (100)

* These 8 patients did not start treatment.

The total number of complications plus co-morbidities, the number of treatment complications and the number of co-morbidities were associated with age (Correlation, 0.22, $p<0.001$ and respectively) with increasing age associated with more complications and co-morbidities (Tables 8.26 a-c). The number of TB complications, on the other hand, was not associated with age (Table 8.26d) but was the only variable associated with gender ($F=4.1$, $p=0.045$) with the mean number of TB complications being 0.54 for males and 0.41 for females.

Table 8.26a: *Association of the total number of complications plus co-morbidities with age*

	25 years and under	26 to 45 years	46 to 65 years	66 and over	Total
No complications or comorbidities	5 (9%)	12 (9%)	1 (1%)	4 (4%)	22 (5%)
1complication or comorbidity	18 (33%)	25 (18%)	11 (10%)	8 (7%)	62 (15%)
2 complications or comorbidities	7 (13%)	33 (23%)	14 (13%)	10 (9%)	64 (15%)
3 complications or comorbidities	9 (16%)	27 (19%)	18 (17%)	14 (13%)	68 (16%)
4 complications or comorbidities	3 (6%)	16 (11%)	17 (16%)	15 (14%)	51 (12%)
5 or more complications or comorbidities	13 (24%)	28 (20%)	48 (44%)	60 (54%)	142 (34%)
	55 (100%)	141 (100%)	109 (100%)	111 (100%)	416 (100%)
Correlation	$r=0.39$, $p<0.001$				

Table 8.26b: *Association of the number of treatment complications with age*

	25 years and under	26 to 45 years	46 to 65 years	66 and over	Total
No treatment complications	14 (26%)	32 (23%)	17 (16%)	21 (19%)	84 (20%)
1 treatment complication	18 (33%)	35 (25%)	23 (21%)	15 (14%)	91 (22%)
2 treatment complications	11(20%)	36 (26%)	23 (21%)	19 (17%)	89 (21%)
3 treatment complications	2 (4%)	16 (11%)	18 (17%)	19 (17%)	55 (13%)
4 treatment complications	4 (7%)	9 (6%)	9 (8%)	13 (12%)	35 (8%)
5 or more treatment complications	6 (11%)	13 (9%)	19 (17%)	24 (22%)	62 (15%)
	55 (100%)	141 (100%)	109 (100%)	111 (100%)	416 (100%)
Correlation	r=0.22, p<0.001				

Table 8.26c: *Association of the number of co-morbidities with age*

	25 years and under	26 to 45 years	46 to 65 years	66 and over	Total
No comorbidities	36 (66%)	81 (57%)	26 (24%)	16 (14%)	159 (38%)
1 comorbidity	11 (20%)	42 (30%)	37 (34%)	26 (23%)	116 (28%)
2 comorbidities	5 (9%)	13 (9%)	21 (19%)	34 (31%)	73 (18%)
3 comorbidities	2 (4%)	2 (1%)	16 (15%)	18 (16%)	38 (9%)
4 comorbidities	1 (2%)	0	3 (3%)	5 (5%)	9 (2%)
5 or more comorbidities	0	3 (2%)	6 (5%)	12 (11%)	21 (5%)
	55 (100%)	141 (100%)	109 (100%)	111 (100%)	409 (100%)
Correlation	r =0.48, p<0.001				

Table 8.26d: *Association of number of TB complications with age*

	25 years and under	26 to 45 years	46 to 65 years	66 and over	Total
No TB complications	35 (64%)	79 (57%)	58 (53%)	58 (54%)	230 (56%)
1 TB complication	16 (29%)	53 (38%)	43 (39%)	43 (40%)	155 (38%)
2 or more TB complications	4 (7%)	6 (4%)	8 (7%)	6 (6%)	24 (6%)
	55 (100%)	138 (100%)	109 (100%)	107 (100%)	409 (100%)
Correlation	r = 0.046, p=0.331				

The level of severity of the most severe complication and/or co-morbidity is shown in Table 8.27.

Table 8.27: *Number of patients and the severity level of their most serious complication and/or co-morbidity recorded during treatment*

Rating	**Level of most severe TB complication**	**Level of most severe treatment complication**	**Level of most severe co-morbidity**
0	203 (44.7)	97 (21.4)	143 (31.5)
1	0	56 (12.3)	77 (17.0)
2	211 (46.5)	225 (49.6)	128 (28.2)
3	32 (7.0	68 (15.0)	98 (21.6)
Missing	8 (1.8)	8 (1.8)	8 (1.8)
Total	454 (100)	454 (100)	454 (100)

Only the level of the most severe co-morbidity was associated with age ($F=53.5$, $p<0.0001$); increasing age is associated with increasing severity. Only the level of the most severe TB complication is associated with gender (chi-squared=9.7, 2df, $p=0.008$) with males having more severe complications than females.

8.4.3.2 Association of need variables with final outcome

To investigate the association of the need variables with final outcome, the outcome variable was dichotomized into whether the patient successfully completed treatment and follow up or not according to the data in Table 6.72. Logistic regression analyses were carried out to determine which of the need variables predicted final outcomes, after controlling* for age, gender and type of housing (private, public estate type A or B, other public housing) as a proxy for socio-economic status. Results are in Table 8.28.

After controlling for age and gender, the total number of co-morbidities and the severity of co-morbidities are significantly associated with a poor outcome (OR < 1 so the relationship of these variables with the good outcome is negative) while having minor treatment complications appears to be associated with a good outcome. Since it does not seem reasonable that the association between complications of treatment and a good outcome could be causal, this might be explained by confounding by some other variable related to both recording of treatment complications and outcome such as regular attendance at a clinic.

8.4.3.3 Interdependence of need variables

None of the severity variables were strongly associated with any other: Kendall's tau=0.0833 ($p=0.05$), 0.0746 ($p=0.075$) and 0.0131 ($p=0.744$) for the association between severity of TB complications and treatment complications, co-morbidities and TB complications and co-morbidities and treatment complications respectively. The number of co-morbidities was associated both with the number of treatment complications ($\chi^2 = 82.0$, 12df, $p<0.00001$) and the number of TB complications ($\chi^2=22.8$, 12df, $p=0.029$).

* Note: these variables were controlled for by including them as independent variables in each regression model; that is, we determined the effect of the variable of interest while allowing for the effects of these potential confounders.

In the light of these findings it appears we should retain the several different types of need indicators but since there is an association between some of these, we might drop some of them in order to simplify later calculations. Hence, only one variable for the number of complications or co-morbidities (that for the total number), is retained along with the three separate variables which indicate the severity of the most severe TB complication, the most severe treatment complication and the most severe co-morbidity.

Table 8.28: *Association of need variables with a good outcome defined as "treatment and follow-up completed"*

Variable	n (%)	OR	p	95%CI for OR
Total complications plus co-morbidities				
• 2-4	196 (43.2)	0.89	0.69	0.50-1.59
• 5-16	161 (35.5)	0.75	0.35	0.41-1.38
Total TB complications (baseline = 0 or 1)				
• 2-4	25 (5.5)	0.55	0.16	0.24-1.26
Total treatment complications (baseline = 0 or 1)				
• 2-4	194 (42.7)	1.27	0.29	0.81-1.98
• 5-16	61 (13.4)	0.69	0.24	0.38-1.28
Total co-morbidities (baseline = 0 or 1)				
• 2-4	135 (29.7)	0.41	0.0003	0.25-0.66
• 5-7	15 (3.3)	0.29	0.03	0.10-0.86
Most severe TB complication classed as (baseline = nil):				
• Moderate	211 (46.5)	1.06	0.79	0.70-1.60
• Severe	32 (7.0)	0.93	0.86	0.42-2.06
Most severe treatment complication classed as (baseline = nil):				
• Minor	56 (12.3)	2.57	0.01	1.21-5.45
• Moderate	225 (49.6)	1.53	0.09	0.94-2.48
• Severe	68 (15.0)	1.50	0.22	0.79-2.87
Most severe co-morbidity classed as baseline = nil):				
• Minor	77 (17.0)	0.92	0.78	0.48-1.73
• Moderate	128 (28.2)	0.70	0.22	0.40-1.23
• Severe	77 (17.0)	0.40	0.004	0.22-0.75

8.4.3.4 Determination of utilisation

Level of care during and after treatment:

Table 8.28: *Highest level of care experienced*

Highest level of care	n (%)
Primary (PP or GOPD) only	0
Chest clinic and primary care	186 (41.0)
Specialist clinic	14 (3.1)
General hospital	50 (11.0)
Chest hospital	193 (42.5)

As Table 8.28 shows, no patient received only care from a PP or GOPD for the whole of their treatment period. However 41% received care only from a chest clinic or from a chest clinic

plus a primary care practitioner. A large number (43%) were inpatients in a chest hospital at some time during treatment while 11% were inpatients in a general hospital but were never admitted to a chest hospital.

Who uses only ambulatory care? Those using ambulatory care only during treatment, that is, having no inpatient care during treatment (n=200) were significantly younger than the others (n=253), having a mean age of 43.9 years (sd 18.3) compared with 53.6 years (sd 20.0) (F=28.3, p<0.0001). There was no significant association between ambulatory care and gender or region in which the patients live.

Who attends specialist clinics? In the group who had only ambulatory care during treatment, 14 (7.0%) attended a specialist clinic. This attendance was associated with gender, females being more likely to attend a specialist clinic (χ^2=4.08, 1df, p=0.043) and with the region of home, with those on Hong Kong Island being more likely and those in Kowloon less likely to attend a specialist clinic (χ^2=8.39, 3df, p=0.038). However, there was no significant association between attending a specialist clinic and age (F 0.9986, p=0.481).

Who is admitted to a chest hospital? Among those admitted to hospital during treatment, those admitted to a chest hospital (n=193) are significantly older (mean age 55.6 years, sd 19.2) than those admitted only to a general hospital (n=50) (mean age 45.8 years, sd=19.4) (F 10.24, p=0.0016). There is also a gender difference with fewer females admitted to chest hospitals (χ^2=3.85, p=0.0499) but no association with region.

Who is admitted to any hospital? During treatment, 61 (13.4%) people were admitted to hospital for reasons other than the management of their TB and 224 (49.3%) were admitted for TB management giving a total of 244 (53.7%) people admitted at some time during treatment. If we take only those admitted for management of TB, there was a significant association with the region of residence and admission to any hospital during treatment. After controlling for age, gender and type of housing, patients living in the New Territories East and Hong Kong Island are half as likely as those in Kowloon to be admitted to hospital. Those in New Territories West, on the other hand, are not significantly different from those in Kowloon (Table 8.29).

Table 8.29: *Admission to any hospital during treatment*

Variable	n (%)	OR	p	95% CI for OR
Age (0-39 as baseline)				
• 40-59	118 (26.0)	1.77	0.02	1.08-2.93
• ≥60	159 (35.0)	2.86	≤0.0001	1.78-4.58
Gender (males as baseline)				
• Female	152 (33.5)	0.72	0.13	0.47-1.10
Type of public housing (no public housing as baseline)				
• Estate type A	149 (32.8)	0.89	0.61	0.58-1.38
• Estate type B	38 (8.4)	0.66	0.27	0.32-1.38
Region of residence (Kowloon as baseline)				
• Hong Kong Island	91 (20.0)	0.57	0.04	0.33-0.97
• New Territories East	71 (15.6)	0.53	0.03	0.30-0.95
• New Territories West	84 (18.5)	0.91	0.72	0.53-1.55

Table 8.30: Index to show the level of care (0 to 3) weighted for the percentage of time (0-100%) spent at that level

Index	n (%)
0-100	33 (7.3)
100	174 (38.3)
101-105	27 (5.9)
106-120	71 (15.6)
121-145	58 (12.8)
146-200	44 (9.7)
201-299	32 (7.0)
300	15 (3.3)
Total	454 (100)

The index variable is defined on page 299 There was an association between the index and age, with age increasing as the index increased (r=0.21, p<0.001) and no significant association with gender or region.

Length of stay in hospital: The average length of stay in hospital during the treatment period was 31.8 days (sd 36.6). There was a significant difference between the average length of stay (ALOS) for those admitted at some time to a chest hospital and those only admitted to general hospitals with the first group having an ALOS of 36.2 days (sd 37.5) and the second group 14.6 days (sd 26.8) (F=14.69, p=0.0002).

Age was associated with length of stay during treatment with older patients having a longer length of stay (r=0.24, p<0.001). There was no significant association with gender (F=2.78, p=0.096).

Frequency of clinic visits: The number of ambulatory visits made while on treatment was assessed for those who had no inpatient admission, that is, the whole of their treatment period was ambulatory (n=200). The number of visits ranged from 1 (n=1) to 36 (n=1) with a mean of 11.4 (sd 5.1) and median of 10. Almost three-quarters of the sample had between 7 and 14 ambulatory visits in total. The rate of visits per month (calculated by dividing the number of visits made over the treatment period by the days on treatment and multiplying by 30) varied from 1 visit in three months (n=1) up to 1 visit per day (n=1) or every 4 days (n=1) with a mean of 1.8 visits per month (sd 2.2) and a median of 1.5. Three-quarters of the sample had visited between 1.1 and 2.3 times a month.

There was no difference between the rate of visits for those attending chest clinics only and those attending specialist clinics only. For the chest clinic patients, the mean rate of visits per month was 1.9 (sd 2.6). For those attending a specialist clinic only, the mean was 1.7 (sd 1.0).

There was no association between the rate of visits per month and gender (F=0.665, p=0.416), age (r=-0.008, p=0.908) or region (F= 1.23, p=0.301).

Length of treatment: The duration of treatment ranged from 11 days to 550 days with an average of 234.0 days (sd 75.8) and a median of 197 days. Three-quarters of the sample had treatment durations between 182 and 276 days. There were two distinct peaks in duration, one around six months and one around nine months.

There was no association with gender (F=0.599, p=0.4396) or with region (F=0.012, p=0.998) but older patients had a longer duration of treatment (r=0.16, p=0.002).

8.4.3.5 Association between need variables and utilisation

Relationship between estimated need and level of care utilised

Hospital/specialist care: A variable reflecting hospital/specialist care (specialist clinic or inpatient) was used as the dependent variable in logistic regression analyses with each of the need variables separately used as independent variables along with the potential confounders, age, gender and housing type (a proxy for socio-economic group).

The total number of co-morbidities and complications recorded was significantly associated with having care in the hospital specialist sector (general or chest hospital or specialist clinic) rather than ambulatory care at a chest clinic or general practitioner (Table 8.32). The severities of TB complications and co-morbidities were also associated with this variable; those with the most severe TB complications were 12 times more likely to have care at a higher specialist level than those with no TB complications.

Table 8.32: Relationship between variables indicating need and those indicating care at hospital specialist level

Variable	n (%)	OR	p	95% CI for OR
Total complications plus co-morbidities (baseline = 0 or 1)				
• 2-4	196 (43.2)	3.83	<0.0001	2.15-6.83
• 5-16	161 (35.5)	8.41	<0.0001	4.46-15.86
Most severe TB complication classed as (baseline = nil):				
• Moderate	211 (46.5)	3.39	<0.0001	2.23-5.14
• Severe	32 (7.0)	12.05	<0.0001	4.00-36.31
Most severe treatment complication classed as (baseline = nil):				
• Minor	56 (12.3)	0.80	0.5222	0.41-1.57
• Moderate	225 (49.6)	1.41	0.1584	0.87-2.28
• Severe	68 (15.0)	1.47	0.2357	0.78-2.80
Most severe co-morbidity classed as (baseline = nil):				
• Minor	77 (17.0)	2.37	0.0033	1.33-4.22
• Moderate	128 (28.2)	4.13	<0.0001	2.40-7.11
• Severe	98 (21.6)	7.15	<0.0001	3.66-13.99

Level of care index: The level of care index was used in the same way as the variable indicating hospital specialist care. The variable was dichotomized by assigning all those having 0 to 100 on the index to the lower category and those above to the higher category.

The number of co-morbidities and complications recorded as well as the severity of TB complications and co-morbidities were all significantly associated with the level of care index (Table 8.33) but the severity of treatment complications was not.

Table 8.33: Relationship of variables indicating need and the calculated level of care index

Variable	n (%)	OR	p	95%CI for OR
Total complications plus co-morbidities (baseline = 0 or 1)				
• 2-4	194 (43.2)	3.85	<0.0001	2.14-6.92
• 5-16	161 (35.5)	6.95	<0.0001	3.69-13.07
Most severe TB complication classed as (baseline = nil):				
• Moderate	211 (46.5)	2.98	<0.0001	1.96-4.51
• Severe	32 (7.0)	9.54	<0.0001	3.44-2.67
Most severe treatment complication classed as (baseline = nil):				
• Minor	56 (12.3)	0.76	0.4232	0.67-1.96
• Moderate	225 (49.6)	1.26	0.3469	0.78-2.04
• Severe	68 (15.0)	1.41	0.2937	0.74-2.67
Most severe co-morbidity classed as (baseline = nil):				
• Minor	77 (17.0)	2.25	0.0061	1.26-4.00
• Moderate	128 (28.2)	3.72	<0.0001	2.17-6.39
• Severe	98 (21.6)	6.65	<0.0001	3.42-12.96

Admission to a chest hospital: Among those admitted at some point during treatment, having moderate or severe TB complications was associated with admission to a chest hospital rather than a general hospital (Table 8.34). However, having co-morbidities was negatively associated with this variable indicating that all co-morbidities, even minor ones, are associated with admission to a general hospital rather than a chest hospital.

Table 8.34: Relationship of variables indicating need and admission to a chest hospital rather than a general hospital (for admitted patients only n=243)*

Variable	n (%)	OR	p	95%CI for OR
Total complications plus co-morbidities (baseline = 0 or 1)				
• 2-4	106 (43.8)	2.69	0.10	0.82-8.81
• 5-16	122 (50.2)	3.18	0.06	0.95-10.67
Most severe TB complication classed as (baseline = nil or minor):				
• Moderate or severe	168 (69.1)	2.00	0.05	1.00-4.03
Most severe treatment complication classed as (baseline = nil or minor):				
• Moderate or severe	168 (69.1)	1.24	0.54	0.62-2.46
Most severe co-morbidity classed as (baseline = nil):				
• Minor	38 (15.6)	0.30	0.0412	0.10-0.95
• Moderate	86 (35.4)	0.29	0.0194	0.10-0.82
• Severe	76 (31.3)	0.57	0.3692	0.16-1.95

* *Admission to a chest hospital or not created as a dichotomous variable and used as a dependent variable in a logistic regression.*

Admission to any hospital: As previously reported, those living in the New Territories East (NTE) and Hong Kong Island (HKI) were less likely to be admitted to hospital for management of TB during TB treatment. A further analysis was carried out to explore this association between region of residence and admission. Two *high need* groups were examined

(1) those with severe or moderately severe TB complications (n=243)

(2) those with 7 or more co-morbidities or complications (n=76).

Using only *high need* groups should ensure that the individuals are more similar in their need for hospital care.

For the first group (1), living in NTE was associated with a reduced chance of admission during TB treatment of 0.39, less than half (95% CI=0.18-0.86, p=0.019) compared with those in other regions, which is consistent with the previous results. For the second group (2), the OR for admission was only 0.18 (95% CI=0.04-0.92, p=0.0386) for those in NTE. The association remains after controlling for severity of co-morbidities, but it is of borderline significance (OR=0.48, 95% CI=0.21-1.09, p=0.0865).

Need and length of stay: The continuous variable representing length of stay was used as the dependent variable in multiple linear regression analyses with the need variables as independent variables.

The total number of complications and comorbidities contributed to the length of stay in hospital (Table 8.35). Along with age, gender and housing type, these variables accounted for 17% of the variation in length of stay. The severity of treatment complications was also associated with length of stay.

Table 8.35: Relationship of variables indicating need and length of stay in hospital

Variable	Beta	p
No. of complications or co-morbidities	0.3924	<0.0001
Severity of TB complications	0.0434	0.5031
Severity of treatment complications	0.2473	0.0001
Severity of co-morbidities	-0.0801	0.3007

Need and rate of visits to ambulatory care: The rate of visiting a clinic was dichotomized above and below the median and analysed using logistic regression with the rate as the dependent variables and the need indicators as the independent variables. Only those attending ambulatory care were included.

After adjusting for age, gender and housing type, the total number of complications and co-morbidities, as well as the severity of treatment complications, were significantly associated with the rate of visits to ambulatory care (Table 8.36), with more severe treatment complications and more total complications and co-morbidities increasing the rate of visits.

Table 8.36: Relationship of variables indicating need and rate of ambulatory care visits for those having ambulatory care only (n=200)

Variable	n (%)	OR	p	95%CI for OR
Total complications and co-morbidities (baseline = 0 or 1)				
• 2-4	90 (42.7)	1.82	0.07	0.95-3.49
• 5-16	39 (18.5)	4.86	0.0005	1.98-11.91
Most severe TB complication classed as (baseline = nil or minor):				
• Moderate or severe	73 (36.0)	1.28	0.41	0.71-2.30
Most severe treatment complication classed as (baseline = nil):				
• Minor	33 (15.6)	1.22	0.70	0.44-3.43
• Moderate	98 (46.4)	4.34	0.0004	1.92-9.82
• Severe	27 (12.8)	5.30	0.0024	1.81-15.52
Most severe co-morbidity classed as (baseline = nil or minor):				
• Moderate or severe	59 (30.0)	1.48	0.24	0.76-2.88

Need and duration of treatment: The variable reflecting duration of treatment in days was dichotomized at the median and used as the dependent variable in logistic regression analyses with each need variable in turn as dependent variables and controlling for age, gender and housing type.

The total number of complications and co-morbidities, the severity of TB and treatment complications and the severity of co-morbidities were all significantly associated with duration of treatment (Table 8.37).

Table 8.37: Relationship between variables indicating need and the duration of treatment

Variable	n (%)	OR	p	95%CI for OR
Total complications and co-morbidities (baseline = 0 or 1)				
• 2-4	196 (43.2)	2.37	0.004	1.31-4.29
• 5-16	161 (35.5)	5.46	<0.0001	2.85-10.47
Most severe TB complication classed as (baseline = nil):				
• Moderate	211 (46.5)	1.95	0.0031	1.25-3.04
• Severe	32 (7.0)	1.71	0.2169	0.73-3.99
Most severe treatment complication classed as (baseline = nil):				
• Minor	56 (12.3)	0.97	0.9317	0.45-2.07
• Moderate	225 (49.6)	2.06	0.0109	1.18-3.60
• Severe	68 (15.0)	3.15	0.0022	1.51-6.56
Most severe co-morbidity classed as (baseline = nil):				
• Minor	77 (17.0)	2.04	0.0241	1.10-3.78
• Moderate	128 (28.2)	4.09	<0.0001	2.26-7.38
• Severe	98 (21.6)	1.81	0.0834	0.92-3.54

8.4.3.6 Summary of association between need and utilisation

There were several significant associations between the variables reflecting need for care and the actual resources used. These are summarised below. For each need variable, the utilisation it is associated with and the direction and strength of the association are shown.

Total number of complications and co-morbidities and utilisation of care: (The value for 5-16 complications and/or co-morbidities is reported here.)

Associated with	*Direction of association*	*Strength of association OR (95% CI or p value)*
Use of hospital specialist care	Positive*	8.41 (4.46-15.86)
Level of care index	Positive	6.95 (3.69-13.07)
Length of stay in hospital	Positive	(p<0.0001)
Rate of clinic visits	Positive	4.86 (1.98-11.91)
Duration of treatment	Positive	5.46 (2.85-10.47)

* *Higher need score = more likely to use hospital specialist care*

Severity of TB complications:

Associated with	*Direction of association*	*Strength of association OR (95% CI)*	
		Severe	*Moderate*
Use of hospital specialist care	Positive	12.05 (4.00-36.31)	3.39 (2.23-5.14)
Level of care index	Positive	9.54 (3.44-2.67)	2.98 (1.96-4.51)
Admission to a chest hospital	Positive		2.00* (1.00-4.03)
Duration of treatment	Positive		1.95 (1.25-3.04)

** This value is for moderate or severe complications*

Severity of treatment complications and utilisation of care:

Associated with	*Direction of association*	*Strength of association OR (95% CI)*	
		Severe	*Moderate*
Length of stay in hospital	Positive	(p=0.0001)	
Rate of clinic visits	Positive	5.30 (1.81-15.52)	4.34 (1.92-9.82)
Duration of treatment	Positive	3.15 (1.51-6.56)	2.06 (1.18-3.60)

Severity of co-morbidities and utilisation of care:

Associated with	*Direction of association*	*Strength of association (OR 95% CI)*		
		Severe	*Moderate*	*Minor*
Use of hospital or specialist care	Positive	7.15 (3.66-13.99)	4.13 (2.40-7.11)	2.37 (1.33-4.22)
Level of care index	Positive	6.65 (3.42-12.96)	3.72 (2.17-6.39)	2.25 (1.26-4.00)
Admission to a chest hospital	Negative		0.29 (0.10-0.82)	0.30 (0.10-0.95)
Duration of treatment	Positive		4.09 (2.26-7.38)	2.04 (1.10-3.78)

The total number of complications and co-morbidities is associated with all of the utilisation variables except admission to a chest rather than a general hospital.

Severity of TB complications is associated with the same four utilisation measures as severity of co-morbidities; however, for one utilisation measure, the association is in the opposite direction with the severity of TB complications increasing the chances of admission to a chest hospital and the severity of co-morbidities decreasing it. The severity of treatment complications has only one associated variable in common with the other two severity indicators, namely duration of treatment. However severity of treatment complications is associated with length of stay in hospital and rate of clinic visits which the other two severity indicators are not. It appears therefore that duration of treatment is affected by the severity of any problem but both the amount of time spent in hospital and the rate of visiting clinics, although not the use of hospital or specialist care, are principally affected by the severity of treatment complications.

If need is usually matched to use of resources in this patient population, then we may conclude that the duration of treatment is a useful indicator of utilisation since it is positively related to all of the four need indicators. The level of care index is related to three out of the four need indicators. Hence it will be useful to examine the characteristics of those patients with high duration of treatment or a high level of care index who score low on the appropriate need indicators and conversely those with a low level of care index who score highly on the need indicators.

Length of stay in hospital, rate of clinic visits and use of specialist care are also worth investigating further since they reflect high use of resources and so those patients who score high on these indicators but low on need, and vice versa, will also be examined.

Since all of the complications and co-morbidities appear to strongly influence utilization and hence probably reflect real need, these are combined, in the next section, into a single indicator which can be used to control for these aspects of need in further analyses.

Complications of TB and its treatment and the presence of co-morbidities are all strongly associated with use of higher levels of care and duration of treatment.

8.4.4 Estimation of avoidable use of resources

8.4.4.1 Methods

A *need indicator* which takes the severity of both complications and co-morbidities into account was created by classifying patients into the following categories:

1) those with no complications or co-morbidities at all,
2) those with only minor or moderate treatment complications,
3) those with severe treatment complications and only minor co-morbidities or TB complications,
4) those with moderate co-morbidities or TB complications and
5) those with severe co-morbidities or TB complications.

Table 8.38 shows the frequency distributions for this classification, the distribution of duration of treatment and the proportions in each need category who use specialist care. As can be seen, those with less need on this scale have, on average, a shorter duration of treatment and use less specialist care.

Table 8.38: *Relationship between indicator of need and utilisation*

Need level	no of patients (%)	mean (sd) duration treatment (days)	n (%) using specialist/hospital care
1	21 (4.6)	188 (42)	1 (4.8)
2	52 (11.5)	212 (55)	8 (15.4)
3	41 (9.0)	218 (74)	13 (31.7)
4	220 (48.5)	247 (77)	136 (61.8)
5	120 (26.4)	236 (82)	99 (82.5)
Total	454 (100)	234 (76)	257 (56.6)

Being at level 1 or 2 on this scale was taken as an indication of relatively low need. These were patients who, throughout their treatment, had no co-morbidities or TB complications and only minor or moderate treatment complications. Being in level 4 or 5 was taken as an indicator of relatively high need. These people had moderate or severe TB complications and/or co-morbidities.

Attempts were made to identify characteristics of those individuals who are in the low need group but have a relatively high level of utilisation. A high level of utilisation was defined as *duration of treatment* above the median, *level of care index* above the median, *length of stay in hospital due to TB* in top 25% (for those admitted), *rate of visits to clinic* above the median (for those in ambulatory care) or use of *specialist or hospital care.*

In a similar fashion, those in the high need group (level 4 or 5) who had relatively low utilisation were examined. Low utilisation was defined as the reverse of high utilisation i.e. *duration of treatment* below the median, *level of care index* below the median, *length of stay in hospital due to TB* in lowest 25% (for those admitted), *rate of visits to clinic* below the median (for those in ambulatory care) or no use of *specialist or hospital care.*

Analyses were then done including the combined need indicator as a covariate to further control for level of need when looking at associations between other aspects of patients' care and membership of the particular need/utilisation group. The aspects of care examined were site of starting treatment, source of notification and region of residence.

8.4.4.2 Results

Low need and high utilisation: The numbers of patients who had low need and high utilisation were small for most of the definitions of high utilisation. For *level of care index* greater than the median, and need in the lowest two groups, there were only 7 cases; for *length of stay in hospital* in highest 25% and low need, there was only 1 case; for *specialist or hospital care used* plus low need there were only 6 and for *duration of treatment* greater than the median and low need there were 16. Hence there is some evidence of a reasonable match between need, at least as measured by this index, and these four utilisation indicators.

For *rate of clinic visits* above the median and low need, there were 24 cases. However, further analysis showed that none of age, gender, region or type of housing, site of treatment or source of notification predicted an individual to be in this low need, high utilisation group.

High need and low utilisation: The numbers of patients who had relatively high need and low utilisation were larger. When low utilisation was defined as *rate of clinic visits* below the median, there were 36 cases who also had high need; when it was defined as *level of care index* below the median, 130 cases also had high need; when it was defined as *duration of treatment* less than the median, 118 cases also had high need; when the definition was *length of stay in hospital* in the lowest 25%, 51 cases also had high need and when the definition was *no specialist care used*, 130 cases also had high need. Two characteristics were associated with having high need and low utilisation, namely, site of starting treatment and region of residence (Table 8.39). Age, gender and type of housing (proxy for socio-economic status) were not significant in any model. The low utilisation definitions which used length of stay in hospital and rate of clinic visits did not result in any associations and so are excluded from Table 8.39.

*Table 8.39: Those variables which predicted high need but low utilisation for three separate definitions of low utilisation (those with p-value of <=0.10 are shown in **bold**)*

	High need but **duration of treatment less than median** (197 days) OR (95% CI) p-value	High need but **level of care index less than median** (104.5)	High need but **do not use specialist care**
Age			
• 40-59	0.87 (0.50-1.52) 0.624	1.41 (0.82-2.41) 0.210	1.24 (0.70-2.19) 0.463
• ≥60	0.75 (0.44-1.27) 0.280	0.84 (0.50-1.42) 0.511	0.77 (0.44-1.36) 0.367
(baseline=0 to 39)			
Male gender (baseline=female)	1.06 (0.66-1.70) 0.804	0.84 (0.52-1.34) 0.457	0.87 (0.53-1.44) 0.590
Live in			
• Public type B	1.29 (0.80-2.09) 0.298	0.88 (0.55-1.42) 0.602	0.98 (0.59-1.64) 0.949
• Private estate	0.81 (0.34-1.93) 0.627	0.57 (0.23-1.41) 0.222	0.81 (0.32-2.02) 0.646
(baseline= Public type A)			
Region of residence			
• HKI	1.61 (0.90-2.89) 0.108	1.23 (0.69-2.17) 0.483	1.41 (0.77-2.59) 0.265
• NTE	1.07 (0.55-2.05) 0.845	**1.73 (0.95-3.15) 0.071**	**1.88 (1.00-3.54) 0.050**
• NTW	1.60 (0.89-2.87) 0.116	0.74 (0.39-1.39) 0.346	0.76 (0.38-1.50) 0.425
(baseline = Kowloon)			
Start treatment in a chest clinic or chest hospital (baseline= anywhere else)	**1.76 (0.98-3.15) 0.059**	**2.10 (1.17-3.78) 0.013**	**3.14 (1.54-6.37) 0.002**

Once again we observe an association between utilisation of care and living in New Territories East (NTE) in that NTE patients are more likely not to use specialist care, despite a high level of need, reflecting the previous finding of fewer hospital admissions for these patients.

The source of care at which treatment is started may be associated with duration of treatment, and level of care after taking the level of need into account. This may reflect the fact that medical decision making within different services often determines the use of resources to some extent independently of the patient's need for care.

Duration of treatment by site of starting treatment: When need is controlled for, it appears that there may be an association between duration of treatment and the place of starting treatment. When *place of starting treatment* is classed as *within the chest service* (chest clinic or chest hospital) and compared with outside the chest service, analysis of variance (ANOVA) shows that those starting treatment outside the chest service have a longer duration of treatment ($F=13.67$, $p<0.001$). There is also some interaction between the source of starting treatment and the need variable ($F=3.47$, $p=0.063$) but the association holds

for the different levels of need (Figure 8.34). This means that the different sources of care do attract patients with different scores on the need indicator but even after allowing for this, using our combined need variable, there seems to be evidence that a patient starting treatment outside the chest service may have a higher chance of having longer treatment duration. Table 8.40 shows the mean duration for each source, adjusted for age.

Figure 8.34: *Duration of treatment for different levels of need by site of starting treatment*

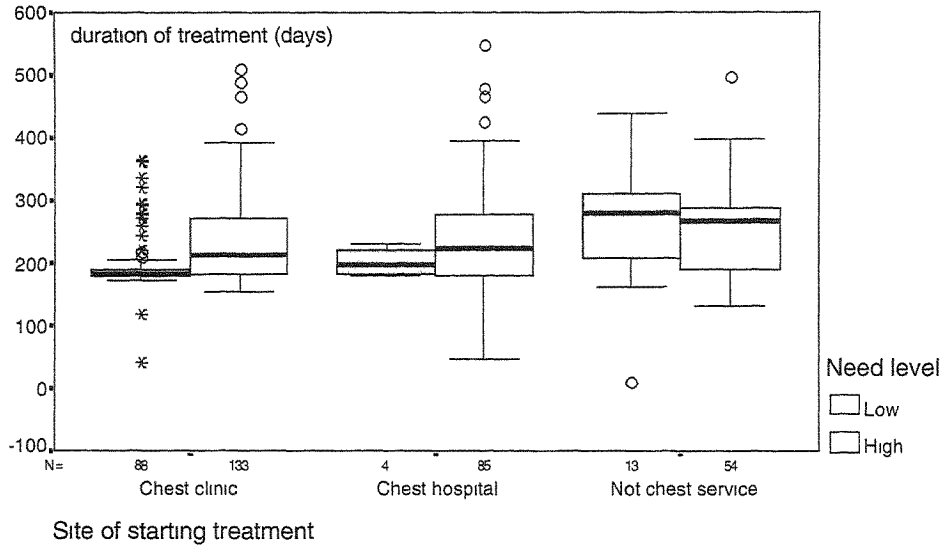


Table 8.40: *Age-adjusted duration of treatment in days for those patients who start treatment at different sources of care and have different levels of need*

Source of starting treatment	Patients with higher need: mean duration of treatment	Patients with lower need: mean duration of treatment
Within the chest service	239.48	201.53
Outside the chest service	259.59	266.62

The data collected in the study on the recorded reasons for extended treatment duration is shown in Table 8.41.

Table 8.41: *Site of starting treatment by reason for extended treatment*

Reason	Within chest service	Outside chest service
Not applicable	213 (59.5)	38 (43.2)
Extensive disease	15 (4.2)	5 (5.7)
Extra-pulmonary	3 (0.8)	5 (5.7)
Drug intolerance	26 (7.3)	6 (6.8)
Poor compliance	12 (3.4)	3 (3.4)
Other conditions	15 (4.2)	6 (6.8)
Re-treatment/relapse	18 (5.0)	4 (4.5)
Drug resistance	5 (1.4)	1 (1.1)
Other	5 (1.4)	2 (2.3)
Unknown	31 (8.7)	13 (14.8)
Total	358 (80.3)	88 (19.7)

At least some of the difference in treatment duration may be due to the higher levels of extra-pulmonary disease and unknown reasons for extended treatment in patients who start treatment outside the chest service.

Use of specialist care by site of starting treatment: In light of the apparent difference between those who started treatment within the chest service and those who did not, a further investigation examined more closely the pattern of care of these groups.

Of those who started treatment in a chest clinic (61% of whole group, Figure 6.13), 93% had at least some further contact with a chest clinic during treatment. For those starting treatment in a chest hospital (28%, Figure 6.14), this proportion was 81% and 7% remained at hospital level. For those starting treatment in a general hospital (Figure 6.15) 78% had contact with a chest clinic and 19% remained at specialist level. Hence out of 6,500 notified patients annually, 235 or 4% might be retained at hospital/specialist level.

To investigate whether this 4% were at a higher level of need for care, an examination of the pathways of care and severities of co-morbidities and complications was carried out for the patients who started treatment at a general hospital.

Use of specialist care by severity of co-morbdities and complications: Of the group who started treatment at a general hospital, 40 patients had contact with a chest clinic at some point in their treatment and 14 did not. The level of severities of co-morbidities and complications are shown in Table 8.42.

It appears that those who were cared for only at a specialist level had lower levels of severity, using our classification, than those who had some or most of their care within chest clinics. While this finding is not, at this stage, conclusive, it certainly does not support the hypothesis that those receiving only hospital/specialist care have greater need. It therefore raises a question which may be examined in a further study.

Table 8.42: *Comparison of severity of co-morbidities and complications between those with and those without follow-up in chest clinics*

	Severity level of co-morbidity or complication		
	Nil or minor n (%)	Moderate or severe n (%)	p
For co-morbidities			
• Attend CC	14 (35)	26 (65)	
• Do not attend CC	8 (57)	6 (43)	<0.05
For treatment complications			
• Attend CC	10 (25)	30 (75)	
• Do not attend CC	7 (50)	7 (50)	<0.05
For TB complications			
• Attend CC	16 (40)	24 (60)	
• Do not attend CC	5 (36)	9 (64)	

Preliminary costing: A very preliminary costing was made using only cost of chest clinic visits and days of spent in hospital for TB treatment (days spent in hospital for treatment of co-morbidities was excluded). The cost of a chest clinic visit was estimated by dividing the total staff cost of the chest service in 1993/94 by the number of visits made to a chest clinic

and rounding up to $120. The cost of a hospital day was estimated as $1700 being the value intermediate between the Hospital Authority's estimated cost of a Group I bed and a Group III bed per day in 1995/96. These costings are very approximate and clearly incomplete since they do not include treatment or investigation costs; nor do they include patient costs such as travel to the clinic. They serve only as an illustration and more detailed costing will be carried out.

The range of costs is $120 to $408,960 with a median of $2,880 and a mean (sd) of $30,335 (53,616). Those who were not admitted have a median cost for their chest clinic visits of $1,200, range $120 to $4,320. Those who were admitted for TB treatment have a median cost of $38,970, range $2,540 to $408,960. For those who completed treatment and follow-up, the median cost was $2,160; and for those still on treatment, it was $79,770. Details are in Table 8.43.

Table 8.43: *Approximate cost of clinics and hospital stay by category of final outcome*

	n	median ($)	range ($)
Completed treatment and follow-up	306	2,160	360-209,200
Lost to follow-up	49	1,560	240-136,600
Still in therapy/relapsed	34	79,770	840-408,960
Migrated before or during treatment	11	17,480	120-99,480
Died	11	18,320	600-253,900

When these preliminary costs are sub-divided by category of need according to the classification on p311 and the means adjusted for age, gender and type of housing, we get the following result (Table 8.44).

Table 8.44: *Adjusted mean preliminary cost of chest clinic visits and hospital days by need classification*

Category of need	n	adjusted mean ($)	s.e.
No complications or co-morbidities	18	5,201	12,273
Minor or moderate treatment complications	52	16,747	7,427
Severe treatment complications and minor co-morbidity or TB complications	37	19,049	8,565
Moderate co-morbidities or TB complications	211	34,816	3,555
Severe co-morbidities or TB complications	111	36,020	5,097
	F=2.882	p=0.022	

8.5 Discussion

In this analysis, each complication or comorbidity is given equal weight so that the presence of a variable at any stage of the study (pre-treatment, during treatment, after treatment) means that the patient is assigned to that category. At least one complication of treatment was present in 79% of patients and 67% have at least one co-morbidity. There are very few

patients in the zero score category but it appears to be a distinct category when cumulative length of stay is examined.

From these data, the probability of a patient being in the increased risk category for CXRs or blood tests can be calculated. For each category, the probability of being offered a CXR or given a blood test during treatment is known from section 8.2, as is the probability of experiencing high or low rates of CXR examination or blood test investigation. It was therefore possible to construct algorithms to illustrate the probability of patients in the main survey experiencing different levels of investigation during treatment (Figures 8.31-8.33). The cut-off points shown eg ≤5 CXR have been chosen to be the median for the high risk group. This is done only to illustrate the process and these models can be developed and refined. For example, discussion with clinicians and further outcome studies on patients investigated during the management of TB will help to determine where this cut-off should be set.

There are strong arguments for the development of a *need* score (as for other specialties) for use in planning and the delivery and evaluation of services. For this we should try to avoid using data which simply reflect the *supply* of health care. We have tried to do this by using an *a priori* classification of complications and co-morbidities. We recognize that this scoring over-simplifies the clinical situation; many conditions have a wide range of severities and that there are other factors which are not included but which may be important, such as psychosocial issues. However, the scoring systems developed here *do* show some interesting associations with utilisation, and may form the basis of future work on developing measures of clinical resource use in tuberculosis services in relation to case mix.

Minor treatment complications are associated with successful treatment and follow-up. The most likely explanation for this is that those patients who attend regularly and have relatively uncomplicated treatment may still have minor problems and have them recorded. The other patients may either have more severe problems or do not attend regularly, both of which are more likely to lead to unsuccessful treatment.

There is an interesting association between admission to hospital during treatment and region of residence. The lower level of admission recorded for those living in the New Territories East (NTE) and on Hong Kong Island, compared with those living in Kowloon may be explained by differing case-mix but may also indicate variation in admission practices and/or psychosocial factors. Possible explanations and conclusions might include inequity in health care for those in NTE or over provision for those in other areas. Further studies on geographic variations in health care for patients with TB are indicated and would provide useful information on where and how services could be improved and more closely matched to patients' needs.

The survey inevitably reveals many areas where services can be improved and particularly where there must be better matching of care to higher need. However, we did not apparently find any significant mismatch between need and care provided for those with lower need. None of the variables, age, gender, region of residence, type of housing or place of starting treatment appeared to predict an individual being in a low need/ high utilisation group.

The principal factor which was identified as possibly contributing to less utilisation by those in the higher need group was the site of starting treatment. Those starting treatment within the chest service (chest clinics or chest hospitals) appear to have low utilisation even when

their need score is apparently high. This could be an artifact of the analysis in that the need score may not (in fact does not) include all possible factors of importance and those beginning treatment in, say, a general hospital may be clinically more difficult cases. However, again, this raises further hypotheses which could be examined.

Key messages and action points

- Patients under active treatment with tuberculosis include a large proportion (about 30%) who have high levels of need with multiple complications and co-morbidities.

- It is feasible and practicable to examine the relationships between levels of need and type of care provided by using need scores.

- At present, levels of care for low need patients appear to be well matched to need. For high need patients the pattern of care is mixed and may be related to site of starting treatment and geographic source of referral.

- Clinical records in TB services should be designed and developed to provide information on *need* and *services provided* to facilitate assessment of the match between need for and provision of care.

- Preliminary costing of care provided shows a clear trend between the selected need indicators and mean costs. For patients with any treatment complications and/or minor comorbidities or TB complication there is a three to four fold increase in costs compared with those who have no complications or comorbidities.

  Patients with more severe comorbidities or TB complications experience a seven fold increase in costs.

- Audit based on need scores and resource use should become an integral part of information management in TB services.

9.0

CLINICAL AUDIT AND MEDICAL RECORDS SYSTEMS FOR TUBERCULOSIS CARE

9.0 CLINICAL AUDIT AND MEDICAL RECORDS SYSTEMS FOR TUBERCULOSIS CARE

9.1 INTRODUCTION

This report makes a strong case for the establishment of a system of clinical audit as one of the principal means of achieving quality assurance in tuberculosis services. Clinical audit can be defined as (Shaw and Costain 1989):

> "a systematic approach to peer review of medical care in order to identify opportunities for improvement and provide a mechanism for realising them"

Clinical audit refers to all aspects of clinical care, including the role of nursing and paramedical staff. We would also include any management or information function which directly or indirectly supports the provision of care for tuberculosis.

9.2 A FORMAL FRAMEWORK

Audit in tuberculosis services should be introduced as a formal framework linked to clear objectives for all aspects of the provision of care. It must be supported by appropriate standard documents, schedules and timetables. The outputs of audit procedures should be subject to independent peer review and a way of ensuring that this can take place in a manner acceptable to all staff should be worked out. Regular audit meetings should include discussion and interpretation of data from audit enquiries. Audit reports should become part of the routine annual Chest Service Report.

This report could be used as a basis for implementing clinical audit in Hong Kong tuberculosis services, using the seven principles enunciated by Shaw and Costain.

9.3 THE SEVEN PRINCIPLES

9.3.1 *The Department of Health and Hospital Authority should define their joint responsibilities for the quality and continuity of patient care.*
In the context of TB services this means that objectives and detailed protocols for all aspects of patient management, including procedures such as notifications, across different sectors and levels of the service should be clearly set out and agreed. The management and resolution of variation in the delivery of care from these protocols would be one of the important benefits of audit.

9.3.2 *The staff responsible for operating TB services should organize themselves into appropriate working groups to fulfil the necessary arrangements for audit and for taking action on the results in order to improve performance.*
One acceptable arrangement might be to have as the main audit committee the Joint Coordinating Committee which in turn would form sub-working groups to deal with the audit of different aspects, including notifications, clinical records and information management, admissions, referrals and outcomes of treatment.

This report reveals several problems which are relevant to the care of patients. A further review of the report by the clinical teams should be used to guide the selection of priority areas for audit. The aim should be to examine trends in specific process and outcome measures over time to demonstrate improvement, or lack of it.

9.3.3 *Audit should be fully documented.*
Audit groups should meet regularly. The report of clinical audit should be fully documented and presented in a way which facilitiates assimilation and understanding.

9.3.4 *Clinical audit should be subject to evaluation*
This means that clinicians and managers within the DoH and HA should be able to complete questions about the key issues relating to structure, process and outcome (see box modified from Shaw and Costain).

1. Structure
   - 1.1 There is formal agreement among health authority (DH/HA), management, and medical, nursing and other supporting staff on responsibility for audit.
   - 1.2 Clinical staff corporately accept responsibility for the quality of medical care within the service.
   - 1.3 There is a named physician and/or other health professional or group, or both, to coordinate medical audit with the clinic or hospital.
   - 1.4 There are formally constituted working groups with responsibility for audit matters relating to e.g. therapeutic policy, management protocols, medical records, notifications etc.
   - 1.5 Time for audit is identified in individual clinician's programmes.
   - 1.6 Timely, accurate local data are available to each area of concern in TB services.
   - 1.7 Clerical and technical support and other necessary resources are allocated for clinical audit.

2. Process
   - 2.1 Each audit working group meets formally and regularly to review audit procedures and data.
   - 2.2 These reviews and other meetings should
     - (a) be attended by all members of the specialty
     - (b) include the work of each unit.
   - 2.3 Conclusions and recommendations should be
     - (a) recorded for reference
     - (b) distributed to all relevant staff
     - (c) reviewed to assess progress.
   - 2.4 Clinical staff, managers, and others should receive regular audit reports.
   - 2.5 The TB service should produce a regular summary of process and outcome of audit each year.

3. Outcome
   - 3.1 Recommendations should lead to documented changes in:
     - (a) availability of services
     - (b) organisation of services
     - (c) written clinical policy
     - (d) clinical practice.
   - 3.2 Improvement is measured in key issues such as:
     - (a) use of resources failure to achieve outcome objectives
     - (b) "avoidable" morbidity and mortality.

9.3.5 *All staff in each unit (eg chest clinic, hospital, ward) involved in providing services should be involved in a regular routine programme of audit*
The audit programme should be tailored to the work of each unit which provides services for tuberculosis patients. The different patterns of care, for outpatients, in-patients, patients receiving DOTS or under longer term follow-up should all be taken into account. Special arrangements should be made to audit notifications, contact tracing and other functions of TB services. These include all diagnostic and therapeutic procedures.

Consideration should be given to the need to apply audit to any roles played by the private sector in the management of TB.

9.3.6 *The design of the process of audit which is introduced should be guided by the standard criteria, including:*

- *relevance to the service*
- *objectivity*
- *quantified measurements*
- *repeatability*
- *capability to effect worthwhile changes in delivery of care*

9.3.7 *TB services should be provided with all necessary resources for audit*
The need for audit and its role should be accepted as an essential feature of any future developments of a modern TB services. There should be sufficient resources to implement the audit cycle, including establishment of comprehensive, accurate, reliable and timely patient data bases and information systems. Clinicians must be closely involved in both the operating and evaluation of these systems to ensure their relevance and application to patient care.

Adequate clerical and technical support should be provided together with additional clinical posts which may be needed to enable audit to become an integral part of the service. If these resources are not provided for audit then it will not be possible for quality standards to be maintained and problems with both individual patient care and the public health function of tuberculosis services will continue.

9.4 Information for effective and efficient care for TB

The treatment of TB is, like the treatment of any health care problem, highly dependent on good quality and timely information. In the TB services in Hong Kong, the use of several health care providers, a variety of sites of care and a multiplicity of diagnostic, investigative and therapeutic strategies make efficient recording and retrieval of information essential, but complex. The necessity of timely and complete notification for disease control and planning adds a further level of importance and complexity to the information processing. Such a situation requires an organised systems approach. In Hong Kong, as this survey has shown, there is variability in completeness of recording of data and in the timeliness of its collection, under-reporting is a potentially serious concern and the quality of information transfer between different sites of care is variable. Furthermore, there are gaps in the data which are recorded. For example, we were unable to collect data on smoking status for many patients; also psychosocial factors are not recorded and some of these would be relevant to our

classification of need as in Chapter 8. The forms used for data collection and for passing information on to further sites of care vary between clinics and hospitals; sometimes the discharge summary is essentially a letter.

There are several steps in developing strategies to resolve these problems. The first is to agree on a systems approach and develop, apply and monitor the procedures for the collection of an agreed data set. The existing clinical record forms in use in the chest clinic are shown in Appendices 5 and 6. The hospitals use different data collection forms. Several organisations, including WHO and IUATLD (Rieder et al, 1996), and the US CDC (CDC, 1995) have advocated a uniform case definition and recording of a minimum set of variables for disease surveillance. These are summarised Appendix 7.

For good quality patient care, this *minimum data set* should go beyond the data elements required for surveillance only and include the relevant clinical information on which the patient's care depends. The surveillance data would then be produced as a by-product. In this way, with data collection which is integral to the patient's clinical care, the system is more likely to ensure the collection of accurate surveillance data. The data must also be available whenever the patient is in contact with the health care system. The best approach to achieve these objectives, and the direction in which the service should be moving, is an integrated patient record available at every site where TB patients are treated, through a computer-based patient record system. Such a system should be linked with laboratory and pharmacy systems already being developed within the HA. Having a reliable linkage between physician notification, laboratory data and pharmacy returns has been shown to be the best approach to obtaining complete coverage of potentially notifiable cases (Brown *et al.* 1995).

In Hong Kong, one approach to linking outcomes to aspects of care is by the use of Patient-Related Groups (PRG). The forms for collection of TB PRG data are in Appendix 8. Ideally this data should also be collected routinely.

Another useful approach to sharing the necessary information at different points of the service is a patient-held record (McGhee *et al.* 1991). This is not suggested as an alternative to an integrated computer-based record but a useful addition and a step which can be taken with minimal additional input of resources.

The effectiveness of any computer-based system is dependent on having established procedures for its use. This procedural structure is also essential for effective operation of a paper-based system, such as that in current use in Hong Kong. An adequate structure with appropriate checks should improve the completeness of notifications and reduce loss to follow-up. Feedback to clinicians would allow for continuous updating of data (eg sputum, smear and culture status, revision of diagnosis) and would encourage clinicians to notify. This can be tackled even before a computer-based record is available. To structure the data collection and to prepare for the computer-based record, a paper-based record can be used. Appendix 9 includes drafts of a) a clinical record and b) a patient-held record both of which could be used as paper records and also as the basis for a computer-based record. The most important components of such a record system are described below.

Development of a medical record system for tuberculosis

Objectives of the record: The development of any record system should be based on explicit agreed objectives. These may relate to the style and content of the record, for example, its comprehensiveness, completeness, reliability and use. It should form a cumulative account of patient problems, management and progress as well as providing the data for contact tracing and disease surveillance. Sufficient information should be included to enable routine audits, such as those described in this report, in order to assess and maintain the quality of patient care.

In describing the role of the record and the procedures for its completion, use and transmission when required, a flowchart is useful. The record, flowcharts and the audits (procedures and outputs) should be an integral part of the training of junior staff and the basis for continuing medical education for all staff.

Design of the record: The format of the record is important. A good structure encourages systematic approaches to the use of the record and good recording practices. It facilitates evaluation and the application of information technology (IT). The problem-oriented medical record (POMR) approach is undoubtedly the best general format, particularly because it provides an index to the record in the form of a problem list. Although a full POMR is not necessary at the outset, it is relatively simple to design and implement a structured record using the POMR concepts. An example of such a record is in Appendix 9.

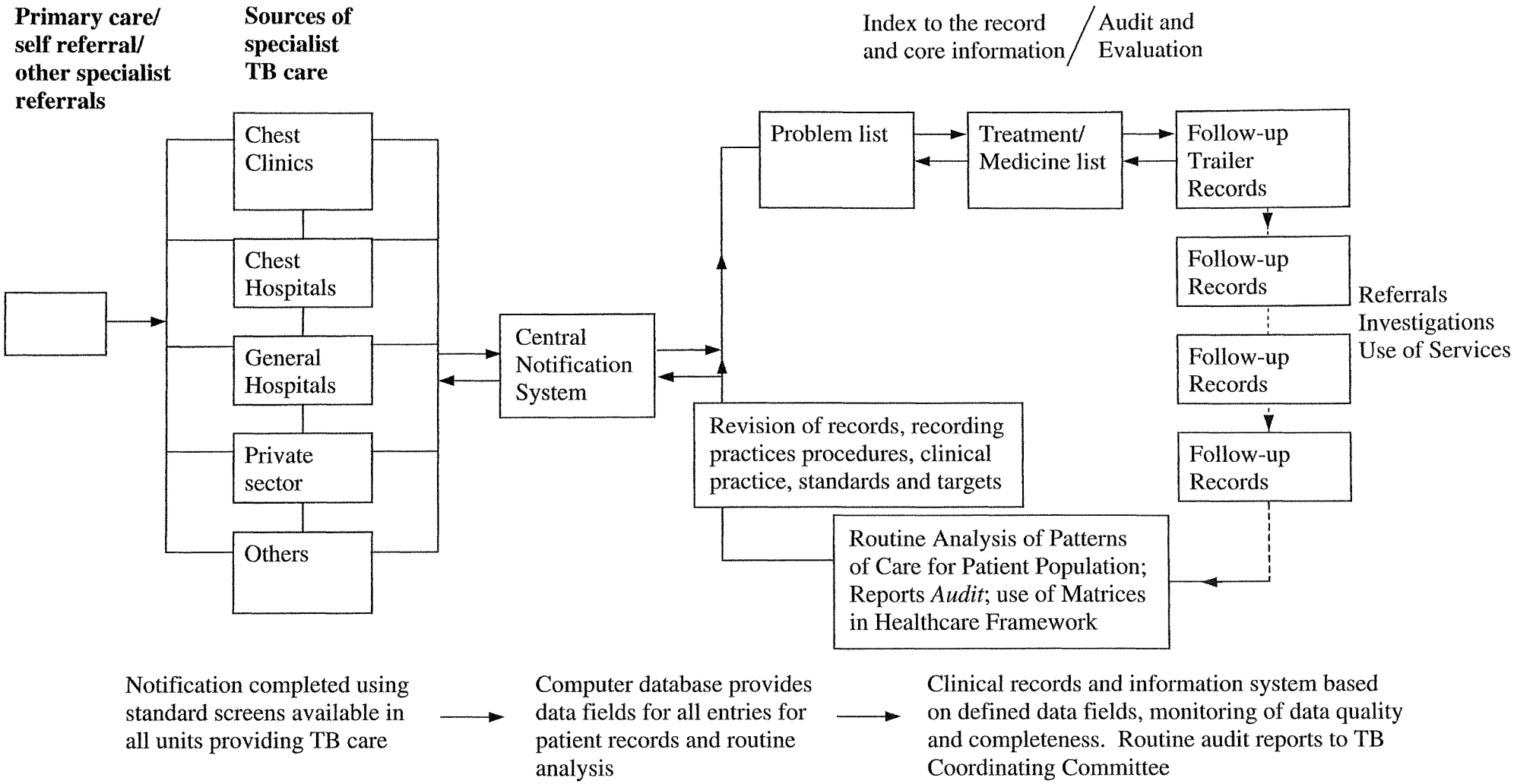
Content of the record: The clinical database should be specified and agreed. This is the only way to set standards and develop a uniform record system. Sections of the data can be optional or obligatory. Making data obligatory helps to ensure completeness but, if that data is difficult to obtain at the time of completion of the record, it causes inconvenience and may result in invalid data being entered as individuals try to escape the limitations of obligatory fields. Optional data fields are, however, more likely to result in incomplete data. Hence education of, and agreement from, all the relevant clinical and non-clinical staff is essential.

Use of the record: Implementation of new records and their use is inevitably difficult since it involves changes in practice. However, this transition must be made and it is important that the requirement to use records, and to use them well, is made a contractual duty. Team meetings based on discussions of data arising from the records is one way to focus attention on the importance of the record as a source of information. The use of the record will eventually be more efficient and potentially more useful, if it is held in electronic form. The production of a patient-held record for the patient's use will also then be simpler, likely to improve patient satisfaction and make the contacts with a variety of different health care staff both safer and more effective. Some concern has been expressed about confidentiality in the use of a distributed clinical information system. However modern encryption methods can obviate these potential problems and the records would be more secure than the current manual versions.

Linking the notification system and routine clinical record and information system

We suggest that a fresh approach is taken to the *continuing development* of a computer based notification system and its eventual linkage to the clinical record system. The clinical record should always carry details of the notification record and the management and analysis of the notification record would be enhanced by having incorporated a defined set of clinical data.

Figure 9.1: Simple schema for links between all care providers



The notification system should be under continuous analysis with regular reports to senior clinicians. Feedback from the system should include a standard document for the patient's clinical record. The problem of information and document transfer between different sets of manual records will eventually be overcome when the tuberculosis services have a standard distributed clinical information system. This will take years to achieve but the work must begin now.

Figure 9.1 schematically indicates how the notification system should be linked to all providers of care and to routine clinical records. The clinical record should, as stated earlier, comprise agreed defined data fields for most data items which might be captured and recorded.

If the development of a linked notification and clinical record system became the central focus of the TB Coordinating Committee, or another specially designated task force, then it is predictable that the quality of information for individual patient care and intelligence for service planning and evaluation would improve.

The benefits would be measurable in terms of information comprehensiveness, completeness, accuracy, reliability, transferability and timeliness and ultimately in quality of care.

Key messages and action points

- The DH and HA should define their joint responsibilities for TB care to provide a truly integrated and seamless service.

- A system for clinical audit should be established. Audits should be carried out regularly and should be evaluated.

- A comprehensive clinical record should be develop and implemented, preferably a computer-based record. The data recorded in this record would form the basis for clinical care, for surveillance and for audit. The use of such an integrated record should resolve the present discontinuities between services, under-notification and duplicate notification, should improve the type and quality of the information available and hence improve the quality of care.

- The outputs from the notification and clinical records systems should be channelled to support the information needs of the *framework* designed to improve quality of care (see p.229 section 6.0).

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APPENDIX 1

TB CASE DEFINITIONS

The US CDC case definition for TB
The case definition and surveillance for TB in Germany
The Canadian TB Reporting System

Unites States: Tuberculosis Case Definition for Public Health Surveillance[1]

Tuberculosis (Revised 9/96)

Clinical description

A chronic bacterial infection caused by Mycobacterium tuberculosis, characterized pathologically by the formation of granulomas. The most common site of infection is the lung, but other organs may be involved.

Clinical case definition

A case that meets the following criteria:

- A positive tuberculin skin test
- Other signs and symptoms compatible with tuberculosis (e.g., an abnormal, unstable [i.e., worsening or improving] chest radiographs, or clinical evidence of current disease)
- Treatment with two or more antituberculosis medications
- Completed diagnostic evaluation

Laboratory criteria for diagnosis

- Isolation of M. tuberculosis from a clinical specimen* or
- Demonstration of M. tuberculosis from a clinical specimen by nucleic acid amplification test†, or
- Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained

Case classification

Confirmed: a case that meets the clinical case definition or is laboratory confirmed

Comment

A case should not be counted twice within any consecutive 12-month period. However, cases in which the patients had previously had verified disease should be reported again if the patients were discharged from treatment. Cases also should be reported again if patients were lost to supervision for >12 months and disease can be verified again. Mycobacterial diseases other than those caused by M. tuberculosis complex should not be counted in tuberculosis morbidity statistics unless there is concurrent tuberculosis.

---

[1]*CDC. Case definitions for infectious conditions under public health surveillance. MMWR 1997;46:40-41.)*

*Use of rapid identification techniques for M. tuberculosis (e.g., DNA probes and mycolic acids high-pressure liquid chromatography performed on a culture from a clinical specimen) are acceptable under this criterion.

†Nucleic acid amplification (NAA) tests must be accompanied by culture for mycobacteria species. However, for surveillance purposes, CDC will accept results obtained from NAA tests approved by the Food and Drug Administration (FDA) and used according to the approved product labeling on the package insert. Current FDA-approved NAA tests are only approved for smear-positive respiratory specimens.

Canada: The Canadian TB Reporting System

Notification of new active case or reactivated TB

a) Cases with M. TB complex (ie M. tuberculosis, M. bovis excluding BCG strain or M. africanum) demonstrated on culture
b) Cases with significant evidence of activity, and preferably a positive (significant) tuberculin reaction even though bacteriological proof has not been demonstrated, such as:
   i) Chest X-ray changes compatible with active tuberculosis, including idiopathic pleurisy with effusion
   ii) Clinically active non-respiratory tuberculosis (meningeal, bone, kidney etc.)
   iii) Pathological or port mortem evidence of active tuberculosis

Germany: The case-definition and surveillance system for tuberculosis

Based on the current law (Bundesseuchengesetz), active TB cases must be reported to the local public health services as soon as possible. TB cases not yet bacteriologically confirmed, but in which treatment has already been started, are active cases and must therefore also be reported. Death due to TB is likewise reported. The local public health services are responsible for contact investigation and therefore obtain the patient's name and address. Real active TB cases are reported anonymously by the public health services to those responsible at Federal State level. The data are then passed on to the statistical offices.

The following information on TB patients in Germany is thus available: gender, age, foreign or indigenous (nationality), and diagnosis, whether the case was bacteriologically confirmed (by microscopy and/or by culture, if available), and which material (sputum or other) was bacteriologically investigated. For site of disease, a special diagnosis key is used which differentiates between pulmonary and extrapulmonary TB. Tuberculous pleuritis is classed as pulmonary TB, which must be taken into account when comparing with international data. Other registered forms of TB are meningitis, urogenital TB, bone and joint tuberculosis, peripheral lymph node TB, and 'other organs ('other organs' includes, for instance, miliary TB).

As this data is not very satisfactory, some changes are planned in the amended notification law (called 'Infektionsschutzgesetz') scheduled to be in force at the beginning of 2000. Based on this new law, we will be able to provide information, adapted to the WHO/IUATLD notification recommendations, on country of birth and nationality, as well as more detailed bacteriological results, including resistance pattern and site of disease (main organ and other organs). If possible, information on first appearance or recurrence will also be given.

Because of the scarce official statistical data on tuberculosis, the German Central Committee has initiated a surveillance study coordinated by Dr. Michael Forßbohm in Wiesbaden. More detailed information on TB patients is collected together with voluntarily participating local public health services (e.g., length of stay if foreign-born, social status, etc.). Approximately two-thirds of all German local public health services participate so far, and the results have helped considerably to understand the TB epidemiology in Germany.

Information provided by Barbara Hauer, M.D., DZK.

APPENDIX 2

EXISTING NOTIFICATION FORMS

Current form introduced in 1995
Old form phased out in 1995

FORM 1
QUARANTINE AND PREVENTION OF DISEASE ORDINANCE
(Cap. 141)

TUBERCULOSIS NOTIFICATION
Particulars of Infected Person

<table>
<tr><td>Name in English</td><td>Name in Chinese</td><td>Age/Sex:</td><td>I.D. Card/Passport No.</td></tr>
<tr><td colspan="3">Address:</td><td>Telephone Number:</td></tr>
<tr><td colspan="3">Place of Work/
School Attended:</td><td>Telephone Number:</td></tr>
<tr><td>Site of TB
Resp. System ☐
Meninges ☐
Bone & Joint ☐
Other(s) ☐</td><td>Sputum
Smear Culture
Positive ☐ ☐
Negative ☐ ☐
Unknown ☐ ☐</td><td>Disposal
On Treatment ☐
On Observation ☐
Referred ☐
Died ☐</td><td>Hospital/Clinic sent to (if any):
Hospital No.:</td></tr>
<tr><td colspan="4">Duration of stay in Hong Kong: _____ Years
Does patient have a history of past treatment for tuberculosis ? ☐ Yes ☐ No
If yes, please state the YEAR in which he first received treatment: 19 ____</td></tr>
</table>

Notified under the Prevention of the Spread of Infectious Diseases Regulations by

Dr. ..... on ..... / ..... / .....
(Full Name in BLOCK Letters) (Date)

Telephone Number: ....
(Signature)

(Please DELETE whichever is not applicable)
"I will arrange for examination of contacts myself."
"Please arrange for examination of contacts to be done by the Government Chest Service".

Further Remarks:

DH 1A(s)(Rev 94)

FIRST FOLD HERE 此處係第一摺

SECOND FOLD HERE 此處係第二摺

ON HER MAJESTY'S SERVICE 香港政府公函

HONG KONG
OFFICIAL
PAID
香港
郵費已付

Director of Health
Attn: Statistics Unit
Department of Health
21st floor, Wu Chung House
213 Queen's Road East
Hong Kong

TO OPEN SLIT HERE 請由此處開拆

4800909 M.D. 1A

FOLD HERE

MD

TUBERCULOSIS NOTIFICATION

Name: In English ..... In Chinese (*if applicable*)	Sex:	Age:
Address:	Notifier's Case Ref. No:	

Place of Work:
School Attended:

Site of TB		**Sputum**		**Disposal**		Hospital/Clinic sent to (*if any*):
Resp. System	☐	Positive	☐	On Treatment	☐	
Meninges	☐	Negative	☐	On Observation	☐	
Bone & Joint	☐	Unknown	☐	Referred	☐	
Other(s)	☐			Died	☐	

Does patient have a history of past treatment for tuberculosis? Yes☐ No☐

If yes, please state the YEAR in which he first received treatment: .....

Notified under the Prevention of the Spread of Infectious Diseases Regulations, 1955

by ..... on ..... 19.....
(Signature of Notifying Doctor) *(Date of Notification)*

NAME in BLOCK LETTERS .....

For Official Use

(PLEASE DELETE whichever is not applicable:)

"I will arrange for examination of contacts myself."

"Please arrange for examination of contacts to be done by the Government Chest Service."

Further Remarks:

MD

DUPLICATE (Tuberculosis Notification)

Name	Date of Notification
Address	

ON HER MAJESTY'S SERVICE

The Honourable,

The Director of Medical & Health Services,

Lee Gardens,

Hysan Avenue,

HONG KONG.

MEDICAL SERVICES

APPENDIX 3

STUDY DATA COLLECTION FORMS

Forms for study on extent and timeliness of notification
Cohort study data abstraction forms
Private practitioner study forms

THE EXTENT AND TIMELINESS OF NOTIFICATION OF HOSPITALISED PATIENTS

OFFICIAL USE ONLY

1. NAME : _____

2. I.D. NUMBER: ☐☐☐☐☐☐☐☐ _____

3. MEDICAL RECORD NUMBER: ☐☐☐☐☐☐☐ _____

4. HOSPITAL NUMBER: ☐☐☐☐☐☐☐☐☐☐☐☐ _____

5. AGE: ☐☐ _____

6. GENDER: (*MALE / FEMALE) _____

7. SITE OF DISEASE: _____ _____

8. SPUTUM SMEAR STATUS: (* POSITIVE / NEGATIVE/ UNKNOWN) _____

9. SPUTUM CULTURE STATUS: (* POSITIVE / NEGATIVE/ UNKNOWN) _____

10. DEFINITIVE DIAGNOSIS : (*YES / NO) _____

11. DATE OF ADMISSION (DD/MM/YY): ☐☐☐☐☐☐ _____

12. DATE OF DISCHARGE (DD/MM/YY): ☐☐☐☐☐☐ _____

13. DATE OF DIAGNOSIS (DD/MM/YY): ☐☐☐☐☐☐ _____

14. DATE OF INITIATION OF TREATMENT (DD/MM/YY): ☐☐☐☐☐☐ _____

15. DATE OF NOTIFICATION IF KNOWN (DD/MM/YY): ☐☐☐☐☐☐ _____

16. SPECIALITY AT TIME OF STARTING TREATMENT: _____
_____

17. PAST HISTORY OF TUBERCULOSIS: (*YES / NO) _____
If YES, YEAR OF PAST TREATMENT : ☐☐☐☐ _____

18. OTHER CURRENT MEDICAL OR SURGICAL CONDITIONS: _____
_____
_____

*Delete as-appropriate

FRONT PAGE

AENO ☐☐☐☐

(I) PERSONAL DATA:

A. Address:
Did s/he move? *Yes/No
If yes, complete the following:
1. Drt: _____
2. Date of move: ___/___/___

B. Date of birth: ___/___/___

C. Date of first presentation:
1. Definite: ___/___/___
2. Probable: ___/___/___

D. Previous TB: *Yes/No/U
1. X-ray evidence only: *Yes/No
2. Year of first treatment: 19☐☐

E. Site of disease:

1. Pulmonary	
2. Pleural	
3. Lymph Node ( )	
4. Other:	

(II) DIAGNOSIS:

A. Treatment:

	Symptoms	Sputum Smear	Sputum Culture
At start of treatment:	*Yes/No	*P / N / U	*P / N / U
At end of treatment:	******	*P / N / U	*P / N / U

B. Definitive diagnosis:
1. Is there a definitive diagnosis? *Yes/No/ U
For the first definitive diagnosis:

Source: *sputum/
Nature: *smear/culture/
Date of lab. report: / /
Date noted in record: / /

2. Other diagnostic tests? *Yes/No/ U
If yes, complete the following table:

	1	2
Source	*sputum/	*sputum/
Nature	*smear/culture/	*smear/culture/

C. Chest X-Ray:

At start of treatment:	normal/abnormal, specify:
At end of treatment:	normal/abnormal, specify:

(III) TREATMENT:

A. Duration of treatment:

	Date	Source
Treatment initiated:	/ /	
Treatment completed:	/ /	

B. Treatment over 6/12? *Yes/No
If yes, why?_____

C. Compliance:
1. level: *full adherence/default (pattern:_____)/U
2. action: *nil/FU/↑ level of supervision/admit/_____

(IV) DRUG SENSITIVITY:

Sensitivity pattern: *Yes / No / NA / U

	S	H	R	M	Z
Date of specimen(/ /)	*R/S/U	*R/S/U	*R/S/U	*R/S/U	*R/S/U
Date of specimen(/ /)	*R/S/U	*R/S/U	*R/S/U	*R/S/U	*R/S/U

(V) HIV TEST:

Offered? *Yes/No; accepted? *Yes/No; source?_____; status? *1/2/9

(VI) OUTCOME:

A. Final outcome at one year:

	√ here	Date
1. completed therapy and follow-up		*****
2. completed therapy but subsequently lost to follow-up		/ /
3. still on therapy		*****
4. lost to follow-up during therapy		/ /
5. migrated		/ /
6. died related to TB		/ /
7. died of causes unrelated to TB		/ /
8. other ( )		/ /
9. unknown		*****

B. Number of episodes during treatment:

1. TB in-patient	
2. TB ambulatory care	
3. non-TB in-patient	

C. Comments:

_____
_____
_____
_____

DATA ABSTRACTION FORM

EPISODE No. ☐

AENO ☐☐☐☐☐

*Delete as appropriate

(I) SOURCE DATA:

A. FOR THIS EPISODE:

SOURCE CODE: ☐ SOCE ☐

Address: _____ DRT ☐

Medical Record #: ☐☐☐☐☐☐☐☐

*Hospital/Clinic #: ☐☐☐☐☐☐☐☐☐

B. FOR OTHER EPISODES:

(1) SOURCE OF REFERRAL TO THIS EPISODE: ☐ SOCE REFL ☐

For PP: Name: _____ Tel #: ☐☐☐☐☐☐☐☐

Address: _____

_____

Patient identifiers:

Medical record #: ☐☐☐☐☐☐☐☐

*Hospital/Clinic #: ☐☐☐☐☐☐☐☐☐

Other identifiers: _____

Start Date: __/__/__ Finish Date: __/__/__

Referral Date: __/__/__ REFRL DATE

Type of referral (for chest clinic's only): *urgent/elective/other: _____ REFRL TYPE ☐

Planned start date (this episode): __/__/__ PLAN START

Clinical Details: _____

_____

_____

Discharge summaries for patients discharged from hospital:

Is discharge summary filed? *Yes/No DS FILED ☐

Date of discharge summary: __/__/__ DS DATE

Are drugs on discharge listed? *Yes/No/NA DS DRUGS ☐

Are results of investigations listed? *Yes/No/NA DS Ix ☐

(2) OTHER SOURCES OF CARE IN PREVIOUS YEAR RELATED TO TB:

Source 1: _____

Patient identifiers:

Medical record#: ☐☐☐☐☐☐☐☐

*Hospital/Clinic #: ☐☐☐☐☐☐☐☐☐

Other identifier: _____

Start date: __/__/__ Finish Date: __/__/__

Clinical details: _____

_____

Source 2: _____
Patient identifiers:
Medical record#: _____
*Hospital/Clinic #: _____

Other identifier: _____
Start date: __/__/__ Finish Date: __/__/__
Clinical details: _____
_____

(3) OUTCOME OF THIS EPISODE: _____ OUTCOME ☐

Where was the patient referred to after this episode?
Source 1: _____ For TB?: *Yes/No SOCE REFD ☐
What type of referral was it (for chest clinic's only)? *urgent/elective TB ☐
Medical Record #: ☐☐☐☐☐☐☐☐☐ REFL TYPE ☐
*Hospital/Clinic #: ☐☐☐☐☐☐☐☐☐☐

Date of referral: __/__/__ REFL DATE
Date of discharge summary: __/__/__ DS DATE
Planned start date of next episode: __/__/__ PLNDSTART

Source 2: _____ For TB?: *Yes/No SOCE REFD ☐
What type of referral was it (for chest clinic's only)? *urgent/elective TB ☐
Medical Record #: ☐☐☐☐☐☐☐☐☐ REFL TYPE ☐
*Hospital/Clinic #: ☐☐☐☐☐☐☐☐☐☐

Date of referral: __/__/__ REFL DATE
Date of discharge summary: __/__/__ DS DATE
Planned start date of follow up: __/__/__ PLNDSTART

(II) EPISODE DATA:

A. DURATION OF THIS EPISODE:

From: __/__/__ to: __/__/__ START / END

B. AMBULATORY CARE ONLY

Was chest clinic record available at first appointment? *Yes/No/NA MRAVL ☐

List dates of follow-up by doctor in clinic:

FREQ FU ☐
DRUGS TTA ☐
SE ☐
OTHER ☐

	Date FU	Reason		Date FU	Reason
1	/ /		13	/ /	
2	/ /		14	/ /	
3	/ /		15	/ /	
4	/ /		16	/ /	
5	/ /		17	/ /	
6	/ /		18	/ /	
7	/ /		19	/ /	
8	/ /		20	/ /	
9	/ /		21	/ /	
10	/ /		22	/ /	
11	/ /		23	/ /	
12	/ /		24	/ /	

C. THERAPY

On treatment at some point? Yes/No
HRMZS only? Yes/No
For Chest Clinic Only:

THER STAT
REGIMEN

Frequency			
Type			
Duration	/ / to / /	/ / to / /	/ / to / /

	1	2	3
F			
T			

(III) CASE-MIX DATA:

A. COMPLICATIONS OF TB:

Did the patient have any complications of tuberculosis? *Yes/No

COMP TB

	Complication	Onset	Action
1			
2			
3			

C	O	A

HIV test offered? *Yes/No; accepted? *Yes/No; status: *1/2/9

HIVOFF
HIVACC
STATUS

	Smear		Culture	
Date/Result	/ /		/ /	
Date/Result	/ /		/ /	
Date/Result	/ /		/ /	
Date/Result	/ /		/ /	
Date/Result	/ /		/ /	
Date/Result	/ /		/ /	

B. COMPLICATIONS RESULTING FROM TREATMENT:

Did the patient have any complications resulting from treatment? *Y/N/NA

COMPRX

	Complication	Onset	Action
1			
2			
3			
4			
5			

C	O	A

For patient with abnormal liver enzymes:

MAX LEVEL

	Enzyme	Max. Level	Date of specimen
1	Bilirubin		/ /
2	ALT		/ /

B		
A		

C. INVESTIGATIONS:

Were there any additional investigations? *Yes/No

ADD IX

In-patient		Ambulatory Care	
Bronchoscopy		EMU	
CT Scan		Other:	
Pleural aspiration +/- biopsy			
Lung function tests			
Cytology			
Monitoring of drug levels			
PTNB			
Other:			

D. OTHER TREATMENT:

Did the patient receive non-medical treatment? *Yes/No NONMED

Non-medical Treatment	
Pleuradesis	
Lung resection	
Other:	

E. OTHER CONDITIONS:

Did the patient have further active conditions suspected or confirmed? *Yes/No CONDS

	Condition	Source of Care	Date referred
1			
2			
3			

C	S	D

Do any of these conditions directly affect management? *Yes/No DIRAFF

If yes, specify how: _____

_____

F. PSYCHOSOCIAL:

Did the patient require additional care for psychosocial reasons? *Yes/No PSYCH

If yes, specify: _____

G. OTHER REASONS FOR ADMISSION:

Were there other reasons for admission? *Yes/No/NA OTHER

If Yes, specify: _____

H. OTHER COMMENTS:

_____

_____

_____

_____

ADMINISTRATION OF ABSTRACTION:

Tracing round			
Data abstraction for episode completed	*Y/N	*Y/N	*Y/N
Data abstracted directly from medical record	*Y/N	*Y/N	*Y/N
Date of completion	/ /	/ /	/ /

(1) Name: (2) ID Number:

(3) Age (4) Sex:

(5) Date of referral to .

PLEASE COMPLETE THE FOLLOWING (* Delete as appropriate):

(6) Please give the main reason(s) for referral to ·

1._____ 3._____

2._____ 4._____

(7) What was the first date that the patient presented to you with the symptoms that resulted in their referral to (dd/mm/yy)? __/__/__

(8) How many times had you seen the patient for these symptoms before you referred them to ? _____

(9) Did the patient undergo any investigations related to these symptoms whilst under your care? *Yes/No

If yes, please list the investigation(s) performed:

1._____ 3._____ 5._____

2._____ 4._____ 6._____

(10) Did the patient receive any treatment related to these symptoms whilst under your care? *Yes/No

If yes, please list the treatment(s) given:

1._____ 3._____ 5._____

2._____ 4._____ 6._____

Thank you for your kind cooperation.

Please return the completed form as soon as possible in the enclosed stamped addressed envelope to:

Dr R. Hardie,
Tuberculosis Project Coordinator,
Department of Community Medicine,
The University of Hong Kong,
Patrick Manson Building South Wing,
7 Sassoon Road, Hong Kong.

APPENDIX 4

SOURCES OF CARE FOR EACH EPISODE

Source of care	Episodes	%
Government chest clinics		
CC1	46	2.3
CC2	70	3.5
CC3	31	1.5
CC4	62	3.1
CC5	142	7.1
CC6	43	2.1
CC7	84	4.2
CC8	90	4.5
CC9	88	4.4
CC10	81	4
CC11	90	4.5
unknown	1	<0.01
Sub-total	**828**	**41.2**
Clinics(GOPD)		
C1	2	0.1
C2	2	0.1
C3	2	0.1
C4	1	<0.01
C5	1	<0.01
C6	3	0.1
C7	2	0.1
C8	2	0.1
C9	1	<0.01
C10	3	0.1
C11	2	0.1
C12	3	0.1
C13	1	<0.01
C14	2	0.1
C15	1	<0.01
C16	2	0.1
C17	2	0.1
C18	1	<0.01
C19	1	<0.01
C20	1	<0.01
C21	1	<0.01
C22	1	<0.01
C23	1	<0.01
C24	1	<0.01
C25	1	<0.01
C26	2	0.1
C27	1	<0.01
C28	3	0.1
Sub-total	**46**	**2.3**
Private practitioner		
PP	**97**	**4.8**
General hospitals		
GH1	20	1
GH2	3	0.1
GH3	1	<0.01
GH5	1	<0.01
GH6	58	2.9
GH7	4	0.2
GH8	51	2.5
GH9	5	0.2
GH10	39	1.9
GH11	24	1.2
GH12	67	3.3
GH13	24	1.2
GH14	3	0.1
GH15	28	1.4
GH16	1	<0.01
GH17	9	0.4
GH18	18	0.9
GH19	8	0.4
sub sub-total	*364*	*18.1*
General hospitals A&E		
GH1A&E	1	<0.01
GH6A&E	4	0.2
GH8A&E	7	0.3
GH9A&E	1	<0.01
GH10A&E	6	0.3
GH11A&E	9	0.4
GH12A&E	24	1.2
GH13A&E	7	0.3
GH15A&E	5	0.2
GH16A&E	16	0.8
GH17A&E	1	<0.01
GH18A&E	10	0.5
GH19A&E	1	<0.01
sub sub-total	*92*	*4.6*
General hospitals ward follow-up		
GH6ward	4	0.2
GH8ward	5	0.2
GH10ward	1	<0.01
GH12ward	2	0.1
GH15ward	1	<0.01
GH19ward	1	<0.01
sub sub-total	*14*	*0.01*

General hospitals outpatient follow-up		
GH1OPD	7	0.3
GH2OPD	1	<0.01
GH3OPD	1	<0.01
GH4OPD	2	0.1
GH6OPD	9	0.4
GH7OPD	5	0.2
GH8OPD	11	0.5
GH9OPD	1	<0.01
GH10OPD	24	1.2
GH11OPD	14	0.7
GH12OPD	25	1.2
GH13OPD	5	0.2
GH15OPD	4	0.2
GH16OPD	4	0.2
GH17OPD	5	0.2
GH18OPD	10	0.5
GH19OPD	4	0.2
sub sub-total	*132*	*6.6*
Sub-total	**602**	**29.9**
Chest hospitals		
CH1	107	5.3
CH2	13	0.6
CH3	102	5.1
CH4	51	2.5
CH5	61	3.0
sub sub-total	*334*	*16.6*
Chest hospitals ward follow-up		
CH1ward	3	0.1
CH3ward	5	0.2
CH4ward	2	0.1
CH5ward	2	0.1
sub sub-total	*12*	*0.01*
Chest hospitals outpatient follow-up		
CH1OPD	4	0.2
CH2OPD	5	0.2
CH3OPD	16	0.8
CH4OPD	13	0.6
sub sub-total	*38*	*1.9*
Sub-total	**384**	**19.1**
Private hospitals		
PH1	1	<0.01
PH2	5	0.2
PH3	1	<0.01
PH4	2	0.1
PH5	1	<0.01
PH6	1	<0.01
PH8	2	0.1
sub sub-total	*13*	*0.01*
PH1OPD	2	0.1
PH7OPD	1	<0.01
PH8OPD	1	<0.01
sub sub-total	*4*	*<0.01*
Sub-total	**17**	**0.01**
Military hospitals		
MH1	1	<0.01
MH2	1	<0.01
Sub-total	**2**	**<0.01**
Correctional institutions		
CI1	1	<0.01
CI2	1	<0.01
CI3	1	<0.01
CI4	2	0.1
CI5	1	<0.01
CI6	1	<0.01
CI7	3	0.1
CI8	6	0.3
CI9	1	<0.01
CI10	13	0.6
sub sub-total	*30*	*1.5*
Correctional institutions OPD follow-up		
CI4OPD	2	0.1
CI6OPD	1	<0.01
CI10OPD	1	<0.01
sub sub-total	*4*	*<0.01*
Sub-total	**34**	**1.7**
Mortuaries		
M	**1**	**<0.01**
Others		
O	**1**	**<0.01**
TOTAL	**2012**	**100**

APPENDIX 5

CHEST CLINIC CLINICAL RECORD FORMS

Chest Service Public Health Unit card
Treatment card: used to record DOT/semi-supervised therapy
Documents used for contact tracing

CHEST SERVICE PUBLIC HEALTH UNIT CARD

DISTRICT CODE NO.

CLINIC NUMBER

DATE OF 1ST ATTENDANCE PHU

AGE

OCCUPATION

SPUTUM STATUS
(Date of all +ves to be recorded in red)

NAME

Male ☐
Female ☐

Single ☐
Married ☐
Other ☐

1. MAIN ADDRESS
(home etc)

Tel. No.

2. SECOND ADDRESS
(work/school)

Tel. No.

3. THIRD ADDRESS
(relative/friend)

Tel. No.

TREATMENT

Date	Drugs

CHANGE OF ADDRESS
(Any)

DH 1289 (Rev)

Date	*Notes* (All complications/complaints/difficulties to be recorded in full)	*Signature*

CONTACTS

Name	Relationship	Age	Sex	Ref. No.	Findings
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

NB—Contacts, 12 years and under, the following findings should be noted:

A. History of B.C.G. (age when given)
B. Presence or absence of B.C.G. scar
C. Tuberculin test result in M.M.
D. Re vaccination with B.C.G.

HOSPITALISATION			TRANSFER		
Hospital	Admitted	Discharged	From	To	Date

X-RAY FINDINGS

Name in English (block letters)	Treatment number:	Clinic/hospital number:	Sex / Age
Remarks:	Weight (kg):		

Dosages of drugs	-42 kg	43–57 kg	58– kg
Streptomycin	1.0g	1.0g	1.0g
Isoniazid tablets	6	8	10
Rifampicin capsules	2	2	2
Pyrazinamide tablets	4	5	6

Date	S dose	Number of tablets or capsules				Complaints (tick)	
		H	R	Z	†	Yes*	No
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
* S							

Date	S dose	Number of tablets or capsules				Complaints (tick)	
		H	R	Z	†	Yes*	No
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							

Date	S dose	Number of tablets or capsules				Complaints (tick)	
		H	R	Z	†	Yes*	No
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							

Date	S dose	Number of tablets or capsules				Complaints (tick)	
		H	R	Z	†	Yes*	No
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							

Name

Treatment number

Date	S dose	Number of tablets or capsules				Complaints (tick)	
		H	R	Z	†	Yes*	No
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							

Date	S dose	Number of tablets or capsules				Complaints (tick)	
		H	R	Z	†	Yes*	No
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							

Date	S dose	Number of tablets or capsules				Complaints (tick)	
		H	R	Z	†	Yes*	No
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							

Date	S dose	Number of tablets or capsules				Complaints (tick)	
		H	R	Z	†	Yes*	No
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							
M							
T							
W							
T							
F							
S							

Complaints or reactions (tick)															
Rash/itchness															
Difficulty in swallowing															
Dizziness															
Nausea															
Vomiting															
Indigestion															
Other															

Date	*Details of other complaints and reactions, and comments

CONTACT CARD
家 屬 檢 驗 證

（兒童用）

Contact No. 家屬編號 ..... Original Case No. 病者編號 .....

Name: 姓名 ..... Age 年齡 ..... Sex 性別 .....

Date Card Issued: 發證日期

Tuberculin Test 結核菌素檢驗

Date Given: 注射日期 .....

Date Read: 量度日期 .....

T.T. Result 檢驗結果

..... mm. Induration 毫米 硬結

Pos. 陽性 ☐ Neg. 陰性 ☐ B.C.G. Given 卡介苗接種 ☐

X-ray X光檢驗

Date Taken: 照肺日期 .....

Report 檢驗報告 .....

.....

.....

.....

.....

.....

.....

D.H. 776A

CONTACT CARD
家 屬 檢 驗 證

（成人用）

Contact No. 家屬編號 ..... Original Case No. 病者編號 .....

Name 姓名 ..... Age 年齡 ..... Sex 性別 .....

Date Card Issued: 發證日期

X-ray X光檢驗

Date Taken: 照肺日期 .....

Report 報告 .....

.....

.....

.....

.....

.....

.....

.....

.....

D.H. 776 (Rev.)

Please bring this card and your child to the Nursing Section of the Chest Clinic for tuberculin testing on

請于星期　　携貴子女及此證到　　胸肺診療所護理組接受結核菌素檢驗。

Please return, in 72 hours after tuberculin test has been given, for reading.

請于檢驗後七十二小時，再來覆診。

Depending upon the result of the tuberculin test B.C.G. may be given or an X-ray ordered.

根據上述檢驗結果，可能作卡介苗接種或X光檢驗。

Please bring this card with you to Chest Clinic
X-ray Section for chest X-ray

請携此咭到胸肺診療所X光部檢驗

If any abnormality is found in your chest,
you will be informed

經X光檢驗後，如發現閣下胸部有不正常情況者，當另行通告。

APPENDIX 6

CHEST CLINIC PATIENT-HELD CARDS

Appointment card
Treatment card

HONG KONG GOVERNMENT
Department of Health
香 港 政 府 衞 生 署

Consultation Room No.
診 症 室 號 數

CHEST SERVICE
胸 肺 科

.... CLINIC 診療所

Name 姓名 ..... Sex 性別 ..... Age 年歲 .....

Ref. No. 登記號數 .....

Date of Attendance 到 診 日 期	Date of Next Attendance 下次到診日期	Remarks 備 註

NOTE:—Keep this card & bring it with you on your return visit.
注意： 此咭係作掛號及記錄有關事項用，應於每次到診時交出，以免不便。

DH 708

Remarks:
備註：

DH 1628 (Rev)

公眾假期服用藥物請早往藥房取藥

年　　月　　日（星期　）
年　　月　　日（星期　）
年　　月　　日（星期　）
年　　月　　日（星期　）

DEPARTMENT OF HEALTH
GOVERNMENT CHEST CLINIC
衛生署
政府胸肺診療所

TREATMENT CARD
治療證

Drugs to be taken on:
服藥日期：逢星期

打針服藥時間：
星期一至星期五
上午八時至一時
下午二時至五時
五時半至七時半
星期六上午八時至一時
星期日及公眾假期休息

服藥後小便呈紅色屬正常
如有其他不適須看醫生

依時治療
恢復健康

Name:
姓名

Reference No.
登記編號

1	16	1	16	1	16	1	16	1	16	1	16	1	16
2	17	2	17	2	17	2	17	2	17	2	17	2	17
3	18	3	18	3	18	3	18	3	18	3	18	3	18
4	19	4	19	4	19	4	19	4	19	4	19	4	19
5	20	5	20	5	20	5	20	5	20	5	20	5	20
6	21	6	21	6	21	6	21	6	21	6	21	6	21
7	22	7	22	7	22	7	22	7	22	7	22	7	22
8	23	8	23	8	23	8	23	8	23	8	23	8	23
9	24	9	24	9	24	9	24	9	24	9	24	9	24
10	25	10	25	10	25	10	25	10	25	10	25	10	25
11	26	11	26	11	26	11	26	11	26	11	26	11	26
12	27	12	27	12	27	12	27	12	27	12	27	12	27
13	28	13	28	13	28	13	28	13	28	13	28	13	28
14	29	14	29	14	29	14	29	14	29	14	29	14	29
15	30	15	30	15	30	15	30	15	30	15	30	15	30
	31		31		31		31		31		31		31

Treatment No.
醫務編號

Drug	*Dosage*
Rifampicin	
Isoniazid	
Ethambutol	
Streptomycin	
Pyrazinamide	
Duration	Ms

Date:

Signature

Drug	*Dosage*
Rifampicin	
Isoniazid	
Ethambutol	
Streptomycin	
Pyrazinamide	
Duration	Ms

Date:

Signature

Remarks:
備註：

APPENDIX 7

RECOMMENDATIONS FOR A MINIMUM DATA SET FOR TB SURVEILLANCE

From MMWR 44/RR-11 1995

TB Registry

To carry out mandatory community public health responsibilities, health department TB control programs should maintain a computerized record system (case registry) with up-to-date information on all current clinically active and suspected TB cases in the community. To ensure follow-up of all TB patients and those persons suspected of having TB, registry information (e.g., smear, culture, and susceptibility results; clinical status; chest radiograph results; and doses of medications being administered) should be obtained and updated on a continuing basis. A specific health department staff member should review detailed registry information for TB cases at least monthly to identify patients who have potential problems with adherence or response to therapy (e.g., patients who have persistently positive sputum or who are taking medications to which their TB organisms are resistant) and to ensure follow-up (e.g., initiating field follow-up visits or arranging medical consultation with providers). TB control programs also should maintain records on the examination and treatment status of the contacts of infectious TB patients and other groups of high-risk infected persons (e.g., persons coinfected with *M. tuberculosis* and HIV).

TB control programs should assess program performance by determining the rates for completion of therapy, contact identification, and initiation and completion of preventive therapy. At least annually, TB control program staff should assess progress toward achievement of program objectives. To facilitate the monitoring of TB morbidity and program performance, programs should implement computerized systems for data collection and analysis. Program evaluation reports should be shared with the appropriate public, private, and community groups.

TB control programs should periodically review screening activities to assess their effectiveness in identifying infected persons and in ensuring that these persons are completing courses of preventive therapy when appropriate. If reviews demonstrate that few or no new cases are being identified by particular screening activities, these activities should be discontinued.

Programs also should conduct periodic reviews of selected records systems (e.g., laboratory reports, pharmacy reports, AIDS registries, and death certificates) to validate the surveillance system and to detect any failure to report cases.

TB control programs should analyze each new TB case and each death caused by TB to determine whether the case or death could have been prevented. Based on such a review, new policies should be developed and implemented to reduce the number of preventable cases and deaths.

From WHO and European Region of IUATLD, 1996

ABSTRACT: Consensus-based recommendations have been developed by a Working Group of the World Health Organization (WHO) and the European Region of the International Union Against Tuberculosis and Lung Disease (IUATLD) on uniform reporting of tuberculosis surveillance data in the countries of Europe.

A uniform case definition and a minimum set of variables for reporting on each case have been agreed which, when collated on a national basis, will allow comparison of the epidemiology of tuberculosis in different European countries.

The Working Group recommends that the case definition includes "definite" cases, where the diagnosis has been confirmed by culture (or supported by microscopy findings in countries where diagnostic culture facilities are not available), and "other than definite cases" based on a clinical diagnosis of tuberculosis combined with the intention to treat with a full course of antituberculosis therapy. Both "definite" and "other than definite" cases should be notified by physicians and, in addition, laboratories should be required to report "definite" cases.

The minimum set of variables to be collected on each case of tuberculosis should include: date of starting treatment, place of residence, date of birth, gender, and country of origin, to characterise the patient. Recommended disease-specific variables include: site of disease, bacteriological status (microscopy and culture), and history of previous antituberculosis chemotherapy.

The minimum set of variables should be collated on all patients and should be as complete as possible. Additional variables may be collected for individual, local or national purposes, but, in general, completeness of reporting on cases is likely to be better if the information requested is kept to a minimum.

Timely reporting of cases is essential for appropriate public health action. Cases should be reported to the health authority at the local and/or regional level within 1 week of starting treatment. Individual-case based information should be reported to the national level by the local or regional level. Feedback to reporters is essential. At the national level, preliminary quarterly reports should be produced and final reports should be published annually.

Eur Respir J 1996; **9**:1097-1104.

APPENDIX 8

PRG DATA COLLECTION FORMS

HOSPITAL AUTHORITY
RUTTONJEE HOSPITAL

PRG DATA COLLECTION FORM

Please Stick Label if Available or Use Block Letters			
HN:		MRN :	
Name :			
I.D. No. :		Sex :	Age :
Dept :		Ward/Bed :	

PRG - PULMONARY TUBERCULOSIS

Inclusion Criteria
All patients admitted with pulmonary TB as notified under the Ordinance are included in this PRG **(only pulmonary TB and not other types of TB).**

This form has also to be completed for patients admitted for complications of pulmonary TB or its treatment.

A code for pulmonary TB requires a 5th digit. Only the numbers 0 and 3 are used.

0	Unspecified (as to how the organism was positively obtained)
3	Tubercle bacilli found (in sputum) by microscopy

All codes for 011 (other than 011.3_) are to be included in 011.9_.

TB Diagnosis: (Please fill in the 5th digit in the space provided # with 0 or 3)

011.3_ #	☐	Tuberculosis of bronchus
011.9_ #	☐	Pulmonary tuberculosis, unspecified (includes haemoptysis)
012.0_ #	☐	Tuberculous pleurisy
012.1_ #	☐	Tuberculosis of intrathoracic lymph nodes
012.2_ #	☐	Isolated tracheal or bronchial tuberculosis (TB endobronchitis)
012.3_ #	☐	Tuberculous laryngitis
012.8_ #	☐	Other specified respiratory tuberculosis
010.1_ #	☐	Tuberculous pleurisy in primary progressive tuberculosis
V09.71	☐	**Multi-drug resistant TB (use as an additional code to TB diagnosis)**

Complications of TB:

518.81	☐	Respiratory Failure
573.3 + E931.8	☐	Drug induced hepatitis
782.1 + E931.8	☐	Drug induced skin rash
579.8 + E931.8	☐	Drug induced G.I. intolerance
386.50 + E931.8	☐	Drug induced vestibular dysfunction
369.2 + E931.8	☐	Drug induced visual impairment
357.6 + E931.8	☐	Drug induced neuropathy
289.9 + E931.8	☐	Drug induced blood dyscrasia

Other Diagnoses (Co-morbidities):

013.90	☐	Unspecified tuberculosis of central nervous system
014.80	☐	Other tuberculosis of intestines, peritoneum, and mesenteric glands
015.90	☐	Tuberculosis of unspecified bones and joints
016.90	☐	Genitourinary tuberculosis, unspecified
017.90	☐	Tuberculosis of other specified organs
018.90	☐	Miliary TB, unspecified
585	☐	Chronic renal failure
250.00	☐	Diabetes mellitus
496	☐	COAD
162.9	☐	Lung cancer, unspecified
502	☐	Silicosis
294.8	☐	Dementia
436	☐	CVA

295.90	☐	Schizophrenia
319	☐	Mental retardation, unspecified
298.9	☐	Psychosis
571.5	☐	Cirrhosis
070.32	☐	Hepatitis B
571.9	☐	Chronic liver disease
571.3	☐	Alcoholic liver disease
279.3	☐	Immunosuppression
042	☐	HIV
304.90	☐	Drug addict, unspecified
263.9	☐	Malnutrition (blood albumin < 30g/l)
V62.9	☐	Psycho-social disability
V60.6	☐	Resident of an old aged home
V62.6	☐	Non-compliant patient
V60.1	☐	Inadequate housing
V60.0	☐	Street sleeper
V60.3	☐	Person living alone

Procedures:

33.24	☐	Bronchoscopy with biopsy
33.26	☐	Percutaneous transthoracic biopsy
34.24	☐	Pleural biopsy
90.42	☐	Rapid culture
88.73	☐	USG - Thorax
87.41	☐	CT scan thorax
34.91	☐	Thoracentesis
34.04	☐	Closed chest drainage
33.91	☐	Bronchial dilatation
33.98	☐	Insertion of bronchial stent
96.70	☐	Mechanical ventilation of unspecified duration
99.23	☐	Injection of steroid (also oral steroid in this PRG)
34.02	☐	Exploratory thoracotomy
32.29	☐	Wedge excision
32.3	☐	Segmental resection
32.4	☐	Lobectomy of lung
32.5	☐	Complete pneumonectomy

HOSPITAL AUTHORITY
RUTTONJEE HOSPITAL

PRG DATA COLLECTION FORM

Please Stick Label if Available or Use Block Letters
HN: _____ MRN: _____
Name: _____
I.D No.: _____ Sex: ____ Age: ____
Dept: _____ Ward/Bed: _____

THERAPY & REFERRAL
PRG - PULMONARY TUBERCULOSIS

Inclusion Criteria
All patients admitted with pulmonary TB as required under the Ordinance, are included in this PRG **(only pulmonary TB and not other types of TB)**

Therapy:

☐ 1. Standard treatment which is HRZ ± S/E for 2 months or more.
HRZ ± S/E given for <2 months is recorded as standard treatment.

☐ 2. Modified treatment.
Modified treatment means change of regimen or desensitisation to chemotherapy.

☐ 3. Expensive drugs
- ☐ 1. Cycloserine
- ☐ 2. Ethionamide
- ☐ 3. Amikin
- ☐ 4. Quinolone (ofloxacin, levofloxacin)
- ☐ 5. Augmentin
- ☐ 6. Others : please specify _____

Date of starting TB drugs: _____

Referral:

☐ to DH Chest Clinic

☐ to HA SOP clinic

Location: _____
SOP clinic No.: _____

☐ to or transfer to HA hospital

Hospital: _____

APPENDIX 9

DRAFT RECORDS

Draft clinical record
Draft patient-held record

HONG KONG INTEGRATED TUBERCULOSIS TREATMENT AND FOLLOW-UP RECORD

Mr T K Ho
200 Pokfulam Road
Hong Kong

Tel: 2512 3456

Patient No:
HK123456

Age. 62 (24/08/38)
Occupation:
Postman
Gp: Dr W Chan

Family Hisotry

Mother	dead (MI)- Hypertension
Father	dead (Lung cancer, Tuberculosis 1952
Siblings	3. 1 treated for TB

Smoking

Age	Material	Amount week	pack yrs
18 – 60	cigarettes	140	42

Drinking Habits

Type	Frequency	Total/week
Wine	<1/week	1 unit

Previous Treatments

Prob #	treatment	Daily dose	Start/stop
1	Aldomet	1200mg	June 75/Mar 84
2	Propranolol	120mg	Mar 84/Aug 85
	Captopril	50mg	Aug 85/present
3	Doxycycline		Intermittent
4	DOTs		June/Dec 1999

Current status

Sputum	Smear negative
Culture	Negative
Drug sensitivity	Isoniazid

Problem List

Active		
1	Hypertension	1971
2	Left Ventricular Hypertrophy + Strain	1982
3	COPD	1990
4	Tuberculosis, pulmonary	1999
Inactive		
	Appendicectomy	1952
Not on patient held record		
	Impotence	1985

Problem Checklist

Please tick any of the following which have occurred since last review and are not listed above. Please ring A for active and I for inactive and add date.

[ ] Chest X-ray changes	A I [ ]
[ ] Respiratory function tests	A I [ ]
[ ] Respiratory symptoms	A I [ ]
[ ] Cerebrovascular accident	A I [ ]
[ ] Ischaemic heart disease	A I [ ]
[ ] Symptomatic angina	A I [ ]
[ ] Peripheral vascular disease	A I [ ]
[ ] Renal disease (specify above)	A I [ ]
[ ] Airways disease	A I [ ]
[ ] Diabetes	A I [ ]
[ ] Overweight	A I [ ]
[ ] Anxiety	A I [ ]
[ ] Social/psychiatric problems	A I [ ]
[ ] Drug sensitivity	A I [ ]

Mr T K Ho, 200 Pokfulam Road, Hong Kong HK123456

Date Clinical Unit	21 Aug 96 SYP OPD	21 Aug 97 SYP OPD	20 Sept 98 SYP OPD	Dec 1999 Wanchai
Weight (kg) **Height (cms)**	91 14st 6lbs 160 5ft 3ins	92 14st 8lbs 160 5ft 3ins	85 14st 10lbs 160 5ft 3ins	80
Urine **glucose** **protein** **blood**	- - -	- - -	- - -	- - -
Chest X-ray			Cardiomegaly emphysema	Old shadow LUZ
Sputum				Smear negative Culture negative
Other			$PCO_2 \uparrow$	Stable hypercapnia
Spirometry/PEFR	120	100	95	95
Blood pressure* **systolic** **diastolic**	 132 90	 130 88	 130 90	 130 85
ECG **date** **report**	 Aug 96 LVH	 Aug 97 LVH + strain	 Sept 98 LVH + strain	 Dec 99 LVV + strain
Symptoms **eg dyspnoea on effort, oedema (please update)**	Dysp ++	Dysp +++	Dysp ++ Cough ++ Sputum +	Dysp + Cough + Sputum +
Treatment Complications (please indicate whether each complication is still present and name suspected drug)				Isoniazid sensitivity

* Note: Diastolic blood pressure should be phase V (disappearance of sound) measured in the right arm with a mercury sphygmomanometer and with the patient seated; other wise please state.

DOTS Management Record: Treatment and attendance

Name in English (block letters)	Treatment number	Clinic/hospital number	Sex / Age /

Remarks

Weight (kg)	Dosage of drugs			42kg	43–57kg	58 kg
	Streptomycin			1.0g	1.0g	1.0g
	Isoniazid tablets			6	8	10
	Rifampicin capsules			2	2	2
	Pyrazinamide tablets			4	5	6

Date	S dose	Number of tables or capsules				Complaints (tick)		Attendance
		H	R	Z	†	Yes*	No	
M								
T								
W								
T								
F								
S								
M								
T								
W								
T								
F								
S								
M								
T								
W								
T								
F								
S								
M								
T								
W								
T								
F								
S								

Date	S dose	Number of tables or capsules				Complaints (tick)		Attendance
		H	R	Z	†	Yes*	No	
M								
T								
W								
T								
F								
S								
M								
T								
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T								
F								
S								

Date	S dose	Number of tables or capsules				Complaints (tick)		Attendance
		H	R	Z	†	Yes*	No	
M								
T								
W								
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F								
S								

Date	S dose	Number of tables or capsules				Complaints (tick)		Attendance
		H	R	Z	†	Yes*	No	
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S								

PATIENT HELD RECORD

Mr T K Ho
200 Pokfulam Road
Hong Kong
Tel: 2512 3456
Occupation: Postman
G.P.: Dr W Chan

Patient no.
HK123456

D.o.B. 24/8/38

MEDICINES

Prob no.	Medicine	Dose	From	To
2	Aldomet	1200mg	6/75	3/84
3	Propranolol	120mg	3/84	8/85
	Captopril	50mg	8/85	
4	Doxycycline		Intermittent	
5	DOTS		6/99	12/99

SMOKING

Cigarettes 20 per day

ALCOHOL

Less than 1 unit per week

FAMILY HISTORY

Mother dead, MI, hypertension
Father dead, lung cancer, TB 1952
Brothers 2 **Sisters** 1
1 treated for TB

MEDICAL HISTORY

Active		Date recorded
1	Appendicectomy	1952
2	Hypertension	1971
3	Left venticular hypertrophy	1982
4	Chronic obstructive pulmonary disease	1990
5	Tuberculosis	1999
6	Isoniazid sensitivity	2000

These pages contain your personal details. If you do not fully understand anything or would like more details do not hesitate to ask your doctor.

Please take this booklet with you whenever you visit the doctor. If your treatment is changed, please alter your booklet or ask your doctor to do this for you. Please also write down any medicines which you have bought for yourself.

If there is anything printed here which has changed or which you think is not correct please make a note of this and we will alter your record at your next annual review.

TB treatment schedule

Name:
姓名

Reference No.
登記編號

1	16	1	16	1	16	1	16	1	16	1	16	1	16
2	17	2	17	2	17	2	17	2	17	2	17	2	17
3	18	3	18	3	18	3	18	3	18	3	18	3	18
4	19	4	19	4	19	4	19	4	19	4	19	4	19
5	20	5	20	5	20	5	20	5	20	5	20	5	20
6	21	6	21	6	21	6	21	6	21	6	21	6	21
7	22	7	22	7	22	7	22	7	22	7	22	7	22
8	23	8	23	8	23	8	23	8	23	8	23	8	23
9	24	9	24	9	24	9	24	9	24	9	24	9	24
10	25	10	25	10	25	10	25	10	25	10	25	10	25
11	26	11	26	11	26	11	26	11	26	11	26	11	26
12	27	12	27	12	27	12	27	12	27	12	27	12	27
13	28	13	28	13	28	13	28	13	28	13	28	13	28
14	29	14	29	14	29	14	29	14	29	14	29	14	29
15	30	15	30	15	30	15	30	15	30	15	30	15	30
	31		31		31		31		31		31		31

Treatment No.
醫務編號

Drug	*Dosage*
Rifampicin	
Isoniazid	
Ethambutol	
Streptomycin	
Pyrazinamide	
Duration	Ms

Date

Signature

Drug	*Dosage*
Rifampicin	
Isoniazid	
Ethambutol	
Streptomycin	
Pyrazinamide	
Duration	Ms

Date

Signature

Remarks:
備註