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Controlling Tuberculosis in New South Wales

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Abstract
This document has three parts. The first part provides an overview of the epidemiology of TB in NSW. The second part defines the goals, targets and implementation indicators for the NSW TB Control Strategy. The third part contains policies and guidelines for TB Services, which were endorsed by a consensus meeting of Chest Clinic Staff, Respiratory, Public Health and Infectious Disease Physicians in October, 1992.

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CONTROLLING TUBERCULOSIS

IN NEW SOUTH WALES

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LIST OF ABBREVIATIONS

ABS	Australian Bureau of Statistics
AFB	Acid Fast Bacilli
AIDS	Acquired Immunodeficiency Syndrome
BCG	Bacille-Calmette-Guerin vaccination
CCS	Chest Clinic Sister
EHSEB	Epidemiology and Health Services Evaluation Branch
HIV	Human Immunodeficiency Virus
ICPMR	Institute of Clinical Pathology and Medical Research
IDSS	NSW Infectious Diseases Surveillance System
NHMRC	National Health and Medical Research Council
PHU	Public Health Unit
TB	Tuberculosis disease
TBAC	NSW Tuberculosis Advisory Committee
TBUs	Signed Health Undertakings
TSANZ	Thoracic Society of Australia and New Zealand
WHO	World Health Organization

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INTRODUCTION

In February 1991 a discussion paper by the NSW Health Department's Epidemiology and Health Services Evaluation Branch (EHSEB) was completed which primarily addressed the epidemiology of tuberculosis in NSW[1]. The paper included a review of the international literature on methods of tuberculosis (TB) control, and compared the methods used in NSW with those used in other parts of Australia, the United States and Britain.

Key recommendations of this document were that the role and organisation of TB Services in NSW be reviewed and that a strategy for NSW be developed which addresses TB surveillance, screening, BCG vaccination, chemoprophylaxis, case follow up and program evaluation. The NSW TB Advisory Committee also recommended that a more in depth appraisal of the epidemiology of TB in NSW be undertaken.

A Review of TB Services in NSW has been prepared by the EHSEB and NSW TB Coordinator, concurrently with the development of this document. Key recommendations from the Review are that:

- all active cases have treatment initiated and ceased by, and be discharged from medical care by, a Specialist Physician at the nearest Chest Clinic;

- the NSW Infectious Diseases Surveillance System (IDSS) database be expanded and be made accessible to Chest Clinics via computer networks with Public Health Units, to facilitate surveillance of disease and infection, patient management and program evaluation;

- routine screening - of staff, contacts, old inactive cases and migrants on Health Undertakings - in localities where Chest Clinic Sisters are not based be undertaken by local hospital or Community Health staff;

- Area/ Regional TB coordinators be responsible for routine program evaluation and ensuring the implementation of Statewide policies and guidelines;

- the NSW TB Coordinator report to the NSW Health Department on TB program indicators for the State;

- updated State policies and guidelines for Mantoux testing, contact tracing, migrant and refugee follow up, BCG vaccination and screening of health care workers be distributed to NSW health services in a 'Policies and Procedures Manual'; and

- consensus guidelines be developed, through consultation with clinicians, related to first line drug regimens and indications for chemoprophylaxis, the role of supervised chemotherapy and duration of case followup.

Recommendations from the 1991 discussion paper and the 1992 Review of TB Services have been incorporated into this Strategy for the Control of TB in NSW.

This document addresses four major methods of TB control: disease containment, case prevention, surveillance and program evaluation.

- **Disease containment**

  Early identification and adequate treatment of cases of infectious TB are the most important measures to prevent spread of the disease. The major obstacle to disease containment is the interruption of and/ or failure to complete therapy with an appropriate drug regimen[2]. The two main causes of treatment failure are inappropriate combinations of drugs, dosages and duration and poor compliance (due to inadequate supervision or communication and social or medical host factors such as alcohol, drugs, poor nutrition, homelessness).

- **Case prevention**

  The main case prevention strategy is screening for, and treatment of, TB infection in high risk groups. No matter how efficient case finding, diagnosis and treatment are, the development of disease in those already infected can only be prevented by appropriate chemoprophylaxis[3]. The associated risks - side effects and possible emergence of drug resistant strains - must be weighed against the potential benefits.

- **Surveillance**

  Timely identification and notification of confirmed and suspected cases facilitates early treatment and preventive intervention. Surveillance is essential for estimating incidence, distribution and trends of disease and infection and for planning services rationally. In low incidence countries, the number and trends in bacteriologically positive cases is the most useful parameter of the epidemiology of TB. The risk of infection is only a useful indicator with large sample sizes which provide reliable estimates. Infection surveillance requires careful strategic planning of screening in high risk populations.

- **Program evaluation**

  The monitoring of parameters related to disease containment, case prevention and surveillance activities provides important information for:

  - evaluating program performance
  - assessing epidemiological trends: eg the incidence of Mantoux conversion in contacts reflects the rate of transmission of TB in the population.
  - evaluating the effectiveness of interventions: eg although the efficacy of modern treatment regimens under controlled trial conditions is well established, there are few data available on the effectiveness and efficiency of treatment under routine conditions in low incidence countries.
  - program planning: Program evaluation, research and monitoring of epidemiological trends should guide program planning, eg screening programs should be regularly evaluated to assess their worth, as screening is generally recommended only where the rate of infection is greater than one per cent[4].
  - patient management: In the case of TB few data beyond those necessary for patient management are required for routine program evaluation.

This document has three parts. The first part provides an overview of the epidemiology of TB in NSW. The second part defines the goals, targets and implementation indicators for the NSW TB Control Strategy. The third part contains policies and guidelines for TB Services, which were endorsed by a consensus meeting of Chest Clinic Staff, Respiratory, Public Health and Infectious Disease Physicians in October, 1992.

The proposed implementation indicators - for each of the four control methods and for TB Services themselves - are intended to provide strategic direction and a means of monitoring progress towards attaining the goals and targets. Each implementation indicator includes a timeline and the person(s) responsible for ensuring its achievement.

This document does not attempt to review the current state of international knowledge of TB control. Such a review was the subject of the 1991 discussion paper and readers should refer to that document[1]. Recommendations from that review have been incorporated into the strategies and policies.

The rationale behind the proposed implementation indicators and policies is that more effective and efficient use of existing prevention and control methods and technologies should lead to significant improvements in TB control.

The development of new preventive, diagnostic and treatment technologies will expedite these improvements. Although not specifically addressed by this document, the NSW Health Department and associated bodies, eg Institute for Clinical Pathology and Medical Research (ICPMR), should encourage the development, evaluation and implementation of rapid diagnostic techniques, improved screening methods, short duration drug regimens and treatments for drug resistant strains. This research should be undertaken in cooperation with the National Health and Medical Research Council (NHMRC) and World Health Organization (WHO) sponsored programs.

1. EPIDEMIOLOGY

1.1 ACTIVE DISEASE NOTIFICATION

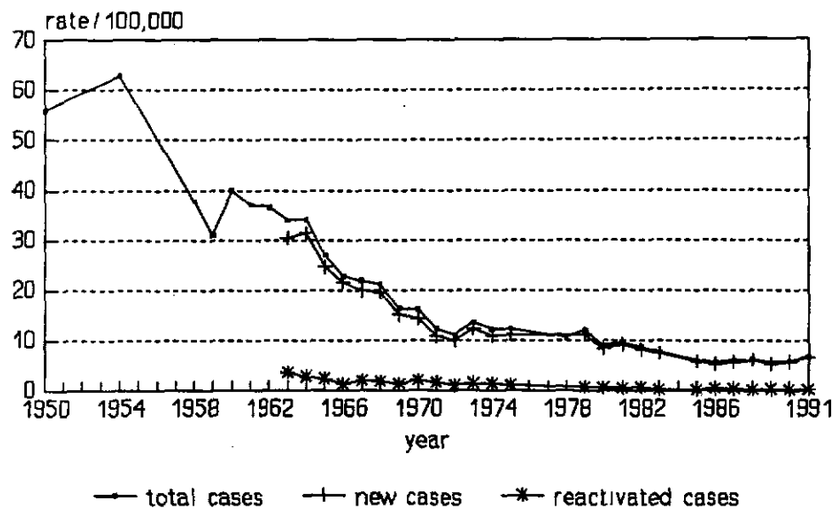
In NSW 393 active TB cases were diagnosed and reported in 1991. Of these, nine (2.3%) were cases of reactivated TB. Of 383 new cases, 289 (76%) had pulmonary disease.

In NSW between 1963 and 1991 notifications of active disease declined from 30.5 to 6.5 per 100,000 for new cases and 3.5 to 0.15 per 100,000 for reactivated cases (Figure 1). The notification rate of smear positive cases in 1991 was 2.8 per 100,000.

Moderate decreases occurred in notifications of **new cases** of TB in NSW in the early 1980s, from a rate of 11.1 per 100,000 in 1979 to 5.2 per 100,000 in 1986. Between 1989 and 1991 there was a slight increase, from 5.8 new cases per 100,000 to 6.5 per 100,000.

The decline in new cases since 1963 is almost entirely accounted for by the decline in new **pulmonary disease** from a rate of 28.7 to 4.9 per 100,000 in 1991 (Figure 2). Over the same period notifications of new **extrapulmonary disease** have ranged between a maximum of 2.3 per 100,000 in 1973 and a minimum of 1.0 per 100,000 in 1985. A moderate increase in notifications of new extrapulmonary disease has occurred since 1985. In 1991 the notification rate of new extrapulmonary disease was 1.6 per 100,000.

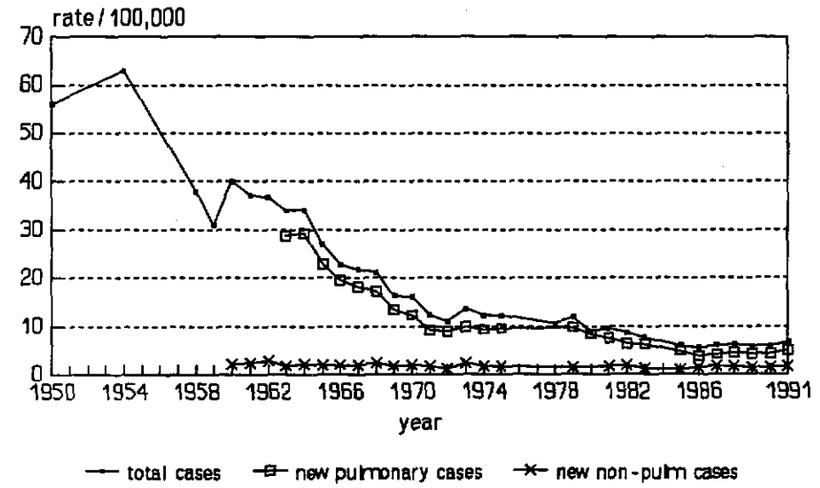
Fig 1: ACTIVE TB NOTIFICATIONS NSW - 1950-1991



Notifications of **reactivated cases** have continued to decline steadily from 0.6 per 100 000 in 1979 to 0.3 in 1986 and 0.2 per 100,000 in 1991. The case load of reactivated disease has also declined. In 1975 9.8% (51) of the notified cases of pulmonary disease were reactivations[5]. In 1991 2.7% (eight) of notified cases of pulmonary disease were reactivations. Of these eight reactivated cases, five were Australian born (all aged over 45), one was Asian born (aged 25-34) and two were born in Europe (both aged over 45). (Until 1992 a reactivation was defined as a case of active TB who had previously received a full course of treatment in NSW and been declared cured.)

In 1991, of the 260 new pulmonary cases for whom direct sputum smear results were recorded, 132 (51%) were **smear positive**. Smear negativity is more common in Asian born cases than Australian born cases[6], proportions having smear positive disease being 58% and 48% respectively in 1991.

Fig 2: ACTIVE TB NOTIFICATIONS BY SITE NSW - 1950-1991



1.2 MORTALITY RATES

Mortality due to TB in Australia has fallen steadily this century[5]. This fall was accelerated by the introduction of effective chemotherapy in about 1954. The majority of deaths occur in the elderly, many of whom die with, rather than from, TB[6].

The death rate from TB in NSW declined from 1.40 per 100,000 people in 1970 to 0.54 per 100,000 in 1988.

Over the period 1989 to 1991 less than 1% of all TB case notifications were from death certification (ie 'delay of diagnosis until death').

1.3 CENTRAL NERVOUS SYSTEM (CNS) DISEASE

For 1988/89 the incidence of TB CNS infections was 0.35 per 100,000 population. The highest age specific incidence was in 35-44 year olds, being 1.4 per 100,000. Of the 20 cases with TB infection of the CNS, 12 (60%) were in the age group 35-44. There was only one child aged less than five years with TB of the CNS.

1.4 DRUG RESISTANCE RATES

Asian immigrants are considered at particular risk of harbouring drug resistant tubercle bacilli because of the likelihood of inadequate, interrupted chemotherapy, usually with one or two drugs, due to the high relative costs of anti-TB drugs in Asia[6]. High rates of drug resistance strains have also been reported overseas in those with HIV-TB coinfection[2].

In 1991 18 new TB cases (4.7%) were resistant to isoniazid, five (1.3%) were resistant to rifampicin, 30 (7.8%) were resistant to streptomycin and one case (0.3%) was resistant to ethambutol. Eight new cases were resistant to two drugs (Australian born: 1, Asian born: 4, Middle East born: 3). Two new cases were resistant to three drugs (Asian born: 2).

Of the eight reactivated TB cases in 1991, only one was drug resistant. This case, who was Australian born, was resistant to two drugs. Of the 10 cases of TB-HIV coinfection, two were resistant to one drug and one was resistant to two drugs.

1.5 INFECTION PREVALENCE AND INCIDENCE

Data on infection prevalence and incidence rates in subpopulations in NSW are limited.

A recent survey of police recruits in NSW found a Mantoux positivity rate on employment of 11%[7]. In those who had not been previously BCG vaccinated the Mantoux positivity rate was 7%. A Mantoux reaction of 5mm or more was considered a positive result. Using a cut-off point for a positive reaction of 10mm or more, 4% of those who had not previously received BCG vaccination were Mantoux positive. These results are considered generalisable to the NSW population.

Preliminary results from a screening survey of Year 8 schoolchildren in Central/ Southern Sydney, an area with a high migrant population, show a Mantoux positivity rate of more than 12%[8]. In children who had had previous BCG vaccination a Mantoux reaction of 15mm, and in non-vaccinated children a Mantoux reaction of 10mm, was considered positive. Other recent screenings in Sydney of Year 4 and Kindergarten children have found TB infection prevalence rates of 16% and 13% respectively[9].

Overseas data have shown that a 1% annual risk of infection in an unvaccinated population represents an annual smear positive case rate of about 50 per 100,000 population[6]. Extrapolating from this, we estimate that the annual risk of infection in NSW is between 0.04% and 0.05%.

1.6 RISK FACTORS

TB morbidity in a population depends upon the risk of infection and the risk of disease following infection. One new TB case on average leads to less than one new infectious case[10] so rates of disease in a stable community should naturally decline.

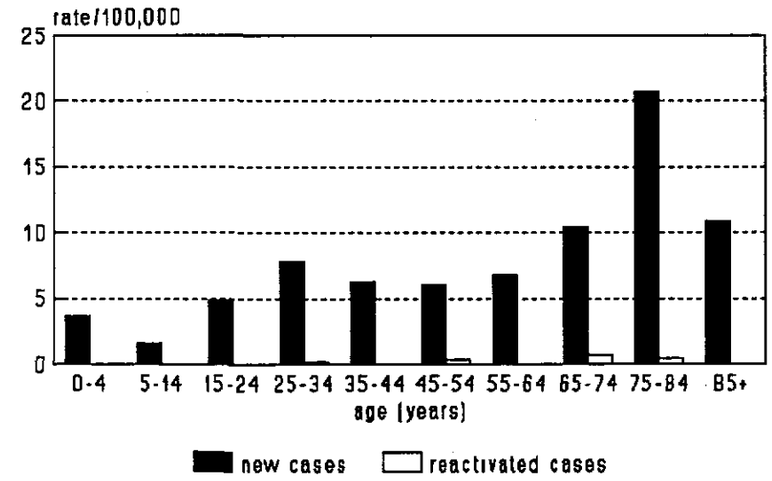
Some groups have a higher incidence of TB than the general population due to a higher prevalence of infection, or higher risk of developing the disease once infected. Most new cases of TB arise from people with latent rather than new infections[10]. There is often a long latent period between infection and development of TB. It is estimated that more than 90% of people with disease have harboured TB infection for at least a year; the remaining 10% have immediate progression of recently acquired infection[11].

Age

The risk of TB infection is associated with increasing age in all races and in both sexes[10]. The risk of progression to disease is highest in infants, young adults and the elderly[10,12]. TB infection acquired in infancy and adolescence carries a high risk of rapid progression to disease[13]; if disease develops, a more serious form (for example meningitis or miliary disease) is more likely to occur[11]. The lifetime risk of TB disease for infected children is up to 10%[10]. The prevalence of disease generally rises steeply with age, particularly for bacteriologically proven disease[6]. Persons over age 50 with unrecognised smear-positive disease are considered major public health risks[6].

1991 NSW notifications show an increasing trend with age, with minor peaks in the age groups 0-4 years and 25-44 years (Figure 3). The highest incidence is in those aged more than 65 with a rate of 13.7 per 100,000 for new cases and 0.6 per 100,000 for reactivated cases.

Fig 3: ACTIVE TB NOTIFICATIONS BY AGE NSW - 1991

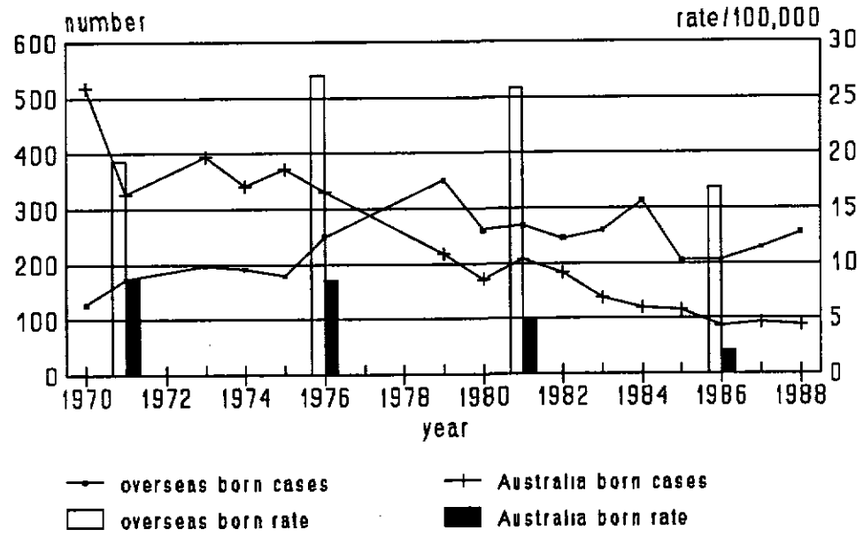


Aboriginality

The active TB notification rate for Aborigines and Torres Strait Islanders of over 50 per 100,000 has been reported in Australia[6]. Among Aboriginal communities in South Australia the infection prevalence rate in the late 1980s was 16.8% with a range of 7.7%-30.8%[9].

In people known to be Aboriginal in NSW the annual notification rate of TB was 3.6-7.2 per 100,000 population in 1986-88. In 1991 only two cases of TB were reported in Aboriginals.

Fig 4: NEW TUBERCULOSIS CASES BY PLACE OF BIRTH NSW - 1970-1988

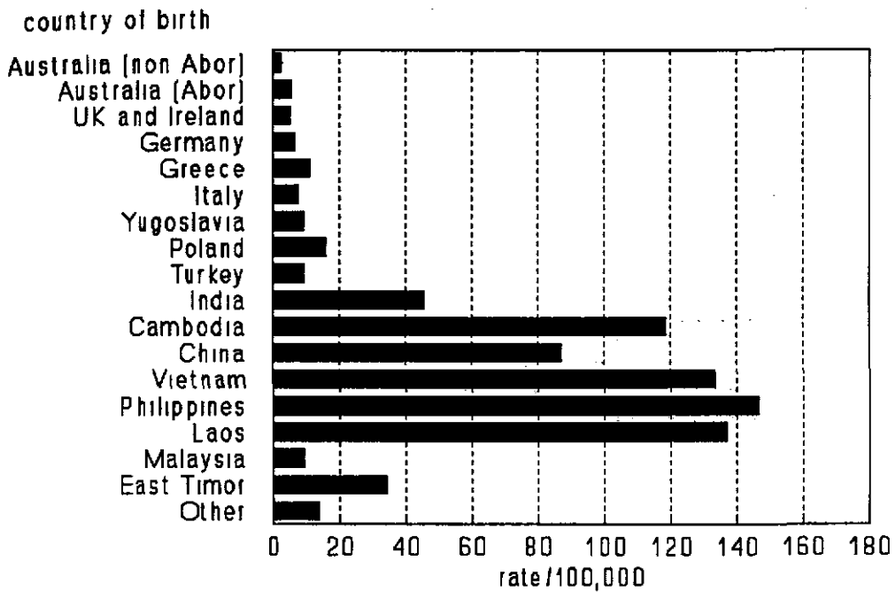


Country of birth and ethnicity

High rates of infection are found in ethnic groups and immigrants from high prevalence TB countries[14]. Most countries in Asia, Africa and Latin America are high prevalence countries. In Australia only immigrants from the USA, Canada, New Zealand and Scandinavia have incidence rates as low as, or lower, than the Australian born population[6]. Disease rates in immigrants are highest in the first few years after arrival. Ethnic groups tend to have a higher incidence of active disease especially in the younger age groups (irrespective of country of birth)[10].

Data from census years show that notification rates of disease in NSW among people born in Australia have fallen steadily since 1971, and among those born overseas only since 1981 (Figure 4). From 1986 to 1988, among people born in Australia and not recorded as Aboriginal, the notification rate of TB was 1.9-2.2 per 100,000 per year. Notification rates of TB among people born in South East Asia exceeded 200 per 100,000 population. Rates of mycobacterial disease for selected countries of birth are shown in Figure 5.

Fig 5: NEW MYCOBACTERIAL DISEASE NOTIFICATION BY COUNTRY OF BIRTH - NSW 1986-1988



In 1970, 80% of notified cases were born in Australia, but by 1988, this figure had fallen to 26%. In 1991 31% of new cases were born in Australia. The age groups with the highest proportion of new cases who were Australian born were the under five and over 65 year age groups, being 75% and 50% respectively (Figure 6).

In NSW most cases of paediatric TB occur in children either born overseas or born in Australia of Non-English Speaking Backgrounds (NESB). Of cases aged less than 15 years notified in 1991, 61% were born in Australia. However, of the Australian born cases, 74% were from NESB. Of these 79% were from Asian backgrounds.

The high notification rate of TB in the age group 25-44 years in NSW is largely accounted for by immigrants, with only 19% of cases in this age group being Australian-born in 1991. In contrast, of those aged over 65 years 48% were Australian born and a total of 60% were from English-speaking backgrounds.

For 1989-1991, among cases not born in Australia, 22% were notified within 12 months, 50% within five years and 79% within 15 years of arrival in Australia (Figure 7). As the proportion of cases declines with years after arrival, 'recent arrival' is a risk factor for TB.

For 1990-1991 the Mantoux positivity rate in Indochinese screened by the NSW refugee screening program was 46% in those who had been previously BCG vaccinated and 40% in those who had not been previously BCG vaccinated[15]. The rates of chest x-ray abnormalities detected by migrant/refugee screening in NSW in 1990 for Vietnamese, Laotians, Kampucheans and Latin Americans were 116.6, 48.0, 95.2 and 105.0 per 100,000 population respectively[16].

Fig 6: TB CASES BORN IN AUSTRALIA AND OVERSEAS BY AGE - NSW 1991

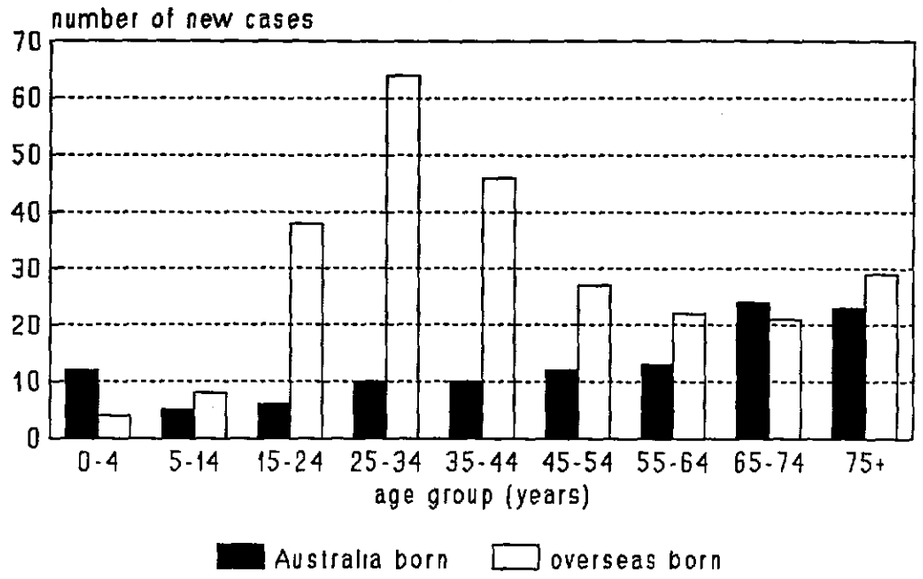
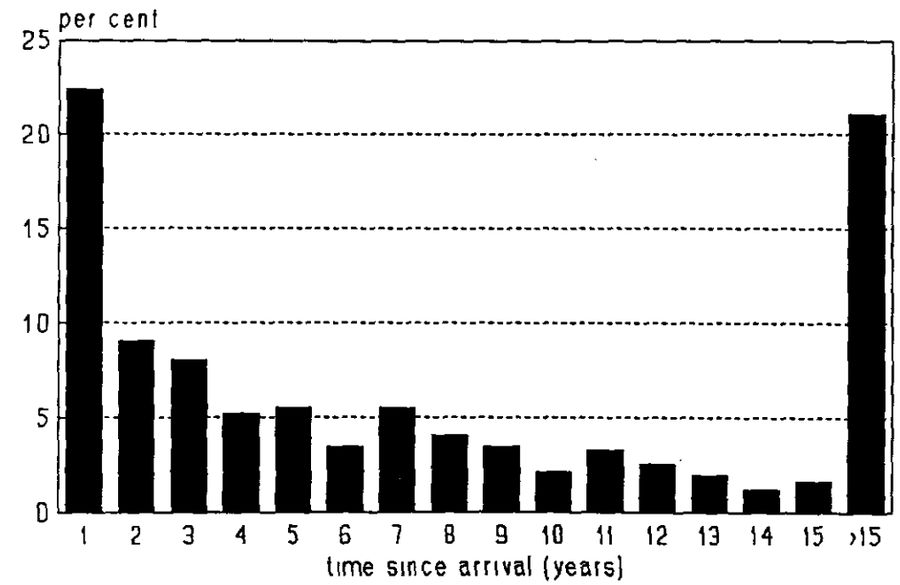


Fig 7: OVERSEAS BORN ACTIVE TB CASES BY YEARS SINCE ARRIVAL - NSW 1989-1991



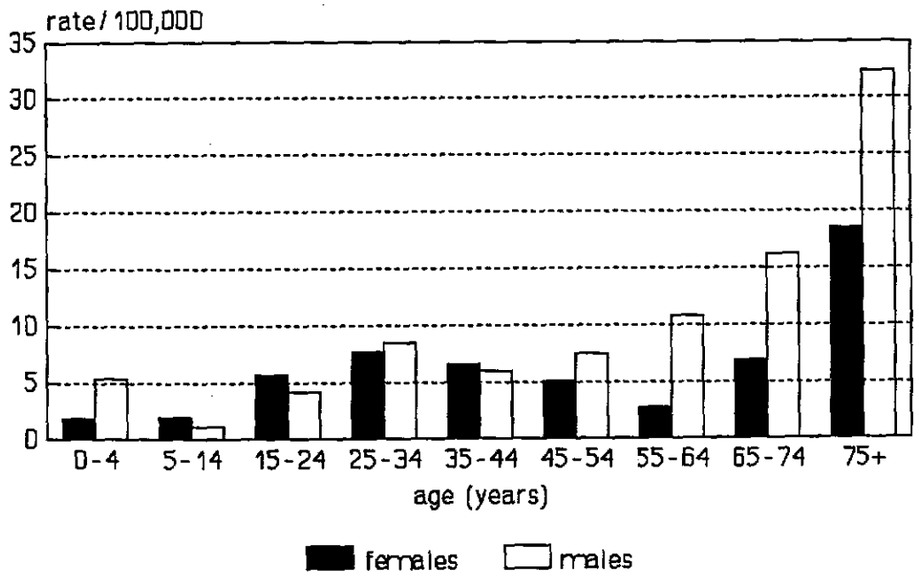
Sex

The risk of TB infection and pulmonary disease is higher in males than females[6,10]. In 1991 in NSW the male to female ratio for pulmonary disease was 1.5 : 1 and for extrapulmonary disease the ratio was 1 : 1.1. The recent Mantoux screening survey of police recruits in NSW estimated that, 7.7% of males and 2.9% of females have tuberculous infection, a ratio of 2.7 : 1[7].

Between 1963 and 1991 the proportion of notified cases who were male declined from 70% to 56%. Over the same period among Australian born people, the proportion of cases who were male declined to a lesser degree, from 70% to 65%. In 1991 the proportion of cases born overseas who were male was 53%. The more rapid decline in disease among males compared with females is therefore largely an effect of immigration.

The notification rate of disease in NSW males is twice that of females in the older age groups. In 1991 the notification rate of active disease in those aged more than 65 years was 20.1 per 100,000 for males and 10.1 for females (Figure 8).

Fig 8: ACTIVE TB NOTIFICATIONS BY AGE AND SEX NSW - 1991



Close contacts

High infection rates are found in close contacts of active pulmonary TB cases. One quarter of contacts of people with TB develop infection with those in close contact being at greatest risk[10,11]. Up to 2% of contacts of newly discovered TB cases have developed TB disease by their first examination[13]. The risk to contacts of extrapulmonary cases is 1%[17].

Infected contacts are more likely to develop disease if infected by a culture positive case with a positive direct sputum smear than a case with a negative smear. The risk of infection depends largely on the density of *Mycobacterium tuberculosis* in droplets expelled into the air by a person with TB and the time a susceptible person is exposed to that air. The density of infected droplets in the air depends on the frequency of coughing, the density of bacilli in the sputum and the volume of the air space.

In NSW in 1991 3.6% of notified active cases were known contacts of other reported cases.

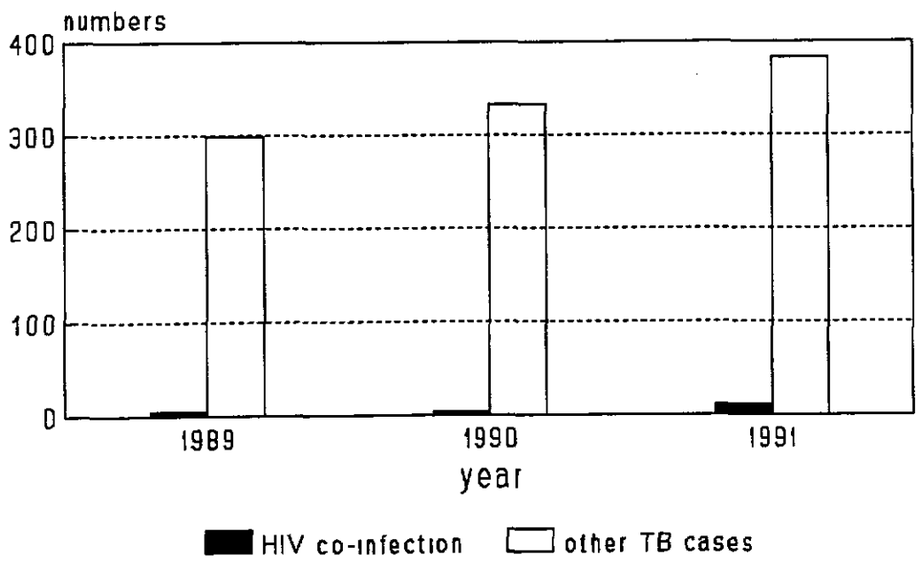
Human Immunodeficiency Virus (HIV) infection

The increased incidence of TB overseas, notably in the US in recent years, is partly due to an excess of active disease in those with TB-HIV coinfection and partly due to increasing poverty and homelessness.

Although *Mycobacterium avium complex* is the commonest mycobacterial species isolated from people with acquired immunodeficiency syndrome (AIDS), infection of people with AIDS with *Mycobacterium tuberculosis* has the potential for more serious health consequences in the general community, because of its capacity to infect people with normal immune systems. TB-HIV coinfection is characterised by more widespread TB disease with unusual clinical features which makes diagnosis difficult.

In NSW at present the notification rate of TB-HIV coinfection is low. In 1991 only ten cases of TB (2.5% of all NSW notifications) were recorded in HIV positive people (Figure 9).

Fig 9: TB-HIV CO-INFECTION IN NSW - 1989-1991



Other medical risk factors

The risk of progression of infection to disease is high in immunosuppressed people. Silicosis, malignant lymphomas, lung cancer, lymphosarcoma, reticulum cell sarcoma, head and neck cancers, haemophilia, end stage renal failure and patients on haemodialysis are associated with an increased risk of TB[10]. Low body weight, gastrectomy, diabetes, corticosteroid therapy, and HLA types A11, B15 and DR2 have also been implicated[10]. Smokers, particularly those with chronic lung disease, are at increased risk[6].

Long term residential facilities

In US prisons TB is a major health problem and is increasing. The incidence among New York State prison inmates increased from 15.4 per 100,000 in 1976-1978 to 105.5 per 100,000 in 1986, 56% of whom were infected with HIV[18]. Eleven outbreaks in US prisons were reported in the period 1985-1988[18]. In the US the incidence of TB in nursing home residents is higher than among elderly people living in the community (39.2 per 100,000 versus 21.5 per 100,000)[19].

In NSW for the period 1989-1991, there were five notifications of active disease in people identifiable as being resident in nursing homes, three notifications from psychiatric institutions and one notification from gaol.

A survey to estimate the prevalence of infection in new prisoners at Tamworth gaol is currently underway.

Homelessness

High prevalence rates of TB disease (1.6%-6.8%) and TB infection (18%-51%) have been reported for homeless people overseas[14]. In NSW for the period 1989-1991 three cases were notified from 'hostels for the homeless' and one case was recorded as being of 'no fixed address'. Chest x-ray screening of homeless men attending 5 hostels in Eastern Sydney during 1991 and 1992 showed that 15-25% of residents had results consistent with active or inactive TB.

Drug and alcohol dependency

Drug users and alcohol dependent people are at increased risk of TB[6]. Between 1989 and 1991 in NSW two notified cases were identifiable as being resident in alcohol rehabilitation centres.

Occupation

In the US estimates of the annual incidence of infection in health care workers (HCWs) in recent years have varied between 1.5% and 10.3%[20]. In South Australia the prevalence of TB infection in HCWs under 45 years is 20%-30%[9]. Research laboratory staff handling infected material are considered at particular risk[6].

Occupation data are available for 951 of the 1044 notified cases (91%) between 1989 and 1991. Thirty seven cases (4%) were identifiable as HCWs. Of these 37 cases, 28 (76%) were born overseas. Of the nine Australian born cases, four were medical practitioners (including one retired and two pathologists) and five were nurses (including two retired and one a pathology nurse).

Other 'occupational groups' considered at high risk are the unemployed and pensioners[6]. The incidence of TB is strongly associated with socioeconomic status and income[11].

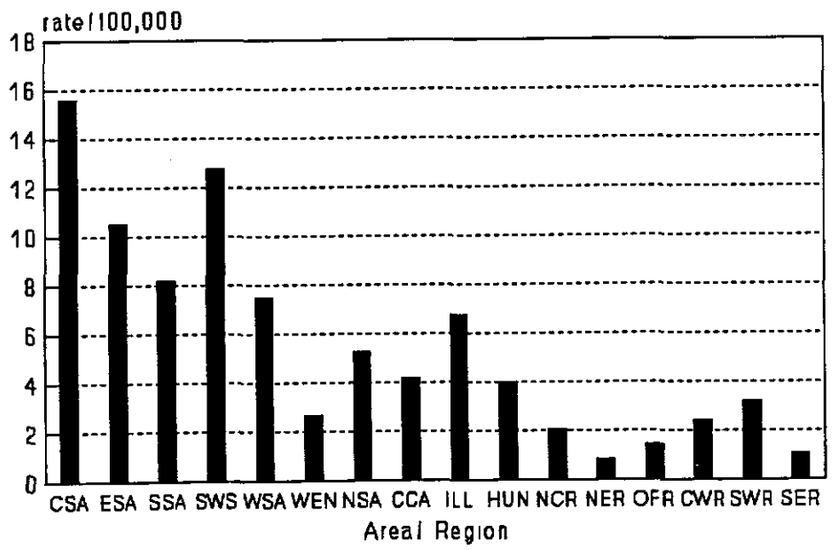
Old healed TB

Those with old healed TB (abnormal chest x-rays with fibrotic lesions consistent with old healed TB) are at increased risk of active TB[10,11].

Geographical area

The notification rate of new TB disease is high in the Sydney metropolitan area and low in rural areas. The highest rates in 1991 were recorded for Central Sydney (15.4 per 100,000) and South West Sydney Area (12.7 per 100,000) (Figure 10).

Fig 10: ACTIVE TB NOTIFICATIONS BY HEALTH AREA/REGION - NSW 1991



Notes: CSA = Central Sydney; ESA = Eastern Sydney; SSA = Southern Sydney; SWS = South Western Sydney; WSA = Western Sydney; WEN = Wentworth; NSA = Northern Sydney; CCA = Central Coast; ILL = Illawarra; HUN = Hunter; NCR = North Coast; NER = New England Region; OFR = Orana & Far West Region; CWR = Central West Region; SWR = South West Region; SER = South East Region.

2. STRATEGIES

2.1 GOALS AND TARGETS

GOALS

By 2001

- To reduce the annual incidence of active TB disease to 2 per 100,000 population.

By 1995

- To reduce the annual incidence of smear positive TB to 2 per 100,000 population.

TARGETS

Disease containment

By 1995:

- To detect 95% of all smear positive cases.
- To ensure that 100% of smear positive cases are commenced on an appropriate multidrug regimen within two weeks of diagnosis.
- To ensure that 99% of smear positive cases have taken chemotherapy continuously for six months after commencing treatment.

By 2001:

- To detect 99% of all smear positive cases.
- To cure 99% of all smear positive cases.

Case prevention

By 1995

- To ensure that 95% of close contacts of smear positive cases are examined within ten days of index case diagnosis.
- To ensure that 90% of infected people commenced on chemoprophylaxis have taken the drug(s) continuously for six months after commencing treatment.

Surveillance

By 1995

- To ensure that 100% of cases are notified.

2.2 IMPLEMENTATION INDICATORS

Disease containment

By 1993 Tuberculosis Advisory Committee (TBAC) to produce consensus guidelines, including a Departmental circular, on TB treatment and case follow up, which are endorsed by the Thoracic Society of Australia and New Zealand (TSANZ) and National Health and Medical Research Council (NHMRC). See Chemotherapy, Chapter 3.11.

By 1993 Epidemiology Branch (EHSEB) and Health Public Affairs (NSW Health Department) to produce TB educational materials in a number of community languages - promoting early diagnosis and treatment, contact follow up and access to TB services.

By 1993 NSW TB Coordinator to make annual projections of drug needs for the State, based on surveillance of disease and drug resistance rates, and to communicate these to suppliers via the Pharmaceutical Services Branch.

By 1993 NSW TB Coordinator to ensure that at least one teaching hospital is established as a site for essential stocks - particularly drugs - and that the site and stocks are regularly monitored.

By 1993 Area TB Coordinators to establish local advisory groups, composed of representatives of high risk populations and agencies providing health (including general practitioners), housing and welfare services to these populations. These local groups will advise on priorities and the development, implementation and evaluation of strategies appropriate to high risk population groups, aimed at increasing awareness of TB, facilitating access to care and improving compliance with treatment.

By 1994 NSW TB Coordinator/ EHSEB to evaluate the acceptability and accessibility of TB Services, from a sociocultural perspective, and to implement and evaluate change as required.

By 1994 Area/ NSW TB Coordinators to develop and evaluate specific strategies for improving compliance with treatment regimens for each identified high risk group. These strategies should be sensitive and responsive to people's beliefs, cultures and environments and reflect an understanding of the difficulties associated with behavioural change.

By 1994 EHSEB to evaluate and report on risk factors for treatment failure: interrupted therapy, failure to complete therapy, relapse and chronicity.

Case prevention

By 1993 NSW TB Coordinator/ EHSEB to produce Departmental circulars of guidelines for Mantoux testing, contact tracing, BCG vaccination, and follow up of refugees and migrants on Health Undertakings (TBUs). See

Chapters 3.2, 3.3, 3.5, 3.6 and 3.9 for guidelines.

By 1993 TBAC to produce consensus guidelines, (including a Departmental circular), on chemoprophylaxis, including indications and recommended first line drug regimens, which are endorsed by the TSANZ and NHMRC. See Chemoprophylaxis, Chapter 3.10.

By 1993 Public Health Unit (PHU) Directors to ensure that:

- 95% of all confirmed and presumptive diagnoses of TB are notified within five working days of diagnosis by :
  - Improving liaison with Clinicians - Respiratory, Infectious Disease, HIV/AIDS Clinicians and Paediatricians and private practitioners. They should be made aware of the notification criteria for TB which includes the presumptive diagnosis. See Appendix 1 for case definitions of tuberculosis.
  - Encouraging doctors and laboratories to notify by telephone.
- Delays in notification of more than five days are investigated and action is taken to prevent similar delays in the future.
- Chest Clinic Sisters (CCS) are phoned immediately on receipt of notifications and copies of doctor and laboratory notifications are forwarded by mail (pending networking of PHUs and Chest Clinics).

By 1993 Area TB Coordinators to ensure that the completeness of notifications is routinely evaluated by review of pharmacy and bacteriology records within all major hospitals for unnotified TB patients.

By 1993 NSW and Area/ Regional TB Coordinators to ensure that the recording and interpretation of Mantoux tests is standardised. See Mantoux testing, Chapter 3.3.

By 1993 Area/ Regional TB Coordinators and PHU Directors to ensure that 90% of close contacts of smear positive cases are examined within seven days of diagnosis for child contacts and ten days for adult contacts.

By 1993 EHSEB to assess the risk of infection in 'high risk' health care workers, by analysis of retrospective and/ or prospective data. See Health Care Worker Screening and Protection, Chapter 3.4.

By 1993 TBAC/ EHSEB to review and update Health Department policy regarding routine health care worker screening and BCG vaccination. See Chapter 3.4.

By 1993 EHSEB to assess the need for modification of TBU follow up and refugee follow up protocols, by analysis of available data. See Chapters 3.5 and 3.6.

By 1993 EHSEB to report on the risk of infection and for disease in the following populations: new prisoners, the homeless and nursing home residents. See Screening, Chapter 3.1 for discussion of the rationale for selecting target groups for screening.

By 1994 EHSEB to report on the risk of infection and disease in intravenous drug users and HIV seropositive people. See Chapter 3.1.

By 1994 EHSEB to report on the risk of infection and disease in Aboriginals.

By 1994 EHSEB to assess the potential value of periodic Mantoux screening of children in 'high risk' areas, by cost effectiveness analysis.

By 1994 EHSEB to assess the value of refugee screening, by cost effectiveness analysis using available data.

By 1994 NSW TB Coordinator/ EHSEB to participate in national collaborative study of overseas born TB cases notified in 1991, with the aim of evaluating the effectiveness of follow up of migrants on TBUs.

By 1994 EHSEB to assess the need for modification of contact tracing guidelines, by analysis of available data.

Surveillance

By 1993 EHSEB to expand the NSW Infectious Diseases Surveillance System (IDSS) database to include additional data related to TB cases, eg drug sensitivities, source of discovery (see Appendix 2).

By 1993 EHSEB to expand the NSW IDSS database to include data related to infection:

- contact follow up - eg new infections detected (contacts relational file)
- other screening - eg. infections detected in health care workers and other high risk populations (screening module).

By 1993 EHSEB to link the NSW IDSS database with Australian Bureau of Statistics mortality data for estimation of prevalence of active and inactive TB disease at death and hence the case detection ratio.

By 1993 NSW TB Coordinator/ EHSEB to report annually at the State level on indicators of TB disease and infection: rates of TB disease (and smear positive disease), hospitalisation and mortality; reactivation; HIV-TB co-infection; drug resistance; TB meningitis (children aged less than five); and infection rates for all screened population groups. See Appendix 3 for proposed set of disease and infection surveillance indicators.

By 1993 Area/ Regional TB Coordinators to report to the NSW TB Coordinator on investigations of contacts of infectious cases within institutions (for example, nursing homes, schools, hospitals, prisons, hostels for the homeless, workplace) within one month of notification.

By 1993 Area/ Regional TB Coordinators to report annually to the NSW TB Coordinator on infection rates for all screened population groups.

By 1993 NSW TB Coordinator/ EHSEB to undertake validation studies of TB notifications every two years, by review of selected records systems (for example laboratory reports, pharmacy reports, death certificates).

By 1994 EHSEB to write a program which translates computerised information from ICPMR mycobacteriology laboratory into a form compatible with the IDSS.

By 1995 At least one Health Area with a high incidence of TB to undertake periodic (three-five yearly) surveys of the prevalence of tuberculous infection in children of various ages.

By 1995 All Area Health Services to provide access for Chest Clinics to the expanded version of IDSS, by computer networking of Chest Clinics and PHUs. Chest Clinics to be responsible for using the network IDSS to update notification details, monitor infection rates in high risk populations and for program evaluation.

Program evaluation

By 1993 TBAC to agree upon a core set of program evaluation indicators for Areas/Regions and the State. See Appendix 3 for proposed set of program evaluation indicators.

By 1993 EHSEB to expand the NSW IDSS database to include additional case follow up details, to facilitate program evaluation and patient management, eg related to drugs prescribed, duration and interruption of chemotherapy, and bacteriologic conversion (TB case module). These additional details should directly relate to the core set of program evaluation indicators (see Appendix 2).

The expanded IDSS should include a programmed reporting facility which generates program evaluation indicators for specified periods of case notifications by cohort analysis.

By 1993 Area/ Regional TB Coordinators to report quarterly to the NSW TB Coordinator on program evaluation indicators for case management and follow up related to: delay in diagnosis and notification; initiation of appropriate drug regimen; drug continuity and completion; treatment failure; cure; case fatality (see Appendix 3).

By 1994 EHSEB to expand the NSW IDSS database to include information from screening, to facilitate program evaluation and patient management:

- contact tracing details eg time until follow up, new infections detected (contacts relational file/ screening module).

- other screening data eg drugs prescribed, duration and interruption of chemoprophylaxis (screening module).

By 1994 Area/ Regional TB Coordinators to report annually to the NSW TB Coordinator on program evaluation indicators for screening related to: delay in examination of contacts; location of contacts; infection rates for all screened populations; initiation of chemoprophylaxis; drug continuity and completion (see Appendix 3).

By 1994 NSW TB Coordinator to report annually to EHSEB on program evaluation indicators for case management/ follow up and screening.

Services

By 1993 NSW TB Coordinator/ PHU Directors to nominate TB coordinators for each Area/ Region, who will be responsible for:

- program evaluation and quality assurance, and

- ensuring and monitoring the implementation of Statewide policies and guidelines, recommendations from the NSW Review of TB Services 1992 and other responsibilities outlined in this document.

By 1993 NSW TB Coordinator/ EHSEB to incorporate updated Statewide guidelines and policies related to TB control into a standard 'Policies and Procedures Manual', which is distributed to NSW Chest Clinics, PHUs and hospitals, as well as Regional Community Health Services.

By 1993 Area/ Regional Health Services should aim to have

- Chest Clinics staffed with Physicians with special training in TB, and

- in rural areas where Physicians with training in TB are not available, all active cases to have treatment initiated and ceased by and be discharged from medical care by such a Physician from the most accessible Chest Clinic.

By 1993 Area/ Regional Health Services to ensure that all Area hospitals, and all major Regional hospitals or Community Health Services, have at least one registered nurse trained in routine Mantoux testing and BCG vaccination of staff and patients.

By 1993 Area/ Regional Health Services to ensure that:

- 'satellite' Clinics (run by CCS at locations remote from their base Clinic) are rationalised,

- in these small rural localities at least one nominated registered nurse (hospital and/ or community based) is trained in and performs all basic TB related duties (Mantoux testing; BCG vaccination; supervision of anti-TB chemotherapy; routine follow up of contacts, inactive cases and migrants on TBUs), and

- the routine follow up of inactive cases, migrants on TBUs and contacts who live remote from a Regional Chest Clinic is coordinated and supervised by the nearest CCS.

By 1993 NSW and Area/ Regional TB Coordinators to develop inservice training modules for health care workers (and workers in long term care facilities) about the risks of TB transmission, signs and symptoms, methods of diagnosis, procedures for minimising risk and accessing TB Services.

By 1993 NSW TB Coordinator/ EHSEB to develop program evaluation training modules and guidelines for Area/ Regional TB Coordinators.

By 1993 Area/Regional TB Coordinators/Health Services to ensure that appropriate mechanisms are in place within hospitals to facilitate effective liaison and coordination between Infectious Diseases, HIV/AIDS and Chest Clinic medical and nursing staff.

By 1994 NSW TB Coordinator to annually update the NSW TB 'Policies and Procedures Manual'.

By 1994 Area TB Coordinators/ Area Health Services to ensure that:

- staff who provide TB Services receive appropriate training to facilitate effective communication with high risk groups, and

- staff are culturally sensitive to the populations being served.

3. POLICIES

3.1 SCREENING - TARGET GROUPS

- Due to the low yield, mass population screening is not justifiable except for subgroups with high rates of infection. The rationale is to identify those who would benefit from chemoprophylaxis (or chemotherapy). Screening, by Mantoux testing, is generally recommended where the rate of infection is greater than 1%[4].

- The predictive value of Mantoux tests is low in populations with a low prevalence of infection. This means that in low risk populations, eg the general population or distant contacts (eg workmates) of cases of low infectiousness, a large proportion of Mantoux positive people will not be truly infected.

- As rates of disease decrease, the value of continued screening should be regularly assessed.

- Screening chest x-rays are rarely justified, except when:

  a) The objective is to identify those with current pulmonary disease and the administration of chemoprophylaxis to infected people is not possible[11]. Those in hostels for the homeless are suitable for screening by chest x-rays (and possibly sputum smears).

  b) There is a high probability of false negative Mantoux reactions, eg in immunosuppressed people. Therefore, a high index of clinical suspicion of pulmonary and extrapulmonary disease should be maintained and appropriate investigations performed for people with clinical AIDS or other HIV related disease, regardless of the results of Mantoux testing[21].

- In NSW the following groups should be screened by Mantoux tests (unless otherwise indicated) on a routine or periodic basis:

  (i) Routine screening

  - Close contacts of people known or suspected to have clinical TB
  - People with medical risk factors for TB
  - People with HIV infection
  - Health care workers/ students at the commencement of employment
  - Immigrants (migrants and refugees) from high prevalence countries

  (ii) Periodic screening

  - Residents of hostels for the homeless - six monthly chest x-ray screening

  - 'High risk' HCWs - 12 to 24 monthly Mantoux tests (depending upon estimated risk).

- To identify other high risk groups in NSW, baseline data should be obtained to estimate risk and hence evaluate the need for screening on a routine or periodic basis. The risk should be estimated either by baseline screening surveys or collation and analysis of available data, as indicated:

  (i) Routine screening:

  - Prison inmates on admission - Mantoux screening survey
  - Nursing home residents on admission - chest x-ray screening survey
  - Injecting drug users - Mantoux screening survey

  (ii) Periodic surveys (frequency depending on the estimated risk)

  - 'Medium risk' HCWs - Baseline screening surveys and/ or collation and analysis of available data (See Chapter 3.4)
  - Aborigines - Mantoux screening survey

3.2 CONTACT TRACING AND FOLLOW UP

A. Aims

The aims of contact tracing are:

1. to identify those infected by the index case, and/ or
2. to identify a source of infection for the index case.

B. Notification of cases to Chest Clinic staff

PHUs should immediately report case notifications to the nearest Chest Clinic, by phone initially, followed up by sending copies of notifications. ('Notifications' include all doctor notifications of TB and laboratory notifications of mycobacterial infection.)

C. Timing and extent of contact tracing investigations

The estimated risk of transmission should guide the priority, rapidity and thoroughness of contact investigation.

The following steps, summarised in the box, should be undertaken. These steps are described in full on the following two pages.

1. **Categorise the case according to the likely degree of infectiousness.**
2. **Obtain a list of contacts and categorise the contacts according to their estimated risks.**
3. **Examine all 'high risk' contacts of pulmonary TB cases first.**
4. **Consider examination of 'medium risk' (followed by 'low risk') contacts of pulmonary TB cases.**
5. **Consult with the Medical Officer of Health and NSW TB Coordinator, if:**
   - **the case works in a hospital, school, day care or long term care facility,**
   - **screening is indicated for more than 25 contacts, or**
   - **if in doubt about the priority/ extent of contact screening required, for any reason.**

(1) Categorise the case according to the likely degree of infectiousness

'High' = direct sputum smear positive and/ or chest x-ray cavitation

'Medium' = sputum culture positive and direct smear negative, no chest x-ray cavitation

'Low' = sputum culture and direct smear negative

'Negligible' = extrapulmonary TB (and atypical mycobacterium)

(As culture and identification results are not routinely available for some weeks, initially cases of 'medium' and 'low' infectiousness will not be distinguishable and atypical mycobacteria will not have been identified.)

(2) Obtain a list of contacts and categorise the contacts according to their estimated risk

A list of close contacts, including names and addresses, should be compiled first. Contacts should be categorised into:

'High risk' group = frequent, prolonged and close contact within last three months (or as far back as a clear history of active TB disease). This group includes:

- all people living in the same dwelling
- relatives and friends who have frequent, prolonged and close contact
- any others who have spent 8 hours or more with the case in a closed environment.

'Medium risk' group = frequent but less intense contact. This group includes:

- other close relatives, friends, schoolmates and work colleagues eg neighbours, relatives who frequently visit the case's home.

The 'Low risk' group includes other contacts at school (especially Primary Schools) or in the workplace or in clubs. However, obtaining details of 'low risk' contacts is not necessary initially and need only be pursued if there is evidence of transmission in the 'high risk' and 'medium risk' groups.

(3) **Examine all 'high risk' contacts of all pulmonary TB cases first**

- 'High risk' contacts of highly infectious cases should be examined within seven days of notification for child contacts and 10 days for adult contacts.
- 'High risk' contacts of cases of 'medium'/ 'low' infectiousness should be examined within 10 days of notification (or before the case is discharged from hospital).
- Contacts of cases with 'negligible' infectiousness need not be examined. (Contacts of cases of pulmonary atypical disease should have been examined once, however, before identification results are available.)

(4) **Consider examination of 'medium risk' (followed by 'low risk') contacts of pulmonary TB cases.**

- **Only if there is evidence of transmission in the 'high risk' contacts group, should screening progress to the 'medium risk' group.**
- **Only if there is evidence of transmission in the 'medium risk' group, should screening progress to the 'low risk' group.**

'Evidence of transmission' means recent Mantoux conversion and no other identifiable source of infection.

If ten or more of the closest contacts have been tested and all are Mantoux negative, testing of more remote contacts is usually unnecessary.

If less than ten contacts have been tested, and all are Mantoux negative, careful consideration should be given to the theoretical risk of infection before stopping the contact investigation.

(5) **Consult with the Medical Officer of Health in your Area/ Region and the NSW Tuberculosis Coordinator if:**

- **the case works in a hospital, school, day care facility or long term care facility (nursing home, hostel or prison), or**
- **screening is required for more than 25 contacts, or**
- **in doubt about the priority/ extent of contact tracing required, for any reason.**

D. Procedures

- **Contacts who are Mantoux negative throughout follow up:**

First visit

i) Mantoux test
ii) chest x-ray - unless aged less than 15 years
- chest x-ray to be reviewed by physician

48-72 hours later

iii) read Mantoux reaction

Second visit - 12 weeks after 1st visit

i) Mantoux test

48-72 hours later

ii) read Mantoux reaction

Third visit - 12 months after 1st visit

i) Mantoux test

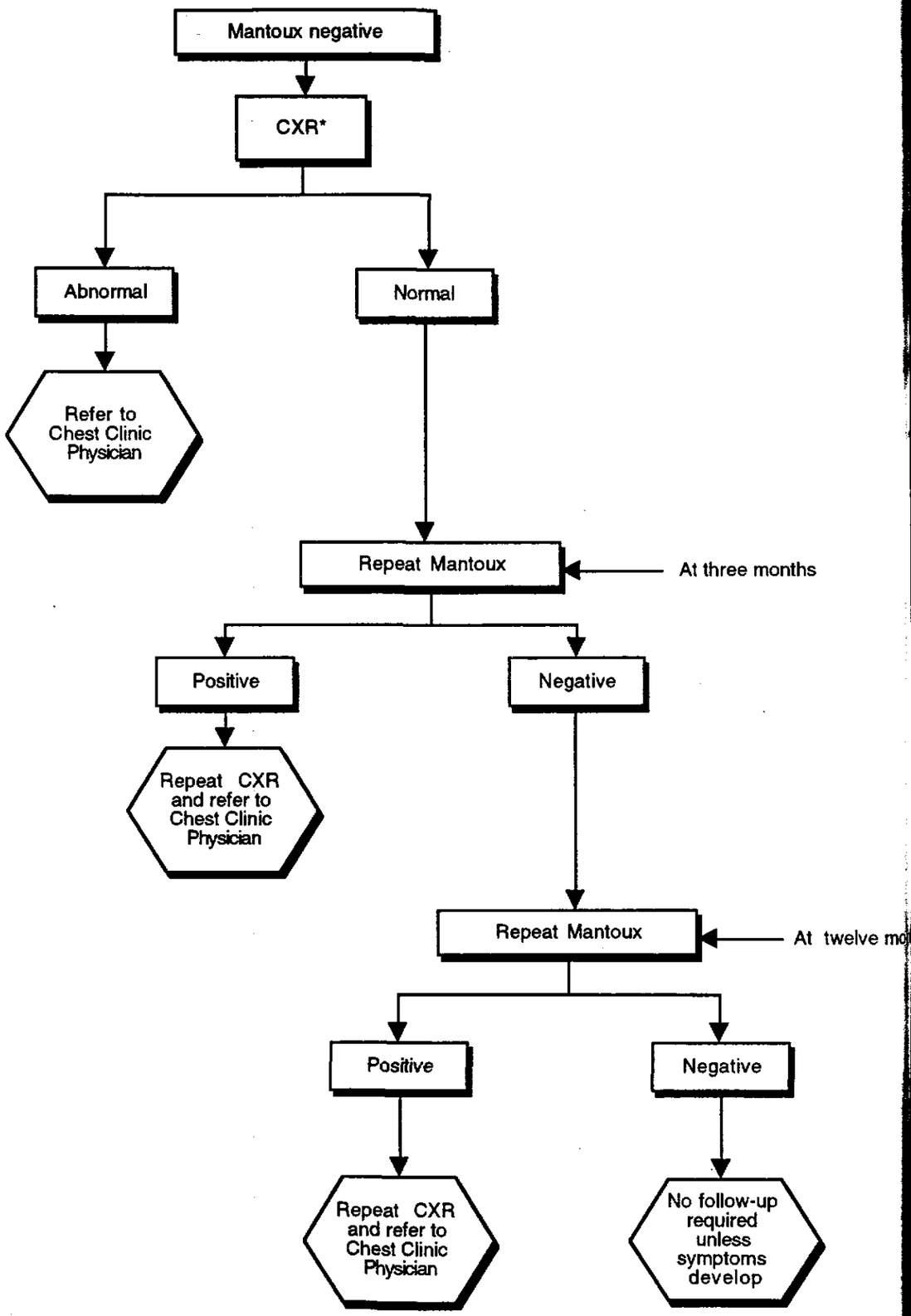
48-72 hours later

ii) read Mantoux reaction

There should be no further routine follow up.

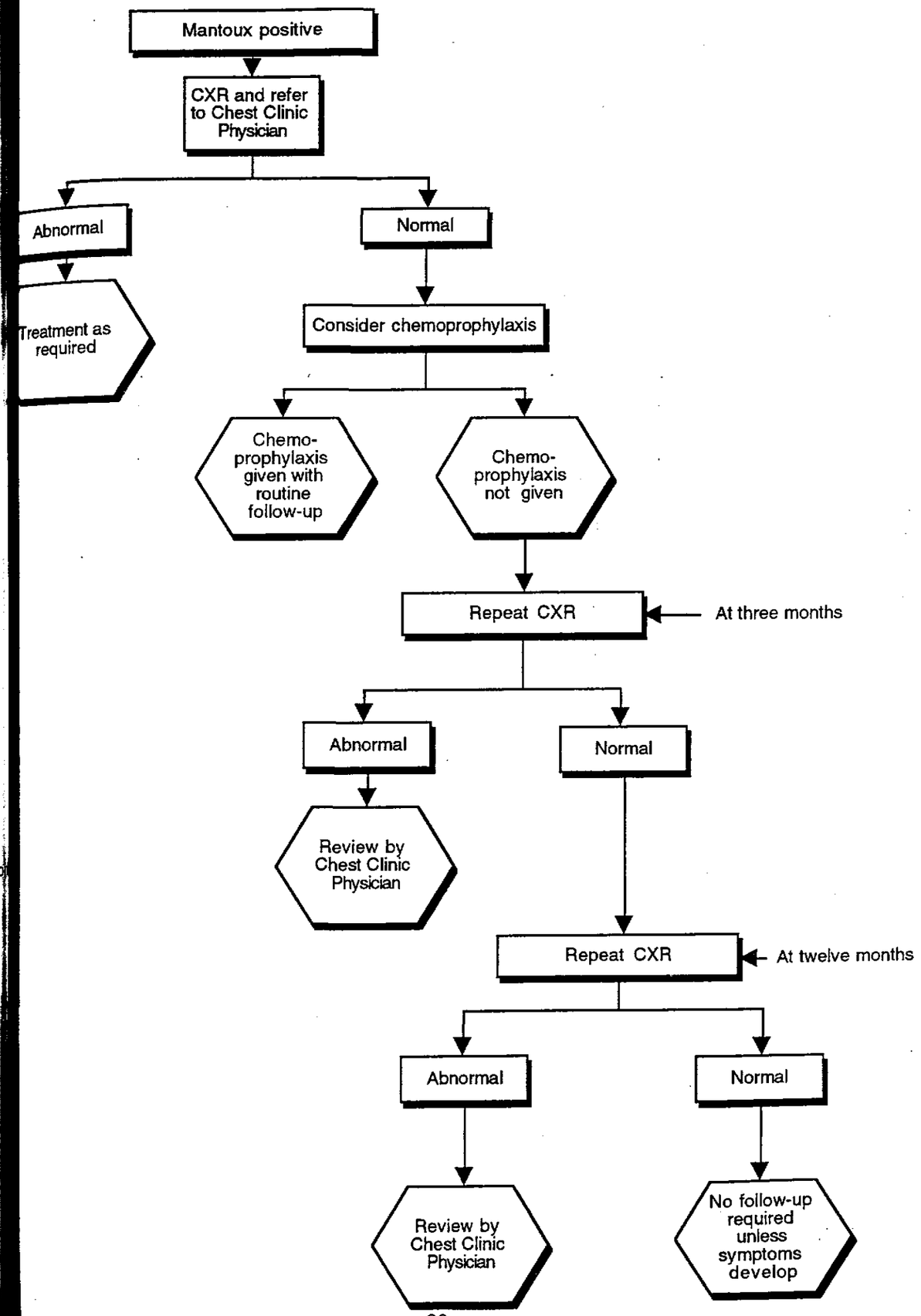
- **Contacts who are Mantoux positive** at any visit **must** have a chest x-ray taken, and be referred to a physician for assessment for chemoprophylaxis (or chemotherapy). The alternative is annual chest x-rays for up to two years.
- **Child contacts aged less than five years who are Mantoux positive** should be referred to a physician for assessment for chemoprophylaxis (or chemotherapy).
- **'High risk' child contacts aged less than five years who are Mantoux negative** on the first visit should be referred to a physician and be given chemoprophylaxis until the 12 week Mantoux test is shown to be negative, unless contraindicated.
- **Child contacts aged less than 16 years who are Mantoux negative and have continuous exposure to an active case** and a) cannot be placed on isoniazid or b) are exposed to a case with organisms resistant to both isoniazid and rifampicin, should be considered for BCG vaccination prophylaxis.
- **These procedures will be reviewed** pending results from a contact tracing survey which is currently being conducted.

Figure 11 : Management of Mantoux Negative Contacts



*Not indicated if aged less than 15 years

Figure 12 : Management of Mantoux Positive Contacts



3.3 MANTOUX TEST

A. Procedure

- **Client position** - Still, seated.
- **Site** - Upper third and middle part of anterior aspect of left forearm for human PPD (unless contraindicated eg large tattoo or birthmark) away from the veins and if possible free from hairs, scars and tattoos. Children with positive Mantoux reactions should be tested with avium PPD in their right forearm.
- **Skin preparation** - Swab the area with an alcohol swab. The skin must be dry before injection.
- **Equipment** - 1ml tuberculin syringe with a 26 gauge needle
- **Dose** - 0.1ml of PPD (Purified Protein Derivative) tuberculin 10IU
- **Method** - Intradermal injection only
- **Character** - A "bleb" of approximately 7-8mm in diameter forms immediately after the injection.

B. Reading the reaction

- **When**? - 48-72 hours after the injection
- **What**? - Induration **NOT** erythema
- **How**? - "BALL POINT TECHNIQUE" is more accurate than the traditional finger tip technique of measuring induration.

  (1) Draw a line with a "medium" ball point pen from a point 2-3cm away from the margin of the skin test reaction towards its centre.

  Maintain skin tension by exerting slight traction opposite to the direction of the pen movement.

  Exert moderate pressure against the skin and move the pen slowly.

  (2) Lift the pen when the ball point reaches the margin of the indurated area and there is definite resistance to further movement.

  (3) Repeat the procedure from the opposite side of the reaction.

  (4) Measure the distance between opposing lines by a calliper or ruler. Record in millimetres and do **NOT** round your reading to the closest 5mm.

C. Interpreting the test

- Reactions are considered positive if there is induration of at least:

  (i) 5 mm: for people with HIV infection or risk factors for HIV infection with unknown HIV status,

  for recent close contacts of infectious TB cases, and

  for people with chest x-rays consistent with healed TB.

  (ii) 10mm: for others (including those who have had BCG vaccination).

- People with positive reactions should be referred for medical assessment.
- **Positive reactions usually mean** that the person has been infected with *M. tuberculosis*. Only 5-10% of people who have been infected are at risk of developing disease at some time in their lives.
- **'False positive' reactions** mean that the person has a positive reaction but <u>has not</u> been infected *M. tuberculosis*. This can occur because of:
  - exposure to other types of mycobacterium which do not usually cause disease, or
  - previous BCG vaccination, especially recent.

  Management would depend upon the risk of infection and should be assessed individually.

- **'False negative' reactions** mean that the person has a negative reaction but <u>has</u> been infected with *M. tuberculosis*. This can occur:
  - before hypersensitivity develops ie during the "incubation period" (usually 4-12 weeks)
  - with faulty technique eg poor or expired tuberculin, leaking syringe, injection too deep
  - during advanced or terminal stages of TB
  - with immunosuppression eg HIV infection
  - during corticosteroid, anti-histamine or anti-inflammatory treatment
  - with severe malnutrition, dehydration or inanition
  - in the elderly, particularly with chronic illness and poor nutrition
  - after an attack of pertussis (whooping cough) or measles

3.4 HEALTH CARE WORKER SCREENING AND PROTECTION

- A high index of suspicion should be maintained to allow early identification and treatment of infectious patients. Effective multidrug therapy should be initiated promptly based on clinical and drug surveillance data.

- Infection control measures should follow established guidelines for AFB isolation precautions; cleaning, disinfecting and sterilising; ensuring adequate ventilation; and special precautions during cough inducing and aerosol generating procedures.

- Policy for TB control among hospital staff should be uniform throughout NSW because movement of staff is common. Health care workers (HCWs) should carry a personal record of BCG vaccination and results of employment related screening from one employment to another.

- All medical, nursing, pathology, radiology and paramedical hospital staff should:

    - receive a Mantoux test on employment unless there is documentation of a positive Mantoux test, adequate treatment for disease or infection, or a negative Mantoux test within the previous three months, and

    - be offered BCG vaccination if Mantoux negative.

- HCWs should not commence work in a high risk area without prior adequate screening.

- Whether and how often screening (Mantoux tests or chest x-rays for Mantoux positive workers) is undertaken during employment should depend on the estimated risk of infection (ie Mantoux conversion rates in cohorts of unvaccinated HCWs).

    - HCWs should be classified into 'high', 'medium' and 'low' risk groups. Categorisation of potential risk should depend on a) occupational group, b) risk in community served by health care facility, and c) area worked in health care facility.

    - 'High risk' Mantoux negative HCWs should be periodically screened by Mantoux tests during employment. The frequency of screening (eg annually or biannually) should depend on the estimated risk of infection.

    - 'Medium risk' Mantoux negative HCWs should also be periodically screened by Mantoux tests during employment, unless the risk of infection is shown to be less than 1% per annum.

    - 'Low risk' HCWs should not be routinely screened during employment.

- Data on skin test conversions in HCWs should be periodically reviewed so that infection risk can be estimated and the frequency of retesting should be altered accordingly.

- All HCWs should be evaluated according to routine contact tracing procedures if they are exposed to a potentially infectious TB patient for whom adequate infection control procedures had not been taken.

- Documentation of the results of employment related Mantoux tests and chest x-rays must be maintained by the health care institutions.

PROPOSED CATEGORIES OF RISK FOR HEALTH CARE WORKERS

1. **'High' risk category**

    - All staff working within respiratory clinics and designated chest clinics

    - Staff in bronchoscopy theatres

    - Medical, nursing staff, radiographers, physiotherapists and students who regularly work with TB or HIV positive patients

    - Laboratory staff working with tuberculous material, for example, mycobacteria laboratory, bacteriology, cytology staff

    - Mortuary staff

2. **'Medium' risk category**

    - Other medical and nursing staff, physiotherapists, radiographers, paramedical staff and students involved in direct patient care not included in 'high' risk category

    - Ambulance personnel

    - Non clinical staff who are regularly in close contact with patients, for example, wardsmen

3. **'Low' risk category**

    - Staff who are not routinely exposed to patients or their clinical specimens, for example, kitchen staff, administration and clerical staff

Note: Occupational risk is not as much a concern in paediatric hospitals as in adult hospitals because children rarely cough sufficiently or have sufficient cavitatory disease to generate viable organisms. TB incidence in paediatric hospital HCWs probably reflects the incidence in the general population, rather than an occupational risk[22] [23]. More of a concern is transmission from HCW with undiagnosed tuberculosis to patients.

3.5 REFUGEE SCREENING AND FOLLOW UP[24]

- **Refugees who are Mantoux negative throughout follow up :**

First visit

i) Mantoux test
ii) chest x-ray - unless aged less than 15 years; chest x-ray to be reviewed by physician

48-72 hours later

iii) read Mantoux reaction

Second visit - 6 months

i) Mantoux test

48-72 hours later

ii) read Mantoux reaction

Third visit - 18 months

i) Mantoux test

48-72 hours later

ii) read Mantoux reaction

There should be no further routine follow up. Refugees should be advised to seek medical advice if symptoms develop.

- **Refugees who are Mantoux positive** at any screen must have a chest x-ray, and see a physician for assessment for chemoprophylaxis (or chemotherapy). The alternative is chest x-ray follow up for up to two years.

- **Refugees with chest x-ray abnormalities** should see a physician immediately.

3.6 HEALTH UNDERTAKINGS (TBU) FOLLOW UP

(A) Migrants who have abnormal premigration chest x-rays (which may or may not be tuberculous in origin) and/ or have had TB treatment may be permitted entry to Australia if they agree to sign a Health Undertaking (TBU) to adhere to the following conditions:

- report to the state/territory contact authority (in NSW, the TB coordinator based at Lidcombe Hospital) initially by telephone within one (or if advised, four) weeks of arrival
- place themselves under the authority's professional supervision
- agree to undergo any further tests (eg, Mantoux test, chest x-ray and medical examinations) as necessary
- agree to undergo any course of treatment which the authority directs
- inform the authority each time they change address in Australia throughout the period during which the authority is monitoring the migrants
- inform the authority whenever they are about to leave Australia and report to the authority on return
- inform the Australian visa office if, before departure, the proposed address in Australia or the travel times change

(B) Migrants are referred by the NSW TB Coordinator to their nearest Chest Clinic.

(C) **Chest Clinic appointments** should be made:

- immediately - if a) migrants have had TB treatment, or b) their pre-migration chest x-ray abnormalities are suspicious of active TB disease, and
- within six months after the pre migration chest x-ray - for others.

(D) **Routine follow up - if had previous TB treatment**

First Visit

i) chest x-ray - to be reviewed by physician
ii) sputum (3) for AFBs - as indicated
iii) see physician

Second Visit - 6 months

i) chest x-ray - to be reviewed by physician
ii) see physician if any changes

Third Visit - 18 months

i) chest x-ray - to be reviewed by physician
ii) see physician if any changes

Further Visits - annually for up to two more years

i) chest x-ray - to be reviewed by physician
ii) see physician if any changes

(E) **Routine follow up - if not had previous treatment**

First visit

i) Mantoux test - if documentation of Mantoux negativity or no documentation of Mantoux status
ii) chest x-ray - if aged 15 years and over and/ or if Mantoux positive and/ or premigration chest x-ray suspicious; chest x-ray to be reviewed by physician
iii) sputum (3) for AFBs - as indicated

48-72 hours later:

iv) read Mantoux reaction

Migrants with abnormal chest x-rays or positive Mantoux reactions should be seen by a physician to be considered for chemoprophylaxis or chemotherapy.

Migrants with clear post-migration chest x-rays and no other risk factors (eg Mantoux positive and recent contact) should be discharged immediately.

Second visit - 12 months

i) chest x-ray - if aged 15 years and over; chest x-ray to be reviewed by physician
ii) see physician if any changes

Migrants with stable minor chest x-ray abnormalities and no other risk factors should be discharged after 12 months follow up.

Third visit - 24 months

i) chest x-ray - if aged 15 years and over; chest x-ray to be reviewed by physician
ii) see physician if any changes

Migrants with stable chest x-ray abnormalities should be discharged after 24 months follow up.

On discharge, migrants on TBUs should be advised to seek medical attention immediately at the nearest Chest Clinic if they develop any symptoms.

3.7 HIV/AIDS AND TUBERCULOSIS

- The changes in cell mediated immunity, that occur in HIV related disease, facilitate the development of TB disease. The defect in the hypersensitivity component of immunity also diminishes host tissue responses, and in the late stages of HIV related disease, results in more easily disseminated disease and a different clinical picture[25].

- A high index of clinical suspicion of pulmonary and extrapulmonary TB in patients with HIV infection should be maintained and appropriate investigations, such as Mantoux testing, should be performed.

- HIV testing should be offered to patients with active TB, if they have a high risk profile for HIV infection, if they have a low risk profile for TB and /or if they have extrapulmonary TB. Risk factors for HIV infection include history of homosexual contact, intravenous drug use, or migration from countries with high prevalence of HIV infection, for example South East Asia and Africa[6 25].

- All HIV seropositive people with a Mantoux reaction > 5mm should have chemoprophylaxis, unless medically contraindicated. Recommended duration is at least 12 months with good supervision and follow up should continue indefinitely[21].

- All HIV seropositive people with clinical AIDS or other HIV related disease should have a chest x-ray and be examined for extrapulmonary TB, regardless of the results of Mantoux testing.

- Active TB in HIV seropositive (and other immunocompromised) people should be treated with conventional medications but for three months longer than for other patients, or for a minimum of six months after sputum cultures become negative. Follow up of HIV/AIDS patients should continue indefinitely[6].

- BCG is contraindicated in immunosuppressed patients[6].

- Infection control measures for TB should be in place when investigating patients with HIV infection.

- Care should be taken with TB patients in health care settings, in particular HIV-TB coinfected people who are direct smear positive, to avoid their contact with immunosuppressed people (including Health Care Workers). Investigations and treatments which induce coughing, thereby spreading infected droplets, should be avoided.

- Mycobacterium isolated from HIV seropositive patients should not be assumed to be atypical mycobacterium, for example *mycobacterial avium*, until confirmation.

3.8 TUBERCULOSIS IN CHILDREN AND ADOLESCENTS[26]

Tuberculosis (TB) in children and adolescents differs markedly from TB in adults with regard to the following aspects.

A. Risk of disease following primary infection

The lifetime risk of post-primary tuberculosis disease in adults following primary infection is in the range of 5-10%. However, this risk is much greater in children[27]:

- <1 year - 50%
- 1-5 years - 25%
- 11-15 years - 15% (females>males)

B. Infectivity

TB in children is "primary" TB, a disease which is predominantly one of delayed hypersensitivity with few organisms and variable immune response. Childhood TB is rarely contagious except in older adolescents with cavitatory disease or laryngeal TB. The reasons are:

- children with TB disease usually have a small tubercle load,
- children very rarely have cavitating disease, and
- children usually swallow their sputum, and have a far less effective cough than adults.

C. Diagnosis

A Mantoux reaction is considered positive[28] in a child if:

- ≥ 5 mm - when child is at high risk of infection.
- ≥ 10 mm - when at moderate risk of infection or BCG ≥ 5 years prior.
- ≥ 15 mm - when at low risk of infection or BCG within 5 years.

Risk Categories

HIGH RISK	MODERATE RISK	LOW RISK
Contacts of infectious cases	Ethnic origin from high prevalence populations	No risk factors
HIV infected or other immunosuppressed (including steroids)	Locally identified high risk populations	
Abnormal chest x-ray	Children < 5 years	

D. Chemoprophylaxis

Due to the increased risk of TB disease in children, especially under the age of 5 years, chemoprophylaxis is more commonly recommended than in adults. Chemoprophylaxis, usually with isoniazid alone, is recommended for all children and adolescents who are Mantoux positive but have no clinical or radiological evidence of TB. In the < 5 year age group, chemoprophylaxis is indicated if very high risk, irrespective of Mantoux status, until the repeat Mantoux test is shown to be negative (three months). Chemoprophylaxis in children, especially under the age of 5 years, should ideally be supervised.

In contrast to adults, the incidence of liver toxicity from isoniazid in children is extremely low. Liver function is evaluated only when clinically indicated, and routine monitoring of liver function is not recommended.

E. Treatment

It is recommended that children are treated with daily therapy with at least three drugs (usually isoniazid, rifampicin and pyrazinamide) for the first two months. Generally 2 drugs (isoniazid and rifampicin) are then used for a further 4 months and can be given daily or three times a week. Short course chemotherapy (6 months) has been shown to be effective in children, but there are insufficient data to recommend it for CNS, bone or joint TB infections. All treatment regimes in children should be fully supervised.

3.9 BCG VACCINATION

BCG (Bacille-Calmette-Guerin) vaccine contains a live attenuated strain of *Mycobacterium bovis* - the mycobacterium has lost its virulence but retains its antigenic property. BCG can produce immunity, overseas trials showing protection varying from 0-75%, but rarely produces disease. In contrast, natural infection with virulent *M. tuberculosis* produces immunity, and causes disease in 5-10% of people.

A. Indications

BCG vaccination should be offered to Mantoux negative people who are:

- children aged less than 16 years who:
  - belong to groups with new infection rates more than 1% per year,
  - have continuous exposure to cases with active disease and cannot be placed on isoniazid therapy, or
  - have continuous exposure to cases with organisms resistant to isoniazid and rifampicin
- children and adults who are travelling overseas to live in a high prevalence country for a prolonged period (12 months or more)
- neonates from ethnic groups with a high prevalence of TB or with a family history of TB
- medical, nursing, pathology, radiology and paramedical hospital staff

B. Contraindications

- Relative:
  - age > 35 years
  - pregnancy
- Absolute:
  - primary or secondary immunosuppression, including people: with HIV infection or high risk for HIV infection where status is unknown; receiving oral corticosteroids, immunosuppressive drugs or irradiation
  - malignancies involving bone marrow or lymphoid systems
  - septic skin conditions
  - Mantoux reaction > 5mm

C. Procedure

- **Mantoux reaction** - Must be < 5mm. For contacts, must be < 5mm at the 12 week follow up. For neonates (less than one month old) BCG vaccination is done without performing a Mantoux test.
- **Client position** - Still, seated with head turned in the opposite direction of the injection site
- **Site** - Middle part of the left deltoid area
- **Skin preparation** - Swab the skin with acetone swab and make sure it's dry before vaccination.
- **Equipment** - 1ml tuberculin syringe with a 26 gauge needle
- **Dosage** - 0.1ml (0.075ml for neonates)
- **Method** - Intradermal injection ONLY ie just under the skin surface (NOT SUBCUTANEOUS)
- **Character**

  i) immediate - "bleb" of about 8mm diameter forms
  ii) 30 minutes later - "bleb" disappears
  iii) 2-3 weeks later - papule of 2-4mm forms
  iv) 2-4 weeks later - pustule forms
  v) 2-3 months later - pustule ruptures and small ulcer forms
  vi) within 3 months - scar of about 5-7mm diameter forms

- **Ulcer care**

  i) Keep it open - ie. no dressings or topical treatments.
  ii) Avoid bumps and scratches.
  iii) Continue normal activities - eg. swimming, sports.
  iv) Apply a sterile gauze loosely - if necessary, for cosmetic purposes. Do not apply strapping near the ulcer.

- **Follow up**

Repeat Mantoux tests are not indicated if a good BCG scar has formed.

3.10 CHEMOPROPHYLAXIS

- Unless specifically contraindicated, chemoprophylaxis should be considered for all high risk Mantoux positive people, such as :
  - contacts of people with TB
  - recent Mantoux converters (within two years)
  - people with medical risk factors for TB
  - HIV infected people
  - intravenous drug users
  - people with chest x-rays suggestive of inactive TB in whom active disease is excluded and who have not completed treatment for TB
  - others under 45 years of age (including migrants/ refugees and residents of long term facilities with no other risk factors).
- Chemoprophylaxis should be offered to all Mantoux negative children under five years of age who are close contacts of high risk (direct smear positive) people with TB. Prophylaxis should continue until a repeat test in 12 weeks (after contact is broken) is shown also to be negative.
- Chemoprophylaxis should be for a minimum of six months. Six month regimens are preferable to maximise compliance and minimise costs. Exceptions are those with HIV infection or an abnormal chest x-ray consistent with old inactive TB who should be treated for at least 12 months.
- Direct supervision with three times weekly short regimens is indicated for children aged less than five years of age and others at high risk of developing TB.
- Multidrug regimens should be considered for people at high risk of severe forms of disease who are likely to be infected with isoniazid resistant organisms.
- Isoniazid chemoprophylaxis is contraindicated for people with chronic liver disease or alcoholism. Where there is doubt long term surveillance is recommended.
- People receiving chemoprophylaxis must be reviewed at least monthly for side effects and to assess compliance.
- Chemoprophylactic drugs have side effects and are potentially toxic. The benefits of treatment must be weighed against the risks and costs, and the decision for treatment must be individually assessed.

3.11 CHEMOTHERAPY

> Chemotherapeutic regimens for tuberculosis should be chosen in accordance with the National Health and Medical Research Council (NHMRC) guidelines[6].

- A high index of suspicion should be maintained to identify cases rapidly. This is particularly the case for patient populations who commonly present atypically, for example, the elderly and HIV patients.
- Effective multidrug anti-TB therapy should be initiated promptly based on clinical (high index of suspicion or confirmation) and drug resistance surveillance data.
- If drug resistance is suspected, cases should be treated as drug resistant until proven otherwise. Drug resistance should be suspected with a history of previous chemotherapy, especially if inadequately supervised or documented, or place of birth in Asia, Africa or Latin America.
- Drug regimens of at least six months duration are recommended for both smear negative and smear positive patients. In any case therapy must be long enough to fulfil the requirements of the given regimen. Pyrazinamide must be included in the first two months of any six month regimen[6].
- Chemotherapy should be fully supervised, with a three times weekly regimen, for all pulmonary and extrapulmonary cases. Full supervision requires the actual observation of drug ingestion and a written record of drug administration (patient and clinic held).
- The progress of smear positive patients on chemotherapy must be monitored by sputum examination at regular intervals until the sputum is smear negative.
- Patients who have had at least six months of supervised chemotherapy for TB should **not** be routinely followed for longer than three years after treatment is completed. They should be given a copy of their latest chest x-ray and advised about TB symptoms and urged to seek medical care immediately if symptoms appear.
- Active TB in HIV seropositive and other immunocompromised people should be treated with conventional medications but for three months longer than for other patients, or a minimum of six months after sputum cultures become negative. Follow up of HIV-AIDS patients should continue indefinitely[6].

3.12 GUIDELINES FOR HOSPITALISATION OF ACTIVE CASES

A. INTRODUCTION

- Transmission of infection is more likely to occur in poorly ventilated and overcrowded conditions, and infection of family contacts is the most common. The risk of infection is related more to the bacteriological status of the patient rather than to the intimacy of contact, so that infection may occur when contact has not been prolonged or close.

- Indirect contact through contaminated articles is extremely rare, as is direct invasion through mucous membranes or breaks in the skin.

- Appropriate antimicrobial therapy reduces communicability within a few weeks; some untreated or inadequately treated patients may be intermittently AFB sputum positive for years.

- Closed extrapulmonary TB is not infectious. There is a risk of transmission in the presence of a tuberculous discharge.

B. HOSPITAL ADMISSION

- Patients diagnosed or suspected of having active TB should be admitted to hospital to:

  - confirm the diagnosis,

  - minimise further spread during the period of high communicability, and

  - initiate the treatment and assess the patients' tolerance of medication.

- Patients with active TB should remain in hospital as long as their sputum is positive for AFB on direct examination. Three specimens collected at 24 hour intervals should be negative for AFB. Exceptional circumstances may justify earlier discharge. A longer time in hospital may be required under the following circumstances :

  - continued infectivity due to severe disease with cavitation or medication failures, or

  - social situation that may lead to non-compliance and disease transmission.

C. PATIENT MANAGEMENT

Isolation procedures

- People with direct sputum smear positive TB should be treated with appropriate anti-TB drugs in a single room for at least two weeks. Acid fast bacilli (AFB) precautions should be continued until the AFBs are clearing from sputum specimens and there is a significant clinical improvement.

- People with infectious TB should be isolated from immunocompromised persons, until sputum is negative for AFB or no sputum is being produced.

- Single rooms, with external ventilation (negative pressure), are necessary for people with infectious TB. Patients may leave their rooms and use hospital grounds.

- The following equipment is needed for each room: masks, thermometer, garbage bag holder with contaminated waste bag.

- The followiing additional equipment is needed if a discharging lesion or sinus is present: plastic aprons/gowns and disposable gloves.

- Separate crockery, cutlery and bed linen are not required, as tubercle bacilli do not survive for long outside the body and are killed by normal machine dishwashing and laundering procedures.

- Soiled linen should be treated as contaminated.

Personal hygiene

- Patients should be instructed in personal hygiene especially the need to cover the mouth and nose when coughing or sneezing and the careful handling and disposal of sputum.

Waste Disposal

- Sharps should be disposed as usual.

- Sputum should be collected in disposable containers, with lids which can be SECURED.

- Patients should be instructed to cough and sneeze into tissues, which should be disposed of in plastic bags.

- Body Substance Isolation Precautions apply as normal to handling of urine etc.

Laboratory Specimens

- Laboratory specimens should be:
  - well sealed with no contamination of the outside of the bottle,
  - transported immediately to laboratory in a sealed biohazard bag.
- A yellow sticker should be placed on the request form which is placed in the separate sleeve of bag.

Visitors

- Visitors should wash hands on entering and leaving the room.
- Visitors do not need to wear gowns or masks.
- Children other than the patient's own children should be discouraged from visiting.

Transport of Patients

- Patients should be adequately clothed, and required to wear a mask only to cover mouth and nose with tissue while coughing or sneezing.

Cleaning of Room

- TB patients' rooms should be cleaned daily with neutral detergent and a disposable cloths. The disposable cloths should be discarded as contaminated waste.
- TB patients' rooms should be cleaned after other rooms have been attended.

D. NOTIFICATION OF CASES

- Tuberculosis is notifiable under the Public Health Act 1991. It is notifiable as tuberculosis by Medical Practitioners pursuant to Section 14, by Hospital Chief Executive Officers pursuant to Section 69 and as mycobacterial infection by laboratories pursuant to Section 16 of the Act. Notifications must be made to the Public Health Unit using Notifiable Disease certificates which are available from the Public Health Units.
- The TB sister at the Chest Clinic serving the area where the patient lives, should be contacted as soon as possible after admission, and certainly before discharge, to discuss arrangements for supervision of post discharge treatment of the patient and examination of contacts.
- All patients should have supervised chemotherapy throughout hospitalisation and after discharge from hospital.

E. STAFF PROTECTION

- Staff involved in the management of diagnosed cases of tuberculosis are at no greater risk of contracting the disease than other staff in a hospital. In fact, there is a **greater risk of contracting tuberculosis from undiagnosed cases.**
- All medical and nursing staff, as well as pathology, radiology and paramedical staff in a hospital should have a Mantoux test at the beginning of employment, and be offered B.C.G. vaccination if Mantoux negative.
- Immunocompromised staff members should not work on wards where there are active cases of TB.
- Mantoux negative staff on wards with active cases of TB should have regular screening with Mantoux tests (see Chapter 3.4).
- Staff should be screened according to routine contact tracing procedures after exposure to potentially infectious cases of TB for whom adequate infection control measures had not been taken.
- Universal precautions should be taken. Specifically:
  - Masks should be put on when patient requires close nursing attention only.
  - Body substance isolation precautions apply when handling sputum or other infected body substances.

3.13 BACTERIOLOGICAL STUDIES IN TUBERCULOSIS[29]

The ultimate success of any modern TB Control Program will be contingent on the availability of high quality laboratory services. Important functions of the mycobacteriology laboratory are:

- microscopy
- culture
- speciation of isolates
- drug susceptibility testing
- statistics
- training
- research

A. Level of laboratory service - mycobacteriology

Obviously, not all pathology laboratories need to provide such services. US authorities have proposed a three tiered 'classification' system for labs carrying out mycobacteriological tests. Australian labs can be categorised in much the same way, as set out below.

Level I This category covers the majority of 'general' bacteriology laboratories (as would be found in hospitals) and smaller private pathologists. Direct acid fast microscopy (AFM) should be available, but culture for MTB should not be attempted. Specimens are referred to a higher level facility for both confirmatory microscopy as well as culture.

Level II This category covers the larger laboratory as would be found in certain metropolitan and provincial hospitals, and some private pathology laboratories*. Such facilities perform both AFM and mycobacterial culture. Species identification is not generally performed at this Level, although this situation might change due to new technology such as radiometric culture and DNA probes. Even so, it is imperative that all new isolates of MTB as well as any likely pathogenic atypical mycobacteria be forwarded to a Level III facility for further testing.

Level III Laboratories in this category will generally be large reference units such as now exist in Brisbane, Sydney, Melbourne, Adelaide and Perth. In addition to AFM and culture, Level III labs provide drug susceptibility tests, and full speciation of isolates. Support should also be available to lower level labs in the form of training, provision of reference methods and mycobacterial strains. Statistics, particularly those dealing with new diagnoses of TB, should be collated and provided to public health authorities. Level III labs should also be involved in the development or evaluation of new tests such as those involving molecular procedures. In the future, serum drug assays might be performed on patients being treated for certain atypical mycobacterial infections.

* **Note:** It would be the opinion of most expert mycobacteriologists that culture should not be undertaken in situations where the number of samples received is small, and/or the frequency of positives (MTB) is very low. In such situations, quality assurance procedures assume greater importance. As a guide, laboratories receiving less than around 40 routine samples per week should be discouraged from performing mycobacterial culture. There would be exceptions, e.g. in the case of a laboratory dealing with regular requests for blood culture in patients with AIDS.

B. Quality assurance

It is essential that laboratories performing diagnostic mycobacteriology at any level carry current NATA accreditation for such procedures by NATA. In addition, there should be continued efforts to monitor proficiency through participation in quality assurance programs (QAP) such as those conducted by the following:

- RCPA (Royal College of Pathologists of Australia)
- CAP (College of American Pathologists)
- ASM (Australian Society for Microbiology)
- State Tuberculosis Reference Laboratories.

The major of Australian pathology laboratories subscribe to the RCPA Microbiology QAP, which regularly includes a test for a laboratory's capability to demonstrate (and recognise) mycobacteria in specimens and in cultures. It must be stressed that satisfactory completion of this exercise should not be taken as proof of proficiency in all facets of mycobacteriology. The RCPA QAP does, however, contribute to the general awareness of mycobacteria as pathogens.

C. Standards

It has been a goal of the Special Interest Group in Mycobacteriology (within the Australian Society for Microbiology) to standardise methods in use in major diagnostic mycobacteriology labs throughout Australia. Although some degree of success can be claimed, each of the reference labs have long established protocols, and most are reluctant to make major changes. Nevertheless, it can be said that methods in use are similar and have comparable sensitivity and outcome, as shown by the results of collaborative trials.

Microscopy

Should be performed on all specimens (blood would be optional), using Ziehl-Neelsen and/or fluorochrome staining. Positive reports should make some attempt quantitation of the number of AFB present.

Culture

Should be performed on all specimens, using either the BACTEC system, or egg based, or agar media or combinations of these. Certain species such as *M bovis, M haemophilum, M marinum* have special requirements in media and/or temperature of incubation, and must be adequately catered for. BACTEC 13A medium is recommended for blood cultures. All cultures should be read at least weekly for at least 6 weeks.

Identification

Level III facilities should have the expertise to identify all human pathogens.

- MTB Complex: identify by recognised criteria, such as niacin production, nitrate reduction, cord formation, lack of growth at room temperature, drug susceptibility. Differentiation within the MTB

complex can also be achieved through such tests. Commercial DNA probes can provide more rapid results and are acceptable substitutes, but will not provide speciation within the MTB complex.

- Atypical Mycobacteria: identify all isolates likely to be pathogens, i.e. repeat isolates from sputum, isolates from sterile sites, tissues, wounds. Authoritative texts provide adequate reference sources fro procedures and identification strategies.

Susceptibility

Should be performed only in Level III facilities.

- MTB complex: test all initial isolates, as well as repeat isolates from relapse cases and 'treatment failures', for susceptibility to at least isoniazid, ethambutol, rifampicin and pyazinamide. The radiometric (BACTEC) method is recommended.

- Atypical Mycobacteria: The value of susceptibility tests on a low-growing atypical mycobacteria remains a topic of debate, although it is likely that more conclusive data will emerge in the near future. As a general policy, drug susceptibility testing of slow-growing species such as *M avium complex* cannot be justified. Some species (e.g. *M kansasii*) are so uniform in their susceptibility patterns that there is nothing to be gained from testing every isolate. Rapid growing species such as *M fortuitum* should be tested against a range of drugs such as tetracyclines, aminoglycosides, sulphonamides, by disc diffusion or disc elution.

D. Technological developments in mycobacteriology

The development of the semiautomated radiometric technique (BACTEC) has been partly responsible for a trend towards decentralisation of mycobacteriological laboratory services. Data accumulated from numerous centres in the past decade has confirmed its reliability, sensitivity, and reproducibility. A noteworthy virtue of the BACTEC system is that it provides a safe, efficient procedure for culturing blood from patients infected with HIV. It also includes options for (i) rapid differentiation of MTB complex and atypical mycobacteria (4 days), and (ii) rapid determination of drug susceptibility (4-7 days). Further, commercial probe kits can be applied directly to the BACTEC cultures for speciation. Thus, BACTEC can shorten significantly the interval between receipt of specimen and issue of results.

The new DNA amplification procedures such as PRC promise to revolutionise diagnostic mycobacteriology. Numerous publications have demonstrated the potential value of such assays, but they remain unproven in prospective clinical studies. Commercial PCR based tests for mycobacteria are likely to be released in the near future. Potentially, these will offer further opportunity for the smaller lab to perform high level mycobacteriology, and might bring about further change in recommendations as to which laboratories perform what tests.

APPENDIX 1 CASE DEFINITIONS

TUBERCULOSIS

Tuberculosis is notifiable under the Public Health Act 1991. It is notifiable as tuberculosis by Medical Practitioners pursuant to Section 14, by Hospital Chief Executive Officers pursuant to Section 69 and as mycobacterial infection by laboratories pursuant to Section 16 of the Act. Tuberculosis case definitions[30] are as follows :

Clinical Criteria

- Signs and symptoms compatible with pulmonary tuberculosis, with an abnormal, unstable chest x-ray, **or**
- Signs and symptoms compatible with extrapulmonary tuberculosis, **or**
- Evidence of disease where treatment, with two or more antituberculous medications, has been prescribed.

Laboratory Criteria

- Isolation of *Mycobacterium tuberculosis, Mycobacterium bovis or Mycobacterium africanum* from a clinical specimen, or
- Demonstration of acid fast bacilli in clinical specimen when a culture has not been or cannot be obtained, in a person suspected of having signs and symptoms compatible with tuberculosis[31].

NEW/ CHRONIC/ REACTIVATED CASES

Relapse or reactivation

- Proven clinically, radiologically or bacteriologically following at least 12 months quiescence after full chemotherapy has stopped and cure was bacteriologically proven.

New case

- Never received antiTB treatment for more than one month.

Treatment failure

- Still direct smear positive at five months or more after the start of chemotherapy for a newly diagnosed case of TB.

Returning defaulter

- Interrupted treatment for more than 2 months after completing the first month of chemotherapy, returned to treatment and was found to be direct smear or culture positive.

Chronic case

- Still discharging AFB after completing a retreatment regimen under supervision.

CAUSE OF DEATH

Deaths caused by TB

- Principal cause of death was TB.

Deaths contributed to by TB

- Principal cause of death is not TB but TB may be a contributing factor.

Deaths incidental to TB

- Principal cause of death was not TB, but TB was present at time of death.

APPENDIX 2 MINIMUM DATA REQUIREMENTS FOR TB CASE FINDING AND MANAGEMENT

- **age, sex, body weight**
- **date of onset, date of diagnosis, date of notification**
- **Chest Clinic/ AHS or Region** - commencing treatment/ supervising treatment
- **postcode of residence**
- **ethnicity** - Asian, Australian Aboriginal, Caucasian, Pacific Islander, Other
- **immigration status** - refugee, SHP, etc
- **country of birth, length of residence in Australia** - date of arrival
- **HIV status** - P/N/U; **BCG status** - Y/N/U
- **diagnosis** - microscopy (P/N), culture (P/N), Mantoux tests (mm, P/N), other skin test (mm, P/N), histology (P/N), radiological signs, clinical signs, other
- **pathogen**
- **site of disease** - Pulmonary/ Extrapulmonary/ Both - pulmonary, pleurisy with effusion, pericarditis, peritonitis, laryngeal/ endobronchial, lymphadenitis, skeletal, genitourinary, meningeal, ocular, gastrointestinal, adrenal, cutaneous, miliary, other
- **past history of disease and anti-TB treatment** - new case/ relapse/ treatment failure/ returning defaulter/ chronic case (see Appendix 1 for definitions); previous anti-TB treatment - Y (one or more months)/ N - dates commenced, stopped, completed
- **refugee screening program/TBU** - attended initial visit, attended follow ups, follow up completed - dates
- **source of diagnosis** - chest clinic (self referral), hospital, specialist, GP, TBU, refugee screening program etc; **transfer** - Y/N
- **medications** (15 possibilities plus 3 other) - dates initiated and completed - codes for standard regimens eg 2HRZ/4HR3; **supervision** - Y/N
- **drug sensitivities** - four drugs
- **treatment outcome** - bacteriology smear results - dates; regularity of drug intake - interruption of therapy, resumed therapy, ceased therapy, lost to follow up - dates; **died during treatment** - Y/N - cause of death TB or other (see Appendix 1 for definitions)
- **contacts** - relational file; **other public health action**

APPENDIX 3 SURVEILLANCE AND PROGRAM EVALUATION - INDICATORS

A. Monitoring active disease

- ***Active TB incidence rates*** - Age, sex and ethnicity specific rates should be estimated, particularly active TB incidence rates in children less than five years of age.

- ***Smear positive active TB incidence rates*** - Smear positive cases provide the most important epidemiological information because smear positive cases are the most infectious; they provide a highly specific core index of cases diagnosed with certainty; they are the most globally comparable; and case holding and treatment outcomes of these patients provides the best measures of program efficacy[32].

- ***TB-HIV coinfection rates*** - Although TB-HIV coinfection does not appear to be a problem in NSW at present, there is a need to carefully monitor the situation.

- ***TB mortality rates*** - The value of mortality data as an indicator of the TB problem is limited in industrialised countries because effective chemotherapy has vastly reduced deaths from TB[32]. Careful analysis of mortality trends, however, contributes to the monitoring of diagnostic and treatment standards.

- ***TB meningitis incidence rates in children under 5 years of age*** - This is a useful indicator of the intensity of *M tuberculosis* transmission and thus also of the effectiveness of case finding and treatment[32]. It is also important as a measure of the need for BCG vaccination of neonates.

- ***Drug resistance rates*** - Drug sensitivity testing for primary and acquired resistance provides useful information not only on the epidemiological situation, but also on the effectiveness of the treatment program.

B. Monitoring infection

- ***Annual incidence (or risk) of infection*** - Direct estimates require periodic screening of cohorts of unvaccinated people.

- ***Infection prevalence*** - Prevalence estimates among unvaccinated children, from Mantoux testing surveys, can be used to derive a crude estimate of the risk of infection in the population.

Infection data are obtained from Mantoux screening. Screening serves a number of important roles, by providing:

- epidemiologic data for assessing the extent of the TB problem (and periodic surveys provide trends of infection in the population),
- data with which to assess the value of continued screening,
- identification of people who would benefit from prophylactic or curative therapy, and,
- the opportunity to increase the awareness of high risk populations about TB and how to access TB Services.

In practice there are limitations to the monitoring of TB infection in the general population because:

- significant resources are required,
- large sample sizes are needed in low prevalence populations to obtain reliable estimates,
- the predictive value of screening tests declines with decreasing prevalence,
- in terms of identifying individuals who would benefit from prophylactic therapy screening is only productive and cost effective in populations with a high prevalence of TB[6], and
- BCG vaccination can make the Mantoux test difficult to interpret and unimmunised individuals may not be representative of the general population.

- ***Mantoux conversion rates in contacts*** - This reflects the current transmission of TB in the population.

C. Evaluating case finding and management*

- ***Case detection ratio*** - Proportion of expected cases that were reported. This reflects the intensity and the extent of the case finding activities. The calculation requires prior knowledge of the annual risk of infection; it may not be valid when the annual risk of infection is low[32].

- ***Delay in diagnosis*** - Time after onset until diagnosis.

- ***Delay until treatment*** - Time after diagnosis until treatment commenced.

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* Calculation of these indicators by cohort analysis is the most informative for evaluating the case holding and treatment program. The cohort should consist of all patients registered in a given time interval (eg three or 12 months). The duration of the interval between the registration of the cases and the analysis is chosen so that all patients can have completed the prescribed treatment and follow-up information has become available (ie the duration of the treatment regimen plus another three months).

- ***Appropriate drug regimen ratio*** - Proportion of active cases initiating treatment with appropriate and/ or standardised multidrug regimen.

- ***Supervised therapy ratio*** - Proportion of active cases on supervised therapy.

- ***Bacteriologic conversion ratio*** - Proportion of cases with bacteriologic conversion of sputum within three months of commencing therapy[33].

- ***Drug continuity ratio*** - Proportion of active cases who have taken chemotherapy continuously for the first six months of treatment; Proportion interrupted therapy; Proportion stopped therapy[33].

- ***Drug completion ratio*** - Proportion of active cases completing therapy within six/ nine/ 12 months[32 33].

- ***Treatment failure ratio*** - Proportion who are still sputum smear positive at five months or more after the start of chemotherapy[32].

- ***Defaulter ratio*** - Proportion who interrupted treatment for more than two months after completing one month of chemotherapy, returned to treatment and were found to be smear positive[32].

- ***Cure ratio*** - Proportion of patients whose cure was bacteriologically documented. This is considered the best and most accurate indicator of treatment program performance[32]. A high cure ratio indicates that both bacteriological follow up was properly done and that sputum conversion occurred.

- ***Relapse rates*** - Proportion of cases who have been previously declared cured (bacteriologically) after completing full treatment more than 12 months before.

- ***Case fatality ratio*** - Proportion of patients who died of any cause during the course of treatment. It is an indicator of the performance of the treatment program but also obviously provides information on the TB problem[32]. However, it should be interpreted carefully in low incidence countries.

- ***Case finding and chemotherapy 'impact' indicators***[34]:

  A summary 'impact' indicator can be calculated from the four indicators:

$$\text{IMPACT} = \frac{\text{new cases diagnosed}}{\text{existing cases}} * \frac{\text{new cases put on CT}}{\text{new cases diagnosed}} * \frac{\text{treatment completed}}{\text{cases put on treatment}} * \frac{\text{cases rendered negative}}{\text{treatment completed}}$$

D. Evaluating case prevention

Screening of contacts

- ***Delay in contact*** - Time from index case diagnosis until close contacts examined.

- ***Follow up ratio*** - Proportion of contacts examined.

- ***Infection rate*** - Proportion of located contacts with new infections.

- ***Prophylactic therapy ratio*** - Proportion of contacts with new infections who are prescribed prophylactic treatment.

- ***Active disease prevalence*** - Proportion of located contacts with active disease.

Screening of other high risk groups

- ***Infection prevalence*** - Proportion of various populations with infections detected by screening.

- ***Prophylactic therapy ratio*** - Proportion with infections who are prescribed prophylactic treatment.

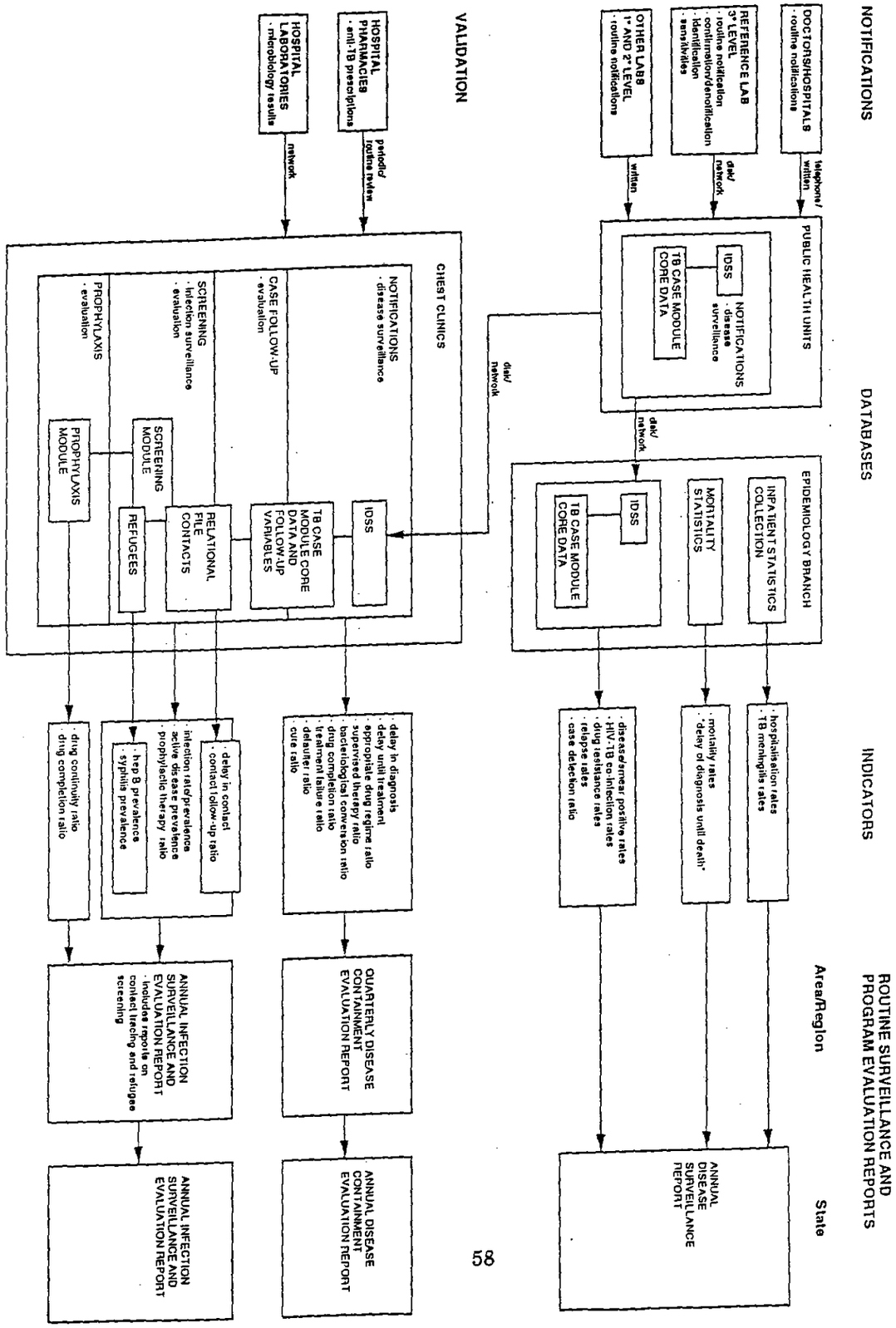
- ***Active disease prevalence*** - Proportion with active TB disease detected by screening.

Chemoprophylaxis

- ***Drug continuity ratio*** - Proportion completed six continuous months of medications

- ***Supervised therapy ratio*** - Proportion on supervised therapy

Figure 13 : TB Surveillance and Program Evaluation



APPENDIX 4 LEGAL ASPECTS OF TUBERCULOSIS CONTROL

A. Public Health Orders

- Public health orders may be made under Part 3, Division 6 of the Public Health Act 1991 by an authorised Medical Practitioner if s/he is satisfied that the person is:
  - suffering from tuberculosis **and**
  - is behaving in a way that is endangering, or is likely to endanger, the health of the public because the person is suffering from the disease.
- A public health order must require the person to whom it applies to do any one or more of the following:
  - refrain from a specified conduct
  - undergo specified treatment
  - undergo counselling by a specified person or by one or more persons belonging to a specified class of persons
  - submit to the supervision of a specified person or one or more persons belonging to a specified class of persons
  - undergo specified treatment and be detained at a specified place while undergoing the treatment.
- An order must indicate:
  - the circumstances purporting to justify making the order **and**
  - the length of time it is to remain in force (up to 28 days).
- Where the circumstances justify continuing the order past 28 days, than an application may be made to the District Court to extend the order for up to a further six months.
- It is an offence to contravene an order and the person may be apprehended by the police for such a contravention.
- It is also an offence to improperly release a person being detained under an order.
- An appeal to the District Court may be made against the order.

23. Aitken ML, Anderson KM, Albert RK. Annual Tuberculosis Screening of Hospital Employees: an idea lacking supporting data. Am Rev Resp Dis 1988;138:3-4.

24. NSW Tuberculosis Advisory Committee, 1991.

25. Goldberg HF, Pigott P. HIV Disease, TB Disease and their Association. Working paper for the TB Advisory Committee of NSW, 1991, NSW Department of Health.

26. Alperstein G, Isaacs D and Mellis C. Working Paper for the TB Advisory Committee of NSW. NSW Department of Health, 1992.

27. Miller F, Seale R, Taylor M. Tuberculosis in Children. Little and Brown. Boston, 1963.

28. American Thoracic Society. Diagnostic Standards and Classification of Tuberculosis. Am Rev Resp Dis 1990; 142: 725-735.

29. Dawson D. Submission to the National Tuberculosis Working Party, Canberra 1992.

30. Infectious Diseases Section, Epidemiology and Health Services Evaluation Branch. Infectious Diseases Manual. NSW Department of Health, 1992.

31. Wharton M, Chorba TL, Vogt RL, Morse DL, Buehler JW. Case Definitions for Public Health Surveillance. MMWR 1990; 39(RR-13):1-43.

32. World Health Organization Tuberculosis Unit. Tuberculosis Surveillance and Monitoring - Report of a WHO Workshop; Geneva, 20-22 March 1991.

33. Centers for Disease Control. Tuberculosis database 1991.

34. Rouillon A, Perdrizet S, Parrott S. Transmission of tubercle bacilli: the effects of chemotherapy. Tubercle, 1976;57:275-299.