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Supplement

Proceedings of the National Consensus Conference on Tuberculosis

December 3-5, 1997

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Health Canada

Proceedings of the National Consensus Conference on Tuberculosis

December 3-5, 1997

Prepared by the
Division of Tuberculosis Prevention and Control
Office of Special Health Initiatives
Laboratory Centre for Disease Control
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ACKNOWLEDGEMENTS

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BACKGROUND

In 1994, in response to the halt in the downward trend of tuberculosis (TB) incidence in Canada and the changing epidemiology in other countries, including the emergence of multidrug-resistant TB and the spreading TB-HIV co-epidemic, the Laboratory Centre for Disease Control (LCDC), Health Canada, held a national conference to define its role in a renewed national strategy for TB prevention and control. One of the recommendations to emerge from the conference was that a national expert advisory group be formed to consider ways of controlling and ultimately eliminating the various threats posed by TB in Canada.

The advisory group that was established, the Expert Committee on Tuberculosis (ECOT), set up several subcommittees to consider issues in specific areas: programming and case management, laboratory issues, Aboriginal peoples, immigration, TB/HIV co-infection, and research. Through a consultative process, each subcommittee drafted a report and recommendations for actions required to achieve elimination of this disease in Canada. The recommendations were presented for consideration by a wider audience at a National Consensus Conference on Tuberculosis, held in Toronto on Dec. 3-5, 1997. This report provides a brief description of the epidemiologic aspects of TB worldwide and in Canada, and presents the final recommendations for a national TB strategy that were achieved by consensus at that meeting.

Electronic key pads were used to measure the degree of consensus on each proposed recommendation and to ensure voter confidentiality. The agreed upon criteria for reaching consensus on a given recommendation were as follows:

(a) 80% or more of all voting participants were in favour of the recommendation;

(b) 80% or more of voting participants who identified themselves as stakeholders in the specific area of the recommendation were in favour of that recommendation.

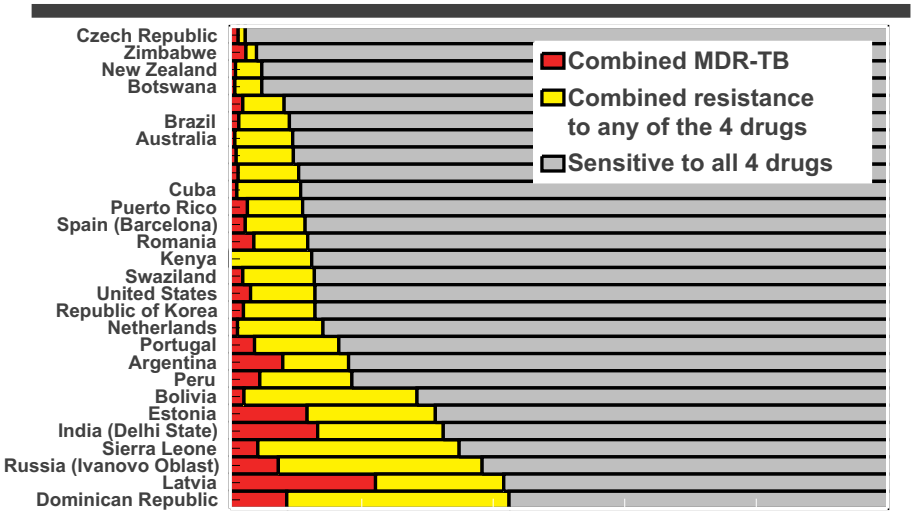
EPIDEMIOLOGY OF TUBERCULOSIS

Globally, tuberculosis (TB) continues to be a major cause of disability and death. It has been estimated that one third of the world's population is infected with the TB bacillus and that the disease is responsible for 3 million deaths annually. In 1993, the World Health Organization (WHO) declared TB to be a global emergency, the first disease so classified in the history of that organization.

In developing countries the impact of TB has intensified with the spread of HIV infection/AIDS, and the disease has reached epidemic proportions; in industrialized countries, changes in immigration patterns, greater rates of homelessness, reduced funding for public health programs and frequent overseas travel have led to a reversal in previously well-established declines in TB notification rates. According to the WHO figures released in 1997[(1)], the reported regional incidence rates of TB in 1995 ranged from 33.0 per 100,000 in the Americas to 98.5 per 100,000 in Southeast Asia.

HIV infection weakens the immune system and thus makes active TB disease more likely in an individual infected with the TB bacillus. As a result of the spread of HIV, an estimated 1.4 million worldwide cases of active TB are expected to occur annually in people co-infected with HIV by the end of the century. Already, TB is the leading worldwide cause of death among individuals who are HIV positive.

Figure 1: Prevalence of combined drug resistance to any drug and MDR TB,



Source: The WHO/IUATLD Global Project on Anti-Tuberculosis Drug Resistance Surveillance

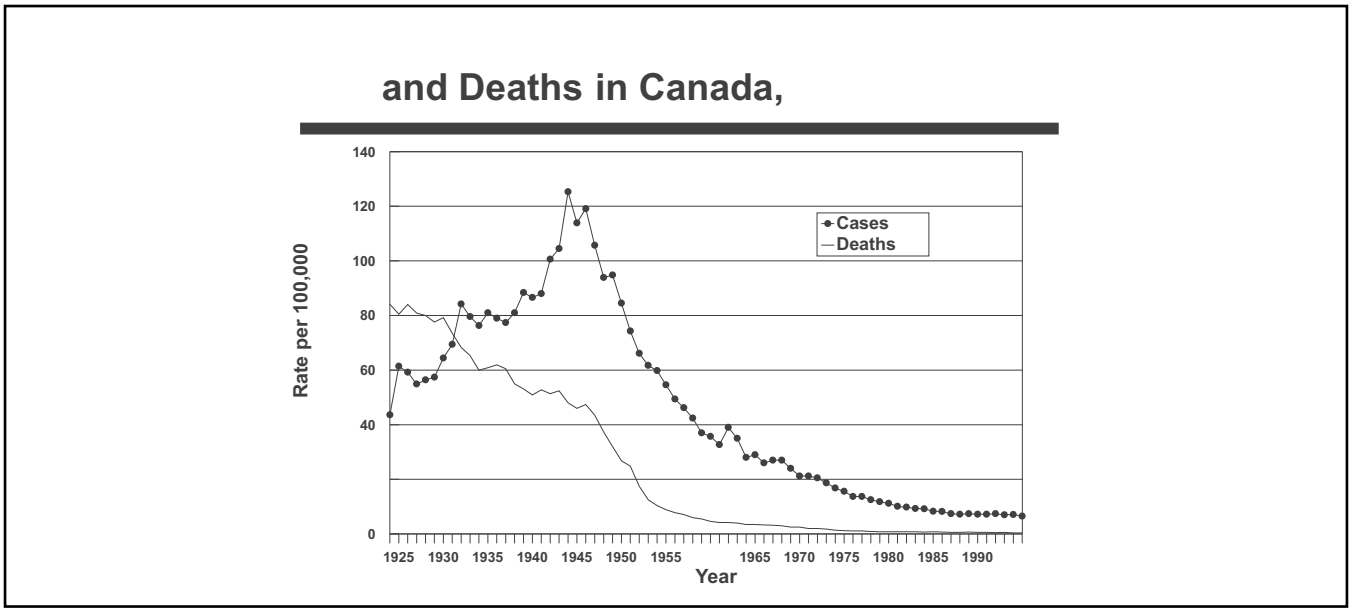
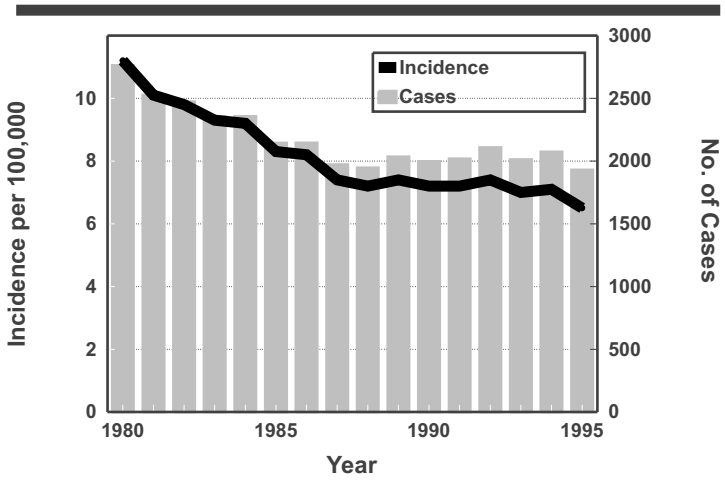


Figure 3 : Reported Tuberculosis in Canada, 1980-1995

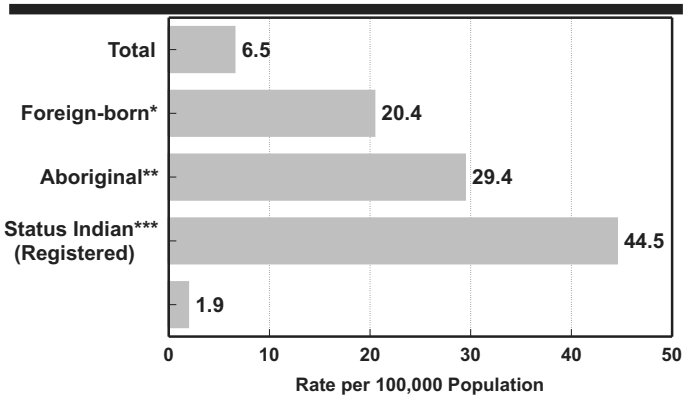


Of great concern to the WHO is the emergence of drug-resistant TB strains, particularly in developing countries. These strains, especially those resistant to more than one of the usual first-line drugs used to treat the disease, will pose a very serious threat if they spread rapidly around the world. Unfortunately, this phenomenon is primarily the result of incomplete or improper treatment regimens. Directly observed therapy, which consists of closely supervised treatment to make sure that every dose is taken to the end of the treatment period, is a highly recommended method of ensuring patient compliance and cure as well as preventing the development of drug resistance.

The recently released report of the WHO/IUATLD (International Union Against Tuberculosis and Lung Disease) Global Project on Anti-Tuberculosis Drug Resistance Surveillance[2] highlights this growing problem (Figure 1). From 1994 to 1997, the prevalence of combined resistance (primary and acquired) to any of the commonly used anti-TB drugs among cases studied in the countries participating in this project ranged from 2.3% in the Czech Republic to 42.4% in the Dominican Republic. The prevalence of multidrug resistance (MDR-TB), defined as resistance to at least isoniazid and rifampin, ranged from 0% in Kenya to 22.1% in Latvia. The weighted mean for overall resistance among the participating countries was 16.7%, and that for MDR-TB was 4.3%.

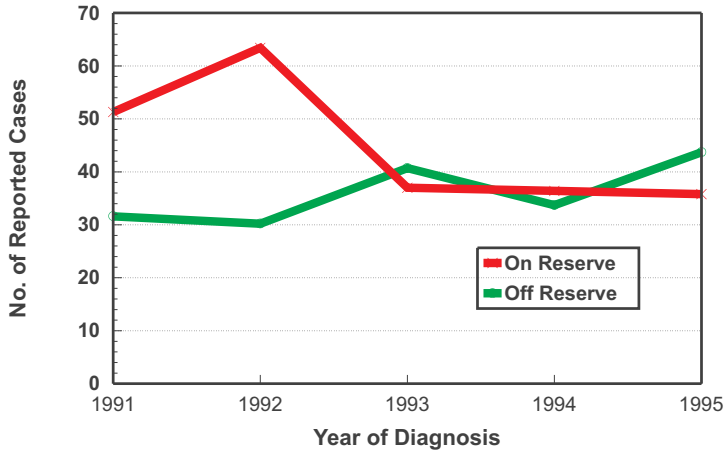
Within the global picture, TB in Canada currently has not reached epidemic proportions. Historically, TB

Figure 4: Crude Rates of Reported Tuberculosis Cases in Canada by Population Subgroup, 1995



* Population estimate source(s): 1991 Census and number of new landings (CIC)
** Population estimate source: STC Employment Equity Data Program, 1995
*** Population estimate source: DIAND Population Projections of Registered Indians, 1995

Figure 5: Tuberculosis Incidence for Status Indians by Residence Status, 1991-1995



was a major cause of morbidity and mortality early in this century. The mortality rate was 84 per 100,000 in 1924, and the reported incidence rate reached a high of 119 per 100,000 in 1946 (Figure 2). With improvements in living conditions, public health programs and the advent of antibiotic therapy, the rates of disease and resulting death have decreased sharply since the mid 1940s. The reported incidence and mortality rates in 1995 were 6.5 and 0.4 per 100,000 respectively. However, the decades-long trend of declining incidence has levelled off since 1987 (Figure 3).

Certain groups in Canada are at increased risk of the disease, including Aboriginal peoples (Status Indians, Non-Status Indians, Metis, Inuit and Innu), foreign-born residents from countries with a high prevalence of the disease, disadvantaged inner city populations and HIV-infected individuals. In 1995, the reported TB incidence rate was 1.9 per 100,000 for Non-Aboriginal Canadian born individuals, whereas those for Status Indians, all Aboriginal peoples and foreign-born residents were 44.5 per 100,000, 29.4 per 100,000 and 20.4 per 100,000 respectively (Figure 4).

The reported incidence rate among Status Indians on reserves has declined since 1992, while the rate for those off reserve has been increasing during the 1990s (Figure 5). Although the overall incidence rate for Aboriginal peoples has remained fairly stable over the past several years, there is wide variation in the incidence rates between the various provinces/territories (Figure 6).

Figure 6: Reported Tuberculosis Incidence Among Aboriginal Peoples in Canada by Territory, 1995 (n=343)

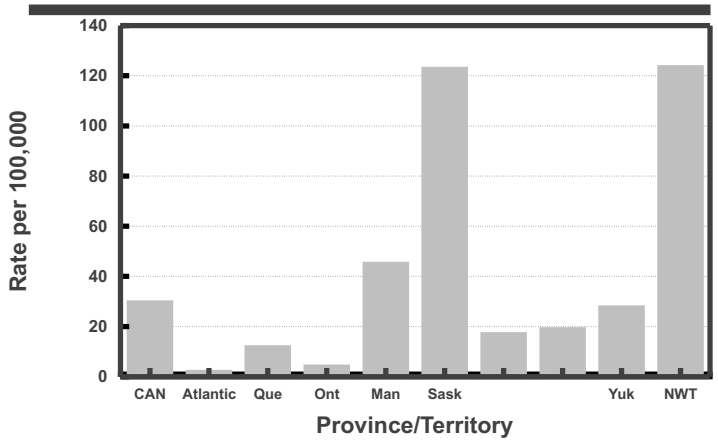
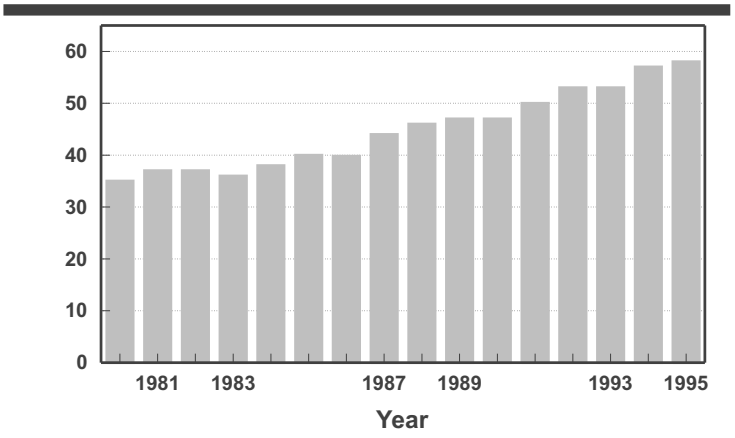


Figure 7: Percent of Reported Canadian Tuberculosis Cases in Foreign-Born Persons, 1980-1995



Over time, the proportion of reported TB cases born outside the country has increased (Figure 7). In 1980, 35% of all reported cases were foreign-born, and in 1995 the proportion had increased to 58%. Not surprisingly, most of the countries of origin reflect areas of the world with a high prevalence of the disease (Figure 8). A significant proportion of these cases are diagnosed within a few years after arrival (Figure 9).

The impact of HIV infection on the epidemiology of TB in Canada has not been well ascertained, although so far it does not appear to have been significant. Groups such as Aboriginal peoples and injection drug users are particularly at risk. By the end of 1996, a total of 606 individuals reported to have AIDS also had a diagnosis of TB, representing 4.2% of the total number of AIDS cases reported. However, this figure most likely represents an underestimate and further investigation is required.

With regard to drug resistance, there are limited national data to date regarding the extent of the problem. A national study conducted in 1993-94 showed that 8.7% of the TB isolates studied were resistant to at least one of the commonly used anti-TB drugs, and 0.6% were MDR-TB (Figure 10).

Figure 8: Leading Countries of Origin for Tuberculosis Cases in Canada,

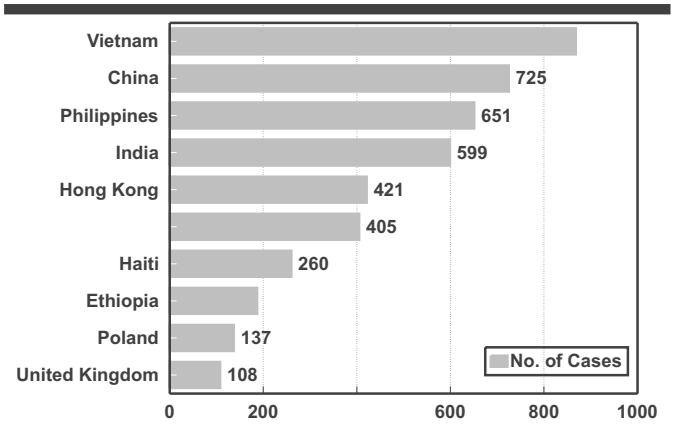


Figure 9: Reported Foreign-Born Tuberculosis Cases in 1995 by Year of Arrival

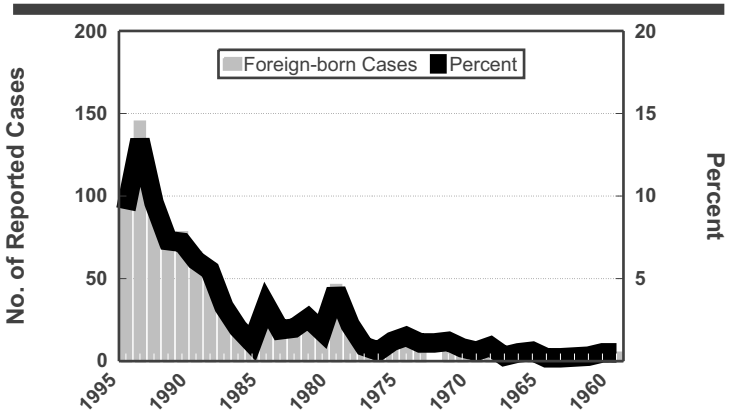
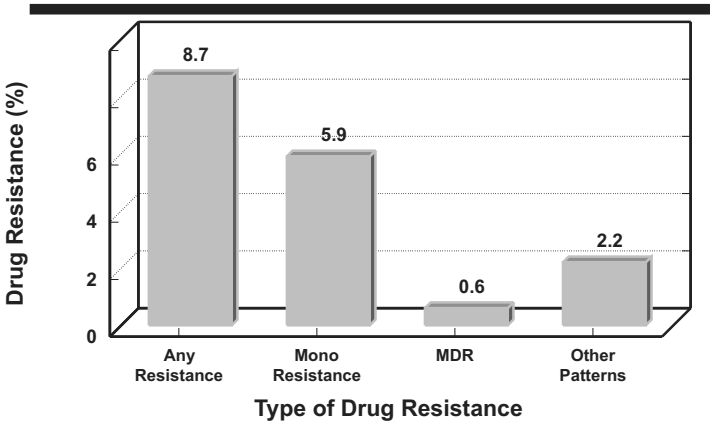


Figure 10: Prevalence of Drug Resistance Cases in Canada, 1993-1994



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2. Global Tuberculosis Programme, WHO. *Anti-tuberculosis drug resistance in the world: the WHO/IUATLD global project on anti-tuberculosis drug resistance surveillance*. Geneva: WHO, 1997.

RECOMMENDATIONS FROM THE NATIONAL CONSENSUS CONFERENCE ON TUBERCULOSIS*

DECEMBER 3 - 5, 1997

Programming and Case Management Recommendations

1.1 Each province and territory in Canada should adopt an overall goal of tuberculosis elimination (less than 1 case per 100,000) through an interim goal of a 5% reduction in the number of cases each year, with a focus on high risk groups (e.g. Aboriginal peoples, foreign-born individuals); this reduction goal should be reviewed every 5 years.

1.2 The provinces and territories jointly should declare a national commitment to tuberculosis elimination with national coordination and assured funding, executed by a coordinating committee of federal and provincial/territorial representatives.

1.3 The principles guiding the national commitment must include the following features:

i) permanent: (a permanent infrastructure should be in place nationally);

ii) nation wide;

iii) adapted to the needs of the region (and in partnership with communities);

iv) integrated into the health care system.

1.4 A nationally agreed upon manual of case definitions and treatment regimens should be developed and approved.

1.5 With attention paid to issues of security and confidentiality, all cases must be reported regionally to the appropriate public health authorities with adequate demographic information to identify risk category, bacteriologic diagnosis and sensitivity pattern. All such information should subsequently be collected and analyzed at the national level.

1.6 From the point of view of program management, directly observed therapy should be the standard treatment, with the recognition that the ultimate goal of treatment in a program is either cure or completed treatment of all cases and that this goal may be secured by other means.

1.7 Adequately trained personnel must be in place to deliver tuberculosis control programs.

1.8 Quality control in laboratory, public health and clinical settings must be ensured through adequate supervision, including work evaluation and outcomes assessment.

1.9 Each province and territory must be responsible for ensuring that its tuberculosis control program achieves agreed upon national standards.

*See page 1, final paragraph, for details on how consensus on these recommendations was assessed.

1.10 Case finding should be enhanced by ensuring that the clinical and control aspects of tuberculosis are part of the core curriculum in the training of health professionals (e.g. physicians, nurses, paramedics), as well as being included in continuing medical/ nursing education programs.

1.11 Screening of high-risk groups for case finding and prophylaxis must be carried out in every jurisdiction. (See the Aboriginal peoples, Immigration and HIV sections for further recommendations on screening of high-risk groups.)

a) In drop-in shelters for the homeless, it is recommended that TB case finding be undertaken for clients.

b) In long-term care institutions for the elderly, it is recommended that baseline tuberculin skin testing (2-step) be carried out on admission and that awareness of tuberculosis be maintained for early diagnosis, treatment and contact follow-up.

c) In correctional facilities, it is recommended that staff, volunteers and inmates be screened on arrival and annually (if longer than a 1-month stay) thereafter. Information on tuberculosis status should be transferred as an essential part of the inmate's health record.

d) In those with other immunocompromising medical conditions, it is recommended that clinical assessment for tuberculosis and prophylaxis be offered as appropriate.

e) In alcohol or drug rehabilitation programs, it is recommended that screening be carried out on clients upon admission.

f) In health care and residential settings it is recommended that screening of staff be carried out as outlined in the *Guidelines for Preventing the Transmission of Tuberculosis in Canadian Health Care Facilities and other Institutional Settings.*

g) Routine screening of children in low-risk populations should be discouraged.

1.12 Canada should establish a goal of finding all active tuberculosis cases and completing treatment in 100%.

1.13 All cases of active tuberculosis, particularly pulmonary ones, must be reported to the appropriate public health officials within 24 hours of diagnosis.

1.14 Every case of active tuberculosis must:

a) have an assigned case manager, either a physician or public health nurse, who will be responsible for monitoring compliance with treatment and checking for drug toxicity on at least a monthly basis;

b) have treatment with an appropriate anti-tuberculosis regimen started within 24 hours of diagnosis;

c) complete treatment.

1.15 All hospitalized pulmonary cases should be managed according to the *Guidelines for Preventing the Transmission of Tuberculosis in Canadian Health Care Facilities and other Institutional Settings*; those treated at home should return to work only when they are no longer infectious.

1.16 Any facility undertaking case isolation must have an effective institutional program to prevent nosocomial transmission of tuberculosis.

1.17 Consultation with a medical tuberculosis expert must be sought in any situation in which drug resistant tuberculosis is identified.

1.18 All anti-tuberculosis drugs must be provided free of charge to the patient.

1.19 All cases should be evaluated at the conclusion of treatment and be reported in terms of the following outcomes:

cure (a case who completed treatment and had a negative sputum smear at the end of treatment);

treatment completed (a case who completed treatment and did not have a sputum examination at the end of treatment);

died (a case who died during treatment, regardless of cause);

failure (a smear positive case who remained or became positive again 5 months or later after starting treatment);

defaulted (a case who, at any time after registration, had not collected drugs for 2 months or more); or

transferred out (a case who has been transferred to another reporting unit and his/her treatment results are not known).

1.20 All contact tracing should begin within 7 days of the index case report.

1.21 All contacts of smear positive cases should be assessed by tuberculin skin testing and if found to be positive (positive result: ≥ 5 mm) should undergo chest radiography and sputum culture within 30 days of the index case report.

1.22 All contacts of active cases should be offered prophylaxis with isoniazid in accordance with the *Canadian Tuberculosis Standards*.

1.23 Groups of individuals at increased risk for the development of active tuberculosis following infection should be considered for chemoprophylaxis in accordance with the *Canadian Tuberculosis Standards*.

1.24 Isoniazid prophylaxis should be continued for 6 to 12 months with monthly monitoring for drug toxicity in accordance with the *Canadian Tuberculosis Standards*.

1.25 Chemoprophylaxis program outcomes should be evaluated.

1.26 LCDC, in collaboration with the provinces and territories, should take the lead to ensure a comprehensive, national surveillance system for tuberculosis.

1.27 Canada should acknowledge the need to address the global tuberculosis epidemic in order to have an impact on the significant proportion of Canadian cases that occur in the foreign born. Accordingly, Canada should invest resources and expertise to provide assistance to tuberculosis control programs in countries where the disease has a high prevalence.

Laboratory Recommendations

2.1 The National Laboratory should provide and coordinate services, such as a full range of proficiency testing, quality control, and standardization, as required by the provinces/territories.

2.2 The National Laboratory should facilitate the transfer of technology where feasible, including training services.

2.3 A format should be developed for the delivery of information from the provinces and territories to the National Laboratory/LCDC.

2.4 A format should be developed to report to the provinces and territories in a regular, timely manner.

2.5 Participating laboratories should send drug susceptibility information with unique identifiers to a centralized surveillance system (database) at LCDC on a quarterly basis as results become available.

2.6 Cumulative reports should be sent back to provincial programs and participating laboratories within an acceptable time frame. Case reports and laboratory reports should be integrated into one surveillance system.

2.7 The national collection of *Mycobacterium* species (including organisms with atypical identification patterns) should be maintained on a continuous

basis. Drug-resistant strains should be collected at either the National Laboratory or the originating provincial/territorial laboratory (i.e. for DNA fingerprinting or banking for future reference) as a resource for the National Tuberculosis Laboratory Network.

2.8 All specimens for mycobacterial culture should be transported promptly and rapidly to an appropriate laboratory as soon as possible, in accordance with the *Canadian Tuberculosis Standards*.

2.9 Laboratories should ensure that the appropriate methods and procedures are used to promote collection of high quality specimens, optimal processing and rapid reporting.

2.10 Laboratories should achieve average turnaround times (from specimen receipt) not exceeding the following:

a. *Smear microscopy*
1 working day

b. *Detection of growth*
14 working days

c. *Identification*
7 days from isolation

d. *Susceptibility testing*
30 days (for first-line drugs)

e. *Reporting*
Within 1 day by telephone to attending physician (or deputy) and public health officials.

2.11 The mechanisms by which reports are received and disseminated should be clearly defined.

2.12 In conjunction with the National Laboratory, provincial/territorial laboratories should develop quality assurance programs for all laboratory methods.

2.13 Amplification methods, if used, should be performed only in addition to microscopy and culture until they are demonstrated to be equivalent or superior in sensitivity and specificity to culture.

2.14 Validation of susceptibility testing by proficiency testing should be continued, to obviate the need for periodic national susceptibility surveys. The National Laboratory should organize and fund this proficiency testing on an ongoing basis.

2.15 All mycobacterial laboratories should satisfy the mandatory biosafety level 3 criteria as described in the *Laboratory Biosafety Guidelines* (2nd edition, 1996).

2.16 Strain typing should be performed in defined circumstances with close cooperation between epidemiologic investigators and laboratory investigators.

2.17 Strain typing should be performed in facilities with experienced personnel, and these personnel should be involved in the interpretation of the typing results.

2.18 Each jurisdiction should ensure that there are appropriate laboratory services to support the jurisdictional tuberculosis program and that the laboratory services are linked to the clinical tuberculosis program.

2.19 Ongoing surveillance of drug resistance in Canada should be conducted at a national and provincial/territorial level to detect changes in drug sensitivity patterns promptly.

Aboriginal Peoples Recommendations

3.1 Federal/provincial/territorial health authorities must work in partnership with the health authorities of Aboriginal peoples (defined as Status Indians both on and off reserve, Non-Status Indians, Metis, Inuit and Innu) as they take control of their health programs, in order to ensure that effective surveillance continues and communities have access to the resources they require to deliver tuberculosis control programs.

3.2 Federal/provincial/territorial health authorities must work in partnership with Aboriginal peoples both on and off reserves to develop a coordinated, cross-jurisdictional approach for managing tuberculosis among Canada's Aboriginal peoples.

3.3 While maintaining individual patient confidentiality, there must be cooperation between agencies that deal with tuberculosis and those dealing with HIV in order to better deal with the risks and issues of care and to gain a better epidemiologic understanding of co-infection.

3.4 Government and communities must recognize and work together to eliminate the social conditions that contribute to the incidence of tuberculosis.

3.5 A national strategy for the elimination of tuberculosis must incorporate recognized activities in tuberculosis control such as directly observed therapy. The costs of funding such initiatives must be supported at all levels of government.

3.6 Similarly, government must commit itself, in terms of policy and resources, to the maintenance of a centralized, ongoing surveillance system for tuberculosis.

3.7 There must be a centralized, dedicated source of funding for the management of community outbreaks. This funding must cover the hidden costs of managing tuberculosis outbreaks, such as those related to transportation, extra nursing time, laboratory and x-ray services.

3.8 Culturally sensitive materials relating to tuberculosis should be developed by and/or with and disseminated among Aboriginal peoples.

3.9 Culturally sensitive training and health education for community health workers must be ensured.

3.10 Because of high rates of tuberculosis among Aboriginal peoples, regionally appropriate screening guidelines must be developed, implemented and evaluated.

Immigration Recommendations

4.1 It must be acknowledged that tuberculosis in immigrants, refugees, visitors, students and those returning from countries where tuberculosis is endemic is the major issue for tuberculosis control and elimination: before, at and after arrival.

4.2 The issue of tuberculosis should not be a reason to restrict immigration.

4.3 Current policies and strategies for the control of tuberculosis in these groups do not appear to be very effective and indicate that they need to be evaluated on a priority basis.

4.4 Strategies must be modified and/or developed as a priority to effectively detect and prevent tuberculosis in these groups.

4.5 The control of tuberculosis in these groups must consider the following issues: screening with tuberculin skin testing, HIV screening, barriers to case finding and case holding, specific procedures for individuals from high-risk countries, the relative burden of illness in particular groups, education, medical insurance, multicultural issues, involvement of affected groups, access to the health care system.

Tuberculosis/HIV Recommendations

Policy Recommendations

5.1 Because of the alarming potential for an increase in the number of HIV-related tuberculosis cases and the risk of multidrug-resistant tuberculosis in this population, policy makers must provide appropriate resources to address the recommendations under Clinical Practice Recommendations.

5.2 LCDC, in partnership with provincial and territorial agencies, should create a national data set of appropriate epidemiologic information about co-infection with tuberculosis and HIV, and should collect, analyze and disseminate these data; the security and confidentiality of such databases must be ensured.

5.3 LCDC and the provinces and territories should adopt HIV/AIDS and tuberculosis surveillance reporting forms to capture tuberculosis/HIV data wherever possible and appropriate.

5.4 LCDC should support, coordinate and collaborate in special investigations to determine the extent of tuberculosis/HIV co-infection in Canada. This support should include expertise, resources and staff.

5.5 LCDC, in collaboration with provincial/territorial, laboratory and community-based partners, should participate in cluster and outbreak investigations of co-infection with tuberculosis and HIV. Participation should include the provision of expertise, resources and staff. Other targeted supplementary epidemiologic investigations should also be carried out as appropriate to characterize the evolving interaction of tuberculosis and HIV.

5.6 LCDC should ensure the timely dissemination of information about tuberculosis/HIV co-infection using collaborative models of communication that are participatory in nature. This is particularly important because of the dynamic and ongoing changes in HIV/TB management strategies, e.g. anti-retroviral therapies (which have the potential to interact with therapeutic agents for tuberculosis). In addition, the utilization of BCG for newborns where vertical transmission of HIV infection has taken place requires caution.

5.7 Sentinel clinical sites and community-based agencies should be used for evaluating interventions related to TB and HIV co-infection and, in particular, the barriers to their successful implementation.

5.8 Physicians and other health care providers should be encouraged to offer HIV testing in tuberculosis clinical settings with appropriate pre- and post-test counselling. Conversely, tuberculin skin testing should be encouraged in HIV clinical settings.

5.9 Improved communication and collaboration between AIDS and tuberculosis programs, where they function in parallel, as well as between these and community agencies should be encouraged. Education of health care workers and individuals in the community is critical.

Clinical Practice Recommendations

5.10 The accumulating evidence that early intervention in the course of HIV infection, especially with combination therapies, including anti-retrovirals, can substantially change its course implies that every opportunity should be taken to identify HIV-infected individuals. HIV serology should therefore be evaluated in all patients presenting with tuberculosis after informed consent and appropriate pre- and post-test counselling.

5.11 The recognition that the development of tuberculosis in an HIV-infected person appears to hasten the progression of the underlying immune deficiency makes it essential for all HIV-infected persons to be regularly screened for the presence of tuberculous infection by tuberculin skin testing. Routine anergy screening is not recommended.

5.12 In the presence of tuberculosis/HIV co-infection appropriate chemoprophylaxis administered in accordance with the *Canadian Tuberculosis Standards* is strongly recommended.

5.13 All hospitalized patients with infectious tuberculosis should be placed in respiratory isolation until there is evidence of non-infectiousness, in accordance with *Guidelines for Preventing the Transmission of Tuberculosis in Canadian Health Care Facilities and other Institutional Settings*. Caution is recommended for patients with multidrug-resistant tuberculosis or those leaving hospital to enter an institutional or community environment with a high prevalence of HIV-infected patients.

5.14 Community agencies should have an appropriate tuberculosis surveillance and screening program in place for staff and users of the agencies to identify as early as possible individuals who may have tuberculosis infection or active disease.

5.15 Governments must recognize the risk of tuberculosis transmission in community agencies that work with people infected with HIV and must participate in developing strategies to reduce the risk. A central factor is early detection and treatment. Work place policies and environmental assessments must be optimized, and consideration given to high-tech interventions in the light of cost and efficacy.

5.16 Health care workers in the area of tuberculosis must have sensitivity training in AIDS and HIV infection with a focus on legal, ethical and human rights issues, and the impact of socioeconomic factors on people with TB/HIV co-infection.

5.17 Staff caring for street-involved HIV-positive individuals should regularly obtain sputum specimens from symptomatic persons to facilitate the early diagnosis of active tuberculosis cases.

Research Recommendations

6.1 It must be recognized that basic, epidemiologic, public health and community-based research is an integral part of the national strategy to eliminate tuberculosis.

6.2 This research must be promoted actively and supported accordingly by all levels of government as well as by other potential funding sources.

6.3 Funding for training, infrastructure and the conduct of research into tuberculosis must be increased, primarily through peer review mechanisms. Specific resources that could increase funding include the Medical Research Council, non-government organizations and industry.

6.4 Mechanisms should be established to set priorities for research into tuberculosis that will assist in the goal of elimination. The process would involve all affected parties and its coordination could be a function of the Expert Committee on Tuberculosis (ECOT).

6.5 There must be a strengthening of coordination and collaboration in tuberculosis research across Canada and promotion of multicentre studies. This coordination function could be undertaken by LCDC, using ECOT as an advisory committee.

6.6 Federal/provincial/territorial governments and funding agencies must work in partnership with communities and commit resources for research initiatives that address the complex issues of tuberculosis.

Appendix I

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