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Preface

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Preface

1. Introduction

The last 8 years have witnessed great strides in our understanding of the pathogenesis, immunology and epidemiology of tuberculosis. In the past decade, after too many decades of inaction, new diagnostics and new treatment regimens for tuberculosis (TB) infection, and drug-resistant TB disease have been developed. This 8th edition of the *Canadian Tuberculosis Standards* (the *Standards*) has been extensively revised to incorporate much of this new information, building upon the 7 previous versions of the *Standards*, which were published in 1972 (with a pediatric supplement in 1974), 1981, 1988, 1996, 2000, 2007 and 2013.

Specifically, in response to feedback from users of previous versions of the *Standards*, some sections have been expanded, while others have been reduced or eliminated. For example, the chapter on Bacille Calmette-Guérin vaccination has been dropped and updated content is now within the chapter on Pediatric TB. The chapter on disease due to non-tuberculous mycobacteria has also been dropped; some parts are now found in the chapter on diagnosis of TB disease. A new chapter on monitoring TB program performance is a fitting new edition to the *Standards* (promoting standards for TB programs).

The objective of this document remains to provide practical management information to public health and clinical professionals on all aspects of the pathogenesis, epidemiology, and management of TB in Canada. The guidance pertains to all individuals at risk for or confirmed to have latent or active TB. Specific target users may include: decision-makers, public health professionals, specialists managing TB (eg, internists, respirologists, infectious diseases specialists) and primary care providers.

Of note, the document does not supersede any provincial/territorial legislative, regulatory, policy and practice requirements, or professional guidelines that govern the practice of health professionals in their respective jurisdictions. The *Standards* also is not intended to replace consultations regarding management of individual patients or other circumstances, between providers and persons with relevant expertise in tuberculosis.

Reference is made to specific tests, procedures and therapies throughout the *Standards*. For the most part, generic terms are used rather than trade names or manufacturers' names. However, in a few instances when only a single manufacturer or product is available, a trade name may be mentioned. This is done only to enhance readers' understanding by providing a name with which they are more likely to be familiar. Use of trade names and commercial sources is for identification only and does not imply endorsement by the Canadian Thoracic Society (CTS).

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We are grateful to the following external reviewers for their valuable input:

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5. Methodology

As in the past, each chapter is written by authors from across Canada with expertise in the specific topic. The editorial board, comprised of members with broad expertise in clinical and/or public health aspects of TB, reviewed multiple versions of each chapter to ensure optimal clarity and consistency of information and related recommendations. This edition was also developed in collaboration with the Association of Medical Microbiology and Infectious Disease Canada (AMMI Canada), whose expert representatives served as chapter authors and external reviewers.

The *Standards* were written in 2021. Between January and March 2021, priority content areas were selected by chapter authors with input from the editorial board. The *Standards* chapters from the 7th edition were evaluated, updates or new sections were added and obsolete sections eliminated based on a consensus of the editorial board and chapter authors and results of a survey of users of the 7th edition of the Canadian TB Standards conducted in 2018-19. Questions of interest were considered in accordance with the PICO method, addressing the Patient group(s) that should be included, the Intervention(s) that should be examined, the Comparison groups that should be part of the studies of the various interventions and the Outcome(s) of interest.

As with previous editions, the 8th edition of the *Standards* is based upon the best available scientific evidence. Each group of chapter authors conducted literature searches between March to July 2021, for their individual chapters. Authors then carefully reviewed all published evidence, emphasizing the most recent studies, particularly recent systematic reviews. Given the scope of the *Standards*, with over 120 good practice statements and over 125 different recommendations across 15 chapters, the full GRADE process was not followed. Although formal appraisal tools were not used, each author was required to appraise any included studies for quality of evidence and risk of bias, in order to determine the level of evidence (see the following section). For each recommendation, the panel of authors established a consensus on the strength of the recommendation (either strong or conditional) based on an established framework (see the following section), including their rating of the overall quality of the body of evidence. The recommendations were then vetted by the CTS Canadian Respiratory Guidelines Committee (CRGC) Chair to optimize the language of each recommendation to ensure implementability.

Key points are presented at the top of each chapter. These were selected for emphasis based on a consensus of each chapter's authors.

5.1. Definitions for statements used in the Standards

Strong recommendation: ("We strongly recommend…")

Meaning: The action/intervention should be performed in most situations and would be the preferred choice for most individuals. The authors have little doubt that the benefits of the intervention exceed the harms (recommendation "for" the intervention) or that the harms exceed the benefits (recommendation "against" the intervention). The authors judged it unlikely that future studies of the

intervention would result in a significant change in the direction or magnitude of the estimated effects (risks and benefits).

These recommendations are usually based on "GOOD" evidence as defined in the following section. Other considerations include greater magnitude of effect and/or magnitude of difference between benefits and harms, alignment with patient values and preferences and strong feasibility based on available resources. These are summarized in the following sections.

Conditional recommendation: ("We conditionally recommend…")

Meaning: The action/intervention should be considered, based on the likelihood of benefits and harms in an individual patient. The authors concluded that there is likely a net benefit of the intervention, but there is uncertainty about the magnitude of the benefits and/or about whether benefits outweigh the risks. There is reasonable likelihood that new studies could change estimates of the magnitude of risks and benefits (and hence result in modified recommendations).

These recommendations were usually based on "POOR" (or low-quality) evidence. Other considerations included smaller magnitude of differences between benefits and harms, uncertain consistency with individual patient values and preferences and/or uncertain feasibility with respect to resource requirements.

Good practice statement

Meaning: The authors would use the intervention/perform the action in most situations and for most patients. These statements are based on a clear consensus of expert opinion that this action should be beneficial (or harmful, if "against"), but there is minimal or no evidence in support of this. This type of statement is reserved for topics/actions for which there is minimal or no published evidence, and it is considered unlikely that any evidence will be available in the future.

Regulation

A recommendation identified as "regulation" is supported by federal, provincial or territorial legislation from the relevant field of authority (eg, building codes, occupational health and safety) so no strength of evidence is assigned. Regulations are a form of law which define the application and enforcement of legislation. Regulations are made under the authority of an Act and are enacted by the body to whom the authority to make regulations has been delegated, such as a minister, etc.

5.2. Judgements regarding quality of evidence used in the Standards

GOOD	**Therapeutic interventions:** • 1 or more published systematic review (SR) of randomized controlled trials (RCTs) that concluded the evidence was of high quality; or • 2 or more RCTs of high quality with consistent results; or • 1 large RCT of high quality (low risk of bias) and clear findings (of benefits and/or harms). **Diagnostic methods**: • 1 or more RCT of high quality comparing alternative diagnostic strategies for effects on patient-relevant outcomes; or • 1 or more published SR of two or more observational studies of high quality comparing a diagnostic test to an appropriate reference standard; or • 2 or more observational studies comparing a diagnostic test to an appropriate reference standard of high quality with consistent findings. **Etiologic research:** • 1 or more published SR concluded that the association was clear and based on good quality observational studies; or • 2 or more observational studies with strong designs demonstrating the risk factor was strongly associated, and that association was consistent across the studies.
POOR	**Therapeutic:** • 1 or more published SR that concluded that the evidence from intervention studies was not of high quality; or • Any/all available RCT(s), were not of high quality, had inadequate numbers of participants, did not directly address the patients of interest; and/or demonstrated inconsistent results (if 2 or more RTCs were available); or • Only evidence form observational studies was available that had weak designs, weak effect estimates or inconsistent results, or generalization from a randomized trial that involved one type of patients to a different group of patients; or • Opinion of the authors and other experts only. **Diagnostic:** • 1 or more published SR that concluded that the evidence was not of high quality; or • 2 or more observational studies comparing a diagnostic test to an appropriate reference standard available but not high quality and/or had inconsistent results; or • Only 1 observational study comparing a diagnostic test to a reference standard available. **Etiologic:** • 1 or more published SR concluded that the association was not clear, and/or based on poor quality observational studies; or • 1 or more observational study of poor quality, and/or with inconsistent results.

5.3. Additional considerations that affected author decisions to make strong or conditional recommendations

Other considerations	Effect/Impact	Effect on Recommendation (potentially can increase to strong, or decrease to conditional)
Relative importance of the outcomes	"Critical" (eg, death, cure, failure) "Not critical" (eg, intolerance, inconvenience)	Strengthen Weaken
Magnitude of the effect and/or difference	Large effect or difference Small or no effect or difference	Strengthen Weaken
Balance of benefits and harms	Benefits clearly outweigh harms (eg, substantial benefit, but minimal harms) Closely balanced benefits and harms (eg, substantial benefit, but also substantial harms)	Strengthen "For" (If harms outweigh benefits would strengthen "Against") Weaken
Patient values and preferences	Judged very likely that patients would prefer intervention Judged very likely that patients would NOT prefer intervention	Strengthen "For" (Weaken "Against") Strengthen "Against" (Weaken "For")
Cost – Resource Use	Low cost, cost saving compared to alternative, cost-effective High cost, higher cost than alternative, not cost-effective	Strengthen Weaken
Implementability	Difficult to implement	Weaken

6. Review and approval process

Each chapter underwent extensive review; all chapters were reviewed by the Editor, at least one Associate Editor and one other chapter author before a 2-day meeting of all authors held on September 23 and 24, 2021. At this meeting, each chapter was presented by authors, followed by the reviewers' comments, after which all authors provided input. Specific sessions during this meeting were devoted to review of evidence and discussion of recommendations for Directly Observed Treatment (included in Chapter 5: Treatment of TB Disease) and review of evidence for effect of treatment on contagiousness and TB transmission with recommendations for discontinuation of respiratory isolation (included in Appendix B - De-Isolation Review and Recommendations). Consensus was reached on recommendations for these two topics during this meeting.

Following the all-authors' meeting, each chapter was revised by chapter authors and then reviewed by the Editor. Subsequent revised versions were sent for external reviews by experts in the topic (selected by the Editor and/or the chapter authors). Selected chapters were reviewed by representatives of AMMI Canada, and all chapters were independently reviewed by members of the CRGC. Each reviewer provided a detailed review and suggestions. Authors responded to these reviews, and all reviews, and subsequent revisions were reviewed by the Editor. Upon acceptance, the CRGC recommended approval of the guideline to the CTS Executive Committee.

7. Future updates

The *Standards* will be formally reviewed every three years or sooner to determine the need for and nature of any updates, in accordance with the CTS Living Guideline Model. Panel members will also use the continuously updated CTS-McMaster Plus database, whereby they will receive alerts when new articles pertaining to key PICO questions are published (starting from the last date of the literature search conducted for this guideline). This will serve to prompt members to consider timely updates with evolving evidence and will facilitate formal literature reviews.

Disclosure statement

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