National Tuberculosis Guidelines for Ireland

2024/2025

Version 1.0

HSE Public Health: National Health Protection Office

DOCUMENT CONTROL

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Please note that this document should be used in tandem with other Tuberculosis guidance on the HPSC website.

Readers should not rely solely on the information contained with these guidance outputs. Guidance information is not intended to be a substitute for advice from other relevant sources including and not limited to, the advice from a health professional. Clinical judgement and discretion will be required in the interpretation and application of this guidance document. This guidance document is under constant review based upon emerging evidence at national and international levels and national policy decisions.

For further information please contact: **rgdu@hpsc.ie**.

ADAPTATION STATEMENT

CHAPTERS AND APPENDICES

GLOSSARY

AFB	Acid-fast bacillus
ADRs	Adverse drug reactions
AGREEII	Appraisal of Guidelines for Research and Evaluation II
ALT	Alanine transaminase
BCG	Bacillus Calmette–Guérin
BPaL(M)	Bedaquiline (B), pretomanid (Pa), linezolid (L) (and moxifloxacin (M))
CDC	Centers for Disease Control and Prevention
CHI	Children's Health Ireland
CIDR	Computerised Infectious Disease Reporting system
CNS	Central nervous system
DOTS	Directly observed therapy
DR-TB	Drug-resistant TB
DST	Drug susceptibility testing
ECDC	European Centre for Disease Prevention and Control
EMB	Ethambutol
EQA	External Quality Assurance
GA	Gastric aspirate
GDG	Guideline Development Group
HCW	Health and care worker
HIV	Human Immunodeficiency Virus
HPAC-ID	Health Protection Advisory Committee - Infectious Disease
HPSC	Health Protection Surveillance Centre
HRZE/RIPE	Isoniazid, Rifampicin, Pyrazinamide and Ethambutol
HSE	Health Service Executive
IGRA	Interferon-gamma release assay
INH	Isoniazid
IRIS	Immune reconstitution inflammatory syndrome
LFX	Levofloxacin
LTBI	Latent TB Infection (now known as 'TB Infection')
MDR-TB	Multidrug-resistant TB

MFX	Moxifloxacin
MMR	Measles, mumps and rubella
MOH	Medical Officer of Health
MTB	*Mycobacterium tuberculosis*
NSIO	National Social Inclusion Office
NHPO	National Health Protection Office
NIAC	National Immunisation Advisory Committee
NICE	National Institute for Clinical and Health Excellence
NTBAC	National TB Advisory Committee
NTM	Non-tuberculous *Mycobacterium*
PCR	Polymerase chain reaction
PID	Paediatric Infectious Diseases
Pre-XDR	Pre-extensively drug-resistant TB
PTB	Pulmonary TB
PZA	Pyrazinamide
RGDU	Research and Guideline Development Unit
RIF	Rifampicin
RR-TB	Rifampicin-resistant TB
SAEs	Serious Adverse Events
SM	Streptomycin
TB	Tuberculosis
TBI	TB Infection
TBD	TB Disease
TBM	TB meningitis
TDM	Therapeutic drug monitoring
TPT	Tuberculosis preventative treatment
TST	Tuberculin skin test
UCTAT	Ukraine Crisis Temporary Accommodation Team
USAID	United States Agency for International Development
VOT	Video observed therapy
WHO	World Health Organization
XDR-TB	Extensively drug-resistant TB

CHAPTER 1: INTRODUCTION

1.1 Purpose

The purpose of the *National Tuberculosis (TB) Guidelines for Ireland 2024/2025* is to provide detailed, evidence-based recommendations for informing clinical and public health decisions around the diagnosis, treatment, and prevention of TB in children and adults. The guidelines are intended for use by public health professionals, clinicians, and other health and care workers.

The National TB guidelines contain recommendations in relation to TB disease (formerly 'active TB') and TB infection (formerly 'latent TB infection'), and drug-resistant TB. They also provide specific recommendations in relation to people from underserved communities who may be at greater risk of acquiring TB, and the steps that should be taken on a programmatic level, both for service organisation and for promoting treatment adherence.

The development of new National TB Guidelines was identified as a priority by the Research and Guideline Development Unit (RGDU) following a proposal submitted by the National TB Advisory Committee (NTBAC) in Ireland. Publication of new National TB Guidelines fulfils strategic action number 13 of the document ***Striving to End Tuberculosis – A Strategy for Ireland 2024 – 2030*** (1).

These guidelines should be used in tandem with other TB resources published on the HPSC website. These National Guidelines, once published in their entirety, will replace and supersede the preceding guidelines.

1.2 Background

Tuberculosis (TB) remains one of the most significant Public Health challenges we face worldwide. In 2024, TB returned to being the world's leading cause of death from a single infectious agent, following three years in which it was replaced by COVID-19 (5). Although Ireland is a low incidence country (<10 cases per 100, 000 population), the aim of TB elimination (<1 case per million population) is under threat. As outlined in 'Striving to End Tuberculosis – A Strategy for Ireland 2024 – 2030', changing migration patterns have greatly influenced disease epidemiology in recent years and people with TB are frequently from

underserved populations (1). Providing diagnostic and therapeutic interventions alone will not be enough; a multi-sectoral “whole system” approach is required.

Globally in 2024, an estimated 10.9 million people developed TB (6). The continued rise reflects the ongoing disruptions to TB services during the worst years of the COVID-19 pandemic (2020 and 2021) and the magnitude of the challenge in relation to TB elimination has increased. The COVID- 19 pandemic resulted in a 15% reduction in the number of people treated for drug-resistant TB, a 21% decrease in people receiving preventive treatment for tuberculosis infection (TBI), and a decrease (from $5.8 billion USD to $5.3 billion USD) in global TB spending between 2019 and 2020 (5).

The upward trend in TB now is likely to be due to a combination of factors. It is certainly possible that we are seeing a ‘catch-up’ phase where TB cases went undiagnosed and unreported during early phase of the pandemic due to health service pressures and social isolation measures. These cases are now presenting and being reported since 2023/2024. This would also result in increased transmission due to delayed diagnosis resulting in more secondary cases now being reported. Direct effects of SARS-CoV-2 on cell mediated immunity may also be a factor (although unlikely to be the major driver) (7). Increasing inward migration to Ireland for many reasons (economic, education and related to people fleeing war or seeking asylum) especially from countries with high levels of TB endemicity is likely to be the major factor.

The need for action has become even more pressing in the context of war in Ukraine, ongoing conflicts in other parts of the world, a global energy crisis, climate change and associated impacts on food security and living conditions, which are likely to further worsen some of the broader determinants of TB. The withdrawal of USAID by the American Administration in 2025 is expected to weaken the fight against TB (8).

In the 2015 End TB Strategy, the World Health Organization (WHO) outlined a vision for a world free of TB. To achieve this, ambitious targets were set for every country to reach by 2030. These include an 80% reduction in TB incidence, a 90% reduction in TB deaths and the elimination of catastrophic costs for TB-affected households by 2030 (9).

At the United Nations General Assembly’s High-Level Meeting on Tuberculosis (September 2022), world leaders approved a Political Declaration with ambitious new targets for the next

five years to advance the global efforts towards ending the TB epidemic (10). The targets include reaching 90% of people with TB prevention and care services, using a WHO-recommended rapid test as the first method of diagnosing TB; providing social benefit packages to all people with TB; licensing at least one new TB vaccine; and closing funding gaps for TB implementation and research by 2027 (See **Table 1.1**).

Due to evolving TB epidemiology, and the WHO targets, it remains important as ever that jurisdictions have access to up-to-date, evidence-based guidelines that are implementable in the relevant context.

Table 1.1 New targets to be reached in the period 2023–2027, adopted by the 2023 United Nations General Assembly's High-Level Meeting on TB

Objectives	Targets
Universal access to WHO recommended treatment for all	90% of people reached with TB treatment between 2023 and 2027
Universal access to WHO recommended rapid diagnostic tests	100% of people diagnosed with TB tested initially using a WHO recommended diagnostic test.
Universal access to TB prevention for all	90% reached with TB preventative treatment between 2023 and 2027.
Financial risk protection for vulnerable people with TB	100%. All eligible people have access to health and social benefits packages to ensure that there is no financial hardship due to TB disease
Licence a new vaccine to accelerate TB incidence decline	Licensing of at least one new TB vaccine within 5 years
Sustained and adequate financing for TB services and TB research and innovation	Reaching $22 billion USD annually by 2027. $5 billion USD per year for research by 2027

1.3 TB in Ireland

1.3.1 Notification

Clinical notification of TB was introduced in 1948 (11) and the Infectious Diseases Regulations 1981 as amended by the Infectious Diseases (Amendment) (No. 3). Regulations 2003 (S.I. No. 707 of 2003) extended the scope of this legislation (12). From 2004, it became mandatory for clinical directors of laboratories to notify a case of TB to the Medical Officer of Health (MOH) in the respective Regional Public Health Department. The 2003 amendment also made reporting of outbreaks, unusual clusters or changing patterns of illness a mandatory requirement (12). Contact details for the Regional Departments of Public Health can be obtained **here.**

Immediate notification enables Public Health Departments to undertake prompt contact tracing and facilitates successful contact investigation. The practitioner notifying presumed cases of TB is also required to inform the MOH if the diagnosis subsequently proves not to be TB. The responsible MOH is required to report possible, probable and confirmed cases of TB to the Health Protection Surveillance Centre (HPSC) using the Computerised Infectious Disease Reporting System (CIDR). The European Commission case definition is currently used for surveillance, which includes all species of the *M. tuberculosis* complex (MTBC) (13). There are currently 10 species of MTBC, in addition to over 170 species of Non-Tuberculous *Mycobacteria* (NTM). The most common causes in humans are *M. tuberculosis (MTB)*, *M. bovis* and *M. africanum* species (14). Sporadic cases of NTM are not notifiable, but outbreaks of NTM are notifiable. Sporadic cases of TBI are not notifiable but outbreaks or unusual clusters are. Foodborne outbreaks of TBI are notifiable under the EU Zoonoses legislation

The specific objectives of surveillance are to:

- Support local management of identified cases, contacts and screening programmes
- Monitor the incidence and distribution of TB disease at both local and national level
- Detect local, national and international clusters and outbreaks
- Identify risk factors to support interventions aimed at the prevention of TB
- Monitor the process and outcome of disease control and screening programmes so that improvements can be introduced
- Monitor drug susceptibility of *M. tuberculosis* complex to guide appropriate use of antibiotics.

Laboratory notifications of tuberculosis diagnoses are uploaded by microbiology laboratories directly onto the CIDR system. TB enhanced surveillance forms are completed by public health clinicians in the regional departments of public health for each TB notification. These forms summarise all available additional clinical and epidemiological data. These data are entered onto the CIDR system by staff in the regional departments of public health (15). Annual epidemiological reports are generally produced three months after the end of the notification year to align with World TB day (15).

1.3.2 BCG Vaccine

BCG vaccines are among the oldest vaccines and were first used in humans in 1921. BCG is a live attenuated bacterial vaccine derived from *M. bovis* that was originally isolated in 1902 (16).

The efficacy of BCG in preventing TB varies. BCG vaccination protects against disseminated forms of childhood tuberculosis (particularly TB meningitis and miliary TB) in up to 80% of children with protection lasting 15 years or longer. BCG is also used as treatment for bladder cancer.

Universal vaccination of neonates was first introduced in Ireland in the 1950s and continued in most parts of the country until 2015 when a vaccine shortage occurred. Most European countries had at this stage moved to a selective BCG vaccination programme providing BCG to those in high-risk groups.

In 2013, a joint recommendation from the National Immunisation Advisory Committee (NIAC) and the National TB Advisory Committee to the Department of Health proposed moving from a universal neonatal BCG vaccination programme to a selective BCG vaccination programme targeting high risk groups only (17).

Following this, the Department of Health requested the Health Information and Quality Authority (HIQA) to undertake a Health Technology Assessment. HIQA reported in 2015 and noted that selective vaccination was more effective and less costly than universal vaccination (18).

Current National Immunisation Guidance regarding BCG vaccination in selective high risk groups is available via NIAC **here**.

1.4 TB Case definitions

Standardised European case definitions are used for notification of TB in Ireland and are available on the **HPSC website** (13).

1.4.1 Epidemiology of TB

Please see the following section for information and links to resources to access the latest information on the epidemiology of TB globally, in Europe and in Ireland.

1.4.1.1 Global

Global trends in TB are analysed by the World Health Organization (WHO) and published on an annual basis. For more information, visit the WHO website: **Global Programme on Tuberculosis & Lung Health**

1.4.1.1 Europe

The European Disease Centre produces an annual report on TB in the 30 countries in the European Union/European Economic Area (EU/EEA). Latest reports are available on the **ECDC website.**

1.4.1.2 Ireland

Reports and data on the epidemiology of TB in Ireland are published annually at the on the **HPSC website** (15).

1.5 Methods

The decision to develop new National TB Guidelines was supported by an evidence-based prioritisation process, following a call for submission of health protection guideline proposals released by the RGDU in early 2023. This prioritisation process was carried out and validated by five researchers independently, via a standardised scoring matrix.

To ensure that these guidelines were produced in a rigorous and robust manner, while recognising the need to distribute new information as promptly as it becomes available, the decision was made to adopt existing international TB guidelines for the Irish context. This was carried out using an evidence-based methodology for guideline adaptation and adoption (2).

Furthermore, to support access to updated recommendations around TB in Ireland, the guidelines were released on a phased basis, published by individual chapter on the HPSC website.

To identify a source guideline, a search of international guidelines was first undertaken, from which five potential guidelines emerged with applicability to the Irish context. The appraisal tool AGREEII (Appraisal of Guidelines for Research and Evaluation II) was used to critically evaluate each guideline identified by international guideline search (3), and assessments were carried out by at least two researchers independently. In addition, a detailed guideline mapping exercise was conducted against the *Guidelines on the Prevention and Control of Tuberculosis in Ireland, 2010,* to ensure that the source guideline identified for adaptation would encompass each of the subject matter areas covered by the 2010 Irish guidelines. Following this extensive process, the TB guideline NG33 produced by the National Institute of Clinical and Health Excellence (NICE) in the UK was identified as the most appropriate and high-quality source guideline (4), with additional source material to be referenced from Canadian TB Standards and the World Health Organization (WHO) guidelines (or other sources) as required. This decision was agreed by a quorum (50% + 1) of the Guideline Development Group (GDG) and the GDG chair. Recommendations were adopted or adapted, and source guideline judgments on the quality and certainty of the evidence were accepted. *De novo* recommendations were developed where required. Evidence searches of peer-reviewed publications were conducted by the RGDU on request of Chapter Lead(s) and/or the GDG chair, to answer specific health protection questions, and to fill knowledge gaps for the purposes of contextualisation.

Following GDG agreement to adapt the NICE guideline, the guideline development process was subdivided into three phases. During each project phase, three to four focused Subject Matter Expert Topic Groups (SME-TGs) were convened to develop individual chapters. SME-TGs were comprised of evidence review experts, all with training in the analysis of data and evidence-based medicine and led by a Chapter Lead with significant subject matter expertise in the topic. No more than four SME-TGs ran concurrently during the guideline development process.

Decisions made within SME-TGs on adapting draft content were conducted via roundtable discussion, and content was amended by collaborative review. This was followed by a formal consensus process for decision-making, conducted with the GDG and GDG Chair. A modified e-Delphi approach was used, followed by consensus committee. Multiple iterations of each chapter were produced and any amendments made, throughout this process, were extensively reviewed by the relevant SME-TG and GDG (See **Review and approval process**

for more information) This process continued until overall consensus was achieved among GDG members. Throughout this process, the GDG and RGDU maintained records of decision-making, including details on how the GDG moved from the available evidence to each recommendation. Recommendations were either acceptable, acceptable with modifications or unacceptable. Based on these decisions the GDG and SME-TGs created adapted guideline chapters, acceptable for an Irish context, to address the relevant health questions. In rare circumstances whereby GDG opinion differed, executive decisions were made by the GDG chair.

1.5.1 Patient and public involvement

The recruitment of patient representative(s) to participate in the GDG was advertised through a number of channels internal and external to the HSE, including the National Patient Forum and the Irish Thoracic Society, and was also communicated to groups and individuals known to clinicians on the GDG. Following an extensive search, it was not possible to identify a representative for this purpose. As an alternative, representation was invited from the National Social Inclusion Office (NSIO), with agreement that consultation would be sought from relevant service-user groups as needed and where deemed appropriate by the GDG.

1.6 Review and approval process

Each chapter of the National TB Guidelines underwent extensive review before publication. Draft chapters were reviewed by the Chair of the GDG, and by the relevant subject matter expert Chapter Lead(s) and/or SME-TG, before circulation to the GDG for input. Iterative rounds of review followed, until the GDG were satisfied that the content was acceptable and implementable. The completed chapters were then reviewed by wider external stakeholders. Upon acceptance, the GDG recommended approval of each chapter, and sign-off was subsequently received following review by the Health Protection Advisory Committee for Infectious Disease (HPAC-ID) within the NHPO, and the Director of National Health Protection. Any feedback received on each chapter was reviewed and incorporated by the relevant Chapter Lead(s) and SME-TG, and/or the GDG chair.

1.7 Future updates

A review of these guidelines will be undertaken no more than three years after publication by the RGDU as part of the routine cycle of guideline review. The RGDU may undertake a more rapid update of specific chapters within these guidelines if new and relevant evidence is published, according to need.

1.8 Disclosure statement

GDG and writing group members were asked to declare potential conflicts of interest at the time of appointment. A policy for the management of conflict of interest was put in place.

1.9 Funding

Funding for the adaptation license was provided through the HSE Public Health: National Health Protection Office. No external funding was received for the development of these guidelines.

1.10 Acknowledgements

The National Health Protection Office (NHPO) and the NTBAC are grateful for the contributions that many individuals and organisations have made to the development of these guidelines. A full list of guideline development group members and external stakeholders involved in the development of these guidelines is outlined in the **Appendix** of this chapter.

Appendix: Contributors to this guideline

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