Seirbhís Sláinte Níos Fearr á Forbairt | Building a Better Health Service

hpsc

Tuberculosis epidemiological reports – technical notes

March 2024 v3.0

1. Tuberculosis case definition

The case definition used for the analyses in this report is the Irish TB case definition under SI No. 452/2011 Infectious Diseases (Amendment) Regulations 2011. This case definition is also the same as the 2012 EU case definition.

Confirmed case – A person meeting the clinical criteria and at least one of the following two:

- Isolation of *M. tuberculosis* complex* (excluding *M. bovis*-BCG) from a clinical specimen

OR

- Detection of *M. tuberculosis* nucleic acid in a clinical specimen
  AND
- Positive microscopy for acid-fast bacilli or equivalent fluorescent staining bacilli on light microscopy

Probable case – A person meeting the clinical criteria and at least one of the following three:

- Microscopy positive for acid-fast bacilli or equivalent fluorescent staining bacilli on light microscopy

OR

- Detection of *Mycobacterium tuberculosis* nucleic acid in a clinical specimen

OR

- Histological appearance of granulomata

Possible case: A person meeting the clinical criteria without laboratory confirmation

Clinical Criteria – Any person with:

- Signs, symptoms and/or radiological findings consistent with active tuberculosis in any site
  AND
- A clinician's decision to treat the person with a full course of anti-tuberculosis therapy

OR

A case discovered post-mortem with pathological findings consistent with active tuberculosis that would have indicated anti-tuberculosis antibiotic treatment had the patient been diagnosed before dying

* *Mycobacterium tuberculosis* complex includes *M. tuberculosis*, *M. africanum*, *M. bovis*, *M. canetti*, *M. caprae*, *M. microti, M. orygis* and *M. pinnipedii*)

2. TB outbreak case definition

In general an outbreak is defined as the occurrence of cases of active TB disease above the expected level usually over a given period of time in a geographic area, facility or within a specific population group.

This definition of a TB outbreak relates to cases of active TB disease only and not to cases of latent TB infection (LTBI).

Outbreaks of Latent TB Infection are only notifiable where foodborne transmission is the suspected source of infection.

In general, the time period considered is within 6 months but outbreaks over longer periods may also be considered where epidemiological/microbiological evidence suggests that cases are linked. This should be based on local risk assessment or in consultation with HPSC if deemed appropriate.

When assessing whether a cluster of TB cases represents an outbreak, indicators to consider include:

- Epidemiological links between cases
- Similar unique characteristics among cases
- Supporting whole genome sequence (WGS) results

3. Surveillance definitions

Pulmonary TB: TB of the lung parenchyma or the tracheo-bronchial tree or the larynx. The World Health Organization (WHO) defines pulmonary TB, for the purpose of analysis, as any case that has a pulmonary disease component.

Extra-pulmonary TB: TB affecting any site other than pulmonary as defined above. Pleural TB and intra-thoracic lymphatic TB by themselves are considered as extrapulmonary.

Pulmonary and extra-pulmonary TB is a case of TB that meets both of the definitions for pulmonary TB and for extrapulmonary TB.

Sputum smear positive case: A patient with the presence of at least one acid-fast bacillus (AFB+) in at least one sputum sample in countries with a well functioning external quality assurance (EQA) system.

A new case is defined as a patient where no previous history of TB was reported.

A recurrent case is defined as a patient with a documented history of TB prior to their current notification.

Multidrug-resistant (MDR-TB) is defined as a TB case resistant to at least isoniazid and rifampicin with or without resistance to ethambutol and streptomycin.

Pre Extensively drug-resistant TB (Pre XDR-TB) is defined as a TB strain resistant to **all** of the following

- isoniazid
- rifampicin
- any fluoroquinolone (such as levofloxacin or moxifloxacin)

Extensively drug-resistant TB (XDR-TB) is defined as a TB strain resistant to **all** of the following

- isoniazid
- rifampicin
- any fluoroquinolone (such as levofloxacin or moxifloxacin)
- bedaquiline OR linezolid (Group A drugs other than fluoroquinalones).

This definition of XDR-TB was agreed by the WHO Global Task Force on XDR-TB in January 2021. Note that resistance to more than one fluoroquinalone does not consititute XDR-TB.

4. Surveillance system details

4.1. Data collection

Laboratory notifications of tuberculosis diagnoses are uploaded by microbiology laboratories directly onto the Computerised Infectious Disease Reporting (CIDR) system. TB enhanced surveillance forms are completed by public health doctors 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.

Standard reporting procedures for the surveillance of TB outbreaks were formally agreed in 2007 and updated in 2022. Outbreak data are collated on the CIDR system. Further information on TB is available at www.hpsc.ie.

National TB data from 1992 to 1997 were provided by the Department of Health (DoH). National TB data from 1998 to 2010 were obtained from the National TB Surveillance System (NTBSS). Data for 2011 onwards are taken from the CIDR system.

4.2. Legislative basis

Tuberculosis has been notifiable in Ireland since its inclusion in the 1948 Health Regulations list of notifiable diseases. This act was later superseded by the Infectious Disease Regulations 1981. These laws exist in order to monitor and control the occurrence of infectious diseases and to help prevent further illness.

In addition to individual cases of TB being notifiable, an amendment to the Infectious Disease Regulations introduced in 2004, made “outbreaks, unusual clusters or changing patterns of illness” notifiable by medical practitioners and clinical directors of laboratories to the medical officer of health. Clusters and outbreaks of TB are reported under this amendment.

In additional to medical practitioners, the amendment of 2004 also requires clinical directors of diagnostic laboratories to notify cases of notifiable diseases to the Medical Officer of Health. The Medical Officer of Health is either a Director of Public Health or Specialist in Public Health employed by one of the eight regional HSE Departments of Public Health.

Personal information is collected on all cases of notifiable diseases. This processing of personally identifiable information for cases of notifiable diseases is permitted under the General Data Protection Regulations (GDPR), Article 6 (1) (e): “processing is necessary for the performance of a task carried out in the public interest”.

Processing of sensitive personal information collected for cases of notifiable diseases, which includes health data, is permitted under GDPR Article 9 (2) (i): “for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care”.

4.3. Data quality

A suite of TB validation reports are available to all CIDR users. The purpose of these validation reports is to allow users to monitor the quality of the data recorded in CIDR and identify where updates are needed.

Validation reports are run by staff in Departments of Public Health each quarter. Relevant updates are made as directed by these reports.

Prior to production of quarterly and annual reports, data are extracted from CIDR, cleaned and validated by HPSC staff. Plausibility checks and internal consistency checks are run and updates are made in conjunction with feedback from Departments of Public Health.

Data quality and completeness summaries are provided to Departments of Public Health along with each quarterly report produced.

4.4. Data analysis

HPSC produces quarterly and annual TB reports using notification data reported by departments of public health and laboratories to the CIDR system.

Data are retrieved from CIDR using Business Objects and exported to MS Excel. Data are then imported into an MS Access database for cleaning and recoding prior to analysis.

Descriptive analysis is performed using MS Excel/R while statistical analysis is carried out using STATA 15/R.

Crude incidence rates were calculated using the following denominators for the following years data:

- 1991 population census – 1991 to 1993
- 1996 population census - 1994 to 1999
- 2002 population census - 2000 to 2003
- 2006 population census - 2004 to 2008
- 2011 population census - 2009 to 2013
- 2016 population census - 2014 to 2019
- 2022 population census – 2020 to 2023

For the calculation of rates in the Irish-born and foreign-born population, denominator data represent persons usually resident in each province and county, and present in the state on census night. The Irish-born population is defined as those persons who were born in Ireland.

Direct methods of standardisation are used to allow comparison of rates between geographical areas using the relevant Irish population census for the years above as the standard population. In order to compare rates between groups of interest, 95% confidence intervals are used.

Three-year moving averages are calculated by applying the formula (a+2b+c)/4 to each three successive points a, b and c (each letter representing a year) in the series. They are useful for smoothing irregularities in trend data and make it easier to discern long-term trends that otherwise might be obscured by short-term fluctuations.

Temporal trends are assessed using negative binomial regression and incidence rate ratios.

Local health offices (LHOs) came into operation on 1st September 2005, replacing Community Care Areas. LHO denominators are used for TB reports rather than community care area (CCA) denominators. LHO rates were calculated using Census 2022 LHO denominator data extracted from Health Atlas for all LHOs.

Regional Health Authorities came into operation on 01/05/2022, replacing the eight HSE areas.