TECHNICAL NOTE

All the 51 countries of the WHO European Region participate in the tuberculosis surveillance activities co-ordinated by EuroTB. Country participation is on a voluntary basis. National surveillance institutions are appointed for participation in EuroTB activities and are responsible for the quality of data provided. The principles, methods and definitions guiding EuroTB activities are those recommended by working groups including WHO and the International Union against Tuberculosis and Lung Disease (IUATLD) and approved by European country representatives **[1, 2].**

2.1 Data collection and management

Data are collected once per year. In order to allow for validation and consolidation at national level, data are collected several months after the end of the calendar year of interest. Data reported for previous years are not routinely updated.

Individual data
Individual, anonymous data, according to a standardised data file specification are collected yearly on TB cases notified at the national level and starting treatment (or diagnosed) in the previous calendar year. Individual data are validated by the EuroTB team and then collated in a European data set.

Aggregate data
When individual data cannot be provided, data on TB cases notified are provided as aggregate data through standard Tables including numbers of TB cases by age and sex, geographic origin, previous anti-TB treatment status (never treated / previously treated), site of disease and bacteriological confirmation (culture and sputum smear results). Since 1999, aggregate data are collected jointly with the WHO Regional Office for Europe, using a common form which also includes sections on characteristics of national surveillance and TB control policies and data on treatment outcome monitoring. The form may be completed through the Internet, via the Computerised Information System for Infectious Diseases (CISID), an application developed by the WHO Regional Office for Europe, or using electronic Tables or on paper. Data provided are validated by both WHO and EuroTB teams. After validation, specific aggregate data sets are created (e.g. data by sex and age group) which also include data initially provided in individual form and constitute the basis for the analyses published in this report. Figures presented in this report may differ from those published by WHO **[3, 4]** mainly due to the use of individual data further validated.

Drug resistance surveillance (DRS)
Since 1998, data on the results of drug susceptibility testing (DST) at the start of treatment for isoniazid, rifampicin, ethambutol and streptomycin are collected, together with information on the organisation of DRS and on laboratory practices for DST. DST results are provided as "susceptible" or "resistant". If the proportion method is used, resistance is defined as growth of $\geq$ 1% colony growth at the critical concentrations of the drug being tested.

In countries where DST results are linked to TB case notifications (i.e. are provided for culture positive cases *notified*), DST results are provided as individual data in the same data file containing other information on TB cases. In countries unable to do so, or where DST results are not linked to TB case notifications, DST results are provided in aggregate form as numbers of resistant cases for each drug or drug combination, by previous anti-TB treatment status and by geographic origin (national / foreigner).

2.2 Definitions

Case definition

Definite TB case
- in countries where laboratories able to perform culture and identification of *M. tuberculosis* complex are routinely available, a definite case is a patient with culture-confirmed disease due to *M. tuberculosis* complex.

- in countries where routine culturing of specimens is not feasible, patients with sputum smear positive for acid-fast bacilli (AFB) are also considered as definite cases.

Other-than-definite TB case
A case meeting the two following conditions:

- a clinician's judgement that the patient's clinical and/or radiological signs and/or symptoms are compatible with tuberculosis,

and

- a clinician's decision to treat the patient with a full course of anti-tuberculosis treatment.

All definite and other-than-definite TB cases starting treatment in the calendar year of interest are notifiable to EuroTB and are included in the figures presented in this report. Cases should be notified only once in a given calendar year, i.e. cases starting a second course of treatment (e.g. after interruption) in the same calendar year as the previous notified episode should not be notified again.

Previous anti-TB treatment status

Never treated case
A case who never received a drug treatment for active TB in the past or who received anti-TB drugs for less than one month.

Previously treated case
A case who was diagnosed with TB and received a drug treatment with anti-TB drugs (excluding preventive therapy) for at least one month.

In countries providing individual data, information is collected on both previous TB diagnosis and previous anti-TB treatments. In countries where information is available only on previous TB diagnosis, cases with a previous TB diagnosis are classified as previously treated.

Note: Previously treated cases include relapses, failures, returns after default and chronic cases **[5]**. Relapses are included in notifications in all countries whereas the notification of other previously treated cases varies across countries **[6]**.

Site of disease

Pulmonary case
A case with TB affecting the lung parenchyma and/or the tracheo-bronchial tree.

Extrapulmonary case
A case with TB affecting any site other than pulmonary as defined above. Pleural TB and intrathoracic lymphatic TB without involvement of the lung parenchyma are classified as extrapulmonary.

In alternative to the recommended "pulmonary" classification above, cases can be classified according to the "respiratory" classification, in which pleural and intrathoracic lymphatic TB cases are classified as "respiratory" cases together with pulmonary cases (as defined above), and extrarespiratory cases include TB affecting any other site.

Cases with both pulmonary and extrapulmonary (or respiratory and extrarespiratory) localisation are classified as pulmonary (or respiratory) cases, including cases with disseminated TB (i.e. TB involving more than two organ systems, miliary TB or isolate of *M. tuberculosis* complex from blood). In individual data, detailed information is collected on the major site and one minor site of disease. The pulmonary localisation is always classified as the major site.

Geographic origin
The geographic origin of TB cases is provided according to place of birth (born in the country / foreign born) or, if place of birth is unavailable, to citizenship (national / foreign citizen). The specific country or continent of birth (or citizenship) is collected in individual data. When presenting individual data by continent of origin, Europe is defined as the WHO European Region and Asian countries within the WHO European Region are excluded from Asia.

Drug resistance

Mono-resistance
Resistance to a single first line anti-TB drug (isoniazid, rifampicin, ethambutol and streptomycin.

Multidrug resistance (MDR)
Concomitant resistance to at least isoniazid and rifampicin.

Polyresistance
Resistance to at least two first line anti-TB drugs, including multidrug resistance.

Resistance among cases never treated
It indicates primary drug resistance due to infection with resistant bacilli.

Resistance among cases previously treated
It *usually* indicates acquired drug resistance, i.e. emerging in a patient during treatment as a consequence of selection of drug-resistant mutant bacilli.

It can also result from exogenous re-infection with resistant bacilli.

2.3 Data presentation

Numbers of cases are shown by year of report and are not adjusted for under-notification or for over-notification, on which most recent country estimates were provided for 1997 **[7]**.

Country population denominators for calculation of notification rates are taken from United Nations demographic estimates (1994 update until 1997 **[8];** 1998 update since 1998 **[9]),** except for Andorra **[10].** Population estimates by geographic origin and regional populations (for Yugoslavia in 1999) were provided by national correspondents.

Based on epidemiological and geographical considerations, the 51 countries of the WHO European Region have been grouped into three geographic areas:

- West: the 15 European Union countries plus Andorra, Iceland, Israel, Malta, Monaco, Norway, San Marino, Switzerland); within the West, subtotals are shown for the European Union;
- Centre: Albania, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic, Hungary, the Former Yugoslav Republic (FYR) of Macedonia, Poland, Romania, Slovakia, Slovenia, Turkey, Yugoslavia.
- East: the 15 Newly Independent States of the former Soviet Union, including the Baltic countries (Estonia, Latvia, Lithuania);

The respective total populations of the three areas were 395, 187 and 292 million in 1999.

Drug resistance surveillance

Proportions of resistant cases are calculated using as a denominator cases with available DST results for at least rifampicin and isoniazid. The results for ethambutol and streptomycin are presented if these two drugs were considered to be routinely tested in 1999 and, in countries providing individual data, if results were available for at least 95% of the cases tested for isoniazid and rifampicin.

In countries where culture or DST are not routinely performed for TB diagnosis, DST results from diagnostic testing (i.e. from testing done for routine diagnosis) may be unrepresentative. Drug resistance surveillance (DRS) data provided to EuroTB may be collected for culture positive TB cases notified or on selected samples of TB cases unlinked to TB notifications, e.g. selected laboratories or clinical Centres. Finally the geographic coverage can be national or partial. According to diagnostic practices, source of data and geographic coverage, countries are divided in two groups for the presentation of drug resistance data in Tables 16-21:

group A includes countries in which:

– culture and DST results are routinely performed for TB diagnosis and
– DST results were collected on all or large national samples of culture positive TB cases notified in 1999;

group B includes countries in which:

– culture and/or DST are not routinely performed at TB diagnosis or
– DST results were collected on TB cases diagnosed in selected laboratories / clinical Centres, not linked to TB notification, or
– data provided had a partial geographic coverage.

Data in group A are considered as representative, whereas data in group B should be interpreted cautiously. Particularly in countries where culture and DST are not routinely performed for TB diagnosis, DST data represent selected groups of TB cases and should not be used for international comparisons.