



Annual Meeting of the European Network for TB Surveillance in Europe

Dubrovnik, Croatia
25-26 May 2009

Annual Meeting of the European Network for TB Surveillance in Europe

Dubrovnik, Croatia
25 - 26 May 2009

Report

ABSTRACT

The 2009 annual meeting of the European Network for TB Surveillance in Europe was organized jointly by WHO and ECDC to obtain an overview of the epidemiological situation in the European Region as regards TB, to present changes in the joint WHO–ECDC TB information system, and to discuss the TB case definitions and the future development of the annual report.

Keywords

Tuberculosis, pulmonary - epidemiology - prevention and control
Epidemiological surveillance
Information systems - trends
Congresses
Europe

Address requests about publications of the WHO Regional Office for Europe to:

Publications
WHO Regional Office for Europe
Scherfigsvej 8
DK-2100 Copenhagen Ø, Denmark

Alternatively, complete an online request form for documentation, health information, or for permission to quote or translate, on the Regional Office web site (<http://www.euro.who.int/pubrequest>).

© World Health Organization 2009

All rights reserved. The Regional Office for Europe of the World Health Organization welcomes requests for permission to reproduce or translate its publications, in part or in full.

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either express or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use. The views expressed by authors, editors, or expert groups do not necessarily represent the decisions or the stated policy of the World Health Organization.

CONTENTS

	Page
Executive summary.....	1
Introduction	3
Session 1: Overview of the epidemiological situation.....	3
The epidemiological situation in Europe with regard to TB, 2007	3
Developments in molecular surveillance	5
Session 1 – discussion	5
Session 2: Information system operations	6
Operations on the ECDC-WHO joint TB information system	6
Data collection – lessons learnt in 2008	6
Session 2 – discussion	7
Session 3: Global TB surveillance strategy	7
Session 3 – discussion	7
Session 4: Working groups	8
Session 5: Final session - presentations of the working groups.....	8
Group 1: EU TB case definitions, TOM cohort conditions and categories	8
Group 2: Future perspectives of molecular surveillance of MDR-TB	10
Group 3: Challenges and problems in TB data collection and lessons learnt in 2008	11
Conclusions	13
Annex 1: Programme.....	15
Annex 2: Background document for the Working Groups.....	19
Annex 3: Participants.....	29

Executive summary

The annual meeting of the European Network for Tuberculosis (TB) Surveillance in Europe held in Dubrovnik, Croatia, on 25–26 May 2009, was organized jointly by the WHO Regional Office for Europe (WHO) and the European Centre for Disease Prevention and Control (ECDC).

The participants included the nominated contact points for TB surveillance from 43 of the 53 Member States of the WHO European Region, including 25 of the 27 countries of the European Union and Norway, as well as experts from the WHO Regional Office, WHO headquarters, ECDC and the National Institute for Public Health and the Environment (RIVM) (Annex 3).

Main conclusions

- TB remains a threat to the population of the European Region. Surveillance is the backbone and at the core of all public health activities.
- The past year has seen significant changes to the European Network for TB Surveillance, which is managed jointly by WHO and ECDC. Not only has there been hard work and commitment on the part of WHO and ECDC, but also by the experts and institutes in the countries, which constitute the basis of European surveillance.
- The transition process for the European TB surveillance system was a success. Important lessons were learned and experience gained, which will be reflected in the collection, analysis and reporting of the 2008 data.
- All feedback resulting from the meeting will be given careful consideration.
- WHO and ECDC will work towards maintaining, strengthening and expanding surveillance activities.

Main points raised¹

- WHO and ECDC were requested not to change the case definition and variables lists often.
- The ECDC TB team needs to address the problem of how to report cases of truly chronic disease versus re-treatment cases. To this end, clear instructions are needed on how and where cases should be reported in the European Surveillance System (TESSy).
- WHO and ECDC need to consider the possibility of non-European Union (EU) countries presenting their own population figures if they disagree with EuroStat or United Nations numbers.
- Consideration should be given to including a list of the TB contact points and contributors in the report on TB surveillance in Europe for 2010.

¹ Presentations are available at: http://www.euro.who.int/tuberculosis/forum/20090622_1, accessed 6 September 2009.

- ECDC should inform the EU candidate countries of the option to report case-based data through TESSy rather than directly to the centralized information system for infectious diseases (CISID).
- TESSy could be improved to better detect logical conflicts when reviewing the definitions of variables.
- Several minor errors found in the 2007 report on TB Surveillance in Europe need to be corrected.
- All countries agreed to the strict deadline of 30 September 2009 for the submission of data - even if they were still preliminary.
- Regarding the suggestion to add additional drugs to drug susceptibility testing, it was felt that to do so would sacrifice quality for the sake of quantity. It was recommended that the current five second-line anti-tuberculosis drugs be retained.
- It was suggested that three variables be deleted from the TESSy data set: date of onset of disease; clinical criteria; and the directly observed treatment, short-course (DOTS) variable.

Introduction

The 2009 annual meeting of the European Network for TB Surveillance in Europe was organized jointly by WHO and ECDC.

The objectives of the meeting were: (1) to provide an overview of the epidemiological situation in the European Region as regards TB; (2) to present changes in the joint WHO–ECDC TB information system (to include the drug resistance surveillance (DRS) questionnaire in the TB data collection form reflected in the CISID); and (3) to discuss the TB case definitions and the future development of the annual report (Annex 1).

Dr Andrew Amato-Gauci opened the meeting and welcomed the participants on behalf of the ECDC. Ms Sibila Žabica welcomed the participants on behalf of the Ministry of Health and Social Welfare of Croatia and Dr David Mercer on behalf of WHO.

Session 1: Overview of the epidemiological situation

The epidemiological situation in Europe with regard to TB, 2007

Report of WHO

The WHO overview of the epidemiological situation in the European Region was based on the TB surveillance report for 2007², which included data from 51 of the 53 countries (San Marino and Monaco did not participate in the surveillance).

- A total of 477 327 cases of TB were reported in the Region as a whole. About 5% of the global burden of TB and 84 % of the European burden is concentrated in the 18 countries of the European Region where there is a high priority to stop TB.
- Although the overall notification rate in this area was 54 per 100 000, 13% higher than that in 2003, a downward trend was observed in 25 countries.
- Since 2003, case detection has increased from 23% to 55% and treatment success rates have decreased from 75% to 70%.
- The estimated prevalence of primary multi-drug resistant TB (MDR-TB) in 2007 was 10.35% but, because of low routine DRS coverage, the detection rate was only 17%.
- The estimated prevalence of HIV in new TB patients was 9.8%. The surveillance system for detecting HIV infection has low sensitivity (4% of notified HIV prevalence) due to low routine HIV surveillance coverage (16 %).
- The non-EU countries of Eastern Europe and Central Asia remain a regional priority for TB control. In these countries the situation is often complicated by:
 - low specificity or poor-quality information; and
 - a persistent lack of the resources necessary to mount a suitable response and/or the inadequate use of existing resources.

² Available at: <http://www.euro.who.int/Document/E92364.pdf>, accessed on 6 September 2009.

- In the western European countries, a diversity of TB patterns persists. The more industrialized countries are becoming increasingly aware of the aggregation of cases in particularly vulnerable populations.
- In intermediate burden countries, such as the Baltic States, the prevalence of MDR TB remains high.

Report of ECDC

The ECDC focussed more on the 27 EU and 3 European Economic Area and European Free Trade Association (EEA/EFTA)³ countries, all of which had reported data from 2007.

- Romania has the highest incidence rate in this group.
- General conclusions:
 - Males dominate among TB patients in nearly all EU and EEA/EFTA countries.
 - 4% of the reported cases were paediatric.
 - 21% of the reported cases were of foreign origin.
 - Most cases of foreign origin were reported in the 25–44 years age-group.
- TB is still an issue in the EU:
 - The situation varies from country to country; some are aiming at TB elimination while others are facing higher incidence rates.
 - Within the heterogeneous epidemiological setting described, the number of countries with high and intermediate rates of TB remained the same.
 - In countries with low incidence rates, cases of TB are more common in particularly vulnerable populations with poor access to health services.
 - The quality of drug-resistance testing and reporting needs to be assessed and further improved. As rates decline, the contribution of drug resistance in slowing down the declining trend of the epidemic will become increasingly important.
- The EU and EEA/EFTA countries need to consider:
 - improving TB surveillance in vulnerable populations by providing better estimates of denominators for at-risk populations;
 - enhancing – at national level – the integration of laboratory reporting of confirmatory TB tests with case notification in order to improve completeness;
 - fully implementing treatment-outcome monitoring and extending coverage of treatment outcome monitoring to all culture-positive cases;
 - optimizing the reporting and analysis of treatment outcome after 12 months, also with respect to MDR-TB patients;
 - extending the implementation of drug-resistance surveillance by collecting initial DST results for all cases.

³ Iceland, Liechtenstein and Norway.

Developments in molecular surveillance

As outlined in the TB transition plan, the ECDC has outsourced the laboratory component for the coordination of MDR-TB activities and surveillance in Europe in 2009–2012 to the Dutch National Reference Laboratory at RIVM.

RIVM gave an overview of earlier surveillance activities on MDR-TB transmission in Europe. In connection with their planned work on optimizing the molecular surveillance of MDR-TB, they have introduced the internationally preferred fingerprint method, mycobacterial interspersed repetitive unit – variable number of tandem repeats (MIRU-VNTR), as the reference method to be used. They also outlined the scope of and their objectives and approach to having all MDR-TB cases typed in Europe.

National surveillance system overview – challenges and advantages

Two national perspectives on surveillance were presented: the development of a national TB surveillance system in the Russian Federation; and the epidemiological situation, data collection system and challenges in reporting TB data in the United Kingdom.

Session 1 – discussion

Concerning the implications of MDR-TB surveillance, RIVM clarified that the project cannot cover all strains or isolates in Europe. The aim is at least to have an overview of the spread of MDR-TB in Europe. Using the faster typing methods can give more up-to-date information on the situation. Monthly analyses on the typing data available in the database will be carried out within the MDR-TB project. The reports will be sent to ECDC so that the information can be compared to the epidemiological data from TESSy. ECDC stated that the typing data will be used for surveillance and not research activities. Typing data will be returned to the countries for matching with the epidemiological data and submission to TESSy for better analysis of those strains and cases where the molecular data are available. One important outcome will be a better understanding of the transmission routes and trends.

The Russian Federation and the United Kingdom discussed the challenges they are facing with respect to human resources for TB surveillance. The United Kingdom brought up some security and data confidentiality issues relating to their website collection and sharing of data.

Session 2: Information system operations

Operations on the ECDC-WHO joint TB information system

WHO gave an overview of the joint information system and website.

- The logins will be improved to minimize errors.
- The new reporting format will reduce the amount of data collected by 60% in high-incidence countries and 80% in low-incidence countries.
- There will be a new notification sub-section for extremely drug-resistant TB (XDR-TB).
- DST data will be requested for routine cases only, not for surveys.
- There are challenges in connection with HIV-TB data collection, such as country legislation, infrastructure and no or poor collaboration with HIV programmes on data operation. Better and more constructive collaboration at the country level on TB/HIV co-infection surveillance is encouraged.
- For the 2008 data collection and analysis:
 - data with standardized case definitions should be used throughout the Region or there should be standing operating procedures (SOPs) for data interpretation;
 - an integrated approach to the collection of TB data at the regional level is required (formats, channels/tools, responsibilities);
 - an improved response rate and better data quality are anticipated;in order to:
 - emphasize the use of cohort analysis for treatment outcome monitoring;
 - develop a better insight into the HIV-TB co-epidemic;
 - conduct careful assessments of the prevalence and trends of MDR-TB at the country and regional levels.

Data collection – lessons learnt in 2008

ECDC discussed the functionality of the system and how it had worked during the year.

Achievements in this period include:

- the smooth transfer of the EuroTB project and systems;
- the synchronization of data collection by WHO and ECDC;
- the development and launch of TESSy;
- the strengthening of CISID;
- the development of the Joint ECDC-WHO Information System for TB Surveillance;
- continuous surveillance in the whole of the WHO European Region (53 countries);
- the publication of the report on TB surveillance in Europe for 2007.

By end September 2008, data had been reported by only two-thirds of the Member States. This delay made it more difficult to finalize the report.

The unofficial data analysis agreement between WHO and ECDC was found to be beneficial. Seventeen countries provided comments on the draft report.

The main lessons learnt from the report on TB surveillance in Europe for 2007 are that the exact format and content should be agreed upon in advance so that time is not wasted discussing details, and that deadlines for data submission, validation, analysis and writing the report should be strictly adhered to by all to avoid data quality concerns resulting from last-minute changes.

Session 2 – discussion

The following solutions to the challenges raised during the session were proposed.

1. To have deadlines that are agreed and adhered to by all.
2. To reduce the number of questions in the questionnaire, which should be more specific.
3. To simplify the logins. There will continue to be two logins and two passwords for the separate databases (TESSy and CISID).
4. To avoid duplication of DRS (this was already in hand).
5. To work on improving documentation for SOPs.

Session 3: Global TB surveillance strategy

Mr Philippe Glaziou spoke about the global TB surveillance strategy and discussed the global targets. It was concluded that:

- although there is strong surveillance in Europe, several areas can still be improved;
- there is a need to strengthen the surveillance of drug resistance and TB-HIV co-infections;
- there is a need for robust and widely endorsed estimates of incidence, prevalence and mortality;
- a comprehensive WHO policy package is about to be published.

Session 3 – discussion

The United Kingdom made the point that the use of measures of wealth to estimate changes over time and MDR figures was not ideal. It was also argued that lack of wealth may possibly provide protection from MDR-TB due to the resulting lack of access to drugs. However, lower economic settings may also provide opportunities for better health care and, in the long run, improve the situation. Dr Glaziou responded that it was not clear which factors were most important in reducing incidence. Also, although the current economic crisis may not lead to a

change in incidence, it might affect funding, especially in countries that depend largely on external sources.

Another point made was about the use of the case-detection ratio as an indicator of the quality of surveillance (the example of the Netherlands was given where the case-detection ratio was around 70%). This may indicate a problem because using the case-detection ratio as an indicator was based on a 50 year-old model. Dr Glaziou agreed that there was some contradiction between the quality of surveillance and the case-detection ratio in the Netherlands and that the latter needs to be reassessed. Also, it is difficult to measure the denominator. The aim is to constantly improve the quality of surveillance systems.

Session 4: Working groups

The tasks of the working groups were presented (Annex 2). The aims were as follows:

- Group 1: To discuss the implementation of the EU case definitions, their future development and their complementary relationship to the WHO definitions. To discuss TOM cohorts.
- Group 2: To introduce and discuss the future perspectives of drug resistance surveillance and the molecular surveillance of MDR-TB cases.
- Group 3: To discuss and make proposals on data collection and the content of the report on TB surveillance in Europe for 2010.

Session 5: Final session - presentations of the working groups

Group 1: EU TB case definitions, TOM cohort conditions and categories

Suggested points for discussion

1. Are the EU case definitions and the WHO case definitions complementary? Is all the necessary information available to make descriptive analyses under the different definitions?
2. How can confusion be avoided regarding clinical criteria and double-reporting of case-based data to TESSy with respect to classification, clinical criteria and laboratory results?
3. Would it be reasonable to include the breakdown of disease by site of disease in the aggregated data collection (CISID) in order to enable the further analyses of extra-pulmonary TB (TB meningitis, disseminated TB, etc.)?
4. The function and use of the “still on treatment” (SOT) category continues to be debatable. Would it be appropriate to focus discussion on possible alternatives for monitoring outcomes (particularly at 12 months) in cases that require treatment for longer than 12 months (i.e. MDR-TB cases)?

5. The issue of reporting and treatment categorization for chronic cases should also be discussed.

Comments of the Group

Re 1: Complementarity of case definitions

- The EU and WHO case definitions complement each other.

Re 2: Avoiding confusion regarding clinical criteria and double-reporting of case-based data to TESSy

- Culture is to remain the standard for case confirmation but with the possibility of using smear confirmation where the capacity for culture is low (as per the WHO case definitions).
- The implementation of the EU case definition is feasible for reporting at EU level. However, the use of the EU case definition at country level is impractical for many.
- Culture quality assurance remains a prerequisite for implementing case confirmation by culture.
- Regardless of whether or not the case definition is used to maintain comparability in time trends analyses, the case notification rate should continue to be based on all notified cases.

Re 3: Breakdown of case reports in CISID

- Most countries reporting to CISID can and will give a more detailed breakdown of site of disease.

Re 4: SOT

- There was agreement on the principle of “one case, one outcome”.
- There was agreement on maintaining SOT at 12 months, recognizing the possibility of performing sub-cohort analyses, particularly for MDR-TB cases. However, this should not affect reporting on TOM and success rates for global targets.
- SOT at 12 and 24 months can be reported by most EU countries.

Re 5: Chronic cases

- ECDC is to provide clear guidance on the reporting and TOM of chronic cases.

Group 2: Future perspectives of molecular surveillance of MDR-TB

Suggested points for discussion

1. Is there a need to include other second-line drugs in routine DRS?
2. What topics relating to MDR-TB surveillance would be most interesting to publish in the report on TB surveillance in Europe for 2010? What kind of tables, graphs and/or maps would be the most appropriate?
3. Could the strain numbers serve as unique identifiers for connecting the molecular typing data with the epidemiological data to avoid double reporting? How could this be done?

Comments of the Group

Re 1: Inclusion of other second-line drugs

Concerns

- The question of quality versus quantity.
- Quality assurance for additional drugs.

Proposals

- Retain the current list of five second-line drugs.
- Consider adding to the list at a later date when quality assurance of methods allows it.
- Since access to certain drugs is limited, it may be necessary for ECDC to send out a public health message concerning pharmaceutical access to these drugs and requirements for reporting.

Re 2: Which MDR should be presented in the annual report?

Concerns

- What is the purpose of ECDC's MDR-TB molecular surveillance? (To standardize methods? To build capacity? To improve effective response through a rapid turnover of results?).
- Country applications and regional applications will differ.
- The regional benefit of molecular typing allows linking cases to specific strains and factors common to clusters.
- Countries use the data for different purposes, including monitoring programme effectiveness and the spread of nosocomial infections.

Proposals

- Publish the results and lessons learnt from the 2002–2007 project, for example, in the journal, "Emerging Infectious Disease".
- The application of this data at regional and national levels, as well as scientifically, requires further clarification, especially as regards case management, public health interventions and research.

Re 3: Linking strain records to case records in the surveillance system

Concerns

- Samples are often taken before the case identity is assigned.
- Systems are case-based not patient-based.
- MDR typing looks for patient clusters and is not linked to patient records.
- Confidentiality protection rules make linking more difficult.

Proposals

- Ideally, an MDR database should be patient-based. Currently this is not a feasible option but should be addressed.
- Ask countries to provide a unique identifier that links strain records with case records.
- Include in TESSy fields for case numbers, strain numbers and individual (patient) numbers.

Group 3: Challenges and problems in TB data collection and lessons learnt in 2008

Suggested points for discussion

1. Are all the recommendations regarding joint action valid for the 2010 report on TB surveillance in Europe?
2. Do we agree that to ensure the quality of the report, the deadlines for data submission and analysis should be fixed and strictly respected by all? Is it agreed that failure to do so on the part of a country will mean that its data will not be included in the report?
3. Does the case-based TB data set include too many variables? If so, how can the variables be prioritized and which of them could be deleted.

Comments of the Group

Re 1: Are all the recommendations for joint action valid for the for the 2010 report on TB surveillance in Europe?

The countries accepted the structure, process and content of the 2007 report on TB surveillance in Europe. However, the following points were brought up:

- The country clearance process needs to be improved for published data.
- Technical information in the country profiles should correspond to the subtitles (comments from TESSy users can be sent via e-mail).
- The definitions used in the report should be more clearly specified so that the differences between the global report and European report are apparent.
- The data relating to the EuroStat population do not always match the national data. Countries should be able to present their own population figures.

- The report should include a list of the national contact points. The exact information to be included (e.g. name, title, institution's email address) is to be agreed.
- The interpretation of country-specific trends in the narrative could be expanded upon.
- If EU candidate countries wish to submit case-based data to TESSy in parallel to reporting to CISID, they should send a written request to the Director of ECDC with a copy to WHO.
- The problems related to reporting HIV/TB co-infection need to be addressed.

Re 2: Adherence to deadlines

- The data collection timeframe was agreed as 1 July – 30 September 2009. All of the countries agreed to meet the deadline.
- It was pointed out, however that some of the countries can provide only preliminary data by the deadline (30 September). It was, therefore, agreed that a remark to this effect would be included in the report.

Re 3: Variables included in the TB case-based data set

- It was agreed that some variables should be deleted, such as “DOTS” and “Date of onset”.
- In connection with the EU case definitions, the question was raised as to whether, in the absence of the clinical criteria, it was possible to confirm a TB case.
- The view was expressed that CISID reporting could be shortened by between 60% and 80% and that the specification for the CISID variables needs to be improved.

Group 3 - discussion

ECDC feels that the current format of the 2007 report on TB surveillance in Europe places too much focus on the tables, making it heavy to work through. Together with WHO, they will work on sharpening the layout. Countries will be informed of updates.

It was agreed that there was a need to reduce the number of variables. “DOTS” and “Date of onset” would be the first to be cut.

In the past, it was possible to download individual sections from the Euro TB website. ECDC agreed that this was beneficial and would look into reinstating the possibility.

WHO headquarters informed the participants that in 2010 they will publish a shorter version of the Global TB report for the 2008 data and a more extensive version for the 2009 data. Therefore, data collection would start earlier in 2010.

Conclusions

Highlighted by WHO

- A strong surveillance system based on notification is an important feature of the Region's surveillance.
- There are many challenges to improving surveillance: the diversity of countries in the Region and difficulty in reaching consensus; an unfavourable epidemiological situation in many locations; and varying levels of the quality of surveillance.
- The Berlin Declaration on Tuberculosis⁴ included a point on strengthening surveillance systems. The first follow-up meeting on the Declaration was scheduled to take place in Luxembourg at the end of June 2009.
- The collaboration between WHO and ECDC on TB surveillance is very valuable and it is important that it continue.

Highlighted by ECDC

- Joint surveillance is working well despite the challenges posed by a very heterogeneous region (geographically, epidemiologically).
- Despite various obstacles, the 2007 report on TB surveillance in Europe has maintained the quality of the earlier EuroTB reports. The discussions at the meeting will help in improving the report.
- The EU-EEA/EFTA countries also contribute to the global picture by:
 - advocating for continued commitment (financial and political);
 - supporting the Framework Action Plan;
 - responding to the Berlin Declaration;
 - monitoring progress towards the elimination of TB;
 - tailoring control measures to the EU setting: BCG, TB in migrants.
- At the request of the European Commission, ECDC is following up on the TB Framework Action Plan by:
 - carrying out stakeholder mapping and analysis;
 - defining the roles of the EU Member States and EU institutions;
 - defining technical packages;
 - providing country support (in conjunction with WHO);
 - developing operational indicators (linked to the objectives of the plan);
 - developing epidemiological indicators and targets.
- In connection with monitoring the Framework Action Plan:

⁴ http://www.euro.who.int/tuberculosis/TBForum/20070621_1, accessed 6 September 2009.

- the report on TB surveillance in Europe for 2010 and the data collected will form the basis for monitoring the Framework Action Plan.
- ECDC plans to work towards interim indicators and does not foresee placing a further burden on the current surveillance system by making new requests.

Annex 1: Programme

Monday, 25 May 2009	
09:30 – 11:30	ECDC/WHO Regional Office for Europe representatives' meeting on TB Surveillance
10:00 – 14:00	Registration
14:00 – 14:15	Opening remarks <i>Sibila Žabica (Ministry of Health and Social Welfare of Croatia)</i> <i>Andrew Amato (ECDC)</i> <i>David Mercer (WHO Regional Office for Europe)</i>
14:15 – 16:00	Session 1: Overview on the epidemiological situation <i>Chair: Shahimurat Ismailov (Kazakhstan)</i> Overview of Epidemiological situation in Europe 2007 <i>Andrei Dadu (WHO Regional Office for Europe) and Vahur Hollo (ECDC)</i> Developments on molecular surveillance <i>Csaba Ködmön (ECDC)</i> <i>Arnold Herrewegh (RIVM)</i> National surveillance system overview – treatment outcome monitoring – challenges and advantages - Experience of Russian Federation <i>Elena Skachkova</i> - Experience of United Kingdom <i>Ibrahim Abubakar</i> Discussion
16:00 – 16:30	Coffee break
16:30 – 17:00	Session 2: Information system operations <i>Chair: Davide Manissero (ECDC)</i> Data collection 2008 – lessons learnt <i>Vahur Hollo (ECDC)</i> Operations on the ECDC/WHO joint TB information system, <i>Andrei Dadu (WHO Regional Office for Europe)</i> Discussion

Tuesday, 26 May			
09:00 – 09:15	Session 3: Key Speaker Chair: <i>Richard Zaleskis (WHO Regional Officer for Europe)</i> Summary of previous day <i>Andrew Amato-Gauci (ECDC)</i>		
09.15 – 10:00	Importance of Surveillance in TB Control <i>Philippe Glaziou, senior epidemiologist, WHO headquarters, Stop TB Department, Tuberculosis Monitoring and Evaluation Unit</i>		
10:00 – 10:30	Coffee break		
11:00 – 11:15	Session 4: Working groups Chair: <i>David Mercer (WHO-Europe)</i> Introduction <i>Csaba Ködmön, Andrei Dadu, Vahur Hollo</i>		
11:30 – 13:00	Working Group 1 (without translation) <i>Davide Manissero</i> EU TB case definitions TOM cohort conditions & categories	Working Group 2 (without translation) <i>Csaba Ködmön</i> Future perspectives for molecular surveillance of MDR-TB	Working Group 3 (with translation) <i>Vahur Hollo</i> Challenges and problems in TB data collection + lessons learned from 2008
13:00 – 14:00	Lunch break		
14:00 – 15:30	Session 5: Final session Chair: <i>Andrew Amato-Gauci (ECDC)</i> Presentations from Working Groups Discussion		
15:30 – 16:00	Closing remarks <i>Richard Zaleskis (WHO Regional Office for Europe)</i> <i>Davide Manissero (ECDC)</i>		

Topic	Expected Outcome	Responsible for organization	Responsible for content
Monday, 25 June 2009			
Report on epidemiological situation 2007	Last data on the epidemiological situation of TB in Europe are presented	ECDC	ECDC, WHO
National surveillance system overview	Participants are informed on the national surveillance setup and epidemiological situation of TB in specific countries and their challenges regarding data submission to Joint TB information System	ECDC, WHO	Countries
Future perspectives for molecular surveillance of MDR-TB in EU	Participants are informed on the developments of project on molecular surveillance in EU	ECDC	ECDC
ECDC/WHO joint TB information system	Developments and lessons learned of TB surveillance in the WHO European Region will be presented	ECDC, WHO	ECDC, WHO
Tuesday, 26 May 2009			
Key Speaker: <i>Philippe Glaziou</i>	Importance of Surveillance in TB Control.	WHO	WHO
Working groups: EU Case Definitions, TOM Future perspectives for MDR-TB Surveillance & Challenges and lessons learned from 2008.	Participants are asked to discuss: <ol style="list-style-type: none"> 1. on problems on implementing new EU case definition and TOM reporting; 2. on problems and advantages of EU case definition in the light of data comparability at the Global level and compatibility of national one with EU's and those recommended by WHO; and to specify TOM cohort categories and definitions to change; 3. problems in TB data collection and possible changes in operational procedures for the next TB data collection period; 4. defined by the Network executive framework of DRS integration into joint TB surveillance framework for the future changes 	ECDC, WHO	ECDC, WHO
Working groups presentation of results	Results of working group discussions are presented. Proposals from working groups.	ECDC, WHO	Working groups

Annex 2: Background document for the Working Groups

Introduction

The annual meeting is a unique opportunity to exchange ideas, views and comments on the main aspects of TB surveillance. In order to facilitate the discussion and to give everyone the possibility to express their views, participants have been assigned to 3 smaller groups to discuss the topics shown in Box 1 below. Russian language translation will be available for groups 1 and 3. The aims of the working groups, main questions for discussion and background documents are described herein.

Aims of the working group sessions

Group 1: Discussion on implementation of EU case definition– future developments and complementarities with WHO definitions. Discussion on TOM cohorts.

Group 2: Introduction and discussion on the future perspectives of drug resistance surveillance and the molecular surveillance of MDR-TB cases.

Group 3: TB report: to discuss and make a proposals on the data collection as well as content of the next TB Surveillance report.

Box 1:

The working group session will take place May 25th –11:00-13.00 in the following groups

Group1- Discussion on the implementation of the EU TB case definitions TOM cohort conditions and categories

Group2- Discussion on the future perspectives for molecular surveillance of MDR-TB

Group3- Discussion on the challenges and problems in TB data collection + lessons learned from 2008

Before the annual meeting - preparatory work

To guide the discussion and to facilitate the preparation of the participants, each group has been provided with some background information on the topic to be discussed and some suggested questions for discussion.

At the annual meeting - structure of the working group sessions

Each group will have a facilitator and a rapporteur. An assigned expert will provide a short introduction to focus the discussion. The facilitator will guide the discussion on the suggested questions and other proposals of the group. At the end of the discussion the group will provide some recommendations. The rapporteur will prepare a short (5 slides) power point presentation summarizing the main discussion points. The last slide should include the recommendations of the group. Each group will have 15 minutes to present its outcome at the final session the 26th May (see agenda).

After the annual meeting

A report with main outcomes is foreseen to be produced after the annual meeting. The rapporteurs are asked to prepare a 2 pages summary of the main outcomes in his/her working group.

Discussion on the EU TB case definitions TOM cohort conditions and categories

*Group 1: Facilitator: Davide Manissero, ECDC; Rapporteur: Name Surname, Country
Working language: English*

Aims of the working group session

To discuss the recommendations from Advisory Committee (held on 26.11.2008 Stockholm), namely:

- Discuss implementation of the definitions: EU Case definitions, Treatment Outcome categories.
- Outcome12Month, vs. Outcome24Month: how could this be better explained?
- Note on the TESSy dataset: keep it the same at least till year 2010.

Context and background

Definitions		
	ECDC	WHO/Europe
TB Case Definition		
	EU Case Definitions:5	WHO Case definition:6
	Confirmed – Probable – Possible	Definite – Other than definite
	Possible: clinical criteria only Probable: [ss+ or NA+ or hist+] and clin crit Confirmed: [cult+ or [NA+ and ss+]] and clin crit	Definite: cult+ or [ss+ where cult not available].
Advantages:	Harmonized with other CDs collected by TESSy, No differences in coding between countries.	Used long time, adopted by data collection systems of MSs worldwide.
Disadvantages:	Different interpretation by countries. Not implemented to electronic data collection and analyses systems – contradictions between laboratory result and corresponding EU case definition e.g.: ResultCulture = P but LaboratoryResult = Probable.	Different interpretation by countries. Defining criteria differs by countries (etc. culture vs smear). Low comparability of definite cases between countries.

5 2008/426/EC: Commission Decision of 28 April 2008

⁶ The WHO report 2009, Global TB control, p174

	ECDC	WHO/Europe
Site of disease		
	Site Classification vs. Major/Minor Site	Extrapulmonary sites are not differentiated
	Possible to analyse severe forms: TB Meningitis, disseminated TB.	No possibility to analyse severe forms of TB like Tb meningitis and disseminated form.
	Pulmonary TB: A patient with TB of the larynx, lung parenchyma or the tracheo-bronchial tree	Pulmonary TB: A patient with tuberculosis disease involving the lung parenchyma.
Outcome categories		
Cohort categories	Percentages should be calculated from registered cases not – included to cohort – suggestion was followed already in 2007 report	
	Still on Treatment Outcome _{24months} is valid only for outcome _{12months} =Still on Treatment. Outcome _{36months} is valid only for outcome _{24months} =Still on Treatment. Allows TOM in case based data collection for M(X)DR-TB cases.	- not appropriate for the Treatment Outcome category - WHO treatment outcome definitions are provided in the Global TB report (p.174) and the Handbook (p43)

Clinical Criteria

Any person with the following *two*:

- 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

Laboratory Criteria

Laboratory criteria for case confirmation

At least one of the following *two*:

- Isolation of Mycobacterium tuberculosis complex (excluding Mycobacterium bovis-BCG) from a clinical specimen

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

Laboratory criteria for a probable case

At least one of the following *three*:

- Microscopy for acid-fast bacilli or equivalent fluorescent staining bacilli on light microscopy
- Detection of *M. tuberculosis* complex nucleic acid in a clinical specimen
- Histological appearance of granulomata

Suggested questions to the group

- Is there complementarity between EU case definition and WHO case definitions (all information available in order to make descriptive analyses under different definitions)?
- How to avoid confusion (ClinicalCriteria) and double-reporting (Classification, ClinicalCriteria, LaboratoryResult) in case-based data collection to TESSy?
- Would it be reasonable to include in aggregated data collection (CISID) the breakdown by site of disease in order to enable further analyses of extrapulmonary TB (TB meningitis, disseminated TB etc.)?
- Function and use of the “Still on treatment” category is still debatable. Would it be appropriate to focus discussion on possible alternatives for monitoring outcomes (particularly at 12 months) for cases that require treatment longer than 12 months (i.e. MDR-TB cases)? The issue of reporting and treatment categorization for chronic cases should also be discussed.

References

1. Commission decision of 28/04/2008 “amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council”, page 70
2. TESSy Metadataset 7 (2009-01-07)
3. ECDC/WHO: Tuberculosis Surveillance report in Europe, 2007, Stockholm, ECDC, 2009 page 131-133
4. WHO Report 2009: Global tuberculosis control: epidemiology, strategy, financing. Geneva: WHO. WHO/HTM/TB/2009.411., page 174
5. Implementing the WHO Stop TB strategy: a handbook for national TB control programmes, WHO/HTM/TB/2008.401, page 17-18 and 43

Discussion on the future perspectives for molecular surveillance of MDR-TB

Group 1: Facilitator: Csaba Ködmön, ECDC; Rapporteur: Name Surname, Country
Working language: English

Aims of the working group session

To discuss the relevance and added value of the molecular surveillance of MDR-TB and the DRS for 2nd line anti-TB drugs at European level and to provide suggestions for the priority improvements in this aspect of TB surveillance at European level.

Context and background

The RIVM in the early 1990s established a network to work on molecular typing of *Mycobacterium tuberculosis*, funded by the EU. This resulted in progress in the standardization of typing techniques, the establishment of database for the analysis of DNA fingerprints and the surveillance of multi-drug resistant tuberculosis in Europe.

The “Molecular Surveillance of Multidrug Resistant Tuberculosis in Europe” (MDR-TB project) activities were funded through the European Commission and coordinated by the Institut de Veille Sanitaire and the RIVM. In the project period of 2003-2007 nearly half of the 562 MDR-TB cases subjected to DNA fingerprint analysis were found in clusters, indicating presumable transmission. Moreover, an overrepresentation of Beijing genotype strains in transmission of MDR-TB was uncovered.

According to its mandate, the European Centre for Diseases Prevention and Control (ECDC) is currently establishing an integrated European surveillance system for the European Union for the surveillance of the diseases outlined in Decision 2000/96/EC, including the epidemiological and the microbiological data. The integration of molecular typing data with epidemiological data at international level is one of the main goals of the overall ECDC strategy for collaboration with laboratories. Therefore the ECDC has contracted the RIVM to take up these activities in a new project.

The objectives of this new ECDC MDR-TB Project are:

- To improve the comparability of the data to provide a clearer view on the (inter) national transmission of MDR/XDR-TB in Europe.
- To expand the implementation of molecular surveillance and molecular typing methods used for typing of *Mycobacterium tuberculosis* isolates.
- To introduce a standardized typing method with sufficient discrimination and reproducibility that facilitates efficient exchange of results, like the VNTR typing
- Capacity building on typing methods and quality assurance.

The high level quality laboratory surveillance of drug resistance is essential for molecular surveillance of MDR-TB. After the transition of the TB surveillance activities to ECDC and WHO Regional Office for Europe the data collection system still remains too complicated. The DRS data were collected in aggregated format by Drug Resistance Surveillance Questionnaire and case-based data by TESSy. The laboratory program management information was collected only by a separate DRS Questionnaire. To reduce this additional workload for the countries, the collection of DRS data has changed. Instead of the separate DRS Questionnaire, the laboratory program management and aggregated DRS data will be collected through CISID; while the individual case-base data by TESSy. The data on 2nd line anti-TB drugs are included in TESSy since 2008 and those will be included into the aggregated dataset from this year. Currently only those 2nd line anti-TB drugs are included into data collection, which are necessary for detection of XDR-TB strains.

The first results of the analysis of MDR-TB surveillance and molecular typing data will be published in the next Annual Report on TB Surveillance in Europe in 2010.

Suggested questions to the group

- Is there a need to include other 2nd line drugs into routine DR surveillance?
- What are the most interesting topics regarding MDR-TB surveillance that should be published in the Annual Surveillance Report on TB in Europe? What kind of tables, graphs and/or maps would be the most appropriate?
- Could the strain numbers serve as unique identifiers for connecting the molecular typing data with epidemiological data to avoid double reporting (or how could this be done)?

Discussion on the challenges and problems in TB data collection + lessons learned from 2008

Group 3: Facilitator: Vahur Hollo, ECDC; Rapporteur: Name, Surname, Country
Working language: Russian and English

Aims of the working group session

To discuss the TB data collection and reporting processes

Context and background

The general **rational** for maintaining the joint surveillance between ECDC and WHO are:

- to maintain the geographic coverage of the system for 53 WHO Member States;
- to maintain completeness of the data collection reflecting all TB control programme indicators recommended by WHO;
- to provide corresponding members with a user-friendly and sustainable tool for data reporting;
- to use a common case definition, ensuring data comparability.

In the past a number of recommendations were made that may still be valid:

- **From EuroTB Advisory Committee Meeting** (26th of November 2007 in Stockholm):
 - To keep changes in Annual Report minimal for this the 2009 report.
 - On the upcoming Annual Meeting data collection dates and deadline for data analysis should be clearly communicated to Member States and followed.
 - The reference date for data analysis “Date used for Statistics” should match either date of notification or date of diagnosis by each country.

An ad-hoc working group should be constituted between WHO/Europe and ECDC with the contribution of external experts to discuss difference between definitions. Discussion results of the working group should be presented on Annual Meeting
- **From the TB Surveillance Annual Meeting** (3rd and 4th June 2008 in Hague):
 - To keep changes in Annual Report minimal for the 2009 report.
 - Size, format, content: unchanged; additional content on the basis of new information that is collected (for future – WG2)
 - Frequency of publication: Annually, in mid-March, before World TB day.

Content: Narrative, text presents an overview of TB epidemiological situation, main achievements on TB control in the Region. Also included:

- a short summary of TB control/eradication;
- more detailed chapter about the regional burden of TB; monitoring of targets and strategies for TB control; and implementing the Stop TB Strategy in the Region

- Tables: Compiled from the most appropriate tables for the Region; content taken from the EuroTB annual report and the global TB report tables.
- Country profiles should be based on WHO country profiles template; profiles should include additional figures on challenges to TB control specific to the European region.
- Country profiles should list the population size to improve user-friendliness.

Addendum: Content will reflect specific topics and will change every year, according to the Region's needs, such as MDR, HIV, prison, migration or other challenges on TB control in the Region. The topics for the specific addendum will be proposed by Member States during annual meetings.

- E-mail addresses of contact persons at the beginning of the report. Alternatively: web site's e-mail addresses updated regularly.

▪ **From the EuroTB Evaluation and Assessment Report (1st June 2007):**

- The future annual TB report should contain less routine data but put a special focus on a specific topic each year (e.g. TB/HIV, risk groups).
- The yearly report could be shorter and consist of tables on the 10 most important variables and a theme to be reported on in more detail.
- Surveillance of treatment completion for MDR-TB requires a longer time period than 12 months.
- Further standardisation of TB surveillance is needed as some countries are not able to submit data on some variables (e.g. treatment outcome and drug susceptibility testing).
- In order to perform TB Surveillance, ECDC would need sufficient staffing related to contacts with participating countries and epidemiological analysis (including plausibility checks on submitted data) and reporting.

Achievements

- TB Data collection of data notified on 2007, but finished by December 2008.
- Data analysis agreement between ECDC and WHO/Europe concluded in September 2008: "TB data management and production of the joint ECDC and WHO/Europe report on TB surveillance in the European Region, 2007".

Main areas of the agreement:

1. The purpose of the Report is to provide MS and stakeholders with most comprehensive and qualitative data about TB burden in the Region for

evaluation of the outcomes and assessing the impact of the actions on TB epidemic

2. The ECDC/WHO merged analytical database will be a product of individual and aggregated data collected by the TB surveillance network in the European Region via TESSy, and aggregated data collected via CISID.
 3. For the data analysis a data file will be extracted from the joint database. This data file is not going to be changed during the analysis. This data file reflects the status of the merged analytical database at the exact time.
- Annual TB Surveillance Report was published on World TB Day.

Critical review of report production timeframe:

Legend of colours: Green – deadline met, Orange – Deadline not met – few days delay or little problems in data analyzes, Red – delay of weeks (months) and big burden on workload.

01 July – 30 September 2008	Data collection Preparation of template of the “joint” database to be used for the production of the report Data validation/data cleaning
01 September 2008	Sending of reminders to non-responding countries
30 September 2008	End of the data collection Sending of reminders to non-responding countries
01 – 20 October 2008	Final data validation/data cleaning
Until 29 October 2008	Data exchange between TESSy and CISID
30 October 2008	Final data synchronization
01 – 30 November 2008	Data analysis
01 December 2008 – 12 January 2009	Writing of the Annual Report
13 January 2009	Sending the draft Annual Report for comments to Member States
26 January 2009	Deadline for comments on draft of Annual Report
27 January – 09 February 2009	Analysis of comments and finalization of the Annual Report
10 February 2009	Submission of Annual Report to Health Communication Unit
24 March 2009	Launching of the Annual Report

Challenges

- Complications on data submission and usage of EuroTB converter to TESSy despite two trainings to data submitters – huge workload on TESSy Helpdesk.
- Burden related to amount of variables currently collected and different data sources.
- Confusions on reporting EU case definitions compared to lab result data – turned out to be the biggest area for discrepancies.
- Deadline for data submission – too early? - by the end of the announced deadline – 30th of September – 19(63%) countries submitted 2007 notification data, 12(57%) Treatment Outcome for 2006 and 14(48%) – DRS questionnaire.
- Complicated procedure to access both modules of the Joint Tb information system: joint website, TESSy, CISID. Not an unique login/password
- Low response rate to the programme management sections in CISID
- Duplication of DRS questionnaire and CISID content
- Complicated, and time consuming data validation procedure

Suggested discussion points to the group

- Do we agree with all the recommendations that were made on this joint process – are they valid for the 2008 data report?
- Do we agree that to ensure the quality of the report, the deadlines for data submission and then analysis should be stated and strictly respected by all? (Some countries that ignore this may be left out of the report.)
- Does the TB case based dataset include too many variables? If yes, please propose the ways to prioritize variables by importance and suggest variables that may be deleted.

Annex 3: Participants

Country representatives

Country	Surname	First name
Albania	MEMA	Donika
Armenia	MEZHLIUMYAN	Narine
Azerbaijan	JAFAROV	Fuzuli
Austria	KLEIN	Jean-Paul
Belarus	ASTROVKO	Andrei
Belgium	FAUVILLE	Maryse
Belgium	WANLIN	Maryse
Bulgaria	BATCHIISKA	Elizabeth
Bulgaria	MILANOV	Vladimir
Croatia	SIMUNOVIC	Alexander
Czech Republic	HAVELKOVA	Marita
Czech Republic	WALLENFELS	Jiri
Denmark	ANDERSEN	Peter
Denmark	ØSTERGAARD THOMSEN	Vibeke
Estonia	KUMMIK	Tiina
Estonia	VIIKLEPP	Piret
Finland	SOINI	Hanna
France	ROBERT	Jerome
Georgia	MIRTSKHULAVA	Veriko
Germany	BRODHUN	Bonita
Germany	RÛSH-GERDES	Sabine
Greece	LYTRAS	Thodoris
Greece	SPALA	Georgia
Hungary	PASZTOR	Monika
Hungary	SZABO	Nora
Ireland	FITZGIBBON	Margaret
Israel	CHEMTOB	Daniel
Italy	CIRILLO	Daniela Maria

Country	Surname	First name
Italy	D'AMATO	Stefania
Italy	FATTORINI	Lanfranco
Kazakhstan	TURSYNBAEVA	Aigul
Kyrgyzstan	ABDURAKHMANOVA	Elmira
Latvia	RIEKSTINA	Vija
Lithuania	DAVIDAVICIENE	Edita
Lithuania	SOSNOVSKAJA	Anaida
Malta	BARBARA	Christopher
Malta	SPITERI	Gianfranco
Netherlands	ERKENS	Corinne
Netherlands	HERREWEGH	Arnold
Norway	MANNSAKER	Turid
Norway	RØNNING	Karin
Poland	AUGUSTYNOWICZ- KOPEC	Ewa
Poland	ZWOLSKA	Zofia
Portugal	FONCESCA- ANTUNES	Antonio
Republic of Moldova	BARBUTA	Raisa
Republic of Moldova	CIOBANU	Ana
Republic of Moldova	CRUDU	Valeriu
Republic of Moldova	DOLTU	Sveltana
Republic of Moldova	PLESCA	Valeriu
Romania	CHIOTAN	Domnica Ioana
Russian Federation	SKACHKOVA	Elena I.
Russian Federation	SON	Irina
Serbia	CURCIC	Radmila
Slovakia	SOLOVIC	Ivan
Slovakia	SVECOVA	Jana
Slovenia	SVETINA-SORLI	Petra

Country	Surname	First name
Slovenia	ZOLNIR-DOVC	Manca
Spain	JIMENEZ PAJARES	Maria Soledad
Spain	RODRIGUEZ VALIN	Elena
Sweden	HOFFNER	Sven
Sweden	JONSSON	Jerker
Switzerland	HELBLING	Peter
The former Yugoslav Republic of Macedonia	ZAKOSKA	Maya
Turkey	OZKAN	Suha
United Kingdom	ABUBAKAR	Ibrahim
United Kingdom	DROBNIIEWSKI	Francis
Ukraine	PAVLENKO	Olena
Uzbekistan	UZAKOVA	Gulnoz

Ministry of Health and Social Welfare, Croatia (Host country)

Surname	First name
ZABICA	Sibila Adviser for European Integration

World Health Organization

Regional Office for Europe

Surname	First name
ABDUSALYAMOVA	Malika
BELILOVSKIY	Evgeny
DADU	Andrei
DANILOVA	Irina
MERCER	David
STORGAARD	Marina Viktorivna
ZALESKIS	Risards

Headquarters

Surname	First name
BIERRENBACH	Ana
GLAZIOU	Philippe

European Centre for Disease Prevention and Control

Surname	First name
AMATO	Andrew
CARLSSON	Charin
HERRERA-VIKLUND	Teresita
HOLLO	Vahur
JUNG	Heidi
KÖDMÖN	Csaba
MANISSERO	Davide

Interpreters

Surname	First name
ALEKSINSKAYA	Olga
PIGNASTYY	Georgy G.

**World Health Organization
Regional Office for Europe**

Scherfigsvej 8, DK-2100 Copenhagen Ø, Denmark

Tel.: +45 39 17 17 17. Fax: +45 39 17 18 18. E-mail: postmaster@euro.who.int
Web site: www.euro.who.int