Meeting of the Joint ECDC and WHO Tuberculosis Surveillance Network

The Hague, Netherlands
29–30 May 2017

ABSTRACT

The 2017 annual meeting of the European TB Surveillance Network was organized jointly by the WHO Regional Office for Europe and the European Centre for Disease Prevention and Control in The Hague, the Netherlands, on 28–29 May 2017. Discussions focused on: the status of the TB epidemic in the Region, progress towards TB elimination and the reporting format for following up the implementation of the TB Action Plan for the WHO European Region 2016–2020; the recent international outbreaks of MDR-TB and countries' experience with molecular typing in TB surveillance and management; standards and benchmarks for the surveillance system assessments in 15 countries of the Region and plans to strengthen them so as to qualify and quantify the impact on the TB epidemic in countries; and definitions of the social determinants and risk factors for TB as well as standards on TB surveillance.

Keywords

TUBERCULOSIS – epidemiology
TRANSIENTS AND MIGRANTS
EPIDEMIOLOGICAL MONITORING
POPULATION SURVEILLANCE

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Abbreviations

DST	drug susceptibility testing
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EU	European Union
LTBI	latent TB infection
MDR-TB	multidrug-resistant tuberculosis
MIRU/VNTR	mycobacterial interspersed repetitive units using a variable number of tandem repeats
TB	tuberculosis
TESSy	the European surveillance system
USAID	United States Agency for International Development
WGS	whole genome sequencing
XDR-TB	extensively drug-resistant tuberculosis

Introduction

The WHO Regional Office for Europe and the European Centre for Disease Prevention and Control (ECDC) jointly coordinate tuberculosis (TB) surveillance in the WHO European Region. To strengthen TB surveillance in the Region, the Regional Office and the ECDC organized a Meeting of the Joint Tuberculosis Surveillance Network in The Hague, Netherlands, on 29–30 May 2017.

The objectives of the Meeting were to:

- provide an overview of the TB epidemiological situation in the Region, including European Union/European Economic Area (EU/EEA) countries;
- discuss TB surveillance in the Region, with particular emphasis on migration and TB and molecular typing for surveillance;
- discuss data reporting and monitoring of the Tuberculosis action plan for the WHO European Region 2016–2020 *(1)* and an analysis of its implementation to be published in the ECDC and Regional Office joint TB surveillance and monitoring report in 2018;
- update the Network on the Regional Office and ECDC's operations including, but not limited to, the Tuberculosis Disease Network Coordination Committee for EU/EEA countries, the social determinants and risk factors for TB, surveillance in the EU/EEA countries, and TB impact analysis and surveillance system assessments in selected countries in the Region.

The expected outcomes of the Meeting were that participants would be updated on the:

- status of the TB epidemic in the Region and progress towards TB elimination;
- recent international outbreaks of multidrug-resistant (MDR) TB for a better understanding of the role of molecular typing in TB surveillance and management;
- reporting format for the implementation of the TB Action Plan 2016–2020 through the European TB surveillance and monitoring report 2018;
- outcomes of the TB impact analysis and assessment of the standards and benchmarks of surveillance systems in selected countries of the Region.

Dr Masoud Dara welcomed the participants on behalf of WHO. He expressed the hope that the joint WHO/ECDC Meeting would allow all participants to have a close look at the data and create an environment for a discussion on how things cud be improved. On behalf of ECDC, Dr Marieke van der Werf welcomed participants and gave an overview of the programme. (The programme is at Annex 1 and list of participants at Annex 2.)

Overview of TB epidemiology in the WHO European Region

TB in the WHO European Region and EU/EEA countries in 2015

The presentation began with an introductory quiz, aiming to elicit basic information about the burden and epidemiology of TB in the Region. This was followed by an overall update on the

TB burden in the Region, including specific details for EU/EEA countries on topics such as drug-resistant (DR) TB, TB/HIV coinfection and treatment outcome monitoring.

The updated TB data for the Region were published in the 2017 Tuberculosis Surveillance and Monitoring in Europe report *(2)*. In 2015, an estimated 323 000 new TB cases and relapses (incident cases) occurred in countries in the Region, equivalent to 35.5 cases per 100 000 population and representing about 3.0% of the total global burden of TB. About 85% of incident TB cases in 2015 occurred in the 18 high-priority countries.

TB incidence in the Region has risen sharply from 1990 onwards, reaching a peak in 1999 before declining again from 2000. From 2006 to 2015, the average decline was 5.4% per year, although from 2011 to 2015 this decline slowed to 4.3% per year and, in 2015, it slowed again to 3.3% compared to 2014. While this is the fastest decline of all the WHO regions, there is a need for an even faster decrease in TB incidence if the Region is to meet the targets of the End TB Strategy by 2035.

In 2015, there were an estimated 32 000 TB deaths[1] in the Region, equivalent to 3.5 deaths per 100 000 population. There was considerable variation across the Region, ranging from fewer than one TB death per 100 000 in western European countries to more than 10 per 100 000 in the18 high-priority countries. At regional level, the TB mortality rate fell by 50% from 7.0 to 3.5 deaths per 100 000 population between 2006 and 2015, which on average is a decline of 7.4% per year. Between 2011 and 2015, this decline quickened to 8.5% per year, but slowed in 2015 to 6.2% compared to 2014. Nevertheless, the decline is notably higher than the global rate of decline for TB mortality (2.7%).

In 2015, notified TB cases in 30 EU/EEA countries amounted to 60 195. The TB notification rates continued the declining trend seen in previous years. The highest notification rate was in the group aged 25–44 years (14.4 per 100 000).

One in five MDR-TB cases globally were estimated to have occurred in the Region in 2015. The alarmingly high rates of MDR-TB in most of the eastern European and central Asian countries represented one of the main challenges in TB control in the Region. Nine out of 30 countries with the highest MDR-TB burden in the world are in the Region. In 2015, an estimated 16% of new cases and 48% of previously treated cases had MDR-TB, accounting for an estimated 74 000 cases of MDR-TB. Belarus had the highest proportion of MDR-TB among newly detected TB cases, whereas Tajikistan had the highest percentage among previously treated TB cases.

In the Region as a whole, the case detection rate of MDR-TB cases is 60%, which shows an increase from 2011 when only about 30% of the cases were notified. The proportion of MDR in new cases is still increasing. The proportion of extensively drug-resistant (XDR) TB is also increasing and has reached 23.4% among MDR-TB cases detected with second-line drug susceptibility testing (DST).

In 2015, there were an estimated 27 000 cases of TB/HIV coinfection, equivalent to an 8.4% HIV coinfection rate among 320 000 incident TB cases. HIV testing coverage among TB patients appears to be high (>88%), although only 16 500 (61%) cases have been detected.

[1] TB mortality estimates exclude deaths among HIV-positive people.

Unfortunately, only 37% of TB patients detected with HIV coinfection were enrolled in antiretroviral treatment. Moreover, treatment success is extremely low (41%). TB/HIV coinfected patients face a seven times higher risk of treatment failure and are at a three times higher risk of dying.

The situation of TB/HIV coinfection in EU/EEA countries is underreported, with only a slight improvement compared to 2014. In 2015, less than 4.6% of all TB cases with known HIV status in these countries were HIV-positive. The proportion of TB cases in persons of foreign origin is increasing, although the notification rates of TB cases of foreign origin among the total population are stable.

With regard to treatment outcomes, data show improved treatment success in all TB patient groups in 2015, except for those who are HIV-positive. No increase was observed in treatment success in the EU/EEA countries compared to 2014, and the rate of treatment success in MDR-TB and XDR-TB was lower than in 2014. The good news is that only 140 cases of XDR-TB were diagnosed in these countries.

Overall, the major achievements from 2011 to 2015 have been the reduction in incidence, the improved notification rate, the existence of full-scale programmes and universal treatment enrolment for drug-sensitive and drug-resistant TB. Greater attention needs to be given to strengthening collaboration in TB and HIV care, with the exchange of good practices and new models of care, as well as to scaling up model diagnostic tools and treatment options.

Ethics of public health surveillance

The presentation included background information, information on ethics and public health surveillance guidelines, followed specifically by ethics and TB guidelines and ethical issues in TB surveillance.

Surveillance represents the eyes of public health. Issues of privacy and confidentiality are, however, challenging. Data security represents a significant issue in the process of data collection, and the right balance needs to be kept between individual data privacy and the public interest. So far no comprehensive international frameworks address these concerns, although there are several guidelines (produced by WHO, the World Medical Association and the United States Centers for Disease Prevention and Control (CDC)) that aim to guide ministries of health, public health agencies and similar entities.

WHO began the process of developing guidelines in May 2014, aided by 28 members of WHO's guidelines development group, representing fields such as ethics, human rights, philosophy, epidemiology and public health. Following several meetings and redrafts of the document, the guidelines were due to be launched by WHO on 23 June 2017.

Public health surveillance is a key instrument to reach universal health coverage goals and the United Nations sustainable development goals. In this context, countries have an obligation to develop comprehensive, sustainable and feasible public health surveillance systems. The global community also has an obligation to support countries which do not have such systems. Where TB is concerned, surveillance is key to reaching greater equity. Given that TB is generally a disease of the poor, people living in poverty suffer greater harm. Public health surveillance systems can discover their conditions and direct resources to those who need them most.

Informed consent is not the default position in public health surveillance but is only required in specific circumstances. In this process, the protection and engagement of marginalized and vulnerable populations are essential because (among other reasons), as well as the benefit from documenting a disease, there might be risks of stigmatization and discrimination. Projects should identify any risks of harm in the planning phase and mitigate them.

Another relevant area is the communication of results and data-sharing. Sometimes researchers wait to get their publications accepted before sharing data. This might be problematic in certain situations, for example in episodes of pandemic influenza and diseases such as Ebola. Journals need to find new mechanisms to publish a paper even when raw data have been shared.

Discussion

The definition of personal identifiers, which are especially needed in TB, is sensitive. The main concern with regard to personal identifiers is whether they need to be kept in the reporting system up to the highest level (national, regional, international). Situations where names of patients are provided, including on websites, need to be avoided at all cost.

As regards the outcome of chemotherapy when names are needed in order to know treatment outcomes in specific cohorts, the issue is one of confidentiality and making data public. A sophisticated electronic system is necessary to ensure that only people who really need to know the information have access to it. There is no problem with names being on record in the ministry of health as long as there are adequate safeguards. Confidentiality must be observed when data (such as treatment regimens and risk factors) are transferred from one facility to another.

The duplication of data for correct surveillance at national level must be avoided. Guidelines are generic for all diseases, and every country and disease programme needs to adjust them to their specific situations. Principles need to be implemented in the spirit as well as the letter to ensure privacy and confidentiality.

At the European level a coherent approach is needed, for example, for cross-border issues. Systems could not function without the same sets of data.

Outbreak investigation and TB surveillance among migrants

The role of molecular typing in TB outbreak management (Finland)

TB data from Finland show a decrease in incidence, with increasing numbers of TB patients being found among young foreign-born population groups. The biggest age group of foreign origin is now represented by young adults, and delays in diagnosis occur more often. The average age of TB patients in 2016 was 50 years. In that year, six MDR-TB cases were detected.

Molecular typing represents the characterization of *M. tuberculosis* isolates by molecular methods. It is used to study transmission routes/outbreak investigation, rule out cross-

contamination of specimens, discriminate between TB relapse and reinfection and study the molecular epidemiology of TB. Internationally harmonized methods are used. International standard 6110 concerning restriction fragment length polymorphism is a labour-intensive method with inadequate resolution, especially for low-copy-number isolates. The current method, mycobacterial interspersed repetitive units (MIRU) using a variable number of tandem repeats (VNTR), has a fairly good resolution and yields data that are easy to compare. Spoligotyping[2] is used to increase resolution.

Whole genome sequencing (WGS) can identify single nucleotide polymorphisms, insertions and deletions. The species name, genotype and mutations conferring drug resistance can be obtained from sequencing data. The drawbacks of WGS are that expensive instruments and tools for analysis are needed, which makes the method not suitable for every country. In addition, some parts of the TB genome are difficult to read and the methods are not harmonized.

In Finland, genotyping has been done since 2001 and WGS has been used since 2013. The method has been validated and the results are promising. Identified clusters have been confirmed with WGS. In the cases of two outbreaks (in Turku and Oulu), WGS was used and proved that all isolates belonged to the same cluster.

As regards outbreak investigation, TB contact-tracing is done in each municipality (n=300) or hospital district (n=20).

Genotyping is an important tool for TB outbreak investigation and good collaboration is needed between laboratories, epidemiologists, clinicians and contact investigators. Even though WGS will probably replace the genotyping methods currently in use in the near future, better ways of sharing data with other countries are needed. The ECDC could play a role in this harmonization process.

Outbreak of MDR-TB in migrants (Switzerland)

Switzerland has seen an increase in the number of MDR-TB cases. On the other hand, there are very few XDR-TB cases (currently, just four XDR-TB cases among the 65 MDR-TB cases). The increase in cases in recent years is mainly explained by the increase in case numbers among asylum-seekers and refugees, who amounted to a third of the case load in 2015.

There are three major regions of origin for MDR-TB cases occurring in Switzerland: China (mostly from Tibet), the Horn of Africa (mostly from Somalia) and countries of the former USSR. These were also the main groups in the years before 2012. People from Somalia and Eritrea are increasingly being tested for TB and MDR-TB. Every case is interviewed with 10 questions typical for TB.

With regard to clustered MDR-TB cases, there were four cases of transmission among immigrants in close contact between 2006 and 2012 and two transmissions within families between 2013 and 2015. In August 2016, the National Reference Laboratory informed the Federal Office of Public Health about a cluster of six cases of MDR-TB identified by MIRU-

[2] A simple, economical and efficient means of identifying slowly growing microorganisms through the use of the polymerase chain reaction to identify pathogens, such as *M. tuberculosis*, in laboratory specimens.

VNTR. The Laboratory decided to perform WGS on every MDR-TB isolate. In November 2016 the Federal Office decided to conduct an outbreak investigation.

In 2016, there were 16 cases of MDR-TB overall. Eight had an identical genome with maximum one single nucleotide polymorphism difference. Most were of Somali ethnicity, in young males who had arrived at a similar time that year and been diagnosed within a few months. Many had displayed symptoms in Somalia and/or while they were travelling. According to the preliminary conclusions, the origin of the cluster probably lies in Somalia, with probable transition along the migration route. No more cases have been seen in Europe since October 2016, but at least some more cases are to be expected.

XDR-TB multinational outbreak 2015/2016 (Romania)

In 2015/2016, a cluster of three cases of XDR-TB were detected in foreign students at a university in Romania. Contact investigations increased the total number of cases in this outbreak to seven, with the same WGS profile: four at the university and three in other close contacts. Two more cases were epidemiologically linked but there was no laboratory confirmation.

According to surveillance data, notifications of XDR-TB are increasing slightly while those of MDR-TB are approximately constant. None of the cases in this outbreak were of Romanian origin, which was the first indication that the probability of finding a Romanian source was low. Further information from WGS results sustained this hypothesis, as the profiles of the Romanian strains were different to that of the outbreak. Despite considerable efforts, the source of the outbreak has not yet been found.

Discussion

The potential role of WGS in the EU/EEA is described in the ECDC roadmap on implementation of WGS in routine surveillance *(3)*. The ECDC has started a project that aims to standardize the use of WGS for MDR-TB strains in EU/EEA countries. WHO has published a consensus statement on the minimum package for cross-border TB control and care in the WHO European Region *(4)*.

In view of the fact that the Somalis found with TB in Switzerland had all spent time in Italy first, the ECDC would work on the processes for cross-border cluster investigation with Member States in the Region in future.

The investigation of the MDR-TB cluster among migrants and the XDR-TB cluster linked to a university in Romania were carried out completely differently (one was coordinated by a laboratory, the other through surveillance), which contains a lesson for the future.

As regards the standardization of analyses of WGS results produced by different laboratories, comparisons can be made when these are sent to the same person, ideally in the same place with the same procedure.

There was a suggestion that in most countries enquiries about epidemiological contacts should be made instead of WGS.

Screening of migrants – recent change of guidelines (Norway)

In Norway, there is a high proportion of TB cases of foreign origin (90% of the cases). In 2015, the number of cases among people born in Somalia began to fall. The incidence rate for 2007–2016 was six per 100 000 population per year.

Screening is compulsory, although not enforced, for people from high-endemic countries, all asylum-seekers and refugees, persons who will work with children or patients and those who have been exposed. WHO and ECDC guidance recommends screening for TB/latent TB infection (LTBI) in groups at increased risk, with a focus on migrants as a vulnerable group.

The screening algorithms for LTBI were changed due to problems with the previous model – interferon gamma release assay (IGRA)-positive with no follow-up, logistics (sending test results), capacity for IGRA analysis and ethical issues. In this context, the new algorithm would reach those with the highest risk of TB and provide the best results of preventive treatment in the simplest, most responsible way. The main changes were in specifying categories for using the IGRA test: only those who will be considered for preventive TB treatment, and in the category: Recent arrival from country with “very high incidence of TB” should be screened for LTBI/TB.

The problems remaining after the change are the continued involvement of many actors, difficulties in exchanging information with each other, low coverage by screening in some groups, lack of a unique identifier, no screening registry and no national TB plan.

Policies on surveillance and monitoring of response to provision of TB care among migrants (Russian Federation)

In 2015, more than 17 million foreign citizens entered the Russian Federation, of whom more than 7 million (46.1%) were included in the migration record. The majority came from Ukraine, followed by Uzbekistan and Tajikistan. There were fewer children than young adults; from the age of 25 years, there was a prevalence of males.

Until 2007, the percentage of TB among migrants was not high. In 2008 and 2009 there was an increase associated with a greater interest in the Russian Federation as a result of the economic crisis. The male to female ratio in new TB cases in immigrants was higher than in other TB cases.

Citizens of foreign countries are tested for TB, which is mandatory if they want to get permanent residence or a work permit. Emergency TB care is provided for them when TB is diagnosed. Planned assistance is provided when they give a written guarantee to pay for medical services or prepay for medical services. Compulsory medical insurance does not cover the costs of TB treatment.

Normative documents are being developed to regulate activities for the prevention and treatment of TB among people who are not citizens of the Russian Federation, and an interdepartmental system is being established to record and monitor the screening of citizens of foreign countries.

From the perspective of cross-border collaboration, the interaction between the health services of countries in the Commonwealth of Independent States needs to be strengthened.

Discussion

In Norway, directly observed prevention therapy is given for children, but for longer regimens it is done individually, sometimes via video or Skype.

As regards the cost-effectiveness of screening and whether access to health care is more or less important than screening on arrival in a country, in the Russian Federation screening is only done if a person applies for a residence permit. No study has been made of its cost-effectiveness. Emergency care is provided regardless of cost-effectiveness. In cases of LTBI among children, they receive chemoprophylaxis but not under direct supervision (other than in certain regions).

In Norway, cost-effectiveness was assessed for IGRA use in contacts, but such assessments had many limitations. Access to care is free and initial screening serves to provide more information about it. The country has not experienced cases of health tourism because of the free access to care.

Guidelines should not only be available but implemented in relevant action. National action plans are important, since any undetected migrant might transmit the diseases to families and other people. The ECDC is developing a guidance document on screening of new migrants for infectious diseases to be published by the end of 2017.

Feedback from countries to the surveillance network

Report on the outputs from the technical working group on social determinants and risk factors for TB

Following the 2014 survey conducted by the Wolfheze Working Group on Social Determinants of TB and Drug Resistant TB, and the 2015 follow-up study conducted by the ECDC and WHO, the results of the 2015 study were discussed in a meeting of the TB Surveillance Network in 2016. This had resulted in the establishment of a working group on social determinants and risk factors for TB.

The working group has reviewed the results of the 2014 survey and developed a proposal to include a list of variables on social determinants and risk factors that can be used at national level to propose the minimum information on social determinants/risk factors to be collected at European level.

The social determinants/risk factors for TB which had been discussed in the working group, and for which the data sources for the variable, definition and categories were given to the Meeting, included:

- education
- imprisonment
- employment status
- homelessness
- year (date) entry to the country
- contact with TB case

- use of alcohol
- use of illicit drugs
- diabetes mellitus.

Participants were asked to state in a short questionnaire whether they agreed with the definitions and to provide comments. The results of the questionnaire would be taken into account in finalizing the report of the ECDC's technical working group on harmonization of definitions for social determinants and risk factors for TB. Since data are collected from colleagues in the field, the definitions needed to be kept simple.

Discussion

People who do not work but categorize themselves as housewife/househusband are put in the category *Other*. People who have been working but are suddenly unemployed following illness need to be labelled either *Other* or *Seeking work*.

The EU definition has been used for TB patients found during screening on entry into prison. In this case, it is argued that prison is not a factor, but a finding factor. These people do not expose others to infection since they are in the prison hospital from the first day.

In the Russian Federation, since there are several types of prison and several categories of penitentiary facility, with medical units working as filters, there was a question as to whether persons who had spent time in detention should be considered prisoners. When people with TB are released, the medical record states that the TB was detected in prison. If TB is detected in a prison, the person is a prisoner and the manner in which this is interpreted is decided at a national level.

Further comments included that: (i) only close contacts should be included in the indicator "In contact with TB case"; and (ii) the CDC has a different definition for "Use of alcohol". The discussion that followed concluded that consensus was difficult to find.

The list of illicit drugs varies from country to country and there are situations when a person can receive drugs that are medically prescribed.

As regards contacts, for TB patients *Close contacts* can be used, but all categories must be put in an LTBI register which should be different from a TB register.

Epidemiological impact analysis and assessment of standards and benchmarks in the TB surveillance system

Among the areas of work of the WHO Global Task Force on TB Impact Measurement, epidemiological reviews look at ways to strengthen the surveillance system. These reviews are funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria and the United States Agency for International Development (USAID), together with domestic funding in some countries. They focus on 30 high-burden countries, providing an investment plan for TB control which feeds into national strategic plans (with updates every five years).

Epidemiological reviews have four objectives:

- to describe and assess current national TB surveillance and vital registration systems;
- to assess the level of, and trends in, the TB disease burden (incidence, prevalence, mortality);
- to assess whether recent trends in the indicators for the TB disease burden are plausibly related to changes in TB-specific interventions;
- to define the investments needed and associated targets aiming at strengthening surveillance and directly measuring trends in the TB disease burden.

To assess a surveillance system, a total of 13 standards and benchmarks are used. The checklist is implemented in several ways, through desk review, discussion with TB surveillance teams (for example, system and data flow), examination of laboratory and TB registers at subnational level, and quarterly reports on and data analysis of key indicators for internal and external consistency.

The benchmarks are as follows.

B1.1 Case definitions are consistent with WHO guidelines
B1.2 TB surveillance system is designed to capture a minimum set of variables for reported TB cases
B1.3 All scheduled periodic data submissions have been received and processed at the national level
B1.4 Complete and accurate data (for paper-based systems) are available
B1.5 (Electronic) data in national database are accurate, complete, internally consistent and free of duplicates
B1.6 TB surveillance data are externally consistent
B1.7 There is internal consistency
B1.8 All diagnosed cases of TB are reported
B1.9 The population has good access to health care
B2.1 Surveillance data provide a direct measure of drug-resistant TB in new cases
B2.2 Surveillance data provide a direct measure of the prevalence of HIV infection in TB cases
B2.3 Surveillance data for children reported with TB (defined as aged 0–14 years) are reliable and accurate and all diagnosed childhood TB cases are reported.

Consultants doing the epidemiological reviews took part in a workshop in Crete, Greece, in May 2016. Twelve consultants were trained. The roster now consists of 45 epidemiologists worldwide, although there is still a gap in Africa.

Some countries have data in multiple Excel sheets. WHO has built a standard module containing graphs, tables and a map of key indicators which has been used in three data analysis regional workshops. An assessment of standards and benchmarks carried out during regional workshops has highlighted the differences between the West Africa Regional Network and Asia (such as problems in reporting and recording and poor diagnosis of children in Africa, and poor HIV testing coverage in Asia).

Molecular typing for TB surveillance: results of a survey in 26 European countries

Molecular typing of *M. tuberculosis* complex is widely used to strengthen TB surveillance. In 2016, the ECDC carried out a survey in 26 European countries which aimed to: provide an overview of the current application of molecular typing; map current capacities for WGS; explore the capability of EU/EEA member states to use molecular typing for investigation of cross-border TB transmission; and understand the added value of molecular typing in TB surveillance.

An online questionnaire comprising 26 items was distributed to the national focal points for TB in EU/EEA countries in September 2016. Data were collected up to November 2016. The data analysis is in the final stage of clearance for submission.

The results showed that 20 countries use molecular typing and nine use WGS for surveillance. Many actors are involved in doing the typing, including national and regional reference laboratories and peripheral laboratories. The estimated median timespan between obtaining a positive culture of *M. tuberculosis* and reception of the typing results by TB surveillance units was 30 days for both 24 MIRU-VNTR (interquartile range 14–60) and WGS (interquartile range 14–40).

Data are usually analysed by the typing laboratory or (sometimes) by the surveillance unit, or jointly, in order to identify molecular clusters. Among the EU/EEA countries using molecular typing for TB surveillance, 16/20 (89%) integrated typing data into the TB notification database on a case-based level.

Nine countries have integrated WGS-based typing into their TB surveillance systems. Two of the most frequently mentioned barriers perceived for WGS-based typing data for TB surveillance were human resources and financial constraints.

The different integration levels and reluctance to share patient data were the most frequently mentioned barriers to cross-border cluster investigation.

The added value cannot, however, be contested. Among the many advantages seen are the detection of clusters across regions, the capacity to rule out transmission events and the detection of unknown transmission links.

Working groups

The Meeting divided into three working groups to discuss:

- epidemiological impact analysis and assessment of the TB surveillance system: a core element of assessing programme performances and impact on the TB epidemic using surveillance standards and benchmarks (epidemiological review);
- monitoring framework for following up the TB action plan for the WHO European Region 2016–2020 and the indicators to be analysed in the TB surveillance and monitoring report, 2018;
- integrated molecular typing for TB surveillance in the EU/EEA as a transition to WGS.

Working group 1. Epidemiological impact analysis and assessment of the TB surveillance system

Background

A major goal of TB surveillance is to provide an accurate measure of the number of new TB cases and related deaths that occur each year, and to be able to assess these trends over time. In some countries, TB surveillance already meets the standards necessary to do this, but in others there are important gaps in the TB surveillance system that make this impossible. In 2014, the WHO Global Task Force on TB Impact Measurement developed standards and benchmarks for TB surveillance and vital registration systems to assess countries' ability to measure TB cases and deaths accurately as well as to identify the gaps that must be addressed in order to improve TB surveillance. Since then, 15 Member States in the Region have conducted joint epidemiological reviews based on a checklist guide and standard terms of reference.

Objectives

The objectives of the working group were to: share countries' experience in carrying out epidemiological reviews; update the steps taken by countries to implement the recommendations made; and update participants on how epidemiological reviews identify the strengths and opportunities of the TB surveillance system and direct measures to strengthen it; and recommend a revision of the estimates of countries' TB burden.

Use of epidemiological impact analysis to assess programme performance and revise country estimates

The four main methods of estimating the burden of TB, which are periodically reviewed by the WHO Task Force, are capture-recapture modelling, expert opinion, prevalence survey and standard adjustment.

- Capture-recapture modelling works in smaller populations. In capture-recapture modelling in Iraq in 2011, 50% of doctors were sampled and asked to report cases on a special form. Cases were grouped by notification by private doctors or private hospitals. Underreporting was estimated at 16%: there were an additional 473 cases apart from the 988 cases diagnosed in three months.
- Prevalence surveys provide an estimate of the prevalent number of people, which is not the same as incidence. Incidence can, however, be derived by using simple modelling. Estimates come with added uncertainty so this is not a precise way of getting to incidence.
- Standard adjustment is used in high-income countries and involves estimating the undocumented level of underreporting.
- Eliciting expert opinion is the method used when nothing else is available. Predictors of TB are looked at. Data reveal that in the total absence of TB control measures, the burden of TB falls at a rate of 3–4% a year, showing that there are other determinants of TB. The rate of developing disease is higher in groups at risk such as people with HIV or diabetes and undernourished and/or older people. The problems with expert opinion are linked to its reproducibility and validity, the limited number of experts, biased opinion, and overdiagnoses from systematic active case-finding programmes that are difficult to quantify (for example, in the countries of the former USSR).

In summary, the best data sources are: (i) TB notifications when the data meet the quality criteria (epidemiological review) and underreporting is low and documented (inventory studies); and (ii) TB mortality from vital registration with standard coding (International Classification of Diseases, 10th revision) of causes of death.

Synthesis of outcomes of the TB epidemiological reviews in the Region

Epidemiological reviews have been carried out in Kazakhstan in 2012, Tajikistan in 2013 (both before standards and benchmarks), Armenia, Belarus, Georgia, Kyrgyzstan, Turkmenistan and Uzbekistan in 2014, Ukraine in 2015, and Bosnia & Herzegovina and the Russian Federation in 2017. The main problems identified were related to consistency of data and coverage.

Main findings of the epidemiological review in Ukraine and follow-up action

In Ukraine various methods were used to validate data. Information from the review was produced in English and Russian and shared nationally and regionally. There is a high level of TB/HIV coinfection. In the past, the two illnesses were tackled by two separate services. Now they are dealt with by a joint centre, which allows the correct measurement of HIV infection in TB.

The data collection and reporting flows are compliant with WHO recommendations. Information comes from various agencies. An eHealth system is being developed. Ukraine has, however, only been able to meet four benchmarks. Taking into account the whole set of data, it is expected that the TB situation will stabilize in the near future.

Main findings of the epidemiological review in the Russian Federation and follow-up action

The final outcomes of the epidemiological review in the Russian Federation are under discussion, with agreement reached on some of them. In recent years, there has been a decrease in TB notifications and an even greater decrease in the number of clinically diagnosed cases.

The incidence of TB increases from west to east, and the incidence of bacteriologically confirmed cases is also increasing. The greatest reduction has been observed in young adults (but not children, in whom there is a smaller reduction). In terms of treatment outcomes, mortality has increased because of other causes, including HIV. The treatment success rate is explained by preventive activities.

The recommendations are to: accelerate the implementation of case-based and web-based reporting after evaluation of piloted areas; discontinue all paper-based recording; and plan for survey-based measurement of catastrophic costs due to TB.

Main findings of the epidemiological review in the Republic of Moldova and follow-up action

Among the strengths of the surveillance system in the Republic of Moldova are the availability of an electronic database at all levels, effective data quality assurance mechanisms and universal access to culture, DST and HIV testing. The weaknesses include the lack of external consistency and limited validity of surveillance data for childhood TB.

The recommendations are that: the Ministry of Health and the national TB programme, in collaboration with WHO and international partners, should identify and address factors contributing to the underdiagnosis of paediatric TB cases; the Ministry of Health should continue

giving priority to TB surveillance and ensure that TB surveillance mechanisms are institutionalized in the national TB programme and receive adequate support and full-scale implementation; and WHO should revise the estimates of TB incidence.

Working group 2. Monitoring framework for following-up the TB action plan for the WHO European Region, 2016–2020

Background

In 2016, the Regional Office, working in close consultation with country representatives, experts and communities, developed the *Roadmap to implement the tuberculosis action plan for the WHO European Region 2016–2020 (5)*. This roadmap is based on lessons learnt from the implementation of the WHO Regional Committee for Europe resolution EUR/R61/R7 of 2011 on a Consolidated Action Plan to Prevent and Combat Multidrug- and Extensively Drug-Resistant TB in the Who European Region 2011–2015. It is applicable to all Member States in the Region, including high-priority countries and those with a low incidence of TB.

At the request of the EU, the ECDC launched *The Framework Action Plan to Fight Tuberculosis in the European Union* in 2008 *(6)*. A follow-up report was published in 2010 which included a monitoring framework *(7)*. In 2014 and 2016, two monitoring evaluations were conducted and the results published in joint ECDC/WHO reports on tuberculosis surveillance and monitoring in Europe *(8,9)*. The evaluations showed that some of indicators were no longer relevant for the monitoring of TB prevention and control activities in the EU. The ECDC decided, therefore, to join the WHO regional action plan and to use the indicators contained in the roadmap.

The objective of the working group was to discuss the monitoring framework of the Tuberculosis action plan for the WHO European Region 2016–2020, and to assess how it can be applied to monitoring TB prevention and control in the EU/EEA. The specific aims were to: introduce the indicators in the roadmap to EU/EEA countries; discuss the availability of data in the countries; and discuss the action needed to improve data collection by the joint ECDC/WHO surveillance system (including the WHO Global TB database and the European surveillance system (TESSy)), particularly in relation to new data.

The indicators to monitor the roadmap are divided into three groups.

1. Indicators for which data are available in TESSy and for which there is no need for changes in data collection.

    1B2 First-line DST coverage among all bacteriologically confirmed TB patients (G7)
    1B3 MDR-TB case detection rate (not core indicator)
    1B4 TB notification rate per 100 000 population (E1)
    1B5 TB case detection rate (not core indicator)
    1B6 Percentage of MDR-TB among new TB patients (E2)
    1B7 Percentage of MDR-TB among previously treated TB patients (not core indicator)
    1C2 Percentage of detected MDR-TB enrolled in treatment (G3) (E4)
    1C3 TB treatment success rate (G4)
    1C4 MDR-TB treatment success rate (G4) (E4)
    1D1 Proportion of detected TB/HIV cases out of estimated incident TB/HIV cases (not core indicator).

2. Indicators that could potentially be included in TESSy.

   1B1 Percentage of newly notified TB patients diagnosed using WHO-recommended rapid tests (G4)
   Summary. Information on WHO-recommended rapid tests is not collected in TESSy. Information on nucleic acid amplification test is collected for EU/EEA countries. This can serve as a proxy for the WHO-recommended rapid test.
   Suggestion. No need for change. Use data on nucleic acid amplification test as proxy.

   1C1 Percentage of hospitalization of new TB patients (E3)
   Summary. Data are available for some countries (Bulgaria, Estonia, Romania).
   Suggestion. Continue collection of information on hospitalization of new TB patients in aggregated format via assessment by the WHO headquarters Tuberculosis Monitoring and Evaluation team.

   1D4 Percentage of TB/HIV patients enrolled in antiretroviral treatment
   Summary. Data are not available in France, Portugal, Slovakia.
   Suggestion. Consider starting the collection of data in TESSy.

   2C1 Treatment coverage with new TB drugs
   Summary. Data are available in Estonia and Romania. Denominator is missing.
   Suggestion. No need to start collecting data via TESSy.

   2E1 Treatment success rate (%) of new and relapsed TB cases among prisoners
   Summary. Important indicator. Data are available in most countries.
   Suggestion. Information on imprisonment could be collected in TESSy as a new variable.

3. Indicators that would need specific data collection.

   1A1 Coverage of population at risk with systematic screening for active TB and LTBI
   Summary. Important indicator. Problem with data availability, often estimations are used, or a specific survey can be an option. Need for standardization.
   Suggestion. The topics of populations at risk and coverage by systematic screening are to be discussed at the next surveillance/prevention and control meeting.

   1C5 TB mortality rate (International Classification of Diseases, 10th revision, A15–19) (G10) (E6)
   Summary. Data submission from the vital statistics is usually delayed by more than one year in Eurostat.
   Suggestion. No need for changes in TESSy.

   1D5 LTBI treatment coverage among people living with HIV (G5a)
   Summary. Data reporting completeness in the Joint United Nations Programme on HIV/AIDS database is low.
   Suggestion. No need for changes in TESSy.

   1E2 LTBI treatment coverage of childhood TB contacts aged under five years
   Summary. Numerator is available. Denominator is hard to assess – the eligibility of treatment is problematic.
   Suggestion. No need for changes in TESSy.

The following indicators for activities related to areas of intervention 2, bold policies and supportive systems, in the roadmap were not discussed due to time constraints.

2A1 Number of Member States that have a regular TB control/elimination performance publication every five years (E8)
2B1 Percentage of TB patients and their households that experience catastrophic financial consequences due to TB (G8) (E9)
2D1 Number of Member States with functioning multistakeholder coalitions advocating for TB care and resources
3A1 European Tuberculosis Research Initiative established by mid-2016.

Working group 3. Integrated molecular typing for TB surveillance in the EU/EEA as a transition to WGS

Background

Quantifying ongoing TB transmission is a key step in monitoring progress in TB control. There are two general complementary approaches to trace TB transmission: (i) the investigation of epidemiological links between patients and their contacts; and (ii) molecular typing, including WGS, of the *M. tuberculosis* complex genome in order to assess the degree of relatedness of pathogens isolated from different patients.

WGS looks at the entire mycobacterial genomic material. It is considered a powerful tool in TB epidemiology because of its higher discriminatory power compared to existing genotyping methods, including multilocus MIRU-VNTR. Compared to molecular genotyping, WGS may help to identify more accurately missed transmission events, previously undetected source cases and the direction of transmission. Moreover, WGS can identify false clustering and rule out false transmission events. WGS also permits identification of genes and mutations that mediate drug resistance.

A survey conducted in 2016 on molecular typing for TB surveillance in the EU/EEA showed that 20 of the 26 participating EU/EEA member states use molecular typing for TB surveillance, including nine already applying WGS and an additional 10 considering doing the same for TB surveillance in the future. The survey stressed the need for standardization of WGS typing data as well as the development of procedures to facilitate international collaboration.

The working group discussed the following questions.

- What outputs could be generated by WGS-based surveillance of TB at European level which would be relevant to the EU/EEA member states?
- Would WGS-based integrated molecular surveillance at the European level be ideally:
  - for drug resistance surveillance, or for identification of the relationship between cases in an outbreak, or both;
  - designed for observational purposes or for intervention (such as in early outbreak detection and response);
  - of a prospective or retrospective nature;
  - comprehensive (all forms of TB) or focused on specific cases, for example MDR-TB?
- How could ECDC and national TB contact points potentially use the outputs generated by such WGS-based integrated molecular surveillance?

- If there is no exact answer to these questions: what action would be needed to take decisions thereon?

The discussion specified some issues that should be solved before WGS is started at international level.

- What do the data mean?
- What is the additional public health benefit?
- Disparities in nomenclature; standardization is needed.
- Data storage (how much, where and for how long should data be stored?).
- Data-sharing (what data should be shared and at what level?).
- Promptness: data should ideally reflect the real-time situation.

Working groups 2 and 3 then joined forces for the following three presentations.

Reporting back from working group 3

The following questions were left open:

- the strengthening of surveillance aspects by the introduction of real-time surveillance, especially for drug resistance surveillance;
- which data should be reported to the EU level and how different systems should be integrated;
- the need for clarification of cost and cost-effectiveness in comparison to current systems;
- how the results of genomics will influence public health activities;
- data storage needs for the large datasets and future proofing (raw).

The next steps are to:

- standardize procedures and instruments (and to cope with changing platforms) and reporting;
- share experiences from countries and bring together laboratory professionals and clinicians through, for example, a meeting organized by the ECDC to: (i) discuss the proposed evaluation of implementation in individual countries; and (ii) make cross-country comparisons of experiences and added value to TB control;
- define time and frequency of outputs.

In summary, WGS can be a powerful tool for designing TB programme interventions such as early outbreak detection and response. A number of details should, however, be agreed before transition begins towards it.

Data reporting, optimizing TESSy TB variables list, analysing principles for ECDC/joint reports

The plans for optimizing the TESSy TB variables list since the 2018 data collection included several proposed additions and deletions.

The following are the proposed deletions.

- Most of the participants (17) voted to delete “Classification” and “LaboratoryResult”, since the same information could be derived from other variables.
- Participants unanimously agreed to delete “SIR_CIP” (susceptibility testing for ciprofloxacin).
- Participants unanimously agreed to delete “RflpCode” due to the transition of molecular typing surveillance to MIRU-VNTR and spoligotyping methods.
- Participants suggested that “Outcome36Months” (the outcomes for MDR-TB and XDR-TB aligned by WHO on a 24-months analysis) should be kept and the publication of the outcome after 36 months should continue for XDR-TB cases.

The following are the proposed additions.

- A majority of the participants agreed to add “SIR_PZA”, DST for pyrazinamide since new methods to determine drug susceptibility for pyrazinamide have become available.
- A majority (17) of the participants agreed to add “DateOfEntryToCountry” since the date (year) of entry to the country would enable recent migrants (a vulnerable group for TB) to be distinguished from long-term residents.
- A majority (11) of the participants agreed to add code “MCAPRAE” to the “Pathogen” code list to allow for the analysis of zoonotic TB caused by *M. caprae*.

Reporting back by the ECDC TB Disease Network Coordination Committee

Discussions in the Tuberculosis Disease Programme Coordination Committee yielded the suggestions that: (i) data collected in TESSy should include the date of entry in the country, the DST results for pyrazinamide and the presence of *M. caprae*; and (ii) DST for ciprofloxacin should be excluded and all duplicating variables collected removed.

The current activities of the laboratory network, focusing on diagnostics, characterization of strains and molecular epidemiology in EU/EEA countries, should continue. The Committee also advised the ECDC to work on improving communications between the laboratory and surveillance networks and clinicians.

Reporting back from working group 1 and discussion

The conclusions from working group 1 were presented. Priorities remained to be defined for the second half of 2017 and 2018 through an inventory study to explore undernotification. Priority will be given to Azerbaijan, Belarus, Georgia and the Republic of Moldova for this purpose.

The benchmark relating to detection of childhood TB was one of the weakest in most countries.

The electronic registry is being well implemented in Azerbaijan and Kyrgyzstan. As yet only a limited amount of data is being collected, but it is planned to expand data collection across the countries with the help of primary care physicians. For Ukraine the priorities are: estimation of the burden at subnational level, the use of subnational data, a comprehensive plan for monitoring and evaluation and a survey of costs to patients.

Estimates for the burden of TB in Azerbaijan and the Republic of Moldova need to be revised; this would be done by WHO headquarters in July. Countries which did not submit data to the Global TB Report have been encouraged to do so.

Epidemiological reviews are applicable and usable tools in every country in the world. They function as a form of business case for TB surveillance, pulling together all other data in a systematic way, making a story and identifying key priorities. It makes sense for EU/EEA countries to carry out epidemiological reviews.

The key themes in working group 1 were routine analysis of national and subnational data and the need to promote cross-border TB prevention and control (through regional and national workshops). Several countries are interested in updating their epidemiological reviews more often than every five years.

Reporting back from working group 2 and discussion

The following indicators could potentially be included in TESSy.

- 1B1 Percentage of newly notified TB patients diagnosed using WHO-recommended rapid tests. No need for change, use current data as proxy.
- 1C1 Percentage of hospitalization of new TB patients. Continue collection of information on hospitalization of new TB patients in aggregated format via assessment by the WHO headquarters Tuberculosis Monitoring and Evaluation team.
- 1D4 Percentage of TB/HIV patients enrolled in antiretroviral treatment. Consider starting the collection of these data in TESSy.
- 2C1 Treatment coverage with new TB drugs. No need to start collecting via TESSy.
- 2E1 Treatment success rate (%) of new and relapsed TB cases among prisoners. Start of imprisonment could be collected via TESSy as a new variable.

The time allocated only allowed discussion of the following four indicators in detail.

- 1A1 Coverage of population at risk with systematic screening for active TB and LTBI. This should be discussed at the next surveillance meeting as it is a very important indicator. A specific survey could be an option.
- 1C5 TB mortality rate. Keep using vital registry data. No need for changes in TESSy.
- 1D5 LTBI treatment coverage among people living with HIV. No need for changes in TESSy.
- 1E2 LTBI treatment coverage of childhood TB contacts aged under five years. No need for changes in TESSy.

There was no time to discuss the remaining four indicators (2A1, 2B1, 2D1, 3A1).

The working group agreed to add antiretroviral treatment at a case-based level, at national level and the ECDC, and to add the variable *Prisoner* to case-based data collection in TESSy.

Closing session

Dr van der Werf summarized the follow-up action for the ECDC.

- The ECDC will implement a pilot project on WGS, starting in 2017.
- The ECDC is working on improving cross-border outbreak investigation procedures following the two outbreaks (MDR-TB and XDR-TB).
- Infectious diseases in migrants is a hot topic and will remain so.
- The inclusion of date of entry in the TESSy database will allow people who migrated recently to be differentiated from those who migrated a long time ago to the EU.
- A guidance document on screening migrants for infectious diseases will published by the ECDC. Guidelines for TB control in vulnerable populations are on the ECDC website *(9)*.
- The ECDC working group on social determinants will continue its work.
- Monitoring of the indicators in the WHO roadmap will be reported on for the first time (data are currently being collected) in a joint ECDC/WHO report to be published in 2018.

It is important that good data are provided for action. TESSy allows assessments to be made of the data needed/not needed for action. It now has 1.5 million cases and its data can be used by everybody. People interested in data (such as universities or PhD students) should approach Dr Vahur Hollo, TB surveillance focal point in the ECDC.

Dr van der Werf thanked the ECDC and WHO teams and the participants in the Meeting for their commitment to improve surveillance at ECDC and national levels.

Stressing again the importance of having a strong surveillance system in place, Dr Dara said that data collection should be used to make decisions and design policy interventions. It was important that the ECDC and WHO should align their work (as is currently the case) so as to avoid duplication. One issue is treatment success of MDR-TB. Unfortunately, the EU countries are not doing better than non-EU countries: not all patients eligible to get new medicines are getting them.

Dr Dara closed the Meeting by thanking WHO headquarters, the WHO team members, the ECDC and other staff involved in making the event possible. A summary of the discussions would be sent to the participants.

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Annex 1

PROGRAMME

Monday 29 May

14:00–14:10	Welcome and introductory remarks	*Masoud Dara (WHO)* *Marieke van der Werf (ECDC)*
Session 1.	**Overview of TB epidemiology in the WHO European Region**	*Aliona Serbulenko (Republic of Moldova)*
14:10–14:40	TB in the WHO European Region and EU/EEA countries in 2015	*Andrei Dadu (WHO) and Vahur Hollo (ECDC)*
14:40–15:10	Ethics of public health surveillance	*Andreas Reis (WHO)*
15:10–15:20	Discussions	
Session 2.	**Outbreak investigation and TB surveillance among migrants**	*Walter Haas (Germany)*
15:50–16:05	The role of molecular typing in TB outbreak management	*Hanna Soini (Finland)*
16:05–16:20	MDR-TB in outbreaks in migrants	*Ekkehardt Altpeter (Switzerland)*
16:20–16:35	XDR-TB multinational outbreak in Romania 2015/2016	*Domnica Chiotan (Romania)*
16:35–16:50	Screening of migrants – recent change of guidelines in Norway	*Trude Margrete Arnesen (Norway)*
16:50–17:15	Policies on surveillance and response monitoring on TB care provision among migrants in Russian Federation	*Serghey Sterlikov (Russian Federation)*
17:15–17:35	Discussions	
17:35–17:45	Closure of the day	*Aliona Serbulenko* *Walter Haas*

Tuesday, 30 May 2017

Session 3.	**Countries' feedback to the surveillance network**	*Yana Tarleeva (Ukraine)*
09:00–09:20	Report on the outputs from the Technical Working Group on Social Determinants and Risk Factors for TB	*Ivan Solovic (Slovakia)*
09:20–09:30	Discussions	
09:30–09:50	Epidemiological impact analysis and assessment of standards and benchmarks of TB surveillance system (second revision of standards and benchmarks)	*Laura Anderson (WHO)*
09:50–10:05	Synthesis of outcomes of the TB epidemiological reviews in the WHO European Region	*Arax Hovanesean (Armenia)*
10:05–10:20	Results of survey: molecular typing for TB surveillance in the EU/EEA	*Lena Fiebig (Germany)*
10:20–10:30	Introduction to working groups	*Vahur Hollo*

Session 4. Working groups

11:00–12:45	Working group 1	Working group 2	Working group 3
	Epidemiological impact analysis and assessment of TB surveillance system as a core element of analysing programme performances and impact on TB epidemic using surveillance standards and benchmarks (epireview).	Monitoring framework for follow-up of the TB action plan for the WHO European Region, 2016–2020. The indicators to be analysed in the TB surveillance and monitoring report, 2018.	Integrated molecular typing for TB surveillance in the EU/EEA on the way to transition to WGS.
	Facilitators: *Masoud Dara and Bhavna Patel (USAID)*	Facilitators: *Vahur Hollo Annemarie Stengaard (WHO)*	Facilitator: *Lena Fiebig*
13:45–15:30	Working group 1 (continued)	Working groups 2 and 3	
		Reporting back from working group 3 *Colin Campbell (United Kingdom)*	
		Data reporting, optimizing TESSy TB variables list and analysing principles for ECDC/joint reports (EU TB definition variables, DST, HIV status, historical data update in TESSy and WHO Global TB database). *Vahur Hollo*	
		Reporting back by the ECDC TB Disease Network Coordination Committee *Raquel Duarte (Portugal)*	
16:00–16:20	Reporting back from working group 1 and discussion		*Natavan Alikhanova (WHO)*
16:20–16:40	Reporting back from working group 2 and discussion		*Dace Mihalovska (Latvia)*
16:40–17:00	Conclusions and closing remarks		*Marieke van der Werf* *Masoud Dara*

Annex 2

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