

Tuberculosis Key Messages



European Diagnostic Manufacturers Association

In Vitro Diagnostics

Making a real difference in health & life quality

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Situation

- ***TB remains a serious public health problem*** and is highly prevalent in many urban areas. In 2004, 8.9 million new TB cases with active disease were estimated globally.
- There are worldwide still 1.6 million deaths a year and ***TB remains the world's second most cause of death from an infectious agent***, after HIV. The HIV epidemic has a huge impact driving up incidence rates dramatically. Compared with an individual who is not infected with HIV, a person infected with HIV has a 10 times increased risk of developing TB.
- No ***radiographic pattern*** is diagnostic of tuberculosis. ***Smear microscopy*** requires a large number of bacilli to be present in the sample in order for the result to be positive, and identifies only the most infectious subset of patients. It has a limited sensitivity (35 to 70%). It even is less sensitive in HIV co-infected patients, ***stressing the need for more sensitive diagnostic tests***.
- ***New challenges are posed also by multi-drug resistant tuberculosis (MDR-TB)***, and now ***extensively drug resistant TB (XDR-TB)*** which are virtually untreatable. The annual number of new cases of MDR-TB was about 423,000 in 2004. In the last 12 months, 16 new countries including Czech Republic, Germany, France, Ireland, Latvia, Lithuania, Norway, Portugal, Romania, Spain, Sweden, The Netherlands, UK, and now recently also in Italy have been reporting XDR cases in Europe (WHO Stop TB Department).
- ***Importation of TB*** including drug-resistant and multi drug resistant (MDR) cases from Eastern European and other countries is a serious concern. Of the almost 100.000 reported TB cases in Europe in 2005, 35% came from the new EU members Bulgaria and Romania. Recently the CDC described a case of an airline passenger with XDR-TB who might have infected other passengers and crew members on 2 trans-Atlantic flights.
- ***About 10% of people who have latent TB infection (with no clinical symptoms) will develop disease at some point***. Progression to active disease is enhanced by a weakened immune status caused e.g. by malnutrition, stress, certain viral infections, diabetes mellitus, alcoholism, treatment with cortisone or radiation, drug abuse. ***Prevention of transmission of infection*** in institutional settings such as jails, prisons, hospitals, nursing homes, shelters for the homeless and new immigrants by diagnostic services and isolation of suspects is important.
- Data from the US and Canada have estimated the direct and indirect cost of a TB infection at between \$ 700 million and \$ 1 billion 2). Transferring cost data from Germany to ***the scale of the entire EU, associated costs would be in the magnitude of more than € 1 billion per year***. Thus a disease which has vanished from the awareness of many in Europe as a matter of fact still has a severe impact not only on public health, but also on economy.



Suggestions

- The expansion of the EU and the looming threat of MDR and XDR-TB make the **re-examination of TB-infection control** an important matter and **allocation of sufficient resources** of high importance for many Public Health experts.
- **Interferon gamma assays** as a replacement for Tuberculosis Skin Tests will help to detect TB infection, which causes TB disease, and open up new opportunities to Public Health officials in the fight against TB.
- **It is of tremendous value, both clinically and economically, to have access to rapid tests for TB detection and drug susceptibility testing**, including NAT tests.

Not only does earlier detection lead to improved patient care for individuals suspected of having the disease, but there is also abundant data which shows that rapid diagnosis leads to overall savings within the hospital.

- There are also growing numbers of MDR cases in Western Europe in certain risk groups such as recent immigrants from high TB-burden countries, and many countries have seen the first cases of XDR-TB.

The rapid determination of drug resistance via culture of *Mycobacterium tuberculosis* in clinical isolates is a prerequisite for the initiation of effective chemotherapy ensuring successful treatment of the patient and preventing further spread of drug-resistant isolates.

This paper has been prepared by the **EDMA Value of IVDs Task Force**.

EDMA, the European Diagnostic Manufacturers Association is the voice of the In Vitro diagnostic industry active in Europe. EDMA membership brings together National Associations and the major companies, representing in total more than **500 companies (or over 700 legal entities)** engaged in **the research, development, manufacture or distribution of IVD products**. EDMA cooperates with other European and international trade associations as well as with scientific societies and patients organisations, to **make a real difference in health and life quality**.

