



DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT A ECONOMIC AND SCIENTIFIC POLICY



Childhood Vaccination and Immunication

Economic and Monetary Affairs

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WORKSHOP

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DIRECTORATE GENERAL FOR INTERNAL POLICIES POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

WORKSHOP

Childhood Vaccination and Immunisation

Brussels, 19 June 2013

PROCEEDINGS

Abstract

This report summarises the presentations and discussions at the Workshop on "Childhood Vaccination and Immunisation", held at the European Parliament in Brussels, on Wednesday 19 June 2013. The aim of the workshop was to provide a forum for discussion on vaccine-preventable diseases (in particular measles and tuberculosis) that still pose significant threats to public health in Europe.

The workshop was hosted by MEP Ms Glenis WILLMOTT (S&D, UK) and MEP Mr Alojz PETERLE (EPP, SL), Co-chairs of the Health Working Group within the ENVI Committee.

This document was requested by the European Parliament's Committee on Environment, Public Health and Food Safety.

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LIST OF ABBREVIATIONS

BCG Bacillus Calmette-Guérin (vaccine) **EC** European Commission **ECDC** European Centre for Disease Prevention and Control **EMA** European Medicines Agency **ENVI** Committee on Environment, Public Health and Food Safety **EP** European Parliament **ESPID** European Society for Paediatric Infectious Diseases **EU** European Union **GP** General Practitioner **HIV** Human Immunodeficiency Virus **HPV** Human Papilloma Virus M/XDR Multidrug and Extensively Drug Resistant MDG Millenium Development Goal MdM Médecins du Monde MDR Multi-Drug Resistant MEP Member of the European Parliament MMR Measles-Mumps-Rubella (vaccine) **TB** Tubercolosis **TBAG** TB Action Group

WHO World Health Organization

EXECUTIVE SUMMARY

On 19 June 2013, the Committee on Environment, Public Health and Food Safety (ENVI) of the European Parliament held a workshop on "Childhood Vaccination and Immunisation". The workshop was hosted by Ms Glenis WILLMOTT (MEP) and Mr Alojz PETERLE (MEP), Co-chairs of the Health Working Group within the ENVI Committee.

Ms WILLMOTT in her introduction highlighted some vaccination success stories, for example the eradication of smallpox. However, several vaccine-preventable diseases, such as tuberculosis and measles, still remain a concern in the EU. Dr Piotr KRAMARZ (ECDC) then provided a general overview of vaccination and immunisation in Europe. He stressed that vaccination is one of the most cost-effective interventions in medicine. Yet, falling confidence in immunisation programmes has seriously undermined the effectiveness of vaccines. It recently led to outbreaks of measles, a highly contagious and vaccine-preventable disease. In his view, significant discrepancies in vaccination schedules between EU Member States represent a threat for effective immunisation. In addition, communication should be improved to counteract the messages of anti-vaccine groups.

The first part of the workshop focussed on tuberculosis (TB). Dr Masoud DARA (WHO Europe) explained that TB is far from being a disease of the past, as it affects over 500,000 patients in the WHO European Region and causes around 44,000 deaths every year. He also noted that the burden of TB is unequally distributed among countries, with high rates in some EU Member States mainly due to multi-drug resistance. The main challenges, identified in the WHO Consolidated Action Plan to prevent and control TB, include prompt diagnosis of the disease as well as equitable access to effective treatment. Implementing the plan, Dr Dara concluded, would save human lives and, at the same time, reduce the economic costs of the disease.

Ms Amy McCONVILLE then introduced the patients' voice into the debate and told the audience about her personal experience as a TB patient. After a late diagnosis of the disease, she went through prolonged treatment and surgery to have one of her lungs removed. Her story showed the impact of the illness - not only as a physical, but also as an emotional and social burden. Ms McConville concluded her presentation by encouraging the uptake of TB vaccine in affected communities and increasing funding for vaccine research at the EU level. In the following discussion, Dr Radu BOTGROS (EMA) explained that to ensure effectiveness of TB treatment and to prevent multi-drug resistance, the dosing of the anti-tuberculosis medicine in children should be increased as recommended by the WHO and latterly by the EMA.

The second part of the workshop concentrated on the current measles outbreak. Dr Ronald de GROOT (European Society for Paediatric Infectious Diseases) highlighted the fact that failure to maintain high levels of vaccine coverage for measles has resulted in a resurgence of the disease, with recent outbreaks in several EU Member States including France, Italy, Spain and the UK. The large majority of cases occur among people who have not been vaccinated; and the consequences of this highly contagious disease can be very severe. If the vaccine's coverage was greater than 95% of the population, then immunisation against measles would be extremely effective - and could result in the eradication of the disease. Raising awareness and informing the public are therefore crucial.

This was further emphasised by the following speaker, Dr Andreas SCHULTZ (Médecins du Monde, Germany), who outlined the main barriers to measles vaccination. In particular, certain vulnerable groups, such as Roma and migrants, often lack access to immunisation services as a consequence of restrictive public policies or insufficient information. In addition, financial barriers exist in countries that have been hit by the economic crisis, for example in Greece where a large number of families cannot afford vaccines any longer. As access to healthcare is a fundamental right, Dr Schultz recommended that full access to vaccination should be ensured for all, especially for vulnerable groups. In the discussion that followed, Dr Daniel BRASSEUR (EMA) highlighted that the main message for health professionals is to increase coverage of vaccination, which is essential to avoid the spread of the disease.

In the workshop's conclusion, Mr PETERLE stressed the need to adopt an EU-wide approach to vaccination and to engage all relevant stakeholders. Ms WILLMOTT finally mentioned that education and awareness-raising are also crucial in this context.

1. LEGAL AND POLICY BACKGROUND

Immunisation is a proven tool for controlling and eliminating life-threatening infectious diseases and represents one of the most cost-effective health interventions worldwide. Some vaccine-preventable diseases, such as diphtheria, poliomyelitis and hepatitis B have become so rare in Europe that parents often fail to realise the benefits of childhood immunisation. However, some of these diseases still pose significant threats to public health, in particular measles and tuberculosis.

EU countries have recently had to fight large and sporadic outbreaks of measles, a highly infectious disease that remains one of the leading causes of childhood mortality worldwide. Between 2007 and 2010, measles outbreaks were reported in several Member States, including in Austria, Bulgaria, France, Germany, Italy, Poland and the UK. For the first quarter of 2013, measles cases were reported by 26 countries in the World Health Organization (WHO) European Region¹. Suboptimal vaccination coverage and persistent gaps in immunisation are the main causes for recent outbreaks: the vast majority of cases occurred among people who did not get immunised based on philosophical reasons or because they lacked access to immunisation services (e.g. migrants). In the United Kingdom, for example, school-age children emerged as a particularly susceptible group due to a general decline in measles-mumps-rubella (MMR) vaccination in the early 2000s. Outbreaks in several countries have also affected minority groups that are still under-vaccinated². To stop these outbreaks, countries within the WHO European Region have renewed their commitment to eliminate measles by 2015³, as the previous elimination target of 2010 could not been achieved.

Another vaccine-preventable disease that is still posing problems in Europe is tuberculosis (TB). According to a joint report by the European Centre for Disease Prevention and Control (ECDC) and the WHO Regional Office for Europe (WHO Europe), the 2015 Millennium Development Goal (MDG) target of halting the prevalence and death associated with TB and reversing its incidence has been partially achieved in 2011, with TB incidence falling in the European region at a rate of about 5% per year between 2000 and 2011⁴. However, the prevalence and mortality of TB are still high and it will therefore not be possible to achieve the target of 50% reduction in TB cases by 2015. In addition, multidrug-resistant tuberculosis (MDR-TB)⁵ represents an issue of growing concern, with a high burden even in some EU Member States⁶.

World Health Organization (WHO) EpiBrief 2/2013. Available at: http://www.euro.who.int/en/what-we-do/health-topics/communicable-diseases/measles-and-rubella/publications/who-epibrief-and-who-epidata/who-epibrief-22013

² Ibid.

³ WHO Regional Committee for Europe, 16 September 2010. Resolution on renewed commitment to elimination of measles and rubella and prevention of congenital rubella syndrome by 2015. Available at: http://www.euro.who.int/ data/assets/pdf file/0016/122236/RC60 eRes12.pdf

⁴ European Centre for Disease Prevention and Control (ECDC) and WHO Regional Office for Europe (WHO/Europe), Tuberculosis surveillance and monitoring in Europe 2013. Available at: http://www.euro.who.int/en/what-we-do/health-topics/communicable-diseases/tuberculosis/publications/2013/tuberculosis-surveillance-and-monitoring-in-europe-2013.

In MDR-TB, drug resistance arises due to improper use of antibiotics in chemotherapy of drug-susceptible TB patients. This improper use is a result of a number of actions, including administration of improper treatment regimens and failure to ensure that patients complete the whole course of treatment. Source: WHO.

The following EU Member States are among the 18 high-priority countries for MDR-TB in the European region: Bulgaria, Estonia, Latvia, Lithuania and Romania.

In this respect, WHO Europe has launched a Consolidated Action Plan to Prevent and Combat Multidrug- and Extensively Drug-Resistant Tuberculosis (M/XDR-TB)⁷. The purpose of the plan is to help Member States adopt evidence-based interventions to improve TB and M/XDR-TB prevention and control.

Recognising the urgency of addressing tuberculosis, the European Parliament launched a written Declaration on the threat of drug-resistant TB⁸ in April 2013. In particular, the Declaration highlights that the European Region is home to the highest rates of MDR-TB in the world, accounting for nearly 20% of the global burden. It therefore calls on the European Commission and the Council to financially and politically support the WHO Europe's Consolidated Action Plan. If the Declaration receives support from at least the majority of the Members of the European Parliament (MEPs), it could pave the way for stronger legislation on TB and drug-resistant TB in the future.

On the broader issue of vaccination and immunisation, all Member States have a vaccination schedule recommending the vaccines to be given during childhood. However, many children in Europe still remain unvaccinated and thus vulnerable to life-threatening diseases. In June 2011, Member States agreed on the need to strengthen vaccination at the EU level with Council Conclusions on childhood immunisation (2011/C 202/02)⁹. The Council Conclusions acknowledge that – while childhood immunisation remains a responsibility of individual Member States – addressing childhood immunisation at the EU level provides an important added value. In particular, the European Commission was invited to identify commonly agreed guidance and methodologies for improving, monitoring and assessing vaccination coverage, as well as to facilitate the development and implementation of effective communication strategies at the national level.

On this basis, the Commission, in collaboration with the ECDC and the European Medicines Agency (EMA), has taken several initiatives to provide advice on best practice measures during outbreaks, to fund projects¹⁰ on immunisation through the EU Health Programme¹¹ and to provide objective and evidence-based information to health care professionals and to the public. For this purpose, multilingual EU vaccination resources were also developed, such as the ECDC overview of immunisation schedules in Member States¹².

EUR/RC61/15 Consolidated action plan to prevent and combat multidrug- and extensively drug-resistant tuberculosis in the WHO European Region 2011–2015. Available at: <a href="http://www.euro.who.int/en/who-we-are/governance/regional-committee-for-europe/past-sessions/sixty-first-session/documentation/working-documents/wd15-consolidated-action-plan-to-prevent-and-combat-multidrug-and-extensively-drug-resistant-tuberculosis-in-the-who-european-region-20112015.

Written Declaration submitted under Rule 123 of the Rules of Procedure on the threat of drug-resistant tuberculosis to the European region, 15 April 2013. Available at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2F%2FEP%2FNONSGML%2BWDECL%2BP7-DCL-2013-0007%2B0%2BDOC%2BPDF%2BV0%2F%2FEN.

⁹ Council conclusions on childhood immunisation: successes and challenges of European childhood immunisation and the way forward (2011/C 202/02).

¹⁰ For example, the PROMOVAX project, which aims at promoting vaccination among migrant populations in Europe. See: http://www.promovax.eu

Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) (Text with EEA relevance). OJ L 301, 20.11.2007, p. 3–13.

¹² Available at: http://ecdc.europa.eu/en/activities/surveillance/euvac/schedules/Pages/schedules.aspx

2. PROCEEDINGS OF THE WORKSHOP

2.1 Introduction

2.1.1 Welcome and opening – Ms Glenis WILLMOTT (MEP) and Mr Alojz PETERLE (MEP)

Ms Glenis WILLMOTT, Member of the Environment, Public Health and Food Safety (ENVI) Committee and Co-chair of the Health Working Group, welcomed the speakers and the attendees to the workshop. In her introduction, she highlighted that a number of diseases, such as smallpox, have been eradicated thanks to vaccination programmes. Another recent success story of vaccination has been the human papilloma virus (HPV) vaccine, which has saved thousands of women from cervical cancer.

However, Ms Willmott stressed that several vaccine-preventable diseases are still an issue in Europe. In particular, the workshop would focus on tuberculosis (TB) and measles. Although a vaccine for TB exists, it is not very effective and there is an increasing number of drug-resistant TB cases. In this respect, Ms Willmott mentioned that she was promoting a written declaration in the Parliament on the threat of drug-resistant TB to the European Region¹³. Measles are also problematic, she added. In this case, an effective vaccine exists. However, coverage has decreased following a lack of confidence in the vaccine as well as problems in reaching some vulnerable groups, e.g. migrants. Recent outbreaks in several EU Member States, including the UK and France, show the dangers of leaving children unvaccinated. Ms Willmott therefore concluded that it was high time to have a debate on these issues.

2.1.2 Vaccines and Immunisation in Europe: General overview

Dr Piotr Kramarz, Deputy Head of the Scientific Advice Unit, European Centre for Disease Prevention and Control (ECDC)

Dr KRAMARZ started his presentation by saying that vaccination is one of the most costeffective interventions in human medicine and public health. Therefore, vaccination should not be seen as a financial burden, but rather as an investment in the future.

One of the seven disease programmes of the European Centre for Disease Prevention and Control (ECDC) deals with vaccine-preventable diseases¹⁴. Showing a graph on the effects of vaccines, Dr Kramarz explained that the rate of epidemic meningitis is much lower in countries with routine meningococcal vaccination. In addition, he mentioned that the vaccine is most effective in certain age groups (in particular below one year), and these are the age groups for which vaccination is recommended.

As a result of historical developments and differences between health systems, large discrepancies still exist in Member States' vaccination schedules. In Dr Kramarz' opinion, such differences represent a threat to immunisation.

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Written Declaration submitted under Rule 123 of the Rules of Procedure on the threat of drug-resistant tuberculosis to the European region, 15 April 2013. Available at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-
http://www.europa.europ

For more information, see: http://ecdc.europa.eu/en/activities/diseaseprogrammes/vpd/Pages/index.aspx

As people tend to move across borders, there might be a lack of continuity in vaccination. He then showed the ECDC Vaccine Schedule Information 15, an online database providing information on vaccination schedules in all EU Member States. This resource for health care providers and the public was developed in response to the 2011 Council Conclusions on Childhood Immunisation. Amongst others, the Council Conclusions invited the European Commission to work with the ECDC and the European Medicines Agency (EMA) on developing multi-lingual resources on vaccines and vaccination schedules.

Dr Kramarz explained that measles are a highly contagious disease, which mostly (but not exclusively) affects children. In the pre-vaccine era, all children would get measles with a rash and fever. However, Dr Kramarz highlighted that this is not a mild disease as it can lead to severe consequences including brain infection, pneumonia, lung inflammation and even death. Countries in the framework of the World Health Organization, including EU Member States, committed to the elimination of the disease by 2015. This goal should be achievable considering that an effective and cheap vaccine against measles exists.

Dr Kramarz then showed a map and a graph indicating that the EU still has measles outbreaks and is far from achieving the elimination target (i.e. less than one case per million). The EU is even undermining the global elimination efforts outside the EU - in 2011, it was the biggest exporter of measles. The U.S., for example, had eliminated measles in 2002, but the country is now affected by a resurgence of the disease mainly due to people travelling from abroad.

Another source of information on measles is the Measles Atlas¹⁶, which has been developed by the ECDC. The Atlas shows differences between Member States in eliminating measles. In particular, some countries are quite close to the elimination target, whereas others still have a long way to go. Cross-border movement of people should be taken into account as measles do not stop at the border and, in some susceptible populations, one case is sufficient to cause an outbreak.

Dr Kramarz explained that anti-vaccine activist groups often use emotional stories to get their message across. To raise awareness on the dangers of measles, the ECDC has therefore tried to couple dry, scientific data with personal stories from people that were not vaccinated and got infected with measles. In particular, he mentioned the case of a boy, who developed a severe form of brain inflammation (Subacute Sclerosis Pan-Encephalitis) as a consequence of measles.

One of the explanations for reduced vaccine coverage is the lowering confidence in vaccination programmes in the EU population. Referring to it as the "vaccination paradox", Dr Kramarz illustrated that when a vaccine is introduced, the incidence of a disease tends to decrease as vaccination coverage increases. This happens up to a point when people in the general population as well as health professionals do not see the benefits of vaccination any longer and scaremongering, anti-vaccine stories start to circulate. As a consequence, loss of confidence in vaccination programmes reduces coverage and increases the risk of outbreaks. To get to the elimination of the disease, it is therefore crucial to bridge this gap in confidence. In conclusion to his presentation, Dr Kramarz highlighted that several information tools are available on the ECDC website, including the Measles Atlas and the vaccine schedule as well as European monthly measles monitoring reports¹⁷.

The ECDC Vaccine Schedule Information is available at: http://vaccine-schedule.ecdc.europa.eu/Pages/Scheduler.aspx

The ECDC Measles Atlas is available at: http://emmageocase.ecdc.europa.eu/atlas/measles/

The European monthly measles monitoring reports are available at: http://ecdc.europa.eu/en/publications/surveillance-reports/vpd/pages/emmo.aspx

2.2 Tuberculosis is not a disease of the past

2.2.1 The fight to beat TB

Dr Masoud DARA, Team Leader of WHO/Europe TB and M/XDR-TB programme

In his introduction, Dr DARA explained that in his presentation he would provide an overview of the epidemiological situation of tuberculosis (TB) and multi-drug resistant tuberculosis (MDR-TB), both globally and in the WHO European Region. He would also summarise the main elements of the WHO Consolidated Action Plan to Prevent and Combat multi and extensively drug-resistant tuberculosis (M/XDR-TB).

Dr Dara then showed the picture of a painting by Cristóbal Rojas, a Venezuelan artist who painted the sorrows of TB back in 1886. More than a century later, Dr Dara explained, TB is far from being a disease of the past: 8.7 million people get TB every year, 1.1 million get HIV-associated TB (especially in sub-Saharian Africa) and half a million get MDR- TB. This leads to 1.4 million deaths each year globally, with almost half a million deaths from HIV-associated infections and approximately 150,000 from MDR-TB.

Even in the WHO European Region, Dr Dara highlighted that there are half a million TB cases every year, leading to 44,000 deaths. Data from the 53 member states of the Region show large differences in the incidence of TB. In particular, 18 countries are considered high-priority countries, including some of the Baltic States, Romania, Bulgaria and Turkey. He showed a graph illustrating that TB had been decreasing in the region until 1990. After the collapse of the Soviet Union, there was a sharp increase in the TB notification rate until 2002-2003, when the trend stabilised. Nowadays, there is a general decrease in TB cases of about 5% every year, which is not enough to reach the 2050 elimination target of having less than one TB case per one million people. For the elimination target to be reached, it would be necessary to achieve at least a 20% reduction every year.

Dr Dara noted that the success rate of treatment is steadily increasing globally. However, the WHO European Region presents the lowest treatment success rate worldwide. This is mainly due to the preponderance of MDR-TB in the region. As a matter of fact, 20% of the global burden of MDR-TB is in the EU. Dr Dara showed a graph indicating that some Member States experience a very high incidence of TB – with half of the cases due to MDR-TB. In Dr Dara's view, the low treatment success rate also derives from a lack of public health and patient-centred approaches on TB. In particular, he referred to the lack of appropriate infection control, long hospitalisation periods and poor treatment.

WHO Europe has recently adopted a five-year Consolidated Action Plan to Prevent and Combat M/XDR-TB (2011-2015)¹⁸, which was developed following an inclusive approach and involving NGOs and other stakeholders. The plan was endorsed fully by all 53 Ministers of Health during a Regional Committee in Baku in 2011. It calls for a number of actions, including prompt diagnosis, equitable access to adequate treatment for all, health system approach to preventing and controlling MDR-TB, involving civil society organisations (participative approach), identifying and addressing social determinants (e.g. alcohol, tobacco, diabetes), working in partnership between countries, and developing a robust monitoring framework to ensure implementation. Progress towards the objectives of the Action Plan will be reviewed during a meeting in Baku in the coming months.

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WHO Europe, Consolidated action plan to prevent and combat multidrug- and extensively drug-resistant tuberculosis in the WHO European Region 2011–2015. Available at: http://www.euro.who.int/ data/assets/pdf file/0007/147832/wd15E TB ActionPlan 111388.pdf

In particular, Dr Dara explained that seven areas of intervention were identified in the Action Plan, namely:

- a) to prevent the development of M/XDR-TB;
- b) to scale up access to effective treatment;
- c) to scale up access to early diagnosis;
- d) to ensure infection control;
- e) to strengthen surveillance;
- f) to expand the management capacity of the programmes;
- g) to address the needs of special populations.

Dr Dara then stressed that Europe is the only region where human immunodeficiency virus (HIV) is on the rise, and that TB is the leading killer among people living with HIV. In particular, the percentage of TB cases with HIV co-infection among all HIV-tested TB cases increased by 20% a year in the period 2006-2011.

The implementation of the WHO Action Plan is expected to achieve: the diagnosis of 225,000 people with MDR-TB; the successful treatment of 127,000 people with MDR-TB; and the prevention of 250,000 cases of MDR-TB and 13,000 XDR-TB cases. These achievements would save 120,000 lives and US\$ 12 billion.

Further on, Dr Dara showed some worrying figures: 78,000 people annually are estimated to fall sick with M/XDR-TB. Yet, unfortunately, only 30,000 patients are detected due to low diagnostic capacity. Treatment outcome are even more worrisome, as fewer than 50% of MDR-TB patients are successfully treated. The other 50% either die or move from one country to the other to be treated. Although some countries are showing progress, it is important to keep the issue high on the political agenda.

In conclusion to his presentation, Dr Dara highlighted the next steps for combating TB, namely: to continuously and closely support the Member States in implementing the Consolidated Action Plan; to prepare a Compendium of Best Practices; to identify and address the social determinants of TB and M/XDR-TB; to scale up best practices and patient-centred ambulatory care; to strengthen country capacity in surveillance for producing reliable estimates of MDR-TB figures; to introduce rational use of new TB drugs; to develop interventions to move toward TB elimination in low TB incidence countries; and to define the role of surgery in TB and M/XDR-TB.

Despite all the efforts that have been made so far, it is still difficult to ensure early diagnosis of TB. In addition, treatment is lengthy (two years) and very cumbersome for patients, and there is low treatment access – which is not acceptable in Dr Dara's view. Sub-standard practices are also often adopted in Europe, because health professionals do not follow the WHO recommendations. Another problem is that the stocks of medicines, vaccines and supplies, even in the EU, are low. TB and M/XDR-TB is a serious public health threat, especially at times of financial crisis and budget cuts. Dr Dara concluded that it is necessary to join forces and to learn from the best examples adopted in the different countries in order to effectively combat TB in Europe.

2.2.2 Patient's voice

Ms Amy McCONVILLE, TB patient

Ms McCONVILLE is a former TB patient, a TB patient advocate and the co-chair of the TB Action Group (TBAG)¹⁹. At the beginning of her presentation, Ms McConville explained that TBAG is the only network of patients affected by TB in the UK and that it has been at the forefront of developing the civil society response on the disease. It was established by TB Alert in 2008 to provide a unique voice to people who have been personally affected by TB. In particular, TBAG works on issues such as drug resistance, migrant health screening and health determinants. Ms McConville showed a picture from a European conference on TB and lung disease²⁰, which took place in July 2012. On that occasion, TB patients and their advocates came together for the first time to hold a demonstration calling for better care and prevention.

Ms McConville then told the audience her personal story as a TB patient. Before becoming ill, she was due to leave home to study at the university and she was looking forward to becoming independent. However, she immediately struggled to participate in the university life as she always felt too tired. Her general practitioner (GP) struggled to interpret the symptoms of the disease and she was initially diagnosed with asthma. By the time she was diagnosed with TB twelve months later, her left lung had completely collapsed and her hair had started to fall off. Ms McConville was therefore forced to interrupt her studies and she went back home to be treated. Initially, she delayed treatment for about four weeks due to fear of the drugs and their potential side effects. During first hospital admission, she said that it was hard for her to get used to the hospital routine. Later on, she started suffering from the side effects of TB treatment, including joint-pain and nausea. However, she considered herself lucky as other patients often live with long-term disabilities.

All in all, she took TB drugs for two and a half years and underwent surgery to remove her left lung. She then hoped to return to her normal life. However, Ms McConville highlighted that the journey of a TB patient does not end when taking the last pill. For a long time, she lived with a feeling of guilt, considering that the disease was her fault. Two years after surgery, in 2009, she was diagnosed with depression and anxiety.

McConville's story illustrates not only the physical suffering, but also the emotional and social impact of the illness. In this respect, she highlighted the enormous economic costs of the disease for health care systems in Europe. To illustrate her point, she explained that a patient who does not experience delays in accessing diagnosis and treatment will have a relatively straightforward cure, leading to a greater cost-effective outcome. It will cost as little as £1,100. On the other hand, a patient who requires extensive treatment for up to two years, including surgical interventions, and develops drug resistance will experience complex treatment costing the health system up to £10,000. It is therefore very important to consider the positive health benefits to the individual and the economy from maximising individual well-being and reducing the social consequences of TB. In particular, she highlighted the long-term costs of the disease for adults and children and the loss of future educational and economic opportunities.

¹⁹ TB Action Group: http://www.tbadvocacy.org/

⁶th Conference of The Union Europe Region, 04-06 July 2012. For more information, see: http://www.theunion.org/index.php/conferences/index.php?option=com_flexicontent&view=items&id=85&Itemid=36

As TB can be considered as a social illness, McConville concluded that it is therefore costeffective and morally right to invest in the health of all citizens.

At the end of her presentation, McConville highlighted some key actions that would need to be taken to combat TB, namely: encouraging the uptake of the Bacillus Calmette–Guérin (BCG) vaccine in affected communities where its impact will be most effective; rolling out safe, effective TB vaccines that can be widely used; and holding to account renewed commitments to increase funding for vaccine research and development at the EU level.

In her view, it would also be important to ensure political leadership on TB. Such leadership should drive a stronger commitment by the global public health community to address this illness urgently. As the human costs and suffering from TB have been recognised, it is now high time to act to stop the disease. This would benefit both present and future generations.

2.2.3 First round of questions & answers

With the participation of Dr Daniel BRASSEUR, Chair of the Paediatric Committee (PDCO) and Dr Radu BOTGROS, Scientific Administrator, European Medicines Agency (EMA)

Ms WILLMOTT thanked the speakers and introduced the experts from the European Medicines Agency. She then opened the floor for comments and questions.

Fanny VOITZWINKLER from TB Europe Coalition²¹ stressed the urgency to tackle the issue of TB as the European Region has 18 of the high-burden countries worldwide. She also mentioned that patients sometimes do not even have access to treatment and have to order medicines online from outside Europe. In particular, Romania has worse treatment success rates than the Democratic Republic of Congo. It is therefore important to ensure enough political commitment at the EU level to tackle this issue.

Hildrun SUNDSETH from the European Institute of Women's Health²² highlighted the importance of vaccination. She noted that nowadays the focus is more and more on chronic diseases, rather than on infectious diseases that could be prevented. Awareness on vaccines as prevention tools should be further raised. For this purpose, leadership and political will at the EU level would be crucial.

Dr Daniel BRASSEUR (EMA) highlighted that vaccination is a national competence. However, the duplication of clinical trials that are performed should be stopped. Fortunately, further to the Paediatric Regulation²³, industry has an obligation to propose a paediatric investigation plan for new vaccines at an early stage. However, problems will remain on the existing vaccines and to harmonise the vaccine schedules across the EU.

Dr Radu BOTGROS (EMA) highlighted that the current TB vaccine is a hundred years old. New candidate vaccines are in the pipeline for approval and EMA is willing to support the development of adequate trials for the new vaccines. The EMA and its Committee for Medicinal Products for Human Use (CHMP) adopted last year the WHO recommendation to raise the paediatric dosages for the major TB drugs.

²¹ See: http://www.tbcoalition.eu/

²² See: http://eurohealth.ie/

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance). OJ L 378, 27.12.2006, p. 1–19.

The dosages used before the recommendation were not high enough to ensure efficacy and could be a factor in the development of drug resistance. The EMA has therefore issued the same recommendation to EU Member States²⁴.

Dr Ronald de GROOT from the European Society for Paediatric Infectious Diseases stressed the need to ensure consistent vaccine administration programmes at national level. He also mentioned that vaccination is an important issue not only for children, but also for adults and older people. Finally, he highlighted the importance of a joint effort by ECDC, EMA, WHO and national authorities to improve the situation.

In this respect, Dr DARA emphasized the need to also involve civil society organisations, in particular through the use of social media, to counteract the messages of the antivaccine groups.

2.3 Case Study: The current measles outbreak

2.3.1 The voice of the professionals

Dr Ronald de GROOT, President of the European Society for Paediatric Infectious Diseases

In his introduction, Dr Ronald de Groot said that the European Society for Paediatric Infectious Diseases (ESPID) is the largest society in the world involved in paediatric infectious diseases. He mentioned that he would focus his presentation on measles, but pertussis is also a vaccine-preventable disease of a similar kind that is emerging as a problem. Measles is a highly contagious disease that affects not only children but also adults. It has a fatality rate between one in 1,000 and one in 3,000 reported cases. Dr de Groot explained that infants who are less than nine month old and immune-compromised individuals are at increased risk of developing severe consequences from the disease.

Dr de Groot highlighted that measles vaccination has been extremely successful, leading to reduced mortality worldwide. In particular, immunisation against measles with two doses of the measles, mumps and rubella (MMR) vaccine is very effective and may result in the eradication of the disease, if the vaccine was taken up by more than 95% of the population. However, failure to maintain high levels of measles vaccination coverage both in Europe and in other continents has resulted in a resurgence of the disease. In particular, Dr de Groot mentioned recent outbreaks in France, Italy, Spain, the UK and the Netherlands. These outbreaks have mostly occurred among unvaccinated people.

Looking at the decrease of the estimated number of measles deaths between 2000 and 2008 worldwide²⁵, Dr de Groot mentioned that the situation seemed to be under control at the end of 2008 and would remain stable for the subsequent five years in the projected status quo. However, even with the status quo, the 2015 elimination target would not be met. A worst case scenario was also presented, with the estimated number of measles deaths increasing exponentially until 2013.

Moss et al., Lancet 2012.

²⁴ For more information, see: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news and events/news/2012/02/news detail 00144 5.jsp&mid=WC0b01ac058004d5c1.

Dr de Groot then presented the case of the current measles outbreak in England and Wales, which shows that action can be taken to counteract the resurgence of the disease. In the UK, between 1990 and 2012, the uptake of vaccination was impacted by a vaccine scare, the so-called Wakefield controversy²⁶. In 2012, more than 2,000 cases of measles occurred in England and Wales, which is the highest figure in two decades. The measles outbreak is on-going and causes substantial morbidity and even mortality. The low vaccination uptake in the UK and several other countries indicates a failure in the public health system and needs immediate action by all stakeholders. On 25 April 2013, the UK health authorities therefore decided the immediate start of a catch-up vaccination programme.

Dr de Groot also stressed that the schedules of MMR vaccination are still rather different across the EU and that attempts to harmonise these schedules has been a failure so far. However, this would be important, because the efficacy of MMR vaccine depends on the timing of the first dose and people are more and more mobile across borders.

In particular, Mr de Groot highlighted that 82% of those who get measles are unvaccinated, 18% only had one dose of the vaccine and 4% had the two doses. He also noted that recent outbreaks also happened in the U.S. The conclusion of a study published in the Journal of the American Medical Association²⁷ indicates that the large majority of the outbreaks were among unvaccinated individuals. The high proportion, however, of individuals vaccinated once or first vaccinated at an early age, raises concerns regarding the effectiveness of the vaccine.

In conclusion, Mr de Groot stressed that, in the light of the recent measles outbreaks, immediate action is necessary in the form of catch-up vaccination programmes in the EU. Strengthening surveillance and the development of rapid point-of-care tests are also crucial actions to tackle measles effectively. In addition, MMR vaccine coverage should be increased above 95% to get to the elimination of the disease. In Dr de Groot's view, progress toward the development of an ideal (one shot, long-standing immunity) measles vaccine must also be strongly supported.

Regarding MMR vaccination schedules, Dr de Groot highlighted that these would need to be harmonised within Europe, knowing that the administration of the first dose at a very young age increases the risk of measles later in life. Administration of a second dose is absolutely necessary, but the optimal timing of the second dose is still an issue of debate and needs further research. It should also be explored whether there is a need for a third dose as it is currently administered to adults entering college in the U.S.

Finally, Dr de Groot stressed the importance to keep the general public informed and engaged, which requires a collaboration between health care professionals and (inter)national societies to combat the outbreak of infectious diseases like measles. There is also a need to engage opinion leaders from various fields on the importance of immunisation. In this context, European consistency is very important and the ESPID will partner with international organisations to issue clear guidelines and to support a strong and well-established scientific and health care network.

²⁷ JAMA 2011;306:2440-42.

²⁶ For more information, see:

http://www.guardian.co.uk/society/2013/apr/06/what-happened-man-mmr-panic.

2.3.2 Why measles outbreaks are so scary?

Dr Andreas SCHULTZ Senior Consultant in Pediatrics, Tropical Medicine and Infectious diseases; Director of Médecins du Monde Germany

Dr SCHULTZ briefly introduced Médicines du Monde (MdM), an international organisation managing around 300 projects worldwide. Half of the projects are carried out in the EU and mainly target individuals at the borders of society, i.e. homeless people, drug users, Roma, etc. MdM is also working on the systematic data collection of the social determinants of health.

Re-emphasising that 85% of measles case across Europe occur among people that are unvaccinated, Dr Schultz stressed that the disease can have severe consequences, including pneumonia and brain infection, as well as long-term disabilities. A safe combined vaccine for MMR exists, which provides life-long protection in most patients. However, 95% of population coverage is needed to have an enduring effect. Dr Schultz then quoted the WHO Regional Director for Europe, saying that "the cost of measles do not allow us to have a low vaccination rate". This means that it makes no sense from a health or an economic point of view to wait for another outbreak before taking action.

Presenting some of the costs related to measles, Dr Schultz highlighted that, in Germany, the cost is estimated at 520 EUR for the diagnosis and treatment of one case. In addition, the child affected by measles misses around nine days at school and parents often have to stay home from work to take care of the child. In case of an epidemic involving around 300 individuals, the costs become then substantial. A study carried out in Italy 10 years ago found that 22 million EUR were spent on diagnosing and treating measles. With the same cost, Dr Schultz highlighted, it would have been possible to vaccinate 1.9 million children instead.

He then showed a graph reporting WHO/UNICEF data and illustrating the critical coverage of 95% of the population to ensure effectiveness of vaccination. It is therefore important to pay particular attention to vulnerable groups and ensure that everyone has access to the MMR vaccine.

Talking about the existing barriers, Dr Schultz mentioned the case of Greece where families can no longer afford routine vaccination (regardless of whether they are insured or uninsured) because of the financial crisis. He then referred to the case of a child, who was rejected from school because he was not fully vaccinated. In Dr Schultz' view, vaccination is important, but should not become a reason for exclusion. In other countries, such as Germany, people that fall out of the vaccination schemes often refer to clinics that do not have the means to address all the needs.

A survey carried out by MdM in 2012 across 14 European cities highlighted that 60% of patients do not know where to receive vaccination due to legal and administrative barriers, language barriers and discrimination of specific population groups, in particular the Roma. Other barriers are the consequences of restrictive policies. For example, in Germany, social welfare centres have a duty to report undocumented patients. Therefore, although vaccination is theoretically accessible, several undocumented migrants fear being reported. In Belgium, on the other hand, theoretical access to health care for undocumented migrants is possible. However, many complex administrative barriers exist in practice. In France, sanitary risks are often used by authorities as an excuse for the violent crackdowns of Roma camps. Yet, these initiatives often cause public health risks, e.g. when they stop on-going vaccination campaigns.

In conclusion to his presentation, Dr Schultz put forward a number of recommendations. First of all, full access to vaccination for all vulnerable groups, including people that are at the borders of society, should be ensured. However, equal access to vaccination alone is not enough and should be accompanied by comprehensive, in-depth prevention and accessible primary care services (e.g. vaccine administration by the family doctor). In addition, the opinions of the EU Fundamental Rights Agency on access to healthcare for undocumented migrants should be implemented, so that everyone can access all forms of essential preventive and curative healthcare (both children and adults), which is a basic human right. It is also important to monitor the accessibility to national immunisation schemes and paediatric care for all children in Member States as well as to put the ECDC recommendations into practice. Finally, Dr Schultz highlighted that it is necessary to evaluate the long-term impact of proposed austerity measures on health systems and to adopt a more rational approach to budget cuts, so that these do not happen to the detriment of public health.

2.3.3 Open discussion

With the participation of Dr Daniel BRASSEUR, Chair of the Paediatric Committee (PDCO) and Dr Radu BOTGROS, Scientific Administrator, European Medicines Agency (EMA)

Dr BRASSEUR opened the discussion by highlighting that the measles resurgence is not a surprise considering the gaps in vaccination coverage. The main take-home message for health professionals and politicians is to increase coverage. He then explained that if 5% of the children escape vaccination on a yearly basis, after ten years this means that 50% of the birth cohort is not vaccinated, and after 20 years it is a full cohort. As long as there is a big enough cohort to be receptive, the virus will spread. Coverage is therefore essential.

Ana Cristina NOGUEIRA from the World Health Organization highlighted that the use of social media is essential to spread the message on measles vaccination among politicians and to raise the awareness of young people. She also stressed that the EU needs to take a proactive role as what happens in the EU has a great impact on what happens in the rest of the world.

Dr KRAMARZ re-emphasised that coverage is really the crucial aspect to effective vaccination. In this respect, the ECDC is building project to pull the best data on vaccination coverage in the EU and make it available online - not only at country level, but also at regional level. He also mentioned that, even with high vaccination coverage, some pockets of unvaccinated groups might remain, e.g. for religious reasons. Health professionals should also be more proactive in offering vaccination.

Ms SUNDSETH highlighted that the world is interdependent and that we all have a responsibility to get the coverage we need to ensure protection. In particular she mentioned that her institute deals with young, well-educated mothers that are often complacent about vaccinating their children, maybe as they have been influenced by the media. She mentioned that, to be effective, communication should be accompanied by strong political leadership on public health.

Dr SCHULTZ stressed that, due to this lack of leadership and effective policies on vaccination, the EU risked losing credibility in other countries.

Mr Stephan SCHULTZ, participating in the workshop as a private citizen, mentioned that, in his opinion, the only way to achieve full coverage is through compulsory vaccination. In this respect, Dr de GROOT mentioned that the issue of obligatory vaccination remains controversial as in some countries this would not work. What is really crucial, in his opinion, is communication to counteract the messages of anti-vaccine groups.

Mr DARA finally mentioned that the availability of the TB vaccine is an issue in some Member States.

2.3.4 Conclusions

In his concluding remarks, Mr PETERLE highlighted that the main concern on measles vaccination is coverage, not the effectiveness of the vaccine. The situation varies a lot from country to country; therefore an EU approach is needed. Mr Peterle also mentioned the importance of engaging new stakeholders in the debate, e.g. employers or trade unions who could ask their employees to be vaccinated. Health insurances may also play a more important role in this respect. Communication at the European level is crucial to raise awareness on the threats of measles and TB. For this purpose, more political action - and not necessarily more research - is needed.

Ms WILLMOTT highlighted that, whereas measles has had a lot of publicity, more awareness needs to be raised on TB and new, more effective treatments have to be developed.

ANNEX 1: PROGRAMME

WORKSHOP Childhood Vaccination and Immunisation

Wednesday, 19 June 2013 from 13.00 to 14.45 European Parliament, A3G-3, Brussels

Organised by the Policy Department A-Economy & Science for the Committee on the Environment, Public Health and Food Safety (ENVI)

AGENDA

13.00 - 13.05

Welcome and opening by Glenis WILLMOTT and Alojz PETERLE, MEPs

13.05 - 13.15

Vaccines and Immunisation in Europe: General overview

Dr Piotr Kramarz, Deputy head of the Scientific Advice Unit, European Centre for Disease Prevention and Control (ECDC)

Part 1 Tuberculosis is not a disease of the past

13.15 - 13.25

The fight to beat TB

Dr Masoud DARA, Team Leader of WHO/Europe TB and M/XDR-TB programme.

13.25 - 13.35

Patients' voice

Ms Amy McCONVILLE, TB patient

13.35 - 13.50

Q&A

With the participation of Dr Daniel BRASSEUR, Chair of the Paediatric Committee (PDCO) and Dr Radu BOTGROS, Scientific Administrator, European Medicines Agency (EMA)

Part 2

Case study: The current measles outbreak

13.50 - 14.00

The voice of the professionals

Dr Ronald de GROOT, president of the European Society for Paediatric Infectious Diseases

14.00 - 14.10

Why measles outbreaks are so scary?

Dr. Andreas SCHULTZ Senior Consultant in Pediatrics, Tropical Medicine and Infectious diseases; Director of Médecins du Monde Germany

14.10 - 14.40

Open discussion

With the participation of Dr Daniel BRASSEUR, Chair of the Paediatric Committee (PDCO) and Dr Radu BOTGROS, Scientific Administrator, European Medicines Agency (EMA)

14.40 - 14.45

Conclusions

ANNEX 2: SHORT BIOGRAPHIES OF EXPERTS

Dr Piotr Kramarz

Dr Piotr Kramarz is a physician by training, with a PhD in immunology of viral infections, and eight years of clinical practice experience in a teaching hospital in Poland in the field of infectious diseases. He is an Epidemic Intelligence Service (EIS) alumn (class of 1997) and worked in the National Immunization Programme of the U.S. CDC during his EIS programme and later on. Since 2007 he has been working as a Deputy Head of the Scientific Advice Unit and, since April 2011, as the Deputy Chief Scientist at the European Centre for Disease Prevention and Control. Among other tasks he leads the Disease Programme Section of the Centre. His main research interests include epidemiology of vaccine preventable diseases including influenza.

Dr Masoud Dara

Dr Masoud Dara is the programme manager and team leader of tuberculosis (TB) and multidrug resistant (MDR-TB) unit of World Health Organization European Region. Dr Dara is a physician and public health expert from Belgium. In addition to his medical degree and clinical experience, he has diploma in tropical medicine and epidemiology from London School of Hygiene and Tropical Medicine and Harvard School of Public Health.

Since 1990, Dr Dara has been working on TB, HIV/AIDS, public health and health in prison in the capacity of senior consultant and Medical Officer in many countries of WHO European Region and other Regions including Middle-East, Africa and Western Pacific Regions. He has also experience in health in emergency and migrants' health as the Head of Mission of Red Cross and Médecins Sans Frontières.

Since 2008, Dr Dara is the Chair of International Scientific Working Group on TB Control in prisons. He is the author of several publications and guidelines.

Ms Amy McConville

Amy McConville is an established TB Patient Advocate in the UK, having been an active participant in the fight against TB since 2006. Amy is co-facilitator of the TB Action Group (TBAG), the only UK-based network of People Affected by TB. TBAG was established in 2008 by the UK's TB charity, TB Alert, to provide a voice to people who have personal experience of TB and a valuable insight into how. As a representative of TBAG, Amy has contributed towards policy development and guidance on TB care and prevention at both a national and international level. Amy is also involved in raising public awareness of issues affecting TB patients, such as low levels of awareness amongst healthcare professionals leading to delayed diagnosis and complications, through high profile media advocacy.

Prof. Dr Ronald de Groot

Professor Ronald de Groot, studied medicine in Rotterdam, followed by a residency in Gynecology/Obstetrics and Surgery as a preparation for a $2\frac{1}{2}$ year period as Senior Medical Officer in Zonkwa Hospital, Nigeria. He subsequently did his pediatric training in Rotterdam (1979-1983), became chief resident (1983-1985) followed by a research fellowship (1985-1988) in pediatric infectious diseases in the University of Washington, Seattle, USA. In 1988 he returned to the Erasmus University in Rotterdam and became in 1998 head of the training program and Professor in Pediatric Infectious Diseases and Immunology. From May 2005 until September 2009 he was head of the Department of Paediatrics of the Radboud University Nijmegen Medical Centre. Since May 2005 he is Professor of Pediatrics at the Radboud University Nijmegen.

Professor de Groot's research activities include clinical and laboratory studies in the fields of vaccinology, infections by pneumococci, meningococci and HIV, respiratory tract infections and immunodeficiencies. Ronald de Groot is (co)author of over 200 peer reviewed English language papers, more than 100 contributions to books, symposia and proceedings and over 40 Dutch language peer reviewed papers. Professor de Groot is a member of the Dutch Health Council, the Central Committee on Research involving Human Subjects (CCMO) and member of a large number of national and international advisory committees. In 2008, he was the recipient of the Bill Marshall Award of the European Society of Paediatric Infectious Diseases (ESPID). Currently, Professor de Groot is the President of ESPID.

Dr Andreas Schultz

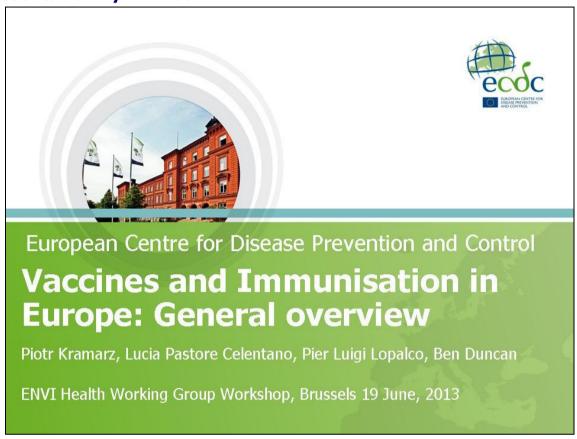
Dr Andreas Schultz is a senior medical officer and a specialist in paediatrics, tropical medicine and international public health. He studied medicine in Germany, France and the US. Over the last 11 years he had various assignments to tropical countries mostly as head of programmes, coordinator or advisor, e.g. in India, Indonesia, Thailand, Laos and Papua New Guinea.

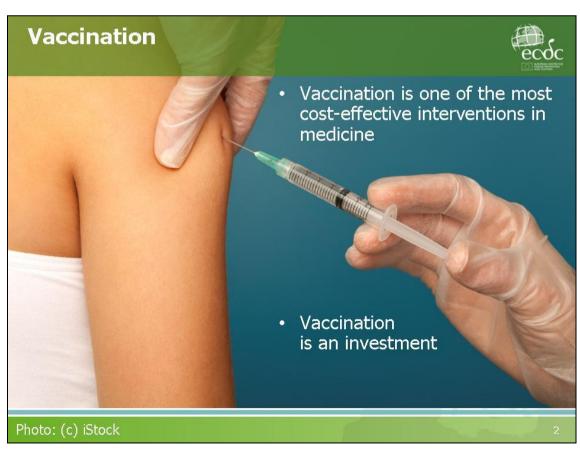
He has a wide experience in strategic and operational planning in health project and programme management. He maintained his academic links and develops and continues to deliver innovative courses in International and Child Health.

Dr Andreas Schultz is currently the country director of 'Doctors of the World' in Germany. Thus, he is responsible for projects in international humanitarian aid and development cooperation and has a strong focus on child and maternal health. Dr Schultz also acts as a board member of several institutions engaged in international health.

ANNEX 3: PRESENTATIONS

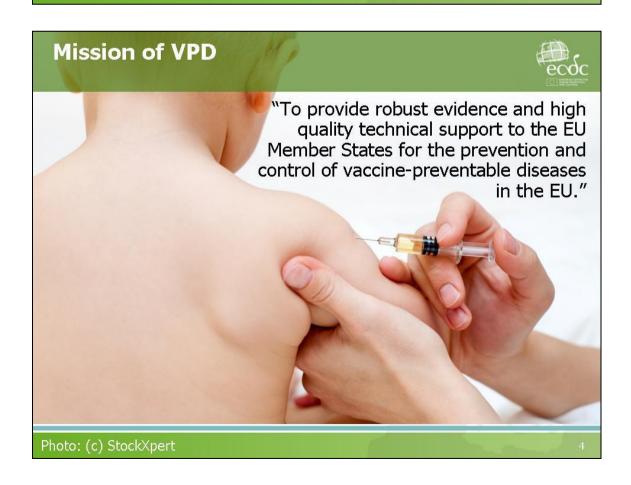
Presentation by Mr Piotr Kramarz

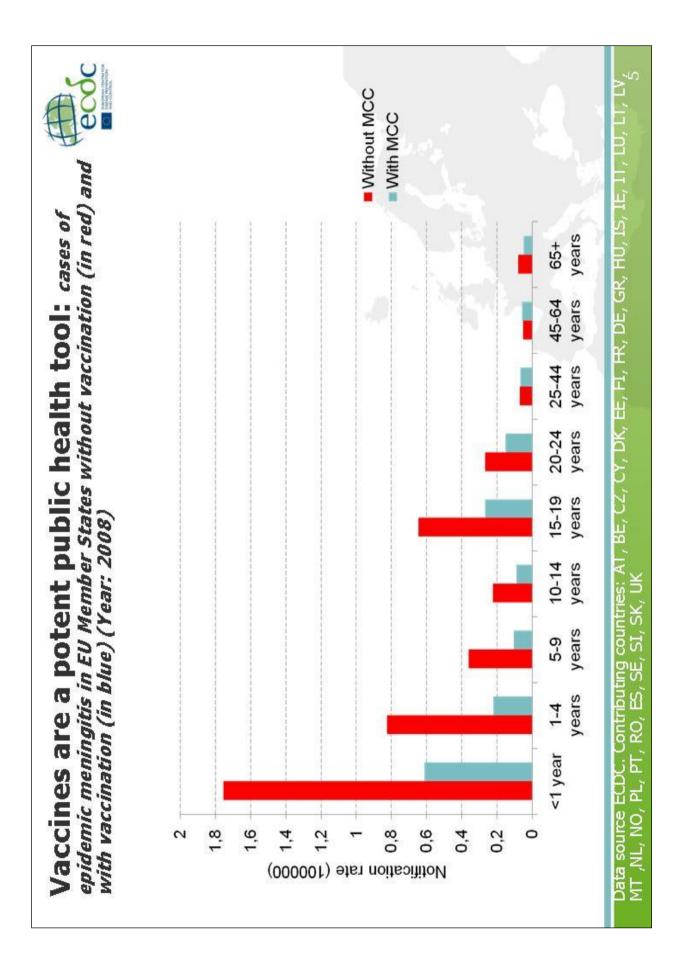


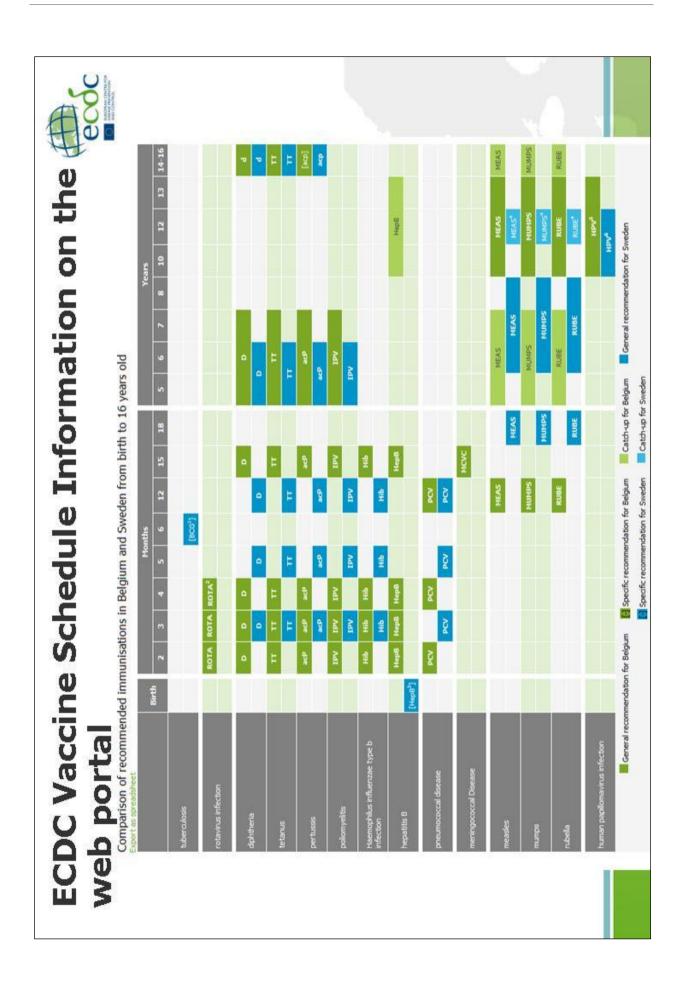




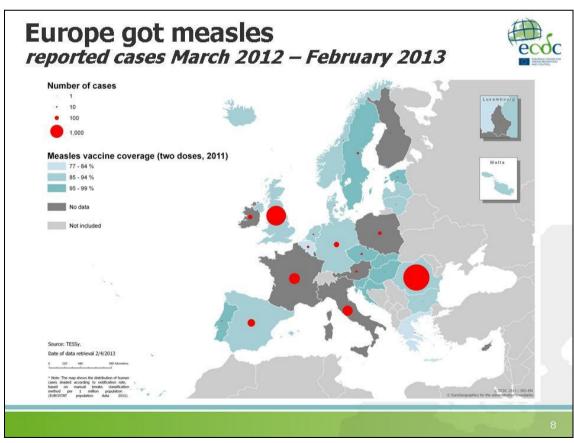
One of the seven Disease Programmes of ECDC deals with the vaccine-preventable diseases (VPD)

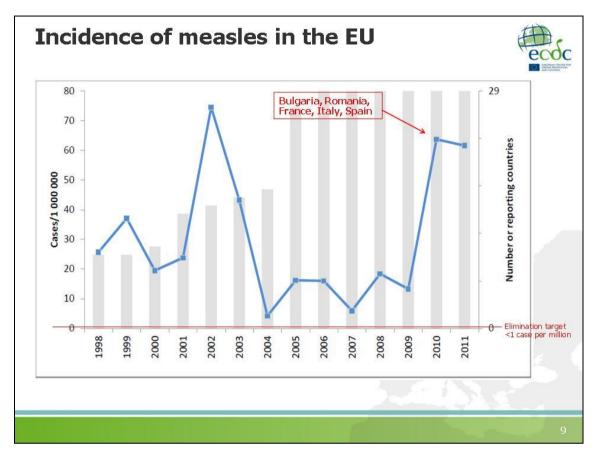


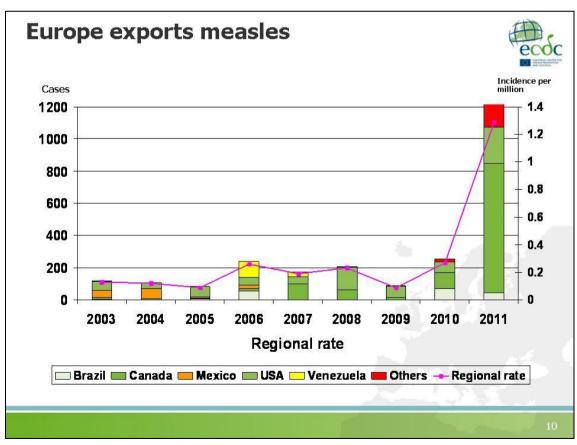


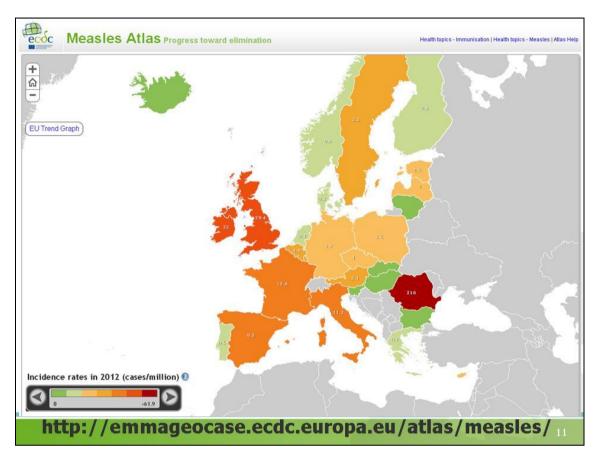




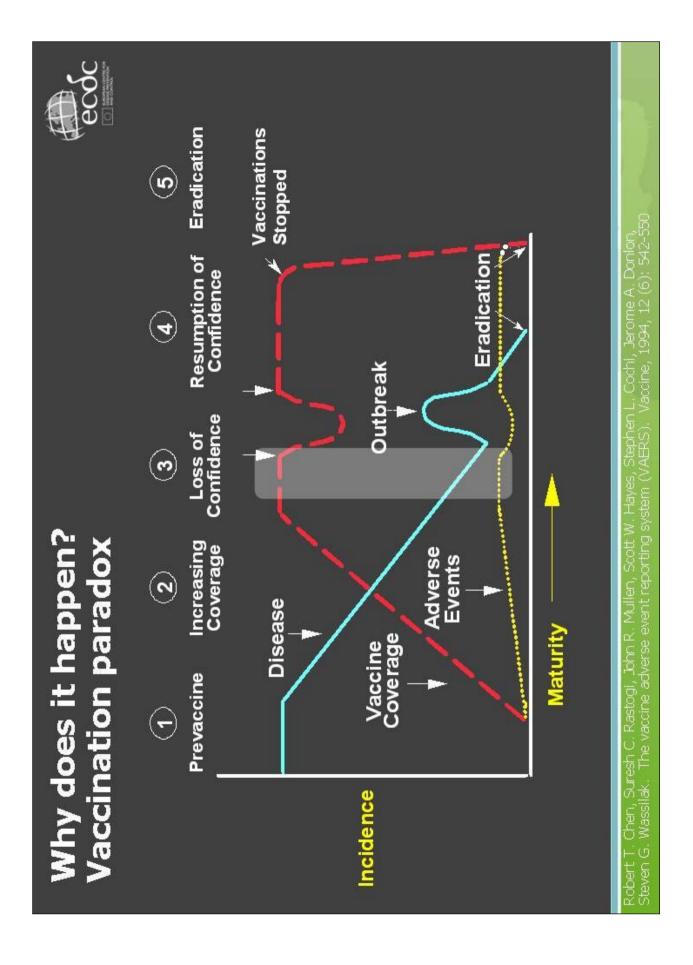














Presentation by Dr Masoud Dara

The Fight to Beat Tuberculosis

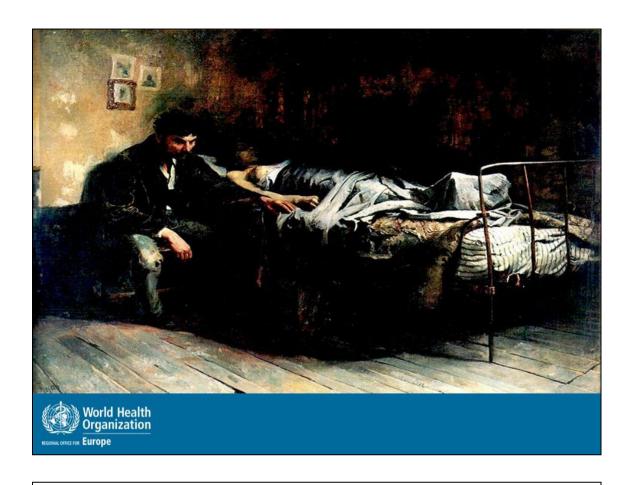
Dr Masoud Dara, Programme Manager TB and M/XDR-TB World Health Organization Office for Europe Brussels, 19 June 2013



Outline of presentation

- TB and MDR-TB epidemiological situation
- Consolidated Action Plan to Prevent and Combat M/XDR-TB (MAP) in a nutshell
- Next steps
- Conclusions





The Global Burden of TB -2011



Estimated number of cases

Estimated number of deaths

All forms of TB

8.7 million

(8.3-9.0 million)

Women: 2.9 million Children: 0.5 million

HIV-associated TB

1.1 million (13%)

(1.0-1.2 million)

Multidrug-resistant TB

Up to 0.5 million

1.4 million*

(1.3-1.6 million)

Women: 0.5 million Children: 64 000

430,000

(400,000-460,000)

Unknown, but probably > 150,000



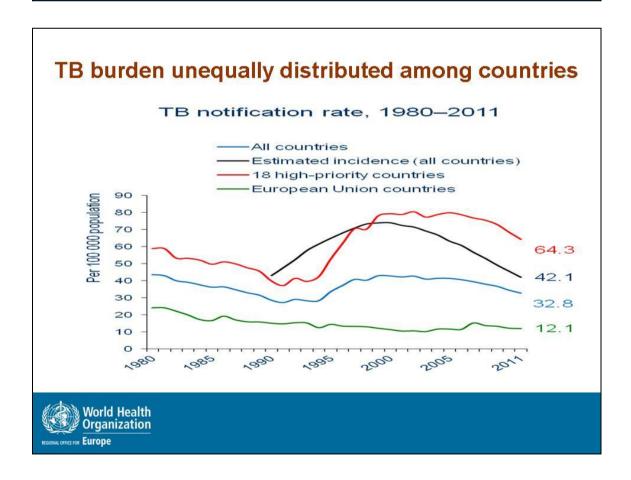
* Including deaths attributed to HIV/TB

No reason to be complacent about TB in the WHO European Region

- Total of over 500 000 estimated TB patients in the Region
- 380 000 new TB cases estimated to occur in a year
- 44 000 deaths, mostly in the east

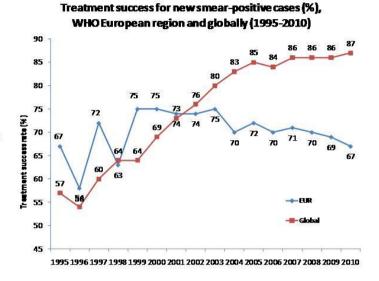




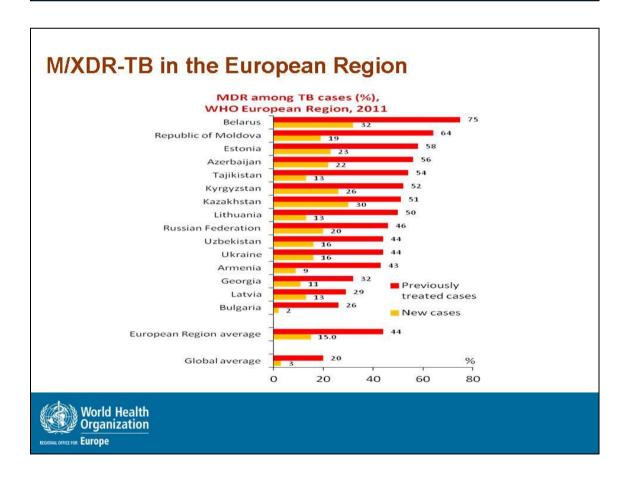


The WHO European Region has the lowest treatment success rate worldwide

While globally in other regions treatment success rate steadily is increasing, in WHO European region it is reducing.







Consolidated Action Plan to Prevent and Combat M/XDR-TB 2011-2015

- <u>Prompt diagnosis</u>, including newly endorsed molecular diagnostic techniques
- · Equitable access to adequate treatment
- Health system approach to preventing and controlling MDR-TB
- Emphasis on involving civil society organizations
- · Identifying and addressing social determinants
- Working in <u>partnership</u>, twinning of cities and programmes
- Robust monitoring framework, <u>accountability</u> and follow-up
- Including neglected aspects (such as palliative care and surgery)





Areas of intervention



Prevent the development of M/XDR-TB



Scale up access to effective treatment



Scale up access to early diagnosis



Infection control



Strengthen surveillance



Expand management capacity of the programmes



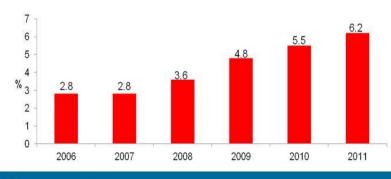
Address the needs of special populations





Leading killer among people living with HIV

- Fewer than 13 000 TB cases with HIV co-infection were detected in the Region, or 56.5% of the estimated total.
- Only 70% of them were offered antiretroviral treatment.

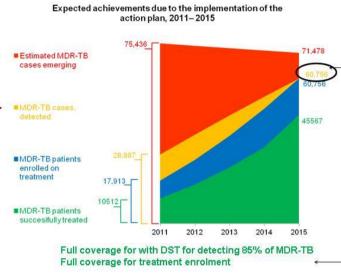


Percentage of TB cases with HIV coinfection among all HIV-tested TB cases increased by 20% a year in 2006–2011.



Expected achievements of MDR-TB Action Plan (MAP) Expected achievements due to the implementation of the

- 225 000 people with MDR-TB diagnosed
- 127 000 people with MDR-TB treated successfully
- 250 000 MDR-TB and 13 000 XDR-TB cases averted
- 120 000 lives and 12 US\$ billion saved

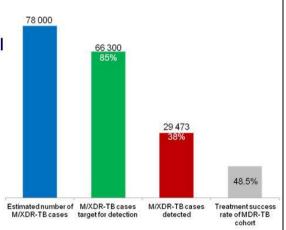




Numbers talk

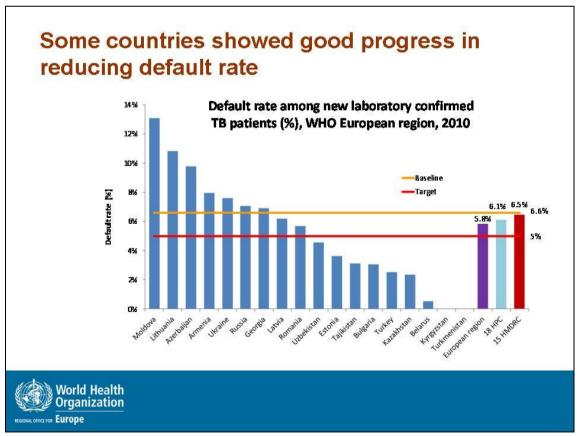
- 78 000 people estimated to fall sick with M/XDR-TB yearly
- Only 30 000 M/XDR-TB patients diagnosed
- Fewer than 50% of MDR-TB patients successfully treated

Core indicators for monitoring the implementation of the M/XDR-TB action plan, WHO European Region, 2011







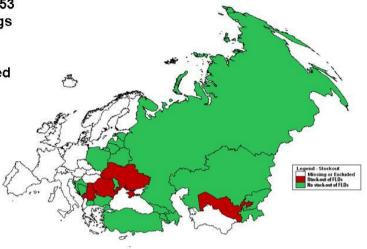


Member states with no stock-out of firstline TB drugs at any level, 2011

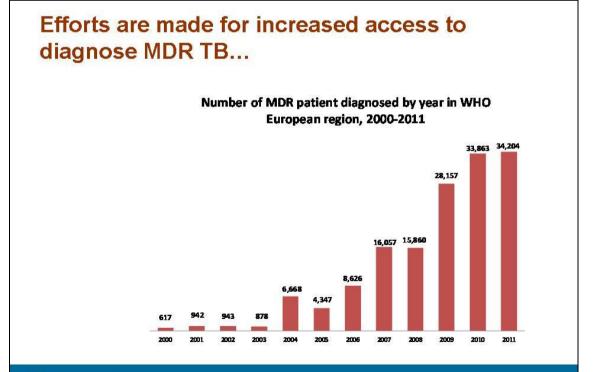
23 Member States out of 53 reported on first line drugs stock-out status;

18 Member states reported no stock-out;

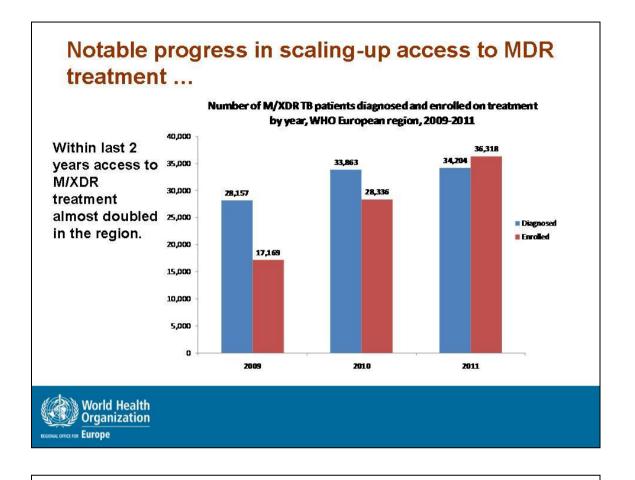
Stock-out reported in Romania, Montenegro, Serbia, Ukraine, Uzbekistan.







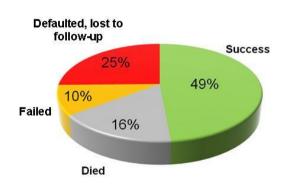




But...still far below to reach target of 75% of successful MDR treatment outcome

Treatment success varied from 16% to 74% among MDR-TB patients started on treatment in 2009 in the 12 MDR-HB countries of European region.

Treatment outcome of MDR TB patients started treatment in 2009, European region (n=12110)



Fourteen countries reported no data on outcomes.







Next steps

- Continuously and closely support the Member States in implementation of the Consolidated Action Plan;
- Prepare compendium of Best Practices
- Identify and address the social determinants of TB and M/XDR-TB
- Scale up the best practices and patient-centred ambulatory care;
- Strengthen country capacity in surveillance for producing reliable estimates of MDR-TB figures;
- Introduce rational use of new TB drugs;
- Develop interventions to move toward TB elimination in low TB incidence countries;
- Defining the role of surgery in TB and M/XDR-TB.



Conclusions

- Despite major efforts in rapid molecular diagnosis, there are still 2/3 of MDR-TB patients not diagnosed
- Treatment lengthy, expensive, difficult and with low success
- Ongoing substandard practices in Europe and particularly in EU with emerging extensively drug resistant TB
- Stock-out of medicines, vaccines and supplies even in EU
- TB and M/XDR-TB a serious public health threat with financial crisis and budget cuts but also due to rise of unemployment, stress and poor nutrition
- We need to join forces and learn the lessons from best examples like TB-MDR-TB epidemic control in New York.



Acknowledgements

WHO headquarters Dr Mario Raviglione and My team members in Copenhagen particularly Dr Andrei Dadu, and WHO country offices, Member States, NTP managers and partners

Thank you very much for your attention

Subscribe to our quarterly newsletter tuberculosis@euro.who.int



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Presentation by Ms Amy McConville



The Patients' Voice

Amy McConville
TB Action Group

Involving People Affected by TB in the fight against the illness

- TB Action Group (TBAG) is the only network of People Affected by TB in the UK and has been at the forefront of the development of the civil society response
- Established by TB Alert in 2008 to provide a unique voice to people in the UK who have been personally affected by TB and therefore have valuable insight in to how TB services are delivered

Involving People Affected by TB in the fight against the illness

- TBAG is increasingly becoming the first port of call for policy makers who need the patient perspective
- The actions of the patient advocates within TBAG are primarily focused on the following areas; providing peer support for people during their treatment journey; raising awareness of TB and advocating for improved TB care and prevention

People Affected by TB must be heard!



BCG: the most widely used tool to prevent TB around the world

- The BCG was introduced in 1953 contributing to the steady decline in TB deaths, among the UK-born population
- Research has shown that the BCG is most effective in early childhood and is usually given to babies to prevent serious forms of TB, such as TB meningitis
- The BCG currently plays an important part in reducing the risk of TB among vulnerable groups

UK BCG Immunisation Policy

- Pre-2005: Universal programme introduced in 1956, initially given to school children between ages of 13-14 years old, according to (then) disease pattern. Current policy remained unchallenged for decades.
- Post-2005: Targeted, evidence based programme, introduced by an independent committee, aimed at populations most at risk of exposure to TB.

(Green Book, Ch 32, tuberculosis, Dept of Health)

UK BCG Immunisation Policy

- Criteria for eligibility
- Babies and older children who are living in high incidence areas of the UK (annual rate of +40/100,000)
- Babies and older children who have grand/parents from countries where TB is endemic (annual rate of +40/100,000)
- Health care professionals and caregivers under the age of 35 who are vulnerable to exposure from TB due to their occupation

Why it is crucial to eliminate TB as a public health threat in Europe and beyond

- Each year, an estimated 9 million people world wide become ill from TB and at least 1.4 million people will die as a result – that's the equivalent of 8 tsunamis occurring each year
- TB is no longer a disease of the past; rates of TB in London have slowly risen by 60% over the last 25 years, with 9,000 new cases in 2011. These striking figures show that London has the highest prevalence of any major city in Western Europe – London is now known as the 'TB capital of Europe'

Why it is crucial to eliminate TB as a public health threat in Europe and beyond

- The current shortfalls with the BCG vaccination
- We are still using ancient tools to fight a 21st century disease - the BCG is the only preventative weapon to date, yet it is more than 90 years old!
- The BCG has a short life span of 15 years it is a common myth among communities that the BCG will offer life long protection, this poses a considerable barrier to accessing early diagnosis and treatment

Why it is crucial to eliminate TB as a public health threat in Europe and beyond

- Overall the BCG has a limited efficacy of 85% which further declines when administered in countries near to the equator, due to occurring environmental forms of TB mycobacterium but it is those countries which carry the highest burden of TB
- The BCG is not effective in protecting adults against the most common forms of the disease such as pulmonary TB, therefore it is weak in preventing the spread of the illness

Why it is crucial to eliminate TB as a public health threat in Europe and beyond

- The urgent need for new TB vaccines:
- It's vital that we develop TB vaccines that will protect against all forms of TB, including drug resistance which is emerging in all parts of Europe — at present, the treatment for drug resistant TB is lengthy, and carries an increased risk of toxic side effects
- A new vaccine would tackle the problem of increasing rates of TB-HIV co infection in Europe by developing a safe vaccine that can be given in children who are HIV-positive – this would enable more communities to live longer, healthier lives

Why it is crucial to eliminate TB as a public health threat in Europe and beyond

- Put quite simply ...
- ... Effective vaccines have an enormous potential to save millions of lives around the world ...
- ... They are vital key tools in the fight to prevent TB deaths ...

The story of one woman's personal experience

- The before, during and after
- Impact of delayed diagnosis of up to 2 and half years - 'frustration and subsequent relief through finally being able to identify illness'
- Implications of potential side effects 'fear of the drugs'
- Severity of illness and prolonged treatment journey with - 'no end in sight'

The story of one woman's personal experience

- Individual costs to the TB patient: Social, physical, emotional burden
- Loss of productivity / disrupted university education due to chronic health
- Feelings of isolation / disconnected from friends and family
- Sense of disempowerment / loss of control
- · Poor emotional health and wellbeing

The story of one woman's personal experience

- Social and psychological costs are not easily quantifiable in economic terms
- These types of costs are 'intangible' and include things such as pain, suffering, depression and self blame
- Additional costs are acquired such as extra food supplements, long term treatment costs, loss of earnings, etc

The story of one woman's personal experience

- The economic costs to the health system
- There are financial considerations of delayed diagnosis and further complications to the health system in countries in Europe
- Uncomplicated v Complicated
- A patient who does not experience delays in accessing diagnosis and treatment will have a relatively straightforward cure, leading to a greater cost effective outcome; as low as £1,100

The story of one woman's personal experience

- A patient in their most economically productive years, who requires extensive treatment for up to 2 years and surgical interventions will experience complex treatment costing the health system £10,000
- It's important to take in to consider the positive health benefits to the individual and the economy, to be gained from maximising wellbeing and reducing the social consequences of TB. It is cost effective and morally right to Invest in the health of all citizens!

How can we save 9 million lives on a global scale?

- Encourage the uptake of BCG in affected communities where its impact will be most effective
- Roll out safe, effective TB vaccines that can be widely used
- Hold to account renewed commitments to increase funding for vaccine research and development at the EU level

How can we save 9 million lives on a global scale?

 Create political champions to facilitate engagement and strong commitment from the global community to address the urgent need to prevent TB; and ultimately reduce the human cost and suffering from this illness

I want ZERO deaths and no more people sick with TB!



Presentation by Dr Ronald de Groot

Current Measles Outbreak The Voice of the Professionals

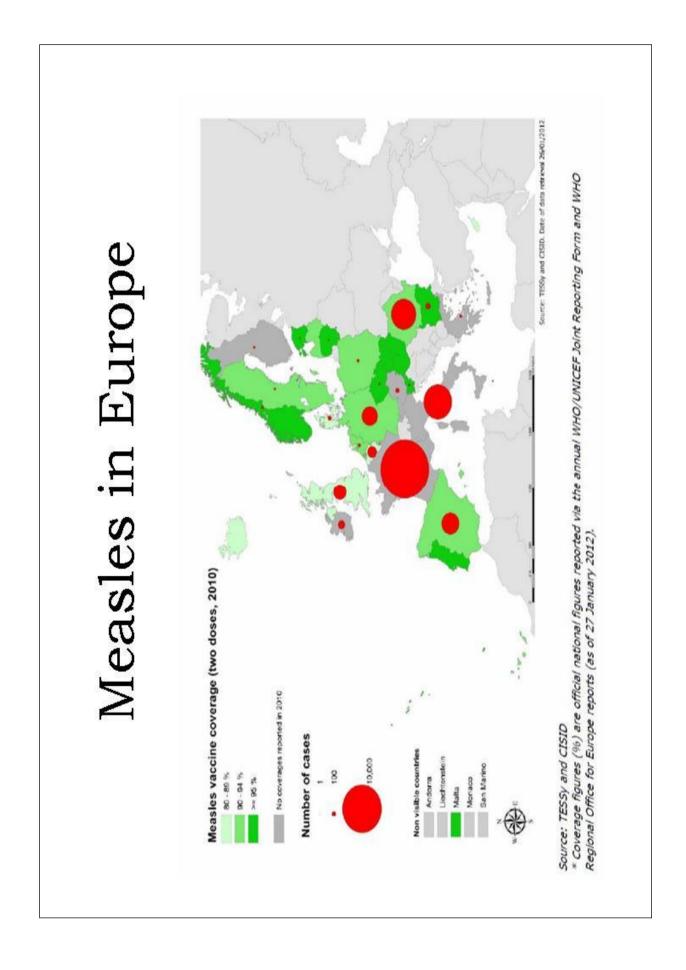


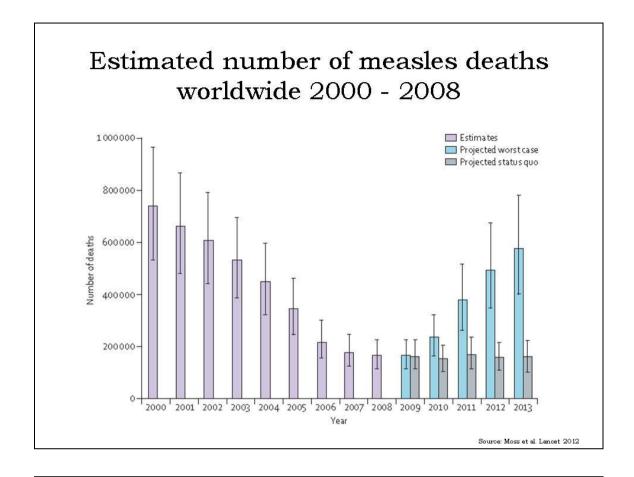
Ronald de Groot

President of the European Society for Paediatric Infectious Diseases Professor of Paediatrics, Radboud University Nijmegen, The Netherlands Member of the Health Council of The Netherlands Member of the NIP Committee of the Health Council of The Netherlands

Measles: background

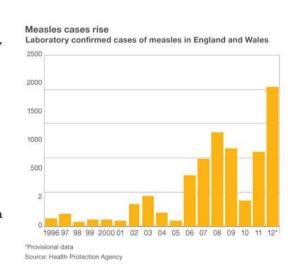
- Highly contagious disease, not only in children but also in adults, with a case fatality rate between 1:1,000 and 1:3,000 reported cases
- Infants < 9 months and immunocompromised individuals are at increased risk for severe disease
- Measles vaccination has reduced mortality worldwide from 873,000 in 1999 to 164,000 in 2008
- Failure to maintain high levels of measles vaccine coverage both in Europe and in other continents – has resulted in a resurgence of disease
- Immunization against measles with two doses of the MMR vaccine is highly effective and may result – assuming that vaccine uptake is >95% - in eradication of the disease

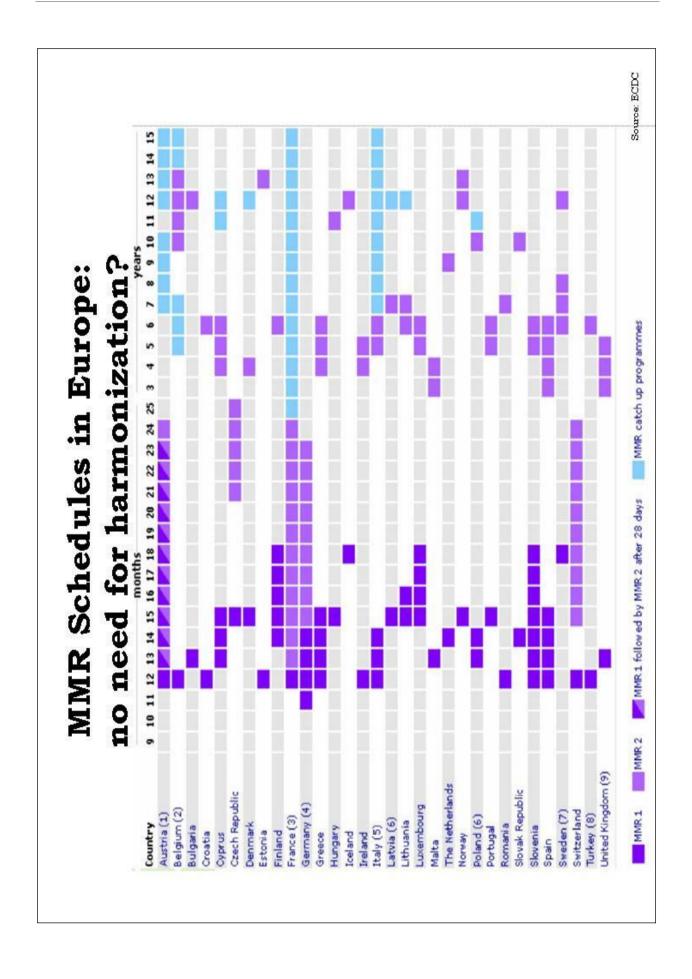


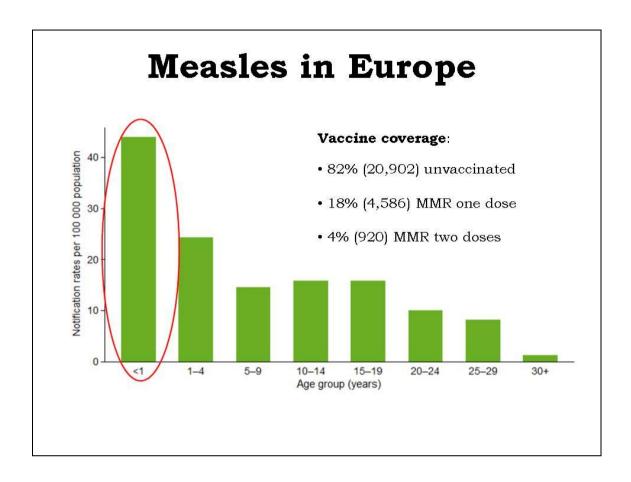


The current measles outbreak in England and Wales: an example

- ✓ In the UK, between 1990 and 2012 the uptake of the vaccination was impacted by a vaccine scare (the Wakefield story)
- ✓ In 2012 there were more than 2,000 cases of measles in England and Wales - the highest figures for two decades
- The measles outbreak is ongoing in the beginning of 2013 and causes substantial morbidity and even mortality
- ✓ The low vaccination uptake in the UK and many other countries indicates a failure in the public health system and needs immediate action by all stakeholders
- ✓ On April 25th the UK health authorities decided the immediate start of a catch-up vaccination program







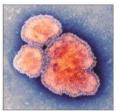


Outbreaks Spur Measles Vaccine Studies

Tracy Hampton, PhD

- · Recent measles outbreaks in the US and Europe
- 84% of US residents unvaccinated or unknown vaccination status
- · Increased importations of measles in the US
- High 2-dose vaccination coverage have limited spread of measles
- Outbreaks in Quebec are raising questions about effectiveness of measles vaccine schedule
- \bullet Many adults in the US get a $3^{\rm rd}$ dose when entering college
- 65% of Canadian cases were reported in individuals aged 10 – 19 years
- 66% of Canadian cases were unvaccinated, 24% had written proof of vaccination and 10% reported being vaccinated without written proof

Conclusion: The Canadian results, but also those of other countries, indicate that the large majority of the outbreaks is in unvaccinated individuals. However the high proportion of individuals who were previously vaccinated once or who were first vaccinated at an early age raises concerns regarding vaccine effectiveness.



Recent measles outbreaks are raising some questions about vaccination to protect against infection with this highly contagious virus.

Hampton JAMA 2011;306:2440-42

Conclusions (1)

- Outbreaks of measles are **resurging** in Europe and elsewhere
- Immediate action is necessary in the form of **catch-up vaccination programs** in European countries where the number of cases of measles is increasing
- Strengthening of **surveillance** is necessary to quickly identify cases and outbreaks
- Data from ECDC suggest significant differences between administrative and survey methods used to determine MMR vaccine coverage in European countries: coverage <95% is common
- The development of rapid point-of-care tests for measles is needed
- The continued progress toward the development of an ideal measles vaccine must be strongly supported

Conclusions (2)

- MMR vaccination schedules need to be **harmonized** within Europe:
 - Administration of the first dose at a very young age
 increases the risk for measles later on in life
 - Administration of a second dose is absolutely necessary to ensure longstanding immunity
 - The **optimal timing** of the second dose needs further study
 - Is there a need for a 3rd dose of MMR as is administered in the USA to adults entering college?

Conclusions (3)

- Keep the general public informed and engaged!
- **Collaborate** with health care professionals and (inter)national societies such as ESPID to **combat** the outbreak of infectious diseases like measles
- Engage **opinion leaders** from various fields on the importance of immunization
 - ESPID provides an existing network with key opinion leaders
- The lessons go beyond measles: in case of a local outbreak of a vaccine preventable disease, the uptake (= % people wanted to be vaccinated) will increase very abruptly due to the media coverage and sudden awareness

Conclusion (4)

- European consistency is a definitive "plus"
- ESPID is willing to play a role by issuing clear guidelines and supporting a strong and well- established scientific and healthcare network base



Presentation by Dr Andreas Schultz

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Why measles outbreaks are so scary? An ENVI committee hearing

Dr. Andreas Schultz, MD, DTMPH, MSc Doctors of the World international network

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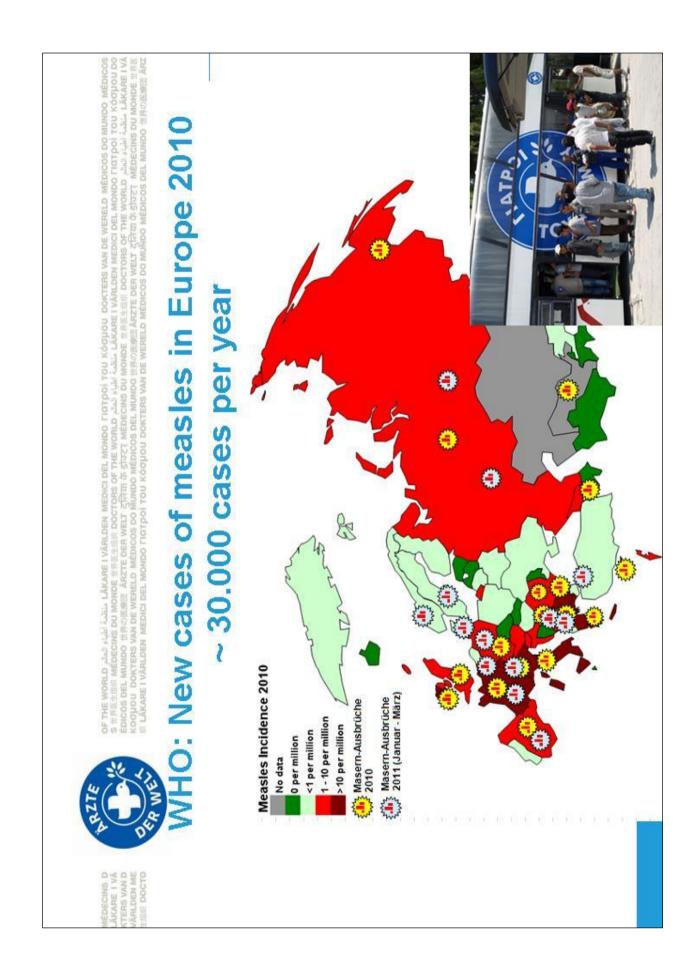
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Doctors of the World - who we are

- → A network across the EU offering service provision through 160 programmes (and 152 outside the EU)
- → targets in Europe: homeless people, drug users, sex workers, asylum seekers, Roma, elderly, destitute EU citizens and third-country undocumented migrants
- → systematic data collection on the social determinants of health
 → 20% fixed / 80% mobile units for harm reduction realized with professional volunteers

SECIA SECIA





Importance of vaccination against measles

- → 85% of measles cases across Europe were unvaccinated (ECDC)
- → highly infectious, pot. severe consequences
- frequent hospitalization for adults
- pneumonia, otitis media, encephalitis
- irreversible neurological damage, death
- malnourished (Vit A, Zinc) are at high risk



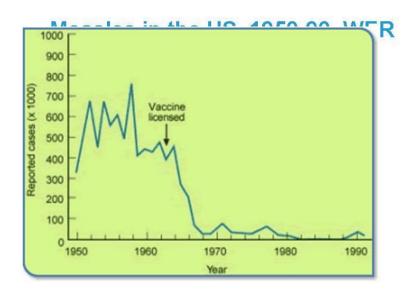
→ combined MMR vaccine is safe, effective and lifelong for most (98% immunity after 2 doses - 95% population coverage needed to eradicate measles)



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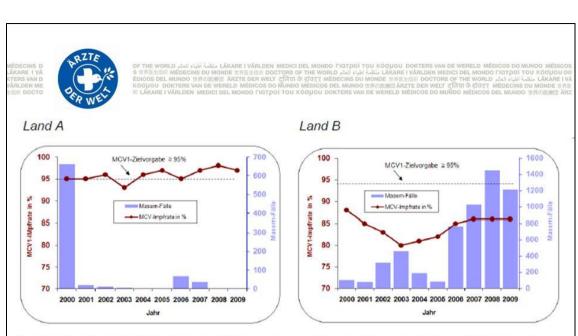
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WHO regional director for Europe

- Human costs of measles (avoidable deaths and disablilities) do not allow to have low vaccination rates. It makes no sense – economically or medically – to await another outbreak if we have the chance to eliminate the disease
- 1 measles case (Germany) ~ € 520 for d & t, per case, a child misses ~ 9 schooldays and every 10th parent loses a working day; 1 epidemic ~ 300 children
- Italy 2002/3, direct measles related costs for the health system €17,6 to 22 Mio. This equals the cost of vaccinating 1.9 Mio children including vaccination agains rubella and mumps. The following 5154 hospitalizations cost € 8,8 Mio



(Quelle: Monatliche Berichterstattung zu Überwachung und Immunisierung in Bezug auf Masern und Röteln über das Meldeformular von WHO/UNICEF)

It makes little sense to go under 95% - Consequently it makes little sense *n* o *t* to pay attention to these (risk) groups



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Barriers to vaccination – MdM field observations

- → financial barriers the example of Greece today, many Greek families do not have health coverage anymore (rising unemployment) and consequently have to pay for vaccines. The majority cannot pay: about 1.500€ to follow the national immunization schedule for a child up to 6 years old, including medical consultation fees...)
- even insured families frequently need to pay (but they cannot)







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Barriers to vaccination – MdM field observations

→ within the last six months, MdM Greece vaccinated 1.091 children from 2 months to 14 years but lack of means to cover all the needs!



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OF THE WORLD は LAKARE I VĀRLDEN MEDICI DEL MONDO FIGTODI TOU KŌGIJOU DOKTERS VAN DE WERELD MÉDICOS DO MUNDO MÉDICOS ま 専用を増加 MEDECURIS DU MONDE 世界を注意 DOCTORS OF THE WORLD よんはARARE I VĀRDEN MEDICI DEL MONDO FIGTODI TOU KŌGIJOU DO ÈDICOS DEL MUNDO 世界の悪態部 ĀRZTE DER WELT 式合理する 賞づて、MÉDECINS DU MONDE 世界医生態 DOCTORS OF THE WORLD よんしましました KOGIJOU DOKTERS VAN DE WERELD MÉDICOS DO MUNDO MÉDICOS DEL MUNDO 世界の悪態語 ĀRZTE DER WELT 式合理する MEDECINS DU MONDE 世界 ME LAKARE I VĀRLDEN MEDICI DEL MONDO FICTODI TOU KŌGIJOU DOKTERS VAN DE WERELD MÉDICOS DO MUNDO MÉDICOS DEL MUNDO 世界の悪態 ĀRZ

lannis is a 13-year-old boy who lives with his mother and his younger brother in Perama. They belong to the Roma community. His mother has no income and they have no relatives to help them. Currently they are hosted in a small flat without electricity and they receive food items from MdM's Polyclinic. lannis cannot go to school anymore because he hasn't been vaccinated and because the director doesn't want him in the school.

"I want to continue school, I like reading... I can't understand why the teacher doesn't accept me at school; all my friends are in school now". His mother told us "I don't know what else to do, the head teacher told me that lannis doesn't have a valid health booklet, I don't have the money to buy the necessary vaccines." A paediatrician from MdM examined lannis and administered the necessary vaccines. Our social worker spoke with the head teacher and explained to her that she was obliged to enrol him in school. Finally, lannis managed to go back to school. "I'm so happy to have books, thank you all so much!"

A misunderstanding of a good instrument leads to exclusion – mass vaccination?





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Barriers to vaccination - MdM field observations

- → 60% of our patients (MdM survey 2012 across 14 European cities) do not know where to receive vaccination...
- → legal and administrative barriers
- → language barriers
- → focus on day to day survival instead of prevention
- → discrimination of specific population groups
- → many people without vaccination booklet that remember "having had at least one shot", unawareness about how many shots are required (insufficient communication by health professionals)





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Myths on Roma and vaccination

- MdM survey in Nadezhda in 2009 (Sliven, Bulgaria) by Roma community mediators 92.8 % of the women in the questionnaire answered that vaccines "are good and we trust them"
- MdM survey among Roma in Brussels (2013): **98%** of mothers said they would accept their children to be vaccinated ("but where?")
- the Roma we met are all sedentary but forced to go from one place to another by the police





OF THE WORLD (A July) 上近人名称目 (VĀRLDEN MEDICI DEL MONDO FIOTOPI TOU KOGIDU DONTERS VAN DE WERELD MÉDICOS DO MUNDO MÉDICOS DE SERBÉBÜRE MÉDECIORS DU MONDO ESTADOS OF THE WORLD SEL LÁRARE IVÂNLDEN MEDICI DEL MONDO CITATO I TOU KÓGIDU DO ÉDICOS DEL MUNDO 世界の医療団 ĀRZTE DER WELT 『石田山 中国 (A July) 上近人 LÁRARE I VĀRLDEN MEDICIOS DEL MUNDO DONTERS VAN DE WERELD MÉDICOS DE MUNDO MÉDICOS DEL MUNDO 世界の医療団 ĀRZTE DER WELT 『石田山 中国 (A July) 上近人 LÁRARE I VĀRLDEN MEDICIOS DEL MUNDO MEDICOS D

Barriers to vaccination - MdM field observations

- → consequences of restrictive policies
- e.g. German social welfare centers have a duty to denounce undocumented patients → although vaccination is theoretically accessible, many undocumented migrants fear being reported
- e.g. **Belgium**: theoretical (legal) access to healthcare for undocumented migrants but many complex administrative barriers → only 13,3% of Roma minors had an up to date vaccination booklet (2013 Brussels survey) despite free vaccination offer in preventive childcare services <7years old (32% of children had already had measles)

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Barriers to vaccination – MdM field observations

- → consequences of restrictive policies
- e.g. France violent crackdowns of Roma camps cause public health risks (e.g. vaccination campaigns are stopped, booklets get lost, interruptions of medical follow-up) but ironically sanitary risks is often the pretext used...









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"It was more than a year ago during the outbreak of measles. My wife Magdalena who was 16 had high temperature, nausea and unwillingness to eat. Pimples appeared on her face and all over her body. I took her to a doctor: she had measles.

She was not the only one in the neighborhood. There were already many kids who got sick from measles, too. The doctor prescribed some pills. The same day it became worse. She started to wriggle and she had very high temperature. In the morning I took her to the hospital and asked them to hospitalize her. The doctors told me that there was no free space in the hospital. They gave an injection and said that she will get better and we should go home. But shortly after we got home she started shaking again with high temperature.

Shortly after, my wife died. I don't understand why she was not hospitalized. It was visible that she was in very bad condition. It seems they don't care much about us since we are Roma. It is like they want to get rid of us."

Mr. A. age 18, Roma, citizen of Bulgaria, living in Nadezhda, the Roma neighbourhood in the city of Sliven (Bulgaria). December 2011.





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Recommendations towards Member States

- → full access to information and to vaccination for all vulnerable people. We see them as part of the society which suffers from the (involuntarily) unvaccinated
- → implement opinions of the EU Fundamental Rights Agency (FRA) on access to healthcare for undocumented migrants: **everyone** can access **all forms of essential preventive and curative healthcare** (basic human right)
- inform health professionals about the right to access healthcare
- → a comprehensive, in-depth prevention work requires accessible, lowthreshold primary care services (vaccine administration by the family doctor works best)

MÉDECINS D LÁKARE I VÁ KTERS VAN D VÁRLDEN ME EMIR DOCTO



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"When I started going to school here it was very difficult. I had to go and see an official doctor from the school, he asked me for my vaccination but we didn't have any vaccination cards. When we left Romania, we could not take everything with us and my mother doesn't know if I am vaccinated. The school told us that I need vaccination for measles, polio, diphtheria and tetanus, but they did not tell us where to get them without health insurance. I was looking forward to go to school and I was afraid that I would not be able to go.

The doctor at the MdM clinic told me after a blood test that it was good that I came here as I wasn't vaccinated at all. So my sister and me got all the vaccinations at the MdM clinic and I started going to school."

Ms S., age 8, living in Germany for the last 3 years January 2012.



MÉDECINS D LÁICARE I VÁ KTERS VAN D VÁRLDEN ME EHIST DOCTO

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Recommendations towards Member States and the Commission

- → monitor the accessibility to national immunisation schemes & paediatric care for all children up to 18 years
- → put ECDC recommendations into practice (technical report on MMR vaccination coverage 2012)
- evaluate the long-term impact of proposed austerity measures on health (systems)
- → times of crisis require more investments in health, not less (rationalisation instead of rationing) WHO





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Thank you

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OF THE WORLD .LEAKARE! VARIDEN MEDICO DEL MONDO ΓΙΟΤΡΟΙ ΤΟυ ΚΌΘΙΡΟυ DOKTERS VAN DE WERELD MÉDICOS DO MUNDO MÉDICO S ΨΕΘΕΨΕΙΜΕ ΜΕΣΙΚΑΙ ΕΙΚΑΚΕΙ ΙΚΑΙ ΕΙΚΑΚΕΙ ΙΚΑΙ ΕΙΚΑΚΕΙ ΙΚΑΙ ΕΙΚΑΚΕΙ ΙΚΑΙ ΕΙΚΑΙ ΕΙΚΑΚΕΙ ΙΚΑΙ ΕΙΚΑΙ ΕΙΚΑ

Symptome Virusinfektion. Zunächst untypische

Entzündungen im Nasen-Rachen-Raum,

Entzündung der **Bindehaut**, trockener Husten und Fieber. Koplik-Flecken in der Mundschleimhaut. Nach 3 - 5 Tagen Fieberschub und punktförmigen Rötungen auf der Haut beginnend hinter den Ohren. Ausbreitung über den ganzen Körper. Rückbildung nach ca. 3 Tagen. Schuppige Haut.

Inkubations- 9 - 12 Tage

zeit

Ansteckungs- 3 Tage vor Beginn des Ausschlags bis zu seinem

gefahr Verschwinden.

Immunität Lebenslang. Vorbeugung Impfung.

Therapie Fiebersenkende Maßnahmen bei hohem Fieber,

Bettruhe, viel Flüssigkeit. Behandlung

begleitender Infektionen. Es besteht Meldepflicht

nach dem Infektionsschutzgesetz.

NOTES



DIRECTORATE-GENERAL FOR INTERNAL POLICIES



Role

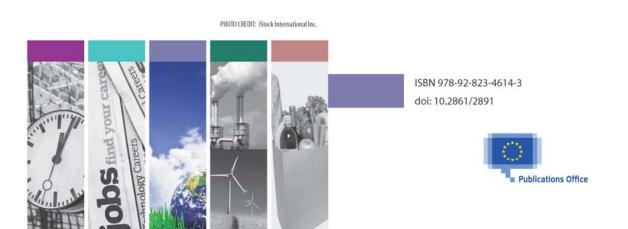
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