Vaccine-preventable Diseases and Immunization programme

Programme report and future initiatives 2001–2005
ABSTRACT

Vaccine-preventable diseases remain an important cause of avoidable disease morbidity and mortality among children the WHO European Region. Although immunization programmes in Member States have been integral parts of their public health services, the success of these programmes has led to the perception that continued strong support might not be necessary to maintain their strength.

The challenges facing immunization programmes in the Region include: 1) access to vulnerable groups of children, who may have very little contact with primary health care services; 2) changes to primary health care services in many countries that can affect who delivers vaccines and the reimbursement for this service; 3) availability of underused vaccines against additional diseases, which can further improve the health status of children but for which national policy makers require detailed cost justification; and 4) frequent appearance of messages by groups opposed to vaccination that are effectively communicated through the media and the internet.

The Vaccine-Preventable Diseases and Immunization programme (VPI), of the WHO European Region, has developed a number of important initiatives to support Member States to strengthen their immunization programmes and these are described in this report, as well as the progress that has been achieved to date.
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Introduction

Immunization saves lives and is considered to be one of the most cost-effective public health interventions available, demonstrated by numerous studies. Immunization has also been widely accepted as one of the great global public health success stories and an essential component of primary health care to protect children from unnecessary death, disease and disability due to highly contagious diseases.

The United Nations Millennium Development Goals (2000) and discussions during the United Nations’ General Assembly Special Session for Children (2002) indicate immunization not only an effective intervention to reduce death and disease in children under five, but a strategy to help address the poverty gap in high risk and vulnerable populations. Every child has the right to be protected against vaccine-preventable disease and preventing disease through immunization is beneficial, not only for health but also for economic and social reasons at global, national and community level. It increases the security of all populations against disease, reduces inequalities and provides an important mechanism to contribute to poverty reduction.

Effective immunization programmes have been an integral part of public health services in the Region for decades. The Expanded Programme on Immunization (EPI) was established globally in 1974 to protect child health by routine immunization against diphtheria, tetanus, pertussis, poliomyelitis, measles and tuberculosis. However, only ten years ago, hundreds of thousands of children in the European Region still suffered every year from these diseases and subsequent complications. Today the Regional immunization effort has been expanded to include underused vaccines including hepatitis B, *Haemophilus influenzae* type b (Hib), mumps and rubella.

In countries where there are well-established immunization services, the vast majority of the target population is reached with immunization. One of the great achievements and a historic milestone in the Region was the certification of the Region as Poliomyelitis-free in June 2002. Building upon this success and the improvements in national infrastructure, substantial progress has been achieved towards the targets for 2010 of interrupting indigenous measles transmission and preventing congenital rubella infection, identified in the Strategic plan for measles and congenital rubella infection in the WHO European Region. Member States have been implementing the key strategies identified in this plan. Other major areas of work including advocating for and improving the quality and safety of immunization services and strengthening surveillance systems, supported by laboratory networks, are showing good progress.

Scientists in the European Region are at the forefront of vaccine research however, ironically, funding levels for health care from government sources are extremely low in some central Asian republics and the Caucasus, sometimes as low as in sub-Saharan countries of Africa. Health care services are stretched to the limits in a number of countries in the European Region where the most basic supplies are lacking and the health care staff is paid very poor salaries. State funding is not even sufficient to ensure free services for vulnerable groups. Access to health care is a priority issue for the Region, since many people are too poor to afford user fees or insurance, thus the role of the State as a health care provider should be strengthened.

With regard to immunization, one of the main issues of concern remaining is access to vulnerable groups of children who may have very little contact with primary health care services,
either due to geographical, cultural, or ethnic reasons. We know that the health gap between the eastern and western parts of the Region is increasing; Immunization is a key area where an egalitarian approach to improving health and well being among the population can be demonstrated. The ongoing changes in primary health care services in some countries of the Region may adversely affect the provision of basic vaccination services and thus the maintenance of population immunity at the necessary levels to prevent outbreaks of disease. A new challenge has also arisen in the wake of the successful vaccination programmes: allegations – with no scientific support – which are causing doubt about the safety of some vaccines are threatening public confidence and leading to declining awareness and attention to the importance of vaccination.

There is an increasing demand from the European Member States for technical guidance and support due to the fact that vaccine-preventable diseases still pose a serious health risk particularly to children, but also to the general population. In addition, with developments in science and technology, there are a large number of new vaccines that are underused and must be made available to countries.

Placing individuals’ health gain and human rights at the centre of attention is a key to achieving change in immunization services. Indeed, a strong immunization programme can contribute to stronger overall health by providing a structural foundation for national health systems. Governments can use immunization models as examples of good practice to improve management, planning, forecasting, evaluation, inventory control, logistics systems, community outreach, provider training and patient outreach.

In order to maintain the current level of achievement and to move further towards new disease control initiatives, many challenges remain, requiring intensive work.

The goal of the Regional Office’s Vaccine-preventable Diseases and Immunization programme (VPI) is to reach and maintain high levels of child immunity – at the appropriate age and at the recommended doses – to protect them against death and illness from vaccine-preventable diseases. VPI pays special attention to children in “hard-to-reach” and vulnerable groups.

To achieve this goal the Regional Office supports Member States in strengthening their control of infectious diseases through partnerships with them, with international organizations and with bilateral agencies to achieve the following objectives to:

- strengthen the existing infrastructures in the countries;
- improve the quality and safety of routine immunization services;
- use every opportunity to reach untreated children with immunization;
- maintain high quality disease surveillance standards backed up with quality assured regional laboratory networks;
- advocate for and support the introduction of new and underused vaccines and technologies; and
- promote the use of high quality data to support problem-solving programme management.

1. Immunization systems

1.1 Routine immunization services

By the year 2003, the reported immunization coverage rates in the Region had increased to over 90% for all standard EPI antigens (BCG, three doses of OPV, three doses of DTP and measles-containing vaccine). However, regional and district data show unequal vaccination coverage in different parts of countries and low coverage rates in some parts of the countries. Studies undertaken by the World Bank\(^1\) indicate large disparities in full immunization coverage between rich and poor communities. On average, of forty two countries surveyed, full coverage was 25–30 percentage points higher in the richest than the poorest quintile of the country. The difference was 41 percentage points for Turkey. Furthermore, one of the principle findings of the study was that as vaccine-preventable diseases are generally thought to be concentrated among the poor, and there is a significant mismatch between the population groups with the greatest burden of disease and the population groups most frequently served by immunization programmes.

Work also needs to be done to improve methods for determining immunization coverage. Problems relating to accuracy of data exist. Low vaccination coverage is related to the problem of reaching specific population groups, as well as the timely immunization of newborns through innovative approaches such as organizing special sessions and outreach campaigns. Figure 1 below shows the coverage with two doses of measles-containing vaccine (MCV2). Based on the data received at the Regional Office reported vaccination coverage rates vary widely between countries and within countries, meaning that population groups susceptible to disease exists across the Region.

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\(^1\) Davidson R. Gwatkin et al., Immunization coverage inequalities, an overview of socio-economic and gender differentials in developing countries. September 2001. Extract from a series of country studies undertaken by the World Bank’s thematic group on health, nutrition, population and poverty.
Various initiatives to address these issues are ongoing. WHO has developed the Reaching Every District (RED) strategy specifically aimed at overcoming the most common barriers to improving access to immunization services. The strategy aims to achieve sustainable and equitable access to quality immunization services for every infant. The focus of RED is on planning at the subnational administrative level appropriate for the country. District-level planning, follow-up and supportive supervision are key to RED. Other initiatives also exist in priority countries. WHO in collaboration with the United States Centers for Disease Control and Prevention (CDC), the Children's Vaccine Program at the Program for Appropriate Technologies in Health (CVP/PATH) and the United States Agency for International Development (USAID) have implemented projects to strengthen information management systems and monitoring district-level performance. These have had a substantial impact on building country capacity and have contributed to the progress in strengthening immunization services in the countries of greatest need. Continued improvements have been made to the WHO Centralized Information System for Infectious Diseases (CISID), a web-based data-entry, collation, analysis and monitoring system. Finally, many training and briefing activities have been carried out including mid-level managers’ training and immunization in practice in additional to regular national programme managers meetings.

1.2 Safety of immunization

Safety is an issue of utmost importance in maintaining public confidence and thereby sustaining high immunization coverage. More and more frequently, countries have to face negative press and immunization managers are caught in difficult situations regarding the quality of vaccines and potential adverse events. Support from the Regional Office has been in line with the regional plan to provide assistance to priority countries and to strengthen their capacity to optimize the safety of immunizations. To ensure the use of quality-assured vaccines, assistance was provided for vaccine procurement and regulation, as well as for cold chain and logistics, while to maximise the safety of patients, providers and the community, support was provided for the safety of injection, waste management and adverse events following immunization (AEFI) surveillance and response.

a) National regulatory authorities and vaccine procurement

The assessment of national regulatory authority (NRA) performance in implementing quality assurance is a continuous process and training of national staff through the Global Training Network (GTN) has proven a very valuable tool to improve capacity.

With regard to vaccine procurement, major progress has been noted in the past decade in securing the provision of vaccines for national immunization programmes. However, countries must now adapt to changes in the global market and find ways to secure the provision of vaccines at an affordable price. An inter-country meeting on Vaccine Procurement for 15 self-procuring countries of central and eastern Europe, Turkey and the newly independent states (NIS) was held in 2002. Assessments of vaccine procurement mechanisms were conducted in four countries and this has helped to identify and address the challenges faced in those countries.

b) Vaccine and cold chain management

The process of application to the Global Alliance for Vaccines and Immunization (GAVI) Vaccine Fund (VF) has reinforced the institution of monitoring the quality of the cold chain. Eleven countries in the Region are eligible for support through this mechanism (Albania, Armenia, Azerbaijan, Bosnia and Herzegovina, Georgia, Kyrgyzstan, Republic of Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan) and support has been used in part to upgrade equipment. The Regional Office is part of the major global effort to redefine policies and strategies for the introduction of new technologies to address cold chain and logistics related issues. A new initiative, the Effective Vaccine Store Management package, which links assessment, training and capacity building, was launched at an inter-country cold chain training workshop in April 2003). Two assessments of national cold stores
have since been carried. In addition, specific training on vaccine and cold chain management for provincial EPI managers was conducted in the Russian Federation.

**c) Injection safety and health care waste management**

Following the development of an assessment tool for the safety of injections, 15 countries in the Region, with support from the Regional Office, evaluated their performance in this area. The results of these assessments highlighted weaknesses in injection practices and health care waste management that need to be addressed through policy development, improved communication and supervision, and the implementation of supplies distribution systems. Eleven GAVI-eligible countries were given the possibility of applying for support from the Vaccine Fund to strengthen their safety of injection programmes. A pilot project on the use of new technologies (needle removers) and on “recycling” the plastic of syringes was launched in one country. Finally, experience gained through the measles immunization campaigns has shown that to ensure immunization safety, special attention and additional effort has to be placed during the campaign preparation phase.

**d) Adverse events following immunization surveillance and response**

Almost all NIS, central and eastern European countries and Turkey have instituted an adverse events following immunization (AEFI) surveillance system. The quality of reporting and analysis of information varies and therefore needs to be assessed. The GTN courses on AEFI surveillance have had a major impact in participating countries. A Russian language AEFI training course was organized at the Tarasevich Institute in Moscow (April 2004), which will help to enhance the quality of these systems throughout the NIS.

The Vaccine Safety net (VSN) project is being developed in collaboration with WHO headquarters. The objectives are to identify and link websites that have met certification criteria established by the Global Advisory Committee on Vaccine Safety. Creation of this network will improve the availability of information on immunization safety and provide a mechanism to identify and quickly address emerging concerns. Certified websites in the Region will be available in English, French, German, Russian, Italian, Spanish and Swedish from the VPI website [www.who.euro.int/vaccine](http://www.who.euro.int/vaccine). Work will be done to further expand this Regional network to include other languages of the Region.
1.3 Introduction of new and underused vaccines and the Global Alliance for Vaccines and Immunization

The Regional Office has supported the Member States by providing mechanisms and tools to expand the number of vaccines offered through national immunization delivery services, assisting in assessing opportunities, disease burden, cost effectiveness and impact of new vaccine introduction, and identifying needs and providing technical guidelines in addressing barriers for a successful implementation.

a) Hepatitis B

Immunization against hepatitis B has been introduced successfully in the Region, addressing a situation that previously resulted in 90,000 chronic infections and 22,000 deaths. In 2003, 43 of the 52 Member States in the European Region introduced hepatitis B vaccine into their immunization programmes, of which 26 targeted newborns, 12 targeted infants and five targeted older children or adolescents. Some countries combine newborn/infants immunization with immunization of older children or adolescents. Nine countries have not introduced universal immunization against hepatitis B. The Former Yugoslav Republic of Macedonia included hepatitis B vaccine in their national immunization schedules and plans to start hepatitis B vaccination in late 2004. Eight remaining countries (Ireland, Netherlands, United Kingdom and the Nordic countries) perform selected immunization against hepatitis B, target high risk groups combined with screening of pregnant women.
Thirty-two countries submitted their reports with data on hepatitis B immunization coverage in 2003. According to data reported to WHO Regional Office for Europe, the Regional immunization coverage rate with three doses of hepatitis B vaccine (HepB3) was 67% in 2003 compared to 64% in 2002, 48% in 2001 and 40% in 2000. These figures are derived using the total regional population of children below one year of age as the denominator and includes children in countries without universal immunization programmes against hepatitis B. Many countries achieved high levels of HepB3 coverage – at least 19 countries reported HepB3 rates of 90% and over. The average immunization coverage rate reported by countries with newborn and infant immunization with was 77% in 2002 and 83% in 2003.

A post-introduction evaluation of hepatitis B vaccine and data gathered from Member States indicated major achievements as; the ability of countries to offer hepatitis B vaccine, free of charge to infants and newborns and to some other high risk groups. Political commitment, high public demand, advocacy and surveillance systems capable to identify major risk groups were also seen as important achievements.
b) *Haemophilus influenzae* type b

Analysis of data from over 70 studies performed in the countries of the European Region, published by WHO in 2002, showed a higher incidence of *Haemophilus influenzae* type b (Hib) meningitis in children under 5 years of age in Western Europe. A lower incidence was observed in countries of CEE. Only one NIS (Russian Federation) performed a Hib study which showed a relatively low incidence of Hib meningitis.

To obtain more information on Hib disease burden in the Region, rapid assessments were carried out in Albania in 2001, Kyrgyzstan and Uzbekistan in late 2002, Armenia, Republic of Moldova and Ukraine in 2003 and Bosnia and Herzegovina in July 2004. A summary of results is presented in table 1 below.

<table>
<thead>
<tr>
<th>Country</th>
<th>Hib meningitis per 100 000 &lt; 5 years old</th>
<th>Total annual estimated Hib cases</th>
<th>Total annual estimated Hib deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albania (2001)</td>
<td>15</td>
<td>366–800</td>
<td>54–74</td>
</tr>
<tr>
<td>Uzbekistan</td>
<td>4–22</td>
<td>139–750</td>
<td>15–78</td>
</tr>
</tbody>
</table>

Thirty-one countries of the European Region, mainly in western and some countries in central and eastern Europe, including Croatia, Czech Republic, Hungary, Latvia, Lithuania, Slovakia and Slovenia, implemented Hib immunization as part of their national programmes. Bosnia and Herzegovina and Estonia introduced immunization with Hib vaccine in some of their territories. The major barriers for the introduction of immunization against Hib in many countries of the NIS and some eastern European countries are:
• the relatively high cost of Hib vaccines
• the inadequate evidence on disease burden
• the uncertain sustainability of the national immunization programme.

The average regional immunization coverage rate with three doses of Hib vaccine (Hib3) according to data reported to WHO was 41% in 2003 compared to 42% in 2002, 40% in 2001 and 38% in 2000. These rates are estimated using the total Regional population of children below one year of age as the denominator.

Twenty four countries reported Hib3 immunization coverage for 2003. The average immunization coverage rate reported by those countries was 92%. Eighteen countries had coverage of 90% and over and four countries had coverage rates between 80% and 90%.

c) Global Alliance for Vaccines and Immunization

The Global Alliance for Vaccines and Immunization (GAVI) was launched in 2000 as a partnership of international organization, national governments, vaccine manufacturers, research institutions and donor organizations. GAVI’s goal is to bring effective preventive health care to the world’s most vulnerable populations – young children living in poorest countries with the GNP of below US$ 1000 per capita.

Through its financial arm, the Vaccine Fund (VF), GAVI provides considerable financial resources to countries to purchase vaccines and other supplies and to support the operational costs of immunization.

Eleven countries in the Region receive support from the GAVI/Vaccine Fund; Albania, Armenia, Azerbaijan, Bosnia and Herzegovina, Georgia, Kyrgyzstan, Republic of Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan. The combined population of these countries is 118 million, with 14 million infants (under 1 year of age).

The European Regional Working Group (RWG) for GAVI was established in November 2000 to coordinate activities and respond appropriately to country needs. The main purpose of the RWG is to optimize the efficiency of support provided by GAVI partners to the immunization programmes in the European Region through a formal and coordinated structure.

The RWG for GAVI identifies national immunization needs through programme monitoring, assessment and evaluation with regard to strengthening immunization services, building country capacity for the introduction of new and under-used vaccines such as HepB and Hib vaccines and improving injection safety. The RWG also coordinates GAVI partners’ support and activities to eligible countries and reviews operational issues relating to the GAVI initiative within the Regional framework.

The European Regional Working Group for GAVI includes representatives from WHO, United Nations Children’s Fund (UNICEF), World Bank, CVP/PATH, Viral Hepatitis Prevention Board (VHPB), USAID, CDC, GAVI Secretariat and the VF.

Regular meetings were held in 2003–2004 where the members discussed the status and coordination of activities relating to national financial sustainability plans and process; new GAVI policies and their implications on working with countries; the preparation of annual progress reports; and the future of GAVI support and partnerships in relation to the sustainability of national immunization programmes.
1.4 Surveillance, assessment and monitoring

The quality of data collection and processing has been reinforced through the use of a modernised website providing Member States with data entry and validation but also customised feedback in the form of tables and graphs. Both the data flow and databases have been standardized and consolidated allowing for a consistent analysis of information at national and subnational level.

The main focus of the routine surveillance remains acute flaccid paralysis (AFP) reporting and polio laboratory weekly surveillance, diphtheria monthly surveillance in newly independent states and an enhanced measles surveillance strategy encompassing epidemiological notification, laboratory network and outbreak reporting. Monthly measles reporting increased from 49% in 2002 to 67% in August 2004. Some 40% of Member States currently report measles data online. They receive a short feedback message whenever they submit information in addition to the updated reports and queries available online and the standard set of newsletters.

The annual WHO/UNICEF joint reporting form data collection on vaccine schedules, coverage and immunization system indicators, was fully coordinated with UNICEF and now allows for faster routing of information and increased validation of the consistency of data. The preliminary analyses of the 2003 data were available very early in 2004 enabling the Programme to identify priority areas of work for each country. Customized data sets are now maintained enabling national counterparts, VPI staff and consultants to use the latest information on national vaccine preventable disease epidemiology and key policy data whilst on mission – this saves much time and effort in the field. This evidence-based approach for decision making is promoted to Member States to ensure optimal use of resources.

Concerning the district level management approach to improving immunization service delivery locally, a project involving Belarus, Ukraine and Moldova is making good progress towards reforming immunization monitoring and reporting systems. The working groups in each country have developed a standard set of key indicators calculated with standard definitions on a monthly basis at the district level. The Reaching Every District (RED) approach in Armenia, Azerbaijan, Georgia and Tajikistan has provided quarterly analysis of subnational immunization coverage indicators at all levels. The approach has shown good examples of improved identification of areas for improvements.

2. Accelerated disease control

2.1 Diphtheria

In the 1990s there was a resurgence of diphtheria cases in the NIS and Baltic states (see Figure 5). The numbers increased to 19 604 in 1993 and to 47 869 in 1994 and finally reached a peak of 50 434 in 1995. With the prominent strain of *C.diphtheriae var gravis* at the beginning of the epidemic, the case fatality rate was very high (more than 20%) in some countries, and a high proportion of cases were among adolescents and adults.

The WHO Regional Office for Europe and its partners led a coordinated response, with mass immunization campaigns covering majority of adults, thus preventing an estimated 20 000 deaths. Since the end of the 1990s, after outbreak response efforts took effect, diphtheria incidence dramatically declined and remains low. The number of cases reported in 2002 was 1 189 (0.14 per 100 000) and in 2003 the number was 897 (0.1 per 100 000). Monthly monitoring of cases among NIS and Baltic states has proven an efficient tool to take appropriate and timely action (preliminary reports from 69% of reporting countries indicate a total of 102 cases as of 1 October 2004). Diphtheria incidence is still higher in Latvia and the Russian Federation, compared to other countries, and as such, still requires constant attention.
2.2 Polio eradication

The year 2004 marks the second anniversary of polio-free status which was declared on 21 June 2002 as a result of the massive poliomyelitis eradication initiative, coordinated by the Regional Office, in partnership with the CDC, USAID, UNICEF and Rotary International. Political commitment to the goal was established, thus ensuring the intensive activities for AFP surveillance and supplemental immunization activities were fully supported. An international mass immunization activity named Operation MECACAR (after the geographical areas targeted in the eastern Mediterranean, the Caucasus, and the central Asian republics) was conducted from 1995–1997. Due to the success of the MECACAR initiative a similar model will be developed for Measles and Rubella in the coming years. This regional effort continued until the 200 annual cases of poliomyelitis (reported by Member States in the early 1990s) dropped to zero. The current status of polio eradication initiative in the Region was reviewed at the last Meeting of the Regional Certification Commission held in Copenhagen (June 2004). The Commission concluded that the overall quality of annual reports received from Member States was good. Regional immunization coverage with polio vaccine remains high at 92.3%\(^2\). The average detection rate for AFP cases is 1.04 per 100 000 children under the age of 15 years (data as of week 28, 2004), which exceeds the WHO target. However, a small decrease has been noted, compared with 2003 data. Furthermore as indicated in the Figure 6 below, disparities exist within countries, where AFP detection rates range from < 0.05 to over 1.00.

\(^2\) WHO/UNICEF Joint Reporting Form, preliminary 2003 (as of September 2004)
The laboratory containment of wild polio virus and infectious materials became an important component of the Global Polio Eradication Initiative in the European Region after certification of Polio-free status. The Regional Office has coordinated and monitored implementation of Phase I of the Global Action Plan (GAP) activities in all Member States. Each Member State has conducted a national survey of biomedical laboratories and a list of all biomedical laboratories from different sectors has been prepared. A national coordinator was appointed in each Member State to coordinate the process. A national inventory of laboratories containing wild polio/infectious materials has been created based on the information from a WHO questionnaire. Currently, 49 out of 52 countries have completed Phase I of the GAP, the remaining three countries will complete the process by the end of 2004.

2.3 Measles elimination and CRI prevention

The reported incidence of measles has declined by 92% in the Region over the last decade, while the number of countries reporting has increased from 67% in 1999 to 98% in 2003. All 52 Member States now have national 2-dose measles immunization programmes; among the 48 countries reporting in 2003, 52% had coverage of at least 95% for the first dose of measles vaccine. However, some countries in the Region continue to have inadequate vaccine coverage for interrupting measles transmission, and large outbreaks have recently occurred in Germany, Georgia, Italy, Russian Federation, Tajikistan, Turkey and Ukraine.

One of the proposed criteria for indicating the lack of indigenous measles transmission is an incidence of less than one per million population, excluding imported cases. The number of Member States reporting this incidence has increased from 13 (25%) to 19 (37%) between 2001 and 2003 (see Figure 7 below). Since many of the Member States have populations of several million or less, it will be very important in the coming years to obtain timely case-based information on all measles cases, including the viral genetic sequence, to ascertain whether cases are imported or import-related secondary cases.
The use of rubella vaccines has also substantially improved recently. The percentage of Member States using rubella vaccine has increased from 78% in 2001 to 90% in 2004; almost all of this is as combined measles-mumps-rubella vaccine. While nine Member States reported a rubella incidence of less than one per million in 2003, countries that have only recently introduced the vaccine continue to have large outbreaks. However, surveillance for rubella is weak in the Region given that many of the countries with the highest reported incidence do not currently have the capability to confirm the clinical diagnosis, and seven countries, primarily in Western Europe, do not currently have national rubella surveillance programmes. Surveillance for congenital rubella syndrome is also very weak – between 2000 and 2003, 89 cases were reported in the Region, with 42% reported from Romania, a country with only 2.6% of the Region’s population.

A strategic plan for measles and congenital rubella infection (2003) has been published in the four official languages of the Region. The plan establishes Regional operational targets for 2010 of interrupting indigenous transmission of measles and preventing congenital rubella infection (< 1 case of congenital rubella syndrome per 100 000 live births). The approach to measles and rubella in the Region is designed to improve surveillance and vaccination coverage for these diseases in an integrated manner. The key strategies for meeting the targets are to:

- achieve and sustain very high coverage with two doses of measles vaccine through high quality routine immunization services
- provide a second opportunity for measles immunization through supplemental immunization activities to populations susceptible to measles, consistent with national targets for measles control;
- use the opportunity provided by supplemental measles immunization activities to target populations susceptible to rubella where appropriate;
- ensure protection to women of childbearing age by providing high coverage with one dose of rubella vaccine;
- strengthen surveillance systems by vigorous case investigation and laboratory confirmation; and
• improve the availability of high-quality, valued information for health professionals and the public on the benefits and risks associated with immunization against measles and rubella.

The plan was developed through an extensive consultation process in 2002. Surveillance guidelines (2003) and guidelines for supplementary immunization activities (SIAs) (2004) have also been developed and printed in English and Russian. All of these documents are available on the Regional Office website.

The Regional Office has provided technical support for the development of national plans for measles and rubella in at least 10 countries, and it has supported many training activities on surveillance and for the strengthening of immunization programmes related to planning and implementation of measles and rubella SIA. The Regional philosophy is that SIA provide a one-time opportunity to strengthen the immunization programme, boosting it to a sustainable higher level of performance so that routine, very high coverage can be subsequently maintained. Pre-SIA assessments are a critical component of the planning and preparation for SIA. In the last four years, SIA have been undertaken in Kyrgyzstan, Republic of Moldova, Serbia and Montenegro, Serbia and Montenegro (Kosovo), Tajikistan and Turkey.

2.4 Enhancing Regional laboratory capacity

A well-functioning Regional laboratory network, providing reliable laboratory-based surveillance, is a pre-requisite to support the disease control targets of the Region. VPI is coordinating the activities of the Polio and the Measles/Rubella laboratory networks.

a) The Polio Laboratory Network

The primary objective of the Polio Laboratory Network in the European Region is to provide timely and accurate virological information that can be used for operational response in the case of importation of the poliovirus, containing the spread of wild polioviruses or circulating vaccine-derived polioviruses (cVDPVs).

All laboratories undergo a process of annual accreditation documenting that the laboratory has the capability and capacity to fulfil its role in polio eradication. The polio laboratory network is a multi-tier system. See Figure 8 below.

Figure 8. WHO European Region polio laboratory network structure
Responsibilities of Subnational/National Laboratories (S/NL)
The main responsibilities of S/NLs are:
- isolation and identification by serotype of polioviruses from faecal samples, using standardized procedures and reagents;
- referral of poliovirus isolates to Regional Reference Laboratories (RRLs);
- reporting results;
- coordination with EPI case investigators; and
- coordination and implementation of containment activities.

Responsibilities of Regional Reference Laboratories
The main responsibilities of RRLs are to:
- serve as NLs to their own countries and to other specified countries which do not have NLs;
- perform intratypic differentiation of poliovirus isolates from the region;
- distribute reference materials such as appropriate cell lines and antisera;
- serve as centres for training courses and for training individual laboratory workers from countries in the region;
- coordinate quality control and validation of NLs in the region by managing the proficiency testing programme, and being available to visit, if necessary, when performance problems arise;
- refer selected poliovirus isolates to the Global Specialized Laboratories (GSLs) for genomic sequence analysis;
- report results in a timely manner;
- coordinate and implement containment activities; and
- coordinate with Expanded Programme on Immunization (EPI) case investigators.

Responsibilities of Global Specialized Laboratories
A limited number of laboratories function in the Network as GSLs. Their responsibilities include:
- definitive identification of poliovirus isolates using all available technologies, including genetic characterization, to reveal the origin of isolates;
- preparation and distribution of relevant standards, reference reagents and training materials;
- preparation and distribution of proficiency test panels;
- provision of consultants to evaluate and advise on laboratory services and provide specialized training;
- participation in collaborative studies to assess proposed standards and reference materials;
- research aimed at improving the speed, sensitivity, specificity and applicability of methods for the diagnosis of poliovirus infection and for the detection of wild polioviruses in clinical and environmental specimens;
- reporting results in a timely manner;
• coordination and implementation of containment activities; and
• coordination with EPI case investigators.

The Regional Polio Laboratory network comprises of 9 subnational laboratories, 36 national, 6 regional (serving as national at the same time) and 4 global (two of which serve as national at the same time) laboratories (see map below). The Laboratory network played a crucial role in providing evidence on the interruption of transmission of indigenous wild polioviruses in the European Region (in excess of 200 000 samples were analysed by the Network in preparation for Regional Certification in 2002).

Currently, the Polio Laboratory Network in the European Region represents highly qualified specialists from NIS, Caucasus, Baltic States, central and eastern Europe and western Europe who work in accordance with the highest international standards of good laboratory practices in laboratories, equipped with modern hardware using the uniform WHO protocol of virological investigation. All polio laboratories passed annual proficiency test and are reaccredited in 2004. The Regional Office is coordinating the everyday functioning of this Network, providing technical and financial support through the provision of modern equipment and supplies as well as organizing annual meetings, consultants’ missions and training courses.

The experience and structure of the Global Polio Laboratory Network has now been modelled into the establishment of the Measles/Rubella Network.

b) The Measles/Rubella Laboratory Network

The main priority of the Measles/Rubella Laboratory Network (MRLN) is to provide to the programme complete and reliable laboratory-based data on the Regional measles and rubella incidence, as well as the analysis of this data to support the disease control activities, seroprevalence, when required and the success of vaccination campaigns. The Network comprises 47 national measles laboratories which have been nominated by their respective governments. Some countries have appointed additional subnational laboratories (in total 20: 10 in the Russian Federation, 7 in Turkey, 2 in Ukraine and 1 in Kyrgyzstan) to complement the Network. Three Regional Reference Laboratories have been appointed in Berlin, Luxembourg and Moscow, each responsible for a particular region within the European Region (see map below). The final structure of the Laboratory Network including the Regional Reference Laboratories was established in 2003.
Each level within the structure of the MRLN has a specific responsibility. The main responsibility of the National Laboratories together with the subnational laboratories is to confirm the diagnosis of clinically suspected Measles and Rubella using validated IgM ELISA kits. The Regional Reference Laboratories’ main task is to perform in-depth virus characterization from samples submitted by Subnational and National Laboratories, as well as validating the results and providing training opportunities. The Global Specialized Laboratory provides technical expertise to the Network, preparation of standards for quality assessment and development of novel techniques. The MRLN was based on the fundament already present in the Polio Laboratory Network. In the European Region, 22 countries have nominated a national polio laboratory or institute to be the measles MRLN as well. Great investment, both financially and technically, have been made in the Polio Laboratory Network. By partially integrating the MRLN into the Polio Laboratory Network many of these early investments have been consolidated.

Two training workshops were conducted in 2002 and 2003 to train virologists from NIS and the Russian Federation in novel diagnostic techniques. On five occasions, a consultant was sent to a National Laboratory for on-the-spot training. Training was also provided to regional virologists at one of the Global Specialized Laboratories in Atlanta, United States of America. In addition, WHO experts carried out 14 national laboratory assessment missions.

3. Management, coordination and partnerships

The success of the poliomyelitis eradication initiative was largely due to the fruitful collaboration of partners working together to provide technical and financial assistance to Member States. The GAVI has been supporting immunization programmes and the introduction of new and underused vaccines in 11 of the WHO European Member States. Immunization is recognised as one of the most cost-effective preventive interventions that exist and has been given much attention by international agencies over the last three decades. Immunization partnerships have a tradition of shared responsibilities. The Regional Office, in close collaboration with the WHO Geneva, Immunization, Vaccines and Biologicals Department (IVB), assists countries in strengthening their immunization programmes and controlling vaccine-preventable diseases. This partnership provides technical expertise as well as financial support.

Major partners in the field of immunization include UNICEF, CDC, USAID, the Canadian International Development Agency (CIDA), CVP/PATH, Rotary International, the European Union and the World Bank.

Efforts continued to coordinate activities between the partners working on Immunization issues, strategically and in the field. Two meetings of partners were held and recommendations were made to address critical programme planning and coordination issues. Additional activities were undertaken to identify resources within the Region, not least engaging further support from WHO Geneva and the Regional Office. A project proposal was submitted to the Regional Director for his direct efforts to mobilize resources for immunization strengthening.

Two briefings were also held to fully brief VPI consultants thus creating a pool of competent experts to work in countries. Activities continued to establish and strengthen national and subnational centres and to find synergies with other relevant initiatives in the field.

In 2003, the terms of reference for the European Technical Advisory Group of Experts for Immunization (ETAGE) were reviewed and updated in line with programmatic progress. Recommendations made at the last two meetings included ETAGE endorsing the Regional strategic plan for measles and congenital rubella infection (CRI), calling for greater recognition of the
strategic importance of immunization as a cost efficient health intervention and urging continued attention to the completion of the Polio eradication effort, while expressing general concern about the levels of funding available to achieve the extensive plan of work laid out for 2004–2005.

Part II. Challenges, current and future initiatives

Vision for the future

During the coming years, the Vaccine-Preventable Diseases and Immunization programme of the WHO Regional Office for Europe will continue its efforts towards the goal of reaching and maintaining the highest possible level of immunization, by strengthening national immunization systems to reduce and control vaccine preventable disease with the following long term vision of all Member States in Europe:

- in which immunization is highly valued and placed among high priority health care services;
- where more people are protected against more diseases;
- where immunization is sustained under conditions of diverse social values, changing demographics, evolving diseases and changing economies; and
- where there is solidarity among the global community to guarantee equitable access to needed vaccines for all people.

Strategic objectives

With this vision in mind, priority will focus on the following objectives:

- improving immunization services through strengthening routine immunization systems, promoting high quality and safe immunization practices and improving surveillance and monitoring for programme management;
- accelerating disease control, including measles elimination and congenital rubella infection prevention and maintaining polio free status, supported by an enhanced regional laboratory network;
- accelerating the introduction of new and underused vaccines; and
- increasing and strengthening communication, coordination and partnerships.

Methods and principles

To achieve these objectives the focus will be on assessing needs and identifying priorities within the countries, supporting country level activities, mobilizing resources (technical and financial), developing national capacity and providing guidance in line with the Regional priorities. The guiding principles of the programme will be equity; ownership, partnership, responsibility and accountability to achieve strong district based immunization systems and sustainability through technical and financial capacity building and policies and strategies based on evidence and best practices.

Programme activities will be directed towards strengthening infrastructure to support the routine immunization of infants and children, including monitoring the implementation of current, new and under utilized vaccines and the laboratory-supported surveillance of vaccine preventable diseases.
Also among the priority areas for country support will be the establishment of effective mechanisms for reporting and monitoring immunization coverage at subnational level to identify under-served areas and population groups and improve immunization delivery. The Regional Office will focus on assisting countries with training and follow up, addressing technical issues with a focus on strengthening immunization services, safety of immunization and introduction of new vaccines and preparation and implementation of the national Financial Sustainability Plans.

In addition, there will be a greater focus on advocating for immunization with effective communication strategies, providing the best available information and evidence for decision-making and prioritisation and increased efforts for partnership development and resource mobilization.

Objective 1. Improving immunization systems

1.1 Strengthening routine services

Future activities will focus on building on the existing national immunization infrastructure, in order to improve access and use of immunization services through capacity building. Innovative methods such as sustainable outreach and pulse campaigns will be advocated, in addition to fixed posts specifically to reach the vulnerable and hard to reach population that exist within the Region. Such innovative methods will also help to reduce the number of children not returning for subsequent vaccination, in addition to reducing risks of non-vaccination due to false contraindications and missed opportunities.

1.2 Improving quality and safety of immunization

This key area of work will be enhanced during the next two years with focus placed on:

- strengthening National Regulatory Authorities (NRA) and vaccine procurement systems by first assessing them in producing and non-producing countries, including support for bulk vaccine procurement options;
- vaccine and cold chain management reviewed by country assessments, focusing on quality monitoring mechanisms, including enhanced training at national and provincial levels;
- injection safety and health care waste management targeted by assessing the current status and identifying weaknesses, including support for the development and implementation of national plans and policies; and
- adverse events following immunization (AEFI) surveillance and management mechanisms will be strengthened, including training workshops and the development of training materials supported for all areas of immunization safety.

1.3 Monitoring and surveillance

The monitoring and surveillance capacity in the Regional Office and in Member States will be enhanced during the coming years. The focus will be on improving the accuracy, timeliness, completeness and data analysis for annual, monthly and weekly data on vaccination coverage rates and disease incidence.

Surveillance systems for measles, rubella and congenital rubella infection, diphtheria and other vaccine-preventable diseases will be built upon and improved.
Regular feedback to country staff on data related issues will continue, using newsletters and personal contact, thus improving the quality and validity of data used for programme management at regional, national and subnational level.

**Objective 2. Accelerating disease control**

**2.1 Measles elimination and CRI prevention**

The regional strategic plan will be revised and republished in 2005 to take into account the progress and consultation with Member States that has occurred since 2002. Countries will be encouraged to develop national plans based on their country-specific needs for improving control of these diseases; and assessments will be carried out in countries with a very low incidence of measles to learn about methods used to achieve this level of control and the strength of surveillance activities.

More attention will be paid to the timeliness and accuracy of data reported, particularly with regard to clusters of cases and outbreaks, the use of WHO-recommended laboratory diagnostic tests to investigate suspected cases, and the collection of specimens for virus isolation or detection. Work also needs to be done to develop standard methods for surveillance of congenital rubella syndrome, including burden estimates, and improve methods for determining immunization coverage.

WHO will provide technical support to countries seeking to implement national plans, addressing their measles- and rubella-susceptible populations. Member States seeking to do SIA will be encouraged to undertake pre-SIA assessments with WHO assistance in order to optimize opportunities for immunization programme strengthening provided for by SIA.

**2.2 Polio eradication**

The Region is at risk from importation of wild poliovirus from neighbouring endemic areas. All Member States of the European Region must remain on high alert, ensuring the capacity of their surveillance systems to respond rapidly to any importation that is reported.

It is also important to maintain high vaccination coverage to prevent emergence of circulating vaccine-derived polioviruses (cVDPVs). The major foci for activity during the coming years are to:

- further enhance surveillance for acute flaccid paralysis, ensuring the standard quality indicators are maintained;
- continue immunization of high risk groups, building capacity to further strengthen national immunization programmes;
- continue progress towards laboratory containment of the poliovirus; and
- continue policy development support for the post-certification era.

To ensure that the European Region will remain polio-free, the Regional Office will provide support to Member States to maintain high routine immunization coverage, particularly in high-risk groups to:

- conduct supplementary immunization activities (SIAs) in selected high risk areas;
- maintain high quality surveillance for poliovirus; and
- continue the laboratory containment process and quality control.

With the increased threat of bio terrorism and as part of the international effort, verification and validation of the country data on laboratory containment of wild polio/infectious materials is critical.
The Regional Office has requested all Member States to conduct a standard self assessment of quality of the phase I GAP activities. Coordination and monitoring of quality assessment of Containment activity in the Region will be continued in 2005. With the progress of the global polio eradication initiative and the approaching global certification, containment activities will be increased and enhanced. Phase II of the GAP has been developed and the Region-specific activities will be initiated in 2005.

2.3 Diphtheria

Control efforts will continue in all countries to maintain and further reduce incidence, particularly in the Baltic States and NIS. During the next two years assessments will be conducted in selected priority countries and support will be provided where relevant for enhancing surveillance systems.

2.4 Enhancing Regional laboratory capacity

The regional objective of accelerated disease control places additional emphasis on surveillance support from a well functioning regional laboratory network. The experience and structure of the Global Polio Laboratory Network is already being used in the establishment of the Measles/Rubella Network. The measles/rubella laboratories in 22 countries of the European Region (out of 52) are located in the polio laboratories or in the same institution where the polio laboratories are situated.

a) The Polio Laboratory Network

The objectives for the coming years will be to:

- maintain the high quality of the existing polio laboratory network including the laboratory support of AFP surveillance;
- implement other types of supplementary surveillance in areas with suboptimal AFP detection or low vaccination coverage;
- develop and implement novel laboratory techniques to improve the timeliness of investigations; and
- allow the expansion of laboratory responsibility in the field of other human pathogens.

To assist with the expansion, the Polio Laboratory Network can offer:

- human resources and expertise in generic technologies and data management
- infrastructure, including reporting and communication
- laboratory equipment
- quality assurance
- global collaboration and coordination.

b) The Measles/Rubella Laboratory Network (MRLN)

The priorities of the MRLN have been modelled using the experience of the Polio Laboratory Network, being:

- the collection, flow and analysis of reliable laboratory-based surveillance data
- the implementation of a quality assurance programme
- the provision of laboratory equipment and supplies.

Technical support is provided to Member States when needed, particularly in the implementation of new technologies to facilitate diagnosis of measles and rubella. The introduction of a full
accreditation programme is planned for the 2004–2005 biennium. This programme will consist of annual proficiency testing combined with an accreditation review by correspondence, followed by an assessment visit where needed. The Regional Office coordinates a monthly laboratory reporting mechanism to obtain accurate laboratory case-confirmation by the Member State Laboratories. Technical assistance and provision of laboratory supplies remains one of the main activities of the MRLN.

**Objective 3. Accelerating the introduction of new and underused vaccines**

Although hepatitis B vaccine has become part of the routine immunization schedule in most countries of the Region, problems remain to sustain funding of the immunization programme in general, including for hepatitis B vaccine.

The relatively high cost of Hib vaccine and the lack of adequate evidence on disease burden remain major barriers for the introduction and implementation of immunization against Hib. In addition, the introduction of Hib vaccine may further affect the sustainability of immunization programmes, particularly in countries of eastern Europe and NIS.

The main objective of the Regional Office will be to continue to support the GAVI-eligible countries to strengthen immunization service delivery, through the provision of technical and policy guidance on the introduction and implementation of new and under-used vaccines.

Focus will be placed on monitoring the introduction and implementation of new and underused vaccines in addition to improving information systems used for programme management.

All countries will be encouraged and supported to collate and use evidence on disease burden, cost effectiveness and efficiency of introducing new and under-used antigens (for example, Hib, meningococcal, pneumococcal and other vaccines). This evidence will be used for decision making and policy development at national level.

The mechanisms developed through the GAVI process will be transferred and used in other countries not eligible for GAVI/VF support. Support from major partners to the GAVI-eligible countries will continue to be coordinated through the RWG mechanism.

**Objective 4. Increasing and strengthening advocacy, communication, coordination and partnerships**

Coordination and further expansion of existing partnerships, particularly with the European Union is a key strategy to improve the health and well-being of children in the Region. Priorities for the coming biennium will be to:

- further develop a strategic plan for advocacy, including partnership development, improved communication and training;
- develop processes to ensure comprehensive joint planning and implementation of activities, in addition to the annual meeting of the Interagency Immunization Coordinating Committee; and
- continue to work closely with and provide regular briefing to the European Technical Advisory Group of Experts (ETAGE), who assist in the direction of the Regional Vaccine-preventable Diseases and Immunization programme.
To help sustain momentum for Immunization strengthening in the Region, it is proposed to hold Immunization Week during Autumn 2005. The objective for the immunization week is to focus on advocacy for strengthening routine immunization using four complementary strategies and associated activities. An effective, operational routine immunization programme provides the foundation for long-term sustainable immunization system that is able to support other vital immunization functions such as the introducing and implementing new antigens, increasing the success of targeted campaigns such as those for hard-to-reach groups and dealing with adolescent and adult immunization.

The overall objective of the immunization week is to draw attention to and awareness to the importance of every child’s need and right to be immunized. A special focus will be placed on vulnerable groups.

We will also be working with Member States to develop national websites meeting the criteria approved by the Global Advisory Committee on Vaccine Safety and in languages appropriate for their population groups; these approved sites will be linked to the WHO Regional Office for Europe Vaccine Safety Net site to ensure appropriate and balanced information relating to immunization will be visible to a wider audience. Further work will also be done to improve the communication among these approved websites to enable timely information on emerging issues related to vaccine safety.

For further information on the VPI programme please visit: www.who.euro.int/vaccine or contact us by email: vaccine@euro.who.int.