Regional Immunization Programme Managers’ Meeting

Vaccine-preventable Diseases and Immunization Programme

Report of WHO meeting,
Rogaska Slatina, Slovenia, 18–20 October 2004
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Abbreviations

AEFI  adverse events following immunization
AFP  acute flaccid paralysis
CISID Centralized Information System for Infectious Disease
CRI congenital rubella infection
CRS congenital rubella syndrome
DTaP diphtheria-tetanus-acellular pertussis vaccine
DTwP diphtheria-tetanus-whole cell pertussis vaccine
EIDIS European Infectious Disease Information Systems
EPI Expanded Programme on Immunization
ETAGE European Technical Advisory Group of Experts
EU European Union
EUR European Region
EVSM Effective Vaccine Store Management
GACVS Global Advisory Committee on Vaccine Safety
GAVI Global Alliance for Vaccines and Immunization
HBV hepatitis B virus
Hep B hepatitis B
Hib *Haemophilus influenzae* type b
HIV human immunodeficiency virus
IICC Interagency Immunization Coordination Committee
IPV inactivated polio vaccine
JRF Joint Reporting Form
MDG Millennium Development Goals
MMR measles–mumps–rubella vaccine
MSF Medecins sans Frontieres
NID National Immunization Days
NIP National Immunization Programme
NIS newly independent states
NGO non-governmental organization
NRA National Regulatory Authority
OPV oral polio vaccine
PATH Program for Appropriate Technology for Health
R&D Research and Development
SIA supplementary immunization activities
STD sexually transmitted diseases
UNGAASS United Nations General Assembly Special Session on Children
UNICEF United Nations Children’s Fund
USAID US Agency for International Development
VDPV vaccine-derived poliovirus
VPD vaccine-preventable disease
VPI Vaccine-preventable Diseases and Immunization Programme
WHO World Health Organization
Introduction

A regional meeting of National Immunization Programme Managers from all 52 Member States of the WHO European Region was held in Rogaska Slatina, Slovenia, from 18 to 20 October 2004. The issues discussed included methods to improve routine immunization coverage, vaccine safety and quality, achieving disease control objectives and strategies to improve communications and advocacy for immunization.

Background

At its recent meeting (Copenhagen, 6–9 September 2004) the WHO Regional Committee for Europe re-affirmed the importance of maintaining immunization services within the Region and restated its support for the WHO Vaccine-preventable Diseases and Immunization Programme (VPI). This confirmation of WHO’s continued commitment to VPI followed the revision and reactivation of the European Advisory Group for the Expanded Programme on Immunization (EAG/EPI), under its new title of the European Technical Advisory Group of Experts (ETAGE). Having established the Regional Office’s continued commitment to immunization, it was necessary to review the status of immunization services within the Region, assess progress in achieving Regional immunization and disease control targets and goals, discuss challenges and constraints experienced by Member States and consider new strategies for improving and extending services. With these aims in mind, a meeting of National Immunization Programme Managers from all 52 Member States of the WHO European Region, together with selected technical advisors and representatives of partner agencies, was held in Rogaska Slatina, Slovenia.

Scope and purpose of the meeting

The scope and purpose of the meeting was to review and discuss the following subjects with participants and provide recommendations for future programme activities:

1. the current status of global and regional immunization programmes, including disease control targets, progress and future priorities for strengthening immunization systems in countries of the WHO European Region;
2. immunization safety issues with particular focus on injection safety and waste disposal;
3. country experiences on strategies and activities to enable vulnerable and difficult to reach population groups to access immunization services;
4. national activities implemented and progress achieved towards regional targets of measles elimination and congenital rubella infection prevention, including surveillance and laboratory support;
5. achievements and challenges in introduction and implementation of new and under-used vaccines in countries and strategies to address the problems identified; and
6. strategies to improve communication and advocacy for immunization, including the role of new European partners.
**Opening of the meeting**

Dr Nedret Emiroglu, Regional Adviser, Vaccine-preventable Diseases and Immunization Programme (VPI) of the WHO Regional Office for Europe opened the meeting. Dr Philippe Duclos, Vaccine Assessment and Monitoring, WHO Geneva, gave the opening address on behalf of Dr Jean-Marie Okwo-Bele, Director, Department of Immunization, Vaccines and Biologicals. Mrs Blanka Mežnar of the Ministry of Health, welcomed meeting participants on behalf of the Government of the Republic of Slovenia.

Dr Nikolaj Chaika and Dr Ray Sanders were nominated as rapporteurs. A full list of meeting participants is provided in Annex 1. The meeting was structured as a series of plenary sessions covering seven major immunization topics, with intervening parallel sessions and workshops covering selected aspects of each topic in greater detail. The full meeting programme is provided in Annex 2.

**Topic 1: Immunization services, with a focus on reaching “hard-to-reach”/vulnerable groups**

**Routine immunization systems and disease control targets – a global overview of current progress and major challenges**

Immunization has had a dramatic effect on child health in every country of the world, preventing many millions of deaths each year and reducing the risk of disability due to infectious diseases. Based on the successes achieved since the launch of the Expanded Programme on Immunization (EPI) in 1974, several international goals for increasing vaccination coverage (United Nations General Assembly Special Session on Children [UNGASS]) and decreasing disease mortality (World Health Assembly and Millennium Development Goals [MDG]) have been set. The aim in setting these goals was to extend the benefits of immunization to those children not being reached by routine immunization services. It is estimated that approximately 37 million children worldwide do not receive routine immunization in their first year of life; that four million child deaths per annum could be prevented with appropriate use of existing vaccines and that a further three million deaths could be prevented through the use of new vaccines.

Despite setting ambitious immunization goals, global vaccination coverage remained at 78% in 2003, having risen only three percentage points in the past three years. Vaccination coverage in the African Region, historically lower than in other WHO Regions, has shown steady improvement in the past five years, but remains at below 60%. The 2010 UNGASS immunization goals of achieving at least 90% national coverage in every country and at least 80% coverage in every district of every country, remain remote. In 2003 only 26% of countries had achieved the UNGASS goals and of the poorest 75 countries (countries eligible for support from the Vaccine Fund) only 12% had achieved the goals.

On a more positive note, progress in disease reduction has maintained its momentum over the past decade, with continued declines in the number of polio cases and in measles morbidity and mortality. Polio has been reduced to endemic foci on two continents, with the greatest reductions
in cases seen in Asia. Most cases worldwide are now in Africa, particularly the northern states of Nigeria, which have continued to harbour the virus and to export it to neighbouring countries. The reintroduction of virus into polio-free countries in western and central Africa has been a massive drain on resources over the past year. Attention is now focussed on achieving high vaccination coverage throughout the Region and particularly in the northern states of Nigeria and the neighbouring country of Niger. There was a 30% reduction in reported global measles morbidity/mortality between 1999 and 2002, with a 35% reduction reported for the African Region. This impressive reduction has been brought about largely through the use of mass campaigns with measles vaccine.

The past decade has seen a progressive increase in the number of countries extending their routine immunization schedules to include additional vaccines. In 1996 only 67 countries worldwide included rubella vaccine in their routine schedule; this increased to 110 by 2003, increasing coverage of the global birth cohort from approximately 12% in 1996 to 25% in 2003. The number of countries delivering hepatitis B vaccine in their routine infant immunization schedules has risen from 37 in 1993 to 147 in 2003 and of these, 83 report coverage of 80% or above with a third dose of vaccine. Similarly, the number of countries using *Haemophilus influenzae* type b (Hib) vaccine had increased to 87 in 2003.

There has also been a dramatic rise in the number of countries able to demonstrate the quality and safety of vaccines used in their immunization programmes. At least 123 countries (64%) now have a national injection safety plan and there has been good progress in formally assessing injection safety practices in many countries. The supply and use of auto-disable (AD) syringes in the context of immunization programs has increased significantly, with the global distribution exceeding 610 million units in 2003. By the end of 2003, approximately 50% of countries routinely used AD syringes for immunization, with 96% of the least-developed countries using them. Much work remains to be done, however, in establishing effective injection waste disposal and injection safety management.

In addition to facing the challenge of meeting international vaccination coverage and disease reduction goals, immunization programmes face other challenges presented by global changes in vaccine provision, funding and public acceptability. Vaccine supply and quality issues have become more complex in the past decade and this complexity is expected to increase further. Despite major breakthroughs in the development of new vaccines over the past 20 years, the needs of children in developing countries are not being addressed by vaccine research and development (R&D) agendas tailored to the needs of children in wealthier countries. With a progressive shift away from public production of vaccines to private production, there has been an increase in the number of vaccine producers in nonindustrialized countries. Fledgling national regulatory authorities (NRAs) in these countries often require extensive expansion and intensive upgrading of capacity to ensure that products of these new manufacturers are both safe and effective.

New international partners and new partnerships for vaccine provision and delivery have emerged in the past decade. This has resulted in an increased need to rationalize and consolidate various immunization initiatives to ensure that the best use is made of available resources. It is also apparent that new vaccines will cost more than the traditional EPI vaccines and funding issues, particularly long-term financial sustainability, become increasingly important.

The past decade has also seen a general increase in the level of public scrutiny of immunization programmes. There has been an increase in the number of allegations of links between vaccines
and childhood illnesses of unknown origin and an increase in the level of sophistication and organization of a vocal anti-immunization lobby. In a response to this challenge the Global Advisory Committee on Vaccine Safety (GACVS) was established in 1999 as an expert scientific and advisory body to WHO. The GACVS provides prompt, independent and scientifically rigorous advice on vaccine safety issues of global importance through an assessment of the evidence for relationships between vaccines and events attributed to them. The GACVS has provided advice on a large number of wide-ranging issues, including investigations into macrophagic myofasciitis (MMF) and aluminium containing vaccines, the health effects of thiomersal, adverse events following mumps vaccination, child survival following routine infant immunization, MMR and autism and hepatitis B vaccine and multiple sclerosis. Findings of the GACVS are widely distributed through WHO publications and web sites http://www.who.int/vaccine_safety/en.

In an effort to improve global communications on vaccine safety issues, the Vaccine Safety-Net was established this year. The project provides internet links to immunization-related web sites that meet criteria for good information practices. The sites are evaluated for credibility, content, accessibility and design and those meeting the criteria are included in the project links http://www.euro.who.int/vaccine/related/20040826_1.

The Global Immunization Vision and Strategy will provide a 10-year vision for reaching the underserved and hard-to-reach population groups, promoting data-driven problem solving and encouraging the adoption of a package of interventions to reduce child morbidity and mortality. Implementation of this strategy will take immunization services beyond infants into other age groups and anticipates the introduction and wide-spread use of new vaccines and technologies. The strategy describes the basis for countries to work with their immunization partners to achieve the 2015 Millennium Development Goals.

**Routine immunization systems and disease control targets – regional progress and major challenges in a changing global environment**

Immunization is not a vertical programme and social, economic, technical and political changes in the Region over the past 15 years have served to underline this. There is an increasing need to further broaden the scope and impact of immunization services within the Region, to integrate immunization more effectively with other areas of health-care provision. Several goals and targets for immunization services have been set by United Nations bodies, the WHO and other international partner agencies. These goals and targets are often not completely complimentary, making it difficult for countries to identify and focus on priority activities. There is a need to rationalize these goals and provide a clear list of priority activities.

The WHO European Region has achieved a large measure of success in provision and maintenance of immunization services. Most countries in the Region have achieved greater than 95% coverage with routine EPI vaccines, but in many cases discrepancies exist between routine reported coverage and immunization survey data. In a number of countries timeliness of delivery of vaccines is often poor, with too many children under-vaccinated at 12 months of age. Reasons for delays in delivery of immunization are varied and complex and to a large extent need to be addressed on a case-by-case basis. Analysis of national data often reveals under-performing provinces and districts in several countries, but collection and analysis of accurate immunization data at subnational levels is often poor.
A clear priority is the provision of services for hard-to-reach and vulnerable groups within the Region. These groups exist to some extent in every country in the Region and include the urban poor, remote rural populations, mobile groups and minorities. These groups can be reached by extending routine services to include outreach activities and pulse campaigns with selected vaccines. Better supervision of immunization staff and performance monitoring are required in several countries for these approaches to be successful. Improvements in community links and more effective targeting of resources will also be required. In general, if hard-to-reach and vulnerable groups are to be served, improvements in the national management of immunization programmes must take place, through the process of national capacity building, with a focus on better and more appropriate data collection, analysis and use. In many countries there is a need to improve strategic planning at a local level. Immunization staff must be prepared to go to the most difficult places to deliver immunization services. Immunization equity issues and the under-use of available vaccines can only be resolved by more proactive immunization services, particularly at the local level.

Despite the disease control successes of recent years, outbreaks of vaccine-preventable disease continue in the Region. There have been repeated outbreaks of measles over the past 15 years. Areas with low measles vaccination coverage have persisted across the Region and the perception continues that measles is a mild childhood illness with few if any complications or serious outcomes. There is a clear regional target for measles elimination by 2010, but achieving the target requires greater political commitment, national ownership and more advocacy. Several countries have experienced recent outbreaks of rubella since the vaccine was recently included in the routine immunization schedules of several countries in the Region. Some countries in the Region have not yet adopted universal hepatitis B immunization and several countries have not acknowledged the benefits of Hib vaccination. Better communication activities and more effective advocacy are required to extend the scope and effectiveness of immunization services throughout the Region.

The focus of the Regional Office’s Vaccine-preventable Diseases and Immunization Programme is now upon programme implementation within the Member States, helping them to reach the least served, but most vulnerable groups. Strengthening immunization systems and policies to reach mutually agreed disease control objectives is being achieved through regional coordination. The overall effect is to strengthen not only immunization services, but general health systems within the Region.

Continuing challenges at regional and national level include the multitude of existing priorities and calls on available resources, maintaining political commitment to sustain and improve achievement levels and increasing public awareness and demand for immunization services. In a Region as diverse as Europe, some countries clearly present a higher priority for action than others and responding to the justified demands of these countries presents a great challenge. Persistently low national funding for health care services and a weakened health infrastructure have stretched resources to the limits in some countries. Ongoing reforms and restructuring of health care systems have also caused massive disruption to services. For the foreseeable future, support for these countries will come from the international partner agencies, but to make best use of available resources, more and more countries that have achieved improvements in immunization will be expected to seek out their own means of support or be self-supporting.

In an environment where the cost of vaccines and vaccine delivery is expected to rise, there are some serious questions over the long-term sustainability of immunization programmes within the Region. The regional vision, expressed through the Regional Strategic Plan, is to emphasize the
greater role of advocacy and national and international policy support. New partners in immunization will help share the burden and new and imaginative methods of resource mobilization will help maintain and extend existing services.

**Reaching “hard-to-reach”/vulnerable groups for equitable coverage – impact of changes in health systems and examples of ensuring sustainable service delivery**

Routine immunization services have made tremendous progress in recent years, delivering safe and efficient vaccination to people across the European Region. However, a significant number of children are more difficult to reach because they have a specific ethnic, community, socioeconomic or religious background or because of their non-official status (e.g. migrants). Standard approaches to immunize these specific populations have proven insufficient in reaching these groups and specific strategies are needed to achieve timely and high immunization coverage in these populations.

The World Bank monitors the overall organization of national health systems, among other things, analysing health expenditure as a percentage of gross domestic product (GDP). This ratio generally provides a good indicator for at-risk countries, but given that outbreaks of disease continue to occur in countries with relatively high health expenditure, other factors are also important. One of the most important of these factors appears to be the changing source of public health revenue. In an environment of limited resources, many countries in transition have progressively decentralized health management and adopted a “fee for services” approach to funding health programmes, effectively reducing the role of the state in providing public health services. In several countries declines in direct government funding have been countered by increased funding from effective social insurance schemes. In these countries end-users are expected to pay approximately 10–20% of the total cost of services. Available evidence suggests services in these countries can be maintained and even expanded. In some other countries, funding from social insurance schemes is insufficient to fully replace direct government support. In these countries end-users can be expected to pay approximately 30–40% of the total cost of services. In general, health services in these countries are in a state of decline and unless more funding support is provided, usually through more efficient social insurance schemes, the decline will continue until services collapse. A third group of countries exists in which health services are already in a state of collapse and illness has become a significant poverty risk-factor.

There are several reasons why health systems decline and collapse, the most important being an institutional failure to respond to changing social, political and economic circumstances. This failure is often associated with weak management, lack of internal control and accountability and the inability to attract and secure adequate funding. The situation is made more difficult by the increased reliance on informal payment systems, rather than formal centralized funding. Many countries have found it difficult to implement new funding models and the downsizing of expensive government facilities has proceeded far too slowly.

To improve and maintain high quality immunization services many countries in the Region need to improve the allocation and control of resources, transform health delivery systems and modernize their health systems, responding more effectively to demand. Immunization programme managers need to look into broader health system issues to be able to address today’s challenges for immunization programmes. Stronger partnerships, both national and international, are needed to address the wider health system issues that affect the performance of immunization
services. A much broader outlook is required if the hard-to-reach and vulnerable groups are to be provided with immunization services.

**Country experience: Bulgaria**

Bulgaria is a country with a health-care system in transition and a growing private sector. Childhood immunization with EPI vaccines is compulsory and is provided as a free service. Vaccines are delivered through the family doctors or through local Hygiene and Epidemiology Inspectorate (HEI) immunization services. Although national vaccination coverage is good, as demonstrated by administrative data and serological surveys, coverage at 12 months of age among the Roma population was found to be lower than average. Although the National Government does not collect information on ethnicity, it is believed that there are approximately 700,000 Roma living in Bulgaria. This population is widely distributed around the country, with most major towns and cities having Roma districts. The health reforms in Bulgaria have placed more responsibility on the parents of babies and young children to actively seek immunization for their children. In this respect it appears that the Roma population has been less active in having their young children immunized. A serosurvey of Roma children showed that less than 73% had received OPV3 at 12 months of age, 78% had received DTP3 and 79% had received HBV3. At 24 months of age less than 70% had received MMR.

To improve coverage among this population more active monitoring of vaccine uptake at district level has been encouraged. Improved advocacy on immunization is being attempted by providing information on diseases and prevention measures, specifically targeted at the Roma population. In addition, several projects have been implemented aimed at improving access of the Roma population to health care facilities. These include the BG Phare project “Ensuring access to health care for Roma minority” which is conducted in 15 towns and cities. This project aimed to inform the Roma of the possibilities and rights of access to health services, to help them to understand the consequences of their own choice, behaviour and habits and to provide basic education on communicable diseases. Médecins sans Frontières (MSF) also has a project, in a predominantly Roma district of Sofia city, to monitor immunization coverage, actively promote immunization activities among the population and provide immunization services specifically to this group.

**Country experience: Netherlands**

In the Netherlands unimmunized individuals generally belong to one of two groups: members of a defined group or community that refuses immunization on religious or philosophical grounds; or individuals refusing immunization on a personal basis due to fear of possible side effects or because they have limited contact with the health services. For groups that refuse immunization on religious or philosophical grounds there is little that can be done in a free and democratic society to persuade them to accept immunization. Approaches to improve vaccination coverage have been directed at individuals refusing immunization on a personal basis, immigrants and those under-served by the health-care system.

Approaches have ranged in scale from whole country initiatives, regional and local activities through to specific local measures. An emphasis has been placed on providing better and more appropriate information on vaccines and the diseases they prevent. Key national and local figures in the community and different forms of communications media most appropriate to the target group are methods that have been used. Attempts have been made to provide concerned parents with an open and realistic assessment of the benefits and risks of immunization. Support has been provided to health professionals to assist them in explaining immunization, and published
information, articles and other media materials have been provided to promote immunization services.

Efforts to improve vaccination coverage in immigrant groups have included the employment of home-visiting nurses assisted by interpreters and educators, to provide individual counselling and services. All new information and promotional material on immunization has been translated into languages appropriate to the main immigrant groups. To promote immunization meetings, discussions and social activities involving key community figures have been arranged. The result of this targeted approach has been that immunization coverage rates in most immigrant groups in the Netherlands are now high.

**Country experience: Serbia and Montenegro**

Reported vaccination coverage in Serbia has largely been maintained at around 90% for many years. Concern was expressed however, over the 10% or more of the infant population that failed to receive vaccines. This group was identified as mainly the socially marginalized, including refugees and displaced persons. After analysis of available national coverage data, high risk districts were identified and immunization campaigns were carried out in 216 towns in 48 municipalities, by 135 immunization teams, 60 of them mobile teams.

Data collected during the immunization campaigns identified more than 25,000 children less than 15 years of age and more than 16,000 women of child-bearing age that were under-vaccinated. Immunization teams discovered that approximately 10% of the infants in these marginalized populations were without birth registration documentation, 25% of the children did not have health insurance certificates and 3% of school-age children were not registered at any school. Because of the high drop-out rate between first and second campaign rounds supplementary rounds were conducted in many districts. In all, 16,759 children were vaccinated during the campaigns and 7,295 women of child-bearing age vaccinated against tetanus. Although the campaigns failed to reach all of the target population, the number of under-vaccinated children and women has been greatly reduced and a number of important lessons have been learned. The first is that reaching the hard-to-reach populations requires additional effort, funding and innovative approaches. The second is that good social mobilization is essential for success, and must be carried out with the full participation of local media and community leaders.

**Dealing with negative public reaction to immunization, rumours and negative media publicity**

The success of immunization programmes, with the massive reduction in incidence of vaccine-preventable diseases, has resulted in the potential for immunization-related adverse events to receive more attention. Furthermore, events that promote immunization, in an attempt to reverse decreases in vaccine coverage, also provide opportunities to generate counter-information. It must be acknowledged that anti-immunization advocates and lobby-groups are increasingly vocal and have become sophisticated in their use of media. It must also be recognized that scientists are sometimes reticent to take on anti-immunization spokespeople, questioning their responsibility for countering anti-immunization claims. However, the consequences of not responding effectively to negative press can be costly to the programme and ultimately costly to the communities the programmes were established to protect.
Following experience gained in several countries, a number of ground rules for responding to immunization-negative press have been established. Immunization staff should:

- respond within 24 hours
- show that they are solving the problem
- demonstrate leadership
- be accessible to the news media
- be honest and show concern
- use their strong points
- cite the positive examples
- respond in the media of record.

In mounting a response or preparing to counter negative press, it is essential that central expertise supports local experts, through the provision of relevant information and appropriate training. Local health-care workers should be confident enough to communicate with parents and the local media and act as strong advocates for immunization, but at the same time be passionate, emotional and human.

To minimize the potential disruption of negative press, it is necessary to adopt a policy of media advocacy. The strategy should define working principles with media or target and specific policy. A routine working relationship with journalists should be developed to ensure an active, pre-emptive approach. It is also necessary to present immunization policy and activities in the format of a ‘story’ in addition to being able to describe the science. The messages given must be delivered to the correct audience in a timely and appropriate format. They must be clear, simple and accessible, evidence-based, honest, positive, consistent and respond to current concerns, whether those concerns are real or perceived.

**Country experience: Bosnia & Herzegovina**

In June 2002 the quality of hepatitis B vaccine supplied through UNICEF was questioned by a local nongovernmental organization (NGO). This was followed by allegations that the hepatitis B vaccine supplied to Bosnia was an experimental vaccine and that vaccines supplied through the Global Alliance for Vaccines and Immunization (GAVI) initiative were sub-standard. The immediate response was to hold a Ministry of Health/WHO/UNICEF joint press conference to reject the allegations and alleviate fears over vaccine safety. In August and September 2002 claims were made that a number of deaths had occurred among recipients of DTP vaccine supplied through GAVI. Again, a joint press conference was called, this time failing to resolve the issue. DTP vaccine was withdrawn from use and calls were made for Government resignations. Under pressure the Federal Government agreed to procure DTaP. Federal elections were held in October, after which time, media interest in vaccines subsided.

As a result of this episode, public trust in immunization, the Ministry of Health and UNICEF/WHO was seriously affected. There was increased sensitivity among health-care workers administering vaccines and considerable confusion on the part of parents. This was accompanied by a significant drop in DTP coverage (anecdotal evidence suggested drops of up to 30% in some areas) and considerable disruption of immunization services. There was also a premature, politically driven decision to procure expensive DTaP.
A review of services by WHO/UNICEF/MOH in July 2003 recommended an upgrade of the immunization Programme, including the establishment of a focal point responsible for handling AEFI. Some allegations resurfaced in June 2004, but the Programme was better equipped to handle them. Experience has taught that allegations of this type can expose areas of weakness in the immunization programme, including lack of strong management, lack of transparency and lack of appropriate information for health care workers and parents. There is clearly a need for a more proactive approach towards AEFI, both from countries and from WHO. There should be more sharing of information between countries on AEFI and how to deal with adverse events.

**Country experience: Sweden**

During a randomized trial of acellular pertussis vaccine in Sweden in 1986–1987, of a total of 4,000 trial participants there were four deaths from invasive bacterial infections. Despite the fact that there was no obvious association between the deaths and the vaccine, a fact supported by an international review of the trial results, there were major media allegations that the trial vaccine had cause the deaths. These unsupported allegations resulted in an 8-year delay in the introduction of acellular pertussis vaccine in Sweden.

Part of the problem in Sweden was the design of the vaccine trial itself. Phase III trials are designed to estimate vaccine efficacy and sample size is determined based on that objective. Safety data are collected for solicited events in the short term and serious adverse events including hospitalizations and deaths during the whole follow-up period for efficacy. The limited sample size in normal phase III trials reduces the possibility of detecting rare events. It is therefore necessary to combine data from several trials to effectively analyse the risk of invasive infections. This allows establishment of the expected background rate of rare events and provides evidence for whether an observed event is associated with delivery of the vaccine or is simply a coincidental occurrence.

**Country experience: United Kingdom (UK)**

The unsupported claim that the MMR vaccine was associated with the development of autism in vaccine recipients has caused damage to the immunization programme, frustration to health care workers and a considerable amount of time, effort and expense to UK Department of Health. Although the scientific basis for the claim was rapidly and almost universally refuted, an intermittent campaign of misinformation and misrepresentation was conducted by elements of the popular press for almost five years. Prior to the MMR scare, there had been claim of a link between measles vaccine and the development of Crohn’s disease. The impact of these two spurious claims was that national MMR uptake dropped from approximately 90% in April 1994 to less than 70% in April 2003.

The claims of a link between MMR and autism were invalidated following a series of additional studies and official reports that criticized the press and the anti-immunization lobby for their actions. Although highly disruptive, the experience has provided a number of lessons as to what parents desire and expect from their immunization services. These can be summarized as clarity, consistency, facts, openness, a range of appropriate information and resources, in addition to someone to talk to who understands the issues and can offer genuine reassurance.
**Topic 2: Information systems for immunization – an evidence base for programme management**

**Surveillance for immunization, Vaccine-preventable Diseases and Adverse Events Following Immunization**

Surveillance is the ongoing, systematic collection, analysis and interpretation of health-related data essential to the planning, implementation and evaluation of public health practice. Its use can serve as an early warning system to identify public health emergencies and guide public health policy and strategies. Effective surveillance can monitor the epidemiology of a condition and document the impact of an intervention or progress towards specified public health targets and goals. In short, effective surveillance provides information for action.

The role of WHO in establishing and maintaining immunization surveillance systems is to provide international standards, so that data are comparable, provide technical advice, provide materials and methods, including protocols, guidelines, laboratory reagents, supplies and software tools and provide quality assurance systems. WHO also has an important role to play in the international coordination of surveillance and laboratory networks, in the analysis and publication of data for global public health good, in advocacy for immunization and in the coordination of international response efforts.

WHO has developed a number of tools for assessing the validity of routine immunization, these include coverage survey methods, including cluster surveys and lot quality assessment (LQA) and data quality self assessment (DQS) tools. The immunization cluster survey tool has recently undergone revision to make it a more flexible survey tool. The revision has made it possible to increase precision, combine the results of several surveys and combine with supplementary immunization activities (SIA) evaluations. There are new guidelines on sample selection, improved recording forms and more background information on survey methodology.

Training materials for AEFI surveillance are available for all levels of the health system. It is clear that different systems suit different country situations. Passive surveillance as a minimum, either as part of the overall pharmacovigilance system or integrated into national disease surveillance system, is appropriate in some circumstances. Only very few countries enjoy active AEFI surveillance systems such as paediatric hospital surveillance systems. At times countries also set up more active systems established specifically to monitor conditions after mass immunization campaigns. The Uppsala WHO Collaborating Centre for Drug Monitoring manages an international database of adverse events. Countries should be encouraged to transmit their data to the Uppsala centre to improve signal generation. There are also other international collaborations, such as the Brighton Collaboration, established to facilitate the development, evaluation and dissemination of standard definitions for AEFI in order to improve analysis and comparability of clinical trial and surveillance data.

**Parallel Session A: Immunization coverage and immunization systems performance indicators**

**Regional Office perspective**

All countries in the Region now collect immunization coverage data and for most, the national coverage figures suggest relatively high coverage. However, analysis of data from the district or
first administrative level often shows a less favourable picture, with poorly performing districts that are masked when looking at national data. There are several methods for collecting information on district level coverage, including review of administrative records and registers and coverage surveys (either cluster surveys or LQA). Several countries in the Region are now monitoring district level coverage through the use of strategies that include monthly assessments, detailing timeliness of vaccination, measuring drop-out rates and making rational estimates of the local target groups for immunization. Two major projects, Reaching Every District (RED), supported by GAVI and European Infectious Diseases Information Systems (EIDIS), supported by WHO, USAID and CVP/PATH are providing assistance to countries wishing to establish effective district level monitoring. The Regional Office routinely collects first administrative level coverage in an attempt to identify problem areas and to detect local areas that fail to report vaccination coverage (“silent areas”).

The WHO/UNICEF annual Joint Reporting Form (JRF) provides a unique opportunity to assess all aspect of immunization using a common standard. Use of the form permits analysis of vaccination coverage results, but also permits an assessment of performance and quality. Performance indicators currently assessed using the JRF include planning and management, system performance, surveillance, policy, quality and safety, supply, financing and maternal and neonatal tetanus. The form also collects information on SIAs. As such the JRF represents not only a tool for monitoring immunization performance, but a framework for better management of immunization services.

**Country Experience: Belarus**

Historically Belarus has used a system of quarterly and annual administrative reporting to monitor implementation of immunization services and achievements. In an effort to provide more accurate and timely surveillance data, a pilot monthly reporting system was established in Minskaya and Vitebskaya provinces (“oblasts”) in January 2004. Indicators monitored in the monthly reporting system include immunization coverage, timeliness of vaccination, drop-out rate, contraindications to DPT 1 to 3 and vaccine distribution and use. Evaluation of this pilot project has been very favourable and there are plans to expand the project to include the whole country from January 2005.

**Country Experience: Germany**

In Germany only 10 to 15% of vaccines are given by public health departments of occupational health physicians, the majority (85 to 90%) are given by physicians. Immunization is voluntary and related costs are covered by health insurance. Although there is a recommended immunization schedule, physicians are free to choose among the licensed and available vaccines. The number of vaccine doses each child receives is recorded on individual vaccine record cards and on databases held by physicians. Surveillance is a regional responsibility, with regional data being forwarded to the national level and costs being covered through the health insurance scheme.

Data on vaccination coverage and seroprevalence in Germany is collected through a number of methods, including recording coverage at school entry and at day-care centres, surveys, studies and sentinel surveillance, data on vaccine sales and seroprevalence studies. School entry vaccination coverage data shows high acceptance of first dose of all vaccines, with steady improvements in coverage since 1996. However, coverage with a second dose of MMR remains at less than 50%. Acceptance of the second dose also shows regional variation, with states in the former east Germany showing almost 20% higher coverage than those of former west Germany.
Vaccination coverage data collected at day-care centres shows a similar drop of approximately 50% coverage between first and second MMR doses. However, improvements in timeliness of delivery and decreases in the drop-out rate have been attained in recent years, particularly with families belonging to the middle socioeconomic class.

Experience in Germany suggests there is a need to extend the range of data collected to include information on gender, nationality and geographical location. There should also be more effective setting and implementation of health targets, with recommendations for active intervention in areas with low vaccine coverage by public health authorities in federal states. Collection of coverage data in day-care centres is very useful as it offers the opportunity to detect under-immunized individuals before they enter school, but there should be more support provided to the states to collect this information.

**Country Experience: Kazakhstan**

Although reported vaccination coverage in Kazakhstan has been maintained at a uniform high level since 1997, concerns were raised over the accuracy of reported levels and whether high coverage was really uniform across the country. To address these issues three independent coverage surveys were conducted simultaneously, in Almaty city, Almaty oblast and in western Kazakhstan oblast. To validate the coverage levels reported by the routine immunization monitoring system classic 30-cluster surveys were conducted in Almaty oblast and western Kazakhstan oblast. To identify those health facilities requiring additional attention to improve immunization coverage, a LQA was carried out in Almaty City. Target population for the surveys were children aged 18 to 42 months. The criterion for vaccination was documented vaccine receipt according to immunization cards maintained in the local health facility or in the household. Caretaker reports of vaccination history were not used to ascertain vaccination status.

Although the LQA in Almaty City identified two health facilities that did not meet the required criteria for immunization coverage, the surveys confirmed that access to immunization services in the areas surveyed is high. Vaccination coverage was confirmed as high when measured both by survey and by routine administrative reports. Furthermore, the surveys provided valuable population-based information that is not easily obtained from administrative reported data. The surveys highlight variation in immunization performances between different regional entities and problems in determining the target population size. As such, conducting surveys in advance of SIA could provide information to ensure that immunization campaigns are more effectively targeted and implemented. The LQA method clearly holds promise for local supervision of immunization services and local performance monitoring.

**Country Experience: Spain**

An administrative coverage method is used in Spain to monitor vaccine coverage. Information on the number of doses administered to the target population is recorded by each autonomous region. The number of doses administered is divided by the estimated number in the target population to estimate the percentage of immunization coverage. Depending on the autonomous region, the size of the target population is estimated either from a register of metabolic diseases or from data collected by the National Institute of Statistics. Every newborn child is tested for metabolic disease and since almost 100% of newborns are tested, the test register is effectively a birth register for Spain. In addition to this register, the National Institute of Statistics collects data on the annual number of births in Spain through a hierarchical data collection system.
Every health centre or vaccination centre provides a monthly report of the number of vaccine doses administered to the local level by type of vaccine, age group and number of doses. This information is forwarded to the regional level, where data is collected and collated. Data from each autonomous region is forwarded to the national level. Some regions also maintain an immunization register, detailing information on each child. Not all regions maintain immunization registers, but in recent years there has been a move towards establishing registers in each region. Murcia Region has maintained an immunization register since 1991 and has successively incorporated new tools and improvements into management of the register. A computerized register makes analysis of data much easier, allows follow-up of each individual and can be used to provide automatic reminders to parents when subsequent doses or boosters are required. In a further refinement in Murcia Region, bar coding is used to save data entry time.

Parallel Session B: Vaccine-preventable Diseases and AEFI Surveillance

Regional Office perspective

Data on the incidence of vaccine-preventable diseases have been collected and analysed in the WHO Regional Office for many years. The system for ongoing collection of this data has changed over the years and has now evolved into the CISID (centralized information system for infection diseases) system allowing online data entry and analysis, internet access and Region-wide accessibility. Cumulative annual data on infectious diseases are also collected through the JRF. Challenges to improve and extend the surveillance system include the adoption of consistent case definitions and common indicators that will permit direct comparison of data from different countries. It is also necessary to adopt common results and performance indicators to assess quality of information from different sources. The Regional Office is also collecting AEFI surveillance data, but it is evident that AEFI reporting thresholds vary from country to country, as does the quality of information available.

Country Experience: Finland

Finland operates a system of passive surveillance of post-licensure adverse events. The system is coordinated by the National Public Health Institute (KTL), which receives approximately 900 reports each year. Reports are generated by health care workers and KTL provide individual feedback to each report received. Replies are made in writing and include a literature review of similar or connected cases and conclusions on the nature of the case reported. The feedback may also include recommendations for further investigations or immunization activities.

Country Experience: Georgia

In 1999 a new system of disease surveillance was adopted in Georgia, based on notification of vaccine-preventable diseases and using standard case definitions. Government guidelines, produced in collaboration with the Program for Appropriate Technology in Health (PATH) and PHR plus through a project funded by USAID were prepared to establish reporting and analysis at all levels of the system.

Surveillance is currently being carried out for polio (acute flaccid paralysis [AFP]), measles, rubella, diphtheria, pertussis, neonatal tetanus, parotitis (predominantly mumps), hepatitis B and tuberculosis. Electronic data collection and analysis systems are being developed. In 2004 a
standard definition of AEFI was adopted and new legislation will make reporting of AEFI a component of the national epidemiological surveillance system.

**Country Experience: United Kingdom**

Public health has traditionally been part of the remit of the National Health Service (NHS). Coordination of clinical reporting (obligatory in part) and laboratory reporting (voluntary) is undertaken directly by the NHS, but surveillance for vaccine-preventable disease is undertaken by dedicated public health organizations separate from the NHS. Health Services in the UK have undergone considerable reorganization in recent years. The UK is now devolved into the semi-autonomous entities of England, Northern Ireland, Scotland and Wales. While surveillance systems in use in these four entities are similar, the health service and public health structures differ. The National Health Service in England was reorganized in 2002 and the public health surveillance body, now the Health Protection Agency (HPA) was reorganized in 2003 in England and Wales and is being reorganized in Scotland.

The main sources of surveillance data are statutory notification, laboratory reporting, enhanced surveillance systems for specific conditions and death registration. Statutory notification relies on reporting by clinicians on suspicion or initial diagnosis of vaccine-preventable disease. As such it provides an “early” warning system, but since laboratory confirmation and clear case definition is not required, the system is of low specificity and cannot easily be assessed for efficacy (for example, many diphtheria and measles notifications are inaccurate diagnoses). Furthermore, data collected is incomplete and sensitivity declines further as disease incidence declines (for example, most pertussis cases are not notified).

Sentinel general practice reporting consists of active weekly reporting by motivated practitioners. This system provides more complete data and tends to be more timely, but may not be representative as it depends on the motivation of individual practitioners. Information provided can be linked to denominator data to provide disease burden estimates, but is restricted to common diseases only. Laboratory surveillance in England and Wales is based on generic laboratory reporting of confirmed infections from 300 NHS microbiology laboratories using a minimum dataset. A network of reference laboratories exists, capable of diagnosing rare diseases, together with sentinel laboratories for specific infections, for example influenza.

When routine surveillance systems are considered to lack sensitivity or specificity to address particular problems, or to miss essential information such as vaccination status, enhanced surveillance systems are established. For most diseases this consists of questionnaire follow-up of all reported cases (diphtheria, tetanus, pertussis, etc) and additional laboratory testing for some (e.g. measles and mumps salivary testing). Serological surveillance is carried out in England and Wales through analysis of residual specimens collected on an annual basis from children aged 1–15 years and on a five-yearly basis on adults aged 16 years and above.

Other sources, particularly for adverse events, include reporting of hospital episodes, sentinel physician reporting and paediatric surveillance. The British Paediatric Surveillance Unit (BPSU) of the Royal College of Paediatrics and Child Health (RCPCH) was established in 1986. The aims of the BPSU are to enable paediatricians to participate in the nationwide surveillance of infections and infection-related conditions, to promote the study of uncommon childhood disorders and to provide a mechanism by which "new" diseases could be detected so that early investigation could take place. There is active monthly zero reporting, with detailed follow up by
questionnaire and further investigation possible. The system is concerned with reporting of rare diseases (<100 cases per year) and has the capacity to identify vaccine-associated adverse events.

Systems for monitoring AEFI include passive reporting as a pharmaceutical product to the Committee on the Safety of Medicines, which is inexpensive and covers the whole population, identifying rare unexpected reactions, but suffers from under-reporting, unknown sensitivity as the denominator may not be known and may be subject to biased reporting. Active AEFI surveillance is used for detection of rare serious adverse events, is more complete and targeted to specific conditions like aseptic meningitis following MMR. Information is collected through a number of routes, including a hospital-episode database linked to child health vaccination data, a General Practice Research Database and specific disease and disability registers.

**Country Experience: Uzbekistan**

Between 1997 and 2003 a total of 23 fatalities following measles vaccination were reported in Uzbekistan. Investigation of the cases found that in all cases vaccine was administered from vials that had been kept open for more than 2–3 days, that vaccine cold chain requirements had not been met, that disposable (single-use) syringes had been used more than once and that knowledge of AEFI among paediatricians, vaccinators and parents was insufficient. In 25% of cases diluents other than those supplied with the vaccine were used for reconstitution. In response, a national AEFI surveillance system was established in 1999. This is a mandatory reporting system of all vaccine reactions and systematic visiting of vaccines by a nurse after vaccination and includes zero reporting. Although functioning well, the system faces some challenges, including strengthening of reporting in some regions and districts and improved standardized supervision at regional and district levels. There is also a need to update the case definitions of side effects and adverse reactions.

**Topic 3: Partnership and advocacy network for immunization**

**European Immunization Week – strategies for advocacy and effective communication**

There is a recognized need for increased advocacy for immunization at regional, national and community levels. A region-wide Immunization Week has been proposed to draw attention to and increase awareness of the importance of every child’s need and right to be protected against vaccine-preventable diseases, with special focus placed on reaching vulnerable groups. By planning activities during the same time period, a far greater impact can be achieved across the European Region, allowing countries to capitalize on the resources available. It is also proposed that adoption of an immunization week strategy would provide a platform to build regional advocacy efforts year on year. To help define activities, a questionnaire was developed for all immunization programme managers and through a process of consultation, the regional plan will be further developed.

If a Regional Immunization Week is going to achieve its objectives, however, there must be extensive and detailed planning and preparation. Participation in a Regional Immunization Week would certainly draw the attention of the anti-immunization lobby in some western European countries, with potential negative repercussions. For this reason, any activity carried out must be well planned and in accordance with the specific advocacy communication needs of the countries involved.
Expanded partnership and advocacy

Advocacy and communication strategies for immunization

A good communication strategy is essential to overcome the effects of low or lacking political commitment, inadequate motivation of health workers, lack of awareness or trust by the community and misinformation and fear around immunization. To establish and maintain an effective communication policy, it is essential to understand community dynamics and decision-making processes in addition to who is perceived to be a trustworthy source of information and accepted as an “agent of change” to work in the community. Effective and ongoing communication is crucial to building and sustaining capacity, but communication resources, both human and financial, need to be assessed, allocated and sustained.

Communication plans, based on a thorough situation analysis, should include clear targets, realistic actions, costing and appropriate roles and responsibilities. There must also be a feedback mechanism, as monitoring is a key element to guiding communication efforts.

The role of advocacy is to win support of key constituencies in order to influence policies and spending and bring about social change. A successful advocacy strategy must identify the key constituents with regard to immunization, determine what policies need to be influenced and establish what spending needs to be increased to achieve the desired goals. The value of immunization programmes must be demonstrated to ensure long-term financial commitment. Policymakers need to understand the political benefits of showing leadership and the potential political consequences of failing to take action on immunization. The advocacy strategy should also be flexible enough to allow new opportunities to engage new partners and new champions for immunization. As with other aspects of immunization, good data provides the basis for advocacy; the more facts and figures on lives saved, productivity increased and costs averted, the more persuasive the argument in favour of an effective immunization programme.

Country Experience: Hungary

In response to the initial signs of a decline in vaccine coverage, in 2002 the Government of Hungary developed and implemented an improved advocacy and communications strategy for immunization services. The improved communication strategy included the provision of improved background information and immunization guidelines to general practitioners and paediatricians, hosting a National Vaccination Congress for more than 800 participants and establishing a congress for Child Health Nurses with 2000 participants. To provide parents with improved information on immunization issues the Centre for Epidemiology published 12 brochures aimed specifically at parents and carers. There was also increased promotion of immunization services on television, radio and in newspapers.

To further promote immunization services the first National Immunization Day was held on 21 June, 2004, on the second anniversary of the certification of polio-free status in Europe. During the National Immunization Day vaccination activities were carried out in every county and district in Hungary. Preparations for the day included training of field epidemiologists, provision of information on the goals and results of immunization, round-table discussions on immunization, including question and answer sessions and provision of handouts, CDs and newspaper articles. A press conference was held by the immunization manager and General Director of National Centre for Epidemiology two days before the National Immunization Day. Press conferences were also held in every county, together with meetings for general practitioners, paediatricians, school doctors and child care nurses. Information was also provided
to parents and carers. Feedback after the National Immunization Day suggested that media involvement had been largely successful, with few attempts to sensationalize or misrepresent immunization activities. The local meetings were successful, with a large number of participants. Reports from the counties suggested that the Immunization Day was popular with the population in general, particularly with young parents.

To improve the ability of health services to make use of the media, the Executive Office of Chief Medical Officer established a Division of Communication in March 2004. The mandate of this office is to provide effective support for epidemiologists in dealing with the media and to establish effective collaboration with infectious diseases specialists to ensure that a common message is being broadcast. The office is developing and updating web sites with immunization-related information and establishing a free immunization telephone enquiry line. Local meetings for general practitioners, paediatricians and health visitors have continued, with autumn meetings focusing on influenza and its complications. A second National Immunization Day is planned for 2005.

Lessons learned in Hungary suggest that providing immunization information to young and “vaccine-hesitant” parents is a cost-effective way of maintaining vaccine coverage. Providing additional training to general practitioners, paediatricians and health visitors is also an effective use of resources. Establishing good working relationships with the media and with particular popular personalities can be very effective in promoting immunization services. To achieve consistency and to increase the impact of immunization-promoting activities, the message should be delivered by both epidemiologists and infectious diseases specialists working together.

**Country Experience: Tajikistan**

The Ministry of Health of Tajikistan, together with several international partner agencies, has achieved considerable success in establishing high immunization coverage and reducing vaccine-preventable disease incidence. With an average daily income of less than US$1 per capita per day, Tajikistan has been dependent on partnership with eight or more international agencies to provide capacity building and institutional development within the country. To better coordinate the activities of all participating bodies and to make the best use of available resources, an Interagency Coordinating Committee (ICC) was formed in July 2000. Members of the ICC are leading health professionals in Tajikistan, together with representatives of international organizations and NGOs. Since the formation of the ICC, additional partner organizations have expressed their interest in supporting immunization services and a desire to join the ICC. In addition to the ICC meetings, regular meetings with partner organizations, NGOs and governmental organizations have been held to attract additional technical and financial support, particularly for social mobilization activities.

**Topic 4: Measles elimination and Congenital Rubella Infection (CRI) prevention**

**Overview of current progress and challenges in the European Region**

The reported incidence of measles has declined significantly in the WHO European Region, with a 92% reduction (28,206 cases reported in 2003, representing a regional incidence of 3.2/100,000) in the annual number of cases reported since 1990, together with substantially improved completeness of reporting. Large outbreaks continue to occur in some countries of the
Region, including some western European countries. Since 2002, countries have been requested to report measles cases monthly by age group, vaccination status, disease outcome and whether they were laboratory confirmed, as well as the number of measles and rubella tests carried out; and to notify WHO of outbreaks.

In 2004, all 52 countries of the Region had national routine 2-dose measles vaccination programmes, compared with 49 (96%) in 2001. In 2003, 27 countries reported greater than 95% coverage with the first measles dose and 36 countries reported greater than 90% coverage. Supplementary measles immunization activities have taken place in seven countries since 2000; five countries used a measles/rubella containing vaccine and three countries offered rubella vaccination for women of child bearing age.

In 2004, the Regional Measles and Rubella Laboratory Network included 47 national laboratories, each linked to one of three Regional Reference Laboratories or the Global Specialized Laboratory, and they are performing well as a diagnostic network. This Network, coordinated by the Regional Office, was created in 2002 to provide support for measles, rubella and CRS surveillance. Laboratory investigation is carried out using standardized protocols and reagents. A quality assessment programme is now in place, including an annual accreditation review, proficiency testing and monthly online reporting of laboratory indicators. The integration of rubella and CRS surveillance into the measles surveillance programme introduces new challenges for the Laboratory Network. Technical capacity for isolation and genetic characterization of rubella viruses currently appears to be limited in the Region.

Forty-seven countries in the Region now use rubella vaccine in their immunization programmes; all but two use MMR vaccine. Even though the incidence of rubella has decreased, 304 320 were cases reported in 2003 and the inter-epidemic periods remains short, only nine countries reported a rubella incidence of less than one case per million in 2003. Very few countries have integrated case-based measles and rubella surveillance with laboratory confirmation. Many countries report cases based on clinical diagnosis and there is still no systematic surveillance for rubella in some countries. The number of CRS cases reported during 2001–2003 was only 47, indicating serious underreporting, 17 (36%) of those reported cases were from one country, Romania, with 2.6% of the European Region’s population.

The Strategic Plan for Measles and the Prevention of CRI calls for the interruption of indigenous transmission of measles and less than one case of CRS per 100 000 live births by the year 2010, using an integrated approach and seeking sustainable long-term impact on immunization systems in countries. Strengthening surveillance systems for measles, rubella and CRS to achieve the Regional targets will be one of the major challenges of the programme.

**Workshop Group 1: Measles and CRI strategic plan for Europe**

The objectives of this group were to review targets and key strategies identified in the Strategic Plan and suggest modifications to improve the clarity and/or strengthen the feasibility of meeting the objectives. Discussion centred on defining the conditions required for measles elimination and rubella control and whether mumps should also be included. It was concluded that the current targets of measles elimination and CRI prevention, although ambitious, were appropriate and achievable by 2010. Participants discussed having a rubella elimination target, however, a few countries expressed concerns about the costs of establishing systematic rubella surveillance. In order to achieve the regional measles and rubella targets, participating country representatives agreed on a strong recommendation to Member States of the European Region to replace
monovalent measles vaccine with MR or MMR in national routine immunization programmes and to ensure that women of child bearing age are protected against rubella. Discussions also addressed the need for emphasis to be placed on surveillance of adverse events related to the mumps component of MMR, depending on the strain being used.

**Workshop Group 2: Issues for policy makers; achieving support in all Member States**

The objectives of this group were to identify country-specific issues, which may need to be addressed in preparation for a possible Resolution on the Strategic Plan at the WHO Regional Committee in 2005. Discussions focussed on the need to share experiences in implementing measles control programmes between Member States in the Region, the need for political support for the targets, the importance of vaccine safety issues, the importance of disease surveillance in achieving the targets and the need for good communication and information on the plan and its objectives. The group also discussed the Regional goal of measles elimination and CRI prevention. The need for a clear rubella elimination target, in addition to the existing CRI prevention target was also discussed. General consensus of the workshop group was to endorse the measles and rubella elimination, while still keeping the CRI prevention target and focusing on CRS as the outcome of interest.

It was felt that the role of disease surveillance in documenting disease burden and guiding programmes was still under appreciated in many countries in the Region and that further efforts to improve surveillance quality, particularly for rubella and CRS, was a priority. Similarly, the importance of good communication and provision of accurate and appropriate information to health care providers and the public was underestimated. More work was required to identify and utilize the most appropriate and effective communication channels. For example, a large amount of information on vaccine safety is already available, but this should be more effectively disseminated. More work also needs to be done to abolish the use of inappropriate contraindications to vaccination that continue to be used in several countries of the Region.

**Workshop Group 3: Expanding partnerships to achieve the goals**

The objectives of this group were to make recommendations on ways to increase the number of regional partners supporting the Strategic Plan. Discussions centred on the need for WHO to continue its pursuit of major international partners to support routine immunization services in high priority countries. Countries should also pursue collaborative associations with key partners through bilateral agreements, host NGOs, improve collaboration with vaccine manufacturers, etc. There is a clear need to develop mechanisms for more effective information sharing on how to establish and maintain effective partnerships in support of immunization. The effectiveness of national ICCs has been demonstrated in several countries and the use and role of the ICCs should be expanded in countries in greatest need of support for routine immunization services. Funding sources to support the measles elimination and CRI prevention goals still need to be identified. There are, as yet, no consistent donor funding arrangements for measles/rubella within the Region. WHO should establish an advocacy mechanism to elicit funding support as a matter of priority.
Topic 5: Polio eradication initiative

Sustaining polio-free status of Europe and preparing for a polio-free world

Since the certification of poliomyelitis-free status on 21 June 2002, the Regional Office has continued to support the maintenance of high quality routine immunization coverage, particularly in high-risk groups. It also supports conducting SIA in selected high-risk areas and maintaining high quality surveillance for polioviruses. Although polio-free, significant risks remain for importation of wild poliovirus into the Region from other endemic areas. Member States must remain on high alert, ensuring the capacity of their surveillance systems to detect, report and respond rapidly to any importation that may occur. Added to the risk of importation of wild poliovirus is the risk of establishing circulation of vaccine-derived polioviruses (VDPV). Since June 2002, VDPVs have been detected on four occasions in the Region.

Activities to implement the Regional Plan of action for containment were initiated in 2000 and have been well supported by Member States. National laboratory surveys were completed in the majority of countries in the Region by June 2002. As of mid-2004 there were only four countries yet to complete the survey and inventory phase of the containment process. The Regional Office initiated an assessment of the quality of national laboratory surveys in late 2002. During 2003, all countries that had completed the survey and inventory phase were requested to conduct a self-assessment of their activities, according to WHO guidelines and provide documentation to the Regional Office.

Given the progress made towards the goal of global eradication of poliomyelitis, the risk of paralytic poliomyelitis is changing in many geographical areas. Vaccination against polio will need to continue because of the threat of wild poliovirus importation. However, an increasing number of polio-free countries are determining that the risk of paralytic poliomyelitis associated with continued routine immunization using oral poliovirus vaccine (OPV) is greater than the risk of importation or laboratory handling of wild poliovirus. Some of these countries have replaced OPV with inactivated poliovirus vaccine (IPV) as the vaccine of choice. Countries considering a change in policy should conduct a thorough evaluation of the epidemiological, operational and financial implications before introducing IPV.

Recognizing the need to address the threat of vaccine-derived viruses, WHO convened an informal consultation on identification and management of VDPVs in September 2003. It was concluded that the only feasible option to prevent generation of VDPVs in the post-eradication period is to stop routine use of OPV. The initiative was called upon to develop a comprehensive strategy for safely stopping OPV use as soon as possible after global eradication of wild poliovirus, at which time population immunity and surveillance sensitivity is anticipated to be high. Subsequent analysis of the situation has prompted the conclusion that universal immunization with IPV following cessation of OPV use is neither necessary nor possible. WHO does not currently recommend the routine use of IPV as a replacement for OPV.
Projected post-eradication policies and strategies – vaccine of choice

**Country experience: United Kingdom**

Until September 2004, the routine childhood schedule included oral polio vaccine (OPV). From September 2004, the UK switched to IPV for all routine childhood immunizations. Use of OPV was maintained because of the perceived risk of importation of wild poliovirus from India, Pakistan and western Africa, all places with strong links with the UK. The other reason for retaining OPV was the need to maintain the use of high quality pertussis vaccine. The UK uses DTP containing a whole cell pertussis component that had been demonstrated to provide a very high level of protection. As this DTwP vaccine contained thiomersal, it was not suitable for combining with IPV and introduction of stand-alone IPV was considered to be impractical. An equally effective acellular pertussis vaccine became available this year. As this vaccine does not contain thiomersal it can be combined with IPV and the decision was taken to switch from OPV and DTwP to a DTaP/IPV combination vaccine.

The schedule used in the UK is to deliver DTaP/IPV/Hib at 2, 3 and 4 months, followed by a dTaP/IPV booster at 3.5 to 5 years of age and a Td/IPV booster for teenagers. A contingency stock of OPV has been retained for use in case of an outbreak. The outbreak response plan included delivery of OPV to all household contacts of polio cases together with OPV for other individuals considered at risk in the immediate neighbourhood.

**Country experience: Turkey**

Turkey has reviewed its policy on polio immunization using the algorithm provided by WHO. As a recently polio endemic country, with a DTP3 coverage of less than 90% and where VAPP (vaccine-associated paralytic polio) is not considered to be a major public health concern, Turkey has decided not to switch from OPV to IPV. In the short-term Turkey will continue to use OPV in its immunization schedule, maintaining high quality poliovirus surveillance, with rapid laboratory confirmation and analysis. In the mid-term Turkey will continue to assess the risks and benefits associated with different immunization policies, but it is unlikely to change to IPV given current information. In the long term it is likely that Turkey will elect to cease all polio immunization, but will continue to observe the global recommendations, policies in neighbouring countries and countries with similar settings.

**Topic 6: New and under-used antigens**

**Overview of current progress and challenges in the European Region**

Immunization against hepatitis B has been introduced successfully throughout the Region, with more than 80% of countries in the European Region using universal hepatitis B in their immunization programmes. Some of these countries combine newborn/infant immunization with immunization of older children or adolescents. Some countries perform selected immunization against hepatitis B combined with screening of pregnant women and also target risk groups. The regional HepB3 coverage rate reported to WHO for 2003 was 67%. This indicator is based on calculations using total regional target population as denominator including children in countries without universal immunization programmes. Reported HepB3 coverage considering the denominator only for countries with newborn/infant universal immunization programmes was more than 80% in 2003. Eleven countries in the Region are eligible for support from GAVI (those with a gross national product of < US$ 1000 per capita; Albania, Armenia, Azerbaijan,
Bosnia and Herzegovina, Georgia, Kyrgyzstan, Republic of Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan) providing an opportunity to introduce hepatitis B vaccine, with supplies for safe injections for immunization.

Analysis of immunization coverage data since introduction of hepatitis B vaccine has identified problems in vaccine delivery systems in some countries. When reported hepatitis B vaccination coverage is compared with BCG and DTP3 coverage rates, major differences in rates can identify countries experiencing difficulties in reaching newborns or in integrating hepatitis B vaccine into existing programmes. Analysis can also reveal problems with uptake of other vaccines, or problems with supply and delivery of traditional EPI vaccines. Excessive drop-out (>10%) between vaccine doses has also been identified in some countries and major subnational regions.

Analysis of data from over 70 Hib studies performed in the countries of the European Region, has documented a higher incidence of Hib meningitis in children under five years of age in western Europe compared with central and eastern Europe. Twenty-seven countries of the European Region, mainly in western and central Europe, have implemented Hib vaccine as part of their national immunization programmes. Reported Hib3 coverage for 2003 was 42% (using all target children in the Region as denominator) with a marked reported reduction of Hib incidence as a result of immunization. The relatively high cost of Hib vaccines, insufficient evidence on disease burden and sustainability of national immunization programmes remain major barriers for introduction and implementation of immunization against Hib in many countries of the European Region, particularly newly independent states (NIS) and some countries of eastern Europe. To obtain more information on Hib disease burden, rapid assessments have been carried out in a number of countries of central and eastern Europe. Although methods used for assessing burden are less than optimal, as they depend on the availability of high quality morbidity and morbidity data, these studies have tended to confirm the relatively low Hib disease burden in many of these countries. An increasing number of countries use combined vaccines containing Hep B or Hep B and Hib antigens.

Information obtained from the WHO/UNICEF Joint Reporting Form suggests that other new vaccines are being introduced into the routine immunization schedules of many countries in the Region. Acellular pertussis vaccine appears to be in use in 25 countries, mainly in western and central Europe. Meningococcal conjugate vaccine is in use in 10 countries, pneumococcal conjugate vaccine in 6 countries and varicella vaccine in two countries.

**Parallel Session A: Hepatitis B**

*Hepatitis B immunization, use of combined vaccines, hepatitis B surveillance*

Hepatitis B vaccines have a perfect safety profile, induce rapid seroconversion and a high level of seroprotection. This is particularly true in newborns, infants, children and adolescents, of whom 98% demonstrate seroprotection. Even among healthy adults, seroprotection is greater than 95% among vaccine recipients. Immunization confers lifelong protection when offered at a young age and there is no requirement for a booster policy for universal hepatitis B vaccination programmes.

Hepatitis B vaccine is usually provided in a 0, 1 and 6 month or 0, 1, 2 and 12 month schedule, but all available evidence suggest the protective effect is equal providing there is a minimum of
four weeks between two primary injections and four months between primary injections and the ‘booster’. As the schedule is very flexible it can be easily adapted to all existing infant immunization programmes.

According to WHO recommendations, universal vaccination of all infants as an integral part of the national immunization programme is the highest priority in all countries. Whenever feasible and according to the local epidemiology, countries should incorporate prevention of perinatal hepatitis B virus (HBV) transmission by beginning vaccination of all infants at birth and/or by screening pregnant women and offering specific anti-hepatitis B immunoglobulin to exposed infants, if possible. Currently 26 out of 43 countries (or regions of countries) have a newborn immunization programme. Reasons for establishing such a programme include countering high or intermediate endemicity, overcoming lack of a screening programme for pregnant women, to save costs associated with screening, to ensure higher coverage and to start protection at birth.

In addition to the perinatal or infant programme, catch-up immunization programmes may be desirable for a limited number of years. These usually involve only single-age cohorts, for example, routine adolescent immunization. Experience suggests that coverage is usually lower than with infant or newborn cohorts. There are also advantages to introducing hepatitis B vaccine in combination with other antigens, taking advantage of existing successful immunization programmes. Combining hepatitis B with DTP vaccine not only facilitates inclusion in existing vaccination programmes, but for many countries in Europe guarantees a high coverage. Combined vaccines are currently licensed and available for use in more than 12 countries.

There are currently three methods used for monitoring and evaluating hepatitis B immunization programmes: immunization coverage surveys, serological surveys and surveillance for cases of acute hepatitis. Immunization coverage data are routinely collected during immunization activities and cluster surveys are used where routine data are not collected or considered unreliable. These data are useful to monitor the programme, measure drop-out rates and compare performance with other immunization programmes, but provide no information about disease impact. Serological surveys provide a more direct measure of impact on the disease (pre-vaccination versus post-vaccination), but require accurate methodologies and appropriate laboratory capacity. Surveillance for acute cases of hepatitis B provides a direct measure of disease burden and is useful in countries with substantial incidence of acute infection in children and younger adolescents. However, a very clear and rigorously applied case definition of acute hepatitis B must be established for surveillance information to be useful.

**Country experience: Belgium – hepatitis B immunization (combined vaccine)**

Belgium belongs to the group of low endemicity countries, with the reported incidence of acute clinical cases decreasing from 25 per 100 000 in 1982–1984 to 6 per 100 000 in 1991–1992. Despite the low general incidence a number of higher risk groups were recognized and hepatitis B vaccine was provided to selected groups. In 1985 vaccine was provided to thalassemia patients, transplantation candidates and institutionalized severe mentally handicapped patients. In 1988 vaccine was provided to those at occupational risk, particularly health care workers. In 1991 screening of all pregnant women was initiated and immunization provided to babies of HBsAg positive mothers. In the same year vaccine was provided to all renal dialysis patients. In 2001 vaccine provision was extended to intravenous drug abusers, STD patients and household members of chronic hepatitis B virus carriers.
Following recommendation from WHO and analysis of the impact of universal hepatitis B vaccination in other countries, Belgium adopted a schedule of immunizing children less than 15 months of age and pre-adolescents. Coverage in children is currently approximately 68% with the third dose of hepatitis B vaccine. In 2004 a hexavalent vaccine including hepatitis B was introduced for use at 15 months of age. However, even the cost-effective, combined vaccines are considered by some local health authorities as too expensive and many local health authorities are reluctant to introduce new vaccines. In addition, the general public has developed a perception that too many vaccines are being used and this could have a detrimental effect on vaccine acceptance levels.

**Country experience: the Republic of Moldova – hepatitis B immunization**

Hepatitis B infection was identified as a high public health priority for the Republic of Moldova. The average incidence rate of acute viral hepatitis between 1980 and 1994 was 54.1 per 100,000 population, with the highest rate, 77 per 100,000, registered in 1987. Carriage rate for hepatitis B surface antigen (HBsAg) was 8 to 12% and death following chronic hepatitis and liver cirrhosis ranked fourth and fifth in the national mortality statistics. A case control study conducted in 1994 showed that among children (average age 5 years), 17.1% were positive for markers of anti-core (anti-HBc), 6.8% were positive for HBsAg and 1.4% were positive for anti-hepatitis C (anti-HCV). Among pregnant women (average age 26 years), 52.3% were positive for anti-HBc, 9.7% were positive for HBsAg and 2.3% were positive for anti-HCV. Of the pregnant women positive for HBsAg, 35.6% were positive for “e” antigen (HBeAg), indication they were highly infectious for hepatitis B and the risk of perinatal transmission was reasonably high. The case-control study also investigated possible routes of transmission. Up to 52% hepatitis infections in adults and 20% in children were attributed to unsafe injections. The most frequent locations to receive unsafe injections were considered to be hospitals, dental surgeries and outpatient clinics.

In an attempt to combat the hepatitis B problem, between 1989 and 1991 there was selective immunization of 19,000 newborns born to HBsAg positive mothers. This was reinforced by attempts to improve safety of blood transfusions, safety of injections and sterilization of medical devices. In 1995 Moldova included universal immunization of newborns with hepatitis B vaccine within 24 hours of birth in its national immunization schedule. In 1998 immunization coverage of newborns reached 90%. In 1999 and 2000 there was selective immunization of 10,000 health care workers. By 2000, up to 90% of children up to four years of age were protected with vaccine against hepatitis B and by the end of 2003, 11 successive birth cohorts had achieved coverage with a third dose of hepatitis B vaccine of more than 95%. During 2004 more than 26,000 health care workers, students at medical faculties, children from orphanages and contacts of acute cases received vaccine. It is planned that in 2005 all children less than 15 years of age will receive a dose of hepatitis B vaccine.

These activities have resulted in a reduction of more than 80% in the overall incidence rate of hepatitis B infection, with the number of cases in children dropping from 1000 to 50. The most impressive reduction of acute cases has been seen in children up to six years of age, with only four cases being registered in 2003 and two cases registered in the first nine months of 2004. The highest incidence rates are now seen among adults and teenagers.

**Country experience: Slovenia – hepatitis B surveillance**

In Slovenia there is an existing database of hepatitis cases established through obligatory notification of all cases and each case is investigated to determine mode of transmission and vaccination status. Hospital records, including admissions and death registers are also used to
detect cases. Screening services, including blood donor screening and testing of pregnant women, also contribute to disease incidence data.

Prior to the introduction of universal hepatitis B vaccination the prevalence of HBsAg carriers among blood donors was 1.5%, with approximately 5% of donors showing some markers of hepatitis B infection. It was estimated that approximately 50% of detected cases were sexually transmitted, approximately 15% were associated with intravenous drug abuse and 2% resulted from dialysis, transfusion and receipt of human blood derivatives prior to the introduction of screening. A very small number resulted from non-medical interventions, such as tattooing and piercing, but the mode of transmission for more than 30% of cases was unknown.

Following the introduction of universal hepatitis B vaccination enhanced surveillance was established to determine the prevalence of hepatitis B infection in children and adolescents, to identify changes in disease burden, to determine the risk from perinatal transmission and to re-evaluate national recommendations for high-risk groups and the universal immunization of children. Surveillance demonstrated that as in other countries with a low rate of chronic disease the infection occurs predominantly in adolescence. Risk of perinatal infection was found to be low and was reduced by administering vaccine and immunoglobulin at birth to babies of HBsAg positive mothers. It was concluded that universal childhood immunization is both reasonable and beneficial.

**Parallel Session B: Hib disease burden and opportunities for other new and under-used antigens**

*Haemophilus influenzae* type b burden and surveillance

*Haemophilus influenzae* is a common cause of serious infection and mortality in children less than five years of age, often presenting as meningitis, epiglottitis, pneumonia, bacteraemia, cellulitis, septic arthritis or osteomyelitis. Infection can result in lasting deafness, learning problems and fits. The majority of serious infections are caused by *Haemophilus influenzae* type b (Hib). Because of the wide range of possible clinical presentations it is important to establish the burden of Hib disease in a country in order to make informed decisions on the need to implement a Hib vaccination programme and the most appropriate schedule of Hib immunization to use. Measuring the local burden of Hib disease is not easy, however, as Hib meningitis and pneumonia are hard to diagnose and there are a number of logistical challenges, including identifying a study site where all sick children have access to health services, where appropriate specimens (blood, CSF) are collected routinely and systematically, where an accurate population denominator is available and where the private sector Hib immunization coverage is known.

Methods used to measure local disease burden have included population-based surveillance using a WHO generic protocol (WHO/VRD/GEN/95.05). Studies funded by WHO have been conducted in Bulgaria, Poland and the Russian Federation (Moscow). The process is relatively slow, taking one to two years to complete and does not measure the burden of Hib pneumonia. Vaccine efficacy trials have been used to measure the efficacy of vaccine in preventing illness that is not culture-confirmed (e.g. X-ray confirmed pneumonia), but this method is both complex and expensive. The WHO rapid assessment tool (HibRAT – WHO/V&B/01.27) estimates the local Hib disease burden and has been used in Armenia, Albania, Bosnia and Herzegovina, Kyrgyzstan, the Republic of Moldova, Ukraine and Uzbekistan. The method is rapid but accuracy
depends on the quality of available data and on the validity of a number of assumptions the method uses.

In 1996 a network within the EU was established for surveillance and epidemiology of *Haemophilus influenzae* (EU-IBIS). From 1999 onwards the network has been funded by the European Commission (DG SANCO) as a Disease Specific Network (DSN), with funding granted until 2006. The intention is to incorporate all new member states of European Union (EU) into the network. The aims of the network are to provide epidemiological information on invasive *Haemophilus influenzae*, to improve laboratory capacity to accurately characterize isolates and to evaluate the impact of vaccination with conjugate vaccines on the epidemiology of *Haemophilus influenzae*. Collecting standardized case-based data throughout the EU-network allows meaningful comparison of national data on Hib disease burden and will facilitate the detection of any emerging trends in Hib disease. There is a need to assess efficacy over a longer period, using accurate coverage data, to control for differences in herd effect, coverage and baseline incidence, as well as determining the impact of booster doses and the choice of vaccine used. It is also necessary to look for long term changes, such as waning protection, the emergence of non-b *Haemophilus influenzae* and the appearance of susceptible older cohorts. Questionnaires on surveillance methods and laboratory capacity to diagnose Hib have been distributed to all non-EU Member States of the WHO European Region.

Hib vaccine was introduced in the UK in 1992 and a dramatic decline in Hib incidence was observed within one year of introducing the vaccine. The most marked decline was seen in children under five (those targeted for vaccination), but there was also a decline in older children and adults. Incidence rates continued to decline until 1998, but there has been a marked increase since 1999. The increase in incidence has been seen mainly in children under four (mostly vaccinated), but has also been detected in adults. Investigations have shown that the increasing incidence of invasive Hib disease following a full primary course of vaccine has been the highest in children born in 2000 and 2001 and has been associated with a decreased age at disease presentation. Concerns were raised over possible low vaccine efficacy in children receiving DTaP-Hib (used since 1999 because of supply problems for DTwP-Hib) and a case-control analysis of vaccine batches was undertaken. It was found that incidence had increased in all cohorts and with all vaccines. It was also found that the catch-up programme had contributed to the control of Hib, with higher vaccine efficacy and boosting of antibody levels, but that the effect was probably temporary. Short-term exacerbation of the problem appears to be related to the use of a lower efficacy vaccine used in response to a vaccine shortage. In response the Department of Health ordered a Catch-up Campaign in 2003, offering an extra dose of Hib vaccine to all infants born after January 2000, with a review of the long-term need for booster doses. Incidence of invasive *Haemophilus influenzae* was lower in all age groups in 2004 than in 2003.

**Rotavirus vaccine**

In developing countries rotavirus causes a greater proportion of severe diarrhoea requiring hospitalization of infants and young children than any other aetiological agent. Transmission is primarily faecal-oral and the peak incidence is 6 to 24 months of age. Almost 100% of children have been infected at least once by 24 months of age. Virus transmission usually shows limited seasonality, but there is no correlation between infection and socioeconomic status, water supply, sanitation facilities, electricity supply, maternal education, household size or gender. Supportive therapy can reduce diarrhoeal mortality through replacement of fluid and electrolyte losses, but vaccine-induced immunity is the best way to prevent rotavirus morbidity and mortality.
There are currently three licensed, but not WHO pre-qualified rotavirus vaccines, another under advanced clinical evaluation and at least another three candidate vaccines under early clinical development. The mandate of the Rotavirus Vaccine Project, a PATH affiliate, is to reduce child morbidity and mortality from diarrhoeal disease by accelerating the availability of rotavirus vaccines appropriate for use in developing countries.

**Country experience: Finland – Hib immunization and prospects for pneumococcal immunization**

In Finland the incidence of *Haemophilus influenzae* disease in children less than five years of age before the introduction of Hib vaccine was 52 per 100,000 population. The most common clinical presentation was meningitis, followed by epiglottitis. The pre-vaccination era incidence of Hib meningitis in children less than five years of age was 24 per 100,000 – one of the highest recorded incidences in the world. Hib vaccine was introduced in 1986, followed by a very rapid decline in the incidence of Hib disease. The impact of vaccination was both greater and more rapid than expected and was probably due to the herd effect protecting non-vaccinated individuals. The original decision to introduce Hib vaccination was made without consideration of the economic advantages, but reassessment has shown that while the vaccine is relatively expensive, the cost per vaccinee being estimated at €18.6 at 2004 prices, the break-even cost per child was estimated to be US$ 54. Introduction of Hib vaccine in Finland has therefore demonstrated to be of public health benefit, safe for the individual, safe for the population and cost-effective.

In considering the potential introduction of pneumococcal vaccine into Finland, it is clear that the potential to decrease pneumococcal disease is significant. From a birth cohort of 55,000 it is expected to experience 50 to 60 cases of invasive pneumococcal disease, 500 to 1800 cases of pneumococcal pneumonia and 10,000 episodes of acute otitis media. Vaccine efficacy studies have shown that pneumococcal conjugate vaccines provide significant protection against pneumococcal disease, particularly invasive disease. It is also likely that, as with Hib vaccine, the herd effect would provide protection for non-vaccinated individuals. However, assessments of cost–effectiveness of available vaccines suggest that introduction would impose a significant net burden on immunization services and would not be cost-effective. It is unlikely, therefore, that routine use of pneumococcal vaccine will be introduced in Finland in the near future.

**Country experience: Latvia – Hib immunization**

Hib vaccine was first introduced in Latvia in 1994. Assessing the impact of vaccination on invasive Hib infection in Latvia has not been simple, even though a clear decline in cases of bacterial meningitis of unclear aetiology occurred with rising vaccine coverage, changes made to the surveillance system do not permit long-term tracking of disease incidence from the introduction of Hib vaccine. All available data suggest, however, that Hib vaccine has had a significant effect in decreasing Hib disease.

A survey of “missed opportunities” for immunization carried out in 2002 showed that refusal of parents to accept simultaneous administration of several vaccines was an issue. Use of false or inappropriate contraindications for vaccination also proved to be a significant cause of missed immunizations. Approximately 4% of children failed to receive vaccine in their first year of life. Introduction of modern combined vaccines with low reactogenicity is being used to improve the coverage and timeliness of vaccination and reduce the missed opportunities for vaccination. Use
of combined vaccines also facilitates easier tracking of Hib vaccination coverage and analysis of coverage data. The intent is to move to combined DTaP-IPV-Hib vaccine as soon as possible.

**Country experience: United Kingdom – meningococcal immunization**

An outbreak of group C meningococcal infection occurred in England and Wales in 1998–1999, with approximately 1530 serious cases and 150 deaths. The response was a meningitis C vaccine campaign in 1999–2000 in which immunization was provided to all infants at 2, 3 and 4 months of age and catch-up doses were provided to other age groups based on risk. The effects of this campaign were assessed in 2000–2001, demonstrating an overall 67% reduction in disease incidence. Further developments in this field will depend on the results of careful surveillance and deliberations on whether or not to reduce the number of doses given in the first year of life from three to two.

**Topic 7: Immunization safety**

**Regional priorities in immunization safety. Monitoring of immunization safety**

Immunization safety is a major area of work identified as a regional priority. The programme objectives are to ensure the use of quality assured vaccines and to promote safe injection practices, including safe and appropriate ways to dispose of immunization waste. The regional strategic approach to achieve these objectives considers the strengthening of countries immunization components related to vaccine quality and safe administration. Interventions aimed at securing the quality and safety of immunization occur at six levels; national regulation, vaccine procurement, vaccine management, injection safety, waste disposal and surveillance of adverse events following immunization (AEFI).

Support to countries is provided following a benchmarking process which starts with an assessment of each of the six components using tools which allow the measurement of the country’s performance against a set of standardized indicators. The second step of the process is to assist in the establishment of relevant policies and the development of action plans to address any weaknesses identified during the assessment. Subsequently, training courses and workshops are implemented to ensure that staff have the requisite knowledge and skills.

Considerable progress has been made in recent years through concerted effort to ensure improvements in immunization safety activities. There have been major improvements in the functioning of NRAs but implementation of licensing and lot release functions remains critical for some countries. The provision of quality-assured vaccines, according to WHO standard definitions, is now assured in most countries. However, concerns remain regarding the institution of countries self-procurement mechanisms, more particularly for those countries switching from UNICEF procurement services. As countries supplied by UNICEF increase their participation in vaccine procurement, they need much support in the establishment of their procurement system. During 2004, no major cold chain breakdowns were reported in the 12 countries under assessment and very few vaccines appear to have been discarded due to cold chain problems, but vaccine stock management is still inadequate in several countries. Since the workshop that took place in April 2003, awareness of vaccine management principles is high amongst immunization managers. However, there are few plans for the replacement of old equipment and the risk of freezing adsorbed vaccine is still not well documented.
In the 17 countries assessed on the safety of injections to date, provision of syringes and needles was secured and the “one syringe – one needle for every child” policy is respected, but needle recapping practices continue to increase the risk of needle stick injuries and sharps waste management remains poor in many countries. Safety boxes are in use, but there are few clear policies and no standardized process for disposal. As countries maintain high immunization coverage, there is less tolerance of adverse events and the influence of anti-vaccination groups becomes critical. The media, in search of sensational events, do not hesitate to discredit the benefits of immunization, thus endangering the success of immunization programmes. It becomes more critical therefore, for countries to institute effective AEFI surveillance and response systems. Response to AEFI must be based on the latest scientific evidence, and WHO has taken the initiative to create the Vaccine Safety Net, where a number of “certified” websites are linked up, thus providing a pool of credible immunization safety information, in a number of languages. In addition, the Global Training Network (GTN) now has a training centre at the Tarasevic Institute in Moscow that offers an annual courses on AEFI. Surveillance systems are now in place in all countries, but the few assessments carried out reveal that improvements are still needed in the functioning and sensitivity of the systems in place.

As a large number of important areas are covered in the immunization safety component, the monitoring of country performance has become essential to better respond to country needs. In addition to the information provided by the numerous country assessments carried out during the last few year, data provided through the WHO/UNICEF Joint Reporting Form is also used to monitor vaccine safety issues in priority countries. This data can be used to identify strengths and weaknesses, rank priorities by areas of action, monitor progress and performance, provide data for regional planning and prioritization and be used for communication and advocacy. Information provided in the JRF with information from WHO country missions allows separate monitoring of five key components of immunization quality and safety, with five or six core indicators per component. The five key components are 1) National Regulatory Authority, Vaccine Procurement and Financing, 2) Vaccine and Cold Chain Management, 3) Injection Safety, 4) Sharps Waste Management, 5) AEFI Surveillance and Media Issues. Using a scoring system to assess performance according to core indicators it is possible to monitor progress in implementation of essential safety policies and identify any major areas of weakness for immunization quality and safety.

Directly derived from the above monitoring system, the regional immunization safety programme has set its five priorities as follows: (1) improving the sensitivity and functionality of AEFI surveillance systems, including effective response and dealing with the media, (2) promoting safe injection practices to reduce needle stick injuries, (3) developing and promoting sound waste management policies, (4) promoting the adoption of national vaccine regulations and strengthening vaccine procurement mechanisms that ensure the provision of a sufficient quantity of quality-assured vaccines, (5) instituting cold chain quality-assurance systems to eliminate vaccine freezing and establishing effective vaccine stock-management systems to monitor consumption, reduce wastage and avoid shortages.

Parallel Session A: Injection Safety for Immunization

Regional Office perspective

Safe injections are those that do not harm the recipient and do not expose the provider to any avoidable risks. Assessment of risks in a number of countries have shown that the greatest risk to
injection recipients comes from the re-use of syringes, usually due to shortage of supply and the
greatest risk to providers comes from needle recapping and needle-stick injury. Auto-disable
(AD) syringes offer the potential to reduce risk to recipients and proper use of safety disposal
boxes offers the potential to reduce risk to providers. AD syringes and safety disposal boxes are
now widely used, but there is yet little evidence available that they have effectively reduced
risks. Some countries continue with a policy of decontaminating used injection equipment and
there are important questions to be answered regarding the appropriateness and continued
necessity of these policies. There should also be more discussion and evaluation of the key issues
to be included in a national policy to ensure the safety of injections.

Country experience: the Republic of Moldova

A number of assessments related to the performance as well as the safety of immunization have
been carried out in the Republic of Moldova over the past 10 years. An assessment of injection
risks carried out in 2002 found that for recipients of vaccination injections risks were low,
although risks were slightly higher for recipients of curative injections. Risks for injection
providers were found to be high, while risks to the community were moderate. The
implementation in the same year of a measles/rubella supplementary immunization activity gave
the opportunity to prepare staff on safety issues. In 2003 an assessment of risks associated with
the immunization campaign was carried out demonstrating a clear progress of practices among
immunization providers. During the campaign a total of 1.3 million injections were given and a
total of 17 cases of AEFI reported. None of the reported AEFI cases were fatal. Sterile AD
syringes were used exclusively during the campaign and following the refresher training
programme the level of needle recapping was seen to be greatly reduced in comparison to the
previous assessments. In 2004 a national plan for injection safety has been issued and application
has been made to GAVI for support for implementing this plan. Although the government is
committed to supporting implementation of the plan, there remains a significant shortfall in
available funding and it is currently unclear how this shortfall will be made up.

Country experience: Ukraine

A 2002 injection safety assessment in Ukraine found that the practices in use posed a relatively
high risk for vaccine providers as injection equipment was subject to chemical decontamination
and plastic syringes were being recycled. In 2003 AD syringes were introduced and an
investigation of the option of a non-burning disposal system was requested by the Government.
A pilot project was established to develop a system of safe disposal of syringes through
alternative processes. This process should include safe needle removal, containment (container
and bags), decontamination (autoclave, centralized/decentralized), transport and disposal
(shredding, recycling). The project should evaluate the cost–effectiveness of the options and
arrive at recommendations for the safest and most viable process for the disposal of syringes.

The project developed appropriate processes, both centralized and decentralized and reviewed
these processes through sampling and ongoing monitoring. Different needle removers were
tested, autoclaving was investigated as a means of disinfection and shredding of plastics for
recycling was evaluated. The preliminary outcome of the project is very positive, but a number
of technical and financial issues remain to be resolved. Although the process devised is relatively
inexpensive a more thorough financial analysis is required and additional investment is required
for needle cutters and autoclaves. It must be recognized that safety has a cost to be weighted
against the system previously in use that put providers at risk. The proposed system seems to
improve safety and be feasible. Results of the pilot project will be finalized and presented at a
national conference early 2005, after which a national decision on whether expanding the project or not will be taken.

**Country experience: United Kingdom**

Passive surveillance for health care workers occupationally exposed to HIV was established in the UK in 1984. This system was developed further in 1997 into an enhanced programme of surveillance for occupational exposures to hepatitis B (HBV) and hepatitis C (HCV) viruses and any health care worker started on post-HIV exposure prophylaxis. An analysis of the results has shown that the most common exposure is to HCV, followed by HIV and hepatitis B. More than 70% of exposures are percutaneous, with 22% mucocutaneous. The highest number of reported exposures involves nursing professionals and most exposures occur on hospital wards and in operating theatres. Many of the injuries occurring are preventable and would be prevented if recommended procedures were followed. In the UK, health care workers remain at risk of blood borne infections, particularly HCV, even though systems are in place to minimize risk.

**Parallel Session B: Sharps Waste Management**

**Regional Office perspective**

Until now, sharps waste management is not an area where much emphasis has been placed by the Regional Office. Firstly it is a complex subject, involving different and diverse sectors, for example Ministries (Health, Environment, at least) and other stakeholders (private sector), but it also covers therapeutic as well as preventive injections. There are great needs in many countries of the Region, as sharps waste management must be considered within the overall healthcare waste management system and several countries are currently lacking technical expertise, funds and commitment to address the issue.

The Regional Office will support countries in developing policies and plans on healthcare waste management, in order to ensure sustainable implementation of safe procedures. However the Regional Office will not be able to support countries in the implementation of their system, but will try to facilitate the setting up of working groups and contacts with stakeholders and donors.

**Country experience: France**

Historically health care waste in France was treated as other forms of waste and disposed of in by incineration or landfills. With the emergence of new environmental standards in the 1990s, the increasing use of disposable equipment and the emergence of new pathogens, it became clear that special provisions were required for disposal of hospital waste. In 1997 new regulations on health care waste were introduced requiring (i) segregation of infectious waste from domestic and other waste, (ii) clear and appropriate packaging of infectious waste and (iii) effective disposal, either by incineration or by thorough decontamination prior to disposal with domestic waste. Health care waste is no longer incinerated onsite at hospitals, but is safely transported to dedicated health care waste or industrial waste incinerators. Alternatively the waste material is incinerated with domestic waste under conditions carefully controlled by local authorities. In some cases prior to incineration infectious waste material is decontaminated by autoclave, microwave or subjecting to chemical disinfectants.

Each year in France approximately 155 000 tons of infectious health care waste is generated, 145 000 tons by 4500 health care units and 10 000 tons by 240 000 health professionals. Of this waste, 87% is incinerated, at a cost of €244 per ton in domestic incinerators and €260 to €440
per ton in dedicated incinerators. A total of 13% of the waste is disinfected, at a cost of €350 to €500 per ton (up to and including final disposal as municipal waste). The waste disposal process is closely monitored and the regulations are strictly enforced by local health authorities. Penalties for disregarding the regulations include up to two years’ imprisonment and fines of €75 000. Although safe disposal of infectious waste from major institutions in France is now in hand, there are remaining questions over the appropriateness and acceptability of currently used decontamination processes and over the safety of disposal of waste produced by private practitioners and patients at home.

Country experience: Germany

As in other countries in western Europe, disposal of infectious health care waste in Germany is well regulated and subjected to ongoing monitoring and assessment. Sharps must be transported and disposed of by approved waste management contractors. Every transport of infectious waste must be accompanied by appropriate documentation and every producer of 2000 kg or more of high risk infectious waste (or 2000 tons of lower risk waste) must provide a waste management plan.

Analysis of waste disposal costs in Germany has shown that incineration of infectious waste in specialized incinerators costs between €900 and €1200 per ton. The incineration process must include appropriate purification of waste gases and neutralization of all residual ash. Energy produced by the incinerators is used to generate electricity, process steam and provide community heating, although the yields could be improved over current levels. Scrap iron and non-ferrous metals are recycled, and residual ash is often utilized for road construction. Pre-treatment of materials and neutralization of ash will be mandatory after June 2005 and landfill of untreated waste will become illegal.

Country experience: Uzbekistan

Recognizing the need to raise the awareness of health care workers and the general public on the risks posed by unsafe injection practices and to establish standard procedures for the disposal of sharps, safety disposal boxes were supplied to all vaccination sites in 2001. According to national regulations established in 2002 it is obligatory to incinerate all waste. Recognizing the need to provide dedicated incinerators, the Government has undertaken the task of providing a total of 223 small-scale incinerators, located in central and rural hospitals. The decision to provide a decentralized waste disposal system was based on the large size of Uzbekistan, making it difficult and expensive to collect and transport waste materials to a central location. In addition, Uzbekistan has a limited budget and small-scale incinerators are an affordable option providing an immediate solution to the problem.

In some regions a system of centralized collection of safety boxes of used syringes is being operated. The collected materials are transported and incinerated in industrial incinerators in large local factories or production plants. In other regions new small-scale incinerators were provided. Twenty-three new incinerators were provided in three provinces in a pilot project run with support from international partner agencies. To allow disposal of waste at primary health centres, temporary, non-standard incinerators have been built at several small medical facilities. Open air burning of waste is only permitted under special circumstances, such as in very remote rural areas. The UNICEF supported project run in three provinces has proved to be successful and agreement has been reach to extend this project to other provinces and provide small-scale incinerators to more health facilities.
Conclusions and recommendations

**Topic 1: Immunization services, with a focus on reaching “hard-to-reach”/vulnerable groups**

**Conclusions:**
- Effective immunization programmes, achieving high vaccination coverage and lowering disease incidence, have been established and effectively maintained for many years in Europe.
- National coverage with EPI vaccines is good in most of the countries of the Region, but many countries continue to have low coverage at the subnational level.
- “Hard-to-reach”/vulnerable groups exist in each and every country.
- Established immunization programmes face the challenge of an evolving global public health environment, with changes in immunization practices, policies and communication.
- There has been an acceleration of research & development into new vaccines and new technologies and Europe has demonstrated a large capacity for increasing the number of agencies and institutions engaged in this work.
- Real or perceived adverse events following immunization (AEFI) and rumours of these events, have increasing potential for disrupting immunization programmes throughout the Region if they are not responded to rapidly and effectively.
- There are mounting concerns over the impact of vaccine refusal groups and a highly organized anti-vaccination lobby on reducing vaccination coverage levels.

**Recommendations:**
- Member States should ensure that all groups have equal access to vaccines and can achieve adequate immunization coverage. Opportunities to develop new and innovative approaches to reaching hard-to-reach/vulnerable groups should be a priority for national immunization programmes.
- Ongoing sensitive and standardized AEFI surveillance should be a component of every National Immunization Programme.
- Member States should be prepared to anticipate and respond to negative perceptions and/or negative media reports in a timely manner through the use of effective and evidence-based communication.
- International partner agencies should conduct further research into the impact of health sector reforms on the performance of the national immunization programmes.

**Topic 2: Information systems for immunization – an evidence base for programme management**

**Conclusions:**
- Monitoring for immunization coverage and surveillance for vaccination-preventable diseases and AEFI exist in every country in the Region, but sensitivity varies considerably from country to country.
• Significant delays continue to exist between data reporting at all levels and management capacity for analysis at local and national level is not always appropriate, thus greatly reducing the timely and appropriate response.

Recommendations:
• Member States should take every opportunity to make improvements in data quality and timeliness of collection and analysis, in line with existing WHO guidelines.
• Data should be used more effectively to guide the programme as a tool for monitoring performance and identifying low performing areas and high risk groups and also for making health policy decisions.
• Member States should make more effective use of data exchange platforms, such as the centralized information systems for infectious diseases (CISID), to ensure efficient and timely information sharing between countries.
• Every effort must be made to ensure that regional partner agencies continue to work with WHO to strengthen and improve coordinated reporting mechanisms for immunization coverage and vaccine-preventable diseases.

Topic 3: Partnership and advocacy network for immunization

Conclusions:
• Some countries are currently developing and implementing advocacy initiatives and there is potential for valuable lessons and experiences to be shared and developed.
• There is a clear need for developing and implementing integrated advocacy and communication strategies for immunization.
• An annual Regional “Immunization Week” presents an opportunity to increase awareness of immunization issues, even though representatives of a few Member States expressed concern relating to “Immunization week” that such an event might actually produce negative press reaction in their countries.

Recommendations:
• Every Member State should have strategies for proactively addressing advocacy and communications issues integrated into their national immunization plans. Communication strategies should include provision of comprehensive information on both the vaccination-preventable disease and the vaccine.
• WHO should continue to consult with Member States and international partner agencies on the potential for holding an annual Regional “Immunization Week” tailored to suit individual country needs, priorities and requirements in those countries of the Region where it would have a positive impact.
• WHO, in collaboration with Member States, should seek out and engage relevant partners, specifically the European Union, to enable further progress on strengthening immunization programmes and achieving specific disease control targets.
**Topic 4: Measles elimination and Congenital Rubella Infection (CRI) prevention**

**Conclusions:**

- Member States have made significant progress towards meeting the targets identified in the *Strategic Plan for Measles and Congenital Rubella Infection in the WHO European Region*.

- Although ambitious in scope, current targets of measles elimination and CRI prevention are appropriate and achievable by 2010. There was strong support for having a Regional rubella elimination target, however ensuring that the CRI prevention (CRS incidence of <1/100,000 live births per year) target is kept as the main focus, although some countries expressed concerns about establishing routine rubella surveillance in the general population.

- Further efforts are required in many countries to improve routine vaccine coverage, offering measles and rubella vaccines to susceptible populations.

- The importance of disease surveillance in documenting the disease burden and guiding the programmes is still under appreciated in many countries in the Region; further efforts to improve surveillance quality for measles and particularly for rubella and CRS, is a priority.

- The importance of good communication and the provision of accurate and appropriate information to health care providers and the public are not generally appreciated. More work is required to identify and utilize the most appropriate and effective communication channels. More work also needs to be done to abolish the use of inappropriate contraindications to vaccination that continue to be used in several countries of the Region.

- An effective Regional Measles Laboratory Network has been established, capable of providing laboratory confirmation of sporadic measles cases and performing outbreak investigation. The integration of rubella and CRS surveillance into the measles surveillance programme introduces new challenges for the Measles Laboratory Network. Technical capacity for the isolation and genetic characterization of rubella viruses is currently limited in the Region.

- There is a need for a strong partnership to support activities related to the goal, particularly in high priority countries. There is a clear need to develop mechanisms for more effective information sharing on how to establish and maintain effective partnerships in support of immunization.

**Recommendations:**

- The Regional objectives for 2010 should be measles and rubella elimination, but keeping a strong emphasis on CRI (incidence of CRS of < 1 per 100,000 live births).

- To ensure political commitment from all Member States, the revised measles/rubella objectives should be a priority agenda item at the 2005 WHO European Regional Committee Meeting.

- Member States should undertake all necessary efforts to strengthen their routine immunization programmes and ensure sustainable, long-term support for measles and rubella immunization, also ensuring that women of child bearing age are protected against rubella.
WHO and Member States should strengthen surveillance for measles, rubella and CRS, identifying and developing specific methods for monitoring progress towards elimination targets, however, the approach needs to be adaptable to countries that currently feel that routine surveillance for rubella is not feasible.

Laboratory network capacity for confirmation of rubella positive samples and detailed characterization of rubella isolates should be assessed and extended, if appropriate.

WHO, Member States, major international organizations and bilateral agencies should work together to establish and maintain effective partnerships in support of the regional objectives.

**Topic 5: Polio eradication initiative**

**Conclusions:**

- The Polio Eradication Initiative has achieved an impressive level of success in eliminating wild poliovirus from the Region and maintaining the Region’s polio-free status.
- Every country in the Region remains at risk of reintroduction of polioviruses and it is essential that high population immunity and high quality surveillance be maintained, particularly in areas and populations at risk of importation of wild polioviruses and establishment of cVDPVs. Worryingly, the AFP rate has decreased in some countries.
- The Regional Polio Laboratory Network is fully operational and consistently demonstrates the highest quality performance indicators. Experience gained by the polio laboratory network should now be used for the establishment and maintenance of laboratory networks for the diagnosis of other vaccination-preventable diseases, particularly influenza and hepatitis B.

**Recommendations:**

- All Member States, especially those bordering remaining wild poliovirus endemic foci, must maintain high quality AFP surveillance until global certification of polio eradication is achieved.
- All Member States should ensure that requirements for high population immunity and high quality surveillance for poliovirus, according to their National Plans for maintaining polio-free status, are met.
- Experience gained by the polio laboratory network should now be used for the establishment and maintenance of laboratory networks for the diagnosis of other vaccine preventable diseases, particularly influenza and hepatitis B.
- All Member States should complete the first phase of the polio laboratory containment process, including submission of quality assurance documentation, by the end of 2004 and prepare for implementation of phase II activities.

**Topic 6: New and under-used antigens**

**Conclusions:**

The Region as a whole has been very successful in the introduction of immunization against hepatitis B, with universal newborn and infant immunization included in the routine immunization schedules of many countries.
• Hib disease burden has not been adequately quantified in many countries in the Region, resulting in the failure to recognize the cost–effectiveness of introducing Hib vaccine.

• Epidemiological surveillance to enable assessment of disease burden and impact of vaccination for new vaccines remains weak. Different case definitions and data reporting systems are currently in use throughout the Region.

• Availability of combined vaccines may aid the introduction of new antigens into existing immunization programmes in countries, where possible and sustainable.

Recommendations:

• Member States should assess their hepatitis B vaccination policies with a view to moving to a universal hepatitis B immunization strategy, if not already adopted.

• Member States that have implemented a universal hepatitis B immunization programme should monitor the impact of their programme through vaccination coverage, seroepidemiological surveys and acute disease surveillance.

• The burden of *Haemophilus influenzae* type b (Hib) disease should be assessed in more countries in the Region. For countries that have introduced Hib vaccine, impact assessment data should be compiled and disseminated to demonstrate the potential benefits of vaccine use.

• The evidence base must be prepared to enable a rational decision on whether or not to introduce a new antigen either currently available or close to commercial availability. Countries should prepare and analyse data on disease burden, cost effectiveness, resource availability and the capacity of the national immunization programme. This is vital to maintain sustainability of immunization in the future and reduce delays between vaccine development and introduction.

• Member States and regional partners are strongly encouraged to share technical resources and knowledge and to support the less-advantaged Member States by providing information for evidence-based decision making on the introduction of new vaccines.

• The Regional Office should provide the Member States with relevant recommendations and guidance on standardized case definitions and standard minimum data sets for hepatitis B and Hib diseases.

**Topic 7: Immunization safety**

Conclusions:

• A substantial amount of work has been conducted in the Region to improve the quality and safety of immunization, with significant progress being achieved in all priority countries.

• The Effective Store Management initiative has been widely adopted and national store assessments conducted in some countries has proven to be an excellent promoting tool to enhance appropriate policies and procedures.

• Most priority countries have assessed the safety of injection, established policies and conducted staff training.

• Auto Disable syringes and safety boxes are now being used in all priority countries.
Major achievements have been observed in injection safety and most priority countries have assessed the safety of injection, developed policies and conducted staff training. Auto Disable syringes and safety boxes are now being used in all priority countries.

AEFI surveillance systems are in place in most of the countries however, the systems vary in quality and sensitivity. The Global Training Network course is now available in English, French and Russian and relevant information is being made available through the website.

**Recommendations:**

- Every opportunity should be taken by Member States and the International Partner Agencies to ensure that AEFI surveillance systems are sensitive and fully functional allowing appropriate response to events related to the quality of vaccines, programmatic errors, as well as any serious adverse event thought to be caused by immunization.
- Countries should review and assess their cold chain practices to ensure that avoidable vaccine spoilage, particularly by freezing, does not occur.
- Efforts to improve immunization quality and safety must continue, progress must be measured to assess impact for advocacy and to secure political and financial commitment.
- All Member States should ensure that adequate training and safety equipment is provided to health care staff, including those dealing with waste, to minimize their risk of infection with bloodborne pathogens.
- Management of injection waste is an area where much attention is needed and policies should be tailored to country specificities. The most appropriate national healthcare waste management policy should be developed with the support of a multisectoral working group.
Annex 1

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## Annex 2

### PROGRAMME

**Sunday, 17 October 2004**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>17:00-19:00</td>
<td>Registration</td>
</tr>
</tbody>
</table>

**Day one: Monday, 18 October 2004**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Speaker/Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:00-08:45</td>
<td>Registration</td>
<td></td>
</tr>
<tr>
<td>09:00-09:10</td>
<td>Opening</td>
<td>Dr Jean-Marie Okwo-Bele, (WHO/HQ)</td>
</tr>
<tr>
<td>09:10-09:20</td>
<td>Welcome notes from the Ministry of Health of Slovenia</td>
<td>Mrs Blanka Mežnar, Representative of the Ministry of Health of Slovenia</td>
</tr>
<tr>
<td>09:20-09:30</td>
<td>Election of the chairman and co-chairs</td>
<td></td>
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</table>

**Topic 1: Immunization services, with focus on reaching “hard to reach”/vulnerable groups**

### Plenary

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Speaker/Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:30-09:55</td>
<td>Routine immunization systems and disease control targets – a global overview of current progress and major challenges</td>
<td>Dr Philip Duclos, (WHO/HQ)</td>
</tr>
<tr>
<td>09:55-10:20</td>
<td>Routine immunization systems and disease control targets – Regional progress and major challenges in a changing global environment</td>
<td>Dr Nedret Emiroglu, (WHO/EURO)</td>
</tr>
<tr>
<td>10:20-10:30</td>
<td>Discussion</td>
<td></td>
</tr>
<tr>
<td>10:30-10:45</td>
<td>Reaching “hard to reach”/vulnerable groups for equitable coverage –impact of changes in health systems and examples of ensuring sustainable service delivery</td>
<td>Dr Nedim Jaganjac, (World Bank)</td>
</tr>
</tbody>
</table>

**Coffee break**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Speaker/Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:15-12:10</td>
<td>Reaching “hard to reach”/vulnerable groups and reducing inequalities. Country experience:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Bulgaria</td>
<td>Dr Mira Kojouharova</td>
</tr>
<tr>
<td></td>
<td>• Netherlands</td>
<td>Dr A.Ambler-Huiskens</td>
</tr>
<tr>
<td></td>
<td>• Italy</td>
<td>Dr M.Pompa</td>
</tr>
</tbody>
</table>
• Serbia and Montenegro

12:10-12:30 Discussion

12:30-14:00 Lunch

14:00-14:20 Dealing with negative public reaction to immunization, rumours and negative media publicity

14:20-15:10 Dealing with negative public reaction to immunization, rumours and negative media publicity. Country experience:

• UK
  Dr Joanne Yarwood

• Sweden
  Dr Patrick Olin

• Bosnia & Herzegovina
  Dr Selena Bajraktarevic

15:10-15:25 Discussion

**Topic 2: Information systems for immunization - an evidence base for programme management**

**Plenary**

15:25-15:45 Surveillance for immunization, vaccination-preventable Diseases and Adverse Events Following Immunization (AEFI)

Dr Philip Duclos (WHO/HQ)
Dr Francois X. Hanon (WHO/EURO)

15:45-16:15 Coffee break

**CISID (Computerized Information System for Infectious Diseases) demonstration**

16:15-18:00 **Parallel Sessions:**

**Parallel Session A**

Immunization coverage and immunization system performance indicators

Moderators:
Dr Francois X. Hanon (WHO/EURO)
Dr Chinara Aidyralieva (WHO/EURO)
Mr Eric Laurent (WHO/EURO)
Dr Ray Sanders

Introduction of EURO perspective
Dr Francois X. Hanon (WHO/EURO)

**Parallel Session B**

Vaccine Preventable Diseases and AEFI (Adverse Events Following Immunization) surveillance

Moderators:
Dr Philip Duclos (WHO/HQ)
Dr Jim Zingeser (WHO/EURO)
Dr Mick Mulders (WHO/EURO)
Mr Denis Maire (WHO/EURO)
Dr Sergei Deshevoi (WHO/EURO)
Dr Nikolai Chaika

Introduction of EURO perspective
Dr Jim Zingeser (WHO/EURO)
<table>
<thead>
<tr>
<th>Country experience:</th>
<th>Country experience:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Belarus</td>
<td>Dr Mikhail Rimzha</td>
</tr>
<tr>
<td>• Georgia</td>
<td>Dr Levan Baramidze</td>
</tr>
<tr>
<td>• Spain</td>
<td>Dr Isabel Pachon</td>
</tr>
<tr>
<td>• UK</td>
<td>Dr Natasha Crowcroft</td>
</tr>
<tr>
<td>• Kazakhstan</td>
<td>Dr G.Kembabanova</td>
</tr>
<tr>
<td>• Finland</td>
<td>Dr Ville Postila</td>
</tr>
<tr>
<td>• Germany</td>
<td>Dr Christiane Meyer</td>
</tr>
<tr>
<td>• Uzbekistan</td>
<td>Dr Dilorom Tursunova</td>
</tr>
</tbody>
</table>

Discussion

18:00-18:30 CISID (Computerized Information System for Infectious Diseases) demonstration  Mr Mark Falvo (WHO/EURO)

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**Day two: Tuesday, 19 October 2004**

**Topic 3: Partnership and advocacy network for immunization**

<table>
<thead>
<tr>
<th>Plenary</th>
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</thead>
<tbody>
<tr>
<td>09:00-09:20 European Immunization Week – strategies for advocacy and effective communication  Ms Louise Gare (WHO/EURO)</td>
</tr>
<tr>
<td>Discussion</td>
</tr>
<tr>
<td>09:20-10:20 Expanded partnership and advocacy:</td>
</tr>
<tr>
<td>o Advocacy and communication strategies for immunization  Dr Dragoslav Popovic (UNICEF)</td>
</tr>
<tr>
<td>o Country experience:</td>
</tr>
<tr>
<td>• Hungary  Dr Adam Vass</td>
</tr>
<tr>
<td>• Tajikistan  Dr Shamsiddin Jobirov</td>
</tr>
<tr>
<td>10:20-10:35 Discussion</td>
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</tbody>
</table>

**Topic 4: Measles elimination and Congenital Rubella Infection (CRI) prevention**

<table>
<thead>
<tr>
<th>Plenary</th>
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<tbody>
<tr>
<td>10:35-11:00 Overview of current progress and challenges in the European Region  Dr John Spika (WHO/EURO)</td>
</tr>
<tr>
<td>Time</td>
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<tr>
<td>---------------</td>
</tr>
<tr>
<td>11:00-11:30</td>
</tr>
</tbody>
</table>
| 11:30-12:30   | **Workshop Groups**                          | **Workshop Group 1**  
Moderators:  
Professor Christiane Perronne  
Dr Nick Ward  
Dr Gary Freed  
Dr Sergei Deshevoi (WHO/EURO)  

Measles and CRI strategic plan for Europe: do we have it right?  
**Objectives:** To review existing targets and key strategies identified in the Strategic plan and suggest modifications to improve clarity and strengthen the feasibility of meeting the goals.  

Discussion       |

**Workshop Group 2**  
Moderators:  
Dr Amra Uzicanin (CDC)  
Dr Philip Duclos (WHO/HQ)  
Dr Galina Lipskaya  
Dr Francois X. Hanon (WHO/EURO)  

Information/evidence for decision making: critical issues to be addressed in Member States.  
**Objectives:** To identify country specific issues that may need to be addressed in preparation for a possible resolution on the Strategic plan at the fall 2005 WHO/EURO Regional Committee meeting.  

Discussion       |

**Workshop Group 3**  
Moderators:  
Dr Leo Weakland (CDC)  
Dr Jim Zingeser (WHO/EURO)  
Dr Dragoslav Popovic (UNICEF)  

Advocacy, political commitment and expanded partnerships for achieving the goals: what needs to be done?  
**Objectives:** To make recommendations on ways to increase the number of Regional partners supporting the Strategic plan, which includes strengthening of routine immunization programmes.  

Discussion       |
| 12:30-14:00    | Lunch                                        |                                                                                              |
| 14:00-15:30    | **Workshop Groups (continued)**              |                                                                                              |
| 15:30-16:00    | Coffee break                                 |                                                                                              |
| 16:00-17:00    | **Plenary**                                  | Feedback from the workshop groups – presentation and discussion of recommendations            |
| 16:00-17:00    | **Topic 5: Polio eradication initiative**    |                                                                                              |
| 17:00-17:20    | Sustaining polio-free status of Europe and preparing for a polio-free world | Dr Jim Zingeser (WHO/EURO)                                                                  |
Day three: Wednesday, 20 October 2004

Topic 6: New and under-used antigens

**Plenary**

08:30-08:50  Overview of current progress and challenges in the European Region  
Dr Andrei Lobanov (WHO/EURO)

08:50-09:00  Discussion

09:00-10:15  Parallel Sessions

<table>
<thead>
<tr>
<th>Parallel Session A</th>
<th>Parallel Session B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B</td>
<td>Hib and opportunities for other new and under-used antigens</td>
</tr>
</tbody>
</table>

Moderators:  
Professor Pierre Van Damme (VHPB)  
Dr Nicole Guerin  
Dr Sergei Deshevoi (WHO/EURO)

Moderators:  
Dr Mary Slack  
Dr Andrei Lobanov (WHO/EURO)  
Dr Robin Biellik (PATH)

Hepatitis B immunization, use of combined vaccines, hepatitis B surveillance.  
Professor Pierre Van Damme (VHPB)

Hib disease burden, immunization and surveillance  
Rotavirus vaccine  
Dr Mary Slack  
Dr Robin Biellik (PATH)

Country experience:  
Moldova: Hepatitis B immunization  
Dr Ion Bahnarel

Finland: Hib immunization and prospects for pneumococcal immunization  
Dr Terhi Kilpi

Belgium: Hepatitis B immunization (combined vaccine)  
Dr Rene Snacken

Latvia: Hib immunization  
Dr Dace Viluma
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>10:15-10:45</td>
<td>Coffee break</td>
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<tr>
<td></td>
<td>“Advanced Immunization Management e-learning modules” demonstration</td>
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<tr>
<td>10:45-12:00</td>
<td><strong>Parallel Sessions (continued)</strong></td>
</tr>
<tr>
<td>12:00-13:30</td>
<td><strong>Lunch</strong></td>
</tr>
</tbody>
</table>

**Topic 7: Immunization safety and quality**

**Plenary**

13:30-13:50 Achievements and focus on future perspectives  
Mr Denis Maire, Mr Eric Laurent (WHO/EURO)

13:50-14:00 **Discussion**

14:00-15:30 **Parallel Sessions**

**Parallel Session A**

Injection Safety for immunization

**Parallel Session B**

Sharp waste management

**Moderators:**

<table>
<thead>
<tr>
<th>Parallel Session A</th>
<th>Moderators:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dr Philippe Duclos (WHO/HQ)</td>
</tr>
<tr>
<td></td>
<td>Mr Denis Maire (WHO/EURO)</td>
</tr>
<tr>
<td></td>
<td>Dr Chinara Aidyralieva (WHO/EURO)</td>
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</tbody>
</table>

| Parallel Session A | Mr Denis Maire (WHO/EURO) |

<table>
<thead>
<tr>
<th>Parallel Session B</th>
<th>Moderators:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dr David Mercer (CVP)</td>
</tr>
<tr>
<td></td>
<td>Mr Eric Laurent (WHO/EURO)</td>
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<tr>
<td></td>
<td>Dr Sergei Deshevoi (WHO/EURO)</td>
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</tbody>
</table>

| Parallel Session B | Mr Eric Laurent (WHO/EURO) |

**Country experience:**

<table>
<thead>
<tr>
<th>Country</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ukraine</td>
<td>Dr Chinara Aidyralieva (WHO/EURO)</td>
</tr>
<tr>
<td>France</td>
<td>Ms Sylvie Drugeon</td>
</tr>
<tr>
<td>Moldova</td>
<td>Dr Ion Bahnarel</td>
</tr>
<tr>
<td>Germany</td>
<td>Mr Stefan Adler</td>
</tr>
<tr>
<td>UK</td>
<td>Dr Fortune Ncube</td>
</tr>
<tr>
<td>Uzbekistan</td>
<td>Dr Dilorom Tursunova</td>
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</tbody>
</table>

**Discussion**
<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>15:30-16:00</td>
<td><strong>Coffee break</strong></td>
</tr>
<tr>
<td>16:00-16:30</td>
<td><strong>Plenary</strong></td>
</tr>
<tr>
<td></td>
<td>Conclusion and recommendations on priority areas for the Regional Immunization Programme</td>
</tr>
<tr>
<td>16:30-17:00</td>
<td><strong>Discussion</strong></td>
</tr>
<tr>
<td>17:00</td>
<td>Closing remarks</td>
</tr>
</tbody>
</table>