



Subregional workshop on the introduction of new vaccines and on the strengthening of national immunization programmes

Kiev, Ukraine, 20-22 January 2003

ABSTRACT

The subregional workshop on the introduction of new vaccines and the strengthening of national immunization programmes was held in Kiev, Ukraine, from 20 to 22 January 2003. Participants from 16 countries of central and eastern Europe, Turkey and the newly independent states (NIS) of the former USSR attended the workshop. The goals of the meeting were to brief participants on the current status of immunization activities in the WHO European Region; to discuss progress and future priorities in strengthening immunization programmes with a particular focus on the issues involved and experience gained in the introduction of new and underused vaccines; and to review the progress made in controlling diphtheria, including issues of surveillance and laboratory support. Training in advocacy, communication and ways to strengthen national interagency coordinating committees (ICCs) was conducted using the Advanced Immunization Management (AIM) training modules.

During several plenary meetings and working group sessions, participants received information on various aspects of regional and selected national immunization programmes. Topics included the decision-making involved in the introduction of new vaccines; the financial sustainability of national immunization programmes and the Global Alliance for Vaccines and Immunization (GAVI); and accelerated vaccine preventable disease control activities, in particular hepatitis B and diphtheria surveillance.

The participants of the satellite workshop on the laboratory diagnosis of diphtheria formulated recommendations to the Regional Office for future support in the continuation and expansion of the "NIS Diphtheria Laboratory Network".

During the satellite workshop on hepatitis B, participants reviewed the current epidemiological situation and the status of the introduction and implementation of the hepatitis B vaccine. They discussed achievements and constraints and recommended further steps to be taken to address the problems identified.

Keywords

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Introduction

A subregional workshop on the introduction of new vaccines and the strengthening of national immunization programmes was held in Kiev, Ukraine, from 20 to 22 January 2003. The workshop was organized by the WHO Regional Office for Europe in collaboration with Children's Vaccine Program at the Program for Appropriate Technologies in Health (CVP/PATH) and the PATH Office in Ukraine.

The scope and purpose of the workshop were as follows:

- to brief participants on the current status of immunization activities in the WHO European Region and discuss progress and future priorities towards strengthening immunization programmes;
- to review the issues involved and experiences gained in the introduction of new and underused vaccines in Member States of the European Region, with a special focus on the introduction of hepatitis B, *Haemophilus influenzae* type b (Hib), measles–mumps–rubella (MMR) and measles-rubella (MR) vaccines and on the progress of the Global Alliance for Vaccines and Immunization (GAVI) initiative;
- to identify and discuss the achievements and constraints experienced in the introduction and implementation of the hepatitis B vaccine and to outline operational plans to address the problems identified;
- to review the epidemiology and progress made in controlling diphtheria in the WHO European Region, including issues of surveillance and laboratory support;
- to conduct advanced management training of senior-level health officers using the methodology and training material recently developed by the CVP/PATH in collaboration with WHO.

The workshop was opened by Dr Nedret Emiroglu, Regional Adviser, Vaccine Preventable Diseases and Immunization, WHO Regional Office for Europe. Dr Emiroglu addressed the participants on behalf of the WHO Regional Director for Europe and passed on greetings from the Director of Division of Technical Support, Reducing Disease Burden. She introduced the scope, purpose and programme of the meeting.

Dr Sergei Deshevoi and Dr David Mercer were elected the rapporteurs.

Dr Olga Bobyliova, Deputy Minister of Health of Ukraine and Mr J. Hartley, Representative of UNICEF in Ukraine, made brief opening remarks.

Participants from 16 countries of the WHO European Region attended the workshop. Experts and staff from WHO headquarters and WHO Regional Office, CVP, PATH, UNICEF, United States Agencies for International Development (USAID) and other partner agencies and organizations also participated.

1. Strengthening national immunization services: current status in the WHO European Region and actions to be taken

By 2001, the reported immunization coverage rates in the WHO European Region had increased to over 90% for all standard Expanded Programme on Immunization (EPI) antigens. These include: BCG, three doses of oral polio vaccine (OPV), and three doses of diphtheria–tetanus–pertussis (DTP) and measles-containing vaccines. As of 2002, universal hepatitis B vaccination programmes were in 40 countries; 32 had infant programmes of which 22 targeted newborns. The overall regional hepatitis B immunization coverage rate for 2001 was estimated to be 37% (using all children in the Region under one year of age as the denominator).

Improving immunization service delivery will remain an EPI priority. The focus will be on three major areas: (1) building on existing infrastructure in order to improve access and utilization of services by innovative methods (outreach services and pulse campaigns), reducing drop outs and false contraindications; (2) improving the quality and safety of immunization in order to develop an overall culture of safety, allowing for the prevention of adverse reactions, their early detection and appropriate response; and (3) building capacity for improved management to ensure the sustainability of the system.

The success of polio eradication activities resulted in the certification of the WHO European Region as polio free in June 2002. Maintaining this status in the post-certification era is one of the highest priorities for the accelerated disease control activities of the WHO European Region. WHO will continue to support and maintain high levels of routine immunization coverage, particularly in high-risk groups, by conducting supplementary immunization activities (SIA) in selected high-risk areas; maintaining high-quality acute flaccid paralysis (AFP) surveillance; and by continuing laboratory containment processes and quality control.

The reported incidence of other vaccine preventable diseases in the Region is low. A large decline in the total number of measles cases has been observed over the past decade. Between the years 1999 and 2002 there was a substantial improvement in the completeness of reporting (for measles, 94% completeness was noted compared to 67% in 1999). However, more attention should be paid to the quality of data – its timeliness and accuracy. Intercountry comparisons should be undertaken cautiously due to variations in surveillance practice, use of standard case definitions, inclusion of laboratory confirmation of clinically suspected cases, and so on.

Following the successful example of polio eradication, many countries in the Region are eager to move towards strengthening measles surveillance and targeting measles elimination and have started implementing elimination strategies, or set elimination goals. As the current measles target for 2007 is increasingly recognized as being difficult to achieve and the combined antigen containing measles and rubella is being used, the strategic plan for the Region is to establish an operational target for measles for 2010 with an assessment during 2005. The objectives for 2010 are to interrupt the indigenous transmission of measles and to prevent congenital rubella infection so that there is less than 1 case of congenital rubella syndrome (CRS) per 100 000 live births. The following key strategies are recommended in order to meet these objectives:

- to achieve and sustain very high coverage (with two doses of measles vaccine) through high-quality routine immunization services;

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

Activities of the Global Alliance for Vaccines and Immunization (GAVI) are coordinated by the GAVI Board and the Regional Working Group (RWG). In addition to support in introducing the hepatitis B vaccine, 4 countries are receiving support for strengthening immunization services, and all 11 countries may receive support for injection safety.

The future policy of the WHO Regional Office for Europe will be to continue to target efforts to meet country-level needs and priorities through coordinated support of country-level activities, mobilization of technical and financial resources, developing national capacities, and through guiding countries in line with regional targets.

Improving management of immunization services at subnational level

Previous international goals – Universal Childhood Immunization, 1990, and the 2000 World Summit for Children – set goals for national immunization coverage of 80% and 90% respectively. More recently, goals have been set that include an attempt at a more equitable geographic distribution of immunization by setting goals for district level achievements. These goals included:

- a minimum goal of 80% immunization coverage in *all* districts in 80% of developing countries by 2005 (set by GAVI);
- a national level of 90% fully immunized children less than 1 year old and at least 80% coverage in every district by 2010 (called for by the United Nations Special Session on Children 2002).

Global immunization coverage reached approximately 75% in 1990 and has remained stable throughout the 1990s and until 2002. The global level masks higher levels of coverage (around 80%) in Central Europe and the Newly Independent States. At the end of 2001 approximately 36 million children globally (600 000 of them in Europe) did not receive three doses of DTP.

Of the 165 developing countries, 103 have districts that have not reached 80% coverage with the third dose of DTP (DTP3).

The barriers to reaching all districts include:

- low quality services resulting from inadequate training and supervision, lack of outreach services and unreliable supplies;
- poor links with the local community;
- inadequate financial commitment;
- inadequate monitoring systems that are unreliable or insufficiently detailed; and
- district plans that do not reflect national priorities.

Strategies for overcoming these barriers include:

- a heightened district focus involving district level assessments, planning, budgeting, and monitoring supported by adequate funding and capacity;
- the use of plans with incremental annual milestones; and
- prioritizing districts to reach children who are not fully immunized.

These strategies may be implemented by:

- establishing (or re-establishing) regular outreach services (that may be packaged with existing outreach services) to communities and populations with poor access;
- regular supportive supervision to build capacity for safe, high-quality immunization services, possibly including on-site training combined with supervisory activities for other service components (patient management, record keeping and reporting, and so on);
- taking advantage of community structures with regular, consultative meetings with community leaders and representatives;
- improving the quality and use of data for identifying problem areas and monitoring progress; and
- improved management of immunization through the use of plans at all levels.

In order to meet current international goals an increased focus on district and local immunization services is essential. The capacity and resources required should be reflected in detailed district plans. District level monitoring is needed in order to plan and monitor immunization services so that immunization is provided to those populations not reached by current methods with current resources. New partners provide an opportunity for additional technical and financial support to reach these goals.

Monitoring of performance: assessment of tools for reporting and data management

Monitoring immunization programmes can illustrate several aspects of programme performance:

- access – the availability of services and the ability to reach these services – can be ascertained by looking at coverage with the first dose of DTP (DTP1);
- utilization, or compliance with programme recommendations, can be ascertained by looking at the difference between the drop-out rate between DTP1 and DTP3;

- effective uptake of new vaccines can be described by comparing the third dose of Hib vaccine with the third dose of DTP if these vaccines are scheduled for the same visit; and
- effectiveness of the services can be described by the number of doses that are given at the correct age – respecting the minimum age, the minimum duration between doses, and before 12 months old.

The most common monitoring indicator of immunization performance is immunization coverage and this is generally measured by the administrative method or by doses administered in the age group of interest over the cohort of the target age group. Reliance on reports of national coverage levels can hide not only large subnational variation but also important programmatic and data quality issues. Reviewing data by region (oblast) or even by district (rayon) can identify low performing areas.

Several tools are available to assist in the monitoring and evaluation of immunization coverage.

- WHO is currently in the process of developing guidelines for monitoring based on routine reports from vaccine service providers – the so-called administrative method. A draft for circulation is planned for late 2003.
- Computer software – Computerized EPI Information System (CEIS) – is available for countries using the administrative method. This software has been updated from the DOS-based CEIS that has been widely used.
- The EPI 30x7 cluster survey guide has been updated to provide more flexibility and improved guidance for adapting and implementing cluster surveys. This method may be used to validate levels of coverage from the administrative method, ascertain the validity and timeliness of immunization, and to provide information on why children are not being vaccinated or fully vaccinated. The field test version is expected to be available in March 2003.
- A Windows version of the DOS-based COSAS software for analysis of cluster surveys has been prepared and is being tested. It is scheduled for release in February 2003.
- A community-based survey method – the Lot Quality Assurance or LQA – has been developed for local use to determine whether coverage exceeds an established threshold. With proper planning, multiple surveys can be combined to produce a point estimate of coverage for a larger area. Software supporting a LQA survey has not been developed but is being planned. A prototype is scheduled to be available in early 2004.
- The Data Quality Audit (DQA), originally developed for the Vaccine Fund, has been modified for self-assessment. The DQA is based on a sample of reporting sites and reviews the accuracy of recording, calculating and reporting in systems using the administrative method. Software supporting the DQA is currently available.

Additional tools for safety assessments, disease burden estimation and others are available through the WHO Regional Office for Europe.

The difficulty encountered in immunization programmes in countries in the WHO European Region is not a failure to reach full primary immunization of children, but rather a failure to reach high levels of age-appropriate immunization coverage that saves lives and lowers the frequency of complications. There are several reasons why the administrative method coverage estimate may not always correspond with the true age-appropriate immunization level in the population. Recent national surveys conducted in European Member States have often confirmed the administrative method as representing age-appropriate immunization, but some have not. The WHO Regional Office for Europe will place higher focus on the accuracy of the administrative method and recommends period surveys to validate this estimate.

Country experience

Ukraine: Management of immunization services at subnational level

The immunization programme in Ukraine is being implemented by two branches of the Ministry of Health (the Mother and Child Health department and the Sanepid Board), with relevant vertical subordinates at the region (oblast), district (rayon) and primary health care (PHC) facilities levels. Vaccination coverage against major children's infections has been maintained at high levels (between 94% and 98%) over the last 5 years.

There are four blocks of activities related to the management of immunization services at all levels.

1. Development of regulations, including:

- a legislative basis;
- strategies for the control of vaccine preventable diseases (Ministry of Health orders and instructions, methodical recommendations and guidelines);
- interagency coordinating committee (ICC) decisions.

2. Pre-service and in-service training of staff, including:

- training on the vertical programmes
- specialist days at the district (rayon) and region (oblast) levels
- distribution of methodological materials.

3. Management information systems, including:

- planning of target groups and vaccine requirements
- monitoring immunization coverage and vaccine stock management
- using data for decision-making and feedback.

4. Targeted work with inadequately informed populations, including:

- management information systems allowing regular monitoring of performance and prompt feedback to the lower levels;
- some issues (inadequate and obsolete cold-chain equipment, non-compliance with injection safety regulations, absence of medical waste disposal strategy) that are yet to be solved.

The Republic of Moldova: Strengthening the national health information system on immunization

The previous system of immunization monitoring in the Republic of Moldova had a number of disadvantages. There was a limited flexibility due to quarterly reporting, the data available was only on fully-immunized children and did not include a timeliness indicator and there was no information on the flow and stocks of vaccines and syringes. The first attempts to improve the reporting system were made in 1997. Before this, improvements were delayed due to the period of transition resulting from the fall of the Soviet Union. The Order of Ministry of Health of the Republic of Moldova, № 286, dated 27 November 1997, approved four forms for reporting and laid out a system for recording the flow and ordering of vaccines, and for the control of their storage conditions.

Forms were printed in quantity on a centralized basis and were regularly supplied to all health settings and country programme managers, free of charge. Still, the system was incomplete and not tied to final results, that is, to vaccination coverage of the population. No information was received at the Ministry of Health level of management.

Implementation of the management information system similar to the one in Ukraine started in 2001 in two pilot territories. Major emphasis was made on the development of a simple and accurate system for primary recording, capable of substituting and unifying working copy-books and which could be used as a basis for preparing monthly reports. A register of monthly vaccination activities was developed for each family doctor. It includes the child's name and address, vaccination records with primary and booster vaccinations and timeliness data (prior to 12 or 15 months of age). At the bottom of each page there are three summary lines (number of eligible children, those vaccinated and vaccinated by target age).

The forms were distributed nationally in 2002 and highlighted major preliminary aggregated data on vaccination coverage for 2002 including timeliness and drop outs.

Planning for the safety of injections for immunization

The main objectives of a safety of injections programme are to ensure that injections will not cause any harm to the recipient, will not expose the provider to any avoidable risks and do not result in any waste that is dangerous for other people. To meet these objectives, systems should be put into place that will bring about a culture of safety. A three-tiered strategy is proposed, comprising:

1. the change of providers' behaviour for better injection practices;
2. the guarantee of adequate provision of supplies; and
3. the assurance of proper waste disposal of sharps.

The support of all stakeholders can be obtained through the implementation of a working group on injection safety and the nomination of a focal point for its coordination. Issues relating to injection safety can be established by carrying out an assessment as described in the WHO tool (V&B/01.30) designed for this purpose. This tool outlines the steps to be followed to obtain the status of the safety of injections by health facility. Results of the assessment can be used to define a national policy and to develop a plan of action. Monitoring, supervision and evaluation are three key activities needed to regularly revise the plan of action and to help set new priorities. Key areas to be observed include the provision of supplies, the compliance with best practices,

the reconstitution of dried vaccines, the proper use and collection of safety boxes and the treatment of waste.

The approach to waste management should consider appropriate technologies in accordance with local conditions. To minimize the risk to injection providers, it is recommended that manipulations after injection be avoided. The methodology for waste treatment should prevent any human contact with potentially infectious waste and take into account environmental concerns. Putting in place a waste management system, with clear staff responsibilities, trained personnel and supervision by health authorities, is critical to the success of the programme.

Activities to address behaviour change will include the development of information, education and communication (IEC) material and the training of immunization providers.

To monitor the implementation of the programme on injection safety and waste management, indicators will be selected to reflect the priorities. These will help to measure progress and allow the follow up of the three major elements: provision of supplies, behaviour change and sharps collection and treatment. The impact can be measured by the number of adverse events following immunization (AEFI) reported that are attributable to unsafe injections or improper disposal of sharps.

2. Introduction of new vaccines

During the last few years, several new vaccines have entered the market and more are being developed. There is a striking difference between high-income countries and low-income countries in terms of the number of antigens included in their immunization programmes. Countries have to decide whether to include new vaccines in their immunization programmes on the basis of a thorough analysis of various parameters.

The rationale for introducing a new vaccine should be based on analysis of the epidemiological data to decide if the disease is a public health problem and which population groups are affected. It should be decided if immunization is the best way to control the disease or whether this can be done through alternative strategies. The cost and benefit of introducing the new vaccine and sustaining immunization to achieve and maintain adequate coverage should also be assessed. It is important to evaluate the capacity of the national immunization programme to absorb the new vaccine and to identify additional needs in the following areas: cold chain and logistics, immunization safety, integration of data related to the new vaccine in the national information system, training of health staff, advocacy and social mobilization.

Epidemiological data for measuring the burden of diseases caused by *Haemophilus influenzae* type b (Hib) can be collected through surveillance systems, prospective and retrospective epidemiological studies, and the rapid assessment tool. Surveillance of Hib disease in the WHO European Region needs to be strengthened: only 25 out of 51 countries provided information on Hib meningitis for 2001. WHO recently performed analysis of Hib meningitis in the pre-vaccination era and found that incidence rates of Hib meningitis in children below 5 years old were significantly higher in Africa and the Americas compared to the WHO European Region. Analysis of data from 72 studies carried out in the Member States of the European Region showed high incidence of Hib meningitis in children below 5 years old in western Europe, whereas lower levels were observed in countries of central and eastern Europe.

In 2001 and 2002, Hib rapid assessments were conducted in Albania, Kyrgyzstan and Uzbekistan. The assessments showed that Hib, in terms of morbidity and mortality, does not represent a high burden of disease in these countries.

In 2001, 27 countries of the WHO European Region, mainly in western and central Europe, had the Hib vaccine in their national immunization programmes. Fourteen countries reported their Hib3 immunization coverage to the WHO Regional Office. Out of these, eight countries reported immunization coverage of over 90% (Denmark, Finland, Hungary, Iceland, Israel, Portugal, Slovenia and the United Kingdom) and four countries had coverage rates between 80% and 90% (Belgium, Ireland, Latvia and Norway).

Hib vaccines available on the market have been proven effective in the prevention of Hib diseases. Countries of western Europe that have been implementing immunization against Hib for many years reported marked reduction of Hib incidence as a result of immunization. Unfortunately, high costs of Hib vaccines are a major barrier to the introduction and implementation of immunization against Hib in many countries of the WHO European Region, mainly in the NIS and some countries of eastern Europe. Long-term political commitment and long-term financial sustainability are crucial issues for decision-making related to Hib vaccine introduction in those countries.

Financial Sustainability Plans

Countries receiving GAVI Vaccine Fund support are required to prepare financial sustainability plans midway through funding support, approximately two and a half years from receipt of funding.

The financial sustainability plan is a statement from governments about how they are going to match financing of the immunization program with program objectives over the medium to long term. The GAVI definition of financial sustainability states that: "Although self-sufficiency is the ultimate goal, in the nearer term, sustainable financing is the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve target levels of immunization performance."

The benefits for countries in preparing a financial sustainability plan include: gaining a clear picture of the programme's financing needs based on good data analysis; getting a description of realistic and specific actions that will increase the likelihood of financial sustainability; identifying the process and the indicators for monitoring progress; being able to use the information to advocate amongst Ministries of Health and Finance and partners; and, equally importantly, feeding the information into and informing broader macroeconomic processes.

A set of guidelines and tools outlining the content and format of the financial sustainability plan have been developed by the GAVI Financing Task Force to assist countries preparing a plan. The guidelines and annexes, including tables and methodologies for costing and projecting financing resources, are available in Russian.

In 2002, the first set of GAVI eligible countries prepared and submitted their financial sustainability plans to the GAVI Secretariat. The GAVI Board decided that these first thirteen countries would be used in a pilot phase to help inform and shape the process for the next set of countries due to prepare their plans.

Country experience

Kyrgyzstan: financial sustainability planning

In 2002, Kyrgyzstan was the first country in the WHO European Region and among the first thirteen countries in the world to prepare a financial sustainability plan. The process started with a request from the Ministry of Health for technical support from the GAVI Secretariat. In August 2002, two international consultants visited the country to provide technical assistance and to spearhead the process. The interagency coordinating committee (ICC) was fully briefed on the process and was involved in developing the plan. A task force was formed, comprised of representatives from the Ministry of Health, the Ministry of Finance, the Mandatory Health Insurance Fund, UNICEF and WHO. Their task included conducting a detailed analysis of the national immunization programme costs and an evaluation of the financing structure of the programme. The task force developed a work plan, followed by data collection and analysis.

The plan was finalized by mid November and then presented to the national ICC for comment and signatures. During the GAVI Partners meeting in Dakar, Senegal, The Minister of Health and Deputy Minister of Finance proudly submitted the Kyrgyzstan Financial Sustainability Plan to GAVI, in front of an international audience. The plan is now being reviewed by an Independent Review Committee at the GAVI Secretariat in Geneva. Following this review, Kyrgyzstan will, with partner support, begin implementing and monitoring the strategies outlined in the plan in order to achieve financial sustainability of its immunization programme.

By September 2003, 6 more countries from the WHO European Region (out of a total of 22 countries) will be required to submit financial sustainability plans. The countries are Albania, Armenia, Azerbaijan, Tajikistan, Turkmenistan and Uzbekistan. To help countries in the process, the GAVI Financing Task Force is working with the European Regional Working Group and partners to provide support to these countries, to organize country workshops and to coordinate technical assistance.

3. Advanced Immunization Management

Training in advocacy, communication and strengthening of national ICCs was conducted using the Advanced Immunization Management (AIM) training modules, developed by CVP/PATH. A CD-Rom containing the AIM modules accompanies this report.

4. Diphtheria control in the WHO European Region

The massive re-emergence of diphtheria in the newly independent states (NIS) of the former USSR between 1990 and 1999 marks the first large-scale diphtheria epidemic in industrialized countries in three decades. Although all the NIS were affected, three quarters of the more than 158 000 cases reported since 1990 were reported by the Russian Federation.

Considerable efforts to vaccinate both children and adults brought the epidemic under control. In 1999, 1616 cases were reported (a 97% decrease from the 50 425 cases reported in 1995). In 2001, 1282 cases were reported and a year later 1129 cases were reported from the NIS to the WHO Regional Office for Europe.

The control of diphtheria requires intensive efforts by the national health authorities and some countries also require sustained aid from international organizations and agencies. The Regional Plan of Action for Prevention and Control of Diphtheria is as follows:

- primary prevention by ensuring high levels of population immunity
- early diagnosis and proper case management
- rapid investigation and management of close contacts
- improved surveillance.

The immunization strategy gives priority to strengthening routine immunization systems and achieving high coverage (greater than 95%) with primary immunization and it addresses adolescents and adults with booster immunizations. It includes the following:

- at least 95% coverage with primary immunization (DTP3), by 12 months old
- very high coverage with DTP4 by 2 years old
- booster doses on school entry and leaving
- at least 90% adult vaccination coverage with Tetanus diphtheria (at 10 year intervals)
- mass immunization of high-risk groups and susceptible populations.

Surveillance for earlier detection of emerging and re-emerging diseases needs to be strengthened at the regional, subregional and national levels. The strategy for improving the surveillance for diphtheria includes five major components:

- using standard case definitions
- improving case detection and investigation
- improving tracing for contacts and carriers
- strengthening the capacity of national and regional laboratory networks
- increasing the number of cases with laboratory confirmation.

Microbiological diagnosis of diphtheria and laboratory support

One of the first microbiological networks to be established at the request of the WHO Regional Office for Europe was the European Laboratory Working Group on Diphtheria (ELWGD) formed in 1993. ELWGD is coordinated by the Public Health Laboratory Services (PHLS) and now has participation from more than 40 countries worldwide, from western Europe, eastern Europe, the United States, Canada, South America, South East Asia, the Indian subcontinent and Australia. The main objectives of ELWGD are to increase both clinical and microbiological awareness of diphtheria within countries and to establish microbiological surveillance of diphtheria in Europe. During the last decade, the Regional Office and ELWGD have worked together to establish a laboratory network and to enhance coordinated and collaborative approaches for laboratory diagnosis within and between countries. Due to generous sponsorship from many donors, they have also been able to standardize methods by establishing and distributing microbiology kits to all NIS.

International collaboration between countries is essential to monitor the spread of the disease and the pathogenesis of the organism and to promote the necessary research and development within this field. Exploitation at the public health level has led to significant improvements and innovations in microbiological surveillance and diagnosis. For example, there has been:

- harmonization of methodologies between countries for laboratory diagnostics;
- the establishment of definitive genotype databases between countries for rapid tracking of epidemic strains;
- the establishment of external quality assurance schemes to monitor laboratory proficiency; and
- training visits for NIS scientists and workshops and symposia throughout Europe to maintain and increase awareness.

These areas need to be particularly maintained in the countries of greatest need. The epidemics in the WHO European Region during the last 12 years remind us of the danger to European populations of infectious diseases, such as diphtheria, and that there is still much to be learned about the epidemiology.

Country experience

Diphtheria control in Latvia

Diphtheria re-emerged in Latvia in the first half of the 1990s after decades of successful disease control through immunization. In the beginning of the epidemic, the majority of diphtheria cases (44%) were registered among 30 to 49 year olds. Later in the epidemic, most diphtheria cases (37%) were registered among 40 to 59 year olds because the susceptible age cohort became older. During the diphtheria epidemic, case distributions by gender were dominated by women (56%). The most affected population group was the unemployed (36%).

Since 1995, the number of diphtheria-affected territories has steadily declined (72% in 1995 and 18% in 2002). In the beginning of the epidemic, the majority of diphtheria cases were registered in autumn and winter but there are no significant differences in seasonal prevalence of cases in the latter period of epidemic. The decrease of bacteriological confirmed cases has been observed since 1998 (94% in 1998 and 55% in 2002).

During the period of the epidemic, 99 diphtheria death cases (7.4%) were registered, 90% of these were registered among adults. The decrease of severe diphtheria cases and death cases has been observed. No diphtheria death cases have been registered among 10 to 19 year olds and only 1 case has been registered among 20 to 29 year olds. The majority (68%) of death cases was registered among 40 to 59 year olds during the beginning of the epidemic and among people older than 50 years (74%) during the latter period of the epidemic. 74% of diphtheria cases and almost 100% of diphtheria death cases were unvaccinated people. The decrease in the number of diphtheria foci with 2 or more cases (from 10.3% in 1995 to 4.5% in 2002) as well as the number of *C.diphtheriae* carriers has been observed.

Adult immunization campaigns in Latvia controlled the severe outbreak of diphtheria between 1994 and 1995. Since 1995, more than one million adults have received vaccination, achieving coverage of 69%. Public opinion poll results demonstrate that it would be possible to reach higher vaccination coverage (of between 85% and 90%).

Despite the definite progress in diphtheria control that has been achieved, diphtheria remains a public health concern in Latvia. Future achievements in diphtheria control depend on the general practitioner's increased role in the vaccination programme as well as on health education activities in the country. Special attention has to be paid to at risk groups – unvaccinated people older than 40 years old and people in marginalized groups.

5. Workshop on the laboratory diagnosis of diphtheria

The key objective of the workshop was to enhance cohesion and collaboration between NIS and European Member States in the fields of diphtheria laboratory diagnostics and surveillance.

Re-emergence of diphtheria during the last decade within the WHO European Region and elsewhere has stimulated renewed interest in this 'vaccine preventable disease'. A major goal for many international agencies (in particular WHO) has been to improve surveillance for the early detection of emerging and re-emerging diseases by the establishment of laboratory networks for communicable diseases.

The European Laboratory Working Group on Diphtheria (ELWGD) was formed in 1993 in response to the diphtheria epidemics in Russia and the NIS. These epidemics and others elsewhere, highlighted the importance of strengthening and maintaining both epidemiological surveillance and reliable laboratory screening. Since December 2001, progress has been made in the surveillance and laboratory screening of diphtheria through European Commission (EC) funding. Funding was provided to undertake a feasibility study for diphtheria surveillance amongst European Union (EU) member states and accession countries, and to establish a definitive and official European diphtheria surveillance network called DIPNET. DIPNET will continue a collaborative and coordinated approach to support countries to improve diphtheria surveillance for early detection of cases and contacts through accurate microbiological and epidemiological surveillance. The network of national and international laboratories includes not only microbiologists, but also epidemiologists from most of the EU member states and accession countries¹.

All participants from the 12 countries who attended the workshop welcomed the Workshop on Diphtheria. The participants included the microbiologist and epidemiologist responsible for diphtheria in each country. The scope of the workshop was to review and identify the laboratory diagnostic capabilities within each country and to identify specific areas of need. The discussion areas included: a general introduction of each participant and their role in diphtheria diagnostics; an overview of each country's diagnostic capabilities; identification of specific needs; a discussion about the external quality assessment within this field; and discussions related to the revision of the WHO manual on laboratory diagnosis of diphtheria.

¹ EURO Surveillance, Vol. 8, No. 10, October 2003

Key Recommendations to the Regional Office for support in the continuation and expansion of the 'NIS Diphtheria Laboratory Network'

It is essential to maintain the current NIS network which includes the key microbiologist (and should also include the key epidemiologist) responsible for diphtheria in each NIS country. There is a danger that the strong NIS laboratory network that has been established during the last few years will disintegrate if there is no support.

Actions

1. To officially identify the key microbiologist, which has been undertaken, and the key epidemiologist from each NIS that is responsible for diphtheria.
2. Standardize the case definition for diphtheria across all countries. Most countries experienced many difficulties with the implementations of the case definition.
3. To assess the laboratory capabilities and diagnostic potential within each key National Diphtheria Reference Centre (NDRC) and also in those laboratories that are not NDRCs but offer a service for their country. This is underway under the auspices of DIPNET.
4. To establish official national designated reference laboratories, particularly for Uzbekistan, Azerbaijan, Turkmenistan and Tajikistan.
5. To identify the immediate and long-term needs (over the next 12 months) in terms of reagents and diagnostic materials required for laboratory diagnosis of diphtheria. There are considerable concerns in many countries that as a result of minimal or no reagents, laboratory diagnosis has declined or not been undertaken. Of particular concern was the lack of activity in some countries due to the unavailability of reagents and laboratory material, for example in Tajikistan.
6. To undertake an 'Update Workshop' on laboratory diagnosis for the key microbiologist in each NIS. This would be a significant update on the workshop held at the PHLS in 1995, with the possible date being in January 2004.
7. To undertake laboratory workshops in 2003 in those countries of urgent need. In order of priority: (1) Latvia and Tajikistan; (2) Ukraine; (3) Uzbekistan; and to consider such workshops in accession countries, for example, Turkey.
8. To monitor laboratory performance by establishing a definitive External Quality Assurance programme within all NIS (for the main Diphtheria Reference Centres). Funds will be required to cover transportation/postal costs and to cover the costs for the preparation of a 'full set of laboratory control strains'.
9. To establish a system of accreditation for the NDRCs. This was highlighted by all participants. In particular, the system used for WHO accreditation of Measles/Polio Reference Laboratories was described. This could be initiated during the laboratory

workshops in specific countries of the NIS. All countries expressed an interest in participating in an official external quality assurance scheme for diphtheria laboratory diagnostics. All participating laboratories requested certificates of participation and progress in performance as part of the 'accreditation procedure'.

10. To ensure representation from Turkey and other EU accession countries. It is essential to have representation from all these countries.
11. To pay special attention in terms of diphtheria surveillance and control to high-risk groups: unvaccinated people, immigrants and those people with socio-economic problems.

6. Workshop on the introduction and implementation of immunization against

Hepatitis B

The participants of the workshop were divided into three groups (one English speaking group and two Russian speaking groups). The objectives were:

- to briefly review the current epidemiological situation on hepatitis B;
- to review the status of hepatitis B vaccine introduction and implementation;
- to review activities of the programme and identify achievements and constraints for countries implementing hepatitis B immunization;
- to decide further steps to be taken and suggest a plan of action to address the problems.

The feedback from the three groups of this workshop is summarized below.

Current epidemiological situation

In all countries, a mandatory reporting system is in place. After reviewing the data, there was a discussion on the clear need for the use of a standardized case definition for acute viral hepatitis. Some countries still report HbsAg carriers in the hepatitis B incidence data, which makes interpretation rather difficult. Despite the lack of standardization of hepatitis B surveillance systems and laboratory methods for hepatitis B virus (HBV) diagnostics, in countries with an HBV programme, acute HBV incidence still shows a tendency to decrease, whereas hepatitis B vaccination coverage increases.

There is also a need to report surveillance data according to standard age groups. For example: less than 1 year old (<1y), between 1 and 4 years old (1–4y), between 5 and 9 years old (5–9y), between 10 and 14 years old (10–14y), between 15 and 19 years old (15–19y), and so on.

Status of hepatitis B vaccine introduction

For the countries with a routine hepatitis B immunization programme, one of the major achievements was the ability to offer a hepatitis B vaccine free of charge to infants and newborns

(with greater than 80% coverage) and also to some other risk groups. Political commitment, high public demand, advocacy and a performing surveillance system (to identify major risk groups) were also seen as important achievements.

However, there are still problems with sustained funding of immunization programmes in general and in particular for hepatitis B. In addition, insufficient and unstable provision of hepatitis B vaccines is also an issue in some countries. Regional and district data show unequal vaccination coverage and low coverage rates in some parts of the countries. This is related to the problem of organizing outreach campaigns and of reaching specific population groups (for example, Armenia and Georgia). Injection safety still remains a problem for health care workers. Finally, there was a consensus in the group on the need to use standard case definition for surveys and reporting. For this purpose, the existing WHO case definition should be used or be reviewed.

The reporting frequency for hepatitis B surveillance should be increased to twice a year, the age categories standardized and national as well as regional data on hepatitis B vaccine coverage made available.

Annex 1.

PROVISIONAL PROGRAMME

Monday, 20 January 2003

- 08:15–09:00 Registration
- 09:00–09:10 Opening remarks
- 09:10–09:20 Election of chairperson, rapporteur and adoption of agenda
- Strengthening national immunization services**
- 09:20–09:40 Immunization programme in the European Region: current status and actions to be taken
N. Emiroglu, WHO/EURO
- 09:40–10:00 Improving management of immunization services at sub-national level
T. Goodman, WHO/HQ
- 10:00–10:20 Management of immunization services at sub-national level: experience of Ukraine
L. Mukharskaya, Ministry of Health, Ukraine
- 10:20–10:45 Discussion
- 10:45–11:00 Coffee break
- 11:00–11:30 Monitoring of performance: assessment of tools for reporting and data management
A. Burton, WHO/HQ, S. Wassilak, WHO/EURO
- 11:30–11:50 Strengthening national information system for immunization programme in Moldova
A. Melnic, Ministry of Health, Moldova
- 11:50–12:30 Discussion
- 12:30–14:00 Lunch
- 14:00–14:20 Development of national policy and plan of action for safety of immunization
D. Maire, WHO/EURO
- 14:20–14:50 Discussion
- Introduction of new vaccines**
- 14:50–15:10 Decision-making on introduction of new vaccines
A. Lobanov, WHO/EURO
- 15:10–15:30 Discussion
- 15:30–16:00 Coffee break

- 16:00–16:30 Financial sustainability
- planning process
L. Kamara, WHO/HQ
 - financial sustainability planning in Kyrgyzstan
S. Abdikerimov, Ministry of Health, Kyrgyzstan
- 16:30–17:00 Discussion

Tuesday, 21 January 2003

Training session on Advanced Immunization Management

- Strengthening national ICCs
- Advocacy and communication

Wednesday, 22 January 2003

Diphtheria control

- 09:00–09:20 Diphtheria in the European Region. Clinical and epidemiological aspects of diphtheria surveillance
N. Emiroglu, WHO/EURO
- 09:20–09:40 Diphtheria control in Latvia
J. Perevoscikovs, Public Health Agency, Latvia
- 09:40–10:00 Microbiological diagnosis and laboratory support for diphtheria surveillance
A. Efstratiou, Public Health Laboratory Service, UK
- 10:00–10:30 Discussion
- 10:30–11:00 Coffee break

Annex 2.

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