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DIPHTHERIA PREVENTION AND IMMUNIZATION PROGRAMMES IN NEWLY INDEPENDENT STATES

Report on a WHO Meeting

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ABSTRACT

A WHO consultation on diphtheria control in Belarus, Estonia, Latvia, Lithuania, the Republic of Moldova, the Russian Federation and Ukraine was held in Berlin, from 18 to 20 January 1995, with support from the Government of Germany. After reviewing the current diphtheria situation in the seven countries, the participants made recommendations on the elaboration of national action plans for diphtheria control including estimates for resource requirements with particular emphasis on vaccines, antitoxin, and antibiotics. The recommendations were based on the WHO/UNICEF strategy for diphtheria control, which was endorsed during the meeting. To ensure the necessary support for the implementation of the strategy, WHO and UNICEF will present the action plans to potential donors.

Keywords

DIPHTHERIA – prevention and control
IMMUNIZATION
NIS

CONTENTS

INTRODUCTION

The WHO Consultation on Diphtheria Prevention and Immunization Programmes in the Newly Independent States (NIS) of the former Soviet Union was held at the Internationales Handelszentrum, Berlin, from 18 to 20 January 1995. The meeting was convened by the WHO Regional Office for Europe, with support from the Government of Germany and the Robert Koch Institute, Berlin.

The objectives of the Consultation were:

(1) to review the progress and constraints of immunization programmes, with particular emphasis on prevention and control measures directed at the epidemic spread of diphtheria in Belarus, Estonia, Latvia, Lithuania, the Republic of Moldova, the Russian Federation and Ukraine;

(2) to elaborate steps for strengthening diphtheria surveillance and control activities in the NIS, based on national plans of action, according to WHO recommendations;

(3) to assess the requirements for prevention and control activities in the NIS with particular emphasis on diphtheria-component-containing vaccines, antitoxins and antibiotics, according to strategic recommendations made by WHO and the United Nations Children's Fund (UNICEF).

Participants included representatives of each of the countries mentioned above; temporary advisers from the Public Health Laboratory Service, United Kingdom and the Robert Koch Institute, Germany; representatives of the US Agency for International Development (USAID); the PATH/USAID project in Ukraine; Centers for Disease Prevention and Control (CDC), USA; Statens Seruminstitut, Denmark; International Federation of Red Cross and Red Crescent Societies (IFRC); Finnish Red Cross; the United Nations Children's Fund (UNICEF); and WHO staff (the list of participants is given in Annex 4). The meeting was chaired by Professor Meinrad Koch of the Robert Koch Institute, Germany;

Professor S. Dittmann served as Secretary and Dr Iain Hardy as Rapporteur.

The list of working papers can be found in Annex 3.

DISCUSSION

The diphtheria situation in Europe, with emphasis on the NIS, and the WHO/UNICEF strategy to control diphtheria

The estimated 47 000 diphtheria cases in 1994 represents an approximate 250% increase over 1993. Epidemic diphtheria has spread to all NIS excluding Estonia. From 1992 to 1994, about 20 cases imported from the NIS were reported in Bulgaria, Finland, Germany, Norway and Poland.

NIS can currently be classified into three groups according to the degree to which diphtheria has already spread:

(1) countrywide epidemic diphtheria: large numbers of cases in all or most regions (e.g. the Russian Federation, Tajikistan and Ukraine);

(2) diphtheria reported from many regions but the majority of cases from a few cities or regions (e.g. Georgia, Latvia);

(3) localized cases/outbreak only (e.g. Estonia).

There are two main patterns of age distribution:

(1) two thirds or more cases occurring among individuals aged 15 years or older (especially the Russian Federation, Ukraine, Baltics);

(2) one half or more cases among children aged less than 15 years (e.g. republics of the Caucasus and central Asia).

When setting priorities for strategies to implement immunization campaigns in steps, the geographical and age distribution of diphtheria in each country should be considered.

Case fatality rates vary between 2–3% in the Russian Federation and Ukraine, 5–10% in Armenia, Kazakhstan, Latvia and the Republic of Moldova, and 17–23% in Azerbaijan, Georgia and Turkmenistan. Major factors responsible for this variation are the availability of antitoxin and the extent of surveillance for mild cases.

Bacteriological confirmation of cases varies from 29% in Georgia up to 90% in the Russian Federation. A major factor is the availability of laboratory supplies.

In view of the severe situation in the NIS, a joint WHO/UNICEF strategy for diphtheria control in the NIS has been developed in close cooperation with USAID, CDC, the Robert Koch Institute and IFRC (Annex 2).

Country reports

Brief updates on the epidemiology of diphtheria were presented by each country represented. Data included in this report are from these presentations and from responses to a questionnaire distributed by the WHO Regional Office for Europe.

Belarus *(population 10.32 million)*

Epidemiology. In 1993, 120 diphtheria cases were reported and in 1994, 230 cases (incidence 2.5 per 100 000 population), of whom 165 (72%) were aged ≥15 years. There were 8 deaths in 1994 (case fatality rate (CFR) = 3.5%). In 1994, one cluster of 21 cases in a psychiatric hospital was reported. An estimated 31 cases in the entire country were imported from the Russian Federation.

Microbiology. Bacterial confirmation with toxigenic strains was obtained for 79.5% of cases. Seventy-five percent of isolated *C. diphtheriae* were biotype gravis.

Vaccination coverage. The most current data available are for 1993. Age-appropriate coverage was 90.5%, 92.1%, 96.6% and 91.4% at 1, 3, 10 and 16 years, respectively. An estimated 70% of adults received a single dose of Td during 1994. Lower coverage rates were achieved among physicians and teachers.

Population immunity. The proportion of the population susceptible to diphtheria was reported as 26%, 17% and 31% for the age groups 3–14 years, 15–17 years and 18–60 years, respectively.

Estonia (population 1.57 million)

Epidemiology. From 1965 to 1990, no diphtheria cases were reported in Estonia. During the 1980s, occasional (≤6 per year) carriers of toxigenic *C. diphtheriae* were reported. From 1991 to 1994, a total of 28 cases were reported, including 11 in 1993 and 7 in 1994 (0.4 per 100 000 population). Of the 28 cases, 10 were aged <10 years and 18 (64%) from 15–59 years. One case died in 1993. The majority of cases fell ill after travelling to the Russian Federation. In 1994, there was an outbreak of 6 cases, of whom 3 had been to the Russian Federation and 3 had not (all of whom were homeless people or gypsies). Of 150 contacts cultured, only 1 person had a positive culture for toxigenic *C. diphtheriae* – the husband of one of the patients, who himself fell ill.

Microbiology. Of the 28 cases reported from 1991 to 1994, 25 (89%) had toxigenic strains isolated (22 gravis, 3 mitis), 2 had non-toxigenic strains, and 1 had negative cultures.

Vaccination coverage. In 1993, 72% of children in their second year of life had completed at least a primary series of diphtheria toxoid; among children in their fifth year, 92.4% had completed a primary series and 76% had received at least one booster. Coverage with the third booster at age 16 increased from 34% in 1992 to 82% in 1993. From 1985 to 1987, 76% of adults aged 26 to 56 years were given a single booster vaccination, and the majority of adults in this age group have already been given a second booster.

Population immunity. Passive haemagglutination (PHA) testing showed that the great majority of children have protective diphtheria antitoxin levels. Serological testing of adults in 1993 showed that among those aged 18–39 years, 85–94% have protective levels; among those aged 40–49 years, the rate was 44–64%.

***Latvia** (population 2.65 million)*

Epidemiology. From 1969 to 1985, almost no diphtheria was reported. Beginning in 1986, cases and carriers of toxigenic *C. diphtheriae* were identified. A total of 51 cases was reported from 1986 to 1993. In 1994, however, there was a dramatic increase in the incidence of diphtheria, with 250 cases (9.6 per 100 000 population) provisionally reported. Children aged ≤14 accounted for 46 (18.4%) of cases, while 75 (30%) were adults aged 40–49. Twenty-four patients died (CFR = 9.6%), of whom 12 were aged 40–49 (CFR = 16% for this age group). Clinically, 108 (43%) of cases were classified as severe in 1994, compared to 33% of cases between 1986 and 1994. There was a high percentage of adult cases among those said to be alcoholics, homeless, or with no regular employment. Diphtheria cases have been reported from 13 of the 33 administrative regions. Most diphtheria is being reported from the eastern region which borders the Russian Federation and Belarus, with the highest numbers of cases in Daugavpils (69.6 per 100 000), Daugavpils region (47.7) and Ludzas (36.4). Diphtheria is also occurring in Tukuma (44.4), where large numbers of Russian troops are stationed. There were four clusters of more than one case (2–13 cases), accounting for 29 (11.6%) of cases.

Microbiology. In 1994, 72% of cases were bacteriologically confirmed with toxigenic strains, a similar rate to the period 1986–1993. There has been an increase in the proportion of isolates of *C. diphtheriae*, biotype gravis, from 46% during 1986–1993 to 71% in 1994.

Vaccination coverage. Coverage in the first year of life was 80–90% from 1989 to 1994. In 1994, 81% of two-year-olds had received their first booster, increasing to 93% at age 3. Receipt of second and third boosters was 96% at age 9 and 98% at age 15 respectively. Mass immunization of adults was launched in 1994. Approximately one third of adults have received ≥1 dose.

Population immunity. Serological studies indicate protective antibody levels in 83–95% of children and 74–89%, 68–71%, 24–55%,

and 27–54% of adults aged 20–29, 30–39, 40–49 and ≥50 years, respectively.

Lithuania (population 3.77 million)

Epidemiology. From 1976 to 1991, only 1–2 diphtheria cases were reported annually, except in 1977 when there were 5 cases. There were 9 reported cases in 1992, 8 in 1993 and 31 in 1994 (0.3 per 100 000 population). In 1994, 9 patients died (CFR = 29%) of whom 6 were aged 40–49 years. Of the 39 cases in 1993–1994, 32 (82%) were aged ≥15 years and 13 (33%) were aged 40–49 years. Thirty-one (79%) of cases were from the Vilnius region on the eastern border with Belarus. Carriers of toxigenic *C. diphtheriae* were more widely distributed.

Microbiology. In 1994, 27 of 31 (87%) cases were bacteriologically confirmed with toxigenic strains.

Vaccination coverage. In 1993, 86.8% of one-year-old children had completed primary immunization. Although final 1994 data for the same age group are not available, coverage is estimated to be over 90%. In 1994, 300 000 of 2.7 million adults received at least one dose of Td.

Population immunity. Serological studies in 1987–1989 found that 10% of six-year-old children and 23% of adults (ages not specified) were susceptible to diphtheria. In 1992, serological studies of prisoners found susceptibility to diphtheria among 26%, 66%, 70% and 75% of those aged 17–31 years, 32–42 years, 42–51 years and 52–71 years, respectively.

Republic of Moldova (population 4.36 million)

Epidemiology. The number of reported cases increased from 14 in 1991 to 22 in 1992 (mostly imported from the Russian Federation and Ukraine) to 35 in 1993. Beginning in the autumn of 1994, there was a dramatic rise in the number of reported cases, resulting in a provisional annual total of 372 (incidence 8.6 per 100 000). During 1994, 19 patients died (CFR = 5.1%). Cases in children (aged <15 years) accounted for 209 (56%) of reported cases; only 10 (2.7%)

were aged ≥50. The CFR was 6.7% among children and 3.1% among adults. Because of inadequate supplies, only 21.7% of cases were treated with antitoxin.

Cases are now spread over the entire country; the highest numbers of cases are reported from Chisinau and the Causeni and Slobozia regions.

Microbiology. In 1994, 95.6% of cases were bacteriologically confirmed with toxigenic strains.

Vaccination coverage. In 1993, coverage with the primary series by age 2 years was 96.5%. One dose of Td was administered to 12% of adults in 1993 and 10% of adults in 1994.

Russian Federation *(population 149.6 million)*

Epidemiology. The diphtheria epidemic began in 1989–1990, with reported cases increasing from 603 in 1989 to 15 229 (10.3 per 100 000) in 1993 and approximately 40 000 (23.2 per 100 000) in 1994. Children aged under 15 years accounted for 30% of cases in 1993 and 34% in 1994. The highest age-specific incidence and highest proportion of severe cases in 1993 were in the 40–49 year age group. In 1994, 28 administrative regions reported an incidence of diphtheria higher than the countrywide average. The highest incidence rates were in Magadanskaya (104.7 per 100 000), Primorski (90.7) and Irkutskaya (86.1). The highest absolute numbers of cases were reported in Moscow and St Petersburg.

Microbiology. In 1993, bacteriological confirmation with toxigenic strains was obtained in 92.2% and 88.9% of cases among children and adults, respectively. Biotype gravis accounted for 78.8% and 68.8% of strains isolated from child and adult cases, respectively.

Vaccination coverage. Coverage among one-year-old children increased from 68% in 1990 to 79% in 1993. In 1993, coverage of three-year-old children (first booster) was 82% and coverage of ten-year-old children (second booster) was 90%. Although the official list of vaccine contraindications has been substantially reduced,

further work is needed to ensure acceptance and implementation of this new policy by physicians.

Approximately 32 million adults received Td boosters in 1994; by the end of 1994, a total of 60 million adults (approximately 50% of the adult population) received at least one booster.

Ukraine (population 52.36 million)

Epidemiology. The provisional 1994 total is 2966 reported cases (5.7 per 100 000), which is very similar to the 1993 total of 2987 cases. In 1994, 111 patients died (CFR = 3.7%). All administrative regions have reported >20 cases, with the highest numbers reported in Kiev (428) and Donjetskaya (315). Sevastopol had a major outbreak: cases increased from 47 in 1993 to 199 in 1994. Children aged under 15 years accounted for 603 (20.3%) of cases. The peak age-specific incidence is among adults aged 40–49 years.

Microbiology. Bacteriological confirmation by isolation of toxigenic *C. diphtheriae* has been obtained for 70.6% of reported cases.

Vaccination coverage. Among adults, 50% have received at least one dose of Td since the beginning of mass vaccination in 1991–1992.

Diphtheria – clinical experience in St Petersburg with adult patients

Of patients reported in St Petersburg in 1993, 1890 (74%) of 2557 were adults. Among adults, 54% were aged 30–50 years. Among 1880 hospitalized adult patients, 356 (19%) had the "catarrhal" form (pharyngitis without membrane), 56% had membrane limited to the tonsils, 14% had spread of membrane to the pharynx or palate, and 151 (8%) had toxic forms of diphtheria with cervical swelling. Overall, 42 adult patients (2.2%) died, of whom 26 (62%) were aged 40–49 years. For toxic cases, initial antitoxin doses of 200 000–500 000 units are used, with total doses up to 2 million units (see Table 1). This is higher than the maximum dose of 500 000 recommended by the Ministry of Health of the Russian Federation. Initial doses used depend on the number of days of illness at presentation

and the degree of neck swelling; subsequent doses depend on the rates of reduction of neck swelling and disappearance of the membrane. In the past, doses of antitoxin recommended in the Russian Federation corresponded with current international recommendations. It was not until the 1980s that such increased doses were recommended. Antitoxin dosage is discussed further later in this report. Steroids are also used to treat toxic forms of diphtheria.

Table 1. Antitoxin treatment strategy
(Botkin's Infectious Diseases Hospital, St Petersburg)

Type of diphtheria	Antitoxin dose	Route
Tonsillar and nasal (local forms)	10 000 – 20 000	IM
Tonsillar-pharyngeal-laryngeal (spread forms)	80 000 – 100 000	IM or IV
Toxic forms (pharyngeal-laryngeal) with extensive membrane and bull neck		
1st–2nd degree	100 000 – 300 000	IV and IM
3rd degree, fulminant and haemorrhagic forms	200 000 – 500 000 (sometimes up to 1 000 000)	IV and IM
Laryngo-tracheo-bronchitis with specific bronchopneumonia	200 000 – 500 000	IV and IM

IM = intramuscular
IV = intravenous

Diphtheria vaccines and immunization

In the pre-vaccination era, adults were immune because of natural exposure to diphtheria and "streetcar boosting". In the post-vaccination era, there was a more than 30-year period without significant exposure to diphtheria; additionally, vaccine-induced immunity wanes without regular Td boosters. For booster vaccination of adults, low quantities of diphtheria toxoid antigen (e.g. 2 Lf)

per dose are sufficient. However, for primary vaccination of adults, an Lf content of 5–6 Lf gives a longer period of protection than 2 Lf vaccines. Adverse reactions are associated with: (i) purity (higher Lf content per mg of protein nitrogen is associated with a lower reaction rate); (ii) Lf content; and (iii) immune status (higher pre-immunization antitoxin level is associated with more reactions).

Immunization schedules in NIS

Current schedules for diphtheria immunization are similar in all NIS, with four doses of DPT in the first two (or three) years of life, and two (or in some cases three) DT and/or Td boosters between ages 6 and 16. Some countries recommend additional routine Td booster immunization of adults.

Calculation of resource needs including vaccines

Vaccines

Assumptions used by WHO for calculating vaccine needs in the NIS in 1994 (based on the traditional strategy used in the former USSR to immunize children and adolescents/adults at high risk) were as follows.

(i) For routine immunization:

DPT:	DPT1 – DPT3	96% of birth cohort × 3
	DPT4	96% of birth cohort × 1
DT:	DT1 – DT3	4% of birth cohort × 3
	DT4	4% of birth cohort × 1
	DT5	100% of birth cohort × 1.

(ii) For supplementary immunization with Td:

1 × Td for 20% children + adolescents, adults <40 years
2 × Td for 20% adults ≥40 years.

(iii) Wastage rate 1.3.

Vaccine needs have been projected for 1995 and adjustments have been made based on the newly elaborated WHO/UNICEF

strategy for diphtheria control in the NIS. This has resulted in increased requirements:

(i) routine immunization: DPT and DT calculated as above;

(ii) "catch-up" immunization of unimmunized or partially immunized children: additional DPT and DT needs calculated as 1 birth cohort × 2 doses each, assuming 80% DT, 20% DPT;

(iii) supplementary immunization with Td (children ≥7 years, adolescents and adults) for 80% of population 7 years and above × 1 dose; additional 2 doses for 80% of population in 20-year age band at highest risk (e.g. 30–50 year age group in the Russian Federation and Ukraine);

(iv) wastage rate 1.3.

Based on these estimates, costs – based on UNICEF prices – will increase five times in 1995 compared to 1994. Current UNICEF prices per dose are (US$): DPT=0.08, DT=0.07, Td=0.07.

The final estimates of need for each country may be different from the estimates derived from these assumptions, depending on the final plan of action adopted by the country (based on the epidemiological situation) and the extent to which mass immunization of adults has already been performed.

Vaccine needs and available vaccine supplies for 1994 and 1995 are summarized in Annex 1. This information is compiled from official reports to the WHO Regional Office for Europe, Information Service on Medical Supplies (ISMS) from Member States; in some cases, supplies received or committed may be substantially higher.

An observation was made on vaccine wastage. According to UNICEF studies, in a 10-dose vial there are only 8 doses and in a 20-dose vial, only 17 doses. UNICEF cannot supply vials containing less than 10 doses because the cost of the container will exceed the cost of the vaccine. (The Russian Federation produces vials containing 2–5 doses, which were formerly used throughout the Soviet Union.) Wastage might be reduced by carrying out WHO's recom-

mended policy, which allows opened vials to be stored for several days at 0–8 °C.

Antitoxin

The equation used in calculating antitoxin needs is as follows: 10 vials per case of diphtheria (10 000 unit/vial) (taking different clinical courses, wastage and loss during distribution into consideration), multiplied by the projected number of cases for 1995.

WHO has very little information about the quantity of antitoxin supplied or already committed to each NIS for 1994 or 1995. Current information (UNICEF) suggests that the total quantity of antitoxin likely to be available for purchase by donors in 1995 is one thousand million units.

Average costs for antitoxin may be in the order of US $7.50 per 10 000 unit vial, or approximately US $75.00 per case. The estimates of reported cases for 1995 used in calculating antitoxin requirements are optimistically low for some countries. For example, in Ukraine only 1500–2000 cases are projected. Antitoxin has not been used to treat milder cases in many countries, but on the other hand, as noted earlier in this report, much higher doses than those used for these estimates have been used to treat severe cases in many countries such as the Russian Federation and Ukraine.

Other resource requirements

No estimate of quantities required or of associated costs has been made at this time for other items such as antibiotics, injection materials and laboratory supplies. Such needs will be elaborated as part of the individual country plans of action.

Prevention and control of diphtheria

The principles for case and contact management, as outlined in the WHO manual for the management and control of diphtheria in the European Region, were presented at the meeting.

Antitoxin treatment

Antitoxin treatment was discussed extensively because of the current practice of using very high antitoxin doses for severe forms of diphtheria. In St Petersburg in 1993, 8% of adult cases had severe forms of diphtheria. The evidence in the medical literature and experience in many western countries (such as the United Kingdom, where case fatality rates have been approximately 5%) suggests that there is no advantage to using antitoxin doses higher than 100 000 immunization units (IU) for the most severe cases.

During the discussion, it was pointed out that after a dose of 100 000 IU, serum levels of 20 mg/ml of antitoxin are obtained. These levels decline slowly over several days unless the patient has had previous exposure to horse proteins, in which case after 2–3 days the antitoxin level may decline rapidly.

The public health implications of using excessive doses of antitoxin were also emphasized. World antitoxin supplies are limited (maximum 1 thousand million units estimated production in 1995) and antitoxin is expensive (e.g. US $7.50 and more per 10 000 unit vial on the world market). During 1994, total quantities in the range of 3–10 million units were supplied to some countries. If a dose of 2 million units is given to one patient, many other patients may be deprived of treatment and may die as a result, as has occurred in countries such as Georgia. Countries that rely on international donors for supply of antitoxin should therefore follow WHO's guidelines on treatment.

Several participants emphasized that clinicians who advocate the use of doses higher than 100 000 IU for severe diphtheria should establish the need for such higher doses by a controlled trial. In such a study, patients with severe forms of diphtheria would be randomized to receive either 80 000–100 000 IU or higher doses such as 300 000–500 000 IU. Outcome (occurrence of complications, survival) would be measured. A problem with designing such a study is that large numbers of patients would be required to demonstrate a statistically significant difference in outcome between the two groups.

Most countries have a policy of not using antitoxin for mild cases of pharyngitis without membrane or with follicular tonsillitis ("lacunar angina"), or for those cases that present late and are already convalescing with the membrane beginning to disappear. In St Petersburg and in Lithuania, for example, about 60% of reported cases did not receive antitoxin.

Use of antibiotics for close contacts

This topic was also extensively discussed at the meeting. It is the opinion of WHO and international experts that antibiotics should be given to close and intimate contacts without waiting for culture results. The participants emphasized that antibiotic prophylaxis should not be recommended for casual or relatively brief contacts, but only when the contact occurs in close quarters (a household or small workroom) or through kissing or other contact of a sexual nature. This strategy has been used successfully in many western countries to prevent secondary spread from imported cases. Antibiotic prophylaxis should also be considered when diphtheria cases or outbreaks occur in closed institutions such as homes for mentally ill children or orphanages or in refugee camps. In such cases, all staff and occupants should be treated.

It is likely that this strategy will be cost–beneficial. A rough estimate is US $0.20 per contact or US $2 per case to treat contacts, assuming 10 contacts per case. By contrast, the cost of treating a case may be more than 20 times greater. There is no evidence that treatment of contacts of respiratory cases will lead to antibiotic resistance in *C. diphtheriae*. However, NIS representatives had considerable reservations about this policy, including doubting its efficacy in preventing diphtheria cases. They also had concerns about induction of antibiotic resistance in *C. diphtheriae* and the side effects of antibiotic treatment, especially in children.

A further point of emphasis was that while this strategy is likely to reduce the number of cases, because asymptomatic carriers who can transmit diphtheria are widely distributed in the population, treating the relatively small numbers of carriers who are contacts of cases will have a relatively marginal impact on the epidemic. It is

possible that the strategy may have more impact in countries in which the epidemic has not become so established and widespread and during the decreasing phase of an epidemic when the last foci need to be eliminated.

The poliomyelitis situation and surveillance, Operation MECACAR and mass immunization

The current epidemiology of poliomyelitis in Europe was presented and the principles behind and plans for Operation MECACAR explained. The objective is to launch a mass immunization campaign in bordering countries of the WHO European and Eastern Mediterranean Regions in order to eradicate poliomyelitis. Up to 10 countries of the European Region and up to 13 countries of the WHO Eastern Mediterranean Region will hold coordinated polio national immunization days in the spring of 1995.

The number of cases of poliomyelitis reported in 1994 from countries represented at the Consultation were as follows: the Russian Federation, 4; Ukraine, 3 confirmed, 7 under investigation; Belarus 1; Estonia, Latvia, Lithuania and the Republic of Moldova all zero cases. In the other NIS, the countries that reported more than 10 cases in 1994 were Azerbaijan, Uzbekistan (national immunization days have already been conducted in these two countries) and Tajikistan.

Discussion of national action plans based on the WHO/UNICEF strategy to control diphtheria

Delegates divided into two working groups to begin the process of formulating national plans of action for diphtheria control. Representatives of the Baltic countries formed one group; the other comprised representatives from Belarus, the Republic of Moldova, the Russian Federation and Ukraine. The latter broke up into individual country working groups, with the exception of the Russian Federation, which is not requesting donor assistance for vaccines, antitoxin or antibiotics at this time.

Countries did not develop detailed plans during the meeting, both because of time constraints and because not all data were available. Detailed plans will be prepared after the Consultation and communicated to WHO.

Ukraine

It was agreed that one of the participants from Ukraine, using the WHO/UNICEF strategy for diphtheria control as a basis for policy and additional input from the other delegates listed, would formulate a draft plan of action within 10 days of the Consultation and circulate it to PATH, CDC, IFRC and UNICEF for comment. A national committee for diphtheria control is being established. Needs for basic immunization are likely to be met by the Government of Ukraine and the Canadian Government, which is willing to donate US $1.5 million (through UNICEF). Needs for supplementary immunization are being partially met by a PATH/USAID project which is to supply 22 million doses of Td between July 1994 and June 1995.

Belarus

UNICEF, Germany, will provide funds for purchasing vaccine and antitoxin. A total of US $105 000 has already been committed, and a further US $500 000 will be provided in the near future.

Republic of Moldova

Vaccine needs and costs have been estimated, but the needs for surveillance, antitoxin and antibiotics have yet to be determined. The detailed plan will be completed and sent to WHO by early February. The Government of Japan has committed US $500 000 for immunization, which will cover needs for routine and supplementary diphtheria immunization.

Baltic countries

In all three Baltic countries, immunization campaigns among preschool and schoolchildren are not considered necessary because of high vaccination coverage and the low incidence of diphtheria

among these age groups. An exception is Latvia where, since 1993, children aged 3–7 years have been given an additional dose of DT. This is particularly for children who received Td at their primary immunization. *Latvia* plans to give 1 Td dose to all adults and an additional 2 doses for those people who were previously unvaccinated or whose previous vaccination history is unknown. *Estonia* plans to give 1 Td dose to all adults, while *Lithuania* plans to give 2 doses of Td to all adults up to 60 years of age.

CONCLUSIONS AND RECOMMENDATIONS

The participants of the meeting endorsed the WHO/UNICEF strategy for diphtheria control.

Based on the WHO/UNICEF strategy, all countries should develop detailed, operational national plans of action for diphtheria control to implement the strategy according to the epidemiological situation and the logistic preconditions. Such plans should include the following components.

- Objectives (for reduction in incidence and for vaccination coverage).
- A clearly stated strategy, especially including target groups (by age group and geographical area) for supplementary immunization and a timetable for execution of the plan.
- Operational components to allow the strategy to be carried out, which should include the following:

  (a) management – a coordinator and committee with responsibility for coordinating diphtheria control at each level (national, regional and local);

  (b) surveillance, including laboratory diagnosis, reporting and analysis of diphtheria cases/incidence, and vaccination coverage;

(c) prevention and control activities, including case management and investigation strategies, contact management, and routine and supplementary immunization activities;

(d) social mobilization;

(e) training of health workers;

(f) detailed budget and statement of resource requirements.

A detailed budget should be prepared as part of the plan, listing all resource requirements. This budget should take the form of a questionnaire (by separate mail countries have already received the questionnaire) in which for each item, the following should be specified: the quantity of resources needed to be provided by the country's own government, the quantity of resources already committed from external sources, and the shortfall in needs. It was pointed out that the costs to donors to provide the same type and quantity of a particular item may vary. Therefore it is more helpful to donors to have a detailed list of which resources are needed, with justification, rather than an attempt by the requesting country to assign costs to these items.

The following components/activities should be included in the statement of resource requirements:

- vaccines
- antitoxin
- antibiotics for both cases and contacts
- injection materials such as needles and syringes
- additional cold chain equipment needed for supplementary activities
- laboratory supplies for isolation of *C. diphtheriae* and toxigenicity testing
- information, education, communication/social mobilization (development of material, printing and production)
- training (laboratory, surveillance, immunization policy and practice, clinical management of diphtheria)
- monitoring and evaluation of the control strategy (e.g. for trouble-shooting in districts)

- technical assistance (from donor countries), especially for training, information, education and communication.

While it is appropriate that needs for transport and additional staff be itemized, these should be provided by local resources.

Annex 1

Summary of vaccine needs and supplies, 1994

Country/ region	Population (millions)	Surviving 1-year-olds (thousands)	Total vaccine needs (thousand doses)			Total vaccine supplied to 31 December[a] (thousand doses)					
			DPT	DT	Td	DPT	%	DT	%	Td	%
European:											
Belarus	10.32	132.4	661	200	2 554	203	31	694	347	184	7
Republic of Moldova	4.36	89.4	446	135	1 079	322.5	72	1138	843	578	54
Ukraine	52.36	722.8	3 608	1 090	12 959	3104.5	86	2639.2	242	750	6
Baltics:											
Estonia	1.57	21.2	106	32	389	148	140	104	325	69	18
Latvia	2.66	35.8	179	54	658	0	0	342	633	0	0
Lithuania	3.77	54.5	272	82	933	0.5	<1	0.5	<1	100	11
Russian Federation	149.6	2348.1	11 722	3 541	37 026						

[a] Data for fourth quarter are incomplete in some cases.

Summary of vaccine needs and supplies – commitments, 1995

Country/ region	Population (millions)	Surviving 1-year-olds (thousands)	Total vaccine needs (thousand doses)			Total vaccine supplied or committed to date (thousand doses)		
			DPT	DT	Td	DPT	DT	Td
European:								
Belarus	10.33	132.5	731	476	16 455			
Republic of Moldova	4.36	89.4	492	321	6 893			
Ukraine	52.47	724.3	3 993	2 599	81 624			
Baltics:								
Estonia	1.57	21.4	118	77	2 453			
Latvia	2.65	35.7	197	127	4 006			
Lithuania	3.77	54.2	298	194	5 950			
Russian Federation	149.9	2352.8	12 968	8 442	237 967			

Annex 2

WHO/UNICEF STRATEGY FOR DIPHTHERIA CONTROL IN THE NEWLY INDEPENDENT STATES

1. Introduction

The current diphtheria situation in all newly independent states (NIS) of the former USSR is extremely serious, and makes coordinated international support for the countries affected by epidemic diphtheria an urgent priority. The rapidly expanding epidemic is an international public health emergency. In the Russian Federation, the epidemic has intensified in each successive year since 1990, and historical records underscore the potential for further increases in the magnitude of the epidemic across the continent.

The following proposed strategy for controlling the diphtheria epidemic has been developed by WHO/UNICEF, in close cooperation with the US Agency for International Development (USAID), the Centers for Disease Control and Prevention (CDC), USA, the Robert Koch Institute, Germany and the International Federation of Red Cross and Red Crescent Societies. The programme is not intended to duplicate WHO's technical recommendations on diphtheria control, but to coordinate the actions taken by WHO, UNICEF and other governmental and nongovernmental organizations in close cooperation with the health authorities of the NIS to provide resources for the implementation of recommended measures. The proposed strategy was discussed and approved during the WHO meetings held between these agencies and senior health representatives of the NIS in Berlin, Germany, 18–20 January 1995, and Ankara, Turkey, 31 January–1 February 1995.

The strategies outlined in this document are applicable to all NIS that are experiencing epidemic diphtheria. Donor support in controlling the epidemic has already been offered to the Baltic countries (Estonia, Latvia and Lithuania) by the Nordic Consortium. However, for the central Asian republics (Kazakhstan, Kyrgyzstan,

Tajikistan, Turkmenistan and Uzbekistan), the Caucasian republics (Armenia, Azerbaijan and Georgia), and Belarus, the Republic of Moldova and Ukraine, the donor support provided to date has not been sufficient and the need for additional assistance is urgent. The Russian Federation has indicated that it is self-sufficient with regard to vaccine, antitoxin and antibiotics, and does not require assistance in this respect.

2. Reasons for the resurgence of epidemic diphtheria in the NIS

The re-emergence of epidemic diphtheria in the NIS can be explained by the reintroduction of toxigenic strains into populations with a high proportion of susceptible adults and children. The susceptible population results from gaps in immunity in unimmunized adults, low immunization coverage of children in many areas and suboptimal immune responses following the common use of low-potency Td vaccines for infant primary series immunization. The spread may have been facilitated by large population migration since the dissolution of the former Soviet Union and by the absence of adequate control measures, especially mass immunization, during the early phase of the epidemic. The erosion of public health services and, in some countries, the inadequate supplies of vaccine have been important contributory factors in allowing the disease to reach epidemic proportions.

3. Recommended strategies

It is not the purpose of this strategy paper to describe the full scope of public health actions, including surveillance, diagnostics, prevention and control measures and social mobilization, necessary to control epidemic diphtheria in the NIS. This is described in detail in the WHO plan of action for the prevention and control of diphtheria in the European Region (1994) and the WHO manuals for the management and control of diphtheria (1994) and for the laboratory diagnosis of diphtheria (1994). The purpose of this paper is to

describe prevention and control strategies with regard to immunization, treatment of cases and prophylaxis of close contacts, and the resulting needs for vaccines, antitoxin, antibiotics, syringes and needles, in order to allow the epidemic-stricken countries and the donor community to act on commonly agreed principles.

Epidemic diphtheria can be controlled by the following three well recognized measures:

(1) primary prevention by ensuring high population immunity through immunization (the most effective measure to control epidemic diphtheria);

(2) secondary prevention of contact cases of diphtheria by the rapid investigation of close contacts and their standardized treatment;

(3) tertiary prevention and prevention of complications and death from diphtheria by early diagnosis and proper management (immediate treatment and hospitalization) of diphtheria cases.

3.1 Immunization

3.1.1 Routine immunization

The first priority is achieving and maintaining high vaccination coverage of children through routine immunization:

- every district of a country should achieve at least 95% coverage with the full course of primary immunizations (DPT4) for children by the time they reach 2 years of age;
- booster dose(s) of a diphtheria-toxoid-containing vaccine should be given according to the national immunization schedule to children of school age, aiming to achieve at least 95% coverage. DT is recommended for children at school entry or in the first year of school, and Td is recommended for older children.

3.1.2 Immunization campaigns

3.1.2.1 Countrywide immunization campaigns for children, adolescents and adults

If the whole country or several regions of the country have reported diphtheria cases and/or diphtheria outbreaks, the following immunization strategy must be implemented as soon as possible.

- Immunization campaigns should be carried out in all preschool institutions, schools and higher educational institutions (technical institutes and universities). A single dose of diphtheria-toxoid-containing vaccine should be given immediately to all persons attending such institutions (DT for children up to and including first grade and Td for older individuals), unless within the last 12 months they have documented evidence of having completed primary immunization or having received a booster.
- Additional dose(s) will be needed if a child/adolescent has not yet completed a three-dose schedule.
- All adolescents and adults should receive one dose of Td. Certain groups of adults may later need additional doses of Td for optimal protection. For example, in the Russian Federation and Ukraine, adults aged 30–50 years will require a total of three doses: two doses given a minimum of 4 weeks apart and a third 6–12 months later. Longer intervals between doses do not reduce the effectiveness of vaccination. In other republics, different age groups may be more susceptible and require additional doses, depending on the epidemiological situation.
- Children not attending preschool institutions should be included in immunization campaigns together with their mothers/parents.

When beginning immunization campaigns, priority should be given to the following groups since they are at high risk of contracting diphtheria:

- health care workers
- members of the armed forces
- refugees
- teachers; staff of kindergartens, crèches and similar institutions
- homeless people
- alcoholics
- drug users.

Homeless people, drug users and alcoholics can be difficult to reach. Special attention must be given to social care institutions and to the involvement of nongovernmental organizations that have developed special programmes for those groups of people who are at higher risk of disease and death from diphtheria.

3.1.2.2 Immunization campaigns for children, adolescents and adults in high-risk areas

The principles mentioned above for countrywide epidemics should be applied for localized areas of risk where outbreaks occur (villages, towns, districts or regions with diphtheria outbreaks). In case of localized outbreaks, immunization should be carried out immediately for all population groups in the affected area.

3.1.2.3 Organization of immunization campaigns

Immunization campaigns can include use of Immunization Days, immunization centres and mobile immunization points. Immunization carried out on a house-to-house basis could be a very useful strategy in villages and small towns. The key to success is proper preparation in collaboration with local mass media and local organizations. It will be necessary to formulate detailed strategies appropriate to the particular conditions (e.g. epidemiological, logistical) of each country.

3.1.2.4 Contraindications to diphtheria immunization

There are virtually no contraindications to the use of diphtheria toxoid or diphtheria-tetanus toxoids. The only valid contraindication

is the occurrence of a severe adverse reaction (anaphylaxis, collapse, shock) after a previous dose.

Simple febrile reaction following a previous dose is not a contraindication and further immunization should not be withheld. Advice should be given to prevent recurrence of these symptoms, i.e. by the use of antipyretic drugs.

3.2 Treatment of close contacts

All persons who in the previous seven days have been in close and intimate contact with a case of diphtheria caused by toxigenic *C. diphtheriae* should be considered at risk. Contacts of cases due to non-toxigenic *C. diphtheriae* or *C. ulcerans*, however, are not at risk.

Close contacts include the following:

- household members
- kissing/sexual contacts or other intimate contacts
- those who share the same small room at work
- health care staff exposed to oropharyngeal secretions of the case.

3.2.1 Surveillance for close contacts

All close contacts should be identified and clinically monitored for symptoms and signs of diphtheria for seven days from the date of the last contact with the case.

3.2.2 Culture

If diagnostic facilities are available, close contacts should have nasopharyngeal cultures for diphtheria. Antibiotic prophylaxis should not be dependent on the results of such cultures, but identified carriers of toxigenic *C. diphtheriae* should be isolated and receive follow-up cultures after treatment to ensure that the organism has been eliminated.

3.2.3 Penicillin prophylaxis

Close contacts should be given penicillin, preferably a single dose of intramuscular benzathine penicillin (600 000 units for children <6 years of age and 1.2 million units for persons ≥6 years of age), for reasons of compliance. Alternatively, oral erythromycin (40 mg/(kg/d)) for children and 1 g/d for adults, in divided doses) may be given for 7–10 days. It is emphasized that antibiotic prophylaxis is not being recommended for casual or relatively brief contacts. Antibiotic prophylaxis (and immunization of close contacts – see below) should also be considered when diphtheria cases or outbreaks occur in closed institutions, such as homes for mentally ill children or orphanages or in refugee camps. In such cases, all staff and occupants should be treated.

3.2.4 Immunization of close contacts

The immunization status of close contacts should be assessed, and it must be ensured that they all immediately receive one dose of a diphtheria-toxoid-containing vaccine (DPT or DT for infants, preschool children, and children in the first year of school, and Td for older individuals), unless within the last 12 months they have documented evidence of having completed primary immunization or having received a booster. People who have not completed primary immunization should continue to receive the additional doses needed in order to be fully protected.

3.3 Treatment of cases

Bacteriological examination may take several days. If diphtheria is suspected, specific treatment with antitoxin and antibiotics must be initiated immediately while bacteriological investigations are still pending. Antitoxin treatment is still the mainstay of treatment; antibiotic therapy is also required to eliminate the organism and prevent spread of the disease.

3.3.1 Diphtheria antitoxin

The dose of antitoxin to be administered depends on the site and extent of the diphtheritic membrane, the degree of toxicity and the duration of illness. A single dose of 10 000 to 100 000 units, depending on the severity of the illness, should be given. The whole of the intended antitoxin treatment should be given immediately. There is no clear evidence that doses above 100 000 units provide additional benefit, and this maximum should not be exceeded. Table 1 (proposed by Krugman, S. et al. in 1992, and slightly modified) provides an example of recommended doses for various clinical situations. This scheme is widely used in many countries of the world. However, manufacturers of antitoxin and national health authorities may recommend certain variations.

Table 1. Dosage of antitoxin recommended for various types of diphtheria

Type of diphtheria	Dosage (units)	Route
Nasal	10 000 – 20 000	Intramuscular
Tonsillar	15 000 – 25 000	Intramuscular or intravenous
Pharyngeal or laryngeal	20 000 – 40 000	Intramuscular or intravenous
Combined types or delayed diagnosis	40 000 – 60 000	Intravenous
Severe diphtheria (e.g. with extensive membranes) and/or severe oedema (bull-neck diphtheria)	40 000 – 100 000	Intravenous or part intravenous and part intramuscular

Source: Krugman, S. et al. *Infectious diseases of children.* 8th ed. St Louis, MO, 1985.

3.3.2 Antibiotics

Antibiotic treatment is necessary to eliminate the organism and prevent spread; it is *not* a substitute for antitoxin treatment. The preferred antibiotics are penicillin or erythromycin. The recommended dose regimens are as follows: penicillin, preferably intramuscular procaine penicillin G (25 000 units/(kg/d) for children and 1.2 million units/d for adults, in two divided doses) *or* intravenous erythromycin (40–50 mg/(kg/d), in four divided doses, with a maximum of 2 g/d) until the patient can swallow comfortably, at which point erythromycin may be given orally in the same dosage, or oral penicillin V (125–250 mg four times daily) may be substituted. Antibiotic treatment should be continued for 14 days.

3.3.3 Immunization

Clinical diphtheria does not necessarily confer natural immunity. Patients with diphtheria should therefore be vaccinated before discharge from hospital. Partially vaccinated or unvaccinated cases should receive a dose of a diphtheria-toxoid-containing vaccine immediately and, if necessary, complete a full primary course.

4. Laboratory diagnosis

Adequate means for laboratory confirmation of diphtheria are an essential component of surveillance and therefore of epidemic control measures. It will be necessary to ensure the availability of culture media in particular and other reagents necessary for basic laboratory diagnosis of diphtheria, i.e. isolation of *C. diphtheriae*, and toxigenicity testing.

5. Monitoring and surveillance

As a minimum, at least, the following data should be collected and analysed in a standard and timely fashion:

- disease incidence by age group and region
- vaccination coverage by age group and region.

Coverage should be calculated using a simple, standard method in which the denominator is the entire population within the specified age group, and the numerator is the number of persons actually vaccinated. The Regional Office for Europe has provided a proposal for data collection.

Serological studies during an outbreak are of limited usefulness. The most useful studies are likely to be of response to vaccination by age and type of vaccine received. Such studies should be carefully designed in order to be meaningful. Routine serological testing is not required to screen individual children prior to immunization nor to assess individual seroconversion.

6. Social mobilization and training

Putting diphtheria control strategies into practice needs strong support for social mobilization and training in the NIS. The general public should be informed of the danger of the disease and the benefits of immunization. An aggressive and comprehensive social mobilization programme should be launched to combat the lack of information or even misinformation about diphtheria and diphtheria immunization, especially when preparing immunization campaigns. The programme should widely involve the mass media. The key messages should be simple, short and clear. Experts should respond promptly to any misleading information given in the media.

Health workers at all levels should be informed and educated about the strategies to control diphtheria, the benefits and importance of immunization, and false contraindications against immunization. Training for medical staff at the national and regional level should include the following topics:

- diphtheria prevention by immunization (national immunization schedule, routine immunization, immunization campaigns, false contraindications);
- case management, clinical diagnosis, treatment of cases;
- laboratory diagnosis;
- preventive measures for close contacts;

- the use of the mass media for informing the public of the dangers of diphtheria and the need for immunization.

7. National action plans for the control of diphtheria and resource requirements and logistics

Based on the strategies described above, national diphtheria control plans, including the resource requirements for 1995 and 1996, should be elaborated in all NIS. The implementation of mass immunization should be given priority according to the epidemiological situation and the logistics available. A questionnaire developed during the WHO meetings held in Berlin and Ankara gives further advice on the planning process.

Each country should send a draft copy of this plan to WHO or UNICEF by 15 March 1995.

Annex 3

WORKING PAPERS AND BACKGROUND MATERIAL[1]

Working papers

CMDS.06.MT.06/6	The management and control of diphtheria, by Dr N. Begg
CMDS.06.MT.06/7	Immunization schedule in the NIS, by Dr Colette Roure
CMDS.06.MT.06/8	The diphtheria situation in the NIS and the WHO/UNICEF strategy for control of epidemic diphtheria, by Professor S. Dittmann
CMDS.06.MT.06/9	Diphtheria – clinical experience in St Petersburg, by Dr Asa G. Rakhmanova
CMDS.06.MT.06/10	Diphtheria vaccines and immunization, by Dr A. Galazka
CMDS.06.MT.06/11	Vaccines and other requirements for immunization programmes, particularly for diphtheria control, by Mr G. Larsen
CMDS.06.MT.06/12	The poliomyelitis situation and surveillance, Operation MECACAR and mass immunization, by Dr G. Oblapenko

Background material

EUR/ICP/EPI 038 Rev. 1	Diphtheria epidemic in Europe: emergency and response
ICP/EPI 038(A)	Plan of action for the prevention and control of diphtheria in the European Region
ICP/EPI 038(B)	Manual for the management and control of diphtheria in the European Region
ICP/EPI 038(C)	Manual for the laboratory diagnosis of diphtheria

[1] Copies can be requested from the ICD unit at the WHO Regional Office for Europe, 8 Scherfigsvej, 2100 Copenhagen Ø, Denmark.

Annex 4

PARTICIPANTS

Belarus

Dr Anatoly A. Astapov
Head, Chair of Children, Minsk

Dr Vladislav G. Zukovski
Senior Physician, Republic Centre for Hygiene and Epidemiology (RCHE), Minsk

Estonia

Dr Ants Jögiste
Chief Epidemiologist, National Board of Health Protection, Tallinn

Mrs Mall-Ann Riikjärv
Adviser, Infant Malady, Tallinn Children's Hospital, c/o Ministry of Social Affairs, Tallinn

Latvia

Dr Anita Brila
State Chief Epidemiologist, Deputy Director of the National Environmental Health Centre, Riga

Dr Arnis Jurevics
Director, Department of Environmental Health, Ministry of Welfare, Labour and Health, Riga

Lithuania

Dr Stasys Panavas
Head, Kaunas Infectious Hospital, Chief, Infectious Diseases, Ministry of Health, Kaunas

Dr Rimantas Valentélis
Head, Department of Organization on Immunization, Republican Immunization Centre, Ministry of Health, Vilnius

Republic of Moldova

Dr Mihai Magdei
Deputy Minister of Health, Ministry of Health of the Republic of Moldova, Chisinev

Dr Galina Rusu
Head, Department of Infectious Diseases, Medical University N. Testemitanu, c/o Ministry of Health of the Republic of Moldova, Chisinev

Russian Federation

Professor Asa G. Rakhmanova
Chief, Infectious Diseases, Health Department of the Mayor's Office, Medical Academy of Postgraduate Studies, St Petersburg

Dr A.A. Yassinsky
Director, Programme Development Department, State Committee of Sanitary and Epidemiological Surveillance, Moscow

Ukraine

Professor Sergey Kramarev
Head, Chair of Communicable Diseases, Medical University of Kiev, c/o Ministry of Health of the Ukraine, Kiev

Dr Victor Marievsky
Deputy Minister of Health, Ministry of Health of the Ukraine, Kiev

Temporary Advisers

Dr Norman Begg
Deputy Director, PHLS Communicable Disease Surveillance Centre, London, United Kingdom

Dr Sonja Kiessling
Robert Koch Institut, Berlin, Germany

Professor Meinrad Koch
Robert Koch Institut, Berlin, Germany *(Chairperson)*

Representatives of Other Organizations

PATH

Dr Roscius N. Doan
Project Director, Special Health Initiatives Project in Ukraine, Seattle, WA, USA

Centers for Disease Control and Prevention

Dr Iain Hardy
Diseases Branch, ESD, Atlanta, GA, USA *(Rapporteur)*

State Serum Institute

Dr Tove Rønne
Copenhagen, Denmark

US Agency for International Development

Dr Murray Trostle
Office of Health, Washington, DC, USA

International Federation of Red Cross and Red Crescent Societies

Dr J.V. Kreysler
Relief Health Adviser, Geneva, Switzerland

Ms Hannele Virtanin
Finnish Red Cross, Helsinki, Finland

Representatives of Other United Nations Agencies

United Nations Children's Fund

Dr Bruno Martin
Health Adviser, CEE/CIS Section, Geneva, Switzerland

World Health Organization

Regional Office for Europe

Mrs Loreta Colatosti
Administrative Assistant, Integrated Programme on Communicable Diseases

Professor S. Dittmann
Consultant, Diphtheria Control *(Secretary)*

Mr Gordon Larsen
Short-term Professional, Vaccines

Dr Georgey Oblapenko
Medical Officer, Poliomyelitis Eradication

Dr Colette Roure
Regional Adviser, Expanded Programme on Immunization

Headquarters

Dr Artur Galazka
Consultant, Expanded Programme on Immunization/Global Programme for Vaccines

TARGET 5

REDUCING COMMUNICABLE DISEASE

By the year 2000, there should be no indigenous cases of poliomyelitis, diphtheria, neonatal tetanus, measles, mumps and congenital rubella in the Region and there should be a sustained and continuing reduction in the incidence and adverse consequences of other communicable diseases, notably HIV infection.

DIPHTHERIA PREVENTION AND IMMUNIZATION PROGRAMMES IN NEWLY INDEPENDENT STATES

WORLD HEALTH ORGANIZATION
Regional Office for Europe
COPENHAGEN