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VACCINE SUPPLY IN NIS

WORLD HEALTH ORGANIZATION
Regional Office for Europe
COPENHAGEN

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.

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VACCINE SUPPLY IN NIS

Report on a WHO Meeting

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ABSTRACT

Senior representatives of ministries of health and ministries of finance of newly independent states of the former Soviet Union (NIS), together with a representative of the Russian vaccine producers and of the Russian State Committee on Sanitary and Epidemiological Surveillance, were invited to meet multinational, governmental and nongovernmental organizations to discuss the vaccine supply situation in the former USSR. Following the dissolution of the USSR, difficulties arose in obtaining vaccines from manufacturers in the Russian Federation. NIS are experiencing problems such as difficulty in making bank transfers to pay for ordered vaccines in advance of delivery, less vaccine delivered due to inflation between the time payments were sent and received, and the introduction by the Russian Federation of export licensing and customs duties which apply to vaccine sales. In addition, there are major deficiencies in the entire cold chain of the former USSR. WHO staff presented an estimate of the donations currently committed to NIS, and the minimum need for additional international donations to sustain primary immunization of infants in the non-Russian NIS. Maintaining quality control was also a major concern. The participants concluded that there is still an urgent need for humanitarian assistance to ensure an adequate supply of vaccine to NIS. It was recommended that a coordinating committee of intergovernmental and nongovernmental organizations be formed to assure the immunization of newborn infants. NIS should be encouraged to draw up plans to ensure adequate vaccine supply in the future, the ultimate goal being self-reliance.

Keywords

VACCINES
IMMUNIZATION
DIPHTHERIA – prevent/control
POLIOMYELITIS – prevent/control
(1) UNICEF
NIS

CONTENTS

INTRODUCTION

The dissolution of the USSR in 1991 had several important implications for childhood immunization in the newly independent states of the former Soviet Union (NIS). The break-up of the Soviet Union led to difficulties in the transport and distribution of vaccines, the lack of quality control and an adequate cold chain, and problems in transferring of funds between republics. These problems have been exacerbated by the economic situation in the NIS as they have limited amounts of hard currency with which to purchase vaccines. Consequently, senior representatives of ministries of health and ministries of finance of the 11 non-Russian NIS, a representative of the Russian vaccine producers and of the Russian State Committee on Sanitary and Epidemiological Surveillance, and representatives of multinational organizations and governmental and nongovernmental organizations held a meeting on vaccine supply in NIS in Copenhagen from 18 to 10 March 1993.

The aims of the meeting were to:

- discuss the occurrence of vaccine-preventable diseases in NIS, particularly in the light of the diphtheria epidemic and the outbreaks of poliomyelitis;
- gather information on the availability of vaccines for routine activities under the aegis of the Expanded Programme on Immunization (EPI), and on additional needs, including those required for special control measures necessitated by the recent epidemics or outbreaks;
- promote dialogue between senior representatives of NIS and organizations with programmes of cooperation on vaccines, to reach a better understanding of the constraints within NIS and of the mandates for cooperation of international organizations;
- promote international cooperation with respect to vaccine production and supply in the NIS, as well as implementation of the EPI;

- agree on specific action to meet emergency needs for vaccines;
- establish follow-up actions that would lead to self-reliance in NIS to safeguard the supply of vaccine.

The meeting was chaired by Dr Alan Hinman; Dr Christian Voumard served as Rapporteur. Annexes 1 and 2 list the working papers and participants, respectively.

The participants were welcomed by Dr Luculescu, Director, Programme Management, on behalf of the Regional Director of the WHO Regional Office for Europe. Dr Roure, Regional Adviser, Communicable Diseases, presented an overview of the objectives of the Expanded Programme on Immunization in Europe, and Dr Oblapenko, Medical Officer for Eradication of Poliomyelitis, summarized the current situation with respect to communicable diseases and vaccination coverage. He also pointed out the problems of vaccine supply, particularly in the light of the potential need to reimmunize up to 10 million children and up to 40 million adults in the Russian Federation and Ukraine to control the diphtheria epidemic that has been worsening over the past several years.

DISCUSSION

Reports from NIS

The diphtheria epidemic in the Russian Federation was described in more detail. There were about 4000 cases in 1992. While the epidemic covered the entire country, incidence was highest in Moscow and St Petersburg, where more than 40% of the cases had occurred. The majority of cases (70%) were in adults, and in children aged 7–14 years. A national programme to address immunization needs had been prepared for approval by the highest government authorities, with the aim of increasing production of preparations containing diphtheria toxoid by 2.5-fold, and initiating the mass vaccination of adults and children. Vaccine coverage in children was about 70% for diphtheria, and also less than desired against other vaccine-

preventable diseases. Nonetheless, the incidence of poliomyelitis was low (.01/100 000), and the incidence of measles was low in children, but increasing in teenagers.

The Deputy Minister of Health of Ukraine reported that diphtheria outbreaks in his country followed after those in the Russian Federation, and had increased from about 100 cases in 1990 to about 1500 cases in 1992. Causes of the epidemic were attributed to past anti-vaccine propaganda, which resulted in reduced coverage, and to the steadily decreasing content of diphtheria toxoid antigen in vaccines recommended and produced for use in the former USSR in the past. Large-scale vaccination programmes were being organized in Ukraine, and assistance was requested in providing additional supplies as not enough could be purchased from the Russian Federation due to banking problems and the limited supply from Russian producers. For the future, Ukraine hoped to be producing or packaging vaccines against diphtheria at a facility in Kharkov, but needed to establish quality control and a national control institute, for which personnel training was required.

Comments were made by representatives from Azerbaijan, Belarus, the Republic of Moldova, Tajikistan and Turkmenistan. Several reported increases in the incidence of diphtheria, measles, pertussis and tuberculosis. In Azerbaijan, poliomyelitis was reported to be increasing.

Common problems relating to the receipt of vaccines from the Russian Federation were noted by most speakers, for example, difficulties in arranging payment to Russian producers because of banking problems, and interference with exports from the Russian Federation as a result of new export licensing procedures and customs duties required by the authorities. This makes the receipt of deliveries highly unpredictable. As Russian producers supply vaccines at the lowest cost, they are of great importance.

Report from WHO on vaccine supply

WHO staff described the information available on vaccine supplies in the NIS. Data on the deliveries of donated vaccines in the past 12 months had been compiled, reflecting activities by the United

Nations Children's Fund (UNICEF) and the United States Government. Information from questionnaires distributed to all NIS at the end of 1992 and returned by several NIS was entered into a model that used standard parameters for numbers of vaccine doses needed per infant born, and estimated operational wastage factors for multidose vaccines.

The model was intended to show only the basic minimum needs for vaccines to permit enough supplies for primary immunizations. Based on differing assumptions about deliveries of vaccines from the Russian Federation to NIS, the model permitted estimates of the range of additional donations that might be needed from international sources to ensure that immunization programmes would not stop because of a lack of vaccine supplies. The model would automatically correct all estimations as data were updated and refined during the meeting to take account of new information provided. It could also take account of information provided on extra vaccine doses needed to catch up on missed vaccinations, or for special campaigns such as "mopping up" with oral poliomyelitis vaccine (OPV). A full set of print-outs was distributed during the meeting to include updated information collected while the meeting was in progress.

The cold chain situation

The Technical Director of Project Reach, USAID, described information collected during work by the Reach organization on behalf of USAID and their activities. He showed the participants the standard container used by Russian producers to distribute vaccines and pointed out the problems that occur even at the first stage of the cold chain as the box was not insulated. Also, manufacturers appeared to be unreliable in providing recipients with adequate information on the time of arrival of vaccines so that proper collection and transport could be arranged.

Additional problems relating to the cold chain were described: many refrigerators used for vaccine storage at point of use needed repair or maintenance; electricity was erratic or unavailable in some areas; EPI programme staff needed instruction and training to

improve their skills in storing and transporting vaccines; and local research was needed on safe procedures in treating measles and polio vaccines produced in the Russian Federation.

Problems with the cold chain were quite well known in the NIS, and as a result extra doses of vaccine were given and in the summer months no vaccinations were undertaken in an attempt to compensate. The situation was believed to have worsened since 1991; USAID-supported workers in central Asian republics recently reported the lack of a central cold store in Uzbekistan, and the lack of deliveries from producers in Moscow to *oblasts* (where refrigeration was usually available). A USAID contract had enabled about US $1 million of cold chain equipment to be delivered, including freezers for viral vaccines, and ice-pack freezers to assist refrigerated transport in cold boxes within the recipient NIS. It was pointed out that proper storage can extend the shelf life of, for example, OPV from 6 months at 4°C to 24 months at -20°C.

UNICEF and WHO support for vaccine supply programmes

Chief, Biologicals, WHO headquarters, described the system used by WHO to certify manufacturers for the sale of vaccines under contracts developed by UNICEF. The system is voluntary, and the first step is the application by the manufacturer to WHO for certification. Both the manufacturer and the national control authority were required to provide evidence to WHO of compliance with WHO recommendations for quality assurance and quality control of vaccines. Documents and facilities were inspected by WHO. Reproducibility of products from sequential batches must be proven. Ultimately, the responsibility rests with the national control authority to ensure that the same conditions of manufacture and testing were maintained at the time of application to WHO for certification.

A consultant for EPI, WHO headquarters, described the Vaccine Independence Initiative, which was a mechanism for UNICEF to enter into a contract with a country wishing to purchase its vaccines from UNICEF with national resources. In countries with a UNICEF programme, and where national currency could be used

to partially cover costs of in country operations by UNICEF, a revolving fund for vaccine procurement could be set up. The country would agree with UNICEF in advance on early needs for vaccines and costs, including the cost of reserve vaccine, which allowed for international inflation. Then funds would be provided to UNICEF in advance, which would enable UNICEF to guarantee delivery of vaccines. International donors could support such projects by providing hard currency during the initial phases, while the country was organizing its budget so that it could take increasing responsibility.

A representative of the Children's Vaccine Initiative described how information had been gathered about where vaccines were produced in the world, and how this fitted into a template accounting for population and economic development. About 60–70% of the world's DPT was manufactured in countries where it was used. Far fewer countries manufactured viral vaccines. In general, it appeared that countries with small populations (under 10 million) would be best served by purchasing finished vaccines. Most of the NIS appeared to fit this category. For the poorer countries, vaccines would need to be donated. In countries where the birth cohort was larger (approaching 1 million) importing bulk vaccine such as DPT and repackaging it might be economically justifiable. Only the very largest countries could economically sustain cost-effective manufacture of vaccines with quality assurance that met international recommendations.

General discussion

A round-table discussion was held, at which time representatives of several governments and multinational organizations described their activities and interests, and a vaccine producer from the Russian Federation had the opportunity to make comments.

A representative from Canada reported on the programme of emergency assistance to Belarus, the Russian Federation and Ukraine which Canada had funded UNICEF to implement. The aim of the project was to improve the health of mothers and children, and included supplies of vaccines to Belarus and Ukraine, and support for materials to assist vaccine production in the Russian

Federation. In addition, Canada is establishing a technical assistance project with Ukraine that will include training in how to control vaccines.

The government representative of Japan reported that, based on the information being developed at this meeting, a contribution towards vaccines would be provided under the NIS assistance programme. The details need to be worked out.

The Director of the Institute of Poliomyelitis and Viral Encephalitides, Moscow, informed the participants that the Institute had delivered 64 million doses of OPV in 1992, and more or less 73 million doses in 1991. Orders for 1993 totalled about 60 million doses. It had been necessary to increase last year's price of 2.5 roubles per dose to 10–12 roubles per dose in 1993 for export. He expressed concern at the level of national quality control in the Russian Federation, and would welcome assistance in implementing quality control measures at the Institute.

A representative of UNICEF gave an overview of the types of support possible from that agency, including (a) emergency donations using UNICEF's own, limited, funds, (b) reimbursable procurement on behalf of non-UNICEF organizations, using their funds, and (c) country programmes when authorized by the UNICEF Executive Board. A meeting in April would determine this latter point regarding NIS. UNICEF provides many supplies including vaccines in more than 120 countries. Vaccines supplied in 1992 were worth more than US $65 million. UNICEF works closely with WHO on quality control issues and negotiates with manufacturers to obtain the best prices possible.

The representative of the United States Government emphasized that, while the United States had made significant donations of vaccines and cold chain equipment as part of a project developed in 1992, it wished to see developments in the Russian Federation and other NIS lead to a normal market approach to the production and supply of vaccines. Thus, the hope for solutions from the perspective of the United States lay in increasing support to investment in privatized manufacturers of vaccines.

A representative of the special WHO programme on vaccines described approaches to partnerships that should be considered by

international organizations and the NIS to resolve short- and long-term needs for vaccine supply. These included encouraging NIS to identify loans and credits of hard currency available to them that could be used to procure vaccines, such as those provided by the European Community for purchases of food and pharmaceuticals, and those expected to be available from the World Bank to some NIS. The ultimate objective is better planning and financial management to enable NIS to become more self-reliant in the procurement of vaccines. Partnerships are desirable to ensure that there is adequate production capacity and quality assurance by Russian producers. Vaccine production or packaging may also be considered in some NIS other than the Russian Federation where it can be cost-effective. Finally, partnerships are needed to improve the cold chain and other aspects that will ensure vaccine quality, such as recording adverse events potentially associated with defective vaccine batches.

A representative of the World Bank said it was expected that Kazakhstan and Kyrgyzstan would be the first NIS to be eligible for rehabilitation loans, and that Belarus and Ukraine would be next. Although these loans were not as cheap as grants (they carried interest charges) they were available to use to support the import of vaccines, which were high-priority items in the opinion of the World Bank. World Bank procurement procedures are based on international competitive bidding to ensure the best value for extra resources. It is compatible with World Bank procedures to buy drugs and vaccines directly from UNICEF.

NIS representatives emphasized that there is a true crisis, with budget deficits of 30–50% in some cases, and no hard currency with which to purchase vaccines. The need for support to improve the production and control of vaccines in the Russian Federation, as well as to resolve the banking problems that hindered purchases from the Russian Federation was stressed. Various opinions were presented by NIS representatives on the issue of quality control, ranging from trusting the Russian manufacturers, to having WHO monitor quality control in the Russian Federation.

In the course of the meeting, Dr J.E. Asvall, Regional Director, stated his strong support for cooperative activities, and affirmed that

the Regional Office would invite interested organizations to meetings periodically to assist this process.

Working groups

The meeting divided into two working groups: Group 1 discussed vaccine supply issues in the NIS, and Group 2 discussed particular problems encountered by the EPI in NIS.

Group 1 concluded that the following needs must be met: support of vaccine production in the Russian Federation; facilitation of transfer of payments to the Russian Federation; prevention of the disruption of vaccine sales from the Russian Federation resulting from new requirements for export licenses; organization of the supply of vaccines not only for the primary immunization of infants, but also for the control of measles outbreaks in other age groups; and development of a supply of hepatitis B vaccine.

Group 2 found that the EPI needs to revise its policies and strategies to reduce contraindications to vaccination and the complexity of immunization schedules. It should also improve public education on the safety and efficacy of vaccines, and provide modern EPI training for all levels of staff. The cold chain needs to be improved, as does the analysis of data collected from immunization programme surveillance activities. Information should be shared better and, where possible, direct collaboration within each NIS as well as among international organizations working to assist the NIS should be encouraged.

CONCLUSIONS

The Chairperson presented a set of conclusions and recommendations (subsequently translated into Russian and provided to each NIS for comment before being entered into the report), which confirmed the great benefits resulting from good immunization programmes, and the importance of giving priority to achieving high coverage rates for the primary immunization series. The most current estimates of likely need for additional international support

in vaccine supply were given, and a proposal was made for urgent, coordinated follow-up actions by donors.

Successful immunization programmes require:

- an assured adequate supply of safe and effective vaccines;
- a procurement and distribution system that will get the vaccines where they are needed when they are needed;
- informed health care providers and a system that does not impose undue financial or administrative barriers;
- willing recipients (this implies that parents are informed about the benefits and risks of vaccines).

Owing to critical shortages of vaccines, it is difficult to maintain a normal schedule of infant immunization, combat outbreaks of diphtheria and advance the eradication of poliomyelitis. In addition, it is clear that adequate mechanisms do not exist in every republic to ensure delivery of potent vaccines to the end user. Plans do not exist in each republic to formulate the short-term, medium-term, and long-term goals for vaccine availability.

Vaccines may be obtained through humanitarian assistance from outside donors. They may be purchased directly from manufacturers, using hard currency, European Community credits or World Bank loans, or purchased through UNICEF, either using the above-mentioned resources or through a revolving fund. They may also be obtained by maintaining and improving existing local vaccine production within the NIS or developing new production facilities. The participants concluded that all of these options may have to be used in different degrees in different places over time.

Vaccines are among the least expensive and most cost-effective of health interventions. We must assure their optimum use in order to protect our children and our children's children.

RECOMMENDATIONS

1. There is an urgent need for humanitarian assistance to ensure that the NIS have adequate supplies of vaccines to immunize

the children being born each day. With regard to meeting the EPI schedule of immunization of infants, it has been estimated that, in 1993 in NIS other than the Russian Federation, there will be a lack of 4–7 million doses of DPT, 4–10 million doses of OPV, 3–5 million doses of measles, and 2 million doses of BCG. In addition, an estimated 20–30 million doses of diphtheria-containing toxoids may be needed to control current outbreaks of diphtheria.

2. A coordinating committee of governmental, nongovernmental and intergovernmental organizations should be formed within the next month to ensure that all NIS are able to fully immunize all newborn infants. An action plan for cooperation should be developed within the next three months. Coordination at the national level is also essential.

3. The NIS should develop short-, medium-, and long term plans to assure adequate supplies for the future. The ultimate goal is self-reliance, either through procurement or production. Ultimately, all manufacturers (whether domestic or international) should meet WHO standards or their equivalents. In considering whether to establish vaccine manufacturing capabilities, countries must consider the likely market available in order to decide whether vaccine production is economically feasible.

4. Comprehensive immunization plans should be developed in each country that address policy and strategy issues, training, surveillance, health education, and vaccine handling distribution and administration (the cold chain and the delivery system).

5. Vaccine schedules and the list of contraindications should be reviewed to ensure they are in accordance with current scientific knowledge.

6. Countries that rely on imported vaccines should give careful consideration to any additional requirements they may impose above those of the originally licensing authority.

Annex 1

WORKING PAPERS[a]

ICP/EPI 030/B/6	Overview of the Expanded Programme on Immunization in Europe, by C. Roure
ICP/EPI 030/B/7	Epidemiological situation and outbreaks in NIS, by G. Oblapenko
ICP/EPI 030/B/8	Consolidated database on vaccine supply and demand situation in NIS, by A.P. Kendal and A. Hovanesian
ICP/EPI 030/B/9	A perspective on partnerships in vaccine supply for NIS, by A.P. Kendal
ICP/EPI 030/B/10	Vaccine independence initiative, by A. Batson
ICP/EPI 030/B/11	Oral poliovirus vaccine (Sabin strains) production in the Institute of Poliomyelitis and Viral Encephalitides (Moscow, Russia) and vaccine distribution: present situation and some perspectives, by S.G. Drozdov

[a] Copies can be obtained from the CCEE Vaccine Programme, WHO Regional Office for Europe, Scherfigsvej 8, DK-2100 Copenhagen Ø, Denmark.

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