Contraindications to Vaccination in the Russian Federation

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Failure to achieve high levels of immunity among children contributed to the epidemic of diphtheria that occurred in the Russian Federation during the 1990s. A major factor in this failure was the extensive list of contraindications to vaccination that was in use throughout the countries of the former Soviet Union. In 1980, the Ministry of Health (MOH) of the Soviet Union adopted an extensive list of contraindications for use of the diphtheria-tetanus toxoids–pertussis (DTP) vaccine. In 1994, the MOH of the Russian Federation revised the list of contraindications to vaccination to be largely in accord with World Health Organization recommendations. Since then, age-appropriate vaccination coverage has increased markedly: In 1996, DTP3 coverage among children 12 months of age had increased to 87% from 60% in 1990.

Failure to achieve high levels of immunity among children was one factor that contributed to the epidemic of diphtheria that occurred in the Russian Federation during the 1990s. Despite a comprehensive system of primary health care, which is accessible to all children, and adequate supplies of highly effective vaccines, children remained susceptible to diphtheria due to the failure to deliver recommended vaccines on time. A major factor in this failure was the extensive list of contraindications to vaccination that was in use throughout the Newly Independent States (NIS) of the former Soviet Union. That list has been dramatically shortened, partly in response to the diphtheria epidemic, but until the mid-1990s official immunization policy of the Soviet Union and later the Russian Federation prevented on-time vaccination of a large proportion of young children.

Contraindications to Vaccination, 1980

In 1980, the Ministry of Health (MOH) of the Soviet Union adopted an extensive list of contraindications to vaccination of children (table 1). This list was developed by a committee of pediatricians and specialists in other pediatric disciplines (e.g., neurology and allergy). Once adopted by the MOH, these contraindications were included in vaccine product labeling as package inserts and formed the basis of training of pediatricians in immunization practice.

Other recommendations also contributed to delayed or incomplete vaccination of children. Many children with minor health problems (e.g., anemia, low weight for age, or frequent upper respiratory infections) were not vaccinated because they were considered "weakened" and had to be "strengthened" before vaccination. Such children routinely received vitamins or other regimens thought to improve the immune response prior to vaccination.

The 1980 immunization schedule also allowed the use of reduced-potency diphtheria vaccine (5 limit of flocculation units [Lf] per cc) combined with tetanus toxoid (Td) instead of diphtheria-tetanus toxoids–pertussis (DTP, 15 Lf per dose) or diphtheria-tetanus toxoids (DT, 30 Lf per dose) for the primary series. Studies had demonstrated that Td, when used for the primary series, produced a satisfactory antibody response for tetanus and diphtheria [1, 2]. This practice widened in the 1980s, leaving many children susceptible to pertussis; in 1985, 53,871 cases of pertussis were reported in the Soviet Union, compared with 13,908 in 1980.

Contraindications to Vaccination, 1988

By the late 1980s, some pediatricians and pediatric infectious diseases specialists were insisting that the list of contraindications be shortened. In 1988, the MOH convened an advisory group to revise the list. The new list of contraindications was shortened (table 1) but still included many contraindications not accepted as valid by the World Health Organization (WHO) [3]. The revised list was not accompanied by implementation guidelines, and the curriculum of pediatric training programs was not revised to reflect the new recommendations; the result was little change in immunization practice. Vaccination coverage (55%–70% in most areas) did not improve, and the practice of using Td instead of DTP for the primary series was continued (figure 1). Allergies remained a major reason that children were not vaccinated, accounting for 21% of referrals to the Moscow Consulting Immunology Center in 1988 [4].

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Table 1. Contraindications to diphtheria-tetanus toxoids–pertussis vaccine (DTP) in Russia.

Contraindication	1980	1988	1994
Acute disease	1 month	1 month	2–4 weeks
Severe acute or chronic disease	—	6–12 months	⩾1 month
Hepatitis A	6 months	—	—
Meningitis, sepsis, dysentery, or hepatitis B	12 months	—	—
Tonsillitis, adenoids (post-operative)	2 months	—	—
Tuberculosis (active or inactive with positive Mantoux test results)	With specialist's approval	—	—
Chronic lung suppuration	+	—	—
Allergies (anaphylaxis, serum sickness, bronchial asthma, eczema, edema)	+	+ (severe only)	+ (severe only)
Dermatitis, localized (after recovery)	+	3 months	—
Allergic reactions	3 months	—	—
Neurologic disorders, progressive	+	+	+
Neurologic disorders, nonprogressive	—	Not contraindicated	Not contraindicated
Hereditary syndromes (e.g., Down's syndrome, phenylketonuria)	+	—	—
Epilepsy or history of convulsions	+	+	+
Cerebral palsy	+	At age 6 months	—
Birth asphyxia without sequelae	At age 1 year	At age 6 months	—
Hydrocephalus, decompensated	+	+	—
Hydrocephalus, compensated	At age 1 year	Not contraindicated	—
Children with ante- and perinatal risks	At age 6 months	Not contraindicated	—
Perinatal infections or trauma with sequelae	+	+	—
Perinatal infections or trauma without sequelae	At age 1 year	At age 6 months	—
Prematurity	At age 1 year	At age 6 months	Not contraindicated
Severe rickets or malnutrition	+	—	—
Hemolytic anemia of newborn	At age 1 year	—	—
Congenital or acquired heart disease or endocarditis, decompensated	+	—	—
Congenital or acquired heart disease or endocarditis, compensated	With specialist's approval	—	—
Rheumatic fever, myocarditis	+	—	—
Glomerulonephritis, chronic renal failure, congenital nephropathies, urinary tract infection	+	—	—
Chronic hepatitis, hepatic cirrhosis, pancreatitis	+	—	—
Leukemia, aplastic states, coagulopathy, vasculitis, dysgammaglobulinemia	+	—	—
Deficiency anemia	+	—	—
Malignancies	+	+	+
Collagen diseases	+	—	—
Endocrine disorders	+	—	—
Enlarged thymus	+	—	—
Ulcerative colitis	+	—	—
Surgery	⩾2 months	—	—
Severe reaction to previous dose of DTP	+	+	+

NOTE. Months and weeks are times vaccination was allowed after recovery or beginning of remission. + and — indicate permanent contraindication to vaccination. + indicates that contraindications were explicitly mentioned in Ministry of Health document.

Contraindications to Vaccination, 1994

With the dramatic increases in diphtheria incidence in the early 1990s, pressure increased to reduce recommended contraindications to vaccination. During this period, a number of studies supported the effectiveness and safety of vaccinating children with chronic diseases and mild acute illnesses. Retrospective analysis of adverse events following the vaccination of 350 children with primary immunodeficiency who had been immunized prior to diagnosis demonstrated the safety of the recommended vaccination series [5].

In 1994, the MOH of the Russian Federation again revised the list of recommended contraindications (table 1): With minor exceptions, the revised list was largely in accord with WHO recommendations [6]. Implementation was facilitated by the efforts of the MOH and other organizations through meetings and seminars in many regions, often with international participation. Handbooks published in 1994 and 1995 contained updated information on immunization practices and the scientific basis for the shortened list of contraindications; these materials were extensively used in training programs. By 1996, DTP3 coverage by 12 months of age had increased to 87% from 60% in 1990 (figure 1).

Reasons for Delayed Vaccination of Children

To better understand the reasons that children were not being vaccinated, we studied a cohort of 347 children born in 1994 in a township near Moscow. Although vaccine coverage was high (by age 1 year, 99.5% of children had completed the primary series for diphtheria, tetanus, and poliomyelitis, and 85.6% were age-appropriately vaccinated for pertussis), only 180 children (52%) had received all doses of vaccines within 2 weeks of the recommended age. Most children were vaccinated late due to inappropriate contraindications to vaccination; pa-

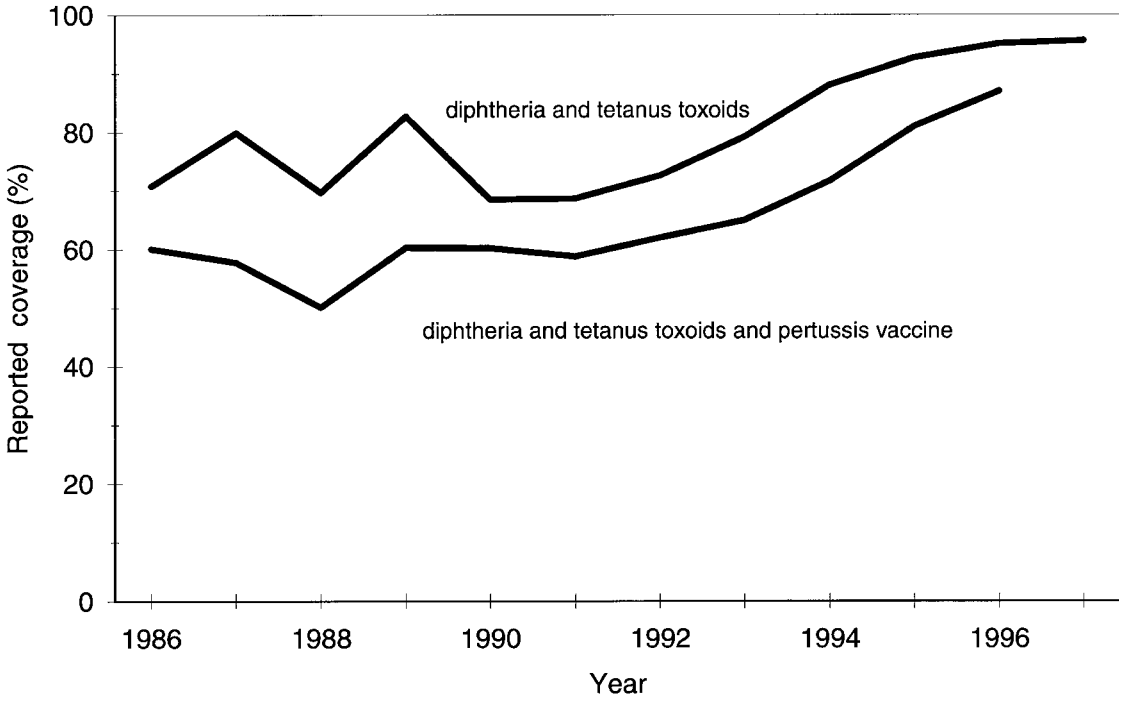

Figure 1. Vaccination coverage, by year, for receipt of a primary series of diphtheria and tetanus toxoids and pertussis vaccine or diphtheria and tetanus toxoids vaccine by 12 months of age—Russian Federation.

rental refusal accounted for only a small number of delayed doses.

The most commonly cited contraindication to pertussis vaccination was "perinatal encephalopathy," a term used by many pediatricians and pediatric neurologists in Russia and other NIS to denote tremors, minor abnormalities of reflexes and muscle tone, or irritability or other changes of behavior ascribed to real or suspected perinatal trauma or hypoxia. In some areas, up to 90% of infants received this diagnosis.

Other Barriers

Pediatricians in children's polyclinics in NIS are each responsible for the health of 800–1000 children who are assigned to their care. The scope of this responsibility is not well defined, but the pediatrician is likely to be alone in being held responsible should an adverse event occur following vaccination. Although he or she is not legally liable if vaccination was done in accordance with current medical practice, parents' complaints and administrative reprimands nonetheless can serve as a powerful disincentive. To help resolve this problem, the Duma (Parliament) of Russia passed a law in 1998 defining the respective responsibilities of vaccine manufacturers, medical personnel, and the State.

Conclusion

Russia paid a high price in the 1990s for its low vaccination coverage among children. Coverage improved substantially with revision of the list of contraindications, development of updated guidelines, and comprehensive training for vaccine providers. Shifts in the attitudes of parents are apparent as well. National Immunization Days (NIDs) for polio vaccination were conducted in 1996 and 1997. These efforts were accompanied by an intensified public-information campaign addressing polio and the importance of all vaccinations. In each of the four NIDs, >98% coverage of the target groups was achieved. This success suggests that with appropriate recommendations, training, and outreach to the public, high coverage with all childhood vaccinations can be achieved.

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