Committee on Infectious Diseases

Revised Recommendations on Rubella Vaccine

The following recommended changes are similar to, but not identical with, those recommended by the US Public Health Service Advisory Committee on Immunization Practices in November 1978. These changes focus on more effective delivery of the vaccine to older individuals, in particular to females in the childbearing age group. All comments related to the vaccine and its use pertain to all licensed vaccines available in the United States, including the recently licensed RA27/3 vaccine.

The major objective of the National Rubella Immunization Program is the prevention of rubella infection in early pregnancy, which in turn will prevent infection of the fetus and consequent congenital rubella. Prior to vaccine licensure in 1969, approximately 15% of women of childbearing age were susceptible to rubella. At the present time, more than 83 million doses of live, attenuated rubella virus vaccine have been distributed in the United States, which has clearly resulted in a widespread reduction of epidemic rubella in preschooland elementary school-aged children. However, since the use of rubella vaccine has not been universal in the target population (only about two thirds of the children 1 to 12 years old have been immunized) and since vaccine usage has disrupted the epidemic nature of rubella, the population for whom antibody protection is desired (women of childbearing age) is still suspected of being as susceptible, or more so, than in the prevaccine era. Indeed, serologic surveys indicate that persons in this age group have a percentage of susceptibility similar to that noted prior to 1969. At the present time, in contrast to the prevaccine era, most cases of rubella occur in adolescents and young adults. In 1977, 70% of all cases occurred in persons 15 years of age and older. Since licensure of rubella vaccine, the incidence of reported rubella in adolescents and young adults has not decreased appreciably. Outbreaks of rubella continue to be reported in junior and senior high schools, colleges, the military, and places of employment—most notably in hospitals.

If the goal of prevention of congenital rubella is

to be achieved, immunity levels (induced largely by immunization) in both children and all young adults must be raised above the 90% level.

VACCINE USAGE

General Recommendations

Rubella vaccine is recommended for all children, most adolescents, and many adults—particularly females—unless it is otherwise contraindicated. Vaccinating children protects them against rubella and prevents their subsequently spreading it. Vaccinating susceptible, postpubertal females confers individual protection against rubella-induced fetal injury. Vaccinating adolescent or adult males and females in population groups (such as those in colleges, places of employment, or military bases) protects them against rubella and reduces the chance of epidemics in partially immune groups.

Dosage

A single dose of vaccine in the volume specified by the manufacturer should be administered subcutaneously. The RA27/3 strain or rubella vaccine virus is not licensed for intranasal administration.

Individuals at Risk

Live rubella virus vaccine is recommended for all children at 12 months of age or older. It should not be administered to younger infants because persisting maternal antibodies may interfere with seroconversion. When the rubella vaccine is part of a combination vaccine that includes the measles antigen, it should be administered to children at about 15 months of age or older to achieve the maximum rate of measles seroconversion. Children who have not received rubella vaccine at the optimum age should be vaccinated promptly. Because a history of rubella is not a reliable indicator of immunity, all children for whom vaccine is not contraindicated should be vaccinated.

Increased emphasis should be placed on vaccinating all unimmunized prepubertal children and susceptible adolescents as well as adult females in

the childbearing age group. Because of the theoretical risk to the fetus, females of childbearing age should receive vaccine only if they are not pregnant and understand that they should not become pregnant for three months after vaccination. Because only approximately 20% of potential vaccinees in the childbearing age group are actually susceptible to rubella, it seems wise to serologically test for rubella antibodies prior to immunization, whenever practical. However, in view of the importance of protecting this age group against rubella, the lack of serologic testing should not act as a deterrent to rubella immunization. Reasonable precautions in rubella immunization programs where serologic testing is impractical, or declined by the potential vaccinee, include asking female patients whether they are pregnant, excluding those who are, and explaining the theoretical risks to those who are not pregnant. In many instances it may be useful to collect a blood specimen at the time of vaccination. This can be tested later if the woman is found to have been pregnant at the time of the vaccination or should become pregnant in the next three months.

Educational and training institutions such as colleges, universities, and military bases should seek proof of rubella immunity (a positive serologic test or documentation of a previous rubella vaccination) from all students and employees in the childbearing age group. Nonpregnant persons who lack proof of immunity should be vaccinated unless contraindications exist.

Susceptible female patients and female employees need protection from exposure to rubella. Therefore, persons working in hospitals and clinics who might contract rubella from infected patients or who, if infected, might transmit rubella to pregnant patients should either have serologically demonstrated immunity to rubella or receive the vaccine.

When reliable laboratory services are available, routine premarital serology for rubella immunity would enhance efforts to identify susceptible women before pregnancy. Prenatal or antepartum screening for rubella susceptibility should be undertaken and vaccine administered in the immediate postpartum period, prior to hospital discharge. Previous administration of anti-Rho (D) immune globulin (human) or blood products is not a contraindication to vaccination; however, a postvaccination serologic test should be done six to eight weeks later on those few patients who have received the globulin or blood products to ascertain that seroconversion has occurred. Obtaining laboratory evidence of seroconversion in other vaccinees is not necessary.

Individuals Exposed to Disease

Use of Vaccine Following Exposure. There is no evidence that live rubella virus vaccine given after exposure will prevent illness or that vaccinating an individual incubating rubella is harmful. Because a single exposure may not result in infection and postexposure vaccination would protect an individual during future exposure, vaccination is recommended, unless otherwise contraindicated.

Use of Immune Serum Globulin Following Exposure. Immune serum globulin (ISG) given after exposure to rubella will not prevent infection or viremia, but it may modify or suppress symptoms. The routine use of ISG for postexposure prophylaxis of rubella in early pregnancy is not recommended. (Infants with congenital rubella have been born to women give ISG shortly after exposure.) The only occasion for which ISG might be used is when rubella occurs in a pregnant woman who would not consider termination of pregnancy under any circumstances. Serologic testing for rubella immunity is useful when an exposure in early pregnancy is suspected.

SIDE EFFECTS AND ADVERSE REACTIONS

Vaccine side effects, such as rash and lymphadenopathy, occasionally occur in children. Joint pain, usually of the small peripheral joints, has been noted, although frank arthritis is reported in fewer than 1% of the patients. Arthralgia and transient arthritis occur more frequently and tend to be more severe in susceptible women than in children. When joint symptoms or nonjoint-associated pain and paresthesia occur, they generally begin two to ten weeks after immunization, persist for one to three days, and rarely recur. The persistent arthritic symptoms that have occasionally been described probably represent coincidental disease rather than a vaccine complication. Transient, peripheral, neuritic complaints (such as paresthesia and pain in the hands and feet) have also occurred but are extremely uncommon.

Some vaccinees intermittently shed small amounts of virus from the pharynx seven to 28 days after vaccination. However, studies of more than 1,200 susceptible household contacts have yielded no evidence that vaccine virus has been transmitted. These data strongly suggest that vaccinating susceptible children whose mother or other household contacts are pregnant is not contraindicated.

Although vaccine is safe and effective for all persons more than 12 months old, its safety for the developing fetus is not fully known. Thus, rubella vaccine is *not* suitable for pregnant women because of the theoretical risk of fetal abnormality caused

by the vaccine virus, which crosses the placenta. Although no recognizable malformations clearly attributable to rubella have been seen in infants born to more than 60 susceptible women, who inadvertently received rubella vaccine during early pregnancy and continued their pregnancies to term, the theoretical risk remains.

PRECAUTIONS AND CONTRAINDICATIONS

Fever

Persons with febrile illness should not be vaccinated until they have recovered. However, minor illnesses, such as upper respiratory infections, do not preclude vaccination.

Pregnancy

Pregnant women should not be given rubella vaccine. If a pregnant woman is inadvertently vaccinated or if a woman becomes pregnant within three months of vaccination, she should be counseled on the theoretical risk to the fetus. The Immunization Division, Center for Disease Control, should be notified of instances of inadvertent vaccination during or just prior to pregnancy.

Breast-feeding is not a contraindication to rubella vaccination.

Allergies

Live rubella virus vaccine is produced in duck embryo cell culture or in human diploid cell culture. The vaccine has not been reported to be associated with allergic reactions and can be given to all who need it, including persons with allergies to eggs, ducks, and feathers. Liver rubella virus vaccine does not contain penicillin. However, some vaccines contain trace amounts of other antibiotics to which patients may be allergic. Those administering vaccines should review the label information carefully before deciding whether patients with known allergies to antibiotics can be vaccinated safely.

Altered Immunity

Replication of the rubella vaccine virus may be potentiated in patients with immune deficiency diseases and by the suppressed immune responses occurring with leukemia, lymphoma, or generalized malignancy or therapy with corticosteroids, alkylating drugs, antimetabolites, or radiation. Patients with such conditions should not be given live rubella virus vaccine.

Simultaneous Administration of Certain Live Virus Vaccines

See "Combination and Spacing of Vaccines" on page 6 in the Report of the Committee on Infectious Diseases.²

OUTBREAK MANAGEMENT

To prevent the spread of rubella in outbreaks, susceptible persons at risk should be vaccinated promptly. Women at risk of exposure who are not aware of being pregnant and agree to prevent conception for three months should be vaccinated. Although prevaccination serologic testing is not necessary, it may be useful to collect a blood specimen at the time of vaccination. It can be tested later if the woman is found to have been pregnant at the time of vaccination or should become pregnant in the next three months.

SURVEILLANCE

Accurate diagnosis and reporting of rubella, the congenital rubella syndrome, and vaccine complications are extremely important in assessing the progress in rubella control. Furthermore, all birth defects suspected of being related to rubella should be thoroughly investigated and reported to state health departments.

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