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# **Vaccinia (Smallpox) Vaccine Recommendations of the Immunization Practices Advisory Committee (ACIP)**

These revised recommendations on vaccinia (smallpox) vaccine update the previous recommendations (MMWR 1985;34:341-2) and include current information on its use among laboratory and health-care workers occupationally exposed to vaccinia, recombinant vaccinia viruses, and other orthopoxviruses that can infect humans. This report also contains revised recommendations on revaccination of high-risk workers and information on contraindications to vaccination.

## **INTRODUCTION**

Vaccinia (smallpox) vaccine is a highly effective immunizing agent that brought about the global eradication of smallpox. The last naturally occurring case of smallpox occurred in Somalia in 1977. In May 1980, the World Health Assembly certified that the world was free of naturally occurring smallpox (1).

Because of vaccination programs and quarantine regulations, the risk of importation of smallpox into the United States was reduced by the 1960s. As a result, routine vaccinia vaccination was discontinued in 1971 (2). In 1976, the recommendation for routine vaccination of health-care workers was also discontinued (3). In 1982, the only active licensed producer of vaccinia vaccine in the United States discontinued production for general use, and in 1983, distribution to the civilian population was discontinued (4). For several years all military personnel continued to be routinely vaccinated. However, only selected groups of military personnel are currently vaccinated against smallpox.

Since January 1982, smallpox vaccination has not been required for international travelers, and International Certificates of Vaccination no longer include smallpox vaccination (5).

In 1980, the Immunization Practices Advisory Committee (ACIP) recommended the use of vaccinia vaccine to protect laboratory workers from possible infection while working with nonvariola orthopoxviruses (e.g., vaccinia and monkeypox)(6). In 1984, these recommendations were included in guidelines for biosafety in microbiological and biomedical laboratories (7). These guidelines expanded the recommendation to include persons working in animal-care areas where studies with orthopoxviruses were being

conducted and recommended that these workers have documented evidence of satisfactory smallpox vaccination within the preceding 3 years. CDC has provided vaccinia vaccine for these laboratory workers since 1983 (8).

Because studies of recombinant vaccinia virus vaccines have been advanced to the stage of clinical trials, health-care workers (e.g., physicians and nurses) may now be exposed to vaccinia and recombinant vaccinia viruses and should be considered for vaccinia vaccination.

## VACCINIA VACCINE

The vaccinia vaccine currently licensed in the United States is a lyophilized preparation of infectious vaccinia virus. \* The vaccine was prepared from calf lymph with a seed virus derived from the New York City Board of Health (NYCBOH) strain of vaccinia; it has a concentration of 10 superscript 8 pock-forming units (PFU) per milliliter. Vaccine is administered by using the multiple-puncture technique with a bifurcated needle.

After percutaneous administration of a standard dose of vaccinia vaccine, >95% of primary vaccinees (i.e., persons receiving their first dose of vaccine) will develop neutralizing or hemagglutination inhibition antibody at a titer of greater than or equal to 1:10 (9). Neutralizing antibody titers of greater than or equal to 1:10 are found among 75% of persons for 10 years after receiving second doses and up to 30 years after receiving three doses of vaccine (10,11). The level of antibody that protects against smallpox (variola)infection is not known, but epidemiologic studies suggest that protection against smallpox persists a minimum of 5 years after revaccination (12). Also, the level of antibody required for protection against vaccinia infection is not known. However, when the response to revaccination is used as an indication of immunity, 30% of persons with titers

## RECOMBINANT VACCINIA VIRUSES

Vaccinia virus is the prototype of the genus Orthopoxvirus. It is a double-stranded DNA virus that has a broad host range under experimental conditions and is rarely isolated from animals outside the laboratory (14). There are many strains of vaccinia virus, which have different levels of virulence for humans and animals. For example, the Temple of Heaven and Copenhagen vaccinia strains are highly pathogenic in animals, whereas the NYCBOH strain, from which the Wyeth vaccine strain was derived, had relatively low pathogenicity (15).

Vaccinia virus can be genetically engineered to contain and express foreign DNA without impairing the ability of the virus to replicate. Such foreign DNA can encode protein antigens that induce protection against one or more infectious agents. Recombinant vaccinia viruses have been engineered to express the immunizing antigens of herpesvirus, hepatitis B, rabies, influenza, human immunodeficiency viruses (HIV), and others (16-21).

Recombinant vaccinia viruses have been created from several strains of vaccinia virus. In the United States most recombinants have been made from either the NYCBOH strain or a mouse neuroadapted derivative, the WR strain. Some recombinants have been made from the Copenhagen and Lister vaccinia strains, which are more pathogenic in animals than the NYCBOH strain. Animal studies generally suggest that recombinants may be no more pathogenic than the parent strain of vaccinia virus. However, no consistently reliable laboratory marker or animal test predicts the attenuation of vaccinia virus or a particular recombinant for humans (22). Laboratory-acquired infections with vaccinia or recombinant viruses have been reported (23-25). However, since no surveillance system has been established to monitor laboratory workers, the risk of infection for persons who handle virus cultures or materials contaminated with these viruses is not known.

With the initiation of human trials of recombinant vaccines, physicians, nurses, and other health-care personnel who provide clinical care to recipients of these vaccines could be exposed to both vaccinia and recombinant viruses. This exposure could occur from contact with dressings contaminated with the virus or through exposure to the vaccine. The risk of transmission of recombinant viruses to exposed health-care workers is unknown. To date, no reports of transmission to health-care personnel from vaccine recipients have been published. If appropriate infection-control precautions are observed, health-care workers are probably at less risk of infection than laboratory workers because of the smaller volume and lower titer of virus in clinical specimens compared with laboratory material (26,27). However, because of the potential for transmission of vaccinia or recombinant vaccinia viruses to such persons, the ACIP suggests that health-care personnel who have direct contact with contaminated dressings or other infectious material from volunteers in clinical studies be considered for vaccination.

Laboratory and other health-care personnel who work with viral cultures or other infective materials should always observe appropriate biosafety guidelines and adhere to published infection control procedures (26-28).

## VACCINE USAGE

Vaccinia vaccine is recommended for laboratory workers who directly handle a) cultures or b) animals contaminated or infected with vaccinia, recombinant vaccinia viruses, or other orthopoxviruses that infect humans (e.g., monkeypox, cowpox). Other health-care workers (such as physicians and nurses) whose contact with these viruses is limited to contaminated materials (e.g., dressings) but who adhere to appropriate infection control measures are at lower risk of inadvertent infection than laboratory workers. However, because a theoretical risk of infection exists, vaccination may be considered for this group. Because of the low risk of infection, vaccination is not recommended for persons who do not directly handle virus cultures or materials or who do not work with animals contaminated or infected with these viruses.

High seroconversion rates and infrequent adverse events (see Side Effects and Adverse Reactions) are two benefits of vaccination. Recipients are given controlled percutaneous doses (approximately  $2.5 \times 10^5$  PFU (29)) of relatively low pathogenicity

vaccinia. The resulting immunity should provide some degree of protection to recipients against infections resulting from uncontrolled, inadvertent inoculation by unusual routes (e.g., the eye) with a large dose of virus of higher or unknown pathogenicity. In addition, persons with preexisting immunity to vaccinia may be protected against seroconversion to the foreign antigen expressed by a recombinant virus (20).

### Revaccination

According to available data on the persistence of neutralizing antibody following vaccination, persons working with vaccinia, recombinant vaccinia viruses, or other nonvariola orthopoxviruses should be revaccinated every 10 years.

## SIDE EFFECTS AND ADVERSE REACTIONS

### Vaccine recipients

A papule develops at the site of vaccination 2-5 days after percutaneous administration of vaccinia vaccine to a non-immune person (i.e., primary vaccination). The papule becomes vesicular, then pustular, and reaches its maximum size in 8-10 days. The pustule dries and forms a scab, which separates within 14-21 days after vaccination, leaving a typical scar. Primary vaccination can produce swelling and tenderness of regional lymph nodes, beginning 3-10 days after vaccination and persisting for 2-4 weeks after the skin lesion has healed. Maximum viral shedding occurs 4-14 days following vaccination, but vaccinia can be recovered from the site of vaccination until the scab separates from the skin (30,31).

A fever is common after the vaccinia vaccination is administered. Up to 70% of children have 1 or more days of temperature of greater than or equal to 100 F from 4 to 14 days after primary vaccination (9), and 15%-20% have temperatures of greater than or equal to 102 F. After revaccination, 35% of children develop temperatures of greater than or equal to 100 F, and 5% have temperatures of greater than or equal to 102 F (13). Fever is less common in adults than children after vaccination or revaccination (31; CDC, unpublished data).

Erythematous or urticarial rashes may occur approximately 10 days after primary vaccination. The vaccinee is usually afebrile, and the rash resolves spontaneously within 2 to 4 days. Rarely bullous erythema multiforme (Stevens-Johnson syndrome) occurs (32).

Inadvertent inoculation at other sites is the most frequent complication of vaccinia vaccination, accounting for about half of all complications of primary vaccination and revaccination ([Table 1](#)). Inadvertent inoculation usually results from auto-inoculation of vaccine virus transferred from the site of vaccination. The most common sites involved are the face, eyelid, nose, mouth, genitalia, and rectum. Most lesions heal without specific therapy, but vaccinia immune globulin (VIG) may be useful for cases of ocular implantation (see Treatment of Complications of Vaccinia Vaccine).

Generalized vaccinia among persons without underlying illnesses is characterized by a vesicular rash of varying extent. The rash is generally self limited and requires little or no therapy except among patients whose conditions appear to be toxic or who have serious underlying illnesses.

More severe complications of vaccinia vaccination include eczema vaccinatum, progressive vaccinia, and postvaccinial encephalitis. These complications occur at least 10 times more often among primary vaccinees than among revaccinees and more frequently among infants than among older children and adults (33-35) ([Table 1](#)).

Eczema vaccinatum is a localized or systemic dissemination of vaccinia virus among persons who have eczema or a history of eczema and other chronic or exfoliative skin conditions (e.g., atopic dermatitis). The illness is usually mild and self limited, but may be severe and occasionally fatal. The most serious cases among vaccine recipients occur among primary vaccinees and appear to be independent of the activity of the underlying eczema (36). Severe cases have also been observed after contact infection (see Contacts of vaccinees).

Progressive vaccinia (vaccinia necrosum) is a severe, potentially fatal illness characterized by progressive necrosis in the area of vaccination, often with metastatic lesions. It occurs almost exclusively among persons with cellular immunodeficiency.

The most serious complication is postvaccinial encephalitis. Most frequently it affects primary vaccinees

Death is rare after vaccinia vaccination, with approximately 1 to 2 deaths per million primary vaccinations and 0.1 death per million revaccinations. Death is most often the result of postvaccinial encephalitis or progressive vaccinia.

#### Contacts of vaccinees

Transmission of vaccinia may occur when a recently vaccinated person has contact with a susceptible person. In the CDC 10-state survey of complications of smallpox vaccination, the risk of transmission to contacts was 27 infections per million total vaccinations; 44% of these contact cases occurred among children less than or equal to 5 years of age (33). Since 1980, several occurrences of contact transmission of vaccinia from recently vaccinated military recruits have been reported, including six cases transmitted by a single vaccine recipient (37-39).

Over 60% of contact transmission results in uncomplicated inadvertent inoculation. Approximately 30% of contact transmission results in eczema vaccinatum, which may be fatal (33). Eczema vaccinatum may be more severe among contacts than among vaccinated persons, possibly because of simultaneous multiple inoculations at several sites (34,40). Contact transmission rarely results in postvaccinial encephalitis or vaccinia necrosum.

## PRECAUTIONS AND CONTRAINDICATIONS

Before administering vaccinia vaccine, the physician should take a careful history to document the absence of contraindications to vaccination among both vaccinees and household contacts of vaccinees. Special efforts should be made to identify vaccinees and household contacts who have eczema, a history of eczema, or immunodeficiencies. Vaccinia vaccine should not be administered if these conditions are present among either recipients or household contacts.

### History or presence of eczema

Because of the increased risk of eczema vaccinatum, vaccinia vaccine should not be administered to persons with eczema or a past history of eczema or to those whose household contacts have eczema. Persons with other acute, chronic, or exfoliative skin conditions (e.g., atopic dermatitis, burns, impetigo, or varicella zoster) may also be at higher risk of eczema vaccinatum and should not be vaccinated until the condition resolves.

### Pregnancy

Vaccinia vaccine should not be administered to pregnant women. On rare occasions, almost always after primary vaccination, vaccinia virus has been reported to cause fetal infection (41). Fewer than 50 cases of fetal vaccinia are known, but cases have been observed as recently as 1978 (35,42). Fetal vaccinia usually results in stillbirth or death of the infant shortly after delivery. Vaccinia vaccine is not known to cause congenital malformations.

### Altered immunocompetence

Replication of vaccinia virus can be enhanced among persons with immune deficiency diseases and among those with immunosuppression (as occurs with leukemia, lymphoma, generalized malignancy, agammaglobulinemia, or therapy with alkylating agents, antimetabolites, radiation, or large doses of corticosteroids). Persons with such conditions or therapies or whose household contacts have such conditions should not be administered vaccinia vaccine.

### Infection with human immunodeficiency virus (HIV)

The risk of severe complications after vaccinia vaccination for persons infected with HIV is not known. At least one case of severe generalized vaccinia has been reported in an asymptomatic HIV-infected military recruit after the administration of multiple vaccines, including vaccinia (43). In addition, a recent report suggests that two HIV-infected persons may have died of a progressive vaccinia-like illness after treatment with inactivated autologous lymphocytes infected with a recombinant HIV-vaccinia virus (44). However, at present there is no evidence that smallpox vaccination accelerates the

progression of HIV-related disease. Nevertheless, until additional information becomes available, it is prudent not to vaccinate persons who have HIV infection.

### Allergies

Vaccinia vaccine contains trace amounts of polymyxin B sulfate, streptomycin sulfate, chlortetracycline hydrochloride, and neomycin sulfate. Persons who experience anaphylactic reactions (hives, swelling of the mouth and throat, difficulty breathing, hypotension, and shock) to any of these antibiotics should not be vaccinated. Vaccinia vaccine does not contain penicillin.

### PREVENTION OF CONTACT TRANSMISSION OF VACCINIA

Vaccinia virus may be cultured from the site of primary vaccination beginning at the time of development of a papule (2-5 days after vaccination) until the scab separates from the skin lesion (14-21 days after vaccination). During this time, care must be taken to prevent spread of the virus to another area of the body or to another person. The vaccination site should be covered at all times with a porous bandage until the scab has separated and the underlying skin has healed. An occlusive bandage should not be used. The vaccination site should be kept dry. When the vaccinee bathes, the site should be covered with an impermeable bandage.

Vaccinated health-care workers may continue to have contact with patients, including those with immunodeficiencies, as long as the vaccination site is covered and good hand-washing technique is maintained.

Semipermeable polyurethane dressings (e.g., Opsite (R)) are effective barriers to vaccinia and recombinant vaccinia viruses (21). However, exudate may accumulate beneath the dressing, and care must be taken to prevent viral contamination when the dressing is removed. In addition, accumulation of fluid beneath the dressing may increase the maceration of the vaccination site. Accumulation of exudate may be decreased by first covering the vaccination with dry gauze, then applying the dressing over the gauze. To date, experience with this type of containment dressing has been limited to research protocols, and further investigation is needed before it can be recommended for all vaccinia vaccine recipients.

The most important measure to prevent inadvertent implantation and contact transmission from vaccinia vaccination is thorough hand washing after changing the bandage or after any other contact with the vaccination site.

### TREATMENT OF COMPLICATIONS OF VACCINIA VACCINE

The only product currently available for the treatment of complications of vaccinia vaccination is vaccinia immune globulin (VIG). VIG is an isotonic sterile solution of the immunoglobulin fraction of plasma from persons vaccinated with vaccinia vaccine. It is effective for the treatment of eczema vaccinatum and some cases of progressive vaccinia

and may be useful in the treatment of ocular vaccinia resulting from inadvertent implantation. VIG is also recommended for severe generalized vaccinia if the patient has a toxic condition or a serious underlying disease. VIG is of no benefit in the treatment of postvaccinial encephalitis.

The recommended dosage for treatment of complications is 0.6 mL/kg of body weight. VIG must be administered intramuscularly and should be administered as early as possible after the onset of symptoms. Because therapeutic doses of VIG may be large (e.g., 42 mL for a person weighing 70 kg), the product should be given in divided doses over a 24- to 36-hour period. Doses may be repeated, usually at intervals of 2-3 days, until recovery begins (e.g., no new lesions appear).

CDC is the only source of VIG for civilians.

#### MISUSE OF VACCINIA VACCINE

Vaccinia vaccine should never be used therapeutically for any reason. There is no evidence that it has any value in the treatment or prevention of recurrent herpes simplex infection, warts, or any disease other than those caused by human orthopoxviruses (45). Misuse of vaccinia vaccine to treat herpes infections has been associated with severe complications (46-47).

#### VACCINIA VACCINE AVAILABILITY

CDC is the only source of vaccinia vaccine and VIG for civilians. CDC will provide vaccinia vaccine to protect laboratory and other health-care personnel whose occupations place them at risk of exposure to vaccinia and other closely related orthopoxviruses, including vaccinia recombinants. The vaccine should be administered under the supervision of a physician selected by the institution. Vaccine will be shipped to the responsible physician. Requests for vaccine and VIG, including the reason for the request, should be referred to:

Drug Service National Center for Infectious Diseases Building 1, Room 1259, Mailstop D09 Centers for Disease Control Atlanta, Georgia 30333 Telephone: (404) 639-3670 Facsimile: (404) 639-3296

#### CONSULTATION FOR COMPLICATIONS OF VACCINIA VACCINATION

CDC can assist physicians in the diagnosis and management of patients with suspected complications of vaccinia vaccination. VIG is available when indicated. Physicians should telephone (404) 639-1870 during the day and (404) 639-3311 during evenings and weekends.

Health-care workers are requested to report complications of vaccinia vaccination to the Vaccine Adverse Event Reporting System (800-822-7967) or to their state or local health department.

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Official name: smallpox vaccine, dried. Produced as Dryvax (R) by Wyeth Laboratories, Inc., and available only from CDC.

### Table\_1

**Note:** To print large tables and graphs users may have to change their printer settings to landscape and use a small font size.

TABLE 1. Rates \* of reported complications + associated with vaccinia vaccinations &   
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Age and status Total **	Inadvertent @ inoculation	Generalized vaccinia	Eczema vaccinatum	Progressive vaccinia	Postvaccinial encephalitis
-----					
Primary vaccination					
=20 yrs	606.1	212.1	30.3	-- ++	-- ++
1515.2					
Overall rates &&	529.2	241.5	38.5	1.5	12.3
1253.8					
Revaccination					
=20 yrs	25.0	9.1	4.5	6.8	4.5
113.6					
Overall rates &&	42.1	9.0	3.0	3.0	2.0
108.2					
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\* Cases per million vaccinations.  
 + See text for descriptions of complications.  
 & Adapted from Lane, et al. (33).  
 @ Referenced as Accidental Inoculation.  
 \*\* Rates of overall complications by age group include complications not shown in this table, including severe local reactions and bacterial superinfection of the vaccination site.  
 ++ No instances of this complication were identified during the 1968 survey of 10 states.  
 && Overall rates for each complication include persons of unknown age.

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