Vaccinia – Adverse Reactions
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Vaccinia
(Adverse Reactions)

Overview[1,2,3]

For a more complete description of vaccinia, adverse reactions refer to the following texts:

- Centers for Disease Control and Prevention. Smallpox Vaccination and Adverse Reactions, Guidance for Clinicians, MMWR Vol 52 / RR 4 February 21, 2003. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm (4/05)
- Epidemiology and Prevention of Vaccine-Preventable Diseases 2004 ("The Pink Book"), Centers for Disease Control and Prevention (CDC). http://www.cdc.gov/nip/publications/pink/def_pink_full.htm (4/05)
- Fulginiti FA, et al. Smallpox vaccination: a review, part 2 - adverse events. *Clinical Infectious Diseases* 2003; 37:251-71. http://www.journals.uchicago.edu/CID/journal/issues/v37n2/30999/30999.html (4/05)

For detailed information on normal reactions (including normal variants) following smallpox vaccination, see http://www.bt.cdc.gov/training/smallpoxvaccine/reactions/normal.html(4/05).

See also the Missouri Department of Health and Senior Services (DHSS) Smallpox Vaccination website: http://www.dhss.mo.gov/BT_Response/Med/m_smallpox_vacc.htm (4/05), and particularly the links contained in the "Adverse Reactions & Management" section.

The smallpox vaccine currently available in the United States is a live-virus preparation of infectious vaccinia virus prepared from calf lymph. Smallpox vaccine does not contain smallpox (variola) virus or cowpox virus. Vaccinia is in the same family as cowpox and variola, but is genetically distinct from both, and its exact origin is uncertain.

Epidemiologic studies demonstrated that a high level of protection (95%) against smallpox persists from 3 to 5 years after primary vaccination and substantial but waning immunity for ten years or more. Smallpox vaccine also provides protection if administered after an exposure to variola. The lowest secondary attack rates occurred in persons vaccinated less than 7 days after exposure. (NOTE: The optimal time for use of vaccination as a control measure for contacts is within 3 days of exposure. The Centers for Disease Control and Prevention [CDC] has stated that vaccination within 3 days of exposure will prevent or significantly lessen the severity of smallpox symptoms in the vast majority of people, and vaccination 4 to 7 days after exposure likely offers some protection from disease or may modify the severity of disease.).

Smallpox vaccine contains live vaccinia virus, which replicates at the site of vaccination. In addition to a lesion at the site of vaccination, vaccination can produce swelling and tenderness of axillary and other lymph nodes, beginning 3 - 10 days after vaccination and

persisting for 2 - 4 weeks after the skin lesion has healed. Fever is less common among adults, than in children after vaccination or revaccination. Vaccinia virus is present at the site of vaccination beginning at the time of development of a papule (2 to 5 days after vaccination) and until the scab separates from the skin lesion. Maximum viral shedding from the vaccination site occurs 4 - 14 days after vaccination.

Following primary smallpox vaccination, the following normal reactions are expected to occur: day 0 vaccination; day 3-5 - papule; day 6-7 vesicle with surrounding erythema, vesicle with depressed center; day 8-11 well-formed pustule; day 12+ pustule crusts over, scab; day 17-21 scab detaches, leaving a permanent scar at the site. (With revaccination, the lesion can progress faster than after primary vaccination.) Response to vaccination is evaluated on postvaccination day 6, 7, or 8.

Along with the expected reactions summarized in the previous paragraph, certain systemic signs/symptoms are normally expected to occur. They usually appear between 8 -10 days after vaccination when the vaccine site reaction reaches the peak of the inflammatory response. These normally expected reactions (not all of which will necessarily occur in an individual vaccinee) could include:

- Soreness and/or itching at the vaccination site
- Intense erythema ringing the vaccination site
- Malaise or fatigue
- Lymphadenopathy (local)
- Myalgia, headache, chills, nausea, fatigue
- Fever

In addition, certain variations of normal reactions may occasionally be seen (note that these are not considered adverse events). These normal variants can include:

- Local satellite lesions
- Lymphangitis
- Local edema (swelling)
- Robust take (intense inflammation surrounding the primary vaccination site lesion)

Serious complications from smallpox vaccination are rare, but occur greater than 10 times more often among primary vaccinees than among revaccinees and are more frequent among infants than among older children and adults. CDC has stated that there are some more minor complications that are not as rare (e.g. *about 1 out of 10 vaccinees have a fever >100^0 F and about 1 out of 10-20 vaccinees feel sick enough to miss work*).

- In the past, about 1,000 people for every 1 million primary vaccinees experienced reactions that, while not life-threatening, were serious.
- In the past, between 14 and 52 people out of every 1 million primary vaccinees experienced potentially life-threatening reactions to the vaccine.
- Based on past experience, CDC has estimated that 1 or 2 people in 1 million who receive the vaccine may die as a result.

In certain groups of people, complications following smallpox vaccination can be severe, see CDC web document: People Who Should Not Get the Smallpox Vaccine (Unless They Are Exposed to Smallpox), http://www.bt.cdc.gov/agent/smallpox/vaccination/contraindications-public.asp (4/05). People most likely to have adverse reactions are those who have ever been diagnosed with skin conditions (especially eczema or atopic dermatitis) and those with weakened immune systems (e.g., persons who have received a transplant, are HIV positive, are receiving treatment for cancer, or are receiving medications that suppress their immune system). These individuals should not receive smallpox vaccine unless they have been exposed to smallpox. Other persons who should not be vaccinated (in the absence of exposure to smallpox) include those who have been told by a doctor that they have a heart condition, as well as those with certain cardiac risk factors, and pregnant and breast-feeding women. In addition, smallpox vaccine is not routinely recommended for anyone under 18 years of age or for older people.

Mild Adverse Reactions

Accidental Administration: Vaccine is accidentally ingested or inadvertently injected by the intramuscular or subcutaneous route.

Inadvertent Inoculation / (or Accidental Implantation): This has been the most frequent complication of smallpox vaccination. It can occur by autoinoculation, where vaccinia vaccine or pustular material containing vaccinia is inadvertently transferred to another part of the body of the person receiving the vaccination. Accidental implantation also results from the inadvertent transfer of vaccinia vaccine or pustular material to a close contact of the vaccinee (resulting in what was previously known as **Contact Vaccinia**). *The resulting illness can range from mild to severe.* If the eye is infected, serious sequelae are possible (see Vaccinia Keratitis, below).

Bacterial Infections / (Pyogenic infections of the vaccination site): This is uncommon in adults; onset is generally 5 days post vaccination. The most common organisms are *Staphylococcus aureus* and Group A Beta Hemolytic Streptococci. Anaerobic organisms occasionally infect the site. Impetiginous vesiculo-pustular lesions are seen in staphylococcal infection and piled-up eschar formation is common in streptococcal infections. Mixed infections may be encountered. No topical medications should be applied.

Erythema Multiforme: Toxic and/or hypersensitivity rashes that occur 1 - 2 weeks after vaccination. The rash varies from erythematous macular lesions, to vesicles, urticaria, pustules and typical bulls-eye lesions, all under the rubric"erythema multiforme". The benign lesions do not progress. Itching may accompany the rash. The most serious reaction, Stevens-Johnson Syndrome (SJS) is rare. Diagnosis is by typical rash seen in temporal association with primary vaccination. The vesicles and pustules do not progress into typical vaccinations and can be distinguished on this basis.

Generalized Vaccinia: Within 6 – 9 days, lesions appear on any part of the body (most often on the trunk and abdomen, less commonly on the face, limbs, palms and soles). Lesions contain vaccinia and undergo rapid evolution to scarring and are usually self-limited. Rarely, lesions may recur at 4-6 week intervals for as long as one year. Differentiate from erythema

multiforme, eczema vaccinatum, progressive vaccinia, severe chickenpox, and smallpox.
Robust take: Here there is intense inflammation surrounding the vaccination lesion. The reaction is greater than 7.5cm with swelling, warmth and pain at the vaccination site, non-progressive with improvement in 24 – 72 hours. Differentiate from bacterial infections / (pyogenic infections) of the vaccination site.
Tape adhesive reactions: Sharply demarcated raised lines of erythema that correspond to adhesive tape placement.

Severe Adverse Reactions

Congenital Vaccinia / (Fetal Vaccinia): The third trimester of pregnancy appears to be a critical time for the risk to the fetus of congenital vaccinia, although there have been cases in all trimesters of pregnancy. The affected infant is often premature. The lesions in the newborn infant may be typical of generalized vaccinia or may be progressive in nature. Lesions are often confluent and extensive. Death almost always occurs before birth or shortly thereafter.
Eczema Vaccinatum: Can occur following vaccination of individuals with a history of eczema or atopic dermatitis, or following transfer of vaccinia virus to such individuals by contact with a vaccinee whose lesion is in the florid stage (i.e., by inadvertent inoculation). Because most individuals have large contiguous patches of eczematous skin in the affected areas, confluent lesions are the rule (on the face and limbs primarily). High fever with risk for secondary bacterial or fungal infections is also seen. A high mortality rate is common.
Postvaccinial Encephalitis: Onset of headache, vomiting, drowsiness, and fever 10 - 14 days after vaccination. Confusion, ataxia, paralysis, seizures, or coma may be present.
Progressive Vaccinia: Progressive vaccinia is a rare complication occurring primarily in T-cell deficient persons. These include congenital T-cell deficient children, and individuals with diseases (e.g., cancer, HIV/AIDS) or receiving treatments (e.g., immunosuppressive therapy) that result in T-cell deficiencies. The primary vaccination site fails to heal and may expand with painless progressive central necrosis at the site. Viremia may spread the vaccinia to other parts of the body; each new lesion spreads without inflammatory response. Complications include septic shock, disseminated intravascular coagulation, and superimposed microbial infections.
Vaccinia Keratitis / (Ocular Vaccinia): Inadvertent periocular or ocular inoculation with vaccinia virus following manipulation of the vaccination site. Keratitis results initially in viral replication with ulceration and ultimately in an antigen-antibody interaction leading to corneal cloudiness. Conjunctivitis and blepharitis can also occur.

Case Definition [3]

Clinical description
See Centers for Disease Control and Prevention. Smallpox Vaccination and Adverse Reactions, Guidance for Clinicians, MMWR Vol 52 / RR 4 February 21, 2003.

Laboratory criteria:
Viral cultures are needed for suspected vaccinia, adverse reactions. **Although for some adverse reactions, such as erythema multiforme, such cultures will not provide positive information because no virus will be present in the lesions, and thus cultures may not be indicated as part of the diagnostic assessment.** The State Public Health Laboratory (SPHL) can perform this test. Additional virologic studies may be required to rule out other viral infections with rash, especially chickenpox, herpes simplex, adenovirus, and enterovirus as well as smallpox. The State Public Health Laboratory can perform most of these tests. ***At this time only CDC can perform testing for smallpox***.

Information Needed for Investigation

Verify the diagnosis / Determine the source of infection to prevent other cases. Has the individual, or a close contact, recently received a smallpox vaccination? What laboratory tests were conducted and what were the results?
Establish the extent of illness. Does the case know anyone with similar symptoms? Does the case or a member of the case's household attend school, a childcare center or nursery school? Does the case or a member of the case's household work as a healthcare provider?
Vaccination History. Obtain date(s) of smallpox and varicella vaccination(s). What clinic(s) gave the vaccination(s)? What is the patient's smallpox vaccination number (PVN)? Determine if vaccinee or contact(s) of vaccinee is pregnant. If so, notify the Department of Health and Senior Services immediately at **(800-392-0272)**.

Notification and Control Measures:

- **Contact the Senior Epidemiology Specialist for the Region** if a vaccinia adverse reaction is identified or suspected. If possible (and appropriate), obtain written consent (form attached) for digital photographs to be taken of the adverse reaction. The digital photographs should be submitted with the Vaccine Adverse Event Reporting System (VAERS) form to DHSS.
- Contact the Bureau of Child Care (573-751-2450) if cases are associated with a childcare facility.
- Contact the Section for Long-term Care Regulation (573-526-0721) if cases are associated with a long-term care facility.
- Contact the Bureau of Health Facility Regulation (573-751- 6303) if cases are associated with a hospital or hospital-based long-term care facility.

Control Measures

General:

- The most important measure to prevent "Inadvertent Inoculation" from occurring is thorough handwashing with soap and water after changing the bandage or after any other contact with the vaccination site, site drainage and/or scab.
- Children who have acquired vaccinia through "Inadvertent Inoculation**"** should be excluded from school or daycare until the lesions are healed.
- Health care workers with adverse reaction should not care for patients until the adverse reaction has resolved. Unless, for example, the vaccinated health care worker develops a tape adhesive reaction, or a robust take, and the area(s) can still be sufficiently covered with an appropriate dressing.
- Isolation procedures are standard and contact precautions for individuals with adverse events requiring hospitalization. **The smallpox vaccine does not cause smallpox.**

Laboratory Procedure

Specimens: The top of the vesicle or pustule and the base of the vesicle or pustule can be tested for adenovirus, herpes simplex virus, enterovirus, varicella zoster, and vaccinia. Specimen collection and shipping containers are located in the Regional Offices, or may be obtained from the SPHL at (573) 751-0633.

In most instances, differentiation of an adverse event after vaccination from other infectious or non-infectious diseases must be accomplished. In such cases, the appropriate diagnostic tests for the alternative diseases, such as chickenpox, should be employed simultaneously with tests for vaccinia virus.

Bacterial testing of the site may be needed to differentiate between Bacterial Infections / (Pyogenic Infections of vaccination site) and Robust Take.

Reporting Requirements

Vaccinia adverse reactions are a Category I disease and shall be reported to the local health authority or to the Missouri Department of Health and Senior Services (DHSS) within 24 hours of first knowledge or suspicion by telephone, facsimile or other rapid communication. **DHSS may be contacted 24 hours a day, 7 days a week at (800) 392-0272.**

1. For all cases, complete a "Disease Case Report" (CD-1), VAERS form, and Smallpox Vaccine Adverse Event Follow-Up Form (Annex 4).
2. Entry of the complete CD-1 into the MOHSIS database negates the need for the paper CD-1 to be forwarded to the Regional Health Office.
3. Send the completed secondary investigation form(s) to the Regional Health Office.
4. All outbreaks or "suspected" outbreaks must be reported as soon as possible (by phone, fax or e-mail) to the Regional Communicable Disease Coordinator. This can be accomplished by completing the Missouri Outbreak Surveillance Report (CD-51).

5. Within 90 days from the conclusion of an outbreak, submit the final outbreak report to the Regional Communicable Disease Coordinator.

References

1. USAMRIID, *Medical Management of Biological Casualties Handbook* (5th ed.), August 2004. http://www.usamriid.army.mil/education/bluebook.htm (4/05)
2. Center for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. "Smallpox", Atkinson W, Hamborsky J, Wolfe S, eds. 8th ed. Washington DC: Public Health Foundation, 2004: 257 – 279. www.cdc.gov/nip/publications/pink/smallpox.pdf (4/05)
3. Centers for Disease Control and Prevention. Smallpox Vaccination and Adverse Reactions, Guidance for Clinicians, *MMWR* Vol 52 / RR 4 February 21, 2003. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm (4/05)

Web Sites

1. DHSS. Smallpox Vaccination Website http://www.dhss.mo.gov/BT_Response/Med/m_smallpox_vacc.htm (4/05)
2. CDC's Smallpox Vaccination and Adverse Events Training Module http://www.bt.cdc.gov/training/smallpoxvaccine/reactions/sitemap.htm (4/05)
3. USAMRIID's Medical Management of Biological Casualties Handbook http://www.usamriid.army.mil/education/bluebook.htm (4/05)
4. Centers for Disease Control and Prevention Smallpox Website http://www.bt.cdc.gov/agent/smallpox/index.asp (4/05)
5. Center for Infectious Disease Research & Policy. Smallpox Website http://www1.umn.edu/cidrap/content/bt/smallpox (4/05)
6. Department of Health and Human Services Smallpox Website http://www.hhs.gov/smallpox (4/05)
7. Centers for Disease Control and Prevention. Smallpox Vaccination and Adverse Reactions, Guidance for Clinicians, *MMWR* Vol 52 / RR 4 February 21, 2003. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm(4/05)
8. Vaccine Adverse-Events Reporting (Annex 4) http://www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-4.pdf (4/05)

TABLE 2. Summary of vaccinia-related adverse events*

Adverse event	Description	Risk factor or predisposition	Treatment
Eczema vaccinatum (EV)	• High fever • Generalized lymphadenopathy with extensive vesicular and pustular eruption • Onset: concurrently or shortly after local vaccinial lesion in vaccinee, or in contacts, 5–19 days after suspected exposure • Risk for secondary bacterial or fungal infections • Virus recovered from lesions • High morality rate with poor prognosis	• History of eczema or atopic dermatitis irrespective of disease activity or severity • Less frequently, persons without a history of dermatological conditions	• Prompt evaluation and diagnosis • Infection-control precautions • Might require multiple doses of vaccinia immune globulin (VIG) (cidofovir, second-line therapy) • Hemodynamic support • Volume and electrolyte repletion • Observe for secondary skin infections
Progressive vaccinia (PV)	• Nonhealing vaccination site • Painless progressive (central) necrosis at the vaccination site • Occasional metastatic lesions in skin, bones, and viscera • No inflammation initially • Absence of inflammatory cells on histopathological examination • Inflammation weeks later • Bacterial infection might develop • Differential diagnosis: severe bacterial infection, severe chickenpox, disseminated herpes simplex, and other necrotic conditions • Prognosis: poor, despite therapy	• Humoral and cellular immunocompromise (e.g., malignancy, human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), severe combined immunodeficiency syndrome (SCIDS), or hypogammaglobulinemia) • Protective level of T-cell count or humoral immunity unknown	• Prompt evaluation and diagnosis • Infection-control precautions • Might require multiple doses of VIG (cidofovir second-line therapy) • Surgical debridement of progressive necrotic lesions not proven useful
Postvaccinial encephalitis (PVE) or encephalomyelitis (PVEM)	• Diagnosis of exclusion • Appears similar to postinfectious encephalomyelitis or toxic encephalopathy caused by other agents • Abrupt onset of symptoms: fever, headache, malaise, lethargy, vomiting, meningeal signs, seizures, paralysis, drowsiness, altered mental status, or coma • Age <2 years (encephalopathy): cerebral vascular changes occurring 6–10 days postvaccination • Age ≥2 years (encephalomyelitis): demyelinating changes occurring 11–15 days postvaccination • Cerebral spinal fluid (CSF): normal or nonspecific; monocytosis, lymphocytosis, or elevated protein • Prognosis: mortality, 25%; neurological sequelae, 25%; complete recovery, 50%	• Age <1 year	• Intensive supportive care • Anticonvulsants as needed • VIG not recommended • Antiviral role unclear • Use of modern imaging studies has not been evaluated
Fetal vaccinia (FV)	• Incidence: rare (<50 reported cases) • Route of transmission: unknown • Outcomes: premature birth, fetal loss, high mortality • Not associated with congenital anomalies	• Cases in all trimesters of pregnancy • Greatest risk, third trimester	• Efficacy of VIG unknown • Antivirals not recommended
Generalized vaccinia (GV)	• Maculopapular or vesicular rash • Onset: 6–9 days postvaccination • Nontoxic, with or without fever • Differential diagnosis: erythema multiforme (EM), varicella, inadvertent inoculation, progressive vaccinia (PV), and smallpox	• Hematogenous spread • Lesions contain vaccinia • More serious among immunocompromised persons	• Usually self-limited in immunocompetent person • Infection-control precautions • VIG usually not indicated • Anti-inflammatory medications • Antipruritic medications • Antivirals usually not indicated

* See text for details.

TABLE 2. (*Continued*) Summary of vaccinia-related adverse events*

Adverse event	Description	Risk factor or predisposition	Treatment
Inadvertent inoculation	• Most common complication • Physical transfer of vaccinia virus from a vaccination site to second site on the vaccinee or to a close contact of vaccinee	• Manipulation of vaccination site • Children aged <4 years • Conditions that disrupt the epidermis (e.g., burns, severe acne, or psoriasis)	• Usually self-limited • Resolution in 3 weeks • Infection-control precautions • VIG if extensive body surface involved or severe ocular disease (cidofovir, second-line therapy)
Ocular vaccinia Inadvertent periocular or ocular implantation with vaccinia virus Can range from mild to severe	Keratitis • Marginal infiltration or ulceration with or without stromal haze/infiltration Conjunctivitis • Hyperemia, edema, membranes, focal lesions, fever, lymphadenopathy Blepharitis • Lid pustules on or near the lid margin, edema, hyperemia, lymphadenopathy, cellulitis, fever	• Manipulation of vaccination site, followed by eye rubbing • More likely with conditions that cause eye itching and scratching (conjunctivitis, corneal abrasion/ulceration)	• Ophthalmologic consultation • Certain ophthalmologists consider off-label topical antiviral medications • Topical prophylactic antibacterial medications for keratitis • VIG for severe blepharitis and blepharoconjunctivitis (without keratitis) • VIG not indicated for isolated keratitis • VIG considered for keratitis with vision-threatening conditions • VIG indicated for keratitis with life-threatening conditions that require VIG
Erythema multiforme (EM) and Stevens-Johnson Syndrome (SJS)	• Typical bull's eye (target) lesions • Hypersensitivity reaction • Pruritis • Onset: 10 days postvaccination • Can progress to SJS	• No known risk factors	• Antipruritic medications • VIG not indicated • Hospitalization and supportive care for SJS • Steroid use for SJS is controversial
Pyogenic infections of vaccination site	• Uncommon • Onset: 5 days postvaccination • Fever not specific for bacterial infection • Fluctuance at vaccination site	• More frequent in children (touching vaccination site)	• Gram stain • Bacterial culture • Antibacterial medications, if clinically indicated • No topical medications
Robust take (RT)	• >7.5 cm with swelling, warmth, and pain at vaccination site • Fluctuant lymph nodes not expected • Peak symptoms: 8–10 days postvaccination • Nonprogressive • Improvement in 24–72 hours	• Might be more likely among first-time vaccinees	• Observation most important • Antibacterial medications not indicated • Rest affected limb • Antipruritic medications • Anti-inflammatory medications • No salves or ointments
Tape adhesive reactions	• Sharply demarcated raised lines of erythema that correspond to adhesive placement • Local pruritis • No systemic illness	• Sensitivity to adhesives	• No salves, ointments, or topical/oral steroids • Frequent bandage changes • Periodic bandage removal

* See text for details.

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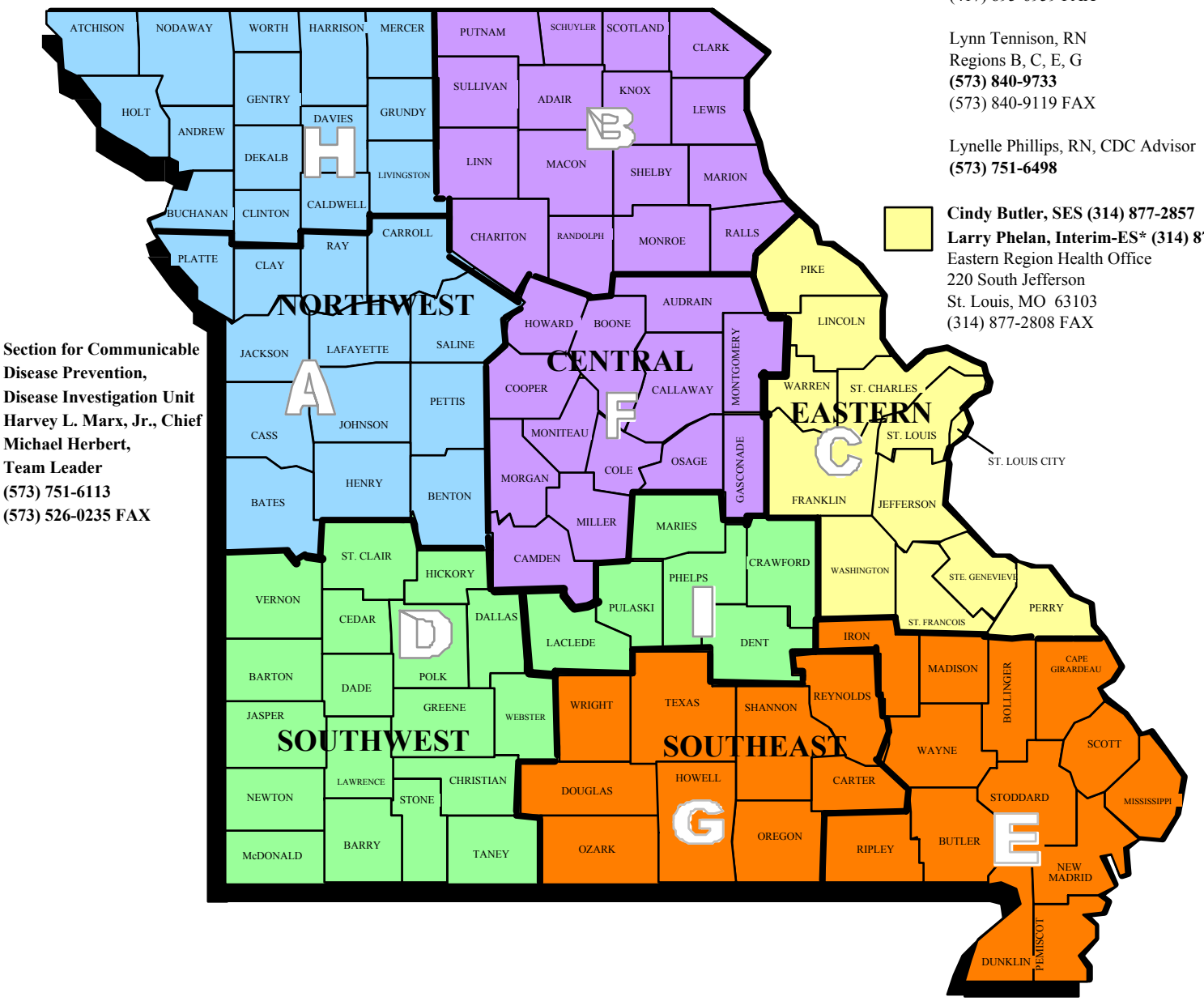

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April, 2005

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RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466
Julia M. Eckstein
Director

I give permission for _____ to be photographed by a representative of the Missouri Department of Health and Senior Services as part of an epidemiological investigation. The photographs will be treated as a medical record and will not be released to anyone without consent, unless otherwise authorized by law.

Signed _____ Date _____

If signed by someone other than person listed above,

Print name _____

And state relationship _____

Witness signature _____ Date _____

I give permission for _____ to be photographed by a representative of the Missouri Department of Health and Senior Services as part of an epidemiological investigation. The photographs will be treated as a medical record and will not be released to anyone without consent, unless otherwise authorized by law.

Signed _____ Date _____

If signed by someone other than person listed above,

Print name _____

And state relationship _____

Witness signature _____ Date _____

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES

DISEASE CASE REPORT

REPORT TO LOCAL PUBLIC HEALTH AGENCY

1 DATE OF REPORT	**2** DATE RECEIVED BY LOCAL HEALTH AGENCY
_____ / _____ / _____	_____ / _____ / _____

3 NAME (LAST, FIRST, M.I.)	**4** GENDER ☐ MALE ☐ FEMALE	**5** DATE OF BIRTH _____ / _____ / _____	**6** AGE	**7** HISPANIC ☐ YES ☐ NO ☐ UNKNOWN

8 RACE (CHECK ALL THAT APPLY) ☐ BLACK ☐ ASIAN ☐ PACIFIC ISLANDER ☐ WHITE ☐ AMERICAN INDIAN ☐ UNKNOWN	**9** PATIENT'S COUNTRY OF ORIGIN	**10** DATE ARRIVED IN USA _____ / _____ / _____

11 ADDRESS (STREET OR RFD, CITY, STATE, ZIP CODE)	**12** COUNTY OF RESIDENCE	**13** TELEPHONE NUMBER ( )

14 PREGNANT ☐ YES (IF YES NUMBER OF WEEKS _____) ☐ NO ☐ UNKNOWN	**15** PARENT OR GUARDIAN	**16** RECENT TRAVEL OUTSIDE OF MISSOURI OR USA ☐ YES ☐ NO IF YES, WHERE _____	**17** DATE OF RETURN _____ / _____ / _____

18 OCCUPATION	**19** SCHOOL/DAY CARE/WORKPLACE ADDRESS (STREET OR RFD, CITY, STATE, ZIP CODE)

20 WORK TELEPHONE NUMBER ( )	**21** OTHER ASSOCIATED CASES ☐ YES ☐ NO ☐ UNKNOWN IS REPORT PART OF AN OUTBREAK ☐ YES ☐ NO ☐ UNKNOWN	**22** TYPE OF COMPLAINT/OUTBREAK ☐ FOODBORNE ☐ WATERBORNE ☐ OTHER (SPECIFY) _____

23 WAS PATIENT HOSPITALIZED ☐ YES ☐ NO ☐ UNKNOWN	**24** PATIENT RESIDE IN NURSING HOME ☐ YES ☐ NO ☐ UNKNOWN	**25** PATIENT DIED OF THIS ILLNESS ☐ YES ☐ NO ☐ UNKNOWN

26 CHECK BELOW IF PATIENT OR MEMBER OF PATIENT'S HOUSEHOLD (HHLD):	PATIENT			HHLD MEMBER		
	YES	NO	UNK	YES	NO	UNK
IS A FOOD HANDLER						
ATTENDS OR WORKS AT A CHILD OR ADULT DAY CARE CENTER						
IS A HEALTH CARE WORKER						

27 NAME OF HOSPITAL/NURSING HOME	
28 HOSPITAL/NURSING HOME ADDRESS (STREET OR RFD, CITY, STATE, ZIP CODE)	
29 REPORTER NAME	**30** TELEPHONE NUMBER ( )

31 REPORTER ADDRESS (STREET OR RFD, CITY, STATE, ZIP CODE)	**32** TYPE OF REPORTER/SUBMITTER ☐ PHYSICIAN ☐ OUTPATIENT CLINIC ☐ PUBLIC HEALTH CLINIC ☐ HOSPITAL ☐ LABORATORY ☐ SCHOOL ☐ OTHER _____

33 ATTENDING PHYSICIAN/CLINIC NAME ADDRESS (STREET OR RFD, CITY, STATE, ZIP CODE)	**34** TELEPHONE NUMBER ( )

35 DISEASE NAME(S)	**36** ONSET DATE(S) _____ / _____ / _____ _____ / _____ / _____	**37** DIAGNOSIS DATE(S) _____ / _____ / _____ _____ / _____ / _____	**38** DISEASE STAGE/ RISK FACTOR	**39** PREVIOUS DISEASE/STAGE	**40** PREVIOUS DISEASE DATE(S) _____ / _____ / _____ _____ / _____ / _____

41 - DIAGNOSTICS

TEST DATE (MO/DAY/YR)	TYPE OF TEST	SPECIMEN TYPE	COLLECTION DATE (MO/DAY/YR)	QUALITATIVE / QUANTITATIVE RESULTS	REFERENCE RANGE	LABORATORY NAME/ADDRESS (INCLUDE STREET OR RFD, CITY, STATE, ZIP CODE)

42 - TREATMENTS

TREATED (Y/N/UNK)	REASON NOT TREATED	TYPE OF TREATMENT	DRUG	DOSAGE	TREATMENT DATE (MO/DAY/YR)	TREATMENT DURATION (IN DAYS)	PREVIOUS TREATMENT	PREVIOUS LOCATION (LIST CITY, STATE)

43 - SYMPTOMS

SYMPTOM (IF APPLICABLE)	SYMPTOM SITE (IF APPLICABLE)	SYMPTOM ONSET DATE (MO/DAY/YR)	SYMPTOM DURATION (IN DAYS)

44 COMMENTS

NOTES FOR ALL RELEVANT SECTIONS:

- Stages, risk factors, diagnostics, treatments, and symptoms shown below are examples. To see a more complete listing, please go to ***http://www.dhss.state.mo.us/Diseases/DDwelcome.htm***. You may also contact the Office of Surveillance at 1-800-392-0272 for additional information or to report a case.
- All dates should be in Mo/Day/Year (01/01/2001) format.
- All complete addresses should include city, state and zip code.
- Required fields referenced below are italicized and bold, however fill form as complete as possible.

(1) Date of Report -- date sent by submitter of document.

(2) Date received will be filled in by receiving agency.

(3-8) **CASE DEMOGRAPHICS/IDENTIFIERS:** ***Last name, First Name,*** Gender, ***Date of Birth,*** Hispanic, Race - please check all that apply

(23) Was patient hospitalized due to this illness?

(32) Type of reporter/submitter (doctor, nursing home, hospital, laboratory) (33-34) Attending physician or clinic (full physician name and degree, address, phone)

DISEASE: ***(35) Disease name or name(s), (36) Onset date(s), (37) Diagnosis Date(s)***

(38) Disease Stage or Risk Factor

Syphilis	**Gonorrhea or Chlamydia**	**TB Infection**
Primary (chancre present)	Asymptomatic	Contact to TB case
Secondary (skin lesions, rash)	Uncomplicated urogenital (urethritis, cervicitis)	Immunocompromised
Early Latent (asymptomatic < 1 year)	Salpingitis (PID)	Abnormal CXR
Late Latent (over 1 year duration)	Ophthalmia/conjunctivitis	Foreigner/Immigrant
Neurosyphilis	Other (arthritis, skin lesions, etc)	IV Drug/Alcohol Abuse
Cardiovascular		Resident, correctional
Congenital		Employee, correctional
Other		Over 70
		Homeless
		Diabetes
		Healthcare worker
		Converter/2 yrs ≥ 10
		Converter/2 yrs ≥ 15

(39) Previous Disease/Stage (if applicable) ***(40) Previous Disease Dates (if applicable)***

(41) Diagnostics (Please Attach Lab Slip)

Test Type

Hepatitis	**TB**	**Other**
Igm Anti-HBc	Not Done	Elisa
Anti-HBs	Mantoux	Western Blot
Anti-HBc Total	Multiple puncture device	Culture
Igm Anti-HAV	X-Ray	ALT
HBsAg	Smear	AST
Hep C	Culture	

Specimen Type (blood, urine, CSF, smear, swab), **Collection Date** (Mo/Day/Yr), **Qualitative** (negative, positive, reactive), **Quantitative Results** (1:1, 2.0 mm reading,) **Reference Range** (1:1neg, 1:64 equivocal, 1:128 positive, > 2 positive), **Laboratory** (name, address)

(42) TREATMENT

Reason not treated	**Drug**
False positive	**TB**
Previous treated	Isoniazid
Age	Ethambutol
	Pyrazinamide
	Rifampin

(43) SYMPTOMS:

Symptom (jaundice, fever, dark urine, headache) **Symptom Site** (head, liver, lungs, skin), **Symptom Onset Date** (Mo/Day/Yr) and **Symptom Duration** (in days)

(44) **Comments:** Attach additional sheets if more comments needed.

WEBSITE: www.vaers.org E-MAIL: info@vaers.org FAX: 1-877-721-0366

VACCINE ADVERSE EVENT REPORTING SYSTEM

24 Hour Toll-Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only

VAERS Number _____

Date Received _____

Patient Name:

Last First M.I.

Address

City State Zip

Telephone no. (____) _____

Vaccine administered by (Name):

Responsible Physician _____

Facility Name/Address

City State Zip

Telephone no. (____) _____

Form completed by (Name):

Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other

Address *(if different from patient or provider)*

City State Zip

Telephone no. (____) _____

1. State	2. County where administered	3. Date of birth mm / dd / yy	4. Patient age	5. Sex ☐ M ☐ F	6. Date form completed mm / dd / yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
- ☐ Patient died (date mm / dd / yy)
- ☐ Life threatening illness
- ☐ Required emergency room/doctor visit
- ☐ Required hospitalization (_____days)
- ☐ Resulted in prolongation of hospitalization
- ☐ Resulted in permanent disability
- ☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

12. Relevant diagnostic tests/laboratory data

10. Date of vaccination mm / dd / yy Time _____ AM PM

11. Adverse event onset mm / dd / yy Time _____ AM PM

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
- ☐ Private doctor's office/hospital
- ☐ Public health clinic/hospital
- ☐ Military clinic/hospital
- ☐ Other/unknown

16. Vaccine purchased with:
- ☐ Private funds
- ☐ Public funds
- ☐ Military funds
- ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously?
- ☐ No
- ☐ To health department
- ☐ To doctor
- ☐ To manufacturer

Only for children 5 and under

22. Birth weight _____ lb. _____ oz.

23. No. of brothers and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/immunization project

24. Mfr./imm. proj. report no.

25. Date received by mfr./imm.proj.

26. 15 day report? ☐ Yes ☐ No

27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

"Fold in thirds, tape & mail — DO NOT STAPLE FORM"

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE

VAERS
P.O. Box 1100
Rockville MD 20849-1100

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.

Item 10 and 11: Give dates and times as specifically as you can remember. If you do not know the exact time, please indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.

Item 13: List ONLY those vaccines given on the day listed in Item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.

Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.

Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.

Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.

Figure 3. VAERS Smallpox Follow-up Form

Smallpox Vaccine VAERS Report Follow-up Worksheet

INSTRUCTIONS: To be used for followup of designated VAERS reports. Please request additional medical records, such as hospital discharge summary as appropriate.

Smallpox Vaccination History

Diagnosis and Therapy

1. Has the patient been vaccinated with smallpox vaccine before 2002? *(Please circle answer)*

Never vaccinated Don't Know Vaccinated
If yes, when? In childhood On entry into the military Laboratory worker

2. Has the patient been vaccinated with smallpox vaccine recently (2002-3)? If so, when?

Vaccination date:____/___/_____ Patient Vaccination Number (PVN):_____

3. Do you have a working diagnosis for this patient? YES NO
If yes, what is it?
_____

4. Was VIG used? YES NO

5. Was cidofovir used? YES NO

6. PATIENT VACCINATED DESPITE CONTRAINDICATION: N/A APPLICABLE (circle one)

Did patient have any of these conditions at the time of vaccination?

____Pregnancy ____Immunosuppression ____Skin Disease ____Inflammatory Eye Disease

Life-threatening allergic reactions to polymyxin, neomycin, streptomycin, tetracycline at previous smallpox vaccination?
YES NO
If patient vaccinated despite contraindications, please
elaborate:_____

CONTACTS: N/A APPLICABLE (circle one):

7. Location of Exposure: ___Home ___Hospital ___Other ___Workplace ___Not known

8. Means of Exposure: ___Known ___Not known
If known, please check:
___Direct to skin
___Needle stick
___Contact with dressing
___Handled objects
___Health care contact within 3 weeks
___Sexual
___Nursing mother
___Other

9. Is the timing and duration of exposure known? YES NO
If yes, complete: Start date:____/___/_____ Start Time:___:___AM/PM End Date:____/___/_____ End Time:___:___AM/PM

10. Contact information of vaccinee to whom patient exposed:

NAME:_____ADDRESS:_____
_____
TELEPHONE NUMBER:_____

Disposition/outcome: _____Recovered_____Recovered with sequelae (specify)_____Recovering (specify)_____
_____Deceased
VAERS ID:_____ E-report #:_____ Date of followup____/___/_____
Reviewer_____