Guide A

Surveillance, Contact Tracing, and Epidemiological Investigation

Guide A – Surveillance, Contact Tracing, and Epidemiological Investigation Guidelines

The State Epidemiologist, Health Officer, or other authorized state official should designate a single person from the state and/or local health department to help coordinate overall case surveillance and epidemiological investigation activities for the state or local public health jurisdiction. This person should work closely with Federal health authorities on all aspects of the epidemiological investigation, surveillance and contact tracing.

Activities and actions described within this section may be altered depending upon the size and characteristics of the outbreak. If this occurs, information regarding the new procedures to follow or actions to take will be communicated to health department personnel by the State Epidemiologist or health officer, and federal health authorities.

Guide A summarizes surveillance and epidemiological investigation activities for use by federal, state and local health departments in preparing for and responding to an outbreak of smallpox. Because smallpox no longer exists as a naturally occurring disease, *an outbreak of smallpox is defined as a single laboratory confirmed case*. Suggested pre-event activities for state and local public health authorities including possible scenarios for smallpox cases presenting to health departments are summarized in Annex 4. These activities include producing an inventory of human and other resources for surveillance-related activities, designating persons/teams for specific surveillance tasks, reviewing/modifying forms, establishing communication protocols and pre-vaccinating a cadre of first responders and essential community health personnel.

This section will cover the following topics:

1. Pre-event rash surveillance
2. Smallpox clinical presentations and differential diagnosis
3. Smallpox case definitions
4. Epidemiological (case and outbreak) investigation
5. Surveillance following an outbreak
6. Contact identification, tracing and surveillance

1. PRE-EVENT RASH SURVEILLANCE

State and local health departments are encouraged to establish enhanced pre-event surveillance for generalized febrile vesicular-pustular rash illness. An algorithm and protocol for evaluating patients with febrile vesicular-pustular rash illness has developed by CDC (Annex 4) in collaboration with the American Academy of Pediatrics (AAP), American Academy of Dermatology, the Infectious Diseases Society of America (IDSA), the Pediatric Infectious Disease Society (PIDS), the Association of State and Territorial Health officers (ASTHO), the American College of Emergency Physicians (ACEP) and the Council of State and Territorial Epidemiologists (CSTE).

2. SMALLPOX CLINICAL CASE DESCRIPTION AND DIFFERENTIAL DIAGNOSIS

Smallpox is characterized by both an enanthem with lesions in the mouth and on the posterior pharynx and an exanthem (rash). Constitutional symptoms prior to onset of rash (exanthem) include fever (100%), which generally occurs about 1-3 days before rash onset, headache (90%), backache (90%), chills (60%), and vomiting (50%). Less common symptoms include pharyngitis and severe abdominal pain. The hallmark of the ordinary (or classic) type of smallpox is a generalized vesiculopustular rash with lesions found more densely on the face and extremities (centrifugal), including the palms and soles. All lesions on any one part of the body are at a similar stage of development and are approximately the same size. Rash progresses from sparse macules (day 1), to papules (days 2), vesicles (days 3-4), pustules (days 5 to approximately 12), and scabs (days 13-18) for a total duration of 2-3 weeks.

Less common presentations of the smallpox rash include flat, or hemorrhagic lesions. A rash that progresses through the stages more rapidly and has fewer lesions characterizes modified smallpox, which occurs more commonly among previously vaccinated persons. Infection via cutaneous inoculation also has a shorter course with appearance of one or several vesicles at the site of inoculation after about 3 days. Asymptomatic cases are very uncommon and their role in transmission is unclear but likely to be minimal.

Because routine childhood vaccination in the United States stopped in 1971, persons currently < 30 years are totally susceptible to smallpox and if exposed, are expected to exhibit classic or atypical presentations. Persons > 30 years may have been vaccinated during childhood or as adolescents or adults for travel or occupational reasons. Vaccination of health care workers and persons traveling overseas continued until the late 1970s and military personnel were vaccinated until 1990. Epidemiological studies have shown that an increased level of protection against smallpox persists for $\leq$ 5 years after primary vaccination and substantial but waning immunity can persist for $\geq$ 10 years. Antibody levels after revaccination can remain high longer, conferring a greater period of immunity than occurs after primary vaccination alone. Although it is assumed that adults > 30 years in the United States have little or no immunity to smallpox, there is evidence that vaccination during infancy results in long term reduction in mortality. Therefore, it is possible that if smallpox virus were introduced into the U.S. population, some vaccinated adults -- especially those who have received 2 or more doses of smallpox vaccine -- may develop modified smallpox following exposure and that mortality would be markedly lower than unvaccinated persons.

The most likely condition to consider in the differential diagnosis of vesiculopustular rash is varicella (see box). Major and minor distinguishing characteristics are listed below:

	Smallpox: clinical features	Varicella: clinical features
Major distinguishing features	Febrile prodrome: temperature >102 and systemic symptoms (prostration, severe headache, backache, abdominal pain, or vomiting) 1-4 days ***before*** rash onset	No or mild prodrome before rash onset
	Lesions are deep, firm, well-circumscribed pustules; may be confluent or umbilicated	Lesions typically superficial vesicles
Other distinguishing features	Rash concentrated on face and distal extremities (centrifugal)	Rash concentrated on trunk and proximal extremities (+/- face, scalp)
	Rash in same stage of evolution on any one part of the body	Rash appears in crops so lesions are in different stages of evolution (papules, vesicles, crusts) on any one part of the body
	First lesions on oral mucosa/palate (enanthem); followed by examthem (rash) on face or forearm	First lesions on trunk (occasionally face)
	Lesions on palms and soles (seen in > 50%)	Lesions very uncommon on palms and soles
	Lesions may itch at scabbing stage	Lesions generally intensely itchy
	Lesions evolve from papule→pustule in days	Lesions generally evolve from macules to papules to vesicles to crusts in <24 hours
	Illness lasts 14 to 21 days	Illness lasts 4-7 days

In herpes zoster, lesions are usually localized to 1 or 2 dermatomes, but can become generalized, especially among immunocompromised persons. The lesions in localized herpes zoster are painful and could likely be differentiated from smallpox based on their appearance. Other diagnoses to including drug eruptions, erythema multiforme, impetigo, disseminated herpes simplex, enteroviral infections associated with a vesicular rash, and others (Annex 4).

3. SMALLPOX CASE DEFINITIONS AND CASE CLASSIFICATION

Preliminary case definitions are included below but may require revision by public health personnel conducting the epidemiological investigation depending upon the specifics of the epidemic.

a. Clinical Case Definition An illness with acute onset of fever ≥101º F followed by a rash characterized by vesicles or firm pustules in the same stage of development without other apparent cause.

b. Laboratory Criteria for Confirmation* (to be conducted in Level C or D laboratories only)

1. Isolation of smallpox (variola) virus from a clinical specimen (Level D laboratory only), or
2. Polymerase chain reaction (PCR) identification of variola DNA in a clinical specimen, or
3. Negative stain electron microscopy (EM) identification of variola virus in a clinical specimen (Level D laboratory or approved Level C laboratory)

*Level D laboratories include the CDC and USAMRIID. Initial confirmation of a smallpox outbreak requires testing in a Level D laboratory. Level C laboratories will assist with testing of clinical specimens following initial confirmation of an outbreak by CDC.

c. Case Classification

- *Confirmed:* A case of smallpox that is laboratory confirmed.
- *Probable:* A case that meets the clinical case definition that is not laboratory confirmed but has an epidemiological link to another confirmed or probable case.
- *Suspected:* A case that meets the clinical case definition but is not laboratory confirmed and does not have an epidemiological link to a confirmed or probable case of smallpox, OR a case that has an atypical presentation that is not laboratory confirmed but has an epidemiological link to a confirmed or probable case of smallpox. Atypical presentations of smallpox include a) hemorrhagic lesions OR b) flat, velvety lesions not appearing as typical vesicles nor progressing to pustules.

d. Definition of Contact: A person who has had contact with a suspected, probable, or confirmed case of smallpox. A contact's risk of contracting smallpox increases with close contact (6 feet or less), increasing length of exposure to a case and the stage and severity of clinical case (increasing with onset of rash and/or cough.) Thus, close contact is defined as any face-to-face contact ($\leq$ 6 feet, able to reach out and touch) with a smallpox case and duration of contact should be quantified, if possible.

The importance of case confirmation using laboratory diagnostic tests differs depending on the epidemiological situation. Laboratory confirmation is important for a first case in a geographic area, leading to release of vaccine as part of a response. In a setting where multiple cases are identified, laboratory capacity may soon be overwhelmed. In such instances, priority for laboratory resources will include 1) testing of clinical or environmental specimens that will provide information about a potential source of exposure, facilitating law enforcement activities and case detection; and 2) testing of clinical specimens from cases with an unclear presentation but who are suspected as cases following expert consultation (see above).

4. POST EVENT RESPONSE - EPIDEMIOLOGICAL INVESTIGATION

Epidemiological investigation

The State Epidemiologist or his/her designee should coordinate the epidemiological investigation in collaboration with federal health authorities. An estimate of the number and kind of personnel necessary for performing these functions should be made and additional assistance requested as needed. The lead state and federal staff will coordinate all aspects of the investigation with other relevant state and federal authorities as relevant including the FBI, police, quarantine officials, and others.

All personnel designated for case interviews must be vaccinated prior to initiating their first face-to-face interview with a suspected, probable or confirmed smallpox case.

Because smallpox no longer occurs as a naturally-acquired infection, the two most likely causes for its initial re-appearance into the human population would be:

- Infection caused by an intentional release of the smallpox virus into the population either via infected person(s) or environmental release of smallpox virus.

- Infection caused by exposure of a non-immune person to smallpox as a result of accidental release or inoculation during approved laboratory research involving the virus or exposure to inadequately sterilized material generated during laboratory research involving the virus. Currently there are only two WHO- approved smallpox virus research and repository laboratories which include the CDC in Atlanta, GA and the Institute of Virus Preparations in Moscow, Russia. Both laboratories have undergone frequent WHO inspections and have stringent safety and security procedures in place.

Once the initial re-introduction of smallpox into the population has occurred, exposure of a non-immune person to an infectious person would be an additional explanation for disease in each individual case. Even one confirmed case of smallpox requires urgent detailed case investigation. The purpose of the case investigations are:

- To establish the diagnosis and case classification;
- To identify contacts for tracing, vaccination and surveillance;
- To impose isolation of confirmed, probable and suspected cases;
- To identify the most likely source of initial exposure for the case;
- To monitor clinical course and outcome of cases; and
- To monitor the epidemiology of the outbreak for analysis and communications purposes.

In order to facilitate case investigation and contact tracing, a detailed case investigation form (Forms 1-4) has been prepared to use in the initial case investigations. Once person-to-person transmission is ongoing and identifying location of exposure to identify a population-at –risk is not needed, shorter case surveillance forms (Forms 5A and 5B) that will record key demographic, clinical and outcome information could be used along with the contact identification module (Form 3).

Much of the epidemiological investigation may be performed in conjunction with identification and evaluation of potential smallpox cases. However, because of the urgency of the outbreak, adequate personnel must be available to collect and analyze data that would allow the rapid:

1. Identification of persons who have had close contact with the smallpox case since date of onset of fever. Since smallpox is a contagious disease, once a case is confirmed, *the highest priorities for public health officials are to reduce risk of ongoing transmission by immediately identifying and vaccinating close contacts of cases and isolating the cases.*

2. Identification of the most likely source of initial exposure (hopefully within 24 hrs of the first confirmation of smallpox). *This may require extensive trace-back capabilities if the initial recognition and confirmation of smallpox occurred later than the first generation of disease in the outbreak.*

3. Identification or estimation of the population at risk. To the extent possible, the population at risk should be identified. Exposure could be due to an infected persons present at a specified location; use of a specified of mode of transportation; or presence at a location of suspected smallpox virus release. These persons should be placed under surveillance; public health action to consider would include offering smallpox vaccine to the exposed population and to their household contacts.

4. Identification of any unexpected epidemiological features of the outbreak (e.g., unusual presentation, morbidity, mortality, incubation period, transmission, affected population)

5. Evaluation of characteristics and extent of the outbreak to develop the most effective containment strategies.

Expected epidemiological features of **smallpox** include:

1. Incubation period 12 days (range 7-17 days)

2. Person-to-person spread by droplet transmission (most common), contact with material from pustules/rash lesions or contaminated clothing or bedding (less common), or small particle aerosol (least common).

3. Although smallpox cases are generally not infectious to others until the onset of rash (approximately 7-17 days after exposure), since exact date of rash onset may not be noted accurately and because of the infectious enanthem which may precede rash onset by 1-2 days, cases should be considered potentially infectious from date of onset of fever.

4. Period of highest transmission is during the first 7-10 days after onset of rash, however, a person is considered infectious until all scabs have separated. Risk of contracting disease increases with length and environment of contact.

5. Persons at greatest risk for disease are household and face-to-face contacts to cases after the onset of rash.

6. During the smallpox era, the seasonal transmission of disease was highest during winter and early spring.

7. Currently, the age distribution of cases would be expected to mimic the age distribution of the population due to virtual non-existent population immunity.

8. An expected case-fatality rate of up to 30%. This proportion may be greater due to: a) lack of natural immunity, b) a high percentage of non-vaccinated persons in the U.S. population, c) waning immunity against smallpox in previously vaccinated persons, and d) a larger immunocompromised population compared to the smallpox era. It may be lower due to: a) better intensive care and medical treatment options than 30 years ago, and b) partial immunity among the adult population.

9. Secondary attack rate among susceptible household contacts is approximately 58% (range 38-88% in 8 studies)

10. In general, secondary spread of the disease from one case to only about 1-10 persons due to the case's severe initial prostration and the prolonged contact required for transmission in most instances.

Epidemiological features of **varicella** that are similar to smallpox include:

1. Incubation period 14 days (range 10-21 days)

2. Person-to-person spread occurs by a) direct contact, droplet or aerosol from vesicular fluid of skin lesions or b) secretions from the respiratory tract.

3. Cases may be infectious several days before rash onset until lesions scab however the period of highest transmission is the first 2-3 days after rash onset. Scabbed lesions are not infectious. Although these transmission features are different from smallpox, they will probably not be helpful in distinguishing between the 2 diseases.

4. The seasonal transmission of disease is highest during winter and early spring though in the United States, in areas where vaccine coverage is high, the spring seasonality is becoming attenuated

Epidemiological features of varicella that should be useful in distinguishing it from smallpox include

1. Most cases occur in children. Only 5% of adults 20-29 years of age are susceptible and only 1% of adults 30-39 years are susceptible. Thus, varicella in adults is uncommon. However, adults from tropical climates are more likely to be susceptible than their US counterparts. Although varicella cases have declined dramatically in areas where moderate to high vaccine coverage has been achieved in the United States, varicella cases have declined in all age groups and approximately 90% of cases are still occurring among children < 15 years.

2. An expected case-fatality rate of 2-3 per 100,000 cases, much lower than smallpox

3. A secondary attack rate among susceptible household contacts, approximately 80% (range 65-90%), higher than smallpox.

5. POST-EVENT SURVEILLANCE

Once a confirmed case(s) of smallpox has been identified, the state, regional, and local public health authorities with jurisdiction in the area where the case or cases were identified should initiate immediate active surveillance for additional suspected, probable and confirmed cases. Although the specific mechanisms and logistics for active surveillance may differ among jurisdictional areas, the following general guidelines should be followed:

1. Distribution of clinical case definitions and case classifications for suspected, probable and confirmed cases of smallpox to public health personnel involved in surveillance, and hospitals, clinics, and individual practitioners involved in patient care.

2. Distribution of reporting forms. CDC has prepared draft smallpox surveillance forms (Forms 5A and 5B).

i) Form 5A (Core data) - for initial case reporting at the time of first notification of the case. This form provides quantitative case monitoring so the outbreak course can be followed temporally, geographically, and to a lesser extent demographically. This form contains minimal information to be reported to surveillance personnel immediately following diagnosis for each suspected/probable/confirmed smallpox case including:

- **First and last name and SS#**
- **Date of birth**
- **Sex**
- **Race and ethnicity**
- **Occupation**
- **Home address of patient**
- **Home telephone number of patient**
- **Pre-existing medical conditions that are risk factors for severe disease and outcome (HIV status, pregnancy, other)**
- **Date of fever onset and symptoms of prodrome**
- **Date of rash onset and initial case presentation**
- **Vaccination status: past and approximate age; current: date**
- **Date of medical evaluation**
- **Place of medical evaluation**
- **Date, time and place of case isolation**
- **Known exposure to suspected/probable/confirmed case**
- **Initial case classification (confirmed, probable, or suspected)**
- **Case status on date of reporting (alive, dead)**

ii) Form 5B - for quantitative monitoring of clinical course and outcome on each case so the outbreak course can be followed temporally, geographically and by person characteristics in sufficient detail to assess vaccine failure, unusual disease presentations, disease morbidity and mortality and risk for adverse outcome to assist in targeting/refining vaccination efforts. Some of the data to be reported on this form could be collected during the hospital course (e.g. laboratory results) or all the data could be abstracted on date of discharge from hospital or death. The forms will be linked by an assigned case ID number and by using developed computer software programs, case demographic information will be printed onto form 2B.

- **Updated clinical description of smallpox at the height of the illness**
- **Duration of rash and fever**
- **Complications and sequelae**
- **Outcome: survival or death**
- **Date of death, autopsy results**
- **Results of laboratory testing for smallpox**
- **Final disposition (discharged to home, deceased, lost to follow-up, etc.)**

- **Final case classification, including not smallpox**

Depending on the circumstances and characteristics of the outbreak, additional or modified forms may need to be developed to address other questions as they arise.

iii) Smallpox daily follow-up sheet (Form 6)– used to track and update on a daily basis the following information on reported cases that will be used to update case classification:
- Laboratory results (positive)
- Epidemiologic linkage to the cases (yes)

Demographic variables from the existing surveillance database with active cases will be listed on this form daily and stratified and/or sorted by variables that will assist with provision of daily lists at the local health department and/or hospital level for updating case information.

iv) The contact identification module (Forms 3, 3A, 3B, 3C and 3D) must be used with Form 5A. This separate module has been developed to enumerate and identify the risk status of all persons (names and contact numbers) who had face-to-face contact with the case and locations that case visited (where names of persons may not be known, e.g., a doctor's office) since date of onset of fever. Although smallpox is considered most infectious during the first 7-10 days of the exanthem (rash), some patients may not notice the first exanthemous lesions. In addition, an enanthem also occurs causing ulcerated lesions in oropharynx; the patient may be highly infectious during this time period, which may immediately precede or coincide with onset of the exanthem (rash). *Contact identification is the most urgent task when investigating smallpox cases since vaccination of close contacts as soon as possible following exposure but preferably within 3-4 days may prevent or modify disease.* This was the successful strategy used for the global eradication of smallpox.

Reporting (see Fig. 2)

1. Public health departments should establish potential redundant mechanisms for communicating to reporting sources. These may include:

   - Broadcast fax
   - Listserv
   - Epi-X
   - Health Alert Network
   - Automated telephone notification

2. Multiple mechanisms for reporting confirmed, probable, and suspected cases to public health surveillance personnel should be established and communicated to all reporting sources (i.e., hospitals, clinics, private physician offices, etc.) as redundant systems may be required due to potential communication problems. Potential redundant mechanisms for reporting include:

   - Secured fax
   - Secured web-based reporting
   - Database transmission via modem to secure server
   - Direct telephone reporting

- E-mail transmission
- Hand-carried reports

3. All sources of reporting (hospitals, clinics, etc.) should be advised to immediately report suspected, probable, and confirmed cases so that activities for disease confirmation, isolation an d contact identification and tracing can be initiated. **A centralized place for initial reporting should be established by health officials and communicated to potential reporting sources.**

4. **Surveillance staff should actively contact major reporting sources** (hospitals, large clinics, or other designated smallpox facilities) at least once a day to encourage timely reporting.

5. A computer system for data entry and analysis of all the collected case investigation and surveillance information will be provided by federal health authorities and must be managed and maintained for all confirmed, probable, and suspected cases.

6. Establish isolation and transport arrangements for confirmed, probable and suspected cases.

7. Methods should be established to follow up on laboratory results and epidemiological links for probable and suspected cases since this will affect case classifications which need to be tracked and reported on a daily basis. A data management system could provide a daily tracking form (Form 6) for monitoring such cases.

   Final classification as a confirmed case is dependent upon laboratory confirmation and linkages with laboratories providing confirmatory testing should be established.

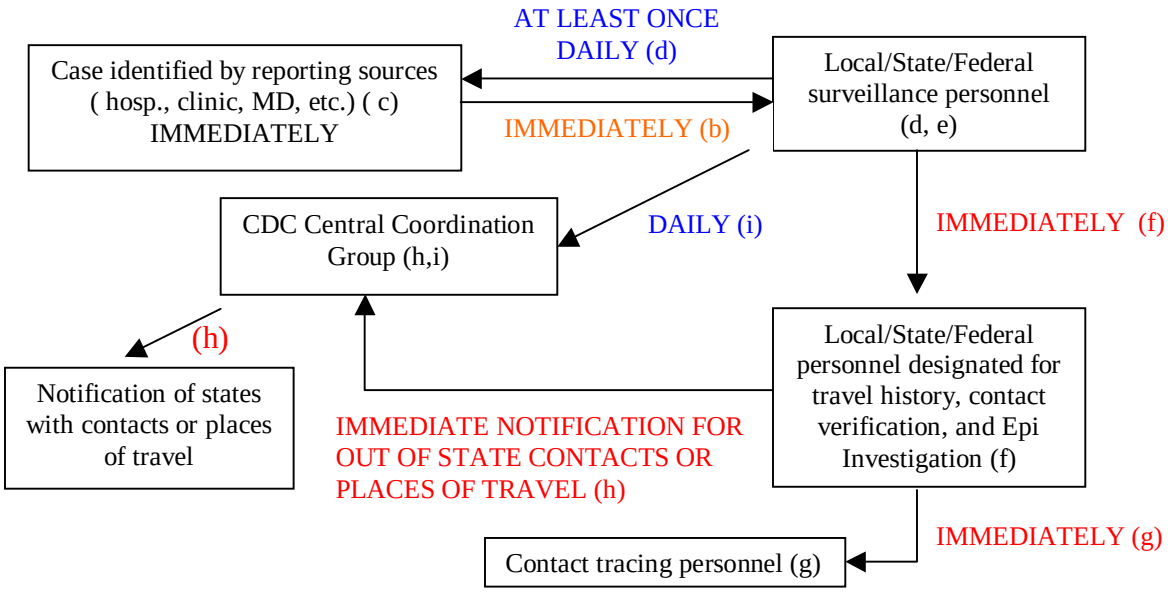
8. **Patient information should be immediately reported to personnel (**local, state, and/or federal) **responsible for confirming cases, conducting the epidemiological investigation and obtaining contact and travel histories of cases.** If possible, personnel should prioritize the risk of contacts and sites based on closeness and duration of contact and stage of the illness.

9. **Confirmed contact lists should be given to personnel responsible for tracing, vaccinating and following up on** contacts. If resources permit, personnel assigned to verify cases, travel histories, contacts, and conduct the epidemiological investigation may also participate in contact tracing activities.

10. **Out-of-state contacts or places of travel should be immediately reported to the CDC Coordination Group** who will assist with the notification of the appropriate health authorities in the effected states.

11. **Surveillance data should be reported on a daily basis to the CDC Coordination Group.** This group will be responsible for maintaining the national surveillance database and helping with notification of out of state contacts. Mechanisms for reporting to CDC including the data format (Excel file, Access file, etc.) will be distributed to surveillance personnel at the time of the outbreak.

Fig.2 - Surveillance Reporting and Information Flow



Methods for enhanced hospital-based surveillance

Once a case of smallpox has been confirmed in the community, patients with febrile rash illnesses will be directed to seek evaluation and care at a small number of facilities (clinics, hospitals) where physicians and health professionals familiar with smallpox and similar rash illnesses will see, diagnose and triage patients. Precautions to prevent spread of possible smallpox will be implemented. In addition, other area hospitals will be asked to initiate active surveillance for cases to identify patients admitted with compatible illnesses. States and localities should identify these facilities in advance and make plans for the evaluation of sizeable numbers of patients with rash illnesses.

Active Surveillance in Hospitals

1) Each hospital in the active surveillance network will identify one person (hospital surveillance officer) who will be responsible for daily active surveillance at that institution (e.g. infection control pract itioner (ICP). Patients will be evaluated and assigned a risk category: high, medium or low. The ICP will notify the health department immediately of any high-risk patient for transfer to the designated type C facility for isolation of smallpox cases. All patients identified as medium risk will be notified to the health department and transferred to a type X facility. In the event that there are no suspected smallpox patients, a report will still be sent to notify the health department that surveillance was conducted and has not yielded suspect patients (“zero reporting”). Smallpox surveillance forms will be completed on all suspect cases. Line lists will be maintained and updated daily and will include both new patients and previously reported patients u ntil smallpox is ruled out.

2. Prospective surveillance: Active surveillance for possible cases of smallpox currently hospitalized will be performed prospectively from the time of first report of an index case in the emergency room, (and any

other unit that could accept patients directly without having ER evaluation), intensive care units, pathology and laboratory departments. Whenever possible, potential cases will be seen by an infectious disease consultant, dermatologist or smallpox consultant to clarify the diagnosis. Surveillance in each department is described below.

3. Retrospective surveillance-- In order to identify cases that may have been admitted before the outbreak was recognized but once transmission in the community was theoretically possible, retrospective screening of patients admitted with compatible syndromes will be conducted from the date determined by local health department personnel. If resources are available, records will be reviewed for all patients who were seen in the ER and discharged home, admitted, or transferred to another hospital. Charts of patients with a **non-lab confirmed diagnosis of varicella, or generalized herpes zoster or HSV, or** those described to have a **diffuse vesicular or pustular rash with fever** and no lab-confirmed diagnosis will be reviewed to determine if the illness may have been smallpox. Patients currently in the hospital will be evaluated, and those transferred to another facility, discharged or expired will be reported to the local/state health department for follow-up.

Classification of evaluated patients

High Risk (epi-linked):

1) Patients epidemiologically linked to a confirmed case of smallpox who have a history of a febrile prodrome and on examination had a maculopapular rash with predominantly face/distal extremity distribution OR involvement of the palms and/or soles.
2) Patients epidemiologically linked to a confirmed case of smallpox who have a viral syndrome with fever >101 and systemic symptoms (prostration, headache, backache, chills, vomiting, or abdominal pain) for <4 days but who do *not* have a generalized rash on examination

High Risk (not epi-linked):

Patients with a severe prodromal illness consisting of temperature > 101°F 1-4 days before rash onset, and at least one of the following: prostration, headache, backache, chills, vomiting, or abdominal pain AND

1) Generalized rash of acute onset that is either: comprised of deep, round, dermal lesions characteristic of smallpox; maculo-papular rash involving the palms and/or soles OR distributed more densely on the face and distal extremities than the trunk AND no other lab-confirmed diagnosis that would adequately explain the illness
2) Prostration or shock AND either maculo-papular rash, hemorrhagic rash, or rash with flat, velvety lesions that may be confluent AND no other lab-confirmed diagnosis that would adequately explain the illness

Moderate Risk (not epi-linked):

Patients with no known contact, brief or uncertain contact to a smallpox case with a prodromal illness consisting of temperature >101°F and at least one of the following: prostration, headache, backache, chills, vomiting, or abdominal pain AND a generalized rash of acute onset that does is atypical for

smallpox (e.g. lesions on oral mucosa only, maculo-papular rash with localized distribution to face, or face and forearms, hemorrhagic/petechial rash) AND no other lab-confirmed diagnosis that would adequately explain the illness

Low Risk (not epi-linked): Patients who are not epidemiologically linked to a smallpox case AND

1) Lack a history of a febrile prodrome
2) Do not have classic smallpox lesions, OR
3) Have a laboratory confirmed non-smallpox diagnosis compatible with their illness

Strategies for Conducting Active Surveillance

1) **ER/ICUs/Wards**: ICP will visit or contact each hospital ward/unit to identify any hospitalized patient that could potentially have smallpox.

   a) **Any patient with diagnosis of varicella, generalized herpes zoster or HSV** or "R/O smallpox" will be evaluated. Any cases not already lab-confirmed will have ID and/or dermatology consultation and rapid laboratory testing for VZV (+/-HSV or other testing if clinically indicated). Those considered high risk will be reported to local/state health department as suspected or probable smallpox cases and be referred to the designated type C facility for isolation. Moderate risk patients will be entered on a separate line list kept by the ICP with status updated at least daily. If a non-smallpox diagnosis is made, the patient is no longer on the active moderate-risk list; if the patient's illness evolves and he/she meets criteria for high risk, the patient is reported as a new high-risk case and reported and transferred accordingly.

2) P**athology Department** (for hospitals where autopsies are performed)

   a) Prospective: ICP will contact chief pathologist daily to identify any previously unreported patients who died with varicella, disseminated **herpes zoster or HSV, R/O smallpox, hemorrhagic or petechial rashes or confluent/flat rashes and any patient with a rash who died within 48 hours of admission**. All these cases will have autopsy requested to confirm cause of rash and a review of records by ID consultant. High-risk cases will be reported to local/state health department and have smallpox surveillance form completed.

   b) Retrospective: all deaths that occurred since smallpox is known to have been transmitted in the community (as determined by local health officials) will be reviewed to using the same criteria as above. All these patients will have autopsy requested to confirm cause of rash and review of records by ID consultant. Physician of record may be contacted to provide additional information. High-risk cases will be reported to local/state health department and have a smallpox surveillance form completed.

3) Laboratory

a) Prospective: Lab requests and results will be reviewed daily for tests ordered for orthopox viruses, varicella-zoster (excluding serology), herpes simplex (excluding serology), rocky mountain spotted fever, rickettsial pox, coxsackie viruses or echoviruses (excluding serology) or blood cultures ordered with diagnosis of possible meningococcemia. Patients with newly ordered tests that have negative or pending results will be

cross-checked against list of reported smallpox cases and hospital daily line list of cases for continued monitoring. Those not on either list will be recorded on lab surveillance list and have chart review to determine if patients has clinically compatible illness. ID consultant will determine risk category of patients in these groups. High-risk patients will be reported to local/state health department as suspected or probable smallpox cases, be reported to health department and transferred to a type C isolation facility. Results on low risk hospitalized patients will be followed daily via line list until a diagnosis is confirmed. Previously ordered tests resulted as negative will also be reviewed in the same manner.

b) Retrospective: If resources are available, lab requests over past seven days will be reviewed for the above tests with negative or pending results, and cross-checked against list of reported smallpox cases and daily line list fo continued monitoring. Those not on either list will be recorded on lab surveillance list and have chart review and ID consultation as above.

4) **List Updates**: ICP will maintain TWO lists (high risk list, moderate risk list) of cases and continually update lists with new cases.

a) All HIGH RISK cases are considered suspected or probable smallpox cases and will be reported immediately health department surveillance officer and arrangements will be made for immediate transfer to the designated type C isolation facility. Persons whose illnesses evolves and who move from moderate to high risk will be reported as suspected or probable smallpox cases. Patient location, status and lab results should be updated daily. The smallpox surveillance forms and updated high-risk list will be delivered to the county surveillance officer once daily.

b) ICP will maintain daily line list of patients at MODERATE risk for smal lpox but who are still under investigation. Patient location, status and lab results will be updated daily. This updated list will be delivered t the county surveillance officer once daily.

6. CONTACT IDENTIFICATION, TRACING, VACCINATION, AND SURVEILLANCE

All personnel designated for case interviews or contact-tracing activities must be vaccinated prior to initiating their first face-to-face interview with a suspect, probable, or confirmed case or contact tracing activities.

Identification of Contacts

A single person should be designated by the State Epidemiologist or Federal health authorities to coordinate overall onsite contact identification, tracing, vaccination assurance and surveillance activities. Additional state and federal resources will be provided to assist with these activities.

Personnel designated for contact identification and determination of case travel history should perform the tasks listed below. Additional staff should be assigned for tracing, interviewing, arranging vaccin ation and surveillance of contacts.

1. Using the contact identification module (Forms 3 and 3A -D), interview each suspected, probable, or confirmed case to get detailed name and contact information (where known) for all persons with whom case had face-to-face contact (within 6 feet) since onset of fever until the time of the interview. The module contains questions to identify household and non -household contacts and asks case to designate duration of exposure for non-household contacts if that information is available. Names of household and non-household contacts should be listed on the appropriate forms.

   The interviewer should obtain as much locating information as possible (e.g., names, addresses, and telephone numbers) for every person with whom the case had known face-to-face contact following the onset of fever. The case should be questioned as to what they did and who they saw each day; beginning with the day their fever began. Care should be taken to include specific questions (e.g. work-related activities, social activities, e.g. "Who did you have lunch with that day?") in the interview that may help the patient remember contacts.

2. Detailed information is sought on places visited since fever onset to determine sites where unknown persons are likely to be exposed to an infectious case. These include:
   a. Doctor's offices, hospital emergency departments, health clinics.
   b. Work and school locations
   c. Regular activities
   d. Occasional activities

   The contact module also requests in -town and out of town travel history since the onset of fever.

3. If time/personnel constraints permit or if the patient is unable to answer questions because of illness, interview the patient's family, close friends, and work associates to verify his/her travel and contact history since onset of fever.

4. If only contacts in one state are involved, give all the information obtained to the personnel responsible for tracing, interviewing, and surveillance of contacts within the state. The names of the contact and household members of contacts should be provided to personnel or clinics responsible for completing contact information (name, address, phone number etc.) and vaccination of contacts. If out-of-state contacts or places of travel are identified, give the information to the **CDC Coordination Group.**

5. Once all contacts are listed, they should be allocated to priority categories for vaccination based on duration of exposure according to the following guidelines:

   a. Highest priority - household contacts, immediate family members and persons who work full time in the household
   b. 2nd priority
      i. Named contacts who spent time in case's home but who do not live there (e.g. close friends who visited, any person who spent the night)
      ii. Named non-household contacts with > 3 hours of exposure
      iii. Persons exposed in a doctor's office or other medical facility
   c. 3rd priority – named non-household contacts with 1-3 hours of exposure

d. 4th priority - named non-household contacts with < 1 hour of exposure
e. Last priority - non-household contacts with < 1 hour of exposure at a designated location

Other factors for contact tracers to consider when assigning contacts to priority groups include case's status, e.g. fever, rash, presence of cough, and the proximity of exposure e.g. sat next to potentially infectious cases for 2 hours at a meeting versus sat in the same room for the meeting.

If the number of contacts exceeds the capabilities of contact tracing to provide rapid identification and interviewing of contacts, state and Federal health authorities may in addition to identifying face-to-face contacts may identify presumptive contacts based on determining locations and times where the case was present following onset of fever. This addition should only be implemented by the State Medical Officer after consultation with Federal health authorities and only if limited personnel resources and the size of the outbreak do not permit effective institution of the standard procedure.

Tracing and interviewing of contacts

A single person should be designated by the State Medical Officer or Federal health authorities to coordinate tracing, interviewing, arranging for vaccination and the surveillance of contacts. Additional personnel should be provided from state resources as needed.

Personnel assigned to trace contacts will receive names and any known address, telephone number(s), or other locating information for these contacts from case investigation personnel. The number of contacts for each case may require a very large number of personnel be identified, trained and available for contact tracing and follow-up activities.

Contact tracing personnel should:

1. Find locating or contact information for each contact of a smallpox case. Use work and school contact numbers, telephone directories, voting lists, neighborhood interviews, site visits,"hangouts" etc., to trace contacts when contact information is unknown or incomplete. If contacts cannot be found through these mechanisms, other sources for notification of potential contacts, such as media announcements, may have to be considered.
2. Locate each contact.
3. Interview each contact to confirm contact with the suspected, probable, or confirmed smallpox case, the presence or absence of symptoms in the contact (fever and/or rash) and to identify additional contacts that may not have been listed by the case. Record this information on Form 8.
4. Make arrangements for immediate vaccination of the contact and his/her household contacts and if this is not conducted at the household by the contact tracer, provide a form that documents names and identifying information of all persons in the household who are referred for vaccination on Form 9.
5. If the contact is symptomatic with fever or rash, the contact should be immediately transported to a Type C Facility or other designated evaluation site for medical evaluation to rule out smallpox. The patient should be interviewed as a suspected case using the Smallpox Case Investigation Form and his/her contacts should be identified, interviewed, and vaccinated while the evaluation for smallpox

is being undertaken.

6. If the contact does not have fever or rash, place the contact under surveillance, so that if they develop fever or rash they are immediately isolated and evaluated and do not expose other persons (see below).
7. Identify household contacts (including regular household visitors and persons who work in the home) of the contact of the smallpox case. Record their names, ages, relationship to the case, and other information on Form 8 (secondary contact person worksheet)
8. If household members cannot be vaccinated due to contraindications, they should avoid contact with the contact until the end of the contact's quarantine period, or until all vaccinated persons in the household are noninfectious for vaccinia virus (after the scab at the vaccine site has separated, 14 to 21 days after vaccination).
9. Notify the person responsible for reporting out-of-state contacts to the CDC Coordination Group if it is learned that a contact has left the state.

Surveillance (monitoring) of health status and vaccine "take" of contacts

Contacts who do not have fever or rash at the time of interview must remain under active surveillance for 18 days after their last contact with the smallpox case, or 14 days following successful vaccination. The contact tracer will establish methods for daily reporting with the contact including methods for daily tracking if the contact does not have access to a home telephone.

1. Contacts must monitor and record their temperature in the morning and early evening each day. (Form 10, under development)
2. Each day before 8 p.m. they must call or be called by a designated person (or staff at a designated phone number) to report their daily temperatures, health status and any severe adverse vaccine reaction in themselves or household members following vaccination.
3. During the surveillance period they may continue their usual daily activities, going to work or attending school, as long as no temperatures $\geq$101ºF (38ºC) are measured. They should not, however, travel away from their city of residence.
4. If they have a temperature $\geq$101ºF (38ºC), they must remain in their own home. If they have two successive temperature readings of $\geq$101ºF, they must contact health department personnel immediately, and remain at home, having contact only with vaccinated household members, until further evaluated by health department personnel.
5. On day 7 following vaccination, depending on local arrangements and staff availability, contacts must visit or report to the health department the status of their vaccine site (does the area of their arm where they were vaccinated look like the picture they were given when they were vaccinated?) and the vaccine sites of their household members.

Personnel assigned to monitor the health status of contacts will answer questions of contacts who are under surveillance, record daily temperature readings and health status, record information on vaccine "take" and severe adverse vaccine reactions among contacts and their household members, and refer for in-home follow-up any contacts who fail to report in and cannot be contacted by telephone. If resources permit, they will visit the household on day 7 following vaccination to record vaccine "take".

1. These personnel will maintain Form 11 for each contact. Record information on the date and type of

follow up (in person or by telephone), recorded temperature, other symptoms of illness, and on day 7 after vaccination, vaccine site reaction.

2. These personnel will obtain information on the vaccine "take" of other persons in the household and record it on the same form.
3. In addition, a daily tracking form should be used to record on a master sheet summary information from all contacts monitored. (Form 11)

If personnel are limited, state and Federal health authorities may institute a passive system of monitoring of health status of contacts. In this approach, contacts under monitoring are only required to call health department personnel if:

1. They have 2 consecutive temperatures $\geq$101º F (38ºC) or develop a rash;
2. They have no reaction at the vaccine site on day 7;
3. They have a severe adverse vaccine reaction; or
4. They have completed the period of monitoring (18 days from last contact with the case or 14 days following successful vaccination) and are reporting in to be officially released from monitoring.

This change should only be implemented by the State Epidemiologist after consultation with Federal health authorities and only if limited personnel resources and the size of the outbreak do not permit effective institution of the standard procedure.

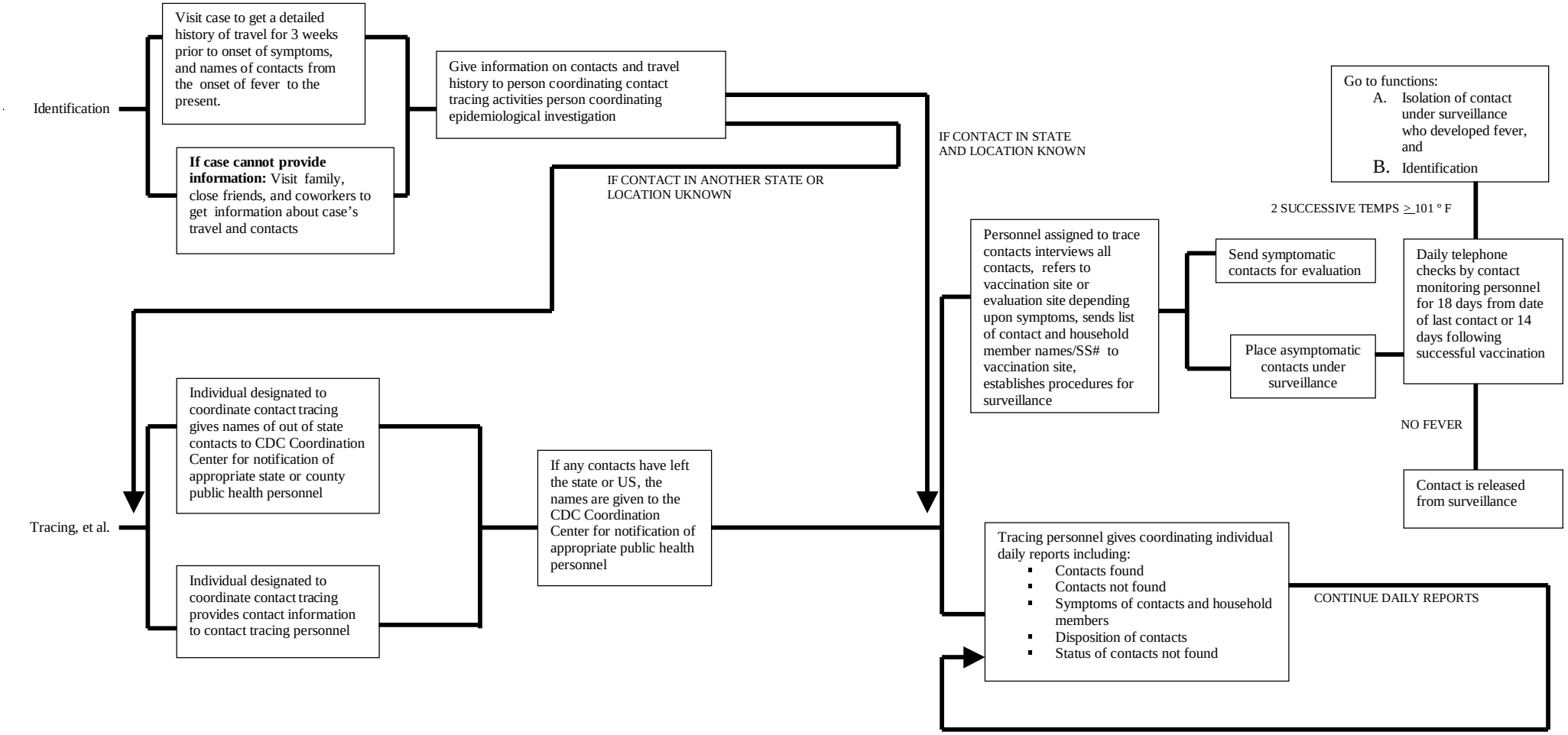
For coordination of contact tracing with vaccination, personnel should:

1. Make a list of names and social security numbers (or drivers license numbers) of contact and household members who will be referred for vaccination and provide this list to the fixed vaccination clinic site where the contacts/household members will be sent. (Duplicate of Form 8)

2. Provide a daily Master Report to the person responsible for coordinating contact tracing which includes:
    - Contacts found
    - Contacts not found
    - Symptoms of contacts
    - Disposition of found Contacts
        1. Interviewed and vaccinated/referred for vaccination
        2. Interviewed and referred for illness evaluation
        3. Isolated if fever or rash develops
    - Status of contacts not found
        1. Whereabouts known but unable to contact for interview
        2. Whereabouts unknown
    - Number of contacts' household members
    - Number of contacts' household members vaccinated/referred for vaccination

SEE ATTACHED Fig. 3 - FLOW CHART FOR RECOMMENDED CONTACT IDENTIFICATION AND TRACING ACTIVITIES

Fig. 3 – Contact Identification, Tracing, and Surveillance



Guide A

Surveillance, Contact Tracing, Epidemiological Investigation

FORMS

Forms for Guide A: Smallpox epidemiological investigation, surveillance and contact identification, tracing and surveillance

Form	Purpose	Comment
Forms 1-4	Detailed case investigation	4 modules*
Form 1	Patient, medical history and clinical case information	
Form 2	Laboratory form	
Form 3	Contact identification module (used as module in detailed case investigation and as required module for surveillance) includes the following forms:	
Form 3A	Household contact Form for listing all household contacts of case	
Form 3B	Non-household contact Form for listing all named non-household contacts plus duration of exposure	
Form 3C	Contact site list for listing sites where unnamed contacts may have been exposed to case	
Form 3D	Contact transportation list for listing sites (cities, states, countries) where case traveled during infectious period and modes of transportation	
Form 4	Source of exposure module which includes the following forms:	
Form 4A	Exposure source site form for listing sites visited during period of possible exposure	
Form 4B	Exposure source transportation form for listing sites (cities, states, countries) where case traveled during period of exposure and modes of transportation	

*Note: The modules represented by the series of forms 1-4 are intended to be used in the initial stages of a smallpox outbreak investigation. The investigation will require 2 or 3 staff working concurrently; using forms 1 and 2, a medical epidemiologist should abstract information from admitting medical record or ER record while another epidemiologist/PHA interviews the case (or family member/friend if case is too ill for the interview) starting with forms 3 (contact identification module) and then forms 4 (source of exposure module). Information needed for form 1 that is not available from the medical record should be obtained from the case or a close family member/friend.

Forms 5A & 5B	Surveillance short forms; these forms will replace forms 1-4 once cases are more common and detailed case investigations, especially to determine source of exposure, are not needed. Note: must continue to use Forms 3: contact ID module with forms 5.
Form 6	Daily tracking case status form, used for updating case information the affects case classification e.g. lab results, epi linkage
Form 7	Hospital surveillance tracking form
Form 8	Form for interviewing each contact and identifying household contacts of contacts
Form 9	Form for referral of Contacts and Household Members For Vaccination to a fixed site
Form 10	Individual contact surveillance form to record vaccine "take" and serious adverse events for vaccinated household members of contacts (for use by contact tracer)
Form 11	Master form for daily tracking of contact list

Forms still under development

Form 12	Form for contact to record daily temperatures, health status, vaccine take and serious vaccine adverse events and vaccine take and serious vaccine adverse events of household contacts *(this could be the same form as form 10 or with minor modifications)*
Form 13	Daily master form to summarize contacts found/not found, symptoms of contacts, disposition of found contacts (vaccinated/referred for vaccination, referred for illness evaluation, isolated if fever or rash develops, status of contacts not found, number of contact's household members and those vaccinated or referred for vaccination. *(this may not need to be a form but rather a computer generated report from contact form data.)*