Summary of October 2002 ACIP Smallpox Vaccination Recommendations

Adapted from: http://www.bt.cdc.gov/agent/smallpox/vaccination/acip-recs-oct2002.asp.

CDC asked the Advisory Committee on Immunization Practices (ACIP) to provide guidance on eight smallpox vaccination implementation issues. Now joint ACIP-HICPAC [Hospital Infection Control Practices Advisory Committee] recommendations will be forwarded to CDC and DHHS for review and consideration.

Note: see also the June 2002 Draft Supplemental Recommendations of the ACIP on the Use of Smallpox (Vaccinia) Vaccine.

Background

In June 2001, the Advisory Committee on Immunization Practices (ACIP) made recommendations for the use of smallpox (vaccinia) vaccine to protect persons who work with orthopoxviruses, to prepare for a possible bioterrorism attack, and to respond to an attack involving smallpox. This recommendation was followed in June 2002 with draft supplemental recommendations that extended the ACIP's smallpox vaccination recommendation to include people designated to respond or care for a suspected or confirmed case of smallpox. Specifically, the ACIP recommended voluntary vaccination of people serving on what subsequently have been designated as "Smallpox Public Health Response Teams" and "Smallpox Health Care Teams."

The June 2002 draft supplemental smallpox vaccine recommendations also clarified and expanded the primary strategy for control and containment of smallpox in the event of an outbreak.

In September, the Centers for Disease Control and Prevention (CDC) asked the ACIP to provide additional guidance on eight smallpox vaccination implementation issues, including the scope and composition of the Smallpox Health Care Teams. The eight issues were:

1. Types of healthcare workers that should be included in Smallpox Health Care Teams;
2. Care of the smallpox vaccination site;
3. Need for administrative leave for vaccinated healthcare workers;
4. Screening for atopic dermatitis as a contraindication for vaccination;
5. Screening for pregnancy as a contraindication for smallpox vaccination;
6. Screening for HIV infection as a contraindication for smallpox vaccination;
7. Simultaneous administration of smallpox vaccines with other vaccines; and
8. Vaccination of smallpox vaccinators.

The ACIP's recommendations reflect consultation with CDC's Hospital Infection Control Practices Advisory Committee (HICPAC) and DHHS's National Vaccine Advisory Committee (NVAC). The ACIP recommendations are being forwarded to HICPAC for their review and consideration on October 22 and 23, 2002. The Healthcare Infection Control Practices Advisory Committee provides advice and guidance to CDC and DHHS regarding infection control practices and strategies for surveillance,

prevention, and control of health care- associated infections (e.g., nosocomial infections), antimicrobial resistance and related events in settings where healthcare is provided (e.g., hospitals, long-term care facilities, and home health agencies).

In the coming weeks, the joint ACIP-HICPAC recommendations will be forwarded to CDC and DHHS for their review and consideration.

Opportunity to Establish Smallpox Health Care Teams

The June 2002 Draft Supplemental Smallpox Recommendations recommended that states should designate initial smallpox isolation care facilities (type C facilities) and these facilities, in turn, should pre-designate individuals who would care for smallpox patients for vaccination. However, further discussions with state health officials and hospital administrators identified problems with this approach. It was problematic to designate type C hospitals since suspected smallpox patients are likely to present at the hospitals and health care facilities which are their usual source of care, and not only at designated hospitals. Therefore, health and bio-terrorism officials indicated it was preferable to offer all acute care hospitals the opportunity to establish Smallpox Health Care Teams.

ACIP Recommendations: Summary of the Eight Issues (October 17, 2002)

1. Smallpox Health Care Teams

The ACIP recommends that in the first stages of a pre-event smallpox vaccination program, each acute care hospital identify a group of healthcare workers who would be vaccinated and trained to provide in-room medical care for the first few smallpox patients requiring hospital admission and to evaluate and manage patients who present to the Emergency Department with suspected smallpox. For the first 7-10 days after patients with smallpox have been identified, this team would be hospital-based and provide care 24 hours a day, using 8-12 hour shifts. Non-essential workers would be restricted from entering into the rooms of patients with smallpox.

The ACIP recommends that Smallpox Health Care Teams include:

Emergency Room Staff, including both physicians and nurses

Intensive Care Unit staff, including physicians, nurses, and in hospitals that care for infants and children, this encompass pediatricians, pediatric intensivists, and pediatric emergency room physicians and nurses

General Medical Unit staff, including physicians, internists, pediatricians, obstetricians, and family physicians in institutions where these individuals are the essential providers of primary medical care

Medical house staff (i.e., selected medical, pediatric, obstetric, and family physicians)

Medical subspecialists, including infectious disease specialists [this may also involve the creation of Regional teams of subspecialists (e.g., local medical consultants with smallpox experience, dermatologists, ophthalmologists, pathologists, surgeons, anesthesiologists in facilities where intensivists are not trained in anesthesia) to deliver consultative services

Infection control professionals (ICPs)
Respiratory therapists
Radiology technicians
Security personnel
Housekeeping staff (e.g., those staff involved in maintaining the health care environment and decreasing the risk of fomite transmission).

Overall, each Smallpox Health Care Team might include about 15 emergency room doctors and nurses, 15 intensive care unit doctors and nurses, and a total of 10-15 personnel from the other areas. It is anticipated that the size and composition of a smallpox medical care team will vary according to the individual institutions and their patient populations. Each hospital should have enough teams to ensure continuity of care. Smallpox vaccination would be voluntary.

Clinical laboratory workers are not included in the initial phase of pre-event smallpox vaccination because the quantity of virus likely to be in clinical specimens of blood and body fluids is low. Consistent adherence to standard precautions and ASM/CDC protocols will prevent exposure to virus in clinical specimens. Although it is not recommended that emergency medical technicians (EMTs), as a group, be vaccinated in this first phase, individual hospitals may identify and include hospital-based EMTs (i.e., personnel who would be dispatched to transport patients with suspected smallpox) on their Smallpox Health Care Teams.

2. Smallpox Vaccination Site Care

Following smallpox vaccination, the ACIP recommends that health-care workers involved in direct patient care should keep their vaccination sites covered with gauze or a similar absorbent material in order to absorb exudates that would develop. This dressing should, in turn, be covered with a semi-permeable dressing to provide a barrier to vaccinia virus. Use of a semi-permeable dressing alone could cause 1) maceration of the vaccination site and 2) increased prolonged irritation and itching at the site, thereby increasing touching, scratching and contamination of the hands. Products combining an absorbent base with an overlying semi-permeable layer can be used to cover the vaccination site. The vaccination site should be covered during direct patient care until the scab separates.

Vaccinia is generally transmitted by direct person-to-person and close contact (within 6 feet), and infection control precautions should be taken to reduce this likelihood. The most critical measure in preventing inadvertent implantation and contact transmission from the vaccinia vaccination site is thorough hand-hygiene after changing the bandage or after any other contact with the vaccination site. Hospitals should include a site-care component to their smallpox vaccination programs in which designated, vaccinated staff would assess dressings for all vaccinated health-care workers daily (whether involved in direct patient care or in other duties), determine if dressings needed changing, and then change the dressing if indicated. This designated staff would assess the vaccination site for local reactions and for vaccine take. They should also use the opportunity to reinforce messages to vaccinees about the need for meticulous hand-hygiene.

Transmission of vaccinia is also a concern in other settings when close personal contact with children or other persons is likely-for example, parenting of infants and young children. In these situations, the vaccination site should be covered with gauze or a similar absorbent material, and a shirt or other clothing should be worn, and careful attention to hand hygiene (hand washing) practiced.

3. Administrative Leave for Vaccinated Health Care Workers

With respect to administrative leave for health care workers, the ACIP does not believe that health care workers need to be placed on leave because they received a smallpox vaccination. Administrative leave is not required routinely for newly vaccinated healthcare workers unless they are physically unable to work due to systemic signs and symptoms of illness, extensive skin lesions which cannot be adequately covered, or if they do not adhere to the recommended infection control precautions. It is important to realize that the very close contact required for transmission of vaccinia to household contacts is unlikely to occur in the healthcare setting.

However, it is also recommended that vaccination of Smallpox Health Care Team members be phased in, starting with a small number of hospitals. Within a single institution, it would be prudent to designate a small proportion, e.g. 20-30% of the candidate healthcare workers, for the first phase of vaccinations to allow institutions to gain experience in post-vaccination management. The ACIP recognizes that the incidence of adverse events following vaccination of previously vaccinated persons is substantially less than in primary vaccinees, and therefore recommends that when feasible, previously vaccinated health care workers be included in this stage 1 vaccination program. It is also advisable to stagger vaccination of healthcare workers within an individual patient care unit by three weeks in order to minimize the number of vaccinated individuals who would be on sick leave concurrently in association with systemic effects of the vaccine, which usually occur at days 8-10 after inoculation.

4. Screening for Atopic Dermatitis as a Contraindication for Vaccination

Atopic dermatitis, irrespective of disease severity or activity, is a risk factor for developing eczema vaccinatum following smallpox vaccination in either vaccinees or in their close contacts. The majority of providers do not routinely make the distinction between eczema and atopic dermatitis, particularly when describing chronic exfoliative skin conditions in infants and young children. Due to the increased risk for eczema vaccinatum, smallpox (vaccinia) vaccine should not be administered to persons with a history of eczema or atopic dermatitis, irrespective of disease severity or activity. Additionally, persons with household contacts that have a history of eczema or atopic dermatitis, irrespective of disease severity or activity, are not eligible for smallpox (vaccinia) vaccination because of the increased risk that their household contacts may develop eczema vaccinatum.

Persons with other acute, chronic, or exfoliative conditions (e.g., burns, impetigo, varicella zoster, herpes, severe acne, or psoriasis) are at higher risk for inadvertent inoculation and should not be vaccinated until the condition resolves. The literature also

reports that persons with Darier's disease can develop eczema vaccinatum and therefore should not be vaccinated.

To assist providers in identifying persons that should defer smallpox (vaccinia) vaccination, the ACIP offers the following two screening questions: 1) Have you, or a member of your household ever been diagnosed with eczema or atopic dermatitis-if you answered "yes," you may NOT receive the smallpox (vaccinia) vaccine due to the risk that you or your household contact might develop a severe and potentially life-threatening illness called eczema vaccinatum; and 2) Eczema/atopic dermatitis usually is an itchy red, scaly rash that lasts more than 2 weeks and often comes and goes. If you or a member of your household have ever had a rash like this-you should NOT receive the smallpox (vaccinia) vaccine at this time unless you and a healthcare provider are sure that this rash is not atopic dermatitis or eczema. In cases where the dermatological risk factor or diagnosis is uncertain, some organizations, such as the military or CDC, may elect to develop more precise screening tools. These secondary screening tools should weigh the individual's risk of developing an adverse event with the requirement of occupational readiness through safe smallpox vaccination to ensure national security.

5. Screening for Pregnancy as a Contraindication for Vaccination

Fetal vaccinia is a very rare, but serious, complication of smallpox vaccination during pregnancy or shortly before conception. Therefore, vaccinia vaccine should not be administered in a pre-event setting to pregnant women or to women who are trying to become pregnant. Before vaccination, women of child-bearing age should be asked if they are pregnant or intend to become pregnant in the next 4 weeks; women who respond positively should not be vaccinated. In addition, the potential risk to the fetus should be explained and women who are vaccinated counseled not to become pregnant during the 4 weeks after vaccination. Routine pregnancy testing of women of child-bearing age is not recommended.

To further reduce the risk of inadvertently vaccinating a woman who is pregnant, at the time of pre-screening, women of child-bearing age should be educated about fetal vaccinia, and abstinence or contraception to reduce the risk of pregnancy before or within four weeks after vaccination. Any woman who thinks she could be pregnant or who wants additional assurance that she is not pregnant should perform a urine pregnancy test with a "first morning" void urine on the day scheduled for vaccination. Such tests could be made available at the pre-screening and vaccination sites to avoid cost or access barriers to testing.

If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after vaccinia vaccination, she should be counseled regarding the basis of concern for the fetus. However, vaccination during pregnancy should not ordinarily be a reason to terminate pregnancy. To expand understanding of the risk of fetal vaccinia and to document whether adverse pregnancy outcome may be associated with vaccination, a pregnancy registry should be maintained and any adverse outcomes carefully investigated.

6. Screening for HIV Infection as a Contraindication for Vaccination

Persons with HIV infection or AIDS are at increased risk of progressive vaccinia (vaccinia necrosum) following vaccinia vaccination. Therefore, vaccinia vaccine should not be administered to persons with HIV infection or AIDS. Before vaccination, potential vaccinees should be educated about the risk of severe vaccinial complications among persons with HIV infection or other immunosuppressive conditions; persons who think they may have one of these conditions should not be vaccinated.

The ACIP does not recommend mandatory HIV testing prior to smallpox vaccination, but recommends that HIV testing should be readily available to all persons considering smallpox vaccination. HIV testing is recommended for persons who have any history of a risk factor for HIV infection and who are not sure of their HIV infection status. Because known risk factors cannot be identified for some persons with HIV infection, anyone who is concerned that they could have HIV infection also should be tested. HIV testing should be available in a confidential or, where permitted by law, anonymous setting with results communicated to the potential vaccinee before the planned date of vaccination. Persons with a positive test result should be told not to present to the vaccination site for immunization. Information about local testing options should be provided to all potential vaccinees, including sites where testing is performed at no cost.

7. Simultaneous Administration of Smallpox Vaccine with Other Vaccines

Vaccinia vaccine may be administered simultaneously with any inactivated vaccine, such as influenza vaccine, to encourage appropriate receipt of all indicated vaccines, e.g., in populations such as health care workers. With the exception of varicella vaccine, vaccinia vaccine may be administered simultaneously with other live virus vaccines. To avoid confusion in ascertaining which vaccine may have caused post-vaccination skin lesions or other adverse events, and facilitate managing such events, varicella vaccine and vaccinia vaccine should only be administered >4 weeks apart.

8. Vaccination of Smallpox Vaccinators

In order to minimize the clinical impact of inadvertent inoculation, should it occur, ACIP recommends that persons who will be handling and administering smallpox vaccine in the proposed pre-event smallpox vaccination program be vaccinated. Vaccination of this group will also contribute to preparedness for smallpox response, should a smallpox release occur, with development of a cadre of vaccinated, experienced vaccinators who could immediately be deployed for outbreak response.

Draft Supplemental Recommendation of the ACIP
Use of Smallpox (Vaccinia) Vaccine, June 2002

Draft approved by ACIP on June 20, 2002
Now Under Consideration by CDC and DHHS

Adapted from http://www.bt.cdc.gov/agent/smallpox/vaccination/acip-guidelines.asp

Introduction

In June 2001, the Advisory Committee on Immunization Practices (ACIP) made recommendations for use of smallpox (vaccinia) vaccine to protect persons working with Orthopoxviruses, to prepare for a possible bioterrorism attack and respond to an attack involving smallpox. Because of the terrorist attacks in the fall of 2001, the Centers for Disease Control and Prevention (CDC) asked the ACIP to review their previous recommendations for smallpox (vaccinia) vaccination. As a result of this review, these supplemental recommendations update those for vaccination of 1) the general population and 2) persons designated to respond or care for a suspected or confirmed case of smallpox. In addition, they clarify and expand the primary strategy for control and containment of smallpox in the event of an outbreak.

Recommendations for vaccination of laboratory workers who directly handle recombinant vaccinia viruses derived from non-highly attenuated vaccinia strains, or other orthopoxviruses that infect humans (e.g., Monkeypox, cowpox, vaccinia, and variola) remain unchanged. Other aspects of the previous recommendations (e.g., screening for contraindications, care of the vaccination site) are being reviewed, and until new recommendations are published, the June 2001 recommendations should be consulted.

Prior to the terrorist attacks in the fall of 2001, the Department of Health and Human Services (DHHS) began to increase public health preparedness through expansion of the existing stockpile of smallpox (vaccinia) vaccine (Dryvax, Wyeth) by purchase of vaccine produced in cell culture (Acambis). The additional purchase of vaccine was initiated to address perceived vulnerability to future terrorist attacks. The anthrax attacks in the fall of 2001 resulted in increased activities to enhance preparedness and response capabilities, including those involving the deliberate release of smallpox and resulted in the accelerated production of additional doses of smallpox (vaccinia) vaccine. This increased supply of vaccine allows for consideration of expanded vaccination options.

The following recommendations were developed after formation of a joint Working Group of the ACIP and the National Vaccine Advisory Committee (NVAC) and a series of public meetings and forums to review available data on smallpox, smallpox (vaccinia) vaccine, smallpox control strategies, and other issues related to smallpox (vaccinia) vaccination. A website was established to solicit public opinion and input on options for smallpox (vaccinia) vaccine use.

The ACIP will review these recommendations periodically, or more urgently if necessary. These reviews will include new information or developments related to smallpox disease, smallpox (vaccinia) vaccines (including vaccine licensure), risk of smallpox attack, smallpox (vaccinia) vaccine adverse events, and the

experience gained in the implementation of the current recommendations. Revised recommendations will be developed as needed.

Smallpox Transmission and Control

Smallpox is transmitted from an infected person once a rash appears. Transmission does not occur during the prodromal period that precedes the rash. Infection is transmitted by large droplet nuclei and only rarely has airborne transmission been documented. Epidemiologic studies have shown that smallpox has a lower rate of transmission than diseases such as measles, pertussis, and influenza. The greatest risk of infection occurs among household members and close contacts of persons with smallpox, especially those with prolonged face-to-face exposure. Vaccination and isolation of contacts of cases at greatest risk of infection has been shown to interrupt transmission of smallpox. However, poor infection control practices resulted in high rates of transmission in hospitals.

The primary strategy to control an outbreak of smallpox and interrupt disease transmission is surveillance and containment, which includes ring vaccination and isolation of persons at risk of contracting smallpox. This strategy involves identification of infected persons through intensive surveillance, isolation of infected persons, vaccination of household contacts and other close contacts of infected persons (i.e., primary contacts), and vaccination of household contacts of the primary contacts (i.e. secondary contacts). This strategy was instrumental in the ultimate eradication of smallpox as a naturally occurring disease even in areas that had low vaccination coverage.

Depending upon the size of the smallpox outbreak and the resources that were available for rapid and thorough contact tracing, surveillance and containment activities in areas with identified smallpox cases was sometimes supplemented with voluntary vaccination of other individuals. This was done in order to expand the ring of immune individuals within an outbreak area and to further reduce the chance of secondary transmission from smallpox patients before they could be identified and isolated. Regardless of the geographic distribution, number of cases, or number of concurrent outbreaks, surveillance and containment activities remained the primary disease control strategy.

Critical Considerations

A number of factors and assumptions were used in developing these supplemental recommendations.

Level of disease risk and threat. Information provided to the ACIP indicated that the risk for smallpox occurring as a result of a deliberate release by terrorists is considered low, and the population at risk for such an exposure cannot be determined. It was further assumed that regardless of the mode of a bioterrorism release, the epidemiology of subsequent person-to-person transmission would be consistent with prior experience. These recommendations also assumed that in addition to vaccination, health care workers and others would be afforded protection from infection through

appropriate infection control measures, including the use of appropriate personal protective equipment.

Expected severe adverse reactions to vaccination. These supplemental recommendations assume that appropriate screening for contraindications to vaccination would be implemented and would include both the vaccinated persons, as well as their contacts. It is further assumed that recommended precautions would be taken to minimize the risk of adverse events among vaccinees as well as their close contacts (e.g., patients, household members).

Vaccine and vaccinia immune globulin (VIG) supply. The supplemental recommendations assume that both would be available for use, in sufficient supply, and handled and administered correctly. Smallpox (vaccinia) vaccine and VIG are currently available only under Investigational New Drug (IND) protocols (i.e., protocols for products that are not yet licensed). As such, it was assumed that appropriate informed consent, patient follow-up, and administrative oversight by federal, state, and local public health officials would be required. Further, any administration of smallpox (vaccinia) vaccine would be voluntary.

State and local vaccination capacity and capability. Surveillance and containment, including ring vaccination, is the primary strategy for the control and containment of smallpox. In addition, state and local health departments would be able, if necessary, to expand immunization to additional groups, up to and including their entire population, in a timely manner.

Smallpox Vaccines and VIG Availability

Currently, there are no commercially available (e.g., licensed) smallpox vaccines. Smallpox vaccines previously produced by Wyeth (Dryvax) and Aventis-Pasteur are available under Investigational New Drug (IND) protocols held by CDC. Both vaccines were prepared from calf lymph with a seed virus derived from the New York City Board of Health strain of vaccinia virus. Studies conducted among young adults with no previous smallpox vaccination history showed that a 1:5 dilution of Dryvax (Wyeth Laboratories, Inc) produced take rates among vaccinees equivalent to those of the undiluted vaccine.

In October 2001, the federal government contracted with Acambis and Acambis-Baxter Pharmaceuticals for at least 209 million doses of smallpox vaccine produced in cell-culture. These vaccines use a clone of the same strain of vaccinia virus (New York City Board of Health), which was utilized in the smallpox vaccines produced from calf lymph. These doses are expected to be available at the end of 2002 or soon thereafter.

Smallpox vaccines are formulated and packaged for administration with a bifurcated needle, which provides a fast, easy, and effective means for administration. All vaccines are packaged in 100 dose vials, except when Dryvax is diluted 1:5 resulting in vials that contain 500 doses.

The CDC National Pharmaceutical Stockpile (NPS) has developed protocols to allow for the rapid, simultaneous delivery of smallpox vaccine to every state and US territory within 12-24 hours. State and local bioterrorism response plans should provide for the rapid distribution of vaccine within their jurisdiction.

Currently, there is enough VIG available under an IND protocol to treat about 600 serious adverse events. This is enough VIG doses to treat the adverse reactions that would be expected to result from the vaccination of 4 million to 6 million people. Contracts for additional supplies of VIG are in progress.

Surveillance

Currently, cases of febrile rash illnesses, for which smallpox is considered in the differential diagnosis, should be immediately reported to local and/or state health departments. Following evaluation by local/state health departments, if smallpox laboratory diagnostics are considered necessary, the CDC Rash Illness Evaluation Team should be consulted at 770-488-7100 or 404-639-2888. As smallpox was eradicated in 1980 and no longer occurs naturally, an initial case of smallpox must be laboratory confirmed. At this time, laboratory confirmation for smallpox is available only at CDC. Clinical consultation and a preliminary laboratory diagnosis can be completed within 8-24 hours.

To assist medical and public health personnel in evaluating the likelihood of smallpox in patients with febrile rash illnesses, CDC has developed a rash illness assessment algorithm. Poster copies of this algorithm are available from state health departments and on the CDC website Orders for copies of the poster can be made over the Internet at: https://www2.cdc.gov/nchstp_od/PIWeb/niporderform.asp

Surveillance activities, including notification procedures and laboratory confirmation of cases, would change if smallpox is confirmed. Additional information regarding surveillance activities following laboratory confirmation of a smallpox outbreak can be found in the CDC Interim Smallpox Response Plan and Guidelines.

Recommendations

Pre-Release Vaccination of the General Population.

Under current circumstances, with no confirmed smallpox, and the risk of an attack assessed as low, vaccination of the general population is not recommended, as the potential benefits of vaccination do not outweigh the risks of vaccine complications.

Recommendations regarding pre-outbreak smallpox vaccination are being made on the basis of an assessment that considers the risks of disease and the benefits and risks of vaccination. The live smallpox (vaccinia) vaccine virus can be transmitted from person to person. In addition to sometimes causing adverse reactions in vaccinated persons, the vaccine virus can cause adverse reactions in the contacts of vaccinated persons. It is assumed that the risk of serious adverse events with currently available vaccines would be similar to those previously observed and could be higher today due to the increased prevalence of persons with altered immune systems.

Pre-Release Vaccination of Selected Groups to Enhance Smallpox Response Readiness.

Smallpox Response Teams

Smallpox vaccination is recommended for persons pre-designated by the appropriate bioterrorism and public health authorities to conduct investigation and follow-up of initial smallpox cases that would necessitate direct patient contact.

To enhance public health preparedness and response for smallpox control, specific teams at the federal, state and local level should be established to investigate and facilitate the diagnostic work-up of the initial suspect case(s) of smallpox and initiate control measures. These Smallpox Response Teams might include persons designated as medical team leader, public health advisor, medical epidemiologists, disease investigators, diagnostic laboratory scientist, nurses, personnel who would administer smallpox vaccines, and security/law enforcement personnel. Such teams may also include medical personnel who would assist in the evaluation of suspected smallpox cases.

The ACIP recommends that each state and territory establish and maintain at least one Smallpox Response Team. Considerations for additional teams should take into account population and geographic considerations and should be developed in accordance with federal, state, and local bioterrorism plans.

Designated Smallpox Healthcare Personnel at Designated Hospitals

Smallpox vaccination is recommended for selected personnel in facilities pre-designated to serve as referral centers to provide care for the initial cases of smallpox. These facilities would be pre-designated by the appropriate bioterrorism and public health authorities, and personnel within these facilities would be designated by the hospital.

As outlined in the CDC Interim Smallpox Response Plan and Guidelines, state bioterrorism response plans should designate initial smallpox isolation and care facilities (e.g., type C facilities). In turn, these facilities should pre-designate individuals who would care for the initial smallpox cases. To staff augmented medical response capabilities, additional personnel should be identified and trained to care for smallpox patients.

Implementation of Recommendations

The ACIP recognizes that the implementation of the supplemental recommendations presented in this document requires addressing a number of issues, and that this will take time. The issues include provider and public education, health care provider training, availability of vaccine and VIG, developing the appropriate investigational new drug protocols, screening, strategies to minimize vaccine wastage, vaccine adverse event surveillance, and other logistical and administrative issues.