Smallpox Q and As

I. Smallpox Disease

A. Smallpox Disease (symptoms, transmission, outcomes, etc)

1	**1**	**What should I know about smallpox?**	Smallpox is an acute, contagious, and sometimes fatal disease caused by the variola virus (an orthopoxvirus), and marked by fever and a distinctive progressive skin rash. In 1980, the disease was declared eradicated following worldwide vaccination programs. However, in the aftermath of the events of September and October, 2001, the U.S. government is taking precautions to be ready to deal with a bioterrorist attack using smallpox as a weapon. As a result of these efforts: 1) There is a detailed nationwide smallpox response plan designed to quickly vaccinate people and contain a smallpox outbreak and that includes the creation of smallpox healthcare teams that would respond to a smallpox emergency and the vaccination of members of these teams. 2) There is enough smallpox vaccine to vaccinate everyone who would need it in the event of an emergency.
1	**35**	**What are the symptoms of smallpox?**	The symptoms of smallpox begin with high fever, head and body aches, and sometimes vomiting. A rash follows that spreads and progresses to raised bumps and pus-filled blisters that crust, scab, and fall off after about three weeks, leaving a pitted scar.
1	**40**	**Is smallpox fatal?**	The majority of patients with smallpox recover, but death may occur in up to 30% of cases. Many smallpox survivors have permanent scars over large areas of their body, especially their face. Some are left blind.
1	**42**	**How is smallpox spread?**	Smallpox normally spreads from contact with infected persons. Generally, direct and fairly prolonged face-to-face contact is required to spread smallpox from one person to another. Smallpox also can be spread through direct contact with infected bodily fluids or contaminated objects such as bedding or clothing. Indirect spread is less common. Rarely, smallpox has been spread by virus carried in the air in enclosed settings such as buildings, buses, and trains. Smallpox is not known to be transmitted by insects or animals.

Smallpox Q and As

1	50	**Is smallpox contagious before the smallpox symptoms show?**	A person with smallpox is sometimes contagious with onset of fever (prodrome phase), but the person becomes most contagious with the onset of rash. The infected person is contagious until the last smallpox scab falls off.
1	76	**If someone had smallpox previously and survived, are they immune from the disease?**	Yes. If someone has been previously exposed to smallpox and survived, they are immune to the disease.
1	342	**When are cases of smallpox infectious?**	Smallpox cases are sometimes contagious with the onset of fever (prodrome phase) but becomes most contagious with the onset of rash.

B. Diagnosis and Laboratory (including virology)

2	45	**If smallpox is released in aerosol form, how long does the virus survive?**	The smallpox virus is fragile. In laboratory experiments, 90% of aerosolized smallpox virus dies within 24 hours; in the presence of ultraviolet (UV) light, this percentage would be even greater. If an aerosol release of smallpox occurs, 90% of virus matter will be inactivated or dissipated in about 24 hours.
2	114	**What is the role of medical examiners in smallpox surveillance?**	Medical examiners have a key role in all aspects of bioterrorism surveillance, acting as a key sentinel for suspicious deaths that might indicate the presence of a bioterrorist agent. Medical examiners are invited to work with their state health departments and/or bioterrorism programs on ways to become part of the effort. For more information, please visit the Medical Examiner and Coroner Information Sharing Program

C. Infection Control and isolation of smallpox patients

Smallpox Q and As

3	81	**If a smallpox event were suspected to have occurred in a particular facility, what would be done to protect the employees?**	If a smallpox event were suspected to have occurred in a facility, response plans are in place to try to document the presence of smallpox and rapidly initiate isolation procedures and vaccinate exposed persons if that is deemed appropriate. You can find out more about containment strategies in the Smallpox Response Plan and Guidelines in Guide A and Guide C
3	100	**Why are we even bringing smallpox patients to the hospitals? Why not just keep them at home where they've already exposed everyone?**	With good infection control practices and rooms with the appropriate air handling features, we can treat patients in the hospital without risking transmission to other patients and staff. The appropriate care and management of smallpox patients will probably require hospitalization. For more information on isolation and quarantine measures, please see Smallpox Response Plan and Guidelines Guide C.
3	103	**What kind of personal protective equipment (PPE, especially respiratory) would be necessary for dealing with a smallpox patient?**	Airborne and contact isolation precautions should be followed. Please see "Guideline for Isolation Precautions in Hospitals" for further information.
3	112	**What is the recommended mode of disposal of dead bodies infected with smallpox?**	This is currently under consideration.

D. Smallpox outbreak response

7	48	**How many people would have to get smallpox before it is considered an outbreak?**	One confirmed case of smallpox is considered a public health emergency.

Smallpox Q and As

7	**84**	**What designates a smallpox emergency to initiate post-event plans?**	Just one confirmed case of smallpox would be considered a public health emergency. The response would be rapid and designed to quickly control spread, isolation of cases, vaccination of all potential contacts, and broader vaccination as deemed appropriate after consideration of further spread or future releases of smallpox and after consultation with local, state, and federal authorities.
7	**87**	**During a smallpox emergency, would children under 18 receive the vaccine?**	During a smallpox emergency, all contraindications to vaccination would be reconsidered in the light of the risk of a smallpox exposure, and persons would be advised by public health authorities on recommendations for vaccination. Children between the ages of 12 months and 18 years would be eligible for vaccination. More information on vaccination strategies can be found in the Smallpox Response Plan and Guidelines Guide B.
7	**97**	**Is the decision that there would be no contraindications during a smallpox emergency based on public health data or studies?**	As with any public health intervention, we try to balance the risk of the intervention against the risk of the disease. During a smallpox bioterrorism event, the risk of disease would increase substantially and be sufficiently high to merit vaccination for many persons who should not be vaccinated now. However, the only situation that would lead to no (or nearly no) contraindications to vaccination is a direct, high-risk exposure to smallpox, such as would occur in a household with a person ill with smallpox case. This recommendation is based on extensive experience in the past that suggests that many people with these types of exposures will contract smallpox if not vaccinated.
7	**108**	**How do federal programs fit into post-event activities?**	All federal agencies would participate in activities as outlined in the Federal Response Plan Emergency Service Function 8. In most instances, the federal agencies would support state and local activities.

F. Treatment of smallpox disease

9	**54**	**Is there any treatment for smallpox?**	Smallpox can be prevented through use of the smallpox vaccine. There is no proven treatment for smallpox, but research to evaluate new antiviral agents is ongoing. Early results from laboratory studies suggest that the drug cidofovir may fight against the smallpox virus; currently, studies with animals are being done to better understand the drug's ability to treat smallpox disease (the use of cidofovir to treat smallpox or smallpox reactions should be evaluated and monitored by experts at NIH and CDC). Patients with smallpox can benefit from supportive therapy (e.g., intravenous fluids, medicine to control fever or pain) and antibiotics for any secondary bacterial infections that may

G. Use of smallpox virus as a biological weapon

Smallpox Q and As

59	26	**How serious is the smallpox threat?**	The deliberate release of smallpox as an epidemic disease is now regarded as a possibility, and the United States is taking precautions to deal with this possibility.
59	28	**How dangerous is the smallpox threat?**	Smallpox is classified as a Category A agent by the Centers for Disease Control and Prevention. Category A agents are believed to pose the greatest potential threat for adverse public health impact and have a moderate to high potential for large-scale dissemination. The public is generally more aware of category A agents, and broad-based public health preparedness efforts are necessary. Other Category A agents are anthrax, plague, botulism, tularemia, and viral hemorrhagic fevers.
59	79	**How do we expect a smallpox attack to occur, if one happens?**	The deliberate release of smallpox as an epidemic disease is now regarded as a possibility. We can't say with certainty how an attack might occur, but we do know how smallpox is normally transmitted. Transmission most often occurs through person-to-person contact, more rarely through contact with materials contaminated with the smallpox virus, rarely through airborne contagion in enclosed settings. Because an attack could have such serious consequences, every effort is being made to prepare for such a possibility even though it is unlikely to ever occur. These preparedness efforts therefore include use of the best way to prevent smallpox: vaccination.
59	271	**Since this is all part of bioterrorism preparedness, why aren't we also vaccinating against other bioterrorist agents?**	There are a number of bioterrorism preparedness activities covering a wide range of activities and potential bioterrorist agents. The type of preparation varies among the different agents. Vaccination is a key part of smallpox preparedness.
59	366	**Would someone comment on the Israeli decision not to continue with mass vaccination?**	Israeli decision is consistent with the Administration's decision to vaccinate only health care workers and first responders.

II. Smallpox Vaccine

A. Characteristics/General

Smallpox Q and As

11	78	**Is the vaccine being administered to members of healthcare response teams full-strength or diluted?**	The vaccine to be used for smallpox response teams is full-strength dried calf lymph type Dryvax vaccine. It is licensed and passes all tests required by the Food and Drug Administration.
11	80	**Will the vaccine be diluted?**	While dilution studies have shown that both Dryvax and Aventis Pasteur vaccine supplies could be diluted by 5 and still retain their efficacy, there are no plans to routinely dilute smallpox vaccine. Existing supplies of smallpox vaccine would only be diluted in the event of an emergency. New supplies of smallpox vaccine (Acam) are being produced and are expected to be licensed in early 2004. This is the vaccine that would be used for wider application among the American public should the decision be made to provide the vaccine to the public.
11	82	**How is vaccinia vaccine manufactured?**	Dryvax was produced by Wyeth Lederle in the early 1980s from calf lymph containing live vaccinia virus. This vaccine is provided as a freeze-dried powder and contains the antibiotics polymyxin B, streptomycin, tetracycline, and neomycin. The diluent used to reconstitute the vaccine is 50 percent glycerin with a small amount of phenol as a preservative.
11	89	**Was the smallpox vaccine given by the military years ago a stronger vaccine? Do people who were vaccinated in the military years ago need to be revaccinated?**	The vaccine administered by the military years ago was the same strength as the vaccine being used as part of the smallpox preparedness activities. Anyone who was vaccinated more than three years ago would need to be revaccinated to be sure they have a high level of protection from smallpox.
11	93	**Is Dryvax FDA-approved?**	Yes. The Dryvax vaccine being used for preparedness activities has been licensed by the Food and Drug Administration.
11	96	**This is the first I've heard about smallpox vaccine being licensed. Is this a new vaccine?**	No, this is the relicensing of the original calf lymph derived Dryvax product from Wyeth-Ayerst.

Smallpox Q and As

11	98	**What is the smallpox vaccine, and is it still required?**	The smallpox vaccine is the only way to prevent smallpox. The vaccine is made from a virus called vaccinia, which is another "pox"-type virus related to smallpox but cannot cause smallpox. The vaccine helps the body develop immunity to smallpox. It was successfully used to eradicate smallpox from the human population. Routine vaccination of the American public against smallpox stopped in 1972 after the disease was eradicated in the United States. Until recently, the U.S. government provided the smallpox vaccine only to a few hundred scientists and medical professionals who work with smallpox and similar viruses in a research setting. After the events of September and October, 2001, however, the U.S. government took further actions to improve its level of preparedness against terrorism. For smallpox, this included updating a response plan and ordering enough smallpox vaccine to immunize the American public in the event of a smallpox outbreak. The plans are in place, and there is sufficient vaccine available to immunize everyone who might need it in the event of an emergency. In addition, the Bush Administration recently announced a plan to better protect the American people against the threat of smallpox attack by hostile groups or governments. This plan included the creation of smallpox healthcare teams that would respond to a smallpox emergency. Members of these teams would be vaccinated against smallpox. The plan also included vaccination of certain military and civilian personnel who are or may be deployed in high threat areas.
11	101	**What is the smallpox vaccine made of?**	The vaccine is made from a virus called vaccinia, another "pox"-type virus related to smallpox but that does not cause smallpox. The smallpox vaccine helps the body develop immunity to smallpox. It does not contain the smallpox virus and cannot spread smallpox.
11	104	**Is it possible for people to get smallpox from the vaccination?**	No. The smallpox vaccine does not contain smallpox virus and cannot spread or cause smallpox. However the vaccine does contain another virus called vaccinia, which is "live" in the vaccine. Because the virus is live, it can spread to other parts of the body or to other people from the vaccine site. This can be prevented through proper care of the vaccination site (e.g. hand washing and careful disposal of used bandages).
11	105	**What is the origin of vaccinia virus?**	The vaccinia virus is the "live virus" used in the smallpox vaccine. It is an orthopoxvirus related to smallpox. When given to humans as a vaccine, it helps the body to develop immunity to smallpox. The vaccinia virus may cause rash, fever, and head and body aches. In certain groups of people, complications from the vaccinia virus can be severe. The smallpox vaccines being distributed for this vaccination program contain the New York City Board of Health strain of live vaccinia virus (dried, calf lymph-type).

Smallpox Q and As

11	106	**Many vaccinations are required. Why don't people have to get the smallpox vaccine?**	The last case of smallpox in the United States was in 1949. The last naturally occurring case in the world was in Somalia in 1977. After the disease was eliminated from the world, routine vaccination against smallpox among the general public was stopped because it was no longer necessary for prevention.
11	107	**Does the smallpox vaccine that will be used today contain a live virus? Did previous vaccines use live viruses as well?**	The smallpox vaccine that will be used does contain a live virus: vaccinia virus. Throughout the history of smallpox vaccination, a strain of live virus has been used. These viruses have been from the Orthopox genus of viruses that contains smallpox virus (variola), cowpox, monkeypox, camelpox, and some other viruses. Edward Jenner, who in 1796 introduced the practice of causing an infection with a different but related virus as a means to protect against smallpox, is believed to have used the cowpox virus. Over time, the species of Orthopoxvirus used to make vaccines shifted to vaccinia. The vaccinia strain has been used in recent times and helped accomplish the eradication of natural smallpox.
11	127	**When is the new vaccine expected?**	The production of new vaccine (Acam) is expected to be completed in May 2003. The vaccine is undergoing testing and licensure of this vaccine is expected to occur in early 2004.
11	132	**Why is the old Dryvax vaccine being used instead of new vaccine?**	Right now, the United States has two supplies of smallpox vaccine: 15 million doses of Dryvax and 85 million doses of Aventis Pasteur. Dilution studies have indicated that these 100 million doses could be safely and effectively diluted by 5, resulting in 500 million doses of vaccine, enough for every American. At the moment, however, only two lots of the Dryvax vaccine (2.7 million doses) are approved for distribution as a licensed vaccine. One million doses are designated for the Department of Defense. The remaining 1.7 million doses are designated for the Department of Health and Human Services. This vaccine will be used as part of the smallpox preparedness vaccination activities. While new vaccine is under production, this will not be available until May of 2003 and it would still need to be licensed. Dryvax has been used extensively and shown to be safe and effective in most people.
11	138	**Does the smallpox vaccine contain thimerosal?**	The current formulation of smallpox vaccine does not contain thimerosal.

Smallpox Q and As

11	193	**Would it be possible to get mad cow disease from the vaccine?**	No. The smallpox vaccine cannot give you mad cow disease. The vaccine was made many years ago before the mad cow disease epidemic in Europe.
11	216	**What are the components of the smallpox vaccine which can cause allergies in recipients?**	The smallpox vaccine contains a live virus preparation of vaccinia virus from calf lymph. The calf lymph is purified, concentrated, and dried. During processing, the following ingredients are added: polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride and neomycin sulfate. The vaccine may contain trace amounts of these. The diluent used to reconstitute the dried vaccine contains glycerin, phenol and sterile water. Anyone with known allergies to any of these ingredients should not get the vaccine.
11	222	**If the vaccine being used as part of this program is 30 years old, how do we know it's still good?**	We know that the Dryvax vaccine being used for smallpox response teams is still good because it has undergone and passed all the testing required by the Food and Drug Administration in order to be approved for distribution as a licensed vaccine. For example, the vaccine gives nearly a 100% take rate and the take indicates you are protected from smallpox.
11	293	**When will new vaccine without antibiotics be available?**	A vaccine for public use that does not contain antibiotics is currently undergoing licensing. No date for release is available at this time.
11	359	**Should the states put a disclaimer on the smallpox brochure prior to disseminating to the hospitals? The information in the brochure is inconsistent with ACIP recommendations.**	Yes, send brochure consistent with ACIP recommendations advising vaccines and health care workers not to touch the scab.
11	463	**Why are we using undiluted Dryvax in the pre-event phase?**	For pre-event smallpox vaccination, Dryvax 100 dose vials undiluted have been licensed. There are several advantages to using a licensed vaccine including no need for IND protocols, no need for local IRB approval, and a higher likelihood of health care companies providing coverage of the cost of the vaccination.

Smallpox Q and As

11	464	**Why was 15 strokes chosen by the ACIP?**	CDC and others are currently in the process of submitting data to the FDA to support changing the recommendation of three needle sticks for primary vaccinations to 15 needle sticks for both primary and revaccination. It is important to note that during the smallpox eradication period, the World Health Organization (WHO) program utilized 15 needle sticks universally to avoid confusion and to help decrease the number of vaccine take failures from flaws in vaccine administration techniques. However, until the FDA approves a package insert change, vaccinators should follow the instructions found on the vaccine package insert on the number of needle sticks to administer for primary vaccinees and revaccinees.

A. Characteristics/Clinical efficacy

12	64	**Are diluted doses of smallpox vaccine as effective?**	Recent tests have indicated that diluted smallpox vaccine is just as effective in providing immunity as full-strength vaccine.
12	99	**If someone is exposed to smallpox, is it too late to get a vaccination?**	Vaccination within 3 days of exposure will completely prevent or significantly modify smallpox in the vast majority of persons. Vaccination 4 to 7 days after exposure likely offers some protection from disease or may modify the severity of disease.
12	174	**Is an inadvertently inoculated person considered immune?**	Yes, an inadvertently inoculated person who develops a “take-like” reaction at the inoculation site should be considered immune.

A. Characteristics/Duration of Immunity

13	66	**How long does a smallpox vaccination last?**	Past experience indicates that the first dose of the vaccine offers protection from smallpox for 3 to 5 years, with decreasing immunity thereafter. If a person is vaccinated again later, immunity lasts longer.

Smallpox Q and As

13	69	**Is there any need for people who have been vaccinated for smallpox as children to be vaccinated?**	Yes. Smallpox vaccination provides high level immunity for 3 to 5 years and decreasing immunity thereafter. Someone who was vaccinated decades ago may retain some immunity but it is not known for certain that this level of immunity would protect them from smallpox. Now, the CDC is recommending that members of smallpox healthcare response teams who have not been vaccinated for smallpox in the past 3 years get the vaccine.

A. Characteristics/Response to vaccination

14	25	**"Equivocal" is given as a category for take evaluation. How is "equivocal" defined?**	A definition for an equivocal response can be obtained at the following web site: http://www.bt.cdc.gov/training/smallpoxvaccine/reactions/normal_accelerated.html. Basically an equivocal reaction is a reaction that is not "typical primary" or "major." Equivocal reactions may include allergic reactions and no reaction.
14	41	**For persons who recall having repeated smallpox vaccinations in childhood, none of which resulted in "takes," should they be allowed to volunteer for response teams?**	People who failed to have a "take" as a child may have a take now and may still volunteer for response teams. If the volunteer still fails to demonstrate a "take" (after two attempts to vaccinate), they should not participate in the smallpox response team.
14	225	**My vaccination record shows that I had a "major reaction" to smallpox in the past, does that mean I should not get the vaccine? Am I at risk from the vaccine?**	No. The term "major reaction" does not refer to a bad reaction to the vaccine, it is the terminology used to describe a successful vaccination. A "major reaction" means that virus replication took place and the person who received the vaccine is protected. Individuals who have had smallpox vaccine in the past and experienced "major reactions" are less likely to have side effects from the vaccine.
14	254	**How often are you allowed to revaccinate if 2nd vaccination is not taken?**	Please refer to http://www.bt.cdc.gov/agent/smallpox/ smallpox vaccination guidelines provided by CDC for the answer to this question.

Smallpox Q and As

14	282	**How much time does it take to mount an effective antibody response once vaccinated?**	The immune response to the smallpox vaccine is a complicated process involving both humoral and cellular immune processes. Studies of antibody production in human subjects showed no antibody up to the 10th day, after which neutralizing and hemagglutinin inhibition (HI) antibodies were present in most and complement fixation (CF) antibodies in fewer than 50%. The neutralizing antibodies persist for years after infection.
14	320	**What advice to do you have for those individuals who have two non-takes? Should an expert be consulted? Blood samples taken?**	Expert consultation will not offer anything. May look at antibody level. The only evidence of protection is a take. Assurance will not come from blood studies. If all others vaccinated had a take, there may be a research interest in doing additional studies on the immuno-response to smallpox.
14	323	**If a person has received secondary vaccinia, are they immune?**	If an individual has received vaccinia indirectly from a vaccinated person, they are immunized if they developed a vesicle, i.e. a "tale."
14	324	**If a vaccinee is vaccinated twice with no "take", but was successful with a childhood vaccination, is the vaccinee immune?**	At this time the only proven indication of protective immunity is a vaccine take. Although lack of a take might indicate persistence protective immunity from the childhood vaccination, we can not be sure this is the cases. Consequently, you should assume that two non-takes indicate that the individual is not immune no matter the history of smallpox vaccination. Persons with high titers of neutralizing antibody to vaccinia may not develop a vesicle after smallpox inoculation. Given that most growing up in the U.S. will not have been vaccinated for 20 or 30 years, most people are unlikely to have high levels of residual immunity to smallpox. Consultation with knowledgeable expert should occur when there are two non-takes.
14	325	**If a vaccinee is vaccinated twice and it does not "take", but has no vaccination history from childhood, does the clinic need to verify vaccination history before vaccinating?**	At this time the only proven indication of protective immunity is a vaccine take. Although lack of a take might indicate persistence protective immunity from the childhood vaccination, we can not be sure this is the cases. Consequently, you should assume that two non-takes indicate that the individual is not immune no matter the history of smallpox vaccination. Persons with high titers of neutralizing antibody to vaccinia may not develop a vesicle after smallpox inoculation. Given that most growing up in the U.S. will not have been vaccinated for 20 or 30 years, most people are unlikely to have high levels of residual immunity to smallpox. Consultation with knowledgeable expert should occur when there are two non-takes.

Smallpox Q and As

14	326	**Do non-health care workers need any type of "site check" other than confirmation of take?**	In general, non-health care workers would not need to have a trained observer evaluate their sites before beginning their work duties. The need for frequent site checks is based on the probability that the worker will come in direct contact (i.e., with their vaccination site or their clothing or hands contaminated with material from the vaccination site) with other persons during the course of their job duties. The need for site checks and reinforcing hand hygiene is even more important if direct contact is likely between the vaccinee and persons at high risk for severe adverse events from the vaccine. If this is likely, then there should be a system that helps assure that the vaccination sites of workers are well covered and they have washed their hands after touching the vaccination site or material from the vaccination site before starting their job duties.
14	329	**How should site checks be performed for the first health care workers to be vaccinated? Since the report of the take will not immediately be known.**	While vaccination of persons doing site care is recommended, good infection control procedures such as wearing gloves, and proper disposal of medical waste is adequate to protect the person doing the site check.
14	445	**What is the recommended timeframe for revaccination on non-takers?**	If their vaccination site is looked at on Day 7 & found to be a non-take, immunize immediately or any time thereafter.
14	524	**How do I know if the vaccination is successful?**	If the vaccination is successful, a red and itchy bump develops at the vaccination site in three or four days. In the first week after vaccination, the bump becomes a large blister, fills with pus, and begins to drain. During week two, the blister begins to dry up and a scab forms. The scab falls off in the third week, leaving a small scar. People who are being vaccinated for the first time may have a stronger “take” (a successful reaction) than those who are being revaccinated.

B. Vaccine Administration/Reconstitution

17	245	**Can we aliquot the smallpox vaccine into smaller containers?**	No. This would be a violation of the FDA licensure regarding the repacking of pharmaceutical supplies.

Smallpox Q and As

17	298	**Once the 100 dose DryVax vaccine is reconstituted what time period must it be used in?**	The package insert indicates 15 days, however a letter was issued by the FDA that extends the shelf life to 60 days. This letter is being forwarded to health officials through ASTHO, NACCHO, CSTE, and APHL
17	303	**Is the policy for storing reconstituted vaccine 30 or 60 days?**	60 days is the office guideline from FDA

B. Vaccine Administration/Site of vaccination

18	296	**What is the optimal size of the semi-permeable dressing for the vaccination site?**	The bandage should be large enough to cover the pustule or scab at the site of the vaccine and provide a barrier to vaccinia virus. In a recent study, the average size of the pustule at the vaccination site was half an inch and the average size of the erythema, or swelling, at the vaccination site was 2/3 of an inch.

B. Vaccine Administration/Method of vaccination

19	68	**How is the vaccine given?**	The smallpox vaccine is not given with a hypodermic needle. It is not a "shot," like many vaccinations. The vaccine is given using a bifurcated (two-pronged) needle that is dipped into the vaccine solution. When removed, the needle retains a droplet of the vaccine. The needle is then used to prick the skin a number of times in a few seconds. The pricking is not deep, but it will cause a sore spot and one or two drops of blood to form. The vaccine usually is given in the upper arm.
19	83	**Is the smallpox vaccine given with a syringe?**	No. The vaccine will be administered with a bifurcated needle. This type of needle is very effective. It w as used in the global smallpox eradication program.

Smallpox Q and As

19	209	**What bifurcated needles can be used with the smallpox vaccine?**	The Food and Drug Administration has approved a new 100-dose kit for the administration of Dryvax smallpox vaccine with Precision bifurcated needles. Only Precision bifurcated needles were included in the approved kit. Any change in the kit would require FDA review.
19	284	**Does the CDC see any problem with the use of the Univec safety (shielded) bifurcated needle?**	This needle is not licensed for use with the smallpox vaccine. It has not yet been shown to be safer than the needle included with the vaccine.
19	290	**What does the bifurcated needle look like?**	The bifurcated needle is approximately 2-1/2 inches long with a very small two-pronged needle at one end. The prongs have a very small opening between them that holds the vaccine to be applied to the arm. The prongs are 1/16 inches long and are used to pierce the outer layer of the skin only. A photograph is available at http://www.bt.cdc.gov/agent/smallpox/images/hand_position_for_vaccination.jpg.
19	291	**Is the CDC recommending that only the bifurcated needle accompanying the vaccine vials be used?**	Yes. The needle accompanying the vaccine in the vaccine kits is the only needle that has been licensed for use with this vaccine. No other needles are recommended for use with this vaccine.
19	315	**Does the use of the bifurcated needles supplied with the vaccine violate OSHA standards regarding use of needles with devices that prevent needle sticks?**	CDC understands and supports the importance of providing a safe work environment for vaccinators. The bifurcated needle that is the only FDA licensed needle for use with the vaccine, and is packaged with the smallpox vaccine as part of the licensed vaccine kit. This needle is immediately discarded after use. No reports of injuries associated with bifurcated needles were reported by CDC before 1972 when routine smallpox vaccination was stopped. Between 1983 and 2001, more than 8,000 laboratory workers received smallpox vaccine and no injuries to vaccinators or others from bifurcated needles were reported by CDC, although there was no surveillance system in place for needlestick injuries. CDC will explore the need to seek new or modified devices to deliver smallpox vaccine.

Smallpox Q and As

19	316	**How many times should a person be pricked with a bifurcated needle when being vaccinated? Is there a difference between persons being vaccinated the first time as compared to persons who have been vaccinated in the past?**	Vaccinators should follow the instruction in the package insert. Persons being vaccinated for the first time should be pricked 2-3 times. Persons being re-vaccinated should be pricked 15 times.
19	317	**Is CDC training vaccinators to insert the bifurcated needles one-eighth inch into the skin?**	CDC is training vaccinators to insert the needle with sufficient pressure to enter the superficial layers of the skin so that a few drops of blood appear after the indicated number of pricks. This is a matter of experience, but does not require that the bifurcated needle be inserted 1/8 inch into the skin. The tines of the bifurcated are approximately 1/8 inch in length and this fact may be the cause of the confusion. However, vaccinators are not being taught to completely insert the bifurcated prongs (i.e. as far as they can go).
19	319	**Which needle has been approved for vaccination?**	The needle that comes with the vaccine is the only evaluated needle that has been approved for vaccination. There is another needle under consideration but it has not been evaluated or approved by the FDA. A Q and A on this will be placed on the Web soon, probably on 12/31/02.
19	395	**Is the statement on the use of the bifurcated needle on the CDC Web Site?**	Yes, it's on the Smallpox site.
19	489	**Is there any way to get an extra supply of bifurcated needles? With only 100 supplied per 100 dose vial, you'll have a problem if you drop a couple on the floor!**	Vaccine kits will include 100 individually wrapped needles as part of the kit. Since each vial contains 100 doses of vaccine, this should be an adequate supply of needles. However, if a project area runs into problems, they should have their NPS coordinator contact the National Pharmaceutical Stockpile at the number provided in the shipping instructions.
19	520	**Some documents say that no skin prep be done, in others it says use acetone. What can be used?**	In general, alcohol, soap and water, or other chemical agents are not needed for preparation of the skin for vaccination unless the area is grossly contaminated. If needed, soap and water are the preferred cleaning agents. If any cleaning agent is used, the skin must be thoroughly dry in order to prevent inactivation of the vaccine.

B. Vaccine Administration/Other

Smallpox Q and As

20	154	**Can vaccinators immediately begin inoculating others after they've been vaccinated or should they wait a period of time and if so, how much time?**	They can begin vaccinating others immediately. Vaccinators are vaccinated in part to assure that they have been screened to receive vaccine, so that someone who has a contraindication is not administering vaccine and taking the chance that they are accidentally exposed. Vaccinators need to remember that they too may experience fever, fatigue and other side effects as well as robust reactions at the site. If they wait to be vaccinated until they begin work immunizing others, they may not feel well enough and will need to deal with the reaction sites in the midst of the vaccination clinics. Consequently, while it is not mandatory, it may be better to try to vaccinate the clinic's staff 2 or 3 weeks before the clinics are scheduled to open.
20	486	**Is the FDA approval document for smallpox vaccine available for distribution to hospitals?**	"This information is available at the following website: HTTP://www.fda.gov/cber/products/smalwye102502.htm"

C. Smallpox vaccine storage and handling

21	90	**How long can reconstituted smallpox vaccine be stored?**	Properly reconstituted and maintained Dryvax vaccine can be stored and used for 60 days after being reconstituted. During that time it may be kept at normal room temperature during the course of a clinic session and then placed back into refrigeration at 2 to 8°C when not in use. The reconstituted vaccine can remain in storage between 2 to 8°C when not in use during those 60 days.
21	91	**The package insert says the reconstituted vaccine should be stored for 15 days. Why is there a discrepancy?**	Wyeth Pharmaceuticals, the manufacturer of Dryvax, sent a letter to the attention of CDC stating that the FDA approved additional data that Wyeth submitted to support the storage of the reconstituted vaccine for 60 days at 2 to 8°C. This letter will accompany each kit of vaccine. Please note that the date of reconstitution should be recorded directly on the vaccine vial in the space provided.
21	141	**Is smallpox vaccine light sensitive?**	The vaccine package insert does not indicate that the vaccine is light sensitive.

Smallpox Q and As

21	**142**	**How do you suggest protecting the smallpox vaccine from light between vaccinations?**	It is not necessary to protect the vaccine from light.
21	**145**	**Can we aliquot the smallpox vaccine into smaller containers?**	No. This would be a violation of the FDA licensure regarding the repacking of pharmaceutical supplies.
21	**253**	**Do we need to worry about maintaining the vaccine at a certain temperature while it's out during the vaccination clinic?**	Normal ambient room temperature is acceptable.
21	**256**	**Do we really need to use cardboard to separate the vaccine from the cold packs? We've always used paper.**	Any inert substance may be used to separate the vaccine from the cold source. This may be corrugated cardboard, crumpled paper, styrofoam peanuts, etc.
21	**258**	**How do you suggest protecting the smallpox vaccine from light between vaccinations?**	It is not necessary to protect the vaccine from light.
21	**263**	**How do we get these "holders" mentioned during the broadcast?**	Stability holders will be shipped to you as part of the supplies provided by the National Pharmaceutical Stockpile.

Smallpox Q and As

21	286	**Other resources indicate different information on the storage and handling of smallpox vaccine. Which is correct?**	Both unreconstituted and reconstituted vaccine should be stored at between 2 and 8 degrees C when not in use. It may be kept at normal room temperature during the course of a clinic session and then placed back into refrigeration. The vaccine is good for 60 days after being reconstituted and may be taken in and out of refrigeration as many times as needed during the course of those 60 days.
21	287	**What are the guidelines for care and handling of the vaccine vial?**	Both unreconstituted and reconstituted vaccine should be stored at between 2 and 8 degrees C when not in use. It may be kept at normal room temperature during the course of a clinic session and then placed back into refrigeration. The vaccine is good for 60 days after being reconstituted and may be taken in and out of refrigeration as many times as needed during the 60 day time frame.
21	288	**What do we do with the smallpox vaccine if we determine it has been frozen? If it hasn't been reconstituted, wouldn't it be okay?**	You should contact the manufacturer for a determination.
21	500	**Can vaccine that has been reconstituted and used for 4 hours be refrigerated overnight and then reused the next day?**	Yes. Please follow the package insert directions (Store reconstituted vaccine at 2-8 degrees C [36-46 degrees F] when not in actual use. The vaccine may be stored for no more than 60 days after reconstitution).

D. Vaccination site care and precautions for recipients

22	131	**Can I share a bed after vaccination?**	Special care must be taken following vaccination with the smallpox vaccine in order to avoid contact spread of vaccinia. If specific precautions are followed, then individuals who have been vaccinated can share a bed with others. These precautions are: The vaccination site must be covered with a gauze bandage held in place with medical tape. As an extra precaution, the vaccinated person should wear a t-shirt or pajamas that cover the vaccination site. If the individual who has been vaccinated is not following these precautions then it is better not to share a bed. These precautions must be followed until the scab that forms at the site of the vaccination falls off on its own (2 to 3

Smallpox Q and As

22	137	**How should bed linens and clothing that has been in contact with the vaccination site be handled?**	Clothing or any other material that may have come in contact with the vaccination site and therefore be contaminated with vaccinia should be handled with special care. A separate hamper should be used for these items. Contact with these items should be kept to a minimum. These items should be laundered in hot water with detergent and/or bleach. After handling, individuals should wash their hands thoroughly in warm water with soap or with an alcohol-based hand rub, such as a gel or foam. If hands are visibly contaminated with fluids from the vaccine, then individuals should wash them with warm water and soap.
22	140	**Is it safe to have clothes that have covered the vaccine site dry cleaned?**	No. Vaccinia is spread by touching a vaccination site before it has healed or by touching bandages or clothing that have become contaminated with live virus from the vaccination site. After you get vaccinated, you must follow instructions for care of the vaccine site in order to avoid spreading vaccinia. (See the fact sheet, Caring for the Smallpox Vaccination Site). This includes washing any clothing or other material that may have come in contact with the vaccine site in hot water with detergent and/or bleach. You should be able to launder any clothes that come in contact with the vaccine site in this way.
22	144	**Can I prepare food for others while my vaccination site is "active"?**	Individuals who have been vaccinated can cook and clean normally as long as they wash their hands after contact with the vaccination site or any potentially contaminated materials.
22	162	**What is the risk of spreading vaccinia to co-workers?**	The risk of spreading vaccinia to co-workers in a health care setting is extremely low if proper hand hygiene and site care instructions are followed. Vaccinia is spread by touching vaccine, a vaccination site, or by touching bandages or clothing that have become contaminated with live virus and then touching yourself or another person. In order to reduce the risk of contact spread of vaccinia, site care instructions mandate that the vaccine site remain covered with a gauze bandage and that health care workers involved in direct patient care cover the gauze with a semi-permeable dressing as an additional barrier to vaccinia spread. In addition, careful hand hygiene is necessary to minimize the risk of contact spread of vaccinia. Hands should be washed after having direct contact with vaccine, the vaccination site, or anything that might be contaminated with live virus (bandages, bedding, etc…) Wash hands with soap and water or use alcohol-based hand rubs, such as gels or foams. If hands are visibly contaminated with fluids, then washing with soap and water is required. In the past, most cases of contact spread of vaccinia occurred in the vaccinees themselves. Spread to other individuals almost always occurred with the type of close physical contact that occurs in the household or in similar situations where careful hand hygiene and site care may not be followed. In the past, spread of vaccinia virus to contacts was reported to occur between 20 and 60 times in 1 million people vaccinated.

Smallpox Q and As

22	169	**Do healthcare workers who have been vaccinated need to wear masks when working with immunocompromised patients?**	No. Vaccinia, the live virus in the smallpox vaccine, is spread by touch. Vaccinia has not been shown to spread through airborne contagion.
22	176	**Can a person travel outside of the country after being vaccinated? How soon?**	There are no restrictions on travel following vaccination. However, you may not feel like traveling for a few days after getting the vaccine (usually about a week or so after vaccination). Most people experience normal, usually mild reactions that include a sore arm, fever and body aches. In recent tests, one in three people felt bad enough to miss work, school, a recreational activity, or had trouble sleeping after getting the vaccine.
22	183	**Can someone who recently has been vaccinated swim in a public pool?**	The vaccination site should be kept dry at all times. A water-resistant pad, such as a waterproof band-aid is required for showering. It would be difficult to keep the vaccination site dry during swimming. It is probably wise not to swim.
22	188	**If a recently vaccinated person goes swimming in a pool or lake before their vaccination site scab falls off, can vaccinia virus spread to others through the water?**	Because the vaccination site should be kept dry at all times, vaccinees should not go swimming until their vaccination site has healed and the scab has fallen off. If, however, someone shed vaccinia virus into a swimming pool, the virus would be killed by the chemicals that are used to keep the pool clean (e.g., chlorine). It is unknown though considered unlikely that the vaccinia virus could be transferred in other bodies of water such as lakes. There have been no reported cases of this type of transmission. Data from the 1950s and 1960s indicate that the transfer of vaccinia virus requires close contact and is an unusual occurrence outside the home (rarely, there have been contact transmission cases in which the contact source was unknown).
22	327	**Are recent vaccinees allowed to work out in a gym and if so, do they need to have a non-occlusive bandage and sleeves?**	There is no reason that the vaccinee cannot work out in a gym; however, care must be taken to ensure that the vaccination is covered with gauze and bandage. The vaccinee should also wear a shirt that covers the site. As they work out, it is important that body fluid from the site does not penetrate their clothing. Vaccinees may want to consider a water-resistant bandage to keep the site dry if they sweat extensively.
22	330	**Firemen who work a 12 on/12 off schedule and sleep at the fire house, should the bed linens be changed prior to someone else sleeping in the bed?**	The bed linens used by a person whose vaccination site has not completely healed should be replaced before another person uses the bed.

Smallpox Q and As

22	331	**Do police officers need to wear the semi-occulsive bandages since they may have physical contact with people with contraindications?**	The need for a semi-occlusive bandage at work is dependent on the possibility of direct contact between the worker's vaccination site and some other person, especially someone at high risk for a severe adverse event. Healthcare workers routinely need to exercise good infection control procedures during patient care and the ACIP recommendations specifically address the use of semi-occlusive dressings in health care workers but this would not preclude other persons from using these dressings if the situation warrants. In general, the level of physical contact (i.e., directly with their vaccination site or their clothing or hands contaminated with material from the vaccination site) between people with contraindications and police officers will than that which occurs between healthcare providers and patients. However, the circumstances and job duties may vary from place to place and should be decided based on the individual situations. For example, if the security officer works in a correctional facility that incarcerates a large number of persons at high risk for HIV and the officer must frequently restrain or otherwise come in direct physical contact with inmates, the vaccination site should be covered (a semi-occlusive dressing may be a prudent measure) and the officer should be reminded of the importance of using good hand hygiene to prevent spread of the vaccine virus to other parts of their body or to others.
22	332	**For vaccinees who do not have direct patient care, do they have to wear the semi-occlusive bandage?**	The need for a semi-occlusive bandage is dependent on the probability of direct contact between workers' vaccination sites and other people, especially those at high risk for adverse events. If a person is using gauze to cover their bandage, then the plain gauze held in place by tape or an adhesive strip should be sufficient. Vaccinees should remember that it is permissible and even desirable to let their vaccination sites go without any covering as long as there is not a risk of direct contact with others (e.g. at home and alone). They should also be reminded of the importance of hand hygiene in preventing transmission of the vaccine virus.
22	333	**For vaccinees who do not have direct patient care, is plain gauze okay or does the gauze need to be coated?**	The need for a semi-occlusive bandage is dependent on the probability of direct contact between workers' vaccination sites and other people, especially those at high risk for adverse events. If a person is using gauze to cover their bandage, then the plain gauze held in place by tape or an adhesive strip should be sufficient. Vaccinees should remember that it is permissible and even desirable to let their vaccination sites go without any covering as long as there is not a risk of direct contact with others (e.g. at home and alone). They should also be reminded of the importance of hand hygiene in preventing transmission of the vaccine virus.
22	334	**For vaccinees who do not have direct patent care, do they need to wear waterproof bandages in the shower or bath?**	The purpose of keeping the vaccination site as dry as possible is to prevent maceration promoting the healing process and also to keep the body fluids at the site from spreading to other places on the body. A drop or two of water accidentally splashed on the site will probably do no harm, but the vaccinee should not immerse the arm into a bath or let the shower water run directly over the site until it is healed. Should the site become very wet inadvertently, then the vaccinee should blot the site dry. The vaccinee can use various methods to keep the arm dry during a shower or bath including use of waterproof bandaging.

Smallpox Q and As

22	360	**What is the specific URL address of the PVS test system?**	The test site will be available to the states after January 6th, 2003. It will be located outside of CDC's firewall.
22	474	**How should I handle bed sheets and clothing that has come in contact with my vaccination?**	Clothing or any other material that may have come in contact with the vaccination site and therefore be contaminated with vaccinia should be handled with special care. A separate hamper should be used for these items. Contact with these items should be kept to a minimum. These items should be laundered in hot water with detergent or bleach. After handling, individuals should wash their hands thoroughly in warm water with soap.
22	502	**Would a "Tagidern" bandage suffice as a semi-permeable bandage for vaccinators giving shots?**	When health care workers are engaged in patient care activities, they should have their vaccination sites covered with a gauze bandage, which then is covered by a semi-permeable dressing. Tegaderm is one of the commercially available dressings that may be used.

E. Transmission of vaccine virus

23	111	**Can vaccinia be spread through the air?**	Vaccinia is spread by touch. Vaccinia has not been shown to spread through airborne contagion.
23	277	**Is it possible to get vaccinia, the virus in the vaccine, from someone who has recently been vaccinated?**	Yes. Vaccinia is spread by touching a vaccination site before it has healed or by touching bandages or clothing that have become contaminated with live virus from the vaccination site. Vaccinia is not spread through airborne contagion. The vaccinia virus may cause rash, fever, and head and body aches.

F. Adverse Events and Vaccine Safety/General

Smallpox Q and As

25	86	**How safe is the smallpox vaccine?**	The smallpox vaccine is the best protection you can get if you are exposed to the smallpox virus. Most people experience normal, usually mild reactions that include a sore arm, fever, and body aches. In recent tests, one in three people felt bad enough to miss work, school, or recreational activity or had trouble sleeping after receiving the vaccine. However, the vaccine does have some risks. In the past, about 1,000 people for every 1 million people vaccinated for the first time experienced reactions that, while not life-threatening, were serious. These reactions include a vigorous (toxic or allergic) reaction at the site of the vaccination and spread of the vaccinia virus (the live virus in the smallpox vaccine) to other parts of the body and to other people. These reactions typically do not require medical attention. Rarely, people have had very bad reactions to the vaccine. In the past, between 14 and 52 people per 1 million vaccinated experienced potentially life-threatening reactions, including eczema vaccinatum, progressive vaccinia (or vaccinia necrosum), or postvaccinal encephalitis. Based on past experience, it is estimated that between 1 and 2 people out of every 1 million people vaccinated may die as a result of life-threatening reactions to the vaccine. Careful screening of potential vaccine recipients is essential to ensure that those at increased risk do not receive the vaccine. People most likely to have side effects are people who have, or even once had, skin conditions, (especially eczema or atopic dermatitis) and people with weakened immune systems, such as those who have received a transplant, are HIV positive, or are receiving treatment for cancer. Anyone who falls within these categories, or lives with someone who falls into one of these categories, should NOT get the smallpox vaccine unless they are exposed to the disease. Pregnant women should not get the vaccine because of the risk it poses to the fetus. Women who are breastfeeding should not get the vaccine. Children younger than 12 months of age should not get the vaccine. Also, the Advisory Committee on Immunization Practices (ACIP) advises against non-emergency use of smallpox vaccine in children younger than 18 years of age.
25	136	**Many of us received smallpox vaccinations years ago and don't recall hearing of risks involved or serious consequences occurring. Why are there so many problems with side effects now?**	Even though you don't recall hearing about problems in past years, there were some, according to the Centers for Disease Control and Prevention. The side effects aren't anything new. About 1,000 people for every 1 million people vaccinated for the first time experienced reactions that, while not life-threatening, were serious. These included a vigorous (toxic or allergic) reaction at the site of the vaccination and spread of the vaccinia virus (the live virus in the smallpox vaccine) to other parts of the body and to other people. Although it has been rare, CDC reports that many people have had very bad reactions to the vaccine. In the past, between 14 and 52 people per 1 million vaccinated experienced potentially life-threatening reactions. Additionally, based on past experience, it is estimated that between 1 and 2 people out of every 1 million people vaccinated may die as a result of life-threatening reactions to the vaccine. Please see our online information at www.bt.cdc.gov/agent/smallpox/overview/faq.asp.
25	164	**Is a history of no adverse reactions in childhood to smallpox vaccine a predictor of no or minor reactions to revaccination in adulthood?**	No. Simply because a person did not experience an adverse reaction to the vaccine in childhood does not mean that they will not experience adverse reactions as an adult. Many of the conditions that increase the likelihood of serious adverse reactions may not have been present in childhood (e.g., skin conditions, taking medication that suppresses the immune system).

Smallpox Q and As

25	262	**What is the planned antiviral prophylaxis for vaccinia/smallpox?**	There currently are no protocols for antiviral prophylaxis for vaccinia or smallpox, only treatment protocols.
25	264	**What should I do if I were to inadvertently get some of the reconstituted smallpox vaccine in my eye?**	If someone accidentally gets vaccinia in their eye, via contact with a glove, hand or a splash, they should flush the eye completely with water, as well as wash their face. Baseline evaluation by an ophthalmologist may be considered but is not necessary. Should vaccinia lesions develop in the ocular area, including the eyelids, further evaluation will be necessary.
25	276	**Is there any way to treat bad reactions to the vaccine?**	Two treatments may help people who have certain serious reactions to the smallpox vaccine. These are Vaccinia Immune Globulin (VIG) and cidofovir. By the end of December 2002 there will be more than 2,700 treatment doses of VIG (enough for predicted reactions with more than 27 million people) and 3,500 doses of cidofovir (enough for predicted reactions with 15 million people.) Additional doses of VIG are being produced, and measures are underway to increase supplies of cidofovir as well. VIG and cidofovir are both administered under investigational new drug (IND) protocol.
25	285	**Should health care providers who are contraindicated by excluded from evaluating and caring for people with vaccination complications?**	No, they should not be excluded if they use proper infection control precautions .
25	367	**Would like someone to write a summary of the Israeli decision and outline the four adverse events associated with their vaccination program?**	We are aware of four adverse events in the 15,000+ persons vaccinated in Israel: 1. Vaccinated healthcare worker transmitted vaccinia to her 1-2 year old grandchild. The child developed a few lesions that resolved without complications. 2. Vaccinated surgeon transmitted vaccinia to his wife who was being treated with immunosuppressive therapy. She developed generalized vaccinia and was successfully treated with plasma from a recently vaccinated person. 3. Vaccinee developed myopericarditis that was presumed to be unrelated to vaccination. 4. Vaccinee developed erythema multiforma which resolved without complications.

Smallpox Q and As

25	403	**Did President Bush have any reactions to his vaccination? Did it take? Any adverse events?**	No definite update, but press reports suggest he is doing fine and suffering no adverse reactions.

F. Adverse Events and Vaccine Safety/Eye disease

27	513	**How should an eye splash of reconstituted vaccine be treated.**	If someone accidentally gets vaccinia in their eye, via contact with a glove, hand, etc, or a splash, they should flush the eye completely with water, as well as wash their face. Baseline evaluation by an ophthamologist may be considered but is not necessary. Should vaccinia lesions develop in the ocular area, including the eyelids, further evaluation will be necessary.
27	514	**Do we have any aggregate numbers of those in the U.S. who have contraindications for smallpox vaccination?**	We have been using this summary slide adapted from Freed et al's article as a general guide (see the URL below). More precision would be nice, but the general estimate that 15% have contraindications themselves is useful, with 10% more excluded because of conditions in the household, although the number on medications as mentioned below is unknown. We are currently evaluating the estimates on immune suppression, non-cancer immunosuppressive conditions, etc.

F. Adverse Events and Vaccine Safety/ Other

33	328	**If a patient has an adverse event and hospital consults with CDC, when will they receive the VIG and how will it get to the patient location?**	CDC will ship from the stockpile directly to the patient location within 12 hours.
33	338	**If a patient presents with an adverse event, who should the physician contact - CDC or State?**	The process will vary from state to state. Each state will establish its own adverse event clinical support and monitoring system. CDC will provide 24/7 hotlines that can be used to supplement and support state systems including consultation regarding use and rapid distribution of VIG and cidofovir.

Smallpox Q and As

33	341	**What are the algorithms for adverse events**	They have not been completed. They will be made available when completed, possibly by the end of next week. These algorithms are designed to help the health care worker diagnose and treat adverse events from the vaccine.
33	355	**How will adverse events be reported to the State Public Health Systems?**	Each state will establish its own adverse event clinical support and monitoring system. CDC will provide 24/7 hotlines that can be used to supplement and support state systems including consultation regarding use and rapid distribution of VIG and cidofovir. To ensure that we have up-to-date and accurate information on adverse events, both in states and nationally, we expect to use electronic reports to VEARS plus other electronic records of clinical consultations to rapidly accumulate and report information from states to CDC and from CDC to state health departments. We are working on addressing privacy issues related to these reporting systems. We understand that some states may also have legal concerns regarding privacy issues. States should also discuss these issues with their legal staff. We are checking into ways that we can facilitate the adverse event reporting. We will provide additional information as it becomes available.
33	356	**Does each state have the legal authority to report an adverse event?**	We are checking into reporting issues related to privacy
33	389	**Is CDC going to publish the algorithms for AE Management in the MMWR? Can this information be shared?**	Yes. It should be published in mid-January but cannot be universally shared.
33	390	**Is it necessary for the adverse event management training to be held on-site at CDC or can it be done via satellite broadcast?**	CDC feels that the staff needs to be on-site for this training.

Smallpox Q and As

33	392	**Are adverse events reported in PVS?**	No. PVS will provide links to VAERS. Comment: NYC has designed a hybrid form that allows a cross-walk from the NYC patient vaccination system to VAERS in order to upload the information to VAERS. NYC will share form with other grantees.

G. Contraindications and Screening/General

35	21	**If a potential vaccine recipient has a household contact under 1 year of age, is that a contra-indication to vaccination?**	Please see the smallpox vaccine guidance for the answer to this question: http://www.bt.cdc.gov/agent/smallpox/.
35	151	**Who should NOT get the vaccine?**	People who should not get the vaccine include anyone who is allergic to the vaccine or any of its components; pregnant women; women who are breastfeeding; anyone under 12 months of age; people who have, or have had, skin conditions (especially eczema and atopic dermatitis); and people with weakened immune systems, such as those who have received a transplant, are HIV positive, are receiving treatment for cancer, or are taking medications (like steroids) that suppress the immune system. (The Advisory Committee on Immunization Practices [ACIP] advises against non-emergency use of smallpox vaccine in anyone under 18 years of age.) These people should not receive the vaccine unless they have been exposed to smallpox.
35	167	**Can clinic staff refuse to vaccinate someone with contraindications who insists upon being vaccinated despite risk/benefit information?**	Clinic staff are not obligated to vaccinate persons who have valid contraindications.
35	170	**If a person is being revaccinated, do the same contraindications apply?**	Yes, smallpox vaccine contraindications are the same for first-time and revaccinations.

Smallpox Q and As

35	186	**What are the contraindications to revaccination or booster shots if there is an equivocal or negative "take"? e.g., erythema multiforme with or without urticaria to the primary or most recent vaccination?**	The same contraindications that apply to primary vaccinations also apply to revaccinations following equivocal or negative takes.
35	518	**In the event of mass vaccination, is there any hard data on the aggregate number of individuals with contraindications?**	We have been using this summary slide adapted from Freed et al's article as a general guide (see the URL below). More precision would be nice, but the general estimate that 15% have contraindications themselves is useful, with 10% more excluded because of conditions in the household, although the number on medications as mentioned below is unknown. Http://www.acponline.org/journals/ecp/marapr02/kemper.pdfIf an individual is exposed to smallpox, vaccinate. If an individual is not exposed to smallpox and has a contraindication, do not vaccinate. We are working on having a good supply of VIG available, if there is an emergency situation.

G. Contraindications and Screening/Immune suppression

36	155	**Should you get the smallpox vaccine if you have a weakened immune system (e.g., you are immunocompromised)?**	No, you should not be vaccinated, unless there is a smallpox outbreak and you have been directly exposed to the smallpox virus. Vaccination can cause death in people with weakened immune systems. Thus, there is no need to take the risks associated with smallpox vaccination unless you have been directly exposed to smallpox—and even then, you should first consult a physician or health care provider.
36	310	**What are the recommendations regarding persons who regularly use inhaled or topical steroids? Is this a contraindication for administration of the vaccine?**	The Advisory Committee on Immunization Practices in the General Recommendations on Immunization has stated: "The exact amount of systemically absorbed corticosteroids and the duration of administration needed to suppress the immune system of an otherwise immunocompetent person are not well-defined. The majority of experts agree that corticosteroid therapy usually is not a contraindication to administering live-virus vaccine when it is short-term (i.e., <2 weeks); a low to moderate dose; long-term, alternate-day treatment with short-acting preparations; maintenance physiologic doses (replacement therapy); or administered topically (skin or eyes) or by intra-articular, bursal, or tendon injection. Although of theoretical concern, no evidence of increased severity of reactions to live vaccines has been reported among persons receiving corticosteroid therapy by aerosol, and such therapy is not a reason to delay vaccination."

Smallpox Q and As

36	311	**Will dialysis patients be added to the list of those who should not be vaccinated?**	Persons on dialysis with uremia have a variety of immunologic abnormalities that can place them at risk for severe adverse events. These persons probably already meet the criteria for a contraindication due to immunosuppression or acquired deficiencies of the immune system.
36	314	**What individuals should not get vaccine? If all autoimmune diseases are contraindications, why was lupus chosen as the example in CDC's smallpox Bulletin? Bulletin makes it sound as if the disease is reason for not receiving the vaccine.**	It is not the disease that is a contraindication for vaccine but the treatment that individuals are receiving for the disease that causes the problem.
36	519	**Is cancer a contraindication or is the contraindication actually chemotherapy?**	Individuals who have had chemotherapy need to check with their oncologist to determine if they are immunosuppressed prior to receiving a smallpox vaccination.

G. Contraindications and Screening/HIV

37	470	**If someone in my household is at risk for HIV infection, should I be vaccinated?**	If in doubt, in a pre-event situation, do not vaccinate. Should you decide to be vaccinated, you should strictly follow the recommendations for site management guidelines for washing, clothes, and bedding.
37	471	**Someone in my household has HIV infection. Can I be vaccinated for smallpox?**	You should not get vaccinated.

G. Contraindications and Screening/Pregnancy

Smallpox Q and As

38	156	**Pregnant women are discouraged from getting the vaccine. Is there a danger to them (or to an unborn child) if broader vaccination occurs, increasing the potential for contact with vaccinated people?**	Pregnant women should NOT be vaccinated in the absence of a smallpox outbreak because of risk of fetal infection. Inadvertent transmission of vaccinia virus to a pregnant woman could also put the fetus at risk. Vaccinated persons must be very cautious to prevent transmission of the vaccine virus to pregnant women or other contacts.

G. Contraindications and Screening/Children

39	304	**Are children under the age of 12 months in a household a contraindication for the administration of a licensed vaccine to household members?**	Some experts have argued that a specific age cut-off for increased risks of some adverse events (i.e. that an 11 month old has a higher risk than a 15 or 18 month old) is arbitrary and not based on precise data. Vaccinated parents of young children need to be careful not to inadvertently expose their children to their vaccination site no matter what the age of the child. Any potential vaccinee who expects to have frequent close contact with another person, e.g. parenting a small child, should take precautions to eliminate the risk of inadvertently transmitting vaccine virus to this person. These precautions include covering the vaccine site, wearing a sleeved shirt or similar clothing, and careful hand washing anytime after touching the vaccination site, bandages used to cover the site, or items with vaccination site exudates. If s omeone is not sure if they can follow these procedures in all situations associated with the close physical contact, they should consider not being vaccinated or have someone else handle the risky duties in their household In addition, the package insert approved by the FDA does not state that a 'household member <12 months of age' is a contraindication to receipt of vaccine in routine, non-emergency settings.
39	306	**Why does CDC recommend that women who are breastfeeding not be vaccinated against smallpox but mothers who are bottle feeding can?**	Women who are breast feeding must hold their baby in a position that can bring the baby very close to a smallpox vaccination site on an upper arm. Women who are bottle feeding can either let someone else feed the baby or the mother can hold the baby away from the vaccination site while she feeds it. In addition, the FDA approved package insert states that smallpox vaccine is not recommended for use in a nursing mother in a non-emergency setting since it is not known if either the vaccine virus or antibodies are excreted in breastmilk.
39	312	**What is the contraindication policy for volunteers from households with children under 1?**	Vaccinated parents of young children need to be careful not to inadvertently expose their children to their vaccination site no matter what the age of the child. Any potential vaccinee who expects to have frequent close contact with another person, e.g. parenting a small child, should take precautions to eliminate the risk of inadvertently transmitting vaccine virus to this person These precautions include covering the vaccine site, wearing a sleeved shirt or similar clothing, and careful hand washing anytime after touching the vaccination site, bandages used to cover the site, or items with vaccination site exudates. If someone is not sure if they can follow these procedures in all situations associated with the close physical contact, they should consider not being vaccinated or have someone else handle the risky duties in their household The package insert approved by the FDA does not state that having a 'household member <12 months of age' is a contraindication to receipt of vaccine in routine, non-emergency settings.

Smallpox Q and As

39	313	**What individuals should not get vaccine? If all autoimmune diseases are contraindications, why was lupus chosen as the example in CDC's smallpox Bulletin? Bulletin makes it sound as if the disease is reason for not receiving the vaccine.**	It is not the disease that is a contraindication for vaccine but the treatment that individuals are receiving for the disease that causes the problem.
39	318	**What is CDC's position on the protection of small children in households where a health care worker has been vaccinated?**	ACIP has recommended that health care workers with children in the household <12months of age can be vaccinated. These workers need to take precautions to prevent transmission in the home such as using a bandage on the site, wearing a sleeved shirt, and careful hand washing anytime after touching the vaccination site. If there is concern that a person cannot follow precautions, they should consider not being vaccinated or defer their child-caring duties to others in their home until the scab falls off.

G. Contraindications and Screening/Eczema and Atopic dermatitis

40	211	**There are contraindications for persons with eczema or atopic dermatitis to not be vaccinated. How are you defining eczema and do the contraindications include any type of eczema, either current or in the past?**	Although eczema and atopic dermatitis are not the same disease, we recognize that many healthcare providers use the terms interchangeably. Because of that practice, the Advisory Committee on Immunization Practices felt that the risk that an individual with a valid contraindication (e.g., atopic dermatitis) might be inappropriately vaccinated was unacceptable. Thus, the committee elected to combine eczema and atopic dermatitis as a single contraindication. However, if the healthcare provider and patient are confident that the rash or diagnosis is not atopic dermatitis or eczema (being used as the label for actual atopic dermatitis), then the patient may be vaccinated provided there are no additional contraindications. An individual who has resolved eczematous rash (e.g., contact dermatitis) may be safely vaccinated because the contraindication would apply while the rash was in the active state.
40	305	**The definition of eczema as "a red, itchy spot that lasts two weeks and then comes and goes" is too broad and could cause a number of unnecessary claims of a contraindication to vaccine.**	The definition of eczema was established by an experienced group of dermatologists on the American Academy of Dermatology's Bioterrorism Taskforce. They reviewed the available literature and proposed the above definition of eczema to the Advisory Committee on Immunization Practices (ACIP).). The ACIP understood that this definition is highly sensitive but elected to be cautious in a non-emergency situation. Persons meeting this definition, without a previous diagnosis of eczema, should consult their treating physician to assess their risk for adverse reactions before they are vaccinated.
40	450	**I have a history of eczema even though I was vaccinated at a child. Is my eczema considered to be a contraindication?**	This person cannot be vaccinated. The contraindication still stands even though he had no adverse reactions to receiving the vaccine as a child. A history of eczema/atopic dermatitis is a contraindication to smallpox vaccination, unless the person has been exposed to actual smallpox and needs the vaccine to lessen the risk that he will come down with smallpox. Even though the Dr. writing reports a history of a previous vaccination without complication, without exposure to smallpox, it is not recommended that he be vaccinated.

Smallpox Q and As

40	473	**I have a history of eczema in childhood? Can I be vaccinated?**	Eczema or atopic dermatitis whether current or in past history is a contraindication for smallpox vaccination.

G. Contraindications and Screening/Other skin diseases

41	451	**How is contact dermatitis defined? Can a person be vaccinated if they have a history of contact dermatitis, but not an active condition?**	A person with a history of contact dermatitis can be vaccinated, but a person with an active case cannot be vaccinated. Contact dermatitis is usually an acute condition that resolves once exposure to the skin irritant ends. A person who truly has this condition, as diagnosed by a physician, can be vaccinated once the skin has healed. A history of contact dermatitis, without active disease, is not a contraindication to vaccination.
41	480	**Is rosacea one of the skin conditions that should keep me from getting vaccinated?**	

G. Contraindications and Screening/Allergies

42	180	**In the webcast, "previous allergic reaction to vaccine" was listed as a contraindication to receiving a smallpox vaccination. Does this apply to reactions to other vaccines as well as the smallpox vaccine?**	No, this only applies to smallpox vaccine or any of the smallpox vaccine's components including polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, and neomycin sulfate.
42	525	**I am allergic to eggs. Can I still get vaccinated against smallpox?**	An egg allergy is not a contraindication to smallpox vaccination. Egg is not used in the manufacture of the vaccine.

G. Contraindications and Screening/Other

Smallpox Q and As

43	159	**Is there any particular risk for adverse reactions from people who wear contact lenses?**	Vaccinia infection of the eye is a potentially serious complication of vaccination and can lead to altered vision. Therefore, all vaccinees need to be very careful to not inoculate the vaccinia into the eye. You should do several things to ensure you do not inoculate virus into your eye. Covering the vaccine site with gauze, tape, and a sleeved shirt or similar clothing, and careful hand washing decreases the chance of inadvertently getting vaccinia virus on your hands and possibly into your eye. Additionally, you should take extra care to wash your hands before handling your contact lenses.
43	307	**Is there an upper age cut-off for vaccine recipients in a non-emergency setting?**	The vaccine's package insert notes that there are no published data that supports the use of smallpox vaccine in a geriatric population and does not recommend its use in this group in a non-emergency situation. The definition of "geriatric" commonly used in vaccination programs is 65 years of age and older.
43	309	**What is the risk to sexual partners of vaccinees?**	Anytime there is prolonged, intimate contact such that a person can come into physical contact with a vaccinee's uncovered vaccination site or fluid from a vaccination site there is the possibility of transmission of vaccinia virus to the contact. Should the contact have risk factors such as a history of eczema or immunosuppression, then there is an increased risk that a severe or life threatening adverse event could occur.
43	321	**How soon can a volunteer donate blood after being vaccinated?**	The FDA is working on guidance regarding blood donation and we expect that it will be available in the very near future. There will be a deferment period for donation after smallpox vaccination, but we're not sure about the recommended length of deferment.

Smallpox Q and As

43	337	**Can pets be vaccinated? and if so, will they transmit vaccinia to humans?**	During the smallpox era, the only known reservoir for the variola virus was humans. Consequently, there was not a need to vaccinate animals (including domestic pets) to protect them from smallpox. If the question is, "Can vaccinia be transmitted to an animal from a human with an unhealed vaccination site?" The answer is Yes. After all, this vaccine was produced from vaccinia infections that occurred in live calves. Should an animal develop an active vaccinia lesion, then it should be possible to transmit vaccinia virus from that animal to another human. The best protection is to avoid exposing domestic pets to unhealed vaccination sites or to fomites contaminated with fluid from a vaccination site. These are recommendations to avoid human to pet transmission: Do not let animals sniff or have direct contact with the vaccination site or the bandages, clothing, sheets, etc that have been direct contact with the scab Keep pets out of the room when you are changing bandages or changing clothes Before allowing your pet back in the room after you have changed your bandage, place the bandage in a sealable plastic bag before disposal into the trash. Put any clothing that had contact with your scab in the laundry and wash your hands well after touching the site or dressing Make sure that pets and other animals do not have access to trash containers that have bandages in them.
43	435	**Are use of inhaled Corticosteroids for the treatment of asthma a contra-indication for receipt of smallpox vaccine?**	Most dosages would not cause immunosuppression. Use of high-dose corticosteroid therapy [i.e., >2 mg/kg body weight or 20 mg/day of prednisone for >2 weeks] is contraindicated. Patients should contact their physician to find out whether their dosage would cause immunosuppression.
43	478	**I have a cat who scratches me. Can I get vaccinated despite the scratches?**	Yes, you can.
43	479	**If I have a significant rash I should not be vaccinated right away. What is a significant rash?**	A significant rash will be any type of rash provoked by an illness or allergic reaction to a medication, unlike a skin rash caused by skin irritation with clothes or a watch.

Smallpox Q and As

43	504	**If a person is allergic to tetracycline HCL, is this a contraindication for Dryvax?**	Chlortetracycline is a tetracycline and there is a possibility of an allergic reaction, if one is allergic to tetracycline. So these patients should not receive vaccines that contain chlortetracycline (Dryvax).
43	523	**Is there a listing of ALL meds contraindicated for being vaccinated against smallpox**	There is no list at this time, but one would be extensive. Persons who are uncertain whether or not they are taking a medication that causes immunosuppression should consult with their prescribing physician before reporting to a vaccination clinic.

H. Laboratory testing related to vaccination/Specimen collection

45	365	**Disposition of Lab questions?**	APHL should send all lab questions directly to Russ Regnery or Inger Damon. If other issues are included, they will forward to Larry for completion.

I. Healthcare Infection control issues re:vacc/Mngmnt of vacc healthcare workers

64	148	**As a healthcare worker who has just been vaccinated, what is considered adequate hand washing? Can I use alcohol wipes?**	Hand hygiene is necessary after direct contact with the vaccine, the vaccination site, or the bandage. This is vital in order to remove virus from the hands and prevent contact spread of vaccinia. You can either wash your hands with soap and water or use alcohol-based hand rubs, such as gels or foams. If your hands are visibly contaminated with fluids from the vaccine, the vaccination site, or the bandage, then you must wash your hands with soap and water.
64	308	**If a clinician is treating a person with an adverse event, should they also be vaccinated?**	Physicians such as infectious disease specialists, dermatologists and other clinicians who are likely consultants for a severe adverse event may also be good candidates for a hospital's smallpox response team and already be vaccinated. However, it is impossible to predict which physicians may see a person with a severe adverse event The treating physician's best means of protection against contact vaccinia infection is good infection control practices. Vaccination is not necessary.

Smallpox Q and As

I. Healthcare Infection control issues re:vacc/Other

65	195	**Should healthcare providers who have contraindications to vaccination be excluded from evaluating and caring for people experiencing complications from vaccination?**	No, they should not be excluded if they use proper infection control precautions.

J. Vaccine Candidates/General

67	92	**If I am concerned about a smallpox attack, can I go to my doctor and get the smallpox vaccine?**	At the moment, the smallpox vaccine is not available for members of the general public. In the event of a smallpox outbreak, however, there is enough smallpox vaccine to vaccinate everyone who would need it.
67	95	**Should I get vaccinated against smallpox?**	The smallpox vaccine is not available to the public at this time.

J. Vaccine Candidates/Lab workers

68	278	**Will Level A and B Laboratory staff be required to get vaccinated?**	No. Level A and B laboratory staff will not be required to be vaccinated, but vaccination will be offered through the Laboratory Response Network. Generally, however, the amount of virus in specimens for routine clinical laboratory testing, and not virus diagnostic testing, would be low and good laboratory safety practices should protect laboratory staff from exposure. For more information on laboratory safety practices, please see the “Biosafety” section of the Public Health Emergency Preparedness and Response Laboratory Information page.

J. Vaccine Candidates/PH and healthcare response teams

Smallpox Q and As

69	322	**Does a vaccinated health care worker need to inform his/her patients of the vaccination?**	This question was considered at the most recent ACIP meeting and the impression from this meeting was that the healthcare worker did not need to inform patients of their vaccination status. We are continuing to consider this issue and will provide additional guidance in the future. In the meantime, each institution should follow the procedures they use for other infections in healthcare workers that can be transmitted to and present a risk to patients, e.g. hepatitis B and HIV infection.
69	374	**What is the current thinking on vaccinating the vaccinators?**	Vaccinators can be vaccinated at the time they begin vaccinating but it may be preferable to vaccinate vaccinators earlier than that to eliminate the possibility that the vaccinators may be experiencing vaccine-related symptoms and not feel well enough to work for a few days (possibly up to 1/3), usually ~7-10 days after begin vaccinated. Each state will determine how they will vaccinate vac cinators.

J. Vaccine Candidates/Military

70	125	**Will National Guardsmen receive the vaccine?**	Members of the National Guard could be included in the initial (stage 1) vaccination program if they were selected to be part of their state's public health response team or healthcare response team. If so, they would be vaccinated through their state's vaccination program. Some members of the National Guard could be vaccinated under the Federal Military (Department of Defense-DoD) Smallpox vaccination program, depending on the nature of their federal role.
70	350	**When will the military begin vaccinating? If a service or family member needs treatment from a civilian health care provider, what is the process?**	DoD has started immunizations at a few sites. Many more installations will begin Jan.6. If a soldier is away from their duty station and develops an adverse event, s/he should seek care based on the emergent nature of the situation i.e. if it is an acute emergency, the soldier should seek care at the nearest emergency care facility. If it is not an emergency, the soldier can call the Military Medical Support Office (MMSO) at 888-647-6676 or they can contact their unit for instructions. Immediate family members of vaccinated active duty personnel are probably covered as a DOD health care beneficiary (Tricare) and can seek medical care at a military facility or through a Tricare provider as they would for other illnesses. However, family members of Reservists would not necessarily be covered under Tricare and these will be handled on a case by case basis. In these situations the family can call MMSO at the number above or they can contact the Reservist's unit.
70	527	**Will members of the Military Reserves or active-duty Service Members will receive smallpox vaccine?**	Some Reservists and some active-duty Service Members will receive smallpox vaccine, according to the Department of Defense (DoD) policy, based on their roles in healthcare or in sustaining critical military missions. This latter category will focus on roles essential to the accomplishment of U.S. Central Command's missions. For additional details on the DoD Smallpox Vaccination Program and its policies, go to www.smallpox.army.mil.

Smallpox Q and As

J. Vaccine Candidates/Other

71	**353**	**Are grantees sending vaccine to the VA hospitals?**	VA wants the capacity to vaccinate their won workers; at this time it is not anticipated that grantees will send vaccine to VA hospitals. The VA is planning to coordinate their vaccination plans with the states. The VA is planning on contacting states through representatives from VISN (Veterans Integrated Systems Network).

III. Smallpox Program Implementation

A. Data and Information Management

46	**23**	**What did "PVN" stand for? Is this going to be web-based reporting? Does a revaccination use the previous PVN number? Will we be creating consent forms on a computer program?**	PVN is an acronym for Patient Vaccination Number. This number identifies a particular vaccination event for a patient. A revaccination for the same patient would require a second PVN for the second event linked to the first PVN for that patient. Yes, this system is web-based and reports will be in PDF format. A revaccination event should use a new PVN. Each vaccination event should have a unique identifier (PVN). The PVS application uses the PVN from the first vaccination as a patient identifier. Subsequent vaccinations will be linked to the patient record.
46	**232**	**Aggregate totals - should everything be re-sent each time (old totals with the new totals) since CDC is doing a full refresh each time?**	Each day's aggregates should include all record counts up to and including the Extract date.
46	**236**	**Organization section - phone extension is in the minimum data section as required. Some places do not have extension numbers. Should the states send all zeros? Is a null value valid?**	Phone extension should be optional, but it should be included when available.

Smallpox Q and As

46	237	**Organization section - is this the primary contact for a particular organization? For example: LA might want to use the name of a secretary.**	It is the contact who should be called if there is information to be provided to the organization, or issues that must be resolved at the organization. Typically, that would be someone involved in the program management for this campaign on an operational level.
46	239	**Organization section - Category needs to be more fully explained. What is this exactly?**	Category should be: Public Health Response Team, Healthcare Response Team, or Not Applicable. For a Vaccination Clinic use Not Applicable. For Healthcare facility use Healthcare Response Team. For State DOH & Local DOH use Public Health Response Team.
46	240	**When sending in Information, does the sending entity need to continue to send patient information even after the person has a successful take?**	Yes, it is a full refresh.
46	242	**Is Annex 7 complete (requirements for file import) or will there be continued revisions?**	There will be some minor updates based on our effort to respond to last minute requests from the states.
46	243	**Why doesn't the Patient Medical History Form match required data elements for immunization history (selection for childhood is not on Patient Medical History Form)?**	This has been updated and will also include ethnicity, race, and places to record the referring organization address, and the take response location name and address (if different from the vaccination clinic).
46	247	**Please provide the requested clarification on batch date –what is the rationale for needing the hour and minute stamp?**	This is only included to support large clinics where multiple batches may need to be created with the same vaccine and diluent lot numbers in the same day. It allows you to distinguish between the two batches and link the vaccination to the correct batch.

Smallpox Q and As

46	251	**The vaccine batch number is extremely long and cumbersome. Can we generate a unique number which could be linked to the vaccine and diluent lot numbers?**	That is what was intended. The unique system generated number would then represent the combination of the individual fields. All fields including the batch number are included in each vaccination record to simplify file creation.
46	257	**Many extraneous required fields are being added which will not be relevant for mass vaccination, e.g., occupation. This will require later changes to remove the required designation from fields.**	This system is intended to support preparedness by the states and the nation to respond to a smallpox outbreak. Therefore, occupation is required. A number of system changes will be required if this system is used to support mass vaccinations. It is not intended that it would be used 'as is' for a mass vaccination campaign.
46	273	**Why is it necessary to track the diluent lot number? It is not being done today and we need to know the rationale behind requiring this data since it is nothing more that distilled water.**	The change in diluent is what made this vaccine an IND. Diluent lot number is being tracked to allow traceability back to the diluent should there be an issue in its manufacturing or formulation.
46	289	**If the patient isn't vaccinated, do you want a patient record? Where should the non-vaccinated individuals be counted?**	If the patient isn't vaccinated, then we don't want the patient record. They should be included in the appropriate count for numbers not vaccinated.
46	292	**Can a badge number be used instead of first and last name?**	Badge number is sufficient as long as it is lined to vaccination records consistently. The idea is to provide the states with a way to detect if there is an issue with vaccination technique, or with the "take" reading and trace it back to the individual who administered the vaccination or interpreted the take.
46	299	**What is the PVN code and how is it used?**	PVN is a unique number that is associated with the vaccination event. It is the vaccination event ID.

Smallpox Q and As

46	300	**What is a batch?**	Indicates that the vial of vaccine used for the vaccination.
46	301	**Is the batch number associated/combined with the PVN number?**	No, it is an independent number associated with reconstitution of a vial of vaccine.
46	335	**Is the VAERS form adequate to capture the information that is needed?**	Box 24 (manufacturer number) of the VAERS form will be used to record the unique vaccination number that will be assigned at the clinic to each smallpox vaccinee. Data usually submitted on the VAERS form will be sufficient to capture information on non-severe reports. This information will be tracked but not investigated. However, the more severe adverse events will warrant collection of more information than what may be submitted originally to VAERS form, and follow-up will be required.
46	339	**Will individuals who have been vaccinated be issued a "certificate of vaccination?"**	Each state will develop their system for documenting a successful vaccination. CDC has developed a "Proof of Vaccination" form that can be stamped by the vaccinating assistant and given to the vaccinee.
46	351	**Are states going to report specific names and numbers of individuals getting vaccinated?**	No patient-specific information will be reported by CDC. CDC may received named data from some states through the PVS system. CDC will only be reported summary of data received. This may include number of individuals vaccinated, number of hospitals participating, types of adverse events, etc. to the media. The PVS system designed by CDC can collect either individual named or un-named patient data based on the state's decision.
46	352	**Is the IOM going to recommend any major changes to CDC's information?**	The IOM held their first meeting on December 19-20 and have not yet issued their report. They have stated that, if needed, they will issue recommendations quickly.

Smallpox Q and As

46	358	**If a state elects to outsource/use CDC's clinician hotline rather than implementing one, how will the states get their reports from the vendor?**	CDC has asked the vendor to provide the reports directly to the states. Reports from each state will be kept confidential.
46	369	**How will CDC ensure that the paperwork gets to the CDC?**	We hope that state health departments will assist in the IND process by helping get the needed paperwork to CDC as well as taking the lead in communications related to the patient and the adverse event.
46	385	**When will grantees be getting information that needs to be entered into PVS prior to vaccinating?**	Will be discussed during the Training on 1/10.
46	386	**Is it feasible to train hospital staff to do the PVS data entry or should we have public health workers enter the data for Stage I?**	It is probably not feasible to train the hospital staff to enter data into PVS and should be the public health workers in state and local departments.
46	404	**Does each computer in each county need to be certified?**	Each computer that uploads data to the PVS system for archival will require a digital certificate which the CDC will provide through the SDN, or Secure Data Network. The PVS team is preparing to issue those certificates, and the states will be able to begin requesting a certificate very soon. So basically every computer in the state will not need a CDC issued certificate if they are utilizing their own state-supported system (although it would be advisable to use some sort of digital authentication for their state-supported system in the interest of security), and the only machines that would need a CDC issued certificate would be the machines utilizing the SDN to upload their data
46	405	**Must vaxicools be returned immediately after receipt of vaccine or may they be kept by the receiver for redistribution statewide?**	Vaxi cools must be returned immediately

Smallpox Q and As

46	439	**How do they address the SISS (Annex 4) and how do they know what it will contain?**	The Smallpox Immunization Safety System is being developed by NIP. Grantees need to address how they will interface with this system. The SISS will include the elements listed on page 3 of Annex 4. Further guidance will be forthcoming.
46	441	**How can you get copies of the 11 annexes.**	Call the state health department in your state.
46	444	**Where can one acquire vaccine take recognition cards?**	These forms are being revised by CDC. After final approval of revisions is obtained, the forms will be sent electronically to state BT programs. States can adapt the forms for their own use.
46	460	**Take Recognition Cards - we have contacted Logical Images and are considering purchasing Take Recognition sheets. Is there anything available from CDC for us to download?**	These forms are being revised by CDC. After final approval of revisions is obtained, the forms will be sent electronically to state BT programs. States can adapt the forms for their own use.
46	465	**We will need to add a lot of people for SDN certification. This usually takes time. How can we speed up the process. Should we download the Microsoft patches we need now?**	We will still have to go through the same process to approve certifications, thus, it is going to take about the same amount of time. We are bringing on additional staff to help with approving certifications and will process them as soon as we can. You will have to have the most up-to-date software and security patches. You should download and install the software and security patches you will need as soon as possible. We only have a limited number of certificates. Therefore we encourage you to think carefully about your needs and only request what you are sure you will use.
46	483	**Has the Mass Vaccination Module developed by Scientific Technologies Corporation been certified?**	No

46	485	**How will we receive the pre-event vaccination numbers?**	Pre-event vaccination numbers will be provided on pre-printed labels that will be distributed with the vaccine. There are more labels per shipment than doses per vial in case of loss or other issues. The PVS application does not generate the numbers, but it does require entry of the number.
46	516	**When will SISS and PVS be ready?**	Please continue to check the website for the most up-to-date information regarding these two systems.

B. Compensation issues

47	402	**What plans does the administration have regarding compensation?**	Workers' compensation may take care of many of these costs but this is state-specific and each state will need to determine what workers' compensation will cover. Several states indicated that worker's compensation would not cover injuries due to smallpox vaccination. It is unlikely that any federal solutions to compensation issues will be available prior to 1/24.

C. Liability Issues

49	15	**What is the purpose of Section 304 of the Homeland Security Act?**	Manufacturers of smallpox vaccine and those healthcare entities that would administer the vaccine have raised concerns about their potential liability for involvement in a federal smallpox vaccination campaign. Section 304 of the Homeland Security Act is intended to alleviate these liability concerns and therefore ensure that vaccine is available and can be administered, particularly in the event of a smallpox-related actual or potential public health emergency such as a bioterrorist incident.
49	16	**In general, what does Section 304 provide?**	Section 304 provides an exclusive remedy against the United States for injury or death attributable to smallpox vaccine, other s ubstances used to treat or prevent smallpox, or vaccinia immune globulin ("smallpox countermeasures"). This means that no claim for liability for injury or death attributable to a smallpox countermeasure could be brought against entities or individuals who are covered by Section 304's protections.

Smallpox Q and As

49	17	**When do the provisions of Section 304 become effective?**	The effective date, as established in Section 4 of the Homeland Security Act, is January 24, 2003. If vaccination is to begin sooner, Section 304 would apply at that earlier time only if Congress enacts legislation moving up the effective date.

C. Liability Issues/General

50	279	**The legal questions are really hampering our program development. When can we expect more feedback on what liability protections exist for this program?**	Liability issues are addressed in a "Smallpox Questions and Answers" document that has been prepared on Section 304 of the Homeland Security Act. You can find it on the CDC Smallpox website at http://www.bt.cdc.gov/agent/smallpox/vaccination/section-304-qa.asp.
50	396	**Are hospitals and clinics open to liability if they don't use the CDC forms?**	The form CDC is providing with the vaccine is designed to document and ensure that the potential vaccine received information about the vaccine and understands the risks associated with the vaccination. This form should be used but states may want to use additional consent forms.
50	397	**Hospitals would like better clarification of the liability issues – who is covered, when, and under what circumstances.**	CDC/HHS/DOJ legal counsel's have considered four potential scenarios as to how the court may interpret an event: 1. Event is covered 2. Event is likely to be covered 3. Event may be covered 4. Coverage is questionable Section 304 may be potentially revised.
50	398	**Are there any changes or activities around Liability and Injury Compensation? NYC is concerned about hospital participation because of liability issues, especially those dealing with negligence.**	CDC, HHS, and DOJ lawyers are continuing to research and consider Section 304 coverage for different situations. We will provide updates as we receive them.

Smallpox Q and As

50	399	**Are State Public Health Dept. and Hospitals considered covered entities as defined in Section 304? It will be important to contact the AHA with the answer to this question.**	CDC, HHS, and DOJ lawyers are continuing to research and consider Section 304 coverage for different situations. We will provide updates as we receive them.
50	400	**If a vaccinee comes in contact with an employee or patient and one or both get secondary vaccinia, does the hospital have secondary liability coverage?**	CDC, HHS, and DOJ lawyers are continuing to research and consider Section 304 coverage for different situations. We will provide updates as we receive them.
50	401	**If a staff member receives vaccination at a clinic site but has follow-up done at hospital, is the hospital covered?**	CDC, HHS, and DOJ lawyers are continuing to research and consider Section 304 coverage for different situations. We will provide updates as we receive them.
50	425	**Liability- what does legislation mean?, protection for hospitals, protection from secondary infections?**	DHHS is working to draft a response.

C. Liability Issues/Filing a claim

51	29	**If I am injured as a result of receiving a smallpox countermeasure, how do I know if I can file a Section 304 claim?**	Section 304 is triggered if and when a smallpox countermeasure is administered pursuant to a declaration by the Secretary of Health and Human Services. The declaration will specify the administration of particular countermeasures to one or more categories of individuals, and it will state how long it is in effect. An individual described in the declaration who receives one of those countermeasures from a qualified person while the declaration is in effect, and who is injured as a result, may file a claim under Section 304.

Smallpox Q and As

51	38	**Who is a "qualified person?"**	Qualified persons are licensed health professionals or other individuals authorized to administer smallpox countermeasures under state law. Section 304 claims may be filed for injuries due to administration of countermeasures only if the countermeasure is administered by a qualified person.
51	39	**If I contract vaccinia without having received smallpox vaccine, can I file a Section 304 claim?**	Individuals who were not inoculated, but who nonetheless contract vaccinia during the period of the Secretary's declaration or 30 days thereafter, or who reside or resided with an individual who was inoculated pursuant to the declaration, may submit claims.
51	43	**What is the process for filing a Section 304 claim?**	Anyone who believes he or she has a claim for money damages attributable to injury or death due to smallpox countermeasures must submit an administrative claim with an appropriate agency of the United States within two years. If the agency denies the claim, or if no action is taken on the claim within six months, the injured individual may file suit in federal court.

C. Liability Issues/Covered Entities

52	55	**What entities are covered by Section 304's protections?**	With respect to administration of a covered countermeasure, manufacturers and distributors of countermeasures, healthcare entities under whose auspices the countermeasure is administered, and licensed health care professionals or other individuals authorized to administer the countermeasure under state law are covered by Section 304. In addition, any official, agent, or employee of any of these entities is also covered.
52	57	**Are state and local health departments and their employees covered by Section 304?**	State and local health departments that act as distributors of countermeasures or that are healthcare entities under whose auspices countermeasures are administered are covered by Section 304. Their officials, agents, or employees are also covered for actions arising out of the administration of a countermeasure.

Smallpox Q and A's

52	59	**Does Section 304 contain any limitations for covering these entities?**	If a claim under Section 304 is based on an action or omission by a particular manufacturer, health care professional, or other person listed under item A.9 above, and that person fails to cooperate with the Government in the defense of the claim, the United States will not be liable for any damages resulting from that person's act or omission. Also, if the United States makes a payment on a claim, and the payment is based (partly or wholly) on gross negligence, recklessness, illegal conduct, or willful misconduct by the manufacturer, health care professional, or other person listed under item A.9, or based on the person's violation of a contract with the United States, the United States may recover that portion of the payment (with interest and litigation costs) from that person.
52	340	**Has the Homeland Security Act been interpreted to include post vaccination care?**	CDC/HHS/DOJ legal counsel's are looking at a variety of situations for the likelihood that they would be covered by Section 304. The courts will ultimately interpret the law and determine who will and who will not be covered. Several groups are working with members of Congress re the possibility of revising Section 304 to expand liability coverage.

C. Liability Issues/Other

53	62	**What effect does Section 304 have upon federal or state workers' compensation schemes?**	Workers covered by state workers' compensation statutes who suffer work-related injuries from the countermeasure may be barred from submitting a Section 304 claim if those state laws constitute an exclusive remedy. Federal employees who suffer such work-related injuries may only file claims pursuant to the Federal Employees' Compensation Act.
53	63	**What legal standards apply to Section 304 claims?**	In general, suits would be governed by state law as to liability and damages, except when provisions of the federal law provided otherwise. For example, a claimant must demonstrate that the injury or death attributable to the countermeasure was the result of a negligent or wrongful act or omission, regardless of the standard in the state where the act or omission occurred.
53	70	**Does the statute authorize payment for lost time from work or health care costs necessary for treating the injury?**	If a claimant prevails on a Section 304 claim, damages would be determined according to state law, within any limits imposed by federal law. While loss of income and health care costs generally are recoverable, Section 304 does not establish a "no-fault" compensation program. See items A.2 and A.13. Individuals may wish to review their health insurance policies to determine whether they cover health-care costs for injuries attributable to administration of a smallpox countermeasure. For information on Section 304's interaction with workers' compensation claims, see item A.12.

Smallpox Q and As

53	72	**Are all persons working in a vaccination clinic covered by Section 304?**	A vaccination clinic, as a healthcare entity under whose auspices a countermeasure is administered, is covered by Section 304 protections. Any official, employee, or agent of such a vaccination clinic would therefore also be covered by Section 304 protections for actions arising out of the administration of a countermeasure. See item A.9.
53	75	**Will hospitals or other institutions who employ vaccinees but who do not operate as a clinic administering countermeasures be covered by Section 304 protections?**	Hospitals and institutions under whose auspices countermeasures are administered are covered by Section 304 protections. The Secretary's declaration may determine that hospitals that designate employees to receive smallpox countermeasures under a state's smallpox plan are considered to be participants in the program and thus are healthcare entities under whose auspices the countermeasure is administered. In these circumstances, we believe that hospitals or other institutions that employ these vaccinees but that do not operate as a clinic administering countermeasures would be covered by Section 304 protections for claims arising out of the administration of a
53	370	**Is hospital IRB approval required for delivery of IND?**	No, local IRB approval is not required but the local IRB can choose to review the protocol.

D. PVS

54	18	**Can we get what the contents of tables for pre-population will be, i.e. occupations? Will we be supplied with the occupation list that PVS will be using?**	Occupation is a required field in your demo. Can the state provide a list of occupations that are tailored to the structure of our public health response teams (such as Lead Investigator, Contact Tracer, etc.) and have these available in the list? Yes, a document specifying the format and content for the pre-populated will be distributed by December 17, 2002.
54	19	**Is there information on what the data structure of the system is? Is it included in any of the annexes?**	Data exchange documentation and functional requirements were distributed on November 22, 2002 and are available for additional distribution. (http://www.bt.cdc.gov/agent/smallpox/).

Smallpox Q and As

54	27	**Where can we find in-depth information about the PVS system?**	The PVS application is a secure web-based application hosted on the CDC Secure Data Network (SDN). Use of the application requires only a web browser and an SDN digital certificate. Application documentation including functional requirements, data exchange specifications and instructions on applying for an SDN certificate is available for distribution. The requirements for pre-event vaccination program administration, can be found in Annex 6 of the Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program (http://www.bt.cdc.gov/agent/smallpox/). These program guidelines are not system specific.
54	30	**How do we get SDN log-ins?**	Information about this was provided with the state guidance sent on November 22, 2002. (http://www.bt.cdc.gov/agent/smallpox/)
54	31	**What is the bandwidth utilization for this application?**	PVS is a thin client, web-based application and has been designed to consume minimal bandwidth. The application could be run over a 56K connection but at least 256K is recommended for better data entry experience.
54	32	**Is there any security measures (i.e. encryption) performed by the application and/or host? If so, what are they?**	Yes, the application runs under the CDC SDN and uses encryption.
54	33	**Is CDC updated with any information collected by this application? If so, what and how?**	Yes, the data is stored at CDC. CDC can run aggregate reports to determine the total number of people vaccinated, monitor vaccine usage, take rates, vaccine adverse events, and other analytical information. Identifying data will not be used.
54	34	**Suggestion to add a VAERS reporting field (could be a radio button) to indicate that a specific severe adverse event has been reported to the VAERS system. Would also be an important element to be produced in a report?**	This functionality will not be available in the first release.

Smallpox Q and As

54	36	**Option for a report "pending log" (i.e. those individuals who are due to have their vaccination examined for a "take". This would GREATLY assist those in the clinic in determining what patients are missing from being examined, and for what reason.**	This is already addressed in the Take Response Callback Report.
54	37	**How are HIPPA compliance issues addressed? How is the option for CDC being able to collect public health demographic data, when they are not a public health entity being addressed?**	CDC is not a covered entity under HIPAA; therefore CDC need not be "HIPAA compliant." CDC is a public health authority under HIPAA, and therefore may collect individually identifiable health information for public health purposes.
54	44	**"Populating the organizational database". Please clarify how this would be done.**	CDC will set up initial support data to ensure that security is applied to appropriately restrict the data that a user can access. For the initial delivery, we will pre-load these fields. State and local administrators will be able to access and modify records to which they are assigned.
54	46	**Where can I get a description or an example of the PVS capabilities?**	This information was provided with the state guidance on November 22, 2002. (http://www.bt.cdc.gov/agent/smallpox/)
54	47	**Is the PVS application going to be centralized at CDC with everyone connecting to the central hub? If so, can the web site handle a large volume of hits?**	Yes, the CDC will host the application. We are prepared to handle the volume expected and we are validating this with volume testing of the system.
54	49	**What are the requirements for Internet access, hardware, software?**	A 256K Internet connection is recommended although lower bandwidth could be used. Any computer with an Internet connection and running Internet Explorer 5.0 or above or Netscape 6.0 with an installed SDN digital certificate can access and run the application.

Smallpox Q and As

54	51	**What is the intended way of using the system direct data entry? Will scanners be provided by CDC as mentioned in the demo?**	Data entry is expected from the data entered on the forms. CDC will not supply scanners for the barcodes and is unable to recommend specific devices. CDC suggests a keyboard attached barcode scanner that is connected to the workstation(s) used for data entry. Barcode scanners fitting this description are available that require no extra software to run.
54	53	**Clarify that CDC will enter all organization, clinic, vaccinator, examiner information etc.? Or can state registry staff be assigned the administrator options?**	The CDC will load the initial data as supplied by the states. The states will be able to modify the data once initially established. States will have local administrative privileges.
54	56	**Does CDC expect all adverse events will be entered into www.vaers.org? If so, will the current form be modified to have smallpox specific information on it? Is additional adverse event information expected to be put into PVS?**	All adverse event information should be entered in VAERS. On the VAERS web application, a field will be used to enter the PVN to link the two systems. We recommend that the PVN number be written on (or a PVN sticker placed on) the VAERS reporting form if using the paper form for submission.
54	58	**Once a state has a certified alternative system, will the data in PVS be available for us to upload or will states be expected to do double data entry?**	If a state switches from PVS to a state certified system, the state's data in PVS will be available for download to the certified state system.
54	60	**What is the procedure if all required fields are unattainable?**	The required fields have been minimized and it is not expected that they will be unavailable in a pre-event capacity.
54	61	**Would it be possible to view the following files from the PVS system?**	PVS_State_Import.xml PVS_State_Import.xsd Yes, these files will be made available on the website for viewing. (http://www.bt.cdc.gov/agent/smallpox/)

Smallpox Q and As

54	65	**What edit checks will PVS have?**	PVS includes edit checks for correct data formats (SSN, Date Fields, Phone Numbers). The fielded system will also include default values where appropriate, and validation to reduce the occurrence of duplicate data (for non-identified data this will obviously present a challenge).
54	67	**What information is CDC expecting to receive and how often? (if a local health department did not use PVS) How do you expect to receive these reports?**	We expect to receive information daily at CDC. This will allow us to monitor the progress and report aggregate data to the Administration.
54	71	**It wasn't clear if reports would be available on the state level that showed the detailed patient information as was available for the clinics. Would that be possible?**	Reports that are available at the state level are included in Annex 8. Of course the data will only reflect people vaccinated in clinics in the state, not in other states.
54	73	**Is there or will there be a vaccine management component to the system as accountability for the vaccine is an important issue?**	The PVS application will be able to report on the number of people vaccinated per batch of reconstituted vaccine but it is not a vaccine management system.
54	77	**Can the basic demographic information on a vaccinee be entered into the system prior to being vaccinated? If sites can pre-enter some of the basic information it would make the clinic locations more efficient.**	There is minimal data entry related to each vaccination event. The clinic modeling that was done did not indicate that this was a requirement.
54	85	**Is the Smallpox Immunization Safety System (SISS) as described in Annex 4 part of the PVS system?**	Actually, SISS is a larger effort of vaccine safety monitoring, of which PVS is a part. The National Immunization Program (NIP) has developed a multi-tiered approach to dealing with adverse events resulting from vaccinations. After the patient is entered into PVS, adverse events are monitored through the process in Annex 4.

Smallpox Q and As

54	88	**It may be helpful to know in more detail the protocols for how the data would be protected and how CDC will ensure that personal information would not be accessible by anyone other than the vaccinating site.**	The PVS application meets HIPAA security requirements. PVS is accessed via the CDC Secure Data Network (SDN) which requires two-factor client authentication using a digital certificate and a password. In addition there is location and role based authorization layer that controls access to data based on the clinic the user is assigned and the role they have at the clinic. The system provides a clinic administrator role, a data entry role and a state administrator role. User with state admin rights would have access to aggregate data from all clinics in their state, clinic administrators would have all rights to data for their clinic and data entry would rights consistent with data entry
54	94	**Would it be possible to build into the system some functionality that allows for basic demographic information on vaccinees being imported from outside data systems (i.e.: hospital employee databases)?**	The XML file transfer that is available could be extended to support this.
54	102	**Is there a possibility of entering some of the initial information on organizations and assignees now, even before the system is fully accessible to end users?**	Yes. We will provide a method for you to send us this information.
54	109	**It may be helpful to have a copy of this database available on 3.5 inch floppy disk so that we can enter in real time and then upload batches of information to the CDC at the days end. Is this an option with your system?**	Since this is a web-based system, that is not an option. You may consider having a central data entry facility (or facilities) for your data collected on paper forms.
54	110	**Can states use a combination of PVS and other system to provide Vaccination data to CDC?**	This is possible however the data provided from other systems would be subject to the validation rules in the data exchange specifications. Depending on how the data is arrayed across the collecting systems, proper linkage of all entities representing a vaccination record could be problematic.
54	115	**Does PVS provide an ad-hoc report generation capability?**	At this time, the PVS application will allow users to run canned reports. We may provide ad hoc reporting functionality in a future iteration. A data export capability is under development which would allow download of data sets for local analysis.

Smallpox Q and As

54	116	**Will secondary security (application level) be handled by CDC or delegated to the states?**	For the first iteration, CDC will handle the application level security. Future iterations will delegate this to the states.
54	117	**Will there be a limit on the number of clinic users/computers who can get digital certificates and be able to link up (via their Internet web browser) with PVS to perform the clinic user data input functions?**	The number of certificates available is not unlimited. We expect that the limiting factor in the need for certificates will be the number of clinic based on the availability of the vaccine. We expect 4-5 people per clinic will need certificates.
54	118	**Can both state and local health departments get digital certificates and be enabled to likewise link up with PVS for the same "State Principal Investigator" functions and information access capabilities?**	Yes, however the data that a user can see will be restricted based on the clinics to which they are assigned.
54	119	**If the clinic is unable to re-locate and determine a vaccinees take status, will PVS accept his/her record with this field blank, and does such a person get counted anywhere in the various PVS reports?**	The records remain in PVS regardless of whether Take Response is completed. Those individuals overdue for a take reading will be included on tabulation reports in a separate column.
54	121	**Can you provide a privacy statement for State's that enter personal identifiers? Does CDC/DHHS plan to use that information in any other way, for example as part of a national contact system?**	CDC does not plan to use this information as part of a national contact system. A statement on the intent of data usage and privacy issues will be provided.
54	122	**What are the technical requirements for using an ID number in lieu of entering personal identifiers?**	The PVN associated with the initial vaccination received by the patient would be used to identify the patient's record. Name, SSN, Birth Date, and contact information would be omitted during data entry. In the reports, the initial PVN would replace the identifying information. The clinic would hold patient identifying information outside of PVS on paper forms, or in a local system that also contained the initial PVN for each patient. The clinic would then cross reference the PVS record to the external record using the PVN.

Smallpox Q and As

54	123	**Before going live with the current system, would it be possible to add a note field, or a few generic text boxes on the PVS site so we could add additional local-use data if needed?**	No, this is not an option at this time.
54	124	**I'm not sure how the "Principal Investigator=State PI" (term used in Annex 8 on p 10) roles and access authority works in PVS (continued in answer field)**	(question continued)...in the sense that, at least in our state, both the state health department and each of our participating local health departments will be functioning as this "User Type" (the term used in Annex 8 on p 17, etc.). Our state health department will be doing this for our state as a whole, and each participating local health department will be doing this (e.g., needing to access and generate at least some of the Reports listed on p 9 of Annex 8) for the vaccinated public health and health care teams in their local jurisdictions. How does this work in PVS? Local health departments will need to know the information (numbers, composition) of both types of teams that are located in their jurisdictions. Answer: The PVS allows users to be assigned to Clinic organizations. The State users will be assigned to all clinics within the state. Local users will be assigned to those clinics within their jurisdiction. This will allow each level of user to view all the information within their jurisdiction. PVS does require the users, clinic assignments, and user roles to be submitted to the CDC for the initial release of this system.
54	126	**Does "password" always = "challenge phrase" as indicated on p 17 of Annex 8?**	Challenge phrases are used in conjunction with the digital certificates as a password. Passwords are used to log into the system.
54	128	**How do local health departments get the "Public Health [team] Report(s)" mentioned on p 9 of Annex 8 for their public health response team(s)?**	PVS will support reporting on referring organizations that are DOHs. If the organization refers patients then it will have a Referral Category indicating that it has response teams, and it will appear on the Public Health reports. Both Local and State Health Department Users will have access to the Public health reports based on their roles in PVS. A detailed roles matrix will be published soon.
54	130	**In Annex 6 a number of the workflow sheets (e.g., Workflow Sheet for section 3.3.1 on page 10) include icons with "page X", etc., on them. To what document do these page numbers refer?**	The page reference is within the same section of the document. The process overview in Annex 6 page 7, associates a page number with each workflow page. Each detailed workflow has a title that includes the page number. The outgoing icon indicates that the flow continues on the indicated page. The incoming icon indicates that the flow was originated from the indicated page.

Smallpox Q and As

54	133	**What if all nurses' names have not been added into the computer system, will staff be able to add new nurse vaccinators?**	In the first iteration, staff will request that the CDC add the new members. These requests will be prioritized for rapid turnaround. Due to the level of training that is required for this vaccine, clinics should have the lead time necessary to submit this request to the CDC.
54	134	**Is it possible to produce a report that would identify assignees not yet vaccinated?**	An assignee is a program staff member, and their vaccination information will only be recorded in the system if they are also recorded as a patient. However, your request will be noted and considered for future implementations.
54	135	**In the PVS the term re-vaccination is used. Does this mean re-vaccination for this program or at anytime?**	This means re-vaccination for this program.
54	139	**Does the PVN allow for multiple vaccine history dates or only the latest? Is a PVN unique to an individual or unique to a dose of vaccine? If it is unique to an individual, why do we add in another PVN for a re-vaccination?**	The PVS application will allow multiple vaccination history dates to be recorded. The PVN is unique to each dose of vaccine administered. The PVN for the first vaccination event for a patient will also be assigned to the patient and used as a Patient identification number in PVS.
54	143	**What do the photo and survey questions relate to in the report section?**	These will be included in the production system and may be used to identify those patients who have consented to active surveillance. The extract or report that includes that subset of patients is separate from the clinic and state level reports.
54	146	**It is my understanding that you will need referring organizations that you will need occupation titles and the names of those staff who will administer and/or read takes. Is that correct?**	That is correct in the first iteration. Future iterations will allow administrators at the state and local level to add this information.

Smallpox Q and As

54	150	**Where appropriate are the drop down boxes going to be configured to retain the previous choice as the default the next time the box is presented? ("Wyoming" is always on the bottom of such a list.....)**	The PVS application will keep a number of variables available in the session. Each time a user logs into the PVS application, the session information will load based on the information that the user enters. Other items such as clinic, vaccinator, and date will be kept in memory and filled in. The user may override these values as needed. The last value entered for these fields is what will be used when the screens are revisited for new entries.
54	152	**If there is no state administrator, how will the state be able to do the biweekly reports required in the guidance? Will the included reports provide the information CDC will want?**	You do not need to be an administrator to run the reports. State users will have the privilege to run Public health reports.
54	153	**What roles will have rights to the analyze data feature, and what data will they have access to? There is a need for a state level person to have access to all of the data from that state.**	State users will have rights to the PVS extract of state information.
54	157	**Can assignees be shifted to new organizations by the state? Can we do this ourselves, or will we have to ask you to do it?**	State level users who are administrators will have the privilege of changing this for organizations under their jurisdiction.
54	158	**What is PVS?**	The PVS is the Pre-Event Vaccination System. It's a secure data exchange Internet-based system designed to collect information on those being vaccinated against smallpox. The states and CDC will use this information to ascertain progress in preparedness activities, as well as to assist in the monitoring of adverse events. For more details on PVS, visit http://www.bt.cdc.gov/agent/smallpox/vaccination/pre-event-info-data.asp.
54	160	**When will PVS be available?**	The CDC will be working with bioterrorism grantees over the next few weeks to help them set up PVS or certify that an alternate system is compatible with the PVS.

Smallpox Q and As

54	161	**Does the system record the user id of the person who entered or edited a particular record? Is there any audit function to check this?**	Yes, the information is collected in the database. An on-line view of audit information is planned for a future phase but will not be available for the January release.
54	163	**Where can I see a demonstration of PVS?**	You can see a demonstration of the Pre-Event Vaccination System at www.genesys.com. Instructions for viewing this webcast are available at http://www.bt.cdc.gov/agent/smallpox/vaccination/pvs-webcast-instructions.asp.
54	165	**Do you expect us to enter the data real-time into the PVS? Or can we do this afterwards**	We are encouraging each clinic to enter the data real-time into the system. This will enable planners to monitor progress in preparedness activities and will allow information to be available should there be an adverse event.
54	166	**Where will the paper copy of the patients' vaccination records be kept?**	This will be at the discretion of the State and Local health departments.
54	168	**How does a local health department access the PVS?**	Each local health agency should work with their state health department to determine how they will access the PVS. In most cases, it will be directly through an Internet connection.
54	171	**What are the certification specifications for using an alternative data storage system other than the PVS?**	This information was provided to bioterrorism grantees as an appendix to guidance issued to develop smallpox response plans. Visit http://www.bt.cdc.gov/agent/smallpox/vaccination/pre-event-info-data.asp and review Annex 7—Data Exchange Requirements.

Smallpox Q and As

54	172	**Will local entities be authorized to transfer data to populate local immunization registries?**	Since the identifiable data is owned by the state, local health departments should work with their state to ascertain what is allowable under state law.
54	173	**CDC will handle administration for all clinics and vaccinators nationwide? Who will have rights to create a new clinic, vaccinator, etc? If distributed administration, what roles do we need to assign for dis tributed administration rights?**	CDC will work with the point of contact listed in each state's plan submitted on December 9, 2002, to get an initial load of data to add into the system. The state will then be able to maintain clinics and personnel that fall under their jurisdiction.
54	175	**Can we use data existing in immunization registries or other data systems to populate the PVS demographic data?**	Data in existing registries or other data systems cannot be directly imported into the PVS web-based application. If your state wishes to modify your registry and send all vaccination support system data to CDC through the data exchange mechanism for state-developed systems, then the data can be accepted by CDC.
54	177	**How can a clinic interact with the PVS if they do not have an Internet connection?**	Local clinics are encouraged to operate in sites with Internet access. If this is unavailable, the clinic should work with their state's PVS contact to determine how the data will be entered into the system.
54	178	**Can you associate a batch # with more than one organization?**	The PVS application is designed and implemented to capture the clinic that created a batch. A clinic may have multiple batches, but a batch is only allowed to be assigned to a single clinic. When a vaccination record is entered in the PVS application, the vaccination clinic is entered and this is used to restrict the list of batches to those created by the clinic.
54	179	**Is it possible for us to capture data on previous smallpox vaccinations in the PVS?**	Yes, there are fields available to record prior smallpox vaccinations in the PVS.

Smallpox Q and As

54	181	**When you enter in the diluent strength can the number of doses be automatically calculated?**	The diluent strength will default to 1:1 and the doses will default to 100.
54	182	**Should the military be entering data into the PVS?**	The military will be tracking its own vaccinations. Military installations should consult with their medical command structure to determine how the vaccination information will be tracked.
54	184	**Just curious how this will interface with my current immunization registry?**	The functional needs required for a vaccine administration support program have been included in Annex 6 and 7of the Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program.(http://www.bt.cdc.gov/agent/smallpox/) This list will help you to determine the role of your vaccination registry in this program. The XML schema in Annex 7, has been developed to enable consistent formatting for uploads of data from existing systems. This method will require certification that the file your system uploads is formatted correctly. The specification that describes how to engage in the certification process will be provided by December 17, 2002.
54	185	**Why isn't the vaccination date a required field?**	It will be required in the production application.
54	187	**How do we go about getting data exchange certification?**	The specification that describes how to engage in the certification process will be provided by December 17, 2002. The certification process will include a functional review, and a data exchange review. The functional review ensures that system capabilities address the requirements of the program. The data exchange review ensures that the extract adheres to the data format and content requirements delineated in Annex 7 of the Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program.(http://www.bt.cdc.gov/agent/smallpox/)
54	189	**Will organization and referring organization pick list be state specific? How prevent duplicate entries or selecting "Baptist Hospital" from another state or community?**	Yes, this information will be specific to the state.

Smallpox Q and As

54	190	**What exactly is the definition of a batch? Is a batch a vial or is it a batch or lot of vials?**	A batch is defined as a vial of reconstituted vaccine. Under the proposed licensed vaccine, 100 doses are expected per batch. A batch is made up of a vaccine lot number/manufacturer, a diluent lot number/manufacturer, and the reconstitution date.
54	191	**I'm confused about the bar codes and where the stickers come from. Are those generated by CDC and are associated with particular patients or particular vaccine batches?**	Barcode stickers with PVNs will be distributed in concert with the vaccine. For each PVN, there will be six labels. These labels can be used for the patient history forms, vaccination cards, and other forms used at the clinic. Each packet will contain 16 sheets of 42 labels (seven sets of six). This means there will be enough labels for 112 patients. The extra 12 sets allow for errors or other issues at the clinic.
54	192	**We feel there needs to be more definition of the difference between a batch number and a lot number for the user of the system.**	The data elements that uniquely define a batch number are: organization (clinic), vaccine lot number/manufacturer, diluent lot number/manufacturer, and date of reconstitution (including hours and minutes). The batch number will be a sequential number that starts with 1. It is unique across all batches in the system. The date of reconstitution includes hours and minutes because a large clinic might reconstitute multiple vials of the same vaccine and diluent lot on a given day. The database links the Batch ID back to the detail information thus saving time during data entry. The vaccine lot number identifies the lot of vaccine produced by a manufacturer. The diluent has its own lot number.
54	194	**Why are you able to record a future date (after today) for the Take?**	Future dates will not be allowed in the production system.
54	196	**Do batches have expiration dates or shelf life?**	Batches of reconstituted vaccine do have a shelf life. That information will be provided with the vaccine.

Smallpox Q and As

54	197	**What are the roles for and local users of system?**	Local users include data entry, nurses, vaccinators, and administrators. They will be assigned either the Local Admin role or the Local Viewer role depending on the access they require.
54	198	**On the 'maintain vaccine batch' module 2.0 listed on page 8 of Annex 8: It's unlikely but possible that a large vaccination clinic may create two 100-dose batches at the same site on the same day. How would these batches be distinguished in PVS?**	The PVS will support this, each batch will receive its own unique Batch ID.
54	200	**What is the meaning of Referral Category?**	Referral Category specifies the type of response team on which vaccinees from the organization would be placed. The only current values are Hospital Based and Public Health Based.
54	201	**Wouldn't the number of forms printed be based on the number of doses in the batch?**	Clinics can either print out the necessary number of forms, or print one form and make the appropriate number of copies. The number of forms that are created may differ from the number of doses in a batch because forms may be completed for patients who are contraindicated to receive the vaccine, they may be filled out incorrectly, or not used if a portion of the vaccine goes unused. Other circumstances may also require more forms to be printed than there are doses for a batch. The system allows the clinic to print the number of forms they want. If the clinic prefers to print 100 forms for the batch, they may do that.
54	202	**What is an example of a referring organization?**	Referring organizations are the organizations where the vaccinees come from. For example, in the first phase of immunizations organizations will include hospitals, clinics, and health departments.
54	203	**We're concerned about confidentiality e.g. re HIV. These forms ask it. Is it required per se?**	We understand the concern about confidentiality. The PVS application available from the CDC does not collect or store contraindication information (such as HIV). The information is collected in the medical history form that is used to screen patients for contraindications. The program does not require that contraindications be maintained for people who do not receive the vaccination. For patients receiving the vaccination, a hard copy of the form is retained. We expect that the form will be maintained by the clinic, state, or referring organization in a medical file.

Smallpox Q and As

54	205	**If you use just patient's age will DOB field hold an age?**	The fielded system will differ slightly from the demo version. It will prompt for year of birth and mm/dd as separate fields, but only the year of birth will be required.
54	206	**Are there any reporting capabilities with this system i.e. for semi weekly reports?**	Yes, reports are available for the system.
54	207	**What database is the CDC tying the PVS application to?**	The PVS application available from the CDC uses Microsoft SQL Server 2000 as the backend database. It should be noted that the database is not relevant for those States who are using their own system, and will therefore be providing an upload to the CDC.
54	208	**Is access to reports limited by role? Who has rights to see this report?**	State level users will be able to run state level reports, local users will be able to run clinic reports.
54	210	**How do we access the PVS system? Is it client server or web based?**	The PVS application available through the CDC is a web-based system. It will be centrally hosted at the CDC. The system requires that the user have access to the Internet (dialup, network connection, etc…) and equipment that adheres to the supplemental specifications described in Annex 8 of the Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program. (http://www.bt.cdc.gov/agent/smallpox/)
54	212	**Will county governments be able to enter data directly into this system or does it need to go through the state?**	Users of the PVS application will be submitting the data directly to PVS. The states will have access to data for clinics in their states to download and run reports on.

Smallpox Q and As

54	213	**Will they have a system for mass input via e-mailed database, for example?**	The system will not support input via email. Email is not considered to be a secure data transmission method, and the contents of this data are sensitive. Once certified, a state can securely upload data in the XML format specified in Annex 7 of the Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program. Security is provided by the CDC SDN as outlined in Annex 8 of the Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program. The annexes can be found at: http://www.bt.cdc.gov/agent/smallpox/.
54	215	**How quickly/readily can the public health reports be generated?**	PVS allows reports to be run/generated on demand.
54	217	**Can we search Patient Information by SSN?**	In the PVS application available from the CDC, SSN can be searched if it is included in the records that a user may access.
54	218	**Can you specify the date of the take response report?**	Yes.
54	219	**Who will have Global Administrator access? Any state-based people?**	The CDC will have the access to be able to support the PVS application and ensure that users are correctly set up and restricted to their assigned subset of data. This will allow CDC to ensure that each state may only see detailed information for their state. States will have local administrator rights to access data within their state. Clinics will have administrative rights over their local data.
54	220	**Are states responsible for creating their own external reference/database containing patient names and PVN's?**	Yes, if your state does not provide named/identifying data, you are responsible for creating an external method for linking PVN to the people.

Smallpox Q and As

54	221	**When will this system be available for use? Will there be a training or demo system available?**	The PVS application is in final development and testing. The system will be ready for use by the timeline announced by the President. We expect a test/demo system will be available for training by January 6, 2003. CDC will also provide training via webcasts to the states for Train the Trainer training. Screen shots and other training material will also be available.
54	223	**Can we get access to sample forms and reports?**	The forms and sample reports will be available for download from the www.bt.cdc.gov/agent/smallpox website. The reports available in the first iteration of the system will be static (i.e., no user modification). Please be advised that these reports may change when the system is put into production.
54	224	**What are the technical requirements for using an ID number in lieu of entering personal identifiers?**	The PVN number provided by the CDC would be used instead of the patient name.
54	226	**Can you submit incomplete documentation for your history?**	In the PVS Application available from the CDC, if the vaccination date is entered, then the system requires that you indicate if the date came from recall or was recorded on a document. If never is selected, then take response cannot be entered. A take response of unknown will be available in the fielded system. The data requirements for pre-event vaccination program administration will accept a vaccination history of unknown.
54	227	**If county governments must submit data to the state governments, must it be in report form or some type of compatible electronic form?**	You should consult with your state on this for further guidance.
54	229	**When will states receive specific lot numbers so they can load that information into state -developed systems?**	NPS cannot provide that information before the shipment is set up. NPS logisticians will contact the project area to coordinate the shipment at least 24 hours before the actual shipment. At that time the project area will get all the details, including the lot number(s) that they will receive. In some cases, that coordination may take place as much as 5 days ahead of time, providing even more advance notice of the lot numbers. Another factor to consider is that sending the temperature monitoring device back to us for cold chain verification takes another day after shipment, so it will give a little more time to enter the lot

Smallpox Q and As

54	230	**Why did you populate report from Favorites? Are reports created by application?**	The reports shown during the demo were sample reports. They were loaded from Favorites only for the demo. When the PVS application goes into production, reports will be run from the web pages and formatted in PDF.
54	233	**In what situation would you not use a patients' name?**	In adherence with pre-event vaccination administration guidelines, the states will need to collect identifying information. Some states may feel compelled to omit patient identifying data from the PVS application. Patient records without names, phone numbers, etc. in the PVS application will limit the usability of the application. For example, the Take Callback Report will have no use without that information.
54	234	**Will there be a report that lists those individuals who need to have their vaccination examined for a "take"?**	Yes, that is the Take Response Callback Report.
54	235	**Is it possible to download the PVS system, use it at a clinic and then upload the results to the web site? What platform is the system going to run on?**	No, the PVS application is web-based and was originally developed to support an IND vaccine, thus it was not designed to be distributed as a standalone application. You could provide a central data entry location that could input data from clinics (via paper forms) without Internet/web access. The PVS application runs on Windows 2000 and uses SQL Server 2000 as the backend database. The web based client runs at a clinic or state site. While an organization would not host the PVS application, they do have the option to use their own system, once it is certified. The system should meet the requirements documented in Annex 6 of the Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program. (http://www.bt.cdc.gov/agent/smallpox/) It should be noted that the general specifications to support the pre-event vaccination program do not restrict the solution to a platform, and the response given above is specific to the application developed by the CDC to support pre-event vaccinations for smallpox.
54	238	**What is the cost of the digital certificate and is the state responsible for the cost?**	The PVS application will be deployed on the CDC Secure Data Network and all digital certificate costs will be assumed by CDC.

Smallpox Q and As

54	241	**Can the state health departments also analyze the data? Can data be exported out of the surveillance datamart? Can states extract their data from the PVS application?**	Yes, states may use the reporting functionality to analyze data. A data extract will be available for states to download their data (a state would be allowed to download data for their state only, not the data for other states) that was entered into PVS. We expect to have this functionality available by January 15, 2003. The datamart is a database that will provide aggregate views of vaccination records and adverse effects linked by PVN for vaccine safety monitoring analysis. This database will be used by CDC personnel to analyze and report national trends as the campaign proceeds. The data analysis is used to determine correlations between take response/adverse events and vaccine lot, diluent lot, batch, clinic, vaccinator, for example. Exports from the datamart are not available via the PVS application.
54	244	**What happens if the patient refuses to give SSN or does not have one?**	The PVS application uses the Patient Vaccination Number (PVN) associated with the initial vaccination to also identify the patient's record for a unique identifier. As stated in the demo, social security number will not be required. It will be an optional field when in production.
54	246	**Is there a video available for the December 4 webcast on Smallpox Vaccination PVS Demo? How do we obtain it?**	The webcasts were archived. The archives can be accessed following the instructions at the following link: http://www.bt.cdc.gov/agent/smallpox/vaccination/pvs-webcast-instructions.asp
54	248	**Can you talk about administration of the two-tiered authentication/log-on?**	This is addressed in separate documentation that was sent out on November 22, 2002, with the state guidance documentation. (http://www.bt.cdc.gov/agent/smallpox/)
54	249	**We missed the front end of the presentation will the application be used on site? Or, will a hard copy be used and then later enter data? Will sites record patient information in real time?**	The PVS application will support either scenario. Clinics could do data entry, or the state or local health department could provide central data entry for multiple clinics based on submitted paper forms. If the clinics do data entry, verses a centralized approach, it could be real time. Timely data entry is important.

Smallpox Q and As

54	250	**Why are adverse events write ins and not more standardized so that they could be included in the reports?**	Detailed adverse events reporting was part of the IND requirement and would have been captured in a standardized manner to support IND. However, since the vaccine is now licensed, it is expected that VAERS will now be used to capture adverse events data and the VAERS record will include the Patient Vaccination Number (PVN). The PVS will only capture adverse events as descriptive text.
54	252	**We are considering using the worksites of the vaccinees as "take evaluation sites". How do you advise us to document take into the system?**	The Take Callback report produced by the PVS Application will include space to record take response and can be used as a worksheet to capture this information if it is collected outside of the clinic. We would suggest forwarding the take responses to the clinic where the vaccinations occurred (via fax, mail, or courier) or to a central data entry facility operated by the state or local health department for data entry.
54	255	**Why can't aggregate reporting be generated from PVS after the extract has been imported rather than have us generate aggregate numbers? This would require additional functionality apart from a simple export file.**	Some of the aggregate data is not included in the export file, such as number not vaccinated fields. The others will be used to verify the file contents.
54	259	**When entering two role levels, the person did show twice, but the role was the same at both listing. Why?**	In the fielded system the person list will also show the responsibility, so an individual may appear multiple times but with a different responsibility. In the PVS application, the responsibilities are limited to: Vaccinator, Medical Examiner (Take Reader), Clinic Contact. These are used to provide lookups in other places within the application. Other responsibilities that are required to support the program do not have to be recorded within the PVS application.
54	265	**Will this system be applicable for general population vaccination or expandable for other BT agents?**	No, the PVS application will only be used for smallpox vaccinations. The system could be used for other similar large-scale vaccinations (such as anthrax), but there are no plans for that at this time
54	266	**Is CDC developing a system that will allow tracking of the adverse reactions of the vaccine that would be external to VAERS that states will be able to link the information from the PVS to VAERS to that system?**	The PVN will be the link between the PVS application and VAERS. Please see the smallpox vaccine program guidance for the answer to this question at: http://www.bt.cdc.gov/agent/smallpox/.

Smallpox Q and As

54	267	**Is there a cost to the states for the system and who will maintain help desk support to the states for the system?**	There is no cost to the states for the system. No client access licenses are required to be purchased. CDC will staff a help desk for user support. Helpdesk personnel will provide support for user interface and role based authorization issues as well as any issues regarding CDC Secure Data Network enrollment, sign-on and usage. The help desk can be reached at 800-532-9929, option 2.
54	268	**What are the actual pc system requirements in order for the system to run? What are the end-user hardware requirements?**	Any computer with a browser and a connection to the Internet is acceptable. Minimum operating system and browser requirements are documented in Annex 8 of the Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program. (http://www.bt.cdc.gov/agent/smallpox/
54	270	**Will CDC require both electronic and paper form reporting?**	The paper based forms are provided as a means for the clinics to collect the information for data entry. They also provide a mechanism to record the patient's consent and they serve as a paper backup to the electronic system. CDC does not require paper based reporting. Entering the data into PVS via the web interface or via a certified data exchange is acceptable.
54	343	**When will Pre-Event Vaccination plans be approved**	The majority of state plans have been approved and will be sent an official letter probably this week. CDC approving officials are in contact with many of the states' technical representatives to resolve any problem areas. We expect all state plans to be approved very soon.
54	440	**Who is the contact person for the CDC Pre-Event Vaccination System? Hawaii would like to use this system in a non-internet environment for field smallpox vaccination clinics.**	Will arrange a three-way call with Brian McKinney to discuss. Call took place on 12/4/2002.
54	446	**Can States get a copy of CDC software to learn it hands on and see exactly how it works?**	No, it is a web based system there will be no copies on any format sent to States.

Smallpox Q and As

54	449	**How is the PVS system going to be deployed and reports be used?**	The PVS system will be deployed via the web. The user only needs a PC with Internet Explorer 5.0 or above or Netscape 6.0 or above to run the application. The reports that are available through PVS are state-specific, and can be pulled by anyone the state deems able through a Digital Certificate (secure data connection). The data for each state is also available for export, if they want to do their own data analysis. PVN labels will be distributed via the NPS (national pharmaceutical stockpile). These numbers must be used to link the patient to the vaccination record and adverse events in VAERS.
54	452	**If a state has internet connection problems, can they get a Pre-event Vaccination System database shell from CDC so they produce a state system to batch information and download to CDC?**	CDC will work with individual states to work out connectivity problems.
54	453	**Will states enter information in PVS live or will they have to download software?**	There is a Q&A list online that answers PVS questions. At http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-qa-pvs.asp .
54	454	**Can PVS be customized by states?**	There is a Q&A list online that answers PVS questions. At http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-qa-pvs.asp .
54	455	**When will the PVS application be available?**	There is a Q&A list online that answers PVS questions. At http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-qa-pvs.asp .
54	456	**How do we get information back from PVS to be entered in our registry?**	There is a Q&A list online that answers PVS questions. At http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-qa-pvs.asp .

Smallpox Q and As

54	457	**What does the term "Name Data" mean?**	There is a Q&A list online that answers PVS questions. At http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-qa-pvs.asp .
54	458	**Who is the CDC web administrator for PVS and howaccessible will this person be?**	There is a Q&A list online that answers PVS questions. At http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-qa-pvs.asp .
54	459	**Are there any special hardware need to use the PVS system?**	There is a Q&A list online that answers PVS questions. At http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-qa-pvs.asp .
54	462	**What are we receiving from CDC related to PVN stickers, vaccine, diluent, needles, and transfer needles?**	The labels will be printed, with numbers, and shipped to states with the smallpox vaccine. A list of what resources will be provided by CDC for vaccination clinics can be found in Annex 3, Page 3.
54	482	**Is CDC looking to build a more robust PVS system that would integrate with systems supporting surveillance, outbreak control, etc and would they be interested in vendor support to do this?**	There are no plans at this time to expand the PVS system into a fully integrated system with other program components such as surveillance and outbreak control. Data in existing registries or other data systems cannot be directly imported into the PVS web-based application. If your state wishes to modify your registry and send all vaccination support system data to CDC through the data exchange mechanism for state-developed systems, then the data can be accepted by CDC. Further, CDC is not interested in obtaining contractor support to build such a system.

Smallpox Q and As

54	484	**What is the URL for the PVS webcast?**	The website for the archived version of the PVS demonstration webcast is www.genysis.com. This is not a trial version for testing, but simply a webcast archive for viewing. We have plans to try to make a test system available soon to users, as well as holding training. I hope the presentation was informative.
54	494	**Is the PVS system available.**	No release date has been set to date.
54	526	**When can we expect to see a consent form?**	Please check the CDC BT website for this documentation. (http://www.bt.cdc.gov/agent/smallpox/)

E. Preparation and Planning

73	20	**How do I find out who the BT grantee is for my state/area?**	All the states, the District of Columbia, territories, and protectorates have been funded for bioterrorism activities. In addition, Chicago, Los Angeles County, and New York City have been funded. You can find contact information for state health agencies at http://www.cdc.gov/other.htm#states. The state health departments will determine who will be offered vaccination as part of their smallpox preparedness plan. We have sufficient vaccine to cover potential vaccinees for stage 1 and stage 2 vaccination programs. We also have sufficient vaccine (as a diluted product) to vaccinate the entire country if need be, and more vaccine is being produced and tested. There are a number of bioterrorism preparedness activities covering a wide range of ac tivities and potential bioterrorist agents. The type of preparation varies among the different agents. Vaccination is a key part of smallpox preparedness. A summary of the Advisory Committee on Immunization Practices (ACIP) meeting in which this w as discussed can be found on this website in the document “Summary of October 2002 ACIP Smallpox Vaccination Recommendations.”

Smallpox Q and As

73	24	**How do federal programs fit into preparedness activities?**	A single case of smallpox in the US would almost certainly signal a biological weapon attack. This would require an immediate, coordinated response by medical and public health systems. The Department of Health and Human Services (DHHS), and in particular its Centers for disease Control and Prevention (CDC), have taken a number of steps to ensure preparedness, including pre-event vaccination of selected populations. Vaccination of staff of federal agencies in pre-event vaccination programs will vary by agency. The Veterans Administration is planning to vaccinate their own staff. For other federal agencies, their staff would be eligible for vaccination if they were included in state response teams and would be vaccinated through state programs. For some agencies, it has not yet been decided how their staff would be vaccinated. The CDC has provided guidance for recipients of federal funding through the Public Health Preparedness and Response for Bioterrorism Cooperative Agreement for the purpose of supporting smallpox preparedness and response. The CDC is prepared to ship smallpox vaccine to grantees and will provide smallpox vaccine handling instructions, cold chain management guidelines, and all appropriate documentation. HHS and CDC also have worked with private industry to expand our supply of vaccine and vaccinia immune globulin and ensure their rapid distribution if needed; worked with the state and federal officials to develop plans to respond to a smallpox release; and worked with federal and state partners to develop and make available clinical and laboratory tools to improve our ability to diagnose a smallpox case if it were to occur.
73	52	**May the Secretary make the declaration prior to the occurrence of a bioterrorist incident or public health emergency?**	A declaration can be made if the Secretary concludes that an actual or potential bioterrorist incident or other actual or potential public health emergency makes the administration advisable. The Secretary can, therefore, make the declaration prior to the occurrence of a bioterrorist incident or public health emergency.
73	272	**If we end up with more volunteers than vaccine, how are we going to decide who gets it?**	The state health departments will determine who will be offered vaccination as part of their smallpox preparedness plan. We have sufficient vaccine to cover potential vaccinees for stage 1 and stage 2 vaccination programs. We also have sufficient vaccine (as a diluted product) to vaccinate the entire country if need be, and more vaccine is being produced and tested.
73	274	**Where can I find a listing of whom in hospitals should be getting smallpox vaccinations as part of this program?**	A summary of the Advisory Committee on Immunization Practices (ACIP) meeting in which this was discussed can be found on this website in the document.: Summary of October 2002 ACIP Smallpox Vaccination Recommendations.

Smallpox Q and As

73	297	**Will waterproof bandages be provided?**	No. Vaccination facilities are expected to provide supplies.
73	336	**How quickly can VIG and/or cidofovir be provided to a physician who needs to treat a patient with a severe adverse event?**	Once CDC has concurred that VIG and/or cidofovir are indicated for a patient, either product can be shipped to reach the patient within 12 hours.
73	345	**What is the earliest date for hospitals/clinics to receive vaccine shipments?**	If the state has an approved plan, CDC may be able to ship earlier than the scheduled January 24 date. We are working on that issue. We do not expect that vaccination will begin until the liability coverage in the Homeland Security Bill is in force.
73	349	**Will vaccine ship prior to January 24, 2003?**	Yes, as long as the appropriate documentation and the cold chain are in place. However, hospitals may not want to vaccinate prior to Jan. 24 because of liability issues.
73	354	**Should the states include VA hospitals in their Pre-event plan**	As noted above, at this time the VA will be vaccinating their employees independently of the states and states do not need to include VA hospitals in their pre-event vaccination plans.
73	357	**For a pre-event plan, how will a state be notified of the status of their plan? And, who will contact them?**	Glen Koops et al have contacted all states regarding the status of their plans.

Smallpox Q and As

73	361	**Has a date been set for the meeting of 3 top level executives from each of the state associations to discuss lessons learned, stage II, needed changes to Section 304?**	Mike Sage is sending a note to the leads of each of the associations proposing a meeting on Friday, January 9th.
73	362	**When will cidofovir be available and will there be a problem with locations getting it?**	Cidofovir is a 2nd line drug that can be purchased locally or through CDC. The preference is to request it through CDC under the IND program. It will be available within 8-12 hours of the request.
73	363	**If local primary investigators identify the need for VIG under IND, who will request and receive it?**	Physician fills out form that is included in the materials CDC sends to the States and then sends form to CDC. The VIG will be delivered where it is needed.
73	368	**Could CDC provide clarification on how the IND protocol or VIG will work, i.e. plan and paperwork flow? As it relates to this process, what are the roles of the CDC, State, Hospital, and attending physician?**	VIG/Cidofovir will be shipped directly to the treating physician along with the IND forms and instructions for administration under the IND. CDC will try to tailor our approach to VIG/cidofovir requests to meet the desires of the states, city or county health departments and rapidly notify the health departments of requests for and shipments of VIG/cidofovir. The State's role will be defined by each state but presumably would include working with the hospital and treating physician to administer the product under the requirements of the IND and handling communication related to such treatments. The treating physician would be asked to complete forms to be made a co-investigator. CDC has requested a waiver of local IRB approval. If this request is approved local IRB approval will not be required but they can choose to review. Paperwork does not have to be completed prior to administering the drug. Some felt that allowing the hospitals to review the IND before the program begins may avert problems regarding local IRB approval later.
73	372	**Has the VIS, currently on the Web, been finalized**	No. The plan is to incorporate comments from the "Stakeholder" group and then finalize.

Smallpox Q and As

73	373	**Have all states been notified about their plans?**	Yes. Most state plans have been approved though for some improvements have been recommended.
73	377	**Is the Secretary going to issue a declaration prior to 1/24?**	Yes. Secretary Thompson is positioned to make the declaration before 1/24 and does not need an imminent threat to make this declaration.
73	378	**What is the timeframe for Stage II?**	We are committed to completing stage I and applying lessons learned from stage I to stage II. The anticipated time frame over which stage I and II are to be completed has not been clearly defined. Mike O. is attempting to get clarification within the next 2 days.
73	382	**Is there an idea of what percentage of states are ready to start vaccinating?**	CDC expects that all plans are likely to be approved by January 24, 2003.
73	384	**Is CDC going to be ready by 1/24?**	Yes, CDC will be ready to support through technical assistance, training and educational materials, adverse event evaluation and treatment support and monitoring, etc. by 1/24/03.
73	388	**What is the name of the contractor who can provide hotline services for the States?**	LHI is providing the services for CDC and will also customize services for each state based on state's requirements. CDC contact for this service is Gary Hogelin.

Smallpox Q and As

73	391	**What is the job description and responsibilities for an adverse event (AE) Coordinator?**	CDC outlined the description and responsibilities for an AE Coordinator in the Pre-Event Guidance document and also requested that the states identify a coordinator in their plans. The coordinators are expected to know all aspects of AE Monitoring and can link to the clinician when necessary.
73	393	**Is the military going to be using VAERS for adverse events reporting?**	Yes.
73	394	**Is CDC aware that NPS is telling some grantees that they will not receive vaccine until the end of January or early February?**	NPS is ready to ship vaccine anytime but is waiting on a directive from the CDC OD prior to changing the existing date. Current directive is to ship vaccine on or after 1/24. NPS will only ship on Monday, Tuesday and Wednesday due to the need to receive the temp-tail back from the grantees before authorizing the grantees to vaccinate.
73	406	**What is the ultimate goal of this stage of the pre-event program? Are states expected NOW to vaccinate personnel needed to conduct a mass vaccination program, or to prepare teams to deal with a potential case?**	The goal of phase 1 is to vaccinate volunteer outbreak investigation and control response teams and health care teams for the purposes of treating and managing initial smallpox cases. This will commence once the Administration has given the go ahead.
73	407	**Are states expected to develop a Health Care Response Team in every acute care hospital in the state?**	CDC is not allowed to alter the guidance document for more specificity so states are to use their judgment in determining if acute care hospitals in their state can effectively vaccinate and after initial assessment, if they can't, that's okay. It is up to each state to decide the number of HCRTs. The ACIP recommends that hospitals should have an option to have an HCRT
73	408	**Can states post frequently asked Q&As on their own Website?**	Good idea! NIP will provide daily updates on a programmatic Q&A list that will either be available on the web or by email to state health officials, state BT contacts and state immunization program managers.

Smallpox Q and As

73	409	**During an ASTHO teleconference, it was suggested that vaccinators could vaccinate one another at the time of the initial clinic. Does this immediate move from vaccinee to vaccinator fulfill the ACIP recommendation?**	Yes.
73	410	**Why is there an urgency to develop a plan?**	While the risk of a smallpox release or attack appears to be low, it is still possible, and since a smallpox outbreak would be a health emergency, we must be prepared to quickly and effectively respond. As part of our preparations, we are recommending smallpox vaccination to those people most likely to respond to the initial cases. By providing smallpox vaccination to those people who would be called upon to respond to a smallpox case or outbreak, we are better able to protect the American people, which is our highest priority.
73	411	**"Can hospitals and health care personnel assume that an immediate return to work after vaccination (as long as appropriate bandaging and hygiene are maintained) is acceptable regardless of the type of patients seen by the health care worker?"**	Yes.
73	412	**How soon will we have to begin vaccination?**	States are encouraged to begin activities as soon as possible after the official announcement from the Administration. The guidance states that anticipated completion date for phase 1 immunization activities is 30 days after the announced start date.
73	413	**Will the Vaccine Adverse Event Daily Cards be provided in bulk or will they have to reproduce them?**	The cards won't be used. Other materials such as VIS will be provided electronically and States will be responsible for reproducing them.
73	414	**Explicitly define the stages/phases of Pre-Event implementation.**	The only stage/phase that can be addressed at present is what is in the guidance document- anything else is only speculation at this time.

Smallpox Q and As

73	415	**How can a state provide communications about its plan and the rationale behind it (such as why EMTs are not included in the initial stage) if the specifics of the plan cannot be discussed with the media?**	It is advised that states talk about a few strong points that they are doing to follow the President's plan to ensure that those health care workers at highest risk are getting vaccinated first without going into major detail, or divulging plan specifics.
73	416	**Should priority be given to vaccinating hospital staff in hospitals that have negative pressure rooms?**	State decision
73	417	**Are we planning now only for the first phase (500,000 vaccinees) or should we be planning expansion to phase 2 (10 million vaccinees)?**	The current guidance requests plans for the first phase of vaccination only. The timing for transition to the next phase is not yet determined.
73	418	**Is the pre-event vaccine system (data collection website/software) going to only be available via the web or will it be available via a CD or diskette?**	PVS will only be available on the web. An additional webcast is planned for Wednesday 12/3, time still unknown. Interested parties can e-mail pvsinfo@cdc.gov to find out time.
73	419	**Is Phase I and Phase II going to be implemented concurrently? We are beginning to panic when we think both are to occur or might occur at the same time!**	Phase 1 and 2 will be implemented separately with phase 1 being first.
73	420	**How many doses of vaccine will states receive?**	Vaccine will be allocated based on the number of people on response teams, the number of hospitals identified and the number of HC workers to be vaccinated in each hospital with corrections for those who may not elect to receive vaccine.

Smallpox Q and As

73	421	**The Patient Medical History Form found in Annex 3, Pg. 19, states: "Can we photograph your vaccine site?" Is photographing the vaccine site a requirement or a suggestion of something that can be done on a case by case basis?**	It is on a case by case basis to let people know (and get early permission) that they might be asked to allow a photo of their site if they have problems (e.g., large site reactions or satellite lesions) to assist with diagnosis/eval and educ./training. Any cost associated with this activity may come out of BT funds.
73	422	**What about the time frame for completion? 30 or 90 days?**	We are asking for plans for completion in 30 days from official announcement. Approval of plans will be based on how well the required elements of plan are addressed, including time frame for completion, identification of response teams, etc.
73	423	**What are the vaccine safety monitoring, medical care, and follow-up plans? National or State based?**	Vaccinated health care workers should seek evaluations for reactions in the hospitals employee health/infection control dept. Health care workers will have contact information with state public health staff. Identify consulting physicians for referral. CDC will provide consultation for physicians at the state on adverse event management and other clinical issues. Additionally, CDC will set up a separate phone line for the public and others seeking clinical information.
73	424	**Who will be responsible for immunizing Indian Health Service and Veteran's Administration personnel?**	We do not have an answer yet. Clarification is needed whether these other federal agencies have their own plans for getting vaccinated or do they fall under state responsibility.
73	426	**National guard- who is responsible for vaccinating?**	National Guard members who are on response teams would be vaccinated by the state.
73	428	**What is stage 1 timeline?**	There is no official timeline at this point. Estimates call for 30 days after the announcement by the administration.

Smallpox Q and As

73	429	**What is the key message to hospitals? Should all hospitals participate? Or will states determine this?**	States will determine. States should work with local health agencies & hospitals to establish plan appropriate for their state. Hospitals interested in participating should contact their state officials.
73	432	**How should a state handle confidentiality issues related to asking potential vaccinees about contraindications, especially related to employment issues?**	We have no alternative plans. Potential vaccinees should be provided educational information in advance so they can decide whether they want to get vaccinated based on contraindications. They should not be required to share their reasons with anyone.
73	436	**Will the CDC furnish the States with a list of the Universities that are currently conducting smallpox research?**	There are no states conducting smallpox research. Currently, only the WHO Smallpox Reference Centers have approval to conduct the WHO approved smallpox research agenda activities (CDC and the laboratory in Russia). There are other academic centers or laboratories that are conducting research using vaccinia virus. Most of those research projects utilize vaccinia virus to make vaccinia vector vaccines for other diseases. Drug Services maintains a listing of the laboratories that have been given vaccine to vaccinate at risk laboratory workers to protect them against infection with vaccinia during their research activities. However, the identify of the workers, the co-investigators, and the sites are covered under the privacy act and patient confidentiality.
73	442	**Does "start date" mean the day the White House makes the announcement that stage 1 vaccinations will take place? Will the start date be the same for all states or is it tied to the arrival in our state of the vaccine?**	Start date is when President Bush makes the announcement; same for all states.
73	443	**What is the correct timing of vaccination for vaccinators?**	They can be vaccinated at any time before beginning large volume vaccine handling or administration. Not necessary for the vaccinator to have had a fully evolved vaccine site following vaccination prior to administering the vaccine to others.
73	466	**What role will infectious disease practitioners play in the small pox vaccination plan?**	Suggested that infectious disease providers interested in having a role in Small pox planning should contact their own local health department BT program.

Smallpox Q and As

73	467	**What are the recommendations for ensuring that State Small Pox plans address small pox pre-event planning for the Native American Population? Are there any plans for providing IHS with separate funding?**	We do not have an answer yet. Clarification is needed whether these other federal agencies have their own plans for getting vaccinated or do they fall under state responsibility. However state health departments should also be reminded or encouraged to include the Native American population in their pre-event small pox planning.
73	468	**What are the plans for continuing vaccinations past stage 1? There may be a large turnover in vaccinated team members?**	Long term plans for continuing vaccinations past the current stage 1 are not yet fully developed. There will likely be opportunities to vaccinate new team members as they are identified.
73	481	**How do states get their state system certified?**	Process will be published and handled by a specified group designated to handle certifications. No definitive date or time has been set for release, but it currently in process.
73	496	**Does the Supplemental Guidance for Planning & Implementing the NSVP requirements only relate to the 2 groups (Public Health Smallpox Response Teams & Healthcare Smallpox response Teams)?**	Yes.
73	498	**Will the VA system be included in the public health activities or will they be implementing their own smallpox clinics with their own vaccines?**	We do not have an answer to this yet.
73	499	**How will information on smallpox adverse reactions be distributed back to the state health department for their data and surveillance needs that are sent directly to VAERS, bypassing the state health departments?**	We will send CDC internal reports daily through email. As we get VAERS information, we will forward state specific information to the respective states.

Smallpox Q and As

73	503	**Do we in public health vaccinate hospital core teams or can we teach them how and let them vaccinate their own?**	The state will set up the vaccination clinics and will identify the vaccinators. The states will use a "train the trainer" concept.
73	505	**Approximately how many doses of vaccinia immune globulin (VIG) will be available when we start vaccinating in December and by January?**	Vaccinia immune globulin (VIG) is a product used to treat certain serious adverse reactions caused by smallpox vaccine. There are about 2,700 treatment doses of VIG (enough for predicted reactions with more than 27 million people). Additional doses of VIG are being produced this year.
73	506	**What are the plans to evaluate this program as it moves on?**	Page 7 of the Smallpox Vaccination Program Guidance states: Grantees will be required to submit semi-weekly status reports on each Monday and Thursday throughout the vaccination program. These reports should be submitted to National Immunization Program, Data Management Division. A reporting form with required data elements is provided in Annex 11. This information will enable CDC to conduct ongoing evaluations during and after program implementation. Additionally, external evaluation will consist of the following: 1) IOM will evaluate the processes of the program, and 2) ACIP will set up a working group to advise on vaccine adverse events.
73	509	**Are there any plans to redistribute the guidance materials to the grantees since they contained numerous inconsistencies?**	The Guidance will not be redistributed since the deadline for submitting the plan was December 9, 2002. However, we will continue to provide technical assistance and will update the annexes. Please inform us of inconsistencies that you may find.
73	510	**Why are we focusing on finding response team volunteers in the hospitals? Why not use community volunteers, instead?**	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 mange patients who present to the Emergency Department with suspected smallpox.
73	512	**The local health agencies appear to have no role in preparedness activities, other than vaccination. Are hospitals supposed to deal directly with the state on all preparedness activities?**	The state will need to collaborate with appropriate local health agencies, medical and hospital organizations and individual hospitals to develop the criteria for and numbers of hospitals to be involved and in identifying individual health care workers to be offered vaccine.

73	**521**	**How will post vaccination events be monitored?**	Please see Annexes 7 and 8.

F. Vaccination and Clinic Operations

74	**199**	**Are nurses the only ones who can administer smallpox vaccine?**	The vaccine can be administered by nurses, doctors, or other licensed healthcare professionals. Whether or not non-clinical personnel can be used in a vaccination clinic is dependent on state laws. Local health agencies should consult with their state health department on what is allowable.
74	**204**	**If all the medical volunteers in a small county have contraindications to receiving the vaccine, can the medical director designate non-clinical personnel?**	Whether or not non-clinical personnel can be used in a vaccination clinic is dependent on state laws. Local health agencies should consult with their state health department on what is allowable.
74	**431**	**How long must health care vaccinators wait before they can vaccinate others?**	According to ACIP recommendations, furloughs are not necessary for hospital staff so vaccinators can begin immunizing as soon as they themselves are vaccinated.
74	**433**	**Our Regional Patient Care Coordinators would like to know if there will be bifurcated needles made available for training purposes to the states in advance of the vaccine?**	There are other bifurcated needles that have been approved by the FDA However, the smallpox vaccine comes in a kit with its own bifurcated needle and the vaccine is licensed to be used with that needle only. Some of the other bifurcated needles are safety needles and designed differently from the needle in the kit, therefore these needles may not be appropriate for training purposes.

Smallpox Q and As

74	447	**Will CDC provide hands on training on giving the vaccine?**	Training will be a collaborative effort between CDC, states and hospitals. CDC will provide materials including satellite courses, internet and training modules. States will need to develop plans to assure training of clinic staff and response teams.
74	461	**Is CDC supplying Patient Immunization Record Cards?**	These forms are being revised by CDC. After final approval of revisions is obtained, the forms will be sent electronically to state BT programs. States can adapt the forms for their own use.
74	469	**I will be part of the team for my state and although I do not have any contraindications, I have a child with a history of eczema. Can I get vaccinated?**	No. Eczema or atopic dermatitis (current or past history) in the recipient or household contact is a contraindication for smallpox vaccination
74	492	**Are grantees required to send information to Phase I vaccine recipients one week in advance as suggested in the ACIP October meeting?**	No. The 17 page information document addressed the IND vaccine and should not be used with the licensed product. The VIS should be used instead.
74	493	**When will the 20 minute patient pre vaccination education video be available?**	The video is scheduled to be finalized next week and made available to the projects.
74	501	**Can vaccinators immediately begin inoculating others after they've been vaccinated or should they wait a period of time and if so, howmuch time?**	They can begin vaccinating others immediately. Vaccinators are vaccinated in part to assure that they have been screened to receive vaccine, so that someone who has a contraindication is not administering vaccine and taking the chance that they are accidentally exposed.

Smallpox Q and As

74	507	**In the post-event clinic plan, a vaccinator witness is suggested. This is not included in the pre-event clinic plan. Should we include one?**	A vaccinator witness is not needed in pre-event vaccinations because only licensed vaccine is being used. Depending upon state law, however, states may have such a requirement and therefore may need to add a witness signature line if we don't include one. A vaccinator witness would be required in a post-event vaccination should it be necessary to use unlicensed vaccine; this is a requirement of the IND protocol.
74	508	**Who specifically among the vaccination clinic staff should be vaccinated? Do we include all clerical staff, as well?**	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. It is not necessary for anyone not handling the smallpox vaccine to be vaccinated.

G. Vaccine Logistics

75	113	**What is the size of the individual vaccine kits?**	Each vaccine kit will contain sufficient vaccine, diluent, and bifurcated needles to immunize 100 persons.
75	120	**What is the size of the vaccine vial itself?**	The vaccine vial will hold 100 doses of vaccine after reconstitution. The vial is about 1-1/2 inches tall and about 5/8 inches in diameter.
75	228	**Do individuals who are involved in the packaging, shipping, general handling, or distribution of the smallpox vaccine need to be vaccinated themselves?**	CDC only provides smallpox vaccine that has been properly packaged by companies with adequate manufacturing and production quality control or quality assurance standards in place. Because these quality control or assurance procedures ensure a properly packaged vaccine product, it is not necessary to vaccinate individuals who routinely package, ship, handle, or distribute small quantities of smallpox vaccine.

Smallpox Q and As

75	231	**Can an individual, who has contraindications for receiving the smallpox vaccine, ship, handle, or distribute open vials of smallpox vaccine that may be returned from a clinic?**	If proper packing and shipping procedures are observed in normal shipping activities, a person handling smallpox vaccine vials would not come into direct contact with the vaccine. Therefore, even if they have a contraindication to the vaccine, vaccine shippers should be able to handle the shipping, handling, and distribution of vaccine vials. However, if there is concern, the shipper can either use gloves when handling smallpox vaccine shipments or another person without contraindications to the vaccine should handle the vials, especially if there has been any damage to the vials in transit.
75	280	**If a clinic has concerns about the viability of vaccine, to whom can they speak?**	They should contact the manufacturer, Wyeth.
75	281	**Is it possible to get extra bifurcated needles in addition to the number provided?**	Vaccine kits will include 100 individually wrapped needles as part of the kit. Since each vial contains 100 doses of vaccine, this should be an adequate supply of needles. However, if a project area runs into problems, they should have their NPS coordinator contact the National Pharmaceutical Stockpile at the number provided in the shipping instructions.
75	294	**Will bandage supplies be provided?**	No. Vaccination facilities are expected to provide bandage supplies.
75	295	**Will CDC be shipping more than one type of vaccine to each site area? (Dryvax and other newer vaccine) Will both be available to each site?**	Only Dryvax vaccine will be shipped for preparedness activities.
75	302	**Must vaccine be received 24 hours prior to administration in order for the vaccine to stabilize?**	The vaccine does not need to be stabilized before use but the National Pharmaceutical Stockpile (NPS) is requesting return to NPS of the temperature monitoring device that accompanies the vaccine. NPS will read the device to document/ensure that the appropriate temperature was maintained during shipment before the vaccine is used. This is presumably what the 24 hour waiting period referred to.

Smallpox Q and As

75	344	**Is there a period prior to vaccination shipment that states can request an amendment to the number of doses stated in their Pre-Event plan?**	Because the state plans were put together within a short period of time, CDC recognizes that states may not have had sufficient time to estimate to the amount of vaccine they will need. We also understand that institutions and potential response team members will be continue to evaluate their role in the program. Consequently, we expect that the amount of vaccine a state will need is likely to change and we will work to ensure that each state has the amount of vaccine that they need for Phase 1.
75	375	**Will vaccine be shipped to states prior to 1/24?**	We are working on completing the vaccine distribution plan.
75	376	**For those states that won't get the full amount of vaccine in one shipment, can they receive a small amount of vaccine for vaccinating the vaccinators?**	We are working on completing the vaccine distribution plan.
75	434	**Must unopened vials be returned to CDC? Shouldn't projects just keep the vaccine if they plan to vaccinate some more people in the next stages of the program? What should they do with opened vials remaining after stage 1?**	There are no written instructions. Unused, opened vials and opened, reconstituted of smallpox vaccine that have been kept beyond the allowed expiration date should be considered a biohazard and should be disposed of following the procedures for all other biohazard materials. Empty, used vials of smallpox vaccine should be disposed of as you would any other empty, used live virus vaccine vial. Both unreconstituted and reconstituted vaccine should be stored at between 2 and 8 degrees C when not in use. It may be kept at normal room temperature during the course of a clinic session and then placed back into refrigeration. The vaccine is good for 60 days after being reconstituted and may be taken in and out of refrigeration as many times as needed during the course of those 60 days.
75	437	**Is there a separate syringe for diluent?**	A separate syringe will be provided.

Smallpox Q and As

75	448	**If we as health care workers who get vaccinated do not have to be furloughed, is it okay if we get vaccinated anyway if we have household contacts who have eczema or atopic dermatitis as long as we are extra careful at home?**	It is not recommended to get vaccinated if you have household contacts who have eczema or atopic dermatitis period! It is a contraindication even if you think you will take extra precautions at home.
75	476	**Are all pre-screening and screening documents for vaccine logistics as recommended in ACIP's Oct 21 statement be provided by CDC?**	All appropriate shipping documents will be included in the vaccine shipment. Annex 2 provides additional details about items included in vaccine shipments.
75	477	**Who is responsible for vaccine shipments?**	CDC will be responsible for security up until the time the vaccine is received by the repository designated by the grantee. At that point, security is the responsibility of the grantee.
75	490	**Is the smallpox vaccine package insert available prior to receipt of vaccine?**	This information is available at the following website: http://www.fda.gov/cber/products/smalwye102502.htm
75	491	**Is the vaccine information statement the only document required for informed consent? Is the 17 page document in the guidance required and if not, can it be used for educational purposes?**	The VIS should be used as the method of informed consent. The 17 page document addressed the IND vaccine prior to licensure and should not be used.
75	517	**What is the size of the delivery for each state and will there be a "clumsy finger" factor of 5% like other vaccines?**	The number of doses of smallpox vaccine to be shipped to a state will be determined by the state's pre-event request and CDC's approval of the request. CDC will work with states on accounting when a vial holds less than 100 doses and for wastage.

Smallpox Q and As

75	**522**	**Are there written instructions regarding the disposal of opened vials of smallpox vaccine?**	There are no written instructions. Unused, opened vials and opened, reconstituted of smallpox vaccine that have been kept beyond the allowed expiration date should be considered a biohazard and should be disposed of following the procedures for all other biohazard materials. Empty, used vials of smallpox vaccine should be disposed of as you would any other empty, used live virus vaccine vial.

H. Vaccine Safety and Security

76	**495**	**What happens when if smallpox vaccine is spilled during transport?**	Use universal precautions to clean it up, whether in powder form or reconstituted liquid form.

IV. Smallpox Information/Education Resources

A. Images

56	**475**	**Will we be getting better pictures for vaccinee "takes".**	Forms with pictures of "takes" are being revised by CDC. After final approval of revisions is obtained, the forms will be sent electronically to state BT programs. States can adapt the forms for their own use.

B. References

57	**371**	**Is an MMWR article scheduled for publication in January**	Yes, two articles targeted at MDs are scheduled for production in January. One summarizing the October meeting of ACIP and the second, on diagnosis, management, and treatment of adverse events associated with smallpox vaccination.

Smallpox Q and As

57	379	**Have Fact Sheets been finalized? States would like to use the Fact Sheets to recruit volunteers in the hospitals.**	No, expect to have final version out early next week but "final" version may change as we continue to get helpful comments and suggestions.
57	380	**Have ACIP Guidelines been adopted by CDC?**	No. The draft guidelines are being reviewed by the ACIP and should be finalized soon. They will then be submitted for review and approval through CDC and HHS and hopefully published in the MMWR in January.

C. Training-related Questions and Materials

58	346	**Is a pre-screening video for viewing in clinics and hospitals available?**	CDC has developed a video, December 20, 2002, that can be used as a pre-screening video. A video designed for the vaccination clinic was completed on December 23, 2002. These videos should be available soon.
58	347	**Does CDC have a list of deliverables and upcoming events e.g., Live broadcast discussing considerations for volunteers? If yes, are they posted on the CDC Web site?**	CDC plans to have a list of all training and educational materials (both those that are completed and those that will be provided) on our Web site by December 24, 2002.
58	348	**Will bifurcated needles be provided during the Atlanta vaccinator training session? Will bifurcated needles be sent to the states?**	Bifurcated needles were made available to each state as part of the vaccinator training program. These needles will be used in subsequent training programs conducted at the state level. Some participants were able to bring their state's batch of needles home with them and some asked that they be shipped. Vaccine kits will include 100 individually-wrapped needles as part of the kit. Since each vial contains 100 doses of vaccine, this should be an adequate supply of needles. However, if a project area runs into problems, they should have their NPS coordinator contact the National Pharmaceutical Stockpile at the number provided in the shipping instructions.

Smallpox Q and As

58	364	**What is the status of the catalog of deliverables and forms?**	Catalog has been created and will be published on the Web next week. Undergoing minor changes to make it user-friendly. Pre-screening forms have been sent to each organization for comments. Comments have no specific submission date but the forms will be finalized by CDC the week of 1/6/03.
58	381	**What are states and others doing to educate the community physicians and other individuals who may want to be vaccinated, e.g., individuals working with WIC?**	CDC is working with the professional associations to develop plans to educate their members about the plan including the front-line clinicians.
58	387	**Who should receive operational questions?**	Each grantee can send operational questions to the Co-Operative Agreement Program Officer or send them to appropriate group (ASTHO/NACCHO/CSTE/APHL) and each will batch the Qs and send them to CDC.
58	427	**How will the public be educated about vaccination of response teams? What tools are available or being developed.**	Education efforts include websites, training courses, CD ROMs, workshops, satellite courses, f act sheets for general public use and health care providers. For more information, visit www.cdc.gov/smallpox or call the CDC public response hotline at (888(246-2675 (English), (888) 246-2857 (Espanol), or (876) 874-2646 (TTY).
58	430	**Will CDC provide trainers and resources for training?**	Training will be a collaborative effort between CDC, states and hospitals. CDC will provide materials including satellite courses, internet and training modules. States will need to develop plans to assure training of clinic staff and response teams.
58	438	**In what languages are Smallpox Vaccine Information Sheets available? What smallpox information is available for non-English-speaking people? Is CDC or a state producing all the forms/brochures in other languages?**	English is the only language currently available. One approved, the English VIS will be going to California who will translate into other languages with Spanish being the first priority.

Smallpox Q and As

58	487	**On the AIM call the other day, it was briefly stated that a smallpox training to be held on December 16 - 18. Is this planned and if so, what issues will be addressed?**	Additional one-day training sessions will be offered on December 17, 18, and 19 on how to administer smallpox vaccine. Per Dr. William Atkinson (during the Part 2 broadcast - 12/06/2002), each BT grantee will be asked to select 2 persons for this training. Further information will be available in the immediate future.
58	488	**On the AIM call the other day, it was briefly stated that a smallpox training to be held on December 16 - 18. Is this planned and if so, what issues will be addressed?**	Additional one-day training sessions will be offered on December 17, 18, and 19 on how to administer smallpox vaccine. Per Dr. William Atkinson (during the Part 2 broadcast - 12/06/2002), each BT grantee will be asked to select 2 persons for this training. Further information will be available in the immediate future.
58	497	**Will there be additional training for vaccinators besides the satellite downlink that will occur Dec. 5 & 6? If additional training is to be offered, then what type of timeframe are we looking at for implementation?**	A letter from Glen Koops went out to State Health Officers on Dec. 5th stating that a one-day course on vaccinator training will be held in Atlanta. The CDC will provide the one day ""train the trainer"" course and pay for two staff. The one day course will be offered 3 times over 3 consecutive days, Dec. 17 - 19, 2002. Responses on who will be attending from each state is due Dec. 11th. Please refer to the Dec. 5th letter from Glen Koops for more details.