

**WEBCAST TRANSCRIPT****Transcript of "Considerations for Hospitals: Developing a Smallpox Healthcare Response Team"**

Presented by Dr. Jane Siegel and Dr. David Fleming, 5 December 2002, on the satellite broadcast of "CDC Bioterrorism Update: Smallpox Preparedness"

(Associated graphics can be found at www.bt.cdc.gov/agent/smallpox/training/webcast/dec2002/files/hospital-consider.ppt and www.bt.cdc.gov/agent/smallpox/training/webcast/dec2002/files/hospital-consider.pdf.)

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(Slides 1 and 2 are title and objectives, respectively)

SIEGEL:

It is a pleasure for me to be here this afternoon with you and to represent the Healthcare Infection Control Practices Advisory Committee. During the next 30 minutes I'm going to review with you the current recommendations and rationale for those recommendations for selection and management of hospital based vaccinated healthcare workers. I will also be discussing issues to be considered by hospitals in order to ensure a safe and successful implementation of the healthcare worker smallpox vaccination program.

Slide 3

First let's start with how the recommendations were actually developed. During a meeting on September 23rd and 24th of this year, the options for selection of healthcare workers for smallpox vaccination and post-vaccination management were developed by the smallpox vaccine working group, which is comprised of various stakeholders including representative members of three federal advisory committees: the ACIP, the Advisory Committee on Immunization Practices that works with the National Immunization Program; NVAC, the National Vaccine Advisory Committee of the Department of Health and Human Services; and HICPAC, the Healthcare Infection Control Practices Advisory Committee of the Division of Healthcare Quality Promotion in the National Center for Infectious Diseases at CDC. Recommendations were then developed and approved by the ACIP and HICPAC at their meetings in October 2002 and are posted on their respective websites.

Slide 4

The goal in creating a hospital-based smallpox healthcare response team is to provide uninterrupted medical care for smallpox patients in acute care hospitals that will be providing care for both smallpox patients and patients without smallpox. In order to do this, we would need to vaccinate a team of healthcare workers who will be protected and feel comfortable managing smallpox patients in the emergency room and providing direct primary medical care for the first patients with suspected or confirmed smallpox admitted to acute care hospitals. This would essentially be creating a "ready-to-go" team of individuals who would be able to provide care immediately in those days after the first smallpox patients are identified when vaccine is being deployed and administered to large numbers of individuals.

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Slide 5

There are several underlying principles that have guided the formulation of the current recommendations for selection of healthcare workers for vaccination. And they are as follows: First of all, we feel that only immune healthcare workers should care for patients with vaccine-preventable diseases. Protection provided to susceptible healthcare workers by protective equipment such as respirators, gowns, gloves, could be overwhelmed by an exposure to a very large inoculum of virus or misuse of equipment. And finally, unvaccinated, non-essential personnel must be restricted from entering areas where smallpox patients are present.

Slide 6

What would be the requirements of a smallpox healthcare response team? First of all, there must be voluntary willingness to be vaccinated. No healthcare worker would be vaccinated against their will or be coerced into accepting vaccination. However, vaccination is required for all members of the healthcare response team. There will be a preference for revaccinees, that is providing vaccination for those individuals who have had vaccine in the past, which in most cases are those who are 32 years of age or older.

Slide 7

Next, this team must be able to have enough members of the appropriate category -- categories of healthcare workers needed to deliver medical care 24 hours a day 7 days a week for the first 7 to 10 days following the initial appearance of smallpox patients. Seven to 10 days was chosen as an estimate because that is the time that would allow us to determine how many of the individuals vaccinated during the first round of mass vaccination efforts would have a take and be protected and be appropriate for providing care to smallpox patients. The categories and number of healthcare workers per hospital will be based on several factors. One factor would be the composition of the patient population, what types of patients are cared for in that institution. Another is the type of medical care delivered in the institution, intensive care units, specialized care units and general medical patients. And then work schedules, vacations and anticipated workload. These are recommendations made to guide hospitals, but it's clear that individual hospitals and health departments may modify the recommendations in order to meet their needs.

Slide 8

Let's look at the suggested composition of healthcare response teams. First of all, if we look at the emergency room staff, the intention would be to have selected numbers of physicians and nurses from the emergency room who would be able to provide care. There could also be some selected emergency medical technicians who would be needed for transport as determined by individual hospitals. The goal is not to vaccinate the entire emergency room staff, but rather those selected in order to have sufficient numbers to provide care in the first week. Then if we look at the intensive care unit, again, it would be selected physicians and nurses. And for these two areas, it is important for hospitals that provide care to infants and children to include those professionals who have training in pediatrics.

Slide 9

Now, if we look at the general medical unit, it is likely that in hospitals where there are appropriate types of negative pressure or airborne infection isolation rooms that would be appropriate to care for patients with smallpox, that there would be general medical units and the individuals to staff those units would be selected nurses and physicians. Those physicians may be hospitalists, internists, pediatricians, obstetricians and in certain centers, where family physicians are the main physicians who are the essential providers of primary medical care, those individuals would be included. Similarly, in hospitals that depend

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on the housestaff for providing primary, direct medical care, there would be selected medical, pediatric, obstetric and when essential, family physician housestaff.

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If we look at the specialists needed in this situation, I think it is reasonable to believe that the infectious disease specialist will be certainly called upon to assist in diagnosis and management. Surgery and anesthesia teams may be indicated in order to provide the supportive care, but not for the primary care. There are a variety of specialists that would be needed and perhaps creating regional teams for consultation would be the most efficient way to make certain there are enough specialists available rather than each hospital having their own specialists vaccinated. The types of specialists that we would include would be: within a community, there may be consultants who have had first-hand experience with smallpox disease or vaccine and adverse effects from vaccine. Those individuals would provide very valuable perspective and information for us. Dermatologists may be called upon to perform diagnostic skin biopsies. Ophthalmologists may be needed to assist in the management of eye complications. Pathologists may also be needed to assist in assessing tissue and assisting us in that way. There may be other specialists as defined by individual institutions.

Slide 11

Another group of individuals that would be very important to vaccinate for primary healthcare response is the infection control staff. The infection control staff certainly provides valuable input in terms of management of patients, of implementation of infection control recommendations and assistance in contact investigation as well. Respiratory therapists and radiology technicians would also be important to provide the supportive care and diagnostic care for smallpox patients and the group of security personnel in the hospital would be very important in order to maintain a calm and safe environment.

Slide 12

Another group of workers are the property services or housekeeping group of workers. These individuals are required, selected individuals would be required to maintain the environment and decrease the risk of fomite transmission. These individuals are present throughout the hospital and it would be difficult to restrict all housekeeping individuals from areas where smallpox patients are present. Therefore, they should be offered the opportunity to be protected with vaccine. One group of workers that is not included in this first round of healthcare worker vaccinations are the clinical microbiology laboratory workers. It is important when considering lab workers to make the distinction between the risk of exposure in research labs where very high concentrations of virus are being handled as compared with the exposure in clinical microbiology labs where the actual viral load in the usually submitted clinical specimens, the body fluids would be quite low. Adherence to standard precautions and to the ASM, American Society of Microbiology and CDC protocols would prevent exposure of clinical lab workers to virus present in lab specimens.

Slide 13

Once we've selected our individuals -- our healthcare workers for vaccination, we need to be prepared to manage these individuals. And before we go on to that, I'd like to review with you some background considerations that were helpful in formulating the current recommendations. First of all, historically, we know that there's a low risk of transmission of vaccinia virus to healthcare worker hospital contacts from recently vaccinated healthcare workers. This information has been reviewed very nicely in a publication by John Neff and colleagues in the October 15th, 2002, JAMA issue. We know when transmission did occur, it was more likely to be in the home setting, where there was a much closer type of contact and also more from primary vaccinees. We also have a tool available to us now that was not available in past years when we used smallpox vaccine. That is the use of semi-permeable dressings. From two publications, we know there's a 100% virus containment in 97% to 100% of cultures obtained from the outside of the semi-permeable transparent dressing over folded gauze; that is, no virus was recovered from 100% and 97%

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of outside dressing cultures in the two studies, respectively. I've listed the citations for you here on the slide. In addition, we know these dressings are very well tolerated when they are changed, as soon as exudate begins to appear at the site, which is approximately every three to five days. This experience has been published in the spring of 2002 in the New England Journal of Medicine.

Slide 14

Another consideration is that we have a hospital-wide distribution of high risk patients. We're all familiar with the risk associated with patients in specialized units, in intensive care units, bone marrow transplant units and burn units. But if we think about the risks such as immunosuppression either to secondary to primary disease processes or secondary to treatment modalities, we know many at risk patients are distributed throughout the hospital. In addition, we know there are patients throughout the hospital who have disruption of the normal protective skin barrier, such as the patients with atopic dermatitis, with burns, with other extensive skin eruptions and the use of medical devices such as central venous catheters and ostomies that further break down the normal skin barriers. It would be difficult to reassign healthcare workers who have been vaccinated to areas where there are no "at risk" patients. The final consideration is the severe nursing shortage that hospitals in our country are facing. We know it's been very well reported in recent publications that these nursing shortages are associated with adverse outcomes. Adverse patient outcomes including shock, cardiac arrest, increase length of stays and increased rate of healthcare associated infections. In hospitals that are experiencing these types of shortages, it would be very difficult to tolerate substantial numbers of healthcare workers being on administrative leave for the time following receipt of the smallpox vaccination, especially in critical areas such as ICUs and the ER.

Slide 15

Therefore, in light of these considerations, administrative leave is not required for newly vaccinated healthcare workers unless certain circumstances are present. One is if an individual is physically unable to work. That is, we know that a small number of individuals at about 8 to 10 days following vaccination will have sufficient systemic signs to not feel well enough to be able to work. Secondly, if there's an extensive reaction at the vaccination site that cannot be completely covered by the dressing, that individual should not work either. Finally, if the healthcare worker is unable to adhere to the infection control recommendations that would prevent potential transmission of virus, especially consistently practicing proper hand hygiene, that individual should not be allowed to work. Although administrative leave is not required for newly vaccinated healthcare workers, it is true that individual institutions may choose to make individual reassignments or if feasible in that institution to place on leave. Those are individual decisions that must be made. However, based on the information that I've reviewed with you, we do not feel administrative leave is necessary.

Slide 16

What are the components of a hospital-based program? One is education. Certainly there will be an educational pre-vaccination day that will be part of the vaccination program, but we think it's important for hospitals to begin education as soon as possible so that healthcare workers may make informed choices in accepting the vaccine. Then we have identification of candidates without contraindications. The use of semi-permeable dressings over folded gauze is a necessary component as is a vaccination site monitoring program.

Slide 17

I know that you can't read this algorithm on the slide. This summarizes the steps in care of the vaccination site. It begins with the decision of what type of product to use based on the presence or absence of tape sensitivity. There are various steps that are outlined here, most of which I will discuss in

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the next few slides. This algorithm will be available to you. I think it may be a useful tool to help individuals see how the site care should be managed.

Slide 18

If we look at the components of site care, number one is to observe thorough hand hygiene, hand washing with anti-microbial soap and water or the use of approved alcohol-based handrubs. Remember that if there is visible soiling on the hands, then handwashing with antimicrobial soap and water is recommended. In the absence of visible soiling, the use of alcohol-based handrubs is preferred and this is described very well in our recently published guideline for hand hygiene in healthcare settings. Hand hygiene should be observed after contact with the vaccination site or any materials that have been in contact with that site, after removal of gloves that have been in contact with contaminated materials and, as always, before and after patient contact.

Slide 19

Another important point is to keep the site covered with folded gauze or similar absorbent material overlaid by a single semi-permeable dressing until the scab has separated, approximately 21 days after vaccination. When the healthcare worker is at work, it's important to cover the dressing further with clothing and probably a long-sleeved item of clothing with a cuff or something to keep that sleeve in place. This would provide maximum protection.

Slide 20

At home, showering is allowed, but again, to improve the margin of protection, the site should be covered with plastic wrap. The vaccination site should be the last site dried. The towels should be kept separate and should be ideally washed with hot water that is at least 160 degrees Fahrenheit, and soap. This is most likely only possible in commercial hospital laundries, but is not achievable in the home. In the home, contact time of 10 minutes at 20-25 degrees C (68 degrees F), using a standard detergent, followed by a hot air drying cycle would be sufficient to inactivate vaccinia virus. The dressing should be changed at the place of work, when the exudate first begins to accumulate, usually every three to five days. Gloves should be changed between removing the old dressing and applying the new dressing.

Slide 21

Finally, contaminated dressing materials should be discarded as regulated medical waste in a healthcare setting or in a sealed bag at home.

Slide 22

I'd like to look at the components of a site monitoring program. We think this is important to safely carry out this smallpox vaccination in hospitals. There would be a daily monitoring at the local institution prior to beginning the day's work assignment. There would be site inspection by a vaccinated staff member and the dressing would be changed when indicated as I described earlier. There would be an assessment of fitness for duty. Are there any contraindications for that individual to assume duty? Also, the site monitoring would provide an opportunity to triage adverse reactions that may need treatment and make sure the appropriate individuals are contacted for that. In addition, there would be a reporting of the experience and a capturing of the individual healthcare worker's daily diary to an active surveillance system. There's an internet-based surveillance tool that is currently being developed through the efforts of staff members in the National Immunization Program and the Division of Healthcare Quality Promotion. Finally, this daily site monitoring would afford an opportunity for educational reminders to vaccinated healthcare workers concerning hand hygiene and proper infection control practices in order to minimize the risk of transmission.

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Slide 23

In the final two slides, I'll summarize the steps involved in implementation of a healthcare worker vaccination program for smallpox preparedness. The first step would be to identify a planning and monitoring team. Each hospital now has a terrorism preparedness team and has members on the team who would be appropriate to oversee this project. There would be infection control and hospital epidemiologists involved, administrative staff and other members designated by the local institution as appropriate to carry out this program. Next, a hospital would need to identify the categories and number of healthcare workers to be vaccinated. And it would be helpful to identify liaisons within each care area who would assist in identifying appropriate candidates, as well as providing education and support to those healthcare workers. Providing education is absolutely essential. We want healthcare workers to make informed choices.

Slide 24

We would identify the suitable volunteer candidates without contraindications and it would be helpful, I think, to plan to stagger these vaccinations by approximately one to three weeks within a clinical area. That is, we would prefer to not vaccinate all of our intensive care unit staff that we've identified as appropriate at one time, so that if there were systemic effects at 8 to 10 days, they would not all be absent at the same time. Finally, we would develop and maintain a site monitoring program.

This concludes my presentation on the considerations for hospitals. I hope that you have found this information useful and will be able to use it as you begin planning your local program. It's important for members of the healthcare community to know and to understand the rationale for the current recommendations and to know that there are many resources available to address questions as they arise.

MODERATOR:

Thank you, Dr. Siegel. We know that a lot of you working in hospitals and healthcare facilities have pressing questions about the possible liabilities for your facilities when deciding whether or not to administer the smallpox vaccine. As a part of this section on Considerations for Hospitals, with us today is Doctor David Fleming. Doctor Fleming is the Deputy Director for Science and Public Health at the Centers for Disease Control and Prevention. Dr. Fleming, welcome.

FLEMING:

I want to assure you we're aware hospitals, healthcare providers, and others have raised IMPORTANT concerns about potential liability for involvement in a smallpox vaccination program. Section 304 of the recently passed Homeland Security Act is intended to alleviate these liability concerns, and therefore to ensure that vaccine is available and can be administered.

Section 304 of the Homeland Security Act provides an exclusive remedy against the United States pursuant to the Federal Tort Claims Act for injury or death attributable to smallpox vaccine, other substances used to treat or prevent smallpox, or vaccinia immune globulin.

CDC is working with other federal partners to answer the many specific questions related to these issues. We very much understand their importance and urgency. As soon as this additional guidance is available, we will provide it to you. We appreciate your patience during this interim period. Thank you.

END

For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

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