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Donor deferral following widespread smallpox vaccination

The Smallpox Response Plan and Guidelines of The Department of Health and Human Services, Centers for Disease Control and Prevention, has caused at least one **transfusion medicine physician in New Mexico** to express concern over what might happen if **every American who was qualified to be a blood donor was vaccinated in a short time span for smallpox**. The concerned physician wonders if blood collection centers would have to defer recently vaccinated donors, and if so, for how long?

The following replies were submitted in response to the concerns of the New Mexico physician.

1. **A Navy physician** reports that all the tri-service military sub-specialty leaders to the surgeon-general concurred with the FDA recommendation of deferral of 21 days post vaccination as long as the vaccination site has spontaneously separated. The responding Navy physician provided the **following excerpt** from Section IV of the Draft Guidance regarding blood donors post vaccination.

"... Standard procedures that are already in place should allow identification of donors who have had complications of smallpox vaccination, or who have contracted localized infection or complications of vaccinia infection from exposure to a vaccinee. However, for donors who state that they have been vaccinated within the past two months, collection center personnel should visually inspect the site of the vaccination (usually on the upper arm) to determine whether the scab has separated, and if there has been recent vaccination they should inquire whether the scab separated spontaneously.

- A. Recipients of smallpox vaccine: The following recommendations apply to donors who have recently received smallpox vaccine, as identified by more general donor questioning concerning vaccines. In the event of **widespread** vaccination, the deferral recommendations for vaccinated individuals may need to be modified according to the circumstances and available scientific information.
 - Donors **without** vaccine complications: You should defer donors for **21 days or until the vaccine scab has spontaneously separated**, whichever is the later date. Donor room staff should visually verify absence of the vaccine scab and ask if it separated spontaneously. In cases where a scab was otherwise removed, the donor should be deferred for two months after vaccination.
 - Donors **with** vaccine complications: You should defer donors who have experienced complications of vaccination until **14 days after all vaccine complications have completely resolved.**"

ADDENDUM Oct. 2, 2002

2. **A transfusion medicine physician from a Gulf Coast state** appreciates the Navy physician for providing a source for a clear discussion of current recommended deferrals. However, the Gulf Coast physician is concerned that the new smallpox vaccination plan clearly envisions vaccinating whole cities or large regions within a very short time frame. In the responding physician's opinion, this would essentially eliminate blood supply from these regions for at least 21 days. In the face of a smallpox or other biological attack, she believes that we would probably want to increase our local blood supplies, not demolish them. Therefore, the physician hopes that the national implications of this problem are considered now, before it comes up. Among the **possible scenarios and solutions** that the Gulf Coast physician suggests for consideration are the following:

- IF the exposure and hence necessity for vaccination is truly local, perhaps **national resources could support the region for 21 days**. The AABB committee that is coordinating response to disasters might be involved here. However, one would have to consider the probability that more than one region, or even the nation, would need to be involved in the vaccination campaign.
- IF it would be relatively safe to use specific components made from a recently vaccinated donor during the 21 day period following vaccination, would it be possible to **label these products** so that they would not be given to the immunocompromised, who would be at risk of disseminated disease.
- It would be good to **bring these concerns to the attention of the authorities** working on

the overall smallpox plan and/or the FDA. She is certain the FDA would react promptly, as it did in the anthrax situation, but it would be good to have plans in place in advance.

ADDENDUM Oct. 3, 2002

3. **The New Mexico physician responds:** "A possible plan to avoid a 21-day loss of blood donors after mass smallpox vaccination would be to have donors vaccinated AT the blood centers AFTER donating blood. The public health officials would likely ask blood centers to do this as a public service. However, our center is very reluctant to have our nurses administer vaccine to the public for a number of reasons, including liability and FDA issues. This would not preclude a public health nurse from operating within the blood center for a few months - which may be the most practical solution. It would create a surge in donations of approximately five-fold for a week or so, but then there would be a dearth of donations for the next month."

ADDENDUM Nov. 26, 2002

4. (CBBS Fastbreaking News) Bush to announce plan for smallpox vaccinations for 500,000 health workers (CNN)

ADDENDUM Jan. 31, 2005

5. **The Editor** wishes to draw forum members' attention to today's FDA/CBER announcement on [Authorization of Emergency Use of Anthrax Vaccine](#).

Please submit comments to the [e-Network Forum](#).



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Posted: October 1, 2002

Addenda: Oct. 2 & 3, Nov. 26, 2002; Jan 31, 2005