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WHERE'S MY SMALLPOX VACCINE?

"U.S. to begin smallpox vaccination!"

SINCE LAST MAY, every major news outlet has run a similar headline. As a consequence, you may be wondering, "and where indeed is my smallpox vaccine?"* In this issue of the *CD Summary* we describe our plans to prepare for smallpox.

PLAN THE FIRST: PREPARATION FOR DISEASE

Oregon Health Services (OHS) turned in its required Pre-Event Smallpox Response Plan (Plan 1) to the Centers for Disease Control and Prevention (CDC) on December 8th. The purpose of the plan is to vaccinate a limited number of public health and healthcare workers so that if smallpox strikes, immunized persons can care for initial victims, investigate the outbreak and initiate ring vaccination for contacts.

Plan 1 assumes that—in accord with intelligence to which we are not privy—the risk of an intentional release of the smallpox virus is considered "low."[†] Plan 1 also assumes that the vaccine will be licensed, that good liability protection exists, that workers' compensation and disability insurance are available to those who receive the vaccine, that there is adequate vaccinia immune globulin (VIG) to treat the expected adverse events and that there will be care and compensation for vaccinees' household contacts and patients should they be harmed by the vaccine.

Based on these assumptions, along with a review of the vaccine's side effects and the advice of two expert groups, Plan 1 calls for limited pre-event smallpox vaccination in Oregon. All pre-event vaccination in Oregon will be voluntary and restricted to two groups: (1) members of the Public Health Smallpox Response Team (PH SRT), and (2) members of Healthcare Smallpox Response Teams (HC SRTs).

SMALLPOX RESPONSE TEAMS

The PH SRT will consist of selected public health nurses and physicians in strategic locations around the state. These vaccinated professionals will assist with diagnosis of the first cases of smallpox, initiate ring vaccination, vaccinate and teach vaccination to healthcare professionals across the state.

HC SRTs will be composed of contraindication-free, consenting healthcare workers selected by willing hospitals. To assist hospitals in picking their teams and formulating their approach to hospital-based SRTs, a work group comprising public health, healthcare, infection control, infectious disease and emergency professionals was convened. In its own words,

"The Work Group recommends that each hospital in the state should identify a team of healthcare workers who would care for first cases of smallpox if the disease does reappear... All potential smallpox care team members would be screened for relative contraindications to vaccination both for themselves and for their immediate family members... Each hospital would then maintain a record, updated every 6 months, of smallpox care team members eligible for and willing to receive vaccination if it became necessary."

The group did not advocate vaccinating HC SRT members before a case of smallpox is confirmed; rather, it recommended a strategy of graduated vaccination as the risk of disease increased. Each hospital system in Oregon should:

- (1) develop its own SRT; (2) screen its SRT members for contraindications; and (3) maintain and update its SRT membership every 6 months.

ADVERSE EVENTS AND SCREENING OF VACCINEES

Two studies looked at adverse events following smallpox vaccination in the late 1960's and found the following rates

of severe adverse events per million among primary vaccinations:^{2,3}

Vaccinia encephalitis	3–12
Vaccinia necrosum	1–12
Eczema vaccinatum	10–42
Death	0.5–1
Generalized vaccinia	18–242
Autoinoculation	25–532.

These figures led to cessation of routine smallpox vaccination in the U.S. in the early 1970's. They do not include adverse events in contacts. A gross, but useful summary statistic that includes these two risk groups is one severe adverse event per 25,000 vaccinations.

It is suspected that adverse events associated with skin conditions and immunosuppression would occur more frequently now because of the increase in prevalence of atopic dermatitis, the advent of HIV, and greater use of chemotherapy and radiation for cancer treatment as compared to the past.⁴

All SRT members will be screened, firstly in private using a self-screening tool, secondly by their institutions, and finally at the time of vaccination. Persons with the following conditions should *not* receive the vaccine:

- HIV or AIDS
- Weakened immune systems from drugs, treatments, or medical conditions
- History of eczema or atopic dermatitis
- Currently active skin ailments (e.g., burns, severe acne, psoriasis)
- Pregnancy
- Anaphylactic reaction to a vaccine component.

Living with someone who has any of the first five conditions is also a contraindication to vaccination, because the live vaccinia virus can be spread to household members. In addition, there is a preference for vaccinating those who have been vaccinated in the past; such persons may suffer fewer adverse events compared to primary vaccinees, regardless of how long ago they were vaccinated.

* Or not.

[†] According to miscellaneous presidential statements in the press.



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In preliminary screening of SRT members, approximately half had contraindications to vaccination. This is not surprising considering that contraindications include everything from the uncommon (cancer chemotherapy) to the ubiquitous (teenaged sons at home with bad zits). And—after reading the informed consent materials—some of the remainder are reluctant to be vaccinated at all. Based on this limited experience, we estimate that only about 800 public health and healthcare workers in Oregon will be vaccinated pre-event.

LIABILITY AND COMPENSATION AS CONTRAINDICATIONS?

Section 304 of the Homeland Security Act provides some protection from liability for those who administer the vaccine. This protection goes into effect on January 24th, and one might presume that pre-event vaccination would proceed on January 25th. But Section 304 indemnifies *only* those who administer vaccine—in general, public health departments. According to the CDC's interpretation of the bill, there is no liability protection for hospitals that employ newly vaccinated staff who may be shedding live vaccinia virus.⁵

In addition, Section 304 provides no real compensation for vaccinees or their contacts who may suffer side effects. To be compensated, those who suffer adverse events must sue the federal government and prove that their maladies resulted from negligent administration of the vaccine, are not of the expected variety listed above, poor immune function, pustular eruptions, pregnancy or the heartbreak of psoriasis.

PLAN THE SECOND: RESPONSE TO DISEASE

If smallpox reappears, the chances of one death per million vaccinees pales in comparison to the 3-in-10 chance of death from the dehydration, hemorrhage, and shock associated with disease. In this scenario, vaccination of healthcare workers is necessary to enable them to care for patients without contracting and spreading the disease themselves.

The Post-Event Smallpox Response Plan (Plan 2) is to identify and contain an outbreak of smallpox. Oregon's Plan 2 was submitted to CDC on December 1. If and when the first cases of smallpox occur in North America, we will begin enhanced surveillance for smallpox in every hospital and county in Oregon, and we will vaccinate those healthcare, public health, public safety and first responder staff who were not vaccinated in Plan 1. All public health departments have identified field investigation and field vaccination personnel to implement search, containment and ring vaccination procedures immediately upon identification of cases or contacts in their counties. And finally, locations have been identified across the state for vaccination of the public should that prove necessary.

ALL IS NOT LOST

Perhaps the only reasonable thing smallpox virus ever did for us was to allow a three-day window after exposure in which to vaccinate and avert disease. The National Pharmaceutical Stockpile folks promise that we will have vaccine within 12 hours of a confirmed diagnosis of smallpox. These two phenomena allow

us to assure SRT members that we will vaccinate them (and all their colleagues) immediately post-event.

These same two phenomena also allow us to focus our plans for disease control on search, containment and ring vaccination. A few vocal critics have expressed doubt about the effectiveness of ring vaccination.⁶ Ring vaccination is, however, the only strategy that has been shown to control smallpox quickly and effectively: it was responsible for the eradication of the disease in the late 1970's (see *CD Summary*, Vol. 51, No. 4, February 12, 2002 for a fine summary; see also Halloran⁷).

While Plans 1 and 2, with their attendant problems satisfy the requirements for emergency planning, we will do what worked before—post-exposure and ring vaccination.

REFERENCES

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