FDA Advises Deferral Period for Blood Donors Given Smallpox Vaccine

NEW YORK (Reuters Health) Jan 01 - The US Food and Drug Administration (FDA) has issued a guidance advising the blood industry that potential donors who have received the smallpox vaccine should be deferred for at least 21 days.

Potential donors should be asked whether they have received the smallpox vaccine within the past eight weeks, the agency said. Those who have had the shot deferred until the scab from the vaccine has separated from the skin or for 21 days post-vaccination, whichever is later.

The smallpox vaccine has some rare but potentially fatal side effects, and those immunized can infect others with the live vaccinia virus used in the shot. The elderly, women, children, those with skin conditions like eczema, and the immunocompromised are especially at risk.

In its notice to blood and plasma collection establishments, the FDA noted that vaccinia virus "is readily recovered from the vaccination site until the vaccination site spontaneously separates from the skin." That means that, while the scab is still present, a vaccine recipient can infect anyone who touches the vaccination site.

The scab usually separates from the skin within 12 to 21 days, but sometimes remains for up to six weeks, the FDA said.

Small studies have suggested that vaccinia virus can sometimes be isolated from the blood for up to 10 days after vaccination, suggesting that a transfusion could result in complications in a patient who receives blood donated during that timeframe. However, the studies were conducted decades ago on a different smallpox vaccine currently used in the US, the FDA noted, so their value is limited. New research is underway, the agency said.

The FDA recommended that people with complications resulting from the vaccine be deferred until 14 days after the complications have completely resolved. The recommendation also applies to potential donors who have not received the vaccine but have become infected by close contact with a vaccine recipient, the agency said.

The guidance also contains a number of other recommendations. The full document can be obtained on the FDA's Web site, www.fda.gov.

The FDA stressed that the steps outlined in the guidance are "preventative measures pertaining to non-emergency smallpox vaccination." If vaccination became necessary on an actual smallpox outbreak or an impending outbreak, the guidelines might need to be revised to reflect "changing risk/benefit assessments and other public considerations," the agency said.

In response to the possibility that smallpox could be used in biological warfare, the Bush Administration recently rolled out a plan to offer the smallpox vaccine at highest risk of exposure, followed by "first responders," such as police and fire officials, and lower-risk healthcare workers. The US military began a vaccination program December 13, and vaccinations of healthcare workers are slated to begin in January.

Under the program, the vaccine eventually will be made available to the general public as well, although the FDA noted that the US government does not currently recommend vaccination for those without an occupational risk of exposure to smallpox.