

Society for Assisted Reproductive Technology position statement on donor suitability of recipients of smallpox vaccine (vaccinia virus)

The Practice Committee of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology

American Society for Reproductive Medicine, Birmingham, Alabama

Although there is presently no definitive evidence linking vaccinia virus transmission through reproductive cells, SART/ASRM accordingly recommends that assisted reproductive technology (ART) practitioners consider deferring donors who have recently received smallpox vaccine or contracted symptomatic vaccinia virus infection through close contact with a vaccine recipient (until after the vaccine or infectious scab has spontaneously separated). Good donor practice further suggests that donors who are not in good health, including those with recent complications from smallpox vaccine, should be similarly deferred. (Fertil Steril® 2004;82(Suppl 1):68–69. ©2004 by American Society for Reproductive Medicine.)

Vaccinia virus is a double-stranded DNA virus related to cowpox virus that has been used to vaccinate against smallpox for more than 100 years. Vaccinia virus is closely related to smallpox (variola) virus, and the immune response to vaccinia is therefore protective against the smallpox. All modern smallpox vaccines are live virus vaccines comprised of the New York City Board of Health (NYCBOH) strain of vaccinia virus.

The last case of smallpox in the United States (U.S.) occurred in 1949. Routine vaccination against smallpox in the U.S. stopped in 1971. The last naturally occurring case of smallpox in the world occurred in Somalia in 1977. In 1980, the World Health Organization determined that the global vaccination effort against smallpox had been successful in eliminating naturally occurring disease. Routine vaccination against smallpox has since been discontinued worldwide. However, the U.S. government has recently become concerned that smallpox virus might be used as a bioterrorism weapon. As a result, new smallpox vaccination strategies have been reinitiated in the U.S. for both military personnel and civilians.

Vaccinia vaccine is administered percutaneously. With a primary vaccination (no prior

vaccination), a papule forms in 3–5 days. The formation of a papule is considered evidence of a “take” or successful immunization. Subsequently, the papule becomes a vesicle. The vesicle becomes pustular, reaching its maximum size at 8–10 days, with surrounding erythema and induration. The erythema and induration then subside and a scab forms. The scab usually separates from the skin 14–21 days after the vaccination but has been noted to persist for up to 6 weeks in some cases (1).

Vaccinia virus may be spread from the vaccination site to other parts of the body and to other people until the scab falls off. At the height of the reaction, there is usually regional lymphadenopathy and sometimes fever and malaise. More serious side effects of vaccinia vaccination occur rarely and include CNS involvement (encephalitis, encephalomyelitis, encephalopathy), progressive skin infections (vaccinia necrosum), and eczema vaccinatum, which occurs in people with eczema and other related skin disorders. Approximately 1 death per million primary vaccinations has been reported (2).

In early studies, viremia had been detected 3–10 days after vaccination, although these studies did not use the less virulent NYCBOH

Committee Opinion

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Correspondence to: Practice Committee, American Society for Reproductive Medicine, 1209 Montgomery Highway, Birmingham, Alabama 35216.

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strain of vaccinia virus that comprises currently available vaccines (1). Studies to determine the presence or absence of viremia in patients receiving currently available vaccines are presently underway. Due to the potential risk, however, the FDA recently issued final guidance to the blood industry regarding deferral of donors who were recent recipients of smallpox vaccine as well as symptomatic contacts of smallpox vaccine recipients (3). The following summarizes current recommendations:

1. Donors who received smallpox vaccine should be deferred until after the vaccine scab has spontaneously separated.
2. Donors who developed complications of smallpox vaccinations (eczema vaccinatum, generalized vaccinia, progressive vaccinia, postvaccinial encephalitis, vaccinia keratitis) should be deferred until 14 days after complete resolution of the complication.
3. Symptomatic contacts (persons infected by close contact with a vaccine recipient) should also be deferred for similar intervals.

Although there is presently no definitive evidence linking vaccinia virus transmission through reproductive cells, SART/ASRM accordingly recommends that ART practitioners consider deferring donors who have recently received smallpox vaccine or contracted symptomatic vaccinia virus infection through close contact with a vaccine recipient (until after the vaccine or infectious scab has spontaneously separated). Good donor practice further suggests that donors

who are not in good health, including those with recent complications from smallpox vaccine, should be similarly deferred. Additional information regarding the presence or absence of viremia in patients who received currently available smallpox vaccines will help to better define the associated risks.

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References

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2. The Medical Letter, Vol. 45 (Issue 1147) January 6, 2003.
3. Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients, FDA Final Guidance, December 30, 2002.