Porcine Endogenous Retrovirus

Disease Agent:

- Porcine endogenous retrovirus (PERV)

Disease Agent Characteristics:

- Family: *Retroviridae*; Genus: *Gammaretrovirus*
- Virion morphology and size: Enveloped, icosahedral concentric nucleocapsid, spherical to pleomorphic particles, 80-100 nm in diameter
- Nucleic acid: Linear, positive-sense, single-stranded RNA, ~8.0-8.5 kb in length
- Physicochemical properties: Sensitive to heat, detergents, and formaldehyde

Disease Name:

- None

Priority Level:

- Scientific/Epidemiologic evidence regarding blood safety: Theoretical
- Public perception and/or regulatory concern regarding blood safety: Absent, given the current moratorium on xenotransplantation in the US. However, this is an issue for public health and regulatory agencies based on the perception that xenotransplant recipients or their contacts will become blood donors and may transmit these agents.
- Public concern regarding disease agent: Absent, given the current moratorium on xenotransplantation.

Background:

- The concern for transmission to humans as a result of xenotransplantation comes from experimental studies disclosing that the virus can be transmitted to human cell cultures in vitro.
    - The A and B strains of PERV can infect human cells in vitro, but the C virus appears to be confined to pigs.
- Porcine heart valve and porcine-derived Factor VIII have been shown to contain viral components, but recipients have not been infected.

Common Human Exposure Routes:

- Xenotransplantation could theoretically transmit to humans. Secondary transmission from these people to their intimate contacts has been hypothesized. Other exposures, such as those related to animal husbandry, would also be theoretical routes.

Likelihood of Secondary Transmission:

- Unknown

At-Risk Populations:

- See common human exposure routes. There is no documented at-risk human population to date.

Vector and Reservoir Involved:

- Reservoir: pigs

Blood Phase:

- Unknown

Survival/Persistence in Blood Products:

- Unknown

Transmission by Blood Transfusion:

- Not demonstrated; human infection has never been demonstrated by any route.

Cases/Frequency in Population:

- Unknown or absent

Incubation Period:

- Not characterized

Likelihood of Clinical Disease:

- No human disease has been recognized.

Primary Disease Symptoms:

- Not applicable

Severity of Clinical Disease:

- Not applicable

Mortality:

- Not applicable

Chronic Carriage:

- Unknown in humans
- Virus is integrated into genome of normal host (pig) cells.

Treatment Available/Efficacious:

- Not applicable

Agent-Specific Screening Question(s):

- No specific question is in use for blood donors; however, questions regarding xenotransplantation are required by FDA for donors of human cell, tissue, and cellular- and tissue-based products (HCT/P).
- Not indicated because human infection by any route, including transfusion, has not been demonstrated, and, currently, there is a moratorium on xenotransplantation in the US.
- In the event xenotransplantation studies resume, blood organizations have emphasized that it is the

responsibility of the transplant team to provide xenotransplant recipients and intimate contacts with a warning against blood, tissue, and organ donation.

Laboratory Test(s) Available:

- No FDA-licensed blood donor screening test exists.
- Research tests include NAT and virus expression by cocultivation with cell lines

Currently Recommended Donor Deferral Period:

- No FDA Guidance or AABB Standard exists for blood donors.
- Permanent deferral was previously proposed in draft guidance from FDA for xenotransplant recipients and their intimate contacts. However, final guidance has not been issued for blood donors, and there is a continuing moratorium on xenotransplantation.

Impact on Blood Availability:

- Agent-specific screening question(s): Not applicable.
- Laboratory test(s) available: Not applicable

Impact on Blood Safety:

- Agent-specific screening question(s): Not applicable.
- Laboratory test(s) available: Not applicable

Leukoreduction Efficacy:

- Unknown; theoretically could have an impact if putative human infection is leukocyte associated.

Pathogen Reduction Efficacy for Plasma Derivatives:

- No specific data available but presumed to be robust, as the agent is an enveloped virus that should be sensitive to many measures used in the fractionation process

Other Preventive Measures:

- Pathogen reduction would be expected to have efficacy, based on studies with other retroviruses.

Suggested Reading:

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