36 | PORCINE PARVOVIRUS

This fact sheet is being archived and will not be routinely updated absent relevant new data suggesting risks from transfusion.

36.1 | Disease agent

- Porcine parvovirus (PPV)

36.2 | Disease agent characteristics

- Family: *Parvoviridae*; Subfamily: *Parvovirinae*; Genus: *Parvovirus*.
- Virion morphology and size: Nonenveloped, icosahedral nucleocapsid symmetry, spherical particles, 20–26 nm in diameter.
- Nucleic acid: Linear, negative-sense, single-stranded DNA genome of 4.95 kb, although mature virions can contain mixtures of positive and negative sense DNA.
- Physicochemical properties: Heat resistant (56°C for 60 min), but relatively susceptible to inactivation by pasteurization at 60°C for 10 h and to dry heat in a freeze-dried state (1.5% moisture) at 80°C for 72 h; stable in lipid solvents; stable at pH 3–9; inactivated by other solvents.

36.3 | Disease name

- No human disease is recognized.

36.4 | Priority level

- Scientific/Epidemiologic evidence regarding blood safety: Theoretical
- Public perception and/or regulatory concern regarding blood safety: Absent
- Public concern regarding disease agent: Absent

36.5 | Background

- Infection is widespread in pigs, with no recent change in prevalence.

36.6 | Common human exposure routes

- No evidence of human infection, although pig handlers are commonly exposed via oral or respiratory routes.
- Recipients of biologic materials made from pigs, for example, porcine factor VIII (Hyate:C) or porcine xenotransplant tissues could be exposed unless the materials were derived from animals raised under special conditions that exclude PPV. Hemophiliacs treated with porcine factor VIII known to contain porcine parvovirus genetic material do not seroconvert, suggesting that infection does not occur.

36.7 | Likelihood of secondary transmission

- No human infection has been documented.
- In pigs, transmission occurs via oral/respiratory route and transplacentally during pregnancy.

36.8 | At-risk populations

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

36.9 | Vector and reservoir involved

- Reservoir: pigs

36.10 | Blood phase

- No human infection has been documented.
- In pigs, viremia is detectable 3 days after infection and persists for 7–14 days.

36.11 | Survival/persistence in blood products

- Unknown for blood components; likely to survive if present.
- Almost all lots of porcine factor VIII were positive for porcine genetic material in the past.
- Virus has been shown to be relatively resistant to pathogen inactivation.

36.12 | Transmission by blood transfusion

- Not demonstrated; human infection has never been demonstrated by any route.
- 98 patients with hemophilia who received presumably contaminated porcine factor VIII were negative for anti-PPV by IFA, and 81 were negative by hemagglutination inhibition assay (HIA) (populations may overlap). Study population included at least 13 patients with HIV infection.

36.13 | Cases/frequency in population

- Zero in humans, but is widespread in pigs

36.14 | Incubation period

- Humans: unknown

36.15 | Likelihood of clinical disease

- No transmission to humans has been documented despite intravenous exposure, so disease potential remains theoretical

36.16 | Primary disease symptoms

- Unknown; no human disease documented

36.17 | Severity of clinical disease

- Not applicable in humans; fetal demise in pigs; clinically insignificant infection in adult pigs

36.18 | Mortality

- Not applicable

36.19 | Chronic carriage

- Not applicable

36.20 | Treatment available/efficacious

- Not applicable

36.21 | 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 United States.
- In the event xenotransplantation studies resume, blood organizations have emphasized the responsibility of the transplant team to provide xenotransplant recipients and intimate contacts with a warning against blood, tissue, and organ donation.

36.22 | Laboratory test(s) available

- No FDA-licensed blood donor screening test exists.
- Research antibody and PCR assays.

36.23 | Currently recommended donor deferral

- 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.

36.24 | Impact on blood availability

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

36.25 | Impact on safety

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

36.26 | Leukoreduction efficacy

- Presumably ineffective based on distribution of virus in pigs and distribution of B19 parvovirus in humans.

36.27 | Pathogen reduction efficacy for plasma derivatives

- Relatively resistant to most plasma inactivation processes and also to amotosalen/UVA light. However, nanofiltration (using a 35-nm pore size filter) in the presence of 0.3 mol/L glycine leads to aggregation of the virus facilitating its removal.

SUGGESTED READINGS

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