10.1 Disease agent

- *Yersinia pestis*

10.2 Disease agent characteristics

- Gram-negative, facultatively anaerobic, bipolar staining, bacillus to coccobacillus, nonmotile, non-spore forming, facultatively intracellular bacterium.
- Order: Enterobacteriales; Family: Enterobacteriaceae.
- Size: 0.5–0.8 × 1.0–2.0 μm.
- Nucleic acid: The genome of *Yersinia pestis* is 4.6–4.7 Mb of DNA.
- Optimal growth at 28°C.

10.3 Disease name

- Bubonic and pneumonic plague
- Black death

10.4 Priority level

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

10.5 Background

- Longstanding pandemic and epidemic disease
- Endemic on all continents, except Australia
- Classified among the highest priority for bioterrorism agents by the US CDC (Category A)

10.6 Common human exposure routes

- Bites of fleas that have fed upon bacteremic rodents.
- Pneumonic plague is passed from person to person through droplet transmission.
- Human-to-human transmission is also thought to occur through the human flea (*Pulex irritans*).
- Direct contact by handling of infected tissues and through contact with respiratory secretions of infected animals

10.7 Likelihood of secondary transmission

- Person-to-person transmission is significant in the case of pneumonic disease.

10.8 At-risk populations

- Anyone in areas with wild rodents with enzootic plague or exposed to domestic animals infected by wild rodents
- In bioterrorism, population exposed to viable organisms or fleas infected with viable organisms

10.9 Vector and reservoir involved

- Fleas, most commonly *Xenopsylla cheopis*, the oriental rat flea, but other fleas can be competent vectors
- Reservoir is various species of mammal depending on the locale.

10.10 Blood phase

- High-grade bacteremia is associated with severe signs and symptoms.

10.11 Survival/persistence in blood products

- No direct evidence but is capable of growth in some media at 4°C

10.12 Transmission by blood transfusion

- Theoretical; however, no reported cases and the virulence of the organism makes asymptomatic bacteremia and transfusion transmission unlikely.

10.13 Cases/frequency in population

- Rare in the United States, with a mean of 10–15 cases per year
- Worldwide, 1000–3000 cases per year, with periodic outbreaks and epidemics
10.14 | Incubation period
- 1–7 days (1–4 days for primary pneumonic plague)

10.15 | Likelihood of clinical disease
- Highly infectious, with small inoculum size, essentially always associated with clinical disease

10.16 | Primary disease symptoms
- Bubonic plague (80%–85% of cases)—buboes (suppurative lymphadenitis), fever, prostration, sepsis, multiorgan involvement, and death
- Pneumonic (3% of cases)—fever, chills, headache, myalgia, fatigue, dyspnea, chest pain, bloody sputum, respiratory failure, and shock
- Septicemic (10% of cases)—sepsis and septic shock, without buboes

10.17 | Severity of clinical disease
- Considered to be the most severe acute bacterial infection in humans

10.18 | Mortality
- Bubonic plague: About 15% mortality rate for sporadic cases in endemic areas and about 60% mortality rate if untreated
- Pneumonic and septicemic plague: 100% mortality rate if untreated

10.19 | Chronic carriage
- No

10.20 | Treatment available/efficacious
- Effective therapy with streptomycin, gentamicin, and chloramphenicol.
- Tetracyclines, fluoroquinolones, and some cephalosporins may also be active.
- Treatment must begin within 24–36 h of onset to prevent mortality.

10.21 | Agent-specific screening question(s)
- No specific question is in use.
- Not indicated because of the low incidence of infection and low probability of asymptomatic bacteremia.
- No sensitive or specific question is feasible.
- Under circumstances of a bioterrorism threat, the need for, and potential effectiveness of specific donor screening questions would need to be addressed.

10.22 | Laboratory test(s) available
- No FDA-licensed blood donor screening test exists.
- FDA-licensed PCR tests exist but access is strictly limited.
- Serology: Detection of antibody to F1-capsular antigen by passive hemagglutination (PHA) and enzyme immunoassay in paired or single serum samples
- Direct detection: *Y. pestis* will grow on most routine bacteriologic media. PCR and DNA hybridization techniques for identifying *Y. pestis* and other agents associated with bioterrorism have been developed.

10.23 | Currently recommended donor deferral period
- No FDA Guidance or AABB Standard exists.
- Prudent practice would be to defer donor until signs and symptoms are gone and a course of treatment is completed.

10.24 | Impact on blood availability
- Agent-specific screening question(s): Not applicable; in response to a bioterrorism threat, impact of a local deferral would be significant.
- Laboratory test(s) available: Not applicable.

10.25 | Impact on blood safety
- Agent-specific screening question(s): Not applicable; unknown impact in response to a bioterrorism threat
- Laboratory test(s) available: Not applicable
10.26 | Leukoreduction efficacy

- Unknown

10.27 | Pathogen reduction efficacy for plasma derivatives

- Specific data indicate that the multiple steps in the fractionation process are robust and capable of inactivating and/or removing bacteria at concentrations that may be present in plasma.

10.28 | Other prevention measures

- Licensed vaccine available for those at high risk of exposure

10.29 | Other comments

- In a simulated bioterrorism exercise, FDA recommended that blood collection cease in the affected area and that donors in other areas be questioned about travel to the affected area.

SUGGESTED READING