5 | *TRYPANOSOMA BRUCEI*

5.1 | Disease agent

- *Trypanosoma brucei gambiense*
- *Trypanosoma brucei rhodesiense*

5.2 | Disease agent characteristics

- Protozoan, 14–33 mm.
- Order: Kinetoplastida.
- Family: *Trypanosomatidae*.
- Hemoflagellates that do not invade cells but inhabit connective tissue space.
- Found in humans as pleomorphic trypomastigotes present in peripheral blood, lymph nodes, spleen, and cerebrospinal fluid.

5.3 | Disease name

- African sleeping sickness
- Human African trypanosomiasis

5.4 | Priority level

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

5.5 | Background

- Steeply declining incidence with elimination targeted by 2030 by WHO; distribution limited to African continent

5.6 | Common human exposure routes

- Bite of infected tsetse fly

5.7 | Likelihood of secondary transmission

- Low

5.8 | At-risk populations

- Residents of endemic areas of Africa
  - *T. b. gambiense*—West and Central Africa (>95% of cases); causes a chronic infection
  - *T. b. rhodesiense*—East and Southeast Africa (<5% of cases); causes an acute infection
- Approximately 55 million people at risk, with 3 million at moderate or high risk but fewer than 1000 new cases/year

5.9 | Vector and reservoir involved

- Tsetse flies (male and female) of the genus *Glossina*.
- Humans are the primary reservoir of *T. b. gambiense*, while domestic and wild animals are the main reservoir of *T. b. rhodesiense*.

5.10 | Blood phase

- Parasitemia is present during the symptomatic phase and can be present for years.

5.11 | Transmission by blood transfusion

- Single, poorly documented case of transmission by blood transfusion.

5.12 | Survival/persistence in blood products

- Unknown

5.13 | Cases/frequency in population

- Screening of an average of >2 million people per year since 2000 and treatment of prevalent infections have reduced the number of people who carry this infection from prior estimates of nearly half a million. The relative importance of remaining asymptomatic or latent infections in maintaining the transmission cycle is unknown.

5.14 | Incubation period

- Local signs present 2–3 days to two weeks following bite of infected tsetse fly and are more common with

T. b. rhodesiense. Generalized symptoms occur 1–3 weeks after the bite with *T. b. rhodesiense*; disease progresses more slowly with *T. b. gambiense*.
- Central nervous system (CNS) signs present a few months (*T. b. rhodesiense*) to several years (*T. b. gambiense*) after infection.

5.15 | Likelihood of clinical disease

- High

5.16 | Primary disease symptoms

- Chancre at the inoculation site, which persists for up to 2 weeks. Thereafter, generalized lymphadenopathy followed by fever, headache, pruritus, skin rash, hepatosplenomegaly, anemia, edema, cardiovascular, endocrinological, and renal disorders.
- Second stage includes neurological effects (sleeping disturbances, alteration of mental state, abnormal reflexes, tone, coordination, and sensory disorders). Progressive, untreated disease leads to deterioration of consciousness and death in 100% of cases.

5.17 | Severity of clinical disease

- Severe

5.18 | Mortality

- Approaches 100% in untreated cases
- 2%–8% in treated cases

5.19 | Chronic carriage

- Months to years.

5.20 | Treatment available/efficacious

- Pentamidine, suramin, melarsoprol, nifurtimox, and eflornithine are used for therapy, depending on the stage of disease (hemolymphatic or CNS) and the subspecies of *T. brucei*.
- Treatments primarily effective during early stages of disease but less effective once CNS involved. Drugs can have serious side effects.

5.21 | Agent-specific screening questions(s)

- No specific question is in use.
- Not indicated in the United States.
- No sensitive or specific question is feasible.

5.22 | Laboratory test(s) available

- No FDA-licensed blood donor screening test exists.
- Options for laboratory testing include blood smear microscopy, culture of blood or tissue biopsies, indirect hemagglutination assay, immunofluorescence assay, enzyme immunoassay, and nucleic acid test. Reliable serologic testing for *T. b. rhodesiense* is unavailable, while screening for *T. b. gambiense* requires direct detection by microscopy for definitive diagnosis. Rapid serological tests have been deployed for population screening purposes in endemic areas in Africa.

5.23 | Currently recommended donor deferral period

- No FDA Guidance or AABB Standard exists.
- Prudent practice, given the possibility of chronic carriage, would be a lifetime deferral for history of infection.

5.24 | Impact on blood availability

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

5.25 | Impact on blood safety

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

5.26 | Leukoreduction efficacy

- Unknown, though probably unlikely, given that only a partial reduction effect in parasite load is observed for *Trypanosoma cruzi*.

5.27 | Pathogen reduction efficacy for plasma derivatives

- No specific data are available, but it is presumed that the agent would be sensitive to many measures used in the fractionation process.

5.28 | Other prevention measures

- Based on studies with *T. cruzi*, pathogen reduction technology for cellular components may be effective.
- Personal protective measures in endemic areas.

SUGGESTED READING

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