|  |  |  |  |
| --- | --- | --- | --- |
| **Brighton Collaboration Viral Vector Vaccines Safety Working Group (V3SWG)**  **Standardized Template V2.1 for Collection of Key Information for Risk Assessment of Viral Vaccine Vector Candidates** | | | |
| **5. Target Pathogen and Population** | **Information** | **Comments/Concerns** | **Reference(s)** |
| **5.1** What is the target pathogen? | Lassa virus | The enveloped, bisegmented, -ssRNA virus is a member of the family *Arenaviridae*, genus *Mammarenavirus*. The strains are grouped into I-V and a possibly 5th (V-Cote d’Ivoire and Mali) lineages. | Hallam HJ et al. npj Vaccines 2018;3:11, doi: 10.1038/s41541-018-0049-5 |
| **5.2** What are the disease manifestations caused by the target pathogen in humans, for the following categories: |  |  |  |
| * In healthy people | The majority (80%) of infections are asymptomatic or mild (fever; cough; general malaise/weakness, pain in throat, chest, and abdomen; headache; nausea, vomiting, and diarrhea); 20% progress to a more severe illness (hemorrhaging; respiratory distress; facial swelling, pleural/pericardial effusions; neurologic including hearing loss, tremor, seizure, encephalitis, and disorientation/coma; shock; multiorgan failure). | Various degrees of sensorineural hearing loss may develop during convalescent phase in both mild or severe cases (25% of the survivors). Near or complete recovery of hearing after 3–4 months in approximately 50% of the affected, and while the remainder experience permanent hearing loss.  Transient hair loss, cerebellar ataxia, neuropsychiatric disorder, and polyserositis may occur during recovery. | Richmond JK et al. BMJ 2002;327:1271, doi: 10.1136/bmj.327.7426.1271  CDC. Lassa fever fact sheet, <https://www.cdc.gov/vhf/lassa/pdf/factsheet.pdf>  WHO. Lassa fever fact sheet, <http://www.who.int/mediacentre/factsheets/fs179/en>.  McCormick JB et al. In Arenaviruses I, 2002; Oldstone MBA(ed). Springer-Verlag Berlin Heidelberg 2002; Chapter 9:75. |
| * In immunocompromised people | Similar to those in health adults. |  |  |
| * In neonates, infants, children | Infection in infants can result in “swollen baby syndrome” with generalized edema (anasarca), abdominal distension, bleeding and death. Symptoms in children 2 years and older are similar to those in healthy adults. |  | Eze K et al. Niger Med J 2014;55:195, doi: 10.4103/0300-1652.132037  Robinson J. <http://vhfc.org/lassa_fever>  Monson MH et al. Am J Trop Med Hyg 1987;36:408, doi: 10.4269/ajtmh.1987.36.408 |
| * During pregnancy and in the fetus | Pregnant women are more likely to have severe illness with infection than women who are not pregnant. The maternal case fatality rate is highest in the 3rd trimester of pregnancy (up to 80%), with spontaneous abortions, stillbirth, or neonatal death (95% fetal mortality) if infection during pregnancy. |  | McCormick JB et al. J Infect Dis 1987;155:445, doi: 10.1093/infdis/155.3.445  Price ME et al. BMJ 1998;297:584, doi: 10.1136/bmj.297.6648.584 |
| * In elderly | Similar to those in healthy adults. |  |  |
| * In any other special populations | No. |  |  |
| **5.3** Briefly, what are the key epidemiologic characteristics of the disease caused by the target pathogen (e.g. incubation period, communicable period*,* route/s of transmission,case fatality rate, transmissibility characteristics such as basic reproductive ratio *(*R0*)* etc.)? | The incubation period is 7–21 days (average 10 days). Routes of transmission include zoonotic (from infected rodents (*Mastomys natalensis*) to human through inhalation, ingestion, or direct contact of secretions or contaminated foods; or human-to-human through direct, breastfeeding, or sexual contacts. Approximately 15%–20% of the hospitalized patients die (roughly 1%–3% of all infected cases). |  | CDC. Lassa fever fact sheet, <https://www.cdc.gov/vhf/lassa/pdf/factsheet.pdf>  WHO. Lassa fever fact sheet, <http://www.who.int/mediacentre/factsheets/fs179/en> |
| **5.4** What sections of the population are most affected by the target pathogen (e.g. pediatric, pregnant, lactating women (breast feeding), adult, elderly) | Lassa fever occurs in all age groups and both sexes. Persons at greatest risk are those living in rural areas of west African countries where *Mastomys* are usually found, especially in communities with poor sanitation or crowded living conditions. Health care workers are at risk if caring for infected patients without appropriate protective measures and infection control practices. Pregnant women, fetus, newborn infants, and immunocompromised people are at risk for severe disease. |  | CDC. Lassa fever fact sheet, <https://www.cdc.gov/vhf/lassa/pdf/factsheet.pdf>  WHO. Lassa fever fact sheet, <http://www.who.int/mediacentre/factsheets/fs179/en>  Eze K et al. Niger Med J 2014;55:195, doi: 10.4103/0300-1652.132037  McCormick JB et al. J Infect Dis 1987;155:445, doi: 10.1093/infdis/155.3.445 |
| **5.5** What is known about the correlates of protective immunity to the target pathogen or to the disease? | In animal studies, protection does not correlate with humoral immunity/ serum neutralizing antibodies, and likely depends more on cell-mediated immunity/cytotoxic T-cell response. |  | Fisher-Hoch et al. Expert Rev Vaccines 2004;3:189, doi: 10.1586/14760584.3.2.189 |
| **5.6** Please describe any other key information about the target pathogen or population that may inform benefit risk | No. |  |  |
| **References** | **Information** | | |
| **1.** |  | | |
| **2.** |  | | |
| **3.** |  | | |
| **4.** |  | | |
| **5.** |  | | |
| **6.** |  | | |
| **7.** |  | | |
| **8.** |  | | |
| **9.** |  | | |
| **10.** |  | | |