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| **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? | Nipah virus | Nipah virus is an enveloped, nonsegmented -ssRNA batborne paramyxovirus of the *Henipavirus* genus of *Paramyxoviridae* family, with two genetically distinct (92% identical on sequences) strains: Malaysia (NiV-MY) and Bangladesh (NiV-BD). | Lo MK et al. Emerg Infect Dis 2012;18:248, doi:10.3201/eid1802.111492 |
| **5.2** What are the disease manifestations caused by the target pathogen in humans, for the following categories: |  |  |  |
| * In healthy people | Infection with Nipah virus can be asymptomatic (8%) or non-neuroinvasive (fever, headache, or myalgia). The virus is also associated with severe neurological (meningitis and encephalitis), respiratory (atypical pneumonia and ARDS), and multiorgan (e.g., spleen, kidneys, and heart) presentations. In addition to acute monophasic encephalitis, recurrence of neurological manifestations after initial recovery (“relapsed encephalitis”) or new onset neurological illness weeks to months after asymptomatic/mild illness (“delayed-onset encephalitis”) have been described. Long-term sequelae have been noted, including persistent convulsion, personality change, and deficit in attention and memory. |  | CDC factsheet: Nipah virus (NiV). Available at: <https://www.cdc.gov/vhf/nipah/pdf/factsheet.pdf>  Tan CT et al. Ann Neurol 2002;51:703, doi:10.1002/ana.10212  Sejvar JJ et al. Ann Neurol 2007;62:235, doi:10.1002/ana.21178  Sherrini BA et al. Med J Malaysia 2014;69 Suppl A:103 |
| * In immunocompromised people | Similar to those in healthy adults. |  |  |
| * In neonates, infants, children | Similar to those in healthy adults. |  |  |
| * During pregnancy and in the fetus | Not available. | There are few published case studies of Nipah virus and human pregnancy. |  |
| * 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.)? | Transmission to humans involves direct contact with *Pteropus* bats or consumption of raw date palm sap contaminated with bat excretions; direct contact with infectious secretions/excretions of pigs; handling or consumption of horse meat; or direct contact with infectious body fluids of patients.  In human-to-human transmission, the incubation period is 5–15 days and median serial interval is 13 days (IQR 12–14). The basic reproductive number (R0) is estimated 0.33 (95% CI 0.19–0.59). Increasing age (≥45 years) and respiratory symptoms are indicators of infectivity.  About 40% of the hospitalized patients with serious neurological illness die. The overall case fatality in Nipah encephalitis outbreaks is 32%–41% in Malaysia-Singapore and 73% in Bangladesh-India. | Bat-to-human and human-to-human transmissions of Nipah virus in India-Bangladesh are regularly reported. In Malaysia-Singapore, infection of humans occurred through close contact with infected pigs. | CDC. Factsheet: Nipah virus (NiV). Available at: <https://www.cdc.gov/vhf/nipah/pdf/factsheet.pdf>  Ching PKG et al. Emerg Infect Dis 2015;21:328, doi:10.3201/eid2102.141433  Luby SP et al. Emerg Infect Dis 2009;15:1229, doi:10.3201/eid1508.081237  Nikolay B et al. New Engl J Med 2019;380:1804, doi:10.1056/NEJMoa1805376  Sherrini BA et al. Med J Malaysia 2014;69 Suppl A:103 |
| **5.4** What sections of the population are most affected by the target pathogen (e.g. pediatric, pregnant, lactating women (breast feeding), adult, elderly) | Nipah occurs in all age groups and both sexes. The risk of infection is higher among spouses, family members, and principal caregivers of infected individuals. Abattoir workers and healthcare workers have been affected by Nipah virus infection in several outbreaks. |  | Nikolay B et al. New Engl J Med 2019;380:1804, doi:10.1056/NEJMoa1805376  Chew MH et al. J Infect Dis 2000;181:1760, doi:10.1086/315443  Ching PKG et al. Emerg Infect Dis 2015;21:328, doi:10.3201/eid2102.141433 |
| **5.5** What is known about the correlates of protective immunity to the target pathogen or to the disease? | Studies in nonhuman primate models (African green monkeys) indicate that neutralizing antibodies may be protective. |  | Prescott J et al. Vaccine 2015;33:2823, doi:10.1016/j.vaccine.2015.03.089  Bossart KN et al. Sci Transl Med 2012;4:146ra107, doi:10.1126/scitranslmed.3004241  Geisbert TW et al. Sci Transl Med 2014;6:242ra82, doi:10.1126/scitranslmed.3008929 |
| **5.6** Please describe any other key information about the target pathogen or population that may inform benefit risk | Countries with reported Henipavirus outbreaks or at risk based on serological evidence or molecular detection in *Pteropus* bats include Australia, Bangladesh, Cambodia, China, India, Indonesia, Madagascar, PNG, Taiwan, and Thailand.  Geographic range of *Pteropus* bats includes Bhutan, Brunei, China, India, Indonesia, Laos, Madagascar, Myanmar, Nepal, Philippines, PNG, Singapore, Taiwan, Thailand, and Vietnam. |  | CDC. Nipah virus distribution map. Available at: <https://www.cdc.gov/vhf/nipah/outbreaks/distribution-map.html> |
| **References** | **Information** | | |
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