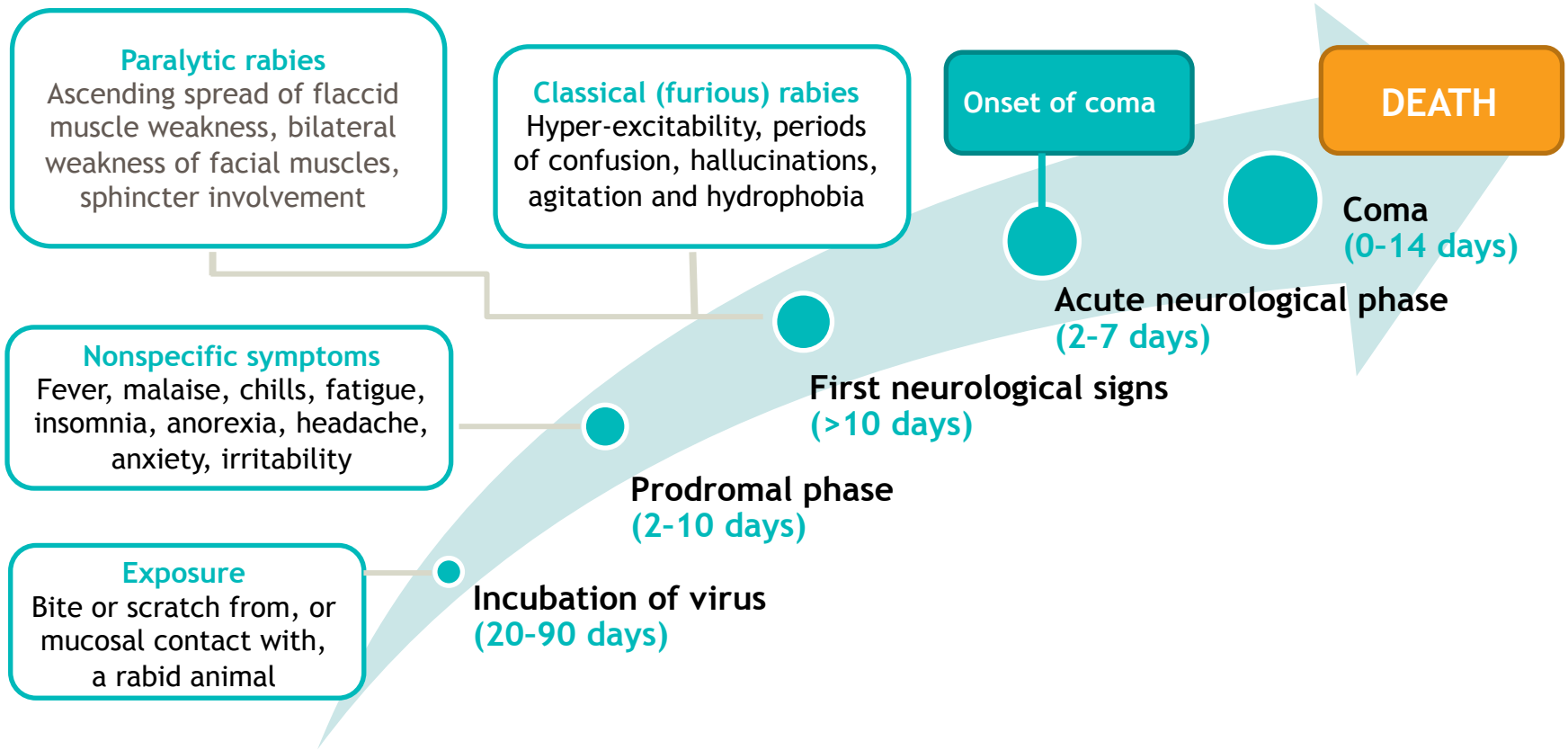
WHAT YOU NEED TO KNOW ABOUT RABIES

ASSOCIATION OF IMMUNIZATION MANAGERS
FEBRUARY 2021

Bavarian Nordic is a fully integrated, leading biotechnology company focused on the research, development, innovation, manufacturing and commercialization of vaccines for the prevention and treatment of life-threatening diseases

BAVARIAN NORDIC

VIRAL DISEASE ALMOST ALWAYS FATAL IF UNTREATED



1. Jackson *et al*. In *Rabies* (2nd edition). Chapter 7. 2007: 309–340; 2. WHO. *Wkly Epidemiol Rec* 2018; 93: 201–20; 3. Hemachudha *et al*. *Lancet Neurol* 2002;1:101–9; 4. WHO. Rabies: Fact Sheet. https://www.who.int/en/news-room/fact-sheets/detail/rabies [accessed July 2020].

PREVALENCE IN THE USA

Rabies transmission in dogs has been **virtually eliminated in the USA**, in part due to widespread canine vaccination programs[5]

- As a result, **wildlife has accounted for >90%** of rabid animals reported in the USA since 1980[5-7]
  - Primary vectors in this region are skunks, foxes, raccoons, bats and mongooses (in Puerto Rico)[5-7]
  - In the US, the primary rabies vector is the bat due to encounters with bats that may be less recognized e.g. saliva/small scratch

41 cases of human rabies have been reported in the USA from 2003-2017[3]

- 11 cases were infected outside the USA[7]
- 24 cases were caused by bat exposure[7]

5. Clark *et al. Vector Borne Zoonotic Dis* 2015; 15: 494–501; 6. Blanton *et al. J Am Vet Med Assoc* 2012; 241: 712–22; 7. Ma X et al. J Am Vet Med Assoc 2018;253:1555–1568

PRIMARILY TRANSMITTED FROM ANIMALS TO HUMANS

- Rabies virus is transmitted in saliva via bites, scratches and direct contact with mucosal membranes[8]
- Rabies infection causes behavioral changes in animals[9]
- Every mammal studied to date is susceptible to rabies;[10] dogs are the source of 99% of human rabies infections[11] worldwide
- Bat rabies has recently emerged as a public health threat
- Rare categories of rabies virus infection:
  - Inhalation of aerosolised rabies virus in caves containing millions of bats or in laboratories[9]
  - Transmission via infected organ transplantation[9]

8. WHO. Rabies: Fact Sheet. https://www.who.int/en/news-room/fact-sheets/detail/rabies [accessed July 2020]; 9. WHO. *Wkly Epidemiol Rec* 2018; 93: 201–20.; 10. Rupprecht *et al. Lancet Infect Dis* 2002; 2: 327–43; 11. Hampson *et al. PLoS Biol* 2009; 7: e1000053

CHILDREN ARE AT GREATER RISK

- Children are at greater risk of rabies exposure than adults because they:[12]
  - Tend to play with animals
  - May not report bites
  - May receive more severe bites and are often bitten around the hands or face
    - These areas have a high density of nerve endings, so bites to these areas may increase the risk of developing encephalitis more rapidly[13]

! Rabies disproportionately affects poor, rural communities, and, particularly, children[13]

12. WHO. Rabies: Fact Sheet. https://www.who.int/en/news-room/fact-sheets/detail/rabies [accessed July 2020]; 13. WHO. Expert Consultation on Rabies, Third Report. 2018. https://apps.who.int/iris/bitstream/handle/10665/272364/9789241210218-eng.pdf?ua=1 [accessed July 2020].

ACIP RECOMMENDATIONS FOR PRE-EXPOSURE VACCINATION

Risk Category	Nature of Risk*	Typical Population	Preexposure Recommendations
Continuous	Virus present continuously. Specific exposures likely to go unrecognized	• Rabies research **lab workers** • Rabies **biologics production workers**	Primary course. Serologic testing every 6 months; booster if antibody titers are below acceptable level
Frequent	Exposure episodic, with source known, but exposure also might be unrecognized	In rabies-enzootic areas: • Rabies diagnostic **lab workers** • **Spelunkers** • **Veterinarians/staff** • **Animal-control and wildlife workers** • All **persons who frequently handle bats**	Primary course. Serologic testing every 2 years; booster if antibody titers are below acceptable level
Infrequent	Exposure usually episodic with source recognized	• **Veterinarians and terrestrial animal-control workers** where rabies is uncommon to rare • **Veterinary students, travellers** visiting areas where rabies is enzootic and immediate access to care is limited	Primary course. No serologic testing or booster needed
Rare (population at large)	Exposure always episodic with source recognized	• U.S. **population at large**, including persons in rabies-epizootic areas	No vaccination necessary

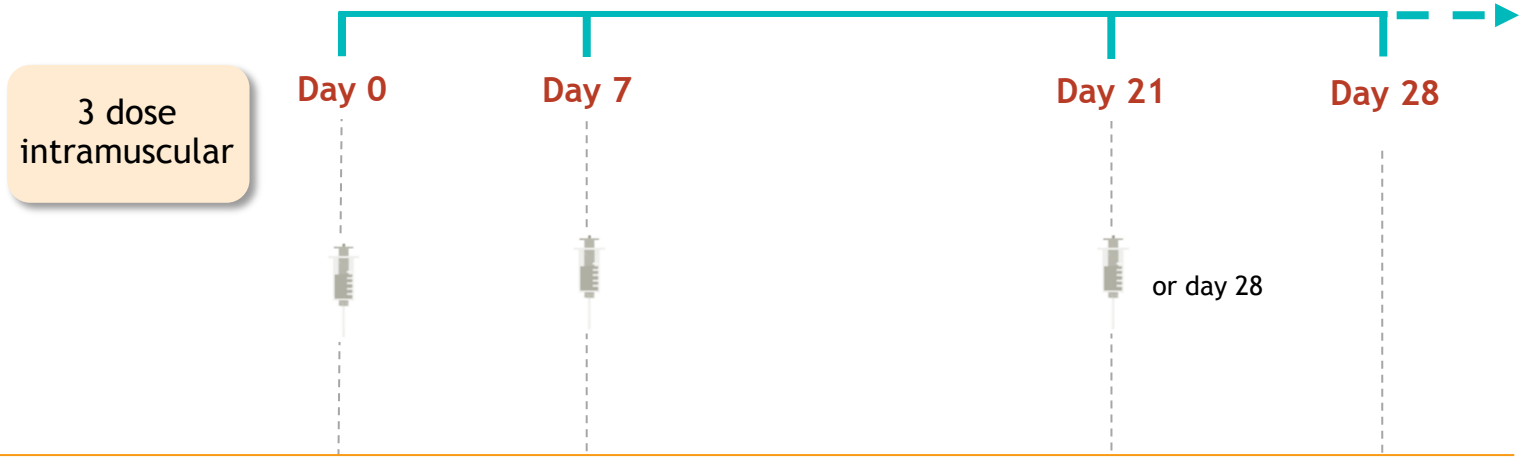
https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/rabies.html#recs

** Exposure can be from a bite, non-bite or aerosol*

FDA-APPROVED RABIES VACCINE DOSING SCHEME – PREP[14]

Pre-Exposure Prophylaxis

- Eliminates the need for passive immunization (RIG)
- Decreases the number of doses of vaccine needed after exposure[14-15]
- Provides partial immunity for individuals whose PEP may be delayed[14-15] or who are at continual, frequent or increased risk of unapparent or unrecognized

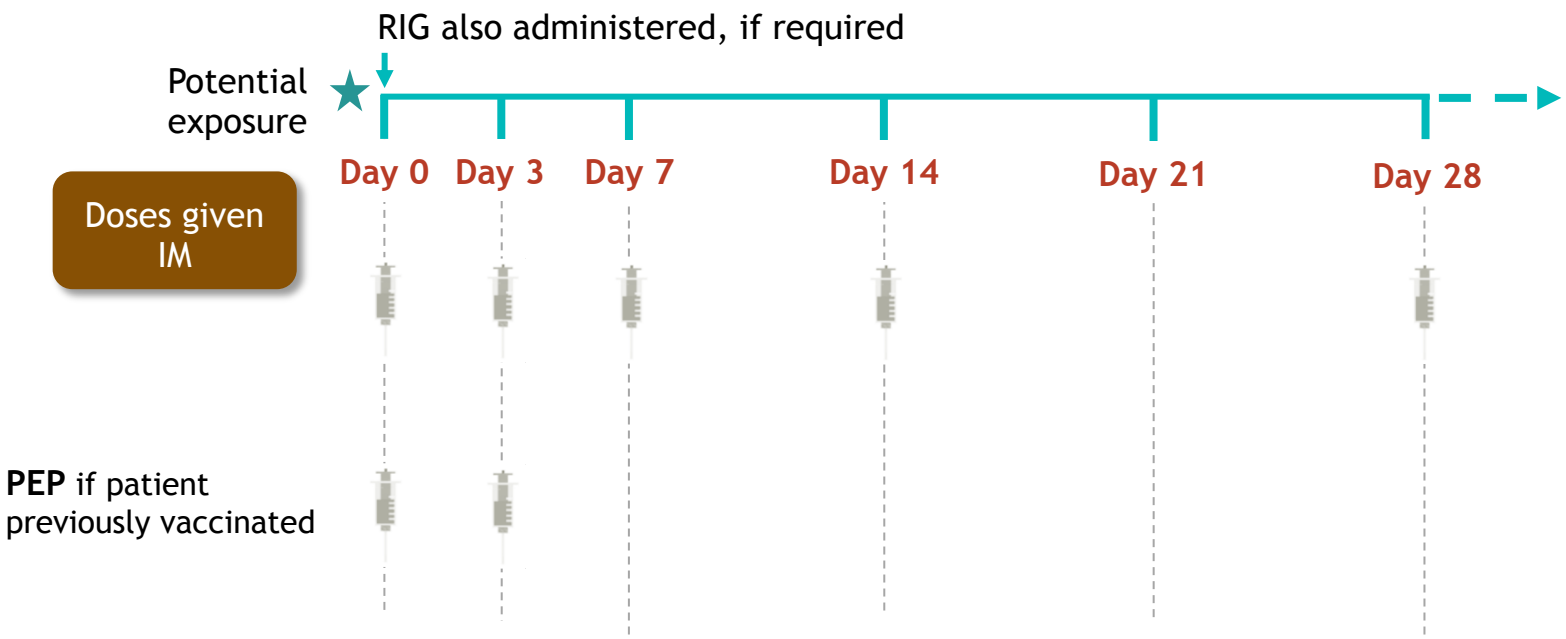


14. Sanofi. Imovax US product information as of Oct 2019 https://www.fda.gov/media/75709/download [accessed Oct 2020]; GSK/Bavarian Nordic, US RabAvert product information, 2018 https://www.fda.gov/media/83874/download [accessed Oct 2020]

FDA-APPROVED RABIES VACCINE DOSING SCHEME – PEP[15]

Post-Exposure Prophylaxis

- Rabies immunization is achieved through rabies vaccination AND rabies immunoglobin (RIG)
- If PrEP was previously given to an exposed individual, RIG is not needed, and fewer PEP vaccine doses are required



15. Sanofi. Imovax US product information as of Oct 2019 https://www.fda.gov/media/75709/download [accessed Oct 2020]; GSK/Bavarian Nordic, US RabAvert product information, 2018 https://www.fda.gov/media/83874/download [accessed Oct 2020]

BAVARIAN NORDIC: THE VACCINES COMPANY YOU DON'T KNOW ABOUT

- **Bavarian Nordic has been an important player in the area of infectious diseases for 25 years worldwide**
  - Longstanding partnerships with various governments
    - Provided smallpox vaccine for US, EU, and CA National Stockpiles under Emergency Use Programs
    - Recent FDA and Health Canada approvals for smallpox and monkeypox vaccines
- **Expert in producing vaccines using CEF cells**
  - 28 million doses produced for the US and other governments
  - Produced Ebola vaccine within one year; 2 million doses donated to DRC and Rwanda in collaboration with Janssen
  - Strategic collaborations with Janssen for vaccine development in HIV, HBV and HPV
  - BN acquired Encepur® (TBE) and Rabavert® from GSK in August 2020
  - Current development plans include oncology vaccines for several pathologies and ID vaccines for RSV and three strains of equine encephalitis
- **As a small company, we are dedicated to providing full service for our commercial vaccines and support at the public health level**

BAVARIAN NORDIC IS DEDICATED TO PUBLIC HEALTH

Support for Increased Rabies Education in the US

- Embarking on various educational partnerships with healthcare providers to increase public awareness of rabies risks through proper treatment protocols
  - ✓ AIM Corporate Alliance Silver Partner 2021

Support for State-Level Immunization Managers

- We made it a priority to align with *Minnesota Multistate Infuse* to ensure a seamless transition of ownership from GSK (no pricing disruption)
- Support Program-Level and Local Health Departments
  - ✓ Dedicated Sales Force to support Health Departments in all 50 states
  - ✓ High priority attention to any sudden need for increased vaccine supply
  - ✓ Create and provide materials to support educational needs (coming soon)

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Corporate Website: https://www.bavarian-nordic.com/
Infectious Disease Website: https://loweringtherisk.com/

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