RCPA Quality Assurance Programs Pty Limited

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Testing for SSBA (Security Sensitive Biological Agents)

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RCPA BioSecurity QAP
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Testing for SSBA (Security Sensitive Biological Agents)

RCPA BioSecurity QAP: What are we doing

SSBA Part 1: What is on the list

SSBA Part 2: Going viral

Beyond SSBA: What is not on the list

RCPA BioSecurity QAP

Anatomical Pathology QAP

Benchmarking in Pathology QAP

BioSecurity QAP

Chemical Pathology QAP

Cytopathology QAP

Haematology QAP

Immunology QAP

KIMMS QAP

Microbiology QAP

Serology QAP

Synovial Fluid QAP

Transfusion QAP

- Broad range of external quality assurance programs across all disciplines of pathology to support the scientific and medical communities in Australia, New Zealand and overseas
- RCPA Quality Assurance Programs provide participants with world class programs including continual assessments and educational opportunities as well as reports indicating how a laboratory is ranked, aimed at enhancing laboratory competency.
- There are approximately 1000 laboratories currently enrolled in over 4000 programs, with 30% of the participating laboratories being International participants.

RCPA BioSecurity QAP

Biosafety

The application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards
AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological aspects and containment facilities

Biosecurity

Protection from biological harm: the protection of the economy, environment, and health of living things from diseases, pests, and bioterrorism

RCPA BioSecurity QAP

Australian Government
Department of Health and Ageing

The *National Health Security Act 2007*

An Act to provide for national health security, and for related purpose

Part 3: Regulation of security sensitive biological agents

- Secure handling, storage, disposal and transport of known and suspected SSBA
- Regulate access to organisms that can be used in acts of bioterrorism or biocrime

RCPA BioSecurity QAP

- Utilising a grant from the Australian Government Department of Health and Ageing (DoHA) to establish a proficiency testing program for selected security sensitive biological agents
- Commenced in June 2009 preparing surveys and reports for the proficiency testing of SSBA
- Available to laboratories within Australia with the appropriate containment facilities
- An online version of the program was introduced in 2011

Security Sensitive Biological Agents

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Rinderpest virus	*Vibrio cholerae* (Cholera) (serotypes O1 and O139 only)
SARS coronavirus	Yellow fever virus (non-vaccine strains)
Variola virus (Smallpox)	
Yersinia pestis (Plague)	

SSBA in the statistics

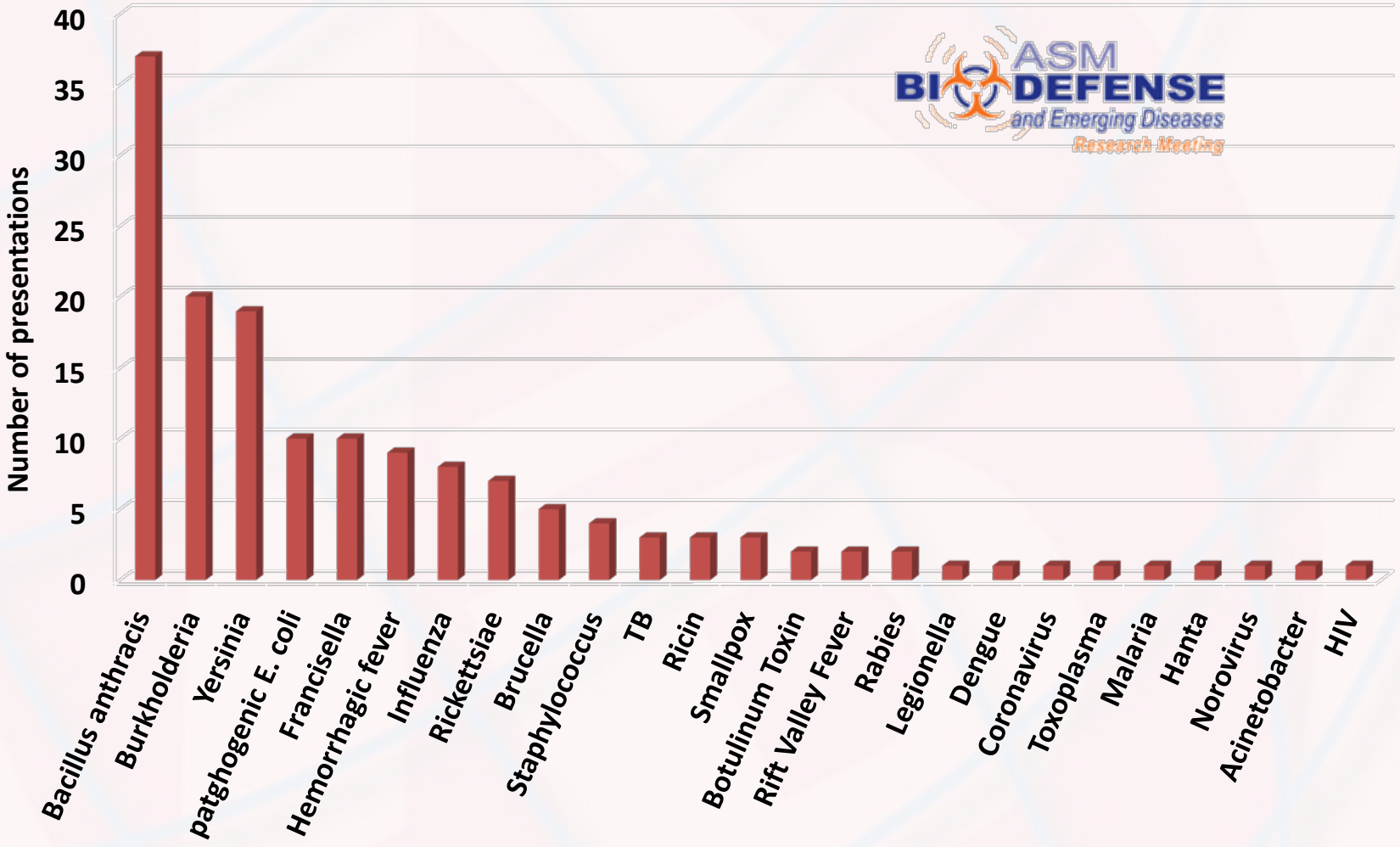
SSBAs & National Notifiable Diseases Surveillance System

	Tier 1 SSBA					Tier 2 SSBA				
	Anthrax	Ebola & Marburg	Influenza	Smallpox	Plague	Tularaemia	Botulism	Typhoid	Cholera	Yellow Fever
2001	0	nil	1,300	nil	nil	0	2	74	4	0
2002	0		3,660			0	0	70	6	0
2003	0		3,458			0	1	50	2	0
2004	0		2,067			0	1	74	5	0
2005	0		4,571			0	3	52	3	0
2006	1		3,325			0	1	77	3	0
2007	1		10,590			0	1	90	4	0
2008	0		9,191			0	0	105	4	0
2009	0		59,028			0	1	115	5	0
2010	1		13,459			0	0	95	3	0
2011	0		27,037			2	2	134	6	2

SSBA in the wild

Suspicious white powder found at Parliament House Canberra (August 2011)

SSBA in research



SSBA in the BioSecurity QAP

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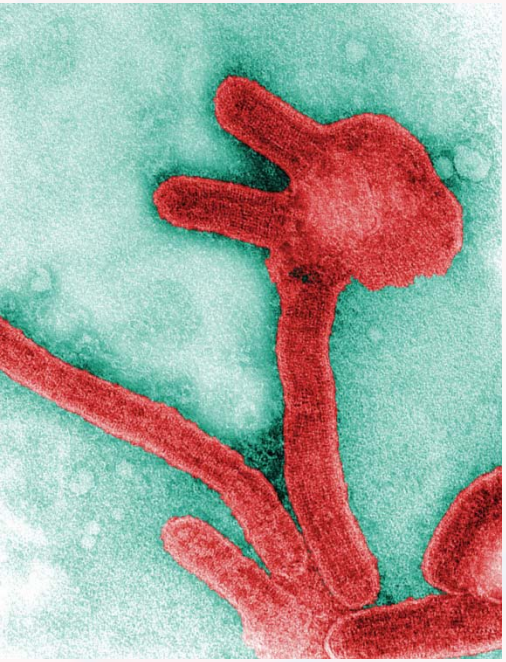
Vaccine status:	BioSecurity QAP survey
Experimental	planned

Marburgvirus

Tier 1SSBA

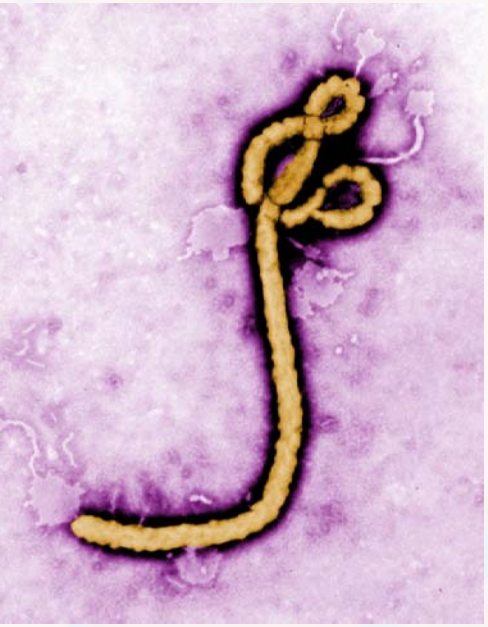


- Marburg hemorrhagic fever is a rare, often-fatal disease in humans and nonhuman primates
- First member of the family *Filoviridiae*
- Recognized in 1967, simultaneous outbreaks in laboratories in Marburg and Frankfurt, Germany and in Belgrade, Serbia
- Infected lab personnel had been exposed to African green monkeys or their tissues (research on polio vaccine)
- Sporadic outbreaks in Africa, with the largest outbreak in 2004/2005 in Angola with 252 cases and 227deaths
- Recent studies implicate the African fruit bat as the reservoir host of the Marburg virus

Vaccine status:	BioSecurity QAP survey
Experimental	planned

Ebolavirus

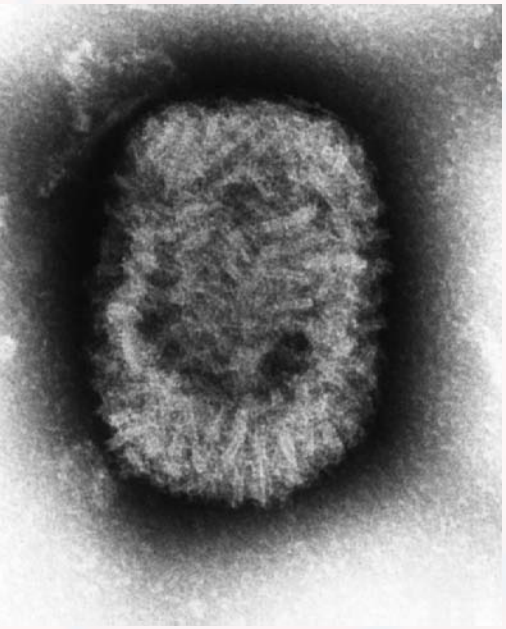
Tier 1SSBA

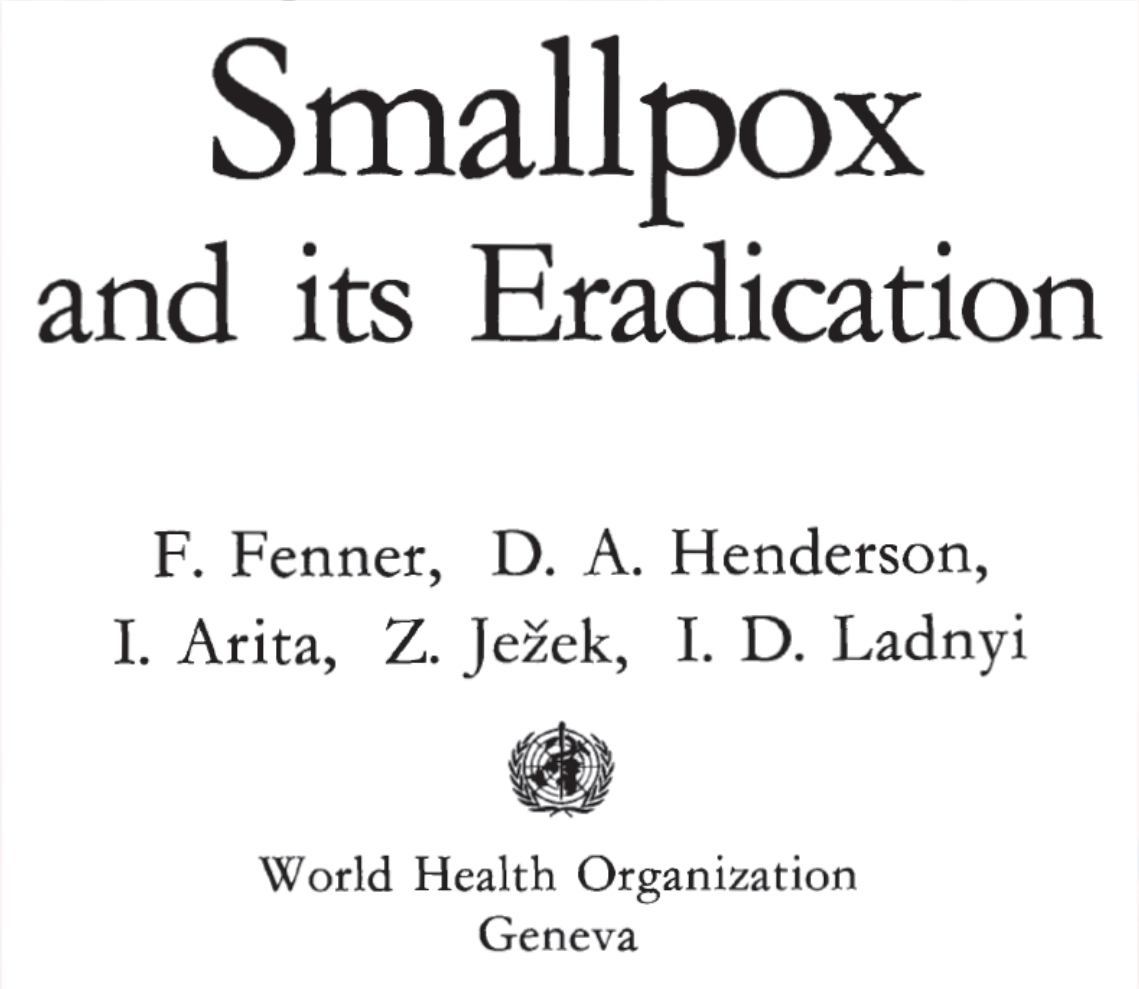


- Ebola hemorrhagic fever is a severe, often-fatal disease in humans and nonhuman primates
- Second member of the *Filoviridae* family
- Named after the Ebola river in the Democratic Republic of the Congo in Africa, where it was first recognized in 1976
- There are five identified subtypes of Ebola virus:
  - Ebola-Zaire
  - Ebola-Sudan
  - Ebola-Ivory Coast
  - Ebola-Bundibugyo
  - Ebola-Reston (does not cause disease in humans)
- Sporadic outbreaks in Africa, with the largest outbreak in 2000/2001 in Uganda with 425 cases and 224 deaths (current outbreak in Uganda)
- Nidom CA et al. (2012) Serological Evidence of Ebola Virus Infection in Indonesian Orangutans. PLoS ONE 7(7): e40740
- Third filovirus, named Lloviu virus, was recently detected from long-fingered bats (*Miniopterus schreibersii*) in Spain. This bat species is widely distributed in Oceania, southern Europe, southern Africa, and southeast Asia

Variola virus (Smallpox)

Tier 1SSBA



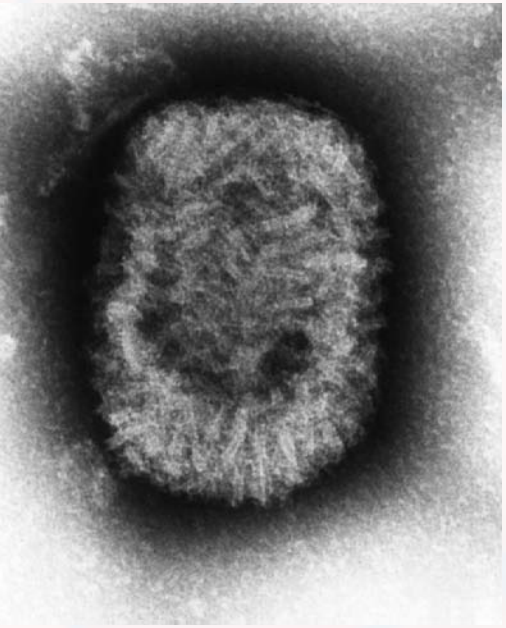


http://whqlibdoc.who.int/smallpox/9241561106.pdf

Vaccine status:	BioSecurity QAP survey
Yes	eLearning draft Nov 2012

Variola virus (Smallpox)

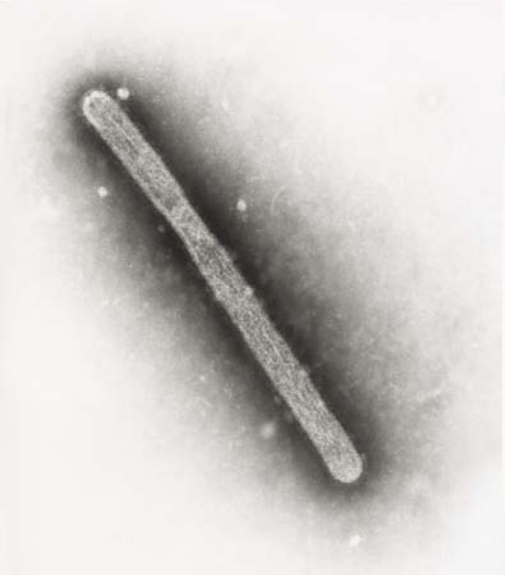
Tier 1SSBA



- Smallpox is highly contagious, caused by the variola virus. ~ 300 million people have been infected in the 20th century
- Variola virus belongs to the genus Orthopoxvirus within the family *Poxviridae*
- Two forms, the more severe and most common Variola major, and the less common Variola minor
- The only human infectious disease ever to be completely eradicated; last naturally occurring case in Ethiopia in 1977; World Health Assembly declaring smallpox eradicated in 1980
- After the eradication of smallpox, the WHO recommended that all remaining specimens of variola be destroyed or sent to 1 of 2 designated high containment reference laboratories located in the U.S. and Russia

Vaccine status:	BioSecurity QAP survey
Yes	avail. from Serology QAP

Highly pathogenic influenza virus Tier 1SSBA



- According to the SSBA Regulatory Scheme, viral strains have to fulfil all of the following criteria
  - Considered highly pathogenic in usual host animal
  - Proven infection of humans
  - Involved in an outbreak of human disease

  Examples of include the 1918 pandemic Influenza virus A and Influenza virus A H5N1

- There are three types of influenza viruses: A, B and C

- Influenza A viruses are divided into subtypes based on two proteins on their surface: the hemagglutinin (H) and the neuraminidase (N)
  - 16 different hemagglutinin subtypes
  - 9 different neuraminidase subtypes

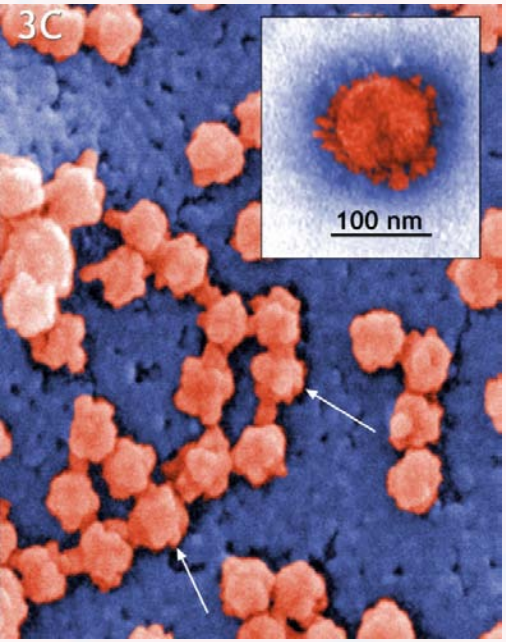
- The current subtypes of influenza A viruses found in people are A (H1N1) and A (H3N2).

- Influenza A (H1N1), A (H3N2), and influenza B strains are included in each year's influenza vaccine

Vaccine status:	BioSecurity QAP survey
Phase I clinical trial	Not scheduled yet

SARS coronavirus

Tier 1SSBA

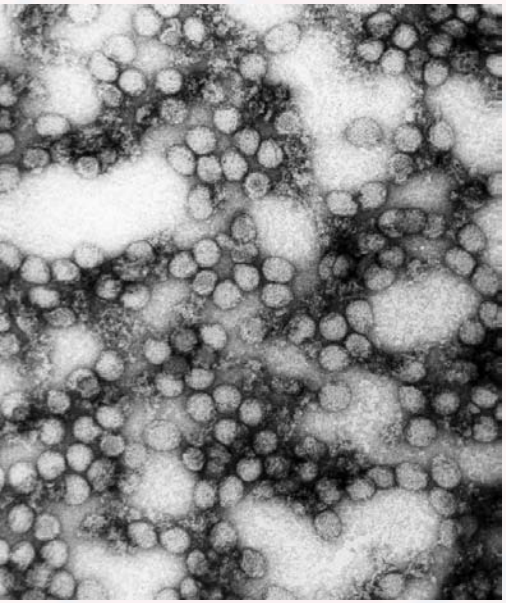


- November 2002: unusual atypical pneumonia emerged in Foshan, Guangdong Province, mainland China,
- February and March 2003: the disease spread to Hong Kong and then to Vietnam, Singapore, Canada, and elsewhere, affecting more than 8000 patients and causing 774 deaths in 26 countries
- Novel coronavirus (SARS-CoV) was identified as the causative agent.
- Coronaviruses are a family of enveloped, single-stranded-RNA viruses causing disease in humans and animals.
- Other known coronaviruses that affect humans cause the common cold
- Since 2004, there have not been any known cases of SARS reported anywhere in the world.

Vaccine status:	BioSecurity QAP survey
Yes	Planned 2013

Yellow fever virus

Tier 2SSBA



- Yellow fever is an acute viral hemorrhagic disease
- YFV is enveloped positive sense RNA virus of the *Flaviviridae* family
- Transmitted by the bite of female mosquitoes (the yellow fever mosquito, *Aedes aegypti*, and other species) and is found in tropical and subtropical areas in South America and Africa
- After an incubation period of three to six days, most cases only cause a mild infection
- 15 % of cases enter a second, toxic phase of the disease with recurring fever, accompanied by jaundice due to liver damage, abdominal pain and bleeding in mouth, eyes, and gastrointestinal tract
- The toxic phase is fatal in approximately 20 % of cases

Viral SSBA

infecting humans

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Vaccine status:	BioSecurity QAP survey
N/A	Not scheduled yet

Foot-and-mouth disease virus

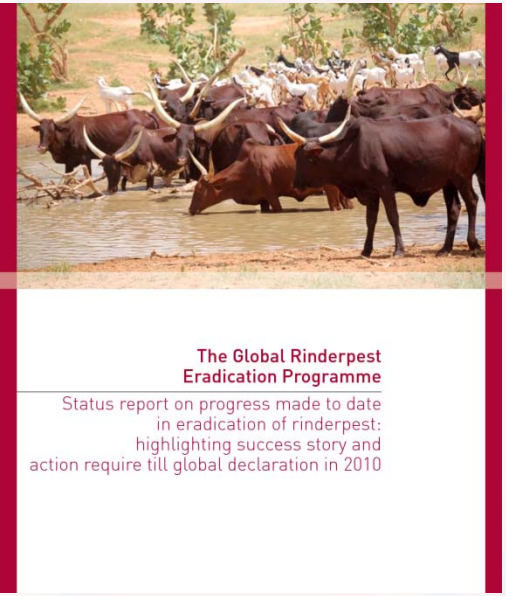
Tier 1SSBA

- Infectious and sometimes fatal viral disease that affects cloven-hoofed animals, including domestic and wild bovids
- Foot-and-Mouth Disease virus is a small RNA virus, classified in the genus Apthovirus within the family of *Picornaviridae*
- FMDV is closely related to rhinoviruses, polio virus and the coxsackie viruses (causing Hand-Foot-and-Mouth disease in humans)
- North America and Australia have been free of FMD for many years
- Outbreak in the UK in 2001:
  - more than 2,000 cases of the disease in farms throughout Britain
  - around seven million sheep and cattle were killed
  - estimated cost £8 billion ($AUD 12 billion)

Vaccine status:	BioSecurity QAP survey
N/A	Not scheduled yet

Rinderpest virus

Tier 1SSBA



- Infectious viral disease of cattle, domestic buffalo, and some other species including large antelopes and deer, giraffes, wildebeests and warthogs
- Rinderpest virus (RPV) is a Morbillivirus, closely related to measles virus
- Disease is characterized by fever, oral erosions, diarrhea, lymphoid necrosis, and high mortality, often reaching 100%
- On 8 August 2011, the United Nations held a ceremony declaring the disease eradicated, making rinderpest only the second disease in history to be eradicated, following smallpox

Possible viral SSBA QAP

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Beyond the SSBA list

Possible Biological Warfare Agents

Bacteria	Toxins	Viruses
Bacillus anthracis	Staphylococcal enterotoxin B	Variola virus
Yersinia pestis	Ricin	Equine encephalitis viruses
Francisella tularensis	Botulinum toxin	Bunyaviruses
Brucella species	Trichthecene mycotoxins	Filoviruses
Coxiella burnetii	Saxitoxin	Flaviviruses

Vaccine status:	BioSecurity QAP survey
restricted for civilians	Not scheduled yet

Equine encephalitis viruses

- **Eastern and Western equine encephalomyelitis** virus cycle in bird populations, and are transmitted mainly by mosquitoes
- **Venezuelan equine encephalomyelitis** viruses cycle between mosquitoes and sylvatic rodents
- EEE is one of the most severe mosquito-transmitted diseases in the United States with approximately 33% mortality and significant brain damage in most survivors
- WEE is usually asymptomatic or mild in adults, with nonspecific signs of illness and few deaths
- VEE is usually an acute, often mild, systemic illness, neurologic disease occurs in less than 1% of symptomatic adults

Vaccine status:	BioSecurity QAP survey
Yes (RVFV & HTNV)	RVFV

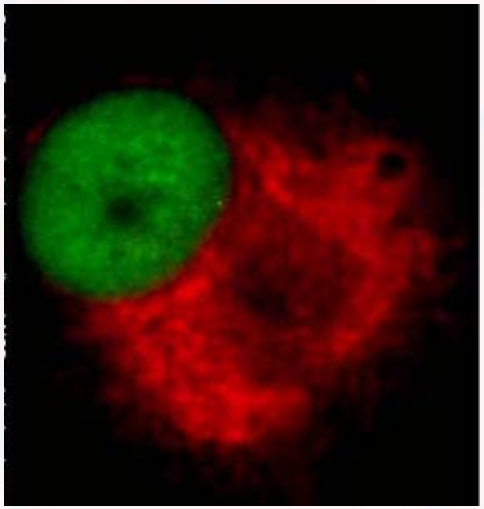
Bunyaviruses

- Named after Bunyamwera, Uganda, where the virus was first found in mosquitoes
- Live in insects and vertebrates and spread by mosquitoes, ticks and sandflies
- Hantaviruses are spread via aerosolized rodent urine and feces
- Most bunyaviruses cause severe hemorrhagic fevers and encephalitides

Virus	Disease
Hantaviruses	• hemorrhagic fever with renal syndrome (HFRS) • hantavirus pulmonary syndrome (HPS)
Rift valley fever virus	• fever, headache, myalgia and liver abnormalities • <2% hemorrhagic fever syndrome, meningoencephalitis

Vaccine status:	BioSecurity QAP survey
YFV, JEV	YFV, DENV, MVE

Flaviviruses



- Named from the yellow fever virus; *flavus* means yellow in Latin
- Flaviviruses are transmitted by the bite from an infected arthropod (mosquito or tick)
- Other routes of transmission:
  - handling infected animal carcasses
  - blood transfusion
  - child birth
  - consumption of unpasteurised milk products

Virus	Disease
Dengue fever virus	• fever, headache, joint & muscle pains, skin rash similar to measles • dengue hemorrhagic fever / dengue shock syndrome
West Nile virus	• asymptomatic infection • mild febrile syndrome termed West Nile fever • West Nile meningitis or encephalitis.
Murray Valley Encephalitis virus	• asymptomatic infection • mild febrile illness • Murray valley encephalitis

Beyond the SSBA list

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		Flaviviruses

The BioSecurity QAP Team

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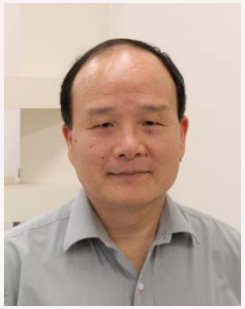

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Australian Government
Department of Health and Ageing

The Laboratory Capacity and Regulation Section
www.health.gov.au/ssba