

High consequence infectious diseases – what are they and why do they matter?

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Disclosures

No conflicts of interest.







- Understand the significance and key features of high consequence infectious diseases (HCIDs)
- Understand approaches to prompt recognition of and initial management of HCIDs





 Importance of preparing for high consequence infectious diseases (HCIDs)
 Definition of an HCID
 Key considerations for prompt recognition and initial management of HCIDs

4. Models of care for management of HCIDs





May 2015

- 55 year-old man recently returned from a trip to West Africa.
- Underwent entry screening at US airport and was afebrile.
- One day after return, he presented to a hospital with fever, chills, myalgias, and sore throat.



Life threatening	Treatable	Transmissible
Malaria Meningococcemia Bacterial sepsis Dengue fever High consequence infectious disease	Malaria Typhoid and paratyphoid fever Rickettsial infections Meningococcemia Bacterial pharyngitis Influenza COVID-19	Tuberculosis Measles Varicella High consequence infectious disease



A case

Exposures: worked in a diamond mine in Liberia, had direct contact with rodents and rodent excreta

Exam

- T 103.1 °F, BP 159/79, HR 101 bpm, RR 20 breaths/min
- Pharyngeal erythema with exudates
- Tender cervical lymphadenopathy

Day after initial medical evaluation	Max temp (°F)	WBC count (cells/mm ³)	Platelet count (cells/mm ³)	Potassium (mEq/L)	BUN (mg/dL)	Creatinine (mg/dL)	ALT (U/L)	AST (U/L)	INR
0	103.1	9,100	153,000	3.8	14	1.1	88	219	_
3	102.6	5,100	189,000	3.5	9	1.0	600	1,347	-
4	100.6	8,700	198,000	3.9	9	0.7	822	1,956	-
5	102.5	11,800	247,000	3.7	9	0.7	1,998	4,952	1.3
6	104.7	26,700	224,000	3.9	22	2.3	2,154	6,620	2.2
7	102.8	41,300	95,000	2.9	71	6.0	_	_	-

ALT = alanine aminotransferase; AST = aspartate aminotransferase; BUN = blood urea nitrogen; date of patient expiration = day 7 after initial medical evaluation; INR = international normalized ratio; Max temp = maximum temperature; WBC = white blood cell.

Microbiological workup

- Streptococcus pyogenes rapid test negative
- Monospot negative
- Malaria blood smear and antigen negative
- HIV Ab/Ag negative
- Hepatitis A-E negative
- Blood cultures no growth





Viral hemorrhagic fever testing by RT-PCR sent to CDC

- Ebola virus negative
- Marburg virus negative
- Crimean-Congo hemorrhagic fever virus negative
- Lassa virus positive





Exposure investigation

Description of contacts of Lassa fever case-patient by type and risk level — New Jersey, May 2015

	High risk	Low risk	Total
Type of contact			
Family or community members	13	13	26
Health-care personnel	2	149	151
Total	15	162	177

Source: Kulkarni PA et al. Am J Trop Med Hyg 2018;99(5):1062-1065.

NYC HEALTH+ HOSPITALS Lassafever



LASSA FEVER DISTRIBUTION MAP

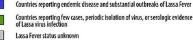
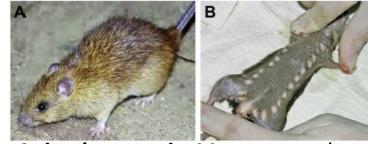


Fig. 1. Map of Africa – geographic distribution of Lassa fever. (*Courtesy of* the Centers fo Disease Control. Lassa fever CDC. http://www.cdc.gov/vhf/lassa/outbreaks. Accessed 6th August 2019.)



Animal reservoir: Mastomys rodent

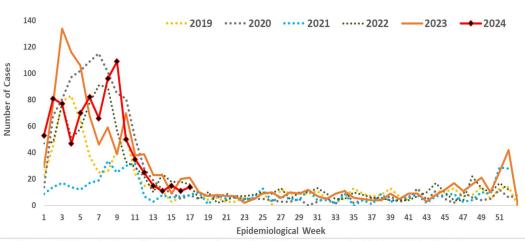


Figure 6: Trend of confirmed cases by epidemiological week, 2019–2024, Nigeria

- Endemic to West Africa
- 500,000 cases, 10,000 deaths annually
- Peak during transition from dry (Nov-Apr) to wet (May-Oct) season
- Difficult to distinguish from other causes of fever in returning traveler (malaria, typhoid, dengue, yellow fever)

Source: Nigeria CDC; Asogun DA. Infect Dis Clin North Am 2019;33(4):933-951.

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Lassa fever outside of West Africa, 1969-2016

- 33 patients traveling to 9 countries
 - 11 healthcare workers with known or suspected exposure to Lassa fever patients in West Africa
 - 4 with known exposure to rodents or history of travel to rural West Africa
 - 8 with no specific risk factor other than living/traveling in West Africa
- Time from healthcare contact to suspicion of Lassa fever, median 5 days (range 1-22)
- Time from healthcare contact to isolation, median 7 days (range 1-25)
- Case fatality rate 39%
- Of 17 patients with available data → 3,420 contacts were followed (median 173 contacts per patient, range 3-552)
 - 2 cases of secondary transmission

Source: Kofman A et al. Emerg Infect Dis 2019;25(2):245-248.



Importance of preparing for high consequence infectious diseases (HCIDs)



2014-2016 Ebola outbreak in West Africa

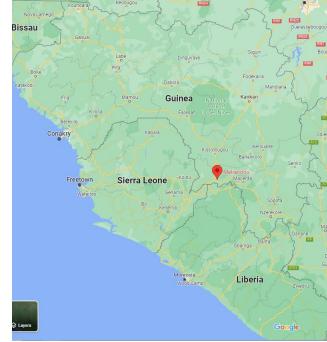
December 2013 – 18-month-old boy (index patient) in Meliandou, Guinea, was exposed to bats.

February 1, 2014 – Infections spread to Conakry, Guinea.

March 23, 2014 – WHO declared outbreak of Ebola Virus Disease (EVD).

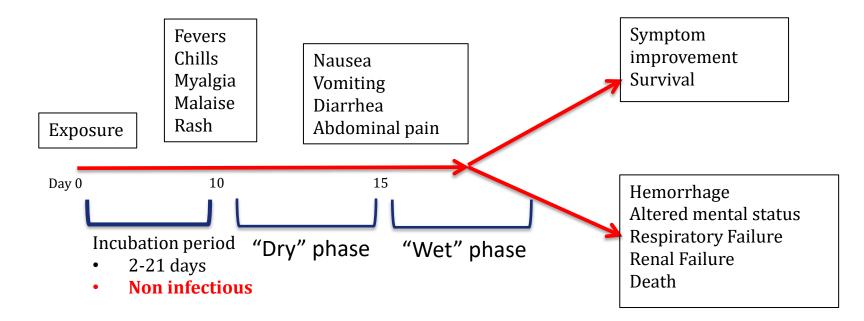
July 2014 – outbreak spread to Liberia and Sierra Leone

June 10, 2016 – WHO declared the outbreak over.



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Ebola virus disease (EVD): Clinical Presentation



Note: Clinical presentation similar for most viral hemorrhagic fevers (VHF)



Ebola Epidemic in West Africa HEALTH+ HOSPITALS

	Died due to Ebola			
	General population (%) Healthcare worker (%			
Guinea	0.02	1.45		
Liberia	0.11	8.07		
Sierra Leone	0.06	6.85		

NYC



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Country	Cases	Deaths	Cases	Locally-diagnosed	Medically-evacuated
	Cases	Deatilis	United States	4	7
Liberia	10,666	4,806 (45%)	United Kingdom	1	2
Sierra Leone	14,122	3,955 (28%)	Spain	1	2
Guinea	3,804	2,536 (67%)	Italy	1	1
Nigeria	20	8 (40%)	Germany		3
in Seria	20	0 (4070)	France		2
Mali	8	6 (75%)	Netherlands		1
Total	28,620	11,311 (40%)	Norway		1
			Switzerland		1

TOTAL

Source: Evans DK et al. Lancet Glob Health 2015;3(8):e439-e440.

HEALTH+ HOSPITALS First case in US, Sept 2014

September 19

- 42-year-old Liberian man travelled rom Liberia to Dallas, Texas. Asymptomatic en route.
- Had helped to carry a young woman who was ill with Ebola weeks earlier.

September 24

- Presented to a Dallas area acute care community hospital
- Abdominal pain, headache, and oliguria x 2 days. Temp 37.8 °C.
- Patient disclosed he had recently been in Africa, but did not report sick contacts.
- Diagnosed with sinusitis and discharged with antibiotics.

September 26

- Returned to hospital in worse clinical condition. Isolated.
- Underwent dialysis and endotracheal intubation.

September 30

CDC lab confirmed Zaire ebolavirus.

October 8

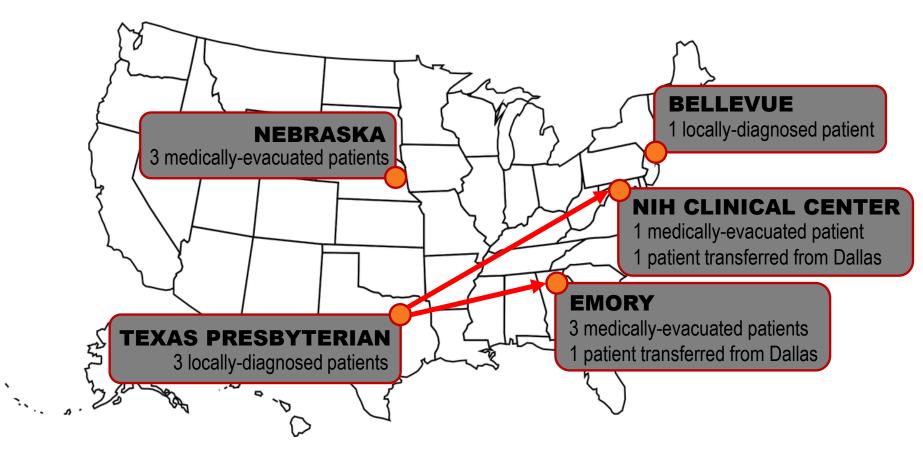
- Patient died from multi-organ failure.
- Two nurses who took care of this patient tested positive for Ebola.
- Texas public health monitored 48 confirmed and possible contacts of the patient.

"The care of Ebola can be done safely, but it is hard to do it safely. It requires meticulous and scrupulous attention to infection control, and even a single inadvertent innocent slip can result in contamination."

-- Tom Frieden, former director of CDC

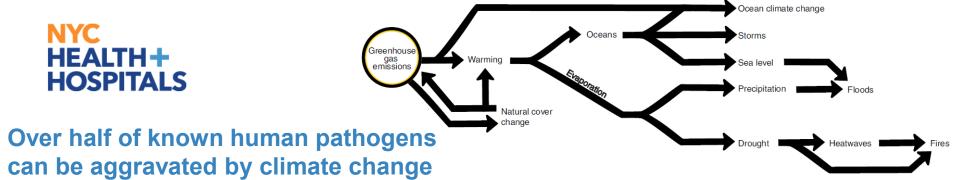
Source: McCarthy M. BMJ 2014;349:g6145; McCarthy M. BMJ 2014;349:g6200.

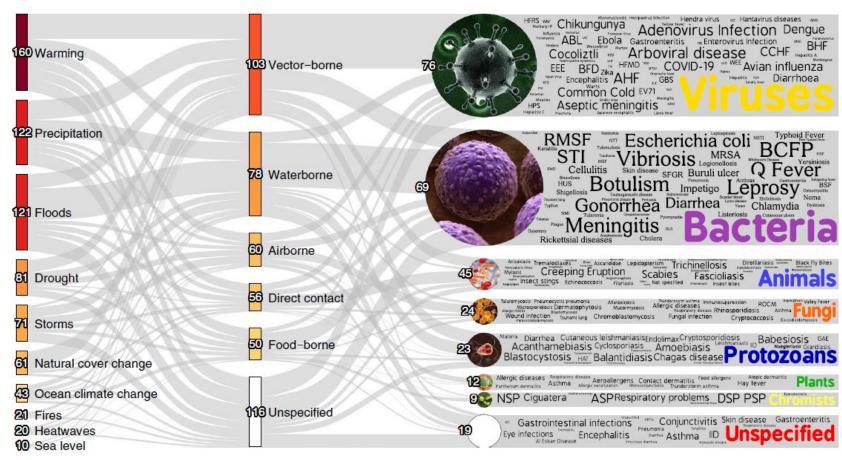
Ebola Epidemic in U.S.





Most recent Ebola Virus Outbreaks					
Country	Cases	Deaths	Species	Year	
Liberia, Sierra Leone, Guinea and others	28646	11323	Zaire ebolavirus	2013-2016	
Dem Rep of Congo (DRC)	66	49	Zaire ebolavirus	2014	
DRC	8	4	Zaire ebolavirus	2017	
DRC	54	33	Zaire ebolavirus	2018	
DRC, Uganda	3470	2287	Zaire ebolavirus	2018-2020	
DRC	130	55	Zaire ebolavirus	2020	
DRC, Guinea	28	18	Zaire ebolavirus	2021	
DRC	4	4	Zaire ebolavirus	April 2022	
	1	1	Zaire ebolavirus	August 2022	
Uganda	164	55	Sudan ebolavirus	September 2022- January 2023	





Mora C et al. Nat Clim Chang 2022;12(9):869-875.

Urbanization can enhance transmission of emerging infectious diseases

UN estimated 57% of world's population live in urban centers.

- Poor housing \rightarrow insect and rodent vectors
- Poor sanitation and waste management
- Poor indoor ventilation
- Density of inhabitants
- Encounters with wildlife and zoonotic diseases
- Hub of transportation to the world

Source: Neiderud CJ. Infection Ecology & Epidemiology 2015;5(1):27060.



Definition of a high consequence infectious disease (HCID)





Terminology

- highly infectious pathogen
- highly hazardous pathogen
- high consequence pathogen
- special pathogen
- high consequence infectious disease

What are high consequence infectious diseases (HCIDs)?

- No master list of pathogens; list evolves
- Important characteristics
 - Acute infection
 - Pathogen with high morbidity and/or mortality
 - May be difficulty to recognize and detect rapidly
 - Pathogen with high likelihood of secondary cases (person-to-person spread)
 - No effective vaccine, prophylaxis or treatment
 - Requires enhanced individual, population, and systems response

Sources: UK Health Security Agency; https://www.gov.uk/guidance/highconsequence-infectious-diseases-hcid



What are high consequence infectious diseases?

Broad Categories:

- Viral hemorrhagic fevers
- Severe (highly-pathogenic) respiratory infections
- Pox viruses

Viral Hemorrhagic Fevers

Family	Viruses	Past outbreak or endemic areas
Arenaviruses	Lassa virus	Nigeria, Guinea, Sierra Leone, Liberia
Bunyaviruses	Crimean-Congo Hemorrhagic Fever (CCHF)	Africa, Middle East, Asia, southeastern Europe
Filoviruses	Marburg	2023 outbreak: Equatorial Guinea, Tanzania
	Ebola	Recent outbreaks: Democratic Republic of Congo, Guinea, Uganda

WHO Outbreak Alerts: www.who.int/csr/don/en/

Highly Pathogenic Respiratory Infections

Family	Species	Past outbreak or endemic areas
Influenza	Avian influenza A (H5N1 and H7N9)	Isolated cases in several countries.
		2024: US, Cambodia, Vietnam
Coronaviruses	MERS	Arabian Peninsula
Paramyxoviruses	Nipah	Southeast Asia: Bangladesh, India, Malaysia, Singapore, Philippines





Pox Viruses

Family	Viruses	Past outbreak or endemic areas
Pox viruses	Variola (Smallpox)	Eradicated, potential bioterrorism agent
	Mpox, clade I	Democratic Republic of the Congo, the Republic of Congo, the Central African Republic, Cameroon, Gabon





Key considerations for prompt recognition and initial management of HCIDs





Challenges associated with initial management of HCIDs

- Delays in clinical recognition, diagnosis, and isolation:
 - Clinical findings often non-specific
 - Travel history and risk factors may not be reliably elicited
 - Rare infection often not endemic to a traveler's destination country



How do we identify patients with suspected HCIDs?

Case definition: a set of uniform criteria that defines a disease

Clinical Criteria

Signs Symptoms

Epidemiological Risk Factors

Travel (within known incubation period) Exposure





Ebola Virus Disease: Suspected Case has both:					
Consistent signs or symptoms + Risk factors					
	Signs or symptoms include:				
Elevated body tempera	Elevated body temperature or subjective fever Fatigue				
Muscle pain	Abdominal pain	Vomiting			
Unexplained hemorrhage Diarrhea Severe headache					
Thrombocytopenia Erythematous maculopapular rash followed by desquamation					
https://ndc.services.cdc.gov/case-definitions/viral-hemorrhagic-fever-2022/					

Ebola Virus Disease: Suspected Case has both:

Consistent signs or symptoms + Risk factors

An Epidemiologic risk factor within the 21 days prior to the onset of symptoms

- Contact with blood or body fluids from a person who is sick with or has died from Ebola Virus Disease (EVD)
- Work in a lab that handles Ebola specimens
- Work in a lab that handles bats, rodents, or primates from an area with active transmission
- Semen from a man who has recovered from EVD
- Travel to or residence in geographical area where EVD is known to be present



Identify, Isolate, Inform (I/I/I)



Travel Screening Country List – July 2023



This document is not meant to be an exhaustive list but is focused on select, current special pathogen disease outbreaks that require prompt identification, isolation and/or specialized evaluation and management.

HEALTH+

HOSPITALS

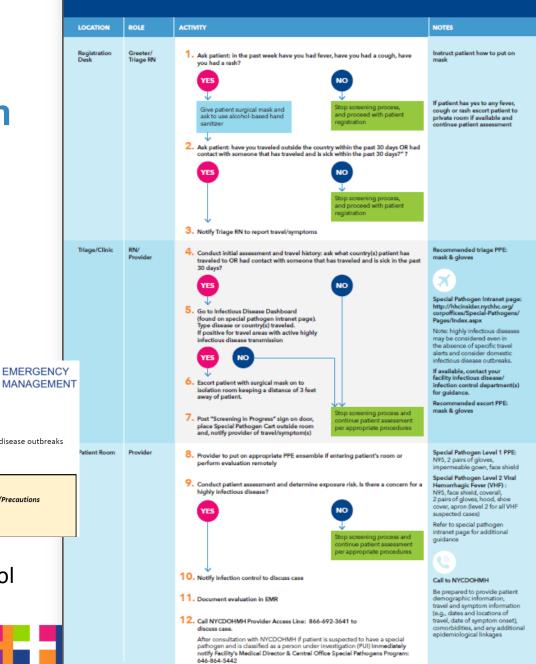
Country Diseases with Active Cases	Surveillance Window (max time from exposure to symptom onset)	Case Definition and Guidance	PPE/Precautions
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Sources: Chea N et al. Am J Infect Control 2015;43(11):1244-5.



Initial Patient Screening Algorithm for Infectious Diseases for EDs







Initial isolation – patient placement

- Single occupancy room
- Private bathroom
- Door closed
- Use airborne infection isolation room if available, and especially if aerosols likely to be generated

Inform

- Facility point of contact: infection control and departmental leadership
 - Clarify required PPE ensemble and other infection control measures
- Public health authority (DOHMH provider access line)

Vulnerabilities for I/I/I HEALTH+ HOSPITALS

Mpox Exposure on a Congregate Inpatient Psychiatry Unit – Description of the Investigation and Outcomes, New York City 2022

NYC HEALTH+ Waleed Malik, MD¹, Simon Dosovitz, MD², Clyde Gilmore, MD³, Jeanne Cosico, RN³, Justin Chan, MD, MPH¹ OSPITALS 1 NYC Health + Hospitals/Bellevue, Infection Prevention & Control, New York, NY, USA Bellevue 2 NYC Health + Hospitals/Bellevue, Psychiatry, New York, NY, USA 2 NYC Health + Hospitals/Bellevue, Occupation Health Service, New York, NY, USA Index patient tests positive for mpox Mpox symptoms discovered and index patient isolated Observation period for exposed patients and staff Index patient admitted Psychiatric admission period Last day of monitoring for exposed patients and staff 2022 au

Figure 1: Timeline of Events

NYC

- Think carefully about vulnerable points of entry
 - Patients with altered consciousness
 - Uncooperative patients
 - Staff who are not trained in internal medicine
 - Congregate settings (behavioral health, correctional facilities)
 - Admission during incubation period
 - **Pediatrics**
- Consider enhanced screening protocols or serial screening during outbreaks of HCIDs

Monkeypox outbreak 2022: "See one, do one, teach one" no longer the rule

Sapha Barkati MD, MSc, DTM&H^{1,2,3}, Luke B Harrison MD, PhD¹

- Frontline staff faced with double challenge
 - Unfamiliar infectious disease
 - Atypical clinical presentation
- Frontline educational content and screening tools need continuous review and updates

Sources: Barkati S et al. J Associ Med Microbiol Infect Dis Can 2022;7(3):157-158; Federal Bureau of Prisons Interim Ebola Protocol: https://www.bop.gov/resources/pdfs/BOP_Ebola_Protocol_2015.pdf; Malik W et al. SHEA Spring 2023, Seattle WA.

NYC HEALTH+ HOSPITALS Clinical lab safety

Challenges:

- 1. Every specimen that arrives in a clinical lab is an unknown.
- 2. It is rare that a clinical lab gets advance warning that a specific pathogen is suspected.

<u>Bacteria</u>: Bacillus anthracis (anthrax*), Brucella species, Burkholderia species (melioidosis and glanders*), Clostridium botulinum (botulism), Coxiella burnetii (Q fever), Francisella tularensis (tularemia), Yersinia pestis (plague)

<u>Fungi</u>: Blastomyces dermatitidis, Coccidioides immitis, Histoplasma capsulatum

<u>Viruses</u>: Ebolavirus*, Eastern equine encephalitis virus, Western equine encephalitis virus, Lassa Virus*, Marburg Virus*, Rabies Virus, Variola virus (smallpox*),

Venezuelan Equine Encephalitis, Yellow Fever Virus

Sources: Singh K. Clin Infect Dis 2009;49:142-147; Pentella MA. Clin Lab Med 2020;40(4):473-482; CDC Guidance for U.S. Hospitals and Clinical Laboratories on Performing Routine Diagnostic Testing for Patients with Suspected Ebola Disease <u>https://www.cdc.gov/vhf/ebola/laboratory-personnel/safe-specimen-management.html</u> https://www.canada.ca/en/public-health/services/infectious-diseases/viral-haemorrhagic-fevers/interim-biosafety-guidelines-laboratories-handling-specimens-patients-under-investigation-ebola-disease.html

Table 1. Ten most frequently reported laboratory-associated infections worldwide.

Disease	No. of cases	No. of deaths
Brucellosis	426	5
Q fever	280	1
Hepatitis	268	3
Typhoid fever	258	20
Tularemia	225	2
Tuberculosis	194	4
Dermatomycoses	162	0
Venezuelan equine encephalitis	146	1
Psittacosis	116	10
Coccidioidomycosis	93	2

NOTE. Data are for the years 1976 [3] and 1978 [4].



Additional considerations

- Patient transport (within and outside of hospital)
- Visitor management
- Post-exposure plan (monitoring during incubation period, PEP, quarantine plans)
- Invasive procedures and surgery
- Special populations: pediatrics, pregnant persons



Models of care for management of HCIDs





National Special Pathogen System



NETEC

System of Care Levels Overview

To align more closely with the Trauma system, the NSPS will be organized by Levels and descriptors for the System of Care facilities.

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el 3	
e l 2	Source: Mukherjee V et al. Health Secur 2022;20(S1):S39-S48.
На	
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NYC HEALTH+ HOSPITALS Role of a Biocontainment Unit (BCU)

A healthcare facility or unit designed to provide safe, secure, high quality and appropriate care with optimal infection prevention and control procedures to a small number of patients with suspected or confirmed HCID

Keeps other patients, healthcare workers and the public safe

Facilitates the use of techniques and standards that are above and beyond normal function in the hospital setting
 Sources: (1) Bannister B et al. Lancet Infect Dis 2009;9(1):45-56; (2) Smith PW et al. Biosecur Bioterror 2006;4(4):351-65.

Guidelines for design and operation of biocontainment units

- Strategically located so that patient and specimen transport times do not exceed 6 hours
- Close to major international ports of entry
- Co-located with a tertiary care facility for specialist support
- Have flexible use when not activated for HCID patient care

Sources: (1) Bannister B et al. Lancet Infect Dis 2009;9(1):45-56; (2) Smith PW et al. Biosecur Bioterror 2006;4(4):351-65.

FIGURE 1. BIOCONTAINMENT PATIENT CARE UNIT CONSENSUS TOPICS

- I. The Role of Units in Overall U.S. Preparedness
 - A. Definition of BPCUs
 - B. The mission of BPCUs
 - C. Integration of units into military and civilian preparedness
 - D. National capacity for BPCUs
 - E. Plans for capacity for hazardous diseases beyond the units
 - F. Federal or local control of regulatory issues
- II. Medical Care Issues
 - A. Clinical services provided in the unit
 - B. Consultants and other personnel
 - C. Care issues
 - D. Pathology issues
 - E. Minimum diagnostic services and regulatory compliance
 - F. Housekeeping and security
 - G. Emergency evacuation
 - H. Additional clinical issues
- III. Infection Control Issues
 - A. Personal protective equipment
 - B. Biosafety program
 - C. Occupational health program
 - D. Environmental disinfection
 - E. Large equipment disinfection
 - F. Infectious waste
 - G. Transportation of patients to the unit
 - H. Visitor infection control issues

IV. Facility Issues

- A. Air-handling system
- B. General facility design criteria
- C. Unit design features
- D. Essential unit construction features
- E. Certification and commissioning
- F. Communication
- G. Additional facility issues
- V. Psychosocial and Ethical Issues
 - A. Patient psychosocial issues
 - B. Staff psychosocial issues
 - C. Ethical issues

Key features of biocontainment units

Features in Common with Existing BCUs at NIH, Emory, and Nebraska	Unique Features of the JHH BCU
 Secure entry and exit points Onsite laboratory Advanced air-handling system for airborne and droplet transmission Highly trained nurse and clinician provider team including adult, pediatric, and obstetrics capabilities Critical care capabilities in each room Onsite portable radiology and ultrasound Advanced telecommunication capabilities Pass-through autoclaves for waste management 	 Unidirectional flow of staff through patient care areas Dedicated donning and doffing rooms for all patient care areas Ample physical space to accommodate obstetrics procedures including labor and delivery and cesarean sections Ample physical space to allow for onsite sterile procedures, including limited surgery Main patient care room with two ICU headwalls to provide care for family (e.g., parent and child)

Definition of abbreviations: BCU = biocontainment unit; ICU = intensive care unit; JHH = Johns Hopkins Hospital; NIH = National Institutes of Health.

Source: Garibaldi BT et al. Ann Am Thorac Soc 2016;13(5):600-8.



- Ideal for limited outbreaks of HCIDs
- Limited resource (2 beds at Bellevue, ~55 in U.S.)
- Capacity can quickly be overwhelmed by pandemics → surge capacity required





Alternative models of care

Isolation System for Treatment and Agile Response for High-Risk Infections (ISTARI)

A revolutionary patient care system that dramatically increases safety, improves quality, and reduces cost for high-consequence infectious diseases.

ISTARI MODEL 1B

Intended Use

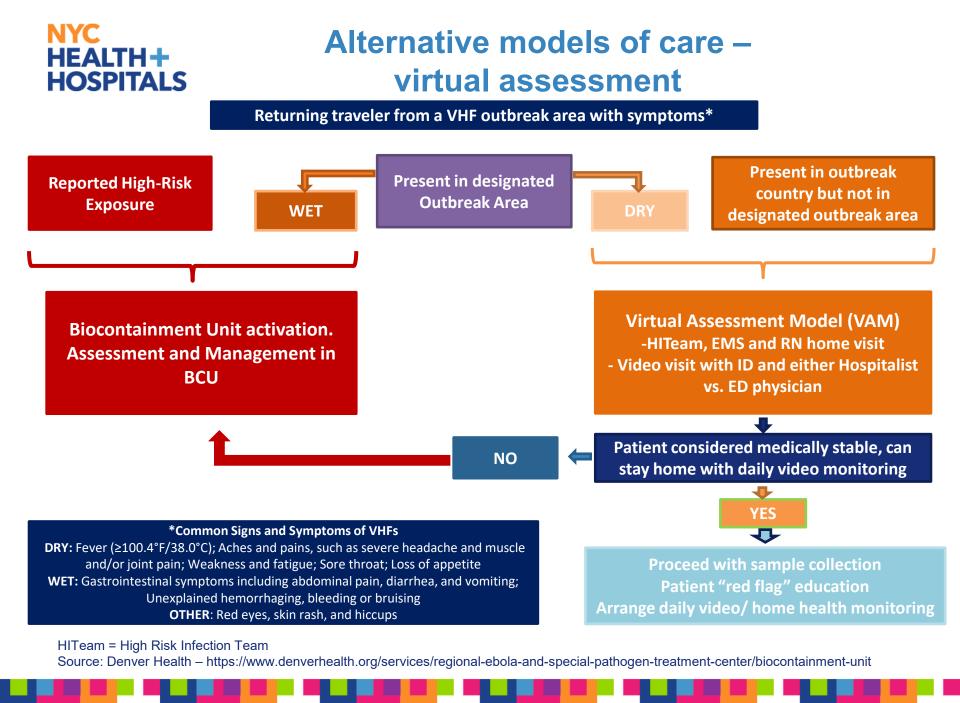
Enclosure for low-acuity care and procedures for patients who require airborne, droplet, or contact isolation precautions in a temporary patient care setting (e.g. urgent care or emergency department).

KEY PRODUCT CHARACTERISTICS

- Suitable for onsite storage and rapid set-up (less than 15 minutes)
- Employs space and utilities of a typical emergency room hallway or bay
- Maintains and monitors negative pressure with airborne pathogen containment and appropriate air exchanges for airborne isolation



Source: University of Nebraska Medical Center – https://innovateipc.org/istari/



Use of telemedicine





The Isolation Communication Management System A Telemedicine Platform to Care for Patients in a Biocontainment Unit

Allison Gossen¹, Beth Mehring², Brian S. Gunnell³, Karen S. Rheuban³, David C. Cattell-Gordon³, Kyle B. Enfield^{4,5}, and Costi D. Sifri^{4,6}

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Reduce exposures by allowing communication and monitoring:

- Healthcare providers in the BCU
 - Observe for breaches in infection control
- Patient and staff outside BCU
 - Facilitate patient transfers
- Consultation by physician not trained in PPE
- Family and other services to provide remote support
- Allow students and learners to be involved

Source: Gossen A et al. Ann Am Thorac Soc 2020;17(6):673-678.



Take home points

- HCIDs are acute transmissible infections with high morbidity/mortality and limited medical countermeasures; list will evolve with time
 - They pose a growing threat due to urbanization, ease of international travel, and climate change
 - They pose a risk to healthcare workers when there is delayed recognition and implementation of infection control measures
- Effective response requires understanding current epidemiology and implementing effective systems for prompt recognition of suspected cases
 - Every healthcare facility have a system to promptly "identify, isolate, and inform" for patients with suspected HCIDs, with special attention to vulnerable points of entry
- Biocontainment units (BCU) are a limited, high-cost resource used to manage a small number of HCID cases

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