National Special Pathogen System (NSPS)
Level 1-4: Facility Minimum Capability Requirements

Facility Overviews

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4
• Can safely identify, isolate, initiate stabilizing medical care, perform required laboratory testing, and inform local public health partners • Can activate internal processes for confirmed patients from nearby Level 2, 3, or 4 facilities within **two hours time,** coordinate transfer within **four hours time**, and are able to **admit** suspect or confirmed high consequence infectious disease (HCID) patients at the direction of the Administration for Strategic Preparedness and Response (ASPR) within **eight hours time**; these may be repatriated US citizens from OCONUS, inter-regional air/ground transports or transfers from a lower tier of the National Special Pathogen System (NSPS) • Represents the capacity to hospitalize HCID patients, provide all levels of care up to and including critical care for the **duration of their illness**, and support continued follow up care when isolation is no longer required • When patient volumes exceed Level 1 facility capacity, supports, in collaboration with ASPR and the NSPS Coordinating Body, coordination, and communication amongst other area Level 1 and 2 facilities for optimal patient placement, quality care, and resource utilization • Provides care for adult, pediatric, and neonatal patients and must be prepared to offer labor and delivery services if necessary	• Can safely identify, isolate, initiate stabilizing medical care, and perform limited basic laboratory testing, and inform local public health partners • Can activate internal processes for suspect case(s) from nearby Level 3 or 4 facilities within **two hours time**, and coordinate transfer within **four hours time,** and are able to **admit** suspect or confirmed HCID patients at the direction of ASPR within **eight hours time** • Represents the capacity to hospitalize HCID patients for the **duration of their illness** and support continued follow up care when isolation is no longer required • When patient volumes exceed Level 2 facility capacity, the Regional Emerging Special Pathogen Treatment Centers (RESPTCs) will support collaboration, coordination, and communication among other area Level 1 and 2 facilities for optimal patient placement, quality care, and resource utilization • Can be adult focused and/or pediatric focused. Obstetric care is preferred but not required for capability of Level 2	• Can safely identify, isolate, initiate stabilizing medical care, and perform limited basic laboratory testing, and inform local public health partners • Can activate internal processes for suspect case(s) from nearby Level 4 facilities within **two hours time,** and coordinate transfer within **four hours time**. • Can safely provide medical care for **12-36 hours** and should initiate transfer after stabilization if/when the suspect case rules in for an HCID and/or potentially meets other criteria for transfer • Maintains transfer relationships with Level 2 and RESPTCs to support inpatient care for suspect HCID patient who rule-in for HCIDs • Can be adult focused and/or pediatric focused	**Considerations to Meet the Standard** • Can safely Identify, Isolate, initiate stabilizing medical care, and Inform local public health partners. • Can safely initiate transfer after stabilization if/when the suspect case rules in for an HCID and/or potentially meets other criteria for transfer. • Can be any type of health care facility (e.g., hospitals, urgent cares, nursing homes, etc.) • Can be focused on any patient population (i.e., adult, pediatric)

Physical Infrastructure

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4

• Has appropriate inpatient isolation space capable of supporting at least 2 viral hemorrhagic fever (VHF) HCID patients with critical illness (including pediatrics and adults; may be at partner facility for pediatric care)
 	
• Has appropriate inpatient isolation space capable of supporting at least 10 HCID patients with airborne transmissible illness (including pediatrics and adults; may be at partner facility for pediatric care); preferably within the same unit
 	
• Has dedicated laboratory space that can be utilized to safely process specimens from HCID patients
	• Has appropriate inpatient isolation space capable of supporting at least 1-2 VHF HCID patients with critical illness
	
	• Has appropriate inpatient isolation space capable of supporting at least 4 HCID patients with airborne transmissible illness
		• Has appropriate isolation space in Emergency Department (ED) or other accessible space (at least a single isolation space/negative pressure room)	**Considerations to Meet Accreditation Standards**
			
			• Develops and implements procedures for transmission-based isolation precautions
			
			Considerations to Advance Readiness
			
			• Has a pre-identified isolation space for HCID suspect patients (including a delineation between the patient care space and the personal protective equipment (PPE) doffing space)
			  • Isolation space has either a dedicated bathroom or a bedside commode for patient care
			  • For an airborne pathogen, negative pressure room has been identified
			
			• Identifies a workflow and path of travel for health care personnel and patients to enter and exit the isolation space
			
			• Identifies methods for optimal communication between care team and patient (e.g., white board, telehealth, in-suit radio packs or technology)

Environmental Infection and Control

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4
• Integrates facility infection prevention and control personnel into biocontainment unit program design, including training, exercising, and clinical care protocols and capabilities	• Integrates infection prevention into program design, physical infrastructure, training, exercising, and patient management protocols. This may be direct or joint oversight.	• Integrates infection prevention into program design, physical infrastructure, training, exercising, and patient management protocols. This may be direct or joint oversight.	**Considerations to Meet Accreditation Standards** • Identifies infection control considerations for HCID isolation when developing processes to protect health care personnel and patients • Develops and implements protocols for suspected HCIDs that are readily available for use at the point of care • Develops and implements procedures for informing the appropriate public health partners and key facility staff • Develops and implements procedures and identifies personnel and products for cleaning and disinfecting patient care spaces, surfaces, and equipment **Considerations to Advance Readiness** • Directly involves facility's infection preventionist(s) in the development of HCID plans and procedures

Personal Protective Equipment (PPE)

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4
• Has identified appropriate PPE and developed protocols for donning/doffing and inventory management. • Has all necessary PPE on hand to support evaluation and care of at least 2 HCID patients for at least 7 days available onsite with a plan for resupply to support 21 days of care	• Has identified appropriate PPE and developed protocols for donning/doffing and inventory management. • Has sufficient PPE on hand to support evaluation and care of at least one HCID patient for at least 7 days available onsite with a plan for resupply to support at least 21 days of care.	• Has identified appropriate PPE and developed protocols for donning/doffing and inventory management. • Has sufficient appropriate PPE on hand to support evaluation and care of up to 3 suspect HCID cases for 12-36 hours before resupply arrives	**Considerations to Meet Accreditation Standards** • Develops and implements protocols for appropriate personal protective equipment and proper donning and doffing techniques • Develops and implements procedures for transmission-based isolation precautions **Considerations to Advance Readiness** • Utilizes Disaster Available Supplies in Hospitals (DASH) tool or state-based requirement as a preparedness planning tool to estimate appropriate amount of PPE to have on-hand • Has protocols to deploy a trained doffing assistant/partner or trained observer to reduce possibility of cross contamination during PPE removal process • Utilizes resources from NETEC, NIOSH, OSHA, the Association for Professionals in Infection Control and Epidemiology (APIC), and the CDC Resource Libraries to develop their internal policies and protocols

Training

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4

• Training is completed by the Special Pathogen Response Team members providing direct patient care and/or processing lab specimens **quarterly** on donning/doffing of PPE
 	
• Training is completed by the Special Pathogen Response Team members providing direct patient care at **quarterly** intervals on skills, including:
  • waste management
  • spill clean for VHF
  • lab specimen collection & packaging
  • PPE breach
  • provider down
 	
• Special Pathogen Response Team members providing indirect patient care may also receive just-in-time refresher training at time of activation
	• Special Pathogen Response Team members providing direct patient care and/or processing lab specimens train at **least twice annually** on donning/doffing of PPE
	
	• Special Pathogen Response Team members providing direct patient care train at least **annually** on skills, including:
	  • waste management
	  • spill clean for VHF
	  • lab specimen collection & packaging
	  • PPE breach
	  • provider down
	
	• Special Pathogen Response Team members providing indirect patient care receive just-in-time refresher training at time of activation
		• Training is completed by the HCID Response Team providing direct patient care at least **annually** on donning/doffing enhanced PPE
		
		• Special Pathogen Response Team members providing indirect patient care receive just-in-time refresher training at time of activation
		
		• ED staff are trained how to utilize just-in-time training resources
			Considerations to Meet Accreditation Standards
			
			• Defines the training competency and frequency for all appropriate personnel
			
			• Implements training for HCID protocols and PPE donning/doffing based on your organization's definition and includes all appropriate personnel
			
			Considerations to Advance Readiness
			
			• Identifies just-in-time training resources (e.g., PPE donning and doffing checklists)
			  • May include leveraging resources from RESPTC and/or NETEC
			
			• Conducts training for PPE donning/doffing and other patient care skills for appropriate personnel at least annually (or as proficiency requires)
			  • May be accomplished by integrating into skills fairs or other annual training
			
			• Conducts training for environmental services personnel

Emergency Management

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4

• Coordinates and safely receives patients from within the region, adjacent regions, and OCONUS transfers via air and ground transportation
 	
• Leads the development and testing of coordinated state and Regional HCID plans in collaboration with co-located Level 1 facility within the HHS Region, other RESPTCs as appropriate, public health partners, tribal, and Emergency Medical Services (EMS) agencies
 	
• Facilitates collaboration across all regional partners, to include information sharing, communication, patient transport, specimen testing, and exercise design/development
 	
• Conducts quarterly exercises throughout the year to test the facility plans
	• Collaborates with Level 1 RESPTC(s) and other regional partners
	
	  • Collaboration includes information sharing, communication, patient transport, specimen testing, and the development/testing of state and regional plans
	
	• Conducts at least 2 exercises per year testing the facility plans
		• Collaborates with Level 1 RESPTC(s) and other regional partners
		
		  • Collaboration includes information sharing, communication, patient transport, specimen testing, and the development/testing of state and regional plans
		
		• Conducts at least 1 annual mystery patient exercise
			Considerations to Meet Accreditation Standards
			
			• Incorporates management of HCID cases into their emergency operations plan(s)
			
			  • Includes procedures for providing patient care and clinical support as well as coordinating with public health partners for patient transfer and communication of patient care information
			
			Considerations to Advance Readiness
			
			• Identifies contact information and collaborates with Level 1 facility(s) within the HHS Region (and other HHS Region(s) if appropriate), EMS agencies, local Health Care Coalitions (HCC), and public health partners in developing and testing of coordinated state and Regional HCID plans
			
			• Conducts at least 1 annual mystery patient exercise

Treatment & Care

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4

• Provides safe clinical care, including critical care services for patients with possible and confirmed high consequence infectious disease (HCID) infections, including VHFs, for the **full duration** of the patient's illness
 	
• Provides care for HCID patients (**at minimum 2 VHF**) and cluster of airborne transmissible illness (**10 respiratory/airborne transmissible**)
 	
• Safely receives HCID patient transfers including neonatal, pediatric, labor and delivery and adult patients
 	
• Provides expert consultation, access to resources, and guidance on HCID response to health care partners in their regions as well as to other Level 1 facilities. This may include but is not limited to support for patient care delivery, infection prevention and control, and transportation considerations
	• Provides safe clinical care, including critical care services for patients with possible and confirmed high consequence infectious disease (HCID) infections, including VHFs, for the **full duration** of the patient's illness
	
	• Provides care for a limited number of HCID patients (**e.g., 1-2 VHF**) and a **small cluster** of airborne transmissible illnesses as capacity allows (**e.g., 4 respiratory/airborne transmissible**)
	
	• Safely receives HCID patient transfers
		• Safely identifies and isolates suspect cases
		
		• Provides safe medical care for **12-36 hours**
		
		• Provides safe clinical evaluation of suspect cases, initiates basic care (intravenous (IV) start, phlebotomy, IV antibiotics, IV fluids), conducts imaging, and monitors care (vital signs)
		
		• Safely receives patients from Level 4 facilities
			Considerations to Meet Accreditation Standards
			• Develops and implements procedures for screening at the points of entry to the facility for respiratory symptoms, fever, rash, and travel history to identify or initiate evaluation for HCIDs
			  • Note: points of entry may include the emergency department, urgent care, and ambulatory clinics
			• Develops and implements infection control procedures to support continued and safe provision of care while the patient is in isolation and to reduce exposure among staff, patients, and visitors using the hierarchy of controls
			Considerations to Advance Readiness
			• Implements universal screening to include symptoms, travel, etc. Tools to screen include:
			  • Screening questionnaires
			  • Pre-arrival virtual screenings/check-ins (e.g., white board, text messages, other innovative technology resources)
			  • Travel screens in electronic health record (EHR) (e.g., EPIC) during active outbreaks
			• Has effective signage (e.g., Centers for Disease Control and Prevention (CDC)) placed at public points of entry to the facility
			• Develops strategies to keep the care team contact limited (e.g., telehealth, technology, on-call team)

Personnel Management

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4

• Has a written staffing model and multi-disciplinary team that is appropriately sized to support required care throughout the patients' hospitalization
  • Types of personnel that are recommended be involved include Providers, RNs, RTs, Laboratory, and Ancillary Staff (e.g., EVS, Security, IPC, facilities) who can be involved in direct and indirect patient care
• Has protocols for occupational health monitoring in place for all health care personnel who are in direct contact with the patient(s) or patient care area.
• Has process/resources in place to provide behavioral health and wellbeing support to all personnel involved in special pathogen response
	• Has a written staffing model and multi-disciplinary team that is appropriately sized to support required care throughout the patients' hospitalization
	  • Types of personnel that are recommended be involved include Providers, RNs, RTs, Laboratory, and Ancillary Staff (e.g., EVS, Security, IPC, facilities) who can be involved in direct and indirect patient care
	• Has protocols for occupational health monitoring in place for all health care personnel who are in direct contact with the patient(s) or patient care area.
	• Has process/resources in place to provide behavioral health and wellbeing support to all personnel involved in special pathogen response
		• Has a suitably sized and multi-disciplinary team and a written staffing model to support required care throughout the patient's hospitalization
		• Has at least 1 clinical laboratory specialist who is certified in Category A specimen packaging to respond within a few hours
		• Has protocols for medical monitoring in place for all health care and support personnel who interact with the suspect case(s) in collaboration with public health partners
		• Has at least 1 staff member from environmental services available to clean room
		• Has process in place to provide emotional and supportive care to all staff that are included in the response to an HCID event
			Considerations to Meet Accreditation Standards
			• Identifies all appropriate personnel supporting the ED or other points of entry who require training and education on the management of HCID cases
			  • This includes training and education on how to appropriately identify and isolate HCID cases and then inform appropriate external partners (e.g., public health partners)
			Considerations to Advance Readiness
			• Utilizes a Log Sheet to track all personnel interacting with HCID cases and has protocols for post-interaction medical monitoring of health care personnel
			• Has plans to mobilize additional health care personnel when HCID patient is identified
			• Develops a staffing model for an HCID patient in isolation (e.g., buddy system)
			• Has a process in place to provide emotional and supportive care to all staff that are included in the response to an HCID event
			• Identifies a primary lead to oversee the HCID preparedness program at the facility (e.g., Infection Preventionist, Emergency Manager, Safety Officer)

Laboratory

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4
• Can perform clinical laboratory testing to support critical care (e.g., basic metabolic panel (BMP), complete blood count (CBC), arterial blood gas (ABG), liver function tests (LFTs), malaria, blood cultures, coagulation testing) • Has on call staff certified in Category A shipping to safely collect/send samples to state and CDC labs	• Can perform clinical laboratory testing to support critical care (e.g., BMP, CBC, ABG, LFTs, malaria, blood cultures, coagulation testing) • Has on call staff certified in Category A shipping to safely collect/send samples to state and CDC labs	• Can perform point of care onsite clinical diagnostic testing following risk assessment (able to test basic electrolytes, hematocrit (Hct)/ hemoglobin (Hgb), and malaria (Binax or other)) • Has on call staff certified in Category A shipping to safely collect/send samples to state and CDC labs	**Considerations to Meet Accreditation Standards** • Works closely with public health partners to determine next steps for testing patients with suspect or confirmed HCIDs **Considerations to Advance Readiness** • Identifies personnel trained in safely collecting and packaging Category A samples to the state lab or CDC • Has plans to safely perform point-of-care clinical diagnostic testing onsite such as basic electrolytes, Hct/Hgb, malaria (Binax or other) • Includes a laboratory risk assessment before specimen collection (if a patient has met criteria for suspected HCID

Waste Management

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4
• Has clear processes to safely manage and dispose of all waste generated by patient care • Appropriately trains staff in the waste management plan, which optimizes safety and appropriate final process (i.e. secures and minimizes waste)	• Has written processes to safely manage all waste generated in any aspect of patient care • Has either engaged with a vendor for waste removal or has validated internal processes for on-site inactivation of Category A waste	• Has clear processes to safely sequester waste in a secure location until a suspect case has been confirmed or ruled out, and if confirmed, proceed with waste plan • Appropriately trains staff in the waste management plan, which optimizes safety and appropriate final process (e.g., secured, minimize waste)	**Considerations to Meet Accreditation Standards** • Develops and implements a protocol for waste management and cleaning and disinfecting patient care spaces, surfaces, and equipment *NOTE: facilities are not required to maintain an active contract with a waste management vendor and/or maintain onsite sterilization capabilities (i.e., autoclave or incinerator)* **Considerations to Advance Readiness** • Identifies process for communication with waste management vendor and public health partners • Leverages resources from RESPTC and the National Emerging Special Pathogens Training and Education Center (NETEC)

Decedent Management

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4
• Has finalized and coordinated plans that are exercised with relevant state agency to manage the remains of an HCID patient who dies in the facility including coordination with the relevant state agency on final disposition of the remains in accordance with public health partner guidance.	• Has plans to manage the remains of an HCID patient who dies in the facility including coordination and outreach for technical assistance with the responsible state agency, public health partners, and Level 1 facility	• Has plans for coordination and outreach for technical assistance with the responsible state agency, public health partners, and Level 1 facility for a suspect HCID case	**Considerations to Meet Accreditation Standards** *N/A* **Considerations to Advance Readiness** • Identifies the steps for contacting their public health partners • Has a defined protocol for how to safely secure a deceased suspect HCID patient until decisions are made about how to manage (e.g., conversation with local mortuary, public health partners) • May include working with their RESPTC and/or utilizing resources from the CDC, NETEC, and their local mortuary • Develops protocols to accommodate family visits, last rites, and cultural/ethnic considerations

Research

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4
• Develops and maintain institutional processes for requesting investigational drugs • Defines institutional processes for participating in investigational drug research • Has the ability to offer and administer investigational drugs while maintaining standard of care (single-patient emergency investigational new drugs (eINDs)) • Has access to an Institutional Review Board (IRB) to support the oversight of research at the institution.	• Can incorporate research protocols for the use of investigational products in the clinical care of HCID patients • Has defined institutional processes to request study drugs (Investigational New Drug (IND) and / or Expanded Access Protocol- EAP) • Has access to an Institutional Review Board (IRB) to support the oversight of research at the institution.	*N/A*	*N/A*

Acronyms (1 of 2)

Acronym	Definition
ABG	Arterial blood gas
APIC	Association for Professionals in Infection Control and Epidemiology
ASPR	Administration for Strategic Preparedness and Response
BMP	Basic metabolic panel
CBC	Complete blood count
CDC	Centers for Disease Control and Prevention
ED	Emergency Department
EHR	Electronic health record
eINDs	Emergency investigational new drugs
EMS	Emergency Medical Services
EVS	Environmental Services
HCID	High consequence infectious disease
HHS	The Department of Health and Human Services
IND	Investigational New Drug
IPC	Infection Prevention & Control
IV	Intravenous

Acronyms (2 of 2)

Acronym	Definition
LFTs	Liver function tests
MD	Medical Doctor
NETEC	National Emerging Special Pathogens Training and Education Center
NIOSH	The National Institute for Occupational Safety and Health
NSPS	National Special Pathogen System
OCONUS	Outside of the Continental United States
OSHA	The Occupational Safety and Health Administration
PPE	Personal protective equipment
RESPTCs	Regional Emerging Special Pathogen Treatment Centers
RN	Registered Nurse
VHF	Viral hemorrhagic fever
VS	Vital Signs