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Planning for the Next Infectious Disease Threat: Considerations to Ensure Every Facility is Prepared

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High-Consequence Infectious Diseases

The term "high-consequence infectious disease" (HCID) is a generalized term used to describe infectious diseases with the potential for severe outcomes and the likelihood to cause disruption to communities and public health infrastructure. Although no formal definition exists, HCIDs are diseases with high morbidity or mortality, limited or no medical countermeasures, high communicability, and the capacity to disrupt local infrastructure.[1-3] In the U.S., the Joint Commission recently added additional metrics related to preparedness for HCID threats, adding considerations such as requiring prompt identification and implementation of infection control procedures and requiring expeditious notification to public health authorities.[4] Examples of HCIDs include viral hemorrhagic fevers such as Ebola Virus Disease (EVD), Marburg Virus Disease (MVD), Crimean Congo hemorrhagic fever (CCHF), Lassa Fever (LF), and South American hemorrhagic fevers (SAHF) and respiratory or aerosol transmitted diseases such as Nipah virus infection, Middle Eastern respiratory syndrome (MERS), Severe acute respiratory syndrome (SARS), and novel avian influenzas. While the focus of this manuscript is on HCIDs, the guidance provided can be applied to other infectious diseases even if not classically categorized as HCIDs.

Why preparedness matters

Prior global outbreaks have forced public health and healthcare leaders to re-evaluate their outbreak response practices. Recent pandemics such as the 2013-2016 EVD outbreak in West Africa, the COVID-19 pandemic, and the global mpox outbreak in 2022 have provided prime examples as to why early preparation for infectious threats is critical. The consequences of not being prepared can have catastrophic effects on our communities and local infrastructure, far beyond the healthcare system. A lack of standardized practices and systems, limited funding invested in development and testing of vaccines and countermeasures, and an inability to participate in shared inter-agency communication and practices, are all detrimental to a community's response. The ability to prepare for an infectious disease event requires identification of gaps in current preparedness methods. The COVID-19 pandemic showed the scale at which communities across the globe were ill-prepared for an outbreak of such magnitude. In 2023, The World Health Organization (WHO) published a list of topics requiring increased attention and consideration: collaborative surveillance, community protection, safe and scalable care, access to medical countermeasures, and emergency coordination.[5] Just as emergency managers prepare for natural disasters, terroristic threats, and other identified potential disasters, HCID preparedness is critical to the health and safety of our communities. The Centers for Disease Control & Prevention (CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) also highlight the seriousness of being unprepared for the next HCID event, signifying this type of event as a major threat to both domestic and global security.[6]

Infectious disease preparedness is not the sole responsibility of healthcare and public health leaders, but should be accepted as a multilateral effort, as a HCID outbreak has the potential to affect and harm many industries aside from healthcare and public health

infrastructures, alone. Although no longer considered a HCID, COVID-19 had many characteristics of a HCID (novel, easily transmitted, no countermeasures) and offers an example of how this sort of disease can disrupt a diverse number of industries and trades beyond healthcare. Supply chain disruption, heightened cyber security threats, and negative economic impact, are just some of the consequences experienced during the COVID-19 pandemic.[7] Though identification of multisector disruption can occur as the result of a disease outbreak, HCID preparedness relies on public health entities and frontline healthcare facilities to lead the charge in preparedness efforts, ultimately encouraging the incorporation of other industry partnerships. Though each community, institution, and system are unique in capability, the importance of shared resources and a structured line of communication assists in building partnerships and strengthens relationships in support of HCID safety and preparedness. Recent events including mpox and COVID-19 showed that strong relationships are needed for responding to infectious disease threats.

The importance of a collaborative approach to preparedness through shared goals, investments, and identified need can bolster response efforts during a HCID threat, strengthening systems, processes, and ensuring the safety of the community (ref). The importance of a collaborative approach to preparedness through shared goals, investments, and identified need can bolster response efforts during an HCID threat, strengthening systems, processes, and the safety of the community.[8]

This manuscript will outline key considerations for institutions wanting to prepare for the next infectious threat. As stated previously, the focus of the suggestions and policies outlined will be on HCIDs (e.g., viral hemorrhagic fevers, severe and novel respiratory pathogens) but many of the concepts can be applied to more common infectious diseases (e.g., measles, mpox, tuberculosis, multidrug resistant bacteria). When possible, multiple suggestions for course of action are presented and considerations for performing a risk assessment are laid out. Each institution should consider their available resources, determine organizational expectations, and develop individual plans and processes. The polices and information presented here is subject to change, and governmental health authorities and governing organizations should be consulted during an infectious disease outbreak.

Considerations When Faced with a Potential High-Consequence Infectious Disease Patient

Identification and Surveillance

Before a confirmed or suspected HCID patient can be appropriately cared for, they must be identified within the healthcare system. Identification should be a collaborative process and should not become the responsibility of a single organization or individual. Communication and information gathering should occur at all levels of involvement, from global and federal agencies down to individual organizations. The World Health Organization (WHO) tracks infectious threats globally and communicates through the WHO Disease Outbreak News (DONs), as does the U.S. Centers for Disease Control and Prevention (CDC) through the Health Alert Network (HAN).[9,10] The CDC maintains the HAN with active listservs to inform subscribers of new and ongoing threats, including infectious outbreaks.[11] The non-government nonprofit organization the International Society for Infectious Diseases hosts the ProMED-mail program which provides daily reports of infectious disease cases and outbreaks.[12] ProMED-mail was the first to receive and post a communication regarding cases of an undiagnosed pneumonia in Hubei, China on December 30, 2019, which later was diagnosed as COVID-19.[13] The public communication led individuals and organizations to delve deeper into the cause and begin preparations for what would later become a pandemic. Those involved in public health preparedness, emergency management, employee health, infection control, epidemiology, and employee travel are key groups that should be included in these news and alert networks and regularly surveilling for outbreaks. Communication should be bidirectional, in which those learning of outbreaks pass information to stakeholders, while those observing individual cases should report to the necessary parties and key decision makers.

As outbreaks are identified, it is important to act upon the information. At the level of public health agencies (federal, state, and local), identification and monitoring programs may be implemented. For foreign and travel related cases, this could appear as directing flight traffic to select airports for documenting travelers and providing quarantine guidance. At a state and local level, resources will need to be diverted to maintain contact with monitored returning travelers and ensure compliance with quarantine guidelines. Local outbreaks will require additional resources to conduct epidemiologic investigations, expanded monitoring, and coordination for providing care, diagnostic testing, and transportation to care facilities as needed. Individual organizations should develop policies and procedures for identifying staff, clients, or visitors that may have traveled to affected areas, be it internationally, nationally, or locally. Employee health programs may consider instituting organizational monitoring programs for returning travelers, or even limiting travel to affected areas. Clients and visitors to an organization or facility can be screened prior to entry on site either through self-reported questionnaires or by answering questions on site. Hospital and healthcare facilities should implement travel and symptom screening procedures during the patient intake and history process and post signage asking patients and employees to self-report exposure or symptoms. For healthcare, the screening process should include collecting information on symptoms and epidemiological links (e.g., cities/countries visited, activities participated in). Electronic medical record systems have processes in place to trigger alerts based on the various responses entered (e.g., symptom + travel history triggers an alert). These alerts should be programmed as soon as

possible after recognition of an outbreak as widespread notification of an ongoing outbreak is often delayed and travelers may already be in transit. In addition, email notifications and awareness flyers serve to educate employees, visitors, clients, and patients about what to be on the lookout for in themselves and others.

Quarantine and Isolation

With any highly infectious pathogen, it is important to have processes in place to limit the spread and impact on a community. The R_0 ("R naught") is often used to define how contagious a pathogen is and is defined as the average number of people that will contract the disease from one infected individual.[1,14] The higher the R_0 the more transmissible a disease is. Determining this value is based on several factors including method of disease spread (e.g., blood borne, contact, respiratory), immunity of the population (e.g., vaccinated, previously infected, naïve) and the number of particles required to cause an infection. It is important to understand the transmission patterns of any pathogen to prevent additional spread.

One such method to limit onward transmission is the use of quarantine and isolation. Quarantine refers to segregating individuals who are at risk of developing a transmissible pathogen due to exposure but are asymptomatic and have not yet been confirmed to be infected or contagious. Isolation refers to segregating an individual who is symptomatic or has tested positive for a pathogen. During certain outbreaks it may be necessary to quarantine individuals while awaiting test results or monitoring for symptoms. The length of time a person is quarantined will depend on the incubation period of the pathogen and may include additional factors such as how the individual was exposed. While it may not be feasible to quarantine large groups of people such as all travelers from a country experiencing an outbreak, it may be reasonable to quarantine individuals who are known to have been exposed to a pathogen, especially if transmission may occur before symptoms develop. Exposures may include known or suspect contact with infected individuals, providing direct care for a patient with the pathogen of concern, handling animals that are suspected or known to be carrying the disease, or those who have experienced a breach in their Personal Protective Equipment (PPE) breach or known exposure incident in a laboratory. Larger quarantine efforts do occur, as was the case in early 2020 as SARS-CoV-2 was starting to spread globally. Many U.S. citizens who were passengers on the Diamond Princess cruise ship were flown back to the U.S. from Japan and placed under quarantine for 14 days at several facilities across the country while being observed for symptoms.[15,16] This process also enabled individuals to receive care rapidly after identification of symptoms.

Whether or not individuals are officially placed under quarantine, an active monitoring program should be established, especially for those who have experienced a known exposure. Monitoring should consist of daily or twice daily check-ins in which individuals report any potential symptoms, including their body temperature. While this can be set up as passive collection where individuals report into a telephone or computer system, checks need to be in place to follow-up with non-respondents and those with concerning results such as a fever or unexplained symptoms. Resources should be made available to all those being monitored including access to a phone and a thermometer. Finally, monitoring and quarantine plans

should include triggers for initiating care and facilities should be identified that will conduct the initial examination and laboratory testing of patients.

Isolation occurs when an individual known to be infected with a pathogen of concern, or suspected based on symptoms is separated from the rest of the healthy population. There are several considerations that should be taken into account when choosing an appropriate location for isolation. If an individual is asymptomatic or experiencing only mild illness and not expected to rapidly deteriorate, it may be reasonable for them to isolate at home. This of course involves a thorough conversation with the individual, may require additional monitoring, and could require legal action (court order to remain at home). For patients requiring clinical care, isolation will need to occur at a healthcare facility capable of providing the level of care needed and institute the appropriate infection control measures to protect staff and the community (see "Staff Safety" section).

Identification of symptomatic patients can occur along two main pathways: 1) identification while in a monitoring program, or 2) identification within a healthcare facility while receiving care. Regardless of how or when a patient is identified, the first step should be isolating them from the general population. Within a healthcare facility, this can occur by placing them in a patient room set apart from other patients. If a patient room is not available, the person can be placed in a waiting room by themselves, or a section of an open waiting room distanced from other patients. Ideally, the patient will remain in one room and not be moved between multiple rooms. If a negative pressure room is available, it should be used. Staff should be made aware of what PPE should be worn and how to safely put on and take off the PPE ensemble. PPE should be used every time someone enters the room, and the number of personnel entering the room should be limited (see "Staff Safety" section).

In conjunction with public health authorities, criteria must be set to determine when a patient can be released from care and/or released from isolation. Depending on the severity of the illness, a patient may still require isolation but can safely do so at home. In other cases, additional care may be required elsewhere in the facility or at a different facility, but isolation procedures may no longer be required. Finally, as there is a possibility for latent or hidden infections (e.g., Ebola virus detected in semen, latent Tuberculosis) guidelines should be considered should the patient need to resume isolation due to a future positive test.

Official Reporting and Situational Awareness

Established HCID surveillance systems can assist with timely identification and rapid response to an event. Global infectious disease surveillance systems are used at the federal level by the CDC, WHO, global ministries of health, and other national and global public health organizations. Monitoring HCID activity on a global scale allows for a broad collection and tracking of data which assists in early warning and detection of a disease, disease prevalence, and guides planning and preparedness strategies that protect communities. Surveillance of disease threats through structured systems allows for global monitoring and provides data to public health and healthcare leaders who can use this data to enforce specific monitoring systems in their respective geographical and jurisdictional locations. The data collected from these monitoring systems can assist in determining the need for increased preparedness

practices such as the execution of health facility travel screening and the implementation of public health alerts and messaging to the community.

Not only does monitoring of global HCID events allow for preparation and planning should HCID cases present locally in the United States, but this situational awareness also relies heavily on information sharing between agencies on a global, national, regional, and local level. No one agency, community, or organization can effectively prepare or respond to an HCID event without established partnerships.

Upon identification of a suspected or confirmed HCID patient, proper authorities and key stakeholders need to be alerted. Ideally, this reporting begins at the first suspicion of a HCID so that proper control measures can be implemented early. It is recommended that institutions create a notification tree incorporating all aspects of communication and reporting, including local, regional, state, and federal contacts.

The first notifications must include notifying personnel who may come in contact with the patient, unit or shift managers, and infection control personnel. Infection control personnel should be brought in at the earliest possible time to guide PPE selection, patient movement, and decontamination practices. Personnel who are expected to care for the patient must be made aware of the appropriate PPE to wear and how to properly don and doff the ensemble. In addition, the care team should be instructed regarding best practices including performing multiple activities during a single entry to the room, what procedures are acceptable to perform, and any modifications to standard procedures. Infection control personnel will likely take the lead in several key decisions including (1) where to room the patient, be it temporarily until test results are returned or transportation arrives, or long-term if the facility will care for the patient for the duration of the illness, (2) decontamination procedures of the room, and equipment (see “Patient Care” section), and (3) handling of waste and specimens (see “Clinical Diagnostic Testing” section & “Waste” section).

Clinical laboratory supervisors will need to be contacted prior to collecting diagnostic specimens, to ensure proper precautions are taken during the transport of specimens and the handling of specimens in the laboratory. Diagnostic tests may be limited for the patient until a diagnosis is made. If point-of-care tests are to be performed, the care team may require training prior to performing tests. Presumptive and confirmatory testing will need to be performed at a Laboratory Response Network (LRN) laboratory and the CDC, respectively.[17,18] Prior approval to ship these specimens for testing will be required and so a consultation call should be made at the earliest appropriate time.

Beyond the care team, key stakeholders and decision-makers will need to be notified. Hospital administration may choose to form an incident command team to stay apprised of the situation and ensure a chain of command. Media and public relations personnel will be vital to handling communications with the public and press, especially in the case of a confirmed HCID patient. Additional communications will need to be made with public health authorities for awareness, possible release of resources (e.g., PPE cache, trained personnel, security), and formal requests for resources (e.g., therapeutics). The appropriate public health authorities to be notified will depend on local infrastructure, but initial engagement should begin locally with a local or regional health authority and work upwards to a state health authority. Ensuring that the chain of command is followed will offer the best chance for success as each entity will know the proper communication channels and processes for making formal requests.

If patient transportation to another facility is expected or required, contact with the appropriate transport agency should begin as early as possible. Courtesy communication can occur prior to a definitive decision so that the transport agency has ample time to notify the appropriate staff and begin to assemble the required trained transport staff, equipment, resources, and support staff. Once the need for transportation is confirmed, a secure line of communication should be established to keep necessary parties apprised of the patient's location and clinical status.

Ground Transportation

Transportation practices for a patient suspected or confirmed to be infected with a HCID are conditional based on transport agency and healthcare facility capability and capacity, location of services, and government jurisdiction. Significant planning and collaboration is required prior to and during patient movement between facilities. Patient transportation policies and practices require multi-agency participation to standardize an agreed upon plan of action and determine application of shared patient transportation practices.

It is common practice that state and local health authorities create and manage transportation plans, often referred to as a transportation Concept of Operations (CONOPS). The CONOPS is an operational guide for transportation/Emergency Medical Service (EMS) agencies, healthcare and public health organizations, and other key stakeholders and governing bodies. It should detail operational procedures within a specified area of operation, offer administrative guidance, outline biocontainment management best-practices, and serve as a manual to ensure safe patient transport, frontline worker safety, and the safety of the community before, during, and after the activity. The CONOPS also outlines established protocols and characteristics of patient movement and incorporates specified policies and procedures.

The CONOPS and other transportation recommendations disseminated by state and local health authorities should reference operational guidance from organizations such as WHO, CDC, Occupational Safety & Health Administration (OSHA), and Federal Emergency Management Agency (FEMA), when necessary. The transportation CONOPS should be monitored and updated at regular intervals determined by the plan proprietor and consider input from all agencies referenced in the plan. Plan components should at minimum include partnered agencies, command structure, isolation options, transport timing, PPE considerations, patient care limitations, decontamination practices, infrastructure challenges, and forecasting statistics.(ref) It should be noted that not all states and local health departments will have a specified transportation CONOPS and understanding of current practices should be identified. .[19] It should be noted that not all states and local health departments will have a specified transportation CONOPS and understanding of current practices should be identified. The CONOPS and other applicable guidance should be made available to all participating agencies and sectors who play a role in HCID patient transportation. If no CONOPS has been established, authorization of cooperation and obligation of each partner can be depicted through a Memorandum of Understanding or Agreement (MOU or MOA), per the discretion of the organizations. Having an MOU or MOA in place allows

for established common terms and expectations of services to be clearly outlined and can include any transfer of funds for anticipated services should this be an agreed upon component.

If it is determined by the proper authorities that a patient needs transportation to a healthcare facility or as an interfacility transport, the CONOPS or other established HCID patient transportation plan is activated. Transport of a HCID patient requires multiple considerations including patient isolation, PPE, transport timing limitations, limitations in patient care during transport, and decontamination procedures, described below.

Isolation Options During Transport: Patient isolation options and procedures during transportation are dependent upon the responding agencies capabilities and capacity before, during, and after transport. To minimize contamination to the ambulance, common practices include the use of a portable isolation unit, and/or a practice referred to as ambulance draping. A portable isolation unit is a portable device used to isolate the patient and the pathogen, from the medical personnel. Units are equipped with a negative air pressure system to prevent the release of unfiltered air into the ambulance or transportation unit. The benefit of using these devices is that the care provider does not need to don a full PPE ensemble when sharing space or caring for a patient as the protective measures are built into the unit (e.g., reach in gloves). These units can be disposable or have the capability of re-use after decontamination. Ambulance draping refers to the practice of lining the interior of the ambulance or other vehicle with impervious sheeting to protect surfaces from infectious bodily fluids, limiting further exposure. A full PPE ensemble is necessary when transporting a patient in a draped ambulance as the provider will come in direct contact with the patient, bodily fluids, and aerosols. Other strategies for EMS providers suggested by the National Emerging Special Pathogens Training and Education Center (NETEC) include adjusting air handling to circulate fresh air into both the driver and patient compartments, turning the exhaust fans on high in the patient compartments, and separating the driver compartment from the patient compartment, ensuring the driver does not come in contact with the patient.[20]

PPE During Transportation: Appropriate PPE ensembles should be donned and worn during transfers of a HCID patient. Exact PPE required will be dependent upon pathogen, mode of transmission, and patient symptoms. The CDC offers guidance of recommended PPE for various HCIDs which at the minimum should include gowns, face shields, facemasks or respirator, and gloves.[21] PPE ensembles should be in accordance with CDC guidelines and prior training of donning and doffing (removing) of PPE should be completed to ensure worker safety. Should there be a PPE breach during transport of a HCID patient, a pre-determined risk assessment should be conducted to determine risk of exposure.

Timing of Transportation: Timing considerations before, during, and after transporting an infected patient should be included and reviewed in the CONOPS or other established HCID patient transport plans. Routes should be pre-determined, and a support vehicle may be required to follow the main vehicle throughout the trip. It should be predetermined if one EMS vehicle and crew will be transporting the patient across the entire distance, or if there will be staged relief crews. As EMS personnel will be suited in PPE, authorized maximum time in PPE should be determined and included in agency protocols, and this can assist in determining the

need for relief crews. If a relief crew or refuel is required during transport, a location for these activities should be pre-decided and protocols for performing such activities walked through. Crews stepping out of the ambulance or transport vehicle may need to doff PPE (if not using an isolation unit) after exit, while the incoming crew will need to don PPE. This should be done in a low-traffic area to prevent media coverage and unnecessary disruption to the local community. A detailed facility hand-off process should be outlined including communication structure with the receiving facility, location of patient drop point, and detailed patient report practices. The patient hand-off between EMS and the receiving facility should be practiced and exercised at cadenced intervals to ensure best practices are utilized to ensure the safety of the frontline workers, the patient, and the community. If possible, a walkthrough of the hand-off procedure from the sending facility to EMS should be done to ensure all parties understand their roles to ensure a safe and efficient process.

Care Limitations During Transport: Determining what care can be provided to a HCID patient during transport is a significant factor in patient and healthcare worker safety. Capability and capacity to treat during transport should be determined by the EMS agency along with an identified list of resources i.e., just-in-time training, relief crews. Using the minimum number of EMS professionals required minimizes opportunities for exposure. Following agency and CDC guidance and protocols can limit EMS personnel exposure while transporting an infected patient. A surgical mask should be placed on the patient and a sheet may be used to drape or wrap the patient to prevent infectious bodily fluid transmission. If the patient is vomiting and cannot wear a mask, a leak-proof container should be given to the patient to collect emesis and limit vehicle surface contamination. The type of procedures that may be required and performed enroute should be determined prior to HCID patient transport, as capacity and supplies will be limited. Understanding capacity limits and potential gaps in patient care capabilities during transport will allow EMS personnel to determine best practices with the resources that are available. Including these limitations in the transport plan and EMS agency processes can assist with continuity of care of the HCID patient.

Decontamination of Transport Vehicle: Once the patient has been successfully transferred to the receiving facility, decontamination of the ambulance can begin. It is important to designate a site for decontamination, ensuring the location is well ventilated and within a structured perimeter. Special attention should be paid to water run-off and draining and air flow patterns. The decontamination site should be determined and outlined in the CONOPS or EMS agency protocols. Agreements with the receiving facility may also be in place if waste disposal capabilities are limited for the EMS agency (see “Waste” section). Other considerations for decontamination include security plans and methods for reducing visibility from public and media sources.

EMS personnel need to have protocols in place for properly disinfecting the ambulance after patient transport. A decontamination policy or list of considerations and precautions can assist personnel in the appropriate and safest decontamination methods. A list of materials and equipment needed for ambulance decontamination should be included within the protocol. Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR) Technical Resources, Assistance Center and Information Exchange (TRACIE) created the

EMS Infectious Disease Playbook which offers enhanced guidance for ambulance decontamination processes and best practice.[22]

The number of personnel assigned to the decontamination process should be limited to minimize potential exposure. NETEC, in the "EMS Ambulance Cleaning and Disinfection" Guidance, suggests 3 designated personnel to undertake the decontamination procedure, with one serving as an observer.[23] All draping within the ambulance should be removed, and all contaminated and potentially contaminated surface areas inside the ambulance should be cleaned using U.S. Environmental Protection Agency (EPA) registered hospital disinfectants according the directions on the label, with special attention to contact time. All medical equipment that comes in contact with the patient, fluids, or waste should be completely disinfected prior to re-use or disposed of. The outside of the ambulance should be wiped down, including patient loading doors.

Patient Care

Patient care must remain a top priority despite the complexity of maintaining health care worker and public safety. The ability to provide care in a manner which limits additional risks to the providers will be dependent on each facility's resources. At a minimum, frontline healthcare facilities (e.g., acute care hospitals, urgent care clinics, other emergency care clinics) should be able to identify and isolate a suspected HCID case.[24,25] In addition, these facilities should be prepared to provide basic care to the patient until transfer to a higher-level facility can occur. NETEC provides a Viral Hemorrhagic Fever (VHF) Preparedness Checklist for facilities to assess their capabilities and needs.[26] Basic care can include symptom management (e.g., antiemetics, fever and pain control) fluid resuscitation, low flow oxygen supplementation, and empiric therapy for treatable conditions. It may also include sample collection for pathogen specific testing by a public health laboratory and/or the CDC. Additional testing may be required and point of care testing can be used to rule out other illnesses such as malaria, COVID-19, influenza A/B, and group A streptococcus. Hypoglycemia may be unexpectedly severe in some diseases and glucose levels should be assessed frequently with handheld glucometers. Laboratory testing will be discussed further in the "Clinical Diagnostic Testing" section.

The provision of more aggressive resuscitative care such as central line placement, high-flow or mechanical ventilation, renal replacement therapy, and cardiac resuscitation have all been implemented in the care of HCID patients. Whether such a level of care can be considered at a specific institution will depend on the capacity of staff to perform such interventions safely. Depending on the pathogen, a patient may deteriorate rapidly, and the medical care team should realistically assess proficiency and staffing issues. Transportation to a facility with higher capabilities should be sought early if the possibility for rapid deterioration exists and the facility does not have adequate medical or infection control expertise to deliver such care.

Staff Safety

OSHA describes five controls to reduce hazards in the workplace, known as the "Hierarchy of Controls".[27] From most effective to least effective, they are: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE.

Elimination and Substitution: In the case of caring for an HCID patient, it is not possible to eliminate or substitute the pathogen hazard, but these controls can be applied to other hazards that would result in a possible exposure, for instance, elimination of sharps except when necessary.

Engineering Controls: Engineering controls refers to separation of the individuals from the hazard. Examples of engineering controls includes having multiple layers of negative air flow between the patient's room and common areas and the installation of HEPA filters to remove infectious particles as air is exhausted. In addition to unidirectional airflow is establishing "zones", sometimes referred to as "hot" and "cold", "red" and "green", or "clean" and "dirty" zones. While designating zones offers a visual to workers about where exposure risks are highest and where or what PPE should be worn in a certain area, it is vital to understand that pathogens do not abide by these lines and breaches in protocol can result in contamination of a labeled "clean" area. Setting up equipment to be controlled and/or monitored from outside the patient room is another example of an engineering control. Equipment that is brought into an isolation room will require decontamination prior to being put back into circulation. It is important that facilities anticipate that if a piece of equipment is used to treat a HCID patient, that equipment will be out of circulation for an extended period while an appropriate, validated decontamination process occurs. Some facilities may choose to not put this equipment back into circulation.

Establishing means of monitoring the staff and patient, as well as clear lines of communication between staff members in and out of the patient room both fall under engineering controls. A monitor can observe the activities in the patient room from the outside. One option is to have a monitor stationed outside the patient room with a clear line of sight on the staff member(s) in the room. In this situation, sites may consider having the monitor dressed in PPE, even if at a lower level than required for room entry, so that they can quickly enter the room and assist if an acute situation arises; if additional PPE is required, they can finish the donning process before entering. Video and audio monitoring can also be used to watch the staff member while they are in the patient room. This should be reserved for stable patients requiring minimal care. Regardless of which option is used, a reliable means of communication should be established between staff so that information, including questions and emergencies, can quickly be relayed in and out of the patient room. Communication can occur through several modalities and will be determined by the number of staff, the PPE being used, and the amount of information needing to be relayed. Possible options for communication include a video/audio conferencing system, this can also be used for remote or telemedicine capabilities, radios with headsets typically using an open mic system, and white boards or paper for short communications. Each method has its own challenges, and it is recommended that the system be tested prior to use during an event

Administrative Controls: This type of control includes modifying the ways which staff work in an environment. A designated entry and exit pathway and procedure should be predefined to ensure there is no cross-contamination of supplies, equipment, or individuals. The doffing or decontamination process of staff or equipment should be completed before moving into the next "zone" (described above). Following a defined exit path and decontamination procedure reduces the likelihood that any contaminants will be brought out of the patient room. Staff assisting in the doffing or decontamination processes should be dressed in appropriate PPE prior to entering the area where the activity is occurring.

The number of staff entering a patient room at any given time should be limited to those essential to perform a given procedure in a safe manner. Cross-training is required to limit the number of personnel with direct patient contact as well as limit the number of times an individual is required to don and doff PPE. Whenever possible, multiple tasks should be completed during a single entry into a patient room. An example of tasks that can be completed during a single entry include providing a meal, performing a physical assessment, administering medication, collecting laboratory specimens, cleaning the room/bathroom, and checking the supply inventory. Performing all these tasks may be outside of an individual's standard job duties but should be considered part of their responsibilities when caring for a HCID patient, assuming the activities fall within their scope of practice.

For administrative controls to work effectively, staff must be aware and trained on the modifications to procedural workflows. In a healthcare setting, experienced staff perform many tasks in a habitual manner. Modifying this workflow will take diligent training and regular reminders. Training in this case refers to both training on the use of equipment or a procedure as well as training to work in PPE. For staff that may be new to the environment, workflow, or procedure, the use of a checklist or instruction sheet can help ease the transition. If a monitor or "buddy" is present, they can read through the instructions step by step while the staff member performing the procedure follows as instructed. This method ensures all steps are followed and the procedure is completed in a methodical manner. Key changes that may occur to a workflow include the addition of disinfection steps, additional changes of PPE (e.g., gloves), and placement of absorbent material or barriers to reduce or prevent contamination. When possible, facilities should walk through procedures ahead of time to determine necessary modifications. Prior to performing any activity, staff should review the procedures and assign roles. Facilities considering caring for a HCID patient should examine their staffing pools to determine how many individuals meet the training requirements and ensure the expected staffing is adequate to care for a HCID patient as well as continue providing care for the rest of the organization.

To ensure staff safety and avoid emergent procedures, a risk-benefit analysis should be performed regularly while a patient is undergoing care. It is strongly recommended that a clinical ethicist is included in this conversation to provide an unbiased viewpoint and draw from historical cases. The risk-benefit analysis should consider the benefit of providing a specific intervention to the patient as well as the risk to the provider in carrying out the procedure. Considerations can include the infectiousness of the patient, the risk of exposures when performing a procedure (use of sharps, aerosol generation, exposure to body fluids), and the likelihood of benefit to the patient.

PPE: PPE is the final control for hazard reduction, and notably the least effective when compared to other controls. While a lot of focus is placed on PPE, it should be remembered that PPE is the *last* line of defense against exposures. Nevertheless, PPE is still incredibly effective in reducing exposure to hazards when used appropriately. Most important when using PPE is understanding the limitations of the ensemble and adjusting accordingly. While dressed in PPE, tactile sensation will be diminished due to multiple gloves, and movement such as reaching or bending over will be limited due to constraints of the PPE. Other senses may also be affected including hearing, especially if wearing a Powered Air Purifying Respirator (PAPR) due to the noise of the fan, and sight due to obstructions from a helmet, face shield, or goggles. Communication may also be hindered, and one may need to speak louder to be heard, for example through a mask or N95 respirator or over the sound of a PAPR fan. Notably, more PPE does not always mean increased protection. Beyond increasing the limitations listed above, wearing more PPE means that there is more PPE to remove. The process of doffing is considered one of the riskiest procedures in isolation care. Caring for a patient or performing activities in a patient room means it is very likely that contaminants will be present on the PPE, even if not visible. One method of removing potential contaminants prior to doffing is through a decontamination shower, but this may not always be possible due to the PPE used and location restrictions. If a full decontamination procedure is not possible, at a minimum visible contamination should be removed using an approved disinfectant and gloves should be disinfected or removed and replaced between steps to prevent movement of contaminants.[28] CDC provides general guidelines and a suggested doffing protocol for facilities to utilize.[29] Facilities may need to modify the PPE ensemble based on available inventory, suitability of different PPE items used in combination, and based on the procedures to be performed and patient status (confirmed or 'wet' patient vs. suspected 'dry' patient). Prior to performing patient activities, the process of PPE donning and doffing should be reviewed with the care team and practiced as necessary. Doffing should be a monitored process and include a checklist or step-by-step instructions to ensure all safety measures are completed.

Occupational Health

When a suspect or confirmed HCID patient is first identified, a record of all staff who encountered the patient should be started. Occupational or employee health should be notified early to maintain this record and perform all necessary health screenings and monitoring following all contact with the patient, samples, or waste. Additional monitoring and reporting may be required by public health beyond institutional policies. Occupational health may also be able to provide guidance on prophylactic treatments (pre- and post-exposure) and perform any necessary medical screenings prior to working in the required PPE.

Staff mental and physical health and wellbeing should be monitored throughout the duration of care and beyond. Physical considerations should include the amount of time spent in PPE and activities performed while in PPE. Limitations to the amount of time spent in PPE can be pre-determined so that staff are not overworked, physically or mentally. Work in PPE may result in dehydration, overheating, premature muscle fatigue, and mental exhaustion. Fine motor skills may be more limited due to the additional layers of PPE resulting in increased strain. Physical exams and health screenings can be utilized when recruiting team members to

determine if any preexisting conditions may limit the ability to work in PPE (e.g., respiratory conditions, low blood sugar, joint or muscle strain). Mental health support should be provided to staff before, during, and after caring for a HCID patient. Sudden loss of a patient, or a decision on a specific care plan based on risk assessment may affect caregivers. Staff may also have concerns about returning home to family after caring for a HCID patient and these concerns should be discussed. Finally, much like other critical care spaces, caring for a HCID patient can be stressful and methods of effective communication between team members should be discussed to limit possible tension.

Clinical Diagnostic Testing

If a HCID is considered, communication with the local and state health department, health department laboratories, and CDC will direct when and where specimens should be sent for diagnostic testing. Commercial assays are available for presumptive *in vitro* diagnostic testing such as the BioFire Global Fever Special Pathogen panel and BioThreat-E (Emergency Use Authorization October 2014). Select LRN laboratories can perform presumptive testing, with all confirmatory testing completed at the CDC. Prior to shipping specimens, appropriate approvals and paperwork must be completed, and Department of Transportation shipping guidelines followed.

While waiting on pathogen testing, it is critical that the patient still receive care, including routine laboratory testing. Routine laboratory testing for suspect and confirmed HCID patients requires careful planning and coordination, but much can be safely done in standard hospital laboratories. Basic studies such as blood counts and electrolyte determination are necessary to provide effective care for an ill patient. It is possible that diagnostic samples can be run using systems already in place, but special care should be taken in handling the specimens and a complete risk assessment should occur, with testing of processes in advance. The CDC provides guidance on performing a laboratory risk assessment and methods for mitigating potential exposures.[30] Staff should already be adhering to OSHA Bloodborne Pathogens Standard (29 CFR § 1910.1030) which provides basic protection from bloodborne pathogens. Additional mitigation measures include packaging specimens in multiple layers including absorbent material and transporting specimens in a hard sided container, avoiding high-traffic areas. Specimens from suspect or confirmed HCID patients should never be transported via a pneumatic tube system. The use of sharps, including glass, should be avoided when possible and immediately disposed of as appropriate for the pathogen. Staff manipulation of specimens, such as opening a tube or aliquoting a specimen, should be minimized and all manipulation should occur in a biosafety cabinet. Other manipulation which would create aerosols, such as centrifugation, should be minimized, and utilize additional safety measures include sealed rotors, sealed cups, and/or a sealed centrifuge. If equipment with these safety features is not available, the work should be completed in a biosafety cabinet if required. Additional PPE may be required, especially if manipulating samples, and can include fluid-resistant or fluid-impermeable gowns (solid front), surgical mask or respiratory protection (N95 or PAPR) depending on the pathogen, eye protection, and disposable gloves. Staff utilizing this additional PPE should be trained on proper doffing techniques to avoid self-contamination during the doffing process.

Point of care (POC) and near point of care tests are a viable option to provide rapid and accurate diagnostic testing. Various devices are available with small footprints that can be set up in a patient's room or in an adjoining room designated as a temporary POC lab. Available POC options to consider include rapid pathogen diagnostics (e.g., malaria, influenza, COVID-19, streptococcus), basic chemistries, (electrolytes, hepatic panels), complete blood count (CBC) with differential and platelet count, prothrombin time (PT), and blood cultures. Regular monitoring of glucose levels with handheld glucometers should be considered to monitor for hypoglycemia, especially in critically ill patients.

Space will be a critical factor and this most often would be limited to smaller and handheld devices. Those who are expected to perform the tests at the bedside should be trained in collecting the specimen, running the test, troubleshooting common issues, disposal of used consumables, and proper cleaning and disinfection of the device. Additional safety training may be required if the device utilizes sharps or necessitates manual manipulation of the sample. Another option is to set up a temporary laboratory near the patient's room. This may be an adjacent patient room, or another nearby room, ideally with negative air flow. This temporary laboratory space should be treated as any other laboratory, utilizing the same infection control and sample handling procedures mentioned prior. Access in and out of this space should be limited to trained personnel and entry and exit procedures should be followed similar to that in a patient room or another laboratory space.

Waste

Waste is an important but often forgotten aspect of HCID patient care. Many pathogens that are considered a HCID are considered a "Category A Infectious Agent" by the U.S. Department of Transportation and waste from patient care must be handled and processed under this category.[31] This includes all waste collected within a patient room, even if it did not come in contact with the patient or body fluids. Prior to inactivation or destruction, the waste must be sequestered in a secure area with limited access. A secure storage space should be designated for this purpose, with the consideration that a large amount of waste can accumulate. To reduce the amount of waste, it is recommended that only the required materials be brought into the patient room and that the room should not be fully stocked except for essential and needed materials based on the patient's status. Additionally, any packaging that can be removed prior to entering the room should be removed and discarded as this will not be considered Category A waste and can be disposed of in the normal hospital waste stream. Waste can either be inactivated on site by the facility or picked up by a vendor for inactivation. Typically heat (autoclave or incineration) is the inactivation method of choice, although other methods are available such as chemical inactivation. The type and volume of waste produced will determine the appropriate inactivation method (e.g., liquid vs. solid, ability to withstand heat). Uncommon products such as devices which may contain a battery or other substance that may not be compatible with heat should be assessed for appropriate decontamination procedures and segregated from the rest of the waste produced. State and local jurisdictions may have additional guidelines for specific waste streams (e.g., chemicals and medications) and these should be consulted prior to waste removal.

Way Forward

The considerations presented in this paper provide a look into the unique planning requirements when preparing to care for a patient infected with an HCID. These complex considerations span across multiple industries and present the importance of a joint approach to limiting disease spread, managing patient care, and ensuring readiness for the next potential threat. HCID events present unique challenges to health systems, communities, public health, and community infrastructure and requires a comprehensive approach to preparedness planning. Often considered low probability, high impact by emergency managers, HCID events can result in catastrophic outcomes to public health and safety if not adequately prepared for or efficiently managed. As we continue to face an increasing number of infectious disease outbreaks globally, a multi-dimensional, cross-industry approach to HCID preparedness is an effective strategy to enhance readiness and maximize response, mitigating disease spread. Given the ability for severe morbidity and mortality, rapid spread, and potential for societal disruption, early detection of an HCID is vital. Individual institutions can utilize the practices presented here to prepare their facilities and staff for future events, and public health leaders can continue to support their communities through preparedness trainings and dissemination of information. While each facility is responsible for their community and patient population, a concerted national and global effort to surveille and share information will limit spread and ensure readiness when the next threat inevitably arrives.

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