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Introduction

Although outbreaks of highly hazardous communicable diseases (HHCD) that require patients to be cared for in a high-level isolation unit (HLIU) can occur at any time, we have seen distinct periods with public health emergencies of international concern that created huge challenges to medical systems throughout many parts of the world, most notably the Ebola crisis in 2014 and the SARS epidemic in 2003. These crises led to an upscaling of isolation capacities in many countries and have also influenced the design of HLIUs as well as our thinking of how advanced the level of care provided under isolation conditions can or should be. Many units in the 1960s and 1970s were essentially conceived with a focus on containment, with comparatively few possibilities of medical care provision [1]. The SARS epidemic produced a dramatic need to provide critical care and ventilatory support under safe conditions in order to avoid transmission of infection to intensive care staff [2], and in the 2014–2016 Ebola outbreak, patients treated in the USA and Europe frequently required intensive care procedures inclusive of ventilatory support and renal replacement therapy [3]. Many of these procedures were performed for the first time in the setting of isolation precautions, even at the few specialized centers that exist. Although diseases like Lassa have sporadically produced import cases of hemorrhagic fevers in Europe and the USA [4], public health emergencies of international concern were generally followed by intervals of many years in which there were few or no cases. Hence, one of the challenges for many HLIUs is to maintain the capability to provide high-level care under isolation conditions in these intervals, which are long enough to undergo considerable staff fluctuation and changes in therapeutic algorithms and technology. Moreover, medical advances that occur in the meantime

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have to be translated into the setting of isolation treatment without the chance to realistically test them under these conditions. Additionally, the provision of high-level isolation medical care requires complicated standards and procedures that can easily be forgotten in “peacetime”. It is thus of crucial importance to maintain a certain level of preparedness over extended periods of time until the next emergency occurs, necessitating HLIUs to be prepared to begin operations very quickly.

“You can plan events, but if they go according to your plan, they are not events.”

John Berger, 1926

At the end of the day, however, we should realize that we have to be prepared for new circumstances, sometimes for even the unplannable. We have to be aware that the management of biological hazards requires a great deal of flexibility.

Infrastructure

HLIUs are part of the critical infrastructure required to react to biological hazards, may they be individual cases of highly contagious diseases, public health emergencies of international concern or the deliberate release of biological agents. HLIUs provide levels of infection control for healthcare workers and the community that cannot easily be provided in another setting. This level of infection control is necessary for HHCDs like Ebola, Lassa, SARS, Crimean-Congo hemorrhagic fever, smallpox and many others but may also be needed in case of new biological hazards of which the impact is yet unknown. There are different plans on the national level concerning the number of HLIUs required to maintain preparedness. Germany, the UK, the USA and Sweden, for example, possess more than one HLIU; however, other countries may have just one HLIU or even just a care agreement with neighboring countries [5]. The advantages of having more than one unit include shorter, safer journeys for patients from the referral point to the unit, cross-covering between units (e.g. when one unit is closed for maintenance), and the potential for a broader range of specialists. The number of staff needed for the treatment of an individual case can become massive if the patient condition requires very intensive treatment [6], and the availability of staff from a unit nearby may provide relief. This however requires coordination in skill maintenance and training, so that healthcare professionals can easily adapt to the local procedures and infrastructure within another unit. Disadvantages include increased costs, less frequent use and dispersion of clinical expertise. It is thus important to adapt the maintenance preparations to the network that an HLIU or a regional hospital is integrated into.

Another aspect of the planning of maintenance is how many patients an individual HLIU would be expected to care for. Even an individual imported case of a disease of high consequence may have contact cases that need to be admitted in case of the development of symptoms. These contact patients may be cared for in separate units but may also be concentrated in one unit, depending on the local procedures. An individual case of a hemorrhagic fever would usually produce very few

contact cases, but respiratory pathogens of high consequence may produce many contact cases, particularly if the exposure occurs within an aircraft, leaving many contact patients with no place to go to where they can be monitored for symptoms of infection.

When planning for an event, it is always important to consider that should such an event occur, it will be necessary to maintain operational and business continuity. Essentially, in the context of a larger hospital, this means that for critical infrastructure areas such as ICUs, ERs, radiology and others that may not be overtly affected, the care of remaining patients should be maintained at an acceptable level. This will mean that staff must not be overly exhausted to a point where staff shortage will be created before or after the event.

The infrastructure utilized will require regular maintenance on a technical level. Waste disposal systems, ventilation systems, decontamination systems, machinery-like point-of-care diagnostics, ventilators, dialysis machines and many more items will require regular use, maintenance and possibly repair. It will become necessary to have technicians and medical professionals perform this in regular intervals, sometimes as short as weekly. This is a crucial amount of work that is often underestimated.

Supply Maintenance

One very fundamental question is what supplies and medications need to be stockpiled prior to event occurrence. It is impossible to give a universal recommendation on what type and how much of each material or medication will be required, as this depends on very individual circumstances. The precise type of personal protective equipment (PPE) used can greatly influence the necessary quantities. For example, some respirator suits use overalls with integrated gloves and some without. When using integrated gloves, the sizes of the complete suits available at an individual center must be very diverse, as a bad fit of a glove can be a safety hazard. Thus, complete suits must be available in all sizes to ensure proper fit. This means that the stockpiling will require larger quantities for the integrated models. Furthermore, the life span of a glove is much shorter than the one of the suit material, so that for the same amount of time, more suits will be needed based on the life span for the integrated model. Suits with no integrated gloves may be stockpiled in fewer size models, and gloves can be ordered separately. It is also important to be aware of what parts of the PPE are reusable and what parts will be discarded after use. Reusable material does not require stockpiling but does require regular function tests. It is extremely helpful to have experience with the amount of a particular type of PPE used in a real case in order to determine on how much stockpiling is needed.

It is economical to keep stockpiling to the absolute minimum necessary and to avoid discarding unused material. Most of the stockpiled material can be used for training purposes. It must be kept in mind, however, that in the situation of a public health emergency, the demand for PPE and other material required may drastically rise [8] and outnumber the production capacity of the various producers. Therefore,

the most critical infrastructure must maintain a safety margin of 3–4 weeks demand of material. Although it may be wise to harmonize the material used in adjacent HLIUs, as this would facilitate cross coverage if available, this may create issues with availability if too many HLIUs are using material by the same supplier.

Most of the diseases that HLIUs will deal with are orphan diseases, for which standard treatment is not available. However, it is helpful to think of substances that could be available for treatment. In some countries, health authorities may keep a supply of orphan drugs or of experimental medication. The CDC and the Public Health Agency of Canada maintain such supplies. Other countries like Germany do not maintain these supplies on a national level and leave this to individual HLIUs and local health authorities. Consideration should be given to maintaining a supply of ribavirin, which has proven useful for the treatment of Lassa as well as RSV pneumonitis in addition to its licenced indication for treatment of hepatitis C. However, particularly for Lassa fever, it should be administered intravenously, and the intravenous formulation may be difficult to obtain. It may also be helpful to have access to vaccines that can be used as a post-exposure prophylaxis, such as the rVSV Ebola virus vaccine [9].

Staff Training

One of the most important and demanding tasks for managers of HLIUs is to have adequate staff from different specialties readily available and capable of providing specialized HLIU patient care. The number of physicians, nurses and other health professionals required rises with the severity of the disease in question. For example, in the Frankfurt HLIU, 88 staff members were involved in the treatment of one Ebola patient [6]. Similarly, the Nebraska Biocontainment Unit and the Emory Serious Communicable Diseases Unit utilized 5–6 and 2–3 nursing staff members per shift, respectively, when caring for Ebola patients [7]. When intensive care and specialized treatments are utilized, certain tasks may not be able to be performed by the core nursing and physician team. Whilst renal replacement therapy and minor technical questions can easily be handled by experienced ICU staff, more difficult questions may necessitate other specialized staff within the unit. Transfusion management, radiology and processing of laboratory specimens may be accomplished by specialists that are trained to enter the unit. Depending on the training of the physicians on the core team, procedures like endoscopy and surgery may require a specialist to enter the unit as well. Many HLIUs also train pediatric and obstetric nurses and physicians in order to ensure a high level of care for children and pregnant women. As an example, Table 13.1 demonstrates an annual training schedule used in the Frankfurt HLIU (Figs. 13.1, 13.2 and 13.3).

Time must be allocated for training staff and for regular maintenance testing of specialized systems. The frequency of training and maintenance is decided by local and technical requirements. A formalized contract will often be needed to maintain these functions. The training is oriented towards an effective standard operating procedure to evacuate any current patients from the unit and to prepare the HLIU for

Table 13.1 Exercise schedule as used in the Frankfurt HLIU

Topic	Required	Duration	I	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII
Education meeting/general information	Once yearly	90 min			X							X		
Drill with other HLIU	Once yearly	6 h	X											
Drill for ICU staff in the HLIU	Every second year	7 h		X										
Educational meeting on viral hemorrhagic fevers	Once yearly	2 h			X			X						
Alarm chain and preparation of HLIU	Once yearly	2 h	X		X								X	
Use of PPE and isolation procedure	Four times yearly	3.5 h	Every second week											
Technical training and waste disposal	Twice yearly	3.5 h		X		X				X				
Emergencies and CPR under isolation conditions	Twice yearly	3.5 h		X		X							X	
Dangerous goods and material shipping	Every second year	1 h										X		

Roman numerals stand for months



Fig. 13.1 Life support training for HLIU staff. Due to limited communication, algorithms for emergencies need to be practiced frequently. Ideally, team members will be able to go through algorithms with very little verbal communication.

Fig. 13.2 Staff member of the Frankfurt HLIU team practicing intravenous techniques while in PPE. The placement of intravenous catheters is more demanding due to the lack of sensitivity in thick gloves. Thorough training needs to be performed in order to avoid needlestick injuries.





Fig. 13.3 The PPE doffing and decontamination process is crucial and bears a higher contamination risk, so practicing this skill is an important part of HLIU maintenance of preparedness programs. Some units may therefore utilize a buddy system, where doffing and decontamination is performed with the assistance of a second staff member in order to avoid mistakes

admission of a patient with a highly hazardous communicable disease within a designated amount of time without compromising patient care. This amount of time is decided by local requirements. For the Frankfurt HLIU, which is only 15 min away from a major international airport, this period is naturally very short. It might be preferable to admit non-HHCD patients to an HLIU only when other isolation facilities are not available and to transfer these patients from the HLIU as soon as practical. On the other hand, regular use of the HLIU facilitates the regular maintenance of systems. The HLIU is however not the only unit involved in maintenance of preparedness training. Procedures need also to be practiced with local emergency departments, emergency medical services, the local health authorities and the reference, high-level security laboratories to provide for safe intersections of announcing and transporting patients and patient material.

Some units have shared their curricula in order to provide information on the content of maintenance of preparedness training [10]. This content provides a minimum threshold of theoretical knowledge and practical skills necessary to safely treat a patient with a suspected or confirmed HHCD. Maintenance of preparedness training should consist of the following:

- Identifying patients with suspected diseases of high consequence
- Disease-specific knowledge, including epidemiology and public health response
- Infection control, including the correct use of personal protective equipment (PPE), decontamination and the safe management of clinical waste
- Providing healthcare in the setting of a high-level isolation unit
- The use of specialized medical devices and equipment (e.g. patient isolators, respirators) found in this setting
- The medical management of contact patients

Other important aspects of preparedness include:

- Bio-security, including safe transport of specimens and safe patient transfer
- Crisis management and crisis communication
- Regular exercises for patient care teams

These recommendations were mainly influenced by the experience of the SARS epidemic. However, during the 2014–2016 Ebola outbreak, the level of care provided and necessary in the treatment of patients was quite different from the experience with SARS. It was formerly thought that procedures like ventilation, renal replacement therapy and CPR would be too risky in the care of a hemorrhagic fever patient, and there was no evidence to support its use. Based on the experience of treating Ebola patients in resource-rich countries, and later also in the endemic area in Western Africa, this limited approach was reconsidered and revised. It was shown that the provision of modern intensive care medicine was possible and successful [11, 12].

Patients with HHCDs may require a range of interventions, including transfusion of blood/blood products; cardiac, respiratory and invasive hemodynamic monitoring; radiography; ultrasonography; minor surgical procedures (e.g. thoracocentesis); renal dialysis; and mechanical ventilation. The input from critical care clinicians is essential to patient management. There is guidance on the application of the most complicated procedures, e.g. for renal replacement therapy (RRT) [13]. This may provide some orientation on which modality of RRT, choice of anticoagulation and PPE is used in conjunction with this method, as well as on the disinfection and decontamination questions that arise in this context. It can be anticipated that the guidelines on the provision of care to patients with HHCDs will constantly evolve and continue to improve.

HLIUs should therefore be equipped to provide the level of care available in an intensive care unit, and critical care clinicians should routinely train alongside the HLIU team. Support from other specialties (e.g. nephrology, pediatrics, cardiology, obstetrics) may also be necessary, so specialist clinicians should be pre-identified and train alongside the HLIU team. Additionally, needs for specialist non-clinical expertise (e.g. to repair ventilation systems or maintain near-patient testing equipment) should be assessed, and relevant staff trained appropriately in advance. Partly trained or newly trained individuals who need to enter the unit should be given just-in-time training, be escorted and be fully supervised. Ideally, psychological support should also be offered to the participants of an HLIU team, so it is important to include specialists in this area in ongoing maintenance of preparedness efforts.

Occupational Health and Safety

The occupational health department needs to be closely associated with the HLIU in order to ensure safety for staff of HLIU. In some countries, there are regulations for personnel who work in respirators or hoods, including pulmonary function testing. Even if not required, it is important to discuss respiratory health with healthcare workers willing to participate in HLIU treatment. The occupational health department can also assist with providing and maintaining records on vaccination and respiratory fit testing for HLIU team members.

It is very important to be aware that some staff will have or may develop anxieties when working with patients with HHCDs, and the occupational health department should work with behavioral health specialists to assist healthcare workers in the HLIU environment. (see Chap. 16) These anxieties may not be apparent in the early stages of training and may arise only when confronted with a “real” situation. It is an important aspect of preparedness to address potential or already existing anxieties, keeping in mind that the expression of fear does not mean that a staff member can no longer work in an HLIU. It rather means that he or she should receive information on the following:

- Facts about biological hazards
- Detailed facts about the transmissibility of a disease

- How healthcare workers can protect themselves most efficiently
- Guidelines on how to care for HHCD patients
- Measures to avoid the spread of pathogens

Along with fear of the disease itself, healthcare workers may also have anxiety stemming from concern that patients cannot be adequately taken care of in the HLIU setting and that individual standards of care cannot be met, placing the patients at a disadvantage. These anxieties can be mitigated through education and discussion with a behavioral health provider.

It is very important to maintain a strong level of team building and trust within the HLIU staff to enhance safety. Preparedness does not only necessitate regular education and skills building but also a good knowledge of the professional capabilities of each team member. Team building events held within or outside of the work environment can facilitate ongoing relationships between members of the team when the HLIU is not activated and serve to enhance preparedness through maintenance of trust within the team [14].

Coordination

Maintaining the functionality of a HLIU requires working in line with other units and professions. Very crucial areas of collaboration that necessitate ongoing coordination are the transport and receiving process of patients. Establishing and maintaining relationships with local emergency medical services is crucial to preparedness, as discussed in the Transport chapter of this text.

It is also possible that a patient with a HHCD will arrive at the emergency department contained within the facility where the HLIU is located. This requires that a team of experts should be ready to organize and establish isolation capacity quickly; thus emergency department personnel should be incorporated into the HLIU maintenance of preparedness schedule on a regular basis.

Most HLIUs rely on reference laboratories that are experienced in the diagnosis of special pathogens. The coordination between laboratory and the HLIU is another focal point of preparedness activities in peacetime. It can be a very demanding task to organize the transport of material to the laboratory, as there are regulations and safety measures to adhere to. There are commercial courier companies that are capable of transporting specimens potentially containing special pathogens, and these relationships should be pre-established. In all cases, the transport of material to the laboratory and an emergency plan for exposed laboratory workers need to be practised and prepared.

Conclusion

Necessities in the Maintenance of Preparedness

- A designated clinical leader
- A designated nurse leader
- Successors for both positions and deputies in case of unavailability
- An HLIU-specific training program with standardized curricula with an accurate recording and documentation system for attendance
- 24/7 availability system to open the unit at the shortest possible notice
- A standard procedure for becoming operational when activated
- A staff roster allowing full coverage as needed within a minimum amount of time
- Regular emergency and evacuation training
- Regular maintenance of medical machinery (POCT diagnostics, ventilators, RRT machines, etc.)
- Regular maintenance and testing of communication systems and camera systems for monitoring the unit from outside
- Regular testing of negative pressure ventilation system and waste disposal system
- Regular training of standard procedures of HLIU treatment provision
- Updating of staff lists necessary for care
- Adaptation of PPE, medical machinery and communication systems to latest standards
- Occupational health maintenance of HLIU team (vaccines, respiratory fit testing, behavioral health, etc.)
- Regular education about emerging infectious diseases and current challenges or outbreaks

The management of HHCDs requires the maintenance of a satisfactory level of preparedness. In order to maintain this preparedness, it is important to have a precise plan on how an individual HLIU is operational in the framework of local, regional and national plans. The maximum number of patients that would be admitted, the level of care provided within the HLIU and the technical prerequisites of the unit determines what measures need to be taken. One of the most important aspects of preparedness is the ability to maintain adequate numbers of trained staff capable of safely working in an HLIU. It is helpful to have protocols that provide guidance for nurses, physicians and others, as well as for the number of staff that need to be included in the training. The materials and supplies required depend on the type of PPE, equipment used and the size of the team. It is important to have a good understanding of the number of supplies that are required for the treatment of a real case in order to inform decisions on stockpiling necessary supplies. Training

requirements are substantial, and adequate time must be provided to accomplish this. The psychological burden of working on an HLIU should be respected, and staff should receive information, counselling and team building measures to reduce that burden. These measures to maintain preparedness need to be well integrated and coordinated with interfaces like reference laboratories, transport organizations and the surrounding hospital infrastructure. Taken together, these measures will enable HLIUs to be ready when they are needed and are investments of time and resources that are necessary, even in the temporal absence of HHCD cases.

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