

Evaluation of the Person Under Investigation

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Introduction and Background

The ability to detect and diagnose patients infected with a highly hazardous communicable disease (HHCD) must be a priority for healthcare facilities in order to limit the morbidity and mortality of infection and to ensure the safety of staff and other patients through the early initiation of appropriate infection prevention measures. A patient presenting to healthcare facilities with specific clinical and epidemiological risk factors for infection with one of these pathogens may be termed a person under investigation (PUI) for the disease, and healthcare staff should utilize carefully developed protocols and procedures to guide their subsequent isolation and clinical evaluation practices until the disease has been ruled in or out.

Unfortunately, many factors challenge the appropriate early identification and appropriate isolation of PUIs in practice. These include lack of familiarity with PUI definitions and lack of knowledge regarding necessary actions once a PUI is suspected or identified. In addition, evolving PUI definitions from public health authorities, as well as changes in clinical guidance regarding recommended actions, as can occur with a new or newly emerging pathogen, further complicate PUI assessment. Inadequate early implementation of appropriate infection prevention measures can have severe consequences, and prior delays have resulted in nosocomial transmission [1–6].

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Therefore, rational and thoughtful approaches to identifying, evaluating, and providing care for HHCD PUIs are essential. Healthcare facilities must support vigilance in the suspicion of these diseases and support safe and effective care for all patients. Plans developed to support the evaluation of PUIs must also minimize the potential disruptions to routine facility operations, since PUIs will most likely outnumber actual confirmed cases, creating substantial operational and economic costs for institutions if not managed efficiently. The identify-isolate-inform framework introduced by the CDC during the 2014–2016 Ebola virus disease (EVD) outbreak can serve as a basic framework upon which further planning for the evaluation of PUIs for any HHCD, not just EVD, and can be used in any setting [7]. In this chapter, we will discuss features of PUI definitions and their implementation by healthcare providers, the various clinical settings that may be used for evaluation of the PUI, an approach to PUIs using the identify-isolate-inform framework, the specific evaluation and management methods that may be used in evaluating PUIs, and the clinical and operational challenges encountered during evaluation and management. We will conclude with a look to the ongoing challenges in PUI evaluation and areas where future advances in knowledge and policy are needed.

Understanding and Applying PUI Definitions

Evaluation of the PUI requires an understanding of each of the factors required to meet the definition. For well-known diseases, the term clinically compatible case [8] may sometimes be used instead of PUI, since formal PUI definitions have only typically been developed during more recent outbreaks such as Severe Acute Respiratory Syndrome (SARS, 2003–2004) [9], Middle East Respiratory Syndrome (MERS, 2012–present) [10], and EVD (during the 2014–2016 West African outbreak) [11].

When new diseases emerge (such as SARS or MERS) or reemerge and new information is learned (such as EVD), a clear and complete clinical description of the disease may not be completely known. Therefore, in such conditions, public health and medical authorities initially develop case definitions to attempt to identify all of the suspect cases in the community according to standardized and current knowledge of the disease. A case definition is a set of uniform criteria used to define a disease for public health surveillance, and the details of the case definition usually form the foundation of the definition of the PUI [8]. Case definitions include the demographic risk factors of persons who may have the disease (age, sex, etc.), the locations where exposure may be occurring, the length of the incubation period of the disease, and the symptoms associated with the disease [12]. A case definition is not equivalent to diagnostic criteria used for a particular disease. Instead, a case definition is intended to ensure maximum sensitivity for disease detection and not necessarily for maximum specificity.

Changes to PUI Definitions during an Outbreak

Maintaining current working knowledge with specific PUI criteria can be extremely challenging for providers, as the case definition may change frequently as new knowledge is learned about the disease. PUI definitions may also be complex and include multiple combinations of risk factors and symptoms to define levels of risk or severity of disease. Symptoms and risk factors may be added to or removed from the formal definition as this process evolves. For example, following two cases of MERS that were diagnosed in healthcare workers from Saudi Arabia traveling to the United States, CDC altered its guidance to emphasize testing for MERS in persons with mild symptoms but with strong epidemiologic risk factors, including particularly prior healthcare exposure [13]. In addition, travel to selected countries or regions may also be included or excluded as a risk factor for disease as an outbreak evolves. During 2015, after the emergence of a nosocomial outbreak of MERS in South Korea, this country was briefly included in the list of countries in the MERS PUI definition and then was subsequently removed when the outbreak ended. When the case definition changes rapidly, information that was recently shared with staff in lectures, webinars, or emails can quickly become obsolete. Unfortunately, it is not uncommon for printed and posted PUI criteria to remain in use long after the content is outdated.

Managing Changes to PUI Definitions

Communicating to Patients

In the setting of evolving PUI definitions, healthcare facilities must focus efforts to encourage patients to identify themselves to staff and to ensure that all those staff who may encounter PUIs have access to the most current information, know how to access that information, and know how to implement necessary actions when a PUI is identified. First, well-placed, clearly written signage in public areas, ambulatory waiting rooms, and ED settings should direct patients to immediately notify specific staff (depending on specific location) if they have either a relevant clinical syndrome (i.e., fever and a cough or fever and a rash) on arrival or if they have traveled internationally during a specified period. The precise time frame for international travel, corresponding to specific infectious incubation periods, will differ based on infection; however a window of travel within the prior 3 weeks will capture the incubation periods of MERS, SARS, novel avian influenza, and EVD and other viral hemorrhagic fevers, which simplifies the message to patients.

Communicating to Facility Staff

Whenever possible, paper or electronic triage forms should be used to prompt staff to ask arriving patients about epidemiologically important risk factors such as travel at each point of entry to the facility and then document the answers prominently in the medical record. However, while prompts can help to increase clinicians' ability to ask about relevant symptoms compatible with HHCD and epidemiologic risk factors (such as travel), it may be challenging for clinicians to remember if the answers they receive from their patients are actually of concern. This is especially true of travel histories, where clinicians may not know which countries are actively affected by outbreaks. Some medical systems have built decision support tools into their electronic medical forms to assist with this challenge and also to guide the subsequent actions a clinician should take whenever a clinical symptom or travel question is answered affirmatively about selected HHCD.

Four Toronto hospitals have described their experience in successfully developing a triage protocol for rapid isolation to limit transmission during the 2003 SARS outbreak [2]. The University of Nebraska ED EVD PUI protocol contains electronic prompts which allow for travel screening completed either by a greeter nurse for walk-in patients or by assigned nurse for patients transported by ambulance services. The travel questions include country of travel and time frame. If the travel screen is positive and the patient has a temperature >101.5 °F, two highly visible alerts appear on the screen, providing specific instructions regarding the immediate next steps including patient isolation and consultation with infectious diseases [14, 15].

Even if decision support tools are not used, providing clinicians with an easily accessible, electronic, expertly maintained list of current infectious diseases of high concern, plus a list, the relevant geographic and other exposure risk factors for each disease can be of tremendous value [16]. Such a list could be curated by hospital infectious diseases or infection prevention staff, local or state public health officials, or others and could be hosted on a local intranet page. Clinical leaders should also consider how they may better direct staff to access expert websites such as that of the CDC, since such sites can sometimes be challenging to navigate for the infrequent user. Quick links built into the electronic medical record (EMR) with bookmarks of relevant internal and/or external website pages related to PUI criteria may be helpful to clinicians and speed their access to relevant information.

In addition to building robust electronic aids into providers' common clinical workflows that can facilitate improving providers' identification of PUIs, it is also essential that frontline clinicians clearly know how to access expert local decision-makers when deciding whether a person meets PUI criteria. Such experts may be infectious disease consultants from the institution where the clinicians work, or a nearby community or tertiary care hospital (if such remote consultation services have been arranged), or may be local or state health department officials. These expert opinions are indispensable to help make the correct determination of whether a patient actually meets PUI criteria.

Maintaining Vigilance

For both patients and staff, in the absence of an ongoing major outbreak during which public attention is highly focused on a specific disease, facilities need to address the challenges of waning interest and vigilance that are likely to occur. During these periods, the continual use of updated signage in public areas, conduct of periodic educational activities, and increasing use of clinical decision support and other types of prompts within the EMR are needed to maintain a consistent level of readiness.

Location of Initial Patient Assessment

PUIs may be identified, and potentially assessed, in several different types of clinical environments.

Telephonic or Remote Triage

The first environment, which is safest for limiting subsequent disease transmission to others, is telephone or Internet triage. Through a remote medical encounter, patients may describe their symptoms to a nurse or other medical provider through a phone conversation, a website questionnaire, or a remote home visit, and it can likely be quickly determined if the patient meets PUI criteria with the required combination of symptoms and exposure risk factors. If the patient does not meet PUI criteria, then his or her triage may be continued as normal. If, however, the patient does meet PUI criteria, then she or he may be directed to a safe portal of entry at an appropriate nearby clinical site for further evaluation and care without unnecessarily exposing other people in a waiting room or other public setting. If EMS is required to help transport the patient to the clinical site, they should be alerted so that they can don the appropriate personal protective equipment (PPE) for transport to limit their own risks of exposure to the disease. In order for this process to be effective, telephone triage staff and providers must have ready access to the most current case definition and PUI criteria.

Ambulatory Triage: Primary or Urgent Care Locations

PUIs may also present in person to a primary care or urgent care office. Primary and urgent care clinics are unlikely to have on-site subject matter expertise in infectious diseases or infection prevention, making the establishment of simple, sustainable protocols essential. These should include (1) use and maintenance of clearly visible signage for arriving patients to instruct them to quickly identify themselves if they have concerning symptoms or risk factors, such as travel, and (2) training of staff who are able to quickly take action (especially including isolation of the patient) should a patient either self-identify with risk factors for an HHCD or be identified

as such during triage. In the case of many of the diseases discussed here (MERS, SARS, novel avian influenza), placement in an airborne infection isolation (AII, "negative pressure") room is required as soon as possible. However, since many ambulatory care settings will not have access to AII rooms, in these cases it is recommended to offer the patient a mask, instruct them to put the mask on, and then direct them to a private exam room with a closed door.

After the patient has been safely isolated, senior clinic staff must be notified and must contact appropriate subject matter experts for direction on next steps including (1) whether (based on information already available) the patient meets PUI criteria or if additional information is required; (2) if the latter, direction on the safe use of PPE and distancing from the patient; (3) advice on what types of care can safely be provided in that setting for patients confirmed as PUIs; and (4) instructions on transferring the patient to another more appropriate location for further clinical evaluation and management if deemed necessary.

Emergency Departments

As with primary care and urgent care settings, emergency departments must also be able to identify and isolate patients with infectious diseases, who may arrive as walk-ins, referrals from local primary care or urgent care offices, or by ambulance. Transferring facilities or clinicians should contact the receiving emergency department staff prior to sending a PUI to ensure appropriate isolation space is available, that the patient is immediately taken to the isolation space in a route that is least likely to expose others, and that staff don the appropriate PPE to protect themselves. Further, at the time of transferring a PUI, local public health authorities must be involved in the decision in order to provide expertise as well as logistical and communications support.

Approach

Once the patient has been confirmed to meet PUI criteria and appropriate infectious disease and/or public health experts have been notified, the patient will require transport to an ED capable of fully evaluating the patient (if the patient is not already located in such an ED). For many outpatient practices and clinics, this may be a local ED or perhaps a regional ED. No matter which ED is chosen, it should be assured that they have appropriate plans and resources available to safely clinically evaluate the PUI.

In some regions, the selection of the receiving ED is made jointly between the transferring hospital/clinic and public health officials. In other regions, the decision is left solely to the transferring providers. No matter how the decision process is conducted, protocols for the safe transfer of PUIs to the correct clinical setting must be developed in advance and exercised. This means that primary and urgent care centers should have formal plans for transfer of PUIs to an appropriate ED in their

area. In addition, the EMS services and receiving EDs involved in these plans should be fully aware of the plans and their roles within them. Community EDs without the capabilities for evaluating PUIs should have similarly established relationships and plans in place to transfer PUIs to predesignated regional tertiary care centers. EMS must be made aware of the suspected infectious disease when planning a transfer, so that their staff is able to utilize appropriate PPE and other infection control precautions. Receiving hospitals and their surrounding EMS services should meet to review plans for supporting doffing of PPE by EMTs and paramedics, for management of waste generated in transit, and for the procedures to be used to clean the ambulance and return it to service.

While arrangements are being made to transfer the patient, appropriate infection control precautions must be maintained. Personnel should avoid unnecessary contact with the PUI, and all personnel should wear appropriate PPE if they must be near the PUI. Selection of PPE for clinical staff should be selected based on the known (or suspected) routes of transmission for the suspected infection and the resources available. It is not realistic to expect all ambulatory clinics to stock and for staff to maintain proficiency in the correct and consistent use of PPE required in the long-term care of patients for specific infectious diseases such as EVD; however, in the setting of a clinically stable patient, staff should be expected to safely don and doff PPE appropriate for limited patient contact. This may include impermeable gown, N95 respirator, gloves, and face shield. All personnel who wear PPE in this setting must have been previously properly trained to do so.

When the patient is transferred out of the sending facility, the path that EMS personnel will travel out of the clinic should be cleared of other patients, visitors, and other medical personnel to reduce potential exposures. After the patient leaves the facility, the patient care area should be cleaned using preexisting protocols created with input from infection control and public health authorities.

Challenges in Management of the PUI

Depending on the specific infection suspected, the clinical evaluation of the PUI can range from being relatively straightforward to being extraordinarily complex. In 2015, one hospital's experiences in evaluating Ebola virus disease (EVD) PUIs were summarized as the following:

- Staff was unfamiliar with donning, doffing, and working in personal protective equipment (PPE) appropriate for care of these patients and therefore was apprehensive about their roles.
- 2. Disproportionate space in clinical areas had to be dedicated exclusively to isolation and care of PUIs, decreasing overall ED capacity.
- 3. Presence of PUIs in the ED was highly disruptive as the spectacle of cordonedoff spaces and staff in PPE could not be disguised, and large numbers of ancillary personnel congregated in the vicinity of the patient.

- 4. Patients fearing for their own and family members' safety left the ED waiting area and avoided hospital facilities known to have EVD or PUIs present.
- 5. The intrusiveness of the media imposed access and flow problems and made it very difficult to protect the identities and protected health information of the PUIs [17].

Other challenges in the evaluation of the PUI have been documented as well. Indeed, during the 2014–2016 EVD outbreak in West Africa, initiation of even basic lab testing and radiologic studies was delayed by 2–3 days in some cases for PUIs in US hospitals, and it was observed that some patients who were PUIs for EVD had poor outcomes because the concern for EVD infection negatively influenced their clinical evaluation and care [18, 19]. Lastly, because the definitive diagnostic tests needed to confirm the presence of HHCD infection may not be available at many hospitals and clinics, and may also take days to confirm or rule out the presence of the suspected infection, the potential period of evaluation for a PUI can extend well beyond a typical clinic or ED visit, further taxing the healthcare system.

Location of Care Delivery

Hospitals must carefully select and prepare the most appropriate location for managing PUIs, ideally well in advance of being asked to care for such a patient. Some hospitals choose to evaluate their PUIs in an ED treatment area, while others use a separate, specialized, inpatient, or other isolation area. When a site within the ED is chosen, there are a few questions that are especially worthy of consideration for planning purposes. First, is the room appropriate to support the care of a patient—is the room AII and is there a private bathroom (or other appropriate individual toileting procedure) available? Second, does the location of the room (or rooms, if multiple rooms will be used) support both safe entry of clean clinical personnel into the room and safe exit for contaminated clinical personnel? Additionally, does the space have a clearly demarcated area for doffing of PPE? One advantageous practice that has been observed is to select a room (or to modify an existing room) that has a separate entrance and exit, so that contaminated staff will not traverse the clean entrance to the room when exiting. Third, is the room in a location within the ED where its use for evaluation of the PUI will not excessively disrupt other ED activities? Evaluation of the PUI can be a labor- and material-intensive process, creating congestion as well as visible distractions for other patients and staff. Therefore, it is advisable, when possible, to choose a room to evaluate PUIs that is located away from the center of the ED to minimize interference to the other important ongoing ED activities and use physical barriers when possible to reduce disruption to routine care. Some facilities plan to keep PUIs in their ED room only until the initial assessment and first round of testing is completed, while other facilities plan to keep their PUIs in the ED room until the diagnosis has been definitively ruled in or out, which can potentially take several days (up to 3 days in the case of EVD).

If it is anticipated that the patient will be required to remain in the room for more than a few hours, plans must consider how both medical waste will safely be removed from the room. Waste management procedures for the PUI must follow the same protocols as for a confirmed patient until the disease is ruled out. If specialized disposal of the waste prior to confirmation of disease is cost-prohibitive for the facility, they must have plans to safely store and secure the waste while awaiting confirmation. One hospital has described the successful use of a portable facility they named a "mobile containment unit" to limit the impact of PUI needs on the main ED while supporting safe patient care [20].

A planning team consisting of an emergency department physician, ED nurse, infectious diseases physician, infection preventionist, facilities manager, and laboratory leadership (at a minimum) should convene to review these questions and begin planning their use of space for PUI evaluation. The team may also wish to explore the utility of video teleconferencing capabilities in the room, which can limit entry to only essential caregivers, allowing others, such as consultants, public health officials, and family members, to remain outside the patient care environment.

Preparation of the Environment of Care

All unnecessary medical equipment and materials should be removed from the room prior to admission of a PUI, leaving only those supplies that will assist with the care and evaluation of the patient. This may include specialized medical equipment, such as a disposable stethoscope or electronic stethoscope, ultrasound machine, or other diagnostic equipment, as well as cleaning supplies and solidification agents for liquid waste if deemed necessary. Biomedical waste receptacles should also be placed in the room. All of the room preparation activities should be guided by the use of predeveloped and exercised checklists, which can ensure that the room and staff are properly prepared to care for the PUI.

Care of the PUI and Establishing a Diagnosis

Once the PUI has arrived in the appropriate clinical location for evaluation, two important parallel processes must begin. The first is to ensure that the patient receives appropriate medical evaluation and care. The second is to undertake the appropriate diagnostic testing to establish a diagnosis. Because the PUI may have immediate medical needs, the receiving clinical facility must be able to provide stabilizing medical care to the patient if necessary, including airway and respiratory support, venous access, and administration of intravenous fluids, parenteral antibiotics, and vasopressor support. The CDC requires that hospitals designated by their states as assessment hospitals for EVD must be able to appropriately manage PUIs, undertaking the necessary diagnostic assays to ensure that other causes of fever (i.e., malaria) are identified and treated in a timely manner [21]. It is important to note that in one hospital's experience, 16% of PUIs who did not ultimately have the HHCD infection suspected did have a life-threatening alternative diagnosis [22].

Receiving facilities must ensure that clinical staff is properly trained to don and doff the necessary PPE in order to provide routine and stabilizing clinical care. In order to do this, hospitals must establish regular training schedules that allow providers to demonstrate proficiency in donning and doffing PPE as well as provide clinical care, manage waste, and obtain laboratory studies according to hospital protocols.

Specialized Care

The range of specific resuscitative and potentially invasive medical services and procedures that will be offered to a PUI before the specific HHCD is ruled out is a highly challenging decision and is one that should be approached carefully. Hospital administrative, medical, legal, and ethical leaders must consider whether they will be able to offer surgical operations (including cesarean sections), hemodialysis, endoscopy, or other procedures that present elevated risks to staff and the facility. These decisions should be made prospectively as part of the hospital planning and preparedness program. If challenging care decisions arise during the care of a specific PUI, an appropriate leadership team should be able to assemble immediately to ensure a fully informed decision-making process. If a specific necessary procedure is not available at the hospital assessing the PUI, public health officials may assist in determining if it may be available elsewhere, such as at one of the ten Regional Ebola and Other Special Pathogen Treatment Centers (RESPTCs) in the United States [10].

Laboratory Testing

Laboratory testing for PUIs may be extremely challenging and requires extensive preplanning in order to support clinical care and establish the diagnosis of specific HHCDs. Prior to the 2014-2016 EVD outbreak, federal guidance stated that all lab testing on patients suspected to have certain highly infectious pathogens (such as EVD) could only be performed in a biosafety level (BSL)-4 laboratory, while most hospitals only have BSL-2 laboratory facilities. Although the CDC provided guidance during the EVD epidemic that was intended to permit appropriate clinical testing outside of BSL-4 labs, these changes were not accepted by many. Many laboratory leaders were concerned about staff safety and impact on use of equipment for routine laboratory studies after processing a sample that could contain EVD [18]. Therefore, clinical and laboratory leaders must jointly decide on the basic menu of laboratory tests to support and to ensure adequate clinical care of the patient with the resources available. Some hospitals have elected to rely on bedside point-of-care testing devices to support much of this need, as the devices eliminate the need to utilize the large, automated laboratory machines. Because malaria is commonly in the differential diagnosis for many PUIs for EVD or other viral hemorrhagic fever, it is important that the hospital have a mechanism for testing for

malaria as part of the basic clinical evaluation. To limit the potential spread of biological contamination outside of the patient's room, special procedures must be developed to properly clean and package blood and other biological samples before they leave the room for transport to the hospital lab. Testing for the pathogen of concern is likely to be coordinated through the state public health laboratory. While commercial assays are available for some of these pathogens, public health laboratories will assist in confirmation of the diagnosis or excluding the diagnosis. Hospital staff must be trained and certified in packaging of specimens for transport to state laboratories.

Imaging

Radiographic imaging is an essential component of the evaluation of most febrile patients. Whenever possible, bedside ultrasound is the imaging modality of choice, since it does not require the patient to leave the room and can be interpreted immediately. Portable x-ray imaging can also be used, but may require the use of special protective covers for the machine and the cassette [15]. The decision about whether to offer additional advanced imaging services, such as CT or MRI, depends on variables such as the specific infectivity and transmission of the infectious disease for which the patient is being evaluated. If there is concern about the hospital's ability to offer such imaging services, a multidisciplinary committee, such as the one used to determine the medical and surgical procedures that can be offered, should be utilized.

If the patient is to be transported to an imaging area within the hospital, or to any other area of the hospital, the clinical staff must have a protocol to determine in advance the safest method of doing so. The decision to transport the patient for this purpose should be made by clinical leadership with all relevant parties involved, weighing the risks and benefits of movement of the patient outside of the area of isolation. Hospitals should plan to be able to clear the corridors and elevators of patients, visitors, and others during patient transport when needed and must also have plans in place to decontaminate the transport corridors if necessary following an unintended spill or other event.

Blood Products

The selection and crossmatching of blood products is challenging, because most current practices require use of open blood tubes. Some programs may choose to utilize uncrossmatched type O blood to avoid this risk when transfusion of red blood cells is needed, though others have successfully used a manual slide agglutination test for blood typing as well [15].

Social and Legal Considerations

Hospitals should also plan for special social and legal circumstances that may arise when evaluating the PUI. Hospitals should anticipate how and where they will screen and care for any family members or others who are transported with the PUI to their facility. Hospitals should also consider how they will plan to support the parents and families of pediatric PUIs and whether they can or cannot safely permit family members to stay with a young PUI (or any other PUI) during his or her evaluation [23]. Hospitals should have the ability to utilize language translation services in the area where the PUI assessment occurs. Additionally, hospitals should anticipate how they will respond in the event that a PUI does not wish to comply with the recommended evaluation and/or wants to leave the facility. The University of Nebraska Medical Center has developed a protocol for the noncompliant PUIs [15]. Their protocol was developed following a joint meeting with local law enforcement, public health officials, hospital security, risk management, and ED and hospital leadership.

Preparing for Multiple PUIs

Hospitals should also consider how they will support all of these efforts if they receive more than a single PUI at the same time. Ensuring the availability of appropriate space and trained staff, as well as all of the other tremendous resources required for multiple PUIs, may seem insurmountable but nonetheless requires forethought and planning. Facilities may wish to consider engaging their neighboring hospitals and their public health partners in crafting plans for these efforts.

Conclusions

The use of the identify-isolate-inform framework is essential when patients present to healthcare facilities with symptoms and exposure risk factors of HHCDs. Identification of these patients as early as possible in their presentation, institution of appropriate transmission-based precautions including use of specific PPE and isolation, and prompt notification of relevant experts and authorities are all essential actions in the care for PUIs with HHCDs. Because the potential period of evaluation for a PUI to rule in or rule out disease can extend well beyond a typical clinic or ED visit, thoughtful and coordinated planning efforts are required across the hospital and across the community to be able to adequately care for the PUI.

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