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Challenges in Managing Patients who have Suspected or Confirmed Ebola Virus Infection at the National Institutes of Health

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In September 2014, the National Institutes of Health (NIH) Clinical Center admitted as a patient a physician who had been working in an Ebola treatment unit in Sierra Leone and who had sustained a high-risk needle-stick exposure to Ebola virus. He was flown to the United States, and was admitted to the NIH Clinical Center's Special Clinical Studies Unit (SCSU), a high-containment infectious diseases ward. Although the patient arrived with symptoms consistent with Ebola virus disease (EVD), he fortunately did not develop the infection and was discharged 10 days later.

In October 2014, a nurse who was diagnosed with EVD after providing care to a Liberian man who had developed fulminant EVD and died at the Dallas hospital where she worked was transferred to our hospital. She received supportive care, recovered, and was discharged 8 days later.

The SCSU, to which both patients were admitted, was originally designed to facilitate management of individuals sustaining occupational exposures to select agents being studied at several US Federal Government-run biosafety level 4 (BSL-4) research laboratories near the NIH. The core SCSU nursing and physician staff had been planning and practicing for several years to provide such care. Donning and doffing techniques, infection control policies, and standard operating procedures had been designed for this possibility. In the weeks prior to the admissions, while the first few repatriated healthcare personnel who had acquired EVD were managed at Emory University and the University of Nebraska, the unit made final preparations for admitting EVD patients: developing staffing rosters; training

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additional nursing and physician staff; refining and rewriting procedures; and restocking supplies. The reality of admitting patients with EVD revealed a wide range of challenges and surprises that we describe here.

Transport

The patients' transportation to a nearby airport was arranged by the US Department of State, which holds the contract for the special isolation flights used to transport American healthcare personnel who acquired EVD, both in West Africa and in Dallas. The patients were transferred from the plane's isolation pod to the waiting ambulance wearing personal protective equipment (PPE), including a Tyvek suit and an N-95 respirator. Each patient was placed in a negative-pressure isolation stretcher enclosure (Demistifier®) in the ambulance. An NIH intensivist and paramedic, both wearing PPE, accompanied each patient. When the ambulance reached the hospital, the patient was transported directly to the SCSU in the Demistifier® by a team wearing PPE, taking a seldom-traveled route through the hospital.

The interior of the ambulance had been draped in plastic to minimize contamination and cleaning requirements. The ambulance crew cleaned the vehicle, stretcher, and motor and frame of the isolation unit using bleach wipes. The plastic walls of the isolation pod were discarded as medical waste to be autoclaved. After cleaning and after its contents were disinfected with hydrogen peroxide vapor, the ambulance was returned to service.

Communication and Patient Confidentiality

The news media were active, if uninvited, participants in both patient arrivals. Both patients were photographed by news organizations as they walked in PPE from airplane to ambulance. The arrival of the second patient was heralded by the sound of helicopters hovering close overhead. The NIH communications team managed media communication; our focus was on communication within our hospital.

Communication with staff consisted of email broadcast announcements, all-hands staff meetings, and distribution of a detailed Ebola white paper describing the virology, epidemiology, pathogenesis, management and prevention strategies for EVD. Letters were distributed to inpatients and were made available to outpatients. These communications were aimed at informing staff and patients about EVD and the extent to which the Clinical Center was supporting the effort. They were intended to reassure patients and staff that detailed and thorough infection control precautions were in place. Despite these measures, more than 40 patients canceled or rescheduled planned visits because of the perceived risk. Most clinical staff were supportive; however, a very few were openly contentious about the risks they perceived EVD patients presented. Others were critical of the plans and standard operating procedures developed to provide care (despite the fact that the team had been developing them for years and despite absence of scientific data supporting one approach over another).

Maintaining patient confidentiality was a challenge, with many concerned employees inquiring earnestly about patient welfare. The electronic medical records of both patients were labeled with warnings about privacy and monitored electronically for inappropriate access. One of the patients' names had been discussed in the press prior to arrival at the

Clinical Center. This publicity made managing her privacy and confidentiality even more challenging.

Managing Anxiety and Hysteria

The anxiety and hysteria that were fueled by the admission of these patients were substantial and oddly reminiscent of the anxiety and hysteria that accompanied the early studies of AIDS patients at the Clinical Center in the 1980s. In fact, ironically, many questions asked in town hall meetings were virtually identical to those posited 40 years ago about AIDS. Whereas fear of the unknown, both in our community and on our campus, is entirely understandable, the circumstances in which we found ourselves were strikingly different from those in the 1980s. For EVD, we understood the causative agent, an easily disinfected, lipid-enveloped RNA virus. We also understood much more about the epidemiology and routes of transmission than we did about AIDS in the 1980s. For Ebola, understood factors associated with increased risks for transmission, as well as techniques that had consistently proved useful in avoiding healthcare-associated transmission, even in resource-poor settings. Nonetheless, we found ourselves repeatedly answering identical questions to those fielded in the 1980s. Experienced team members remarked that we were experiencing (to quote Yogi Berra) “déjà-vu all over again.” The disease piqued both media attention and the attention of legislators quite similarly to the previous outbreak.

Clinical Center staff used many of the same approaches to managing these issues as we did in the 1980s. The keystone of our approach was transparency. We answered questions, saying, ‘We don’t know’ when we didn’t know the answer, but we promised to try to find the answer, if it existed. Alternatively, we noted mechanisms used to mitigate risks associated with our inability to answer a question with precision. The clinical leadership consistently offered a calm presence to staff who had anxieties. Institutions cannot ignore these anxieties, as they can become paralyzing. They must be approached immediately and with candor.

Staffing

Infectious diseases specialists and intensivists volunteered to provide night coverage, and nurses from the ICU and medical wards volunteered to work in the unit. Staff from ancillary services (e.g., laboratory technologists, radiology technologists, and respiratory therapists) also volunteered. These staff were trained in PPE use. Some disciplines, especially those potentially involved in interventional procedures or in caring for critically ill patients, conducted simulations and drills of their procedures while wearing PPE.

We did not anticipate that, during the first days following the EVD patient’s arrival, the volume of calls to the unit would require the full-time attention of a staff member. We did not have the foresight to limit calls to the unit. Many calls were from other medical centers curious about unit operations, and some were from members of the public conveying a range of questions and (often untoward) opinions about the transfer of the EVD patient.

The use of an all-volunteer patient care staff was occasionally a source of anxiety, primarily related to the concern regarding whether 24/7 staffing could be maintained through a

voluntary mechanism, coupled with internal debate over whether voluntary versus mandatory service should be the expectation for federal employees. The voluntary approach to staffing ultimately proved feasible and effective. Some roles within the containment unit workforce did not fall clearly to a certain discipline. Examples included workers transporting and autoclaving medical waste, staff transporting laboratory specimens to our BSL-3 laboratory, staff charged unit cleaning (described below), and trained observers for the PPE donning and doffing processes.

The trained observer, or “WatSan,” (a term borrowed from Médecins Sans Frontières as a portmanteau of “water” and “sanitation”) issues step-by-step instructions (directly from a script) to guide and monitor each staff member through the doffing process, all the while monitoring and, when necessary, correcting procedural steps to prevent errors that could result in self-contamination. The WatSan must be meticulously oriented to detail and must convey authority, both to ensure that procedures are performed effectively and to inspire staff confidence. Because we believe that the doffing process is associated with the single highest risk for self-contamination, we viewed the WatSan role as critical to guaranteeing staff safety. We determined that, in our unit, the task required the knowledge base and assertiveness of a nurse or physician, and we solicited and trained volunteers from among the institution’s many research nurses, infection control professionals, and clinical fellows. We were able to staff this position around the clock. Conversely, we identified only two WatSan participants willing to accept shifts after midnight, which revealed a thin link in our volunteer schedule.

Unanticipated Consequences of Volunteering

Unintended consequences for staff volunteers related to the public perceptions were generally minor, with a handful of exceptions. One staff member who had volunteered to care for Ebola patients and whose child was enrolled in a home day care was asked to find alternative child care because another NIH employee used the same center and was aware the individual had volunteered. The spouse of another volunteer was reassigned to telework so that coworkers in his company would not risk indirect exposure to EVD. Fortunately, such serious complications were few.

Training

A large cadre of staff was trained in advance of the admissions. The training process prioritized nurses, infectious diseases and critical care physicians, and respiratory therapists who would provide direct care, as well as laboratory technologists who would manage patient specimens. Radiology technologists were trained to perform portable film procedures. Training is both time consuming and labor intense.

We had to triage training requests from other services, prioritizing those whose involvement in the care of an EVD patient seemed most likely. Despite the stated intention to minimize laboratory testing and invasive procedures on EVD patients, many departments expressed anxiety that they might be called upon to perform testing or procedures (e.g., bone marrow biopsy, red blood cell antigen assays, nuclear medicine scans, surgical procedures,

interventional radiology procedures, etc.) and requested training to prepare for these possibilities.

Equipping the Unit

The powered, air-purifying respirators (PAPRs) and disposable hoods that are essential to our PPE became a scarce commodity. After the admission of an Ebola patient to a Dallas Hospital and subsequent EVD transmission to 2 nurses, hospitals realized that the likelihood of having EVD patients present to their facilities was no longer zero. Although some tertiary centers had already been preparing for weeks, suddenly all hospitals needed to be equipped and trained. Our unit received scores of calls from throughout the country asking precisely what specific models of PPE we had chosen and precisely how our procedures were designed.

In addition, as we scrutinized the environment where we would provide care in detail, we discovered aspects that required modification. NIH staff were extraordinarily responsive, making structural changes to increase unit safety and efficiency and installing 2 autoclaves immediately proximate to the SCSU to facilitate waste disposal (discussed below).

Laboratory Testing

Diagnostic testing was limited to point-of-care (POC) testing, (currently being expanded to include some microbiology diagnostics) and a handful of assays that were performed on dedicated POC analyzers in our BSL-3 clinical laboratory. Samples tested for EVD PCR were sent via courier to the US Army Research Institute of Infectious Diseases (USAMRIID), 30 miles away, where they were processed in a BSL-4 laboratory.

The Waste Stream

We had been forewarned by colleagues at Emory that the volume of waste generated during care of an EVD patient would be enormous. As noted above, we had used the 2 weeks prior to admitting our first patient to install 2 medium-sized autoclaves immediately adjacent to the SCSU. The warnings by our Emory colleagues prompted a rethinking of our plan; we ultimately negotiated with NIH leadership to use a huge autoclave (used to sterilize animal bedding) that could treat a large cart full of waste, in addition to using the recently installed autoclaves. The large volume of PPE yielded a large volume of potentially contaminated medical waste; the fact that waste management was going to be a major hurdle in managing the SCSU became clear. Indeed, more than 170 bags of waste were filled and autoclaved during one 10-day admission. Because no staff member could devote the time required to transport and autoclave the waste, we hired trained contractors. The hospital's environmental services contract staff had not been trained prospectively about the disease and were understandably frightened. Thus we asked them only to remove uncontaminated trash from "cold" zones in the SCSU.

In accord with federal and state policies, the medical waste contractor who transported our boxed medical for incineration was required to (and did) obtain a US Department of Transportation hazardous materials waiver to transport medical waste from an EVD patient

(despite the fact that all this waste had been autoclaved and was sterile). We worked with Maryland Department of the Environment authorities to assure adherence to state requirements. Nonetheless, landfill owners refused to accept the ashes of autoclaved waste incinerated at 1,800–2,200°F, stating, emphatically, that “[they] didn’t want Ebola ashes” in their landfills. This bizarre waste disposal bottleneck forced the incinerator contractor to turn away our sterilized medical waste.

Despite USPHS guidelines stating, “Sanitary sewers may be used for the safe disposal of patient waste,” and that US sewage handling processes are designed to inactivate infectious agents, early on in our patient’s hospital stay, local sewage management authorities contacted us to inquire what measures were being taken to prevent infectious waste from entering the sewage system. In the SCSU, human waste was routinely treated with 90 ml of a strong quaternary ammonium compound and allowed to dwell for 10 minutes prior to flushing down the drain. This protocol was based on the practices used at Emory, and not on any evidence that failure to treat the waste would create a hazard. The procedure satisfied our local sewage management authority.

Discharge

The criteria for discontinuing isolation for patients were met, or exceeded, before patient discharges. However, transportation and follow-up required extensive collaborative discussion with local, state, and federal public health officials. The primary consideration for our first patient was continued monitoring through the 21-day incubation period. Our second patient was returned to Dallas via private plane, due to privacy and security concerns. She spoke at a press conference upon discharge and received widely broadcast hugs from NIAID Director Dr. Anthony Fauci and President Obama, underscoring her lack of infectivity, but she still met with challenges getting home and reintegrating into the workforce.

Cleaning the Unit

Following discontinuation of isolation, the SCSU was cleaned and decontaminated. The nursing staff routinely cleaned the patient room and anteroom using bleach wipes. Electrocardiogram, ultrasound, and portable radiology machines were cleaned after use and disinfected with hydrogen peroxide vapor. Because environmental services workers were assigned only to clean “cold” areas, the task of terminal cleaning fell to the core nursing staff. Although they feel ownership for the unit, terminal cleaning is not an optimal use of time and energy of skilled healthcare professionals. After terminal cleaning, we decontaminated the patient room and anteroom with hydrogen peroxide vapor, thereby deactivating the containment unit.

Monitoring Patient Care Staff

Health monitoring of personnel who entered the patient room or anteroom was a moving target. All staff who were considered potentially exposed to Ebola were registered automatically in an electronic system to track compliance with temperature monitoring. Throughout the course of the 2 admissions, as public debate about travel restrictions and

quarantine raged, federal guidelines about the extent of monitoring were progressively ratcheted upward. A requirement for personnel to self-monitor body temperature and record absence of fever and symptoms suddenly became a requirement for direct daily monitoring by others, with any planned travel noted prospectively. One occupational medicine physician worked long hours to achieve compliance with this mandate. Staff were so relieved that they would not be subject to travel restrictions or quarantine that they were generally very willing to comply with escalated monitoring requirements.

Ultimately, all staff involved in the care of EVD patients were entered into a 21-day, active monitoring fever-watch program, beginning 24 hours after initial EVD patient engagement. This active monitoring program required staff to take temperatures twice daily, observed by another individual, and to submit this information online daily. Each time a staff member re-entered either the anteroom or the patient room, the 21-day monitoring period was reset. Each staff member signed an entry log indicating time of entry. At the end of each shift these forms were collected, copied, and sent to Occupational Medical Service (OMS) physicians to update the 21-day monitoring schedule. Educational sessions provided by OMS updated staff on the expectations for active monitoring. Staff also answered online questions regarding development of unusual physical symptoms and reported and discussed any travel plans with OMS.

Years of planning and drills for care of a patient exposed to or infected with EVD could not anticipate the external scrutiny or the public milieu in which care was delivered. Some precautions were taken to prevent spread of the virus, and many were taken to mitigate fear, even if science did not support those fears (e.g., autoclaving and then incinerating medical waste). Taking care of patients who had known or suspected EVD required tremendous flexibility and ability to adjust procedures quickly. We were humbled at the commitment of our colleagues, healthcare providers and others, to the mission of caring for these patients, and at their willingness to drop everything to aid the mission. Provision of care for EVD patients is stressful and labor intense. Not all the obstacles we encountered were intuitive. We report our experience in the hope that our account will benefit others who undertake this challenge.

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