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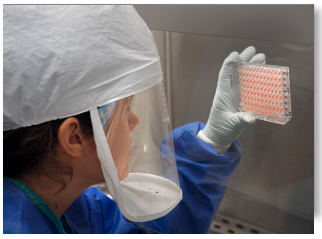
CDC, NIH lab lapses with deadly agents lead to calls to halt research

IPs should assess lab safety in light of incidents

By Gary Evans, Executive Editor

A recent series of stunning lapses and oversights in federal research labs working with deadly pathogens and potential bioterror agents has heightened calls for a moratorium on such research until biosafety and security can be assured.

"Such incidents have been accelerating and have been occurring on average over twice a week with regulated pathogens in academic and government labs across the country," a group of scientists and researchers warned in a position statement on the issue." An accidental infection with any pathogen is concerning. But accident risks with newly created 'potential pandemic pathogens' raise grave new concerns." (*See related story p. 89*) The agents involved — anthrax, highly pathogenic H5N1 avian flu and, astoundingly, smallpox — were as shocking as the top tier federal agencies that mishandled them: the Centers for Diseases Control and Prevention and the National Institutes of Health.



While the incidents involved research labs, infection preventionists can seize the highly publicized events as a "teachable moment" to review practices and biosecurity with their clinical lab colleagues.

"Even though lab personnel most likely knew about [these lab breaches] at the same time as IPs from their professional associations, I think sharing the incident would be a moment to bond even more with some of our number one infection prevention partners," says **Patti Grant**, RN, BSN, MS, CIC, an infection preventionist at Methodist Hospital for Surgery in Addison, Texas. "It is frightening, but it is always great when an opportunity arises where we can discuss a mutual topic outside of our daily work routines."

Though a safety review would be wise in any case, some may

The year of living dangeously

A confluence of recent events puts anthrax, H5N1 avian flu, smallpox and Ebola all in this *HIC* issue.

In This Issue

AHC Media

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argue that hospital clinical labs would never deal with such pathogenic agents. True enough in the main, but as recent incidents with MERS and other pathogens demonstrate, an infection of any etiology from anywhere in the world can show up unannounced in any given U.S. emergency department. To precisely that point, the CDC recently released patient isolation guidelines for Ebola for U.S. hospitals, emphasizing the need for basic preparation in case a traveler infected in the ongoing outbreak in West Africa is admitted for treatment. (*See relatedly story p. 90*)

"I would hope that — if these kinds of incidents can take place at the CDC — that every laboratory director would take this as an opportunity to take a time out and review their own laboratory safety policies and procedures," says **William Schaffner**, MD, chairman of the Department of Preventive Medicine at Vanderbilt University Hospital in Nashville. "This is another example that human beings don't get it right all the time. We have to guard ourselves against ourselves."

A troubling trifecta

After lab incidents involving anthrax and H5N1 avian flu occurred at the CDC, the NIH completed the trifecta by reporting that six long-forgotten vials of smallpox were discovered in a lab cold storage area. The sealed glass ampules had been apparently sitting in a box, buffered in cotton, since the 1950s.

"I could not believe that when I heard it," Schaffner says. "At least 2 of the six vials have grown live smallpox. There have been some further explanations that this was the kind of storage area that [the NIH] had not anticipated that anyone would ever have put smallpox virus in to."

With smallpox eradicated in the wild in 1980, the vaccine is no longer routinely administered and much of the planet's population would be susceptible to the variola virus — a disfiguring killer that plagued human kind for centuries. (*See smallpox story, p 89.*)

Before breaking down the details of the anthrax and H5N1 incidents, it should be noted that the CDC has issued a strong response to the incidents that included forming a new expert advisory committee on laboratory practices and safety to provide expertise and oversight.

"CDC director Tom Frieden has taken responsibility and very forthrightly has looked at this as a CDC-wide potential problem and instituted a series of corrective actions," Schaffner says. "I think when these are fully implemented it will restore the CDC to its justified role of primacy in the public health lab area. Not only in the United States, but around the world."

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One approach that should be considered in labs is the kind of checklist or "time out," approaches that have proven effective in health care and other industries, he adds.

"We are terrifically reassured that pilots — each and every flight — have to go through a check list before the plane pulls away from the gate," he says. "In surgery we now have instituted time outs. Everybody stops and reviews exactly what the surgery is going to be. They actually put a mark where the surgery is going to take place so we don't take out the left kidney when we meant to take out the right. These events have happened in the past and now we have simple, rigorous procedures to preclude that from happening. They all have to be adhered to rigorously whether you are doing surgery, flying a plane, or working in a laboratory. Clearly, these kind of checklists and timeouts need to be put in place at the CDC."

Anthrax and avian flu incidents

The anthrax incident at the CDC began on June 5, 2014 when a laboratory scientist in the Bioterrorism Rapid Response and Advanced Technology (BRRAT) laboratory prepared extracts of *Bacillus anthracis* under biosafety level (BSL) 3 containment conditions. The purpose was to render the pathogen non-infectious so it could be used to evaluate a method of rapid identification of anthrax, which would help considerably in dealing with false "white powder" events which have caused chaos since the 2001 anthrax mail attacks.

However, the lab scientist used a modified protocol and tested the anthrax for viability at 24-hours rather than the recommended 48. No growth on any of the 16 plates was observed at 24 hours, but it would be later discovered that live anthrax remained. Not just any live anthrax mind you, but the notorious Ames strain that killed five people and infected 17 others in the 2001 mail attacks. This was discovered after a few days of experiments had already been conducted in two step-down labs, where workers thinking they were dealing with inactivated anthrax were like so many unprotected electricians wiring circuits and switches after being assured that the main power was off. Dozens of CDC workers were potentially exposed, particularly since there was concern that one of the lower lab procedures "agitated" the anthrax and could have aerosolized the pathogen. Ultimately no one was infected, but the incident was nerve wracking for all involved.

"We're very concerned about the health and well-being of our own staff," CDC Director **Tom Frieden**, MD, said at press conference. "The fact that they had to deal with uncertainty, stress, potential risk and to take preventive medicines that can have adverse effects as a result of this incident is something that I feel terrible about."

A CDC report found the primary contributing factor to the incident was the lack of an approved, written study plan reviewed by CDC senior staff to ensure that the research design was appropriate and met all laboratory safety requirements. The report also noted the following other contributing factors: use of unapproved sterilization techniques; transfer of material not confirmed to be inactive; use of live anthrax inappropriate for this experiment; inadequate knowledge of peer-reviewed literature related to inactivation of anthrax; and lack of a standard operating procedure or process to document inactivation in writing in the BRRAT lab. In the wake of the incident the director of the BRRAT lab, **Michael Farrell**, PhD, submitted his resignation, according to published reports.

Following the anthrax lab breaches, more than 80 CDC employees were offered post-exposure prophylaxis with a 60-day regimen of ciprofloxacin or doxycycline and/or the anthrax vaccine used by the military. However, the CDC occupational health response was beset by controversy as well, according to a damning independent investigation by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS).

"There … was no clear, single manager overseeing the overall CDC incident response, which resulted in employee confusion about how to manage the response to the incident," **Jere Dick**, PhD, associate administrator of the APHIS testified at a July 16 Congressional hearing. "In addition, CDC's Occupational Health Clinic was inadequately prepared to respond to the potential exposure of a large number of workers, resulting in some staff not knowing if they were at risk and at least one person who was in contact with contaminated material without proper personal protective equipment not being examined for 5 days."

Director kept in dark about flu incident

On the heels of the anthrax incident, reports surfaced that the CDC had sent a presumably low-pathogenic H9N2 avian influenza virus sample to a federal poultry research lab that was found to be contaminated with deadly avian influenza

H5N1. The worst case scenario is fairly easy to imagine because H5N1 has a 60% mortality rate in humans. Again, no one was infected — in part because the receiving lab took necessary precautions instead of just assuming the flu was benign. In fact, the receiving lab — a USDA research facility at the University of Georgia in Athens — actually alerted the CDC that the shipment was contaminated with H5N1.

"At this point everything we've looked at strongly suggests that there was no exposure of anyone to influenza," Frieden said. "The people who were involved were wearing what are called 'PAPRs' or positive air pressure respirators. They were working in an enhanced BSL-3 facilities [with] multiple redundant checks to prevent infection with flu."

Though the flu incident was bad enough, an aggravating factor that speaks volumes about the lab safety culture at the CDC is that Frieden was not notified of the incident until six weeks after it happened. In addition, the cross contamination of flu strains occurred in the influenza lab, a world class facility that is a point of pride at the CDC.

'An unacceptable delay'

"For me personally, this is the most distressing of the [recent] incidents for two reasons," Frieden said at a July 11 press conference. "First, because it happened in our influenza laboratory. And second, because it happened six weeks ago, and I learned about it less than 48 hours ago."

The flu incident remained under investigation as this issue went to press.

"We're still just beginning the investigation to determine how this happened," Frieden said. "The work was done in one room. So that leads to some early hypotheses of what might have happened. But it's going to take a detailed investigation. And we may not know for certain exactly what happened, but we'll do everything we can to find out."

In response to the incidents, the CDC shut down some labs and placed a moratorium on biological material leaving BSL-3 and BSL-4 laboratories until further notice. "We will assess laboratory by laboratory before reopening," Frieden said. Though no one was infected at either the CDC or the other lab, the incident was clearly disturbing to Frieden.

"The fact that something like this could happen in such a superb laboratory is unsettling because it tells me that we need to look at our culture of safety throughout all of our laboratories," he said. "[It is] deeply troubling that there was an unacceptable delay in providing this information. It's very important to have a culture of safety that says if you've got a problem, talk about it. The biggest way to get into more trouble is not to talk about something when you've got a problem."

Among the other actions CDC is taking are a comprehensive review of its lab procedures and appointing a single point person to assess lab activities and report directly to Frieden. That person is **Michael Bell**, MD, a veteran medical epidemiologist and hospital outbreak investigator in the CDC Division of Healthcare Quality Promotion.

'Work of safety is never complete'

"There's some major systematic issues that we want to look at," Bell said at the press conference. "It's not the little mistake that we're concerned about in this instance. We're concerned about what is the framework that everyone's using? And that framework includes rapid reporting. It includes an understanding of the chain of communication and who you tell when.

"Add to that the fact that people need to be comfortable doing this," he added. "We can bolster that and make use of this series of events to make sure that in the future there is much less likelihood of this happening again. The work of safety is never complete. We will continue to innovate. We'll be continuing to have new technologies. There will be new diseases. And this is part of the work that we do in public health to maintain safety and grow with the science so that we can assure that what we do doesn't harm anybody that's doing the work or is nearby." ■

Lab incidents divide scientists on research

Some warn of unleashing a pandemic

A series of biosafety breaches in federal labs working with highly pathogenic agents has created a rift in the research community, with some calling for a moratorium until safety can be assured and other scientists arguing that this important work should continue with appropriate precautions to prepare for pandemics and bioterror attacks.

"There is no doubt that the episodes of laboratory safety that have been in the news recently have reignited the scientific discussion about whether this type research should take place, whether specific projects ought to be reviewed, and — if the research takes place — should it be restricted to only certain investigators in certain institutions. I think it is a valid debate," says **William Schaffner**, MD, chairman of the Department of Preventive Medicine at Vanderbilt University Hospital in Nashville.

Distinguished scientists and researchers are divided on the issue, as evidenced by the signatures on position states by the opposing groups, one calling itself the Cambridge Group and the other Scientists for Science.

The Cambridge Group said the recent series of laboratory breaches with potential pandemic agents indicates an urgent need for a thorough reassessment of biosafety. "Laboratory creation of highly transmissible, novel strains of dangerous viruses, especially but not limited to influenza, poses substantially increased risks," the group said in a position statement. "An accidental infection in such a setting could trigger outbreaks that would be difficult or impossible to control. Historically, new strains of influenza, once they establish transmission in the human population, have infected a quarter or more of the world's population within two years."

For any experiment, the expected net benefits should outweigh the risks, the group argued. "Experiments involving the creation of potential pandemic pathogens should be curtailed until there has been a quantitative, objective and credible assessment of the risks, potential benefits, and opportunities for risk mitigation, as well as comparison against safer experimental approaches," the Cambridge group recommended.

Scientists for Science issued a countering statement expressing confidence that biomedical research on potentially dangerous pathogens can be performed safely and is essential for a full understanding of microbial disease pathogenesis, prevention and treatment.

"The results of such research are often unanticipated and accrue over time; therefore, risk-benefit analyses are difficult to assess accurately," the pro-research group said. "If we expect to continue to improve our understanding of how microorganisms cause disease we cannot avoid working with potentially dangerous pathogens. In recognition of this need, significant resources have been invested globally to build and operate BSL-3 and BSL-4 facilities, and to mitigate risk in a variety of ways, involving regulatory requirements, facility engineering and training. Ensuring that these facilities operate safely and are staffed effectively so that risk is minimized is our most important line of defense, as opposed to limiting the types of experiments that are done."

There are preliminary indications that the debate may ultimately be bound for some type of meeting overseen by a neutral third party like the American Society for Microbiology or the National Academy of Sciences. ■

Live smallpox long forgotten at the NIH

Much of the planet would be susceptible

The most shocking of the recent laboratory mishaps and biosafety breaches was the discovery of a long-forgotten cache of live smallpox in a lab storage area at the National Institutes of Health in Bethesda, MD.

The last case of smallpox in the wild occurred in 1977 and the disease was declared eradicated in 1980. The vaccine is no longer routinely administered, leaving much of the human population susceptible to the disfiguring killer. In the 20th century an estimated 300 million people died from smallpox, which has a mortality rate of roughly one-third of those infected. Suffice it to say, a single case of smallpox anywhere in the world would be a public health emergency.

On July 1 the NIH notified the Division of Select Agents and Toxins (DSAT) at the Centers for Disease Control and Prevention that employees discovered vials labeled "variola" in an unused

portion of a storage room in a Food and Drug Administration lab located on the NIH campus.

The laboratory was among those transferred from NIH to FDA in 1972, along with the responsibility for regulating biologic products. The FDA has operated laboratories located on the NIH campus since that time, and the vials were discovered when the lab was being moved to the FDA's main campus. The vials appear to date from the 1950s, according to a CDC report of the incident. Upon discovery, the vials were immediately secured in a CDC-registered select agent containment laboratory in Bethesda. There was no evidence that any of the vials had been breached, and onsite biosafety personnel did not identify any infectious exposure risk to lab workers or the public, the CDC found.

On July 7 the vials were transported with the assistance of federal and local law enforcement agencies to CDC's high-containment facility in Atlanta. Overnight PCR testing done by CDC in a BSL-4 lab confirmed the presence of variola virus DNA, and two of the six vials contained live smallpox. Additional testing of the variola samples was continuing as this issue went to press.

"The problem was not in the creation of the materials but in the inventory control which allowed them to remain unsecured for decades," CDC Director **Tom Frieden**, MD, said at press conference. "They should have been destroyed decades ago, and once we complete the work here, we will destroy them."

The officially acknowledged stocks of live smallpox virus — the so-called "demon in the freezer" — are stored at the CDC in Atlanta and the State Research Centre of Virology and Biotechnology in Novosibirsk, Russia. The discovery of the vials at the NIH has raised the question of whether there could be other unaccounted stores of smallpox. In scouring the NIH campus for other misplaced biologics, no other smallpox was found but the FDA reported uncovering 12 boxes containing a total of 327 carefully packaged vials labeled with names of various biological agents such as dengue, influenza, Q fever, and rickettsia. The vials were turned over to the appropriate NIH program safety officers. ■

Out of Africa: Ebola cases come to U.S.

As the first two cases of Ebola ever treated in the U.S. were recently admitted to a special containment unit at Emory University Hospital in Atlanta, clinicians and public health officials continued to reassure a jittery public that infection control measures would prevent transmission and contain the virus.

"We are talking about a virus that is spread in a way that we are quite used to — HIV, hepatitis B, hepatitis C. It's the same algorithm and we use the same kind of precautions on those patients on a daily basis," **Bruce Ribner**, MD, an infectious disease physician at Emory, said at an Aug. 1 press conference. "All of these viruses are spread by close contact with blood and body fluids. I will be one of the individuals coming into direct contact with the patients. I have no concerns about either my personal health or the health of the other health care workers who will be working in that unit."

This reassurance, while accurate from a medical standpoint, could nevertheless be seen as something of a disconnect when you are admitting patients into a specially designed unit with elaborate and redundant systems to contain any pathogen within. There are a few such units in the country, so the Ebola patients — a volunteer American physician and a medical missionary worker infected in the ongoing West African outbreak — were hospitalized under extreme infection control precautions that belie Ribner's business-as-usual tone. (*See related story p. 92*)

The Centers for Disease Control and Prevention often finds itself delivering a similar mixed message with an exotic pathogen, reassuring that there is little threat to public safety while taking extensive measures with the first cases out of an abundance of caution.

CDC issues Ebola isolation guidelines

Even as the Ebola patients were bound for the high containment unit at Emory, the CDC released Ebola patient isolation guidelines for all hospitals.[1] The CDC recommends a combination of standard, contact, and droplet precautions for management of hospitalized patients with known or suspected Ebola hemorrhagic fever. The recommendations were based upon the best available information as of July 30, 2014 and took into account the following considerations:

- High rate of morbidity and mortality among infected patients
- Risk of human-to-human transmission
- Lack of FDA-approved vaccine and therapeutics

The CDC recommends an Ebola patient should

be placed in a single patient room containing a private bathroom with the door kept closed. Facilities should maintain a log of all persons entering the patient's room. Consider posting personnel at the patient's door to ensure appropriate and consistent use of PPE by all persons entering the patient room. All persons entering the patient room should wear at least, gloves, gown (fluid resistant or impermeable), eye protection (goggles or face shield), and a facemask.

Additional PPE might be required in certain situations (e.g., copious amounts of blood, other body fluids, vomit, or feces present in the environment). These would include but are not limited to: double gloving, disposable shoe covers, leg coverings.

Ebola does not spread through the air, but workers should wear respiratory protection at least to the level of an N95 respirator if they are doing procedures on an Ebola patient or fluids that could generate aerosols. The CDC recommends avoiding aerosol generating procedures (AGPs) on Ebola patients if possible. If performing AGPs, use a combination of measures to reduce exposures. Conduct the procedures in a private room, ideally in an Airborne Infection Isolation Room (AIIR) when feasible. Room doors should be kept closed during the procedure except when entering or leaving the room, and entry and exit should be minimized during and shortly after the procedure. In addition to a respirator, health care workers performing an AGP on an Ebola patient should wear gloves, a gown, disposable shoe covers, and either a face shield that fully covers the front and sides of the face or goggles.

Dedicated medical equipment (preferably disposable) is recommended, with the use of sharps and needles limited as much as possible. All needles and sharps should be handled with extreme care and disposed in puncture-proof, sealed containers, the CDC recommends.

No transmission during incubation period

Ebola does not spread in the absence of symptoms while the patient is in the incubation phase. "Ebola is spread as people get sicker and sicker, they have fever and they may develop severe symptoms," CDC director **Tom Frieden**, MD, said at a press conference. "Those symptoms and the body fluids that may be shed during that time, those are the infectious risk entities."

U.S. hospitals should have no problem isolating Ebola patients, but personnel must be meticulous in following the measures, he added.

"American health care workers are much more familiar with how to isolate patients and how to protect themselves against infection," he said. "In fact, any advanced hospital in the U.S. — any hospital with an intensive care unit — has the capacity to isolate [Ebola] patients," Frieden said. "There is nothing particularly special about the isolation of an Ebola patient other than it's really important to do it right. So ensuring that there is meticulous care of patients with suspected or confirmed Ebola is what's critically important."

Seeking a second opinion, we asked an Ebola expert if U.S. hospitals adopting such measures could contain Ebola and protect their health care workers.

"Yes, I think they can," says **Thomas Geisbert**, PhD, Ebola researcher and professor of microbiology and immunology at the University of Texas Medical Branch at Galveston. "Because there is an understanding and a recognition in the U.S., especially after the anthrax letters and 9/11. There is [heightened] awareness in U.S. hospitals. Most of them have isolation rooms, good barrier precautions and things like that. Quick identification is the key. Identifying that you have a problem quickly — a definitive diagnosis to rule [Ebola] in or out. I think any of the really good hospitals in this country that have good isolation procedures and rooms would have no problem."

The CDC recommends that U.S. health care settings be alert for possible incoming cases of Ebola, emphasizing these basic points:

- Take good travel histories of patients to identify any who have traveled to West Africa within the last three weeks.
- Know the symptoms of Ebola — fever, headache, joint and muscle aches, weakness, diarrhea, vomiting, stomach pain and lack of appetite and, in some cases, bleeding.
- Know what to do if you have a patient who has Ebola symptoms. First, properly isolate the patient. Then, follow infection control precautions to prevent transmission. Most importantly, avoid contact with blood and body fluids of infected people.

REFERENCE

1. CDC. Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals. July 30, 2014. http://1.usa.gov/1pvUSQz

CDC surges Ebola response, sends 50 more personnel

HIC Q&A with Ebola expert

The ongoing record outbreak of Ebola virus in West Africa is killing six out of every ten people infected. And that, grimly enough, is the good news.

"The mortality rate in some outbreaks can be as high as 90%, but in this outbreak it is currently around 60%, indicating that some of our early treatment efforts may be having an impact," said **Stephan Monroe**, MD, deputy director of the National Center for Emerging Zoonotic and Infectious Diseases at the Centers for Disease Control and Prevention.

According to the World Health Organization, since the first report of Ebola infection in March there have been approximately 1323 confirmed and suspected cases reported, with 729 deaths in Guinea, Liberia and Sierra Leone as of July 31st.

The CDC recently surged its response to the outbreak, sending 50 additional disease control specialists into the three countries in an effort to stop the epidemic. However, epidemiologists face not only the problems of low functioning health care systems, but hostility and violence by some who think the medical respondents may be part of the Ebola problem.

The first priority is to find the infected patients, isolate them and then trace down their contacts, CDC director **Tom Frieden**, MD, MPH, said at a press conference. "Finding every single contact of each Ebola patient and following each of the contacts for 21 days, each day checking to see if they have fever," he said. "If they develop fever then they should go to an area where they can be kept apart from other people, tested for Ebola and, if positive, isolated and that whole cycle of identifying their contacts starts again."

Q&A with leading Ebola researcher

As the record outbreak continues we sought further information and insight from a leading Ebola expert, **Thomas Geisbert**, PhD, Ebola researcher and professor of microbiology and immunology at the University of Texas Medical Branch at Galveston. Geisbert and his team have received a $26 million grant from the National Institutes of Health to develop counter measures against Ebola and Marburg virus. The ongoing research includes both treatments and vaccine development. He fielded the following questions from *Hospital Infection Control & Prevention*.

HIC. What is it about Ebola biologically that makes it so lethal — 60% to 90% mortality rate — once infection sets in?

Geisbert: "The disease is almost identical in monkeys as man, and through the studies we've done in non-human primates, we know that the first cell types that are infected are primary immune cells. So it infects monocytes, macrophages, and dendritic cells. Those are really first-line defense cells in developing an effective immune response to a foreign antigen. And so if you knock out the first line of defense then it's easier for the virus to replicate and multiply. If you think about it, it's not really an effective pathogen because an effective pathogen doesn't kill its host. It has a lot of similarities with septic shock. So there are coagulation disorders, disseminated intravascular coagulation, and multiple organ failures. Typically it starts with flu-like symptoms, fever, vomiting, and diarrhea. Then it goes into a systemic infection and the spleen and liver are big targets. The body just kind of shuts down. It is an acute infection with a very rapid disease course."

HIC: This outbreak has many troubling aspects, including the ability to sustain itself and spread and cause infections in health care workers using full barrier precautions. Is there anything different about this particular strain of Ebola?

Geisbert: "There are five different species of Ebola. Three of them have been associated with human outbreaks and significant mortality

in humans. Bundibugyo is one of those species, Sudan is one and Zaire is one. This outbreak is caused by the Zaire species, which is associated with the highest case fatality rates. 'Strain' is kind of taking it down defining it even further. It does appear to be a slightly different strain of the Zaire species than some of the outbreaks. I don't think at this point there's any evidence that suggests that there's something different about this strain that's causing it to be more transmissible. However, I don't think that we really know for sure. I think the probability is low but I don't think we are able to rule it out yet. An example would be a small genetic change in the virus that can cause it to be more or less pathogenic. Historically these Ebola outbreaks have really not been transmitted through the air like influenza or something like SARS. There's really been no evidence that Ebola is transmitted that way and we don't really see any evidence from this outbreak. I think the only thing that we don't know that could potentially make it more transmissible — person-to- person through close contact — would be if there's something about this particular strain that makes it shed higher levels [of virus]. We know that Ebola from this species and all the Ebola can be found in all kinds of body fluids. Obviously blood, but also feces, urine, sweat — things like that. So it's theoretically possible that for some unknown reason this strain maybe is found at higher levels or higher concentrations in body fluids. So for example, if you had a drop of some kind of body fluid with this strain maybe you had ten thousand particles in there and with another strain maybe you have 10. Your absolute exposure would be higher, but this is all hypothetical. We don't know that yet.

HIC: Another deep concern of course, is that health care workers have been infected despite wearing elaborate barrier precautions to treat patients. What do you think is happening there?

Geisbert: "I think that's the $64,000 question. We really don't know. These are heroes who go into these outbreak situations and put their lives on the line working with something that's this deadly. So, you certainly don't want to criticize people that take that risk. At the same time, I mean this outbreak is so large compared to any past Ebola outbreak that the public health folks that really have the expertise in responding to these outbreaks like WHO and the CDC are stretched to the limit. I wish I had an answer for you.

HIC: Have any clear exposure events like a blood splash or a needlestick been reported in the health care worker infections?

Geisbert: "I've heard rumors. I don't have first or second hand information — I have third hand information [that there] may have been a needlestick in one. That's understandable. No matter how well you're trained or how good your skill set is, stuff happens. That kind of thing you can understand."

HIC: Is it possible some transmission is occurring from contaminated environmental surfaces and fomites? Can Ebola spread effectively this way and how long can it survive in the environment?

Geisbert: "There's data that suggests that depending on different environmental conditions it can survive for a fair amount of time. There's some anecdotal information that during the 1995 outbreak of Ebola in Zaire that someone from the CDC found a syringe in a desk drawer that had dried blood in it. I think this was like 30 something days after the syringe was in there they were still able to isolate virus. But that's also telling you there's some kind of a protected serum in blood as it dries down -- kind of almost lyophilized in protecting it. The Russian literature is hard to follow but if you look at that there's some information that says that Ebola virus in cell cultures in culture fluid — their data says it took 53 days to completely have 100% loss where they were not able to detect the virus. So I think a lot of it depends on the environmental conditions. Is the virus subjected to sunlight? UV and heat can inactivate it. Historically if you look at what's happened [in outbreaks] there really isn't any evidence that suggests that it really hangs around for a long time and poses some kind of a problem on a surface.

HIC: The length of this outbreak runs counter to the usual perception of Ebola appearing in explosive short-term outbreaks? What do think are the factors behind this sustained transmission?

Geisbert: I think it's because of the wide area that it's scattered across. Historically, if you look at what's happened in central Africa where these outbreaks have tended to occur sporadically in the Congo or Sudan, there's identification of a small episode or outbreak and WHO, humanitarian aid organizations like MSF, and the CDC jump in and quarantine the patients. They do a great job of getting in there, talking to people, finding out who is infected and quarantining a village or small area. And it just burns out. It's sad, but I mean

you're talking about viruses with really high mortality rates. If you stop the chain of transmission you kill the outbreak. What's been so difficult with what's going on now in West Africa is it's sporadic, random, in the way it's spread out over these different countries. It's popping up in different places across these three different countries and it's a huge geographic area. That makes it really challenging to try to contain."

HIC: There's got to be an epi link there somewhere.

Geisbert: "I couldn't agree with you more, I've told a lot of reporters that I don't think we know why and how. There's probably multiple factors, multiple variables. Transportation is easier now, infrastructure better and in Africa it's easier to go from point to point than maybe it was 20 or 30 years ago.

Their cultural practices are different — the whole burial procedure and touching of the body and things like that. Somebody goes to a funeral or whatever, comes in contact with the virus and then goes a couple hundred miles somewhere else carrying the virus. That could be part of it. I think there is an epi component. We know that fruit bats are a major reservoir, but we don't know if they are the only reservoir. Did something ecological happen to cause the bats to shed more virus or have more people been in contact with bats than they have before? I think these are all plausible explanations — and it may be not one but a combination, a perfect storm." ■

Nebraska biocontainment unit preparing for Ebola

Ten-bed unit has volunteer staff at the ready

Federal public health officials recently contacted clinicians at the Nebraska Biocontainment Patient Care Unit in Omaha to determine if the facility could house Ebola patients if needed as the record outbreak in Western Africa continues. No plans have been set, but the the nation's first and largest biocontainment unit stands at the ready to handle patients with Ebola and other emerging and deadly infections.

The 10-bed biocontainment facility is located 10 minutes from the Omaha airport and near a military base, making it possible to receive patients from anywhere in the country, notes **Angela Hewlett**, MD, MS, associate medical director of the Nebraska Medical Center in Omaha, which houses the unit.

Some of the pathogenic agents the unit is qualified to hand include Ebola and other hemorrhagic fevers, plague, anthrax, and smallpox. The biocontainment unit has its own air handling system with negative airflow and HEPA filtration. It also has a pass-through autoclave and specimen decontamination tank, specialized patient transport systems, and personal protective equipment.[1]

When the biocontainment unit was developed in 2005, the Nebraska health department's goal was to provide a safe health care environment for working with emerging infections without putting other patients at risk, says **Philip W. Smith**, MD, professor in the division of infectious diseases at Nebraska Medical Center.

"The unit has 20 air exchanges per hour and can deal with airborne or contact diseases," Smith says. "We are experts in isolation."

National training center

Front-line infectious disease personnel come to Nebraska for training.

"We do drills with military and people from institutions in other states," Smith says. "We even have a mock patient with Ebola. Our staff will put on protective equipment, and we go through full training."

The hospital and unit also provide training for emergency response teams in the community, Hewlett notes.

MERS is a perfect example of a disease the unit would handle because it has a high mortality rate and, while rare, it was brought to the United States in this year by travelers returning from Saudi Arabia, Hewlett says.

"We are one of only four of these kinds of units across the country, and one of those was shut down," Hewlett notes. "We're the largest unit in the U.S., and one of our major assets is our volunteer staff of people."

Since biocontainment is rarely needed, staff volunteers are sought to move over to the unit when a need arises, she explains.

"Health care workers often are afraid to take care of these patients, but we have a completely volunteer staff that is willing to come in and care for these patients when needed," Hewlett says.

"We had a near miss a few years ago where the unit was activated and a call went out to the volunteer staff, and 100% of the health care providers who got the call were willing to come in to

the unit," she says. "It was a real time drill for an illness that sounded like viral hemorrhagic fever."

The Nebraska unit's volunteer staff, consisting of about 30 people, includes a high skill mix of nurses, respiratory therapists, care technicians, and physicians. They work in their own units, but meet monthly to test and drill protocols established for the biocontainment unit, says **Kate Boulter**, RN, lead nurse of the unit.

"We have drills on the protocols and special equipment, and the staff is very comfortable working in that unit," Boulter adds. "When we all get together we have a huge skill mix and we share knowledge with each other."

The biocontainment unit staff is on call 24/7, but they are only paid for time they work on the unit, she adds.

The unit's communication system is immediate. When a crisis arises, volunteer staff will receive a page and cell phone call within a one minute period, Hewlett says.

Protocols for the unit are stored on the hospital intranet, available to all hospital staff, Boulter says.

"We've had other hospitals contact us and ask for access to our protocols, and we do share," she says.

"We've also done just-in-time videos that people can watch," she adds. "Recently I gave a talk to school teachers on bloodborne pathogen training."

The unit also has an active research program and has done work on decontamination, modeling and pathogen trajectory, Hewlett says.

"We study where particles go in the room based on the air handling system, and we study the various types of protective equipment and its safe removal," she explains. "We've looked at modalities for screening patients during a pandemic." ■

REFERENCE

1. Boulter K, Hewlett A, Schwedhelm S, et al. The Nebraska biocontainment patient care unit. Poster: 10-326. Association for Professionals in Infection Control and Epidemiology (APIC). Anaheim, CA, June 7-9, 2014.

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CNE/CME Objectives

Upon completion of this educational activity, participants should be able to:

- Identify the clinical, legal, or educational issues encountered by infection preventionists and epidemiologists;
- Describe the effect of infection control and prevention issues on nurses, hospitals, or the health care industry in general;
- Cite solutions to the problems encountered by infection preventionists based on guidelines from the relevant regulatory authorities, and/or independent recommendations from clinicians at individual institutions. ■

COMING IN FUTURE MONTHS

- AHA's new antimicrobial stewardship toolkit
- Take-home points from the stop CAUTI project
- CMS: Hospital infection control survey on agenda for FY '15
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CNE/CME Questions

1. The infectious agents involved in a recent series of lapses and oversights in federal labs included:
   A. Pneumatic plague
   B. Botulism
   C. Ebola
   D. None of the above

2. A low-pathogenic H9N2 avian influenza virus sample the CDC sent to a federal poultry research lab was contaminated with which of the following
   A. H5N1 avian flu
   B. 1918 pandemic flu
   C. H7N9 avian flu
   D. MERS "

3. In light of the laboratory breaches, scientists calling themselves the Cambridge Group argued that biomedical research on potentially dangerous pathogens can be performed safely and is essential for a full understanding of microbial diseases.
   A. True
   B. False

4. The CDC Ebola patient isolation guidelines for hospitals call for health workers to wear respiratory protection at least to the level of an N95 respirators if:
   A. the patient is coughing
   B. they will be within three feet of the patient for a prolonged period
   C. they are doing procedures that could generate aerosols
   D. All of the above

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