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Kurt B. Nolte
Office of the Medical Investigator and Departments of Pathology and Radiology (Nolte [https://orcid.org/0000-0003-0257-6284]), University of New Mexico Health Science Center, Albuquerque, New Mexico

Timothy B. Muller
The Office of Research, University of New Mexico Health Science Center, Albuquerque, New Mexico

Adam M. Denmark
The Department of Science and Technology, SmithGroup, Phoenix, Arizona

Ron Burstein
Studio Southwest Architects, Inc, Albuquerque, New Mexico

Yvonne A. Villalobos
The Office of the Medical Investigator , University of New Mexico Health Science Center, Albuquerque, New Mexico

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Design and Construction of a Biosafety Level 3 Autopsy Laboratory

Kurt B. Nolte, MD; Timothy B. Muller, MS; Adam M. Denmark, BArch; Ron Burstein, MA; Yvonne A. Villalobos, MBA

• ***Context.***—**Autopsy pathologists, including medical examiners, provide valuable public health support for infectious disease deaths through surveillance for deaths of public health concern including emerging infections, identifying causative organisms for unexplained deaths, and providing insights into the pathology and pathogenesis of novel or unusual infections. However, autopsy poses biosafety risks to workers within and outside the laboratory. The highest rates of laboratory-acquired infections occur in autopsy workers.**

Objective.—**To design and construct an appropriately biosafe autopsy laboratory.**

Design.—**We conducted a biosafety risk assessment for autopsy workers using the process developed by the US Centers for Disease Control and Prevention and National Institutes of Health and applied these findings as the basis of laboratory design and construction.**

Results.—**Autopsy workers are unpredictably exposed to a variety of infectious organisms, including hepatitis C virus, HIV, and *Mycobacterium tuberculosis*. Hazardous autopsy procedures include using and encountering sharp objects and the generation of aerosols from dissection, fluid aspiration, rinsing tissues, and dividing bone with an oscillating saw.**

Conclusions.—**Exposure to blood-borne and airborne pathogens from procedures that can cause cutaneous inoculation and inhalation of aerosols indicates that human autopsies should be performed at biosafety level 3. We designed a large, entirely biosafety level 3 medical examiner autopsy laboratory using design principles and characteristics that can be scaled to accommodate smaller academic or other hospital-based autopsy spaces. Containment was achieved through a concentric ring design, with access control at interface zones. As new autopsy laboratories are planned, we strongly recommend that they be designed to function uniformly at biosafety level 3.**

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Although few consented autopsies are performed in hospital settings,[1] a large number are currently performed by forensic pathologists working in medical examiner and coroner offices or by hospital-based anatomic pathologists under contract to a medicolegal authority. This medicolegal death investigation system is a platform that supports public health, public safety, and criminal justice.[2] In terms of infectious diseases, this system supports public health by conducting autopsy-based surveillance for deaths of public health concern including emerging infections, identifying causative organisms for unexplained deaths, and providing insights into the pathology and pathogenesis of novel or unusual infections, including, most recently, coronavirus disease 2019 (COVID-19).[3,4] Medical examiners and coroners investigate about 20% of the deaths that occur each year in the United States, including those that are sudden, suspicious, violent, or unexplained. Approximately one-half to two-thirds of these deaths are due to natural causes; of those receiving autopsies, up to 25% are found to result from infections.[5,6] Additionally, consented hospital autopsies also play a vital role in identifying emerging infections and fostering a deeper understanding of pathogenesis.[7] This role has become increasingly valuable during the COVID-19 pandemic.[8]

Performing autopsies on infectious disease fatalities has risks for prosectors and other occupants of autopsy facilities.[9] Concerns about these risks diminish the likelihood that pathologists will perform these important autopsies.[10,11] This paper discusses the risk assessment for performing human autopsies and the design and construction of a medical examiner autopsy laboratory with the biosafety features required to protect the laboratory workers within this environment, as well as the workers and other individuals outside of the autopsy laboratory.

Our institution, the New Mexico Office of the Medical Investigator, is a statewide, centralized, academically based medical examiner agency within the University of New Mexico School of Medicine. Inadequate biosafety protection

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From the Office of the Medical Investigator and Departments of Pathology and Radiology (Nolte [https://orcid.org/0000-0003-0257-6284]), the Office of the Medical Investigator (Villalobos), and the Office of Research (Muller), University of New Mexico Health Science Center, Albuquerque; the Department of Science and Technology, SmithGroup, Phoenix, Arizona (Denmark); and Studio Southwest Architects, Inc, Albuquerque, New Mexico (Burstein).

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Preliminary results from this study were presented at the National Association of Medical Examiners Annual Meeting; September 9, 2008, Louisville, Kentucky; and at the Centers for Disease Control and Prevention 11th International Symposium on Biosafety; January 26, 2010, Atlanta, Georgia.

Corresponding author: Kurt B. Nolte, MD, Office of the Medical Investigator, MSC 07-4040 1, University of New Mexico, Albuquerque, NM 87131 (email: knolte@salud.unm.edu).

and laboratory space created a need for a new facility. A state risk management evaluation indicated that our institution had more than $50 million in potential liability from exposure of autopsy prosectors and other personnel to airborne infectious pathogens, especially *Mycobacterium tuberculosis*.[12] The state legislature provided funds to design and build a new facility.

BIOSAFETY PRINCIPLES

Biosafety is based on the principles of containment and risk assessment. Containment refers to safety methods used to manage infectious materials in a laboratory environment. The purpose of containment is to protect laboratory workers, other persons outside the laboratory, and the external environment from exposure to potentially hazardous agents. Containment is created through facility design, safety equipment, and laboratory policies and practices.[13]

For biosafety purposes, risk assessment is the process that identifies appropriate practices, safety equipment, and facility characteristics that can prevent laboratory-associated infections. Risk assessment is based on the hazardous characteristics of agents (eg, capability to cause disease, virulence, and the availability of effective treatments), the hazardous characteristics of laboratory procedures (eg, generation of infectious aerosols), the potential hazards associated with work practices, and the use of safety equipment and facility safeguards (eg, biosafety cabinets).[13]

The Centers for Disease Control and Prevention and the National Institutes of Health characterize 4 biosafety levels.[13] Each biosafety level is composed of differing combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Infectious agents are stratified by the biosafety level at which they should generally be handled. Germane to autopsy, biosafety level 2 (BSL-2) is used for indigenous and moderate risk agents that cause disease with varying severity (eg, the blood-borne pathogens hepatitis B and C viruses and HIV). The principal hazard related to working with these agents results from percutaneous and mucous membrane exposures and ingestion. Biosafety level 3 (BSL-3) is for work with indigenous or exotic agents with a potential for aerosol transmission (eg, *M tuberculosis*). Biosafety level 4 (BSL-4) is for activity with dangerous and exotic agents that have a substantial risk of causing fatal disease (eg, hemorrhagic fever viruses such as Ebola).

RISK ASSESSMENT FOR PERFORMANCE OF AUTOPSIES

Using the process developed by the Centers for Disease Control and Prevention and the National Institutes of Health, we conducted a risk assessment for workers performing autopsies.[13] Some of the decedents evaluated by medical examiners had died from infectious diseases, of which approximately 58% were infections of public health concern (eg, influenza, tuberculosis, and plague).[3,6] A 1983 study showed that hospital autopsies found significantly more systemic bacterial, viral, and fungal diseases than in previous decades, and that 24% were undetected clinically.[14] Unfortunately, pathologists, and especially forensic pathologists, often do not know which cases have infectious diseases, and, if they suspect an infection based on antemortem information, they usually do not know the specific pathogen. In addition, many infections, such as hepatitis C, HIV, and tuberculosis, are incidental to the cause of death. Up to 90% of intravenous drug users are infected with hepatitis C virus in some parts of the United States.[15] These individuals, when they present to an autopsy service, have usually died from other causes, such as drug poisoning or cirrhosis. Similarly, tuberculosis commonly remains undetected until death. From 1985 to 1988, 5.1% of all tuberculosis cases in the United States were recognized at autopsy.[16] A recent study in Taiwan showed that tuberculosis was present in 0.57% of medicolegal autopsies, and almost half of these cases were unsuspected.[17]

Autopsy poses risks to prosectors within the laboratory and to other individuals outside the immediate autopsy laboratory environment.[9,18] Studies of British clinical laboratories[19–23] have demonstrated that the highest rates of laboratory-acquired infections occur among autopsy prosectors. Autopsy-transmitted infections can potentially occur through percutaneous inoculation and inhalation of infectious droplets and aerosols.[9]

All autopsy prosectors, and especially forensic prosectors, are routinely exposed to blood, open tissues, and a wide variety of sharp objects, including scalpels, needles, broken glass, bone shards, and fragmented projectiles.[24] These sharp objects can perforate gloves and transmit various different types of infections, including hepatitis B and C, acquired immunodeficiency syndrome, tuberculosis, streptococcal sepsis, blastomycosis, coccidioidomycosis, rabies, tularemia, diphtheria, erysipeloid fever, and some of the viral hemorrhagic fevers.[13,20,23,25–44] A calculation of the theoretical career risk for occupational blood-borne infections among forensic pathologists was 2.4% for HIV and 39% (range, 13%–94%) for hepatitis C.[45] These risks are now largely mitigated by using cut-proof mesh undergloves.[46,47]

More insidious than blood-borne pathogens are the agents that can be carried by autopsy-generated aerosols and inhaled by both prosectors and individuals outside of the autopsy laboratory environment.[9] The prototypical organism transmitted in this manner is *M tuberculosis*.[48,49] Other infections, including rabies, plague, legionellosis, meningococcemia, rickettsioses (eg, Q fever), coccidioidomycosis, anthrax, severe acute respiratory syndrome, and COVID-19 can be potentially transmitted in this way.[13,50–62]

Aerosols are composed of particles approximately 1 to 5 μm in diameter that remain suspended in the air for long periods of time and when inhaled can reach the pulmonary alveoli.[63] Particles larger than 5 μm in diameter (eg, droplets generated by splashes) can be inhaled into the mouth or impact other mucosal surfaces and transmit infections.[64,65] However, these droplets travel shorter distances, falling to the ground. All autopsies generate aerosols and larger droplets that can carry infectious agents.[9] Oscillating saws used to divide bone and soft tissue, aspirator hoses used to suction fluid that vent into sinks, and hoses used to spray water onto tissues all generate potentially infectious aerosols.[66–68] Oscillating saws generate large quantities of respirable particles, with concentrations measured as high as 5700 particles/mL in the breathing zone of autopsy prosectors.[66,69] In an experiment where oscillating saws were applied to HIV-infected blood, HIV was recovered from the aerosols generated.[70] Even using autopsy tools such as knives to cut lungs can generate infectious aerosols.[71]

Autopsy can efficiently transmit tuberculosis from the decedent to prosectors and observers. For example, 8 of 35 medical students were infected from a 1-hour autopsy exposure to a decedent with tuberculosis.[72] Autopsy-generated tuberculosis outbreaks have been observed in

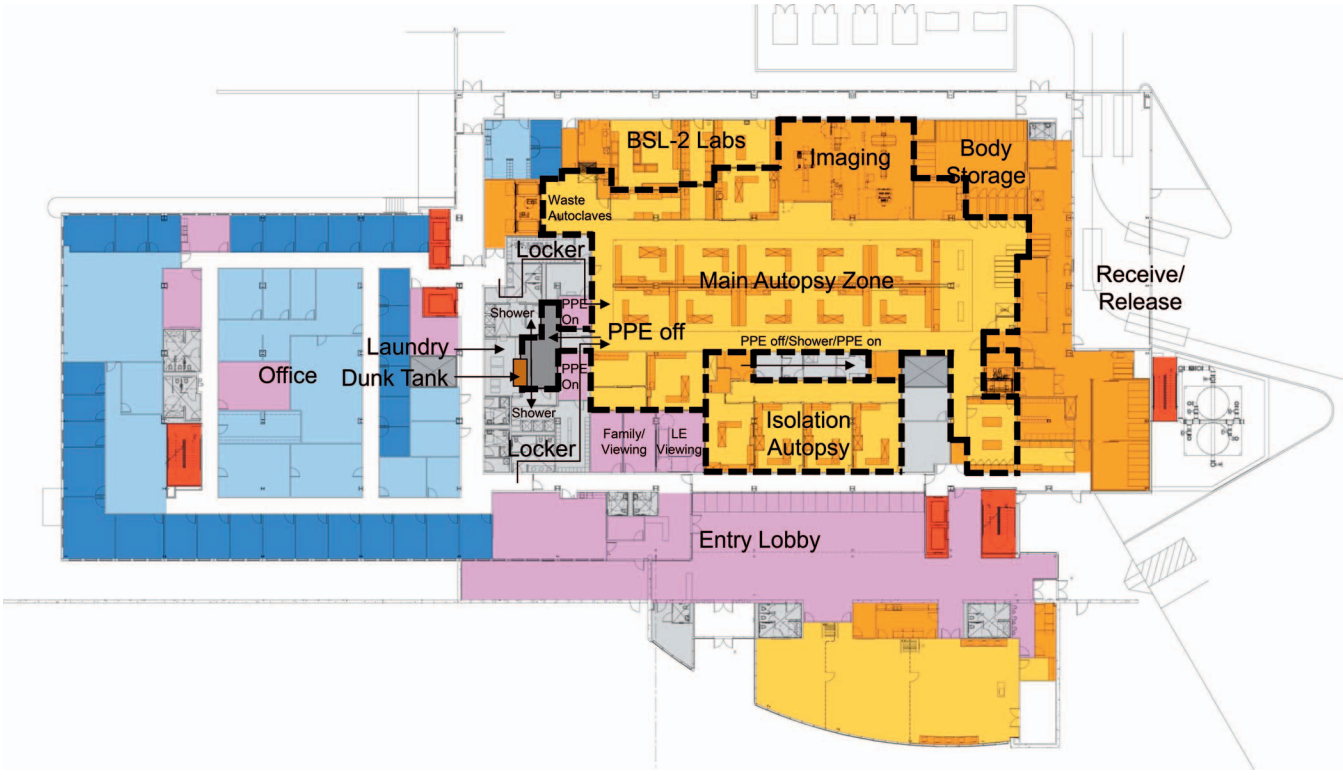

Figure 1. *Facility floor plan. Biosafety level (BSL)-3 envelope circumscribed by dashed line. The routes through which personnel enter and leave the BSL-3 laboratory are identified with fine arrows. A pass-through chemical dunk tank and laundry room to process contaminated personal protective equipment (PPE) are noted with heavier arrows.*

several medical examiner offices and hospital autopsy services.[73–77] In 2 of these situations, the infections were attributed to inappropriate and inadequate facility ventilation.[75,76] Positive pressure ventilation resulted in the infection of a secretary and an investigator who worked outside of the autopsy room.[75] In 2 other outbreaks, prosectors wore inadequate respiratory protection.[73,74]

In summary, every autopsy potentially has a biosafety risk for prosectors.[9,78] Autopsy prosectors are unpredictably exposed to a variety of infectious organisms, including hepatitis B and C viruses, HIV, and *M tuberculosis*.[9] Hazardous autopsy procedures include the use of sharp instruments, dissecting and encountering unexpected sharp objects,[24] and the genesis of aerosols.[66,67,69,71] The combination of exposure to both blood-borne and airborne pathogens from procedures that can cause cutaneous inoculation and inhalation of aerosols indicates that autopsies should be performed at BSL-3 for the safety of prosectors and others.[9]

DESIGN OF A BSL-3 MEDICOLEGAL AUTOPSY FACILITY

Although biosafety standards have been well characterized for biomedical and microbiological laboratories, including agent-specific degrees of risk,[13] less attention has been paid to biosafety in autopsy laboratories. However, the principles of biosafety developed for clinical and research laboratories can be translated and applied to autopsy laboratories.[9] The key BSL-3 features identified for autopsy facility design are a separate autopsy room with lockable doors that restrict access to autopsy personnel; balanced room ventilation, so that airflow is unidirectional and inward (negatively pressured) and then exhausted to the outside; sealed penetrations through the laboratory envelope (walls, floors, and ceiling), including door frames; easily cleaned and decontaminated walls, floors, and ceilings; monolithic and slip-resistant floors; vacuum lines with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters; and containment features verified by experts before work is initiated and annually.[9]

A team of specialists with expertise in forensic pathology and autopsy performance, architecture, laboratory design, and biosafety designed our medical examiner laboratory. Because of the risk assessment conducted internally and detailed above, the autopsy laboratory was designed to function fully at BSL-3 and have the capacity to handle the entire institutional autopsy caseload (approximately 2000 autopsies per year at time of design). This 12 511-sq-ft (1162-m^2) autopsy laboratory is one of the largest BSL-3 laboratories in the world.

General Design Concepts

The Office of the Medical Investigator autopsy and support laboratory space occupies a distinctly separate area of the building from administrative space and the decedent drop-off/pickup zone (Figure 1). The BSL-3 autopsy laboratory design uses the principles of concentric ring containment and access control.[13,79] The concentric ring construction puts the area of highest biosafety need (BSL-3 isolation autopsy) at the core of the laboratory, surrounded by zones of decreasing biosafety (BSL-3 general autopsy followed by BSL-2 support laboratory space) (Figure 2). The concentric ring design allows for unidirectional airflow. Because of constraints created by the building lot, these concentric rings are eccentric in shape. Both the BSL-3

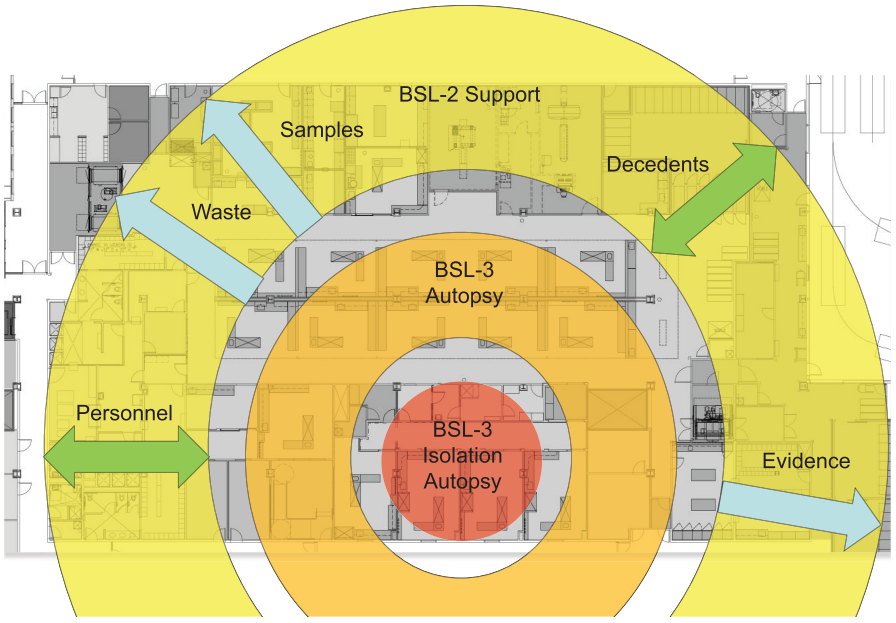

Figure 2. *Concentric ring design depicting relationships between biosafety zones and flow of personnel, decedents, samples, evidence, and waste overlying corresponding floor plan.*

isolation autopsy zone and the BSL-3 general autopsy zone are within the BSL-3 envelope, which is an airtight boundary created by the walls, ceiling, and floor. All penetrations of the envelope (power, water, sewer, air) and passage points for personnel, decedents, specimens, and waste are sealed to prevent air leakage and potential exfiltration of airborne biological contaminants from the laboratory space to the external environment. The prevention of air leakage is also largely dependent on a unidirectional negative pressure ventilation system. To prevent contamination of the environment beyond the autopsy laboratory, access to and egress from the BSL-3 zone is controlled for personnel, decedents, samples, evidence, and waste.

BSL-3 Isolation Autopsy Zone

The BSL-3 isolation autopsy zone is separated from the BSL-3 general autopsy space and is composed of 4 separate autopsy rooms designed to handle cases in which the decedent's antemortem symptoms or diagnoses indicate a likelihood of an infectious disease being present at autopsy.[3] The isolation rooms limit the number of prosectors potentially exposed to a case. The rooms contain downdraft autopsy tables (Figure 3) designed to pull air away from the prosectors' breathing zone, protecting them from airborne pathogens.[9,80] The isolation rooms are outfitted with fully exhausted chemical fume hoods with HEPA-filtered exhaust. They can be used to dissect and sample specific organs and tissues that pose special biological or chemical hazards to prosectors (eg, tuberculous lungs and cyanide-containing stomachs).[71,81] The isolation autopsy zone has an integrated decontamination transition path (personal protective equipment [PPE]-doffing room, shower/locker room, PPE-donning room) that bridges to the general autopsy zone. Each isolation autopsy room has an external vaporous hydrogen peroxide port for chemical decontamination.

BSL-3 General Autopsy Zone

The BSL-3 general autopsy space has an open floor plan with 12 downdraft autopsy tables (Figure 4) and is designed for handling the daily caseload of decedents without symptoms or diagnoses predictive of infections. This zone connects to passage points for personnel, decedents, specimens, and waste. The zone also houses a radiologic imaging suite with computed tomography and magnetic resonance imaging scanners, an anthropology/decomposed body autopsy room, and an autopsy bay with an external observation area for police officers. The general autopsy zone is fully surface decontaminated daily. If there were to be a catastrophic event, this laboratory zone would be sterilized with chlorine dioxide, similar to how chlorine dioxide was used to decontaminate the Hart Senate Office Building and other facilities after the anthrax attacks[82] in 2001.

BSL-2 Support Laboratory Zone

The BSL-2 support laboratory space is outside of the BSL-3 envelope and provides space for fixed tissue dissection, chemical preparation, dry bone anthropology examination, and specimen processing. The BSL-2 zone can be accessed by personnel through a proximity card–secured door directly from the administrative zone.

Worker Access to Autopsy Laboratory

The entrance and egress of autopsy workers, decedents, and specimens to and from each area of the BSL-3 autopsy laboratory is controlled. Prosectors enter the laboratory from the administrative zone by first passing through a proximity card–secured door to a locker room. After removing street clothes and donning scrub suits and special autopsy socks and shoes, prosectors pass through a unidirectional door into an anteroom, where they don PPE. From the anteroom they pass through another unidirectional proximity card–secured door into the autopsy laboratory.

The PPE-removal process is isolated from the PPE-donning process (Figure 1). When leaving the autopsy laboratory, prosectors remove the most exterior and contaminated PPE (eg, aprons, sleeve covers, outer gloves, and middle mesh gloves) in the autopsy room while still wearing respirators and pass through a door into a dirty atrium, where they remove their gowns and high-top autopsy shoe covers, also while still wearing respirators.

Figure 3. *Downdraft autopsy table.*

Figure 4. *Biosafety level 3 general autopsy zone.*

Figure 5. *Body transfer coolers: pass-through from autopsy zone to storage cooler.*

Figure 6. *Pass-through air lock for autopsy specimens.*

Figure 7. *Gurney washer.*

They then pass through a disinfectant-filled foot bath and through another door into a second atrium (which has a chemical safety shower that issues water in the event of a chemical exposure) to remove and decontaminate face shields and powered air-purifying respirators or remove N-95 respirators, surgical caps, and interior gloves and wash hands and arms in hands-free sinks. As a last step, prosectors return to the locker room to remove scrub suits, socks, and shoes; shower; and change into street clothes. The doors between all of the vestibular rooms are interlocked so that only one door to a room can be open at a time. An interlocked pass-through chemical disinfectant dunk tank is used to decontaminate autopsy gowns and autopsy towels before laundering.

Air Handling

The autopsy suite is negatively pressured with regard to the adjacent rooms (eg, anteroom) and has greater than 12 air exchanges/h.[63] There is a stepwise gradient of negative pressure between the rooms as the prosectors move from the administrative zone through the intermediate rooms and into the general autopsy room. The BSL-3 isolation zone is negatively pressured with regard to the BSL-3 general autopsy zone. The pressure gradients are verifiable from pressure gauges. Air moves from clean zones to progressively dirtier zones and eventually is forcefully ejected from the roof of the building away from occupied areas and air intake locations. All of the air from the isolation autopsy rooms and from each of the downdraft autopsy tables in the general and isolation zones is HEPA filtered prior to exhaust. We decided not to use HEPA filtration for the entire BSL-3 laboratory because it would require a much larger mechanical system and consume more energy.

Decedent Access

Decedents are transported to the facility in body bags and are dropped off at a sally port, where they are accessioned and moved on a gurney/tray to a rack in a large refrigerated cooler (capacity 150 bodies). The body cooler is connected to the BSL-3 general autopsy zone by 6 transfer coolers housing 2 tiers of trays (Figure 5). The doors on each end of the transfer cooler are interlocked so that only one door can be open at a time. Bodies move out of the autopsy room to the refrigerated coolers in decontaminated body bags through the same transfer coolers.

Specimen Processing

All specimens (eg, toxicologic, microbiologic) move out of the autopsy laboratory from a room where the specimen containers are surface decontaminated and pass through an air lock with interlocked windows (Figure 6) into a specimen-receiving laboratory in the BSL-2 zone. They are received by PPE-clad technicians, who log the specimens, generate the request forms, and prepare the specimens in correct biohazard transport containers. From the receiving laboratory, the specimens are transferred to analytical laboratories. Personal effects from the decedents and

medicolegal evidence from cases are processed in an evidence-processing zone. These materials are then transferred through an air lock in decontaminated containers to evidence and personal effects lockers in the BSL-2 zone for disposition. Postmortem specimen containers are decontaminated in the autopsy suite prior to being submitted to the specimen-receiving laboratory through the pass-through air locks with interlocked windows shown in Figure 6.

Solid and Liquid Waste Handling

Solid wastes that result from the autopsy process (eg, contaminated surgical sponges and PPE) are collected in biohazard trash bags and transferred to large pass-through autoclaves positioned between the autopsy zone and an external hallway adjacent to a service elevator. Autoclaved waste is stored short term outside of the autopsy laboratory for later collection as medical waste. The doors on the autoclaves are interlocked so that only one side can be opened at a time. Contaminated liquid waste from the autopsy tables, sinks, autoclaves, and gurney washer (described below) is drained to a large effluent decontamination system in the basement, where it is heated to 250°F (121.1°C) before passing into the sanitary sewer system. The system was designed to have the capacity for continuous running water at the autopsy tables. Contaminated surgical instruments can be cleaned and chemically decontaminated at each autopsy table or processed with dishwashers in an instrument preparation room within the BSL-3 general autopsy zone.

Gurney Cleaning

Contaminated gurneys and body trays are cleaned in an adapted large pass-through animal cage washer positioned between the BSL-3 general autopsy zone and the body-receiving area outside the envelope (Figure 7). Gurneys and trays can be put into the washer from either side. However, only one door can be open at a time.

DISCUSSION

Accurately assessing the risks of autopsy allowed the design and construction of a high-throughput forensic autopsy laboratory that uniformly protects worker health and mitigates risk. The Office of the Medical Investigator BSL-3 autopsy laboratory, combined with corresponding policies and procedures and PPE commensurate with the facility, uniformly provides prosectors with a high level of protection from both airborne and blood-borne pathogens. Additionally, the facility design contains airborne pathogens through secondary barriers and thereby protects nonautopsy workers and others occupying office space outside of the autopsy laboratory.

There have been other attempts to achieve containment for the purposes of autopsy. In response to the need to perform autopsies on individuals dying of an illness thought to be a viral hemorrhagic fever and later determined to be a novel disease (hantavirus pulmonary syndrome), our institution created a single BSL-3 isolation autopsy room[6] in 2000. The US Army Medical Research Institute of Infectious Diseases has a suite designed for BSL-4 autopsies. This suite was rarely needed or used for its original purpose, so it was often used as a necropsy suite for selected nonhuman primate studies on BSL-4 agents, primarily Ebola and Marburg viruses (Nancy K. Jaax, DVM, written communication, May 19, 2020). In response to the outbreak of severe acute respiratory syndrome caused by a highly infectious coronavirus, authorities in China created a single-table BSL-3 isolation autopsy facility.[60] Similarly, in response to the same epidemic, authorities in Singapore created a mobile and containerized BSL-4 single-table autopsy laboratory.[83] Although the BSL-3 isolation facility in China protected autopsy workers, it was not designed for comfort, efficiency, or throughput and had no water supply or sewer connection. The advantages of the BSL-4 facility developed in Singapore are its mobility, low cost, and high level of autopsy protection. It, too, is only ideal for handling small numbers of cases.

Unfortunately, a large majority of autopsy facilities both nationally and internationally were designed with limited biosafety features. A 2018 survey of US medical examiner and coroner offices serving populations greater than 300 000 people, including at least 1 respondent from 47 of 50 states and the District of Columbia, showed that only 19% had some form of BSL-3 autopsy space.[84] An earlier survey of US medical examiner and coroner offices serving similar populations revealed approximately half of the facilities had some features of BSL-3 (negative pressure ventilation, double-door access, air exchanges for ventilation).[85] However, none were designed to fully function at BSL-3. Indeed, it is thought[6,9,58,84] that many medicolegal autopsy facilities barely function at BSL-2. A survey of 48 medical isolation facilities for managing cases of highly infectious diseases in 16 European Union countries showed that only 16.6% had access to a BSL-3 autopsy room.[86]

To be able to safely handle decedents with emerging infectious agents such as COVID-19 and infections of public health significance seen in a typical autopsy caseload, our national and international autopsy infrastructure needs to improve. In general, US medical examiner and coroner offices are aging.[6,9] Although there are no published data on the biosafety statuses of hospital autopsy laboratories, the mean age of medicolegal facilities accredited by the National Association of Medical Examiners in 2011 was 26 years,[87] making them a challenge to retrofit for biosafety features, especially ventilation. As these facilities are replaced by new facilities, we recommend that future autopsy laboratories be designed and constructed to function at BSL-3. As it is impossible to accurately predict which autopsy cases have an infection potentially transmissible by autopsy aerosols, we believe that all autopsy laboratories should uniformly function at BSL-3, rather than having a separate, stand-alone BSL-3 autopsy room to be used only when a highly transmissible infection is suspected. This all-hazard approach will best protect autopsy workers and facility users and ensures that autopsies important for the maintenance of public health will continue to occur in an appropriately safe laboratory. Although we designed and constructed a large BSL-3 medical examiner autopsy facility, the design principles and characteristics can be scaled to accommodate smaller academic or other hospital-based autopsy spaces. Although some hospitals no longer provide space for autopsy facilities,[1] a regional academic model is emerging to support this critical service,[88] and these facilities should also be constructed to function at BSL-3.

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