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MEETING REPORT

HIGH-CONTAINMENT BIODEFENSE RESEARCH LABORATORIES: MEETING REPORT AND CENTER RECOMMENDATIONS

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ON JULY 11, 2006, THE CENTER for Biosecurity of the University of Pittsburgh Medical Center (UPMC) convened an invitational meeting to discuss high-containment biodefense research in the United States. Our goal was to analyze whether and how the growing numbers of laboratories could be operated safely, productively, and with respect for the communities in which they are placed.

The group was composed of distinguished scientists and experts in biosafety, biosecurity, and public health and included proponents of the laboratories as well as those who oppose the recent expansion. Participants were not asked to reach consensus on the topics discussed; rather, the intention was to spur an open discussion of key issues related to high-containment laboratory research and to seek proposals for constructive actions. Meeting participants are listed in Appendix I. Individual comments were not for attribution, but some quotations that make a compelling case for particular actions are cited without attribution.

In this report, the Center for Biosecurity analyzes a number of critical issues related to high-containment laboratories and offers recommendations intended to improve their productivity, safety, and public engagement practices. These recommendations have been informed by pre- and post-meeting discussions with a range of experts, a survey of peer-reviewed literature, press reports, and discussions during the meeting on the issues summarized in this report. Our recommendations are not necessarily endorsed by the participants in the July 11 meeting.

BACKGROUND ON HIGH-CONTAINMENT BIOLOGICAL LABORATORIES

Laboratory biological research in the U.S. can be categorized by the safety level at which it is performed. The four safety levels are termed Biosafety Level (or BSL) 1 through 4. They are described in detail at the National Institutes of Health (NIH) website: http://www3.niaid.nih.gov/Biodefense/Public/Biolab.htm.[1] For the purposes of this report, high-containment biological research refers to work performed in the two highest levels, BSL-3 and BSL-4. BSL-3 laboratories are used to study biological agents that are potentially lethal and transmissible by the aerosol route and require special safety design features, such as sealed windows and specialized ventilation systems. BSL-4 laboratories are typically used to study lethal agents for which no vaccine or therapy is available. They incorporate the BSL-3 laboratory safety features, plus additional safety features such as full-body suits ventilated by life support systems.[2] In general, necessary biosafety precautions are dictated by the specifics of a biological experiment. Additional safety protection can be added to any biosafety level, from BSL-1 to -4, depending on the needs of a specific experiment.

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A few years ago, only a handful of laboratories in the world operated at BSL-4, the highest level of containment. In the coming years, BSL-4 capacity will be expanded at least tenfold in the U.S., as laboratories currently under construction begin operations (see Figure 1 for a world map of BSL-4 laboratories, and Table 1 for a list of planned and operational BSL-4 laboratories).

A 2005 National Institutes of Health (NIH) survey estimates that there are currently 277 BSL-3 laboratories in the U.S.[3] The number may be higher: A 2005 Department of Homeland Security (DHS) and Department of Health and Human Services (HHS) report estimates that there are more than 600 BSL-3 laboratories in the U.S.[4] More BSL-3 laboratories are being built specifically for biodefense research, principally funded by the National Institute of Allergy and Infectious Diseases (NIAID) within the NIH (see Table 2 for a list of planned biodefense BSL-3 laboratories funded by NIAID).

The rapid expansion of high-containment laboratories has raised a number of policy issues, such as the adequacy of existing biosafety and biosecurity measures, personnel training in biosafety, transparency of laboratory policies and research directions, and the rationale justifying the BSL-3 and BSL-4 laboratory expansion. Additionally, public protests have occurred in many of the laboratory locations, raising the question of how the public should be involved in decision-making processes related to the labs, both in the siting process and once they are operational. Protests may have diminished some universities' success in receiving federal funding to build a high-containment laboratory.[5,6] In addition, public protests against the siting of the Boston University National Biocontainment Laboratory eventually led to citywide regulations on research activities and practice.[7]

Our meeting focused on these policy issues as they relate to high-containment laboratories in the U.S. However, we recognize that high-containment laboratory expansion is an international phenomenon. For example, in Southeast Asia, newly constructed BSL-3 laboratories are projected to become operational in 2006: in India (16 new laboratories), Thailand (5), Indonesia (2), Bangladesh (1), and Myanmar (1).[8] Our premise is that processes that make U.S. labs safer, more productive, and more transparent to the public will be helpful to laboratories and communities elsewhere in the world.

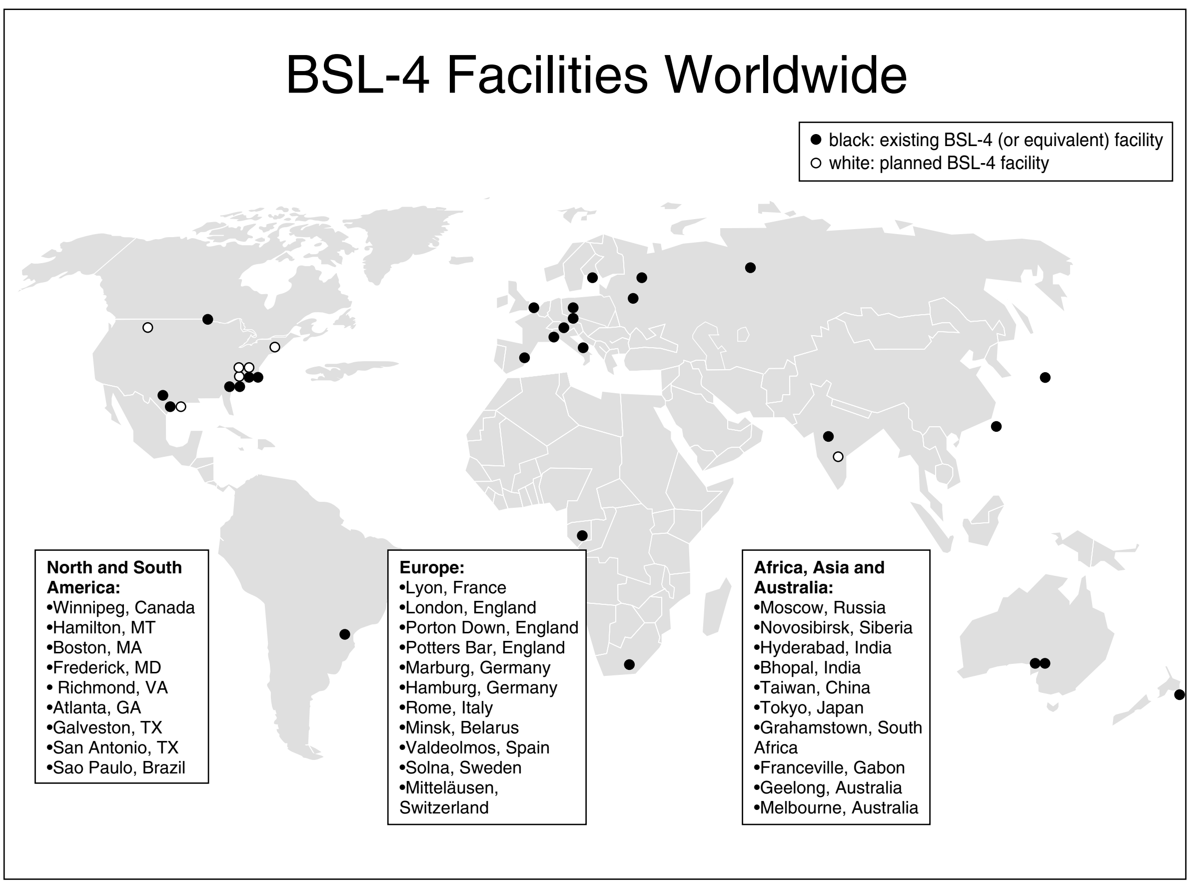

Figure 1. BSL-4 Facilities Worldwide

Table 1. BSL-4 Laboratories in the United States

Institution	Name of the Laboratory	Funds Allocated	Operational Status	Other Information
Centers for Disease Control and Prevention (Atlanta, GA)	CDC Special Pathogens Branch, Emerging Infectious Diseases Laboratory http://www.cdc.gov/ncidod/dvrd/spb/mnpages/whoweare.htm#what	$214 million to complete the Emerging Infectious Diseases Laboratory in October 2005[26]	New facility opened in 2005; prior lab opened in 1988[26]	
USAMRIID (Ft. Detrick, MD)	http://www.usamriid.army.mil/	$6 million upgrade to BSL-4 facilities in 2005; expansions projected to begin in 2006	1969; estimated completion date for upgrades is 2012[27]	
Southwest Foundation for Biomedical Research (San Antonio, TX)	BSL-4 Laboratory, Department of Virology and Immunology http://www.sfbr.org/pages/virology_index.php	As of 2005, endowment exceeds $80 million,[28] 70% funded by competitive peer-reviewed NIH grants, 12% private endowments.	Gloveboxes since the 1970s;[29] went to full biocontainment in 1999; opened in March 2000[30]	Conducts classified research; also has a national primate research center.[30] Serves as part of the BSL-4 Core of the NIAID Western Regional Center of Excellence in Biodefense.[31]
University of Texas Medical Branch (Galveston, TX)	UTMB Robert E. Shope, MD, BSL-4 Laboratory http://www.utmb.edu/CBEID/safety.shtml	$15.5 million[32]	June 2004[32]	Serves as part of the BSL-4 Core of the NIAID Western Regional Center of Excellence in Biodefense.[31]
Georgia State University (Atlanta, GA)	Viral Immunology Center http://www.cas.gsu.edu/units/default.aspx?unit=biotech&section=viral	NIH grants,[33] National Center for Research Resources (NCRR)	operational	
Virginia Commonwealth University (Richmond, VA)	Virginia Division of Consolidated Laboratory Services (DCLS) http://dcls.dgs.state.va.us/	$63 million to complete BSL-4 facilities building[34]	operational	
Department of Homeland Security (Ft. Detrick, MD)	National Biodefense Analysis and Countermeasures Center (NBACC) http://www.dhs.gov/xres/labs/gc_1166211221830.shtm	$128 million appropriated over FY2003–2005; estimated construction cost $141 million[35]	Broke ground June 2006; planned opening in 2008[38]	Governed by DHS Science and Technology Directorate; will conduct bioforensics and biological threat characterization.[36] The NBACC facility will provide biocontainment laboratory space for the National Bioforensic Analysis Center (NBFAC) and the Biological Threat Characterization Center (BTCC).[37]
National Institute of Allergy and Infectious Diseases (Hamilton, MT)	Rocky Mountain Laboratory (RML) Integrated Research Facility http://www3.niaid.nih.gov/about/organization/dir/rml/integratedResearchFacility.htm	$66.5 million budgeted by Congress[38]	Construction began in 2004; slated for occupancy in 2007[39]	
National Institute of Allergy and Infectious Diseases and University of TX Medical Branch (Galveston, TX)	Galveston National Biocontainment Laboratory http://www.utmb.edu/GNL/faqs/3.shtml	Total anticipated cost: $167 million ($110 million funded by NIH; UTMB to provide remainder) Estimated annual operating costs: $20 million+[40]	Projected opening date: June 2008[41]	To study anthrax, plague, hemorrhagic fevers (such as Ebola), typhus, West Nile virus, influenza, drug-resistant TB, etc.[42]
NIAID and Boston University (Boston, MA)	BU National Center for Emerging Infectious Diseases and Biodefense http://www.bu.edu/neidl/	$178 million ($128 million by NIAID)[43]	Expected construction completion date: 2008[44]	
National Institute of Allergy and Infectious Diseases (Fort Detrick, MD)	NIAID Integrated Research Facility at Fort Detrick http://www.niaid.nih.gov/factsheets/detrick_qa.htm	$105 million budgeted[45]	Estimated completion date: summer 2008[27]	

(*continued*)

Table 2. NIAID-funded Regional Biocontainment Laboratories (BSL-3)

Institution	Name of the Laboratory	Funds Allocated	Operational Status	Other Information
Colorado State University (Fort Collins, CO)	Regional Biocontainment Laboratory http://ghrc.colostate.edu/index.asp[47]	$22.1 million for construction of the building,[46] $16 million from NIAID[47]	Estimated completion: August 2008[47]	This site will also hold the new CDC $80 million Division of Vector-Borne Infectious Diseases, and the Regional Center of Excellence for Biodefense and Emerging Infectious Diseases.[48]
Duke University Medical Center (Durham, NC)	Global Health Research Building (GHRB) http://humanvaccine.duke.edu/modules/home/index.php?id=1	$20 million for construction:[49] $12 million from NIAID specifically for the RBL; $4 million from Duke	Estimated completion: 2006[50]	Will also house the federally funded $45 million Regional Center of Excellence for Emerging Infections and Biodefense (SERCEB), a consortium of which Duke is a member.[49]
George Mason University (Fairfax, VA)	George Mason University Biomedical Research Laboratory http://brl.gmu.edu/	$42 million in total: $25 million from NIAID; $15.3 million in matching funds from GMU; $2.5 million from the state[51]	Estimated completion: 2009[52]	Administered by the National Center for Biodefense and Infectious Diseases (NCBID) at George Mason University[51]
Tufts University, Cummings School of Veterinary Medicine (Grafton, MA)	Regional Biosafety Laboratory-New England (RBL-NE) http://www.tufts.edu/vet/rbl/	$20.8 million in total: $15.6 million from NIAID; $5.2 million from Tufts[53]	Estimated completion: 2009[53]	
Tulane National Primate Research Center (Covington, LA)	Regional Biocontainment Laboratory http://www.tulane.edu	Total project cost: $20 million;[54] $13.6 from NIAID[55]	Estimated completion: 2006[56]	
University of Alabama at Birmingham School of Medicine	Southeast Biosafety Laboratory Alabama (SEBLAB) http://main.uab.edu/show.asp?durki=61656	Total cost $22.3 million:[57] $15.9 million from NIAID;[58] $5 million from state;[57] $1.4 million from UAB[57]	Estimated completion: late 2007[57]	Southern Research Institute is a partner of University of Alabama in the operation of the laboratory.[59]
University of Chicago (Chicago, IL)	The Ricketts Laboratory http://www.htrl.uchicago.edu/	$31 million to build;[60] $25 million from NIAID[61,62]	March 2008[63]	Will also support the Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research, a consortium of research institutions funded by NIAID.
University of Hawaii at Manoa	Pacific Regional Biocontainment Laboratory http://www.hawaii.edu/	$37.5 million total; $25 million from NIAID;[64] $12.5 million from the state[65]	Construction begins in 2008; estimated completion: 2010[65]	
University of Louisville (Louisville, KY)	The Center for Predictive Medicine http://www.louisville.edu/community/biosafetylab/	$34.6 million total; $22 million from NIAID; $12.6 million from the university[66]	April 2009[66]	
University of Medicine and Dentistry of New Jersey (Newark, NJ)	New Jersey Medical School Center for Infectious Disease Research—RBL http://www.umdnj.edu/	$27.8 total; $20.9 million from NIAID;[67] $6.9 million from UMDNJ[68]	Construction to be completed in June 2008[69]	
University of Missouri–Columbia College of Veterinary Medicine	University of Missouri–Columbia Regional Biocontainment Laboratory http://www.rbl.missouri.edu	$16.5 million total; $12 million from NIAID[70]	Construction to be completed 2007[70]	
University of Pittsburgh (Pittsburgh, PA)	The Regional Biocontainment Laboratory at the Bioscience Tower III (BST3) http://www.pitt.edu/	$17.5M grant from NIAID specifically for the RBL[71]	Completed	BST3 will cost $205.5 million in total, and will house other research laboratories in addition to the RBL.[72]
University of Tennessee Health Science Center (Memphis, TN)	University of Tennessee Health Science Center Regional Biocontainment Laboratory http://www.utmem.edu/	$25 million total; $17.7 million from NIAID; $7.3 million from UTHSC[73]	2008[73]	

BIOSAFETY TRAINING

More people will soon be working in high-containment laboratories than ever before. For example, the Boston University National Biocontainment Laboratory will create an estimated 600 jobs,[9] and the not-yet-sited National Bio and Agro-Defense Facility may employ more than 300 researchers, technicians, and support staff.[10] Not all of these new employees will work in high-containment conditions, but it is widely agreed that the influx will strain the current national capacity for biosafety training.

Most research institutions require that all laboratory workers take a short class in biosafety principles. For workers in high-containment laboratories, advanced biosafety is usually taught within a mentor-apprentice relationship. Generally, as trainees improve, they move to higher levels of containment and independence. While there are some training programs available to supplement on-the-job experience (e.g., the Center for Public Health Preparedness and Research program at Emory University[11]), they are insufficient to build the workforce of researchers, technicians, and biosafety professionals needed to make the newly developed high-containment labs productive and safe.

Biosafety training entails more than learning to operate safety equipment, such as the full-body suit worn in many BSL-4 laboratories. Working safely with pathogens requires sound judgment, informed mostly by technical training and experience. As one meeting participant said, "I fear that some of our researchers believe that the engineering controls will provide their safety. And yet . . . it's the procedural controls and the practices of biosafety within the laboratory, regardless of what kind of building you're in, that are going to be the most critical in maintaining good safety." This was demonstrated in the SARS laboratory accidents that occurred in Singapore, China, and Taiwan, which were thought to have been caused not by equipment failure but by human error.[12–15]

Safety procedures for working with biological pathogens are more complicated and contextual than those for more quantifiable risks, such as radiation. Biological experimentation holds risks that change depending on the details of an experiment. Thus, each experiment requires a separate analysis of potential risks to determine appropriate research procedures. For example, an experiment that could normally be performed at a low biocontainment level may need increased biosafety protections if the researcher is immunocompromised, or if a large volume of infectious material is being handled. Likewise, a procedure that was always conducted at BSL-4 may be performed at BSL-3 if a vaccine becomes available that can protect the laboratory worker. A good biosafety officer can help a researcher determine the best biosafety procedures and practices for these laboratory-specific, experiment-specific decisions, so that the laboratory remains productive and safe. Unfortunately, as one meeting participant said, "I don't know of any program in the country right now that is really focusing attention on building that body of biosafety professionals that we need." One exemplary training program for biosafety officers, the National Biosafety and Biocontainment Training Program (NBBTP),[16] only graduates one or two biosafety professionals per year.

The diverse research backgrounds of the scientists now entering work on pathogens also increases the need for safety training in high containment. As one meeting participant said, "We're going to have all of these researchers and PIs who have crossed out 'plant' on their grants and written in 'anthrax' and have gotten funded."* The causative agent of anthrax can be worked on in a variety of biosafety levels, but the point is that many researchers will be working on potentially lethal organisms for the first time. Participation by scientists with diverse scientific backgrounds can be a positive development for research in new directions in a field and is the norm for scientific discovery. For example, when funding for HIV/AIDS research became available in the 1980s, researchers who had never previously worked with an infectious disease poured into the field. Nonetheless, for many researchers beginning to work with dangerous pathogens, the change in safety culture and safety practices will be serious. In many other areas of biological research, it is more important to protect the experiment from being contaminated by bacteria or viruses in the air than to protect the researcher from the experiment. Scientists coming from these low-risk fields into high-containment research will not be accustomed to the risks of infection and will need additional training. There also may be scientists coming from outside the biological sciences, from such areas as physics and chemistry, who may need additional training. One meeting participant remarked that there are "engineers . . . coming into [biodefense research] now through synthetic biology . . . who don't think of things as being self-replicating. And they are treating their experimental substrates as if they are not self-replicating."

The workforce that is needed to make the high-containment laboratories productive and safe is not yet in place. To develop the workforce, NIH should first assess how many people will require training for work in the high-containment laboratories, and develop and fund training programs that can supplement on-the-job training. Biosafety professionals with experience in laboratory research will be needed to provide training for and consultations with the researchers. Now that the Pandemic and All Hazards Preparedness Act (S. 3678) has been enacted, the National Science Advisory Board for Biosecurity (NSABB),[17] an advisory

*Bacillus anthracis, the causative agent for anthrax disease, is usually worked on in BSL-2 facilities, although it can be worked with at varying BSLs. However, the point remains that new biodefense researchers may be unused to working with lethal pathogens.

board to the Secretary of HHS on life science issues, may be directed to give their advice on "a core curriculum and training requirements for workers in maximum biological laboratories."[18] The diverse perspectives and backgrounds of NSABB members will be useful in establishing biosafety training standards on which to base on-the-job training.

Ultimately, it is the laboratory director's responsibility to ensure that all laboratory personnel "demonstrate high proficiency in standard microbiological practices and techniques," as stated in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidebook, published by the Centers for Disease Control and Prevention (CDC) and NIH.[2] But relying solely on the mentor-apprentice tradition of training for biosafety will not be sufficient to train the influx of high-containment scientists and technicians. Developing core competencies and standards will be useful in order to conserve mentors' valuable time and abilities.

Center for Biosecurity Recommendation #1:

> Biosafety training programs need to be expanded to accommodate researchers entering high-containment biological laboratory research. HHS should perform a needs assessment for training laboratory workers and biosafety officers at high-containment facilities. HHS should develop standardized core competencies for safety training of workers and scientists, to increase the efficiency of the current mentor-apprentice tradition.

Information Exchange Between Laboratories

The implementation of the Select Agent Rule[19] and concerns about legal liability have inadvertently become major barriers that are preventing high-containment laboratory researchers from learning from each other's experiences in biosafety practices.

Individuals who wish to work with a wide range of pathogens must abide by the Select Agent Rule, as defined by 45 CFR 72. Under the rule, HHS and the U.S. Department of Agriculture (USDA) keep lists of pathogens that require select agent clearance. The rule regulates the possession, use, and transfer of those agents; imposes security requirements for the facility in which the work will be performed; requires inspections; and can impose criminal and civil penalties on those who do not adhere to the law.

Security risk assessments are administered to individuals who work with select agents by the Department of Justice (DOJ), a process that is renewed every five years. Once cleared, an individual is allowed to work with a specific biological agent, but only within a specific laboratory. The specificity of this clearance procedure inhibits the practical exchange of safety-related information and techniques between high-containment laboratory researchers, by preventing, for example, a technician in one laboratory from demonstrating techniques in another laboratory without going through a separate lengthy clearance process.

In addition to the clearance barriers that prevent timely sharing of practical safety techniques, there is a perception that laboratories will be liable for accidents that occur to scientists who are visiting for training purposes. Whether or not these perceived concerns are real, they need to be examined in detail and addressed so that experienced scientists can more easily demonstrate techniques and safety procedures developed in one laboratory to another. This would speed up the process for new laboratories to become productive, and, more important, should enhance their safety.

As one meeting participant remarked, "As someone who has actually taken a lab hot, I have experience with how you train people. . . . There were no guidelines. There was no checklist. There was nothing. And we reached out to CDC. We reached out to Fort Detrick. We got as much help as they could give. After 9/11, they couldn't give us as much help as they could give before. And so, now that we've been hot, and we've worked with animals, and we've had to do it on our own with just commonsense rules, people are now coming to us and saying, will you help train us? Well, now our lawyers are saying, no, you can't let any nonemployee into the lab. I think what we need to do as a group is to try to develop a policy that says we will assist each other in this training procedure." NIH and CDC should work to make this possible.

Center for Biosecurity Recommendation #2:

> High-containment laboratories need to share lessons learned. Mechanisms should be put in place to enable and encourage interlaboratory training and information exchange. This requires modifying the Select Agent Rule to accelerate the process of safety and technical training, and examining whether perceived barriers, such as legal liability concerns, actually prevent information and safety sharing.

Learning from Biosafety Mistakes

In the decades of research performed at BSL-4, with hundreds of practitioners, there have been only a handful of laboratory-acquired infections reported. In U.S. BSL-4 laboratories, there have been no reported cases of secondary transmission, which is defined as the transmission of a laboratory-acquired infection from one person to another. The meeting participants who have experience in BSL-4 conditions did not feel that the reporting of accidents is a problem. As one participant said, "There isn't anybody in there that wants to catch their experiment, for the simple reason [they] don't want to die."

The record of laboratory-acquired infections at lower levels of containment is less clear, but the meeting participants thought it was much less laudable. In fact, no one knows precisely how many accidents occur at the lower containment levels, including diagnostic clinical laboratories, because laboratory-acquired infections are generally not severe and are not reported. Illnesses may not even be recognized as having been acquired in the laboratory. The Select Agent Rule requires reporting of infections of all select agents, whether they occur at BSL-2, -3, or -4 laboratories. However, there are many infectious diseases that are not on the select agent list, for which there are anecdotes of laboratory-acquired infections but few documented reports.

Research institutions are typically required by NIH grants to report any serious accidents or research-acquired infections, but there is no regulatory requirement to report and no penalty for not reporting. The Occupational Safety and Health Administration (OSHA) within the Department of Labor has illness notification requirements,[20] but the threshold for reporting is considered to be several infected individuals. The lack of reporting has consequences beyond the individual affected laboratory. Unless someone chooses to write a scientific paper documenting the incident, lessons learned from the experience are generally not reflected in new editions of the BMBL (the biosafety guidebook written by NIH and CDC), so that procedures can be analyzed and future accidents perhaps avoided.

There are several explanations for the lack of reporting. Generally, there is a disincentive to report acquired infections and other mishaps at research institutions, because negative publicity or the scrutiny from a granting agency may adversely affect future research funding. In addition, when a scientist acquires an infection in the laboratory, it is almost always his or her fault, and neither the scientist nor the laboratory wishes to advertise the mistake. For example, the mistake may have resulted from a researcher being inattentive, tired, or distracted by other tasks; perhaps the worker had done the procedure many times before and became inured to the risks. Finally, even if reporting were required, once a worker gets infected and becomes ill, he or she becomes a patient—and thus is afforded certain protections and privacy.

These barriers need to be cleared so biosafety can be enhanced through shared learning from mistakes, and also so the public may be reassured that accidents are thoroughly examined and contained. One possible analogous mechanism discussed by meeting participants is the reporting system used for aviation incidents, administered by the National Transportation Safety Board and the Federal Aviation Administration (FAA).[21,22] Mistakes are analyzed and learned from, but they are not attributed to individuals (except when mistakes result from criminal actions, such as drunkenness).

If a similar system were applied to high-containment laboratories, publicizing the names of those involved would be unnecessary; the participants in the meeting agreed that personal anonymity would bolster incentives to report. Participants in the meeting disagreed, however, about whether the laboratory's research institution could remain anonymous as well after an accident or a near-miss. Some felt that institutional anonymity may be necessary to get robust reporting (the FAA does not include the names of the airlines in their incident reports). As one participant said, "If people are whacked on the head when they report anything going wrong, whether it was an honest mistake or an error or a piece of equipment failing, they will find ways not to report. . . . So the more transparency you have, the fewer penalties you must have." But as another meeting participant pointed out, "If I live in Seattle and the [researchers] in Seattle that are fooling around with 1918 [influenza] constructs start screwing up and dropping things in the lab, . . . to have a national reporting system that doesn't reflect or doesn't inform anybody in and around Seattle . . . is a total letdown to the people."

Center for Biosecurity Recommendation #3:

> A system should be established by NIH or CDC to provide an analysis of mistakes and near-misses in high-containment laboratories. Institutional anonymity may be necessary in order for overall safety goals to be achieved; however, procedures need to define thresholds and mechanisms for reporting if mistakes pose a danger to the community surrounding the laboratory.

Public Engagement

High-containment laboratories have become increasingly controversial because of highly publicized laboratory errors, such as the missteps of Boston University in handling tularemia infections in three laboratory workers.[23] The issue of public engagement was the most important to our meeting participants but generated the least consensus regarding appropriate actions.

NIAID has a great deal of information about all of the biodefense laboratories on its website, including a collective rationale for why the laboratories are being built.[1] However, engagement with communities where the laboratories are actually being built is typically handled by the institution proposing the laboratory. Thus, the strategies and outcomes of public engagement, as well as the transparency of laboratory operations to the public, have varied considerably. Public resistance was experienced during efforts to build facilities in Boston, in Davis, California, in Hamilton, Montana, and in

Seattle, whereas generally positive support was achieved for the Galveston laboratory administered by the University of Texas Medical Branch. In the end, both the Davis and Seattle facilities were not built, in part due to public opposition.

Laboratories that have been accepted by their communities have by and large instituted procedures that not only encourage active reporting of problems but also keep the community informed about operations. Studies have been written contrasting successes and failures of various high-containment laboratories; this work should be expanded, learned from, and implemented for all laboratories.[5,24] Individual laboratories bear final responsibility for their relationships with their communities, but there should be a more aggressive and proactive federal effort to standardize public engagement and transparency of operations and to direct funds to this purpose.

A public engagement program needs to address the concerns that have surfaced in siting high-containment laboratories. A fundamental error made by some proponents of these labs is to conflate all protests against the laboratories as a lack of understanding of science (R. Lofstedt, personal communication, July 11, 2006). In the media reports that describe the controversies about the labs, a number of specific concerns appear repeatedly: People fear that weapons will be worked on in the labs, and that the Biological Weapons Convention will be violated; that diseases will be released into the public; that the government could not manage an accident response (as was the case in the aftermath of Hurricane Katrina); and that the lab would make the area a target for terrorism. Some who protest the labs are not against the lab per se, but feel that the location chosen for the lab is unacceptable, or that the lab would not provide jobs or other benefits to locals. Some feel that giving more people access to select agents will lead to an increased chance of accidents or, even worse, an increased risk of terrorism. Each of these issues needs to be actively addressed both by HHS and NIAID and by the institution sponsoring the laboratory.

The larger question of whether these laboratories are justified at all also needs to be addressed by focusing on the specific roles of individual laboratories and how they fit into the overall biodefense strategy. The community that surrounds the laboratory should know the strategic importance of their laboratory and why its existence is necessary. The NSABB, in their charge to provide the HHS Secretary with "periodic evaluations of maximum containment biological laboratory capacity nationwide and assessments of the future needs for increased laboratory capacity," should specifically address the individual role each laboratory should play in the overall federal biosecurity strategy.[18]

For many years, there was a clear shortage of biological high-containment laboratories.[25] Now, after funds have been committed and construction has begun, there should be greater clarity about whether there is enough capacity, the right kind of capacity (e.g., sufficient animal facilities or laboratories that can meet FDA requirements for Good Laboratory Practices), or an excess. Defining the roles of specific laboratories in terms of a larger biodefense strategy will not only help to justify their existence to their neighbors and funders; it will also help to design safety programs for the laboratories and to ensure that the laboratories are doing important, nonduplicative research in the future.

Center for Biosecurity Recommendation #4:

Public engagement should be a priority for all laboratories, and federal funds should be made available specifically for that purpose. As part of a proactive public engagement program, the need for individual high-containment laboratories in the context of the overall U.S. biodefense strategy should be clearly articulated to the public by the federal government and the laboratories themselves.

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