

Preventing Accidental Disease Outbreaks: Biosafety in East Asia

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Preventing Accidental Disease Outbreaks: Biosafety in East Asia

Christian Enemark [*](#)

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Introduction

Christian Enemark from the University of New South Wales (Australian Defence Force Academy campus) writes that the expansion of interest and investment in biotechnology in East Asia is "being driven mainly by infectious disease challenges, economic interests, and security concerns about biological weapons."

However, he cautions,

"a key challenge will be to ensure strict biosafety measures extend to all new laboratories-it would be tragically ironic if a leaky laboratory became the source of an infectious disease outbreak crisis. In East Asia, it is clear that biosafety lags dangerously

behind expansions in the biotechnology industry."

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Essay - Preventing Accidental Disease Outbreaks: Biosafety in East Asia

The term 'biosafety' refers to measures and procedures for protecting the health and safety of people working in laboratories and preventing the accidental release of pathogenic micro-organisms into the environment. Biosafety is an important issue in East Asia because investment in biotechnology is assuming greater significance in the region's economies, bringing with it more scientists and laboratories to support pathogen research. For example, Indonesia plans to expand its existing biotechnology infrastructure to include three Inter-University Centres on Biotechnology as well as numerous research facilities and culture collections. The Malaysian government has invested \$US26 million to build three institutes in the new BioValley Malaysia, a large complex that is part of a plan to attract \$US10 billion in biotechnology investment within a decade. The South Korean government envisages total investment in biotechnology to reach \$US15 billion by 2007, while the Chinese biotechnology sector has been estimated to be growing at over 15 per cent annually. And in 2001 Singapore embarked on a 15-year, \$US8.2 billion plan to make Singapore a high-technology hub with a strong focus on biotechnology'the plan includes the \$US500 million BioPolis complex. [1] This expansion of interest and investment in biotechnology is being driven mainly by infectious disease challenges, economic interests, and security concerns about biological weapons.

The ongoing health emergency of H5N1 avian influenza, of which East Asia is the epicentre, is a particularly important incentive for establishing more diagnostic laboratories in the region to enhance the technical capacity of medical staff to identify and treat the disease. Testing for H5N1 antibodies in a human tissue sample is technically difficult, time-consuming and expensive. And because it involves the use of live H5N1 virus, it should be carried out in high-containment laboratories, of which East Asia has few. As of May 2005, for example, laboratory facilities in Hanoi (Vietnam) were so limited that it was taking up to a week for the return of blood test results, by which time influenza patients were sometimes already dead. [2] And Japanese scientists who in April 2005 retested 30 blood samples from Vietnamese people declared to be free of the H5N1 virus discovered that seven people had in fact been infected. [3]

If the diagnostic capacity of poorer countries in East Asia is to be increased, however, a key challenge will be to ensure strict biosafety measures extend to all new laboratories'it would be tragically ironic if a leaky laboratory became the source of an infectious disease outbreak crisis. The purpose of this paper is to outline the basics of laboratory safety and containment, to examine the lessons from three recent accidents involving the virus that causes severe acute respiratory syndrome (SARS), and to assess the state of biosafety in East Asia.

Basics of Biosafety

Physically, biosafety is about placing barriers or filters between a pathogen and the researcher, and between the laboratory and the environment. Accordingly, there are two categories of containment: primary (safety equipment) and secondary (facility design). Primary barriers against exposure to infectious agents include: good laboratory practice and technique; protective gloves and coats; respirators and face shields; and sealed biological safety cabinets. The kind of secondary barriers

required depends upon the risk of transmission of specific agents (see Table 1). Laboratories working with less hazardous agents should have sinks available, and windows fitted with fly screens. And in laboratories where containment is more important, there should be specialised air filters and fans that generate negative atmospheric pressure'any containment breach would cause air to flow into rather than out of a facility.

Were a biological agent to escape from a laboratory, the danger is that this may lead to its reproduction and establishment in some niche in the ecosystem. There it may remain for long periods of time, causing great economic and/or public health disruption'for example, spores of *B anthracis* (which can cause anthrax in humans) are able to persist for more than 40 years. An escaped pathogen might also be dispersed by natural forces such as wind, water or insect/animal vectors.

Table 1: Levels of biosafety

Biosafety Level	Description
BSL-1	Suitable for work with agents not known to cause disease in healthy humans. Minimal potential hazard to laboratory workers and the environment.
BSL-2	Suitable for work involving agents of moderate potential hazard to personnel and the environment.
BSL-3	Suitable for work with infectious agents that may cause serious or lethal disease as a result of exposure by inhalation, but against which vaccines and/or therapies are available.
BSL-4	Suitable for work with dangerous and exotic agents that pose a high risk of life-threatening disease, and which may be transmitted by aerosol and for which there is no vaccine or therapy available.

Source: [Laboratory Biosafety Level Criteria](http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s3.htm) (CDC Web Site), 30 November 2000.
<http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s3.htm>

For laboratories in general, a strong biosafety regime would require:

- documented safety procedures;
- monitoring of compliance and reporting of incidents;
- adequate staff, receiving ongoing training, to minimise the temptation of workers to cut corners;
- adequate physical facilities to avoid overcrowding;
- adequate and well-maintained equipment;
- laboratory access limited to trained staff and supervised visitors; and
- secure storage and inventory controls for pathogen stocks.

A high level of containment does not, however, eliminate the risk of accidents. In 2004, two scientists working in BSL-4 laboratories, one American and one Russian, became infected with the Ebola virus after accidentally sticking themselves with a syringe. [4] And in the United States, plans to expand the number of high-containment laboratories have generated fears that this will result in more laboratory-acquired infections and accidental releases of pathogens into the environment. [5] For the East Asia region, where the extent of research on pathogenic micro-organisms is also expanding, accidents are similarly a concern, especially in the light of three recent laboratory-acquired infections involving the SARS virus.

Three SARS Accidents

After the SARS outbreak of 2003 ended, three accidents involving the disease in Singapore, Taiwan and China had the potential to produce subsequent outbreaks - all were the result of poor laboratory safety.

Singapore

In September 2003 a 27-year-old postgraduate medical student working in a laboratory at the National University of Singapore (NUS) was infected with SARS. The patient was isolated in hospital after developing a fever, and later recovered. No secondary cases arose from this infection. [6] An epidemiological investigation found that inappropriate laboratory safety standards and a cross-contamination of West Nile virus samples with SARS virus in the NUS laboratory led to the infection. [7]

At the request of the Singapore government, an 11-member team, including biosafety experts from the World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (CDC), was assembled to investigate equipment and procedures at all Singaporean facilities housing BSL-3 laboratories. At three out of the four facilities, the team found evidence of biosafety shortcomings. The training of laboratory workers at Singapore's Environmental Health Institute was found to be insufficient and the investigation team recommended the implementation of a good record keeping policy. At Singapore General Hospital, there was a mixing of BSL-2 and BSL-3 activities which prejudiced good safety practices. And at NUS, limited space and overcrowding were revealed as chronic problems, and the investigating team recommended the development of a practical safety culture among scientists and students. [8]

Taiwan

Lax laboratory safety procedures were also to blame when, on 17 December 2003, a medical researcher (Lieutenant Colonel Chan) in Taiwan tested positive for SARS. Working in a laboratory at the National Defence University's Institute of Preventive Medicine, Chan had been screening antiviral drugs for effectiveness against SARS. He was working in a BSL-4 laboratory in which virus samples were handled within a closed cabinet using attached gloves. Attached to the cabinet was a chamber for transporting waste materials to a sterilization unit. On 6 December Chan noted that some liquid waste had spilled into the transportation chamber but he could not reach it using the attached gloves. He sprayed the area with alcohol and waited 10 minutes. Presuming disinfection had been successful, Chan then opened the chamber to finish cleaning up the spill. That action exposed him to the SARS virus. Chan attended a conference in Singapore the following day and developed a fever on 10 December 2003 after returning to Taiwan. On 16 December he was admitted to hospital and the next day it was confirmed he had SARS. Ninety people who had been in close contact with him in Singapore and Taiwan were quarantined. Fortunately, at the time he was travelling, he did not pass the disease onto anyone because he was asymptomatic and not infectious. There was no outbreak and Chan recovered. His infection was blamed on poor safety procedures at the laboratory in which he worked. [9]

China

The laboratory-acquired infections resulting from accidents in Singapore and Taiwan did not result in spread beyond the affected workers. By contrast, in April 2004, China narrowly avoided another major SARS outbreak after the virus escaped from a laboratory at the Beijing Institute for Virology. On 7 March 2004 a 26-year-old medical student (Ms Song) began studying at the Institute. She and a fellow student (Mr Yang) were in a laboratory that handled samples of the SARS coronavirus. Ms

Song finished her studies on 22 March and the next day travelled by train back to her home in Anhui Province. Three days later she developed a fever and afterwards returned by train to Beijing for treatment. On 29 March she was admitted to hospital as a pneumonia patient. For some reason, on 2 April, Ms Song was transferred by train to a hospital in Anhui where her mother (Mrs Wei) was most often by her side. The mother developed a fever on 8 April and died 11 days later. Meanwhile, Mr Yang had developed a fever on 17 April. Chinese health officials classified Ms Song and Mr Yang as suspected SARS patients along with Ms Li, one of the nurses who had cared for Ms Song in Beijing. Ms Li's father, mother, aunt and roommate fell ill as well. [10]

The Beijing Institute for Virology was closed and its 270 employees quarantined along with more than 700 others who may have come into contact with suspected SARS cases. The incident reached a critical juncture on 1 May 2004, the beginning of a week-long vacation in China when millions of people would start moving around the country. The concern was that, if SARS was out there, this mass movement could spark outbreaks throughout China. The government increased health screenings at airports and train stations to prevent a wider spread of the disease, and anyone with a fever was prohibited from travelling. [11] After Beijing confirmed that two patients had SARS, the government in neighbouring Taiwan responded by tightening the monitoring of travellers from the mainland. All air passengers arriving from China, Hong Kong and Macao were required to fill out a questionnaire on SARS and other communicable diseases and have their temperature taken. The Taiwan Department of Health also advised government and non-government institutions with large flows of people ' schools in particular ' to screen the temperatures of people entering their facilities. [12]

Fortunately, the outbreak was limited to eight cases of illness in Beijing and Anhui Province and one death. A report issued by the Chinese Ministry of Health blamed the outbreak on a series of flaws at the Beijing Institute for Virology. A batch of supposedly inactivated SARS virus had been brought from its BSL-3 storage location into a regular laboratory (with lower safety standards), where Ms Song and Mr Yang were working on diarrheal viruses. The process for inactivating the virus ' adding a mix of detergents ' had not worked properly, [13] thus laying the ground for an accidental outbreak event.

Biosafety in East Asia

The three SARS accidents of 2003-2004 demonstrate that biosafety is a real concern in East Asia. Under slightly different circumstances, each could have triggered effects comparable to a biological weapon attack or a natural disease outbreak. In the aftermath of the accidents, the WHO recommended that national programs for SARS biosafety should include:

- a containment policy to reduce the number of laboratories storing and working on SARS coronavirus;
- a laboratory accreditation system based on standardized biosafety criteria;
- an occupational health service to monitor the wellbeing of laboratory workers;
- comprehensive biosafety and training programmes in all diagnostic and research institutes supported by a management framework that facilitates compliance with evidence-based guidelines and the adoption of a positive biosafety culture; and
- a legislative framework and independent advisory body to assist in the development, implementation and evaluation of a national biosafety program, the investigation of biohazard incidents, and the dissemination of lessons learned to the global scientific community. [14]

Biosafety guidelines, issued by the WHO and other bodies, are a valuable resource for such matters as laboratory containment procedures and the training of personnel. However, these guidelines are not binding, and nor is there an international legal mechanism for enforcing a uniform biosafety standard. Individual scientific institutions in East Asia may choose to adhere to such guidelines for professional and scientific reasons, but a number of countries have taken the added step of incorporating biosafety principles into national regulations. For example, the Malaysian Penal Code criminalises 'any unlawful or *negligent* or malignant act which is likely to spread the infection of any disease dangerous to life.' [15] And in Indonesia, biosafety measures are regulated by 'the Decision of the Department of Health on the Safety in Microbiological Laboratory and Biomedics.' [16] However, the best examples of a comprehensive national commitment to biosafety in East Asia are provided by Japan, China and Singapore.

In **Japan** the standard for biosafety is set by the National Institute of Infectious Disease. In 1981 the Institute established the Laboratory Safety Regulation for Biological Agents. This Regulation has been revised several times to take into account the WHO Laboratory Biosafety Manual and the biosafety systems of other countries, and it is widely referred to by other research institutes, businesses and universities in Japan as a model for biosafety management guidelines. The Regulation lists pathogens to be controlled and divides them into four biohazard levels. It also prescribes safety standards for equipment and laboratory management, emergency measures, and health care and safety training for personnel handling biological agents. [17]

Japan does not have a separate law that defines safety standards and physical protection requirements for facilities that store pathogens, however certain standards and requirements are set forth in other laws. An example is the Pharmaceutical Affairs Law which requires pharmaceutical production facilities using pathogens to meet plant and equipment standards to prevent the leakage of pathogens. In addition, Japan's Guidelines for Recombinant DNA Experiments (established in 1979 and revised in 2002) contain detailed requirements for containment methods and equipment, transport and post-experiment disposal of genetically modified micro-organisms, and health care and training of personnel who conduct experiments. [18]

In **China** regulatory coverage on biosafety matters is extensive. The 1986 Regulations on the Storage and Administration of Microbial Bacteria Species set out procedures for the 'separation, selection, collection, storage, identification, indexing, supplying and exchange' of bacteria species. China's Law on the Prevention and Control of Infectious Diseases (adopted in February 1989) and its Implementation Regulations (promulgated in December 1991) establish three categories of infectious bacteria and viruses based on toxicity and the seriousness of the diseases they cause. The Law also administers the use, storage and transportation of such micro-organisms. [19] In 2004, following the laboratory-acquired SARS infection at the Beijing Institute of Virology, revisions to this Law included new biosafety requirements'disease-control agencies, medical laboratories, or research bodies must manage virus samples correctly, and violations that lead to the spread of any disease could lead to criminal punishment. [20] In addition, the Regulations of Labor Protection in Workplaces Where Toxic Substances Are Used (promulgated in April 2002) prescribe safety measures related to facilities, equipment, health of personnel, handling and transport of toxic substances, accountability, licensing and accreditation. And China's General Guidelines on Biological Safety in Microbial and Medical Laboratory (promulgated in December 2002) establish detailed requirements for the administration and design of laboratories designated BSL-2 and above, and the handling of pathogens therein, so as to prevent laboratory-acquired infections and leakage into the environment. [21]

With laws such as these in place, there remains the question of the degree to which biosafety is in fact being enhanced. In October 2005 a government survey of 8,000 medical and research facilities

in Japan indicated that, out of the 114 facilities possessing samples of anthrax or multidrug-resistant TB (or both), 58 did not have manuals on how to handle these dangerous pathogens. [22] And in China, in the aftermath of SARS, there has been a rush to set up what Cong Cao refers to as 'Class III pathogen labs.' This has generated concerns over whether such facilities will have sufficient suitably-trained personnel, and whether they will meet international biosafety guidelines 'and not become a location where a horrific leakage of toxic materials occurs.' [23] As such, it would appear that biosafety in Japan and China needs constant monitoring.

The newest biosafety regulations in East Asia are those of **Singapore**. The team that investigated that country's SARS accident of September 2003 recommended that the government establish a legislative basis for biosafety standards in laboratories. [24] Accordingly, in October 2005 the Singapore parliament passed the Biological Agents and Toxins Bill against the backdrop of an increase in the number of Singaporean institutions working with high-risk biological agents. The impetus for extra research on pathogens has been resurgent concern about infectious disease outbreaks of natural origin and the prospect of BW attacks, as well as Singapore's desire to become a centre of biotechnology excellence in Asia. [25] The key provisions for biosafety contained in the new legislation are:

- An operator of a facility handling certain high-risk biological agents is responsible for the safety of staff and visitors to the facility. Risk assessment must be carried out and staff adequately trained.
- The facility and its equipment must be in safe working condition, and biological waste may not be discharged into the environment.
- The facility must establish a biosafety committee, have a designated biosafety coordinator, and undergo certification by an independent assessor approved by the Ministry of Health.
- A facility handling biological agents with potential to be weaponized needs to be gazetted as a 'protected place' to ensure proper security measures are in place.
- Government approvals for possession and import, and notifications of transfer, are required for high-risk biological agents and toxins to enable effective inventory control and tracking.
- Biological agents to be transported must be packaged and labelled according to International Air Transport Association standards.
- Transport vehicle drivers must hold a Hazardous Materials Transportation Driver Permit and the vehicles must be prominently labelled. [26]

In East Asia overall, however, biosafety regulations are lacking. Compounding this problem, it is difficult to know exactly how many putative BSL-3 and BSL-4 laboratories exist in the region and whether they operate in accordance with international biosafety guidelines. At the Third Biological Weapons Convention (BWC) Review Conference in 1991, member states agreed to confidence-building measures (CBMs) including exchanges of data on national research centres and BSL-4 laboratories. On the whole, the annual CBM returns of BWC member states have been few in number and of poor quality. Countries that have recently published their CBM returns on the internet include Australia, Canada, the United Kingdom and the United States, but no country in East Asia had done so as of August 2006. [27] A draft verification regime for the BWC, which would have required member states to permit international inspections of declared microbiological laboratories, was abandoned in 2002 for want of political support.

Conclusion

Laboratory research on pathogenic micro-organisms is an essential response to infectious disease

threats, whether of deliberate and natural origin. However, if such research is not carried out safely, it poses a risk of causing accidental outbreaks. In East Asia, three recent incidents of laboratory workers being exposed to the SARS virus have highlighted the necessity for safe research practices. Although some countries already have comprehensive biosafety regimes in place, biosafety regulation in the region as a whole is insufficient in the context of greater investment in biotechnology stimulating more pathogen research. Of particular concern is a February 2006 report on a survey of 300 scientists in 16 Asian countries, commissioned by Sandia National Laboratories in the United States, which showed that pathogen researchers often use insufficient biosafety practices. For example, nearly two-thirds of respondents investigating Japanese encephalitis, avian influenza, and SARS ' which are all BSL-3 agents ' perform their research under BSL-2 conditions. [28]

In East Asia, it is clear that biosafety lags dangerously behind expansions in the biotechnology industry. As more laboratories and scientists are assigned to address the region's infectious disease problems, whether of natural origin or biological weapons-related, it is vital that such research does not increase the risk of outbreaks occurring by accident.

Information about the author

Christian Enemark is Lecturer in Global Security at the University of New South Wales (Australian Defence Force Academy campus) and Deputy Director of the Centre for Biosecurity at the College of Medicine and Health Sciences, Australian National University. His recent PhD dissertation was entitled 'Disease and Security in East Asia: Nature's Plagues and Biological Weapons.'

E-mail: c.enemark@adfa.edu.au

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Nautilus Institute

608 San Miguel Ave., Berkeley, CA 94707-1535 | Phone: (510) 423-0372 | Email:

nautilus@nautilus.org