Strengthening Biosecurity and Managing Biorisk

Forum: World Health Organization
Student Officer: Gyuyeon Choi, Head Chair

Introduction

The term biosecurity refers to the "institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or the intentional release of pathogens and toxins." Until the very beginning of the 21st century, the importance of biosecurity has been neglected by policymakers worldwide because they have underestimated the likelihood of biological threats (or bioterrorism) and their consequences. But, as the threat of biological attacks increases with the advances in technologies and scientific research, there is an imperative need for an international standard to address biological risks, and the need for strict, risk-proof methods of managing them.

Background

Humans have used infectious agents in conflicts for hundreds of years; however, the terrifying potential and its destructive power of biological weapons were neglected until recently. In 1984, members of the Rajneeshee community contaminated ten local salad bars in The Dalles, Oregon, with Salmonella, purchased from a medical supply company in Seattle, in an attempt to take over the region. As a result, 751 people were affected, and forty-five people were hospitalized from the poisoning. It took one year for the Center of Disease Control to confirm that it was deliberate poisoning when the DNA of the salmonella from the salad bar infection matched the DNA of the salmonella found in the commune's medical laboratory during a raid. The salmonella was deliberately spread with malintent; they planned to immobilize the voting population of the town so that the Rajneeshee candidates would win the 1984 county elections. To this date, this remains the largest and first known bioterror attack ever in the United States.

A mailroom worker examining letters in New York City after reports of anthrax in the mail on 15 October 2001

On 29 June 1993, a liquid form of Bacillus anthracis was aerosolized from the roof of an eight-story building by a religious cult, Aum Shinrikyo, in Kameido, Tokyo, Japan. One of the Aum Shinrikyo members claimed that aerosolized Bacillus anthracis was released to cause an inhalational anthrax epidemic; however, the Kameido incident yielded no casualties or victims. Similarly, on 18 September 2001, powdered Bacillus anthracis spores were sent in envelopes to

U.S. Senators and media organizations via the U. S. mail. The powder form allowed anthrax to float in the air, hence made it easier to be inhaled. The powder also polluted the postal offices and the buildings, where they were processed and opened, putting more people at risk of exposure to anthrax. It is known that twenty-two people contracted anthrax, of which five people died and seventeen people were sickened. The exact reason behind this bioterror attack still lies unclear; however, the anthrax incident of 2001 triggered the improvement of national biosafety policies in the United States. The U.S. National Institutes of Health and the Centers for Disease Control and Prevention said that this event has "reshaped and changed, forever, the way we [United States] manage and conduct work in biological and clinical laboratories." Other countries, upon witnessing such an unprecedented threat, expressed the same concerns and came to focus on the need to fortify biosecurity.

Problems Raised

One World, One Health

Even if More Economically Developed Countries such as Japan, the United States, and South Korea have well-established regulations and guidelines regarding the handling of biological agents, the world will not be able to guarantee complete safety if some countries or regions are highly vulnerable in terms of biosecurity. Not all laboratories around the world are well-equipped to protect themselves securely and leakage of a biological agent on a smaller scale, within a town or city, could put the global community under threat at large.

International Actions

ISO 35001

ISO 35001 is "the international standard for any organization that tests, stores, transports, works with or disposes of hazardous biological materials." The standard was developed by the ISO technical committee for a clinical laboratory test and in vitro diagnostic test systems. ISO 35001 was first published in November 2019, enabling control, identification, evaluation, and tracking risks related to biological agents. Like all other international standards, ISO 35001 compiled the consensus and contributions of specialists in the field worldwide. The standard ensures that everyone, particularly those countries that lack clear regulations and guidelines regarding biorisk and biosecurity, to be safe by suggesting s framework for effective program management in biological laboratories. The implementation of ISO 35001 is expected to "help organizations prepare for all future risks, from simple laboratory-acquired infections to future pandemics."

Possible Solutions

Strengthening Personnel Reliability

From diagnosing diseases to pharmaceutical and scientific research purposes, various

types of biological materials are used in laboratories worldwide. One of the most important aspects of a biosecurity plan is personnel management. According to Biosafety in Microbiological and Biomedical Laboratories (BMBL), personnel management includes "identifying the roles and responsibilities for employees who handle, use, store and transport dangerous pathogens and/or other important assets." To ensure the safety of the public, biological agents and toxins must be kept out of the hands of those individuals who intend to misuse them. Personnel reliability measures must examine threats both from within and outside the biological research facilities. This process may include background investigations, security clearances, psychological evaluations, and medical examinations. Furthermore, policies should be established for personnel and visitor identification and management, granting access, and immediate reporting of security incidents. In the United States, personnel are required to be screened by the Federal Bureau of Investigation (FBI) before they can be qualified to handle biological select agents and toxins. Not all countries have implemented such biosecurity regulations for laboratory yet, but those that have followed a similar method. For example, Denmark, Japan, Singapore, and South Korea have recently established biosecurity legislation in place, with regulatory requirements for the security of pathogens and toxins and how to track and keep a record of them. Many countries, especially those of developing states, are yet to adopt regulations for laboratory biosecurity and biosafety. All member states must be prepared to address these issues as the vulnerability in one of those facilities could put the whole community or the whole world at risk.

Caution - Biological Authorized Personnel Only Sign. This label is placed on products, packaging, equipment or locations to warn workers about hazards that could result in death or serious injury.

Reinforcing Physical Security

Physical security involves measures and physical barriers to protect and prevent unauthorized access to potentially harmful biological materials in the laboratory. A biosecurity risk assessment determines practices to keep biological assets protected. According to BMBL, physical security should be included within a laboratory biosecurity program, which should include "a thorough review of the building and premises, the laboratories, and biological material storage areas." In the United States, a separate National Institute of Health (NIH) Security Design Policy and Guideline exists to make sure all biomedical research laboratories and facilities comply with a detailed regulation which sets the minimum performance design standards. This

An example of biometric security system, fingerprint, that can be used to prevent authorized access in a laboratory.

ensures that those facilities include physical security procedures that hinder unofficial access. Examples of measures could be as simple as to locking up all select agent areas when unoccupied, using biometric identification to secure and monitor access, and recording any entries into and out of select agent areas. Currently, not all laboratories can meet these minimal standards to safely protect the public from biohazards. However, the physical security of laboratories and protective mechanisms for storing biological agents must be thoroughly reviewed and implemented to ensure a safer environment for all.

Glossary

Biohazard: the risk to human health or the environment arising from biological work, especially with microorganisms.

Biological Agents: biological agents include bacteria, viruses, fungi, other microorganisms, and their associated toxins which have adverse effects on human health.

Biorisk: the probability or chance that a particular adverse event, such as accidental infection or unauthorized access, loss, theft, misuse, diversion, or intentional release will occur.

Biosecurity: procedures intended to protect humans or animals against disease or harmful biological agents.

Bioterrorism: terrorism involving the release of toxic biological agents.

Personnel: people employed in an organization or engaged in an organized undertaking.

Pharmaceutical: relating to medicinal drugs, or their preparation, use, or sale.

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