

# The Life Sciences Enterprise "Soup"



# The Biosafety-Biosecurity Culture Interface in Life Sciences Research

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IRDR is an international scientific programme under co-sponsorship of the International Science Council (ISC) and United Nations Office for Disaster Risk Reduction (UNISDR) and with support from China Association for Science and Technology (CAST) and Chinese Academy of Sciences (CAS). Started in 2010, the Programme has been pioneering in the promoting international and interdisciplinary studies on Disaster Risk Reduction (DRR) and has made its contributions through scientific publication and policy papers as well as dialogue toward shaping international agenda in the understanding disaster risks, bridging science and policy gaps and promoting knowledge for actions, all required in the Sendai Framework for Disaster Risk Reduction 2015-2030 (SFDRR) and its top priorities. Over time, the scientific agenda of IRDR has attracted many international renowned expertise and institutions. IRDR community is now, institutionally speaking, characterized by its strong Scientific Committee and six thematic working groups, thirteen IRDR national committees (IRDR NCs) and one regional committee (IRDR RC), sixteen international centres of excellence (IRDR ICoEs), a group of some one hundred fifty Young Scientists (IRDR YS) and a broad partnership with national, regional and international institutions working for SFDRR.

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Team of IRDR-IPO



# The Biosafety-Biosecurity Culture Interface in Life Sciences Research

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### Abstract of this Working Paper

Infectious diseases place great health and economic burdens on society, and the relationship between humans, animals, and microbes is ancient and continually evolving. During the last 30 years, 20-30 new diseases emerged, and dealing with an opponent that greatly outnumbers us will require humankind's collective intelligence (Mahmoud 2012). To that end, the society needs to find new ways to deal with emerging diseases, which necessitates doing research in laboratories with different safety levels. Working with pathogenic microorganisms requires developing health and safety measures that adequately protect laboratory workers and others, and also the environment. Laboratory-Acquired Infections (LAIs) have also started to receive more attention in recent years, in particular with regard to high (biosafety level 3, or BSL-3) and maximum (BSL-4) containment laboratories (Bavoil 2005). LAIs may occur in research labs, clinical labs, or animal facilities, and sometimes it is difficult to determine whether the infection was acquired in the lab or from the community. In view of the complexity of both containments laboratories and the human, animal and agricultural health challenges, implementing biosafety and biosecurity measures can contribute to reducing the full spectrum of natural and man-made biological risks. In this regard, creating a biosafety culture to improve our capacity to effectively respond to outbreaks of disease caused by known and unknown dangerous pathogens necessitates that scientists should work closely together and agree on biosafety rules drawn from experience. Moreover, biosecurity practices cannot be built without a strong safety culture and it is therefore generally agreed that training should be a precondition for starting work in specialized, safety- and security-sensitive BSL-3/4 laboratories. On the other hand, there are numerous ways to combine the various elements of biosafety and biosecurity into a successful biosafety and biosecurity framework. Each region in the world proceeds from a different starting point of current practice, legislative environment, levels of resources and facilities, cultures, and needs and demands. Thus, a detailed examination of specific situations often helps in optimizing allocation of resources.

## Main Text

#### 1. Introduction

Extraordinary advances in biotechnology have brought enormous benefits to medicine, public health, food industry, agriculture, and industrial processes. However, the increased access to advanced technologies also bring with them risks to public safety and security through the possibility of their misuse. Furthermore, in addition to man-made biological risks, humans continue to face natural biological risks such as the threat of pandemics of new and re-emerging infectious diseases. Thus, it is essential to address relevant issues in life sciences research to ensure that natural diseases are detected and contained as soon as possible, harmful unintended consequences of research are minimized, laboratories operate safely both for their workforces and for the communities in which they are situated, and plans and infrastructure are in place to respond effectively to biological emergencies.

In this respect, fine-grained ethical analyses of dual-use research<sup>1</sup> in the biological sciences would seek to quantify actual and potential benefits and burdens, and actual and potential recipients / bearers of these benefits and burdens (WHO 2014). These analyses would also identify a range of salient policy options. Each option would embody a set of trade-offs between present and future benefits and burdens, and recipients and bearers thereof. The construction of these options and the process of selection between them would consist in large part in the application of various ethical principles, including human rights principles—e.g., right to life, freedom of inquiry, and free speech— and principles of utility and of justice. Here we note that there is no simple inverse relationship between specific benefits and burdens such that, for example, any increase in security requires a reduction in scientific freedom. Rather an increase in security might simply involve greater safety precautions and, therefore, a financial cost without any commensurate reduction in scientific freedom. At any rate, relevant benefits and burdens need to be disaggregated and subjected to individual analysis in the context of any process of determining trade-offs and selecting options (Van Aken 2006).

On the other hand, the issues of biosafety and biosecurity have evolved to different positions for different countries and regions<sup>2</sup>. In developed countries, the issues of biosafety and biosecurity have evolved to cover issues that question the need for regulation and control of scientific activities and research that may open an avenue for the potential abuse and misuse of biological agents that are infectious. The oversight of science is an example that reflects this need to provide a framework that ensures a certain

<sup>&</sup>lt;sup>1</sup> By definition, dual-use research is morally problematic. On the one hand, such research provides benefits (at least potentially); on the other hand, there is the risk of misuse by rogue states, terrorists groups, and the like. <sup>2</sup> Chua, T.M. Biosafety and Biosecurity Challenges in the Asia Pacific Region.

degree of biosecurity measures without adversely affecting the progress of science. Furthermore, most developed countries have by now instituted whole-of-government biosafety and biosecurity strategies. For example, the UK and the Netherlands have created national risk registers incorporating biological risks. The UK has a risk assessment methodology, which all policy-makers are required to apply to policy issues across the board. Other countries, such as Australia, ensure that biosafety and biosecurity strategies are incorporated at all levels of government (federal, state, city) and that they are internally consistent and compatible<sup>3</sup>.

However, in many developing countries, the focus could still be on the fundamentals of biosafety as many of the facilities handling infectious agents were built more than 10 or 20 years ago with little or limited provision for biosafety and biosecurity measures in their design and practices. This can pose as the weakest link in that chain of control in biosecurity against the misuse of biological agents to inflict harm. Better laboratory design and security can help prevent accidents resulting in outbreaks, and prevent break-ins by others resulting in the release of dangerous pathogens or in dangerous technologies falling into the hands of those who would build biological weapons.

Safety and security perceptions and needs vary across different regions, as does sustainability of the programs put in place to implement them. Every region of the world is different; significant diversity also exists within the same region. Within the Middle East and North Africa (MENA) region, there is considerable need for training in and awareness-raising of biosafety and biosecurity issues, not just for life scientists but also for laboratory directors and policy makers (Trevan, Kauffman, et al 2010). Life sciences professionals in the MENA region needs to learn from the experiences in other regions of the world, and to adopt practices and develop networks of experts.

On the other hand, national action, while absolutely necessary, cannot always be sufficient to contain or manage biological risks. The need for effective concerted supranational efforts means that cooperating countries need to have a common understanding of the global and regional risks, which in turn requires a common risk assessment methodology and common prevention activities. While biological risks do vary from region to region and country to country, without a common methodology for assessing risks and formulating appropriate policies and practices to manage and mitigate these risks, any international effort will be neither concerted nor effective (The International Council for the Life Sciences 2010).

#### 2. Biosafety and Biosecurity Culture

Recent developments throughout the world in laboratory practices have created many drugs, vaccines and diagnostic tests that have had a tremendous positive impact on health. These developments have helped us learn from each other. However, the

<sup>&</sup>lt;sup>3</sup> Trevan, T. Building National Biosafety and Biosecurity Strategies in the Middle East and North Africa (MENA). The International Council for the Life Sciences (ICLS).

expansion in infectious disease research throughout the world and the increased access to advanced technologies means that we must ensure that laboratories are made as safe as possible.

Notable lapses in biosafety in a number of countries in the previous years have demonstrated the importance of laboratory safety — and hinted at the potential impact a serious biosafety lapse could have on human health (Harding and Brandt Byers K 2006; Coelho and Diez JG 2015). The critical issues are related to proper training of staff in research and management, staff taking responsibility for safety and bio-containment, openness in reporting incidents and discussing safety concerns, and seeing safety as a culture (the way to work) rather than as an imposed obligation. Unfortunately, there are few labs that meet these requirements and it is expected to see further incidents, infections, and possibly the release of agents into the community.

Increased travel and globalization have meant an increased risk of spread of diseases. A biosafety lapse in one country can now become an immediate threat to the health and economy of another country, and indeed to the entire world. Despite the fact that the lapses happened in different countries and involved different pathogens, the incidents have much in common. They all involved people, poor practices and, at times, lack of policies.

Preventing the misuse of biological agents and toxins, and mitigating the risk of large outbreaks of diseases through increasing laboratory biosafety and biosecurity can be used as a tool for stability and development. To be safe, people need to work in a culture that emphases safety and discourages risk-taking. The promotion of a culture of scientific integrity and excellence, distinguished by openness, honesty, accountability and responsibility, is the best protection against the possibility of accidents and deliberate misuse of life sciences research and offers the best prospect for scientific progress and development.

Researchers need to be well trained and supported by co-workers and managers who make sure that training does not go to waste and that safe practices are implemented every hour of every day. Besides, managers need to ensure that systems are in place that support their workers and view biosafety as an important occupational health and safety issue. Strong legislation, good policies and appropriate guidelines that can easily be turned into simple-to-follow standard operating procedures, are essential — but sadly are often lacking.

Therefore, people, practices and policies are all vital components of biosafety. However, ultimately the success of any biosafety programme is dependent on commitment. Commitment of a government to ensure that the right policies are in place to protect its people. Commitment of the government to ensure that commercial and academic interests do not stand in the way of safety. In addition to commitment of all those involved to share experiences and work together to strengthen biosafety.

### **3**. Enhancing Biosafety and Biosecurity Culture in BSL-3 & BSL-4 Laboratories by Training

New construction of biosafety level 3 and level 4 (BSL-3 & BSL-4) laboratories in different regions of the world has increased in the past decade to facilitate research on combating Emerging Infectious Diseases (EID). When level 3 and level 4 facilities are designed, it is essential to consider what biological agents will be handled within the facility, the characteristics of the biological agent, and any potential routes of infection that can occur. This ensures that the proper barriers and safety equipment will protect lab personnel and the environment from exposure to potentially infectious agents.

On the other hand, the rapid expansion of BSL-3 & BSL-4 laboratories creates an increasing demand for well-trained professionals from many fields in order to operate, protect and conduct research in these facilities. Proper and ongoing biosafety and bio-containment training for all staff of these facilities can significantly reduce the chance that a laboratory incident or accident will become a threat to the community and surrounding environment. A recent literature review concluded that deviation from general "good microbiological practice" is the most frequent cause of Laboratory-Acquired Infections (LAIs) and that training for compliance with procedures and regulations seems to be the best method to avoid such infections (Pike 1976; Risi and Bloom et al 2010; Kozajda and Bródka 2013).

Working with BSL-3 pathogens (avian influenza, rift valley fever, etc.) requires diligence from all users to maintain safe laboratory conditions, which includes essential knowledge of both the pathogen and the procedures, proper training, donning of Tyvek suites and adherence to safety practices. An ideal BSL-3 training curriculum covers biosafety and personal safety, and is delivered through lectures and practical demonstrations. Participants are first introduced to the concept of biosafety and the BSL-3 laboratory in general before being instructed on operations at biosafety level 3. Most specifically, training focuses on informing participants on the hazards associated with the facility and possible ways of eliminating personal harm while minimizing the risk of exposing other people to danger. Maintenance and management of a BSL-3 laboratory is also covered. Effectiveness of the training session is evaluated through an assessment test whose outcome can inform the institution on gaps of knowledge and areas of weakness, for which refresher courses can be scheduled.

Working in a BSL-3 laboratory is a good basis for moving on to work at BSL-4 level, especially as the danger of infection at BSL-3 level, which provides a biosafety shell to protect the environment, is higher than in a BSL-4 laboratory, which offers superior personal protection. Formal training in preparation for work in a BSL-4 laboratory should consist of three elements: didactic or classroom-style theoretical preparation, one-on-one practical training in the facility, and mentored on-the-job training (Xia and Huang et al 2019).

For providing training in a BSL-4 facility, the safety rules and technical restrictions (e.g., working space, air supply) limit the maximum number of people allowed in the laboratory at the same time. Thus, training should be provided on a one-to-one basis to highly committed individuals. Mock laboratories could be used to acquaint the would-be BSL-4 worker with specific sets of practices and procedures, but this approach would not substitute for on-site BSL-4 tutoring by scientists with extensive experience of handling infectious agents. Practical training in BSL-4 facility should take into account specific biosafety requirements, such as those dictated by the type of laboratory (e.g., suit-based or cabinet line).

#### Box 1: BSL-3 Laboratory Training

The training courses are designed to prepare new staff for the basics of safely working in BSL-3 laboratories and includes a mixture of practical and classroom courses covering:

- 1. Review of biosafety principles and levels
- 2. Risk assessment and management
- 3. Waste management
- 4. Laboratory management
- 5. Safety procedures
- 6. Emergency management
- 7. Biosafety cabinet practices and procedures
- 8. Small and large spill decontamination
- 9. Donning and doffing PPE
- 10. Laboratory operations and preventative maintenance
- 11. Data and material management
- 12. Inventory and records management
- 13. Biosecurity

#### Box 2: BSL-4 Laboratory Training

#### Theoretical Training

The theoretical courses are designed to help trainees gain a comprehensive understanding of biosafety and biosecurity principles and regulations. Theoretical training provides an overview of the features of the maximum biocontainment laboratory, especially the design features, maintenance and management, the code of practice, the key facilities and equipment, and the standard operating procedures for working at our BSL-4 laboratory.

#### Hands-On Training

The hands-on practicum provides training in a laboratory setting, strengthens trainees' knowledge and skills, and delivers a comprehensive orientation to the BSL-4 facility. During hands-on training, staff become familiar with laboratory features, such as

airtight doors, dedicated airflow supply and exhaust systems, autoclave, chemical shower, negative-pressure environment, Personal Protective Equipment (PPE), Standard Operating Procedures (SOPs), and safety procedures, including alarms and emergency operations.

Hands-on training is conducted through demonstration and practice using noninfectious materials at the training laboratory. Trainees take topics according to their job category. During these sessions, an assigned mentor or trainer demonstrates the correct procedures before the trainee practices under observation. In this phase, all trainees learn about the positive pressure suit, including how to inspect and wear the suit and use compressed air hoses. In addition, they learn emergency plans and proper techniques for entering and exiting the BSL-4 laboratory, working in or using laboratory equipment, disinfecting surfaces, disposing of waste, cleaning spills, removing equipment or material from the laboratory, and conducting decontamination. Because laboratory accidents often involve animal bites and sharps, an additional module specific to these issues is required for staff who will work with animals; those whose work is mainly in vivo may take this course as an elective.

On completion of this section, the mentor or trainer observes the trainee performing assigned procedures and evaluates whether they are performed correctly per SOPs. These evaluations are recorded through an online training management software tool.

#### Mentored On-the-Job Training

Before they can be certified, trainees who will work at the BSL-4 laboratory must complete a specified number of hours and entries into the laboratory in mentored onthe-job training. During this phase, trainees work in a functioning BSL-4 laboratory under supervision of a senior staff scientist or other experienced laboratorians. After an orientation, they perform specific tasks, such as routine inspection and BSC testing, moving equipment, setting up BSCs before conducting experiments, disinfecting surfaces and removing generated waste, centrifugation, virus propagation and storage, plaque assays, inoculation, and animal care and use.

The assigned mentor evaluates the trainee's performance, advises on safe and secure operations, and records areas in which the trainee needs further instruction or practice. The mentor then makes recommendations on whether the trainee is prepared for independent access to laboratory facilities.

Training for all workers in high (BSL-3) and maximum (BSL-4) containment laboratories must be specific to the facility, procedures, and equipment that the workers will encounter when working in containment. Specialized training must be given to all workers who will have access of any kind to containment areas.

An interdisciplinary approach—that is, training courses where health care workers from different disciplines (physicians, microbiologists, nurses, engineers specialized in construction and maintenance of high containment facilities, and biosafety professionals) can be trained together—would be extremely beneficial.

Development of rigorous standards for BSL-3 & BSL-4 laboratory training will instill confidence in the public, policy makers, and security officials that the expanded international network of BSL-3 & BSL-4 laboratories will continue to be operated safely and will pose no risk to scientific staff, local communities, surrounding environment, and host nations.

Besides, the development of a basic common training protocol, acceptable to all BSL-3 & BSL-4 laboratories, would hopefully allow an easier exchange of trained staff in the future. Clarification and coordination of training standards will help to develop a cadre of highly qualified bio-containment workers and will result in a series of robust BSL-3 & BSL-4 laboratory programs that will enable scientists to develop measures to deal with existing threat agents and to cope with new diseases that emerge. BSL-3 and BSL-4 laboratory networks are valuable in facilitating information and resource sharing, scientific exchange and training, and organizing external quality control assays.

#### 4. Biosafety and Biosecurity in Research on Emerging Viruses

The ongoing controversy surrounding research on emerging diseases has generated considerable discussion among life scientists, public health researchers, and biosafety/biosecurity experts all over the world. However, there is still considerable need for awareness-raising of life sciences research, not just for researchers but also for laboratory directors and policy makers. Scientists and policy makers often have difficulty identifying what are the risks that need to be assessed or addressed in relation to life science research, particularly the research that focuses on emerging viruses.

While SARS-CoV-2 is an emerging coronavirus that is currently causing a global public health emergency, it will not be the only CoV threatening the world. Little is known about the antigenic relationships among the different CoVs or how these relationships influence the capacity of different zoonotic strains to emerge in human populations.

Diagnostic tools and some information on clinical features of and risk factors for SARS-CoV-2 are now available. There is, however, limited information on the sensitivity and specificity of diagnostic tools and many clinical questions remain unanswered, including the route and time course of infection, pathogenesis of disease, and treatment options. Epidemiologic questions still not fully answered include identification of animal reservoirs and possible intermediate sources of human infection; the relative importance of different modes of human-to-human transmission, e.g. fomites and aerosols; and risk factors for transmission and infection.

Basic research priorities for SARS-CoV-2 could include:

- Identifying basic research priorities in replication and pathogenesis;
- Understanding CoV biodiversity;
- Studying mechanisms that regulate potential for cross-species transmission;

- Constructing panels of representative heterologous viruses to design, develop, and test broad-based vaccines and therapeutics; and
- Improving translational outcomes of vaccines, therapeutics, and diagnostics.

Sharing scientific expertise *via* research collaborations and training opportunities is essential in order to address the above research priorities. In this regard, a process needs to be developed that would enable responsible and rapid sharing of research resources and data among the scientific community.

The process should emphasize that the researchers who are working on this emerging virus:

- i. Must be well trained and proficient in handling the virus safely.
- ii. Should make a detailed risk assessment under the direction of the Institutional Biosafety Committees (IBC) consisting of biological safety professionals before starting to work on the virus, analyze the worst case scenarios that may occur and prepare a strategy to mitigate the impact of the negative event if it happens.
- iii. Should strictly follow the safety procedures and manage the research materials by adherence to appropriate materials management procedures.
- iv. Should report to their supervisors or biosafety officials immediately if they encounter a dangerous situation or identify a new virus with significantly increased human transmissibility and/or virulence.
- v. Must establish material accountability procedures to track the inventory, storage, use, transfer and destruction of viral materials and assets when no longer needed.

In this respect, and in order to implement a systematic program for emerging life science research that is effective and sustainable, a certain infrastructure at the national level has to be in place as a first step to support and implement these programs. Such programs should have considerable regional and international benefits in the form of

- 1. reduced risks from pandemics and epidemics of any nature and from any source, be it natural, accidental or deliberate, by enabling earlier detection of and reaction to outbreaks resulting in earlier control and elimination so that fewer casualties and a considerably lower risk of the outbreak spreading to other regions of the world;
- 2. better responses to biological crises through better risk protocols, better education, and better preparedness;
- 3. reduced unintended consequences of research, activities and policies through a greater awareness of the issues and through better communication and wider adoption of best practices and codes of ethics;
- 4. better governmental policy-making and policy choices;

- 5. reduced biological accidents through better biosafety and biosecurity standards and practices;
- 6. reduced risk of intentional biological crises through better design of and better security systems and procedures at biological facilities.

A step forward is to identify or establish partners or channels that can assist in the implementation of these programs regionally and internationally.

The above discussion tells us that, in the global arena, we have a way to go in planning for success from the perspective of biosafety and biosecurity, which may include *early involvement of regulators* and *oversight bodies* in the planning stages. As science and technology continue to advance, the challenges associated with "planning for success" will increase exponentially, and policy makers will need to determine how to adjust, for example, to a reality where one can create an entire biological system that has never been seen before.

### 5. Conclusions for the project

In the context of international security, biosafety and biosecurity converge at the nexus of science and security and of health and security. This convergence has the potential to generate not only new opportunities, but also novel and unforeseen biological threats.

For maximum benefit to society, policies and practices aimed at reducing and managing biological risks should be planned in a holistic, whole-of-government manner, as part of a national biosafety and biosecurity strategy. The development of national and regional biosafety and biosecurity strategies enables the countries to identify the biological risks to which they are exposed and mitigate them through the development of appropriate legislative system, human and physical infrastructure, and improving the national preparedness and contingency planning. The approach is a holistic one - a whole-of-government, one worldview of all biological risk across the spectrum of natural, accidental and intentional threats as they pertain to humans, animals, plants and the environment, including water. In countries of the MENA region, there is a necessity to disseminate best practices in research institutions, strengthen human and laboratory capacity for handling, importing and exporting biological agents, improve standards and oversight of life science research, and involve practitioners in the development of better regulations and facilities.

Besides, there is a necessity to share and harmonize the practices and experience of the laboratories operating in different regions of the world. A cooperation between existing high biosafety-level laboratories is another effective tool to respond to the threat of a new EID and the fight against highly infectious diseases.

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