Global BioLabs Report

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Executive summary

Trends and Key Messages

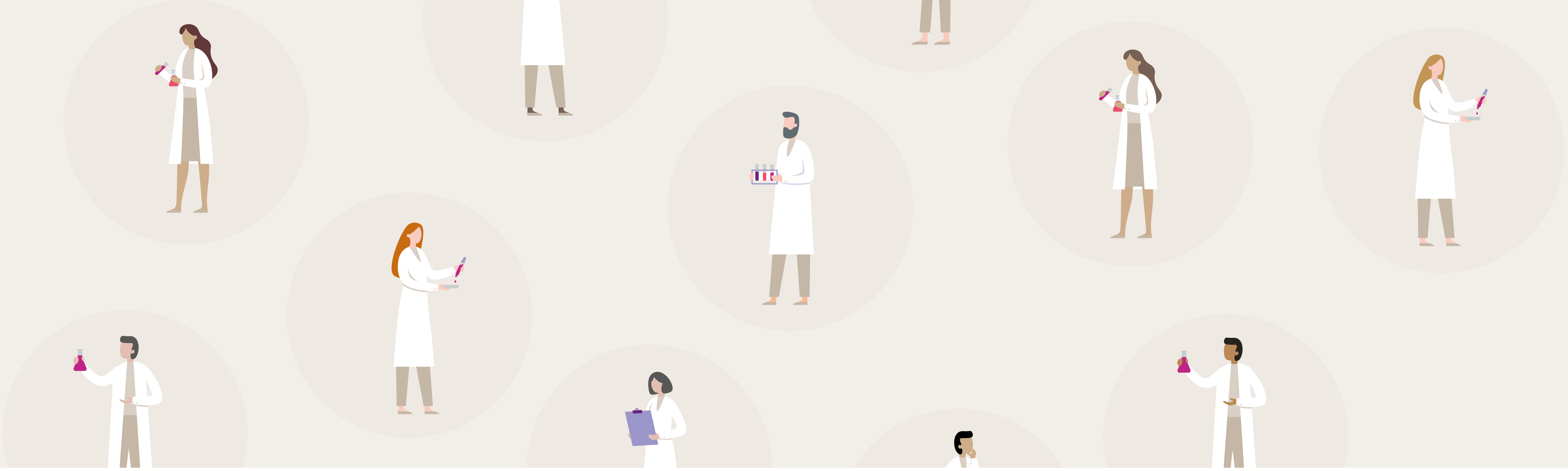
Since its inception in May 2021, the Global BioLabs initiative has identified notable trends in global data on BSL4 and BSL3+ laboratories and on biorisk management at both the national and international level. Overall, there are several trends that raise biosafety and biosecurity concerns given the global boom in construction of BSL4 and BSL3+ labs, particularly where biorisk management oversight is weak.

BSL4 Labs

The number of BSL4 labs is rapidly increasing, with most of the new construction taking place in Asia. India alone has announced plans for four new BSL4 labs. Additionally, approximately 75 percent of existing operational BSL4 labs are in cities, where dense populations could exacerbate the impact of an accidental release. Over 60 percent of BSL4 labs are government-run public health institutions, primarily focused on human health rather than on biodefence. More than half of the BSL4 labs that work with infected animals – ABSL4 labs – are in the United States.

We also identified two notable trends regarding specific characteristics of BSL4 labs. First, about half of all BSL4 labs are less than 200 square metres in size, and only nine of the labs are over 1,000 square metres. In other words, roughly half of BSL4 labs are less than the size of a tennis court. Second, in terms of personal protective equipment, the majority of BSL4 labs require personnel to work in full-body, positive pressure suits with their own air supply. Only seven BSL4 labs conduct their work solely in biosafety cabinets.

Executive summary continued



BSL3+ Labs

'BSL3+' and 'BSL3 enhanced' labs are BSL3 labs that adopt additional physical and/or operational biosafety and biosecurity precautions when carrying out particularly risky research, but where the risks do not necessarily warrant BSL4 precautions. There is very limited national biosafety guidance, and no international guidance, on what constitutes BSL3+ and little to no research demonstrating that these enhancements actually provide an adequate level of additional safety for the riskier research conducted in these labs.

BSL3+ labs are primarily utilised by public health institutions and universities, and focus more on animal health research than BSL4 labs. The majority of BSL3+ labs are in Europe within urban centres.

Biorisk Management and National Context

Biorisk management scores based on national legislation reveal that biosafety governance is much stronger than biosecurity governance. However, the weakest component of biorisk management is dual-use research of concern; only one of the 27 countries with BSL4 labs has comprehensive national dual-use research oversight legislation in place.

The boom in BSL4 lab construction appears so far not to have been accompanied by strengthened biorisk management oversight. Additionally, most planned BSL4 labs will be in countries with relatively low scores for governance and stability. Most countries with operational BSL4 labs earned higher scores for stability and effective governance.

International Governance of Biorisk Management

International networks play an important role in the governance of biosafety and biosecurity. Several informal, multinational groups, including the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR), the Global Health Security Agenda (GHSA), the Global Partnership's (GP) Biosecurity Working Group (BSWG), and the International Federation of Biosafety Associations (IFBA) emphasise biorisk management in their missions, but have limited membership or lack the authority and/or resources to mandate meaningful changes at the national or international level. International organisations with more resources, more inclusive membership, and official mandates that could cover biorisk management, including the World Health Organization (WHO), the World Organisation for Animal Health (WOAH), and Interpol, place biorisk management lower down on their list of priorities. With a diverse array of actors with competing agendas, coordinated action is often difficult and agreement on key issues is challenging to achieve.

Key Recommendations

The following recommendations provide concrete steps that laboratories, national authorities, non-governmental entities, and international organisations can take to strengthen biorisk management.

#1

Labs conducting high-consequence work with pathogens should adopt the international standard for biorisk management: ISO 35001.

#2

States should incorporate voluntary global standards on biorisk management into legislation and guidance, including the 2022 WHO Global Guidance Framework for the Responsible Use of the Life Sciences, the 2019 WOAH Guidelines for Responsible Conduct in Veterinary Research, and the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists.

#3

States should develop national standards for field biosafety.

#4

States and their high-consequence biolabs should implement and share best practices and participate in peer reviews of biorisk management practices in counterpart labs.

#5

States that do not already have a national biosafety association should encourage and support the creation of one by biosafety and biosecurity professionals.

#6

States should provide complete, regular, and transparent reporting as required by the annual confidence building measures of the Biological Weapons Convention and under UN Security Council Resolution 1540.

#7

The WHO should take three concrete actions to strengthen international biorisk management oversight:

a. Develop criteria and guidance for BSL3+ labs.

b. Provide guidance on field biosafety.

c. Establish collaborating centres for biorisk management in Africa, Southeast Asia, the Eastern Mediterranean, and the Western Pacific so that every WHO region has at least one such centre.

#8

States should leverage existing international biorisk management organisations, such as IFBA, the European Research Infrastructure on Highly Pathogenic Agents (ERINHA), the Biosafety Level 4 Zoonotic Laboratory Network (BSL4ZNET), and IEGBBR, to strengthen global biorisk management by providing education, training, and best practices for the widespread adoption of ISO 35001 and an international mechanism to audit compliance with the standard.

Introduction

The biological risk landscape is rapidly evolving and presents significant new challenges to preventing the accidental, reckless, or malicious misuse of biology. At the same time, oversight systems to ensure that life sciences research is conducted safely, securely, and responsibly are falling behind. An urgent overhaul to realign biorisk management with contemporary risks is needed.

The Global BioLabs Initiative

The Global BioLabs initiative was launched in May 2021 in response to increased public interest in high-risk biological research and the facilities in which it takes place. The aim was to create an authoritative source on maximum containment laboratories and biorisk management policies around the world.

Initially, we focused on Biosafety Level (BSL) 4 labs, where work takes place with lethal and contagious pathogens for which there are few or no effective treatments, like the viruses causing Ebola, Lassa fever, and smallpox. We identified how many BSL4 labs there were, mapped them, and provided basic information about the individual labs such as when they were established and what size they were. We also provided indicators on the biorisk management policies and practices in place at these labs and in their host countries.

Over the last year and a half, we have updated this information as well as significantly expanded our scope to also include data on 'BSL3+' labs; assessments of the strength of biorisk management governance in each of the countries that has, or plans to have, a BSL4 lab; indicators on the implementation effectiveness of biorisk management policies; profiles of international networks of countries and labs active in biorisk management; and new educational materials on biosafety, biosecurity, and dual-use oversight.

This report presents our new data and resources, and it offers a set of policy recommendations to strengthen biorisk management at the lab, national, and international level.

This report is composed of six chapters:

Chapter 1

The first chapter provides an update on BSL4 labs around the world.

Chapter 2

The second chapter presents new data on BSL3+ labs.

Chapter 3

The third chapter provides an analysis of the strength of biorisk management policies, including biosafety, biosecurity, and dual-use research oversight, in countries housing or planning to build BSL4 labs.

Chapter 4

The fourth chapter examines the ability of countries to implement their biorisk management policies by measuring the strength of their governance and stability.

Chapter 5

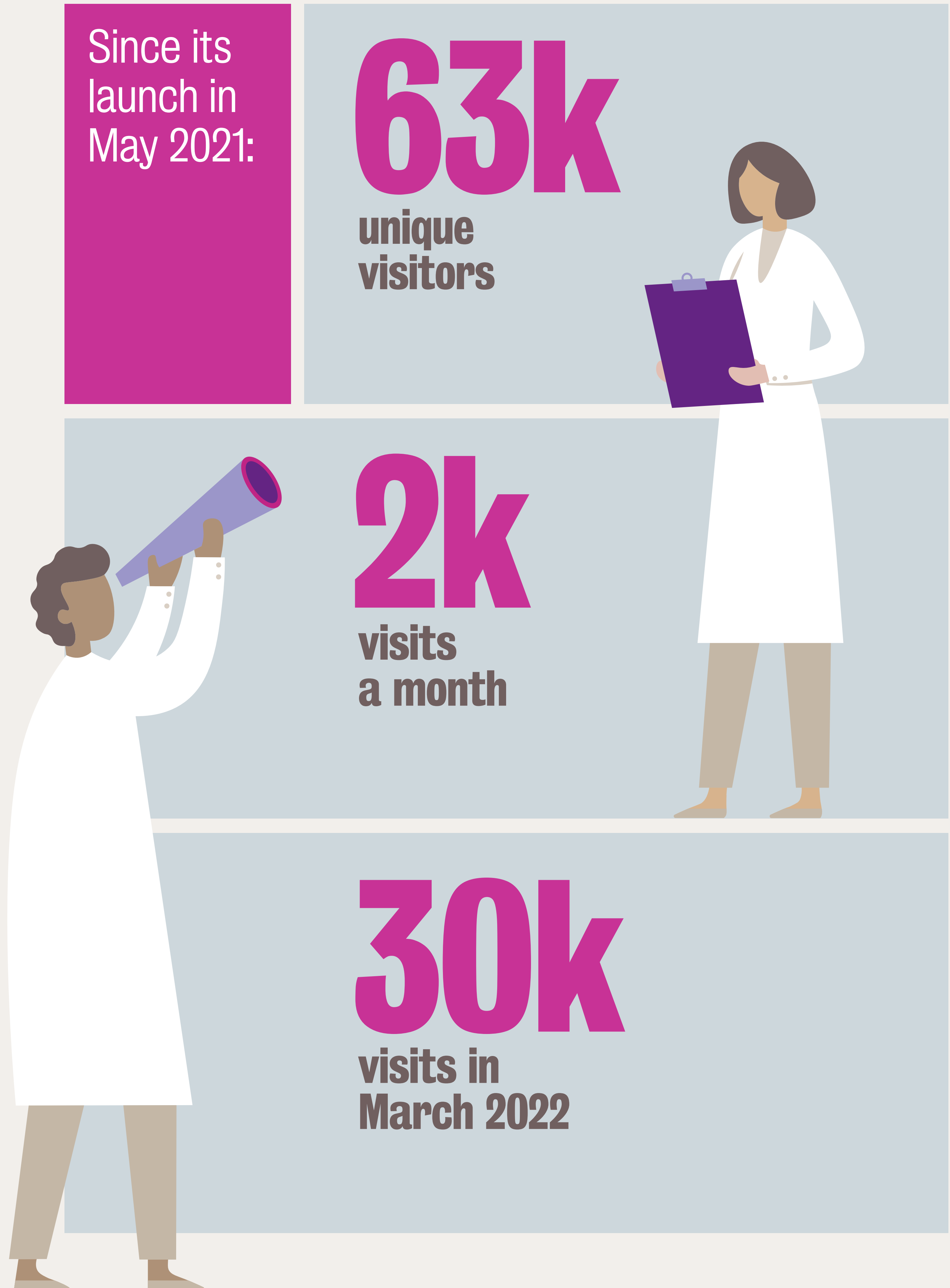
The fifth chapter examines the global biorisk management landscape.

Chapter 6

The sixth and final chapter provides recommendations for strengthening global governance of biosafety, biosecurity, and dual-use research.

GlobalBioLabs.org in Facts and Figures

Since its launch in May 2021, GlobalBioLabs.org has hosted over 63,000 unique visitors, roughly half of which were from North America. The site consistently hosts an average of nearly 2000 visits a month. The website had over 30,000 visits in March 2022 alone—presumably a response to the Russian invasion of Ukraine in February 2022 and Russia's unfounded allegations of bioweapon activities in Ukrainian public health labs conducted by the United States and its allies.



Chapter 1: New and Updated Trends in Global BSL4 Lab Data

Key Message:
BSL4 labs are rapidly increasing in number

In 2021, we identified 59 BSL4 labs that were in operation, under construction, or planned in 23 countries. By the beginning of 2023, that number had increased by ten to 69 labs. There are 51 BSL4 labs in operation, three under construction, and 15 planned, all spread over 27 countries.

The number of BSL4 labs around the world has grown steadily since the 2001 anthrax letter attacks in the United States and the 2003 SARS outbreak in Asia stoked fears of naturally occurring and human-made biological threats. The COVID-19 pandemic has triggered another building boom for BSL4 labs. Since the start of the pandemic, nine countries have announced plans to build 12 new BSL4 labs. Most of these new labs will be built in Asia including in India, Kazakhstan, the Philippines, and Singapore. India alone has announced plans to build four more BSL4 labs in addition to the two it currently has. For five of these countries, this will be their first BSL4 lab.

The largest concentration of BSL4 labs remains in Europe, with 26 BSL4 labs, one of which is under construction in the United Kingdom and one of which is planned in Spain. Asia has 20 BSL4 labs, 11 of which are planned in China, India, Kazakhstan, Taiwan, the Philippines, Saudi Arabia, Singapore, and Japan. North America has 15, one of which is under construction in the United States and two of which are planned in Canada and the United States. Oceania has four BSL4 labs, all operational and located in Australia. Africa has three, two operational in Gabon and South Africa, and one under construction in Côte d'Ivoire. South America has one planned BSL4 lab in Brazil.

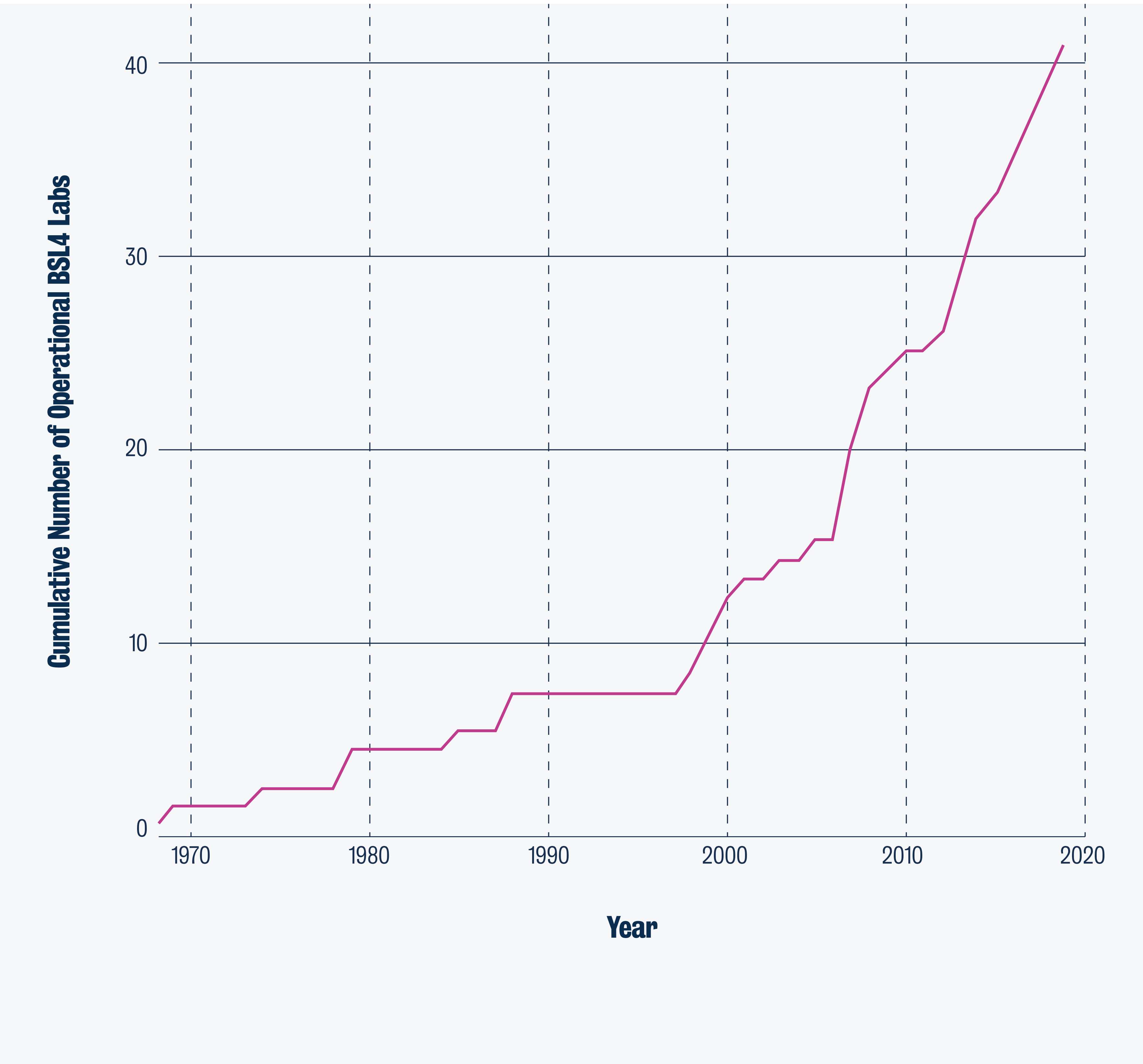


Figure 1. Global proliferation of BSL4 labs. Only BSL4 labs with a known year in which operations began are included in the graph

12 New

BSL4 labs planned across nine countries since the start of the pandemic

Chapter 1: New and Updated Trends in Global BSL4 Lab Data – continued

Key Message:
BSL4 labs are primarily located in cities

Of the 62 BSL4 labs with available location data, 46 are, or will be, based in urbanised population centres and 16 are, or will be, located in less populated areas. In other words, approximately 75 percent of BSL4 labs are located in urbanised areas, exacerbating the impact of any accidental releases. We categorise urbanised population centres as containing over 50,000 people living within 2.5 miles of the lab.

Key Message:
The focus is public health, not biodefence

BSL4 labs can serve several functions including diagnosis of suspected infections, scientific research to better understand the properties of pathogens, and development of new and improved vaccines, therapeutics, and diagnostics.

We categorise labs into four types: university-owned, defence, public health, and privately-owned. Of the 66 labs where ownership data is available, 41 are government-owned public health labs, 13 are primarily defence labs, ten are university-based research labs, and two labs are privately owned.

In other words, over 60 percent of BSL4 labs are government-run public health research institutions, 15 percent are academic labs, and less than 20 percent are defence labs.

A significant majority (54/65) of the labs where data is available focus their work on human health. Seven labs focus solely on animal-related research, and four conduct both types of research. Of the 69 BSL4 labs, 51 are operational, 15 are planned, and three are under construction.

Over 60%

of BSL4 labs are government-run public health research institutions

Key Message:
BSL4 labs specialising in animals and insects are mainly in North America

Some BSL4 labs have capacities for specialised work with animals that have specific biosafety requirements. We have collected data on two of these: 'ABSL4' (Animal Biosafety Level 4) labs and 'ACL4' (Arthropod Containment Level 4) labs.

There are 15 BSL4 labs that work with infected animals under ABSL4 conditions. More than half (8/15) of these are located in the United States. In addition, Canada and China each have two ABSL4 labs and Australia, Germany, and India each have one ABSL4 lab.

There are two BSL4 labs with special ACL4 containment measures to work with infected arthropods like ticks. There is one ACL4 lab in Australia and one in the United States.

Key Message:
There are more small labs than large labs

BSL4 labs vary greatly in terms of size (floorspace). Of the 46 labs where data is available, nine labs are over 1,000 square meters, 15 labs are between 200-1000 square meters, and 22 laboratories are smaller than 200 square meters. In other words, roughly half of BSL4 labs globally are less than 200 square meters. That is about the size of a singles tennis court or less than half the size of a professional basketball court. About one fifth of BSL4 labs globally are the very large labs usually featured in media imagery of maximum containment labs.

Key Message:
Suits are favoured over glove boxes

BSL4 labs are generally designed as either a 'suit lab' where personnel work in full-body, positive pressure suits with their own air supply or as a 'cabinet lab' where personnel handle pathogens in a series of interconnected biosafety cabinets or 'glove boxes'. Of the 49 labs where primary containment data is available, 41 are suit labs, seven are cabinet labs, and one uses both suits and cabinets.

Research Methodology for Global BSL4 Lab Data

We followed a five-step process for collecting and confirming information on BSL4 labs:

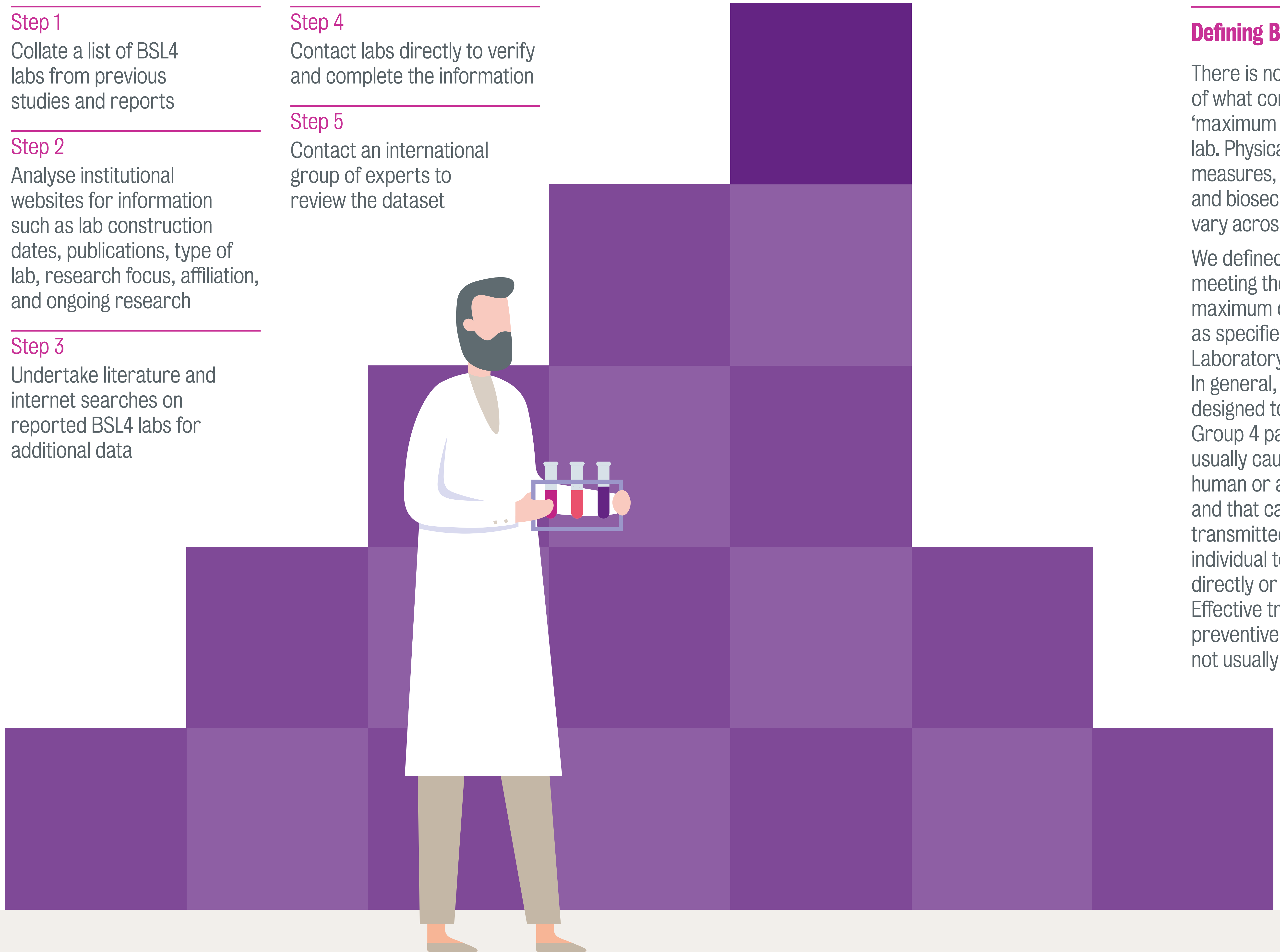
Step 1
Collate a list of BSL4 labs from previous studies and reports

Step 2
Analyse institutional websites for information such as lab construction dates, publications, type of lab, research focus, affiliation, and ongoing research

Step 3
Undertake literature and internet searches on reported BSL4 labs for additional data

Step 4
Contact labs directly to verify and complete the information

Step 5
Contact an international group of experts to review the dataset



Defining BSL4

There is no single definition of what constitutes a 'maximum containment' lab. Physical containment measures, as well as biosafety and biosecurity practices, vary across countries.

We defined BSL4 labs as meeting the criteria for maximum containment as specified in the WHO Laboratory Biosafety Manual. In general, this relates to labs designed to work with Risk Group 4 pathogens that usually cause "serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available."

Want to Learn More?

Educational resources on requirements for biosafety precautions in BSL4 labs are available in the Resources section on GlobalBioLabs.org

1 out 4

BSL3+ labs deal exclusively with threats to animal health

Chapter 2: Introducing Global BSL3+ Lab Data

Key Message:
Additional precautions are tagged on to BSL3 labs to enable riskier research

A new addition to the Global BioLabs initiative is our global inventory of 'BSL3+' labs, or 'BSL3 enhanced' labs as they are also referred to. These are BSL3 labs that adopt additional physical and/or operational biosafety and biosecurity precautions when carrying out particularly risky research, but where the risks do not necessarily warrant BSL4 precautions. The most common pathogen studied in BSL-3+ labs is highly pathogenic avian influenza (HPAI). BSL-3+ labs have also been used to conduct research on novel pathogens such as the reconstruction of the 1918 influenza pandemic virus, as well as to conduct experiments to enhance the virulence or transmissibility of potential pandemic pathogens, more commonly known as 'gain of function' research.

There is very limited national biosafety guidance, and no international guidance, on what constitutes BSL3+ and little to no research demonstrating that these enhancements provide an adequate level of additional safety for the riskier research conducted in these labs. Unlike for BSL4 labs, there is no requirement under the Biological Weapons Convention confidence-building measures to declare such labs and their activities.

We have located 57 labs that self-identify as BSL3+. Roughly three-quarters of these are based in Europe, which has 21 BSL3+ labs, and in North America, which has 19 BSL3+ labs. The remaining BSL3+ labs are located in Asia (ten labs), South America (four labs), Africa (two labs), and Oceania (one lab). These labs are all operational, except for one in the United States which is still under construction and one in Brazil which is planned.

Defining BSL3+:

BSL1, BSL2, BSL3 and BSL4 labs are defined in international guidelines, regulations, and standards. This is not the case, however, for 'BSL3+' labs—also referred to as 'BSL3 enhanced' labs or 'BSL3 plus' labs.

We identified the available scientific literature, national guidelines, and reports from international organisations that recommend performing specific types of research in BSL3+ labs. We found the enhancement requirements vary from one document to another. In general, however, work conducted at the BSL3+ level usually involves work with biological agents that would normally be conducted in a BSL3 lab, but where certain types of pathogens (e.g. HPAI and 1918 pandemic influenza) and certain types of practices (e.g. using a higher than normal volume of samples, higher concentrations of cultures, or increased production of aerosols) are involved. Examples of enhancements to BSL3 labs can include additional training for staff, more rigorous emergency response plans, enhanced respiratory protection for personnel against aerosols, adherence to clothing change, personal protective equipment (PPE) use and shower-out protocols, HEPA filtration of lab exhaust air, pass-through autoclaves, effluent decontamination systems, and strengthened access controls and monitoring.

Key Message:
BSL3+ is principally utilised by public health and academic labs

The 57 BSL3+ labs are evenly divided between government-run public health labs and university-based research labs, with 40 percent, or 25 labs, in each category. The proportion of university-based BSL3+ labs is significantly higher than for BSL4 labs, where only 15 percent are university-based research labs and over 60 percent are government-run public health labs. Of the remaining seven BSL3+ labs, four are privately owned and three are defence laboratories.

Key Message:
BSL3+ labs focus more on animal health research than BSL4 labs

About a quarter of BSL3+ labs (13/57) focus their work on animal health. Roughly half of BSL3+ labs (32/57) deal exclusively with threats to human health, compared with the bulk of BSL4 labs (54/65). The remaining quarter (12/57) conduct research relevant to both human and animal health.

Chapter 2: Introducing Global BSL3+ Lab Data – continued

Key Message:
BSL3+ labs are primarily located in cities

An even higher percentage of BSL3+ labs are in urban areas compared to BSL4 labs. 80 percent of BSL3+ labs (46/57) are in urbanised population centres. The remaining 11 labs are in non-urbanised areas, with a population of less than 50,000 people living within 2.5 miles of the lab.

Key Message:
Europe houses nearly half of world's highest-containment facilities

Overall, when BSL4 and BSL3+ labs are added together, there are well over 100 highest containment facilities that conduct high-consequence research around the world, with more planned and under construction (see Table 1). Europe is home to almost half of the operational labs (45/106) with roughly a third located in North America (30/106).

The United States is home to the single largest concentration of such labs with 28 BSL4 and BSL3+ labs in operation and three more under development. Asia houses 19 operational BSL4 and BSL3+ labs. Oceania houses five BSL4 and BSL3+ labs, and Africa four, and South America three.

Key Message:
There's a building boom of highest-containment labs in Asia

11 out of the 20 highest-containment facilities that are planned or under construction are in Asia. Four are in North America, two in Europe, two in South America and one in Africa.

Table 1: Global distribution of BSL4 and BSL3+ labs

	BSL-4			**BSL-3+**			
	Per Region	Operational	Planned/Under Construction	Per Region	Operational	Planned/Under Construction	**Total**
Europe	26	24	2	21	21	0	**47**
Asia	20	9	11	10	10	0	**30**
Africa	3	2	1	2	2	0	**5**
North America	15	12	3	19	18	1	**34**
Oceania	4	4	0	1	1	0	**5**
South America	1	0	1	4	3	1	**5**
Total	69	51	18	57	55	2	**126**

Research Methodology for Global BSL3+ Lab Data

We followed a five-step process for collecting and confirming information on BSL3+ labs:

Step 1
Collate a list of BSL3+ labs from previous studies and reports

Step 2
Analyse institutional websites for information such as lab construction dates, publications, type of lab, research focus, affiliation, and ongoing research

Step 3
Undertake literature and internet searches on reported BSL3+ or enhanced labs for additional data

Step 4
Contact labs directly to verify and complete the information

Step 5
Contact an international group of experts to review the dataset

Want to Learn More?

Educational resources on containment levels as explained in Biosafety in Microbiological and Biomedical Laboratories of the US National Institutes of Health and Centers for Disease Control and Prevention (CDC) are available in the Resources section on GlobalBioLabs.org

21 out of the 27 countries with BSL4 labs score high on biosafety governance

Chapter 3: National Biorisk Management Scorecards

While COVID-19 demonstrated that no country is safe from a pandemic and that all countries need a strong public health infrastructure, it is important to also ensure that pandemic preparedness activities are carried out safely, securely, and responsibly.

A new element of the Global BioLabs initiative assesses the strength of biorisk management governance—encompassing biosafety, biosecurity, and dual-use oversight—in each of the countries that has, or plans to have, a BSL4 lab. In 2022, the WHO endorsed biorisk management as an overarching concept for ensuring the responsible use of the life sciences.

The Global BioLabs initiative's Biorisk Management scorecards are designed to provide concrete, quantifiable indicators of how well countries are implementing this concept.

These scores are based primarily on whether a country has laws, regulations, or policies in place that address the metrics on our list. The score cannot and should not be interpreted as evaluating how comprehensively or rigorously a country is implementing those laws and regulations or the level of compliance by labs on their territory. On the other hand, since these are scores based on national governance measures, they cannot capture biorisk management policies at lower levels of governments or policies and practices within individual labs that are more stringent than national laws and regulations.

Key Message:
Biosafety governance is stronger than biosecurity governance

Biosafety scores

We assess that 21 out of the 27 countries with BSL4 labs—roughly 80 percent—score high on biosafety governance overall (Table 2). Two countries score medium and four score low.

Effective biorisk management requires that a whole-of-government biosafety system is in place for human, animal, and agriculture facilities. This whole-of-government approach is generally created through national biosafety legislation. Countries that score high on biosafety governance have legislation, laws, regulations, administrative requirements, policies, or other government instruments in place for biosafety. They also have a dedicated entity responsible for the enforcement of biosafety legislation and a national list of dangerous pathogens. Countries that score high on biosafety governance tend to have whistleblower protection laws in place which could apply to workers that report issues with biosafety to laboratory management or government regulatory authorities, even if these laws are not specifically mentioned in the biosafety legislation.

Countries scoring high on biosafety generally have most of the 12 metrics we measure as components of effective biosafety governance implementation (Table 3; See section on Research Methodology for National Biorisk Management Scorecards for more details). The highest scoring metrics are physical/engineering controls, occupational health, and transportation safety, for which 22 countries have applicable measures.

The lowest scoring metric is inventory requirements, found in 17 out of the 27 countries.

To ensure on-going promotion of biosafety, countries should have a national biosafety association or be part of a regional biosafety association. Additionally, countries should participate in, and contribute to, global biosafety efforts. Countries scoring high on biosafety governance generally participate in three or more international initiatives such as the WHO's Joint External Evaluations (JEE), the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR), the Global Health Security Agenda (GHSA) Action Package Prevent-3 (APP3) on Biosafety and Biosecurity, and other similar initiatives.

Table 2: Biosafety scores by country

Biosafety (score out of 20)	
Country	**Score**
Australia	20
Canada	20
France	19
Germany	19
Japan	19
United States	19
Brazil	18
China	18
Italy	18
Singapore	18
Spain	18
Taiwan	18
United Kingdom	18
Sweden	17
Kazakhstan	16
South Africa	16
Switzerland	16
Hungary	15
Republic of Korea	15
Russian Federation	15
Belarus	14
Czech Republic	11
Philippines	7
India	5
Côte D'Ivoire	3
Gabon	3
Saudi Arabia	1

12 out of 27 countries with BSL4 labs score high on biosecurity governance

Table 3: Scoring metrics on biosafety

Biosafety	
Scoring metric	**Number of countries**
Governance Framework	
1. National biosafety legislation	23
2. National biosafety oversight entity	22
3. National list	22
4. Whistleblower protections	15
Implementation	
5. Physical/engineering controls	22
6. Good microbiological practices	20
7. Biosafety risk assessments	21
8. Administrative controls	21
9. Training	20
10. Personal protective equipment	19
11. Occupational health	22
12. Inventory	17
13. Transportation safety	22
14. Decontamination	21
15. Incident response plan	20
16. Incident reporting	21
17. **Biosafety Association**	
National	16
Regional	8
None	3
18. **International Engagement**	
Participation in 3 groups	7
Participation in 1 or 2 groups	14
No participation	6

Biosecurity scores

Only 12 out of the 27 countries with BSL4 labs score high on biosecurity governance (Table 4). That is roughly 40 percent, or half of the percentage scoring high on biosafety. Nine countries score medium for biosecurity governance and six score low.

As with biosafety, effective biosecurity requires that a whole-of-government system is in place for human, animal, and agriculture facilities. Countries that score high on biosecurity governance have legislation, laws, regulations, administrative requirements, policies, or other government instruments in place for biosecurity. They also have a dedicated entity responsible for the enforcement of biosecurity legislation, a national list of dangerous pathogens, and whistleblower protection laws.

While only 12 countries score high on biosecurity governance, 17 countries have national legislation on biosecurity, 16 countries have national biosecurity oversight entities, 22 have a national list, and 15 have whistleblower protections.

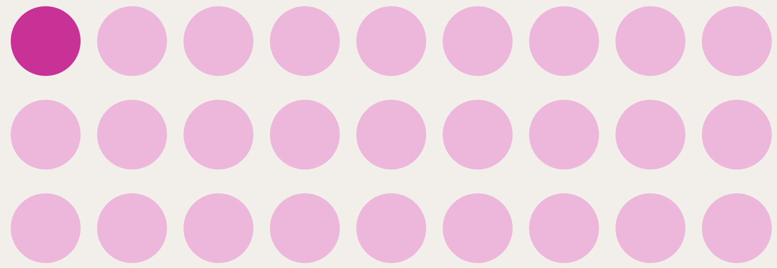
Countries that score high on biosecurity generally have most of the 11 metrics we measure as indicators of essential biosecurity governance implementation (Table 5). More details on how we measure biosecurity is in the section on Research Methodology for National Biorisk Management Scorecards. The highest scoring metric is export controls, which 24 countries have, followed by transportation security requirements, found in 20 countries. The lowest scoring metrics are governance measures related to DNA screening, found in only two countries; information and cybersecurity protections, found in 11 countries; and biosecurity risk assessment, found in 12 countries.

International engagement is a key part of an effective biosecurity framework. All countries, but particularly countries with BSL4 labs, should have signed and ratified the Biological Weapons Convention (BWC) and provide annual, publicly-accessible 'confidence-building measures' submissions for heightened transparency. All countries should also be complying with the United Nation Security Council Resolution (UNSCR) 1540 requirements to adopt measures to prevent the acquisition of biological agents by non-states actors and provide national reports and action plans regarding their implementation of this resolution. Countries should also participate in, and contribute to, global biosecurity efforts.

Countries scoring high on biosecurity governance generally participate in three or more international initiatives, such as the Australia Group (AG), the Global Partnership's Biosecurity Working Group (GP BSWG), the WHO's JEE, IEGBBR, GHSA APP3, and similar initiatives.

Table 4: Biosecurity scores by country

Biosecurity (score out of 18)	
Country	**Score**
France	18
United States	18
Australia	17
Canada	17
Japan	17
United Kingdom	17
China	15
Taiwan	14
Kazakhstan	13
Republic of Korea	13
Singapore	13
Spain	13
Hungary	12
Russian Federation	12
Sweden	12
Czech Republic	11
Belarus	9
Brazil	9
Germany	9
Italy	6
Switzerland	6
India	5
Philippines	4
South Africa	4
Saudi Arabia	2
Côte D'Ivoire	1
Gabon	1



Only one out of the 27 countries with BSL4 labs scores high on dual-use research governance

Table 5: Biosecurity scoring metrics

Biosecurity Scoring metric	Number of countries
Governance Framework	
1. National biosafety legislation	17
2. National biosafety oversight entity	16
3. National list	22
4. Whistleblower protections	15
Implementation	
5. Physical security	17
6. Information and cyber security	11
7. Personnel reliability	14
8. Biosecurity risk assessments	12
9. Inventory	15
10. Export controls	24
11. DNA screening	2
12. Training	16
13. Transportation security	20
14. Incident response plan	15
15. Incident reporting	16
International Engagement	
16. BWC	
Ratified and public CBM	9
Ratified and private CBM	16
Ratified but no CBM	2
Signed but not ratified	0
Not signed	0
17. UNSCR 1540	
Part 1: Implementation of national legislation and domestic control measures: 66-100%	20
Part 1: Implementation of national legislation and domestic control measures: 34-65%	2
Part 1: Implementation of national legislation and domestic control measures: 0-33%	3
Part 2: National report and action plan	8
Part 2: National report but no action plan	16
Part 2: No national report	1
18. Membership in International Biosecurity Initiatives	
Member of 5 groups	6
Member of 4 groups	3
Member of 3 groups	4
Member of 2 groups	7
Member of 1 group	4
Member of 0 groups	3

Key Message: **Statutory oversight of dual-use research is rare**

Dual-use Research

Only one out of the 27 countries with BSL4 labs scores high on dual-use research governance (Table 6). Two score medium and 24 score low on dual-use research governance.

Only one country has national dual-use research legislation in place for oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research (Table 7). Two countries have dedicated entities with national oversight responsibilities for dual-use research. A funder-based oversight system is less comprehensive than one implemented by a national agency, but it does provide monitoring of some potentially high-risk research.

We assess that three countries have dual-use research review processes overseen by funders. As a cross-cutting insurance of proper governance, countries should have whistleblower protection laws in place which could apply to workers that report issues with dual-use research to laboratory management or government regulatory authorities. We assess 15 countries to have statutory whistleblower protections.

Awareness amongst stakeholders also forms a crucial component of dual-use governance. On-going education and standardised training related to dual-use research should be required, in addition to awareness-raising and capacity-building for dual-use risk assessment and mitigation. Three countries have national awareness-raising measures.

Finally, we also assess self-governance measures, as part of a stakeholder management and oversight portion of dual-use research governance. These self-governance measures could include standards, guidelines, best practices, codes of conduct or ethics, and/or research review processes, introduced by professional societies, private, and/or academic consortia, and other standard-setting institutions. We identify 11 countries where stakeholders have adopted self-governance measures.

Table 6: Dual-use research scores by country

Dual-Use Research (score out of 10) Country	Score
Canada	9
United Kingdom	5
United States	5
Germany	4
Australia	3
Taiwan	3
Hungary	2
Italy	2
Japan	2
Switzerland	2
Brazil	1
Côte D'Ivoire	1
France	1
India	1
Kazakhstan	1
Republic of Korea	1
South Africa	1
Sweden	1
Belarus	0
China	0
Czech Republic	0
Gabon	0
Philippines	0
Russian Federation	0
Saudi Arabia	0
Singapore	0
Spain	0

Chapter 3: National Biorisk Management Scorecards – continued

Table 7: Dual-use research scoring metrics

Dual-Use Research	
Scoring metric	**Number of countries**
Governance Framework	
1. National dual-use legislation	1
2. National dual-use research oversight	
Entity with national oversight responsibility	2
Funding agency review process	3
No oversight	22
3. Awareness-raising	3
4. Whistleblower protections	15
Stakeholder Management and Oversight	
5. Self governance measures	11

Key Message:
The post-COVID building boom in BSL4 labs is so far not matched by accompanying biorisk management policies

Combined biorisk management scores

No country has a perfect score for overall biorisk management governance. Among the seven countries that score high on biorisk management governance, each have a minimum of two and a maximum of 13 metrics in which they do not receive a point (Table 8). While these points may seem inconsequential when looking at the overall score, each point not achieved within the scorecard represents a potential gap in governance that could allow for a biosafety or biosecurity incident or for research with dual-use potential to be conducted without appropriate oversight or safety measures.

More than half the countries with BSL4 labs (15/27) fall within the medium scale for overall biorisk governance and five countries score low.

Many of the countries building new labs, some for the first time (marked in bold on Table 8), score poorly on biorisk management. However, since the labs are not yet built, there is still time to strengthen national laws and regulations on biosafety, biosecurity and dual-use research to bring them up to international standards.

The international biorisk management engagement score represents membership in organisations relevant to biosafety and biosecurity governance as well as the extent of engagement in international treaty regimes and multilateral accountability (Table 9). The score was based on participation in the AG, GP BSWG, WHO's JEE, IEGBBR, and GHSA APP3 as well as the BWC and UNSCR 1540.

Compared to the overall biorisk management scores, the international engagement scores are strong. The only country which earned less than 30% of the available points is Taiwan, which is barred from participation as an independent state in many of the relevant regimes and groups. Over half of countries with BSL4 labs (14/27) earned a high score for this metric.

Table 8: Overall biorisk management scores by country

Overall Score (out of 48)	
Country	**Score**
Canada	46
United States	42
Australia	40
United Kingdom	40
France	38
Japan	38
Taiwan	35
China	33
Germany	32
Singapore	31
Spain	31
Kazakhstan	30
Sweden	30
Hungary	29
Republic of Korea	29
Brazil	28
Russian Federation	27
Italy	26
Switzerland	24
Belarus	23
Czech Republic	22
South Africa	21
India	11
Philippines	11
Côte D'Ivoire	5
Gabon	4
Saudi Arabia	3

Table 9: International biorisk management engagement score by country

International Engagement Score (out of 14)	
Country	**Score**
Canada	14
Germany	14
United States	14
Australia	13
Japan	13
Switzerland	13
United Kingdom	13
France	12
Republic of Korea	11
Sweden	11
Czech Republic	10
India	10
Italy	10
Spain	10
Hungary	9
Saudi Arabia	9
Singapore	9
Belarus	8
China	8
Philippines	8
South Africa	8
Brazil	7
Kazakhstan	7
Russian Federation	7
Côte D'Ivoire	6
Gabon	5
Taiwan	4

"National legislation should require labs to have control measures for the physical security of biological materials."

Research Methodology for National Biorisk Management Scorecards

The National Biorisk Management Scorecards assess biorisk management on the basis of 41 metrics: 18 for biosafety, 18 for biosecurity and five for dual-use research.

We define biosafety to include the principles, technologies, measures and practices of containment that can be used to prevent inadvertent release or unintentional exposure to biological agents or biological material. National biosafety legislation should require labs to undertake assessments and prioritisation of biosafety risks and to implement, maintain and document safety measures. The biosafety risk assessments should take into account the activity or protocol-specific information and should be based on the unique context of those activities and protocols, including factors related to facility, environment, and personnel. Biosafety measures include physical/engineering controls, equipment, personal protective equipment (PPE), and good microbiological practices (the working methods applied to eliminate or minimise exposure to biological material). Regular and standardised approaches to training using a common curriculum should be required. Labs should also be required to establish local biorisk management oversight, such as a biorisk management committee or dedicated biosafety officers, and to assign and communicate responsibilities and authorities for relevant roles. National governance should cover inventory requirements to keep track of dangerous pathogens. Governance should require that an accurate, verifiable, and up-to-date inventory, or itemised record, of biological materials is specified, established, and maintained within each lab. Oversight entities should keep track of any safety incidents within labs. National governance should establish processes for reporting, investigating, and taking action on incidents and nonconformities. Any incidents regarding material accountability such as lost materials or occupationally acquired infections should be reported to a national entity responsible for biosafety oversight. Additional lab policies should include transportation safety, decontamination, and incident and emergency response plans.

We define **biosecurity** to include the principles, technologies, measures, and practices that can be used to prevent unauthorised access to or loss, theft, misuse, diversion or intentional release of a biological agent or biological material.

National legislation should require labs to have control measures for the physical security of biological materials. There should be multiple layers of physical security to deter, detect, and delay an intruder from gaining access to areas containing biological agents. Labs should also be required to establish and maintain an information security programme to identify, protect, and control access to sensitive information. National governance must also ensure that only appropriate and trustworthy personnel have access to dangerous pathogens. Specific measures should be required to determine and provide assurance that workers are reliable, trustworthy, and competent, and to identify individuals who may pose a security risk.

National governance should cover additional security measures of international importance. Governance should require export controls so that the transfer and export of certain materials, technology, or software abroad is restricted. Related to synthetic biology, national governance should require a comprehensive and integrated screening framework that includes customer and sequence screening, as well as follow-up screening when customer and/or sequence screening raises a concern. As with biosafety, biosecurity governance should cover risk assessments, inventory, training, transport, and incident response plans. Any incidents regarding material accountability such as stolen materials or security breaches should be reported to an entity responsible for biosecurity oversight.

We define **dual-use research** to be life sciences research conducted for peaceful and beneficial purposes that could provide knowledge, information, methods, products, or technologies that could also be intentionally misused to endanger the health of humans, non-human animals, or the environment.

Table 10 provides the scorecard with details about the metrics and total possible points for each component of biorisk management. Points for metrics are awarded based on publicly-available, statutory measures such as laws, regulations, acts, standards, ordinances, and rules; points are not awarded for guidance documents or voluntary guidelines.

Our selection of metrics was drawn from industry best practices. We compared standards and practices in six international frameworks for biorisk management:

(1) ISO Standard 35001 Biorisk management for laboratories and other related organisations,

(2) CEN Workshop Agreement CWA 15793:2008 on Laboratory biorisk management standard,

(3) WHO's Joint External Evaluation,

(4) NTI's Global Health Security Index,

(5) the Global Health Security Agenda (GHSA) Action Package Prevent-3 (APP3) on Biosafety and Biosecurity, and

(6) the WHO's Benchmarks for International Health Regulations (IHR) Capacities.

We pulled out cross-cutting standards and practices from these frameworks, and we included additional metrics such as whistleblower protection and dual-use research oversight structures.

On the interactive map available on GlobalBioLabs.org, raw scores for biosafety (max 20), biosecurity (max 18) and dual-use research oversight (max 10) were converted to percentages and rounded to the nearest whole number. For example, a '15/18' for biosecurity became an '83'. Countries were then placed in rankings of high, medium, and low for biosafety, biosecurity, and dual-use research oversight (Table 11). Once overall-scores were tabulated, countries were given a category of high, medium, or low based on the sum of their subcategory scores (Table 12). Figure 2 provides the comprehensive list of all scoring for the countries covered by this research.

Table 10: Global biolabs biorisk management scoring card

Global Biorisk Management Scorecard			48 points
Biosafety			**20 points**
Governance Framework			**4 points**
1.	National biosafety legislation	0=no applicable national governance, 1=related national governance	
2.	National biosafety oversight entity	0=no applicable national governance, 1=related national governance	
3.	National list of dangerous pathogens	0=no applicable national governance, 1=related national governance	
4.	Whistleblower protections that could be applied to laboratory personnel with concerns about biosafety	0=no applicable national governance, 1=related national governance	
Implementation			**12 points**
5.	Physical/engineering controls	0=no applicable national governance, 1=related national governance	
6.	Good microbiological practices	0=no applicable national governance, 1=related national governance	
7.	Biosafety risk assessments	0=no applicable national governance, 1=related national governance	
8.	Administrative controls	0=no applicable national governance, 1=related national governance	
9.	Training	0=no applicable national governance, 1=related national governance	
10.	Personal protective equipment	0=no applicable national governance, 1=related national governance	
11.	Occupational health	0=no applicable national governance, 1=related national governance	
12.	Inventory	0=no applicable national governance, 1=related national governance	

Global Biorisk Management Scorecard			48 points
13.	Transportation safety	0=no applicable national governance, 1=related national governance	
14.	Decontamination	0=no applicable national governance, 1=related national governance	
15.	Incident response plan	0=no applicable national governance, 1=related national governance	
16.	Incident reporting	0=no applicable national governance, 1=related national governance	
Biosafety Association			**2 points**
17.	National or regional biosafety association	0=no biosafety association, 1=participation in regional biosafety association, 2=national biosafety association	
International Engagement			**2 points**
18.	Participation on global scale, e.g. engagement with WHO's JEE, IEGBBR, GHSA APP3, or other similar initiatives	0=no participation, 1=participation in 1 or 2 groups, 2=participation in 3 groups	
Biosecurity			**18 points**
Governance Framework			**4 points**
1.	National biosecurity legislation	0=no applicable national governance, 1=related national governance	
2.	National biosecurity oversight entity	0=no applicable national governance, 1=related national governance	
3.	National list of dangerous pathogens	0=no applicable national governance, 1=related national governance	
4.	Whistleblower protections that could be applied to laboratory personnel with concerns about biosecurity	0=no applicable national governance, 1=related national governance	

Chapter 3: National Biorisk Management Scorecards – continued

Table 10: Global biolabs biorisk management scoring card – continued

Global Biorisk Management Scorecard		48 points
Implementation		**11 points**
5. Physical security	0=no applicable national governance, 1=related national governance	
6. Information and cyber security	0=no applicable national governance, 1=related national governance	
7. Personnel reliability	0=no applicable national governance, 1=related national governance	
8. Biosecurity risk assessments	0=no applicable national governance, 1=related national governance	
9. Inventory	0=no applicable national governance, 1=related national governance	
10. Export controls	0=no applicable national governance, 1=related national governance	
11. DNA screening	0=no applicable national governance, 1=related national governance	
12. Training	0=no applicable national governance, 1=related national governance	
13. Transportation security	0=no applicable national governance, 1=related national governance	
14. Incident response plan	0=no applicable national governance, 1=related national governance	
15. Incident reporting	0=no applicable national governance, 1=related national governance	
International Engagement (14 points into 0-3 score: 0=score lower than 4; 1=score between 4-7; 2=score between 8-11; 3=score between 12-14)		**3 points**
16. Biological Weapons Convention	0=not signed, 1=signed, 2=ratified no CBM, 3=ratified and private CBM, 4=ratified and public CBM	

Global Biorisk Management Scorecard		48 points
17. United Nations Security Council Resolution 1540	1= <33% implementation of Operative Paragraphs 2 & 3, 2=34-65% implementation, 3=66-100% implementation	
18. Membership in the following groups: AG, GP BSWG, WHO's JEE, IEGBBR, GHSA's APP3	0=none, 1=1, 2=2, 3=3, 4=4, 5=5	
Dual-Use Research Oversight		**10 points**
Governance Framework		**9 points**
1. National dual-use legislation	0=no applicable national governance, 4=related national governance	
2. National dual-use research oversight	0=no applicable national governance/oversight, 2=funding agency review process, 3=entity with national oversight responsibility	
3. Awareness-raising	0=no applicable national governance, 1=related national governance	
4. Whistleblower protections that could be applied to laboratory personnel with concerns about dual-use	0=no applicable national governance, 1=related national governance	
Stakeholder Management and Oversight		**1 point**
5. Self-governance measures such as standards, guidelines, best practices, codes of ethics, and research review processes, introduced by professional societies, private consortia, academic groups, or other standard-setting institutions	0=no applicable national governance, 1=related national governance	

Figure 2. Scoring metrics by country

Category	Sub-Category	Specific	Australia	Belarus	Brazil	Canada	China	Cote d'Ivoire	Czech Republic	France	Gabon	Germany	Hungary	India	Italy	Japan	Kazakhstan	Philippines	Republic of Korea	Russia	Saudi Arabia	Singapore	South Africa	Spain	Sweden	Switzerland	Taiwan	United Kingdom	United States
Biosafety	Biosafety Governance Framework	National Biosafety Legislation	1	1	1	1	1	0	1	1	0	1	1	0	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1
		National Biosafety Oversight Entity	1	1	1	1	1	0	1	1	0	1	1	0	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0
		National List	1	1	1	1	1	0	1	1	0	1	1	1	1	1	1	1	1	1	0	1	0	1	1	0	1	1	1
		Whistleblower Protections	1	0	1	1	0	0	0	1	0	1	1	1	1	1	0	0	1	0	0	0	1	0	1	1	0	1	1
	Biosafety Implementation	Physical/Engineering Controls	1	1	1	1	1	0	1	1	0	1	1	0	1	1	1	0	1	1	0	1	1	1	1	1	1	1	1
		Good Microbiological Practices	1	1	1	1	1	0	1	1	0	1	0	0	1	1	1	0	0	1	0	1	1	1	1	1	1	1	1
		Biosafety Risk Assessments	1	0	1	1	1	0	1	1	0	1	1	0	1	1	1	1	0	1	0	1	1	1	1	1	1	1	1
		Administrative Controls	1	1	1	1	1	0	1	1	0	1	1	0	1	1	1	0	1	1	0	1	1	1	1	0	1	1	1
		Training	1	1	1	1	1	0	0	1	0	1	1	0	1	1	1	0	1	1	0	1	1	1	1	0	1	1	1
		Personal Protective Equipment	1	1	1	1	1	0	0	1	0	1	1	0	1	0	1	0	0	1	0	1	1	1	1	1	1	1	1
		Occupational Health	1	0	1	1	1	0	1	1	1	1	1	0	1	1	1	0	1	1	0	1	1	1	1	1	1	1	1
		Inventory	1	1	1	1	1	0	1	1	0	1	0	0	0	1	1	0	1	1	0	1	0	1	0	0	1	1	1
		Transportation Safety	1	1	1	1	1	0	1	1	0	1	1	0	1	1	1	0	1	1	0	1	1	1	1	1	1	1	1
		Decontamination	1	1	1	1	1	0	0	1	0	1	1	0	1	1	1	0	1	1	0	1	1	1	1	1	1	1	1
		Incident Response Plan	1	1	1	1	1	0	0	1	0	1	1	0	1	1	1	0	1	1	0	1	0	1	1	1	1	1	1
		Incident Reporting	1	1	1	1	1	0	1	1	0	1	1	0	1	1	1	0	0	1	0	1	1	1	1	1	1	1	1
	Biosafety Association	National or Regional Biosafety Association	2	1	2	2	2	2	0	1	1	1	1	2	2	2	1	2	2	0	0	2	2	2	1	2	2	1	2
	International Engagement	Participation on global scale	2	0	0	2	1	1	0	2	1	2	0	1	1	2	0	1	1	0	1	1	1	1	1	2	1	1	2
	Biosafety Total Score		**20**	**14**	**18**	**20**	**18**	**3**	**11**	**19**	**3**	**19**	**15**	**5**	**18**	**19**	**16**	**7**	**15**	**15**	**1**	**18**	**16**	**18**	**17**	**16**	**18**	**18**	**19**
Biosecurity	Biosecurity Governance Framework	National Biosecurity Legislation	1	1	0	1	1	0	1	1	0	0	1	0	0	1	1	0	1	1	0	1	0	1	1	0	1	1	1
		National Biosecurity Oversight Entity	1	0	0	1	1	0	1	1	0	0	1	0	0	1	1	0	1	1	0	1	0	1	1	0	1	1	1
		National List	1	1	1	1	1	0	1	1	0	1	1	1	1	1	1	1	1	1	0	1	0	1	1	0	1	1	1
	Biosecurity Implementation	Whistleblower Protections	1	0	1	1	0	0	0	1	0	1	1	1	1	1	0	0	1	0	0	0	1	0	1	1	0	1	1
		Physical Security	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	0	1	1	0	1	0	1	1	0	1	1	1
		Information and Cyber Security	1	0	0	1	1	0	0	1	0	0	0	0	0	1	1	0	1	0	0	0	0	1	0	0	1	1	1
		Personnel Reliability	1	0	1	1	1	0	1	1	0	1	1	0	0	1	0	0	1	0	0	1	0	0	0	0	1	1	1
		Biosecurity Risk Assessments	1	0	0	1	1	0	0	1	0	0	0	0	0	1	1	0	0	1	0	1	0	0	0	1	1	1	1
		Inventory	1	1	0	1	1	0	1	1	0	0	0	0	0	1	1	0	1	1	0	1	0	1	0	0	1	1	1
		Export Controls	1	1	1	1	1	0	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1
		DNA Screening	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
		Training	1	1	1	1	1	0	0	1	0	0	1	0	0	1	1	0	0	1	0	1	0	1	1	0	1	1	1
		Transportation Security	1	1	1	1	1	0	1	1	0	1	1	0	1	1	1	0	1	1	0	1	0	1	1	0	1	1	1
		Incident Response Plan	1	0	0	1	1	0	0	1	0	1	1	0	0	1	1	0	1	1	0	0	0	1	1	0	1	1	1
		Incident Reporting	1	0	1	1	1	0	1	1	0	0	1	0	0	1	1	0	0	1	0	1	0	1	1	0	1	1	1
	International Engagement	BWC; UNSCR 1540; Membership of AG, GP BSWG, GHSA APP3, IEGBBR, JEE	3	2	1	3	2	1	2	3	1	3	2	2	2	3	1	2	2	1	2	2	2	2	2	3	1	3	3
	Biosecurity Total Score		**17**	**9**	**9**	**17**	**15**	**1**	**11**	**18**	**1**	**9**	**12**	**5**	**6**	**17**	**13**	**4**	**13**	**12**	**2**	**13**	**4**	**13**	**12**	**6**	**14**	**17**	**18**
Dual Use	Dual Use Governance Framework	National Dual Use Legislation	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		National Dual-Use Research Oversight	0	0	0	3	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	2	2
		Awareness Raising	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
		Whistleblower Protections	1	0	1	1	0	0	0	1	0	1	1	1	1	1	0	0	1	0	0	0	1	0	1	1	0	1	1
	Stakeholder Oversight	Self-governance Measures	1	0	0	1	0	1	0	0	0	1	1	0	1	1	1	0	0	0	0	0	0	0	0	1	0	1	1
	Dual Use Total Score		**3**	**0**	**1**	**9**	**0**	**1**	**0**	**1**	**0**	**4**	**2**	**1**	**2**	**2**	**1**	**0**	**1**	**0**	**0**	**0**	**1**	**0**	**1**	**2**	**3**	**5**	**5**

> "In general, countries with well-established democratic governments scored highest on the national context indicators."

Chapter 4: Governance and Stability

The national biorisk management scorecards provide a snapshot of the status of national legislation and regulations, but they do not provide evidence of how well these measures are being complied with or enforced in a given country. To provide a general sense of the ability of countries with BSL4 labs to effectively implement their biorisk management policies, we created two indexes.

The first index measures the general quality of governance in a country and the other measures its general level of stability. These indexes are based on data generated by the World Bank, Transparency International, Freedom House, the Nuclear Threat Initiative, Fund for Peace, and others (see section on research methodology for national context). We combined the scores that countries received from each of these sources to create a composite score indicating how well governed and how stable the country is.

Only countries with operational or planned BSL4 labs were included in the scoring. As the scores are percentiles, they were then ranked against each other. A relatively low score is therefore only relative to other countries with BSL4 labs, not to the rest of the world.

Key Message: Countries with operational BSL4 labs generally score well on governance and stability, but the bulk of planned BSL4 labs are in countries that score in the bottom-half of these indexes

The Governance scorecard assesses to what extent a country's political system is effective, equitable, accountable, and independent (Table 13). Sweden scored highest with a score of 94, while Russia and Gabon scored lowest with a score of nine. The average composite score is 50, as expected with percentile scoring, while the median is 56.

The Stability scorecard assesses the level of domestic and international conflict, government repression, terrorism, political stability, and perceived government legitimacy, among other factors (Table 13).

Switzerland scored highest on the Stability scorecard with a score of 82, while the Philippines scored lowest with a score of ten. The average score is 50; the median 52.

In general, countries with well-established democratic governments scored highest on the national context indicators. The Governance and Stability scores were usually congruous, with only four countries yielding a discrepancy greater than 20 points between the two scorecards.

There are significantly more operational BSL4 labs in countries that have a Governance and Stability score greater than or equal to 50. However, planned or under-construction BSL4 labs are disproportionately located in countries that score less than 50 on both Governance and Stability (Table 14). Similar trends exist for the distribution of BSL3+ labs across countries which scored above the 50th percentile for Governance (Table 14).

There are 28 operational BSL3+ labs in nine countries that have a Governance score greater than or equal to 50. For countries with a Governance score of less than 50, there are six operational BSL3+ labs in five countries. In contrast, however, there are only 11 operational BSL3+ labs in countries with a Stability score of greater than or equal to 50, while there are 23 operational BSL3+ labs in countries with a Stability score of less than 50. The United States, which has a Stability score of less than 50 and accounts for 18 of the 38 operational BSL3+ labs, is the primary driver of this difference in the spread of the Governance and Stability metrics amongst BSL3+ labs.

We also calculated the average of the Governance and Stability percentile scores for each country and named this averaged score the 'National Context.' This score was then plotted against the overall Biorisk Management scores to create a scatter plot (Figure 3).

The data shows a positive correlation between the two scores, with a Pearson correlation coefficient of 0.61. Further, to assist with visualisation, we divided the plot into quadrants using the 50th percentile and percentage, respectively, as the division between 'upper' and 'lower' scores for national context and biorisk management. It was rare for countries to have both an upper national context score and lower biorisk management score, with only the Czech Republic falling into this quadrant. Between the countries in the quadrant with lower scores for both categories, there are a combined seven planned BSL4 labs and five operating BSL4 labs. It must be noted that these are very broad groupings, distinguishing only between scores above and below the 50th percentile and 50 percent. The spectrum is far more incremental than indicated by these quadrants, but the scatter plot proves a useful tool for visualising the correlation between national context and biorisk management, along with grouping countries with similar opportunities for improvement when it comes to responsible management of their high consequence facilities.

It is worth reiterating that the percentile rankings were calculated taking into account exclusively countries with operational or planned BSL4 labs. Rather than indicating the Governance or Stability of a country worldwide, our national context indicators compared countries responsible for high-containment laboratories against each other. As a result, well-governed countries might have a seemingly inaccurate ranking, but this is comparative only to the other countries evaluated.

Table 13: Governance and Stability composite scores by country

Country	Governance	Stability
Australia	83	68
Belarus	12	26
Brazil	26	23
Canada	86	66
China	25	26
Côte d'Ivoire	16	18
Czech Republic	56	80
France	63	52
Gabon	9	45
Germany	81	72
Hungary	40	67
India	30	15
Italy	50	52
Japan	74	79
Kazakhstan	22	42
Philippines	22	10
Republic of Korea	57	67
Russian Federation	9	17
Saudi Arabia	29	25
Singapore	77	79
South Africa	34	36
Spain	56	58
Sweden	94	80
Switzerland	91	82
Taiwan	71	75
United Kingdom	76	63
United States	60	35

Table 14: Distribution of lab types and status by percentile cutoff in countries with BSL4 labs that are operational, under construction or planned

		Number of Labs in Countries with Percentile Score	
Lab Type and Status	**Metric**	**Less than 50**	**Greater than/equal to 50**
Operational BSL4	Governance	12	39
	Stability	20	31
Planned and Under Construction BSL4	Governance	10	8
	Stability	12	6
Operational BSL3+	Governance	6	28*
	Stability	23*	11
Planned and Under Construction BSL3+	Governance	1	1
	Stability	2	0

*The United States has 19 operational BSL3+ laboratories.

Figure 3. Quadrant scatter plot of national context percentiles against biorisk management score percentage (out of maximum possible score) for all countries with operational or planned BSL4 labs

Research Methodology for National Context Indexes

We identified seven indexes that measure national attributes like government accountability, civil unrest, terrorism incidence, and corruption:

- Transparency International: Corruption Perceptions Index (2021) [Governance]
- World Bank: Worldwide Governance Indicators (2020) [Governance and Stability]
- Freedom House: Freedom in the World (2021) [Governance]
- The Nuclear Threat Initiative: Global Health Security Index (2021) [Stability]
- The Fund for Peace: Fragile States Index (2021) [Stability]
- Institute for Economics and Peace: Global Terrorism Index (2021) [Stability]
- Gibney, et al.: The Political Terror Scale (2020) [Stability]

We normalised the scoring across the indices by calculating percentile rankings for each index using a standard percentile ranking equation: where Percentile=

$$\frac{M+0.5*R}{Y} * 100$$

M = The number of ranks below X (the country's score)

R = The number of ranks equal to X (the country's score)

Y = The total number of ranks

Percentile ranking takes the absolute scores identified in the indexes and ranks each country's scores relative to one another. Under this approach, the index scores referenced were also weighted equally. The major advantage of this approach is that it enables cross index comparisons through normalisation of the scores on a scale of 0 to 100. Only countries operating or planning BSL4 labs were involved in the percentile calculations, so the scores are relative to the subgroup of relevant countries. Composite scores were then calculated by averaging the percentile rankings for each score to find the final "Governance" or "Stability" composite score.

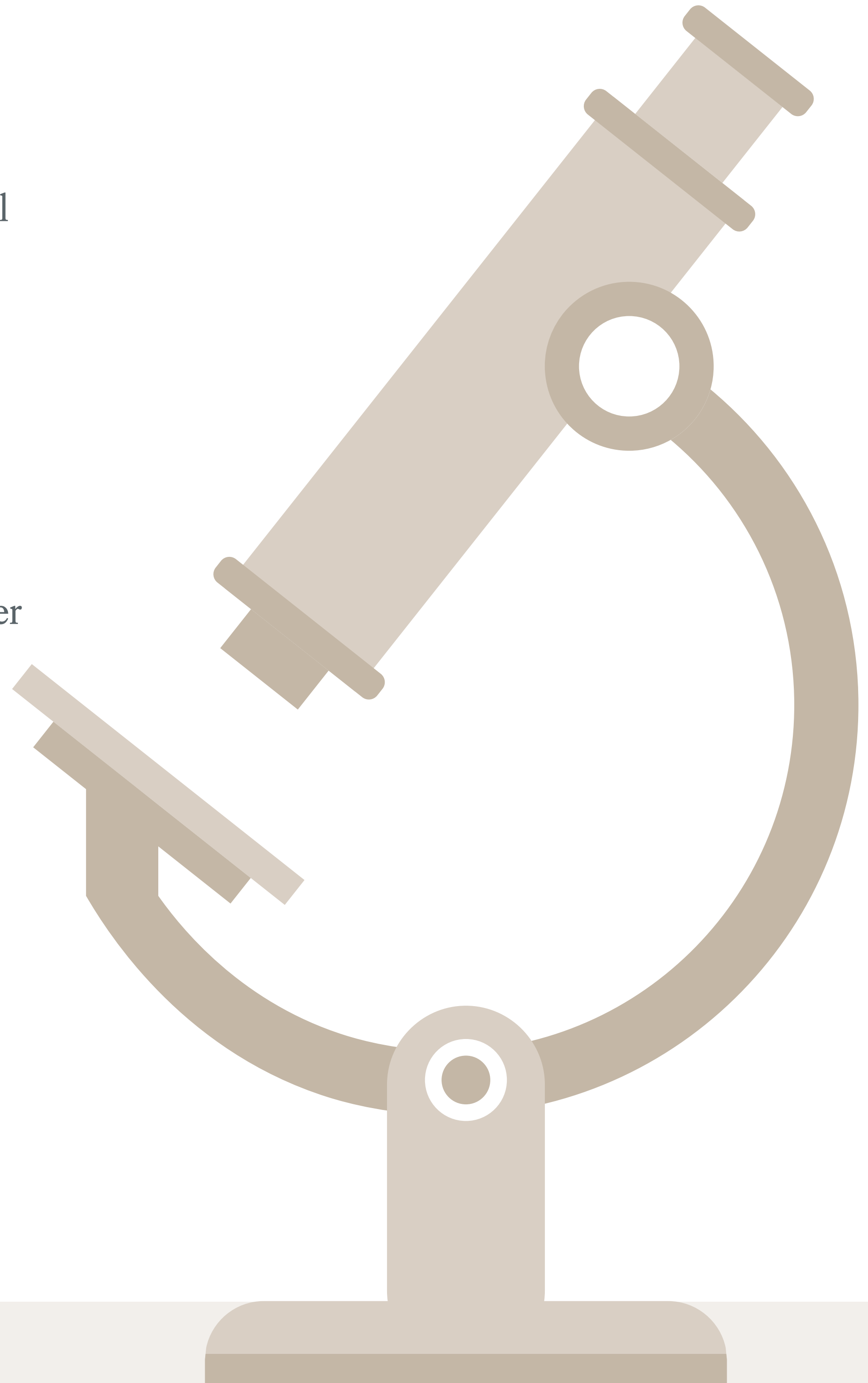
Chapter 5: International Governance of Biorisk Management

At the international level, current biorisk management efforts are fragmented across regulatory, public health, and nonproliferation domains with wide variation in the levels of resources and attention devoted to biosafety, biosecurity, and dual-use research oversight. There are few legally-binding requirements in any of these three fields and even fewer mechanisms for ensuring compliance with such requirements.

"At the international level, current biorisk management efforts are fragmented across regulatory, public health, and nonproliferation domains with wide variation in the levels of resources and attention devoted to biosafety, biosecurity, and dual-use research oversight."

International efforts to govern and strengthen biorisk management are conducted by a mix of formal international organisations, such as the World Health Organization (WHO), the World Organisation for Animal Health (WOAH), the Food and Agriculture Organisation (FAO), and Interpol; UN bodies such as the UN Security Council's 1540 Committee, the UN Biorisk Working Group (UN-BRWG), and the UN Secretary General's Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons (UNSGM); treaty-based initiatives such as the Biological Weapons Convention (BWC); informal, multinational groups such as the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR), the Biosafety Level 4 Zoonotic Laboratory Network (BSL4ZNET), the Australia Group, the Global Health Security Agenda (GHSA), and the Biological Security Working Group (BSWG) of the Global Partnership Against Weapons of Mass Destruction; and international non-governmental groups such as the International Standards Organization (ISO), the International Gene Synthesis Consortium (IGSC), the European Research Infrastructure on Highly Pathogenic Agents (ERINHA), the International Federation of Biosafety Associations (IFBA), and the InterAcademy Partnership (IAP).

This section provides a brief description of the roles of key international institutions. The next chapter provides recommendations for strengthening the authorities and capabilities of these actors to promote safe, secure, and responsible life sciences research and operation of high-consequence research facilities.



The 1972 **Biological Weapons Convention** (BWC) prohibits the development, production, stockpiling, acquisition, and transfer of biological weapons. The treaty provides the foundation for the global biological weapons nonproliferation and disarmament regime. It has 185 member states and a small secretariat, the Implementation Support Unit (ISU), which administers the treaty meetings, the quinquennial review conference, and collects the annual declarations under the treaty's confidence building measures (CBMs). One of these CBMs (Form A) requires countries to provide information about maximum containment (BSL4) labs on their territory or their high containment (BSL3) labs if the country does not have a BSL4 lab. Another CBM (Form E) requires countries to provide information on legislation, regulations, and other measures related to biosafety and laboratory biosecurity. Between 2017 and 2021, between 78 and 92 countries submitted their CBMs and 35-40% of them made these documents publicly available.

The **World Health Organization** (WHO) provides guidance on laboratory biosafety and biosecurity and the responsible conduct of life sciences research to its 194 member states. In 2022, WHO published the Global Guidance Framework for the Responsible Use of the Life Sciences. The framework is intended to raise the awareness of the diverse stakeholders involved in the conduct, funding, utilisation, and governance of life sciences research and biotechnology and to provide them with conceptual and practical tools to develop, implement and promote biorisk management at the individual, institutional, national, and international levels. In addition, WHO supervises research with variola virus (the virus that causes smallpox) at the two remaining repositories for the virus in the United States and Russia and conducts biennial biosafety and biosecurity inspections of these facilities. WHO has also designated four public health agencies—in the United States, United Kingdom, Canada, and Mexico—as collaborating centres on biosafety or biosecurity. These centres produce biosafety and biosecurity manuals, develop biosafety technologies and practices, conduct training and education, and assist WHO with capacity-building activities in other countries. WHO also administers the Joint External Evaluation (JEE) which is a voluntary, collaborative, multisectoral process to assess a country's capacity to prevent, detect, and rapidly respond to public health emergencies. The independent expert evaluations that are the centrepiece of the JEE include an assessment of lab biosafety and biosecurity.

Chapter 5: International Governance of Biorisk Management – continued

The **International Organization for Standardization** (ISO) develops environmental, safety, and other standards for a wide array of products and processes. In 2019, ISO published the ISO 35001 biorisk management standard for labs that work with dangerous pathogens. Rather than focusing on hardware or prescribing specific practices, the standard promotes the development of a management system that prioritises biosafety and biosecurity across the entire lab, including commitments by top management to provide adequate resources, to communicate biosafety and biosecurity policy, to train staff, and to establish performance expectations. The standard also stresses the need for continual improvement of practices and processes to determine the causes of incidents and other issues, to correct problems so they do not recur, to identify opportunities for improvement, and to recognise and award improvement. Moreover, the standard is designed to produce a documentary record that a national regulatory authority or other external entity can audit.

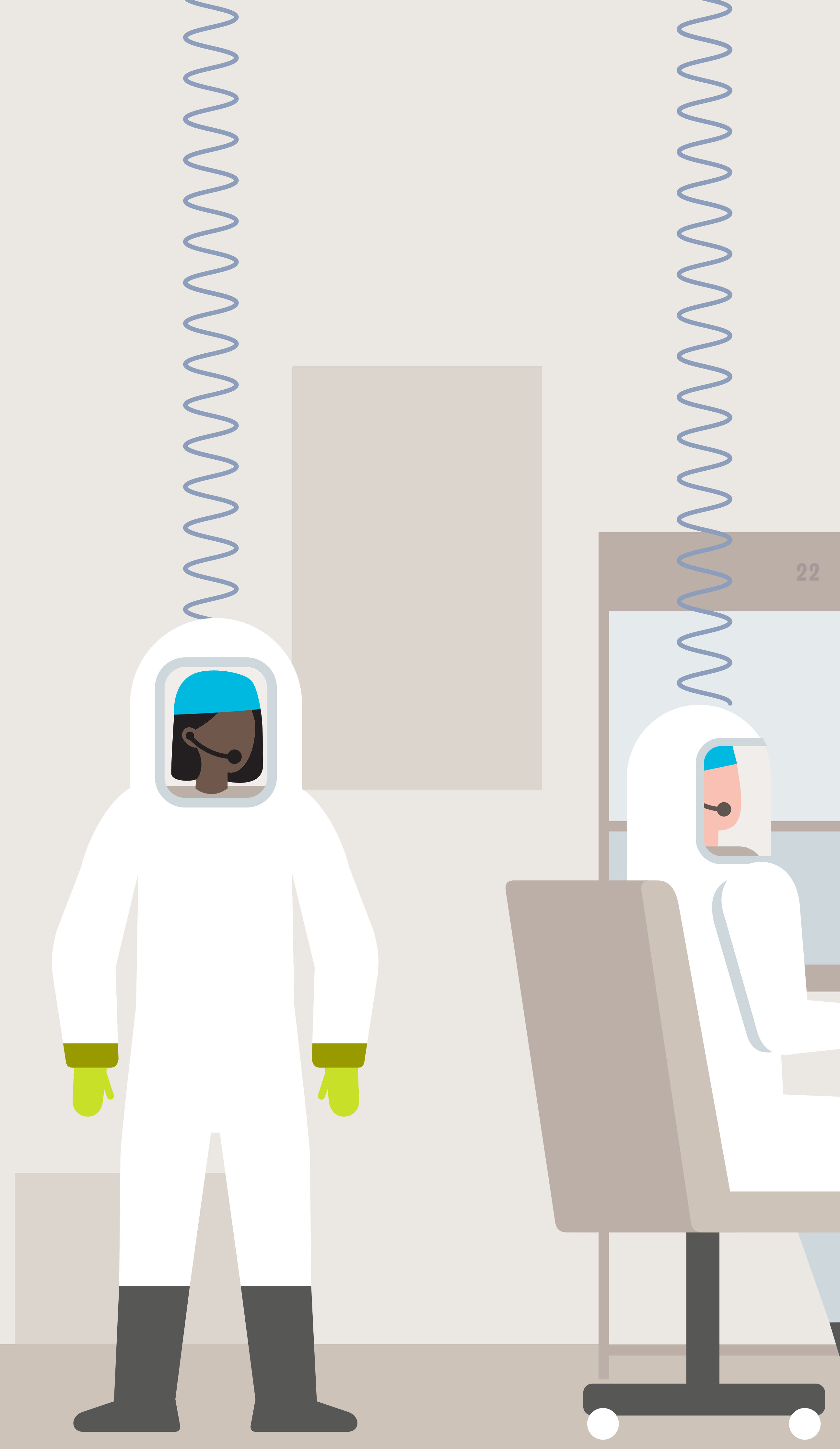
The **Global Health Security Agenda** (GHSA) involves more than 70 countries and matches donors with recipients committed to building public health capacities, including labs that comply with biosafety and biosecurity measures. The **Biosecurity Working Group** (BSWG) of the **Global Partnership Against the Spread of Weapons of Mass Destruction** (Global Partnership), provides a clearinghouse for biosecurity capacity-building programmes provided by more than 20 countries. Through the **International Experts Group of Biosafety and Biosecurity Regulators** (IEGBBR), national regulators from 11 nations share best practices on biosafety and biosecurity.

The **Biosafety Level 4 Zoonotic Laboratory Network** (BL4ZNET) comprises a dozen BSL4 laboratories in five countries that share knowledge, provide training, and respond to disease outbreaks. The **European Research Infrastructure on Highly Pathogenic Agents** (ERINHA) is a pan-European network of ten BSL3+ and BSL4 labs that provide access to their facilities for scientists conducting research on dangerous pathogens. The **Australia Group** is an informal international forum that enables more than 40 countries to harmonise their export control legislation to prevent the proliferation of chemical and biological weapons. The **International Federation of Biosafety Associations** (IFBA) is a non-governmental organisation made up of national and regional biosafety associations that provides training and professional certification in biorisk management.

Additional details about many of these key international actors can be found in the Biorisk Management Memo series available in the Publications section on GlobalBiolabs.org.

Table 15 provides a list of all countries with planned or operational BSL4 labs and their participation in international biorisk management networks (all of these states are also active members and participants of the BWC and UNSCR 1540). Figure 4 provides a visual depiction of the worldwide level of participation in these different biorisk management networks and their overlapping membership.

> "Rather than focusing on hardware or prescribing specific practices, the standard promotes the development of a management system that prioritises biosafety and biosecurity across the entire lab."



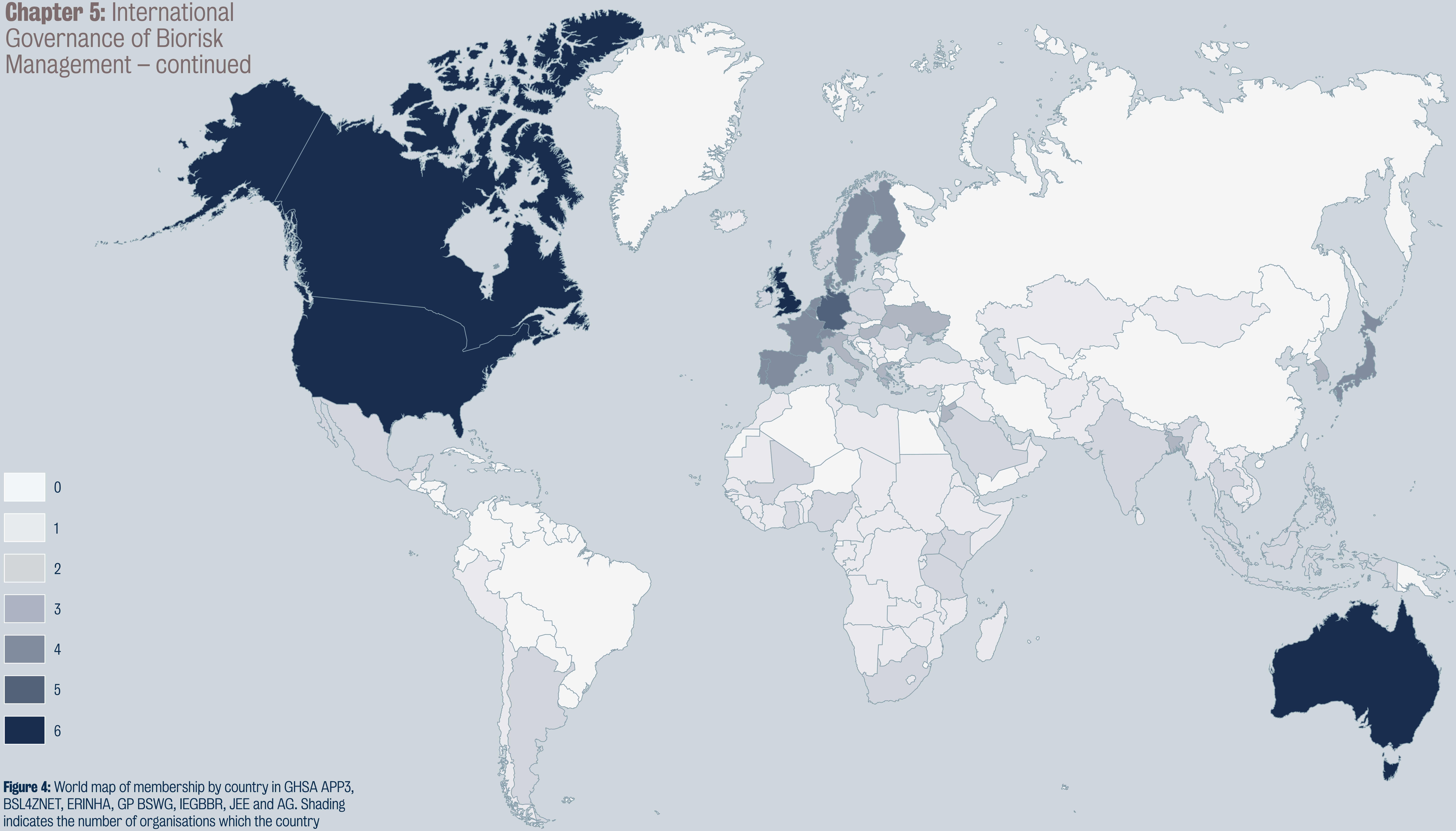


Figure 4: World map of membership by country in GHSA APP3, BSL4ZNET, ERINHA, GP BSWG, IEGBBR, JEE and AG. Shading indicates the number of organisations which the country belongs to – no country is a member of all seven.

Chapter 5: International Governance of Biorisk Management – continued

Table 15: National membership in international biorisk management networks. Only countries with a planned or operational BSL4 lab are included

Countries	APP3	BSL4ZNET	ERINHA	GP BSWG	IEGBBR	JEE	AG
Australia	✓	✓		✓	✓	✓	✓
Belarus							
Brazil							
Canada	✓	✓		✓	✓	✓	✓
China							
Côte d'Ivoire						✓	
Czech Republic				✓			✓
France			✓	✓	✓		✓
Gabon						✓	
Germany	✓	✓		✓	✓		✓
Hungary			✓	✓			✓
India	✓						✓
Italy		✓	✓				✓
Japan				✓	✓	✓	✓
Kazakhstan				✓			
Philippines				✓		✓	
Republic of Korea	✓			✓		✓	
Russia							
Saudi Arabia	✓					✓	
Singapore	✓				✓	✓	
South Africa	✓					✓	
Spain	✓		✓	✓			✓
Sweden			✓	✓		✓	✓
Switzerland				✓	✓	✓	✓
Taiwan							
United Kingdom	✓	✓	✓	✓	✓		✓
United States	✓	✓		✓	✓	✓	✓

Each of these international actors has an important role to play in biorisk management. However, the resources and authorities of these actors is inversely proportional to the degree of their emphasis on the biorisk management mission.

Groups with a strong focus on biorisk management, such as IEGBBR, GHSA, BSWG and IFBA, tend to have more limited memberships, resources, and/or authorities while larger organisations with more members and resources, such as WHO, WOAH and Interpol, tend to place biorisk management lower down on their list of priorities. In addition, formal international organisations and treaty-based initiatives face constraints imposed by the diverse interests of their members and challenges achieving the level of agreement necessary to make significant changes to the organisation or treaty's authorities and capabilities.

Furthermore, while these actors consult with each other, they do not coordinate their activities in a meaningful way. As a result, not only is there no single entity at the international level that has the mandate and capability to identify and mitigate the full range of biorisks, but there is no mechanism to manage the disparate efforts currently underway to address these risks in a comprehensive, sustained, and impactful manner. While creating a single, powerful entity with the requisite authority and capability to strengthen biorisk management globally is intellectually appealing, it is a long-term project requiring a great deal of political capital with an uncertain outcome. In the meantime, the existing institutions, both formal and informal, have untapped potential that could be better harnessed to strengthen biorisk management in the short and medium term.

Want to Learn More?

More details about key international actors and efforts to govern and strengthen biorisk management are explained in our Biorisk Management Memo series available in the Publications section on GlobalBiolabs.org

Chapter 6:
Key Recommendations

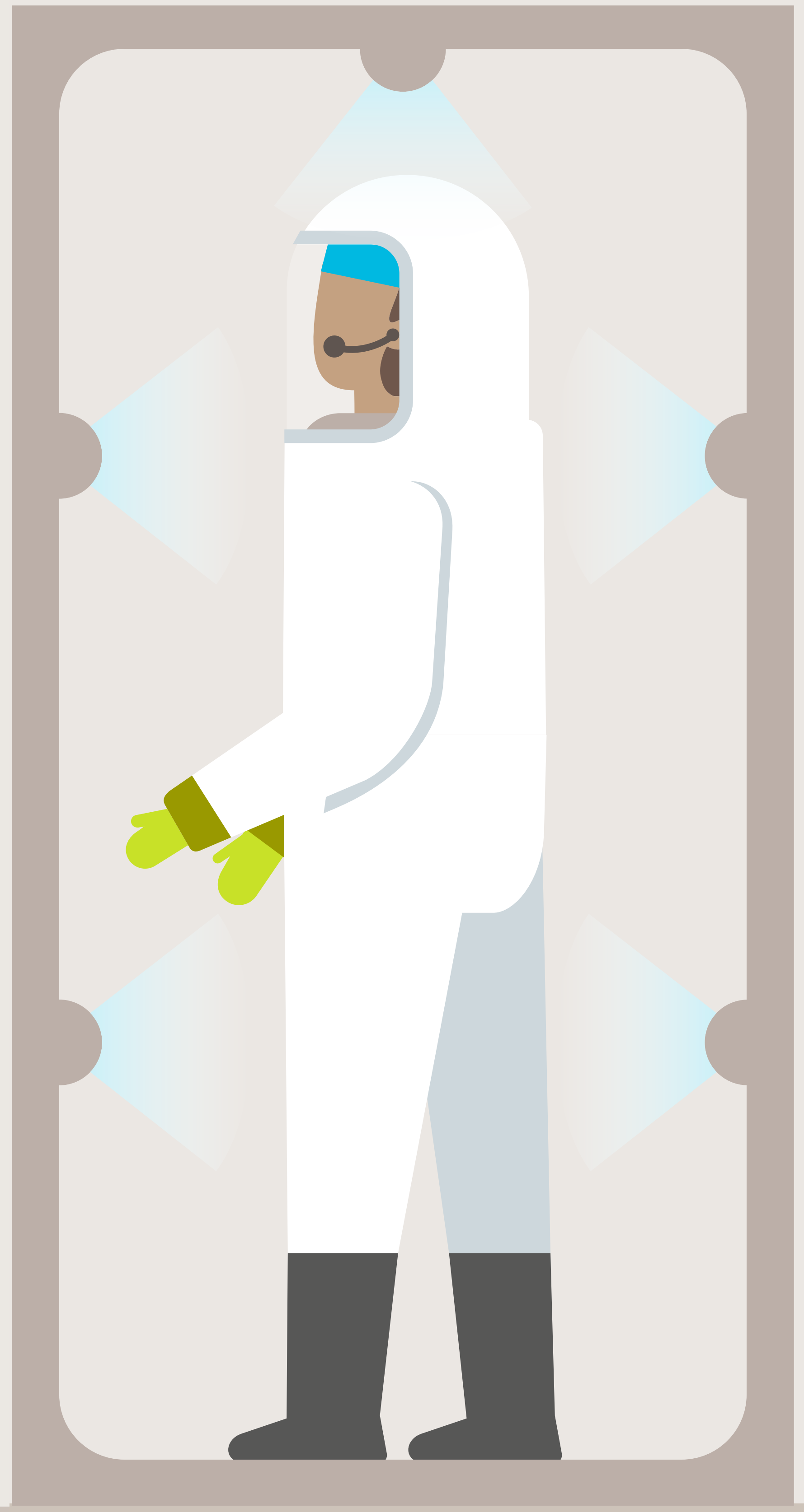
Strengthening biorisk management requires concerted effort by multiple stakeholders including labs that conduct high-consequence work with pathogens, national governments, and international actors such as intergovernmental organisations, treaty-based institutions, informal networks, and non-governmental organisations.

"Developing a culture of safe, secure, and responsible working practices is not a one-off event, but a continual effort."

Laboratory level

All labs, but particularly labs conducting high-consequence research, should cultivate a strong culture of safety, security, and responsible research. This does not just apply to BSL4 labs; as this report has demonstrated, high-consequence work with pathogens is also being conducted at BSL3+ labs, and even lower containment level labs should also be nurturing a culture of safe, secure, and responsible working practices. This dedication to biorisk management should encompass all levels, from students and technicians to principal investigators and laboratory directors. Developing a culture of safe, secure, and responsible working practices is not a one-off event, but a continual effort.

A concrete step that labs conducting high-consequence work with pathogens can take to institutionalise the importance of biorisk management is to adopt the international standard for biorisk management known as ISO 35001. This standard provides a template for establishing a management system to identify and mitigate safety and security risks as part of a continual improvement process. Since the standard is more concerned with the risk assessment and mitigation process than specific containment or security measures, it is compatible with existing national biosafety and biosecurity laws and regulations. For labs operating in countries without comprehensive biosafety and biosecurity laws and regulations, it provides a roadmap to best practices in biorisk management. The standard is low-hanging fruit since it has already been negotiated, is sitting on the shelf, and can be adopted relatively quickly.



> "Countries that do not already have a national biosafety association should encourage and support the creation of one by biosafety and biosecurity professionals."

National level

At the national level, all countries with high-consequence research facilities (BSL4 and BSL3+) should have whole-of-government biorisk management systems, including comprehensive laws, regulations, and institutions that require multidisciplinary risk assessments of proposed research for safety, security, and dual-use implications. The gold standard is a national-level government entity or entities with jurisdiction over public and private facilities that can enforce these laws and regulations.

In adopting, implementing, reviewing, and updating national laws, regulations and other measures on biosafety, biosecurity and dual-use research, states should take into account relevant voluntary global standards on biorisk management including the 2022 WHO Global Guidance Framework for the Responsible Use of the Life Sciences, the 2019 WOAH Guidelines for Responsible Conduct in Veterinary Research, and the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists.

Standards for field biosafety are much less developed than for laboratory biosafety. Field biosafety policies and practices are designed to prevent researchers from becoming exposed to an infectious disease while collecting biomedical and environmental samples in the field and handling wild animals. Few, if any, countries have national field biosafety standards and there is no international guidance available on this subject. States should develop field biosafety standards as a matter of priority.

In addition to laws and regulations, countries and their high-consequence research labs should also implement and share best practices and participate in peer reviews of practices in counterpart labs. Countries with experience in designing and operating high-containment laboratories should share their expertise in building risk-based laboratory infrastructure that is fit for purpose, is safe and secure, and can be maintained over the long term.

Countries that do not already have a national biosafety association should encourage and support the creation of one by biosafety and biosecurity professionals. These non-governmental groups can provide valuable support to labs that conduct high-consequence research by, amongst other things, providing training and professional certification, sharing best practices, and supporting the expansion of professional networks.

Countries with high-consequence research facilities should also provide complete, regular, and transparent reporting as required by the annual confidence building measures of the BWC and under UNSCR 1540. While most countries with BSL4 facilities generally submit these documents, there is no international requirement mandating this information, and countries are not specifically encouraged to submit information on BSL3+ labs. Confidence-building information should be made publicly available by all countries. So far, only nine of the 20 countries with operational BSL4 labs that submit confidence-building measures make these reports public. Only 45 percent (23/52) of the BSL4 labs in operation provide links to their publications on their institutional websites.

It would not be difficult for governments and labs to increase transparency by making BWC CBMs publicly available since the existence of these facilities is not secret and nearly every BSL4 laboratory has a website. This measure would strengthen international transparency and confidence, and it would assist further research to strengthen global biorisk management governance. Transparency is also the best antidote to disinformation. Such transparency is more important than ever given how maximum containment labs in multiple countries have become the targets of disinformation in recent years.

International level

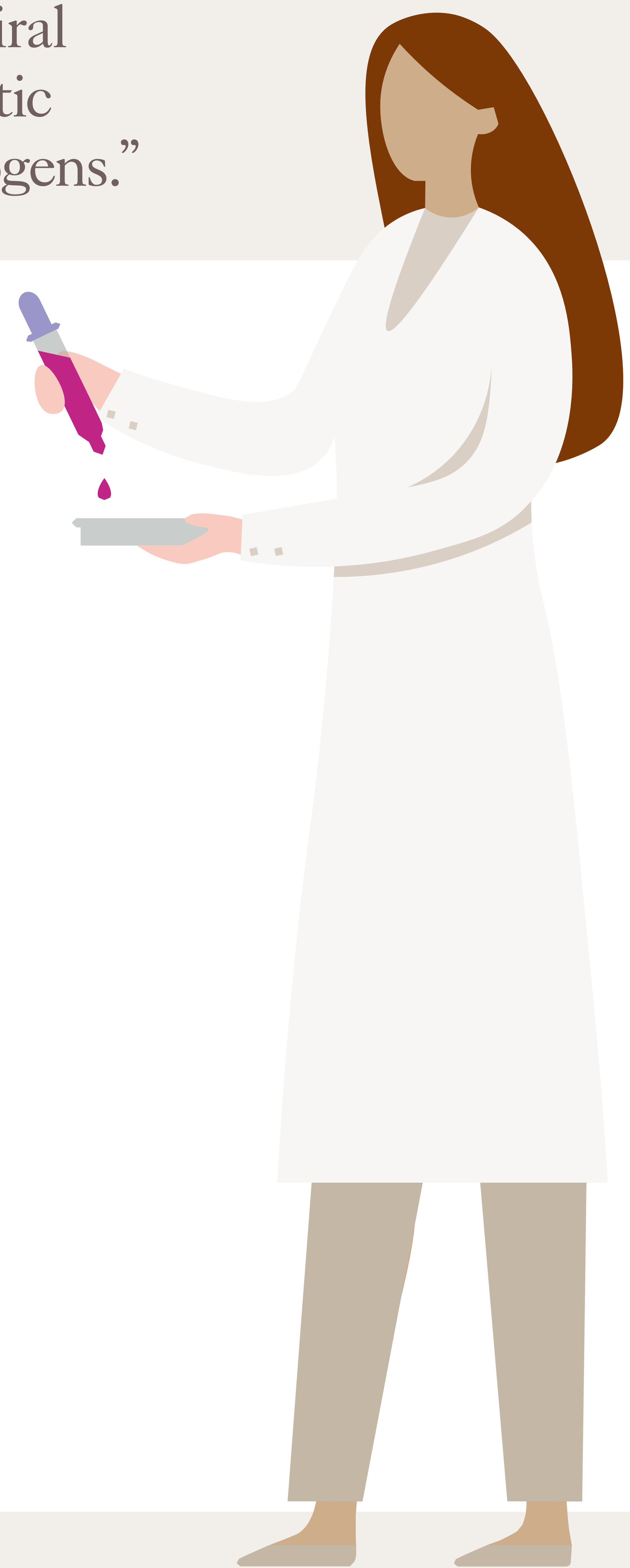
There are also high-impact measures that can be adopted at the international level to strengthen biorisk management. We first describe steps that can be taken by the bulwarks of global health and biological weapons arms control, the WHO and the BWC, to strengthen biorisk management multilaterally. We then outline a complementary 'minilateral' strategy to achieving this objective by capitalising on the activities and capabilities of less formal international groups active in this domain.

Want to learn more?

Educational resources on disinformation related to biolabs and biological weapons are available on bioweaponsdisinformationmonitor.com

Chapter 6: Key Recommendations – continued

> "There is a great need for better guidance on field biosafety given ongoing and planned large-scale efforts to collect thousands of viral samples to identify novel zoonotic and potentially pandemic pathogens."



Reinforcing multilateral approaches to biorisk management

WHO's role in global biorisk management could be strengthened in at least three ways. First, WHO should use its convening and standard-setting powers to lead an effort to develop guidance on BSL3+ labs to ensure that the physical and procedural safety measures adopted by these labs are evidence-based and commensurate with the level of risk associated with the research they conduct. Given the number of BSL3+ labs already in operation, the almost complete lack of national guidance on the type of enhancements that such labs need, and the lack of evidence-based research evaluating whether these enhancements provide increased protection commensurate with the level of risk of the research performed at these labs, we sorely need an international effort to more clearly specify the BSL3+ category.

Second, the safe collection of samples from wild and domesticated animals that may be infected with a zoonotic pathogen is an underdeveloped component of biosafety. There is a great need for better guidance on field biosafety given ongoing and planned large-scale efforts to collect thousands of viral samples to identify novel zoonotic and potentially pandemic pathogens. WHO should lead an international effort to develop guidance for field biosafety applicable to Risk Group 4 pathogens and their most common animal reservoirs, hosts, and vectors. This guidance should be incorporated into the next edition of WHO's Laboratory Biosafety Manual.

Third, WHO should establish collaborating centres for biorisk management in Africa, Southeast Asia, the Eastern Mediterranean, and the Western Pacific so that every WHO region has at least one such centre. The purpose of these centres would be to conduct and sponsor applied research in field and laboratory biosafety and laboratory biosecurity, develop biorisk management policies and practices, provide training on biorisk management, assist with capacity-building programmes, and serve as forums for exchanging information and sharing lessons learned among the key stakeholders. The awareness-raising, training, and education activities sponsored by this network should consider the lessons learned from previous such activities. Together, these centres could form the basis for a WHO-supported 'Global Network for Biorisk Management' which could oversee the process of implementing the WHO's Global Guidance Framework for the Responsible Use of the Life Sciences at the individual, institutional, and national levels.

The World Health Assembly should pass a resolution to guide WHO's critical role in enhancing biorisk management, including endorsing the Global Guidance Framework, ISO 35001, and Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists; calling for the creation of WHO collaborating centres on biorisk management; updating the WHO biosafety manual to include guidance on BSL3 enhancements and field biosafety; and requiring annual progress reports from the Director-General on measures taken by WHO to strengthen biosafety, biosecurity, and oversight of dual-use research.

Over the longer term, it would be desirable for an international system to be put in place to register high-consequence biolabs and provide oversight to ensure that all research with high-risk pathogens, including potential pandemic pathogens, is being conducted safely, securely, and responsibly. WHO could be made directly responsible for this oversight, in much the same way that it conducts biennial biosafety and biosecurity inspections of the two labs that store the remaining samples of variola virus. In an alternative iteration, WHO could organise regular biorisk management peer review exercises by international teams of government and non-government experts.

The BWC can also be leveraged to enhance biorisk management through increased transparency. Once WHO has provided guidance on the criteria for what constitutes a BSL3+ lab, the standard forms for submitting confidence-building measures under the BWC should be amended to require declaration of these labs since they are capable of conducting high-consequence research and there is minimal transparency about them. The forms should also be amended to include whether declared labs comply with ISO 35001 or equivalent international standards related to biorisk management, what biorisk management policies are in place at the facility, and whether they have codes of conduct.

The CBM forms should also be amended to include declaration of legislation, regulations and other measures relating to dual-use research as described in the WHO Global Guidance Framework for the Responsible Use of the Life Sciences, including oversight, education, awareness-raising, codes of conduct for researchers, review by funding agencies, and prepublication review. In addition, states should be required to provide a description of how they administer and enforce the full range of national implementation measures, including laws, regulations, policies, institutions, codes of conduct, and other measures, listed on the form.

“A coordinated approach to enhancing global biorisk management that harnesses these minilateral groups to promote adoption and implementation of ISO 35001 would have a powerful synergistic effect.”

Adopting a minilateral approach to biorisk management

Today’s biological threats are too diverse, urgent, and complex to be held hostage by geopolitics and rigid diplomatic rules. The international community can supplement the traditional multilateralism embodied by WHO and the BWC with a minilateral approach.

Minilateralism is a collective action strategy that brings together the smallest number of countries that can have the greatest impact on an issue. Comprehensive treaties supported by international organisations have been the gold standard for cooperation, but they can take many years to negotiate or amend. In contrast, minilateralism seeks to create a ‘coalition of the willing’ with the capability and motivation to take substantive actions that multilateral institutions cannot or will not undertake because of political, legal, or resource constraints. By starting with a small core group of dedicated states, such a coalition can reach agreements on shared objectives more quickly and avoid problems posed by spoiler states and lowest-common denominator outcomes. Minilateral initiatives can pursue many goals, including information-sharing, standard-setting, policy-coordination, capacity-building, and implementation-evaluation. As progress is made, such initiatives can expand in scope, raise their standards, and invite new members to join. For example, minilateral groups have become enduring features of the nonproliferation regime despite the lack of international legal status or bureaucracy. Although states are central to minilateralism, this approach can interact with and supplement efforts involving treaties, international organisations, and nongovernmental actors.

These groups complement—rather than replace—multilateral regimes, such as the BWC and WHO. Overall, these types of initiatives enable more ambitious countries to engage in a higher level of cooperation, albeit at the cost of inclusivity.

Existing minilateral initiatives on biorisk management could advance widespread adoption of ISO 35001 by integrating implementation of the standard into their missions. GHSA and BSWG could organise and coordinate funding for projects to help labs in low-income countries adopt ISO 35001. IFBA, which has already integrated ISO 35001 into the training and certification it offers to biosafety professionals, could offer educational and training opportunities to lab management on how to implement ISO 35001. Labs participating in BSL4ZNET and ERINHA could become test beds by adopting ISO 35001, developing guidance on implementing the standard, and sharing best practices and lessons learned.

To promote this new activity, BSL4ZNET should establish a working group dedicated to biorisk management to complement its existing ones focused on scientific and operational issues. ERINHA should integrate dual-use research oversight into the ethical guidelines that govern research conducted by its Labs in both networks should develop standards, guidelines and codes of conduct based on the 2022 WHO Global Guidance Framework for the Responsible Use of the Life Sciences, the 2019 WOAH Guidelines for Responsible Conduct in Veterinary Research, and the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists.

To maximise the potential of ISO 35001, which like all ISO standards is designed to be validated by an outside entity, there should be an international mechanism to ensure compliance. While national regulators could act as the third-party, this would have limited credibility internationally, especially for jurisdictions without proven track records for transparency and accountability. Given its regulatory expertise, IEGBBR could take on the mission of auditing laboratory compliance with ISO 35001 using a peer-review model. Peer review is the systematic evaluation of the performance of a state by other states for the purpose of helping the reviewed state improve its policies and practices and comply with established international standards. Peer review is integral to the international oversight of nuclear safety and nuclear security and is conducted by both international NGOs such as the World Association of Nuclear Operations (WANO) and by international organisations such as the International Atomic Energy Agency (IAEA). Several members of the BWC have also voluntarily trialled peer reviews of their compliance with the treaty to build confidence in the convention, improve national implementation, and provide an opportunity to share experiences and best practices. WHO’s JEE includes an assessment of a nation’s lab biosafety and biosecurity capacities as part of its peer review of a state’s progress in implementing the 2005 International Health Regulations (IHR). However, since biosafety and biosecurity are just one category out of 19 reviewed by the JEE, this evaluation is not as comprehensive as those conducted in the nuclear safety and security fields. In addition, the JEE is focused on the national level, not the policies and practices of individual labs. IEGBBR would be able to sponsor not only in-depth reviews of national biorisk management legislation, regulations, and institutions, but also laboratory-level management systems, policies, and practices as outlined in ISO 35001. IEGBBR could also contribute to the biosafety and biosecurity capacity-building programmes funded by GHSA and the Global Partnership by helping countries fix gaps and weaknesses in their biorisk management regulatory system that are identified by peer review.

A coordinated approach to enhancing global biorisk management that harnesses these minilateral groups to promote adoption and implementation of ISO 35001 would have a powerful synergistic effect.

“The dangers posed by an accidental or deliberate release of a pandemic-capable pathogen means that strengthening international oversight of high-consequence life sciences is critical.”

Conclusion

More countries are building high-containment laboratories, developing dual-use biotechnologies, and conducting risky research with pathogens. The dangers posed by an accidental or deliberate release of a pandemic-capable pathogen means that strengthening international oversight of high-consequence life sciences is critical.

Given the growing complexity of the biorisk landscape and the geopolitical constraints on adopting a robust multilateral response, a concerted effort to harness existing informal international mechanisms, while laying the groundwork for future multilateral initiatives, offers the best chance to advance collective action on ensuring that life sciences research around the world is conducted safely, securely, and responsibly.

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Thank you for reading

Want to Learn More?

Educational resources on BSL3+ and BSL4 labs, biosafety, biosecurity, and dual-use research are available at GlobalBioLabs.org