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Mapping Maximum Biological Containment Labs Globally

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High-risk pathogen research

Clinical work and scientific studies on pathogens, or disease-causing biological agents, are important for public health, biomedical advances, and disease prevention. Some of these activities, however, pose significant risks.

Work with high-risk pathogens carries substantive safety risks to laboratory workers, the wider society, and the environment. A lab worker may be accidentally infected by a pathogen, causing disease in the individual, and potentially also in other lab workers, family members, and the wider community. A pathogen may also be accidentally released directly into the environment through a lab containment breach, leading to potential spread of disease in the community.

Key security risks include pathogens or other related material being stolen from a laboratory, and lab insiders using their knowledge, skills, and access for malevolent purposes. There is also a risk that scientific knowledge and methods used by lab workers to understand and manipulate biological and epidemiological properties of pathogens for public health purposes is repurposed by others to cause harm.

High-risk pathogen work also carries risks to peace and international security. Increases in the number of facilities and researchers working with dangerous pathogens may contribute to a perception that capacities to weaponise biology are increasing, which may provide justification for a country to initiate or expand an offensive biological warfare programme.

The risks of work with dangerous pathogens mean that extremely high-levels of safety and security protection must be applied and that the work must be conducted responsibly. This is especially important for work with pathogens that may have devastating consequences for local, regional, and global communities, if an exposure or accidental release were to occur.

Maximum containment laboratories, commonly referred to as biosafety level 4 (BSL4) labs, are designed and built to work safely and securely with the most dangerous bacteria and viruses that can cause serious diseases and for which no treatment or vaccines exist. There is, however, currently no requirement to report these facilities internationally, and no international entity is mandated to collect such information and provide oversight at a global level. Moreover, there are no binding international standards for safe, secure, and responsible work on pathogens in maximum containment labs.

This study provides an authoritative resource that:

1) maps BSL4 labs that are planned, under construction, or in operation around the world, and

2) identifies indicators of good biosafety and biosecurity practices in the countries where the labs are located.

The study aims to increase public knowledge about these specialised facilities, and to strengthen national and international biorisk management policies and practices.

59 maximum containment facilities

Key message 1:
BSL4 labs are booming

Today, there are nearly 60 maximum containment facilities that are planned, under construction, or in operation around the world.

The number of BSL4 labs being built and operated has significantly increased over the past ten years. Of the 42 labs where foundation dates are available, approximately half have been established in the last decade. This means potential risks are proliferating.

The facilities are spread over 23 countries. The largest concentration of BSL4 labs is in Europe, which has 25 labs, in Belarus, Czech Republic, France, Germany, Hungary, Italy, the Russian Federation, Sweden, Switzerland, and the United Kingdom. Asia and North America have a roughly proportional number of BSL4 labs. Asia has 13 labs, located in China, India, Japan, Republic of Korea, Saudi Arabia, Singapore, and Taiwan. North America has 14 labs in Canada and the United States of America. Africa has three BSL4 labs in Cote d'Ivoire, Gabon, and South Africa. Australia has four.

More than three quarters (46/59) of global BSL4 labs are located in urban centres, exacerbating impacts of any accidental releases.

3 out of 5 BSL4 labs are government-run public health institutions.

Key message 2:
More public health than biodefence

60 percent (36/59) of global BSL4 labs are government-run public health institutions.

These labs serve a number of 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.

There are roughly proportional numbers of biodefence-related institutions (11/59) and academic institutions (10/59). Only three percent (2/59) of labs are private institutions.

The research focus of 48 labs is human health, while seven focus primarily on animal health and four focus on both human and animal health.

Less than 1/5 are university labs.

Less than 1/5 are defence labs.

Only 2 labs are wholly privately owned.

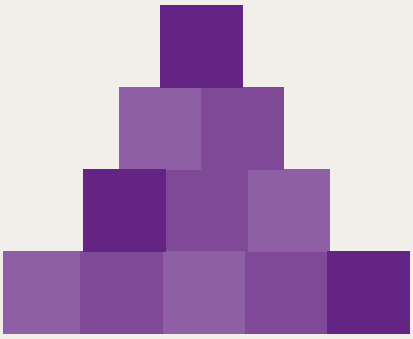
The vast majority focus on human health.

Key message 3:

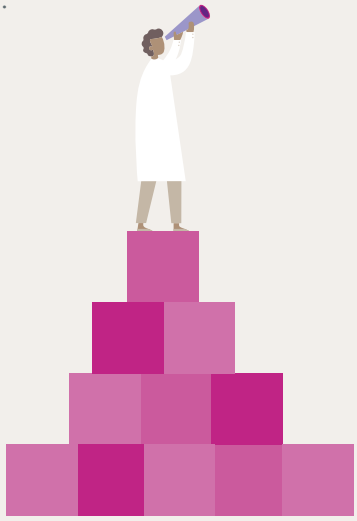
More small labs than large labs

BSL4 labs range in size from 28 m² to 4084 m².

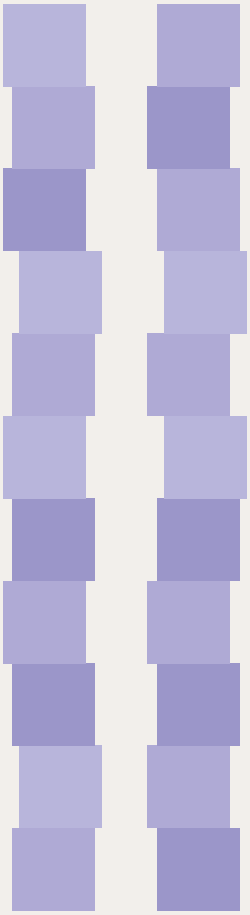
Of the 44 labs where BSL4 lab size data is available, half (22/44) are under 200 m². One quarter (11/44) of the labs are in the 200-1000 m² range, and a quarter (11/44) of the labs are above 1000 m².



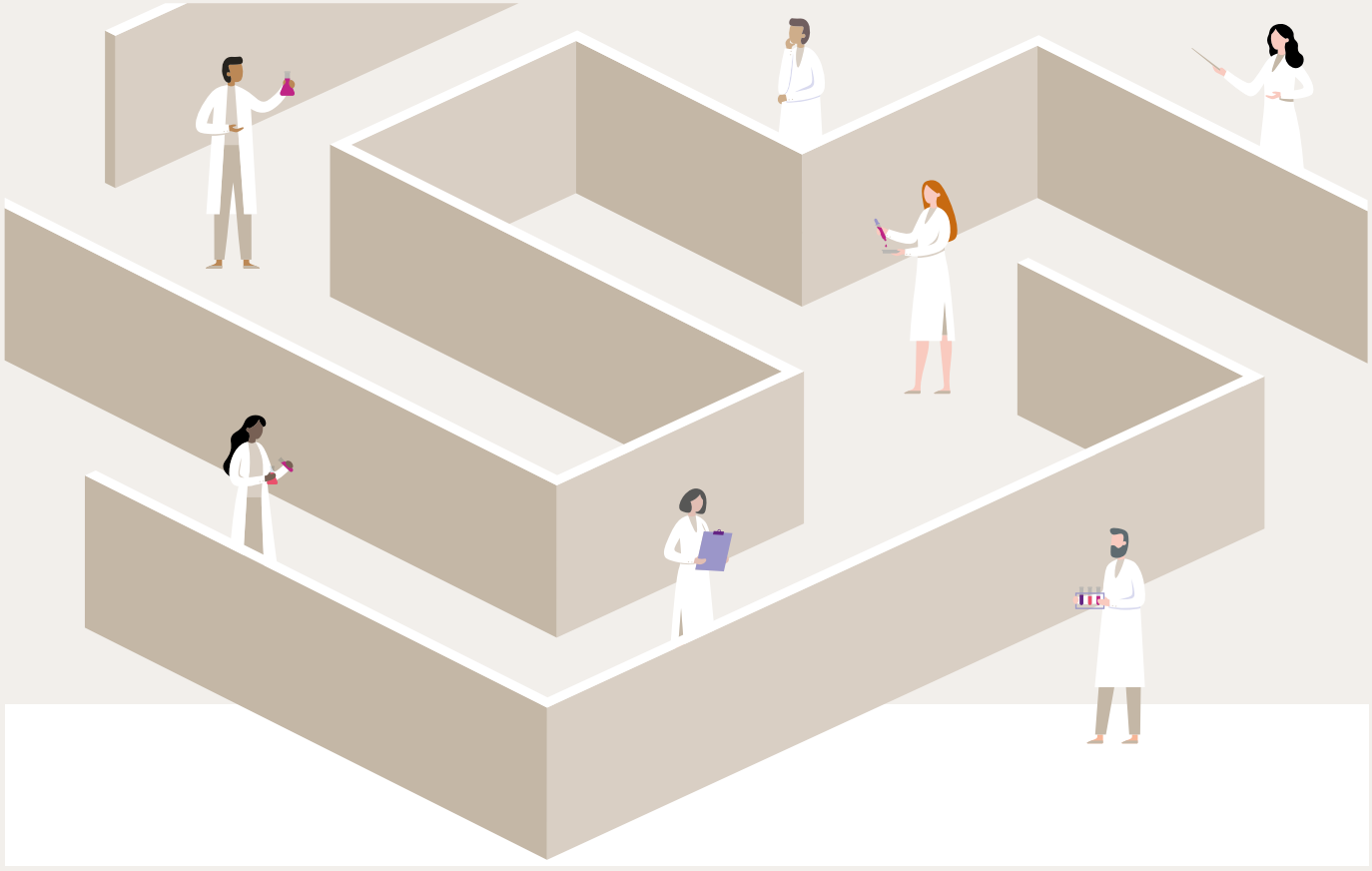
11 labs are over 1000 m²



11 labs are 200–1000 m²



22 labs are under 200 m²



Key message 4:

Sound biosafety and biosecurity practices exist but are not widely adopted

Only one-quarter of countries with BSL4 labs score well on best practice indicators for biosafety and biosecurity. Moreover, few have dual-use policies, and none have yet signed up to a new international biorisk management standard.

The Global Health Security Index, developed by the Nuclear Threat Initiative (NTI), characterizes 27 percent (6/22—excluding Taiwan) of countries with BSL4 labs as having 'high' levels of biosafety preparedness, 50 percent (11/22) as having 'medium' levels of biosafety preparedness, and 23 percent (5/22) as having 'low' levels of biosafety preparedness. The Global Health Security Index characterizes 23 percent (5/22) of countries with BSL4 labs as having 'high' levels of biosecurity preparedness, 36 percent (8/22) as having 'medium' levels of biosecurity preparedness, and 41 percent (9/22) as having 'low' levels of biosecurity preparedness. In comparison, on average for the 195 countries surveyed by NTI, around 60 percent have 'low' levels of biosafety preparedness and around 80 percent have 'low' levels of biosecurity preparedness.

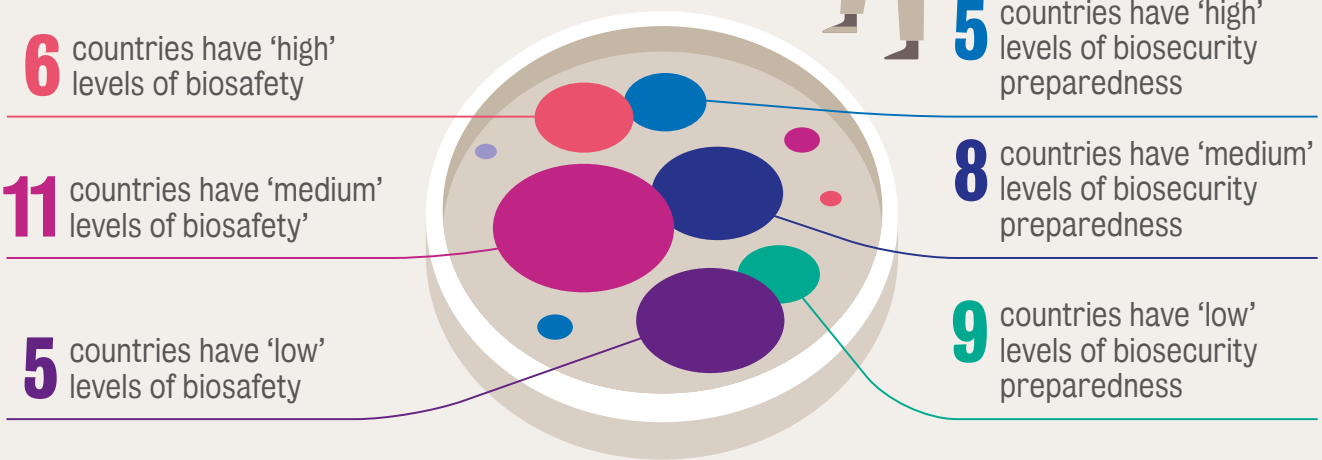
All countries with BSL4 labs that have obligations under international agreements to self-declare national biosafety and biosecurity legislation and to self-report their labs, do so. They all (22/22) report their labs under the confidence-building information-sharing process of the Biological Weapons Convention—the international treaty that bans the development and possession of biological weapons. To further increase their transparency, nine of the countries make these reports publicly accessible, and 55 percent (28/51) of the BSL4 labs in operation provide links to their publications on their institutional websites. All countries (22/22) required to self-report national biosecurity legislation under United Nations Security Council Resolution 1540, designed to prevent the proliferation of weapons of mass destruction to non-state actors, do so. 86 percent of these countries have a score of 90 percent or greater from the 1540 Committee on the strength of their national legislation to prohibit the hostile use of biology. 67 percent of these countries have a score of 90 percent or greater from the 1540 Committee on national legislation regulating access to biological materials that could be misused.

Over 70 percent (17/23) of countries with BSL4 labs have national biosafety associations or are members of regional or international biosafety associations. 40 percent (9/23) of the countries are members of the International Experts Groups of Biosafety and Biosecurity Regulators, a forum for national regulatory authorities to share their knowledge, experience, and best practices on biosafety and biosecurity.

No labs have yet signed up to the voluntary standard-setting biorisk management system ISO 35001 (Biorisk management for laboratories and other related organisations), introduced in 2019 to establish principles, essential components, and management processes to mitigate biosafety and biosecurity risks.

Only one-quarter of countries with maximum containment facilities score highly on indicators of biosafety and biosecurity preparedness.

Sample size: 22 countries.



Key message 5:

Risk assessments for dual-use are lacking

Only three out of the 23 countries have national policies on dual-use biological research and development activities with significant potential to be repurposed by state or non-state actors to cause harm.

3 out of 23 countries have dual-use policies

Study methodology and challenges

The study 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 date, publications, 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.

The study 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."

The scope of the study was restricted to labs working on pathogens that can affect humans, including zoonotic disease. Labs that only work on pathogens causing disease in animals were excluded. Mobile BSL4 labs were also excluded.

There were several challenges to the study:

- 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.
- Characterizing the size of a BSL4 lab will vary depending on whether lab space is tightly defined as the space where work is actually conducted or whether it is more broadly defined to include supporting infrastructure such as chemical showers, animal cubicles, utility rooms, etc.
- Some biosafety and biosecurity concepts and terms do not have well-defined meanings in some languages, or translate well between different languages.
- There was a limited response (13/59) from labs to information requests.

Key recommendations

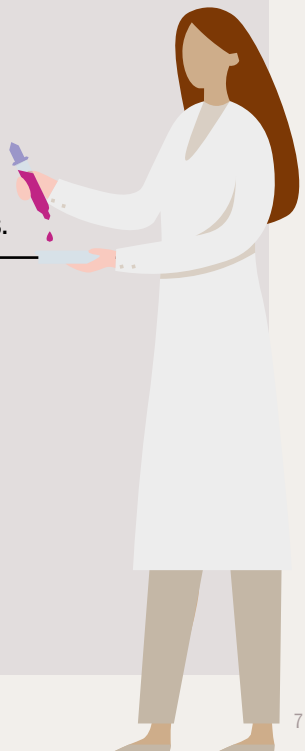
BSL4 labs must continually work to cultivate a culture of biosafety, biosecurity and responsible research with high-risk pathogens at all levels, from students to principal investigators to laboratory directors.

BSL4 labs must adhere to national laws and regulations on biorisk management, implement and share best practices, participate in peer reviews, and adopt international standards such as ISO 35001 *Biorisk management for laboratories and other related organisations.*

All countries must ensure comprehensive risk assessments are conducted for dual-use activities with significant potential to be repurposed to cause harm. This is particularly important for countries where high-risk pathogen work is carried out. Internationally-recognised guidelines governing high-risk dual-use work must also be developed.

Countries possessing BSL4 facilities must provide complete, regular, and transparent reporting under the annual confidence-building measures of the Biological Weapons Convention, and under UN Security Council Resolution 1540.

International and national structures must be put in place to systematically register and oversee maximum containment facilities.



Study leads

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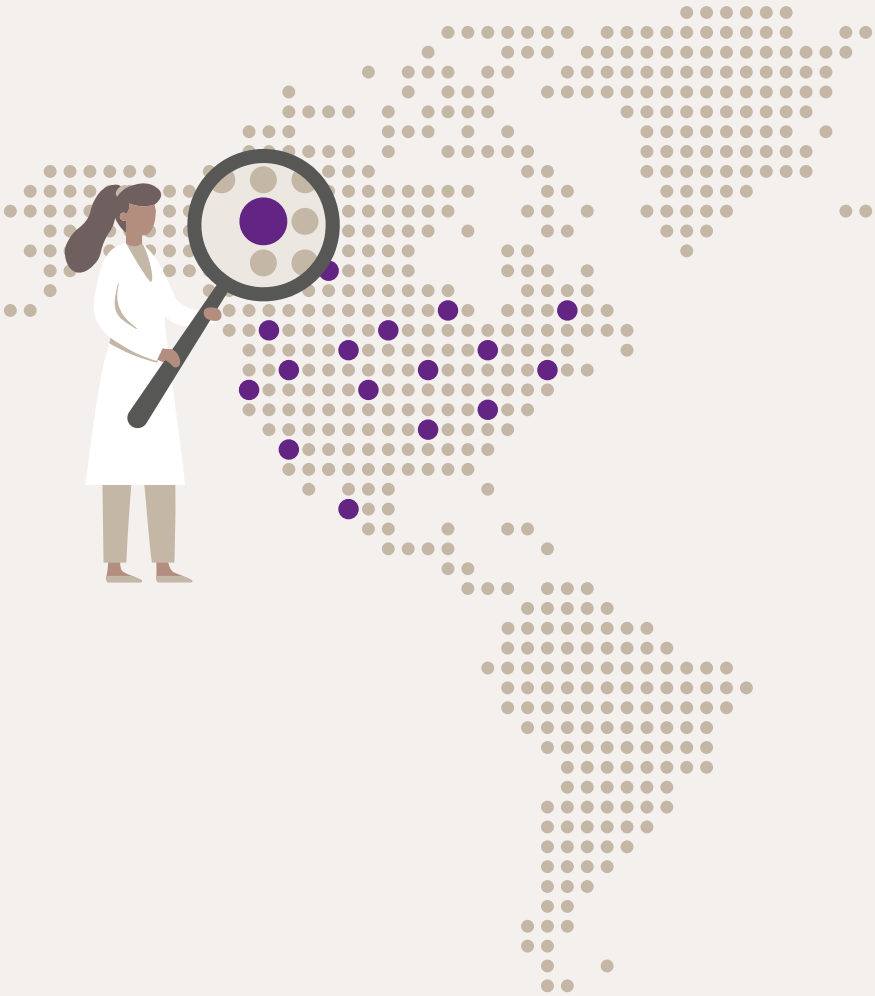

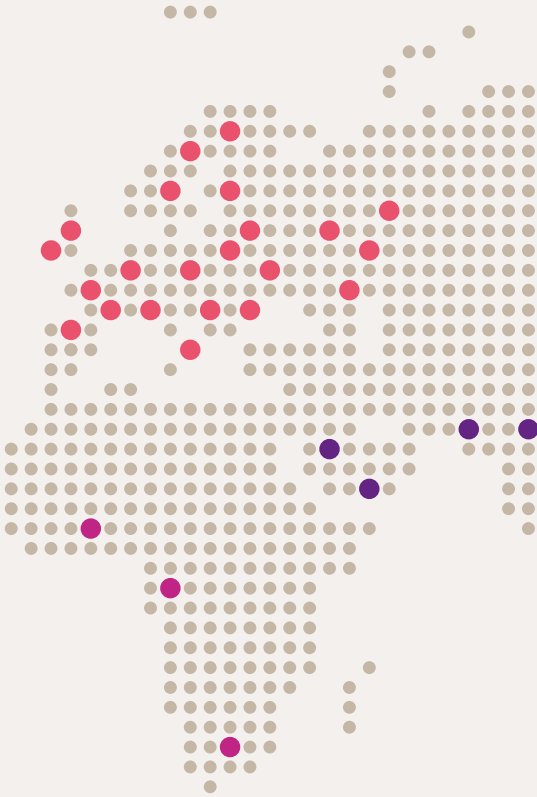

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