# The Evolving Global Biosecurity Landscape

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The COVID-19 pandemic, while most likely caused by a natural zoonotic spillover event, has also highlighted the risks posed by human-made biological threats and gaps in the national and international systems for ensuring that life sciences research is conducted safely, securely, and responsibly.

The pandemic has accelerated changes to the global biosecurity landscape that have been underway for several years. Ironically, greater efforts to prevent future pandemics and to strengthen biopreparedness could lead to increased risks of accidental or deliberate pandemics occurring. Meanwhile, our biorisk management policies are failing to keep up with these new threats. The answer is simple. We need to strengthen biorisk management, which encompasses field and laboratory biosafety, laboratory biosecurity, and oversight of dual-use research, to reduce the risk posed by biological threats resulting from the accidental, reckless or deliberate misuse of biotechnology.

## Changing Global Biosecurity Landscape

The global biosecurity landscape is becoming more complicated and challenging due to several trends that were underway before COVID-19 but have been accelerated by the pandemic. Unfortunately, national and international measures to ensure that life sciences research is conducted safely, securely, and responsibly are not keeping pace with these changes.

First, the number of maximum containment labs that can conduct research with the most dangerous pathogens, commonly called BSL-4 labs, is expanding. As research by myself and Filippa Lentzos at King's College London has demonstrated, there are already 60 such labs in operation or under construction in 23 countries. Most of these labs are located in urban areas and only a quarter of countries housing these labs score high on international measures of biosafety and biosecurity.[1] Furthermore, since the start of the pandemic, we have seen signs that 20 more

BSL-4 labs are planned for construction. With more labs come increased risks of accidents. International standards for biorisk management in labs exist but they are not widely adopted and there is no international mechanism for ensuring compliance with these standards.[2]

Second, research activities outside of labs are also increasing biosafety risks. Last year, USAID launched a new $125 million program to discover potential pandemic pathogens in Southeast Asia and Chinese researchers have also called for more field research to improve their ability to predict the risk of zoonotic spillover events.[3] The growth in large-scale viral prospecting to identify potential pandemic pathogens in the wild increases the risk of researchers becoming infected while collecting biomedical and environmental samples in the field. The emergence of SARS, MERS, and SARS-CoV-2 has already demonstrated that such viruses are currently circulating in animals, can jump to humans, and can spread internationally under the right conditions. However, standards for field biosafety are much less developed than for laboratory biosafety. For example, neither the United States nor China have national field biosafety standards and there is no international guidance available on this subject.

Third, the COVID-19 pandemic will likely increase the number of laboratories and scientists engineering viruses to have enhanced virulence or transmissibility compared to naturally occurring strains. This "gain of function" research is motivated by the desire to better understand how easily these viruses can infect human cells which is indicative of the potential for the virus to jump from animals to humans and to spread from human-to-human.

We saw a significant increase in such research by influenza virologists following the 2005 H5N1 and 2009 H1N1 outbreaks. This research led to the creation of a strain of H5N1 avian influenza that could be transmitted by mammals.[4] We have already seen a dramatic surge in scientific publications about SARS-CoV-2 and related coronaviruses, most of which is being conducted in countries that provide little to no oversight of dual-use research.[5] There is at least one lab in the United States, and possibly elsewhere, that is trying to add genetic material from the original SARS virus to SARS-CoV-2 to create a chimeric virus of the two strains.[6] There is no international guidance for how to conduct such research safely, securely, and responsibly. While the United States does have such a policy in place, it has been poorly implemented and needs to be revised in light of lessons learned over the course of the pandemic.

Fourth, the biosecurity landscape has been altered by changes in how scientific research is disseminated. The emergence of pre-print servers, where scientists can post their findings online before going through the peer review process, has removed one of the layers of review that could be used to check for dual-use research of concern before publication. The urgency of responding to the pandemic led a dramatic rise in the use of pre-print servers. During the first 9 months of the pandemic, half of all scientific publications on SARS-CoV-2 were posted to pre-print servers. In contrast, during previous outbreaks, only 5% of scientific research was disseminated this way.[7] In addition, the rise of the open science movement, which seeks to make protocols, datasets, and computational tools as widely available as possible, has introduced new potential risks of misuse.[8] For example, the publication of a detailed protocol for how to synthesize the SARS-CoV-2 virus has raised concerns that such protocols have lowered the barrier to creating engineered version of the virus.[9]

Fifth, the private sector is increasingly driving the innovation process in the life sciences and biotechnology. Nongovernment sources of funding, such as corporations, foundations, individuals, and crowdfunding sites, are accounting for an increasingly large share of life sciences research. This presents a serious challenge to dual-use research oversight in the United States since such oversight only applies to researchers who receive Federal funding. The potential risks posed by privately funded research is illustrated by the synthesis of horsepox virus which is closely related to smallpox. This experiment was financed by an American biotech company for only $100,000.[10] During 2021, synthetic biology firms in the United States raised $18 billion in private funding, more than the combined investment that the industry received over the previous ten years.[11] Given the increasing size of the global bioeconomy and the growing commercialization of products generated with synthetic biology and genome editing tools, exclusion of the private sector from dual-use research oversight is an increasing large loophole.

Sixth, there are important developments taking place in fields of the life sciences other than microbiology and molecular biology that pose dual-use risks.[12] For example, advances in immunology, population genomics, gene therapy, viral vectors, genome editing, synthetic biology, and neuroscience raise concerns about potential misuse.[13] However, the vast majority of research in these fields are not covered by existing biosecurity and dual-use research policies. Furthermore, scientists in these fields are generally unaware of how their research could be misused by a reckless or malicious actor. Current oversight policies also do not take into account how risks can be generated by the convergence of multiple disciplines within the life sciences or by the application of emerging technologies, such as machine learning, artificial intelligence, data analytics, and nanotechnology, to the life sciences.[14] One recent example of this type of risk is the development of an AI-trained algorithm that identified hundreds of new compounds even more toxic than known chemical warfare agents.[15]

Seventh, there is a growing risk to biosecurity from misinformation and disinformation. The problem has gotten so bad that the WHO even coined a new term to describe the problem: an infodemic.[16] We need to expect every biological attack and unusual disease outbreak to be accompanied by disinformation from both domestic and foreign sources. This disinformation not only undermines the credibility of public health institutions that are advising political leaders about how to respond, but also directly affects the behavior of the public. There are important implications here not only for the public health community but also the intelligence community and diplomats.

For many years, Moscow has spread disinformation about US support for public health labs in former Soviet states such as Ukraine and Georgia.[17] Russia has now made these unfounded allegations the centerpiece of its domestic and international disinformation campaign to justify the unprovoked and illegal invasion of Ukraine. Approximately, one-quarter of all Russian disinformation targeting Ukraine is related to the biolab allegations and these allegation dominate Russian state media.[18] While this type of disinformation is designed to score short-term political points, it poses long-term risks to transparency and international cooperation on biosurveillance, biosafety, biosecurity, and arms control. In the worst-case scenario, this type of disinformation could create enough suspicion and mistrust to provoke a biosecurity dilemma and lead countries to take steps to defend themselves against phantom threats.

## Conclusion

Given the increasing number of countries developing dual-use biotechnologies and conducting potentially risky research with pathogens, the transnational nature of modern life sciences research, and the global impact of an accidental or deliberate release of a pandemic pathogen, national and international mechanisms for ensuring that this research is being conducted safely, securely, and responsibly are vital. While biosafety, biosecurity, and dual-use research oversight serve distinct purposes, they are interrelated enough to warrant consideration together under the biorisk management framework. Therefore, an integrated approach to biorisk management will be more comprehensive, coherent, and effective then addressing each of these risks in isolation.

Whether or not the current pandemic was caused by a laboratory accident, it does not mean the next pandemic won't be. Indeed, efforts to prevent and prepare for the next pandemic, ironically, include a range of activities that serve to increase the risk posed by an accident. Given that existing national and international systems to ensure that such research is conducted safely, securely, and responsibly are already inadequate, we need a new global architecture for biorisk management that can address the growing challenges we face in this domain.

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