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A Minimum Information about a High Containment Laboratory Experiment (MIHCLE) reporting standard

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Experiments with high-risk pathogens are routinely conducted under strict conditions of biosafety and biosecurity. In this Comment, we propose a Minimum Information about a High Containment Laboratory Experiment (MIHCLE) reporting standard. Although conceived particularly for work in biosafety level (BSL) 4 laboratories, it can be generally applicable to any research performed in both high (BSL-3) and maximum (BSL-4) containment facilities.

Recent events have refocused attention on epidemic- and pandemic-prone pathogens, the research that is conducted to study them, and the development of essential medical countermeasures. In many countries, pathogens are categorized, on the basis of their potential to cause harm, into four risk groups (RG), with RG4, including hemorrhagic viruses such as Ebola (for example, *Orthoebolavirus zairense*), being the most dangerous. There is a corresponding classification of containment or biosafety levels (CLs or BSLs; we use BSL here), so that BSL-4 facilities are used to conduct experiments with RG4 pathogens, and so on. National and/or regional regulations should govern the construction, maintenance and operation of BSL-3 and BSL-4 laboratories (see, for example, https://bwcimplementation.org/ and https://iegbbr.org/tools.html#mobileapp). As exemplified by European BSL-4 laboratories[1], the work, and these facilities themselves, are under intense regulatory scrutiny. Only vetted, highly qualified and trained staff can access these technically complex environments, where they work under physically and psychologically challenging conditions[2]. In many countries, information about an individual laboratory and its activities fall under national security legislation and cannot be publicly shared. These legal constraints on information sharing, often incorrectly perceived as reflecting researchers' opposition to transparency, have compounded long-standing legitimate concerns about the inherent risks involved in work with highly pathogenic agents, especially those in RG4. Given the mounting threat from high-consequence pathogens, in the form of both naturally occurring outbreaks and potential accidental or intentional release (for example, bioterrorist activity), and that more BSL-3 and BSL-4 laboratories are now operating than two decades ago[3], there are increasing questions about acceptable levels of biorisk.

High and maximum containment facilities must address important issues related to biosecurity, particularly BSL-4 laboratories, since RG4 pathogens are considered to be potential bioweapons. As such, certain details of the activities of BSL-4 laboratories in some countries (for example, Australia, the UK and the USA) are voluntarily provided by the respective States Parties to the Biological Weapons Convention (BWC), in annual Confidence-Building Measure (CBM) reports that are publicly available. For reasons related to domestic security and national defense, other countries (for example, France and Russia) choose not to make their BWC-CBM reports public. The provision of pertinent and accurate information regarding this research is warranted, however, particularly when those activities, while intended to provide a clear benefit, could easily be misapplied to do harm — that is, fall under the category of "dual use research of concern" (DUR/C). Many countries have specific DUR/C policies for publicly supported research or are part of international agreements. In the USA, the National Institutes of Health's was planned to be updated in May 2025 (via notice NOT-OD-25-061; rescinded by NOT-OD-25-112), and will now be revised in the light of the Executive Order on Improving the Safety and Security of Biological Research. Australia is often considered to have the most restrictive legislation regarding DUR/C involving pathogens. In addition to its national Biosecurity Act 2015, the Defense Trade Controls Act 2012 regulates the export, supply and publication of pathogens and dual-use biological materials. In contrast to more than 170 countries, however, neither the USA nor Australia are signatories to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The implementation of the Protocol that governs the "transboundary movement of any living modified organism resulting from modern biotechnology" relies in part on the Biosafety Clearing-House (BCH), an online platform for information exchange and a repository for details about living modified organisms, including methods of ensuring their safe handling, storage, transport and use.

While the elements that contribute to biorisk management are well established (Fig. 1), there is no consistency in the scientific literature with regards to how experiments conducted under BSL-3 or BSL-4 conditions are reported. This can, in part, be ascribed to the absence of accepted guidelines and the lack of any standard framework or obligation. Under the Materials Design Analysis Reporting framework[4], the prescribed biosafety conditions and containment levels are considered "best practice" but are not mandatory.

In other areas of experimental biological sciences, reporting standards exist and adherence to them is a prerequisite for publication in reputable journals. For example, with the advent of high-throughput methodologies came the realization that experimental reproducibility, as well as the ability to interpret results and to reuse data, required a

Fig. 1 | The spectrum of biological risk management: examples of overlapping elements of biosafety and laboratory biosecurity. Adapted with permission from *Laboratory Biosecurity Guidance*, World Health Organization, 2024 (ref. 15), CC BY-NC-SA 3.0 IGO.

formalized framework both for data and for metadata. This led to the formulation of the first reporting standard: Minimum Information About a Microarray Experiment (MIAME). Further minimum information standards followed, covering a broad range of methodologies, such as Minimum Information About a Cellular Assay (MIACA) and Minimum Information about Tissue Imaging (MITI). Although the aim of these standards is distinct from those related to reporting conditions of biorisk management, they provide an inspiration for the Minimum Information about a High Containment Laboratory Experiment (MIHCLE) that we propose here. We describe guidelines for complete reporting balanced with information-security imperatives to protect sensitive data. We also discuss possible mechanisms for determining the appropriateness and veracity of the provided information. Finally, we envision the broad adoption of a MIHCLE standard as a critical step toward ensuring fuller accountability of the vital but intrinsically risky work involving high-consequence pathogens.

The MIHCLE framework

The MIHCLE framework aims to provide guidelines for reporting both scientific methodologies and biosafety and biosecurity parameters and protocols. We identified ten categories of information that can be used to determine whether the reported experiments have been conducted in a responsible manner and conform to the relevant regulatory requirements. The elements of each are outlined in Box 1 and discussed in more detail below. In some cases, we also indicate the type of metadata to be provided, bearing in mind the need for them to adhere to the FAIR principles — namely, to be Findable, Accessible, Interoperable and Reusable — while at the same time taking into consideration their high sensitivity.

1. The first type of required information concerns the nature of the study, including a brief standalone statement describing the overarching aim, the motivation for the study and the experimental approach. This section must also include details of the investigators leading the BSL-3 or BSL-4 work and the location where the research is conducted to determine which local and national regulations apply. As regulations can change with time, it is important that the dates of the research activity be recorded. Similarly, certain research funders apply their own specific research guidelines and restrictions, so it is pertinent to record this information too. As an example, as specified by European Commission, no dual-use research pertaining to "goods, software and technology that can be used for both civilian and military applications" may be conducted using funding from Horizon Europe. A research project to develop aerosolization methods for an RG4 pathogen would thus fall under this definition of dual-use research and be flagged by the relevant review body. We also recommend that all the information be presented in a structured manner, using established ontological terms and common identifiers, so that it is machine readable. For example, open persistent identifiers (PIDs), such as the Open Researcher and Contributor ID (ORCID) for individual researchers and the Research Organization Registry (ROR), have been widely adopted because of their long-term utility.
2. The second section details the high-consequence biological agent. As species names can change, we recommend the mandatory use of recognized identifiers such as those derived from a centralized resource like the NCBI's Taxonomy ID. As taxonomy databases are regularly updated, it would be essential to record the database release to ensure correct species identification on a later occasion. Researchers should also provide complete information about the pathogen's provenance not only to allow adhesion to the conditions of access and benefit-sharing frameworks to be verified, but also to ensure that appropriate measures were taken during pathogen collection, transport and handling. If the pathogen has been obtained from a reputable biological resource center that follows Organisation for Economic Co-operation and Development recommended practices[5], this information will be readily available. The European Virus Outbreak Research Alliance has recently produced the EVORA Ontology, which provides a structured and harmonized vocabulary for describing pathogens, along with their derived products and associated services, and this would be appropriate here.
3. The next section deals with elements of biosafety in the physical environment. Here we suggest that the details of the regulatory regime(s) under which facility operates and that govern its research activities, from the local to the international level, be provided. This includes documentary evidence of adhesion to recognized norms, such as certification of the implementation of appropriate International Organization for Standardization (ISO) standards. In cases where national guidelines, laws and/or local codes governing high and maximum containment facilities already include most of the required information, the researchers can reference the appropriate official frameworks or the collated information held by the BCH (see below) with a confirma-

BOX 1

The ten sections of the MIHCLE standard

Whenever the requested information is included in one of the biosafety level frameworks mentioned in the main text, or other publicly available documents (for example, open BWC-CBM reports or articles in the scientific literature), it would be enough to refer to that framework, report, article or other document. Otherwise, the level of detail should be at least that of the minimally descriptive framework.

1. General experimental information

- **Overall research project title**: Clear and descriptive title of the research.
- **Research activity**: Concise description of the research activity conducted under high or maximum containment conditions.
- **Date of research activity**: Start and end of the research activity.
- **Principal investigators**: Names and affiliations of the accountable researchers, required to ensure compliance with country- and institution-specific ethical and biorisk regulations.
- **Funding sources**: Information on funding, required to ensure compliance with funding body-specific ethical and biorisk regulations.

2. Biological agent information

- **Pathogen or agent description**: Taxonomy, strain identification and relevant characteristics of the pathogen or agent, such as virulence factors, infectivity and natural modes of transmission. Include the accession number of its complete nucleotide sequence if available.
- **Source and acquisition**: Information about the source of the pathogen or agent (for example, laboratory reference strain, natural isolate including information of the sample used for isolation, synthetic construction).
- **Handling and storage**: Description of how the pathogen, agent or pathogen-containing sample was handled and transported before arriving in the laboratory and handled, stored and transported within the laboratory, referencing all relevant regulations, demonstrating that this was in accordance with appropriate risk assessment evaluation. Should complete information not be available here, or in any other section, a concise explanation would need to be given.

3. Laboratory environment and facility information

- **Biosafety level**: Specify the level (for example, BSL-4) and the classification system used: the European Union's Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work, US Centers for Disease Control and Prevention's *Biosafety in Microbiological and Biomedical Laboratories* 6th edn, or equivalent national guidelines. If these prescribe physical containment measures, such as air filtration systems (for example, HEPA filters), pressure differentials and access controls, there is no need to detail them here.
- **Oversight and regulation**: List of regulatory bodies, oversight committees and internal or external audits conducted. Describe compliance to national or international guidelines (for example, National Institutes of Health, World Health Organization) and any relevant certifications or implemented standards.
- **Laboratory design**: Overview of general design principle (for example, purpose built or conversion of existing facility, year of construction), with details of containment features, decontamination systems (autoclaves, chemical showers), waste management, and equipment placement to ensure proper containment.

4. Biosafety and biosecurity practices

- **Personnel training**: Description of training protocols for all personnel, including the frequency of training, emergency preparedness, and the scope of the training in pathogen handling, spill response and containment breach scenarios.
- **Personal protective equipment (PPE)**: Description of the PPE required for personnel (for example, full-body suits, respiratory protection, gloves), and information on decontamination after use.
- **Entry and exit procedures**: Detailed procedures for controlled access, personnel monitoring, and decontamination before and after entering and exiting the containment area.
- **Emergency procedures**: Description of contingency plans in case of containment breach, exposure or other emergencies, including evacuation protocols and medical monitoring of personnel.
- **Waste decontamination and disposal**: Description of waste management protocols, including how contaminated materials (for example, biological waste, PPE, liquids) are inactivated, contained and disposed of.

5. Experimental procedures

- **Experimental design**: Detail of any modifications to standard protocols based on containment requirements (for example, steps to inactivate or destroy pathogens), unless specifically included in a Materials and Methods section.
- **Instrumentation and equipment**: Description of the instruments and equipment used (for example, incubators, biosafety cabinets, centrifuges) and decontamination measures after use.
- **Sample collection and processing**: Methods for collecting and processing samples, with emphasis on how samples were handled to minimize contamination or exposure risks.

6. Ethics and risk assessment

- **Ethics approval**: Description of the approval process by ethics review boards and institutional committees, ensuring that the research follows ethical standards, especially when using animals or human samples.
- **Risk/benefit analysis**: Description of the process used to establish that the benefit to be derived from the study outweighs the potential risks (for example, by the reference to the World Health Organization's *Laboratory Biosecurity Guidance*[15]).

(continued from previous page)

- **Dual-use research concerns**: When relevant, and unless divulging the information would itself present a risk, information on how the research raises potential dual-use concerns (that is, research that could be misused for harmful purposes) and any mitigation measures taken to reduce these risks. In all cases, the automatically generated report from Dual Use Quickscan can be appended.

7. Personnel and roles

- **Key personnel**: Identify the primary staff involved in the experiments, including their roles, experience, and certification to work in high-containment environments.
- **Shift work and monitoring**: Procedures for ensuring personnel monitoring, including the use of buddy systems, surveillance during experiments, and post-experiment monitoring.

8. Event reporting

- **Incident log**: Provide details of how any biosafety or biosecurity incidents are recorded, along with general mechanisms in place to translate these into actions taken to mitigate future risks and rectify issues.
- **Incident log count**: Record the number of times during the research activity that incidents were recorded. When possible, give details of the incident and recommendations to avoid such incidents happening to others.
- **Accident log**: Provide details of how any biosafety or biosecurity accidents, exposures or containment breaches are recorded, along with general mechanisms in place to translate these into actions taken to mitigate future risks and rectify issues.
- **Accident log count**: Record the number of times during the research activity that accidents were recorded. When possible, give details and recommendations to avoid such accidents happening to others.
- **Lessons learned**: When possible, description of any improvements made to biosafety and biosecurity protocols based on incidents, near misses or accidents.

9. Post-experiment procedures and maintenance

- **Final agent disposition**: Explanation of how remaining pathogenic biological materials are stored, destroyed or transferred after the completion of the experiment.
- **Decontamination and equipment maintenance**: Description of how long-term maintenance of equipment and facility is conducted to ensure biosafety and biosecurity integrity.

10. Data sharing and transparency

- **Data availability**: Clear guidelines for data sharing while ensuring that sensitive information about the pathogens and containment protocols does not fall into malicious hands.
- **Reporting to authorities**: Information on which governmental and institutional regulatory agencies or boards, if any, were informed before the experiment was performed, informed when the experiment was performed, and provided with the experiment's results and compliance status before submission of a publication.

tion of adherence. A given institution should prepare a standard template for reporting standards, since most of the information (for example, about oversight, containment features and decontamination systems) is not expected to change between research projects. Not all institutions would be legally authorized to share publicly some of the elements of this section, such as those on laboratory design. This illustrates one of the dilemmas of reporting activities from high and maximum containment facilities that will require an innovative solution acceptable to all stakeholders.

4. The following section also addresses biosafety, as well as biosecurity, but more in their operational aspects, such as training, protective equipment and decontamination procedures. This also includes the contingency plans in place should ever there be an accident leading to the exposure of personnel to an infectious agent. As many of these elements are covered by national frameworks, such as the US Select Agent Occupational Health Program Guidance, it would be sufficient for authors to identify them and confirm that they are adhered to.
5. After these more general considerations, the authors would then provide information pertinent to their particular study, detailing the protocols and equipment. Although here the use of a facility-level template would not be possible, we envision the progressive establishment of descriptive catalogs from which the relevant information could be picked.
6. The sixth section contains the ethics and risk assessment. Here researchers should refer to the information that is included as a mandatory reporting element in all reputable journals, guaranteeing that research has followed all appropriate ethical guidelines. Similarly, one would expect the research to have undergone review by an Institutional Biosafety Committee (IBC) or equivalent, to weigh the likely benefits and possible risks before its execution. One would hope that journals would encourage authors to share the pertinent parts of their IBC review report whenever possible. Finally, it is important to consider the potential for research outputs, material or information to be misused. The recently released World Health Organization (WHO) Dual-use Research and the Responsible Use of the Life Sciences online training provides a useful overview of the topic. We expect that all personnel working in BSL-4 and BSL-3 laboratories are already acutely aware of any potential for such dual use, particularly DUR/C. Nevertheless, as part of the reporting practices, all authors should be encouraged to append the automated report that is generated by the online tool Dual Use Quickscan to confirm that they have indeed considered this specific type of risk, especially in the unlikely event that this not part of their standard IBC, DUR/C committee or equivalent review process.
7. The seventh section describes the research personnel who conducted the work and how the work was monitored in real time. It is likely that national laws restrict the sharing of this information. In addition, as researchers are unfortunately increasingly under attack by those vehemently opposed to experimentation with pathogens, transparent reporting here may expose them to

increased risk of cyberharassment or physical harm. We discuss ways to resolve these constraints below (see Perspectives).

8. The next section concerns the reporting of incidents and accidents. Across high and maximum containment facilities, there are diverse mechanisms for logging these (see. for example, ref. 6). In Canada, in addition to the mandatory reporting obligations for specific types of laboratory incidents specified in the Human Pathogen and Toxins Act and Regulations, the Public Health Agency of Canada provides facilities with a way to voluntarily report incidents, including near-misses. Here we envision that details of how such information is recorded and shared (internally and, when applicable, with national authorities) and feedback for improvements in biorisk management will lead to the establishment of community-validated best practices and potentially an alignment at the international level. Understandably, there would generally be a reluctance to share publicly details of safety and security breaches, but lessons learned at one facility could contribute to improvements at others.
9. This section deals with the disposal and storage of the biological materials. As in the above sections on biosafety and biosecurity, the details here are likely to be constant across studies at a given facility and may be covered by established national rules or local codes, such as existing standard operating protocols or procedures (SOPs) used in BSL-4 laboratories to inactivate RG4 viruses. Here too, if they do not already have collections of SOPs, we expect that institutions will build up SOP catalogs from MICHLE reports. Almost all the information in this section could be made publicly available and could contribute to the harmonization of best practices. For example, the description of storage would, if possible, include the type of cold storage, recipient and medium but, for security reasons, avoid details of physical location.
10. Many national and international funding agencies now require grantees to formulate coherent data management plans (DMPs). Should authors not already have a DMP for their project, we strongly recommend it as DMPs are a practice considered key to guaranteeing the reproducibility of research. The information these DMPs contain can be reused to populate the final section, on data sharing and transparency. DMPs report the manner in which the data are stored, shared and archived, bearing in mind the very particular constraints that apply to the field of high-consequence pathogens, especially the potential for misuse. Similarly, for transparency in this section, authors would provide details about the different local, regional and national bodies that were made aware of the research at various stages of the study, without requiring the information itself to be disclosed.

It is important to note that in many countries, work in BSL-3 and/or BSL-4 facilities is governed by regulatory bodies such as an IBC, an Animal Care and Use Committee, a DUR/C committee or their equivalents. These committees may be legal entities with 'Terms of References', which define their purpose, scope and limitations, and formal records of project submissions, meetings and decisions. Facility operation and experimental procedures may also be written down in SOPs. Collectively, these documents may include much or all of the information included in the proposed reporting standard. In such cases, especially if the corresponding documents are in the public domain, or are accessible upon request, a MIHCLE report could be condensed to approval numbers and references to SOPs. There are, however, notable exceptions. In the USA currently, for example, an IBC is only mandatory if an institution receives federal funding[6] whereas research conducted by private companies falls outside governmental oversight.

With this MIHCLE standard, we have aimed to cover the main factors that contribute to biorisk management. We hope that this will serve as a checklist and reporting template for all researchers working with high consequence pathogens, ensuring both scientific transparency and adherence to high levels of biosafety and biosecurity. We encourage researchers to provide as much information as possible, even voluntarily supplementing the MICHLE framework with any other pertinent information — for example, listing stakeholders consulted regarding the implementation of their biorisk management system and the financial, physical and human resources committed to support it.

Perspective

While there have been attempts — for example, through the WHO; the International Experts Group of Biosafety and Biosecurity Regulators; and ISO, through ISO35001:2019 "Biorisk management for laboratories and other related organisations" — to align standards for biosafety and biosecurity, regulation and implementation of biorisk management globally remains a patchwork. For example, in the USA at least seven different agencies have a role in the oversight of different aspects of federally funded research in BSL-4 and BSL-3 laboratories[7], and biosafety practices are far from uniform[8]. On the international level, countries do not even necessarily class a given pathogen into the same risk group[9]. In some cases, this may be because, in a region where a disease-causing pathogen is endemic, it will be considered less of a risk than in a country where it is absent. In other cases, the strictness of hazard management may reflect the resources, infrastructure or technical capacity to implement standards. Any work conducted in a high or maximum containment laboratory should, however, be subject to authorization at least from an IBC and/or national regulatory body involving stringent review to evaluate the relative risks and benefits of the proposed research.

Despite many calls for their creation (for example, ref. 10), there have never been any obligatory reporting standards when publishing pathogen-related studies, particularly those involving RG4 pathogens, because aspects of the oversight of work with high-consequence pathogens has historically involved national security agencies. Although the precise limits of the information that can be made public vary among countries, how researchers can describe work in any BSL-4 laboratory and some BSL-3 laboratories will always be circumscribed by national law. Thus, unlike other minimum information standards, and beyond ensuring broad adoption by journals, ideally within the Materials Design Analysis Reporting framework[4], we expect that a MIHCLE-based mechanism will face significant challenges for full implementation.

A key part of any reporting framework is verification. This is particularly true in the case of MIHCLE since, to be useful, not only must the information be complete and accurate, but it must also provide confirmation that experiments have been conducted under appropriate conditions of biorisk management and in conformity with the relevant regulations and commonly accepted norms. But, as explained above, several of the mandatory fields concern types of information that cannot be made public. Setting aside the limitations imposed by national security information laws, there remain barriers to implementation, verification and confidentiality. To overcome these challenges, co-operation will be required from not only scientific editors at journals but also peer reviewers to ensure that the reporting is accurate and the experiments conducted in a safe and secure manner, in line with

regulations and codes of practice and with appropriate oversight. Editorial and peer-review processes may, however, not be equipped with the necessary expertise or familiarity with the diversity of complex national regulations. Further, a full MIHCLE report, especially for experiments in a BSL-4 laboratory, might contain sensitive information that cannot be shared outside a secure government-sanctioned system, such as the UK's Rosa IT service. Thus, researchers may not be authorized to share this type of information with reviewers and editors. In such cases, the public report would only indicate where the information has been recorded and/or that the work was conducted in compliance with local or regional laws and codes covering the precise rubrics of the MIHCLE.

To mitigate confidentiality and security concerns, we propose the use of an independent expert clearinghouse with independent professional staff that could evaluate the appropriateness of the applied biorisk management strategies and their alignment with regulatory standards. The clearinghouse would have the same breadth of expertise as the centralized IBC recently proposed by Le Duc and Weaver[11] to evaluate Notification of Use requests before any new studies are started in a maximum containment facility. Indeed, ideally, there would be an alignment of the information in the Notification of Use requests required for IBC approval and in future MIHCLE reports, with the use of a common standardized vocabulary, incorporating PIDs and using the EVORA ontology, as this would further facilitate adoption of the MIHCLE standard by the research community. Similarly, in addition to any local, regional or national framework, the IBC approval process would follow the carefully crafted global guidelines provided by the WHO[12], simplifying the task of the clearinghouse.

The proposed clearinghouse would need to operate under clearly defined and strictly enforced rules of confidentiality. It would also need to work with the stipulations set by participating countries regarding what information may be made publicly available. The clearinghouse, or the IBCs, would be the secure repository for the full reports. If necessary, the clearinghouse itself could further restrict the published information should its staff identify overlooked risks. The ballpark figure for the number of manuscripts describing research with RG4 pathogens, a few hundred per year, gives an idea of the dimensions of the necessary data infrastructure and the level of financial investment that would be needed for such a program to become operational. We estimate that timely review of the riskiest research would initially require between three and five highly qualified full-time staff and so would be likely to cost several hundred thousand euros annually.

We expect that the clearinghouse would complement sovereign regulatory authorities, never overrule them, and could play other important roles with regard to incident and accident reporting. On the one hand, it could promulgate best practices for institutions, covering, for example, the tools for recording these events, the optimal granularity, and mechanisms for translating them into concrete actions. On the other, using an appropriate level of anonymization, it could make recommendations for changes in practice to increase biosecurity and biosafety, helping to reduce the number of laboratory-acquired infections[13].

One could imagine an expansion of the mandate of the Convention on Biological Diversity's BCH to include MICHLE verification, or the use of UNODA or WHO to create an equivalent, dedicated structure, or even an accreditation procedure for IBCs, further lessening the need for the clearinghouse to always evaluate MIHCLE reports from scratch. To be useful, sustained investment would be required, but this would be an important way to demonstrate that research with high-consequence pathogens conforms to the expected exemplary standards. There is a risk that, without it, public and political support for this type of work will gradually be eroded and research vital for pandemic preparedness hobbled. There are already worrying signs of this in certain countries.

In the wake of the COVID-19 pandemic, as RG4 pathogens are recognized as a more pressing global threat, research in BSL-4 laboratories continues to intensify. Their number is expected to increase in the coming years. Having a reporting standard in place would ensure best practices are demonstrably applied in existing BSL-4 facilities and help establish a strong culture of biorisk management in future facilities. We believe that the knowledge that a MIHCLE report is required for publication of studies in reputable journals would in itself promote biosafety and biosecurity internationally. In addition, we expect that it would contribute to a transition toward a just culture that aims to support effective risk management through a combination of bottom-up scientific responsibility and top-down oversight and accountability[14]. National security imperatives will never be compatible with fully transparent reporting of work with high-consequence pathogens, but a future mechanism, including a trustworthy and FAIR-enabling information repository, would provide a step toward rebuilding public confidence and broad political support for essential research, preventing misuse while still allowing legitimate scientific enquiry to counter the ever-increasing threat of epidemic and pandemic disease.

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References

1. Brechot, C., Szekely Björndal, Å. & Ewbank, J. *Science* **383**, 1187–1188 (2024).
2. Shurtleff, A. C. et al. *Viruses* **4**, 3932–3951 (2012).
3. Peters, A. *Rev. Sci. Tech.* **37**, 857–883 (2018).
4. Macleod, M. et al. *Proc. Natl. Acad. Sci. USA* **118**, e2103238118 (2021).
5. Organisation for Economic Co-operation and Development. *OECD Best Practice Guidelines for Biological Resource Centres* https://doi.org/10.1787/9789264128767-en (OECD, 2007).
6. Vogler, A. J., Jones, S. & Keim, P. *Appl. Biosaf.* **19**, 192–200 (2014).
7. Gillum, D. R., Moritz, R. & Koblentz, G. D. *Front. Bioeng. Biotechnol.* **12**, 1474120 (2024).
8. Chamberlain, A. T. et al. *Appl. Biosaf.* **14**, 135–143 (2009).
9. Tian, D. & Zheng, T. *PLoS One* **9**, e101163 (2014).
10. Dettmann, R. A., Ritterson, R., Lauer, E. & Casagrande, R. *Health Secur.* **20**, 376–386 (2022).
11. Le Duc, J. W. & Weaver, S. C. *Health Secur.* **22**, 343–346 (2024).
12. WHO. *Global Guidance Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-Use Research* (WHO, 2022).
13. Gillum, D., Krishnan, P. & Byers, K. *Appl. Biosaf.* **21**, 203–207 (2016).
14. Snyder, B. C., Wentzel, J. M., Epstein, G. L., Kadlec, R. P. & Parker, G. W. *Appl. Biosaf.* **30**, 107–111 (2024).
15. WHO. *Laboratory Biosecurity Guidance* (WHO, 2024).

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