

**Towards a global guidance framework for the
responsible use of life sciences: summary report of
consultations on the principles, gaps and challenges
of biorisk management**

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Glossary

Accident: An unintended occurrence that could result in harm, such as infection, illness or injury in humans and animals or contamination of the environment

Awareness-raising: Actions to inform the scientific community and the broader global community of the essential place of biosecurity in responsible basic and applied life sciences

Biological diversity: Variation among all living organisms, including those in terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part and diversity within and among species and ecosystems

Biorisk: The risk that a biological event – such as naturally occurring disease, accidental infection, unexpected discovery, unauthorized access, loss, theft, misuse, diversion or intentional release of a biological agent or biological material – will adversely affect the health of humans, nonhuman animals and the environment

Biosafety: Principles, technologies, measures and practices of containment that can be used to prevent inadvertent release or unintentional exposure to biological agents or biological material

Biosecurity: Principles, technologies, measures and practices that can be used to prevent unauthorized access to or loss, theft, misuse, diversion or intentional release of a biological agent or biological material

Civil society network: Groups or organizations that works in the interests of citizens outside of government and for-profit sectors

Code of ethics: Non-legislated guidelines intended to establish standards of practice

Collaborative ambition: Situation in which people put more into and get more out of work, such as advocacy, which benefits themselves and others; i.e., collaboration to achieve a common ambition

Convergent technology: Integration of insights, principles, approaches and actors from distinct fields

Disinformation: The sharing of information that is known to be false, inaccurate or misleading with the intent to mislead, confuse, introduce doubt or incite violence for the purpose of causing harm

Dual-use: Findings, techniques and knowledge generated by peaceful, legitimate life sciences that may be appropriated for non-peaceful or harmful purposes with no, or only minor, modification

Dual-use research: 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, animals and the environment

Education: Systematic provision of knowledge, competence, skills and tools on aspects of biosecurity

Empowerment: Strengthening engagement to increase active participation in, e.g., agenda- and priority-setting

Engagement: Involvement of scientists, the scientific community and other stakeholders in biorisk management, biosecurity and governance

Global health security: The activities, both proactive and reactive, required to minimize the risk of public health events that could endanger the health of humans, animals and the environment across national boundaries, geographical regions and generations

Governance: Systematic use of frameworks, tools and other mechanisms to provide direction and oversight consistent with a chosen set of values, principles and goals

Infodemic: An overabundance of information, including mis- and disinformation, during a health crisis that is spread via digital, physical and verbal information systems

Intergenerational justice: Commitment to fair distribution of (sometimes scarce) resources among different age groups, often (but not always) with a focus on future generations

Life sciences: All sciences that address living organisms, including humans, animals and the environment, or the products of living organisms or that incorporate components derived directly or synthetically from living organisms, including biology, biotechnology, genomics, proteomics, bioinformatics, pharmaceutical and biomedical research and technologies

Misinformation: Sharing of false, inaccurate or misleading information without malicious intent to mislead, confuse, introduce doubt or incite violence, with or without awareness of the falsehood(s) or inaccuracy(ies)

Participatory governance: Governance focused on deepening democratic engagement

Pathogen: A biological agent capable of causing disease in humans, animals or plants

Policy: Includes laws, regulations, standards, guidelines, best practices, codes of ethics, research review processes, training and education

Publics: Just as there is no monolithic “science”, there is no unified “public”; a term used to emphasize the plurality and diversity of perspectives, locations and engagement of groups and collectives

Risk: Probability of harm

Risk assessment: Systematic collection of quantitative or qualitative information on processes and evaluation of the nature, probability and magnitude of potential harm and determination of appropriate control measures

Risk management: Quantitative or qualitative forecasting and evaluation of potentially harmful consequences (risk assessment) with identification and use of technologies, measures or practices to avoid or minimize their impact (risk mitigation)

Scientific community: A network of interacting scientists and other (public or private) actors involved in research organizations, life sciences funding, standard-setting, project management, publication, dissemination, development and commercialization, education, training, regulation and governance as well as academics and scholars, including social scientists and humanists

Scientist: A person with expertise in natural or social sciences who systematically uses research and collects information to produce knowledge

Social justice: Concern with equity and fair access to social goods such as rights, privileges and opportunities; different from distributive justice, which concerns the fair distribution of quantifiable goods (e.g., vaccines, food, shelter). The aim of social justice is to ensure that political and social structures do not perpetuate systematic disadvantages in society

Stakeholder: Scientist, the scientific community, member of an ethics committee, institutional or repository manager, biosafety officer, security official, regulator, institutional or other authority, civil society network and publics

Executive summary

Research and application of the life sciences offer both opportunities and risks to health, safety and security. To ensure that current and future advances in the life sciences are used for the betterment of humans and the planet's biodiversity, ecosystems and environment, it is important that the scientific community adhere to high scientific, safety, security and ethical standards.

To further this aim and to motivate and strengthen safe, secure, responsible practices, WHO is developing a Global Guidance Framework for the Responsible Use of Life Sciences. As part of this process, WHO formed four working groups of experts. This report provides a short summary of the work of the expert working groups and their principal recommendations.

Recommendation 1: The World Health Organization should endorse and actively promote the values and principles presented in this document.

Recommendation 2: The World Health Organization (where appropriate, in collaboration with other United Nations agencies, and diverse stakeholders) should raise awareness about the importance of biorisk management.

Recommendation 3: The World Health Organization (where appropriate, in collaboration with other United Nations agencies, and diverse stakeholders) should support progress in development of governance tools and mechanisms for basic and applied life sciences.

Recommendation 4: Member States should establish tools and mechanisms for governance of basic and applied life sciences by introducing and enforcing comprehensive biorisk management policies, including laws, regulations, standards, guidelines, best practices, codes of ethics, research review processes, education and training.

Recommendation 5: Academic institutions should educate students and trainees in science, technology, engineering and mathematics about biorisk management.

Recommendation 6: Research institutions, funders and other stakeholders should promote a culture of biosafety and biosecurity in research environments at every stage of basic and applied life sciences.

Recommendation 7: Publishers should promote and practise a culture of biorisk management in scientific publishing.

Recommendation 8: Scientists should educate themselves about biorisk management and their responsibilities and foster broader awareness-raising of the importance of biorisk management.

1. Challenges and goals for better biorisk management

1.1 Opportunities and risks in an evolving context

Research in and application of the life sciences (and convergent research and technologies) offer both opportunities and risks to health, safety and security. As technology and scientific understanding in the life sciences, related fields and converging disciplines have advanced and continue to provide many societal benefits, risks to safety and security not only remain but have in some instances significantly increased. Accidents can occur in basic and applied life sciences that potentially endanger humans, nonhuman animals or the environment outside the laboratory. Furthermore, new scientific information and techniques developed for the common good can be misused and result in serious harm to humans, nonhuman animals and the environment.

Despite these and other risks, governance of advancing technologies and their applications has lagged behind innovation in the life sciences, for a number of reasons. Many countries do not have laws or regulations to govern biosecurity or biorisk management practices more broadly, and many scientific institutions (both public and private) lack biological risk management governance tools (instruments or apparatus) and mechanisms (a process, technique or system). Other countries and institutions have such tools and mechanisms, but they are not adequate to address current, let alone future, technologies. Life sciences also increasingly converge with other fields (e.g., chemistry, artificial intelligence, nanotechnology, neuroscience), and risks can emerge at the interfaces that are not always covered by traditional biological risk frameworks. More generally, the rapid development and diffusion of biotechnology capability increases the challenge of keeping pace.

Chronic, overarching, fundamental challenges in this area include lack of clear expectations by funders and institutions and of appropriate incentive structures to support good biorisk management practices. There is often little basic awareness among students, trainees, practising scientists, technologists and other managers and funders of scientific research and technology development that basic and applied life sciences predominantly undertaken to advance knowledge and develop tools and mechanisms to improve health, economies and societies could be conducted or misused in ways that result in risks to the health and security of the public. The topic is typically overlooked or underemphasized in both educational curricula and on-the-job training. Further, the problem is exacerbated by lack of leadership and role models, as well as lack of institutional or professional incentives to attend to safety and security concerns, coupled with ambiguity about the roles and responsibilities of different stakeholders. Box 1 lists a series of mini-scenarios that illustrate common gaps in understanding about biorisk management in basic and applied life sciences.

Box 1. Scenarios of common gaps in biorisk management

Scenario 1

Nyhema Curd is a new graduate student, who is excited to explore her chosen field of microbiology. Nyhema's supervisor is allowing her to design and conduct her own experiments between their weekly check-ins. Nyhema has never had this much freedom to explore her research interests and is excited to make new discoveries. She has had some training in microbial research safely (including how to protect herself, her samples and her peers), and she has heard the head of security at her university talk about the importance of not opening door of the laboratory to strangers. She has never heard of "biosecurity" or "dual-use research of concern", and, beyond the possibility of gaining new knowledge, she hasn't thought through the potential implications or consequences of her research.

Key questions: What are her responsibilities and obligations in considering the potential implications or consequences of her research? How should she start thinking about them? Who can she ask? How should this shape her research?

Scenario 2

A city hospital houses a medical diagnostic laboratory. The laboratory often receives samples of live viruses and bacteria collected from patients to identify the causative agents of their diseases. An unexplained outbreak of Crimean-Congo haemorrhagic fever in a neighbouring country coincides with the discovery in the laboratory of missing vials containing the viruses that cause the disease. It is well known that rival criminal gangs operate across borders in the region, and there is a long history of animosity and conflict among neighbouring governments.

Key questions: Has the management of the laboratory taken precautions against a threat from insiders or of organized crime? Who has access to the city hospital laboratory? How are staff members screened for potential security threats? How are samples stored? Is there controlled access to the freezers? What are the reporting responsibilities of the technician who discovered the missing vials? What are the reporting responsibilities of the laboratory management? To whom should they report the missing vials?

Scenario 3

Dr Tapia and Dr Naqvi study zoonotic diseases. Dr Naqvi and her team have conducted extensive training and developed several protocols for field collection of viral samples as safely as possible and for monitoring laboratory staff for exposure. Dr Tapia has asked Dr Naqvi to share influenza samples with his laboratory, which is in another country. Dr Naqvi refuses to ship samples, citing potential risks associated with the shipment, and instead invites Dr Tapia to conduct his experiments in her laboratory. Dr Tapia sends a postdoctoral student, Dr Davis, to Dr Naqvi's lab. Once in Dr Naqvi's laboratory, Dr Davis develops a new method for genetic manipulation of the influenza virus and, upon completion of his research, submits a paper to a top-tier journal. The managing editor of the journal is unsure whether the paper contains information that could potentially be misused.

Key questions: What are the responsibilities and obligations of scientific publishers in considering the potential security implications of the research they publish? How should the journal editor determine whether the manuscript is associated with a security threat? Who should review the manuscript for potential security threats? What are the responsibilities of laboratories for training visiting scientists? Should collaborators be vetted?

To ensure that current and future advances in basic and applied life sciences are used for the betterment of humans and the planet's biodiversity, ecosystems and environments, the scientific community must adhere to high scientific, safety, security and ethical standards. To advance this aim and to further motivate and strengthen safe, secure and responsible practices, WHO is developing a Global Guidance Framework for the Responsible Use of Life Sciences (the Framework). As part of this process, WHO formed four working groups of experts to (i) elaborate guiding values and principles; (ii) investigate major gaps in biosafety, biosecurity and oversight of dual-use research; (iii) identify governance tools and mechanisms to address the gaps; and (iv) make recommendations for strengthening global biorisk management. This report provides a short summary of the work of the expert working groups.

1.2 Biorisk management

In this report, the umbrella term "biorisk management" is used to cover the full spectrum of risks associated with the life sciences, broadly defined. This approach recognizes that risk mitigation measures must address many different types of risk. A biorisk is defined as a biological event – such as a naturally occurring disease, an accidental infection, an unexpected discovery, unauthorized access, loss, theft, misuse, diversion or intentional release of a biological agent or biological material – that could adversely affect the health of humans, nonhuman animals and the environment.

The three pillars of biorisk management are biosafety, biosecurity and oversight of dual-use research. Definitions of biosafety, biosecurity and dual-use research differ among countries and entities and often overlap. For the purposes of this report, "biosafety" is defined as containment principles, technologies, measures and practices that can be used to prevent inadvertent release or unintentional

exposure to biological agents or biological material. “Biosecurity” refers to the principles, technologies, measures and practices that can be used to prevent unauthorized access to or loss, theft, misuse, diversion or intentional release of a biological agent or biological material. “Dual-use research” refers to life sciences research conducted for peaceful and beneficial purposes that could also produce knowledge, information, methods, products or technologies that could be intentionally misused to endanger the health of humans, nonhuman animals and the environment. A glossary of the terms used in this report is presented above.

Biosafety has received more attention than biosecurity and dual-use research, but all must be better governed. The domains of biosafety, biosecurity and oversight of dual-use research are closely related, in theory if not in practice. Approaching these domains collectively under the term “biorisk management” has the advantage of recognizing and capitalizing on their interconnections without sacrificing the specific demands, challenges and risks of each.

1.3 Work of the consultative groups

WHO convened a consultation in March 2021 on the scope, terminology and critical elements of the Framework. Subsequently, in May 2021, WHO established three working groups to seek input and further discussion on three themes:

- the values and principles that should be the basis of the Framework and guide policies (laws, regulations, standards, guidelines, best practices, codes of ethics, research review processes, training and education) in this area;
- tools and mechanisms to promote responsible use of the life sciences and minimize the risks of accidents and misuse; and
- awareness-raising, capacity-building and engagement.

The participants and rapporteurs of these three groups are listed in Annex 1.

WHO convened a second consultative meeting in September 2021 to share the findings and recommendations of the three working groups and to discuss the next steps in the development of the Framework. A fourth working group was established by the WHO to produce a document integrating the work and recommendations of the earlier working groups and a glossary of terms. This document is the result of their work.

1.4 Structure of the summary report

Section 2 introduces the values and principles agreed by the working group to guide the development and effective implementation of tools and mechanisms for biorisk management in basic and applied life sciences. Section 3 outlines practical tools and mechanisms to ground the values and principles and their application in life science practices and highlights major gaps and challenges in effective biorisk management. Section 4 reviews one of the major gaps – lack of awareness and education about biosecurity among life scientists – and what is necessary to empower life scientists to engage more effectively in protecting their research from misuse. The recommendations derived from the work of the expert group are presented in section 5 of the report.

2. Values and principles to guide the development and implementation of governance tools and mechanisms for life sciences

2.1 Values and principles

Effective biorisk management involves continual risk assessment and, as required, use of mitigation strategies. The process is based on ethical judgements about the amount of risk to communities that can be considered reasonable or tolerable in relation to the anticipated benefits and the appropriate measures for addressing the identified risks. The establishment of international guidance for the development and effective implementation of biorisk management must be organized on the basis of common, integrated values and principles that serve as “touchstones” for considered ethical judgements. They serve as reminders for decision-makers to consider a wide range of contextual factors. They are not discrete, and there is some overlap.

The purpose of the values and principles underpinning the Framework should be threefold:

- delineate the ethical commitments that should guide scientists and the scientific community;
- encourage the use of ethical commitments as an anchor for policy and a community of practice that is aligned with recognized (international) standards, best practices and good governance; and
- serve as a common and unifying language among stakeholders when social, cultural and religious beliefs and ethical values diverge.

The values and principles developed by the working group during the consultation are anchored in a clear commitment to use the knowledge, material and skills of basic and applied life sciences for the common good. The overarching aim is to make life better for humans and nonhuman animals and to protect and promote the planet’s biodiversity, ecosystems and environments. The goal is to promote health, safety and security, which, in turn, should contribute to peace.

Of critical importance to the pursuit of this goal is a commitment to responsible stewardship of science. This entails a commitment to rigorous, evidence-based basic and applied life sciences in order to minimize risks to health, safety and security. This commitment must be coupled with a commitment to responsible communication of accurate scientific information and to report any illegal, unethical or unsafe basic and applied life sciences to relevant institutional, national and international authorities. All this is required to ensure fairness, social justice and intergenerational justice, which are among the values and principles listed in Box 2.

Box 2. Values and principles for safe, secure and responsible use of life sciences

Values and principles	Associated commitments
Health, safety and security	<p>Use knowledge, material and skills from basic and applied life sciences for peaceful purposes and for the betterment of humans and the planet’s biodiversity, ecosystems and environments.</p> <p>Use appropriate biosafety and biosecurity measures to prevent knowledge, material and skills from the life sciences from causing harm, so that we can live together peacefully.</p> <p>Preserve biodiversity where possible, both as a means to promote health, safety and security and as an intrinsic value.</p>
Responsible stewardship of science	<p>Pursue rigorous, evidence-based basic and applied life sciences to generate ideas, knowledge, data, products or technologies for peaceful purposes and for the betterment of humans and the planet’s biodiversity, ecosystems and environments.</p> <p>Exercise caution (e.g., appropriate use of safe practices, appropriate biosafety equipment and biosecurity measures) in planning and pursuing</p>

	<p>basic and applied life sciences in order to minimize risks to health, safety and security.</p> <p>Identify, manage and mitigate reasonably foreseeable potentially harmful consequences of basic and applied life sciences as a result of accidental, inadvertent and intentional actions by assessing, through multidisciplinary review process, whether (i) the identified risks are proportionate to the potential benefits of the research, (ii) less risky forms of research could be equally beneficial and (iii) modifying the research design or the dissemination and publication plans (as the research proceeds or after the research has been completed) is advisable.</p> <p>Develop and support policies (including laws, regulations, standards, guidelines, best practices, codes of ethics, research review processes, training and education) at all levels of governance that are specific to basic and applied life sciences and could result in harm to health, safety or security. These policies should reflect the community's values, priorities and risk-taking strategies.</p> <p>Develop and support ethical practices (with particular attention to issues of intent, integrity and conflicts of interest) to align the processes and outcomes of basic and applied life sciences with societal values, needs and expectations.</p> <p>Stay informed of current policies and associated best practices for safe, secure, responsible basic and applied life sciences; educate stakeholders about these policies and practices; and contribute time and expertise to improving relevant policies and practices.</p> <p>Align incentive structures and rewards with these guiding values and principles.</p>
Integrity	<p>Uphold the integrity of the scientific process by generating and responsibly communicating high-quality information (e.g., ideas, knowledge and data), in sufficient detail to permit its reproduction and careful peer review to identify and effectively deal with biosafety and biosecurity risks.</p> <p>Counter the dissemination of information that misinterprets or mischaracterises ideas, knowledge and data, with particular attention to issues of authorship as well as fabrication and falsification of data.</p> <p>Report possible illegal, unethical or unsafe basic and applied life sciences to relevant institutional, national, regional and international authorities.</p>
Fairness	<p>Ensure fair dealings in conducting basic and applied life sciences, including benefit-sharing (which includes sharing research benefits, research skills and research capacity).</p> <p>Develop and implement fair processes for confidential reporting and investigation of possible illegal, unethical or unsafe basic and applied life sciences in pursuit of fair outcomes. These tools and mechanisms should provide appropriate support and protection for both those who report concerns and those alleged to have engaged in illegal, unethical or unsafe activities.</p>
Openness, transparency, honesty and accountability	<p>Use open, transparent, honest and accountable processes to share relevant information about biosafety and biosecurity risks with (i) the scientific community, including project managers, funders, editors and publishers; (ii) biosafety officers, security officials, regulators, institutional and other authorities; and (iii) civil society networks.</p> <p>Make scientific information (e.g., ideas, knowledge and data) accessible, except when an assessment concludes that wide dissemination (including publication) would pose a safety or security threat, in which case wide</p>

	<p>dissemination should be curtailed. Thus, manuscripts might have to be modified before publication (with this information duly noted in the publication, consistent with a commitment not to intentionally mischaracterize or falsify ideas, knowledge or data) or not published.</p> <p>Hold scientists and the scientific community accountable for the design, pursuit and consequences of basic and applied life sciences.</p> <p>Conduct regular audits to ensure compliance with relevant policies for eliminating or minimizing biosafety and biosecurity risks.</p>
Inclusiveness and collaboration	<p>Actively involve people in social sciences and humanities disciplines in the design and pursuit of basic and applied life sciences, consistent with the recognized value of interdisciplinary research.</p> <p>Carefully consider perspectives on basic and applied life sciences that are based on different social, cultural and religious beliefs, ethical values, organizational sectors (e.g., academia, government, industry), experiential knowledge and skill sets.</p> <p>Adopt an international outlook, including consultation, sharing, negotiation, coordination and related forms of active engagement (such as awareness-raising and education programmes), with other countries and the wider international community.</p> <p>Practise basic and applied life sciences in a manner that invites collaborative ambition and work.</p>
Social justice	<p>Consider the needs (and aspirations) of all, and ensure adequate access to the potentially beneficial outcomes of basic and applied life sciences.</p> <p>Provide scientists in low- and middle-income countries with equitable access to relevant research training and capacity-building.</p> <p>Include and empower scientists in low- and middle-income countries in both the pursuit and governance of basic and applied life sciences</p>
Intergenerational justice	<p>Protect and promote the health, safety and security of humans, nonhuman animals and the environment by respect for past generations and for the benefit of future generations. These responsibilities include (i) accepting responsibility for the consequences of one's actions, (ii) pursuing life sciences of potential benefit to future generations, (iii) managing and mitigating any harm that might accrue to future generations and (iv) ensuring that biodiversity, ecosystems and environments are preserved where possible.</p>
Public education, engagement and empowerment	<p>Educate civil society networks and publics about the potential benefits, potential harms, limitations and capabilities of basic and applied life sciences in ways that balance competing influences and demands.</p> <p>Engage civil society networks and publics in deliberations about possible future uses (and potential accidental, inadvertent and intentional misuses) of basic and applied life sciences.</p> <p>Empower civil society networks and publics by enhancing participatory governance and promoting collaborative ambition so as to promote trust and strengthen global solidarity in support of health, safety and security.</p>

3. Tools and mechanisms for biorisk management

3.1 Elements of biorisk management

Values and principles alone cannot advance responsible use of life sciences. This section outlines tools and mechanisms for actualizing the values and principles outlined in section 2 for safe, secure, and responsible use of life sciences.

Effective biorisk management is multifaceted and requires attention to the following elements:

- **Goals** that include reducing accidents and security incidents, enabling early detection of safety and security incidents, reducing future opportunities for malicious misuse of research tools and knowledge, enabling rapid response to safety and security incidents and increasing information exchange and learning.
- **Stakeholders** that are best positioned to achieve the relevant goals. These include academic institutions, public health and medical microbiology research institutions, commercial research companies, standard-setters, funders of research, editors, publishers and scientific societies. Governments play a critical role in reinforcing, funding and requiring governance tools and mechanisms from many actors.
- **Governance tools** and mechanisms to achieve explicit goals and to engage a range of stakeholders. Key tools and mechanisms for biorisk management include statutory laws and regulations, standards, guidelines, best practices, codes of ethics, research review processes, training and education.

Biorisk management systems necessarily involve many governance tools and mechanisms to reinforce different goals. The tools and mechanisms operate at different levels of formality, incentives and enforcement (e.g., requirements, guidelines or codes of ethics). Some tools and mechanisms may apply to several goals and stakeholders; others are more narrowly focused on one or two goals and stakeholders.

An effective biorisk management system should fulfil all goals.

3.2 Stakeholders, tools and mechanisms

Different stakeholders have different roles and options in biorisk management.

Individual scientists conceive and implement their ideas (even as those ideas are clearly shaped by their environments and communities) and, as such, are the first line of control for assessing and mitigating risks. While scientists are incentivized to consider, articulate and defend the potential benefits of their research, they also have a duty to consider and mitigate any risks that the knowledge, information, methods, products or technologies that they develop and disseminate could be used for harmful purposes. In many countries, including those that have robust biorisk management systems, many scientists are unaware of their individual responsibility for managing risks associated with their research. Some scientists may be aware of their responsibility but lack the knowledge, relationships or will to fulfil it. This is especially concerning when novel risks arise and roles may be ambiguous, where proactive engagement is necessary.

Research institutions, as the employers of scientists, are responsible for their professional activities. They include all organizations that conduct basic and applied life sciences and are not limited to universities, institutes, companies, government laboratories and community laboratories. Research institutions are the second line of control for biorisk assessment and mitigation.

Stakeholders other than individual scientists and research institutions include **funding bodies, the private sector, professional societies and other standard-setting institutions, editors, publishers, educators, international organizations, civil society networks and publics**. As research is

increasingly conducted across organizations and countries, the roles of various stakeholders in promulgating and translating standards have become more complex and interconnected. Examples of biorisk management tools and mechanisms for these stakeholders are illustrated in Box 3.

Box 3. Examples of biorisk management tools and mechanisms for different stakeholders

Stakeholder: Individual scientist

Training. All life scientists should be familiar with biorisk assessment and mitigation. At a minimum, students, trainees and scientists at all levels must know how to assess and document biorisks in a way that is accessible to their co-workers as well as to internal and external auditors and to identify and implement technologies, measures or practices to avoid or minimize the impact of biorisks. Training in risk assessment and risk mitigation is essential to assist students, trainees and scientists in understanding what is expected for effective biorisk management and how to achieve it. For example, the International Federation of Biosafety Associations facilitates training in partnership with national biosafety organizations and provides certification for biosafety and biosecurity professionals (1). Critically, training must go beyond competence to address commitments, especially when risks may require going “beyond compliance” to proactive monitoring for non-routine biorisks. If a biorisk is identified, scientists are responsible for reporting it. Training should ensure that the responsibility is well understood and that it is clear what to report and to whom. Training should be interdisciplinary to demonstrate that researchers in different disciplines could be resources for identifying a larger range of risks, especially in convergent areas or for providing best practices for risk mitigation.

Codes of ethics. Codes of ethics can be useful for raising awareness about the importance of biorisk management and for norm-setting standards. An early example of a national code of conduct for biorisk management is the Biosecurity Code of Conduct in the Netherlands, developed by the Royal Netherlands Academy of Arts and Science (2). Initiatives have also been made to outline high-level principles to serve as references in developing or amending national or institutional codes of conduct. The most recent is the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists (3). Inspired by the Hague Ethical Guidelines developed by the Organisation for the Prohibition of Chemical Weapons, the Tianjin Biosecurity Guidelines emerged from foundational work by China and Pakistan and were developed collaboratively by InterAcademy Partnership leaders, Tianjin University’s Centre for Biosafety Research and Strategy and Johns Hopkins University’s Center for Health Security, with input from scientists from 20 geographically diverse countries.

Aligned research agendas. A strategic opportunity to create incentives for scientists to engage in proactive biorisk management is support for research programmes to develop new knowledge, tools and mechanisms to improve biorisk management. Applied biosafety and biosecurity research programmes can span technological solutions (e.g., new types of biological or physical containment or monitoring strategies), social and behavioural solutions (e.g., innovations in training) and/or innovative policy approaches (e.g., revisions of regulatory frameworks and the supporting science). This work is often most effective when coupled directly with science and technology research programmes in their earliest stages of development. One example is the integrated policy and practices research programme supported over 10 years by the multi-university US National Science Foundation Synthetic Biology Engineering Research Consortium, which involved both natural and social scientists and stakeholders in industry and policy. Some of the scientists trained in these settings now have research laboratories dedicated to developing technologies to support biosafety and have become champions of proactive engagement in biorisk management. The international Genetically Engineered Machine Competition – a synthetic biology research competition that has engaged over 50 000 students in over 60 countries – rewards and recognizes not only technological advances but also innovations in safety, security and social responsibility and has become a testbed for policy implementation, engaging groups responsible for biorisk management in many countries (4).

Institutional oversight. Scientists have many demands on their time, and, even within a robust research culture, there is possibly sub-standard biorisk assessment and mitigation. Institutional oversight of scientist-led risk assessments (e.g., by internal audits, internal peer review, internal committee approval) can be used to standardize processes within an institution and improve or ensure the quality and timeliness of risk assessments. For example, in Germany, institutions that receive funding from the German Research Foundation must create a committee to review security-relevant research and suggest mitigating measures. This process is overseen by the Joint Committee on the Handling of Security-relevant Research, which is a

collaborative biorisk management initiative of the German Research Foundation and the Leopoldina National Academy of Sciences (5).

National legislation, regulation and guidance. National legislation, including regulations and guidance, can be applied to individual scientists and/or institutions to ensure that adequate steps are taken to manage biorisks. For example, Canada's comprehensive, nationwide biorisk management system was promulgated in the Human Pathogen and Toxin Act and is overseen by the Centre for Biosecurity in Public Health Agency of Canada (6).

Stakeholder: Funding bodies

Research design review. While funding bodies are not usually involved in designing research, they may play a significant role in mitigating biorisks during evaluation of research applications. Many leading life science funders include questions on their funding application forms to determine whether applicants have considered safety, security and dual-use aspects of their research. These funders also ask peer reviewers to consider the biorisk aspects of the proposals they review.

Funding requirements. For research that involves particularly risky materials, techniques or technologies, funders can make it a condition of funding that scientists (i) proactively identify and manage risks possibly connected with their research, (ii) explain how the risks (as managed) are proportionate to the potential benefits of the research, (iii) consider whether less risky forms of research could be equally beneficial and (iv) modify the research design or dissemination and publication plans (as the research proceeds or after the research has been completed) to mitigate risks. For example, in the United Kingdom, the Biotechnology and Biological Sciences Research Council, the Medical Research Council and the Wellcome Trust impose conditions for funding that include compliance with risk-related regulations (7). To facilitate knowledge-sharing and instil norms for biorisk management, funders may also require disclosures throughout the research lifecycle, including in publications, presentations and other communication of results. Nascent efforts for public reporting include the Materials Design Analysis Framework (8), developed by a consortium of publishers, which was recently updated to include a question about dual use, and the Visibility Initiative for Responsible Science, developed by an international consortium of funders, publishers, researchers and oversight groups, which is developing frameworks to increase transparency in biorisk management practices through scenarios and reporting (9, 10).

Agenda-setting. Funding bodies may have a role in setting the research agenda in certain fields. This is an executive function and allows funders to engage with institutions individually and collectively to provide guidance on assessment and control of biorisks, requiring institutions to undertake and maintain certain levels of biorisk assessment, education and training as a condition of eligibility. For example, a consortium of organizations that fund and otherwise support gene drive research, including Wellcome Trust, the Institut Pasteur and the Bill & Melinda Gates Foundation, developed guiding principles for sponsoring gene drive research, including promoting the safety and governance of the technologies, ensuring transparency in data-sharing and fostering accountability (11).

Funding bodies may also be involved in setting agendas by providing support for research to develop and evaluate tools and mechanisms to support biorisk management, including both technical and social and behavioural approaches.

Active accountability. In the case of known or public examples of scientists and/or their institutions failing in their duty to identify, assess and control biorisks, funding bodies may consider whether to review extant (as well as pending) grants. This would be a powerful means to encourage scientists and institutions to take their responsibilities seriously.

Stakeholder: Private sector

Self-governance. In 2009, a group of leading gene synthesis companies formed the International Gene Synthesis Consortium and adopted a voluntary system for screening customers and orders for gene sequencing. During screening, orders are compared with a database of nationally and internationally regulated pathogens and toxins to determine whether any of the ordered sequence poses a security risk. If the automated screening system detects a close match between an ordered sequence and a regulated agent, the order and the customer are scrutinized manually (12).

National legislation. While research, development and use of genetically modified organisms is subject to national legislation in many countries, governance is typically limited to considerations of biosafety and

biodiversity. Even in countries with governance of dual-use research, the oversight is often restricted to publicly funded research.

Stakeholder: Standard-setting institutions

Science academies. Local and regional science academies, such as the InterAcademy Partnership and the European Academy of Sciences and Arts, play important roles in setting science policies, strategies and ethical considerations for use by universities and other research organizations in developing their own standards of scientific integrity and codes of ethics. For example, the Swiss Academies of Arts and Sciences and the Swiss National Science Foundation, the umbrella organization of the Swiss universities, and the Swiss Innovation Agency published a code of conduct for scientific integrity in May 2021, which includes the following statement on dual-use research of concern: “Researchers are obliged to proactively recognize and consider possible harms and risks in connection with their research work and to take appropriate precautionary measures. This is especially true for dual-use research of concern.” (13)

Local and regional biosafety associations. Biosafety and biosecurity officers assess biorisks and implementing mitigating measures (14). WHO recommends that a biosafety officer be nominated in all laboratories to provide advice and guidance to scientists and the laboratory management. The competence of such officers and their capacity to support their institutions in biorisk management and awareness-raising depend largely on sufficient training and being empowered, trusted members of the research teams. Formal and informal peer training can be conducted through local and regional biosafety associations and other entities dedicated to minimizing biorisks (15). The Croatian Society for Biosecurity is a national biosafety association that is active in advancing training in biosafety and biosecurity and in sharing information among biosafety professionals (16). Other examples are found in Canada (17) and The Netherlands (18). Support for the work of local and regional biosafety associations is key to enhancing biosafety and biosecurity globally.

International standards. In 2019, the International Organization for Standardization (ISO), released ISO 35001, a standard for biorisk management for laboratories that work with dangerous pathogens. Rather than focusing on scientific hardware, the standard emphasizes commitments by top management – to provide adequate resources, to prioritize and communicate biosafety and biosecurity policy, to train staff and to establish performance expectations. The standard also requires continual improvement of practices and processes to determine the causes of incidents and other issues, to correct problems so that they do not recur, to identify opportunities for improvement and to recognize and reward improvement. Some institutions have begun to adopt the standard. Further promotion and awareness-raising will undoubtedly lead to safer, more secure biological activities. Development of an international certification scheme for ISO 35001 would promote its use (19).

Stakeholder: Publishers

Manuscript review. Review of manuscripts by editors, peers and, in some cases, advisory boards for information that may pose significant biorisks or allow others to inappropriately repeat risky experiments is critical. While editors and publishers have an obligation to make scientific ideas, knowledge and data accessible, this does not apply when a risk assessment concludes that wide dissemination through publication poses a safety or security threat. In these cases, dissemination should be curtailed. This could mean that manuscripts are not published or are seriously modified before publication. The developers of the aforementioned Materials Design Analysis Framework (8) have experimentally included a question related to dual-use in standardized reporting of methods, which must be answered when submitting a paper. Related initiatives such as the Visibility Initiative for Responsible Science (10) are improving standards for reporting throughout the research life-cycle.

Guidelines. Some publishers have established guidelines for identifying, reviewing and publishing manuscripts that may pose a risk to health, safety and security. These guidelines require periodic revision and updating to ensure inclusion of novel types of potential risk. In 2003, the editors of several renowned journals issued a statement on scientific publications and security that included recommendations on editorial processes for publications that may pose a safety or security threat (20). Moreover, the Council of Science Editors published a white paper on publication ethics in 2006 that is regularly updated (21). The paper includes a section on the responsibilities of editors towards the public, encompassing guidance on biosafety and biosecurity. Further, the US National Science Advisory Board for Biosecurity has integrated guidance to editors and publishers in several reports on biosecurity, dual-use and gain-of-function research (22).

Stakeholder: Educators

The inclusion of concepts such as responsible science, biosafety, biosecurity and dual use in scientific and medical curricula can increase awareness of risks to health, safety and security in basic and applied life sciences. Academic institutions and scientific institutes should ensure that awareness and understanding of these concepts are part of all relevant educational activities, including courses.

Training. Curricula that include laboratory and practical sessions could reinforce concepts of best practices taught in theoretical sessions. Active learning is effective for demonstrating the practical utility of concepts such as biosafety, biosecurity and dual use. The Academy of Sciences of Malaysia has developed an educational module based on active learning principles for responsible conduct of research in the life sciences that includes a module on dual-use research and the importance of creating a culture of safety (23).

Stakeholder: International organizations

Guidance documents. While many countries (and regions, territories and institutes) have developed regulatory frameworks for responsible science and provide guidance on related matters, other countries have not. International organizations such as WHO, the Food and Agriculture Organization of the United Nations, the United Nations Educational, Scientific and Cultural Organization and the World Organization for Animal Health can provide guidance in developing local regulations and also in reinforcing global best practices. Multilateral work has been undertaken to establish metrics for biorisk management and to track countries' performance according to those metrics. For example, United Nations Security Council Resolution 1540 (24) includes provisions on biosecurity and the prevention of non-State actors from acquiring and using biological weapons. Another example is the Joint External Evaluation for WHO's International Health Regulations (2005), which is a voluntary, collaborative, multi-sectoral process for comprehensive assessment of countries' capacity to prevent, detect and rapidly respond to public health risks (25). Countries' biosafety and biosecurity measures are evaluated according to metrics developed within the Global Health Security Agenda (26). A third example is the framework of the Biological Weapons Convention, which provides the normative foundation for international efforts to prevent the misuse of biology and biotechnology. The treaty's Implementation Support Unit provides assistance to countries in joining the treaty and implementing their obligations (27).

Access to information and resources. International organizations can act as platforms to facilitate access to the information required for biorisk assessment, training, conducting responsible science, risk mitigation and the development of regulations and other relevant activities. Moreover, international bodies can assist local authorities, scientific institutions and investigators in identifying resources for complying with responsible science practices. For example, the United Nations Interregional Crime and Justice Research Institute has a global network of stakeholders invested in biorisk management and acts as a clearing-house for stakeholders to share best practices and training materials (28). The annual meetings of States Parties and experts under the Biological Weapons Convention bring together governmental and nongovernmental experts in biorisk management to share best practices and lessons learnt and to develop new ideas for strengthening global biosecurity (29). The treaty's confidence-building measures, especially those related to BSL-4 labs and biodefence programmes, also ensure transparency of national activities in these areas (30).

Communication. Novel global threats and growing sources of biorisk can be identified by transparent communication among countries and entities; international organizations can facilitate communication among stakeholders and can publish the data or information necessary to identify such risks. Good examples that are supported by civil society include the Global Biosecurity Dialogue (31) (in particular its workstream on emerging biological risks) and the Global Health Security Agenda (including its workstream on biosafety and biosecurity).

Stakeholder: Civil society networks

Transparency. Civil society is a stakeholder in research and laboratory activity insofar as the risks and potential benefits of such activities affect society at large. Civil society networks should have access to information and discussions about research and laboratory work that may affect publics. For example, the Nuclear Threat Initiative's Global Health Security Index is a measure of the level of national biosafety and biosecurity preparedness (32).

Informing and educating. Civil society networks can play a significant role in informing publics and educating various sectors of society and can act as a bridge and “translator” of scientific information for various publics.

Policy-making. An informed public can make better decisions about political strategies and policies that govern scientific activities. Civil society networks can act as liaisons between the scientific community and various publics to balance competing interests, such as the desire for unfettered science and for caution and control. For example, after the devastating outbreak of Ebola virus disease in western Africa in 2014–2015, a partnership was formed between experts and civil society networks that resulted in the Global Emerging Pathogens Treatment Consortium (33), which played an important role in organizing the African Voices and Leadership conference on Ebola in Dakar, Senegal, in 2014 (34), where deficiencies, including those related to biosecurity, that compounded the outbreak were identified. The consortium was also able to secure commitments from several governments and develop memoranda of understanding with those governments to limit possible threats.

National governments are the stakeholders ultimately responsible for defining biorisk management standards for others and for enacting and enforcing relevant policies (including laws, regulations, standards, guidelines, best practices, codes of ethics, research review processes, training and education). National legislation, including regulations and guidance documents, is a tool that can set out the legal requirements of institutions for biorisk management, training and internal oversight. Without clear guidance from government and strong communication systems among institutions to share best practices and facilitate innovation and consensus-building, research institutions may face ambiguities in their responsibilities for biorisk management. National legislation can also help research institutions to understand that their responsibility to ensure effective biorisk management is not secondary to academic, commercial or other goals.

In any country, the ability of institutions to undertake research safely, securely and responsibly will vary. A statutory governance system in which institutions must be registered as suitable to conduct certain activities (e.g., genetic modification) or must document biorisk assessment and mitigation when new, particularly risky types of research are proposed, is a tool that can be useful for setting minimum national standards, increasing oversight, enabling external audits, encouraging transparency and accountability and, ultimately, reducing biorisks.

Certain life sciences research is already recognized as particularly risky in some countries, such as human genome editing and genetic modification of human pathogens; however, other areas of biorisk are evolving rapidly with advances in technology that are not as clearly defined or governed. In the USA, for example, the Select Agent Regulations provide the legal framework for laboratory biosecurity, and several Government-policies on dual-use research oversight have been implemented during the past decade (35). Approaches to governance of the life sciences by lists can, however, be limited: because of the speed of advances, lists can quickly become outdated, with “holes” in the biorisk management system as new technologies and their associated risks are not listed. Sufficiently flexible frameworks for including new technologies as they arise may resolve this problem. Some countries have adopted regulatory systems based on risk assessments. In the United Kingdom, for example, the Health and Safety Executive requires all organizations involved in genetic manipulation to register and receive approval for particular types of research. In their Compendium of Guidance, all organizations that conduct genetic manipulation are legally required to have an internal committee to review the research and risk assessments and can refuse permission to proceed (36).

While many countries have statutory frameworks to regulate biosafety, and several have biosecurity-specific legislation, very few currently have legislation or regulations that explicitly address dual-use.

3.3 A comprehensive governance approach

Risk management depends on (i) the values, principles and training of the scientists directly involved in research (the research culture); (ii) active management of biosafety and biosecurity risks by institutions; and (iii) the responsibilities and obligations of individuals and institutions and tools and mechanisms of enforcement and accountability (e.g., guidance and/or legislation) established by the government.

As science, risks and social contexts evolve, it is important to develop the capacity for regular assessment of how distinct goals might best be realized by various combinations of stakeholders and governance tools and mechanisms. Building effective biorisk management systems requires experimentation and systematic review of tools and mechanisms and their implementation (37–39). It also requires tools and mechanisms for information exchange among stakeholders.

A comprehensive governance approach to biorisk management must include a range of governance tools, mechanisms, as well as stakeholders at international, regional, national, institutional and individual levels. The tools must be coherent (40, 41), and the governance approaches must be adaptable to include innovations in both policies and practices. Simple frameworks can be helpful in assessing which combinations of approaches taken by different stakeholders might best achieve several goals and be adapted for different organizational contexts (see Box 4 for an illustrative example).

Box 4. Illustrative framework for systematically evaluating tools and mechanisms towards a comprehensive governance approach for biorisk management

Goals	Stakeholder A (e.g., scientific society)	Stakeholder B (e.g., government authority)	Stakeholder C (e.g., funding body)
	Tool (e.g., code of conduct)	Mechanism (e.g., oversight and reporting requirements)	Mechanism (e.g., funding of applied safety and security research)
Reduce accidents	++	+++	+
Reduce security incidents	++	+++	+
Enable early detection of safety and security incidents	+	++	++
Enable rapid response to safety and security incidents	+	++	+++
Reduce opportunities for malicious misuse of research tools and knowledge	++	+++	+
Increase information exchange and learning	+	++	+++
Other goals, e.g., cost-effectiveness, feasibility, enabling constructive applications			
Scoring key (qualitative and relative) ++++ most effective +++ relatively effective			

- ++ moderately effective
- + somewhat effective
- not effective

Notes on example framework and scoring

A systemic approach to biorisk management requires assessment of how different goals might be most effectively realized by different stakeholders, tools and mechanisms. Mapping of this approach, as the limited table above illustrates, can facilitate planning and assessment both within and among tools and mechanisms. Comparison across rows indicates the effectiveness of each tool for achieving different goals. Comparison across columns indicates tools and mechanisms that are more or less effective for achieving a certain goal. A comprehensive approach should seek to fulfil all goals in a suite of approaches. It is only through a mutually reinforcing set of tools that can countries reach the most effective level.

Note: The examples and scores are illustrative only, as the most effective tools and mechanisms and their combinations will depend on the context.

4. Awareness-raising, education, training and capacity-building

4.1 Examples of awareness-raising, education, training and capacity-building

Values and principles are the ethical foundations for responsible use of basic and applied life sciences. Tools and mechanisms for biorisk management provide practical grounds for application of the values and principles. To ensure uptake and use of these foundational elements, awareness-raising, education, training and capacity-building are required for stakeholders in the research ecosystem, including scientists, research institutions and funders.

Much has already been done in support of awareness-raising and engagement in basic and applied life sciences and related fields (see, e.g., 42–45), particularly in the field of chemistry. Several illustrative examples—this is not a comprehensive account—are provided in Box 5. Although some have completed evaluations that demonstrate success, the extent of the activity is sometimes un- or under-acknowledged. Moreover, although some initiatives have proven both successful and sustainable, it is not always clear whether all were either successful or sustained.

Box 5. Illustrative examples of awareness-raising, education, training and capacity-building in the life sciences and related fields

Argentina	The Argentine National Authority for the Chemical Weapons Convention developed a national project on education and outreach to (i) improve knowledge about the role of the treaty and the national legislation that implements it, (ii) raise awareness about the dual-use nature of knowledge in the chemical sciences and the risks that it implies and (iii) promote a culture of responsible use of technical and scientific knowledge (46). The work was undertaken by, for example, the chemistry department at the University of Rosario, where chemical safety, security and responsible conduct of science are part of the chemical curriculum, with various curricular activities, elective subjects (e.g., bioethics, green chemistry, educating for sustainable future) and complementary activities (e.g., workshops, seminars). New activities are being designed to improve discussion of these topics in the curriculum, with evaluation of their impact in a research project financed by the University.
Australia	Biosecurity Emergency Response Training Australia was established as a collaboration among several Australian state and territorial governments, the Commonwealth of Nations, Animal Health Australia and Plant Health Australia. To maintain consistency in biosecurity training, the National Biosecurity Committee funded Tocal College to develop training and assessment materials.

Canada	<p>Several Government agencies, such as the Centre for Biosecurity of the Public Health Agency of Canada and the Office of Biohazard Containment and Safety of the Canadian Food Inspection Agency, have developed biosafety and biosecurity training materials and also an online training portal.</p> <p>Tri-agency framework: Responsible conduct of research (47) is a reference for the three major Canadian funding agencies and guides all funded research as well as research institutions eligible for funding. It sets out the responsibilities and corresponding policies for researchers, institutions and agencies to support and promote a positive research environment.</p>
China	<p>The Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists (3) are high-level principles that serve as a reference for a broad range of stakeholders to develop or amend national or institutional codes of conduct, practices, protocols or regulations. Inspired by the Hague Ethical Guidelines developed by the Organisation for the Prohibition of Chemical Weapons, the Tianjin guidelines emerged from work by China and Pakistan and were developed collaboratively by InterAcademy Partnership leaders, Tianjin University's Centre for Biosafety Research and Strategy and Johns Hopkins University's Center for Health Security, with input from scientists from 20 countries.</p>
France	<p>The aim of the Agence Nationale de Sécurité du Médicament et des produits de santé [National Agency for the Safety of Drugs and Health Products], established in 2011, is to ensure the safety of medicines and health products and support health policy decisions on the safe use of drugs and biological products. It is responsible for inspecting sites for the manufacture of medical and health products, and it regulates and inspects work with microorganisms and toxins. The National Consultative Council for Biosecurity was created in 2015 (48) to develop guidance to mitigate misuse and dual-use research in the life sciences.</p>
Kenya	<p>Academic chemistry institutions in Kenya have emphasized training in safety to the detriment of security concerns, and gaps in awareness and implementation of chemical security have resulted in reported cases of theft and attacks involving chemicals. Over the past 5 years, the Kenya Chemical Society has conducted training in chemical security and outreach campaigns to academia and industry to address this gap. These have revealed insufficient basic knowledge among chemical practitioners about chemical security to prevent misuse, theft and diversion of hazardous and dual-use chemicals (49).</p>
Lebanon	<p>Several biosafety and security-related initiatives have been undertaken in Lebanon, including establishment of a biosafety and biosecurity association (50) and outreach to spread responsible science concepts. The outreach initiatives have primarily targeted faculty and students and trainees at universities and hospitals and have provided education on basic biosafety principles and biosecurity measures through seminars, symposia, poster sessions, workshops, online courses and forums and train-the-trainer events.</p>
Malaysia	<p>The agenda for responsible conduct of research education in Malaysia was initiated by the Educational Institute on Responsible Science in Kuala Lumpur. In collaboration with the US National Academies of Sciences, Engineering and Medicine and with support from the Malay Ministry of Education, the Young Scientists Network of the Academy of Sciences Malaysia produced the first Malaysian Educational Module on responsible conduct of research, including a chapter on the culture of safety and dual-use research, in 2018 (51). In 2019, sponsored by the International Science Council, the 2-year ASEAN programme on responsible conduct of research was initiated to train the first cohort of instructors (52).</p>
Mexico	<p>The Mexican Biosafety Association was established in 2009 as a member of the International Federation of Biosafety Associations (58). Its aim is to provide information on biosafety and biosecurity and to promote training in these fields.</p>
Morocco	<p>The Moroccan Biosafety Association (59), in partnership with the US Biosecurity Engagement Program, the Task Force for Global Health and Gryphon Scientific, organizes biosafety and biosecurity training workshops, meetings and train-the-trainer events.</p>
Netherlands	<p>The Dutch Government established a Biosecurity Office in 2013 as an information centre for biosecurity (53). The office collaborates with many international organizations, and an internal working group organizes lectures, webinars and workshops and provides tools and</p>

	<p>web applications for biosecurity education to identify potential biorisks. The Office also organizes an annual Biosecurity Knowledge Day.</p> <p>At the request of the Dutch Ministry of Education, Culture and Science, the Royal Netherlands Academy of Arts and Science developed a Code of Conduct for Biosecurity (2). The aim of the Code is to prevent direct or indirect contribution of life sciences or their application to the development, production or stockpiling of biological weapons, as described in the Biological Weapons Convention, or to any other misuse of biological agents and biological material.</p>
Pakistan	In collaboration with other countries, Pakistan has been raising awareness and producing educational materials on bioethics, biosafety, biosecurity and dual-use since 2010 (60). The aim of the activities is to strategize and promoting awareness of biorisk management, emphasizing “holistic biosecurity”, which is not limited to laboratories.
Ukraine	In 2018, the Organization for Security and Co-operation in Europe conducted a thorough review of biological safety and security in Ukraine and identified major gaps, one of which was appropriate training in biosafety and biosecurity. Several projects were launched to address the gaps, including training and raising awareness for life scientists. In 2019, the Council of the European Union decided to support strengthening of biological safety and security in Ukraine, including awareness-raising, education and training (61).
United Nations Interregional Crime and Justice Research Institute	The United Nations Interregional Crime and Justice Research Institute, in collaboration with the US Federal Bureau of Investigation, administers the International Network on Biotechnology, a global network of academic and research institutions committed to advancing education and raising awareness about responsible, secure conduct in basic and applied life sciences (62). The Network also supports the development and sharing (via an online portal accessible to network partners) of modular educational resources such as awareness-raising videos, scenarios and active learning exercises, covering the themes of biosafety, biosecurity and bioethics.
United Kingdom of Great Britain and Northern Ireland (the)	The University of Bradford has produced an education resource, Preventing biological threats: What you can do: A guide to biological security issues and how to address them (54) and Biological security education handbook: The power of team-based learning (55). London Metropolitan University has published an innovative set of biological security education cartoons (56). These products are available in several languages.
United States of America (the)	The US Department of State Bureau of International Security and Nonproliferation, Office of Cooperative Threat Reduction initiated a Biosecurity Engagement Program in 2006, which supported training and capacity-building in the USA and elsewhere. Since 2010, the Program has supported several institutions in raising awareness and education about responsible, secure conduct in the life sciences. For instance, the US National Academy of Sciences, Engineering and Medicine organized three international meetings on conducting responsible science in the Middle East and North Africa region with local partners and workshops on responsible conduct of science and bioethics for people working in the life sciences. Gryphon Scientific organized several workshops and produced modular educational resources (assessment videos, scenarios and mock research review) and developed an online platform, Bio-Chem COMPASS, to provide a safer, more secure work environment for biological and chemical professionals in the region (57). The Frontline Foundation organized an online course on biorisk management accredited by the International Association for Continuing Education and Training in these countries.

4.2 Lessons from previous experience

Previous awareness-raising, education, training and capacity-building in relation to biorisks provide several general lessons for future undertaking of such activities.

- **Purpose:** While calls for more awareness-raising, education, training and capacity-building in relation to biorisks have been made for a number of years, their purpose has differed

considerably. Past and current aims include enabling self-governance, underpinning formal oversight and promoting discussion. It is not always clear what is expected of those who are “educated” or “engaged”. Moreover, the challenges and gaps in awareness-raising, education, training and capacity-building vary from addressing accidents (biosafety) to preventing deliberate outbreaks of disease (biosecurity). To prevent accidental disease, implementation of institutional safety procedures is required, whereas addressing hostile use of biology requires considerable work to fully enable students, trainees, scientists and others to deal with such concerns.

- **Priorities:** Biosecurity and dual use are not immediate priorities for most people associated with basic and applied life sciences and are generally not well understood. Particularly in countries grappling with severe health and environmental challenges, it is a demanding task to weigh security threats associated with life sciences against other concerns.
- **Definitions:** Lack of shared terminology, including the meaning of key terms such as “biosafety”, “biosecurity” and “dual use”, complicates the sharing of best practices.
- **Discussion:** Given the uncertainty about what education and training should entail, how it should be done, why it is necessary and who should be involved, education and training to prevent biorisks must be widely promoted and discussed. As no single approach can meet the needs and conditions of all, the strengths, opportunities and challenges of initiatives should be evaluated to assess the tools and mechanisms and how the necessary capacity-building can best be provided.
- **Inclusion:** Previous initiatives involved a wide range of stakeholders. As concerns about biorisks extends beyond those working with pathogens, research organizations, funders, laboratory technicians, professional societies, data managers and curators, editors, publishers, ethics committees, institutional and repository managers, regulators and civil society networks have all roles to play, both as teachers and learners.
- **Innovation:** The design and creation of awareness-raising and educational materials should integrate best practices. Innovative approaches such as active learning and team learning exercises have proven valuable and have enduring value. Moreover, once created, these approaches could be adapted for future training and shared with other teams.
- **Integration:** Material on biorisk management could be integrated into existing training courses on laboratory practice or courses on bioethics or research ethics as part of wider discussions on responsible conduct of research.
- **Bottom-up versus top-down:** Some initiatives have been bottom-up, essentially emerging organically from individual champions. Others have been top-down. Both bottom-up and top-down support is required, with the latter particularly important to institutionalize initiatives.
- **Local materials:** Various materials have been developed for awareness-raising, education and training. Different institutions and countries require material that is appropriate for their circumstances. In general, it may be difficult to promote security, as the definition of “security” and the publics depend on the context. Both the content and delivery must be tailored to the local context. There are insufficient locally appropriate scenarios for low- and middle-income countries. Context-specific content must address local risks and challenges in addition to scenarios of global biosafety, biosecurity and dual use.
- **Champions:** Industrial and academic leaders, among others, should be urged to promote and promulgate materials for promoting biorisk management. Informal and formal networks are important in creating, identifying and fostering individual or groups of champions. Cooperation through sustainable, resourced networks is important to capitalize on the growing attention to responsible conduct of research and open science education.
- **Resources:** While several educational initiatives have been launched, many have been difficult to sustain, often because of lack of funding. Both financial and technical support will be required for activities in these areas and to sustain cooperative networks and the curation of educational

materials. This will be particularly important for low- and middle-income countries with limited resources for effective biorisk management.

- **Enabling measures:** There is uneven awareness of biorisks and limited training. Awareness-raising, education, training and capacity-building are important to address these gaps. Tools and mechanisms should be developed to respond to concerns, such as by providing channels for whistle-blowers, in tandem with awareness-raising and other measures. This is particularly true in reporting or responding to the suspicions of trainees, students, scientists and other relevant stakeholders.
- **Sustainability:** Measures to sustain awareness-raising, education, training and capacity-building should be built into initiatives from the beginning. This will require careful consideration of possible incentives for engagement, including relevant career metrics – a step that could ensure longevity and bottom-up engagement.

Clear lessons can be drawn from experiences of biorisk awareness-raising, education, training and capacity-building; however, the scale of the task to improve practice should not be underestimated. Worldwide, practising life scientists number in the millions, and this number will inevitably increase with the current biotechnology revolution. The evidence suggests that only a small percentage of life scientists are both aware of and can manage biosafety and biosecurity issues. Improving biorisk management will require resources, and collaborative ambition among stakeholders would help to meet the challenge.

5. Recommendations

- **Recommendation 1:** The World Health Organization should **endorse and actively promote the values and principles** presented in this document. These values and principles can usefully inform governance frameworks, biorisk management standards, institutional policies and practices, funding requirements, editorial standards, curriculum development, awareness-raising, and individual and groups behaviours.
- **Recommendation 2:** The World Health Organization (where appropriate, in collaboration with other United Nations agencies and diverse stakeholders) should **raise awareness about the importance of biorisk management**.

The World Health Organization should clearly communicate to all Member States and stakeholders the reasons for placing high priority on biorisk management and identify improvements in governance individual, institutional, national, regional and international levels.

The World Health Organization should develop and implement biorisk management awareness-raising campaigns tailored to a variety of audiences in several languages. Awareness-raising should be conducted for students, trainees and scientists in basic and applied life sciences and related fields; public, private and academic research laboratories, including diagnostic laboratories in public health and hospital settings; private and public funders of research; editors and publishers of research; and publics.

- **Recommendation 3:** The World Health Organization (where appropriate, in collaboration with other United Nations agencies and diverse stakeholders) should **support progress in development of governance tools and mechanisms** for basic and applied life sciences.

The World Health Organization should establish and keep an up-to-date central repository of biorisk management governance tools and mechanisms that have been used in the past, either successfully or unsuccessfully, so that Member States, institutions and individuals may learn and adapt strategies to their needs. The World Health Organization should (i) highlight how Member States and other stakeholders can most effectively start a biorisk management programme, (ii) compile and share resources and (iii) provide examples of governance activities at different levels that could be undertaken to introduce biorisk management programmes.

The World Health Organization should provide a hub to facilitate bilateral or multilateral collaboration among basic and applied life science stakeholders as a means of raising awareness and reinforcing education on biorisk management. For instance, the World Health Organization could (i) develop a programme of institutional twinning to facilitate sharing of best practices and experiences and of joint curricula or e.g., research programmes and researcher exchanges, and (ii) encourage bottom-up actions by recognizing or rewarding the best examples of successful twinning. This could be particularly helpful to low- and middle-income countries with limited resources for effective biorisk management.

The World Health Organization should create WHO collaborating centres for biorisk management in each WHO region to increase the importance of this issue and enable better communication among regions and stakeholders. Again, this could be particularly helpful to low- and middle-income countries with limited resources for effective biorisk management.

The World Health Organization should also play a leadership and coordinating role among other international and United Nations entities that have jurisdiction over any aspect of biorisk management, including the United Nations Office of Disarmament Affairs, the Food and Agriculture Organization of the United Nations and the World Organization for Animal Health, to create a holistic international strategy across sectors.

The World Health Organization should convene a diverse set of stakeholders to consider whether and to what extent certain types of potentially dangerous basic and applied life sciences should be tracked, monitored, restricted or otherwise overseen at national or international level.

- **Recommendation 4:** Member States should **establish tools and mechanisms for governance of basic and applied life sciences** by introducing and enforcing comprehensive biorisk management policies, including laws, regulations, standards, guidelines, best practices, codes of ethics, research review processes, education and training. The range of governance tools and mechanisms should cover biosafety, biosecurity and dual-use research and should be complementary and mutually reinforcing.

Over time, all Member States should implement more formal, institutionalized approaches to governance (e.g., a regulatory system in which research institutions are registered as suitable for certain types of research activities such as genetic modification and are required to conduct risk assessments related to such research).

Member States should set out the legal roles and responsibilities of institutions for risk assessment, education, training and internal oversight of biorisk management practices. Particular attention should be given to the governance of research that could present the most consequential societal risk(s).

- **Recommendation 5:** Academic institutions should **educate students and trainees in science, technology, engineering and mathematics about biorisk management**. They should incorporate biorisk management ideals and skills into scientific curricula from secondary school biology classes through to doctoral research in basic and applied life sciences, including in biology, biochemistry, bioengineering and other related fields. In addition, all members of the scientific community should receive continuing education.
- **Recommendation 6:** Research institutions, funders and other stakeholders should **promote a culture of biosafety and biosecurity in research environments** at every stage of basic and applied life sciences.

Research institutions, funders and other stakeholders should require and incentivize (i) regular education and training on biorisk management, including training in standardized risk assessment and risk mitigation, and (ii) life scientists to obtain professional certification in biorisk management. Knowledge, expertise and programmes offered by professional associations and science academies should be leveraged.

Research institutions, funders and other stakeholders should establish, train and empower institutional and external committees with diverse and interdisciplinary membership to review

research proposals, assess possible harm and decide on appropriate precautionary measures. If the risks of research are deemed too high (i.e., are not proportionate to the importance of the research question or the potential benefits), the research should not be allowed to proceed.

Research institutions, funders and other stakeholders should better align biorisk management ideals and practices with career expectations, career incentives and professional reputations. They should also encourage and fund applied biosafety and research projects, including development of new science and technology solutions, social and behavioural solutions and innovative policy approaches to reduce biorisks.

- **Recommendation 7:** Publishers should **promote and practise a culture of biorisk management in scientific publishing**. At a minimum, they should have (i) editorial guidelines for identifying, reviewing and publishing manuscripts that raise concern about potential biosafety, biosecurity or dual-use concerns, and (ii) advisory committees with diverse, interdisciplinary membership to review manuscripts that raise concern. If, following a review, publication of certain information is deemed to pose significant risks for biosafety, biosecurity or dual use, the reviewed manuscript should be modified (and the fact acknowledged in the publication) or not published. If a decision is made not to publish because of biosafety, biosecurity or dual-use concerns, other publishers should be so notified.
- **Recommendation 8:** Scientists should **educate themselves about biorisk management and their responsibilities** and foster broader awareness-raising of the importance of biorisk management. The aim is proactive identification of potential safety, security and dual-use risks associated with basic and applied life sciences and appropriate mitigating and precautionary measures.

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