World Health Organization

SEVENTY-FOURTH WORLD HEALTH ASSEMBLY **A74/18**
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Enhancement of laboratory biosafety

1. In 2005, the Health Assembly adopted resolution WHA58.29 on the enhancement of laboratory biosafety. Following a series of laboratory-acquired infections of severe acute respiratory syndrome (SARS), WHO Member States recognized that the containment of microbiological agents and toxins in laboratories was a major global public health issue, and critical to preventing outbreaks of epidemic-prone diseases. They noted with concern that some facilities had inadequate biosafety controls in place. In resolution WHA58.29, the Health Assembly urged Member States to: review safety practices, implement specific programmes, promote appropriate biosafety practices, develop national preparedness plans in line with WHO's biosafety guidance, mobilize sufficient national and international resources, cooperate with other Member States in facilitating access to biosafety equipment, and encourage the development of biosafety training. The resolution also requested the Director-General to ensure that WHO played an active role in improving laboratory biosafety and in providing support to Member States, including by updating the relevant guidance documents as well as through knowledge generation and best practice sharing.

2. Since the adoption of resolution WHA58.29, the Organization has made consistent efforts in the area of biosafety in cooperation with Member States. Some of these efforts were portrayed in the progress report in 2017;[1] they included but were not limited to: the publication of strategic and technical documents; the development and implementation of instruments and tools; and capacity-building relating to laboratory biosafety.

Status and challenges

3. The scope of biosafety is broad, ranging from point-of-care testing through simple diagnostic laboratories to work in complex research establishments, involving the isolation and propagation of high-consequence pathogens, transportation, storage and disposal, where every step or stage poses diverse risk profiles. The progress and the present landscape of biosafety and laboratory biosecurity are widely deemed uneven across the world at different levels. However, the depth and breadth of the subject make it inherently difficult to generalize with regard to the status and draw a universal picture.

4. Nevertheless, the Joint External Evaluation mission reports under the International Health Regulations (2005),[2] do help outline voluntarily assessed countries' capacities, gaps, opportunities and challenges in the 19 technical areas, which include "biosafety and biosecurity" among the listed subjects. Thus, the Joint External Evaluations have commonly revealed important gaps in biosafety and

[1] Document A70/38.

[2] More information concerning Joint External Evaluation mission reports is available at: https://www.who.int/ihr/procedures/mission-reports/en/ (accessed 29 March 2021).

biosecurity in the African[1] and Eastern Mediterranean[2] regions, where a majority of countries have relatively limited capacities in that technical area and accordingly obtain low scores in the evaluations. Globally, there was a correlation between national income and scores of biosafety and biosecurity indicators, where high-income countries tended to enjoy reasonably good scores while the contrary was the case for low-income countries.

5. Recommendations made by the external evaluators varied from one country to another. However, common elements appeared in the following areas: the development and updating of a biosafety and biosecurity regulatory framework and guidelines; national coordination and oversight mechanisms; proper collection, transportation, handling, management and disposal of pathogens; mapping of capacities and capabilities in handling high-consequence pathogens; provision of adequate funding and training; and clarification on the roles, responsibilities and mandates of all parties concerned.

6. The ongoing pandemic of coronavirus disease (COVID-19) has had an unprecedented impact on all aspects of society and on the lives of people around the world. It has also posed a particular biosafety challenge, with the need to establish an unparalleled level of surge testing capacity as rapidly as possible, despite serious shortages in, or total lack of, devices or even basic consumables that are considered indispensable for the protection of workers and the local environment.

7. Moreover, the pandemic has concentrated the attention of the media on the safe and secure handling and containment of high-consequence microbiological agents, which can have global ramifications in case of inadvertent exposure or release to the environment. The recent development and application of new technologies in life sciences have brought another layer of complexity to biosafety, adding to concerns about low-probability, high-consequence events inherent to high containment facilities. This arises from the possibility of misuse for purposes contrary to public health: for example, reverse genetics and synthetic biology that could be used for de novo creation of eradicated or extinct pathogens. A further recent development is the rise of a biotechnological social movement in which genetic engineering and other technologies are becoming increasingly available, even in unconventional private establishments.

Activities and achievements

8. Bearing in mind all these present and emerging challenges, the Secretariat has ramped up its efforts, in tandem with Member States and partners including international and regional organizations, WHO collaborating centres, public health institutions, competent authorities, global financing instruments and biosafety associations, to help attain and ensure safe and secure laboratory operations, containment of biological hazards, and prevention of natural, accidental or deliberate release. These concerted endeavours on the part of all parties have resulted in the following progress in enhanced biosafety.

[1] World Health Organization, various authors. Joint external evaluation of the International Health Regulation (2005) capacities: current status and lessons learnt in the WHO African region. BMJ Global Health. 2019; vol. 4–6 (https://gh.bmj.com/content/4/6/e001312, accessed 29 March 2021).

[2] World Health Organization, various authors. Analysis of Joint External Evaluations in the WHO Eastern Mediterranean Region. EMHJ. 2018; vol. 24 No. 5. (https://applications.emro.who.int/emhj/v24/05/EMHJ_2018_24_05_477_487.pdf, accessed 29 March 2021).

9. WHO's *Laboratory biosafety manual, fourth edition*,[1] widely considered the de facto global standard defining and setting trends in biosafety, was published at the end of 2020, following a broad and transparent consultation process with diverse stakeholders. With its novel evidence- and risk-based approach, the manual promotes attainable and sustainable biosafety in all countries that lays emphasis on resource optimization and enabling equitable access to laboratory services and biomedical research, without jeopardizing safety.

10. In order to implement the principal revisions, tools and training to facilitate proper local risk assessment are being urgently developed, while active collaboration has been launched with the World Organisation for Animal Health (OIE) and other partner agencies in identifying gaps in evidence base and research priorities to improve the application of evidence-based biosafety, particularly in low-resource settings.

11. Another key guidance document on the regulatory requirements of biosafety and biosecurity was published by WHO in 2020[2] in order to respond to the commonly observed weakness in, or indeed absence of a regulatory framework, as discussed above. The guidance document supports the development of biosafety and biosecurity regulations in countries with limited capacity in this area, proposing an easy-to-follow, stepwise approach that sets out the best practices currently in place in exemplary countries as policy options. In addition to this publication WHO, in various capacities, has responded to individual requests to provide tailored support and consultation to enable national and regional unions to strengthen and update their regulatory frameworks.

12. In January 2020, immediately after the outbreak of the novel coronavirus disease (COVID-19) caught global attention, the WHO Laboratory biosafety guidance for SARS-CoV-2 was developed and published. To date, there have been three subsequent updates to incorporate the latest developments.[3] The document provides important biosafety guidance and recommended practices for the global audience in all six official United Nations languages. In addition, interagency collaboration was actively engaged with the United Nations and other organizations, including the International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies, with regard to the safe transportation both of human remains and of novel types of COVID-19 vaccines. WHO's joint work with the International Civil Aviation Organization (ICAO) garnered the unanimous support of the international transport regulatory community for the urgent issuance of an ICAO addendum to the existing Technical instructions for the safe transport of dangerous goods by air. The addendum clearly exempts viral vector-based COVID-19 vaccines from regulations governing genetically modified microorganisms, in order to facilitate the uneventful and smoothest possible urgent deployment of all types of vaccines.[4]

13. To promote appropriate biosafety at all levels of laboratories, two regional hands-on biosafety workshops were held for anglophone and francophone countries in Africa in 2018 in a "training of

[1] Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240011311, accessed 29 March 2021).

[2] WHO guidance on implementing regulatory requirements for biosafety and biosecurity in biomedical laboratories – a stepwise approach. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/bitstream/handle/10665/332244/9789241516266-eng.pdf, accessed 30 March 2021).

[3] WHO Laboratory guidance related to Coronavirus disease (COVID-19) interim guidance. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/WHO-WPE-GIH-2021.1, accessed 30 March 2021).

[4] Addendum No. 1, 31 December 2020 to the Technical instructions for the safe transport of dangerous goods by air. International Civil Aviation Organization; 2020 (https://www.icao.int/safety/DangerousGoods/Pages/default.aspx, accessed 30 March 2021).

trainers" format. Follow-up support was actively provided for the organization of training courses in local settings. The workshops enabled 1000 laboratory personnel across the continent to receive primary training. The newly trained trainers requested replication of the hands-on course, and in response WHO formulated and produced a series of audio-visual aids, now known as the WHO biosafety video series, which are available on WHO YouTube for the global audience.[1] The videos, which cover all critical elements of good microbiological practices and procedures as well as primary containment devices, have already amassed over 70 000 views in total.

14. Maximum containment (also known as biosafety level 4) laboratories represent the highest level of biological containment, offering unparalleled safety and security for the user, sample and environment. Irrespective of geographical location, all high-containment laboratories share numerous issues regarding training opportunities, maintenance and the building of confidence in the broader community. A first global meeting on the subject of biosafety level 4 laboratories was organized by WHO in December 2017, with a view to creating a global forum to identify best practices, standards and opportunities for collaboration.[2] The meeting brought together experts from more than 20 countries and 53 institutions: effectively representing all such high-profile facilities in operation or under planning.

15. In accordance with resolution WHA60.1 (2007),[3] WHO's team of international experts conducts biennial inspections of authorized variola virus repositories and maximum containment facilities. The aim of the inspections is to safeguard the global community from high-consequence occurrences, and ensure that the storage conditions of variola virus and the research conducted in the laboratories meet the highest requirements for biosafety and biosecurity. The mission reports are published for public information after scientific and security redaction.[4]

16. The WHO Global Action Plan for Poliovirus Containment[5] provides a globally harmonized approach guiding countries in their efforts to implement Global Action Plan III and certify facilities retaining eradicated polioviruses. In line with resolution WHA71.16 (2018),[6] WHO's new GAPIII Auditor qualification and auditor support plan 2021–2023[7] proposes additional technical support to Member States engaging in poliovirus containment certification activities.

17. Ensuring safe, compliant and timely shipment of dangerous goods, typically infectious substances, is another cross-linked area that presents challenges in many parts of the world. In March 2018, WHO held a global consultative meeting on the safe shipment of infectious substances to

[1] The WHO biosafety videos can be viewed at: https://www.who.int/ihr/publications/biosafety-video-series/en/ (accessed 30 March 2021).

[2] WHO consultative meeting high/maximum containment (biosafety level 4) laboratories networking, 13–15 December 2017, https://apps.who.int/iris/handle/10665/311625 (accessed 30 March 2021).

[3] See document WHA60/2007/REC/1.

[4] The WHO biosafety inspection reports related to variola virus repositories are available at: https://www.who.int/health-topics/smallpox/smallpox-publications/biosafety-inspection-reports (accessed 30 March 2021).

[5] Containment certification scheme to support the WHO global action plan for poliovirus containment. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/279988, accessed 30 March 2021).

[6] See document WHA71/2018/REC/1.

[7] GAPIII auditor qualification and audit support plan 2021–2023. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/279988, accessed 30 March 2021).

address such universal issues with the participation of a broad group of stakeholders.[1] Some of the key recommendations of this meeting have already been piloted and implemented, such as the biennial publication of a guidance document[2] and a distance learning course,[3] while others are being developed, including guidance for each country to develop a contingency plan for urgent shipment of samples for outbreak response and other purposes. In addition, WHO's training efforts in various parts of the world have continued, and training has now been provided to 2000 WHO certified shippers.

18. Since the last progress report in 2017, WHO has continued to expand its network with partners and to collaborate with relevant public health institutions and similar entities. Progress achieved includes the designation or re-designation of four WHO collaborating centres for biosafety and biosecurity: the Institute of Epidemiological Diagnosis and Reference (InDRE), Mexico; Public Health England (PHE); the United States Centers for Disease Control and Prevention (CDC); and the Public Health Agency of Canada (PHAC). All these achievements and deliverables, it should be noted, could not be accomplished without generous and commendable support from dedicated individuals and numerous institutions, as well as from the WHO collaborating centres.

Update on activities in the regions

19. There have been efforts and achievements of note in all WHO regions. Training and support have been provided by WHO and other actors in various parts of the world, including specific guidance in support of containment facilities as well as diagnosis and containment of high-threat pathogens in Latin America.

20. The strategic framework for strengthening health laboratory services (2016–2020), formulated by the Eastern Mediterranean Region,[4] places biosafety and biosecurity among the Organization's strategic goals. Under the framework, various forms of action have been taken, such as promoting the inclusion of biological risk management in national policies; efforts to improve infrastructure and maintain key primary containment equipment; the provision of training courses on the safe transport of infectious substances; and developing the competencies of biosafety officers.

21. In addition to these regional approaches, efforts are being or have been made in some Member States of the Western Pacific Region to develop national biosafety and biosecurity guidelines and to conduct detailed capacity assessment and auditing to assist in planning for improvement. New biosafety regulations have been developed and enacted in a number of countries in the Region, while some countries have continued strengthening their systems and processes for active monitoring and maintenance of up-to-date records and pathogen inventories.

[1] The report of the Global Consultative Meeting on the Safe Shipment of Infections Substances is available at: https://www.who.int/ihr/publications/WHO-WHE-CPI-2018.46/en/ (accessed 30 March 2021).

[2] Guidance on regulations for the transport of infectious substances 2019–2020. Geneva: World Health Organization; 2019 (https://www.who.int/ihr/publications/WHO-WHE-CPI-2019.20/en/, accessed 30 March 2021).

[3] Infections Substances Shipping Training (e-IST) Global, available at: https://extranet.who.int/hslp/training/enrol/index.php?id=346 (accessed 30 March 2021).

[4] Strategic framework for strengthening health laboratory services 2016–2020. World Health Organization Regional Office for the Eastern Mediterranean; 2016 (https://apps.who.int/iris/handle/10665/254902, accessed 30 March 2021).

The way forward

22. The COVID-19 pandemic has posed numerous unforeseen challenges, but also provided practical proof of the operability and usefulness of the evidence- and risk-based approach upheld in the fourth edition of the Laboratory biosafety manual, given that assessed risks vary substantially from rapid diagnostic tests to polymerase chain reaction probes and tests, and on to virus isolation and genetic manipulation. The Laboratory biosafety manual is adaptable and scalable in establishing appropriate requirements and recommendations and at the same time enables resource optimisation. It is nevertheless still necessary to strengthen the risk assessment capacities of each entity and to develop an applied biosafety research programme to inform evidence-based biosafety practices. Collaborative development of national biosafety and biosecurity policies and regulatory frameworks remains a key priority.

23. Each Member State may face similar challenges domestically, and WHO could serve to provide guidance and advice on those issues. WHO holds a unique position that could be leveraged to influence and prioritize biosafety work in Member States. The Organization also provides a forum, widely accessible to all biosafety professionals around the world, for the publication and promotion of information. To operationalize such initiatives, WHO is planning to extend its network of WHO collaborating centres, national regulatory authorities and other contributors as well as enhancing the function and building the membership of its long-standing consultative platform, the Biosafety Advisory Group.

24. The landscape of biosafety and biosecurity has been in a state of constant change since the adoption of resolution WHA58.29 in 2005. That change has been characterised by advances in, and widespread use of technologies, as well as by the emergence of epidemic-prone diseases. Constant efforts by Member States and the WHO Secretariat have overcome some shared problems and the fourth edition of the Laboratory biosafety manual has paved the way for greater sustainability and fairness through the development and promotion of a risk-based approach. However, in many countries there still are gaps in regulations and shortfalls in the technical and financial resources required to maintain adequate biosafety infrastructure. Global coordination is needed to ensure the safe and secure operation of a growing number of high and maximum containment facilities, and that is another area where WHO could play a leading role.

25. The enhancement of biosafety therefore deserves greater recognition and investment from each Member State. Collaboration, both bilateral and multilateral, is also called for, with a view to attaining the shared goal of the safe and secure operation of biomedical laboratories, where WHO would continue its pivotal role in advocacy, coordination and guidance.

ACTION BY THE HEALTH ASSEMBLY

26. The Executive Board at its 148th session in 2021 adopted decision EB148(9), in which it recommended that the Seventy-fourth World Health Assembly decide to sunset reporting in respect of a number of resolutions. As resolution WHA58.29 on enhancement of laboratory biosafety is included among the resolutions concerned, the Health Assembly is invited to note the present report and to provide any additional guidance on reporting considered pertinent in respect of the enhancement of laboratory biosafety.

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