Second WHO consultative meeting on a global guidance framework to harness the responsible use of life sciences

Meeting report

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Executive summary

On 7 September 2021, 47 participants attended the second World Health Organization (WHO) consultative meeting on the development of the global guidance framework to harness the responsible use of life sciences. Participants were drawn from all six WHO regions and brought a wide range of expertise, representing academia, scientists and researchers, publishers and editors, public health officers, policy-makers, research donors, and representatives from regional and United Nations entities.

The objectives of the meeting were to discuss the findings and recommendations of the three working groups, which were established as a follow-up activity of the first consultative meeting held on 11 March 2011. In addition, participants were invited to discuss the next steps in the development of the global guidance framework to harness the responsible use of life sciences (the Framework). Finally, this meeting was intended to pursue the consultation and engagement processes on this area of work.

Participants welcomed and supported the findings and recommendations of the three working groups. The set of guiding values and principles underpinning the Framework was adopted and common understanding was reached on tools and mechanisms for governance and awareness raising, education, capacity building and engagement activities. It was agreed to link and cross reference the three documents developed by the working groups, noting the need for consistent language and terminologies across the three documents. The comprehensiveness of these documents was highlighted along with the need to have a practical and actionable Framework, which would refer to the current working groups' themes.

Future activities include the development a glossary of key terminologies and the work on a series of case studies and scenarios to test the utility of the Framework and to demonstrate how the different elements of the Framework could be used in real and hypothetical situations. Two working groups will be established to carry out these activities. WHO will continue to consult with relevant individuals, groups, Member States and the regions on the development, dissemination and implementation of the Framework in the coming months.

1. Background

Advances in the life sciences and the advent of new technologies hold great promise for new and improved ways to address global health and support healthier populations worldwide. Science and technology have an undisputed role in working towards WHO's Thirteenth General Programme of Work 2019–2023 to achieve the triple billion targets. Yet progress in the life sciences and associated technologies are not without risk. The risks under consideration in this report are those posed by accidents and the deliberate misuse of life sciences research, knowledge and technologies to cause harm.

The landscape of innovation in the life sciences is a global endeavour that is moving at a fast pace. The diffusion of knowledge, technologies and data, the diversity of actors involved in the life sciences and the convergence of the life sciences with other disciplines such as chemistry, engineering, artificial intelligence, machine and deep learning, computer science, and the physical sciences constitute major trends and developments that could benefit society and global health but could also pose new risks or increase existing risks.

The applications of research, knowledge and technologies may generate risks caused by accidents, by inadvertent applications and by deliberate misapplications with the intention to cause harm. These risks need to be identified, mitigated and managed. Related to this is a need for a greater awareness among scientists, students, policy-makers, the security communities and private sector on the potential risks of accidents and misuse associated with the life sciences, and a need for continued training and education for the responsible use of the life sciences.

In 2020, the WHO Science Division organized three dialogues on dual use research of concern with the scientific communities, science editors and publishers and research donors to better understand the perspectives of different stakeholders and to identify areas of collaboration. On 11 March 2021, the first consultative WHO meeting on the development of a global guidance framework to harness the responsible use of life sciences (the Framework) was convened to address the risks of accidents and deliberate misuse within the context of promoting the global health benefits of the life sciences (*1*). This meeting focused on the scope and the critical elements of the Framework. Participants recommended the development, at international level, of a common terminology covering safe, secure and responsible research. Two major themes emerged during the discussions: the need for an overall unified risk management approach; and the importance of awareness, education and training across the different stakeholder groups. As a follow-up activity, the following working groups were established to address the specific topics raised during the first consultative meeting:

1. a working group on values and principles;
2. a working group on tools and mechanisms; and
3. a working group on awareness-raising, education, capacity-building and engagement activities.

2. Objectives of the meeting

The second WHO consultative meeting on the development of a global guidance framework to harness the responsible use of life sciences (the Framework) was convened to present and discuss the findings and recommendations of the working groups and to identify the next steps in the development of the Framework. On 7 September 2021, 47 participants attended this virtual second WHO consultative meeting, drawn from all six WHO regions and bringing a wide range of expertise, representing academia, scientists and researchers, publishers and editors, security actors, public health officers, policy-makers, research donors, and representatives from regional and United Nations entities (see Annex).

The objectives of the meeting were:

1. to discuss the findings and recommendations of the three working groups
2. to discuss the next steps in the development of the Framework
3. to continue the consultation and engagement processes.

3. Key points of the meeting

Opening the meeting, Anna Laura Ross, Head of the Emerging Technologies, Research Prioritisation and Support unit, informed the participants that the three working groups had met on a total of 25 occasions since the first consultative meeting. Three papers had been produced, which were discussed during the current meeting.

The participants were briefed on the background and progress of the project. The Framework would update the WHO guidance document on responsible life sciences research for global health security (2010) and its integrated biorisk management approach (*2*). Similar to the approach taken by the governance framework and recommendations on human genome editing (*3, 4*), the Framework would identify a set of principles and values that would guide policies; review a range of tools and mechanisms for governance, adapted to different national settings; and discuss the role of case studies and scenarios to illustrate how the Framework could work in specific situations and what practical challenges might arise during implementation.

The Framework would also build upon existing mechanisms and activities and would be informed by the discussions and reports of the working groups. Finally, as agreed during the first consultative meeting, the target audience of the Framework would include scientists and research institutions, policy-makers, publishers, funding bodies, security actors, and private-sector and other relevant stakeholders. Its scope was intended to cover life sciences and converging sciences and technologies; it would address risks stemming from accidental, inadvertent and intentional actions and would acknowledge their impact on humans, biodiversity and the environment.

The meeting was then divided into two sessions: a first session focused on reporting the findings and recommendations of the three working groups, and a second session on the next steps in the development of the framework. Each session was moderated, opened by presentations and followed by plenary discussions.

3.1 Reports from the working groups

These findings and recommendations were reported in three draft papers, which were shared with all participants before the meeting.

3.1.1 Report from the working group on values and principles

The working group on values and principles was aimed at establishing a list of principles that would guide the policies and actions of the multiple stakeholders and sectors in this area. Filippa Lentzos, the facilitator, outlined the set of values and principles identified by the working group and explained how the commitments implied had been decided upon. These principles would underpin the guidance framework and were viewed as "touchstones" for considered moral judgements about the safe, secure and responsible use of life sciences. They would serve as reminders to decision-makers of the beliefs that were important to individuals and organizations and that should guide decision-making.

The following values and principles were identified:

- health, safety and security
- responsible stewardship of science
- integrity
- fairness
- openness, transparency, honesty and accountability
- inclusiveness and collaboration
- social justice
- intergenerational justice
- public education, engagement and empowerment.

A range of commitments were associated with these values and principles. In addition, the working group underscored that the development of a glossary, case studies and scenarios would constitute helpful next steps.

3.1.2 Report from the working group on tools and mechanisms

Anita Cicero, the facilitator of the working group on tools and mechanisms, briefed the participants on the main findings and recommendations identified by the members of the working group. This working group was tasked with identifying existing tools and mechanisms for governance, identifying the most important challenges, gaps and priorities, and developing a set of recommendations for next steps.

The challenges concern the risks, which exist beyond pathogens and cover information technologies, the field of neuroscience and synthetic biology. But risks also extend beyond the life sciences to convergent fields of artificial intelligence, chemistry and nanotechnology. Similarly, risks extend beyond the traditional laboratory environment, as research and technology developments also occur in small start-up companies, non-profits, DIY spaces and other non-traditional laboratory spaces. These developments highlight the need to update and standardize unclear and outdated terminology.

The working group on tools and mechanisms identified three major gaps. One fundamental gap was the predominant lack of awareness among more than 3 million scientists working worldwide. This was largely due to a lack of emphasis on risks and misuse in education, curriculum development, training, structural incentives, institutional support and forums for learning. A second gap concerned insufficient institutional,

national and international policies and governance mechanisms. Third, a lack of forums to facilitate the sharing of effective tools and mechanisms, such as central repositories of resources and ongoing improvements in governance approaches, was a further gap identified by the working group.

In terms of a vision for the future, the working group acknowledged that there was no one-size-fits-all approach. The governance of biorisks should be an ever-evolving and locally adapted set of tools and mechanisms for a variety of stakeholders and for a range of different security objectives. Members of the working group believed that picking just one appropriate tool or mechanism would be insufficient; the ultimate goal would be for Member States and the regions to include several types of activities. These could include institutional oversight; national legislation and oversight; international guidance and accepted norms in the area of curriculum development through education, awareness raising, self-governance and structural incentives for continued learning and career development.

In terms of stakeholders, the working group stressed that, although scientists are a key stakeholder, governance tools and mechanisms should extend to all different types of stakeholders. Biorisk management therefore involved multiple governance strategies that reinforced different goals and could be applied to different stakeholders. Governance was thus a multidimensional endeavour.

The development of curricula, education and awareness-raising; fostering a culture of individual and institutional investment in biosafety, biosecurity, and oversight of dual use research should be the top priority. This would require resources and funding. Another priority concerned the importance of ensuring top-down policies, legislation, regulation, and guidance to complement bottom-up approaches. Finally, the working group believed that WHO was well positioned to make a difference in this space, and that it should play a leadership role in this area.

The working group on tools and mechanisms made the following recommendations.

1. First, a call to action. WHO should communicate to all Member States and stakehoderls that they should place a high priority on biorisk management.
2. Secondly, ongoing education on the biorisk management framework guidance should be created, disseminated and provided. it called for the creation, dissemination, and provision of ongoing education on the biorisk management framework guidance.
3. Ongoing educational outreach activities and forums should be established to facilitate the sharing of effective tools and mechanisms.
4. WHO should play a leadership role across United Nations agencies and lead/coordinate initiatives to mitigate biosecurity, biosafety and dual use risks.

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