Dual use life science research (DUR/C): perspective from donors of life sciences research

MEETING REPORT

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ISBN 978-92-4-003195-1 (electronic version)
ISBN 978-92-4-003196-8 (print version)

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1. Background

Advances in science and technology hold great promises and hope for new and improved ways to address global health and support healthier populations worldwide. Science and technology have an undisputed role in working towards the Thirteenth General Programme of Work 2019-2023 (GPW 13) of the World Health Organization (WHO) to achieve the triple billion targets. Yet progress in life sciences and the advent of new and emerging technologies are not without risk; indeed, research in the broad area of life sciences inherently holds the risk of being misapplied either inadvertently or intentionally to cause harm and should as such be considered "dual use research" (DUR) and "dual use research of concern" (DUR/C).

Regular reviews are required to adequately assess the implications of science and technology advances. Over the last years many new developments have occurred, including the emergence of novel technologies and the presence of new actors and stakeholders. In view of this, the recently created Science Division in WHO is organizing an iterative consultative process to explore the current DUR/C landscape to establish baseline knowledge and a common point of understanding on the issues and concerns related to DUR/C within the global context.

WHO convened three DUR/C dialogues with the following stakeholders: with academies and councils, with science editors and publishers and with donors of life sciences research. The DUR/C virtual dialogue with donors of life sciences research was organized solely to understand their perspectives on DUR/C and was not a resource mobilization effort.

The purposes of the DUR/C dialogues were to present WHO Health Foresight function and DUR/C activities; to gather and exchange different stakeholder perspectives on approaches to DUR/C and to raise awareness on DUR/C issues among different stakeholder groups; to identify critical issues and lessons learned from past experiences on addressing issues and concerns in DUR/C; and to identify key priority areas for action and appropriate areas for collaboration with different stakeholder groups.

The expected outcomes of these dialogues are to get a better understanding of DUR/C from the perspectives of different stakeholders; to translate knowledge and expertise into concrete tools, resources and frameworks to support interested actors and WHO Member States to adopt changes in practices; and to increase collaboration and engagement with stakeholders on DUR/C.

2. Meeting key points

On 1 December 2020, seven donors of life sciences research virtually attended the third DUR/C Dialogue (Annex). The meeting was opened by Dr Anna Laura Ross, Unit Head of the Emerging Technologies, Research Prioritisation and Support of the Research for Health Department. Dr Ross started the meeting by reminding the audience that the meeting is in no way associated with a resource mobilization effort, but it was organized because life science research donors are a key actor in the research cycle. Dr Ross briefed the participants on the recent creation of the Science Division of WHO in 2019. The Science Division integrates pre-existing WHO activities falling under the areas of general science and research and expanded into new areas. The Science Division is composed of three departments, Research

for Health, Quality Assurance of Norms and Standards and Digital Health Innovation and is associated with the research programmes of WHO. In the Research for Health department, the Emerging technologies, Research Prioritisation and Support unit constitute one of the three pillars of the department.

Dr Ross underlined that fundamental S&T advances are transforming global health and hold important potential for the future. The Science Division intends to identify these advances in a proactive manner and to link them to appropriate frameworks, which harness their benefits for global health. There is a recognition that the landscape of stakeholders is changing and that the scientific community is more diverse than before. In addition, life sciences research development cannot be separated from global health security. These links between research and global health security are tight, especially in the context of the current global pandemic. In this diverse environment, there are also some convergences between biotechnologies (e.g. genome editing, drug discovery and delivery, DNA synthesis) and AI, cybertechnologies, big data and nanotechnology.

The purpose of the newly established WHO Foresight Function is to identify and connect known, new and emerging issues that could significantly impact global health within the next two decades. It identifies what are the most impactful, plausible and novel issues in global health and how these will affect health in the next few decades. The WHO Foresight Function also analyses how these issues interrelate and which scenario will emerge. The Foresight approach uses different tools, including backcasting, forecasting, foresight and horizon scanning. While the WHO Foresight Function has a global vision with an emphasis on low and middle-income countries (LMIC), the team is collaborating with existing initiatives and organizations conducting foresight and horizon scanning activities in order to avoid duplication.

With the restructuring, the broader areas of biosecurity have been located in different areas. The Science Division focuses on DUR/C and its foresight aspects. Additional activities include the mitigation strategies to reduce the risks associated with DUR/C and the ethical considerations raised by DUR/C. The Science Division works closely with the WHO Health Emergencies Programme (WHE), whose activities focus on the management of biorisks.

The expected outcomes of the DUR/C activities include having increased collaboration and engagement with a broad range of DUR/C stakeholders. In particular, there will be a focus on tools and resources and on supporting Member States and other interested actors to adopt changes in practices and policies to support responsible life sciences research and DUR/C oversight. Future work includes the development of a global WHO framework on DUR/C and responsible life sciences research, which will build upon previous WHO activities.
Dr Ross noted that for the purpose of this dialogue, DUR/C is considered as "*Dual Use Research of concern as life sciences research that is intended for benefit, which might easily be misapplied to do harm*". As there are different interpretations of DUR/C, a workstream of future activities will invite stakeholders to reflect upon the terminology of DUR/C and will explore whether a common understanding can be reached.

In the second session, the participants discussed the key activities undertaken by a number of donors of life sciences research and identified some challenges and lessons. The session was organized around key questions informing the meeting objectives, with a briefing by two

panelists on existing initiatives and lessons learned to date:

- Dr Carrie D. Wolinetz, Acting Chief of Staff and Associate Director for Science Policy, Office of the Director, National Institutes of Health (NIH), the United States of America (the USA); and
- Dr Katarina Timofeev, Programme officer at the German Research Foundation (DFG), Germany.

The panelists briefed the meeting about the relevant DUR/C activities and different approaches undertaken by their respective institutions. A number of points were made on the frameworks adopted by these countries. The scope of the 2012[1] and 2014[2] United States Government (USG) Policies for the oversight of DUR/C focus on fifteen infectious agents and seven experiments of concerns. It was noted that these policies intend to resolve the question of how to ensure that a DUR/C oversight system does not over or under compensate in a way that either allow security concerns to go forward or inhibit research progress. Another point was made about the definition of DUR/C, which has been the subject of debates for many years. USG policies attempted to have a clear scope with the intention to create a definition that was practically applicable in terms of implementation and compliance. A further lesson stemming from the implementation of the USG policies is that many institutions have taken advantage of the flexibility of these policies to extend oversight and training beyond the list of agents and experiments. Participants heard that having tangible policies and a concrete framework in place have been extremely useful tools for raising awareness.

Moreover, even though these policies have a limited scope, they developed something described as *"enforced thoughtfulness",* which allows for a reflection upon the research being undertaken and for the uptakes of thoughtful risk-based approaches on research. These policies further helped to foster a culture of responsibility, one of the reasons underpinning the work of the National Science Advisory Board for Biosecurity (NSABB) and the development of these policies. The USG has also asked the NSABB to examine the implementation of these policies for the oversight of DUR/C along with the Potential Pandemic Pathogen Care and Oversight (P3CO) policy[3] in order to evaluate their functioning and whether modifications are needed in light of new and emerging technologies, for example, genome editing and synthetic biology.

In 2014, the German Research Foundation together with the German National Academy of Sciences Leopoldina issued *Scientific Freedom and Scientific Responsibility*. *Recommendations for handling security-relevant research.*[4] These recommendations are aimed at individual scientists but also research institutions. They are not legal regulations nor oversight measures. The DFG believes that scientific research needs freedom, and that

[1] The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (2012) (https://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf, accessed 27 May 2021).
[2] The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (2014) (http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf, accessed 27 May 2021).
[3] White House Office of Science and Technology Policy. Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO) (9 January 2017) (https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf, accessed 27 May 2021).
[4] The German Research Foundation (DFG), German National Academy of Sciences Leopoldina. Scientific Freedom and Scientific Responsibility Recommendations for Handling Security-Relevant Research (June 2014) (https://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2014/dfg-leopoldina_forschungsrisiken_de_en.pdf, accessed 27 May 2021).

freedom entails responsibilities, which are deferred to the scientists. Because of the difficulty to define DUR/C, the DFG believes that scientists who are doing research and working with technologies are those that can foresee the potential misuse of the results of such research and technologies.

The DFG and Leopoldina established an advisory panel called the Joint Committee for the Handling of Security-Relevant Research to raise awareness amongst researchers of dual use issues in security-relevant research and to further develop and foster both a responsible approach to security-relevant research and self-governance within the research community.

Overall, participants heard that the level of awareness has been increased in the past years in academic and scientific communities. Likewise, opportunities for discussion on DUR/C issues have been created.

However, in terms of challenges and lessons learned, it was noted that scientists are still not always aware of the potential misuse of their research. To further address this issue, the DFG enquires scientists to deal with and make statements regarding ethical and legal aspects of the project when applying for funding. For cases of research that raise DUR/C concerns, scientists have to weigh the benefits against the harms of their research, and they need to take precautions for their research to not be misused. However, these evaluations do not constitute a criterion for funding requirement.

These briefings were followed by a general discussion. On the terminology of DUR/C, the scope of DUR/C issues and timing, participants heard the DUR/C definition as developed by the NSABB and which fed into the USG policies did not put metrics around harms but did put a time boundary in terms of the immediacy of a threat. Otherwise, many hypothetical risks or scenarios could have been covered by the policies and it would have become unmanageable from a practical oversight standpoint. The P3CO policy does however enter a bit more into the magnitude and provides review for events that could be seen as having pandemic potential.

On criteria and on identified characteristics for misuse, comments about the elements of risks, biosafety, the legitimacy and acceptability of research were made. Besides these characteristics, there is also the intentionality of research. At times, the intentionality and responsibility of research are not very clear at the outset of research, or intentionality may change over the course of research. Participants agreed that DUR/C issues can emerge at different points in the research cycle, from inception to publication.

Participants noted different areas where dual use arise including high consequences