Dual use life science research (DUR/C): dialogue with science editors and publishers

MEETING REPORT

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1. Background

Advances in science and technology hold great promise 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 in order to establish baseline knowledge and a common point of understanding on the issues and concerns related to DUR/C within the global context.

A series of DUR/C Dialogues will be organized in the coming months with the following objectives: 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 in DUR/C from the perspective of different stakeholder groups; to highlight 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 stakehodlers; to translate knowledge and expertise into concrete tools, resources and frameworks to support stakeholders 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 28 July 2020, a group of eleven science editors and publishers virtually attended the second 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 briefed the meeting on the recent creation, in 2019, of the Foresight function within the Science Division of WHO, the approaches taken towards the identification of emerging issues and its links to DUR/C activities. The aim of the WHO Foresight Function is to identify and connect known, new or emerging issues that could significantly impact global health within the next two decades. It relies on a set of guiding questions and on four main different approaches. And while WHO Foresight Function has a global scope, the team is collaborating with existing initiatives and organizations that have undertaken Foresight and Horizon scanning

activities. One of the expected outputs of this new function is that WHO will be more attuned to science and technology (S&T) advances and techniques and their global health potential.

Dr Ross pointed out that while fundamental S&T advances are transforming global health and hold important potential for the future, there is a clear recognition that these developments could have implications for global security through, for example, the potential convergences between biotechnologies (e.g. genome editing, drug discovery and delivery, DNA synthesis) and AI, cybertechnologies, big data and nanotechnology. These developments are occurring in a changing environment characterized with the emergence of new actors and stakeholders, which include, for instance, Do-It-Yourself (DIY) communities.

Dr Ross underlined that, ultimately, these dialogues will engage different stakeholders, with an emphasis on low and middle-income countries (LMIC). Within WHO, the Science Division works closely with the WHO Health Emergencies Programme (WHE). The Science Division addresses DUR/C from a combination of risk mitigation, ethical and foresight perspectives while WHE focuses on the risk management of DUR/C. The overall expected outcomes of these DUR/C activities are threefold: first, to increase collaboration and engagement of a broad range of stakeholders on DUR/C; second, to increase tools, resources and access to stakeholders to adopt changes in practices, procedures and/or policies to support responsible life science research and DUR/C oversight; and finally to improve evidenced-based decision-making in a continuously evolving life science research landscape. Finally, Dr Ross noted that while there is currently a dialogue around the definition of DUR/C, for the purpose of this dialogue, DUR/C is defined as "*Dual Use Research of concern as life sciences research that is intended for benefit, which might easily be misapplied to do harm*".

In its first session, the participants were presented with key activities undertaken by a number of science editors and publishers and the key challenges they faced. The session was organized around key questions informing the meeting objectives and all participants were encouraged to provide their inputs. The meeting participants were briefed on existing initiatives and lessons learned to date by:

- Dr Maria Hodges, Managing Editor, BMC Series at Springer Nature, and
- Dr Stella Hurtley, Deputy Editor for Science magazine.

In addition to relevant activities undertaken by their respective journals, panelists raised a number of points including that the BMC Series has developed a DUR/C policy in 2019, which was rolled out to all their journals in April 2020. This involved the training of a team of in-house editors that checks all relevant manuscripts for DUR/C when these are submitted to the journals. An expert panel might be convened if there is a need. Participants heard that correctly identifying manuscripts that raise DUR/C issues is a challenge and that, as science editors and publishers want to err on the side of caution, the important volume of manuscripts being screened, and the high number of false positives equally pose challenges.

The meeting was also briefed about the past experiences of handling manuscripts raising DUR/C issues and the lessons learned from that experience. Past experiences have shown that an in-depth and technical peer-review process was not enough to assess DUR/C but that experts with the knowledge of how to anticipate DUR/C issues need to be involved in these assessments. In

addition, developing trust and common understanding of risks are important but remain difficult. Among the lessons learned, it was shown that a) having in-house processes and resources to carry out assessments manuscripts with potential DUR/C is important and b) that recognizing manuscripts raising DUR/C issues requires experienced staff as well as experts primed with such knowledge. For journals that receive many manuscripts on a daily basis, these processes might however be challenging. However, for journals with less resources, WHO could provide a list of vetted experts to whom these can turn to for advices. Two additional key issues were underscored: first, authors of manuscripts who did not alert journals about the potential dual use implications of their research paper could imply that upstream risks and benefits assessments, which were carried out before the onset of research and its submission to a journal, have not be done or have failed. Second, the decision of holding back information from publication should involve, in addition to researchers and publishers, funding bodies.

The briefings were followed by a general discussion. Participants commented about their respective experiences with DUR/C and highlighted several points including the importance of having relevant processes into place which rely on subject experts and the recent development of extra measures for authors of manuscripts who need to alert journals through the use of a checklist that includes a section with DUR/C questions. Moreover, identifying DUR/C issues beyond those lists of high-risk pathogens might be difficult. The use of checklists varies among journals with some participants reporting their use while others relying mainly on the knowledge of in-house staff and external experts.

On the issue of upstream and downstream DUR/C evaluations processes and subsequent responsibilities, participants underlined that privately funded research should also undertake DUR/C assessments before submitting their manuscripts to journals; that although the assessment of submitted research papers for DUR/C by science editors and publishers is important, these assessments are done once the research has already been undertaken; and that institutions, Institutional Review Board (IRBs) and research administrators should take responsibilities for the research taking place under their premises and evaluate whether their research raise any DUR/C issues.

In addition, there is a need to strengthen training for Responsible Conduct Research (RCR) in IRBs and ethics review committees because there is a lack of knowledge on this topic. Participants however noted that medical and clinical journals have not been impacted so far by DUR/C issues; their main concern has been safety. Participants agreed that there is a larger set of responsibilities and a broad chain of responsibilities and accountabilities in which the journals play an important role but are the last resort. In addition, one of the challenges of DUR/C over the coming years will be that identifying research with DUR/C implications might become a broader exercise than is the case today, as it has so far mainly focused on particular research. Because such a wide scope might make it difficult to understand what should be specifically looked for, it was suggested to concentrate the attention, and associated assessments processes, on research that has the potential to cause the greatest harm to a large number of people.

In its second session, participants identified several priority actions. This session was organized

around two key questions informing the meeting objectives. Participants were briefed by:

- Dr Joerg Heber, Editorial Director, PLOS, and Editor-in-Chief of PLOS ONE
- Dr Eric J. Rubin, Editor-in-Chief, New England Journal of Medicine, and
- Dr Niki Scaplehorn, Editorial Director, Nature Life Science Journals of Nature Research.

Among the priority actions, the panelists highlighted the importance of identifying DUR/C beyond the usual classification of DUR/C. This requires formal documentation and assessment processes for recognizing certain kind of functions or areas which are problematic or to detect areas that have not necessarily been clearly identified. While the identification of DUR/C has been originally list-driven, the necessity to think more broadly was underlined because it is very difficult to anticipate and control DUR/C with a list criteria. Further priority actions included the need to have access to DUR/C experts who can provide advices to journals; to have general guidance on DUR/C publications, including on issues of who has access to data; to develop a set of international standards for DUR/C and the importance of ensuring that assessment processes are carried out before the onset of research projects and before the submission of manuscripts to journals.

The briefings were followed by a general discussion. In addition to sharing relevant DUR/C screening processes by journals and preprint publishers, participants reiterated that publication is often seen as the last resort for DUR/C assessment, as the final gatekeeper and they welcomed the development of international standards for DUR/C. About the scale of the problem, participants noted that there appears to be only a few cases of research with DUR/C implications per year. Most of the time, assessments have concluded that the benefits outweighed the risks. Participants raised additional issues with the DUR/C screening processes including that, because DUR/C issues are relatively rare and raise different types of concerns, there is also a lack of institutional memory on how to handle these issues. Moreover, concerns about missing out some relevant research papers during these assessments were mentioned. In this context, the role of the WHO Horizon Scanning activities was underscored as a way of raising awareness on emerging issues. It was also suggested that WHO could establish a process of deliberation for reviewing the occurrence of research that could create epidemics.

Finally, participants highlighted the need to collaborate with other stakeholders, including when the potential for research misuse needs to be evaluated, as scientists and publishers may not have all the necessary elements of knowledge for undertaking such assessments. In addition