

Widening the Framework for Regulation of Dual-Use Research in the Wake of the COVID-19 Pandemic

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Executive Summary

In the wake of the COVID-19 pandemic, the global scientific community has directed increased resources and attention towards the study of viruses and emergency medical countermeasure development. Our analysis of publicly available data on publications, preprints, and clinical trials coupled with the Global Health Security Index measure of dual-use oversight suggests that some research activities raise dual-use concerns that have gone unaddressed. While most of the research in this domain is essential to advance vaccines, therapeutics, and diagnostics against SARS-CoV-2, improving responses to natural pandemics must not come at the expense of increasing risks of accidental or intentional biological threats. We argue that certain categories of research that receive more attention following a pandemic pose unique dual-use risks that must be addressed by a comprehensive approach involving:

- 1) a broader definition of dual-use research of concern that captures experimental techniques that could feasibly be translated to harmful pathogens.
- 2) creation of regulatory frameworks to oversee the funding and publication of dual-use experiments, especially in countries with large biomedical research output and countries where the GHSI has highlighted shortcomings in national dual-use policies.

These policy changes must also be accompanied by stronger social norms among grant makers and scientists alike, in order to effectively address biosecurity concerns in advance of the next outbreak.

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Background

According to the 2019 Global Health Security (GHS) Index, 81% of countries had “inadequate policies for biosecurity”, and only 1% of countries appropriately reviewed dual-use aspects of life science research for “especially dangerous pathogens” (Global Health Security Agenda). These shortcomings are only amplified by the ongoing COVID-19 pandemic, which has resulted in a significant influx of investment and research for medical countermeasure development. Since the beginning of the pandemic, research relating to COVID-19 has accelerated rapidly – with the number of publications doubling every 20 days between January and May, on average – and as of July, there were almost 4500 registered COVID-related clinical trials (Coronavirus Research Publishing). Much of this research, however, is being conducted without much concern for dual-use potential.

Dual-Use Research of Concern (DURC) is defined by the US National Institutes of Health (NIH) as “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety [...]” (NIH Office of Intramural Research). Research within this category must adhere to project-specific risk-management plans. The current framework is limited to fifteen “biological select agents and toxins” pertaining to seven classes of experiments, and insufficiently captures the full extent of research with potential dual-use implications. Regulation of dual-use research is one of the criteria of the “prevent” score of the Global Health Security Index and is assessed on the basis of existing oversight policies and DNA screening requirements.

From a biosecurity perspective, there are several reasons to believe that academic output produced during or after a pandemic should be subject to particular scrutiny. First, increased attention towards characterization of a specific virus lends itself to initiatives such as identification of mutations that increase infectivity, or more accessible methods for *de novo* reconstruction of the virus (Starr et al.; Thi Nhu Thao et al.). Additionally, the advancement of certain technologies, such as platforms involving self-replicating viruses or vector-mediated delivery, pose a greater risk for misuse. Large-scale pandemics such as COVID-19 also highlight the weaknesses of our social, economic and political systems, thereby increasing awareness among malicious actors of the threat that biological agents pose (Deutsche Welle). Paradoxically, the need for rapid scientific collaboration during a pandemic has also led to increased engagement with preprint servers, making the proper review of such research with dual-use potential even more difficult.

At the moment, the most well-known application of DURC guidelines relates to the publication of gain-of-function (GoF) research. For instance, the US National Science Advisory Board for Biosecurity (NSABB), which is responsible for assessing the potential risks of life science research, played an active role in reviewing two manuscripts on the experimental adaptation of highly pathogenic avian influenza in ferrets to enable airborne mammal-to-mammal transmission. While the published manuscripts ultimately omitted certain experimental details, data, and conclusions, the H5 influenza case revealed how dual-use risk management aimed at the publication stage of research is inadequate and inefficient, since critical dual-use information can still be dispersed via informal preprints, presentations and collaborations, and significant resources have already gone towards the work by the time regulation applies.

In this paper, we argue that increased attention to virology research in response to the COVID-19 pandemic has raised distinct dual-use concerns that should inform how government agencies and funding organizations invest in technologies against future outbreaks. To evaluate these trends, we use publicly available data on publications, preprints, and clinical trials to analyze dual-use oversight by linking them to the Global Health Security Index. We recommend a comprehensive approach to managing dual-use risks that accounts for the dual-use implications of technologies that are not intended to produce, but could enable, the production of dangerous pathogens. Importantly, efforts must be made to implement such measures at the earliest stages of the research process (e.g. grantmaking and pre-clinical work), rather than simply prior to the dissemination of results.

Analysis and Discussion

Inadequate Dual-Use Policy in Countries with High Research Output

Since January, researchers across the world have engaged in unprecedented levels of viral infectious disease research with the aim of understanding and responding to the COVID-19 pandemic. Yet according to the 2019 Global Health Security Index, only six countries had a score higher than 0 with respect to dual-use research policy and a culture of responsible science. Consequently, a substantial fraction of SARS-CoV-2 research is conducted in settings where DURC-management is – according to the standards of the GHSI – far from adequate. For example, six of the leading producers of viral infectious disease and clinical research – boasting a combined 28,360 publications and 6,766 preprints on the topic of SARS-CoV-2 as of 24 August 2020 – all received a score of 0 on the 2019 GHS dual-use indicator (Table 1). Moreover, of the 24,197 publications that originated from the United States during this time period, only 2,313 of them received funding from the United States government, meaning that all remaining research activity was not necessarily subject to federal DURC policy. This represents a significant shortcoming in how we treat research with potentially harmful implications and requires urgent attention given the increasing access that state departments and unaffiliated actors have to the standard tools of biotechnology.

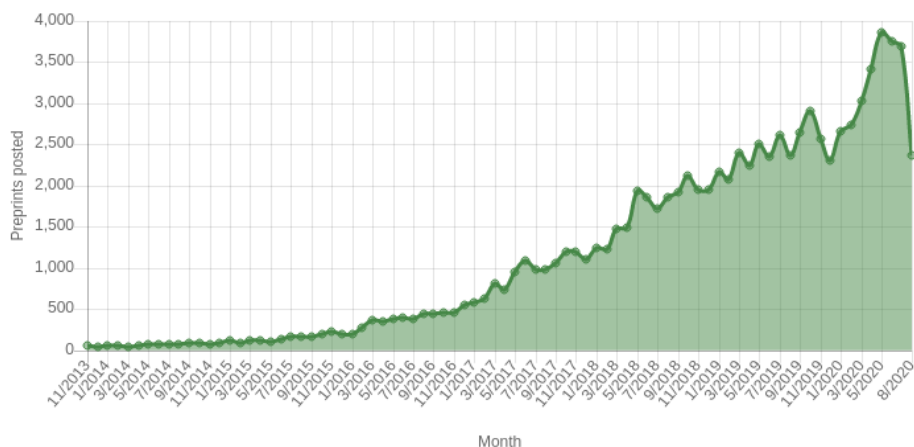
Table 1: Breakdown of COVID-19 journal articles and GHS Dual-Use Indicator score by country.

Country	Articles	Preprints	GHS Dual-Use Indicator
United States	19544	4395	50
China	9174	3201	0
United Kingdom	8633	1775	33.3
Italy	6122	824	0
India	3678	961	0
Germany	3405	756	0
Spain	3124	449	0
Canada	3077	578	33.3
France	2895	687	0
Australia	2706	558	33.3

Data as of 24 August, 2020.

Further exacerbating this lack of oversight is the dramatic growth in submissions to preprint servers such as medRxiv and bioRxiv. In fact, between January and July 2020 the amount of preprint submissions to bioRxiv was 2.35 greater than in all of 2019; additionally, 25% of submissions to medRxiv and bioRxiv were related to the COVID-19 pandemic, meaning that the increase is largely attributable to the current pandemic (Figure 1) (*BioRxiv Summary Metrics*). While this trend favors the rapid dissemination of information and reagents essential to scientific collaboration and medical countermeasure development, it also enables the disclosure of information that typically may have been subject to further examination for validity and reproducibility during the standard scientific review process.

Figure 1: bioRxiv preprints volumes by month.



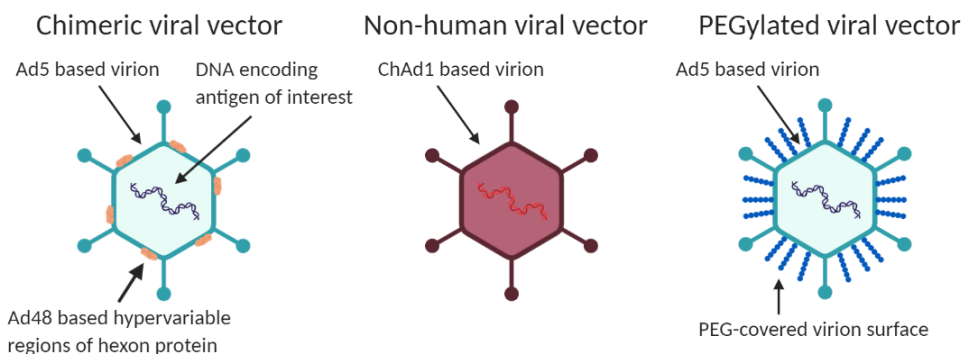
Expanding Dual-Use Definitions

The increase in the volume of published research poses challenges for traditional mechanisms of scrutinizing and moderating dual-use research. In 2018, research on *de novo* horsepox synthesis received swift and widespread condemnation among health security experts after it was published without an adequate review of biosecurity implications (Inglesby; Esvelt). In contrast, the publication of work describing the reconstruction of viral pathogens, including SARS-CoV-2, on bioRxiv and in *Nature* has received comparatively little attention or scrutiny, despite the clear biosecurity risks associated with disclosing methods and experimental details for pandemic pathogen reconstruction (Thi Nhu Thao et al.). In response to the horsepox work, Dr. Tom Inglesby of the Johns Hopkins Center for Health Security suggested that dual-use experiments should not be pursued without clear benefit, especially if they can be substituted with techniques that pose fewer risks (Inglesby). For the same reason, cloning of live viruses should be replaced with sample collection from infected patients (which is naturally accompanied by more stringent safety protocols), or virus-like particles (non-infectious particles that closely resemble the virus) that are both easier to obtain and less prone to dual-use.

While current definitions of DURC encompass such work on viral *de novo* synthesis, research and development of certain pandemic countermeasures exhibits dual-use potential that is not captured within existing frameworks. Accordingly, countries should adopt a wider DURC framework which encompasses research conducted on viruses of little pathogenic concern, which may inform engineering of pathogens of pandemic concern.

For example, while the advancement of vaccine platforms such as virally vectored vaccines promises improved response time to novel pandemic pathogens, genetic modification of non-pathogenic vaccine vector viruses to encode the antigen of interest can potentially inform engineering of pathogenic viruses. Particularly, the engineering of viral vectors posed to elicit immune evasion characteristics is an example of a research approach with dual-use potential. Through this vaccine technology, insights may be generated that could be translated to pathogens of pandemic potential. For instance, genetic engineering has been used to create chimeric adenovirus vectors to circumvent existing adenovirus serotype 5 anti-vector immunity (Figure 2) (Roberts et al.). While this approach is relatively specific to a pathogen with a relatively safe profile of functionality, similar modifications of attenuated versions of viruses with pandemic potential might produce easily translatable insights on how to overcome pre-existing or vaccine-induced immunity.

Figure 2: Approaches for avoiding pre-existing anti-vector immunity.



Authors' illustration, created with BioRender.com.

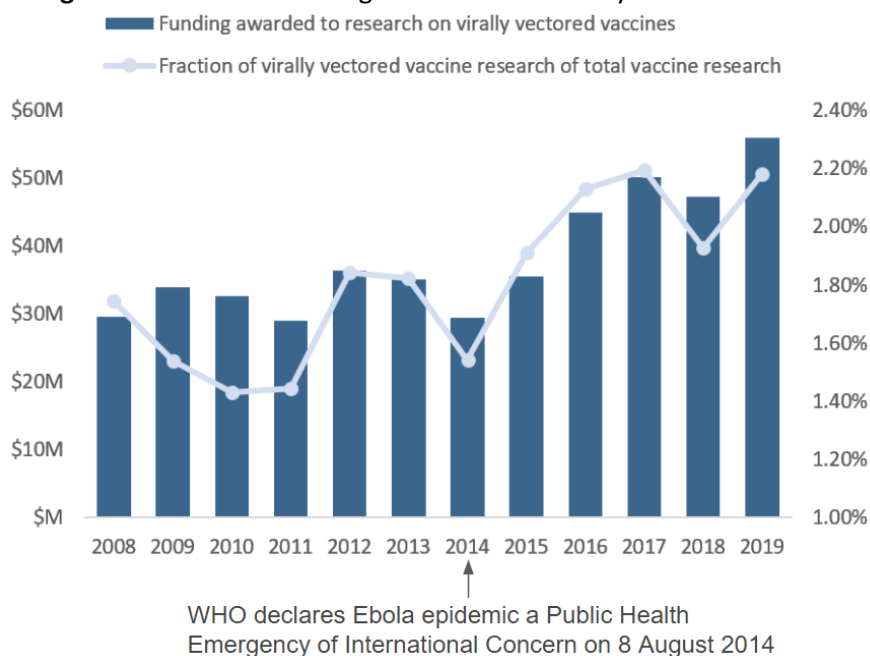
Considering Safer Alternatives to Dual-Use Research

Viral vectors are an example of a versatile technology with uses in vaccinology, immunotherapy, and gene therapy, but specific aspects of their application may be associated with dual-use risks and therefore amenable to safer alternatives. For instance, genetic-based immune evasion may be the most elegant solution to the problem of anti-vector immunity, but other available approaches pose fewer dual-use concerns. To work around the issue of pre-existing anti-vector immunity, one could use vectors with low seroprevalence such as non-human adenoviruses, as is the case for the chimpanzee adenovirus-based COVID-19 vaccine developed by the University of Oxford and AstraZeneca (Figure 2) (Folegatti et al.). Additionally, most virally vectored vaccines do not rely on replication competence for effectiveness, hence, approaches that are not passed onto potential viral progeny may be part of a safe solution. For example, the modification of viral surfaces through PEGylation to decrease anti-vector immunity, while involving an additional manufacturing step, seems promising and safe (Figure 2) (Weaver and Barry). Due to the use of replication-incompetent viral vectors in gene therapy, these same considerations and conclusions apply there. Currently, virally vectored vaccines are an important part of our vaccine portfolio due to their ability to induce robust cellular immune responses potentially necessary for protection against pathogens such as poxviruses and filoviruses (Graham and Sullivan). Nevertheless, another strategy for mitigating dual-use risks might be to preferentially pursue alternative approaches that seem less worrying from a dual-use perspective, such as nucleic acid or recombinant protein-based platform vaccines. To reduce the need to overcome the limitation of anti-vector immunity, virally vectored vaccines could be conserved for tackling pathogens for which their unique immunogenic profile is needed. This would prevent the population-wide build-up of immunity against the vectors with the most promising properties.

Managing dual-use risks in the wake of the COVID-19 pandemic

Reframing the work on research with dual-use potential is of particular importance now, as the pandemic will likely lead to an unprecedented infusion of funding for work on pandemic countermeasures, including research on virally vectored vaccines. As we cannot yet determine the longer-term effects of the COVID-19 pandemic on funding of pandemic countermeasures, we investigated the effect the Ebola epidemic had on the funding of virally vectored vaccines. Looking back, the 2014-2016 Ebola epidemic led to a clear uptick in funding of research on virally vectored vaccines (Figure 3) (WHO, *Statement on the 1st Meeting of the IHR Emergency Committee on the 2014 Ebola Outbreak in West Africa*). Between the period of 2009-2014 US federal funding for research on virally vectored vaccines increased annually on average by just 0.9% compared to an average annual increase of 14.3% in the years following the Ebola epidemic. This increase in virally vectored vaccine funding needs to be seen in light of the success of this approach during the Ebola response - all Ebola vaccines that have been approved for emergency use are viral vector-based. Therefore, the success of different platform approaches with regards to the development of a COVID-19 vaccine might decide over the extent of funding which different technologies will receive following the pandemic.

Figure 3: US federal funding of research on virally vectored vaccines.



US research grants reported on <https://federalreporter.nih.gov>, with funding of virally vectored vaccines defined by the query “‘viral vector’ AND vaccine’ and total vaccine funding by the query ‘vaccine’.

Similarly, private grantmakers such as the Coalition for Epidemic Preparedness Innovations (CEPI), founded in 2016 in the aftermath of the Ebola epidemic, have shown large interest in virally vectored vaccines. As of November 2019, CEPI had awarded \$279m out of \$458m invested in vaccine research for neglected pathogens and platform advancement to approaches based on viral vectors (Bernasconi et al.). Additionally, 10 out of 42 active clinical trials for the development of a SARS-CoV-2 vaccine rely on viral vectors (WHO, *Draft Landscape of COVID-19 Candidate Vaccines*). Comprehensive DURC regulations should thus account for the roles played by both public and private grantmakers conducting such research.

Furthermore, a wider DURC regulatory framework applied at the grantmaking stage would allow for a comprehensive review of proposed research such as novel pandemic countermeasures with dual-use risk. For instance, one such proposal that should be carefully evaluated for its biosecurity risk is the development of self-disseminating vaccines to combat zoonotic spillovers, which could incentivize research into improving viral propagation and immune evasion (Nuismer and Bull). Review of new research proposals would enable better control of research of high dual-use potential and hence decrease the risk of biological events caused by deliberate release of engineered pathogens. Nevertheless, some studies may not pose clear risks until a certain discovery is made or data is collected. To address such scenarios, mechanisms to report new developments in the risk profile of a project and stronger social norms around dual-use must be established.

Recommendations

- 1) A broader definition of dual-use research of concern should be adopted, including research beyond specific experiments on select pathogens in order to capture dual-use knowledge from work on commonly applicable GoF techniques and approaches.

Even in the US, the GHSI frontrunner on dual-use regulation, such regulations are insufficient as the GHS “prevent” index demonstrates. By existing conventions, dual-use classification is limited to any research performed on 1 of 15 specified agents, and one of 7 categories of experiments. This scheme does not encompass the regulation of work on other agents that could be applied to one of the specified agents (e.g. the translation of horsepox research to smallpox). Therefore, a wider framework for defining dual-use research is needed, which encompasses such considerations and could then be used as a foundation for national policies.

A tiered system could be used to qualify the level of concern associated with different activities and to determine appropriate oversight measures. Categories of concern could look similar to those proposed by The Center for International and Security Studies at the University of Maryland (Steinbruner et al.). For instance, while direct work on eradicated or specified agents would fall into the category of highest concern, work on homologous viruses or pathogens within the same family as specified agents would fall into the next highest tier. Furthermore, research on any agent that aims to improve properties such as pathogenicity, transmissibility, immune evasion, or genetic stability and might produce insights applicable to other agents should be considered as research of potential concern. Importantly, any DURC framework should be reviewed and updated regularly to account for emerging technologies and insights of potential concern.

Ultimately, determining which research activities should or should not be allowed to proceed requires careful investigation of at least three factors: (1) the overall risks inherent in a particular activity; (2) the potential benefits of the research; (3) and the availability of safer approaches to solving the given problem. Such efforts can build on previous evaluations of risk-benefit ratios, such as the commissioned report on H5N1 conducted by Gryphon Scientific (Gryphon Scientific; Farquhar et al.).

Dual-use regulations must be introduced in advance of the next outbreak so that they are factored into research, funding, and publication decisions occurring during and after a pandemic, given that research which takes place under such circumstances might be of particular dual-use concern and the fact that containing insights after their discovery may be exceedingly difficult.

- 2) Countries should update or create regulatory frameworks for oversight of dual-use research.

The GHS Index shows that the majority of countries, including many key players in research on pandemic countermeasures, have not introduced robust policies to manage dual-use research. We strongly encourage countries to implement such policies in order to limit the accessibility of knowledge and tools necessary for creating engineered pathogens. This includes provision for a regulatory agency to oversee proposals for such research, as well as mechanisms to screen DNA synthesis against a predetermined list of toxins and agents of concern before sale. Countries can either implement policies for dual-use research through executive orders or regulations or they can pass relevant legislation. Additionally, countries should identify a concrete agency responsible for dual-use oversight. For

example, under the Slovenian Strategic Materials Act, the Chemical Office of the Ministry of Health has the jurisdiction to oversee and prohibit dual-use research and research with especially dangerous pathogens (Global Health Security Index; Republic of Slovenia - Legal information system (PisRS)). Improvement on this front can be concretely measured by the existing scoring assigned by the GHS Index for “Dual-use research and culture of responsible science” and should be continuously updated in light of novel technological advances.

- 3) Robust mechanisms beyond policymaking must be introduced to reinforce dual-use considerations in biomedical research.

Oversight of research of dual-use concern should be enacted at the earliest stages of research, such as when giving out grants, and continue to follow its progression in cases where dual-use risks are unclear at its conception. The rapid dissemination of scientific results during a pandemic has demonstrated that controlling the flow of such information is somewhat futile once such research has been completed. Instead, public and private funders of biological research should follow the example of the Wellcome Trust, the UK Biotechnological and Biological Research Council, and Medical Research Council, which require grant applicants to explicitly account for risks of misuse in applications and notify funders and other relevant authorities of any previously unanticipated changes in the dual-use risk status of their research (Williams-Jones et al.).

Building stronger social norms around dual-use research will be critical for the practical implementation of regulatory frameworks as optimal adherence will depend on the cooperation of researchers. To this end, education programs on such risks need to become part of university life science teaching. In the US, the NSABB should take the lead on creating guidance for education on these topics.

New approaches to surveillance and attribution of genetic sequences are also necessary to enable an early response to the creation or distribution of agents of unknown consequence (Alley et al.). These could come under the purview of commercial DNA sequencing companies, similar to the surveillance measures imposed by DNA synthesis companies to prevent genetic reconstruction of agents or toxins of concern.

Conclusions

One of the rare upsides to the pandemic has been the scientific collaboration that it has encouraged between researchers globally, as well as new efforts to accelerate pre-clinical and clinical work in response to an outbreak. While these positive outcomes are significant, it is important to note that the pandemic has also clearly demonstrated the vulnerability of our healthcare, political and economic systems to infectious pathogens. Consequently, it is critical to ensure that the progress made from responses to naturally-occurring pandemics does not increase the risk of malicious actors engineering harmful pathogens.

Our analysis demonstrates that technology and countermeasures developed in the wake of COVID-19 require more robust regulatory frameworks for biomedical research with potential dual-use applications. This can be implemented by expanding the current definitions of DURC to also include research beyond specific experiments on select pathogens to capture dual-use knowledge from work on

readily translatable GoF techniques. Such a wider framework should be introduced through oversight policies in countries with large research contributions, as well as strengthening norms surrounding safety among public and private grant makers and scientists. Introduction of these measures in the near-term will be essential to ensuring a more secure future in the event of accidental or intentional biological events.

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