

How should dual-use research be restricted?

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The recent H5N1 avian influenza transmissibility and pathogenesis studies sparked the debate over how to deal with dual-use scientific research. Dual-use research of concern (DURC), in the life sciences, may ultimately yield new information critical in the development of diagnostics, therapeutics, and vaccines, but also has the potential to be used maliciously by some individuals or groups. If DURC results are misused, it not only poses a threat to national security but also to the survival of human beings. Therefore, the debate should not be focused on if DURC research should be restricted but on the degree to which DURC research should be restricted.

Dr. Yoshihiro Kawaoka (University of Wisconsin, USA) and Dr. Ron Fouchier (Erasmus Medical Center, Netherlands) constructed variants of the H5N1 avian influenza viruses to identify the genetic mutations that affect transmissibility of the virus in ferrets. Kawaoka and Fouchier submitted manuscripts to the journals *Nature* and *Science*, respectively. The National Science Advisory Board for Biosecurity (NSABB) became involved and recommended that the general conclusions should be published, but that the manuscripts should not include the methodology that could immediately enable replication of experiments [1]. The authors and journals agreed to the restriction on the condition that the government develops a mechanism for restricted circulation of non-redacted manuscripts. In February 2012, the WHO held an international, non-decisional meeting and concluded that publishing the full manuscripts at a later date was preferable to publishing in redacted form, at least, from a public health perspective [2].

Fouchier argued that they did not develop novel methods and that they only used information and methods freely available from the scientific literature [3]. Additionally, he argued, the risk does not outweigh the potential public health benefits. Both Fouchier and Kawaoka noted that two, out of the five, amino acid substitutions in the transmissible A/H5N1 influenza virus are already found in virus reservoirs in the wild. They argued that an avian influenza virus is likely to naturally evolve into more transmissible phenotypes [4]. And so, in June 2012, revised manuscripts were published along with the specific experimental details [5,6]. The H5N1 avian influenza transmissibility studies illustrate the need for a more specific definition of what constitutes DURC.

However, enacting restrictions on DURC research must strike a careful balance between protecting public health and fostering ongoing and new life science research. Prohibiting scientists from communicating important results will dampen research momentum. Additionally, stringent restrictions may discourage new investigators from pursuing DURC research. Too much caution will impede critical discoveries that may save hundreds of thousands of lives. Fouchier described nature as the "prime bioterrorist," emphasizing that viruses emerging from animal reservoirs have already killed millions of lives without direct human interference [3]. DURC research is high risk but also high reward if the research yields knowledge of specific pathogenic virulence mechanisms before evolution chances upon them.

The US government released a policy in March 2012 which was to establish regular review of research with the potential to be DURC

[7]. During the review, federal agencies will collaborate with the researchers to determine if risk is generated by access to information resulting from research. Both parties will develop an appropriate risk mitigation plan. Unfortunately, this policy is merely a stopgap measure as there are serious flaws: the policy ignores less lethal agents and does not distinguish between highly virulent and attenuated strains of listed pathogens. Additionally, this policy cannot be enforced in other countries.

Clearly, a decision on the restriction of DURC requires a coordinated international effort. A panel of experts from multiple countries can reach reasonable advisory conclusions on these DURC restrictions. The recommendations from this panel must also have fully worldwide government support for enforcement. The complex logistics are very necessary for preventing DURC results from disseminating to individuals with malicious intent.

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