

# The NSABB Recommendations: Rationale, Impact, and Implications

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**ABSTRACT** The National Science Advisory Board for Biosecurity (NSABB) has recommended that two scientific papers concerning the laboratory adaptation of avian H5N1 influenza virus to mammal-to-mammal respiratory transmission restrict their content to prevent others from replicating their work. After hearing from experts in the field of influenza research and public health, the benefits of the research were deemed less important than the potential negative consequences. The evaluation followed established NSABB procedures and prior policy recommendations for identifying dual use research of concern (DURC). This recommendation was received by the United States Government, endorsed and forwarded to the research teams and scientific journals involved with the publications.

In October 2011, the U.S. National Science Advisory Board for Biosecurity (NSABB) was asked to review two papers for their potential as dual-use research of concern (DURC). These papers contained results on the adaptation of the highly pathogenic avian influenza A/H5N1 virus to mammalian hosts such that it could be transmitted via respiratory droplets from animal to animal. We found that this work had great potential for harm or misuse and “recommended that the general conclusions highlighting the novel outcome be published, but that the manuscripts not include the methodological and other details that could enable replication of the experiments by those who would seek to do harm” (NIH Press Release, <http://www.nih.gov/news/health/dec2011/od-20.htm>). The recommendation “not to publish scientific results” was highly unusual and the first such recommendation by the NSABB membership. We are primarily a group of actively practicing basic research scientists, and we have consistently advocated for open publication practices. As per our advisory nature to the U.S. Government, these recommendations were not binding and could have been ignored. However, after careful consideration, the U.S. Government accepted the recommendations and relayed them to researchers and the scientific journals.

There was agreement by NSABB voting members for these recommendations, though the rationale of individual members as they arrived at the same conclusions varied. We had to judge the beneficial attributes of these research results against their potential to cause harm. Over the last 7 years, NSABB has studied the issues associated with dual-use research, including risk/benefit assessments, and developed principles and tools to guide the deliberative process. Much of this has been formalized in a series of reports and recommendations that are available at a public website (<http://oba.od.nih.gov/biosecurity/biosecurity.html>). Despite this experience and carefully crafted guidance, there are points in the deliberations where uncertainties and even contradictory information necessitate subjective decisions. When do the negative consequences of research results outweigh the beneficial ones? Is there a clear and bright line to be crossed or is this a more nebulous and fuzzy region of “yes” or “no” for this research? I will present only my personal rationale and how I came to the strong conclusion that this work had the potential to be very dangerous and that its communication should be restricted at this time.

I heard from members of the influenza research community and reviewed the World Health Organization (WHO) data indicating that this avian virus had a very high mortality rate in hu-

mans. While the influenza A/H5N1 virus rarely infects humans, when it does it causes catastrophic disease. We are all aware of the rapid global spread of human-adapted influenza both on a yearly basis and during less common pandemics. The documented devastation of the 1918 influenza pandemic, even with its lower mortality rate, was a testament to the powerful potential of influenza. The thought of combining the high human mortality of influenza A/H5N1 with a highly transmissible human-adapted phenotype was sobering. A pandemic by such a pathogen could reasonably be concluded to cause such devastation that it should be prevented at all costs.

I carefully considered how restricting the information would compromise scientific research progress and even how it would hinder public health efforts to prevent such a horrific pandemic. I know from firsthand experience that the free flow of information is part of the best and most productive research endeavors and that any restrictions burden the progress. The conclusion that this virus could be adapted to mammal-to-mammal respiratory transmission was, in my mind, the foremost beneficial part of the research. With this firm conclusion in hand, policy makers, granting agencies, public health officials, and vaccine and drug developers should have both the motivation and a compelling argument to move forward to improve our influenza-fighting infrastructure. The details of the research, on the other hand, would add little to this short-term effort and could enable someone to replicate the work in a short period of time. The short-term negative consequences of restricting experimental details seemed small in contrast to the large consequences of facilitating the replication of these experiments by someone with nefarious intent. Current public health surveillance and public health responses would be enhanced little by these details. This comes not only from my own professional experience in globally tracking dangerous pathogens but also from personally watching the 2009 H1N1 influenza pandemic spread globally. It was impossible to contain, and I believe that the same would be true for an H5N1

Published 31 January 2012

**Citation** Keim PS. 2012. The NSABB recommendations: rationale, impact, and implications. *mBio* 3(1):e00021-12. doi:10.1128/mBio.00021-12

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influenza pandemic. We were lucky in that the H1N1 virus has low virulence, but the best current data suggest that this would not be the case for the H5N1 virus. Publishing a detailed experimental protocol on how to produce a highly transmissible H5N1 virus in a highly regarded scientific journal is a very bad idea.

Since our recommendations were announced in mid-December, there has been considerable response from scientists, policy makers, funding agencies, and global health organizations. There have been criticisms that we were censoring and compromising academic freedom. There have been criticisms that restriction of the publications was insufficient and that even performing such experiments should be restricted. The debate has touched upon both biosafety and biosecurity aspects, with some calling for the destruction of the virus or for moving all such research to the highest safety level, biosafety level 4 (BSL-4). The NSABB has not yet offered specific recommendations concerning these statements, and my personal opinions are relatively unimportant. What is gratifying and essential is that the debate is occurring; it is occurring on an international stage, and it is occurring rapidly.

In the midst of NSABB deliberations and formulation of our recommendations, the need for a global debate to develop policy

has always been in our discussions. Why should the NSABB be telling the world what to do? Why has not the world already had these discussions and debates? How could the NSABB stimulate the process such that global leaders in science, policy, and public health engage in a broad-based conversation on these issues? The specific NSABB recommendations seem to have been accepted and are being implemented by two research groups and two scientific journals; more importantly, the research issue of adapting an avian virus to mammals, potentially humans, is a topic that is being widely discussed. The influenza research community is voluntarily suggesting a moratorium on this type of research. The WHO has agreed to participate and facilitate in policy development. And the U.S. Government is working on guidelines for the distribution of restricted information.

Research and public policy will be developed from this global engagement process, a process that should increase the public's confidence in the scientific endeavor, in scientists' ethical behavior, and in the transparency that a free research environment embraces. The NSABB recommendations have been effective in both their primary and secondary goals. They are the right recommendations for this time and this problem.

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*The views expressed in this Commentary do not necessarily reflect the views of the journal or of ASM.*