

Research on enhanced transmissibility in H5N1 influenza: Should the moratorium end?

October 9 2012

How can scientists safely conduct avian flu research if the results could potentially threaten, as well as save, millions of lives? In a series of commentaries appearing on Tuesday, October 9 in *mBio*, the online open-access journal of the American Society for Microbiology, prominent microbiologists and physicians argue the cases both for and against lifting a voluntary moratorium on experiments to enhance the ability of the H5N1 virus to move from mammal to mammal, so-called "gain-of-function" research, and discuss the level of biosecurity that would be appropriate for moving that research forward.

In January 2012, in response to the controversy caused by the unprecedented recommendation of an advisory board to the government to redact methods sections of two research studies showing how [genetic changes](#) could make H5N1 become transmissible between mammals, a group of influenza researchers agreed to a voluntary pause on any research involving highly pathogenic avian influenza H5N1 viruses leading to the generation of viruses that are more transmissible in mammals. Despite both articles eventually being published in full in May and June 2012, the research moratorium remains in place.

"The scientific community and the greater society that it serves are currently engaged in a vigorous debate on whether and how to carry out experiments that could provide essential information for preparedness against a pandemic of avian influenza. To foster discussion and to

provide a venue to record the arguments for or against this moratorium, *mBio* has commissioned a series of views from experts in the field," write Arturo Casadevall of the [Albert Einstein](#) School of Medicine, editor-in-chief of *mBio*; and Thomas Shenk of Princeton University, Chair of the ASM Publications Board, in an introductory editorial.

Enhancing and analyzing the transmissibility of the [H5N1 virus](#) could, on the one hand, provide insights that could help prevent or treat a future outbreak of H5N1, or, on the other hand, it may provide a roadmap for a "bad actor" to deliberately bring about an influenza pandemic or lead to an inadvertent release of a virus with enhanced transmissibility.

Authors of the commentaries are prominent scientists, including:

- Ron Fouchier of Erasmus MC Rotterdam in The Netherlands, Adolfo García-Sastre of the Mount Sinai School of Medicine, and Yoshihiro Kawaoka of the University of Wisconsin-Madison, lead authors of the two papers that began the controversy, argue that in the eight months since the moratorium was agreed upon, the international research community has had sufficient time to review biosafety and [biosecurity](#) measures and that H5N1 transmission studies ought to proceed.
- Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases contributes his voice as a representative of an organization that is a key funder of influenza research. Although Fauci acknowledges that the benefits of gain-of-function research outweigh the risks, he argues that scientists have yet to fully meet their responsibility for engaging the public in weighing these matters and making the case for proceeding. He outlines how the U.S. government plans to augment policy guidelines related to "dual use research of concern" like the experiments on enhanced influenza [transmission](#).

- Marc Lipsitch and Barry R. Bloom of the Harvard School of Public Health explain why they view H5N1 with enhanced transmissibility as a "potential pandemic pathogen," representing an even greater threat to global health than Ebola and other biosafety level 4 (BSL-4) pathogens. They argue that research on enhanced H5N1 and other potential pandemic pathogens requires a new, more stringent set of guidelines for safety, thorough public discussion of the risks and benefits involved, and global guidelines for laboratory procedures, among other measures to minimize the risk of laboratory-released infections or epidemics.
- Ian Lipkin of Columbia University argues that once research on enhanced strains of H5N1 continues it may be advisable to conduct the work only in BSL-3 Ag laboratories that meet additional, enhanced guidelines for handling agents with pandemic potential. Lipkin proposes that any course should be charted in consultation with and oversight from the global scientific and regulatory community.
- Stanley Falkow of Stanford University provides perspective on the H5N1 research moratorium based on his own experiences with a similar situation in the 1970s, when research in recombinant DNA techniques was halted while a committee of scientists and non-scientists could establish a set of guidelines for conducting the work safely. Falkow argues that research on H5N1 viruses with enhanced transmissibility should move forward once scientists work with the public to establish standardized guidelines using common sense and scientific creativity.

"This is a historic time in science," says Casadevall. *mBio* has solicited the views of experts in the field, he says, in order to provide a venue for recording the arguments for and against continuing H5N1 gain-of-function research. "Society is asking for a pause of research that is perhaps the best defense against pandemics because of concern about

both biosafety and biosecurity." With the research moratorium continuing well past the 60-days originally planned, it is time these conflicting views were aired in a public forum, he says.

Provided by American Society for Microbiology

Citation: Research on enhanced transmissibility in H5N1 influenza: Should the moratorium end? (2012, October 9) retrieved 3 May 2024 from <https://medicalxpress.com/news/2012-10-transmissibility-h5n1-influenza-moratorium.html>

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