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Bird flu and the future of biosecurity

Plans for restricted access to bird flu papers expected 'within the next few weeks'.

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In December, the US National Science Advisory Board for Biosecurity (NSABB) decided that two papers on avian flu (H5N1) could pose a biosecurity risk if published in their entirety (see Fears grow over lab-bred flu). The NSABB advised against full publication of the papers, setting off a mad dash to develop a mechanism by which important details from the papers could be withheld from the general public while remaining accessible to public-health officials and researchers studying the virus. The advice also unleashed a debate about the oversight of 'dual-use' research – research that could benefit society but that could also be misused (see Call to censor flu studies draws fire).

Amy Patterson, director of the National Institutes of Health (NIH) Office of Science Policy, which administers the NSABB, is taking the lead on the bird flu issue for the agency. *Nature* asks her what led to the NSABB's decision and what will come out of it.

Lui Siu Wai/Xinhua/Photoshot

A mutated strain of bird flu that can easily pass between humans could cause a deadly pandemic.

At what point did the Office of Science Policy become involved in the debate over publication of the two H5N1 papers?
Programme staff at the institute that funded the work, the National Institute of Allergy and Infectious Diseases (NIAID), were contacted by the investigators about their findings, which had been written up into preliminary papers. We were then contacted by the staff at NIAID about potentially holding an NSABB review. Simultaneously, there were discussions with some reviewers of the papers flagged dual-use issues of concern.

Do you think you should have been notified earlier? Some aspects of the work had already been presented at a scientific meeting and were written up in the press.
The earlier the better. There's no doubt about it. One thing to keep in mind is that when a grant proposal comes in for review, it's not necessarily evident at the get-go whether something is going to raise dual-use issues of concern. Often you really don't see the dual-use potential until the results are in.

But I think it's important to be mindful of the potential throughout the course of the work, from the moment the research is proposed through all the points of communication along the way.

Whose job is it to come up with a way to disseminate the full details of these papers to those who legitimately need them?
Many agencies and departments across the US government have a role in that. The lead role is being played by the Department of Health and Human Services and details about that are still being worked out. One sensitive and important issue is recognizing that H5N1 is endemic in many countries around the world. The ability to share information that could inform public-health surveillance in those countries is an important issue.

Will international organizations participate in the design of this mechanism?
There are ongoing efforts to work with a variety of international organizations on this. The most I can say at this juncture is that it's very important to us that there be strong international participation in this mechanism. That will be a hallmark of its success. This is really uncharted territory for the life sciences in so many ways, and the United States cannot do this alone.

Which organizations might be consulted?
For this particular case, the international flu community – both the research community as well as the pandemic preparedness community.

This is the first time that the NSABB has advised against the full publication of scientific research. But similar issues have come up before, for example in relation to the papers on the 1918 influenza virus (see The 1918 flu virus is resurrected). Was no mechanism for restricting information discussed then?

The current circumstances are really unprecedented. Before, people thought that there would be ways of dealing more locally with such research. But there really hasn't been a situation before where there's been both the sense that there was important information that could inform public-health efforts and scientific enquiry around the world, but at the same time could, in the wrong hands, be misused or harm national security.

But was there no thought previously that one day access might have to be restricted?

The NSABB has looked at many, many examples of grants and papers and research proposals and research findings, to both test and exercise their initial criteria for recognizing dual-use research of concern and to test whether there is a readily identifiable subset that should be restricted in some way. Nothing emerged out of this that they felt should not be published. The two papers [on bird flu] are the first that rise to that level of concern.

When do you anticipate providing recommendations on how to restrict access to the full content of these papers?

There are great efforts under way right now, with people working deep into the night seven days a week. We're pushing to have something ready in the next couple of weeks. I think it will be a learning experience that we'll go through with the scientific community, with the public, and with the international community. Whatever mechanism is put in place will need to evolve in light of that experience.

The NSABB is only an advisory body. Some security experts want an non-voluntary oversight system for potentially sensitive research; for example, a special level of grant review and restrictions on what could be disclosed to the public as a requirement of funding. Is this a possibility?

Even with the research aims and objectives set out in advance, exactly what the research is going to show on a day-to-day basis can't be predicted at the outset or captured in an annual report. Whatever system is put in place needs to have both aspects: some consideration up front when the work is funded, but also a component of local oversight and review. It starts with the investigator — he or she knows best what is emerging out of their work. But we also need a level of institutional review to provide a second set of eyes taking a fresh look. The earlier something is recognized, the more options for management you have.

What form would that take at the local level?

Different institutions might have different groups best suited to take this on, but I think it would be a review panel that is equipped to look at infectious disease and biosafety risks posed by a body of work, but which would also be comfortable with thinking about security issues. That's somewhat unchartered territory, particularly for some institutions.

That would require significant resources and expertise. How could you ensure that local review is adequate, or even takes place?

The US government will be coming out with a draft policy that will present a comprehensive framework for oversight of dual-use research, and the local review component of that will be outlined. This will be very much informed by our recent experiences. There will also be an opportunity for comment from the scientific community, from institutions, and of course from the general public. So people will have a chance to weigh in and help shape what the ultimate requirements will be.

When will that draft be coming out?

We're shooting for early this spring.

Do you think that the current system handled the two H5N1 papers satisfactorily?

Well, I think it worked in so far as the issues were flagged. Again, whether this could have been done earlier or if we had a different or enhanced system in place that was informed by these really unprecedented examples — there's always room for improvement. Earlier notification would be better.

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