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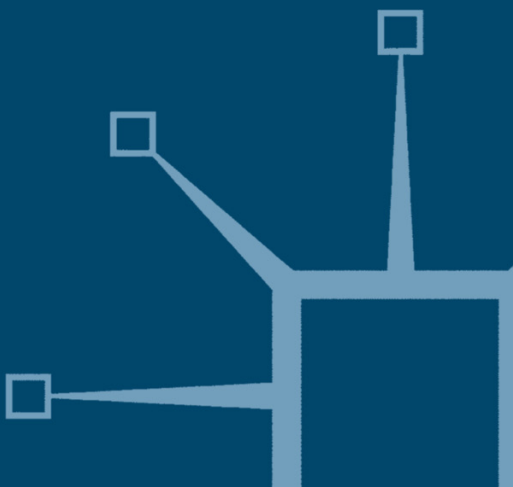
Biotechnology, Security and the Search for Limits

An Inquiry into Research and Methods

Brian Rappert



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Biotechnology, Security and the Search for Limits

An Inquiry into Research and Methods

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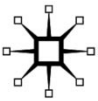

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Abbreviations

ASM	American Society for Microbiology
BTWC	Biological and Toxin Weapons Convention
CDC	Centers for Disease Control
CWC	Chemical Weapons Convention
DoD	Department of Defense
DHHS	Department of Health and Human Services
ESRC	Economic and Social Research Council
IAP	InterAcademy Panel
IUBS	International Union of Biological Sciences
ICSU	International Council for Science
IUBMB	International Union of Biochemistry and Molecular Biology
IL	Interleukin
NAS	National Academy of Sciences
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NSABB	National Science Advisory Board for Biosecurity
OBA	Office of Biotechnology Activities
PNAS	Proceedings of the National Academy
SARS	Severe Acute Respiratory Syndrome

Notes on Transcription

By the middle of Chapter 5, this book makes use of certain transcription conventions that many readers will be unfamiliar with. Steve Clayman and John Heritage's *The News Interview* served as the main source for these conventions, though what they did was itself informed by a long line of work in the field of Conversation Analysis. As this *Biotechnology, Security and the Search for Limits* is not primarily written for those that examine conversation in its finest detail, I only employ certain of the most significant notational conventions in the transcriptions and well as other commonly used transcribing symbols.

Symbol	**Example**
*** indicates deleted words for purpose of the non-identification of participants	A little piece of my research work, the last line in the paper, I was doing some work on *** toxins, the last line in the paper *** spawned the little bit of work that I'm doing now
Underlining denotes stressed words	And unless you have a policy of open publishing, you,those assumptions are never going to be right. I mean, why just because it's published in the scientific world that it's used for good rather than bad, who's to define what's good or bad, I mean.
Words in (single parentheses) are the author's guess at what was said when the recording was unclear	I know the seriousness with which people tick the ethics box and, and people don't sit down and weigh up the ethical (.) implications of their research, they quickly start ticking (out the boxes) and I sure this do exactly the same.
Words in ((double parentheses)) are the author's description of what happened.	((Group laughter))
Numbers within single parentheses, such as (0.5),	I'd, I'd like to throw the whole thing open by saying(3.0) it would be (1.0)

Continued

Symbol	Example
indicate the estimated time of the pause in seconds. The symbol '(.)' indicates a micro pause of less than 0.2 seconds.	it feels very artificial to pose this question
Pairs of equal signs indicate:	
(a) Either when two individuals spoke with no intervening silence	MD: My = P1: = How do you read it?
(b) When the same individual continued at statement without pause but that statement was broken up overlapping talk from another individual	BR: So this was maybe = P1: [Yeah] BR: = a bit superfluous?
Overlapping talk between two individuals is designated by square brackets. The start of an overlap is indicated by '[' in two adjacent lines. The end of the overlap is indicated by ']' in those separate lines. The ']' might indicate that the overlap ends at the same time or that one speaker carries on after the initial overlap.	BR: … military issues or [anything] P10: [Well] I think this is a very handy way …
Where a remark by one individual is inserted into a continuous statement by another, but without any overlap of words, only one set of brackets is used.	BR: So this was maybe = P1: [Yeah] BR: = a bit superfluous?

In addition to these conventions, in the transcribed excerpts 'P' denotes a participant's statement and the number next to that indicates the order in which that participant first spoke in the group discussions. For instance, 'P2' indicates the second participant that spoke in the seminar and any subsequent statement by this person throughout the rest of the discussion is likewise indicated by 'P2'. 'BR' and 'MD' are used to indicate when Brian Rappert and Malcolm Dando were the speakers. In some excerpts, contributions from more than one member of the audience are indicated by 'AUD'.

Introduction: What Should be Done?

In early October 2005, numerous reports appeared in the scientific press and general news media regarding research conducted on the '1918 Spanish Flu'. During 1918 and 1919, this virus was responsible for the deaths of tens of millions of people in a worldwide pandemic. Unlike many strains of influenza that targeted the newborn, elderly, or unhealthy, the 1918 virus killed healthy adults. An estimated one-third of those infected died from breathing complications, contracting pneumonia, or other debilitating conditions. Nearly as quickly as it emerged, the virus vanished. Medical doctors of the time had little understanding of its origins or characteristics.

The attention given to 1918 Spanish Flu in the autumn of 2005 centered on two articles that appeared in prestigious scientific journals. One was the publication in *Nature* of the sequences for the remaining unsequenced parts of the virus's genome.[1] A team lead by Jeff Taubenberger of the US Armed Forces Institute of Pathology had reconstructed the genome by assembling fragments from hospital specimens collected during the pandemic and the remains of victims buried in permafrost. Through an analysis of its genetic makeup, they argued that rather than being a mix of human and avian (bird) flu, the 1918 virus was 'more likely an entirely avian-like virus that adapted to humans.' The second article published in *Science* described the reconstruction of the virus by a research team headed by Terrence Tumpey at the US Centers for Disease Control (also including Jeff Taubenberger).[2] They used the sequence data provided by the Institute of Pathology to physically recreate the virus. Laboratory mice and other specimens were then infected with the 1918 flu strain and genetically modified variants to test the function of certain genes in the transmissibility and virulence of the virus. Through this process a protein on the surface of

the 1918 virus was identified as playing a significant role in making it so lethal.

Some reports of the research projects included decidedly positive appraisals. The *New York Times* quoted a British virologist as saying 'This is huge, huge, huge … It's a huge breakthrough to be able to put a searchlight on a virus that killed 50 million people. I can't think of anything bigger that's happened in virology for many years.'[3] *Nature* ran its own news story in which another virologist was reported as saying 'It's a landmark … Not only is this the first time this has been done for any ancient pathogen, but it deals with the agent of the most important disease pandemic in human history.'[4]

Both these news reports though (along with many others), included comments of a different kind. Remarks were included suggesting that while some 'scientists have already hailed the work as giving unprecedented insight into the virus', there were also concerns about darker implications.[5] As stated in the *Nature* news report, while some said the benefits were potentially substantial:

> … others have raised concerns that the dangers of resurrecting the virus are just too great. One biosecurity expert told *Nature* that the risk that the recreated strain might escape is so high, it is almost a certainty. And the publication of the full genome sequence gives any rogue nation or bioterrorist group all the information they need to make their own version of the virus.[6]

A scientist was quoted in the *New York Times* article saying that 'There is a risk verging on inevitability of accidental release of the virus and a risk verging on inevitability of deliberate release.'[7] In a later article for the newspaper, two technology analysts called the decision to publish the flu's genome 'extremely foolish' since it amounted to 'the design of a weapon of mass destruction'.[8] In anticipation of possible concerns and the behest of others (see below), the authors of the article in *Science* included a note which stated: 'This research was done by staff taking antiviral prophylaxis and using stringent biosafety precautions to protect the researchers, the environment, and the public. The fundamental purpose of this work was to provide information critical to protect public health and to develop measures effective against future influenza pandemics.'

The research into the 1918 flu was just one of a number of reasonably high-profile cases since 2001 where concerns had been voiced about the security threats that might stem from work in the life sciences. Some of

these have asked whether the research should have been openly communicated or even undertaken at all. Various discussions have taken place in science policy arenas regarding whether some communication restrictions were justified and whether their introduction might have compromised scientific advancement. As in many accounts of the sequencing and recreation of Spanish Flu, the issues at hand in these were widely regarded as highly problematic since the knowledge and techniques generated had the potential for 'dual use': they could aid in the fight against disease or be used to further spread it. Thus the matter of what should have been done raised fundamental questions about the place of science in society.

The proper governance of research deemed 'controversial' was directly addressed in the *New York Times* and *Nature* news reports. As both noted, not only did the 1918 flu research go through conventional safety assessments as well as institutional and peer review, the journals had in place their own security review system. In these the benefits of publication were considered against potential security risks, with the former deemed much more substantial. In addition, the virus reconstruction article in *Science* was scrutinized by the newly established National Scientific Advisory Board (NSABB) at the request of US Health and Human Services Secretary Michael Leavitt. NSABB had been established, in part, to devise criteria and procedures for appraising dual use research. Dr Anthony Fauci of the National Institute of Allergy and Infectious Diseases in the National Institutes of Health said NSABB had 'voted unanimously that the benefits outweighed the risk that it would be used in a nefarious manner.'[9]

Weighing the risks and benefits

The framing of the decision about publishing as one where benefits had to be weighed against risks was widely repeated.[10] A front-page editorial in *Science* by Philip Sharp (MIT) found it 'reassuring that the NSABB was asked to consider these papers before publication and concluded that the scientific benefit of the future use of this information far outweighs the potential risk of misuse. People may be reassured that the system is working, because agencies representing the public, the scientific community, and the publishing journals were involved in the decision.'[11]

The Editor-in-Chief of *Nature* was less enthusiastic about the new NSABB oversight procedures, suggesting the danger that 'government bureaucracies and committees may push to avoid perceived risks, at the potential expense of benefits to public security.' A week after the initial

publications, *Science* ran another front-page editorial, this time by its Editor-in-Chief. This second editorial struck a rather different tone than the first by describing some of the 'backstage' maneuverings regarding the decision to publish. Herein, the suggestion to refer the virus reconstruction article to NSABB was characterized as an '11th-hour intervention from the [Health and Human Services] secretary's office'.[12] The previous week's editorial had been finished 'at the last possible moment', as had the added 'authors' note' which was suggested by NSABB to assuage possible concerns. Significant issues were raised by the editor of *Science*, including 'a real question of authority here. Government officials can advise, and should be listened to thoughtfully. But they can't order the nonpublication of a paper just because they consider the findings "sensitive".'[13] In a rather defiant close, the editor finished by writing 'So would I, given our own convictions, the timing, and what we had learned from our consultations with Gerberding, Fauci, and others, have published the paper even if the NSABB had voted otherwise? Absolutely— unless they had it classified.'[14]

Setting aside disputes about institutional authority and timing, appraisals of what should have been done with the 1918 experimental results were inextricably bound with the way in which possible risks and benefits were handled. Central to this was the identified range of germane matters for consideration. Although scientific and general media reports about the studies shared many commonalities, they also differed. While reports in *Nature* and the *New York Times* gave space to concerns about the accidental releases of the reconstructed 1918 virus based on past experience with other laboratory-held pathogens,[15] others did not mention such fears.[16] Most, though not all,[17] news accounts explicitly linked the 1918 influenza research to the high-profile media concerns at the time about the deaths to birds and some humans in Southeast Asia from the H5N1 avian flu virus. Arguably this linkage underscored the possible benefits of the research. Some accounts went so far as to retrospectively claim the reason for the research was to counter bird flu.[18] *Nature* not only published a paper detailing the remaining sequences of the 1918 virus and a related news story, but along with these the sequence results for a major collaborative study of human influenza A viruses. Attesting to the importance of sequencing virus genomes, the latter promised 'to provide a more comprehensive picture of the evolution of influenza viruses and of their pattern of transmission through human and animal populations.'[19]

While some arguments and commentators could be neatly categorized as justifications or criticisms of the publication choices made, other

statements were more ambiguous. Presenting seemingly both pros and cons, Ron Atlas of the Center for the Deterrence of Biowarfare and Bioterrorism at the University of Louisville was quoted in *The Guardian* (UK) as stating that the results heightened concerns about a new pandemic coming from bird flu. In addition, '[a]ssuming this is a replicant of the 1918 flu strain, if it got out, it could initiate disease in humans and given the work they've done, one had to say it would be infectious'.[20] Yet, just what overall appraisal Atlas made of the decisions to publish was difficult to gauge. *The Guardian* also stated that despite the beneficial potential of the work mentioned by some, 'other researchers warned yesterday that the virus could escape from the laboratory. "This will raise clear questions among some as to whether they have really created a biological weapon," said Professor Ronald Atlas ….'[21] Here the report itself was arguably ambiguous in that it is not certain from the wording whether Atlas was one of those researchers taken by *The Guardian* as actually warning of dangers or merely pointing out that unidentified others would be concerned.

Off the front page

While the citing of credible experts offering assessments of the merits of the 1918 virus research was central to reports in the scientific and general presses, by moving beyond mainstream accounts, questions can be asked about just who was cited and the bounds of the debate subsequently generated. Although news reports in *Nature* and *Science* described numerous concerns about the research articles they published, these pitched possible safety and misuse risks against likely benefits to human health. Certain commentators challenged this way of thinking, though their assessments were not widely picked up. The Sunshine Project, a watchdog of US activities in this area, maintained that 'We are no safer from a pandemic today than yesterday. In fact, we're in greater danger, not only from influenza; but from the failure of the US to come to grips with and address the threats posed by the research it sponsors, in terms of legislation, ethics, and self-restraint.'[22]

In support of this position, the organization made a variety of points that did not figure in many mainstream accounts: a proposed lack of valid scientific justification for the 1918 flu research projects, the way in which these activities blurred the boundary between internationally permissible defensive and non-permitted offensive biological weapons-related work, the inappropriateness of the massive increase in US research into dangerous pathogens post 9/11, and the past and likely

spread of viruses with 1918 genes to many laboratories. Accounts of the motivations for the 1918 Spanish Flu research figured in reports by the Sunshine Project. One of its 2003 publications argued:

> It appears that this work was not triggered by a search for flu treatments, or the search for a new biowarfare agent, but by a rather simple motivation: Taubenberger and his team were just able to do it. In previous experiments they had developed a new technique to analyse DNA in old, preserved tissues and for [sic]now looking for new applications: 'The 1918 flu was by far and away the most interesting thing we could think of', explained Taubenberger [giving] the reason why he started to unravel the secrets of one of most deadliest viruses known to humankind.[23]

The telling of motive here (based on a web profile of Taubenberger) served to reinforce the said distance of the 1918 research from practical health concerns. Taken together, these points provided a counter-narrative to the dominant stories presented elsewhere. This one questioned not just the actions of individual scientists or publishers, but the policies of the US government.

The reference to the 2003 Sunshine Project report points to the pre-history of debate about 1918 flu research prior to the international high-profile attention in October 2005. While many of the widely voiced concerns expressed in 2005 about the 1918 virus research centered on the adequacy of the protections in place to prevent its accidental release and deliberate misuse, the Sunshine Project had drawn attention to a prior question: whether the research should have been undertaken in the first place. Although accepting the need to sequence the 1918 strain, it said: 'there is no valid reason to recreate the virulent virus, as the risks far outweigh the benefits.'[24] Rather than conducting the latter said dangerous research, in 2003 it said funds could be better spent on existing naturally occurring diseases such as malaria and HIV.[25]

In contrast, many of the reports prior to October 2005, concerns about the deliberate misuse of research did not figure into what was reported. Taubenberger and colleagues, for instance, wrote an article for the journal *Scientific American* in January 2005 that recounted various lines of work taking place into the 1918 virus, but without any reference to their potential to facilitate novel bioweapons.[26] In this article, rather than their work being motivated out of mere curiosity, it was said to be motivated by a desire to devise treatments and measures for alleviating any future pandemic outbreaks. A news report in *New Scientist* in 2004

discussed research led by Yoshihiro Kawaoka that entailed inserting some of the genes from the 1918 virus into influenza strains, but again without citing any causes for concern.[27]

The usefulness of research

As mentioned, the Sunshine Project not only criticized the 1918 virus reconstruction research on the basis of concerns about its negative implications but also its said limited utility. Considerations of usefulness figured widely within accounts both during and before October 2005. The utility of the projects in *Nature* and *Science*, however, was a matter alternatively characterized. Some accounts of the research and of experts' appraisals of it were rather categorical and definite. The news article in *Science* said 'researchers have figured out the traits that made the 1918 influenza virus, which killed between 20 million and 50 million people, so virulent.'[28] It went on to state that the team involved in the recreation efforts said 'its work will provide crucial knowledge for heading off the next influenza pandemic, which could be brewing in Asia, where the H5N1 bird flu has killed more than 60 people.'[29] The authors' note, added to the *Science* reconstruction paper at the request of NSABB, drew attention to the practical benefits of the research in stating the 'fundamental purpose of this work was to provide information critical to protect public health and to develop measures effective against future influenza pandemics.' SciDev.Net reported that 'Taubenberger said that studying the 1918 virus should provide a "checklist" of genes that H5N1 would have to acquire to become infectious enough to cause a pandemic.'[30] Such statements suggested the research had already yielded valuable insights that provided concrete justifications for the work.

Other accounts though were more reserved in their claims about the imminent benefits of the research for the state of knowledge or therapeutic interventions.[31] The news story in *Nature* said that future follow-on research would 'hopefully be of use in vaccine and drug design, but so far the work is more about obtaining a basic understanding of the virus than any immediate health benefits.'[32] Rather than stating the work should provide a 'checklist' of genes for studying how bird flu could become a human pandemic, the *New York Times* article reported Taubenberger as contending 'The ultimate goal … is to make a checklist.'[33] A joint statement by the directors of the National Institute of Allergy and Infectious Diseases and Centers for Disease Control and Prevention offered a highly qualified assessment that the 'mysteries of the 1918–1919 influenza pandemic … are finally beginning to be solved'. The directors

said the *Science* and *Nature* publications may help predict pandemics and 'may lead to identification of new targets for drugs and vaccines' but more research would be required.[34] While individual publications might not in themselves necessarily lead to significant outcomes, the *New York Times* article stressed the importance of continuing with an unfettered program of research. At this level of the program, it said 'the certain benefits to be obtained by a robust and responsible research agenda aimed at developing the means to detect, prevent and treat these threats far outweigh any theoretical risks associated with such research.'[35]

An October 2005 report by *New Scientist* adopted a fairly mixed position about the usefulness of the research. It questioned a statement made by the leader of the reconstruction of the 1918 virus that 'This work will help us make vaccines and antivirals against pandemic strains' by adding its own comments that 'It is unclear how, as the next pandemic is likely to be a different kind of flu.' Yet immediately following this challenge the article stated: ' "But", says Taubenberger, "the 1918 sequences are already helping in another way: they prove that a bird flu can go pandemic without combining with a human flu, and suggest which mutations it needs." '[36]

Additional queries about the practical utility of the publications were noted elsewhere. While highly supportive of the decision to undertake and publish the research, in his *Science* editorial Philip Sharp noted that the reconstructed virus was based on one full genome sequence. Given variations in the genetic makeup within viruses and uncertainty as to the exact causes of pandemics, he concluded 'there is no certainty that the reconstructed 1918 virus is capable of causing a pandemic'. The claim that the particular virus studied might be significantly dissimilar to that (or those) which caused the brunt of the pandemic performed a number of functions. It at once suggested a reduced utility of the results than that given in many other accounts, justified the need for further research to determine the identity of the reconstructed virus, and reduced the potential harm from the deliberate or accidental misuse of the research.

While most accounts did not raise doubts about the relevancy of the particular genome sequenced for grasping the Spanish Flu pandemic, some gave reason for downplaying concerns about the possible negative consequences of laboratory release. Both the Reuters and *New Scientist* reports included statements by the director of the Centers for Disease Control and Prevention that the human immunity developed from the 1918–19 pandemic meant any release of the virus would limit the risks.[37] In such accounts, arguably a tricky line was walked of both treating the