Emerging Leaders in Biosecurity Workshop, UK (August 3-6, 2015): Summary and Analysis

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Introduction

"Leadership and learning are indispensable to each other." — John F. Kennedy

The Emerging Leaders in Biosecurity Workshop was hosted in August 2015 at the Defence Academy of the UK, and was coordinated and facilitated through partnership with the UK Embassy and King's College London Centre for Science and Security Studies in the Department of War Studies. The workshop brought together the 2015 Emerging Leaders in Biosecurity Initiative (ELBI) Fellows with US and UK policymakers, academics, industry representatives and biosecurity professionals for discussion and analysis of current and anticipated biosecurity challenges, as well as issues and opportunities for collaboration internationally. The workshop featured expert panels, keynote talks, panels for the fellows to present their own ideas, and an interactive table-top exercise of an international bioterrorism scenario. In order to capture key ideas as well as identify questions and issues for future research, this report provides summary and analysis of six key themes that emerged during the three day workshop: the importance and role of biosecurity; the role of national governments in biosecurity policy; risk assessment; the burdens of biosecurity; risk perception and communication, and governing new and emerging technology. [1] Before turning to these themes, we provide background on the ELBI program.

The Emerging Leaders in Biosecurity Imitative Fellowship Program

The Emerging Leaders in Biosecurity Initiative (ELBI) Fellowship program was established in 2012 to develop a path into the world of biosecurity and biodefense for young scholars and practitioners from a wide range of backgrounds by providing opportunities to learn about historical and current issues in biosecurity and by facilitating growth into positions of leadership. Supported by the US Department of Defense (DoD), Defense Threat Reduction Agency (DTRA), and run by the UPMC Center for Health Security, each year the ELBI program selects a talented group of US, UK, and Canadian fellows representing the highly diverse biosecurity field in government, defence, private industry, science, law, public health, medicine, global health, journalism, the social sciences, and academia.

The ELBI fellowship allows participants to continue work in their current field, while creating opportunities for them to consider biosecurity policy in the context of their work. ELBI fellows are invited throughout the year to a number of formal and informal events that facilitate knowledge exchange and collaboration. Each fellowship class also has occasion to present their own views on biosecurity policy dilemmas and potential solutions. These ideas are shared with government officials and experts, and in some instances are invited for peer-review and publication in the Journal *Health Security*.

Each fellowship class also has the opportunity to attend 2 multi-day workshops where they can learn from and network with current biosecurity experts. This year, the second workshop, and the focus of this report, was convened in the UK.

The Importance and Role of Biosecurity

[1] The workshop was held under Chatham House rules, so the summary and analysis draws generally on the presentations and discussion at the workshop without attributing particular material to any individual participant.

Biosecurity represents the nexus between biological science and national and international security. It is a broad and complex field encompassing many disciplines, including agricultural security and veterinary science, public health, laboratory biosafety, bioweapons non-proliferation, and bioterrorism preparedness and response. Each of these disciplines is critically important on its own, but each also contributes to and is strengthened by the others, and all are connected by the common goal of making the world safer from biological threats and hazards.[2] It is with this connection in mind that this workshop included discussion of the range of approaches to address both naturally occurring and intentional biosecurity risks.

Naturally occurring outbreaks and emerging infectious diseases were key issues for many experts and Fellows during the workshop, given the recent experiences with the 2014-2015 Ebola epidemic. Panellists discussed the Ebola response from both national and international perspectives, highlighting important gaps in our collective biosecurity that became apparent during the response, including:

- Weak healthcare and public health systems limited the capacity of West African countries to respond effectively at the local level;
- Poor infection control practices around the world, including in the US and UK, made Ebola dangerous in both developing and developed countries;
- Poor surveillance data and poor procedures for identifying and sharing relevant information among and within countries delayed recognition of the need for international support and slowed identification of resource needs and appropriate response;
- Lack of capacity and leadership for infectious disease response in the international community led to delays in response and allowed the epidemic to expand unchecked for some time;
- System and market failures in preparing for response to a major infectious disease emergency, including a failure of governments to incentivise research and development (R&D) and procurement of medical countermeasures for Ebola, left us without medical countermeasures ready to use in the epidemic.

Workshop participants recognized the tension between developing generic capabilities at the national and international level that are useful for any outbreak, and the development of capabilities necessary for specific diseases. In addition, the response to a local health crisis with international implications like Ebola has to be effective within the local context, with local experts who can look at how the disease is spreading through interactions on the ground and who have sensitivity to the local impact of the disease and the recommended responses. A key question is thus: What kind of national and international health infrastructures can best support the development of bespoke responses that will be effective against a specific disease outbreak in a particular context?

Discussants agreed that it is within the purview of biosecurity, currently under the umbrella of the Global Health Security Agenda (GHSA), to help address these issues, and that the Ebola epidemic provides a unique window of opportunity in which to do so. Participants discussed on-going and potential projects in the US and UK that fall into 3 main themes: creating stronger health systems and international architectures, smarter policies for research and development of countermeasures, and swifter response with international assets during the next crisis. Ideas for further action included:

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[2] Meyerson L. A Unified Definition of Biosecurity. *Science*. 2002;295(5552):44. http://www.ncbi.nlm.nih.gov/pubmed/11780645. Accessed December 11, 2015.

- Agreements between governments to allow for emergency assistance;
- Pre-designated national capabilities that can be mobilised for epidemic response;
- International policies about the role of national militaries in epidemic response;
- Further investment in implementation of IHR, Global Health Security Agenda goals, and development of health systems around the world;
- Investment in better disease surveillance AND communication and analysis of epidemiologic information;
- Prioritization of diagnostics development for use in epidemic response;
- More thought and consensus about medical countermeasures development priorities internationally, and about vaccine trial approaches in international crises;
- Further international discussions about how national medical countermeasures stockpiles will be used in global disease emergencies.

Intentional use of biology to cause harm to humans, animals, and economies was also a critical component of the workshop discussion. Speakers and Fellows first highlighted the role of Biological and Toxin Weapons Convention (BWC) in prohibiting development and use of biological weapons. Implementation of the BWC provisions leading up to the 8th Review Conference in 2016 was a particular focus, with discussion surrounding promulgation of possible regulatory frameworks to guide biosecurity and biosafety efforts at the national level, possible oversight mechanisms, education and awareness, and codes of conduct and self-governance. While implementation is difficult and verification does not at this time exist for the BWC, this Convention does play a major role in setting the international norms surround biological weapons, and is helpful in defining the scope of global governance and the role of international measures. Outstanding questions and areas of future research identified during this discussion included:

- How will States Parties to the BWC approach the upcoming Review Conference?
- What will it mean to strengthen national implementation of the BWC?
- What verification mechanisms could be agreeable to States Parties?
- What are the best frameworks for national governments to use to guide biosecurity and biosafety regulation and legislation?
- How can emerging science and technology be best addressed under the BWC?
- What is the future of the BWC if verification is not implemented?

Because of the possibility that the BWC and other efforts to prevent the acquisition and use of biological weapons could fail, preparedness for a bio attack—including planning for public health, medical and possibly military response to mitigate the effects of such an attack-- is essential. The workshop devoted significant time to learning about key initiatives of the US and UK governments in this area. In the US, these initiatives largely began after the Anthrax letter attacks that occurred in 2001. Subsequent to those attacks, the US Government took a number of steps to identify and further its biosecurity priorities, including the Project BioShield Act of 2004,[3] which established a standing fund for research, development, purchase, and stockpiling of effective Medical Countermeasures (MCMs) against CBRN agents; establishment of an Emergency Use Authorization (EUA) process,[4] which allows the Food and Drug Administration (FDA) to make MCMs in

[3] US PL 108-276. Project BioShield Act of 2004. July 14, 2004. https://www.govtrack.us/congress/bills/108/s15. Accessed December 11, 2015.
[4] US Food and Drug Administration. Emergency Use Authorization [webpage]. Updated December 10, 2015. http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm. Accessed December 11, 2015

development available to the public more quickly in an emergency; and the establishment of a Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) process to coordinate across government to accelerate development of needed medical countermeasures.[5]

UK participants highlighted their counterterrorism strategy (CONTEST), which includes a significant biosecurity/biodefense component.[6] The UK Government has a large base of expertise in many government departments for management of biological risks and biosecurity policy objectives for intentional and naturally occurring hazards. Those at the workshop endorsed the importance of bringing these two communities together to develop cooperation and identify areas where knowledge and capabilities can be shared.

The smallpox *Viral Storm* table-top exercise, which closed out the workshop, served to reinforce prior discussions about the importance and complexity of biosecurity. In response to a fictitious scenario involving multiple Trans-Atlantic attacks using smallpox as a weapon, Fellows and workshop participants were asked to consider the policy dilemmas that they as leaders and future leaders might some day face. The group was asked to weigh in on decisions about travel restrictions, quarantine policies, vaccine and countermeasures use, international treaty commitments, and attribution and military response. Participants found these decisions nearly impossible to make during the emergency period. The simulation thus highlighted the need for discussion in international fora in advance of such a crisis, and in particular of the need for further consideration of how the international community can best prepare for such a crisis, including the extent to which international norms and agreements are needed to facilitate an effective response that recognizes the need to share what may be very scarce resources.

Role of national governments

The US and the UK are allies with a common interest in advancing biosecurity. One purpose of this workshop was to discuss national approaches to biosecurity with the aim of fostering common understanding and building new connections between the officials, scientists, and emerging leaders who participated. The workshop opened with a panel of policy experts who compared and contrasted UK and US approaches to biosecurity. Through this discussion, it became clear that the two countries share similar assessments of the severity of the threat, and have a similarly strong commitment to addressing it. However, it also became clear that there are important differences in emphasis and approach.

Biosecurity is inherently multi-disciplinary, requiring extensive collaboration among policymakers, biological scientists, social scientists, security experts, and experts in human and animal health. In the UK, risks associated with natural biological hazards are addressed by the Department of Health and Defra, while deliberate biological threats are managed through the UK Home Office and Ministry of Defence. Importantly, these components are brought together at the national level so that both natural and deliberate biological threats are considered together in risk assessment, scientific collaboration, and policy development. While the compartmentalization of information and resources can be a problem, the agility of the UK government and a strong commitment to cross-agency collaboration helps to create a unified approach.

[5] US Department of Health and Human Services. 2014 PHEMCE Strategy and Implementation Plan. http://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx. Accessed December 11, 2015.
[6] United Kingdom's Strategy for Countering Terrorism. July 2011. https://www.gov.uk/government/publications/counter-terrorism-strategy-contest. Accessed December 11, 2015.

In the US, responsibility for biosecurity policy and implementation is also distributed across government, but with less distinction in responsibilities between deliberate and naturally occurring biosecurity threats. The Department of Health and Human Services (HHS) is responsible for public health and healthcare preparedness and response to both intentional and naturally occurring threats. The Department of Homeland Security (DHS) has the lead for the national response to deliberate attacks, but also has responsibility for bioterrorism risk assessment, threat characterization, and coordination of national biosurveillance efforts. The Department of Defense (DoD) is responsible for protecting the warfighter against both deliberate and natural threats. The Department of State focuses on biosecurity engagement and response to epidemics internationally. Finally, the Department of Agriculture (USDA) addresses naturally occurring and intentional plant and animal biosecurity threats. So, while deliberate and natural threats are addressed at the agency level, the US lacks the high-level coordination afforded by the UK process.

The US and UK both had important biosecurity successes to share. American experts highlighted successes in developing an effective Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which has facilitated advanced development, procurement, and stockpiling of medical countermeasures to prepare the country for response to biological threats. Success in this area is exemplified by the US response to the Ebola epidemic, where research into a number of Ebola drugs and vaccines that otherwise would not have been developed were supported by the federal government in the name of biodefense.

UK representatives discussed successes in cross-governmental biosecurity coordination and policy development, including the National Risk Assessment/National Risk Register process which draws upon expertise from a range of government offices, compares deliberate and naturally occurring risks, and places biological risks into relative context with other types of risks of consequence to the UK; and the designation of chief scientific advisors (CSAs) for each government department who are responsible for advising the government on all aspects of science and technology policy, and contributing to the development of a commonly recognized information picture (CRIP) in biological emergencies.

The UK and US often collaborate on risk assessment and threat characterization, intelligence collection and analysis, international response to biological emergencies, and international biosecurity engagement programs. Representatives from both governments and emerging leaders made new connections during this workshop, which will likely strengthen collaboration in these and other areas of biosecurity. In particular, the US and UK plan to work together on the Global Health Security Agenda (GHSA), to strengthen national health systems, facilitate compliance with the International Health Regulations, and bolster resilience to biological threats globally.

Later in the Workshop it was noted that one important difference between the US and the UK is that for the UK, because of the National Health Service, health is a primary activity of government in UK. This has implications for funding—in the UK there is a commitment to maintain a significant level of public spending on health; in the US, it tends to be defence funding that gets 'ring fenced.' This also has implications for who the actors are on the front-lines: In the UK it is the government that is on the front-lines, while for the US it is private doctors, hospitals and insurers, with government more behind-the-scenes with the National Institutes of Health and the Centers for Disease Control and Prevention able to set policies on biosecurity but much of the rest of government policy limited to the regulation of private actors (e.g. insurers).

Discussion of these issues highlighted the need for analysis of success stories and identification of best practice that can be shared, both within and across governments. But it was

also recognised that evaluation and assessment of policies quickly becomes politically sensitive, suggesting that outside researchers and academics need to be involved in the identification of best practice.

By highlighting the relative strengths of policymaking on biosecurity in both the US and the UK, the workshop generated further questions: How can we best capitalise on strengths of individual countries in the international effort to improve biosecurity? To what extent does a government's structure and resources constrain biosecurity policies, and how can we adapt 'best practice' in biosecurity to local structures and conditions?

Risk assessment and policy

At the heart of understanding and preparing to defend against threats is a process of risk assessment. But the process of risk assessment is particularly challenging in the area of biosecurity, because of the diverse nature of possible threats (e.g. natural versus deliberate, zoonotic versus human disease agents), the difficulty of estimating the likelihood of an attack or disease outbreak, and the difficulty of estimating effects of an event if it occurs, in part because of the diverse nature of possible impacts (economic impact, health impact, impact on bio-diversity, as well as possibility of secondary impacts and compound risks). At the same time, workshop participants agreed that a shared understanding of threat promotes effective and coordinated response. It was also suggested that while it is difficult to generate good models of any particular threat because of the uncertainties involved, a comparative risk assessment can help us to focus resources on the most serious threats.

Speakers at the workshop were able to present their understanding of the different ways biosecurity risk assessment is approached within the US and the UK. It was suggested that a key task is to bring together the communities that work on natural and deliberate threats in order to understand the different approaches to risk assessment of natural, accidental and deliberate threats. Questions included: Is a standard approach to risk assessment of all biosecurity threats possible? Can a comparison of the timelines of deliberate, accidental, and naturally occurring threats help identify areas where it is useful for different government agencies to cooperate? Does drawing together work on natural and deliberate threats allow for the consideration of more diverse ways of assessing threat as well as enabling a wider assessment of secondary impacts and compound risks?

It was also noted that within government, while cross-department cooperation is desirable in theory, it can be difficult to initiate and to institutionalise—this is true not only in area of risk assessment but in response as well. Issues to think about here include the role of events in driving policy, the fact that budgets matter (funds may have to be appropriated in a way that encourages cross-department cooperation to overcome each department safeguarding its own budget), and the degree to which cross-department interaction (and the broader biosecurity agenda) can be institutionalised within governments, especially as elected leaders change. It was also suggested that cross-department cooperation in threat assessment is essential if we are then to get cross-department buy-in to policies and response; for example it can be difficult to get a health department to act on a threat assessment if it does not agree with it; resources are limited and each department will give highest priority to the threats that it assesses as high.

Similar challenges exist for international cooperation on biosecurity, but everyone at the workshop agreed on its importance. National governments need to be aware that health threats can come from the outside, and this underlines the need for both national and international infrastructures that can promote responding to health threats where they emerge as opposed to waiting for them to become an issue at home (and this infrastructure needs to range from support for basic science to

vaccine development to emergency assistance in crisis). Just as cross-department risk assessment can provide a shared understanding of threat that enhances policy response, shared work on risk assessment internationally may also provide an improved basis for international action. The hope is that GHSA and other initiatives at the international level will allow more opportunity for this.

Burdens of biosecurity

The importance of appropriate risk assessment is usually discussed in terms of effective policy response, but the potential burdens of biosecurity for public health, industry and researchers provide another reason why appropriate risk assessment is important. In order to get buy-in from all the actors who can increase biosecurity, it is necessary to carefully assess the benefits of biosecurity improvements against their costs, and to weigh that against the threat. A process that can generate agreement on and knowledge about the shared threat seems likely to lead to more 'buy-in.' And as discussed further below, openly acknowledging uncertainty may be key to maintaining trust and involvement.

The discussion at the workshop raised many questions about the potential costs involved in biosecurity policies; many of these questions are not susceptible to technical answers but require political debate over the values involved.

- Has the emphasis on biosecurity skewed public health research priorities?
- Should we privilege disease outbreaks over diseases of attrition?
- How do you balance national security with other values, including scientific and academic freedom?
- How do we balance what might be lost (in economic and governance terms) from *not* pursuing a technology against the risks of new technologies that might pose security threats?
- Who should pay the costs of biosecurity policies? (Biosecurity does not scale well.)
- Should we—and if so how--increase the diversity of the policies that we consider as a response to bio-threats (e.g. to include basic health care, medical counter-measures, etc.)?
- How do we keep the public onside and maintain public trust in science and government?

Risk perception, communication, and policy

Communication is key to an effective response to an actual 'biological event,' whether it be bio-terrorism or a natural disease outbreak. Understanding the relation between risk-perception and behaviour, and how these interrelate with different styles of communication, is therefore important. Both heightened and low risk perceptions can lead to non-optimal behaviours that impede effective response; obvious examples include an unnecessary burden on public health resources on the one hand and low uptake on recommended behaviours on the other. While characteristics of the risk (e.g. familiar versus unfamiliar or natural versus technological) can influence risk perception, communication is also important. Research suggests that communication is more effective when it takes perceptions of the target audience into account. For example, if the public understands the threats and risks differently than the government, this difference in perception has to be recognised and addressed before government communication can be effective. A similar point could be made about communicating and working with other relevant actors: industry, academia, etc.

It is also important to understand how perceptions influence individual motivations to act: in particular, research suggests that risk communication needs to be targeted at specific behaviours and that the efficacy, ease and cost of recommended behaviours needs to be taken into account. As

one person said at the workshop, if Ebola is understood to be a death sentence, there is little incentive to get diagnosed.

Given the importance of both government representatives and medical professionals as sources of information for the public in a health emergency, communication between these two groups is critical both before and during an event. Again, this is something where the UK's nationalised health service may have an advantage in comparison to the US. In thinking about efforts at the international level, further thought is needed about how to optimize communication about biosecurity issues and how to adapt communication to local conditions, both in terms of what sources of information are trusted and how best to understand and influence local perceptions of threat and of the efficacy, ease, and cost of recommended behaviours to address that threat.

One speaker noted that the policy focus has to be on the management and mitigation of risk, not its elimination, which is impossible—and this ties into an important point about communication: Research suggests that the public's trust in the government and the credibility of a source depends on a willingness to acknowledge uncertainty and on an avoidance of overselling a government's capability to address threats. Recent US experience with risk perception surrounding Ebola, supports this research; when the government stated that there was zero risk or that Ebola would be "stopped in its tracks," and subsequently Ebola transmission occurred in the US, public trust was significantly lowered and the perceived risk from Ebola became much higher in the general population. This is important for all biosecurity issues—for disease outbreaks but also for public engagement in the regulation and development of new technology (e.g. synthetic biology).

Governing New and Emerging Technologies

As with other aspects of biosecurity policy, a shared understanding of risks is important for effective governance of new and emerging technologies. Much of the discussion of new technologies at the Workshop focused on the difficulties inherent in the attempt to predict the possible benefits versus costs of new technology. Some participants noted that the trend lines indicate that synthetic biology is currently too difficult and not advantageous for an adversary seeking to use biological weapons. Other participants were more concerned that synthetic biology is breaking down the expert and non-expert boundary and making malevolent use much easier.

There was also discussion of the difficulty and complexity of potential applications of advanced biological techniques for bad intent. The possibilities discussed ranged from easy (relatively) to difficult: from selecting for advantageous biological enhancements like antibiotic resistance or vaccine and diagnostic evasion; to manipulation of genetic material of existing pathogens to make them more virulent; to recombination of genetic material from different pathogens; to creation of wholly new pathogens in the laboratory. Participants noted that while concern about use of synthetic biology for ill is currently more focused on the easy end of the spectrum, as technology becomes more advanced and accessible, the more difficult applications may at some point come within reach of non-experts, including bad actors.

Risk assessment for such inherently unpredictable systems also becomes increasingly challenging. This is not a new issue in the bio sciences, as both the 1975 Asilomar conference on Recombinant DNA Molecules in 1975 and the recent 2015 International Summit on Human Gene

Editing make clear.[7] The uncertainties inherent in such prediction suggest we should focus on a shared and transparent process for assessing the risks and benefits, and, again, work on public communication suggests that it is important to acknowledge the uncertainties involved.

It was asserted that biotechnology has the potential to create new kinds of risks: both 'existential risks' that threaten our own civilisation and future generations, as well as risks that arise from the manipulation of processes of cognition development, reproduction and inheritance. Given the magnitude of the potential threats and the deeply political and ethical questions involved, this highlights the importance of a broad discussion and debate about these risks and possible policies to mitigate them—a debate that goes beyond 'technical' solutions to encompass the political and ethical values involved.

It was also suggested that future research should address how our understanding of technological development factors into our risk perceptions and policies. Just as different disease models may yield different estimates of the threat posed by a particular disease, different models of technological development may yield different understandings of the costs and benefits of regulating new technologies. In addition, the point was made that because science is dynamic, convergent, and collaborative, identifying threats or benefits requires understanding the driving forces of scientific development. We thus need to examine the role of states but also the role of industry and academia, and to assess economic incentives and constraints as well as technology 'life-cycles' and practicalities.

There is room for a comparative study of the best strategies and processes for the development of effective policies ranging from 'top down' international strategies to 'bottom up' approaches such as education and awareness, codes of conduct and self-governance were stressed as important measures alongside regulation, oversight, and domestic legislation. In addition to looking at the BWC and CWC and conferences on Recombinant DNA and Gene Editing, case studies could include the emergence and regulation of new technologies in other industries with dual use concerns. Such case studies could help us understand the strengths and weaknesses of different approaches as well as when different strategies are most likely to be successful. Specific questions include: Are codes of conduct effective? Have personnel reliability programmes been successful? What peer review processes are actually helpful in addressing the dual use problem? Which government regulations best address security concerns while still promoting innovative science? Overall, the need is to understand which combination of policies has the best chance of creating an effective response to the dynamic process of technological development.

Conclusions

This workshop provided a unique opportunity for discussion of the large range of biosecurity issues facing the UK, US, and international community, implications, and potential technical and policy solutions. The workshop discussion illuminated a number of topics that require more intensive discussion, particularly scientific development and implications for biosecurity, international response to epidemics of global concern, international cooperation on medical countermeasures development and testing, and the future of the Biological Weapons Convention. One topic that was

[7] For more information on the 2015 Summit see http://www.nationalacademies.org/gene-editing/Gene-Edit-Summit/index.htm; for the summary statement from the Asilomar conference, see Paul Berg, David Baltimore, Sydney Brenner, Richard O. Roblin, and Maxine F, Singer, 'Summary Statement of the Asilomar Conference on Recombinant DNA Molecules,' Proc. Nat. Acad. Sci. USA Vol. 72, No. 6, pp. 1981-1984, June 1975.

not directly addressed, but is nonetheless important was the effect of climate change on health and biosecurity. This workshop was a good step in further promoting cooperative action and discussion of these issues, but it should be the first of many such workshops aimed at sustaining this important international work.