

Pandemics and Dual-Use Research

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‘A plague on both your houses’.

William Shakespeare

Biological agents are not constrained by sovereign borders and can have a devastating effect either in the form of an infectious disease pandemic or as a result of scientific experimentation. This chapter analyses key issues and problems associated with biological security issues and dual-use research including governance arrangements to address those concerns.

PANDEMICS

Although a pandemic is determined by the spread of the disease rather than the number of deaths it causes, the mortality rates of global disease outbreaks are noteworthy particularly because of the wider impact on civil society and machinery of governance. For example, the first recorded outbreak of bubonic plague in 541–542 AD in Constantinople and Egypt known as the Plague of Justinian, resulted in approximately 50 to 60 % of the population dying. ‘The plague acted as a stressor or a solvent on the machinery of empire’ (Price-Smith 2009: 38), resulting in erosion of

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civil and state cohesion, prosperity and power. The 1918–1919 influenza pandemic had a mortality rate of 2.5% of those infected and, at the time it had the highest mortality rate since the fourteenth century plague known as the ‘Black Death’. More recently, according to the World Health Organization, almost 78 million people have been infected with the HIV virus and about 39 million people have died of HIV. Globally, 35.0 million (33.2–37.2 million) people were living with HIV at the end of 2013 (WHO 2016b). In 2005, avian influenza (H5N1) also known as ‘bird flu’ had a laboratory confirmed mortality rate of 60 % in those infected with the disease (WHO 2016c). In 2012 the Middle East Respiratory Syndrome (MERS) was first identified and it has a mortality rate of 36% in reported cases in twenty-six countries (WHO 2016d).

As noted above there are different types of infectious disease including different forms of influenza that have resulted in pandemics. An influenza pandemic occurs when key factors converge: an influenza virus emerges with the ability to cause sustained transmission from human-to-human, and there is very low, or no, immunity to the virus among most people. Biological risks arising from disease can be developed as part of natural processes or deliberately, and diseases can be spread unintentionally or intentionally. In the interconnected world of today, a localised epidemic can rapidly transform into a pandemic.

In the first half of the nineteenth century, cholera was prevalent throughout Europe. This resulted in an early example of the way a health issue was formally reframed within a politico-diplomatic context by actors outside the health sector. The spread of infectious disease became the subject of international diplomacy and it was raised at the first International Sanitary Conference in Paris in 1851 (Elbe 2010:163). In the twentieth and twenty-first centuries, the world experienced several infectious diseases that have had the potential to, or did, spread sufficiently to become a pandemic. In addition to health concerns, infectious diseases hold implications for human security as well as having several socio-economic implications that are not necessarily immediately evident, such as absenteeism, loss of productivity, and increased levels of insecurity in civil society.

The mortality rates of pandemics across different demographics and regions sometimes equate to those in war-zones, although the accuracy of mortality data can inhibit appropriate policy responses. Estimating the actual number of individual cases and deaths is challenging because, in addition to laboratories stopping testing when overwhelmed, many people do not seek medical care; secondly, only a small number of those who do

seek care are tested; and thirdly, more people who are hospitalised or die of pandemic-related causes are tested and reported. But under-reporting of hospitalisations and deaths occurs as well because they are not always accurately attributed to an epidemic or pandemic. This has implications for pandemic planners and implicitly means that any planning assumptions need to be rigorously objective and equally, civil society needs to be engaged as part of the planning process to ensure ongoing resilience in adverse circumstances. Fundamental to the planning process are the assumptions relating to the pandemic and the basis of those assumptions. Flawed assumptions can have significant policy and resource implications as well as potentially devastating effects on civil society. For example, planning for an Ebola pandemic based on the 1918–1919 influenza pandemic with its mortality rate of 2.5% of those infected, would be grossly inaccurate. Ebola has a mortality rate of approximately 50% of those infected (World Health Organization 2016a).

Following the re-emergence of H5N1 in 2003 and the outbreak of SARS in the same year, nation-states and relevant international institutions have invested in pandemic preparedness. While the World Health Organization has assisted with planning guidance, the ability of a state to respond depends on the extent of health resources, their disease surveillance capabilities, reporting system, health system surge capacity, and access to health facilities.

From a global perspective, because of the transnational nature of pandemics, international cooperation and coordination are critical elements. Consequently, the cross-border nature of pandemics has contributed to greater cooperation and information sharing and these are reflected, to some extent, in the 2007 International Health Regulations (Hagen 2013:165). The Regulations set out the obligations of member-states and the WHO in responding to cross-border public health risks. The IHR require countries to report certain disease outbreaks and public health events to the WHO. The regulations aim to prevent, protect against, control and respond to the international spread of disease while avoiding unnecessary interference with international traffic and trade. Under the IHR, States are required to notify the WHO of all events that may constitute a public health emergency of international concern and to respond to requests for verification of information regarding such events. Secondly, States are required to notify and report events and other information through their National IHR Focal Points to a regional WHO IHR Contact Points Focal points and Contact points must be available on a

24 hour-a-day basis, seven days a week. Thirdly, each State Party is required to develop, strengthen and maintain core public health capacities for surveillance and response by using existing national resources, such as the national plans for influenza pandemic preparedness.

The ethical and governance issues associated with a pandemic are equally complex. During a pandemic, few people's lives would be unchanged and many existing values would be challenged, such as freedom of movement, or the assumption that everyone would have equal access to antivirals and health services. The WHO recognised the importance of addressing ethical issues as part of governance arrangements related to a pandemic, and produced a series of discussion papers on key issues associated with pandemic preparedness. Following consultation with its 193 member-states, it subsequently produced public health response guidance in 2008 (Gadd 2013:182). Consideration of ethical issues may be further complicated if resources are limited. This may influence the extent to which a nation-state imposes mandatory measures, which would need to be monitored and enforced to be effective. The allocation of scarce resources leading to benefits for some people over others may conflict with expectations in civil society and generate further levels of anxiety and insecurity. This could have wider implications such as for the maintenance of law and order and general levels of safety in civil society, which in turn affect the authority of a nation-state and its governance.

Some nation-states, such as New Zealand, France, and Switzerland have a national ethics committee that has examined pandemic influenza as well as other problems. Yet many others do not, and they have not engaged in community consultation or provided guidance regarding ethical values for a pandemic and how to make associated decisions. Development of a social contract between governing institutions and civil society about critical issues and the roles, responsibilities and expectations of all actors concerned needs to be developed. Such an arrangement would go some way to mitigate insecurities and uncertainties associated with a pandemic.

INFECTIOUS DISEASES AND CONFLICT

Biological security issues are not a twenty-first century phenomenon. Infection disease has been associated with civil conflict and war over the centuries and it has been used deliberately as a form of biological warfare

by state and non-state actors. In 1763 the British army deliberately gave smallpox contaminated blankets to Native American Indians and in World War One, packhorses used by the Allies were targeted by the German military with disease-causing organisms to disrupt supply lines. At the time the French signed the 1925 Geneva Protocol,¹ they were also developing a biological warfare program to complement the chemical weapons program established in the First World War (Rosebury and Kabat 1947: 7–96). Similarly, the former Soviet Union commenced its biological weapons program in the 1920s although it too was a signatory to the 1925 Protocol.

In the Second World War, in addition to human biological experimentation carried out in Nazi Germany, the United States launched its biological warfare program to produce a number of biological agents such as anthrax, botulism, and plague. In Britain, programs were underway to develop anthrax spores and to develop a way to disseminate them when delivered with a conventional bomb, and between 1936 and 1944 Hungary conducted an offensive biological weapons program (Faludi 1988: 67–72). Outside Europe, a major offensive biological warfare program began in Japan and ran from 1931 to 1945. The Japanese tested biological agents on humans as well as employing biological agents in military field operations. In China, for example, artillery shells filled with germs were used. The Japanese human experimentation was largely conducted in China on Chinese prisoners of war. The Japanese developed capabilities to produce kilogram quantities of bacteria for plague, anthrax, typhoid, cholera, dysentery and other diseases (Dando 2006: 22–23). It is estimated that about 600 people died each year as a direct result of experimentation conducted by the Japanese Unit 731.

In the early 1980s the South African Defense Force is alleged to have begun a small-scale biological weapons program, primarily investigating *B anthracis* and *V cholerae*. The biological agents were allegedly used, but details are not available. The program was closed in 1993 after diplomatic interventions by the United States and the United Kingdom, coincident with the demise of the apartheid regime (Leitenberg 2001).

DUAL USE RESEARCH OF CONCERN

Some research experiments involving infectious pathogens have inherent dangers and are known as Dual Use Research of Concern (DURC). All life science techniques and discoveries might be inherently dual-use (Atlas

2009: 293–301) and biological DURC is of particular interest because it can have both beneficial and dangerous consequences. Almost all items necessary to produce lethal biological agents are dual-use, meaning they would be found legally in pharmaceutical laboratories or in biological weapons facilities.

In 2003, a panel of life science experts within the US National Academy of Sciences convened the Strategic Assessments Group. An unclassified report summary by the Central Intelligence Agency (Office of Transnational Issues 2003: 1) of the Panel's findings states in part, that, 'the same science that may cure some of our worst diseases could be used to create the world's most frightening weapons'. The report summary highlighted that the knowledge to develop some bio-weapons already exists. The Panel cautioned that because the processes, knowledge, techniques, and equipment for advanced bio-agent development were dual-use, it would be 'extremely difficult to distinguish between legitimate biological research activities and production of advanced bio-weapons agents'. On this point, there is little difference between the two manufacturing processes until a decision is made to produce a weapon rather than manufacture a vaccine (Thompson 2006: 6–7).

Mousepox

The skills, knowledge, and technology to create new viruses, and therefore potential bioweapons, are available in almost any biotechnology laboratory. A dangerous virus can be created, even unintentionally, as the following example demonstrates.

An experiment in 2001 by Australian scientists inadvertently showed that the virulence of the mousepox virus could be significantly enhanced by the incorporation of a standard immuno-regulator² gene. Although the goal of the research was benign, the results held dual-use concerns and implications for the development of future bio-weapons. In response to a mouse plague, scientists set out to create a strain of mousepox virus that would cause sterility in female mice. However, they accidentally found a way to genetically engineer the 100 % lethal mousepox virus, which is related to smallpox and is highly contagious. Inadvertently, the researchers genetically engineered a powerful virus which could kill mice that were naturally resistant to, as well as mice that had been vaccinated against, ordinary mousepox. Even those mice which had been vaccinated against

mousepox, fared badly with half dying immediately (Jackson et al. 2001: 1205–1210).

Until that time, biological weapons concerns had focused on the use of existing pathogens. However, the mousepox study demonstrated that not only was it possible to develop a lethal virus, but it also indicated that the necessary skills and capabilities were readily available. The scientists involved in the study raised concerns and debated about making the data public. The research was published in the *Journal of Virology* in 2001. This resulted in critics raising concerns that they had alerted would-be terrorists to new ways of making biological weapons and had provided them with explicit instructions (Selgelid and Weir 2010: 18). This study highlighted a number of concerns which were revisited 10 years later in the H5N1 experiments.

H5N1 Experimentation

The confluence of developments in biotechnology genetic engineering and technologies has added a further level of complexity regarding the governance and control mechanisms for the research and use of biological agents in the twenty-first century. Given the prospect of dual-use and progress in biotechnology, proliferation of biological weapons can be achieved relatively easily – particularly if there is intent. Gene-designed organisms can be used to produce potential bio-weapons. Concern about the development and use of biological agents in the twenty-first century has largely been focused on non-state actors. However, state funded research continues to raise concerns not necessarily about the initial intent, but of the potential for the research outcomes to be misappropriated, misused, or exploited.

For example, in 2011, two separate international research studies were funded by the US National Institute of Health to examine the mammalian transmissibility of highly pathogenic avian influenza (HPAI) H5N1 viruses. While the gain-of-function³ research is typically defined more broadly as a mutation that confers a new or enhanced activity to a protein, for the purposes of the two research studies, it refers specifically to those that increase the transmissibility, increase the pathogenicity, or alter the host range of HPAI H5N1 viruses (National Institute of Health 2012). Researchers at the University of Wisconsin in the United States and the Erasmus Medical Center in Rotterdam, Netherlands based their study around two questions regarding why the virus had not become a

human-to-human spreadable virus; and whether it was an event which could occur naturally.

In brief, they found that for it to become a human-to-human spreadable virus five mutations or tiny changes were necessary, and at that stage three changes had already been found in a single viral chain. They also found there was no impediment to the changes occurring. The two groups created mutant forms of H5N1 that could be transmitted between ferrets, and viruses that are easily transmissible between ferrets are often also easily transmissible between humans (Briseno and England 2013: 12–14).

While the research was assessed as having been conducted properly and under the safest and most secure conditions (Fauci 2012: 1–2), the issue that has been intensely debated is whether knowledge obtained from these experiments could inadvertently affect public health in an adverse way. There has been debate about whether the Precautionary Principle had been the guiding principle. Scientists generally have argued that the benefits of such experiments and the resulting knowledge outweigh the risks. This has been countered by a number of professional and institutional actors outside the scientific and health sectors who have expressed deep concern. The public nature of the debate also generated unease and concern within civil societies globally, and raised further concerns about accountability and control mechanisms (Resnik 2013; Shamo and Resnik 2009). By adopting the Precautionary Principle, the burden of proof rests with the scientific community to demonstrate that the research should be carried out and, importantly, that it be undertaken in a responsible way. It also requires that researchers consider the potential harms as well as the potential benefits of undertaking the research. Such considerations may result in limiting the proposed research to take account of ethical and professional values.

In the United States, the National Scientific Advisory Board for Biosecurity (NSABB) is responsible for advice, guidance, and leadership regarding biosecurity oversight of dual-use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. However, the NSABB does not have compliance powers. There is no international governing body to monitor or to advise on such issues and there are no overarching compliance requirements with the result that biological dual-use research of concern continues with few constraints. For example, in October 2013, Chinese scientists announced they had created new strains of the influenza virus in a bid to develop vaccines. The announcement generated international criticism including from former president of the

UK Royal Society, Lord May, who denounced the work of the team under Professor Chen Hualan, Director of China's National Avian Influenza Reference Laboratory. While the research was reportedly conducted in a laboratory with the second highest security level to prevent the virus escaping containment, May is reported to have said: 'The record of containment in labs like this is not reassuring. They are taking it upon themselves to create human-to-human transmission of very dangerous viruses. It's appallingly irresponsible' (Connor 2013).

INFECTIOUS DISEASES AS BIOLOGICAL WEAPONS

Biological agents include bacteria, viruses, and toxins that have the potential to cause major public health impacts; cause widespread panic and/or social disruption; are readily communicable, and have high mortality rates (Chang and Blackmond Laskey 2008: 1–5). The US Centers for Disease Control and Prevention (CDC) has identified several categories of biological agents that could be used to initiate a terrorist attack. The CDC lists eighteen agents considered to be potential bio-terrorism threats with anthrax, botulism, plague, smallpox, tularemia⁴ and viral haemorrhagic fevers which have the highest potential for lethal impact (for example Ebola and, Marburg) identified as 'Category A'. The CDC notes that these high-priority agents pose a risk to national security because they

- can be easily disseminated or transmitted from person to person;
- result in high mortality rates and have the potential for major public health impact;
- might cause public panic and social disruption; and
- require special action for public health preparedness.

Delivery Systems

Both nation-states and non-state actors have an ongoing interest in the development and use of biological agents and the use of infectious bacteria as bio-weapons. The main past impediment has been effective delivery systems, and the difference between the delivery requirements of non-state actors and nation-states is worth noting (Ackerman and Moran 2006: 4). To achieve the strategic effect of diminishing military capability on the battlefield it would be necessary to have uniform, stable aerosol droplets containing trichothecene mycotoxins.⁵ However, non-state actors may

seek to cause fear and chaos in civil society and therefore would not require such consistent delivery, and a less effective delivery of a less exotic agent, such as ricin, might serve their purposes.

A decision to weaponise a biological agent means it needs to be prepared in a form that can readily infect people and then be delivered efficiently to its target. The choice of biological agent will influence the delivery system. For example, a non-contagious disease like anthrax would require a sophisticated delivery system to disperse the agent over a wide area because every victim would have to come in contact with the agent. However, the delivery system for a contagious disease, such as pneumonic plague or smallpox, would not need to be highly sophisticated because it would only be necessary to infect a small number of people. After that the initial victims would themselves spread the disease to others. Highly contagious and lethal pathogens can present an even greater danger than nuclear weapons in that they are not limited to the geographical target area, and can continue to spread indefinitely.

Based on past examples of the unsuccessful deployment of biological weapons, there has been a view that there is relatively little future threat of their use by non-state actors. However, the ability to obtain a pathogen, weaponise the agent, and employ or disperse the weapon needs to be considered in terms of capability and intent. As groups such as Al Qaeda, Daesch, and ISIS (Islamic State of Iraq and the Levant), and nation-states gain capability, the overall level of risk and threat to nation-states and to their civil societies increases. Relatively low barriers to entry combined with the high impact potential of bio-weapons are important considerations. Both chemical and biological weapons can be less expensive to manufacture and require fewer infrastructures than nuclear weapons. The availability of open-source information and material, developments in biotechnology sciences, and inexpensive equipment, make the production of bioweapons an attractive option for non-state actors, and some nation-states (Office of Technology Assessment 1993: 38). The Rajneeshee cult, which attempted to use salmonella to achieve a political outcome in the US state of Oregon in 1984, obtained pathogens legally from culture collections (Carus 1984: 118–135).

The release of harmful biological agents has the potential to cause significant damage to civil society and the way it operates. Consequently, it is imperative that a nation-state has appropriate preparatory and response measures in place to ensure the resilience of civil society, and that insecurities are minimised.

When looked at in a holistic systemic way these cases crystallise a number of the issues associated with biological challenges including the potential adverse use of biological agents and their effect on civil society. Clearly, knowledge gained from the experiments is valuable and can be used to inform future pandemic planning. However, the global research community is no longer as tightly knit as it used to be, and access to research experiments and studies is now more easily obtained and potentially can be used for adverse effect. In a statement in 2011 before the Senate Committee on Homeland Security and Governmental Affairs, Assistant Director, Weapons of Mass Destruction Directorate Federal Bureau of Investigation, Vahid Majidi reported that the FBI was concerned that many US biological and medical laboratories were vulnerable to insiders based on several incidents involving the illicit acquisition of bacterial and viral cultures. He further reported that there had been numerous attempts to utilise biological toxins to threaten, injure, or kill individuals. In addition the FBI was concerned about the availability of those agents for potential criminal use and that the biological threat is further increased with advances in technologies in the biological sciences that have become more powerful, cheaper, and readily available to much wider audiences (FBI 2011). A subsequent report by UNICRI highlighted that research developments in this area could rekindle military interest in biological weapons and potentially undermine existing national and international oversight regimes (UNICRI 2012). Within this context, relevant legislative and policy controls over such types of research require consideration, such as appropriate security measures and personnel screening at a local level and international controls over the shipment of pathogenic (disease-causing) organisms.

CONTROL AND VERIFICATION MEASURES AS A FORM OF RESILIENCE

In 1925, following World War One, nation-states developed a specific international ban on the use of chemical and biological weapons. Nation-states further strengthened this prohibition with agreement of the Biological Weapons Convention in 1972 and the Chemical Weapons Convention in 1993. Nonetheless, pathogens can be deployed against military forces, and they can be used against civilians. This means that pathogens themselves, as well as military threats, can be a core security concern and undermine resilience of civil societies.

The governing Convention for biological agents is the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*. It was developed to establish a new instrument that would supplement the 1925 *Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare*, known as the Geneva Protocol. The Convention was opened for signature in 1972 and entered into force in 1975. Notwithstanding that previous biological weapons had demonstrated their potential effectiveness, when the Convention was negotiated in the 1970s there was a perception that they had little military utility. The Convention in its title and in Article 1 does not explicitly prohibit the ‘use’ of biological weapons. However, the final Declaration of the 1996 Treaty Review Conference reaffirmed that although ‘use’ was not explicitly prohibited under Article 1 of the Convention, it was still considered to be a violation of the Convention.

Compliance with the Convention is self-regulatory and there is the possibility of investigation by the UN Security Council of alleged breaches. All States Parties are expected to be in compliance with the Convention as they are legally bound to implement it fully and comprehensively. However, as noted earlier in this Chapter, there has been evidence that since the Biological and Toxic Weapons Convention (BTWC) entered into force, some signatory nation-states have developed biological weapons programs.

A key issue is the degree of transparency associated with research activities in the biological sciences undertaken by a nation-state, industry, or academia. Greater transparency would assist in ensuring appropriate ethical and safety considerations, encourage best practice, mitigate against ill-intentioned and nefarious activities, and any dual-use nature of research activities (Walther and Whitby 2012). However, levels of transparency vary between nation-states and within institutions, and this undermines attempts to achieve common norms, partnerships and thus, international security.

One of the major criticisms of the Convention is that it has no provisions for verification or for monitoring compliance. After several review meetings at which the persistently divergent views of States Parties hindered progress, it was not until 2006 when the Sixth Review Conference was reportedly successful in reviewing the Convention and adopting a final document by consensus (United Nations Office for Disarmament Affairs 2013). The States Parties adopted a plan for promoting universal

adherence, and decided to update and streamline the procedures for submission and distribution of the Confidence-Building Measures.⁶ Nonetheless, there is still no verification regime, and compliance remains self-regulatory.

In recognition of the limitations of formal institutions to achieve progress in this area, a group of non-governmental organisations concerned at the failure of nation-states to fortify the norm against the weaponisation of disease was established in 2003. The BioWeapons Prevention Project (BWPP) is a global civil society activity that aims to strengthen the norm against using disease as a weapon. The BWPP tracks governmental and other behaviour that is pertinent to compliance with international treaties and other agreements, especially those that outlaw hostile use of biotechnology. The project works to reduce the threat of bioweapons by monitoring and reporting throughout the world. BWPP supports and is supported by, a global network of members drawn from the Americas, Europe, Africa, Asia, and Oceania. While the work of this group and the Australia Group are commendable they, like the Convention, lack the ability to enforce compliance or to implement sanctions for non-compliance. To some degree the NSABB in the United States provides a model for other nation-states notwithstanding its lack of compliance powers. However, globally there appears to be a lack of policy development and an apparent lack or absence, of policy debate regarding oversight of dual-use research.

CONCLUSION

The geopolitical environment of the twenty-first century has been challenged in an unprecedented way by a number of transnational security issues including from biological sources which are evident at a nation-state as well as at a global level. Nation-states have different levels of governance arrangements, capacity, capability, and resources to deal with infectious diseases as pandemics or dual-use research of concern which could be used to create biological weapons. The way forward could include mechanisms and strategies at a civil, national and global level addressing community communication, ethical, policy, and definitional issues as set out briefly below.

First, there is an unexplored opportunity for a nation-state to take the initiative by beginning an incremental public conversation about the risks associated with biological research and potential bioweapons threats. This

could lead to the development of a social contract between governing institutions and civil society. However, it is unclear whether nation-states through their political elites and civil society are sufficiently robust to allow public debate about the risks arising from biological challenges and potential threats to civil society, particularly regarding the tipping point of dual-use research and potential bioweapons.

Development and implementation of such an engagement strategy would require input from a spectrum of areas and disciplines. While such an approach may be fraught with difficulties and obstacles, the initial stage of the process would be to engage with representative individuals and interest groups about the way decisions are made, and then to develop strategies for wider engagement with civil society. Engagement directly with civil society about issues such as the way decisions are made would further provide an opportunity to raise and to address complex ethical issues associated with response planning and implementation of decisions.

Secondly, consideration could be given to the establishment of National Security Ethics Committees – drawing on models already established and outlined earlier in New Zealand, France, and Switzerland – to explore and to provide advice and guidance for the development of relevant policies about biosecurity issues. Collaboration between such Committees would assist in achieving global consistency. A global framework would address the ethical issues associated with contemporary biological security concerns which do not appear to be considered in the current policies of a number of nation-states.

Thirdly, biological research studies would benefit from the development of a comprehensive policy framework which would include clear guidance and make explicit the Precautionary Principle. Such a policy framework would clarify the existing situation where issues of responsibility rest primarily on the integrity and professional responsibility of individuals, or their affiliated institution. Such a policy approach would also contribute to greater resilience and the reduction of insecurity.

Another aspect of policy consideration concerns the challenges associated with lower barriers of access to the information, materials, and resources necessary for the development and production of bio-weapons by non-state actors. Development of relevant policies and protocols with input from the research community and the professional national security sector could be a positive step towards limiting production. Signatory Member States to the Biological and Toxic Weapons Convention could take a more active role in establishing verification protocols. Those

Member States which also participate in the Australia Group could leverage their participation to achieve this goal. Biological concerns associated with scientific developments and experiments such as synthetic biology, dual-use research, and gain-of-function research have added a new level of complexity and challenge for policymakers. While a number of nation-states appear to be quite well prepared to deal with an epidemic or a pandemic, many lack policy structures to deal with more complex aspects of dual-use research. Individual nation-states could review their definitions of biosecurity to reflect more accurately the complexities of biological security challenges. The definition of biosecurity developed by the Federation of American Scientists (Federation of American Scientists, 2012) provides an appropriate foundation. The FAS defines biosecurity as

any measure aimed at preventing the purposeful misuse of science. It includes measures to prevent access to dangerous pathogens and toxins as well as raising barriers to the production or use of bioweapons. Beside such typical security measures, it includes basic awareness efforts that decrease the possibility of people misusing science from within the academic research community.

While these proposed steps would not provide a perfect solution, they would offer a positive and constructive way forward to reduce insecurity and to enhance resilience within nation-states and globally.

NOTES

1. The 1925 Geneva Protocol refers to the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare. The Protocol prohibits the use of chemical and biological weapons in war. The Protocol was drawn up and signed at a conference which was held in Geneva under the auspices of the League of Nations from 4 May to 17 June 1925, and it entered into force on 8 February 1928.
2. Immuno-regulation is the control of specific immune responses and interactions.
3. Gain-of-function research uses experiments to introduce or amplify a gene product. This type of research is intended to increase the transmissibility, host range, or virulence of pathogens.
4. Tularemia is a disease of animals and humans caused by the bacterium *Francisella tularensis*. Rabbits, hares, and rodents are especially susceptible

and often die in large numbers during outbreaks. Humans can be infected and it can prove fatal.

5. The trichothecene mycotoxins are a group of toxins that occur as contaminants from mould or may occur naturally in foodstuffs or in livestock feeds.
6. Confidence-building measures were developed between military alliances during the Cold War to avoid nuclear attacks by accident. They have widened into other areas, military and non-military. The United Nations Office of Disarmament Affairs (UNODA) identifies CBMs in three categories: information exchange; observation and verification; and military constraint.

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