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Executive Summary

- The main drivers in the UK's biosecurity risk landscape are rapidly changing
- New and emerging biotechnological developments, enabling lower cost manipulation of pathogens with increasing technical ease, present a key biosecurity risk
- There is an urgent need in the UK to understand the entire range of biosecurity risks and develop effective and sustainable solutions to address modern biological threats
- By leveraging existing domestic expertise, biosecurity risk reduction in the UK will not only be achievable but help support the growing UK bioeconomy
- Through an expert group meeting on 23 August 2019 at the University of Oxford, the inquiry topics were considered in detail and four key recommendations emerged:
    1. **Appoint a liaison** between the biosciences and security communities
    2. **Assign responsibility** for dual-use research and technology to a Minister in the Home Office
    3. Form a **Biosecurity Leadership Council** to serve as a central convening point for all UK biosecurity stakeholders
    4. Establish a **National Centre for Biosecurity and Biosafety** to drive forward positive culture change in industry and academia

Background

On 23 August 2019, fifteen expert academic researchers and biosecurity practitioners from a diverse range of fields, ranging from global health law, mathematical biology, medicine, public health, bioterrorism prevention, infectious disease modelling, synthetic biology and bioethics, met at the University of Oxford to discuss the UK Government's approach to emerging infectious diseases and bioweapons, and ways it could be improved. This inquiry was acknowledged as important and highly relevant to the work areas of all participants and the workshop centered around the topics specified in the inquiry's terms of reference. In generating recommendations, 46 ideas were initially long-listed by the group. Through discussion and debate over the

course of the four-hour workshop, eight short-listed topics were examined in detail, and four final recommendations emerged and were endorsed by the participants.

A summary of the main points of discussion on the seven inquiry topics is presented below, followed by those key recommendations.

Inquiry Topics

A) Main Drivers of Biosecurity Risks to Human Health

1. There is a broad trend of biosecurity risk increasing over time due to a rise in both event likelihood and potential impact. However, there are distinctions in the main drivers behind **natural**, **accidental** and **deliberate** biological threats:

    a. The majority of naturally emerging infectious diseases in humans originate from animals and the frequency of spillover into human populations is increasing over time.[1]

    b. Accidents in laboratories doing research on pathogens with pandemic potential could increasingly be a source of high-consequence disease outbreaks if breaches of biosafety protocols are not brought to zero.[2]

    c. Ongoing developments in synthetic biology and biotechnology enable the production of dangerous pathogens with greater ease at decreasing cost, widening the pool of actors with the capability to carry out a deliberate biological attack.[3]

2. There are three main drivers of risk associated with contagious human diseases: **transmissibility**, **lethality**, and availability of **effective countermeasures**. While natural pathogens like influenza can cause devastating pandemics, there is an increasing concern that the accidental or deliberate release of an engineered pathogen, manipulated to be more deadly, more contagious and/or to resist existing countermeasures such as vaccines, could have even greater catastrophic consequences for human health.

3. **Dual-use research**, so-called because it offers benefits to society but can also cause harm through accidents or deliberate misuse, is a driver of modern biosecurity risks. Dual-use research comes in many forms, including experiments of concern that modify pathogens to have greater pandemic potential or resist medical countermeasures such as vaccines. Dual-use research can also drive risk primarily through spreading **information hazards**, where it is not biological material itself that is the research risk, but information enabling someone to cause harm.[4]

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[1] Jones KE, Patel NG, Levy MA, Storeygard A, Balk D, Gittleman JL, et al. Global trends in emerging infectious diseases. Nature. 2008;451(7181):990. Available here.

[2] Peng H, Bilal M, Iqbal H. Improved biosafety and biosecurity measures and/or strategies to tackle laboratory-acquired infections and related risks. Intl J of environmental research and pub health. 2018 Dec;15(12):2697. Available here.

[3] Mukunda G, Oye KA, Mohr SC. What rough beast? Synthetic biology, uncertainty, and the future of biosecurity. Politics and the Life Sciences. 2009 Sep;28(2):2-6. Available here.

[4] Lewis G, Millett P, Sandberg A, Snyder-Beattie A, Gronvall G. Information hazards in biotechnology. Risk Analysis. 2019

4. **Dual-use technology** also poses a significant and growing biosecurity risk. For example, DNA synthesis and gene editing technologies enable beneficial scientific research in the UK, but could also be misused to synthesise dangerous pathogens using freely available genomic data and published techniques. For example, an extinct orthopoxvirus was recently synthesised using online genomic data and mail-order DNA.[5] This raises the concern that a cousin of this virus, smallpox, which killed more than 300 million people in the twentieth century alone before eradication in 1980, could one day be synthesised for use as a bioweapon without needing access to a source of live virus.

B) Risk Monitoring and Assessment

5. The biosecurity risk landscape is rapidly changing as new technologies emerge and converge, highlighting the need for risk monitoring and assessment to be an ongoing process. For example, **cyberbiosecurity** is a new discipline for detecting vulnerabilities and enhancing security in the biological sciences. However, cyberbiosecurity risks are currently poorly understood, acknowledged or addressed in the UK setting.[6] While cyber security leadership in the UK is in the mandate of the National Security Secretariat, cyberbiosecurity is not addressed in the UK National Cyber Security Strategy 2016-2021, indicating this risk is not currently being monitored or assessed at the highest levels of government.

6. To address modern biosecurity threats, there needs to be **comprehensive mapping** of the current risk landscape. For example, a large range of current biotechnology could be misused by a careless or nefarious actor, and there is currently no systematic structure for assessment, regulation and governance of new emerging biotechnology which may pose a threat.[7]

7. Monitoring and assessment of potential dual-use research is required at **all stages of the research cycle**, including grant application, experiment and publication phases. However, there is currently little clarity amongst UK scientific researchers, funders and journal editors about roles and responsibilities in maintaining oversight of dual-use research.

8. It is important to recognize that emerging biosecurity risks may not fit into the pathogen-causing-human-disease paradigm. Other forms of biological agents could harm human health and biological attacks directed at non-human animals or plants could massively disrupt the UK economy and food supply. **Risk assessment needs to be comprehensive** and consider the potential for deliberate bioterrorism, agroterrorism and other emerging threats to the growing UK bioeconomy.

May;39(5):975-81. Available here.

[5] DiEuliis D, Berger K, Gronvall G. Biosecurity implications for the synthesis of horsepox, an Orthopoxvirus. Health security. 2017 Dec 1;15(6):629-37. Available here.

[6] Millett K, dos Santos E, Millett P. Cyber-biosecurity Risk Perceptions in the Biotech Sector. Frontiers in Bioengineering and Biotechnology. 2019;7:136. Available here.

[7] Chubb J, Montana J, Stilgoe J, Stirling A, Wilsdon J. A review of recent evidence on the governance of emerging science and technology. Wellcome Trust. 2018 Nov. Available here.

9. Biosecurity risk monitoring in the UK has the potential to become more comprehensive and effective through the utilisation of emerging **biosurveillance tools**.[8] For example, the increasing accuracy and declining cost of whole-genome sequencing and metagenomics techniques could lead to a revolution in environmental biosurveillance capabilities. A targeted strategy is needed in the UK for identifying and funding further technological developments in this area and assessing the most effective timelines for their implementation. Encouraging the development of biosurveillance tools could enhance biosecurity risk monitoring in the UK and internationally while also supporting the growing UK bioindustry to play a leading role in this field.

10. It is necessary to look beyond the short-term for emerging threats and opportunities to address them. Regular synthetic biology and biotechnology **horizon scanning** exercises could examine how plummeting costs and growing capabilities in DNA synthesis will shape UK biosecurity risks over the next decade. For example, the UK company Nuclera Nucleics is developing a benchtop DNA printer capable of enzymatic DNA synthesis far superior to chemical synthesis processes, with the potential to reduce numerous barriers to DNA synthesis. While such developments are beneficial to the UK's growing bioeconomy, they also may bring risks if there is not oversight. Horizon scanning should enable timely development and implementation of legislative and policy responses to emerging risks identified.

C) Domestic Preparedness and the 2018 Biosecurity Strategy

11. With the upcoming **British exit from the European Union**, ensuring adequate biosecurity measures is increasingly important. While the 2018 Biosecurity Strategy covers a range of domestic preparedness initiatives being undertaken in the UK, there is a lack of mention of some biosecurity risks associated with Brexit, such as those posed by land borders in Northern Ireland and Gibraltar. Other specific biosecurity vulnerabilities not mentioned include the potential for medical countermeasure shortages and changes to international surveillance data sharing mechanisms. Comprehensive risk mapping is needed, and while there was a Brexit assessment done on animal and plant biosecurity,[9] there has not been one completed on biosecurity related to human health.

12. The 2018 Biosecurity Strategy does not address the emergence of biosecurity-relevant **intersections of technology**, such as those brought by the convergence of cybersecurity and biotechnology. There is an urgent need for this, exemplified by the 2018 cyber-attack on the Genomics England 100,000 Genomes Project to access NHS patient genetic data.[10] Biological data vulnerabilities present a range of biosecurity risks and need to be addressed in future UK policy.

13. Dual-use research mapping and horizon scanning are not addressed in the 2018 Biosecurity Strategy, and while the Strategy states that a **central government point of contact** for dual-use research will be

[8] Kilianski A, Roth PA, Liem AT, Hill JM, Willis KL, Rossmaier RD, Marinich AV, Maughan MN, Karavis MA, Kuhn JH, Honko AN. Use of unamplified RNA/cDNA–hybrid nanopore sequencing for rapid detection and characterization of RNA viruses. Emerging infectious diseases. 2016 Aug;22(8):1448. Available here.

[9] House of Lords European Union Energy and Environment Sub-Committee. Brexit: Plant and Animal Biosecurity. 2018 Oct 24. Available here.

[10] Teiss. Hackers mounting cyber-attacks to access DNA data of thousands of Brits. 2018 Dec 7. Available here.

created, this has yet to occur. Currently, there is no individual within government to serve as a point of contact or have ultimate responsibility for dual-use research and technology.

D) Role of Private and Academic Sectors

14. The UK bioeconomy is strong and on a trajectory to continue growing. Through public-private partnerships, the UK can **leverage its existing expertise** in both the academic and business sectors to contribute to biosecurity solutions. For example, the UK is home to companies such as Oxford Nanopore which, if harnessed to their full potential, could revolutionise biosurveillance and showcase British excellence in biosecurity innovation to the world.

15. While biosafety training is championed in UK institutions, biosecurity education remains low. Where there is awareness, UK researchers largely want to contribute to biosecurity efforts. Initiatives that have received support include the Bradford University's "Preventing Biological Threats: What you can do" and Biosecure and Bath University's online course "Next Generation Biosecurity: Responding to 21st Century Biorisks."[11] Commitment for continued support and expanded reach for these initiatives from the UK government could dramatically **improve biosecurity awareness**.

E) Roles and Responsibilities of the UK Government

16. To build resilience in the UK's approach to biosecurity, a **process for accountability** needs to be established to monitor implementation of the 2018 Biosecurity Strategy's objectives, inclusive of an ongoing scrutiny role for parliament.

17. Despite the infamous incident in 2006 where The Guardian newspaper mail-ordered a short smallpox DNA sequence to a residential London address, there are still currently no guidelines, legislation or regulation in the UK concerning **screening of commercially synthesized DNA** before it has been sold. To reduce biosecurity threats from dual-use technology, rigorous gene sequence and customer screening are recommended by various bodies including the International Gene Synthesis Consortium.[12]

18. There needs to be a ministerial level of ultimate responsibility for **oversight of dual use research** with high misuse potential.

19. The Health and Safety Executive should be leveraged to draft technical guidelines to assist in **evaluating the risks** associated with emerging dual-use technologies.

F) Cross-Government Scientific and Technology Expertise

20. The UK Government can draw upon existing cross-government expertise to **create a roadmap to next-generation biosecurity and deterrence technologies**, including broad spectrum drug

[11] Bradford University's Preventing Biological Threats: What you can do (2015) available here and Biosecure and Bath University's online course "Next Generation Biosecurity: Responding to 21st Century" available here.

[12] International Gene Synthesis Consortium. Harmonized Screening Protocol v2.0: Gene sequence and customer screening to promote biosecurity. 2017 Nov 19. Available here.

development, platform-based diagnostic technologies, and meta-genomic environmental sequencing. This could support UK industry by leveraging domestic technological expertise at leading biotechnology companies.

G) Opportunities and Challenges in International Collaborations

21. Infectious diseases do not respect international borders and vulnerabilities in health systems around the world pose a direct biosecurity threat to the UK. The 2018 Biosecurity Strategy states that the UK has given £16 million for International Health Regulations (2005) capacity building, but this small amount, representing only 0.12% of the annual DFID budget, will not go nearly far enough to accomplish what is needed to help strengthen health systems in developing nations. Larger, substantive commitments could help **strengthen health system preparedness** around the world.

Four Key Recommendations

The final outcome of our discussion of how the UK Government, in collaboration with private and academic sectors, can most effectively promote the objectives of the UK Biological Security Strategy, prioritised four recommendations. While these are presented separately, they are complementary and would have a greater impact in combination.

A) Appoint a liaison between the biosciences and security communities

22. We recommend the **appointment of a liaison** to act as a 'human bridge' between the UK biosciences and security communities. Sitting within the Home Office, such a person would help advise, build relationships and support connections across law enforcement and intelligence agencies, academic and private sector research communities, and UK do-it-yourself laboratories. This liaison could also help bridge UK cross-government biosecurity activities undertaken between the Home Office, Defra, and the Department for Health and Social Care.

23. As a model, a similar role exists in the US system, held by a Supervisory Special Agent in the FBI's Weapons of Mass Destruction Directorate, Biological Countermeasures Unit charged with building partnerships with the life sciences community.[13]

B) Assign responsibility for dual use research and technology

24. We recommend assigning a Minister within the Home Office with the **ultimate responsibility of oversight on dual-use research and technology** in the UK. This Minister could oversee an independent body or regulator tasked with mitigating dual-use biosecurity risks.

25. While some risks identified by the National Security Secretariat in the National Risk Assessment are assigned to specific Departments, there is currently no department or individual within government taking responsibility for addressing the risks associated with dual-use research and technology, nor acting to address future dual-use risks that may arise. Assigning a Minister and independent body with this responsibility will serve to address this gap.

[13] Hummel K. FBI Biological Countermeasures. 2017 Aug. Available here.

C) Form a Biosecurity Leadership Council

26. We recommend the formation of a **Biosecurity Leadership Council**, modelled after the UK Synthetic Biology Leadership Council,[14] which could serve as a central convening point for all UK biosecurity stakeholders.

27. Such a Council, co-chaired by individuals internal and external to Government, could have as its mandate to establish a two-way system of information flow, drawing in expertise from individuals and groups across the biosecurity ecosystem to inform UK biosecurity policy, and directly outreaching to the main audience(s) for this policy.

28. The Council could also conduct a comprehensive biosecurity risk and opportunity mapping process. This would help to identify gaps in understanding and key priorities for biosecurity-relevant academic research and development and contribute targeted policy recommendations as the risk landscape evolves.

29. The Council could oversee the inclusion of biosecurity considerations into research ethics committees and lead on education and structured outreach to the next generation of biosecurity leaders. Through the inclusion of participants from multiple disciplines and sectors and use of structured subcommittees, UK biosecurity governance could be showcased as a standard of excellence internationally.

D) Create a National Centre for Biosecurity and Biosafety

30. We recommend the creation of a **National Centre for Biosecurity and Biosafety**, mandated with the creation of resources and protocols for academic and private sector researchers, biosecurity practitioners, and individuals working in do-it-yourself biology laboratories.

31. This Centre could be modelled after the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs),[15] which has led the way for changes to the use of research animals in the UK. The National Centre for Biosecurity and Biosafety would be able to lead cultural change on biosecurity awareness and change practices around laboratory accident reporting. Such a Centre would also serve as an exemplary model and biosecurity material resource for UK international partners.

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[14] UK Synthetic Biology Leadership Council. Available here.
[15] National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). Available here.