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NTI-GHSN Biosecurity Competition Proposal: Addressing Biosecurity and Associated Technological Risks by Creating a Database to Knowledge-sharing and Utility

Abstract

To augment the International Health Regulations (IHR) 2005, a legal instrument recognized by the WHO, the Global Health Security Agenda (GHSA) was launched in 2014 as a framework to pursue nine related objectives under aims to detect, prevent, and respond to future infectious disease outbreaks and related preparedness. As in IHR, GHSA has a biosafety and biosecurity (BS&S) objective to promote these practices at a national level. Using existing biosecurity best practices, standards, and policies, our proposal aims to outline related research and learning to inform national policy development and create a novel platform for networking across sectors and regions to achieve GHSA and JEE biosecurity objectives. In order to effectively implement the GHSA, one must recognize that there are clear biosecurity gaps in both the GHSA and JEE. Our goal is to create a model for next generation biosecurity professionals to engage with experts in the field by means of a question and answer forum, as well as the creation of a centrally located database of biosecurity resources and tools to assist users in achieving the biosecurity targets within the GHSA and JEE. The biosecurity forum and resources will be accessible both globally and remotely to build knowledge-sharing across the veterinary, and biotechnology research sectors and two countries from the former Soviet Union region.

Introduction

As in IHR, GHSA has a biosafety and biosecurity (BS&S) objective to promote these practices at a national level. To assess a country's GHSA-related objectives, partnerships are formed where one country performs a joint external evaluation (JEE) of another country's capacities (1). To date, fifty-four countries have completed JEEs (thirty-five full reports and eleven executive summaries published), with an additional twenty-three scheduled for the remainder of 2017 and 2018. Thirteen roadmaps have also been developed to plan activities in support of GHSA activities and IHR.

Although BS&S is related to each of the GHSA's nine objectives, there are two challenges to assessing BS&S under GHSA JEE. One, the BS&S items are blended so neither biosafety nor biosecurity best practices are addressed individually; and two, the topic of reducing biological risks related to technological advances, such as gain of function (GOF) and dual use research of concern (DURC), are new and lack formal guidance. Furthermore, biosecurity, especially laboratory based biosecurity, as related to reducing biological risks introduced by technological advances is not prioritized at the same level among, low, low-middle, middle-high, and high income countries as defined by World Bank.

In order to effectively implement the GHSA, one must recognize that there are clear biosecurity gaps in both the GHSA and JEE. The JEE, via GHSA's Prevent 6 aim: Biosafety and Biosecurity, addresses the need for a whole-of-government national biosafety and biosecurity system though a national framework and comprehensive oversight system for pathogen control (2). Through the JEE, these systems are generally found to require significant improvement; however, improvements in these areas are challenging to develop and require access to information and resources that are often difficult to locate, especially for those in resource-limited settings. We aim to create a centrally accessible database for next generation biosecurity professionals to engage with experts in the field by means of a question and answer forum, and provide laboratory biosecurity and related research type resources to assist users in achieving

the biosecurity objectives within the GHSA and JEE. Our vision is to stimulate knowledge-sharing and encourage networking across the public health, veterinary, and research sectors, and via the team's initial connections across the USA and former Soviet Union and later building into West Africa, Southeast Asia, and Europe.

Proposal Details

To further achieve the GHSA and JEE biosecurity targets, and to incorporate the rapid changes of reducing biological risks related to technological advances, our team consists of three individuals who all have current membership in the Next Generation GHS network. Our team lead (Ashley Tseng) is currently enrolled at an academic institution (McGill University) and our other two team members are current professionals in the field of global health security. Lyzzat Musralina is a Scientific Researcher in the Population Genetics Lab at the Institute of General Genetics and Cytology in Kazakhstan. Elshad Rzayev is the Deputy Director of the Republican Veterinary Laboratory (RVL), a national level BSL-2 facility under the Ministry of Agriculture of the Republic of Azerbaijan. Ms. Tseng is also a student mentee in the current NextGen GHSA's pilot mentoring program; Ms. Musralina and Dr. Rzayev both have extensive experience in global health security working in the US Dept. of Defense Cooperative Biological Engagement Program (CBEP). We addresse two sectors: biotechnology research and veterinary medicine in the USA, Kazakhstan and Azerbaijan. Our team also received advice and insight from three active professionals (Martin Adams, GSS Health; Dr. Edith Marshall, Washington State University; and Kenneth Yeh, MRIGlobal) who are also members of the Next Generation GHS network.

Our proposal has three facets: 1) to create a database of reliable, pre-existing laboratory biosecurity tools, research/training guides; 2) to create a glossary of biosecurity terms and acronyms in multiple languages to simplify international communication and collaboration; and 3) to create a laboratory biosecurity assessment tool to aid in awareness and education of potential biological risks posed by advancements in technology. Eventually our team plans to host our collection of biosecurity resources on an existing website, such as a local biosafety association pending agreement, to further encourage user ownership while minimizing the operational costs and maintenance upkeep.

The first facet of our proposal identifies and presents existing tools, so we plan to produce a database similar to the GHSA's Action Package Prevent 3 Biosafety and Biosecurity Resource Catalogue, but our database will be further tailored to next generation biosecurity professionals who may be familiar to the practice but lack the implementation experience. Most of the BS&S resources listed in the GHSA's catalogue are not applicable to low-income and low-middle income countries especially those that require a fee to use and available in limited languages. In addition, the lack of contact information limits the utility by users in those resource limited settings. By including additional information on how to better access and use these resources, we seek to increase the utility by expanding that database of biosecurity resources that are free to access and are available in multiple languages. We will also identify crucial laboratory biosecurity aspects which are missing from each reference such as the WHO Guidance for Development of National Laboratory Strategic Plans which provides a stepwise, phased checklist to develop laboratory diagnostics strategies but lacks a biosecurity component (3).

The second facet is to create a glossary of biosecurity terms, which is lacking since the field of biosecurity is extremely interdisciplinary across the various sectors of public health, veterinary services, and research. The glossary would be an open-sourced effort with the expectation that biosecurity experts globally would be constantly adding to and updating the terminology as they discuss and come to a consensus about meanings and syntax. By drawing on an international membership, the glossary will be developed in multiple languages to facilitate communication between countries and provide a point of reference and common dictionary for technical terms. Such a resource would be paramount among next generation biosecurity professionals by easing the learning curve created by acronyms and terminology since it would be an informationally accurate document that could be referred to at any moment in time.

Our third facet is to create a practical GHSA laboratory biosecurity tool in terms of risk-based flowchart. The biosecurity tool we envision does not reinvent the wheel, but rather will examine and be modeled after well-executed pre-existing tools with the addition of certain components we have deemed lacking and should unequivocally be included. A current ongoing discussion regarding biological risks posed by advances in technology revolves around the *de novo* synthesis of horsepox virus by a Canadian scientist. This scientist synthesized an orthopoxvirus with the goal of creating a safer vaccine against smallpox, though the potential risks and implications due to this laboratory experimentation are grave and exponential (4). In order to fully examine the biological risks correlated to a technological advancement, one should analyze all possible resulting scenarios that could be caused by scientific progress of any magnitude. To address and prioritize potential biological risks, we seek to develop a working flowchart using known tools that will assist scientists in the laboratory by conducting a rundown of the potential biological risks that their research done via advanced technology may pose to public health.

For example, we have considered three biosecurity tools: 1) the Dutch Biosecurity Self-scan Toolkit, 2) the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist, and 3) the FAO Laboratory Mapping Tool (LMT) Safety Module. The Dutch Biosecurity Self-scan Toolkit (5) is exceptionally constructed, though we feel there should be the addition of a "pillar" that directly addresses advanced technological threats to biosecurity. One suggestion we propose would be ensuring that the questions are phrased appropriately so laboratories have the same checklist that compares national standards to supplement the JEE. Both the SLIPTA Checklist and FAO LMT Safety Module are very focused on areas for raising laboratory quality and enhancing laboratory safety respectively (6, 7) and we would aim for a more generalized version that can be easily adapted and interpreted.

Next Steps and Timeline
In the absence of funding, some risks to implementing our proposal include the potential problem of lack of internet access in low resource settings, the challenge of engaging both next generation and expert biosecurity professionals to actively use and update the forum given the distance proximity and time zone challenges, and the language and translation requirements since ideally the biosecurity forum and resources would be universally accessible and applicable. We estimate a twelve-month period of performance and a commensurate budget for our proposal in the $100,000 or less range which will provide the three deliverables described in our proposal facets and reduce implementation risks. The budget will include a provision for travel, labor, and other overhead costs.

If our proposal is approved, our team will attend the 2017 GHSA Ministerial Meeting in Kampala and present the proposal to an international audience of biosecurity professionals. Our team will use the opportunity to engage with the meeting participants to gain insight and feedback on our proposal and strategies to pursue and secure funding. Our three active global health security professionals, who have donated their time pro bono, will continue advising us to ensure our team is prepared for this conference activity. Mr. Adams is a senior biosecurity specialist at GSS Health and member of the Emerging Leaders in Biosecurity Initiative. Dr. Marshall is a practicing veterinarian and assistant professor at Paul Allen School of Global Animal Health at Washington State University. Mr. Yeh is a senior science advisor at MRIGlobal and is mentoring Ms Tseng through the Next Generation GHSA pilot program. After this presentation, we will seek funding for implementation of our proposal with the assistance of the Nuclear Threat Initiative (NTI) Biosecurity program and the Global Health Security Network (GHSN).

Conclusion
Today there are a constant array of biosecurity threats both known and unknown. With the technological advances such as the *de novo* synthesis of horsepox virus, it has become imperative that biosecurity professionals need to be well-trained and well-equipped to recognize these risks. Our proposal seeks to address the overarching problem that although there is an abundance of resources available, there is no straightforward roadmap to follow or central location for individuals to access them. We emphasize the use and tailoring of existing, open-source tools and creation of a centralized hub to share current resources that will form a framework to increase utility and knowledge sharing.

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