STRATEGIC MULTILATERAL BIOSECURITY DIALOGUE AMONG SINGAPORE, MALAYSIA, INDONESIA, AND THE UNITED STATES

with Participating Observers from Thailand and Philippines

MEETING REPORT FROM THE

APRIL 3-5, 2017 DIALOGUE SESSION

UNITED STATES INSTITUTE OF PEACE, WASHINGTON, DC

JOHNS HOPKINS CENTER FOR HEALTH SECURITY

JULY 7, 2017

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*This publication results from research supported by the Naval Postgraduate School's Project on Advanced Systems and Concepts for Countering Weapons of Mass Destruction (PASCC). The views expressed in written materials of publications, and/or made by speakers, moderators, and presenters, do not necessarily reflect the official policies of the Naval Postgraduate School nor does mention of trade names, commercial practices, or organizations imply endorsement by the US Government.

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Executive Summary

Biosecurity issues in the Southeast Asia region are dynamic and challenging due to natural outbreaks of emerging and potential pandemic pathogens, porous borders and highly mobile populations, rising terrorism threats, and a rapidly growing biotechnology industry. Several countries in the region are actively investing in new high-containment laboratories and expanding their research portfolio of high-consequence diseases, creating the opportunity for both accidental and deliberate release of dangerous pathogens. As global trade and travel continue to increase, so does the likelihood that local and regional outbreaks and epidemics will have international effects. Regional coordination and collaboration are vital to rapidly detecting, characterizing, and responding to infectious disease events to reduce the chance of global transmission, but many practical, financial, and political barriers make close coordination a challenge.

Multilateral biosecurity dialogue participants: Back Row (left to right)- Noreen Hynes, Angkana Sommanustweechai, Jeremiah Chng, Chong Chee Kheong, John Schaefer, Ben Rimba, Bill Hostyn, Gigi Gronvall, Matthew Shearer, Ken Bernard, Julie Fischer. Front Row (left to right)- Tawee Chotpitayasunondh, Michelle Yap, Endy Bayuni, Zalini Yunus, Daniel Tjen, Tom Inglesby, Chen Chaw Min, Suwit Wibulpolprasert, Kwa Chong Guan, Pratiwi Sudarmono, Irma Makalinao, Seth Carus.

The Johns Hopkins Center for Health Security (formerly the UPMC Center for Health Security) hosted—from April 3-5, 2017—the second year of the multilateral dialogue on biosecurity with participants from Singapore, Malaysia, Indonesia, and the United States. This biosecurity dialogue brings together a multi-sectoral group of leaders and experts from across biosecurity including public health and healthcare, military, homeland defense/home affairs, foreign affairs and international relations, public policy, academia, WMD non-proliferation, and journalism. In response to participant feedback during the previous year's dialogue, observers from Philippines and Thailand were invited to participate as observers in the April meeting to further build collaborative regional relationships. The multilateral

dialogue grew out of the initial bilateral biosecurity dialogue between Singapore and the United States in 2014, adding formal participants from Malaysia and Indonesia in 2015. With continued support from the Defense Threat Reduction Agency (DTRA) and the Project on Advanced Systems and Concepts for Countering WMDs (PASCC), this multilateral dialogue continued into its second year. Over this period of time, the participants have developed trust with each other, which has resulted in increasingly frank and constructive exchanges about complex and often sensitive biosecurity challenges. This year's dialogue meeting was held at the United States Institute of Peace in Washington, DC and included a spirited meeting at the White House with members of the National Security Council (NSC) staff as well as site visits to the National Institute of Health (NIH) Integrated Research Facility (IRF) and the US Army Medical Research Institute for Infectious Disease (USAMRIID) at Fort Detrick in Frederick, MD.

Dialogue participants and observers discussed a wide range of biosecurity concerns in their respective countries, national and regional biosecurity priorities for future investment and collaboration, and lessons learned from previous biosecurity events. The following represents key areas of shared priority emerging from the dialogue:

1. **Strengthening Early Detection and Response**

   The need for early warning of epidemics and other biological events became quite vivid in Southeast Asia during and following the SARS epidemic in 2003 and has been reinforced by recent events such as the discovery of Nipah virus in 1999, the West Africa Ebola epidemic in 2013-2016, imported MERS cases via South Korea in 2015, and the emergence of Zika virus in 2016. Dialogue participants noted that these events illustrate the scope and severity of the threat posed by emerging infectious diseases in Southeast Asia. These events have occurred even as important longer-term disease threats in the region, such as Dengue, continue. Dialogue participants generally agreed with the need to build and maintain strong surveillance and detection tools and systems, programs that would be valuable for natural, deliberate or, accidental biological events. Biosurveillance priorities identified in this dialogue include integrated systems that facilitate rapid detection and case reporting at the local level, especially rapid field diagnostics and training for human and animal clinicians. Additionally, participants noted the need for developing both formal and ad hoc relationships to improve collaboration on a regional level in support of coordinating rapid detection, reporting, and response mechanisms for biological events and for openly sharing valuable surveillance and clinical data. Participants also stressed the need for more collaboration across certain sectors—including law enforcement and homeland defense/home affairs, animal health, and environmental health and protection—to better address the spectrum of biosecurity threats and identify the origin of biological events, particularly those suspected of being deliberate.

2. **Making the Case for Biosecurity Investments as Part of National Security Planning**

   Participants agreed that one of the principal challenges of establishing effective biosecurity-related programs is securing long-term governmental support and funding. After strong impetus (eg, triggering events like SARS and the 2001 anthrax attacks), countries were able to make the clear case for biosecurity investment; however, participants described how, over time, it has become difficult to justify to senior government leadership the need for ongoing biosecurity investment in the absence of new acute shocks. Because biosecurity includes a number of non-health–related sectors (eg, law enforcement, homeland defense/home affairs, environmental

health and protection), dialogue participants believe raising awareness and appreciation of biological threats in these sectors is crucial to ensuring proper engagement and collaboration in preparation for and response to biological threats. A number of dialogue participants noted that it was uncommon for defense officials in their countries to be part of biosecurity dialogue discussions, even while biosecurity threats could pose severe challenges to national security. There was a good deal of agreement that Ministry of Defense officials should be central to national biosecurity policy and strategy, alongside public health leaders. Furthermore, participants agreed that Ministry of Finance officials should be part of national biosecurity planning, if they are not already part of them. Framing the importance of biosecurity investments in terms that senior government officials can appreciate (eg, economy, trade, national security, infrastructure) would clarify the need for their full engagement.

Many participants also queried about the future of the Global Health Security Agenda (GHSA)—a mechanism recognized for its ability to garner vital national-level support across relevant biosecurity sectors. The GHSA was designed as a global collaborative effort; however, it relies heavily on funding and leadership from the United States, and participants expressed concern about the extent to which this support will continue under the current Presidential Administration. Participants wondered whether the existing momentum to improve global preparedness and response capacity for biological events, and the associated national-level interest, could be lost in the absence of strong US support.

3. Reducing Biosecurity Threats and Risk in Laboratories

Several dialogue participants expressed concern about ensuring laboratory safety and security and establishing stronger systems to detect and prevent deliberate biological events. As laboratory capacity and capabilities grow in the Southeast Asia region, dialogue discussions suggest that additional attention is being paid to the potential for accidental and deliberate releases of dangerous pathogens. The dialogue included a focus on the broad needs around laboratory safety and security, including operational, regulatory, and physical security as well as personnel monitoring programs. One of the biggest challenges discussed by dialogue participants was how to implement personnel reliability programs that would ensure that laboratory staff take the appropriate safety and security precautions and conduct their research in a responsible manner as well as identify personnel who may intend to obtain or use dangerous pathogens for a nefarious purpose. While similar personnel reliability programs have been implemented by some countries in the past to protect items such as classified documents and nuclear material, this area of effort is still fairly new and best practices are not well-established globally. A number of participants indicated that their countries have recently implemented or are considering the development of nationwide personnel reliability programs, but they acknowledged the difficulty inherent in determining the intent of individuals' actions and acting on this determination.

Southeast Asia is experiencing a boom in the biotechnology sector similar to those seen in other regions around the world. Some countries, like Singapore, have a long history in the biology and technology sectors and have well-established oversight mechanisms and safety and security standards, whereas other countries are just beginning to develop these programs in response to recent increases in commercial and industrial activity. It was suggested in the dialogue that

more concerted regional collaboration on this issue might enable countries with developing laboratory security and safety programs to incorporate best practices from those with more established programs. Even nations with experience in the biotechnology sector, like Singapore, are facing new challenges, particularly in the context of synthetic biology and gain-of-function research. These emerging fields currently have little regulation or oversight in many countries, and both offer the potential for the development and release—accidental or deliberate—of dangerous and/or novel pathogens that could affect national, regional, and global health security.

4. Advancing National Implementation and Transparency for the Biological Weapons Convention

The Biological and Toxin Weapons Convention (BWC)—entered into force in 1975—prohibits the development, production, acquisition, or stockpile of biological weapons. While all participating nations in this dialogue, including the observer nations of Philippines and Thailand, are states parties to the BWC, several participants commented that there is little guidance or support for implementing the BWC at the national level, including developing national-level legislation. Additionally, some noted that because the BWC lacks an enforcement mechanism—and several countries have violated various articles of the BWC in the past—it is difficult to wholly trust that other states parties are meeting their obligations to fully implement the BWC. Confidence-building measures are one mechanism to promote transparency in nations' implementation and compliance; however, dialogue participants noted that countries unfamiliar with the process are finding it difficult to conduct the assessment and submit the required paperwork. They suggested that international assistance, bilateral or multilateral, would be welcome for many of the participating countries in implementing and enforcing the BWC at the national level and in completing and submitting confidence-building measures. At least one dialogue participant stated that their nation had already begun preparations for the 2017 BWC Meeting of States Parties. In the past, that nation had not developed official positions on BWC-related issues in advance of formal BWC meetings (eg, Review Conference, Meeting of States Parties) and subsequently felt pressured during the meeting to fall in line with the official position of their regional group.

Dialogue participants also raised questions about enforcing the BWC in the context of non-state actors. Terrorist activity has increased in Southeast Asia, and the recent use of a nerve agent in a high-profile assassination at the Kuala Lumpur International Airport illustrates the challenges of controlling material that can be used to make non-conventional weapons. The BWC explicitly addresses state biological weapons efforts, but additional support may be required for many countries to address terrorist and other deliberate releases of dangerous pathogens by non-state actors within their borders.

Dialogue participants indicated that they have briefed or intend to brief senior health and security leadership in their home countries on the discussions held during the multilateral dialogue. One of the principal aims of this dialogue is to identify biosecurity priorities with the ultimate goal of raising key issues to the level of formal Track I engagement between the participating countries. Malaysian and Indonesian participants have briefed the dialogue to their Ministers of Health and Defense, and Singaporean participants provide regular updates on the dialogue at the Permanent Secretary level. Malaysian participants also briefed their National Public Health Laboratory on the need to examine

personnel reliability and biosafety screening programs. The Thai observers briefed emerging infectious disease experts in their Ministry of Health. The Filipino dialogue participant has briefed Philippines' Chemical, Biological, Radiological, and Nuclear (CBRN) National Focal Point on the visits to USAMRIID and IRF. She is also scheduling briefings for the Office of the Philippine President, including the National CBRN team, and she hopes to establish a Center for Health Security in the Philippines to continue dedicated work in this area. Additionally, dialogue participants have introduced topics discussed at the dialogue meetings in international fora such as the World Health Assembly. As dialogue participants bring these discussions back to their respective home countries and further them with senior leadership, they build interest in and attention to biosecurity and foster opportunities for formal international engagement on these issues.

Introduction

On April 3-5, 2017, the Johns Hopkins Center for Health Security hosted a meeting of the Multilateral Dialogue on Biosecurity at the United States Institute of Peace in Washington, DC. This Track II dialogue—comprised of representatives from Singapore, Malaysia, Indonesia, and the United States as well as participating observers from Philippines and Thailand—built on the success of previous biosecurity dialogues and included experts from a wide range of fields pertinent to biosecurity. Funding and support for the dialogue was provided through the Project on Advanced Systems and Concepts for Countering WMD (PASCC) at the Naval Post Graduate School and the US Defense Threat Reduction Agency (DTRA).

This dialogue originated in 2014 as a bilateral effort between Singapore and the United States, and it expanded in 2015 to include Malaysia and Indonesia. In this second year of the multilateral dialogue, Philippines and Thailand were added as observer nations to further develop regional collaboration on biosecurity issues.

The multilateral biosecurity dialogue was held April 3-5, 2017 at the US Institute of Peace in Washington, DC.

As with previous dialogues, many sectors were represented by the participants, including public health and healthcare, military, homeland defense/home affairs, foreign affairs and international relations, public policy, academia, WMD non-proliferation, and journalism. Over the course of three days, participants discussed a range of biosecurity topics, including national biosecurity priorities, biosurveillance, emerging infectious diseases, laboratory safety and security, emerging technologies and advanced biology (including synthetic biology and gain-of-function research), media relations, bioweapons non-proliferation, cross-sectoral coordination, and regional and international collaboration mechanisms.

In addition to the dialogue sessions, several site visits were arranged to enable the participants to engage with leaders on biosecurity issues from across the US government. On the first day of the dialogue, participants visited the White House to speak with several members of the National Security Council staff about future US priorities for global health security and international engagement on biosecurity issues as well as domestic preparedness planning and operations. Participants also visited the National Biodefense Research Campus at Fort Detrick in Frederick, Maryland. There, they received briefings and tours at the National Institute of Health (NIH) Integrated Research Facility (IRF) and the US Army Medical Research Institute for Infectious Disease (USAMRIID). Researchers and leadership from

these leading scientific facilities discussed with the participants US bioscience and biodefense research priorities, existing and future research capabilities, and opportunities for international research engagement.

Over the course of the dialogue sessions, many of the participants commented on the value that the multilateral biosecurity dialogue provides, offering an opportunity for biosecurity experts and practitioners from around Southeast Asia to address issues that may not receive the necessary attention and resources they require. Participants agreed that building informal relationships across borders facilitates international collaboration, even in the absence of formal bilateral or multilateral biosecurity programs or agreements, and supports detection and response capabilities for biological events. Participants noted the value of including experts from across a wide range of relevant sectors, particularly the defense sector, which are often not included in biosecurity planning. Participants noted their desire to include representatives from the finance and economic sectors in future dialogues, either as participants or invited speakers.

Strengthening Early Detection and Response

The need for early warning of epidemics and other biological events became quite vivid in Southeast Asia during and following the SARS epidemic in 2003 and has been reinforced by recent events such as the discovery of Nipah virus in 1999, the West Africa Ebola epidemic in 2013-2016, and imported MERS cases via South Korea in 2015. Participants in the dialogue noted that the emergence of Zika virus in the region in 2016 illustrated the scope and severity of the threat posed by emerging infectious diseases. These events have occurred even as important longer-term disease threats in the region continue and evolve, such as Dengue. Porous borders and highly mobile populations increase the risk of disease transmission in the region, potentially across many islands, posing significant challenges for national and regional biosurveillance systems. For example, Taiwan identified its first case of Zika in January 2016 in a traveler originating in Thailand—at the time, a country not identified by the WHO as having local Zika transmission.[1,2,3] Densely populated cities in Southeast Asia present conditions quite suitable for the spread of communicable diseases. The capacity for urban disease transmission was illustrated during the West Africa Ebola epidemic, which exhibited the first reported widespread transmission of Ebolavirus in urban areas. It was also seen in the emergence of Zika in Singapore, during which the country identified nearly 400 cases in the first four weeks.[4] Disease reporting networks and systems in Southeast Asian countries are divided between two WHO regional offices, WPRO and SEARO, which can complicate international reporting and response.

During the meeting, one of the principal areas of discussion with respect to biosurveillance and response was the need to develop an integrated and comprehensive regional network capable of detecting and responding to a range of local, national, and regional biological events. Participants indicated that current international biosurveillance efforts are ad hoc and disconnected rather than coordinated and comprehensive approaches. Participants also discussed the importance of diagnosis and testing to event detection and the vital role that local clinicians (human and animal) and laboratorians play in any surveillance system. Participants emphasized that biosurveillance training should be included in medical training to facilitate clinicians in collecting and reporting appropriate data. There was also discussion regarding the value of rapid and reliable field or point-of-care testing—particularly if it enables testing for a wide range of pathogens—which could decrease the amount of time required for diagnosis and reporting of infectious disease events. This would hold especially true for remote areas (eg, island communities) that are far from reference laboratories, which tend to be clustered near high-population urban areas. Continued vigilance for emerging pathogens among front-line clinicians is important to identifying these types of events. As was the case with Nipah virus in 1999,

astute clinicians can play a critical role in detecting and characterizing novel pathogens, a vital step in initiating an effective response. The human-animal interface (and other cross-species interfaces) in Southeast Asia provides opportunities for the evolution and zoonotic transmission of novel pathogens. The rapid development and production of diagnostics for these pathogens, especially those that can be deployed locally, could be vital to mounting an adequate response and containing outbreaks of novel diseases.

The integration of local reporting systems into national or regional networked databases could help facilitate the detection of biological events that are unfolding across borders. Participants noted, however, the challenge of operationalizing data sharing agreements, which are difficult to implement due to privacy and security concerns at the national level. In these cases, many participants have found that personal relationships with their counterparts in other countries are a more effective means of coordinating cross-border detection, response, and data sharing in the absence of formal national-level programs and agreements. Participants also noted that, even if their countries are able to identify the onset of a biological event, many times they do not have the capacity necessary to contribute to the response, and detection without a response is ineffective in terms of containing an outbreak.

Participants agreed that international capacity building and cross-border collaboration throughout the region would strengthen epidemic response activities. In light of the volume of regional travel and the challenge posed by extensive and largely open borders, outbreaks can quickly result in regional transmission, so nations have a strong incentive to build response capacity and facilitate regional response assistance to prevent regional and global epidemics. Participants noted that achieving this goal, however, has been difficult due to financial limitations, competing national priorities, and political realities.

As the scope of public health has expanded over the past ten-to-fifteen years to include deliberate events (eg, bioterror attacks), additional challenges have arisen, particularly with respect to distinguishing deliberate attacks from naturally occurring or accidental events. As discussed above, clinicians, both human and animal, are critical to early identification and characterization of infectious disease events, but in most cases, dialogue participants noted that clinicians might not consider deliberate events as a potential cause of an outbreak. If clinicians were more aware of this possibility, they might be in a better position to consider and test for unusual biological agents when the situation

warrants it and to rapidly report their concerns and test results to the appropriate public health officials to initiate an investigation.

Participants noted that the advent of advanced synthetic biology tools like CRISPR-Cas9 enables scientists to create novel strains of pathogens which could complicate the process of identifying the source of an outbreak were such pathogens to be released deliberately or accidentally. Non-health sectors like law enforcement and homeland security/home affairs (and potentially even the military) would likely be involved in investigating suspected deliberate events, and participants emphasized that close coordination is required with healthcare and public health to ensure that all agencies and organizations are able to adequately respond without impeding the actions of others. It was acknowledged, however, that in some places this level of coordination between sectors is not yet strong enough. Some dialogue participants are working in their countries to explain that experts with expertise in public health and infectious disease science could assist by educating law enforcement professionals about what to look for and how to protect themselves during the investigation of a biological event. Collaboration in advance of an event could help strengthen the relationship between sectors in future incidents. Participants noted that sectors relevant to biosecurity are unfortunately often siloed, viewing their responsibilities for biosecurity events as independent of one another, which poses a significant challenge in developing and training comprehensive response protocols.

Participants also noted that efforts like this multilateral biosecurity dialogue, the Global Health Security Agenda (GHSA), and the Joint External Evaluation (JEE) help to bring together experts and officials from across relevant sectors and encourage cross-sectoral collaboration on biosecurity threats.

Making the Case for Biosecurity Investments as Part of National Security Planning

Participants agreed that one of the principal challenges of establishing effective biosecurity-related programs is securing long-term governmental support and funding. After strong impetus (eg, triggering events like SARS and the 2001 anthrax attacks), countries were able to make the clear case for biosecurity investment. However, participants describe that it then becomes difficult to justify over time to senior government leadership the need for ongoing biosecurity investment in the absence of new acute shocks. Since biosecurity includes a number of non-health–related sectors (eg, law enforcement, homeland defense/home affairs, environmental health and protection), dialogue participants believe raising awareness and appreciation of biological threats in these sectors is crucial to ensuring proper engagement and collaboration in preparation for and response to biological threats. Political leadership may view lack of a recent public health emergency as evidence of low risk or successful completion of program implementation, as compared to the more likely scenario in which such programs are actively preventing or mitigating public health emergencies and doing necessary preparation for future events. Dialogue participants also noted that it can be difficult to quantify the total investment in biosecurity, particularly because it is often unclear what actually qualifies as biosecurity (eg, does laboratory equipment qualify as a biosecurity investment, particularly when it can serve other purposes?).

A number of dialogue participants noted that it was uncommon for defense officials in their countries to be part of biosecurity dialogue discussions even though biosecurity threats could pose severe challenges to national security. There was a good deal of agreement that Ministry of Defense officials should be central to national biosecurity policy and strategy, alongside public health leaders. There was further agreement that Ministry of Finance officials should be part of national biosecurity planning if they are not already part of them.

Participants explicitly discussed the need to address the impact of biosecurity risks in terms to which elected officials can relate. Specifically, participants commented that framing the importance of biosecurity programs in economic terms (eg, the negative impact on tourism, exports, and infrastructure) rather than solely focusing on the human impact (eg, case counts, deaths) helps elected officials better understand and relate to the broad-reaching effects of biosecurity threats. For example, the SARS epidemic in 2003 had an incredible impact on international travel and tourism, particularly in

the affected countries in Asia. In the early weeks of the epidemic, tourist arrivals in East Asia were 41% lower than the same period in 2002, and SARS' effect on tourism in Asia and the Pacific is estimated to have been five times greater than the 9/11 attacks on the United States. Beijing alone is estimated to have lost 1.3 billion USD in tourism over the first five months of 2003, and losses to Ontario's "leisure industry" are estimated at approximately 1.4 billion USD and 28,000 jobs. Additionally, China lost high-profile international events including the Women's World Cup soccer tournament.[5,6] Similarly, the 2015 MERS outbreak in South Korea resulted in a 17% decline in department store sales early in the outbreak as well as losses of 38%–82% for public leisure activities like "movies, amusement parks, baseball games, and museums." Early estimates of the total economic impact of the outbreak were a 0.2% decrease in South Korea's total GDP growth for the year.[7] It was also reported that South Korea experienced a 40% decrease in tourism in June 2015, at the height of the outbreak.[8] In addition to strictly economic terms, other measures of outbreaks' or epidemics' effects could include food security, military readiness, regional stability, infrastructure reliability, and public trust in government. Meeting participants suggested that these types of figures could potentially resonate better with non-health experts, which can help persuade elected officials to commit to investments in biosecurity programs aimed at preventing or combatting these types of events.

One of the major areas of concern for the participants was the future of the Global Health Security Agenda (GHSA). The GHSA was envisioned as an international collaborative effort to improve global preparedness and response capacity; however, a significant portion of the funding and support for the GHSA comes directly from the US government. As the new Presidential Administration begins outlining their priorities, it is unclear to what extent the United States will remain involved in the GHSA. Without US support, many dialogue participants expressed concern that the GHSA will fail. The GHSA has established considerable momentum over the past several years, particularly with the implementation of the Joint External Evaluation (JEE) mechanism to assess countries' respective preparedness and response capabilities. These assessments, however, are very resource-intensive, often requiring dozens of external evaluators from around the world in addition to the domestic personnel and resources needed to complete the internal assessment and host the evaluators. Countries which have completed the JEE have noted the assessment's value, particularly its ability to draw expertise and interest from across many relevant sectors of government in addition to raising awareness of existing biosecurity capabilities and remaining gaps at the highest levels of government leadership. The loss of the GHSA

would potentially eliminate a major tool in building governmental support for biosecurity and highlighting areas for continued investment. Certain countries have made significant investments in the GHSA, both in resources and leadership, but many participants were concerned about the future of the GHSA if the United States elects to withdraw all or some of its support. One meeting participant raised this issue directly during the meeting with representatives from the National Security Council at the White House.

Finally, the group discussed the value of the media and journalism in raising awareness for biosecurity issues. One participant emphasized the importance of health and security officials actively engaging with the media and the public. Active participation in the media can take many different forms, including press conferences, interviews, and even writing op-ed articles on biosecurity topics. Participants also noted the importance of developing strong relationships with journalists as a means of supporting research and publication of articles aimed at building public support for biosecurity efforts. Building support in the public is an excellent way to, in turn, raise awareness of these issues with elected officials and establish support for biosecurity programs and continued allocation of resources.

Growing Importance of Laboratories in Biosecurity

Participants of the multilateral biosecurity dialogue on the steps of the Eisenhower Executive Office Building at the White House.

Participants noted that as laboratory capacity, particularly high-containment laboratories, grows in the Southeast Asia region, so do the risks of accidental or deliberate releases of dangerous pathogens. Additionally, the increasing capabilities and availability of emerging biotechnology and synthetic biology (including research into gain of function) raise their own concerns. Some countries, like Singapore, have long histories in the biology and biotechnology sectors with physical and operational safeguards in place to reduce the risk of accidental or deliberate release. Others, however, are developing these programs in parallel with their growing research and industrial sectors.

Participants noted that laboratory diagnostic capacity tends to be concentrated near major cities. This can pose significant challenges in detecting and characterizing disease cases in more remote areas. Countries like Malaysia, Indonesia, and Philippines cover vast geographic areas and are comprised of hundreds or thousands of islands. In fact, Indonesia is the world's largest island nation and the 15th largest country in terms of combined land and sea area, covering nearly 2 million square kilometers (nearly 750,000 square miles).[9] The populations of these countries are spread out across many of these islands or in rural areas. For example, in Philippines and Indonesia, 56% and 46% of the population, respectively, live in rural areas. Similarly, 50% of the population in Thailand lives in rural areas.[10] Limited access to quality diagnostic or reference laboratories in some of these areas could result in delays in detecting or responding to an outbreak. One participant commented that technologies like next-generation sequencing, high-throughput diagnostic equipment, and field diagnostics can help mitigate these challenges, but they are not widely available in the region. Considering the volume of travel in the region, laboratory diagnostic delays could result in delayed recognition and reporting of new outbreaks and ongoing disease transmission. One participant noted that his/her country utilizes mobile laboratories as a means to facilitate response for identified outbreaks in rural areas, a tool that other nations in the region might consider developing to help mitigate the challenges of rural disease surveillance and response activities if lab capacities are not already in place. Participants did not dispute

that it is a worthwhile goal to move some laboratory capabilities to the field or point of care to reduce the need to transport specimens to distant, centralized reference laboratories and to shorten the time required for initial diagnosis; however, this goal faces many barriers due to lagging technology development and the lack of resources and will needed to change current practices.

Local laboratory capacity, or at least the ability to readily access laboratory capacity in other areas, is critical to biosurveillance efforts; however, with additional laboratories comes additional risk. Several pathogens of interest in Southeast Asia—including Nipah virus, Hendra virus, and SARS—are highly transmissible and lethal and require high-containment laboratories and properly trained personnel to handle. For example, the serum neutralization test is the accepted reference test for Nipah virus infection, but it requires BSL-4 containment to perform.[11] Similarly, *in vitro* culture is currently the only means of detecting live SARS virus, but this requires BSL-3 containment.[12,13] Particularly in light of laboratory-associated infection with SARS in 2003,[14] there is concern about biosafety standards for high-consequence pathogens. Additionally, as academic and industrial research programs in the region expand to include high-consequence pathogens, synthetic biology, and advanced biotechnology, it is critical that high-consequence work is conducted under the appropriate biosafety and biosecurity standards. Participants expressed concern that gain-of-function research is taking place in the region without proper transparency and oversight. In fact, one participant commented that we do not know how many laboratories in the world are currently doing these types of experiments.

Participants of the multilateral biosecurity dialogue met with members of the National Security Council staff and the White House Office of Science and Technology Policy in the Diplomatic Reception Room at the Eisenhower Executive Office Building.

In addition to physical biosafety and biosecurity safeguards, several participants noted the need for mechanisms that assess and monitor personnel who handle dangerous pathogens in the course of their work. Personnel reliability programs aim to protect against the deliberate or accidental misuse of dangerous pathogens by encouraging the active involvement of laboratory staff and leadership in ensuring compliance with safety and security regulations. Currently, there is little definitive research in this area and very little by way of best practices. Several participants stated that their respective countries are in the process of implementing or have already implemented these types of

programs. At this time, these programs are aimed more at establishing research codes of conduct and cultures of safety and awareness as opposed to actively evaluating personnel for factors or traits that could indicate future nefarious or negligent actions. Current efforts are presented as a safety issue designed to protect fellow personnel and the public rather than as punitive programs designed to single out particular laboratorians for disciplinary action.

Participants noted the inherent challenge of determining an individual's intent, particularly before an action has even been taken. Developing and assessing personnel reliability programs is an excellent area for future multilateral collaboration, as representatives from all participating countries, including the observer nations, indicated that they face this challenge.

Advancing National Implementation and Transparency for the BWC

As noted above, many biosecurity programs in Southeast Asia originated in response to the SARS epidemic in 2003, but the scope of these programs has expanded beyond naturally occurring disease outbreaks to include biological weapons and other deliberate threats. As a result, this has increased nations' attention to bioweapons nonproliferation, particularly with respect to national implementation and transparency for the Biological and Toxin Weapons Convention (BWC) and other international agreements. All participating countries in this multilateral biosecurity dialogue, including the observer nations, are states parties to the BWC; however, some participants expressed concern that there is insufficient international support available to assist states parties in implementing the BWC at the national level. Specifically, participants commented that there are no official guidelines for states parties to follow with respect to implementing specific aspects of the BWC in their respective countries. For example, Article IV of the BWC mandates that every state party shall "take any necessary measures to prohibit and prevent the development production, stockpiling, acquisition or retention of" biological agents or equipment for the purpose of employing them as a biological weapon "within the territory…under its jurisdiction or under its control anywhere."[15] Separately, United Nations Security Council Resolution 1540 explicitly states that countries shall:

> "*…adopt and enforce appropriate effective laws which prohibit any non-State actor to manufacture, acquire, possess, develop, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery, in particular for terrorist purposes*."[16]

Participants emphasized that assistance from those countries that have already implemented these programs or enacted this legislation would be beneficial to those that are just beginning these efforts. Success in achieving national-level BWC implementation has benefits far beyond the borders of those countries.

One of the biggest issues, currently, with international bioweapons nonproliferation agreements is a lack of transparency. In a discussion with Christopher Park, Director of Biological Policy for the US Department of State, several meeting participants noted that it is challenging to work together with countries such as the United States and Russia on BWC issues given activities in those countries. For example, in recent years the United States shipped live anthrax samples around the world and also failed to secure viable smallpox samples at a federal facility after declaring that all specimens were consolidated at the CDC or destroyed.[17,18] The Russian Federation, in direct violation of the BWC and other international treaties, operated a massive covert offensive bioweapons program for 17 years after ratifying the BWC.[19] Additionally, concerns about current and historical state-sponsored chemical weapons use in Syria and Iraq are, by proxy, eroding the norms against biological weapons use as well. Participants acknowledged that mechanisms such as confidence-building measures (CBMs) are designed to promote transparency for existing biodefense programs; however, few states parties elect to complete CBMs and even fewer make these reports public. Participants also indicated completing CBMs is cumbersome and that many countries are unfamiliar with the process to do so. International assistance in completing CBMs would better enable them to conduct appropriate assessments and process the necessary paperwork. One participant commented that his/her country was ill-prepared for

the Eighth Review Conference of the BWC—held in Geneva, Switzerland in November 2016. He/She indicated that, because they did not have official positions on a number of important issues, his/her country felt pressured by leading states parties in the Non-Aligned Movement and Other Countries (NAM) regional group to support the group's position, even if it did not necessarily align with his/her country's priorities. In preparation for the 2017 Meeting of States Parties, his/her country is making a concerted effort to develop a national platform to ensure that they are better able to pursue their national interests. A coordinated regional effort to better prepare Southeast Asian countries for the BWC could help promote their priorities with respect to bioweapons nonproliferation in these international fora. Mr. Park indicated that dialogue participants may want to consider submitting policy statements for the 2017 Meeting of States Parties on behalf of this dialogue and host a side event to discuss BWC priorities and challenges in Southeast Asia.

Robert Kadlec—Deputy Staff Director, US Senate Select Committee on Intelligence—delivered the keynote presentation and joined the multilateral biosecurity dialogue for a spirited discussion on current and future biosecurity priorities.

All participants agreed that international mechanisms like the BWC are critical to preventing the proliferation of biological weapons. While the system is not perfect, it promotes international engagement on vital issues pertaining to global health security and establishes and maintains norms against bioweapons development, production, and use. Transparency and trust are certainly a concern with respect to BWC implementation; however, several participants noted that multilateral Track II efforts such as this dialogue facilitate establishing informal international relationships, build trust between states parties, and foster discussion and collaboration below the Ministerial level.

Future Strategic Engagement

At the conclusion of the dialogue meeting, participants discussed how to move forward with the multilateral biosecurity dialogue and leverage the meeting's success to enact meaningful change in their respective home countries. Participants determined that a policy report should be composed by the Johns Hopkins Center for Health Security project team and provided to the dialogue participants for the purpose of sharing with their senior ministry and government leadership. This report would discuss biosecurity priorities identified in the dialogue sessions and elucidate recommended actions that can be taken at the national and regional level to develop, implement, and maintain sustainable programs and build biosecurity capacity throughout the region. It was suggested that recommendations in the report potentially could also lead to future Track I diplomatic discussions.

Among the suggested priorities for future multilateral engagement were regional and multi-sectoral collaboration. Regional surveillance and response mechanisms are vital to managing infectious disease events that can quickly spread across borders to involve multiple countries. Of particular note, participants desired to implement systems that facilitate regional or international data sharing to support the detection of and response to infectious disease events. Many barriers to openly sharing data currently exist, including political and economic, but access to data is critical to identifying and characterizing biological events, particularly those unfolding across borders. Multilateral efforts can raise awareness for this issue, and short of implementing formal national-level programs, efforts like this dialogue can help build trusted relationships at the operational level that can enable *ad hoc* data sharing during future events. Continued effort is needed in the Southeast Asia region to incorporate non-health sectors—particularly law enforcement, homeland security/home affairs, and defense—into biosecurity programs.

It is also important to collaboratively represent biosecurity priorities and platforms to regional and international treaty organizations and similar political and economic mechanisms. For example, by coordinating in advance, nations in the Southeast Asia region can present a cohesive position in fora such as the BWC. All participating and observer countries are part of the Non-Aligned Movement and Other Countries (NAM) regional group at the BWC, which represents nations from all around the world. Having a unified position wherever possible can help Southeast Asian gain leverage and promote their collective interests, particularly when they may not necessarily align with those of the coordinating nation or other members of the NAM group. Dialogue countries could also submit policy statements and/or host a side event at the 2017 Meeting of States Parties to discuss regional priorities and challenges with respect to the BWC. Additionally, regional fora such as ASEAN, while not specifically aimed at health or security issues, could provide additional mechanisms to engage on biosecurity issues both informally as well as at the ministerial level.

Biosecurity's scope reaches far beyond health, but it may not receive the appropriate level of attention or support in other sectors. Actively engaging officials from other sectors prior to an event not only develops working relationships and familiarity that can improve preparedness and response efforts, it can help demonstrate to senior and elected officials the scope and importance of biosecurity programs with the aim of securing long-term, dependable funding and support. Participants also suggested that existing international programs such as the GHSA provide an excellent mechanism to raise awareness of biosecurity issues to the highest political level and highlight areas of success, gaps requiring increased

support, and illustrate the need for continued investment in ongoing biosecurity programs. The future of the GHSA may be uncertain at this point, due to concerns about future investment by the United States, but the program has established considerable international momentum that may enable it to continue independent of US funding and leadership, particularly with international and multi-sectoral support from other countries.

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Appendix A: Meeting Participants

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Appendix B: Meeting Agenda

DAY 1- 3 APRIL 2017

08:45 – 09:30 **Welcome, Goals for Meeting, and Introductions**

Tom INGLESBY, Director, Johns Hopkins Center for Health Security

Anita CICERO, JD, Deputy Director, Johns Hopkins Center for Health Security

09:30 – 10:45 **Dialogue Session One: *What are your country's current biosecurity priorities?***

For the purposes of this dialogue, "biosecurity" refers to the actions, policies, and programs that countries implement to prevent and respond to the greatest biological threats facing their nation—including natural, deliberate, and accidental events.

During this opening dialogue session, we will hear from each country about their current concerns, greatest strengths, and most serious challenges related to national biosecurity. What are the greatest biosecurity concerns in your country? Are current geopolitical issues affecting or likely to affect your country's biosecurity priorities? What is the national reaction to the number of avian flu outbreaks and the regional proliferation of strains seen this year? Is your government concerned about the threat posed by either terrorist or nation-level use of biological weapons? In your view, is your country allocating adequate resources for biosecurity, considering the relative threats posed by potential outbreaks, lab accidents, and other biological risks? If not, why not?

A representative from each of the participating countries will provide opening remarks (5 minutes) on this topic, followed by a discussion by all participants.

Opening Remarks: Ken BERNARD, Daniel TJEN, Michelle YAP, and Zalini YUNUS

10:45 – 11:00 **Coffee/Tea Break**

11:00 – 11:25 **Philippines Observer Presentation with Follow-on Group Discussion**

Biosafety and Biosecurity in the Philippines: Current Challenges and Opportunities

Presentation by Irma MAKALINAO, Professor of Pharmacology and Toxicology, College of Medicine, University of the Philippines, Manila

11:25 – 12:15 **Thailand Observer Presentations with Follow-on Group Discussion**

Recent Policy Movements and Regional/Global Networking for Health Security and AMR

Presentation by Suwit WIBULPOLPRASERT, Senior Advisor to the Thailand Ministry of Health and Former Vice Minister of Health, Thailand

Emerging Infectious Diseases and Other Biological Threats in Thailand and the Region

Presentation by Tawee CHOTPITAYASUNONDH, Faculty of Tropical Medicine and Hygiene, Department of Tropical Pediatrics, Mahidol University

12:15 – 13:30 **Lunch**

13:30 – 14:30 **Dialogue Session Two: *How can countries best utilize advanced science and technology to develop early warning for and response to biosecurity threats?***

The rapid pace of progress in the biology and biotechnology sectors has the potential to yield advanced products and processes that can improve the health of populations worldwide. How can these advancements be leveraged to rapidly develop solutions to new and unanticipated problems? How can the public and private sectors best engage in this arena to support creative advancements—including medical countermeasures, diagnostics, and surveillance systems—that can affect a broad range of known and unknown biological threats?

What disease surveillance and warning systems are most effective in your country, and what are the greatest surveillance challenges? What investments are being made to address deficits in surveillance? What are your near-term priorities for surveillance?

Opening Remarks: Jeremiah CHNG, CHONG Chee Kheong, Noreen HYNES, and Pratiwi SUDARMONO

14:45 **Shuttle departs for the White House**

15:30 – 17:00 **White House Discussion on Biosecurity**

Hosted by Hillary CARTER, Director for Countering Biological Threats, White House National Security Council

17:00 **Meeting adjourns**

DAY 2- 4 APRIL 2017

08:45 – 9:15 **Roundtable Discussion: *The Financial Costs of Biosecurity***

Discussion led by CHEN Chaw Min, Secretary General of Health, Ministry of Health, Malaysia

09:15 – 10:45 **Dialogue Session Three: *How can we prevent and respond to biosecurity threats in laboratories?***

Advances in the life sciences are continuing at a brisk pace and have opened the door to promising new discoveries that bring with them the potential to improve the health and safety of the public, agriculture, animals, the environment, and national security. Technological advances in molecular biology and biotechnology will play an increasingly important role in the growth of national economies.

Despite these benefits, certain types of research conducted for benevolent reasons could be used for harmful purposes and present risks to national, regional, and global security. Funders of life sciences research and the institutions and scientists who conduct life sciences research have a shared responsibility to establish systems to prevent misuse. How does your country work to instill a culture of responsibility in labs? What strategies have been successful in establishing and maintaining buy-in from your scientific community without making them feel that they are not trusted?

In your country, how and to whom would laboratorians report concerns about potential misuse? Does your government reach out to laboratorians to make them aware of potential misuse or educate them on potential indications of misuse? In your country, what is law enforcement's general level of awareness about biological threats? Does your country have companies that provide gene synthesis services, and, if so, do they have procedures in place to screen requests and customers?

Who do companies contact if their screening processes identify potentially high-risk requests or customers?

A representative from each of the 4 countries will provide opening remarks (5 minutes) on this topic, followed by a discussion by all participants.

Opening Remarks: Julie FISCHER, Daniel TJEN, Michelle YAP, and Zalini YUNUS

11:00 **Bus departs for Fort Detrick**

13:00 – 14:30 **Site Visit at IRF**

The Integrated Research Facility (IRF), operated by the National Institute of Allergy and Infectious Diseases (NIAID), is one of several facilities that comprise the National Interagency Biodefense Campus at Fort Detrick. IRF provides high-containment facilities (including advanced BSL-4 laboratories) to support research on the prevention and treatment of human diseases. IRF incorporated specially designed imaging equipment into planning and construction of the facilities to enable researchers to study disease progression in a range of animal models in ways not previously possible.

15:30 – 17:00 **Site Visit at USAMRIID**

The United States Army Medical Research Institute for Infectious Diseases (USAMRIID), established in 1969, is one of the world's premier infectious disease and biodefense research facilities. USAMRIID operates high-containment research laboratories to investigate a wide range of deliberate and naturally occurring biological threats. While the primary mission is to protect US military personnel from biological threats, research at USAMRIID has made critical contributions to the development and testing of countless medical countermeasures and diagnostics that benefit both military and civilian populations.

17:00 **Meeting Adjourns**

DAY 3- 5 APRIL 2017

09:00 – 10:00 **Presentation: *The Biological Weapons Convention: Recovering from the 8th Review Conference***

Presentation by Christopher PARK, Director of Biological Policy, US Department of State

10:00-10:45 **Keynote Address: *Biosecurity Priorities in the Time Ahead***

Address by Robert KADLEC, Deputy Staff Director, US Senate Select Committee on Intelligence, and Former Senior Director for Biodefense, White House National Security Council

10:45 – 11:00 **Coffee/Tea Break**

11:00 – 12:00 **Dialogue Session Four: *What are the priorities for new regional coordination activities in Southeast Asia?***

Exchange of information occurs on an informal basis between peers working on biosecurity matters in countries across Southeast Asia. On what topics is such information exchange most robust? Where is it most lacking? Are there untapped opportunities to increase regional initiatives on biosecurity and, if so, in what areas? What are the most important problems that would require regional coordination (eg, development and stockpiling of medical countermeasures and personal protective equipment; data sharing for surveillance/early warning systems, epidemiological investigations, and pathogen sequencing; labs and lab network; emergency operations centers)? What regional capabilities would you want? What types of outbreaks, terrorist events, or laboratory accidents—if they were to occur in the region—should spur regional coordination? Should regional coordination occur only for emergencies, or should it serve even routine biosecurity needs? Countries in the Southeast Asian region have come together in the United Dengue initiative, which is committed to establishing a local surveillance system and facilitating and developing mutually beneficial cooperation for dengue control. Are there other desired regional initiatives that would be practically and politically feasible?

Opening Remarks: Seth CARUS, CHONG Chee Kheong, KWA Chong Guan, and Ben RIMBA

12:00 – 13:00	**Lunch**
13:00 – 13:45	**Presentation: *Public and Media Reaction to Epidemics and Crises in Indonesia and Southeast Asia*** Presentation by Endy M. BAYUNI, Editor-in-Chief, *The Jakarta Post*
13:45 – 14:00	**Coffee/Tea Break**
14:00 – 16:00	**Group Discussion on Creation of Joint Statement or Peer-Reviewed Journal Article** • Purpose • Possible Venue and Audience for Piece • Use of Joint Statement or Article • Potential Content of Piece • Process for Creation and Approval
16:00 – 16:30	**Group Discussion of Agenda for Next Dialogue Session and Next Steps**
16:30	**Dialogue Adjourns**