

Regional Science Plan - Southeast Asia

The primary purpose of the Cooperative Biological Engagement Program (CBEP) research is to support, enhance and integrate programmatic threat reduction objectives. These objectives are aimed at developing capacity and infrastructure to prevent, detect and respond to the intentional release of a dangerous pathogen, accidental release of a dangerous pathogen, and naturally occurring outbreaks of pandemic disease agents.

Southeast Asia (SEA) is a diverse region in which social and environmental factors facilitate the emergence of infectious diseases more so than in any other region. These factors include high human population density and growth, changes in land use, prevalence of subsistence agriculture and a close proximity of humans to animal reservoirs. The unique environment in SEA creates challenges to delivery of health care while increasing the likelihood of disease emergence and the potential for animal-to-human pathogen transmission.

Therefore, the SEA CBEP science plan emphasizes improvement of diagnostic capabilities to identify common pathogens of CBEP relevance (including those on the U.S. Health and Human Services (HHS) and United States Department of Agriculture (USDA) Select Agent and Toxins list, and referred to as Priority Pathogens), and to engage partners to develop multi-sectoral strategies to mitigate the risk of a dangerous biological event. The science plan considers risks in a tripartite approach including health security (i.e., naturally occurring threats), laboratory biosecurity (i.e., accidental laboratory release), and law enforcement biosecurity (i.e., intentional pathogen release and first responders). CBEP recognizes that partner nations differ substantially in their absorptive and sustainment capacities for new technologies and capabilities. Therefore, Cooperative Biological Research (CBR) projects will be tailored appropriately, with resource-intensive pathogen characterization and discovery functions limited to appropriate countries and institutions. Where possible, regional strategies will be encouraged in which appropriate linkages can be built between more resource-rich partner countries and neighboring countries that lack the infrastructure and capability in these three areas.

The SEA Science Program aims to integrate capacity building efforts managed by regional and country teams with coordinated research projects that address local and regional priorities. Projects will be designed to enhance and facilitate the provision of capabilities and infrastructure that will ultimately support the overarching CBEP mission to provide sustainability in:

- Biosafety and biosecurity (BS&S);
- Disease surveillance; and
- Compliance with World Health Organization (WHO) International Health Regulations (IHR) and World Organization for Animal Health (OIE) reporting guidelines.

In order to achieve the greatest impact, both nationally and regionally, CBEP research activities will be developed and evaluated in accordance with the following priorities:

Priority: CBEP will support research activities that are designed to be sustainable within the partner countries.

Rationale: It is essential that the capabilities established in partner countries are sustainable and enduring. CBEP research will support and enhance this sustainability by ensuring that the appropriate entities within a partner country are engaged and included in research projects. This engagement of relevant ministries and national disease surveillance entities is a highly weighted evaluation criterion when considering proposals. Priority is given to projects that demonstrate an understanding of this need and have either established the appropriate relationships in country or have a strategy to do so. CBEP recognizes that projects involving the appropriate entities at all levels are most likely to result in outcomes that provide capabilities that will endure beyond the lifetime of the project.

Priority: CBEP will identify, foster and leverage Centers of Excellence (COE) possessing regional capabilities and reach as a means to ensure that advanced technical capabilities can be absorbed and sustained by partner countries.

Rationale: Because the surveillance and diagnostic capabilities that CBEP seeks to provide will require significant resources and training to establish in our more resource-challenged partner countries, the identification of institutions and academic centers in more resource-rich countries to provide collaborative support will help ease the resource burden while creating strong, sustainable regional partnerships.

CBEP will support the establishment of linkages between these COEs and individual countries based on matching specific capabilities to critical needs.

Priority: CBEP will focus on research that aids in early disease detection through provision of appropriate diagnostic capabilities to sub-national elements of disease surveillance systems and will support utilization of interoperable surveillance tools at the country, regional and international levels.

Rationale: Unlike historic CBEP engagements in the Former Soviet Union, there is relatively little Select Agent work or expertise in SEA partner laboratories below the national level. In order to enhance early disease detection at the sub-national level, CBEP will support provision of selected capabilities and expertise, focused on assays and methods that can be performed under Biosafety Level-2 laboratory conditions and that do

not require isolation or amplification of live pathogen. If facilities, equipment, practices and procedures are in compliance with appropriate international BS&S guidelines and regulations as outlined in the CBEP Biorisk Management Implementation Guidance CTB-11-094, culture-based laboratory techniques (in addition to routinely supported molecular techniques) may be supported at the designated national reference laboratories.

CBEP will support research efforts that utilize interoperable electronic surveillance tools and support efforts to harmonize existing electronic surveillance networks with country, regional and international reporting systems.

Constraint: CBEP will not support establishment of additional pathogen repositories, expansion of Select Agent culture or isolation-based laboratory techniques, or provision of pathogen-specific expertise with Dual Use Research of Concern (DURC) implications.

Priority: CBEP will leverage partnerships to maximize use of collected samples to inform surveillance for diseases of priority for CBEP, partner countries, and other United States Government or international stakeholders.

Rationale: The diseases of primary concern to SEA partner countries' public health authorities are often outside the scope of CBEP's focus on Priority Pathogens. As significant time and expense can be expended upon the *de novo* collection of samples, efficiencies can be gained by leveraging existing samples collected under other programs and ongoing efforts. Furthermore, any samples collected under CBEP may be made available to other programs to test for their priority pathogens using their own funding.

Priority: CBEP will support field-testing of low-cost, point-of-need detection technologies and sustainably integrating the use of such devices into national biosurveillance strategies.

Rationale: Paramount to early disease detection is the wide-distribution and utilization of sensitive and specific point-of-need diagnostics. CBEP will support field-testing of diagnostic technologies of interest to the U.S. Department of Defense in both Role 0 (very simple and rugged devices suitable for self-use) and Role 1 (handheld electronic systems for use in forward (medical level 1 care) environments) categories. CBEP will collaborate with organizations (to include DTRA, Research and Development (J9)) developing point-of-need diagnostics to field test these technologies. These collaborations will provide the developers critical data on the technology's performance under austere conditions, while providing CBEP and partner countries with valuable lessons learned in support of developing strategies and implementation plans for pushing diagnostic capability as close as possible to the point-of-need.

Constraint: CBEP generally does not support assay development or laboratory validation studies. Exceptions may be made on a case-by-case basis where a critical gap in resources for validation exists and there is a substantial and direct benefit to the partner country in enhancing their surveillance capabilities.

Priority: CBEP will prioritize pathogen identification for syndromes with unknown etiologies.

Rationale: Diseases of CBEP interest are routinely misdiagnosed and misreported as commonly occurring illness by the lower tiers of partner nations' disease surveillance systems. CBEP will focus on improving capabilities to differentiate etiologic agents (including select agents) and understanding the local select agent disease burden as it relates to the symptomology.

Constraint: CBEP will not support research that is focused solely on pathogens not considered to be CBEP priorities. Research that includes such pathogens in addition to CBEP priority pathogens will be evaluated on a case-by-case basis considering the intent of the research, ability to aid in differential diagnosis, and contributions to inform biosurveillance and support CBEP mission objectives.

Priority: CBEP will prioritize research projects that will improve understanding of pathogen and disease distribution and to establish baselines for prevalence through human and animal host and vector populations, as well as environmental reservoirs including soil and water throughout SEA.

Rationale: Research projects that aim to characterize the prevalence and/or distribution of priority pathogens within host and environmental reservoirs in SEA are of particular interest to CBEP. Surveillance and prediction efforts depend upon an established baseline of pathogen prevalence, and an understanding of the impact and relationship of host vectors and environmental factors to the distribution of these pathogens. By developing a comprehensive understanding of the interrelationship of all these factors, CBEP will then be able to identify and inform risk factors for disease propagation.

Priority: CBEP will focus on advancement of the One Health initiative through improving communication and collaboration between human and animal health practitioners within and between partner nations as well as increasing understanding of zoonotic disease transmission.

Rationale: Humans live in close proximity to domestic and wild animals in rural SEA. Coupled with limited veterinary capacity and the widespread animal trade (both legal and

illegal) in the region, SEA is vulnerable to zoonotic and Transboundary Animal Diseases. CBEP will support zoonotic and transboundary disease surveillance research that offers opportunities for early detection of disease threats, improved assessment of risks posed by enzootic pathogens, and identification and targeting of effective prevention and control measures. Priority will be placed on research that promotes a One Health approach to disease investigation and response.