

Cooperative Biological Engagement Program Biosafety and Biosecurity Overview

***Cooperative Threat Reduction Program Defense Threat
Reduction Agency and United States Strategic Command
Center for Combating Weapons of Mass Destruction***

***Peter Pesenti, Ph.D.
Chief Scientist
Cooperative Biological
Engagement Program***





Agenda

- Cooperative Threat Reduction (CTR) and Cooperative Biological Engagement Program (CBEP) Mission & Overview
- CBEP Objectives and Engagements, Primary Mission Areas
- CBEP Biosafety and Biosecurity (BS&S) Program



Agenda continued

- BS&S Tools
 - Global Biorisk Management Curriculum (GBRMC)
 - Protocol Risk Assessment Tool (PRAT)
 - Pathogen Asset Control System (PACS)
 - BS&S Core Documents
- “Top Down” and “Bottom Up” Approach
- Key Takeaways

Nunn-Lugar DoD Cooperative Threat Reduction...



Major objectives:

Strategic Offensive Arms Elimination (SOAE)



Chemical Weapons Elimination (CWE)



1. *Dismantle and destroy* stockpiles of nuclear, chemical, or biological weapons, equipment or means of delivery that partner countries own, possess, or that is in their control
2. *Account for, safeguard, and secure* nuclear, chemical, and biological materials, equipment or expertise which, if vulnerable to theft or diversion, could result in Weapons of Mass Destruction (WMD) threats
3. *Prevent and detect* acquisition, proliferation, and use of nuclear, chemical, or biological weapons, weapons-usable and related materials, equipment or means of delivery and knowledge

Global Nuclear Security (GNS)



Proliferation Prevention Program (PPP)



Cooperative Biological Engagement Program (CBEP)





CBEP Mission

CBEP's mission is to reduce the threat posed by pathogens of security concern and related materials and expertise; other emerging infectious disease risks; terrorist acquisition, and use as biological weapons.



CBEP Objectives

- 1) Dismantle, destroy, and prevent the sale, theft, diversion, or use of stockpiles of biological weapons, means of delivery, and biological weapon-related equipment, technology, and infrastructure.
- 2) Enhance partner country/region's capability to identify, consolidate, and secure collections of pathogens and diseases of security concern in order to prevent the sale, theft, diversion, or accidental release of such pathogens and diseases.



CBEP Objectives continued

3) Enhance partner country/region's capability to rapidly and accurately survey, detect, diagnose, and report biological terrorism and outbreaks of pathogens and diseases of security concern in accordance with international reporting requirements.

Current and Future CBEP Engagements

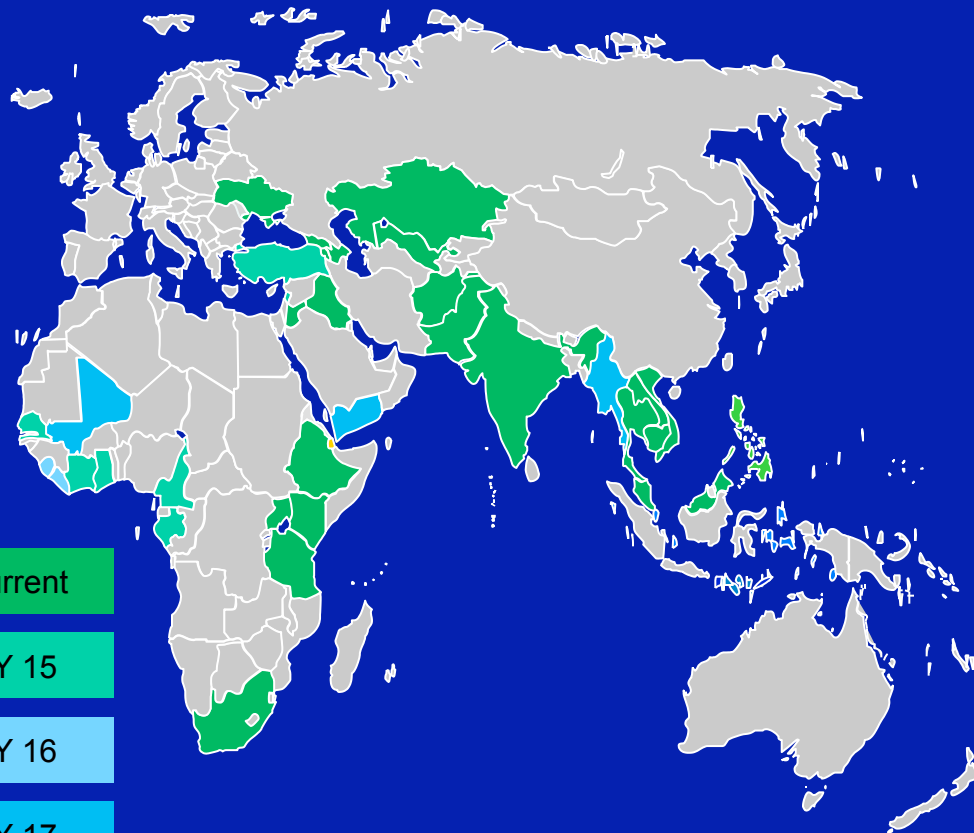


EUCOM

- Armenia
- Azerbaijan
- Georgia
- Ukraine
- Turkey

AFRICOM

- Kenya
- South Africa
- Tanzania
- Uganda
- Ethiopia
- Cameroon
- Côte d' Ivoire
- Gabon
- Ghana
- Senegal
- Sierra Leone
- Liberia
- Mali



CENTCOM

- Afghanistan
- Iraq
- Jordan
- Kazakhstan
- Pakistan
- Uzbekistan
- Lebanon
- Yemen

PACOM

- Cambodia
- India
- Lao PDR
- Malaysia
- Philippines
- Thailand
- Vietnam
- Myanmar (Burma)



CBEP U.S. Engagement Partners



- Center for Disease Control (CDC)
- Department of State (DOS)
 - U.S. Agency for International Development (USAID)
 - Biological Engagement Program (BEP)
- U.S. Department of Agriculture (USDA)
- Department of Energy, Sandia National Laboratories (DOE SNL)
- Naval Medical Research Unit – 2 (NAMRU-2)
- Federal Bureau of Investigation (FBI)
- Center for Disaster and Humanitarian Assistance Medicine (CDHAM)
- Naval Medical Research Center (NMRC)
- U.S. Army Research Medical Institute of Infectious Disease (USAMRIID)
- Edgewood Chemical and Biological Center (ECBC)
- Armed Forces Research Institute of Medical Sciences (AFRIMS)
- American Society of Clinical Pathology (ASCP)

Note: graphic is for visual use only, not a representation of level of effort



CBEP Global Collaboration

CBEP supports and works with the following organizations to promote international standards, regulations, and guidelines related to biological threat reduction and global health security:



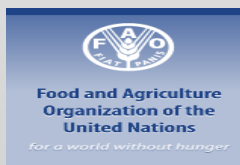
Global Partnership Against the Spread of Weapons and Materials of Mass Destruction



World Health Organization (WHO)



International Organization for Animal Health (OIE)



U.N. Food and Agriculture Organization (FAO)



European Committee for Standardization (CEN)

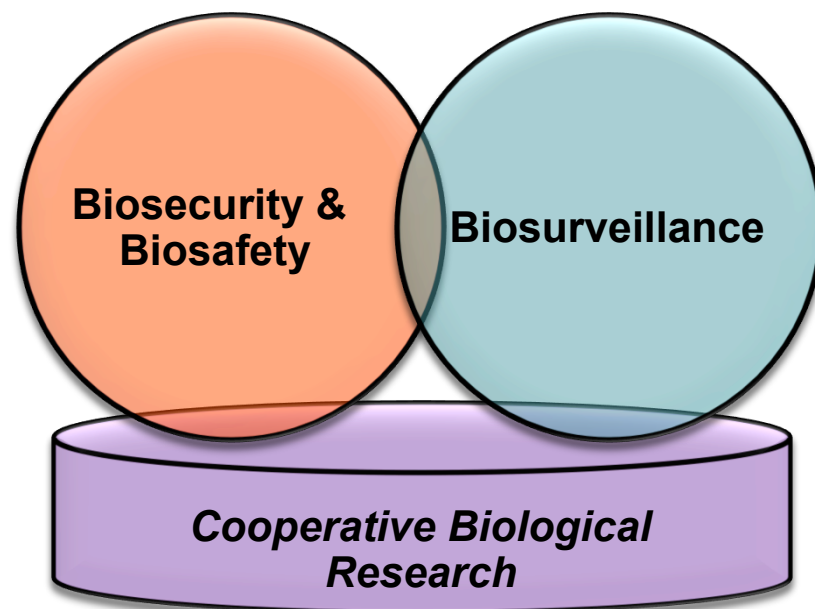


CBEP Primary Mission Areas

Biosurveillance (BSV): Strengthen capacity for public health and veterinary health systems to detect, diagnose, and report infectious disease outbreaks.

Biosafety and Biosecurity (BS&S): Strengthen biosafety and biosecurity practices and operations by securing collections of especially dangerous pathogens into safe and secure facilities. Provide technical consultations, risk assessments, and trainings to build capacity and internal expertise to create a sustainable culture of laboratory biorisk management.

Cooperative Biological Research (CBR): CBEP uses projects to assist the BSV and BS&S focus areas by encouraging transparency in all functional areas of human and veterinary networks, and integrates partner country scientists and institutes into the international scientific community.





CBEP BS&S



Biosecurity: focuses on pathogen collections, the security measures protecting them, and the regulatory framework governing them

Biosafety: focuses on reducing the risk of laboratory acquired infections and improving regulatory framework involving research with infectious agents



Why have BS&S Program?

Benefits of a CBEP BS&S Program:

- Builds capacity in countries to prevent the spread of infectious diseases
- Aids the establishment of national biorisk frameworks
- Enhances a country's overall biosurveillance system
- Helps foster an international culture of responsible and ethical conduct in biological research
- Protects nations from the threat of bioterrorism by properly securing especially dangerous pathogens
- Ensures personnel handling and storing pathogens use internationally recognized and accepted practices





Available CBEP BS&S Tools

- BS&S Training: GBRMC and Library/ Network (GBRMCNet)
 - ✓ BS&S training courses, including internationally recognized best practices, risk-based approaches to BS&S issues, sustainability, and more.
- PACS
 - ✓ An electronic system for accounting, management, and control of biological agent stocks.





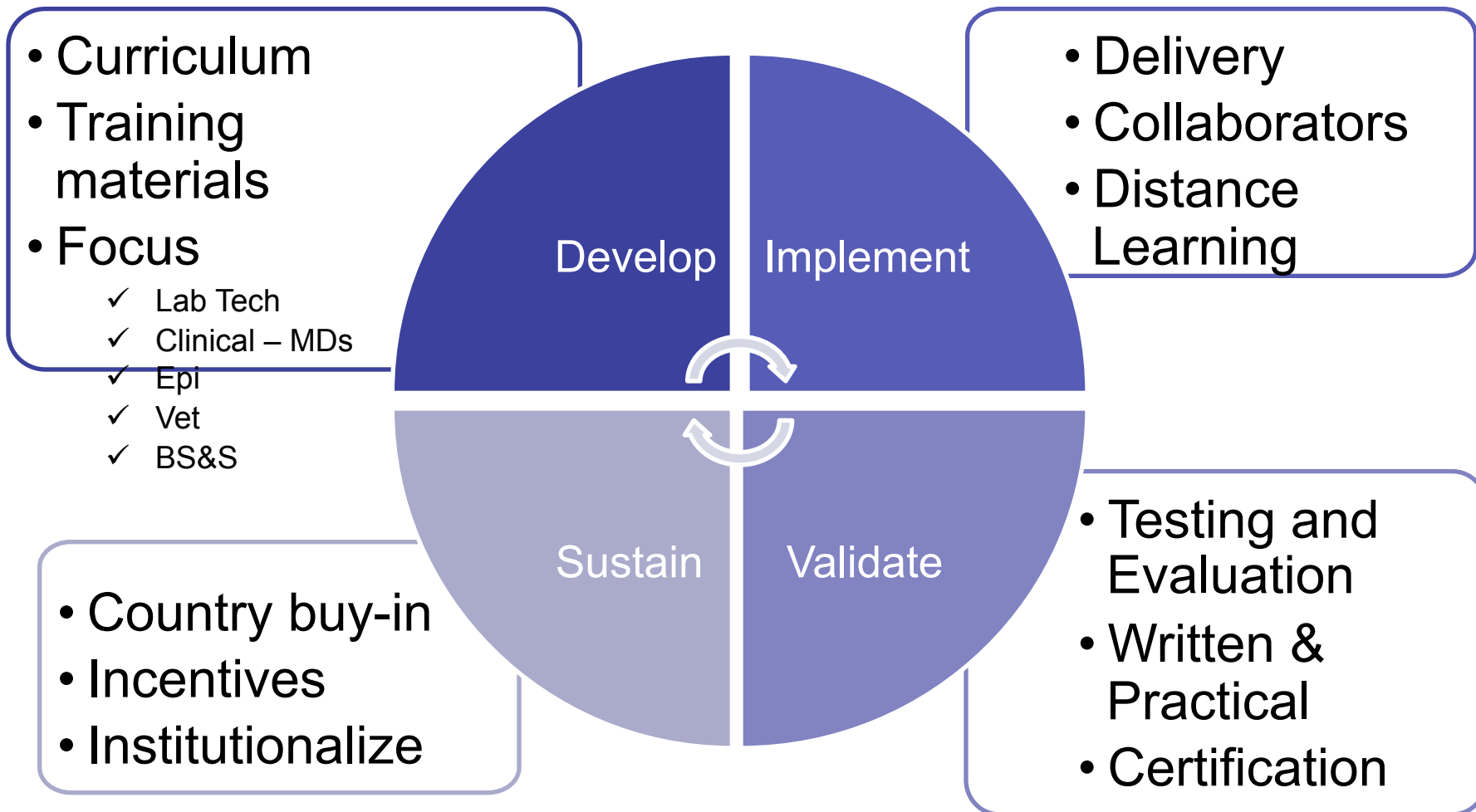
Available CBEP BS&S Tools continued

- PRAT
 - ✓ A risk assessment form that ensures CBEP research projects are conducted safely and securely.
- Biorisk Management Core Document Collection
 - ✓ Consists of customizable standard operating procedures (SOPs) and manual templates to promote a sustainable biorisk management program.





CBEP Training Strategy





CBEP BS&S Tools: GBRMC

BS&S Training: GBRMC Library/Network (GBRMCNet) & Training Courses:

- Growing collection of 42 peer-reviewed biosafety and biosecurity training courses directed towards building biorisk management capacity
- Based on internationally recognized biosafety and biosecurity practices
 - ✓ WHO Biosafety and Biosecurity Guidance
 - ✓ CWA 15793, Laboratory Biorisk Management
 - ✓ CDC/NIH: “Biosafety in Microbiological and Biomedical Laboratories”, 5th edition (BMBL-5)
- Uses highly-interactive training techniques designed to sustain biorisk management knowledge and skills
 - ✓ Based on adult education and instructional design
- Can be customized for different roles and responsibilities
 - ✓ Basic track, Management and leadership, and Laboratory workforce



CBEP BS&S Tools: PACS

PACS:

- System for accounting, management and control of biological agent stocks
- Comprehensive and flexible solution for tracking detailed information on samples and strains throughout their lifecycle
- Absolute location of vials: room, freezer, shelf
- Audit trails and event logs per sample
- Repository inventory feature for quick and accurate inventory reconciliation




Freezer 1 [HSDO-1303].Shelf 1.Box 1						
	Container ID	Pos	Material #	Container Type	Microorganism / Sample type	
1	 C100061	4	M100008	Ampoule	Brucella suis	
2	 C100062	5	M100008	Ampoule	Brucella suis	
3	 C100066	18	M100008	Ampoule	Brucella suis	

FIGURE 6: Freezer content report.



CBEP BS&S Tools: PRAT

PRAT: a comprehensive risk assessment form incorporated as part of CBEP's Cooperative Biological Research proposal review process to ensure projects are implemented in a safe and secure facility appropriate for the work proposed.

PRAT helps to ensure that:

- ✓ Appropriate laboratory facilities and BS&S equipment are used for research projects
- ✓ Laboratory equipment maintained and certified
- ✓ Specific activities with biological agents conducted safely and securely
- ✓ BS&S review is provided for research activities
- ✓ SOPs and manuals are approved and used for research projects
- ✓ BS&S training completed by project personnel
- ✓ Appropriate personal protective equipment available and used





CBEP BS&S Tools: Biorisk Management Core Document Collection

- CBEP Core Document Collection is comprised of:
 - BS&S international guidelines and references
 - BS&S SOPs
 - BS&S templates and manuals:
 - ✓ Biorisk management manual
 - ✓ Respiratory Protection Manual
 - ✓ Chemical Hygiene Plan
 - ✓ BS&S SOP templates
 - ✓ Risk assessment template
- Additionally, the documents are:
 - Made available alongside training materials on GBRMCNet
 - Peer-reviewed and quality controlled



CBEP BS&S Approach - Current

“Bottom up” engagement:

- Work with partner countries’ “people and places” to reduce threat from pathogens of security concern & improve global health security
- Provide physical security upgrades at locations with pathogen collections in support of consolidation efforts
- Provide staff level training to ensure safe and secure laboratory work
- Upgrade and expand PACS in partner countries
- Increase ability to detect, diagnose, and report outbreaks of diseases of security concern via biosurveillance network



CBEP BS&S Approach-In Development

“Top down” engagement:

- Establish the legal framework via codification of an enforcement mechanism
- Leverage CDC’s Model – “National Biological Laboratory Monitoring Program”
- CBEP supports CDC as interlocutor for program standup
- Time phase implementation with CBEP regional pilot program



Key Takeaways

CBEP BS&S Program:

- Focuses on reducing biological threats
- Supports implementation of international BS&S guidelines and best practices
- Promotes consolidation of pathogen collections
- Requires “top down” and “bottom up” approaches for successful engagement
- Enhances host nation disease surveillance
- Provides mechanism for sustained engagement

Questions?