

| Country | Existing Level of Capabilities | Recommendations for priority actions | P.6.1 (Whole of Gov't BSBS) Areas that need strengthening/ challenges | P.6.2 (BSBS Training) Areas that need strengthening/ challenges | Summary of Gap Analysis |
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| | addressed include bio-risk management training for regional laboratory personnel, pre- and in-service training for medical laboratory personnel, and IPC trainings for health workers. | | | | |
| Slovenia (<i>limited data available;</i> 06/2017) <u>Scores</u> P.6.1 = 3 P.6.2 = 4 | <ul style="list-style-type: none"> • Slovenia has a strong public health system that is well-integrated into the national healthcare infrastructure. • Despite the strong overarching emergency management structure and skillful implementation of many systems, day-to-day activities and emergency response action could be strengthened by taking full advantage of an “all-hazards” approach. | <ul style="list-style-type: none"> • Coordinate programs for addressing antimicrobial resistance and ensuring BSBS among laboratory facilities. | <ul style="list-style-type: none"> • Establish a comprehensive, national-level body for BSBS, and develop a formal, multisectoral oversight mechanism and monitoring of dangerous pathogens. • Ensure sustainable governmental funding for biosafety facilities and programs. | <ul style="list-style-type: none"> • Consolidate common curriculum for BSBS for human, veterinary, and agricultural laboratories, as well as industry partners. • Establish a common train-the-trainers program in the area of BSBS, and maintain staff training at all facilities. | Help build a comprehensive national BSBS system and oversight mechanism; develop a sustainable funding mechanism; consolidate BSBS curriculum; establish a BSBS train the trainers program |
| Somalia (10/2016) <u>Scores</u> | <ul style="list-style-type: none"> • The whole-of-government BSBS system is not in place | <ul style="list-style-type: none"> • Establish a multisectoral BSBS team to enhance collaboration and | <ul style="list-style-type: none"> • Multisectoral collaboration is needed to assess | <ul style="list-style-type: none"> • BSBS training needs should be assessed, and a training | Help build a comprehensive national BSBS |

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| P.6.1 = 1 P.6.2 = 1 | <p>for human, animal, food or environmental laboratories.</p> <ul style="list-style-type: none"> • There is currently no national BSBS legislation, regulation or guidelines. • Awareness of biosafety, biosecurity and biorisk management needs to be improved. • Multisectoral collaboration is needed when a whole-of-government BSBS system is developed across the country. • Sharing information, SOPs and best practices on BSBS between laboratories should be encouraged. • Some training in BSBS has been organized by international organizations but no training programs are available for all laboratories and all laboratory staff. | <p>information sharing on BSBS best practices and SOPs:</p> <ul style="list-style-type: none"> - Assess the existing gaps on BSBS - Make a workplan for developing BSBS in laboratories. • Establish a multisectoral BSBS committee to review the development of BSBS legislation and to develop a program in collaboration with the BSBS team: <ul style="list-style-type: none"> - Assess BSBS training needs and develop training material - Increase awareness of BSBS among the laboratory workforce. | <p>existing gaps on BSBS, prepare a workplan and strategies to develop BSBS in laboratories, including a legal framework for BSBS, along with oversight and monitoring capacity.</p> <ul style="list-style-type: none"> • Awareness of biosafety, biosecurity and biorisk management needs to be raised. BSBS practices should be adopted in all facilities working with biological materials. • Availability of funds to support BSBS implementation should be ensured. • How infectious waste, handled by private companies, is treated needs to be clarified. • BSBS measures should be implemented in all laboratories across public health, | <p>program to address gaps in BSBS developed and implemented.</p> | <p>system; assess need for and deliver BSBS trainings; build basic lab capacities; create a workplan for all labs; implement BSBS measures all labs across multiple sectors; share BSBS SOPs and best practices across all labs; develop waste management guidelines for private sector</p> |

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| | <ul style="list-style-type: none"> • Linkages with the African Biological Safety Association and other international organizations concerned with BSBS should be strengthened. • The lack of BSBS systems has already caused problems since laboratories cannot be sent reference strains. • Personal protective equipment (PPE) and biosafety equipment are available in some laboratories but maintenance of equipment is inadequate due to the lack of resources. • There was no opportunity to visit laboratories during the assessment. There was no BSBS related documentation available. • In 2014, an attempt was | | veterinary, agriculture and food sectors. | | |

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| | made to develop an annual work plan for all laboratories. | | | | |
| Sri Lanka <i>(limited data available; 06/2017)</i> <u>Scores</u> P.6.1 = 2 P.6.2 = 1 | <ul style="list-style-type: none"> • Has evidenced high levels of expertise and operational capacity for dealing with public health threats and emergencies. • The country also benefits from teams of experienced public health professionals who are trusted by the public. | <ul style="list-style-type: none"> • N/A | <ul style="list-style-type: none"> • Develop a comprehensive, multisectoral BSBS strategy and accompanying legislation. • Based on the strategy, develop an action plan for implementation at the national level for both the public and private sectors, including: <ul style="list-style-type: none"> - A BSBS training program that includes professional awareness training; - Measures to update the inventory dangerous pathogens and toxins • Update the laboratory licensing accreditation process to include BSBS requirements. • Identify how sustained funding can be | <ul style="list-style-type: none"> • Establish a BSBS training program as referenced in the previous column. | Support the development of BSBS legislation; develop a national implementation action plan; inventory pathogen samples; update laboratory accreditation processes; establish BSBS training programs |

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| | | | ensured for BSBS programs. | | |
| Sudan (10/2016) <u>Scores</u> P.6.1 = 2 P.6.2 = 2 | <ul style="list-style-type: none"> The high staff turnover affects all areas of work that requires a skilled workforce. A Laboratory Working Group has drafted a national policy on BSBS. At facilities such as the National Police Laboratory, biosecurity concepts are implemented comprehensively including the control of entry by security guards, code access doors for manipulations, storage rooms and inventory of samples. Licensing is only mandatory for private human and animal medical laboratories, and BSBS are not part of the licensing process. There is no national record or inventory of | <ul style="list-style-type: none"> Develop a BSBS system to apply the national strategic plan in collaboration with partners. Map all laboratories to collect information on their existing capacities and identify any agents and pathogens of concern that they store. Secure financial and human resources for the implementation of BSBS plans. Develop and conduct a national training program for all staff in all facilities. Raise awareness among staff and the community by developing academic training and facilitating the establishment of BSBS associations. | <ul style="list-style-type: none"> Agents and pathogens of concern have not been identified and there is no inventory by each ministry or facilities housing dangerous pathogens and toxins. BSBS policies and guidelines are not yet implemented at all levels throughout the country including private sector laboratories. There is insufficient maintenance and service contracts for key equipment (e.g. certification of the biological safety cabinet, gloves boxes, reverse transcription polymerase chain reaction (RT-PCR) machines). An immunization policy for laboratory | <ul style="list-style-type: none"> There is no national training program in BSBS for all laboratories in all sectors. Academic training is lacking on BSBS for all public and private professionals to enhance their knowledge and skills. | Implement BSBS guidelines across all sectors nationally; identify and inventory pathogens of concern; support lab equipment maintenance; consider workforce retention strategies; develop a national BSBS training program and implement universally; develop a BSBS curriculum for health sector professionals; develop laboratory licensing requirements |

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| | <p>pathogens within facilities that store or process dangerous pathogens and toxins.</p> <ul style="list-style-type: none"> • The central laboratory capacity is good in the public sector, but a well-defined national laboratory network for both animal and human health is needed from health facility to effective referral level. • The Government has national legislation that allows the public health sector to request the support of the security sector to implement public health measures. • Training in BSBS is carried out at some central laboratories, but there are no national training programs available for all laboratories and staff in the private, public sector and sciences. | | <p>staff is needed.</p> | | |

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| Tanzania (02/2016) <u>Scores</u> P.6.1 = 2 P.6.2 = 3 | <ul style="list-style-type: none"> Tanzania is making progress towards the “One Health All Hazards” approach. While laboratory accreditation and testing and training in biosafety are adequate, biosecurity needs strengthening. Sharing of equipment, reagents and personnel between animal and human laboratories particularly for molecular biology work should be easier. Consideration should be given to those with relevant training to be registered to allow them to work in specific areas of medical laboratories. It is important that regional and district laboratory capacity are strengthened and linked more closely with epidemiological | <ul style="list-style-type: none"> Improve sustainable laboratory capacity in districts and regions; including guidance, SOPs, reagents, equipment, personnel and BSBS training. Allow registration of personnel with relevant training so that they can work in specific areas of medical laboratories. Map out current capacity for biosecurity (including sample storage, documents, guidance and required legislation) and incorporate these into formal and in-service training. | <ul style="list-style-type: none"> Sustainable laboratory capacity in districts and regions needs to be strengthened with improved guidance, SOPs, reagents, equipment and personnel, as well as BSBS training. A baseline evaluation of the current state of affairs for biosecurity should be mapped out, including sample storage, available documents and guidance. Biosecurity legislation does not exist and needs to be developed. Personnel with relevant training should be considered for registration to allow them to work in specific areas of medical laboratories. Using available resources, a map with | <ul style="list-style-type: none"> Biosecurity should be incorporated into training, both formal and in-service, with an overseeing body to implement and monitor. Personnel with relevant training should be considered for registration to allow them to work in specific areas of medical laboratories. | Support the development of biosecurity legislation; map out BSBS capacities; create a registry of staff with BSBS trainings; develop SOPs and guidance and strengthen lab capacities in locations of need; incorporate biosecurity into trainings |

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| | surveillance data. | | <p>location of trained staff should be developed (MoHCDGEC, academic/research/partner agencies, private laboratories) to enable/ensure surge capacity.</p> <ul style="list-style-type: none"> • Effort should be made to retain trained laboratory equipment engineers and future rollout training to build up capacity. | | |
| <p>Thailand (<i>limited data available; 06/2017</i>) <u>Scores</u> P.6.1 = 4 P.6.2 = 4</p> | <ul style="list-style-type: none"> • N/A | <ul style="list-style-type: none"> • N/A | <ul style="list-style-type: none"> • Ensure the detection and follow up of incidents by biosafety officers. Serious potential or occurred incidents should be investigated and lessons learnt. • Enhance existing networks between ministries, such as the emerging infectious disease network by including responsible biosafety officers from | <ul style="list-style-type: none"> • Develop and strengthen national training on BSBS using a unified public and animal health manual with equal outreach in the public and animal health sectors. | <p>Strengthen role and capabilities of biosafety officers at institutions; build multisectoral coordination and networks; develop a national BSBS-One Health integrated training</p> |

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| | | | the public health and animal health sectors and from other related ministries. | | |
| Turkmenistan (06/2016) <u>Scores</u> P.6.1 = 2 P.6.2 = 2 | <ul style="list-style-type: none"> The Anti-Epidemic Emergency Commission regulates the registration, storage, transfer and transport of pathogens at all four biosafety levels. Licensing is carried out with accuracy and a minimal number of designed laboratories at the central level ensure that especially dangerous pathogens are identified, held, secured and monitored. In 2014, the Museum of Living Microorganisms was established at the Center for the Prevention of Especially Dangerous Infections. A Practical Guide to Biological Safety in the Laboratory is awaiting | <ul style="list-style-type: none"> Approve comprehensive national BSBS legislation and establish a clear framework for medical, veterinary and agricultural agencies. Activate a multisectoral task force to perform risk assessments for BSBS and develop comprehensive SOPs in accordance with international requirements. Propose academic high-level BSBS courses for laboratory professionals and build an integrated database of BSBS experts. Conduct simulations and drills on BSBS scenarios. Improve laboratory waste management. | <ul style="list-style-type: none"> A national biosafety framework for medical, veterinary and agricultural agencies should be introduced. It is necessary to develop comprehensive medical, veterinary and agricultural SOPs for all staff working with at risk biological materials in accordance with previous risk assessments and international standards. Lack of awareness among the laboratory workforce of international BSBS best practices for safe, secure and responsible conduct. | <ul style="list-style-type: none"> Common curricula and train-the-trainers programs for both BSBS in all sectors. Training on BSBS should be provided to staff at all facilities (of all sectors) that work with dangerous pathogens and toxins. Build an integrated database of BSBS academically certificated experts. | Support the development of BSBS legislation and a national biosafety framework; support development of risk assessments and appropriate SOPs; develop advanced BSBS training programs; share best BSBS practices with laboratory workforce; provide BSBS trainings; develop BSBS curriculum and a train the trainers program |

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| | <p>approval; however, an appropriate International Organization for Standardization (ISO) accreditation is not yet in place.</p> <ul style="list-style-type: none"> • Basic BSBS processes and trainings are in place, such as wearing PPE and training for work in BSL 1-2 labs. • Despite the legislation in force, not all elements of a comprehensive BSBS system are in place, especially for animal health and the agricultural sector. • Safeguards to minimize the potential improper removal or release of biological agents or related documentation should be enforced and extended throughout the country. • Mechanisms for biosecurity oversight of | | <ul style="list-style-type: none"> • Appropriate ISO accreditation. | | |

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| | <p>dual use research and responsible code of conduct for scientists exist and once every two years specialists undergo knowledge testing on laboratory functions and activities.</p> | | | | |
| <p>United States (06/2016) <u>Scores</u> P.6.1 = 4 P.6.2 = 4</p> | <ul style="list-style-type: none"> • The USA has built a comprehensive national BSBS system covering all areas of society. • These extensive oversight requirements and guidelines on biosafety and biocontainment exist both at the governmental and state levels, and at academic and other research institutes. • The strengths of the system lie in active federal outreach and education, and promoting and improving BSBS overall. • A number of recent | <ul style="list-style-type: none"> • Continue to implement recommendations by Federal Expert Security Advisory Panel and Fast Track Action Committee on Select Agent Regulations. • Enhance partnerships with biomedical industry and scientific community to comprehensively evaluate gain-of-function research and develop federal policies and guidelines. • Finalize and implement recommendations on gain-of-function studies involving pathogens with pandemic potential. | <ul style="list-style-type: none"> • N/A | <ul style="list-style-type: none"> • General oversight framework. • Revisions to the Select Agent Regulations to require documentation of problems identified during drills/exercises and the corrective action(s) taken. • No single mechanism exists to ensure and monitor staff competence and proper training at all laboratories. | <p>Continue to evaluate regulatory policies and implement recommendations; consider developing a single unified monitoring mechanism for staff training; enhance multistakeholder partnerships and engagements</p> |

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| | <p>laboratory incidents involving inappropriate handling of dangerous pathogens highlight the need for improvements in the national BSBS technical areas.</p> <ul style="list-style-type: none"> • The priority areas for action and new recommendations are addressing issues of training, institutional cultures, governance, risk assessments and documentation in laboratories handling select agents. • Open reporting of these incidents underlines both the transparency of the USA system and the exemplary risk communication strategy that the USA has undertaken to build confidence and trust within the global health security community. | | | | |
| Viet Nam (11/2016) | <ul style="list-style-type: none"> • Has made important progress in biosafety, | <ul style="list-style-type: none"> • Strengthen capacity of provincial health | <ul style="list-style-type: none"> • Strengthen: - Development of | <ul style="list-style-type: none"> • Mechanisms to monitor and | Support the development of |

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| <p><u>Scores</u> P.6.1 = 3 P.6.2 = 3</p> | <p>as part of a broader plan for strengthening national capacity in public health laboratories.</p> <ul style="list-style-type: none"> • Progress has been made in developing a biosafety legislative framework and biosafety training capacity in the regional institutes that would enable delivery of training to staff from provincial and district laboratories. • Biosafety would be further strengthened by reviewing biosafety legislation and regulations against the international standards and investment in maintenance and certification of key biosafety equipment such as biosafety cabinets in all BSL-2 laboratories. For this to happen, there is a need | <p>departments to certify and inspect diagnostic laboratories (BSL-1/2).</p> <ul style="list-style-type: none"> • Commit resources to maintain key biosafety infrastructure, such as biosafety cabinets, in a sustainable manner. • Implement targeted biosafety and biorisk management training throughout the country in a coordinated manner, to develop a large network of trainers and trained laboratory workers who can regularly access expertise, tools and manuals to support biosafety practices. • Develop and monitor implementation of the biosecurity regulatory framework, combined with targeted education and awareness of procedures among key stakeholders. | <p>national biosecurity legislation, regulations and guidelines, which should enable monitoring of selected dangerous pathogens and toxins.</p> <ul style="list-style-type: none"> - Implementation of adequate pathogen control measures. - Consolidation of dangerous pathogens and toxins into a minimum number of facilities. - Establishment of oversight mechanisms to monitor and enforce biosecurity legislations. • The current national laboratory system, including human, animal and agricultural sectors, needs investment to build workforce, equipment and capability to achieve and maintain a quality | <p>document the effectiveness of training on BSBS for laboratory workers are required.</p> <ul style="list-style-type: none"> • Targeted biosafety and biorisk management training in a coordinated manner is needed throughout the country to improve biosafety practices by developing a network of trainers and trained laboratory workers who can regularly access expertise, tools and manuals. • Continuing education and professional development in biosafety and biorisk management and further development within | <p>BSBS legislation; support health department capacity building; invest in lab capacity building; deliver biosafety infrastructure; implement biorisk management training; develop network of biosafety professionals; strengthen auditing and assessments of laboratories and develop oversight mechanisms; consolidate dangerous pathogens; improve and deliver BSBS trainings; integrate biorisk management procedures into education</p> |

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| | to build capacity in provincial health departments and preventive medicine laboratories to inspect and certify laboratories in the provinces. | | <p>biosafety system and develop a biosecurity system.</p> <ul style="list-style-type: none"> • Build capacity and resources to service and certify biosafety cabinets to a national standard. This could be linked to a broader effort to develop capacity at provincial health departments to oversee relevant laboratories, including development of materials and training to strengthen assessment of BSL-1/2 laboratories. • Promote regular internal audits and strengthen the assessment mechanism for certification of BSL-1/2 laboratories. • Integrate assessment of biosafety within the broader efforts to improve laboratory | academic training for medical laboratory technicians is required. | |

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| | | | quality management systems in Viet Nam, as relevant to the national laboratory system (see Detect indicators 7.1–7.4). | | |

U.S. Funded Programmatic Activities Compared to JEE Results

In 2014, the United States committed to working with at least 30 partner countries to advance model systems of Global Health Security to prevent, detect, and respond to infectious disease threats, whether naturally occurring, accidental or deliberately spread. Through the Global Health Security Agenda, the United States seeks to accelerate progress toward a world safe and secure from infectious disease threats and to take action to promote global health security as an international priority. The United States has made a commitment to assist 31 countries over five years to achieve the targets of the Global Health Security Agenda. To achieve these goals, it is important to coordinate closely across the many departments and agencies that play a role in the agenda, including the Departments of Health and Human Services, State, Defense, Agriculture, and the U.S. Agency for International Development.

In collaboration with partner country governments, the U.S. developed GHSA strategic roadmaps that inform annual work plans to build capacity in selected countries. These roadmaps include specific priorities for biosafety and biosecurity activities. The table below highlights programmatic activities for the first two years of U.S. supported capacity building in countries selected to receive GHSA technical assistance, as compared to the gaps identified in their JEE results. Not all countries receiving U.S. assistance have undergone JEEs as of July 25, 2017.

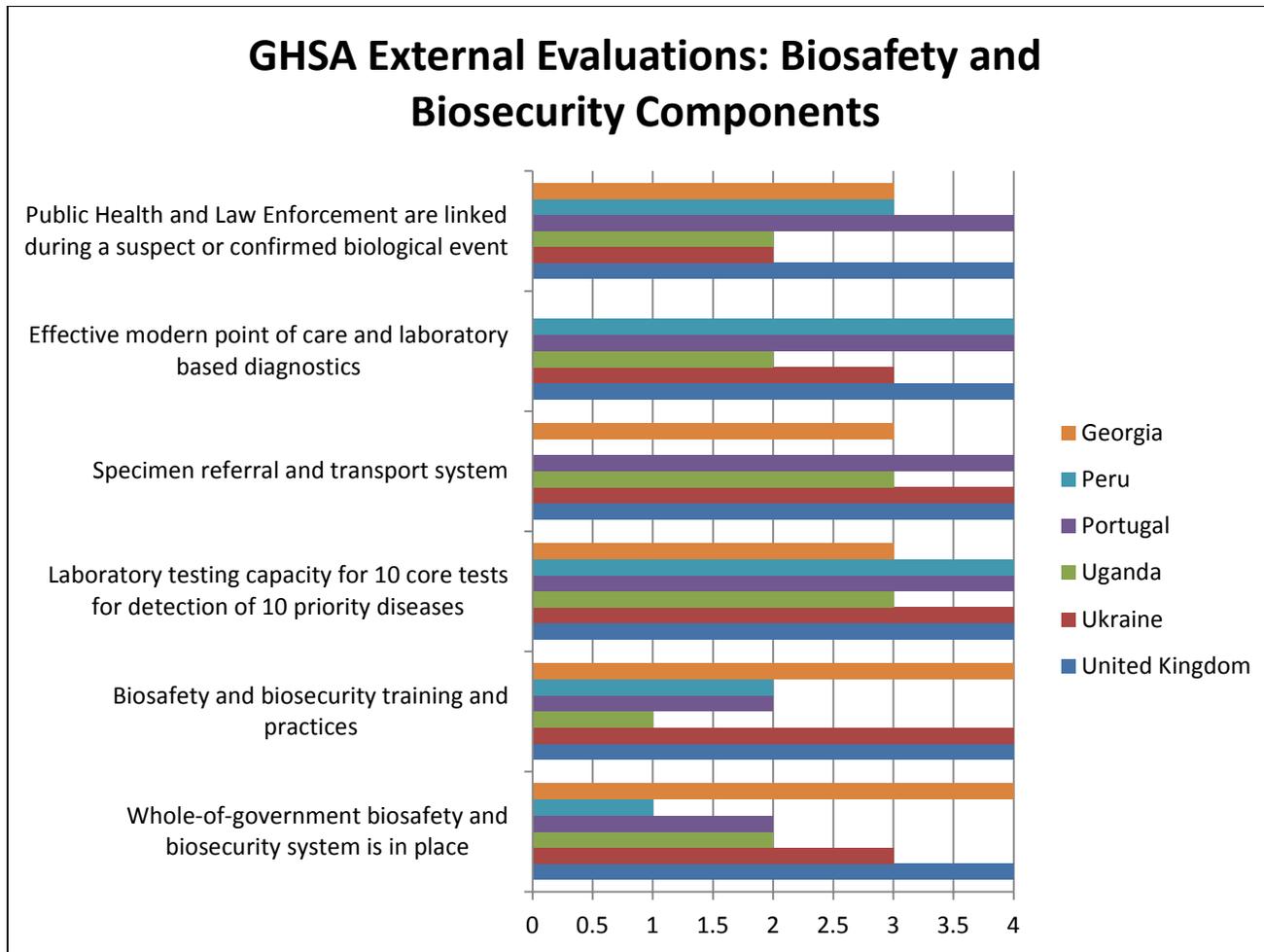
This comparison shows how activities can advance progress along capacity building efforts and how JEEs can inform future activity priorities.

| Biosafety and Biosecurity Capacity Building Activities Compared to JEE Identified Needs | | |
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| Country | Roadmap Priorities | JEE Priorities |
| Bangladesh | <ul style="list-style-type: none"> • Develop foundation for a national BSBS system. • Identify public health laws that could be used to strengthen biosafety and biosecurity efforts and identify current gaps. • Conduct inventory of public laboratories. • Address key gaps through targeted trainings. • Increase resources and capabilities for BSBS. | <ul style="list-style-type: none"> • Update BSBS guidelines to include microorganisms other than GMOs, and include the proper collection, transportation, handling, management and disposal of dangerous pathogens and toxins. • Develop and adopt biosecurity legislation at the national level for both the public and private sectors. • Once these measures are undertaken, implement exercises to measure compliance and identify institutional needs. • Map the current biosecurity capacity, including recording and updating an inventory of facilities that store or process dangerous pathogens and toxins, recording and updating an inventory of dangerous pathogens and toxins within these facilities, and maintaining an active roster of professionals trained in BSBS. • Sustain funding for maintenance of laboratories including BSBS training and the availability of personal protective equipment is needed. • Review the need for a new BSL-3 laboratory at the central level and |

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| | | identify where it should be installed (public or private sector) and if it should be used for both human health and animal health. |
| Cambodia | <ul style="list-style-type: none"> • Hold bimonthly meetings of Biosafety Committee and annual training workshop on biorisk management and sustainable biosafety program. • Conduct inventory of dangerous pathogens • Develop national BSBS framework to secure and consolidate dangerous pathogens and their associated research at a minimum number of secure facilities. • Support national legislation for a national BSBS program. • Conduct baseline assessments at central and provincial level labs. • Provide training in animal health sector and at government microbiology labs. • Establish national professional training with preexisting and new BSBS curriculums in compliance with WHO, IAEA, and OIE standards. | <ul style="list-style-type: none"> • Develop and keep up-to-date a complete inventory of dangerous pathogens stored at facilities. • Improve facilities to ensure physical containment of dangerous pathogens. • Develop and roll out a national training curriculum for BSBS. • Invest in maintenance and servicing of biosafety cabinets, including through training of staff locally. • Additionally, training of national staff should be continued and laboratory mentorship necessitated for the implementation of biosafety and biosecurity practices. |
| Côte d'Ivoire | <ul style="list-style-type: none"> • Conduct baseline assessment for humans, animals, and environmental health systems, including sample transport system, and dangerous pathogens inventory. | <ul style="list-style-type: none"> • Develop national BSBS regulations, particularly on the secure and safe use, storage, disposal and confinement of pathogens in laboratories. • Establish a program for national BSBS training and supervision at laboratories, including those in research institutions and diagnostic and biotechnology laboratories. • Provide biological risk management experts with the necessary skills to train others within their respective institutions. • Promote BSBS by using rapid testing methods rather than cultures, for better waste management at the peripheral level. • Implement a plan for the transport of infectious substances (human, animal and environmental sectors). |
| Ethiopia | <ul style="list-style-type: none"> • Establish national multi-sector team. • Draft and publish select agent and toxins list. • Review and develop biosecurity legislation and guidelines. • Strengthen BSBS Department. • Expand training opportunities for labs on BSBS. | <ul style="list-style-type: none"> • Finalize and implement national BSBS legislation. • Establish a multisectoral national BSBS team to enhance collaboration, information sharing about BSBS best practices, and to develop and implement BSBS policies and guidelines at all levels throughout the country, including private sector laboratories. • Identify, by each ministry, pathogens of concern and facilities housing |

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| | | <p>those agents.</p> <ul style="list-style-type: none"> • Develop regulations; implement them to safeguard the people, agents, and facilities working with dangerous pathogens. |
| Liberia | <ul style="list-style-type: none"> • Draft legislation to support a national BSBS program. • Create multi-sectoral BSBS governance structure at the national level with representatives at the sub-national level. • Identify, document, and destroy or store dangerous pathogen collections in a central regional repository. • Assess BSBS capacities and conduct assessments among key laboratories. • Strengthen security of Ebola samples. | <ul style="list-style-type: none"> • Develop and implement a comprehensive national policy on BSBS that includes all relevant sectors. • Establish linkages between the human, animal and environmental health sectors to address BSBS concerns in line with the One Health approach, build capacity and implement strategic action. |
| Sierra Leone | <ul style="list-style-type: none"> • Establish comprehensive government policies and mechanisms for specimen tracking, transport, and storage. • Identify, document, and destroy or store dangerous pathogen collections in a central regional repository. • Assess BSBS capacities among key laboratories. • Strengthen the security of Ebola samples. • Conduct assessment of BSBS requirements at key One Health laboratories. | <ul style="list-style-type: none"> • Establish and enact legislation and regulations on BSBS. • Develop national guidelines on BSBS. • Establish a regulatory framework for laboratory practice in line with the national laboratory strategy. • Ensure implementation of the Strengthening of Laboratory Management Towards Accreditation program as a quality improvement process. |
| Viet Nam | <ul style="list-style-type: none"> • Obtain comprehensive understanding of management system and leverage points of relevant government agencies. • Strengthen biosafety and bio-risk management at national level. • Assess current BSBS research, practices, and teaching methods at academic institutes of human and animal medicines. • Draft and pilot a national BSBS framework to secure and consolidate collections of dangerous pathogens and their associated research at a minimum number of secure facilities. • Collaborative revision/upgrade of BSBS regulations and guidelines aligned with WHO/OIE standards and core competencies. | <ul style="list-style-type: none"> • Strengthen capacity of provincial health departments to certify and inspect diagnostic laboratories (BSL-1/2). • Commit resources to maintain key biosafety infrastructure, such as biosafety cabinets, in a sustainable manner. • Implement targeted biosafety and biorisk management training throughout the country in a coordinated manner, to develop a large network of trainers and trained laboratory workers who can regularly access expertise, tools and manuals to support biosafety practices. • Develop and monitor implementation of the biosecurity regulatory framework, combined with targeted education and awareness of procedures among key stakeholders. |

APPENDIX I. Graph of GHSA External Evaluation Scores



GHSA External Evaluation Scoring System:

- 0 = No Capacity
- 1 = Limited Capacity
- 2 = Developed Capacity
- 3 = Demonstrated Capacity
- 4 = Sustainable Capacity

APPENDIX II. Global Health Security Agenda External Evaluations Assessment Data

| Country | Existing Level of Capabilities | Overall GHSA Recommendations for priority actions(Relevant to APP3) | P.3.1 Whole-of-Government BSBS system is in place for human, animal, and agriculture facilities | P.3.2 BSBS training and practices | Summary of Gap Analysis |
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| Georgia (01/2015) <u>Scores</u> P.3.1 = 4 P.3.2 = 4 | <ul style="list-style-type: none"> • Systems seem to have been developed which indicate internationally taken advanced BSBS measures, at least centrally; the lack of visit(s) to peripheral sites prevents validation of the acquired information on the lower levels of the tiered laboratory system. • Has consolidated all of the Especially Dangerous Pathogens at the Lugar Center in Tbilisi, Georgia; consolidation is required by law. • The Lugar Center is a regional resource for public health surveillance and research and for BSBS training. | <ul style="list-style-type: none"> • Vetting of Georgian and foreign laboratory workers should be documented to ensure the biosecurity of the laboratory infectious agents. • A standard operating procedure should be developed to prevent, detect and respond to potential laboratory-acquired infections and laboratories should have occupational health programs. | <ul style="list-style-type: none"> • As donor funding decreases in the future, the Government of Georgia must work to determine funding for the sustainability of the public health system. | <ul style="list-style-type: none"> • The BSBS training infrastructure is in place at the National Level at the Lugar Center, at the Zonal Diagnostic Laboratories and the Laboratory Support Stations in the human and veterinary laboratories. • Sustainability may be an issue in the future when donor funding is withdrawn. | Develop sustainable systems for laboratory maintenance; provide vetting training procedures |

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| | <ul style="list-style-type: none"> Public health laboratories are required to have comprehensive BSBS programs in place and all personnel with laboratory access are required to complete BSBS training prior to accessing the laboratories. | | | | |
| Peru (01/2015) <u>Scores</u> P.3.1 = 1 P.3.2 = 2 | <ul style="list-style-type: none"> Biosecurity is a new concept in Peru so biosecurity concepts are not yet elaborated. General laws for worker risk prevention exist and are applied to laboratory work but there is no specific BSBS legislation. The biosafety law is focused on risk prevention in biotechnology when working with live modified pathogens. The export legislation is strict and inhibits the | <ul style="list-style-type: none"> Not Applicable | <ul style="list-style-type: none"> There is no specific BSBS legislation and biosecurity is still a new concept in Peru. Based on the information given, the development of BSBS is focused on the human side of laboratories. | <ul style="list-style-type: none"> There is a training program at INS laboratories including the BSL-3 laboratory, but more training is needed. The team was not able to assess the BSBS training and practice measures in other laboratories. There is no academic education on biosafety, biosecurity or dual use issues. There is in-house training on biosafety at INS but there is a need | Since the team did not visit peripheral laboratories and focused on human health, there might be room for more assessment work to get the whole picture of BSBS in Peru. From this assessment, possible interventions include support development of BSBS legislation; develop train-the- |

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| | <p>ability to send samples outside the country for referral, confirmation, or research purposes.</p> <ul style="list-style-type: none"> • There are no national requirements for using certified couriers when transporting infectious pathogens locally. • The National Institute of Health (INS) has personnel that are WHO certified in packaging infectious materials for shipment. • Peru has no specific list on especially dangerous pathogens. • There is no laboratory licensing system. • Laboratories have especially dangerous pathogens that are endemic but they do not have an inventory. • Biosafety proceedings and regulations are in place and enforced in INS laboratories and | | | <p>for more BSBS training. There is no formal train-the-trainer program.</p> | <p>trainer BSBS programs; help identify a list for pathogens of concerns; inventory samples in country; ensure full implementation of BSBS concepts across country</p> |

| Country | Existing Level of Capabilities | Overall GHSA Recommendations for priority actions(Relevant to APP3) | P.3.1 Whole-of-Government BSBS system is in place for human, animal, and agriculture facilities | P.3.2 BSBS training and practices | Summary of Gap Analysis |
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| | biosecurity measures are being developed. | | | | |
| Portugal (08/2015) <u>Scores</u> P.3.1 = 2 P.3.2 = 2 | <ul style="list-style-type: none"> • A coordination network mechanism (LabPt) for BSBS has been established. • Especially dangerous pathogens and toxins are consolidated in 3 main laboratories and IHR core testing can be conducted. • The country has molecular diagnostic tests in place both at human and animal health level as well as environmental, eliminating the need for culturing pathogens. • Has a list of dangerous pathogens and toxins used at BSL-3 laboratories. • Appropriate security measures are followed in the most important laboratories (INSA) to | <ul style="list-style-type: none"> • No third party has assessed BSBS at national laboratory facilities and there is a gap in terms of laboratory licensing monitoring, especially for the private sector even though a national accreditation system is in place. • The establishment of a national authority for the laboratory system as a whole, including both human and animal labs, would help to assure a better management of BSBS issues. • Channels to facilitate a more comprehensive communication between human and animal laboratories could be useful to solve some specific | <ul style="list-style-type: none"> • The establishment of a national authority for the laboratory system as a whole, including both human and animal labs, would help to assure a better management of BSBS issues. • Channels to facilitate a more comprehensive communication between human and animal laboratories could be useful to solve some specific issues involving both types of laboratories, part of this issue is addressed through the LabPt network activities. | <ul style="list-style-type: none"> • Establish an adequate and sufficiently strong national mechanism to support BSBS programs and initiatives. • Portugal has a training program in place and a common curriculum is in preparation. • Staff is trained on BSBS procedures every year and workshops are planned throughout the year; moreover staff is tested or exercised every two years, at least at INSA laboratories. • Monitoring and assessment of these exercises are carried out by the same institution that proposes them so to put in place correction plans when needed. • A train the trainer | Support the development of country-specific legislation; support the establishment of a national authority for the country's lab system; fill the gap present in laboratory licensing monitoring (especially for the private sector); support BSBS training and nationwide access to materials; support uptake of biorisk management practices |

| Country | Existing Level of Capabilities | Overall GHSA Recommendations for priority actions(Relevant to APP3) | P.3.1 Whole-of-Government BSBS system is in place for human, animal, and agriculture facilities | P.3.2 BSBS training and practices | Summary of Gap Analysis |
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| | <p>minimize potential inappropriate removal or release of biological agents; no assessment has been carried out in the other public or private laboratories throughout the country.</p> <ul style="list-style-type: none"> • BSBS monitoring activities are not fully implemented; internationally validated checklists are used in some labs to this scope. • BSBS legislation and/or regulations are in place but assessments outside the INSA haven't been carried out. Legislation concerning BSBS is linked to national and European legislation as for BSBS at workplace and protection against biological agents, but Portugal is developing a | <p>issues involving both types of laboratories, part of this issue is addressed through the LabPt network activities.</p> | | <p>program has not been implemented yet.</p> <ul style="list-style-type: none"> • Portugal doesn't have yet a sustained academic training in institutions that train those who maintain or work with especially dangerous pathogens. • Training programs are available on the internet at INSA website but it was not possible to assess the BSBS training and practice measures in other laboratories. | |

| Country | Existing Level of Capabilities | Overall GHSA Recommendations for priority actions(Relevant to APP3) | P.3.1 Whole-of-Government BSBS system is in place for human, animal, and agriculture facilities | P.3.2 BSBS training and practices | Summary of Gap Analysis |
|---------|---|---|---|---|-------------------------|
| | <p>specific proposal for the implementation of an inter-ministerial BSBS authority.</p> <ul style="list-style-type: none"> • There is no specific funding to support BSBS programs/initiatives and their oversight and enforcement at the ministry level. • As for the BSBS risk management practices, they are available only in few laboratories in the contingency plans (in the LabPt network labs) as well as the responsibilities related to BSBS officers and managers are defined in the labs protocols. The absence of information refers mainly to BLS-2 laboratories that come within the scope of universities. | | | | |
| Uganda | <ul style="list-style-type: none"> • The National | <ul style="list-style-type: none"> • There is recent | <ul style="list-style-type: none"> • Is developing a | <ul style="list-style-type: none"> • Has identified critical | Support goal to |

| Country | Existing Level of Capabilities | Overall GHSA Recommendations for priority actions(Relevant to APP3) | P.3.1 Whole-of-Government BSBS system is in place for human, animal, and agriculture facilities | P.3.2 BSBS training and practices | Summary of Gap Analysis |
|--|---|---|--|---|---|
| (02/2015) <u>Scores</u> P.3.1 = 2 P.3.2 = 1 | <p>Biotechnology and Biosafety Bill focuses on genetically modified organisms; a National Biosecurity Plan and Bill, including provisions on bioterrorism preparedness, is being developed.</p> <ul style="list-style-type: none"> • A national biosecurity manual is being developed. • Safety policies in national hospitals and laboratories are in place (SOPs, guidelines, safety manuals, fire drills, etc.), based on WHO guidelines. • Labs have access controls and pathogens are secured. • Inventory of samples and reagents is carried out at the national reference laboratories. • The assessment focused on human | <p>interest, awareness, and political willingness for BSBS measures to be put in place; the new Biosafety Bill should allow further progress on these issues.</p> <ul style="list-style-type: none"> • In the process of developing the Biosecurity Bill, all involved parties should be consulted to have consistent policies and coordinated practices and mandates. | <p>comprehensive national BSBS system Accreditation process (SANAS, ISO) has been obtained in conducted in some laboratories (NTRL);) and being pursued in other laboratories.</p> | <p>gaps in BSBS training and implementation but has not yet implemented comprehensive training or a common training curriculum.</p> <ul style="list-style-type: none"> • BSBS is part of the core curriculum for medical doctors, but the curriculum is not harmonized at the national level. • Laboratory licensing is mandatory, both for private and public laboratories, but there is not a specific component for biosafety and security that is consistently applied across licensing bodies. | <p>develop a CBRN Center of Excellence; assist lab accreditation process for remaining/ interested labs; develop a specific component for biosafety and security that is consistently applied across licensing bodies</p> |

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|---|--|--|---|--|--|
| | health. | | | | |
| Ukraine (11/2015) Scores P.3.1 = 3 P.3.2 = 4 | <ul style="list-style-type: none"> • Has BSBS regulations in place since the 1990s. There is currently a regulatory reform process taking place in order to harmonize existing Ukrainian legislation on BSBS with international standards. • Has WHO laboratory networks with proficiency in polio, measles, rubella, rotavirus, influenza, diphtheria and invasive bacterial diseases. • Has identified a number of collections of pathogens and is working to consolidate them to a minimum number of laboratories. • Has a BSBS training program. • Has an active Biosafety Association. | <ul style="list-style-type: none"> • Continue with structural and legislative reform, including institutional consolidation, to create a public health system. • Should seek new and reliable sources and mechanisms for expeditious procurement of essential vaccines, MCMs, lab reagents, and other laboratory supplies. | <ul style="list-style-type: none"> • There are challenges obtaining consumables. There is an absence of development and manufacture of domestic diagnostic preparations and nutrient media for laboratory use. • No effective system for forecasting of epidemics and biological risk exists. • There is a need for the development and introduction of modern methods of research and biotechnology which could reduce the risk of biohazard exposure to personnel. | <ul style="list-style-type: none"> • BSBS training would be beneficial for institutes which have experienced staff turnover. • Additional funding should be provided to ensure the availability of PPE and for the maintenance and monitoring of existing physical security systems for veterinary and human health. | Support development of BSBS legislation; support obtaining PPE, consumables, other essential laboratory supplies; develop systems for sustainable lab equipment sourcing |
| United | • The country has | • No recommendations | • No recommendations | • desNo | During the |

| Country | Existing Level of Capabilities | Overall GHSA Recommendations for priority actions(Relevant to APP3) | P.3.1 Whole-of-Government BSBS system is in place for human, animal, and agriculture facilities | P.3.2 BSBS training and practices | Summary of Gap Analysis |
|--|--|---|---|-----------------------------------|---|
| Kingdom (08/2015) <u>Scores</u> P.3.1 = 4 P.3.2 = 4 | documented a listing of especially dangerous pathogens and toxins. <ul style="list-style-type: none"> • The country has identified a small number of facilities to secure, monitor and maintain especially dangerous pathogens and toxins. • The country has protocols in place for monitoring collections of especially dangerous pathogens and toxins. • Laboratories have undergone BSBS evaluations conducted by a third party (WHO, US CDC, or other). | | | recommendations | assessment, the UK also took the opportunity to identify areas of best practice and resources which could be useful to support other GHSA countries |

APPENDIX IV. JEE Summary Analysis from 2017 WHA IHR Implementation Report

An analysis of scores of 27 joint external evaluations conducted in 2016 indicates that surveillance and laboratory systems are relatively well advanced in the countries that volunteered for the evaluation. Vaccine coverage, access and delivery are also very well established, with almost all of the 27 countries having demonstrated capacity in these areas. Of these 27 countries, 7% (2/27) had developed or demonstrated capacity in the area of antimicrobial stewardship; 33% (9/27) had developed, demonstrated or sustainable capacity in identifying their priority public health risks; 33% (9/27) had developed, demonstrated or sustainable capacity in terms of the availability of multihazard emergency response plans; 52% (14/27) had developed, demonstrated or sustainable capacity in terms of having procedures for emergency operation centres; and 52% (14/27) had developed, demonstrated or sustainable capacity in activating an emergency operations programme. An initial comparison of the 2016 monitoring questionnaire data and joint external evaluation data from 26 countries (for which both datasets were available) confirms the areas identified above as priorities (human resources, capacities at points of entry, chemical events and radiation emergencies) and the joint external evaluations, in addition, show that the areas of response and preparedness also require attention.