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ORIGINAL ARTICLE

Assessment of the Biosafety and Biosecurity Landscape in the Philippines and the Development of the National Biorisk Management Framework

Raul V. Destura¹, Hilton Y. Lam², Rohani C. Navarro¹, Jaifred Christian F. Lopez², Reneepearl Kim P. Sales^{2,*}, Ma. Ida Faye A. Gomez², Angelo dela Tonga¹, and Gianne Eduard Ulanday¹

Abstract

Introduction: The emergence of biological threats that can potentially affect millions emphasizes the need to develop a policy framework in the Philippines that can mount an adequate and well-coordinated response. The objective of the study was to assess, strengthen, and harmonize efforts in biorisk management through the development of a National Biorisk Management Framework.

Methods: The development of the National Biorisk Management Framework was carried out in two phases: (1) assessment of the current biosafety and biosecurity landscape and (2) framework development.

Results: This study identified policy gaps in the incorporation of biosafety in course curricula, professional development, and organizational twinning. The desired policy outcomes focus on increasing the capacity and quality of facilities, and the development of the biosafety officer profession. The tabletop exercises revealed weak implementation of existing protocols and unclear coordination mechanisms for emergency response. Based on these, a framework was drafted composed of eight key areas in biosafety and biosecurity, and four key contexts in risk reduction and management.

Discussion and Conclusion: Reforms in biosafety and biosecurity policies are expected to improve coordination, ensure sustainability, capacitate facilities, and professionalize biosafety officers. Because of the complexity of reforms necessary, success will require a consistent and coherent policy framework that (1) provides well-coordinated mechanisms toward harmonized risk reduction and management, (2) establishes and enforces guidelines on biosafety, biosecurity, and biorisk management, (3) regulates facilities essential for occupational safety and public health, and (4) is financed by the General Appropriations Act as part of the national budget.

Keywords: biosafety, biosecurity, biorisk management, policy analysis, policy gaps

Introduction

The Philippines is the first country in Southeast Asia to adapt a national biosafety guideline. The guideline, published in 1991, focuses on genetic engineering and other activities that require the importation, introduction, field release, and breeding of nonindigenous organisms.¹ The country signed into the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in 2000. The pro-

ocol aims to “ensure an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.”² After this, a national biosafety framework was developed in 2004 and formally established

¹National Training Center for Biosafety and Biosecurity, National Institutes of Health, University of the Philippines-Manila, Manila, Philippines.

²Institute of Health Policy and Development Studies, National Institutes of Health, University of the Philippines-Manila, Manila, Philippines.

*Address correspondence to: Reneepearl Kim P. Sales, Institute of Health Policy and Development Studies, National Institutes of Health, University of the Philippines-Manila, Manila 1000, Philippines, Email: ksales@aiho.org.ph

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through executive order (EO) 514 in 2006. The framework applies to products of biotechnology and exotic and invasive alien species, with focus on their research, development, handling, use, transboundary movement, release into the environment, and management.³

Despite the progress made in the mentioned areas, there are issues included within the field of biosafety and biosecurity that needs to be given attention in the Philippines similar to how they are considered in other countries. In developed countries, this involves the regulation of dual use of research concern (DURC).⁴ Scientific research has benefited the world population through the development of health, agriculture, and environment technologies.^{5,6} However, there continues to be a concern regarding the potential of biological research to be misused. Research with high misuse potential include those that (1) manipulate pathogenicity or virulence; (2) synthesize pathogens and toxins without cultivation of microorganisms; (3) identify new mechanisms to disrupt the healthy functioning of humans, animals, or plants; and (4) develop novel means of biological agents and toxins delivery.⁷ Management approaches to DURC have focused on policies that govern research mechanisms, funding agencies, journal publishers, codes of conduct and ethics, and education initiatives for a wide range of audiences.⁷⁻¹³

In the Asia-Pacific region, the idea of biosafety and biosecurity holds stronger ties to agricultural security, biodiversity, and public health over national security concerns such as biological warfare or terrorism. In particular, outbreaks of zoonotic viruses over the past two decades have given way for governments to prioritize the public health aspect of biosafety and biosecurity through the lens of agricultural and animal farming practices.¹⁴ The quick spread of these outbreaks (severe acute respiratory syndrome [SARS] in 2003, Influenza A virus subtype H5N1 [H5N1] in 2005, Influenza A virus subtype H1N1 [H1N1] in 2009, and coronavirus disease 2019 [COVID-19] in 2020) has highlighted the need to consider biosafety and biosecurity as a national and even global issue.¹⁵⁻¹⁸

As the bioscience and laboratory industry grows in Asia, so does the need to consider the industry's role in national biosafety, biosecurity, and the larger global health security.¹⁹ Handling pathogenic organisms requires good laboratory practices, risk assessments, and biorisk measures to prevent accidental or deliberate infection.²⁰ Between 1982 and 2016, 27 laboratory-acquired infections (LAIs) were published in the Asia-Pacific. Fifty-two percent of the LAIs occurred in research laboratories.²⁰ These LAIs occurred amid an ongoing lack of specialist-level training for biosafety and biosecurity protocols in the region. In a 2010 survey of 197 life science degree courses from 58 Asian universities, it was found that only 2% had biosecurity modules, 18% had biosafety modules, and 10% had topics on the dual use of science.¹⁴ It is important to

note that 78% of the reported LAIs in Asia-Pacific were from developed countries, who likely report LAIs as part of both national and international standards compliance.²⁰

In addition, the perceived weakest link among developing countries in biosafety is that many facilities that handle infectious agents were built >10 years ago and designed with limited consideration for biosafety and security.⁴ A 2007 survey on bioscience research practices in Asia found that 20% of scientists do not use personal protective equipment, 50% of facilities do not have an autoclave, 50% do not restrict laboratory access at all times, and up to 33% lack training on biosafety protocols.²¹

The emergence of biological threats that can potentially affect millions emphasizes the need to develop a policy framework that can mount an adequate and well-coordinated response. The objective of the study was to assess, strengthen, and harmonize efforts in biorisk management through the development of a National Biorisk Management Framework.

Methodology

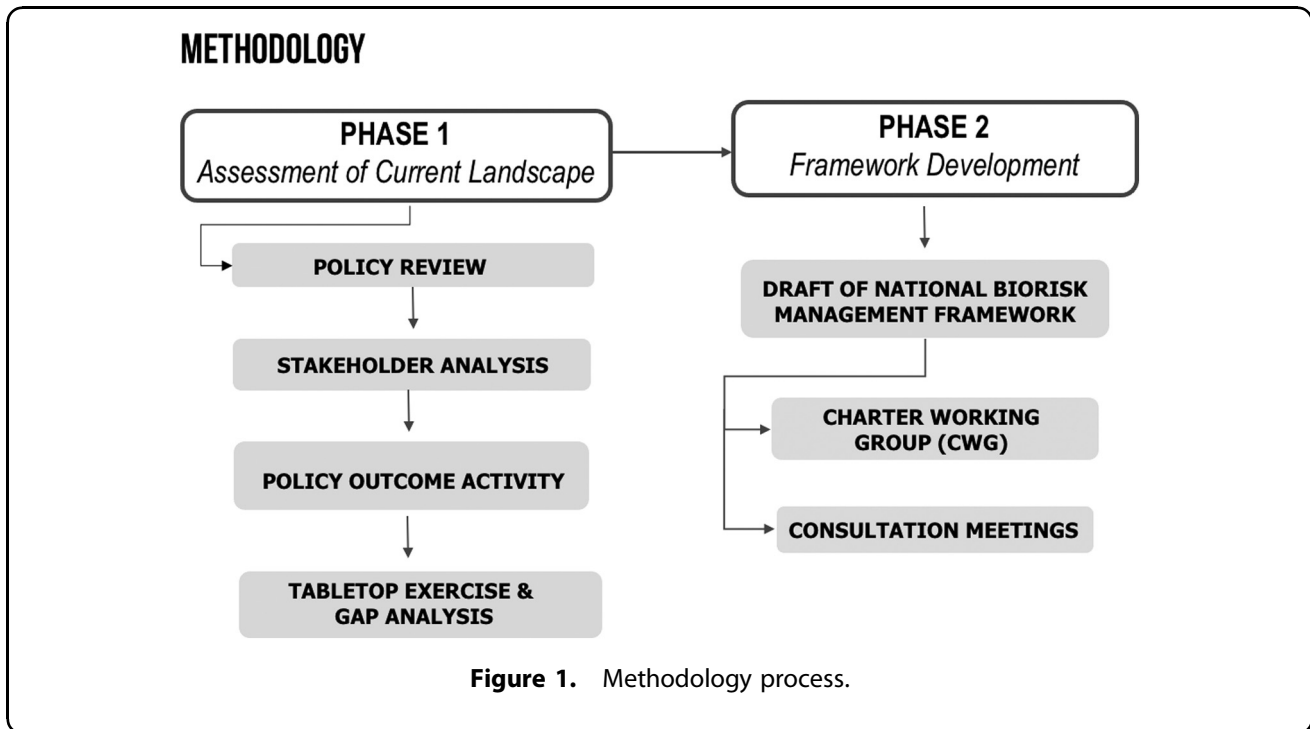
This initiative was funded by University of the Philippines Manila National Institutes of Health and U.S. Defense Threat Reduction Agency-Biological Threat Reduction Program. This study did not require ethics approval as it did not involve any studies with human or animal subjects. The development of the National Biorisk Management Framework was carried out in two phases (Figure 1): (1) assessment of the current biosafety and biosecurity landscape and (2) framework development.

Phase 1: Assessment of the Current Landscape

Policy review. This step entailed a rapid scan and review of existing policies related to biosafety and biosecurity in the Philippines. Policies were searched in the laws and policies databases of six concerned government institutions. After retrieval of policies, a data extraction table was made to map the policies. Data extracted from the policies included title of policy, entity or subject covered by the policy, date published, type of policy, agency that published the policy, and its objectives.

The review and analysis of the policies were anchored to the nine categories for developing sustainable capacity for biosafety and biosecurity in low-resource countries: (1) country-/region-specific regulatory framework and guidelines or standards, (2) biosafety and biosecurity awareness, (3) infrastructure, (4) equipment, reagents, and services, (5) management and administrative controls, (6) biosafety curricula, (7) training, (8) biosafety associations, professional competency, and credentialing, and (9) individual mentoring and organizational twinning.²²

Stakeholder analysis. Stakeholder analysis is “a process of systematically gathering and analyzing information to determine whose interests should be taken into account when developing and/or implementing a policy



or program.”²³ This analysis is conducted before policy is implemented for policymakers to detect and act to prevent potential misunderstandings about and/or opposition to the policy or program.

Forty-six participants were involved in the stakeholder analysis activity. The participants, majority of whom are biosafety officers, were divided into seven groups categorized as academe (3), clinical (2), research (1), and associations and private sector (1). Each group was first asked to identify stakeholders with the following guide questions²⁴:

- Who will be affected?
- Will the impact be local, national, or international?
- Who has the power to influence the outcome?
- Who are the potential allies and opponents?
- Are there people whose voices or interests in the issue may not be heard?
- Who will be responsible for managing the outcome?
- Who can contribute financial or technical resources?

After stakeholder identification, each group was tasked to fill in a stakeholder analysis table designed to provide the following information:

- Stakeholder involved
- Ideal roles of the stakeholder
- Basis of each ideal role
- Resources available to stakeholder
- Adequacy of resources available to the stakeholder
- Possible reaction of the stakeholder to a biosafety framework for nongenetically modified organism (GMO) facilities

Groups presented their outputs to the plenary, followed by a synthesis to verify, consolidate, and agree upon the identified stakeholders, and their roles, resources, and reactions to the policy framework being developed.

Policy outcome activity. Policy outcomes are short- or long-term changes after policy implementation and the extent to which those changes can be attributed to the policy.²⁵ As part of the policy process, early identification of desired outcomes and its evaluation may inform and improve policy development, adaptation, implementation, effectiveness, and build evidence for policy interventions.²⁶

Thirty-eight participants were involved in the activity. The participants, majority of whom are biosafety officers, were divided into six groups: academe (3), clinical (2), and research, associations, and private sector (1).

Each group was tasked to come up with a list of their desired policy outcomes with this question in mind: “What does success look like for this policy framework?” The lists were collected and synthesized by the moderator then presented to the plenary for validation. As a plenary, the pros and cons of each desired policy outcome were identified.

To identify the top three desired policy outcomes, each participant was allotted three votes. Participants could distribute their three votes equally to their top three choices, limit themselves to two choices by preferring one over another, or give all their three votes to one desired policy outcome. A secret ballot method was used to ensure anonymity of choices by the participants. The casting of votes by each participant was overseen by two moderators to ensure each participant did not exceed their three-vote limit.

Tabletop exercise and gap analysis. A tabletop exercise makes use of the participatory approach and calls on key emergency response personnel to discuss a given simulated emergency situation. Participants usually discuss which specific steps to take and what roles are assigned at each stage of the emergency.²⁷ Tabletop exercises provide insights into the strengths and weaknesses of public health emergency preparedness and address these gaps by assessing capabilities, training staff, and forging relationships.²⁸

Fifteen participants in total were involved in the tabletop exercise, representing government agencies and academe. Two groups were formed, one group with eight members and another with seven members. Both groups were tasked to discuss existing response mechanisms activated and communications required in all phases and subevents in a scenario involving a suspected disease outbreak of African swine fever in a setting similar to the Philippines (Table 1). Discussions were facilitated within each group as each phase of the biological incident was presented. If a capability or communication was considered a necessity by the circumstances outlined in the scenario but was not a real-world capability, it was thus identified as a gap.

Table 1. Events and subevents in the tabletop exercise

Response phase	
Event 1: Dead piglet brought to the RADDL for testing	Subevent 1.1: Initial laboratory testing for suspected ASF Subevent 1.2: Samples negative for ASF and stored in refrigerator for next day Subevent 1.3: 36 pigs dead not reported to RADDL during weekend Subevent 1.4: Dead pigs of two more farmers brought in for testing Subevent 1.5: 6 farms affected with high pig mortality
Activation phase	
Event 2: Samples brought to another laboratory for testing 250 km away	Subevent 2.1: Meat of dead pigs sold in the market Subevent 2.2: Children getting sick Subevent 2.3: Analyst getting sick and not reporting in; samples missing from laboratory Subevent 2.4: 17 affected farms, pig mortality >50%
Coordination phase	
Event 3: Confirmed diagnosis	Subevent 3.1: Local media asking for update Subevent 3.2: Samples from vet reference laboratory positive for ASF Subevent 3.3: Pig carcasses buried on-site Subevent 3.4: Visit to analyst's home reveals samples used in "DIY home experiments"

ASF, African swine fever; RADDL, Regional Animal Disease Diagnostic Laboratory.

Phase 2: Framework Development

Key assessment results from Phase 1 were used to draft the National Biorisk Management Framework. A Charter Working Group (CWG) was formed to aid in framework development. Representatives were rigorously chosen based on their authority and expertise in the field of agriculture, health, laboratories, industry, and security.

Three consultations were held on November 5, November 28, and December 3, 2018. During the series of meetings, the CWG members were presented the draft biorisk management

Table 2. Four main policies and their objectives

<i>Four policies</i>	<i>Objectives</i>
EO 514 Establishing the national biosecurity framework, prescribing guidelines for its implementation, strengthening the national committee on biosafety of the Philippines, and for other purposes	<ul style="list-style-type: none"> Strengthen the existing science-based determination of biosafety to ensure the safe and responsible use of modern biotechnology Enhance the decision-making system on the application of products of modern biotechnology Serve as guidelines for implementing international obligations on biosafety for other purposes
1991 Philippine Biosafety Guidelines	Covers work involving genetic engineering, and activities requiring the importation, introduction, field release, and breeding of nonindigenous or exotic organisms even though these are not genetically modified
Cartagena Protocol on Biosafety	To contribute to ensuring an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements
UN Security Council Resolution 1540 (2004)—Permanent Mission of the Philippines to the United Nations	The Security Council decided that all states shall refrain from providing any form of support to nonstate actors that attempt to develop, acquire, manufacture, possess, transport, transfer, or use nuclear, chemical, or biological weapons and their means of delivery, in particular, for terrorist purposes. The resolution requires all states to adopt and enforce appropriate laws to this effect as well as other effective measures to prevent the proliferation of these weapons and their means of delivery to nonstate actors, in particular for terrorist purposes

EO, executive order.

Table 3. Summary of policies and regulatory subjects covered according to nine categories for developing sustainable capacity for biosafety and biosecurity in low-resource countries

<i>Entity</i>	<i>Country- or region-specific regulatory framework and guidelines or standards</i>	<i>Biosafety and biosecurity awareness</i>	<i>Infrastructure</i>	<i>Equipment, reagents, and services</i>	<i>Management processes and administrative controls</i>	<i>Training</i>	<i>Biosafety curricula</i>	<i>Biosafety association, professional competency, and credentialing</i>	<i>Individual mentoring and organizational twinning</i>
All health products	✓				✓				
Animal facilities			✓		✓				
Animal transport	✓		✓	✓	✓	✓			
Animals	✓		✓		✓	✓			
Biosafety policies, measures, guidelines	✓	✓	✓		✓	✓			
Clinical laboratory	✓		✓	✓	✓	✓			
Disease outbreaks	✓	✓			✓				
Foreign rendering plants					✓				
Genetically modified plant and plant products	✓				✓				
GMOs	✓		✓		✓				
HIV testing laboratory			✓	✓	✓				
Human stem cell and cell-based or cellular therapy facility	✓		✓	✓	✓	✓			
Indigenous, exotic, and genetically modified arthropods			✓						
Inspection, testing and certifying bodies, and other bodies offering conformity assessment services	✓		✓	✓	✓				
Medical devices	✓				✓				
Nonindigenous or exotic organisms	✓			✓	✓	✓			
Quarantine	✓		✓	✓	✓				
Specimens for confirmation testing of HFMD				✓					
Specimens for EVD testing	✓			✓		✓			
Specimens for <i>Leptospira</i> spp				✓					
Specimens for MERS-COV and novel influenza viruses	✓			✓					
Specimens for TB testing	✓			✓					
Tissue culture laboratories			✓	✓	✓				
Veterinary clinics and hospitals			✓	✓	✓				
Veterinary diagnostic laboratories			✓	✓					
Veterinary drugs, products, biologics, medicinal preparation, and their establishments and outlets			✓	✓	✓				
Weapons	✓	✓	✓	✓		✓			
Total	17	3	16	16	19	8	0	0	0

Heckert et al.²²

EVD, Ebola virus disease; GMOs, genetically modified organisms; HFMD, hand, foot, and mouth disease; MERS-COV, Middle East respiratory syndrome coronavirus; TB, tuberculosis.

framework and asked to investigate the framework in detail, provide feedback, identify key issues, and provide valuable technical input relevant to their area of expertise.

Results

Policy Review

The search strategy yielded a total of 41 issuances composed of 22 administrative orders, 6 republic acts, 7 guidelines, 2 department circulars, 2 EOs, 1 manual, and 1 United Nations Resolution. Biosafety and biosecurity in the Philippines is mainly anchored on four policies (Table 2).

The policies and issuances scoped cover 27 regulatory subjects, which include health products, facilities, animals, plants, and drugs, among others. Issuances covering each regulatory subject were analyzed according to the nine categories for developing sustainable capacity for biosafety and biosecurity in low-resource countries (Table 3).²²

Country-/region-specific regulatory framework and guidelines or standards. Seventeen of the 27 entities follow a specific regulatory framework, guideline, or standard. These are determined by a government agency, a committee or board, or follow existing international guidelines. The frameworks are usually concerned with regulation of an entity and include establishment of standards, practices, and monitoring and evaluation plan.

Biosafety awareness. Three out of the 27 entities have policies that discuss awareness. It includes mandates on biosafety promotion, participation, and development of advocacy materials and risk communication plans. It also states the need for policymakers to be aware and provided with sufficient and current information on biosafety.

Infrastructure. Sixteen of 27 entities have policies related to infrastructure. The level of detail provided in the guidelines for infrastructure varies between entities. Some entities, such as animal facilities and clinical laboratories, are provided with broad guidelines. Conversely, guidelines for GMOs provide detailed information for physical containment according to four biosafety levels.

Management processes and administrative controls. Nineteen of the 27 entities are provided with governance mechanisms through a policy. A government agency, a network of agencies, or a committee created through an issuance oversees the implementation of a policy framework, guidelines, or standards. These policies also outline the responsibilities of municipal, city, and regional counterparts of national offices, when applicable.

Training. Eight of 27 entities are provided with training guidelines in their handling, transport, and use for staff. The policies outline capacity-building programs, continuing education programs, and minimum training and skill requirements for staff.

No mandates were found for the following categories: biosafety curricula; biosafety association, professional competency, and credentialing; and individual mentoring and organizational twinning.

Stakeholder Analysis

A total of 28 stakeholders were identified by the participants. Twenty-two of the 28 identified stakeholders were government institutions. Six stakeholders identified include academic institutions, training centers, associations, and civil society organizations. Identified stakeholders were further analyzed according to ideal roles, basis for ideal role, resources available and adequacy, and reaction to framework.

Table 4. Ideal roles of identified stakeholders

<i>Ideal roles</i>	<i>Agency involved</i>
Accrediting and auditing body for laboratories	Department of Trade and Industry
Background checks and vetting of laboratory workers	Intelligence agencies
<ul style="list-style-type: none"> • Calibration of laboratory equipment • Management of financial resources 	Department of Science and Technology
Conduct of investigation on alleged bioterrorists	Department of the Interior and Local Government
<ul style="list-style-type: none"> • Creation of a National Emergency Response Team • Issuance of permits for packaging and transport of biologicals • Maintenance of BMC list • Creation of national action plan • Emergency response beyond control of the institution 	Department of Health
<ul style="list-style-type: none"> • Emergency response in disease outbreak in plants and animals • Human and animal surveillance • Issuance of guidelines and license to operate for clinical laboratories for animal specimen 	<ul style="list-style-type: none"> • Anti-Terrorism Council • Armed Forces of the Philippines • Department of National Defense • National Disaster Risk Reduction and Management Council • Office of Civil Defense • Philippine National Police
Integration of biorisk management in curriculum and laboratory activities	Department of Agriculture
Regulation of entry and exit of BMCs	<ul style="list-style-type: none"> • Commission on Higher Education • Department of Education • Bureau of Customs • Bureau of Immigration
Regulation of transport of BMCs/infectious substances by land, water, and air	Department of Transportation

BMC, biological materials of concern.

Table 5. Resources available and adequacy of identified resources

<i>Adequacy</i>	<i>Agency</i>
Adequate	<ul style="list-style-type: none"> • Anti-Terrorism Council • Armed Forces of the Philippines • Department of National Defense • National Economic Development Authority, • Office of Civil Defense • Philippine National Police
Current legislation does not include biorisk	Commission on Higher Education
Insufficient manpower	<ul style="list-style-type: none"> • Civil Service Commission • Commission on Higher Education • Department of Agriculture • Department of Education • Department of Environment and Natural Resources • Department of Labor and Employment • National Training Center for Biosafety and Biosecurity
Lacking regional counterparts	Department of Agriculture
Limited capacity building efforts	Department of Agriculture
Limited experts on biosafety	<ul style="list-style-type: none"> • Commission on Higher Education • Department of the Interior and Local Government
Limited funding	<ul style="list-style-type: none"> • Civil Service Commission • Department of Education • Department of Labor and Employment • National Training Center for Biosafety and Biosecurity
Limited in general	<ul style="list-style-type: none"> • University of the Philippines-National Institutes of Health • Private sector
Meets minimum requirements	<ul style="list-style-type: none"> • Bureau of Fire Protection • Data Privacy Commission • Department of Foreign Affairs • Department of Health • Department of Science and Technology • Department of Transportation • Intelligence agencies • National Disaster Risk Reduction and Management Council • Professional Regulation Commission
Varies	<ul style="list-style-type: none"> • Civil society organizations • International partners • Local Government Units • Nongovernment organization

Ideal roles and basis for ideal role. Ideal roles identified by the participants closely follow current functions that the various stakeholders already perform. Most roles are concerned with the integration or strengthening of existing rules and regulations for biosafety and biosecurity. Twenty-four out of 28 stakeholders have a legal mandate as basis for the roles identified to them by the participants (Table 4).

Table 6. Possible reaction to inclusion in framework

<i>Possible reaction</i>	<i>Stakeholder</i>
Receptive	<ul style="list-style-type: none"> • Anti-Terrorism Council • Armed Forces of the Philippines • Civil Service Commission • Civil society organizations • Data Privacy Commission, • Department of Budget and Management • Department of Environment and Natural Resources • Department of Health • Department of Labor and Employment • Department of National Defense • Intelligence agencies • International partners • National Disaster Risk Reduction and Management Council • National Training Center for Biosafety and Biosecurity • Nongovernment organization • Office of Civil Defense • Philippine National Police • Private sector • University of the Philippines-National Institutes of Health
Receptive with reservations	Department of Agriculture
Initially argumentative to eventually receptive	<ul style="list-style-type: none"> • Commission on Higher Education • Department of Education • Private hospital associations
Neutral	<ul style="list-style-type: none"> • Department of Science and Technology • Department of Foreign Affairs
Varies/mixed reactions	<ul style="list-style-type: none"> • Department of Interior and Local Government • Department of Transportations • Hospital/laboratory owners • Local government units
Not sure/no consensus reached/no reaction identified	<ul style="list-style-type: none"> • Bureau of Customs • Bureau of Fire Protection • Bureau of Immigration • Department of Trade and Industry • National Economic Development Authority • Professional Regulation Commission

Resources available and adequacy. Commonly identified resources available to the stakeholders were legislation, funding, capacity building, manpower, and facility/technology/machinery (Table 5).

Possible reaction of stakeholder to being included in proposed policy framework. Participants strongly linked receptiveness with the ideal roles identified to the stakeholders. Stakeholders who are currently performing their ideal roles or have the resources to perform them were perceived to be more receptive.

Table 7. Policy outcome activity results

Policy outcome	Pros	Cons	Votes	%
Capacitating existing facilities to comply with the proposed policy	<ul style="list-style-type: none"> • Compliance improves quality • Employee retention • Opportunities for ABOT graduates to be subject matter experts 	<ul style="list-style-type: none"> • Acceptability • Burden, timeline, manpower • Responsibility 	29	25.44
Professionalization of biosafety officer/creation of plantilla	<ul style="list-style-type: none"> • Authority, recognition • Capacity building • Career opportunity • Local monitoring entity • Self-reliance 	<ul style="list-style-type: none"> • Greater responsibility • Increase in qualification • No CPD units • Overlap of function 	27	23.68
Enhancing the quality/outputs of laboratories	<ul style="list-style-type: none"> • General safety, client satisfaction • Income • Integrity • Reproducible outputs • Satisfied employees 	<ul style="list-style-type: none"> • Accountability • Budget, timeline • Extra work • Manpower, sustainability 	20	17.54
Penalize erring laboratories	<ul style="list-style-type: none"> • Income • Prompt corrective measure • Quality/accreditation • Strict compliance 	<ul style="list-style-type: none"> • Cheating • Corruption • Fines • Possible shut down 	10	8.77
Specialized unit for biorisk management	<ul style="list-style-type: none"> • Chance to become a certifying body • Ensures biorisk management is not neglected 	<ul style="list-style-type: none"> • Budget • Manpower • Space 	9	7.89
Creation/regulation of Institutional Biosafety Committee	<ul style="list-style-type: none"> • Monitoring • Prestige • Safe research • Speed of processing • Strict compliance 	<ul style="list-style-type: none"> • Authority • Budget • Conflict • Lack of expertise 	8	7.02
Trained personnel	<ul style="list-style-type: none"> • Compliance improves quality • Employee retention • Opportunities for advanced biosafety officer training graduates to be subject matter experts 	<ul style="list-style-type: none"> • Acceptability • Burden, timeline, manpower • Insider threat • Responsibility 	5	4.39
Controlling the number of new laboratories	<ul style="list-style-type: none"> • Easier management • Less competition • More efficient use of research quality • Traceability and monitoring 	<ul style="list-style-type: none"> • Failure to meet needs • Increased risk during transport • Less accessibility to public • Monopoly • Worker fatigue 	3	2.63
Positive reinforcement	<ul style="list-style-type: none"> • Employee retention/promotion • Income • Motivation • Prestige 	<ul style="list-style-type: none"> • Academic dishonesty • Budget • Commercialization 	3	2.63

ABOT, Advanced Biosafety Officer Training; CPD, Continuing Professional Development.

Stakeholders with unfamiliar functions or mandates to participants were less likely to be perceived as receptive (Table 6).

Policy Outcome Activity

A total of 114 votes were cast by 38 participants (Table 7). The top three desired policy outcomes were (1) capacitating existing facilities to comply with the proposed policy, (2) professionalization of biosafety officer/creation of plantilla (a government-approved regular position), and (3) enhancing quality of laboratories.

The desired policy outcomes were concerned with improving responsiveness and equity of facilities. This is manifested in the identified pros and cons of the out-

comes. Pros include improved quality, increased client satisfaction, conduct of safe research, and increased employee satisfaction and retention. Cons identified include lack of budget, unrealistic timelines, lack of accountability, decreased access to facilities due to shutdowns, worker fatigue, and lack of manpower.

Tabletop Exercise and Gap Analysis

Based on the discussions, current response mechanisms are initiated with (1) an investigation and preparation of a case report by the lead veterinarian, (2) handling and transport of samples to the designated Regional Animal Disease Diagnostic Laboratory, (3) coordination between animal and human health response, (4) activation of reporting mechanisms to the local government unit and

Table 8. Gap analysis results

<i>Response phase</i>		<i>Gaps identified</i>
Event 1: Dead piglet brought to the RADDL for testing	Subevent 1.1: Initial laboratory testing for suspected ASF Subevent 1.2: Samples negative for ASF and stored in refrigerator for next day Subevent 1.3: 36 pigs dead not reported to RADDL during weekend Subevent 1.4: Dead pigs of two more farmers brought in for testing Subevent 1.5: 6 farms affected with high pig mortality	<ul style="list-style-type: none"> • Weak implementation of existing SOPs and policies • Lack of quality assurance of skills and training of veterinarians and laboratory staff on proper knowledge and practices in animal testing • The need to regulate laboratory practices among government and private facilities through strict monitoring and evaluation processes • The need to ensure availability of controls in the laboratory, in relation to the validity of testing • The need to strengthen HR capacity for 24/7 emergency staff response • The need for guidelines and reliable reporting mechanisms to RADDL through the adoption of possible strategies such as an electronic geographic information systems-enabled reporting mechanism • Lack of protocols for waste disposal
Activation phase Event 2: Samples brought to another laboratory for testing 250 km away	Subevent 2.1: Meat of dead pigs sold in the market Subevent 2.2: Children getting sick Subevent 2.3: Analyst getting sick and not reporting in; samples missing from laboratory Subevent 2.4: 17 affected farms, pig mortality >50%	<ul style="list-style-type: none"> • Noncompliance to SOPs for the handling, transport, and referral of samples in larger distances to reference laboratories • The need for coordinated action among different government agencies • The need for clear coordinating mechanisms between animal and human health responders • Shortage of personal protective equipment for responders • Incorporating proper documentation as part of laboratory SOPs; recording and tracking system should be in place • There is a need for retraining and re-educating laboratory personnel on safety practices
Coordination phase Event 3: Confirmed diagnosis	Subevent 3.1: Local media asking for update Subevent 3.2: Samples from vet reference laboratory positive for ASF Subevent 3.3: Pig carcasses buried on-site Subevent 3.4: Visit to analyst's home reveal samples used in "DIY home experiments"	<ul style="list-style-type: none"> • There is a need to ensure compliance to laboratory SOPs on divulging information to media • There is an absence of facility for burying of carcass and waste decontamination and disposal • Implementation of policy to monitor laboratory personnel, as part of safety and security precaution

HR, human resource; SOPs, standard operating protocols.

other concerned agencies, (5) monitoring and surveillance of other farms in surrounding areas, (6) quarantine efforts, (7) interagency coordination at the local level, (8) channeling of information from local to national actors, and (9) media and press relations.

Across the existing response mechanisms already mentioned above, the following common gaps were revealed (Table 8): weak implementation or noncompliance to existing standards and protocols, unclear coordination mechanisms for emergency response, lack of training and education, and limitations in human resources and infrastructure.

Framework Development

Discussions in the three CWG meetings resulted to feedback on (1) framework design and (2) political strategy. Key recommendations are described hereunder.

To reconsider the formation of a new agency. Early drafts of the framework incorporated the establishment of the Biorisk Management Coordinating Agency, but the CWG advised against putting up a new agency, as it creates more bureaucratic processes. Instead, clarifying roles, capacitating existing institutions, and harmonizing existing efforts were recommended.

To anchor on key functions in biosafety and biosecurity. The design must be based on functions that need to be fulfilled in terms of biosafety and biosecurity, adopting a bottom-up approach, and incorporating inputs from frontline actors. These functions form the key areas of the framework in its current form.

To incorporate the four pillars of disaster risk reduction and management in the context of

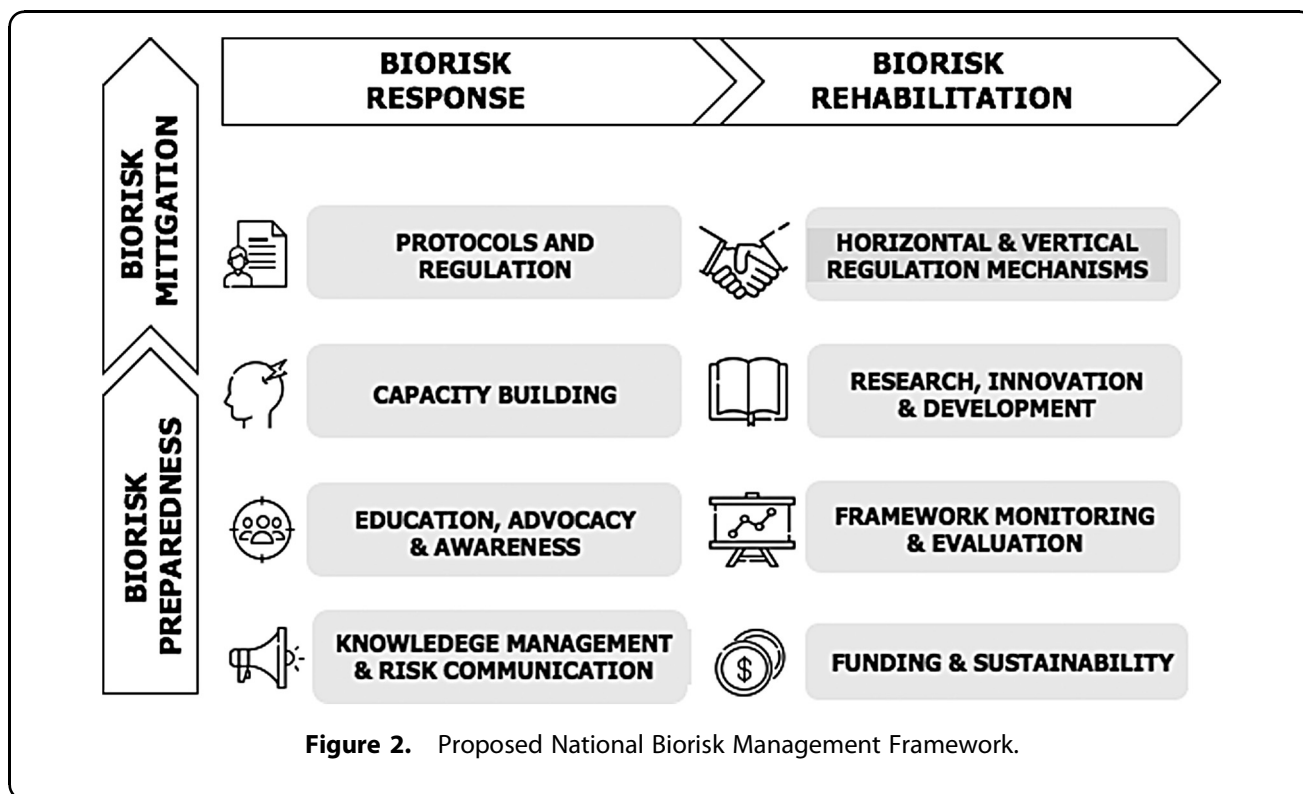


Figure 2. Proposed National Biorisk Management Framework.

biohazards. Early drafts of the framework lacked proper emphasis on disaster risk reduction and management. The CWG advised the incorporation of the four pillars of disaster risk reduction and management, namely prevention and mitigation, preparedness, response, and rehabilitation and recovery, as the key contexts of the framework in its current form.

To consider the pivotal role of the Office of Civil Defense under the Department of National Defense. As the secretariat of the National Disaster Risk Reduction and Management Council, the Office of Civil Defense has the power to direct various agencies when facing a threat. Thus, it was discussed as strategic to house biosafety and biosecurity functions under this office.

To consider the better policy route. The framework may be passed into law through a senate bill, house bill, or an EO signed by the president. It was agreed upon by the CWG that an EO would be the most strategic pursuit for this policy.

To address funding gaps in policy and implementation. There is a possibility that the bill may be passed into law, but not funded and thus, not properly implemented. The CWG emphasized the importance of stating clear funding mechanisms in the document.

Based on these results of the Phase 1 assessment and recommendations of the CWG, a National Biorisk Management Framework was formulated (Figure 2). The pro-

posed framework is composed of eight key areas in biosafety and biosecurity and four key contexts in risk reduction and management.

Discussion

In an increasingly connected world, emerging or re-emerging diseases and the deliberate or undeliberate release of infectious agents hold greater potential to affect populations across borders.²⁹ Global experience with SARS (2003), H1N1 (2009), and COVID-19 (2019) shows that pandemics have extensive health, social, and economic impact that has made the importance of biosafety and biosecurity preparedness more evident.^{30–34} Advances in biotechnology has also leaped the application of biological sciences in the fields of health, agriculture, and environment, among others. However, this advancement comes with an increased risk for DURCs.^{35,36} Although there are obvious benefits to biological research, the increased DURC risk has created a moral and ethical dilemma for the life sciences: do the benefits of the research outweigh the risks?³⁷ Creating a biosafety and biosecurity framework, therefore, presents the challenge of striking a balance between protecting public health while creating a sound regulatory environment necessary for research and innovation.^{32,38}

Expanding the Concepts of Biosafety and Biosecurity

The current Philippine National Biosafety Framework, EO 514, was part of a UN Environment Programme-Global Environment Facility initiative to assist countries

in developing a national framework after the ratification of the Cartagena Protocol on Biosafety. The Philippines EO 514 definition of biosafety suggests that biosafety policies may apply to multiple sectors related to biosafety. However, the scope of the framework is limited to products of modern biotechnology, exotic species, and invasive alien species, leaning heavily toward the agriculture and environment sector.

This concern was also raised by participants during the stakeholder analysis. First, established policies that have already defined “biosafety” may mean that a different terminology should be used in the framework being proposed that encompasses all activities related to biosafety, extending to public health, laboratory management, and outbreak response. Second, the current definition in EO 514 focuses on the potential harm of regulated articles. However, there is a growing recognition that access to information, processes, practices, and equipment is equally important as having access to a biological or hazardous material.³⁹ An expanded concept may be necessary that balances the perspectives of science, security, prevention, and preparedness beyond laboratory work.¹⁵

Adopting Principles of Disaster Risk Reduction and Management

Consistent with the definitional limitation, the current policy framework lacks emphasis on risk reduction and management functions in response to the rise of complex biological threats, regardless of the cause. The integration of biosafety and biosecurity efforts to prepare for and respond to these threats should be found at the heart of biorisk management, broadly defined as the assessment of risks, identification of measures to reduce risks, and development of processes to implement and review risk-reduction measures.⁴⁰ Although existing regulatory processes already form a significant part of risk prevention and mitigation, there should be improvement in how these functions tie up alongside other efforts in the country’s overall disaster risk reduction and management framework, particularly in risk preparedness, response, rehabilitation, and recovery.

Limited Institutional Capacity and Sustainability for Regulatory Systems

The debate on whether regulation impedes innovation persists today as new technologies, particularly in the field of biological sciences, generate calls for application of the precautionary principle.⁴¹ The precautionary principle is an approach to innovations with potential for causing harm when extensive scientific knowledge is lacking.⁴² The relationship between regulation and innovation is complex and different regulatory instruments have varying effects on technological progress.⁴¹ Although international legal frameworks for biosafety and biosecurity exist, these provide limited guidance on

what constitutes a functional national regulatory framework. It is the responsibility of national governments to produce and implement evidence-based policies that apply the precautionary principle emphasized by the Cartagena Protocol on Biosafety.³⁶

Spearheaded by the National Committee on Biosafety of the Philippines, the implementation of policies related to biosafety is a task shared by four government agencies. The Department of Agriculture, Department of Environment and Natural Resources, Department of Health, and Department of Science and Technology have multifaceted roles that involve biosafety and biosecurity policy development, accountability, and capacity building. This current system utilizes a combination of network and traditional command and control regulation. These agencies regulate overall biosafety activities in the country while also being the sole regulatory arm of entities under their mandate.

Results of our policy review shows that the four agencies have developed policies to regulate biosafety through enforcing guidelines and standards (Table 2). Although these policies have been implemented, stakeholder analysis results show limited capacity of regulators to maintain this (Table 5). Insufficient institutional capacity manifests in the limited training of regulatory personnel and variations in the level of detail between and within biosafety policies of different agencies. Current policies in training refer to continuing education for facility workers in relation to biosafety but do not include regulatory personnel. This is consistent with stakeholder analysis findings, wherein participants noted that some agencies should but do not currently have the technical expertise to develop or implement policies on biosafety and biosecurity.

The lack of consensus for some agencies also shows the need to determine their structure, current competencies, and how regulators are regulated. In appointing a regulator, there should be consideration that the regulator should be as informed as the regulatees. The question of “Who regulates the regulators?” must examine which external bodies or individuals have the authority to reconsider the decisions made by the regulators.⁴³

Responsive regulation maintains that regulators are more likely to succeed by using mechanisms that are responsive to the context, conduct, and culture of those being regulated.⁴⁴ A command and control approach, as is currently applied in the Philippines, is an appropriate form of regulation when all parties agree to minimum standards of quality.⁴⁵ However, there is currently little involvement of the general public in regulatory functions. The Philippine National Biosafety Framework limits public participation to information related to biosafety decisions and begins only from the time an application is received. There is still a need for collaboration in disseminating regulatory standards and establishing the state’s authority as a regulatory body.

Coordination Mechanisms for Emergency Response at the Local Level

The gap analysis shows that at the local level, there are existing scenario-based protocols at each phase of the emergency response to potential disease outbreaks, but harmonization is lacking. Based on the findings of the tabletop exercise, efforts in the implementation of protocols in laboratory testing and operations; monitoring and surveillance; quarantine response; veterinary and clinical disease investigation; waste disposal and decontamination, media, and; law enforcement are concrete but uncoordinated.

In an ideal setting, these mechanisms are implemented by local responders from the Bureau of Fire Protection and Philippine National Police. However, clear coordination mechanisms required to bridge the gap between public health and national security are either lacking or slow in activation. To set up a robust response strategy, multidisciplinary networks with diagnostic capabilities in law enforcement and public health, including environmental, agricultural, food, veterinary, and clinical institutions, are necessary to handle both intentional and unintentional biorisk incidents.⁴⁶

A common framework for biosafety and biosecurity must be created to accurately assess the risks posed by biological threats and ensure understanding of multidisciplinary strategies needed to mitigate them. This can be achieved by considering four key points⁴⁰: (1) difficulty in estimating likelihood and consequences of a biological threat, (2) the need for broad and comprehensive definitions of biosafety and biosecurity to bridge the gap between national security, life sciences, and public health communities, (3) inaccurate perception of risk and its implications in the response, and (4) synergy in research and formulation of policy.

Conclusions and Recommendations

Reforms in biosafety and biosecurity policies are expected to improve coordination, ensure sustainability, capacitate facilities, and professionalize biosafety officers. Because of the complexity of reforms necessary, success will require a consistent and coherent policy framework that (1) provides well-coordinated mechanisms for multidisciplinary and multilevel communication and interaction toward harmonized risk reduction and management; (2) establishes, benchmarks, develops, implements, and enforces guidelines on biosafety, biosecurity, and biorisk management; (3) regulate facilities where implementation of such guidelines is considered essential for occupational safety and the health of the public; and (4) is financed by the General Appropriations Act as part of the national budget.

The COVID-19 pandemic has manifested the gaps identified in this study. Policies and support mechanisms that focus on workforce development, particularly on trainings and workshops, provide a low-investment but high-impact solution in reaching the reform goals. An ef-

fective training program provides a cost-efficient longer term solution for lower to middle-income economies as heavy reliance on infrastructure and engineering safeguards involves overhead costs being accrued over time, impeding local acceptance and sustainability. Awareness-level trainings to policymakers also provide a common language among stakeholders and start an avenue for collaborative discussions. These introductory trainings allow engaging champions from various sectors, increasing the likelihood of program sustainability and accelerating simultaneous capacity building among stakeholders. The multidisciplinary approach enables collaboration and linkage among agencies and other concerned entities to prepare for and respond to a biological event of any scale in a timely and consistent manner.

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