

CHAIR'S SUMMARY

Biosecurity Game Changers Workshop

3rd-5th September 2024

Addis Ababa

PREAMBLE

Workshop Key Outcomes: The Biosecurity Game Changers workshop convened over 50 next-generation and current experts from across the African Continent and around the world to discuss and decide on key challenges to address future worst-case biological scenarios, as well as next steps to further develop the Biosecurity Game Changers network, fellowship, and novel training approaches across the security and public health sectors in Africa. The group discussed and agreed on three major challenges: (1) improving biosafety and biosecurity to safely and responsibly achieve the goals of the 100-Day Mission; (2) developing new and more comprehensive approaches to detecting known and unknown threats early and aligning detection triggers with public health actions; and (3) building and financing the capacity to produce, manufacture, and distribute medical countermeasures across Africa and around the world more rapidly, equitably, and sustainably. Next generation leaders envisioned specific immediate actions that could be taken in each of these three areas, outlined below, and decided to convene regular meetings across the network to further these goals. Through a scenario-based discovery session, the group also identified key needs for incorporating biosecurity and biosafety innovations into the development of biodesign tools enabled by artificial intelligence. Going forward, the Game Changers cohort agreed to meet at least monthly as a larger network to further policy actions in identified areas. The group will also identify next steps for adapting workshop content into short courses aimed across the disciplines of public health, biomedical sciences and bioengineering/synthetic biology, international security, artificial intelligence, and nonproliferation.

Policy Outcomes:

- (1) **Advancing Biosafety and Biosecurity as Key Components of the 100 Days Mission:** The group proposed the establishment by the African Union (AU) of a committee to address AI use in vaccine development. Specifically, the group proposed that the AU Committee should, within 6 months, establish a regulatory framework to maximize benefits and minimize the risk of AI for vaccine design. The group also discussed dual use research and high consequence pathogen storage and the importance of understanding institutions involved in both and implementing guardrails.
- (2) **Building Early Warning and Early Disease Detection Capacity in Africa:** To more quickly and efficiently detect novel outbreaks, the group proposed establishing a regional wastewater monitoring program hosted by Africa CDC. This program would harmonize and standardize protocols for wastewater surveillance on the Continent, strengthen regional capacity through the integration of wastewater monitoring systems, and advance funding for sample collection, sample processing, data storage and integration, and requisite workforce. As next steps, the group proposed: (1) advocating for a directive from Africa CDC to create the recommended regional wastewater management program; (2) convening a meeting of wastewater and epidemiology

experts to draft program guidelines to include setting up a database for data and information sharing; and (3) convening additional regional meetings hosted by Africa CDC's Regional Coordination Centers (RCCs) toward the creation of specific programs tailored to RCC specific needs.

- (3) **Enhancing Access to MCM in Africa:** The group proposed operational and policy solutions toward achieving a continent with enhanced local vaccine manufacturing capacity to address pathogens of concern. Specifically, the group proposed advocating for funding to enhance manufacturing capacity in preexisting manufacturing industries in Africa and the establishment of regional-specific manufacturing and procurement mechanisms. The group also proposed consideration of policy solutions to further these goals, including economic incentives – such as custom waivers and tax rebates, and regulatory frameworks to ensure quality assurance in vaccine production.

Immediate Next Steps:

1. The Game Changers fellowship will launch as a part-time (50%) opportunity in Africa for early-to-mid career professionals, with the potential to expand to Asia and Latin America. Placements will expand to include Africa CDC, and placement activities will be coordinated across the host organizations (CEPI, Gavi, IBBIS, BWC ISU, PAN, the Brown Pandemic Center, and – in the future – Africa CDC.) The work will involve and coordinate with National Public Health Institutions (NPHIs), as well as other institutions involved in health security biosecurity, biosafety, biotechnology, and related endeavors.
 2. The Game Changers network, including all Next Gen participants gathered in Addis, will meet monthly to discuss relevant agreed policy topics and next steps for furthering their aims. These meetings will take the form of a Journal Club (monthly) and Seminars (bi-monthly). **Proposed bimonthly seminar topics will be circulated shortly to all participants, with an option to sign up to facilitate or identify guest speakers for discussion.** The first monthly Journal Club session will happen in early November, and the first Seminar has been scheduled to happen in December or early February 2025.
 3. The Biosecurity Game Changers initiative, spearheaded by the Brown Pandemic Center, Stellenbosch University, in coordination with the Science for Africa Foundation and one or more additional universities on the African Continent, will identify and pilot short courses and other academic programming aimed at training the next generation of biosecurity and pandemic decision-makers to lean forward and get ahead of worst-case biological scenarios. This curriculum will be created to serve emerging leaders across the disciplines of public health, biomedical sciences and bioengineering/synthetic biology, international security, artificial intelligence, and nonproliferation.
 4. The Brown Pandemic Center will meet with relevant members of the Steering Committee to design a fundraising approach with an eye toward Africa-focused organizations interested in building biosafety, biosecurity, pandemic preparedness, and S&T capacity on the African Continent, as well as organizations interested in expanding the activities of the Biosecurity Game Changers Initiative to Asia and Latin America.
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DETAILED REPORT

I. INTRODUCTION

The Biosecurity Game Changers Workshop was held from September 3-5, 2024, in Addis Ababa, Ethiopia, and it brought together experts, policymakers, and health security practitioners to address critical challenges in global biosecurity.

The workshop aimed to assess the current state of biosafety and biosecurity and to identify innovative, cross-cutting solutions to prevent, detect, and respond to biological threats in an era of increasing global interconnectedness and rapid technological advancement.

II. WORKSHOP OBJECTIVES

The workshop primary objectives were to:

- i. Officially, launch the 2024 Biosafety Game Changer Fellowship project, formally introducing the Fellows and connecting them with leaders in biosafety and biosecurity from Africa and around the world.
- ii. Identify gaps, key challenges and barriers in biosafety & biosecurity, particularly in the Africa region.
- iii. Discuss lessons from past outbreaks and ongoing biological threats.
- iv. Explore the implications of emerging biotechnologies, with a focus on the AI x Biosecurity nexus.
- v. Develop operational and policy recommendations to address some of the challenges identified and enhance global health security architecture.

III. POLICY BARRIERS

The workshop's second day delved into operational and policy barriers in biosecurity. Through rotating breakout sessions on prevention, detection, and response, participants identified persistent gaps in preventing and responding to biological threats. This interactive approach fostered dynamic discussion and the creation of a collaborative "wall of change" listing potential solutions.

These were the key challenges identified.

a. Roadmap and Authority Identification :

- Need to develop clear roadmaps and designate responsible authorities.
- Define roles and responsibilities across institutions for biosafety, biosecurity, and outbreak response.
- Biosafety and biosecurity are terms that are defined differently globally.

b. Response Planning :

- Urgent need for comprehensive response plans that integrate acute event responses into existing systems.
- Standardized procedures and timelines for addressing outbreaks or biosecurity threats are lacking.

c. Vaccine Development and Medical Countermeasures:

- Prioritize regional vaccine development policies and establish local medical countermeasure (MCM) production and availability.
 - There are challenges in accessing medical countermeasures on time, with insufficient focus on regional capacity-building.
- d. *Early Awareness and Supply Chain Strengthening:*
- Address gaps in early disease detection and awareness to improve rapid response.
 - Build and strengthen supply chain infrastructure for essential health services and medical supplies
- e. *Policy Gaps and Business Continuity:*
- There is a lack of policies for business continuity planning, especially for monitoring essential health services during crises.
 - National policies on biosafety and biosecurity are either underdeveloped or absent, and there is weak or no overarching response plan or strategy.
- f. *Coordination and Leadership:*
- There is a siloed and disjointed approach to biosecurity at the global, regional, national, and institutional levels. There is a need for coherence and systematic coordination at all levels.
 - Different government agencies may have overlapping responsibilities but lack clear communication and collaboration, leading to fragmented efforts. There is need for collaboration.
 - There is need of standardized policies and regulations across countries in the implementation of biosafety and biosecurity.
 - Challenges in political engagement and leadership in biosecurity and a need for stronger leadership and political commitment.
 - Establishing a platform for sharing information and coordinating multisectoral, multi-disciplinary efforts is essential for early detection and timely response to biological events.
- g. *Diagnostic and Genomic Capacity:*
- Insufficient diagnostic tools and capacities for timely biological testing.
 - Field-based genomic sequencing capabilities need to be developed to enhance outbreak surveillance and response.
- h. *Community Engagement and Resource Gaps:*
- Community engagement is inadequate, and resources are limited, making it difficult to implement health initiatives effectively.
 - There is an urgent need for a multisectoral coordination mechanism to align efforts across health, governance, and other critical sectors.

IV. EMERGING BIOLOGICAL RISKS

The workshop underscored the need for a comprehensive, global approach to address emerging and recurring biological risks, emphasizing international cooperation, information sharing, and capacity building as critical areas. Participants also stressed the need for clear definitions and a context-dependent integration of biosafety and biosecurity.

Case Studies and Scenario Insights

Workshop participants engaged in case studies on H5N1 Influenza, Anthrax, Mpox, and Viral Hemorrhagic Fevers (VHFs).

- a. H5N1 Influenza:
 - Current challenges: Testing and vaccine infrastructure insufficient and unadapted if existing
 - Highlighted biosafety concerns with gain-of-function research
- b. Anthrax:
 - Emphasized the need for laboratory inventory, sample tracking, risk communication, designate reference laboratories for diagnosis and detection, and local production of medical countermeasures.
 - Work in collaboration with the private sector
 - Raised questions about funding, stockpiling, and the complex medical/public health to military nexus.
- c. Mpox:
 - Current challenges: Risk communication, risk perception, diagnostic criteria, and capacity, inequities in access to vaccines and therapeutics, and lingering COVID-19 impacts
 - Highlighted issues of stigma and social determinants in disease response
- d. Viral Hemorrhagic Fevers (VHFs):
 - Stressed the need for strong healthcare infrastructure and robust testing capabilities
 - Emphasized the paralytic effect a single case can have on health systems, and the need for preparedness efforts to have a robust plan for continuity of essential health services during a biological event.
 - The need for agility, elasticity and resilience of health systems as a baseline
 - Emphasis on the need to put massive efforts in arresting outbreaks at source

V. GLOBAL HEALTH SECURITY ARCHITECTURE

The workshop highlighted critical components and gaps in the current global health security architecture:

- a. International Health Regulations (IHR):
 - Requires countries to detect, assess, report, and respond to public health events
 - Challenges in practical enforcement despite good legal standing
- b. Global Health Security Index: Provides a global preparedness plan, which was revised in 2021 to reflect some of the limitations observed in the 2019 version.
- c. Medical Countermeasures (MCM) Development and Distribution:
 - The current cycle is not equitable
 - Overemphasis on vaccines at the expense of diagnostics and therapeutics
 - Focus on procurement rather than structural issues and research and development (R&D)
- d. Pandemic Accord:
 - Current gaps in pathogen access, benefit sharing, and operational mechanisms for MCM access.

Participants emphasized the need for:

- i. Strengthening multilateral cooperation in the face of current challenges

- ii. Addressing vaccine hesitancy, which varies across regions and is dependent on diverse sociocultural factors (e.g., religious beliefs and illiteracy)
- iii. Improving pathogen and benefit-sharing mechanisms

VI. CHALLENGES IN BIOSAFETY & BIOSECURITY

1. *Prevention*

- Resource allocation and financing difficulties outside of emergencies
- Political neglect of preparedness
- Need to address factors that drive disease emergence: climate change, industrial agriculture impacts and other factors that narrow the human-animal interface such as habitat encroachment, as well as human movement
- Importance of health economics in prevention strategies

2. *Detection*

- Necessity of a One Health approach, including environmental and animal health surveillance
- Addressing stigma associated with diagnosis (e.g., Mpox)
- Challenges with border health control and regional classifications, including the negative consequences on the IHR mandate of declaring PHEIC
- Information gaps in global needs and capacity, especially for diagnostic testing
- Recurrent challenges with laboratory capacity (human resource, knowledge, logistics, and infrastructure) that delay detection
- Investment in innovation for diagnostic testing and genomic and wastewater surveillance in resource-limited settings

3. *Response*

- Multiple stakeholders and siloed working at the global, regional and national levels which complicate response coordination, and waste resources through mass duplication
- Challenges with MCM production, acquisition, and distribution
- Importance of engaging non-traditional actors, including religious leaders and civil society to enhance uptake of MCM
- Critical role of anthropological aspects in response efforts
- Need for improved field biosecurity measures
- Resource Allocation : The need for a demobilization and repurposing plan for infrastructure, surge staff and logistics that are mobilized during outbreaks

VII. POLICY AND OPERATIONAL INNOVATIONS

The workshop produced several innovative policy recommendations and actionable next steps:

1. Science & Technology Developments:

- Enhance policymaker engagement through courses, training, and exercises on emerging technologies (e.g. AI, synthetic biology, and CRISPR).
- Conduct and evaluate internal workshops and training on AI and biosecurity.

- Examine/ build policy frameworks for assessing and addressing the novel risks that Bioconvergence presents
2. Simulation Exercises:
 - Develop/deploy exercises on AI risks and rewards in biosecurity, targeting local governments, the European Commission, and/or the African Union.
 - Create dissemination materials and platforms for the public, politicians, and policymakers.
 3. Manufacturing Capacity:
 - Expand manufacturing capacity of medical countermeasures in Africa. Beyond a focus on vaccines, this effort should include PPE and diagnostics.
 - Address IP, tech transfer, financing, and stockpiling challenges
 4. Capacity Building:
 - Develop a biosecurity curriculum for implementation in tertiary institutions in Africa and elsewhere (Brown?)
 - Implement biosafety and biosecurity trainings for next-generation experts, including national and regional stakeholders in the biosecurity space
 - Enhance community engagement and communication. These include non-traditional actors, such as faith leaders and non-western medicine providers.
 - Develop and share cyber biosecurity guidelines and best practices.
 5. One Health Approach:
 - Create frameworks for information/sample sharing, swift response, and testing guidelines, within and across government(s).
 - Integrate animal health and environmental surveillance with human/public health.
 6. Next Generation Leadership:
 - Establish a forum or platform to network and connect African (rising) leaders in biosafety and biosecurity.
 7. Resource and Vulnerability Mapping:
 - Perform gap analysis on infrastructure, networks, and MCMs
 - Identify regulation gaps in AI, biosafety, and biosecurity
 8. Political Engagement
 - Develop a playbook that guides technical experts on how to communicate science to political decision-makers.
 - Take advantage of different regional and global political meetings and conferences and use them as a platform to present/ advocate and lobby for biosecurity through presentations, side-events, etc. (e.g., the AU Council, Africa CDC, WHO, the UNSC, GHSA, G20, etc.)
 9. Success Stories:
 - Showcase and learn from successful biosafety and biosecurity initiatives, including those championed by the Games Changers Fellows.
 10. Knowledge Sharing
 - The Pandemic Center to create a “One-Stop-Centre for Global Biosecurity”. A platform which generates, collects and compiles all credible information on biosecurity from all global stakeholders, and becomes an authoritative source on biosecurity literature. (academic literature, blogs, links to courses, podcasts, videos, research, etc.)
 - Create a platform/resource center where people can request information, and learnings and resources that can be shared between countries (e.g. bio risk mapping tools, biosurveillance tools, outbreak case-studies, etc.)
 11. Community Engagement as a Pillar

- The need to develop effective, contextualized community engagement strategies
- Leverage this network to learn from other countries in the region – what strategies they have deployed that have worked.

VIII. NEXT STEPS AND FUTURE DIRECTIONS

1. Collaborate with key stakeholders, including Africa CDC and regional partners (e.g., NEPAD, SADAC, EAC, ECOWAS, etc.) to implement a comprehensive biosafety and biosecurity framework tailored to the region’s unique challenges, in alignment with the Africa CDC Biosafety and Biosecurity Initiative (2021-2025) strategic Plan, the CEPI Biosecurity Strategy, the WHO Biosafety Manual, and various international biosecurity guidelines. The new framework should encompass clear guidelines, designated roles, and implementation strategies to strengthen regional preparedness and response capabilities.
2. Establish a communication platform that enables sharing of materials and information. This platform could also serve as a forum for discussion and knowledge exchange, facilitating ongoing collaboration. To further support capacity-building, the platform should offer online training sessions led by network experts, ensuring that stakeholders across the region are equipped with the necessary skills and knowledge to address emerging biosafety and biosecurity threats effectively.
3. For Capacity Building, the program could initiate a comprehensive capacity-building strategy in collaboration with various stakeholders across the network. This approach will focus on providing continuous training and certification opportunities in biosafety, biosecurity, and emergency response. Suggested topics should include principles of biosecurity, cybersecurity, Dual-use Research of Concern, and risk communication.
4. Create a political engagement playbook for technical experts in biosecurity that will give a roadmap and strategies on how to communicate science in political language, identify and leverage stakeholder interests, and recognize tipping points for policy reform.

IX. CONCLUSION, POLICY OUTCOMES, AND IMMEDIATE NEXT STEPS

The Biosecurity Game Changers Workshop successfully brought together diverse stakeholders to address critical challenges in global biosafety and biosecurity. The discussions, exercises, and policy recommendations developed during this workshop will guide the efforts of the 2024 Biosecurity Game Changers Fellows and contribute to enhancing our collective ability to prevent, detect, and respond to biological threats.

Workshop Key Outcomes: The Biosecurity Game Changers workshop convened over 50 next-generation and current experts from across the African Continent and around the world to discuss and decide on key challenges to address future worst-case biological scenarios, as well as next steps to further develop the Biosecurity Game Changers network, fellowship, and novel training approaches across the security and public health sectors in Africa. The group discussed and agreed on three major challenges: (1) improving biosafety and biosecurity to safely and responsibly achieve the goals of the 100-Day Mission; (2) developing new and more comprehensive approaches to detecting known and unknown threats early and aligning detection triggers with public health actions; and (3) building and financing the capacity to produce, manufacture, and distribute medical countermeasures across Africa and around the world more rapidly, equitably,

and sustainably. Next generation leaders envisioned specific immediate actions that could be taken in each of these three areas, outlined below, and decided to convene regular meetings across the network to further these goals. Through a scenario-based discovery session, the group also identified key needs for incorporating biosecurity and biosafety innovations into the development of biodesign tools enabled by artificial intelligence. Going forward, the Game Changers cohort agreed to meet at least monthly as a larger network to further policy actions in identified areas. The group will also identify next steps for adapting workshop content into short courses aimed across the disciplines of public health, biomedical sciences and bioengineering/synthetic biology, international security, artificial intelligence, and nonproliferation.

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