

# **Literature Review**

# **Balancing Innovation, Biosecurity, and Biosafety in Dual-Use Research in the Middle East**

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#### **Abstract**

Dual-use research is known for its double use, contributing to positive advancements and serious risks, especially in regions with political instability and low biosafety and/or biosecurity protocols. This paper offers background knowledge, regional challenges, and much more about the situation in the Middle East.

Case studies compare biosafety and biosecurity practices in the Middle East with global standards to highlight the effectiveness of regional regulations and the consequences of not following them. We conclude that regional and international cooperation are essential when sharing the region's information and policy alignments. We also provide recommendations to improve lab facilities' regulatory framework and financing to increase awareness of bioethics and dual-use concerns through education and training initiatives.

This review aims to help researchers and policymakers bridge these gaps, enhancing the integrity of Middle East research and biosecurity by creating more secure and accountable scientific environments in the region.

**Keywords:** Dual-Use Research of Concern, Gain of Function Research, Loss of Function Research, Biosafety, Biosecurity, The Middle East

#### Introduction

Dual-use research involves biological studies with scientific importance that could be misused to threaten public health or security; this research can be applied to technologies with both military and civilian applications [1]. Nuclear research offers benefits like energy and radiology but also poses a risk for nuclear weapons development. Similarly, viral research advances biodefense but can be misused to create bioweapons. Synthetic biology aids genetic enhancement and biomedicine but may also lead to

bioweapons, while nanotechnology, though improving products and healthcare, also presents risks in surveillance and weaponry [2]. Research in the life sciences that aims to improve human health, animal welfare, or agricultural productivity but acknowledges the potential for hostile actors, like terrorist organisations or rogue states, to use the study to compromise public welfare is known as dual-use research [3, 4].

#### Gain-of-Function (GoF) and Loss-of-Function (LoF) Research

Gain-of-function (GoF) research studies genetic changes that enhance traits like transmissibility, replication, or virulence, helping us understand disease development and aid vaccine creation [5]. However, despite how beneficial it is to pandemic preparedness, ethical and safety issues are still considered, particularly when handling potentially infectious diseases [5]. A recent example includes using MERS, SARS mimics, and synthetic SARS-CoV-2 platforms for analysis and research [6]. Dual-use research involves science that can be applied for good or harm, including studies that could aid bioterrorism, like vaccine development. While both raise safety and

ethical concerns, GoF focuses more on understanding and reducing pathogen threats but carries higher risks of accidentally creating pandemic agents[7].

Loss-of-function (LoF) research studies genetic changes that reduce or eliminate a gene's function through mutations like frameshifts, deletions, and nonsense mutations [8]. LoF variations, common in many disorders, can drive diseases like cancer by disabling tumour suppressor genes such as TP53. While genomic advances help identify LoF variants, distinguishing harmful mutations remains challenging [8]. Figure 1 illustrates the difference between GoF and LoF researchers.



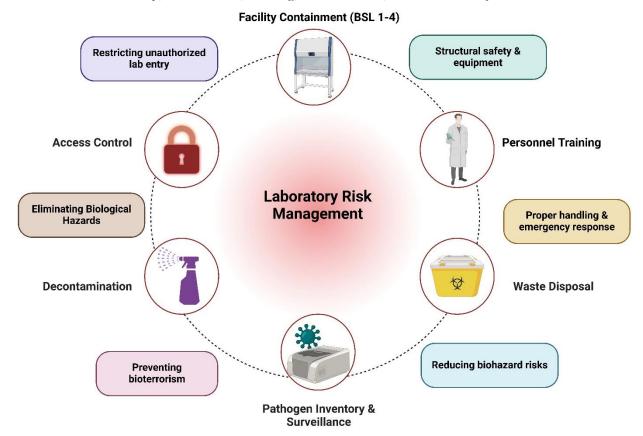
**Figure 1:** The differences between GoF and LoF disease studies. GoF research improves organism functioning by enhancing virulence, transmissibility, or resistance, whereas LoF research inhibits or turns off gene or pathogen functions, aiding vaccine development and functional studies.

Approach	Gain of Function  Control  Con	Loss of Function  Disabling/reducing gene or pathogen function
MANN Methodologies	Genetic editing (e.g., CRISPR, mutagenesis), serial passaging	
Applications	Understanding pathogen evolution, vaccine development, risk assessment	Developing attenuated vaccines, studying gene function, disease modeling
Risks	Higher biosecurity risks, potential for pandemic-causing agents	Generally safer, widely accepted

Biological research risks often stem from biosafety or biosecurity failures, with biosafety policies designed to prevent lab accidents exposing people to infectious agents [9]. In contrast, biosecurity measures focus on protecting sensitive information and materials from misuse by those with harmful intentions. While biosecurity addresses security risks associated with sharing scientific information, robust biosafety practices support responsible research that strengthens biosecurity. Research involving major biosafety concerns may also lead to biosecurity risks [10]. Figure 2 shows laboratory risk management and how complete safety systems are biosafety, biosecurity, and emergency preparedness.



**Figure 2:** This illustration shows a complete risk management system for biological labs, highlighting biosafety, biosecurity, containment, training, access control, and incident response.



Implementing biosafety and biosecurity in the Middle East is challenging due to regional instability, resource shortages, and weak infrastructure, with wars further straining health systems and limiting access to necessary facilities [11]. High-risk pathogens must be contained in facilities like biosafety BSL-3 (level 3) and BSL-4 (level 4) laboratories. Additionally, a lack of institutional and political backing has limited the uniform cross-border execution of biosecurity legislation [12]. This led to most biosafety initiatives in

the Middle East and North Africa (MENA) region focusing only on increasing public awareness while falling behind in local expertise development, including professionals skilled in risk assessment, lab design, equipment handling, and the safe transfer of genetically modified organisms (GMOs) and infectious materials. At the same time, only 2.67% offered hands-on training. Key training needs included practical biosafety procedures, equipment use, and risk management [13].

#### Case Studies of DUR and GoF in the Middle East

Between 1985 and 1991, Iraq developed biological weapons, including Anthrax, Botulinum toxin, and Aflatoxin, arming bombs and missiles with these agents. However, their impact during the Gulf War would likely have been limited due to a small arsenal, poor delivery systems, and overwhelming coalition military superiority. Although the war ended, concerns persisted about Iraq's continued interest in weapons of mass destruction, emphasising the need for strict international oversight and enforcement to prevent further development [14].

Investigations by the International Atomic Energy Agency (IAEA) uncovered that Egypt conducted unreported experiments using natural uranium compounds at the ETRR-2 reactor. Although the experiments were for medical isotope production and did not involve plutonium or U-233 separation, the lack of timely reporting highlighted compliance issues with international safeguards [15].

In 2014, Egypt launched the "100 Million Healthy Lives" initiative, combining mass HCV screening with subsidised direct-acting antivirals like sofosbuvir, reducing treatment costs from \$84,000 to \$84. By 2023, Egypt became the first country to achieve the WHO's "gold tier" status for HCV elimination. While major public health successes have been achieved, the extensive use of patient data raises privacy concerns, and antiviral-driven mutations could lead to drugresistant strains[16].

The (MERS-CoV) epidemic started in 2012, with Saudi Arabia having the highest number of reported cases [17]. It was a highly lethal respiratory virus with



zoonotic origins linked to dromedary camels. Saudi Arabia played a crucial role in MERS research aimed at understanding viral mutations that could enhance human transmission; the study focused solely on improving the diagnostic tools and potential vaccine development. However, if misused or released, the modification of MERS-CoV could be a biosecurity risk [17]. When the modified Grunow-Finke Tool (mGFT) was used for the Saudi Arabian MERS-CoV outbreak, the probability that the outbreak was of unnatural origin was 67% [18]. Although the evaluation did not provide conclusive evidence of bioterrorism, it did identify many peculiar epidemiological characteristics that should be considered, including irregular

transmission patterns, unclear zoonotic exposure in more than half of the cases, and restricted spread even in the face of large crowds [18].

Due to heavy reliance on camel industries and close human-animal contact, Saudi Arabia established a Command-and-Control Center and a National Health Laboratory to enhance diagnostics and contain the virus [17, 19]. These results highlight the significance of strict monitoring of GoF and dual-use research of concern (DURC) research in the Middle East, where geopolitical unrest and weak biosecurity regulations might increase the likelihood of intentional or unintentional abuse.

#### International Regulations, Guidelines, and Policies

The 2012 U.S. Policy for Oversight of Life Sciences DURC set guidelines for managing research on highrisk pathogens like H5N1, identifying 15 agents and experiments as "Dual Use Research of Concern." It requires a federal review of DURC proposals, risk assessment, and controls such as limiting publication details. The policy shifts from self-regulation to structured federal oversight and international cooperation, aiming to protect public health and national security [20]. Additionally, this was seen in the policies set by the United States in 2012 and 2014 on DURC oversight, as guidelines were established on managing and monitoring dual-use research to mitigate risks associated with high-consequence pathogens [21, 22].

As such, institutional frameworks were established to help principal investigators (PIs) and research institutions identify DURC, emphasising that public trust and transparent communication are essential to justify regulatory actions while supporting responsible scientific progress [20]. The European Union (EU) Guidebook on dual-use research policies outlines how regional authorities and small and enterprises (SMEs) can balance innovation and safety in dual-use technology. It highlights funding programs like the European Structural and Investment Funds and Horizon 2020, which support technology partnerships, development, and international expansion [23].

Stronger biorisk governance is critically needed to keep up with the quick advancements in biotechnology and life sciences, according to the World Health worldwide guideline Organization (WHO)'s framework issued in 2022. It presents a thorough method of biorisk management built on three pillars: dual-use research supervision, biosafety, and biosecurity [24]. The framework emphasises the dangers of intentional acts, such as creating or releasing dangerous biological agents, accidents, and inadvertent usage. In order to guarantee the safe and responsible use of life sciences, the guidance urges proactive, morally sound measures adapted to various national contexts, acknowledging that present

governance structures frequently fall behind scientific advancement [24].

To handle the use of dual-use issues regarding bioterrorism and biowarfare, we need to enforce national laws that forbid the creation of bioweapons. and we also need to strengthen the terms made by the Biological and Toxin Weapons Convention (BTWC) [25]. Detecting hidden bioweapon programs requires strict inspections, transparency through confidencebuilding measures (CBMs), and stronger international regulations on biological agents and dual-use equipment. The 2003-2005 BTWC highlighted the need for global scientific involvement to prevent biotechnology misuse [26, 27]. Table 1 shows a comparison between the DURC policy from 2012 and 2014. Jordan has been actively engaged in implementing the Biological Weapons Convention (BWC), with a focus on preventing the proliferation of biological weapons [28].

After years of conflict, Iraq has worked to rebuild its biological non-proliferation efforts by passing new laws, establishing a national authority to oversee the BWC, and engaging in international training initiatives. Challenges remain, including improving laboratory biosafety, biosecurity, and border controls to prevent the spread of biological agents [29]. Figure 3 shows an Integrated Framework for Enhancing Biosafety and Biosecurity widely used in the Middle East

Iran has been a State Party to the BWC since 1973, passing laws and creating a national body to oversee its implementation. However, concerns remain over Iran's ambiguous compliance, with calls for greater transparency and cooperation with international organisations [30]. The threat of biological weapons in Iran requires a tailored non-proliferation approach, factoring in political, technological, and security concerns. However, Iran's nuclear ambitions have dominated attention, with experts stressing that addressing the root causes of proliferation is key to preventing instability [31].

Saudi Arabia has supported the BWC since 1972, establishing a national body to oversee its



implementation and passing legislation to ban the use of biological agents for non-peaceful purposes [32].

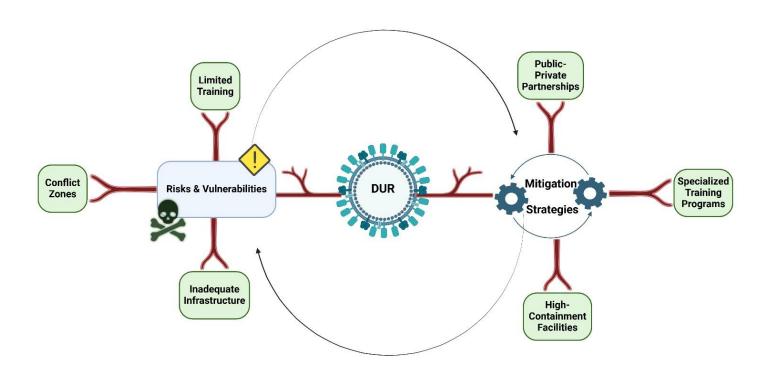
Yemen has been a State Party to the BWC since 1991, but ongoing conflict has hindered effective implementation. Despite establishing a national body to oversee the BWC, Yemen struggles due to instability. The country participates in regional and global initiatives, but external support is needed to strengthen its internal capabilities and successfully implement the BWC [33].

Since 2002, the United Arab Emirates (UAE) has joined the BWC. Establishing a national authority to supervise implementation is one of the UAE's actions in implementing the BWC [34]. The country also implemented legislation forbidding the use of biological agents for purposes apart from peace. The UAE has participated in regional and international efforts to accelerate the adoption of the BWC through

training programs and seminars to enhance national capabilities. Additionally, the UAE has highlighted the need for global cooperation and support in halting the spread of biological weapons [34].

Israel has a structured dual-use research plan in the biological sciences that balances scientific innovation with biosafety. Its framework regulates sensitive research to lower risks, advance development, and prevent abuse, particularly in biotechnology and virology [35]. Yet, Israel has maintained a position of purposeful ambiguity by refusing to sign the BWC and by never explicitly outlining a national policy on biological weapons. It signed the Chemical Weapons Convention (CWC) in 1993 but hasn't ratified it yet. Therefore, the nation has no legal force enforcing BWC [36].

**Figure 3:** Measurements of biosafety and biosecurity in the Middle East. These measurements focus on policy creation, training programs, infrastructure upgrades, and international collaboration to minimise biological threats.





**Table 1:** The USG DURC policy in 2012 and 2014 and comparison from various aspects.

Aspect	2012 DURC Policy	2014 DURC Policy
Date of Issue	Released in March 2012.	Released in September 2014.
Purpose	Focused on federal agencies reviewing their research portfolios for DURC and implementing mitigation strategies.	Expanded oversight to include institutional responsibilities and detailed risk management plans.
Scope	Applied only to federally funded or conducted research.	Required all institutions conducting federally funded research to identify and manage DURC risks.
Agents Included	15 high-risk agents and toxins were listed, such as Bacillus anthracis, Ebola virus, and Avian influenza (highly pathogenic).	Maintained the same list of 15 agents as in the 2012 policy.
Requirements	<ul> <li>Federal departments/agencies identify DURC in intramural and extramural research portfolios.</li> <li>Develop risk mitigation strategies.</li> </ul>	<ul> <li>Institutions must establish a system to identify DURC.</li> <li>Institutions must work with funding agencies to mitigate risks.</li> <li>A formal DURC review process at the institutional level is required.</li> </ul>
Categories of Experiments	It included seven categories of concern, such as enhancing agent transmissibility or disrupting immunity.	The same seven categories of concern were maintained in the 2012 policy.

 $<sup>\ ^*</sup>DURC: Dual-use\ research\ of\ concern.$ 

# Biosafety and Biosecurity: A More Profound Approach for Meaningful Understanding

Countries like Iran and Israel have made progress with advanced biosecurity systems and research investments. However, political instability and resource shortages hinder comprehensive biosecurity programs in many other countries [37]. On the other hand, international standards, such as those from the World Health Organization, promote stronger global biosecurity frameworks, standardised procedures, and collaboration to tackle biosecurity issues. The mixed success in the Middle East highlights the need for greater regional cooperation and alignment with global best practices [38]. The lack of sustainable hands-on training and certification programs is inconsistent. International training programs are frequently unavailable or inadequately financed, and most projects prioritise raising awareness over developing skills. Lack of funding, problems with governance, a shortage of human resources, a lack of knowledge, and a lack of infrastructure and equipment are some of the obstacles that regions face when attempting to mitigate risk [39]. In the Middle East, reporting security breaches or biosafety violations is uncommon due to underreporting caused by a lack of whistleblower protections, fear of reputational harm,

and weak monitoring systems. This lack of transparency hinders effective incident response and learning from past mistakes [40]. Institutional Biosafety Committees (IBCs), which review research involving biohazards and provide guidance to ensure public health and environmental safety [41], are often missing or ineffective in institutions across the Middle East, and very few institutions reported the creation of IBCs. This is due to a lack of trained personnel and clear mandates; sometimes, institutions are unaware of the need for such bodies. The absence of IBCs hampers the ability to conduct thorough risk assessments and implement appropriate safety measures [42, 43].

Middle Eastern biosafety practices prioritise pathogen containment, hazardous chemical handling, and training. However, regulatory gaps persist, with Jordan and Lebanon lacking fully integrated laws and Iraq still finalising its framework [44]. Labs face issues like outdated infrastructure, poor maintenance, and a shortage of certified biosafety cabinets, which increases exposure risks. There are recurring issues regarding inconsistent training focusing on broad awareness rather than specialised skills.



Strengthening training programs, centralising pathogen databases, and limiting hazardous material access is essential for compliance with international biosafety standards [44, 45].

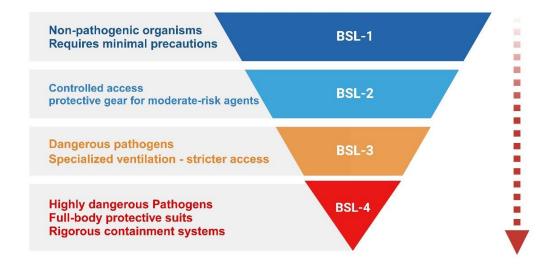
The structured safety regulations known as biosafety levels (BSL) shield the environment, the general population, and researchers from potentially dangerous biological contaminants. As shown in Figure 4 [46]. BSL-1 is the least restrictive, while BSL-2 covers the moderate-risk agents. Dangerous pathogens require BSL-3, with unique ventilation systems and stricter access controls to prevent airborne transmission. Finally, the highest level, BSL-4, is used for hazardous agents like Ebola and

Crimean-Congo haemorrhagic fever [47-49]. Biosafety precaution classifications based on risk groups aim to minimise infections acquired within laboratories, but the real-world conditions of daily laboratory practices must also be factored in [50].

Saudi Arabia operates several BSL-3 laboratories, particularly for research on Middle East Respiratory Syndrome Coronavirus (MERS-CoV). For instance, a certified BSL-3 laboratory in Jeddah has been utilised for MERS-CoV microneutralization assays [51]. The U.S. Naval Medical Research Unit No. 3 (NAMRU-3) in Cairo is a prominent BSL-3 facility that has been instrumental in the region's infectious disease research and surveillance [52].

**Figure 4:** This diagram displays the four biosafety categories, from BSL-1 (minimum risk) to BSL-4 (high-risk pathogens), together with the accompanying containment measures, protective equipment, and operational requirements for handling infectious agents safely.

# **Biosafety Levels**



#### Challenges and Gaps in the Application of Biosafety and Biosecurity in the Middle East

The biosafety systems in the Middle East do not align with the international standards established by the WHO and the Global Health Security Agenda. Nations such as Iraq, Jordan, and Lebanon fail to meet key criteria of the Joint External Evaluation (JEE), especially in laboratory certification, real-time monitoring, and pathogen control [44]. Even if integrating the public health and security sectors has been relatively successful, additional effort is needed to ensure the sustainability and universality of international standards [53].

Modern BSL facilities that can handle highly pathogenic organisms requiring BSL-3 or BSL-4 protocols are lacking in many countries. Resource limitations hamper critical biosafety equipment certification and maintenance [12]. Additionally, laboratory settings are exposed to biological hazards due to differences in applying global biosafety standards, which are exacerbated by inadequate regulatory frameworks [54]. One notable example is a *Brucella melitensis* laboratory-acquired infection in a hospital in Saudi Arabia, where improper handling and biosafety lapses were identified as key factors [54]. Gaps in education and training threaten biosafety efforts, as many lab staff lack proper training, increasing the risk of exposure. Universities' limited biosafety curricula worsen the skills gap between researchers and public health workers. Political instability further hinders the resources and infrastructure needed for biosafety [55].



Despite broad support, several challenges hinder effective biosafety and biosecurity training. Governance issues, such as poorly drafted policies and financial constraints, which lead to underfunding biosafety initiatives, are major obstacles [56]. The UAE has implemented a comprehensive approach to managing biological risks, focusing on risk

assessment, documentation, and controlled material management. Biological agents are tracked, material transfers are regulated, and emergency response plans are in place. Facilities classify agents by risk level, establish standard procedures, and update protocols as needed to ensure safety, traceability, and regulatory compliance [57].

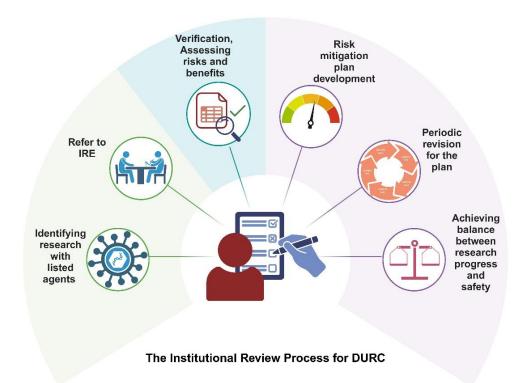
#### Bioterrorism and Biological Warfare Due to Biosecurity Breaches

Bioterrorism and biological warfare are significant threats, with hostile countries and non-state actors potentially using germs as weapons. The dual-use nature of life sciences research adds complexity, as legitimate scientific discoveries can be misused. Insufficient enforcement and monitoring increase these risks [58]. Inadequate enforcement and monitoring increase these dangers; regional enforcement varies widely, and global governance systems are often incoherent [59]. Additionally, inadequate oversight of private sector research and disjointed international collaboration leave critical gaps. Standardizing risk assessments, bolstering regulatory frameworks, and encouraging global cooperation are crucial in addressing vulnerabilities [59, 60].

Poor supervision and inadequate strategies complicate biosafety in GoF research in the MENA

region. Improving cooperation, legal frameworks, and containment standards can reduce risks, align with global best practices, and promote innovation while enhancing preparedness for pandemics [61]. A different process of DURC institutional review includes identifying studies involving specified medications or potential side effects, submitting them to the Institutional Review Entity (IRE) for validation, and balancing the risks and benefits [62]. If DURC is established, a draft risk mitigation strategy is developed to manage risks appropriately. This approach is regularly reviewed to allow for adjustments, ensuring continuous oversight and balancing safety and scientific progress [63]. These steps promote accountability while safeguarding against potential misuse of life sciences research [63, 64]. Figure 5 shows the steps of the DURC review process.

**Figure 5:** Overview of the DURC review process steps, including identifying dual-use potential research, risk assessment, supervision systems, and mitigation techniques to guarantee responsible scientific practices.





Generally, the possibility of unintentional leaks can be reduced by improving the capabilities of monitors, air filtering systems, and sophisticated containment techniques, which can also increase general safety [65]. Strong infrastructure guarantees adherence to global safety regulations and fosters scientific innovation. Also, supply chains and logistics must be strengthened for a smooth biosafety lab operation, particularly in times of emergency, political unrest, or pandemic; dependable supply chains allow for steady access to necessary supplies, including reagents, personal protective equipment and bio-secure containment systems [66].

# The Impact of DURC on Biosafety and Biosecurity

Biosafety and biosecurity are greatly affected by DURC, which underscores the double-edged nature of scientific breakthroughs; they can bring incredible benefits but also present significant risks [67]. From a biosafety standpoint, DURC highlights the need for stronger containment measures and improved operational protocols to prevent the accidental release of engineered or modified pathogens [66]. Highcontainment facilities and strict protocols are vital to protect against bioterrorism risks in DURC, and regulatory frameworks must balance responsible research with preventing misuse of life sciences discoveries like synthetic biology and gain-of-function studies[68]. A balanced strategy that prioritises while upholding innovation stringent management is necessary for DURC. Strong governance, moral principles, and international cooperation are required to reduce risks while facilitating scientific progress to address global health issues [69].

#### **Conclusion**

This review highlights the critical need for region-specific risk management strategies that integrate international best practices with local governance realities, especially in conflict-affected and low-resource regions. In the Middle East, systemic issues such as political instability, underdeveloped infrastructure, limited financial resources, and insufficient regulatory oversight compound the challenges of dual-use research governance. Our review points to specific institutional vulnerabilities, including the absence of whistleblower protections, underreporting of biosafety breaches, and weak

#### **Authors Contributions**

Laith N. AL-Eitan: Writing – review & editing, Writing – Original draft, Visualisation, Validation, Data curation, Conceptualisation.

#### **Conflicts of Interest**

All the authors declare that they do not have conflicts of interest.

Addressing biosecurity gaps in the Middle East requires more substantial infrastructure and regional collaboration, such as establishing partnerships with global powers such as the United States, the European Union, and China. A possible plan is for the USA to bring its extensive biosurveillance and disease prevention expertise to address a full-spectrum threat [70, 71]. While the EU provides frameworks for regulatory compliance and financial contributions for health security initiatives, its 2022 Global Health Strategy supports global health security through equitable healthcare, primary care improvement, and digital health, which may aid biosecurity in the Middle East [72]. With its advancements in biotechnology and epidemic control, China would also play a key role in strengthening capacity-building efforts [73, 74]. This multi-approach would enhance the ME's biosafety and biosecurity measures, integrating expertise, funding, technological innovation to mitigate regional biosecurity threats and advance global health goals.

monitoring mechanisms, as central factors hindering effective implementation. To mitigate these risks, we recommend targeted investments in high-containment laboratories, robust hands-on training programs, the formation of functional biosafety committees, and stronger public-private and international partnerships. These actions will enhance health security, scientific innovation, and regional stability, positioning the Middle East as a responsible and collaborative actor in global biosafety and biosecurity governance.

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