

Autoimmune mucocutaneous blistering diseases after SARS-Cov-2 vaccination: A Case report of Pemphigus Vulgaris and a literature review

- PMID: 35278817
- PMCID: [PMC8896864](#)
- DOI: [10.1016/j.prp.2022.153834](#)

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Abstract

Background: Cases of severe autoimmune blistering diseases (AIBDs) have recently been reported in association with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination.

Aims: To describe a report of oropharyngeal Pemphigus Vulgaris (OPV) triggered by the mRNA BNT162b2 vaccine (Comirnaty®/ Pfizer/ BioNTech) and to analyze the clinical and immunological characteristics of the AIBDs cases reported following the SARS-CoV-2 vaccination.

Methods: The clinical and immunological features of our case of OPV were documented. A review of the literature was conducted and only cases of AIBDs arising after the SARS-CoV-2 vaccination were included.

Case report: A 60-year old female patient developed oropharyngeal and nasal bullous lesions seven days after the administration of a second dose of the mRNA BNT162b2 vaccine (Comirnaty®/ Pfizer/BioNTech). According to the histology and direct immunofluorescence findings showing the presence of supra-basal blister and intercellular staining of IgG antibodies and the presence of a high level of anti-Dsg-3 antibodies (80 U/ml; normal < 7 U/ml) in the serum of the patient, a diagnosis of oropharyngeal Pemphigus Vulgaris was made.

Review: A total of 35 AIBDs cases triggered by the SARS-CoV-2 vaccination were found (including our report). 26 (74.3%) were diagnosed as Bullous Pemphigoid, 2 (5.7%) as Linear IgA Bullous Dermatitis, 6 (17.1%) as Pemphigus Vulgaris and 1 (2.9%) as Pemphigus Foliaceus. The mean age of the sample was 72.8 years and there was a predominance of males over females (F:M=1:1.7). In 22 (62.9%) cases, the disease developed after Pfizer vaccine administration, 6 (17.1%) after Moderna, 3 (8.6%) after AstraZeneca, 3 (8.6%) after CoronaVac (one was not specified). All patients were treated with topical and/or systemic corticosteroids, with or without the addition of immunosuppressive drugs, with a good clinical response in every case.

Conclusion: Clinicians should be aware of the potential, though rare, occurrence of AIBDs as a possible adverse event after the SARS-CoV-2 vaccination. However, notwithstanding, they should encourage their patients to obtain the vaccination in order to assist the public health systems to overcome the COVID-19 pandemic.

Keywords: Bullous Pemphigoid; Covid-19 vaccine; Pemphigus; SARS-Cov-2.

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Figures



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Bavarian Nordic Receives NIH Grant to Investigate the Potential of an MVA-BN® based Vaccine against Ebola and Marburg Viruses

Kvistgård, Denmark, October 13, 2010 - Bavarian Nordic A/S (OMX: BAVA) announced today that the company has received funding from the U.S. National Institutes of Health (NIH) to advance its early research in filoviruses (Ebola and Marburg virus).

As previously announced, the company is investigating the potential use of its core vaccine technology, MVA-BN® as a combined vaccine encoding genes for both the Ebola and Marburg strains. The funding from NIH will support an animal efficacy study performed in non-human primates.

Upon evaluation of the initial data from this study, which are expected next year, Bavarian Nordic will determine the future of this project in the company's pipeline.

Bavarian Nordic's President & CEO, Anders Hedegaard commented: *"This research grant is yet another sign of the continued strong relationship between Bavarian Nordic and the US government. We have already successfully advanced the development our IMVAMUNE® smallpox vaccine under a fully-funded programme from the US government and with continued support and funding from the US authorities, we are committed to developing innovative vaccines against other potential biological weapons like anthrax, Ebola and Marburg as well. Also, with this initiative we fulfil part of our short term goal to investigate new opportunities to expand the pipeline within our Infectious Disease Division."*

About filoviruses

Filoviruses belong to a virus family called *Filoviridae* and can cause severe hemorrhagic fever in humans and nonhuman primates. So far, only two members of this virus family have been identified: Marburg virus and Ebola virus.

Both diseases are rare, but have a capacity to cause dramatic outbreaks with high fatality. Outbreaks of the diseases have been frequently reported since the discovery of the viruses around 40 years ago, mainly in Africa where the viruses have their origin.

Due to their severe fatality rate and ease of transmission, both viruses are considered potential biological weapons.

Currently, there exists no standard treatment or vaccine against the diseases.

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Bavarian Nordic is a fully integrated vaccine company focused on the development, manufacturing and commercialization of life-saving vaccines.



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[Biosaf Health](#). 2020 Mar; 2(1): 6–8.

Published online 2020 Feb 5. doi: [10.1016/j.bsheal.2020.01.003](https://doi.org/10.1016/j.bsheal.2020.01.003)

PMCID: PMC7144510

PMID: [32562482](https://pubmed.ncbi.nlm.nih.gov/32562482/)

A strategy to prevent future epidemics similar to the 2019-nCoV outbreak

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Abstract

A novel bat-origin coronavirus emerged in Wuhan, China in December 2019 and continues to spread across China and the world. At the time of writing, a massive global response has been implemented to control the disease as it spreads from person to person. Yet the high-risk human-wildlife interactions and interfaces that led to the emergence of SARS-CoV and of 2019-nCoV continue to exist in emerging disease hotspots globally. To prevent the next epidemic and pandemic related to these interfaces, we call for research and investment in three areas: 1) surveillance among wildlife to identify the high-risk pathogens they carry; 2) surveillance among people who have contact with wildlife to identify early spillover events; and 3) improvement of market biosecurity regarding the wildlife trade. As the emergence of a novel virus anywhere can impact the furthest reaches of our connected world, international collaboration among scientists is essential to address these risks and prevent the next pandemic.

Keywords: Novel coronavirus, Disease emergence, Surveillance, Risk reduction, Market biosecurity, 2019-nCoV

The emergence of a novel coronavirus, 2019-nCoV in Wuhan December 2019 has led to a global response to the first epidemic of this decade. It has also highlighted two key issues: First, China's rapid and efficient capacity to identify and investigate a newly emerging disease; and second, our continued global vulnerability to epidemics and pandemics. From the date of the first cluster of cases admitted to a local hospital on December 27, 2019, Chinese scientists identified this disease as a new syndrome, discovered the pathogen as the cause, and reported its genetic sequence to the world in less than 14 days [1,2]. At the time of writing, we have detailed information on its relationship to other bat coronaviruses, many of which were discovered in a collaboration among EcoHealth Alliance, the Wuhan Institute of Virology, and Duke NUS [3]. We also have data from experimental cell line infections [4], on the clinical findings [5], the epidemiology of viral transmission [6], and on its spread to other countries. These rapid and successful results are a resounding endorsement of China's emergence as a 21st Century scientific superpower, and of a country with a modern and

efficient public health system, technically supported by the China CDC with a system of Provincial and City CDCs that are trained in effective outbreak investigation and control [7].

However, despite these efforts, this novel virus was able to spread via infected people traveling within China and internationally. Furthermore, the mechanism of spillover that led to human infection is still uncertain, although it has all the hallmarks of a bat-origin SARS-related coronavirus (SARSr-CoV) [4]. This leads us to two questions that we need to think through even now to get ready to prevent the next 2019-nCoV-like pandemic:

The first question is why did this virus spread so rapidly, and how can we deal with this risk? China has changed significantly since the emergence of SARS in 2002–2003. The economy has expanded, and many people have become wealthier, leading to an expansion of air and high-speed train travel. It is estimated that 3 billion individual journeys were planned during the Lunar New Year holiday (Chunyun), around 80 million of these being flights. The flight habits of Chinese citizens have changed also — with many more flying internationally for business or tourism. In addition, since 2003, there has been an increase in travel between China and African countries, across Southeast Asia and into the New World as part of China's expansion of business and trade. This largely explains why the virus was able to spread out of China much more rapidly than SARS-CoV, which took over 2 months to move to Hong Kong then to the rest of the world.

The second question is what is the source of this virus? The evidence is fairly clear: Most of the initial cases were linked to a seafood market that also sold butchered livestock meat and some wildlife. The virus itself appears to have a wildlife (bat) origin similar to SARS-CoV, which also emerged in a wildlife market through the interactions of humans and other animals that acted as the intermediate hosts of the virus [3,8,9]. With two disease outbreaks originating in China significantly linked to wildlife markets, this is an obvious target for control programs to prevent future epidemics and pandemics. Indeed, there have already been calls from Chinese conservationists, public health leaders and policy makers to reduce the wildlife consumption. However, banning or even reducing the sale of wild game may not be straightforward and it is challenging to change behaviors that are influenced by Chinese culture and traditions. In addition to a strong belief in the purported curative power of wildlife and their by-products, the consumption of the rare and expensive wildlife has become a social statement of wealth boosted by economic growth. Changing these cultural habits will take time, however, recent behavioral questionnaire data suggests a generational transformation with reduced wildlife consumption in the younger generation [10]. There is no doubt, however, that the wildlife trade has an inherent risk of bringing people close to pathogens that wildlife carry, that we have not yet encountered, and that have the potential of leading to the next outbreak.

Here, we propose three key steps to helping reduce the risk of a future epidemic similar to that caused by the novel coronavirus 2019-nCoV:

- 1)

Surveillance of wildlife for high-risk pathogens

Over the past 10 years collaborating with scientists in China, we collected samples from over 10,000 bats and ~2000 other mammals across South China and discovered 52 novel SARSr-CoVs, 122 other β -CoVs, more than 350 novel α -CoVs (including the new Swine Acute

Diarrheal Syndrome Coronavirus SARS-CoV), and a new “lineage E” β -CoV clade [11,12]. We found SARS-related CoVs that can bind to human cells, and that cause SARS-like disease in humanized mouse models that was not prevented with a vaccine candidate against SARS-CoV, and were not treatable with almost all of the monoclonal therapies being developed for SARS [8,13, 14, 15, 16]. Finally, we showed serological evidence that people living at the wildlife-human interface in rural China were being exposed to SARS-related coronaviruses, perhaps even the same virus as nCoV-2019, between the emergence of SARS and the current outbreak [17,18]. Together these data mark wildlife-origin coronaviruses as a ‘clear and present danger’. They also highlight exactly the issue of key concern in the current outbreak — that there is a large diversity of viral strains in wildlife in China with significant potential for emergence in people. Further, we estimate that there are thousands of other CoVs in bats across Southeast Asia, many of which will have pandemic potential. We strongly urge that scientists in these countries work to discover all of these viruses so that we can catalog them, develop a reference library for rapid pathogen identification and risk assessment, and test vaccines and therapies against them [19,20].

- 2)

Surveillance and risk reduction in people at high risk of contact with wildlife

The finding of people in a small sample of rural communities in southern China seropositive for a bat SARSr-CoV suggests that bat-origin coronaviruses commonly spillover in the region [18]. Single cases or small clusters of human infection may evade surveillance — particularly in regions and countries that border China with less healthcare capacity or rural areas where people don't seek diagnosis or treatment in a timely fashion. Surveillance programs can be designed by local public health authorities to identify communities living in regions with high wildlife diversity and likely high diversity of novel viruses [21]. People with frequent contact with wild or domestic animals related to their livelihood and occupation, and patients presenting acute respiratory infection (ARI) or influenza-like illness (ILI) symptoms with unknown etiology can be included into the surveillance as a cost-effective method to identify novel virus spillovers. This ‘pre-outbreak surveillance’ strategy can be coordinated with different sectors of public health, healthcare, agriculture and forestry to implement sample collection and testing of wildlife, domestic animals, and people in collaboration with research institutions. These efforts will help identify and characterize viral genetic sequence, identify high-risk human populations with antibodies and cell-mediated immunity responses to wildlife-origin CoVs [22], as well as the risk factors in human behaviors and living environment through interviews. Evidence-based strategies to reduce risk can then be designed and implemented in the communities where viral spillover is identified.

- 3)

Improve biosecurity of the wildlife trade and animal markets

The wildlife trade has clearly played a role in the emergence of 2019-nCoV, as well as previous diseases in China (SARS) and across the world (e.g. monkeypox in the USA, Ebola in Africa, salmonellosis in the USA and Europe). China's response in the current outbreak was swift and broad: The index market was closed down immediately and once the virus spread, the wildlife trade was banned temporarily in certain provinces, then nationally. Our recent behavioral risk investigations in China identified low levels of environmental biosecurity and high levels of human-animal contact as key risk factors for zoonotic disease emergence,

particularly in local wet and animal markets [23]. While the current wildlife trade bans may help disease control at this moment, to prevent future disease emergence, market biosecurity needs to be improved regarding the hygiene and sanitation facilities and regulations, and the source of animals traded at the market. From a viral emergence perspective, farmed animals are likely a lower risk than wild-caught animals. However, given the size of the wildlife farming industry in China, routine disease surveillance and veterinary care at farms and in transport to markets would need to be improved. The connection between this outbreak and wildlife trade have triggered a strong public opinion against wildlife consumption, and scientists have jointly called for an urgent amendment of the Wildlife Protection Law to standardize and manage wildlife trade as a public health and security issue. It requires collaboration among the State Forestry and Grassland Administration, Ministry of Agriculture and Rural Affairs, State Administration for Market Regulation and public health authorities to tackle this issue as a long-term goal.

Dealing with the risk of future epidemics and pandemics requires a global effort. China is located within a major ‘emerging disease hotspot’ in Southeast Asia, but there is also a high risk of future diseases originating in sub-Saharan Africa, South Asia and Latin America [24]. Furthermore, the drivers of disease emergence are human activities that are expanding on a global scale, including deforestation, agricultural intensification and the wildlife trade. This has led to an exponential increase in the frequency of animal-human contact and likelihood of novel disease emergence and spread, suggesting that pandemics will become more frequent and more devastating in the future. These threats face all countries because once diseases emerge, they travel rapidly and freely through our global networks of travel and trade. We look forward to continued collaboration among scientists from China and the rest of the world, and to helping develop these new strategies to preventing the next pandemic.

[Go to:](#)

Acknowledgements

This work was supported by the United States Agency for International Development (USAID) Emerging Pandemic Threats PREDICT project [Cooperative Agreement No. AID-OAA-A-14-00102] and the National Institute of Allergy and Infectious Diseases of the National Institutes of Health [Award No. R01AI110964].

Conflict of interest statement

The authors declare that there are no conflicts of interest.

[Go to:](#)

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July 26, 2018

Meeting of the Blue Ribbon Study Panel on Biodefense to Address Devastating Economic, Corporate, and Financial Consequences of a Biological Attack Against the U.S.



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******MEDIA ADVISORY******

**MEETING OF THE BLUE RIBBON STUDY PANEL ON BIODEFENSE TO
ADDRESS
DEVASTATING ECONOMIC, CORPORATE, AND FINANCIAL CONSEQUENCES
OF A BIOLOGICAL ATTACK AGAINST THE U.S.**

*Panelists Include U.S. Senators Ron Johnson (R-WI) and Bob Casey (D-PA);
also Peter Daszak of EcoHealth Alliance and Henrik Birk of Bavarian Nordic*

WASHINGTON, D.C. (July 26, 2018) – Business leaders, U.S. Senators, and other experts will gather at the U.S. Chamber of Commerce in Washington, D.C. on July 31 to discuss the impacts of large-scale biological events on business, finance, and the American economy. The transnational spread of disease can have huge, long lasting economic impacts, draining the coffers of local, tribal, territorial, and state budgets as much as they do federal resources. The bipartisan Blue Ribbon Study Panel on Biodefense is working to change the way America

defends against biological threats. This public special focus meeting will take a closer look at the cost of resilience and foster greater dialogue about public and private sector stakeholders to determine how they can work together to address the threat. “We know unequivocally that terrorists have the desire to create and use pathogens as weapons,” said Panel Member and former Representative Jim Greenwood, who is chairing this special focus meeting. “The Director of National Intelligence reiterates this point before Congress year after year. Globalization has empowered the modern bioterrorist. While some in the business community understand the need to address the biological threat, too few have taken steps to prepare for the spread of diseases that could bring their business operations to a halt and result in significant financial losses.”

The meeting will feature a prestigious panel of experts, including United States Senator Ron Johnson (R-WI), Chairman, Senate Committee on Homeland Security and Governmental Affairs, and Senator Bob Casey (D-PA), Co-Chair, Senate Weapons of Mass Destruction Terrorism Caucus and Member, Senate National Security Working Group. Also speaking will be Peter Daszak, President, EcoHealth Alliance and Henrik Birk, COO, Bavarian Nordic. The meeting is set to begin at 10 a.m. Tuesday, July 31, at the U.S. Chamber of Commerce, 1615 H Street, NW, Washington, D.C. The complete agenda can be found [here](#). Your coverage is welcome. Media should RSVP to either attend the event or watch a live stream by contacting steve@SRACommunications.com.

About the Blue Ribbon Study Panel on Biodefense

The [Blue Ribbon Study Panel on Biodefense](#) was established in 2014 to conduct a comprehensive assessment of the state of U.S. biodefense efforts, and to issue recommendations to foster change. The Panel’s 2015 report, A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts, identified capability gaps and recommended changes to U.S. policy and law to strengthen national biodefense while optimizing resource investments. The Panel continues to assess biodefense challenges and to urge reform. Former Senator Joe Lieberman and former Governor Tom Ridge co-chair the Panel, and are joined by former Secretary of Health and Human Services Donna Shalala, former Senate Majority Leader Tom Daschle, former Representative Jim Greenwood, and former Homeland Security Advisor Ken Wainstein. [Hudson Institute](#) is the Panel’s fiscal sponsor.

[Dermatol Ther.](#) 2021 Nov 30 : e15208.
doi: [10.1111/dth.15208](https://doi.org/10.1111/dth.15208) [Epub ahead of print]
PMCID: PMC8646458
PMID: [34786801](https://pubmed.ncbi.nlm.nih.gov/34786801/)

Bullous pemphigoid triggered by COVID-19 vaccine: Rapid resolution with corticosteroid therapy

[Massimo Dell'Antonia](#),¹ [Speranza Anedda](#),¹ [Federica Usai](#),¹ [Laura Atzori](#),¹ and [Caterina Ferreli](#)¹

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Associated Data

[Data Availability Statement](#)

Dear Editor,

Bullous pemphigoid (BP) is an acquired autoimmune blistering disease characterized by autoantibodies against basement membrane zone antigens. Several trigger factors have been identified for this disorder, such drugs, ultraviolet radiation, trauma and burns. Pemphigoid cases have been reported in association with vaccination, including rabies, [1](#) influenza, pneumococcus, tetanus, diphtheria, [2](#) pertussis, poliomyelitis Haemophilus influenzae B, hepatitis B and Meningococcus C [3](#) vaccine, indicating that vaccination can trigger pemphigoid.

We report here a case of a 83-year-old man with a 30 days history of multiple erythemas and blisters with itching. The patient has been affected with hypertension for 20 years, for which he was in treatment with perindopril 10 mg DIE and amlodipine 5 mg DIE. He was otherwise in quite good health with no other significant medical conditions. His family history was negative for significant diseases and skin disorders. The patient developed the first bullous lesions 1 week after the first dose of Comirnaty (Pfizer–BioNTech COVID-19 vaccine). Blisters were few and located only on his legs and they were initially misdiagnosed as post-traumatic lesions by his general practitioner. Three days after the second dose of vaccine, which was administered 1 month after the first, the patient started developing new blisters on his limbs and trunk. When he was eventually admitted to our department he presented several erosions and tense bullae on erythematous base measuring 4–11 cm in diameter on trunk and limbs (Figure [1A](#)). Nikolsky sign was absent and the remainder of the physical examination was normal. Blood exams were carried out, including routine clinical chemistry, neoplastic markers, viral hepatitis markers, autoimmunity panel and quantiferon test. All were within normal limits. Tzanck test performed from a fresh bulla showed eosinophils. Histopathology from a bullous lesion demonstrated subepidermal blister with occasional lymphocytes and eosinophilis. Direct immunofluorescence revealed a linear band of C3 along the basement membrane. A diagnosis of bullous pemphigoid was made and the patient treated with topical steroids and prednisone 30 mg daily (0.5 mg/kg daily [4](#)) for 4 weeks, then reduced by 5 mg

every week, then stop. A complete resolution of the blisters was obtained after only 3 weeks of treatment (Figure [1B](#)).



FIGURE 1

Erosions and blisters on the left leg (A); complete resolution after 3 weeks of treatment (B)

Herein we describe a case of BP triggered by Comirnaty (Pfizer–BioNTech COVID-19 vaccine). The temporal association between administration of vaccine and appearance of bullous lesion was a pointer that vaccine might be the trigger while reemergence of bullae following the second dose of vaccine confirmed the association. Naranjo algorithm was 9 (definite adverse drug reaction).

Owing to the ongoing COVID-19 pandemic a mass vaccination campaign has been initiated worldwide. Different types of vaccines are available nowadays. [5](#) The adverse reactions occurring with messenger RNA (mRNA) COVID-19 vaccines mostly appear within the first 30 min after the vaccination and can likely be interpreted as immunoglobulin E-mediated hypersensitivity. [6](#), [7](#) The reported delayed cutaneous adverse events, other than injection site inflammation, are rare. Since a growing percentage of the population becomes vaccinated, delayed cutaneous reactions are likely destined to increase. To date few cases of delayed cutaneous reactions are reported. Among these, delayed urticaria [7](#) and erythema multiforme like eruption, eczematous eruptions, generalized pruritic morbilliform and pityriasis rosea-like

eruptions, urticarial vasculitis, leukocytoclastic vasculitis [8](#), [9](#) and psoriasis exacerbation. [10](#)
Also few cases of BP are reported. [9](#), [11](#)

The appearance of blisters after the first administration of Comirnaty should not be underestimated and carefully considered as an early sign of BP. However, given the risks of SARS-CoV-2 infection and the rarity of these events, clinicians should encourage full vaccination.

In our experience, BP triggered by Comirnaty can be easily managed with corticosteroid therapy with a rapid resolution achievable in only 3 weeks.

[Go to:](#)

AUTHOR CONTRIBUTIONS

All authors contributed equally to the manuscript preparation and revised the final version.

[Go to:](#)

ETHICS STATEMENT

The patient gave consent for publication of this manuscript.

[Go to:](#)

Notes

All authors state that the manuscript is original, it has not been published before and it is not currently being considered for publication elsewhere.

[Go to:](#)

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

[Go to:](#)

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[S. news](#)

Airline says it will cease shipments of monkeys after some got loose in Pennsylvania crash

The move is the latest skirmish in a long-running battle between animal-rights groups and researchers over the use of animals in medical experiments.

Crates holding live monkeys are collected next to the trailer they were being transported in along state Route 54 at the intersection with Interstate 80 near Danville, Pa., on Jan. 21, 2022. Jimmy May / Bloomsburg Press Enterprise via AP file

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Feb. 1, 2022, 9:22 PM EST / Updated Feb. 2, 2022, 12:25 AM EST

By The Associated Press

The airline that carried monkeys part of the way to a U.S. research laboratory before they were involved in a [highway crash in Pennsylvania](#) says it will stop the shipments.

Kenya Airways will not renew its contract with the shipper when it expires this month, airline CEO Allan Kilavuka said in an email to The Associated Press.

Kilavuka did not identify the shipper who paid the airline to fly the animals from Mauritius, an island nation in the Indian Ocean, to New York.

The move by the African airline is the latest skirmish in a long-running battle between animal-rights groups and researchers — with airlines caught in the middle — over the use of animals in medical experiments.

On Jan. 21, a truck towing a trailer with 100 monkeys collided with a dump truck on a Pennsylvania highway. Several of the monkeys escaped. Authorities said later that three were shot [and killed](#) and they accounted for the rest.

De handen van iemand die is besmet met apenpokken (archieffoto) Reuters
NOS Nieuws • [Binnenland](#) • vrijdag, 18:38 • Aangepast vrijdag, 22:20

Eerste geval van apenpokken in Nederland vastgesteld, RIVM wil meldingsplicht

Vanmiddag is voor het eerst bij een patiënt in Nederland apenpokken vastgesteld. Onderzoekers hebben de besmetting met een PCR-test aangetoond.

Het RIVM verwacht dat er in Nederland nog meer mensen besmet geraakt kunnen zijn. Na het weekend volgt een update over eventuele nieuwe besmettingsgevallen.

Het RIVM wil dat er [een meldingsplicht](#) komt voor artsen en ggd-medewerkers bij wie zich een patiënt met apenpokken aandient. Een advies met die strekking is naar minister Kuipers van Volksgezondheid gestuurd.

Het instituut wil dan dat er bron- en contactonderzoek wordt gedaan en dat de patiënt wordt geadviseerd in isolatie te gaan. Nauwe contacten moeten dan mogelijk tot drie weken in quarantaine.

"We moeten alle maatregelen nemen om het virus nu in het beginstadium de kop in te drukken", zegt directeur Jaap van Dissel van het Centrum Infectieziektenbestrijding van het RIVM.

Verdachte gevallen

Eerder vandaag zei het RIVM al dat er in Nederland meerdere verdachte gevallen worden onderzocht. Volgens Van Dissel zou het raar zijn als het virus hier niet zou opduiken, terwijl dat in andere West-Europese landen al wel het geval is.

De Belgische viroloog Marc Van Ranst deelde vandaag deze foto's van mensen met symptomen, zodat iedereen er bij zichzelf op kan letten:



[Marc Van Ranst](#)

[@vanranstmarc](#)

[Een tweede geval van het apenpokkenvirus werd vannacht gediagnosticeerd op ons labo in Leuven in een staal van een man uit Vlaams-Brabant. Mensen die bij zichzelf ietsels zoals op deze foto herkennen, kunnen best contact opnemen met hun arts.](#)

[2 dagen geleden](#)

Apenpokken

Apenpokken werd voor het eerst vastgesteld bij apen in 1958, vandaar de naam. Het virus is een zoönose, wat betekent dat het van dier op mens kan overgaan. Bij de mens werd apenpokken voor het eerst in 1970 geconstateerd in de Democratische Republiek Congo. Anders dan de naam doet vermoeden, wordt het virus vooral door knaagdieren overgebracht.

Het virus kan binnendringen via de slijmvliezen in de mond, neus of ogen en via open wondjes, [schrijft](#) het RIVM. Het virus kan zich ook verspreiden via druppels uit blaasjes of uit de mond-keelholte, maar niet via zwevende druppeltjes in de lucht.

De ziekte begint vaak met griepachtige klachten als koorts, hoofdpijn en moeheid. Na 1 tot 3 dagen volgt een uitslag die meestal in het gezicht begint en die daarna over het hele lichaam verschijnt. Deze uitslag begint met vlekken die overgaan in blaasjes. Na het indrogen van de blaasjes blijven korsten over die uiteindelijk na 2 tot 3 weken van de huid vallen.

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First case of monkeypox confirmed in US this year in man who had traveled to Canada

By

[Patrick Reilly](#)

May 18, 2022 6:30pm

[Updated](#)

Massachusetts confirmed the country's first case of monkeypox from a man coming back from Canada. Star Tribune via Getty Images

This first US case of [monkeypox](#) this year was confirmed in Massachusetts Tuesday as health officials said an adult man who recently returned from Canada contracted the disease.

The patient has been hospitalized in good condition and “the case poses no risk to the public,” according to the [Massachusetts Department of Public Health](#).

The department said it was working with the Centers for Disease Control and Prevention and other local health boards to contact and trace any individuals who may have been exposed to the patient.

Cases of the virus have been surging worldwide.

On Wednesday, officials confirmed five cases of monkeypox in Portugal and were investigating over a dozen others — all of which were men, most of them young.

Earlier in the week, UK officials said they identified four cases of monkeypox spread in London among gay and bisexual men around London. Nine cases have been confirmed in the country since May.

The disease is uncommon outside of central and west Africa and is part of the same family of viruses that includes chickenpox and smallpox.

Typical symptoms of monkeypox include fever, chills, a rash and lesions on the face or genitals resembling those caused by smallpox.

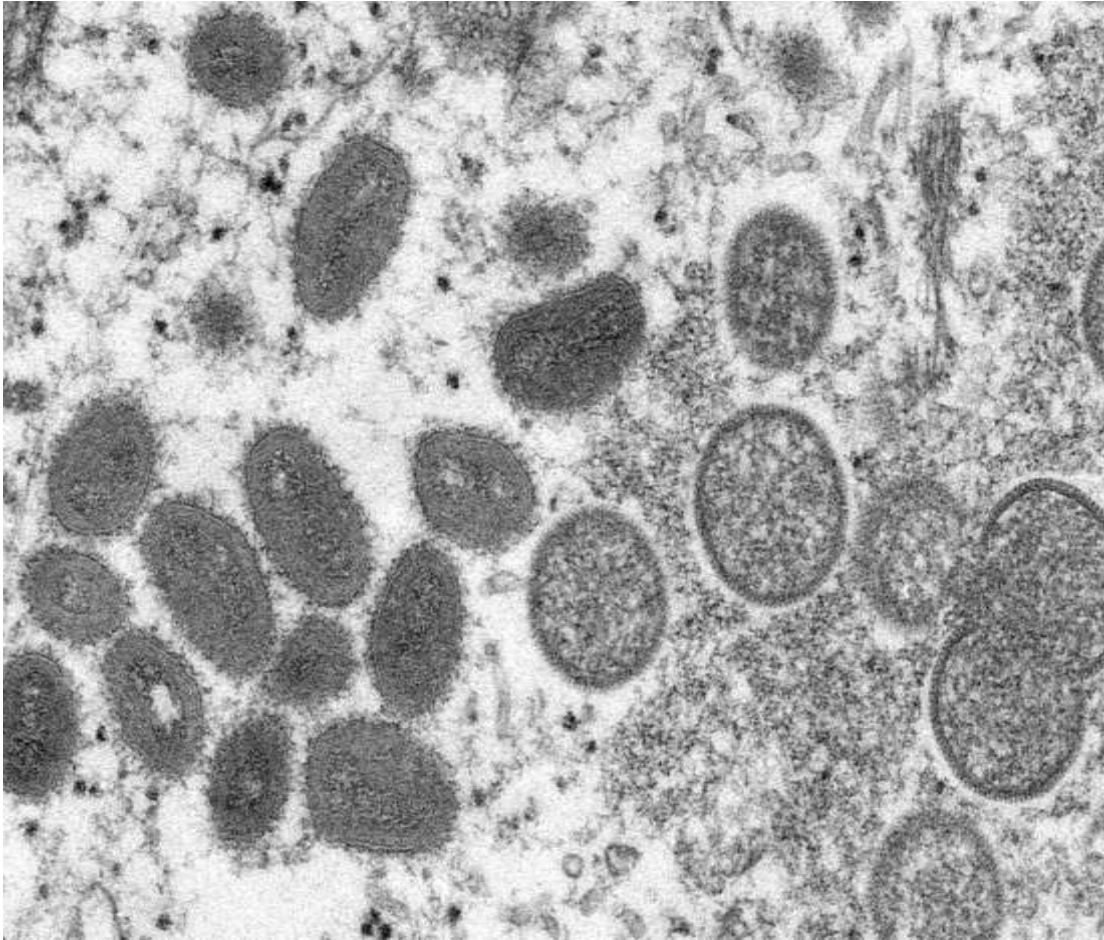


Monkeypox patients endure symptoms such as rashes.CDC/Brian W.J. Mahy/Handout via REUTERS

“Illness could be clinically confused with a sexually transmitted infection like syphilis or herpes, or with varicella zoster virus,” MPDH said. Infections typically last 2-4 weeks.

People are believed to be exposed to the virus in Africa through bites or scratches from rodents and small mammals, preparing wild game, or having contact with an infected animal or possibly animal products, officials said.

However the virus “does not spread easily between people,” MPDH said. Transmission through contact with body fluids, monkeypox sores, or clothing, or bedding contaminated with fluids or sores. It can also be exchanged through “respiratory droplets following prolonged face-to-face contact.”



Portugal previously detected five cases of monkeypox. Cynthia S. Goldsmith, Russell Regnery/CDC/Handout via REUTERS

A vaccine developed against smallpox has been approved for monkeypox, and several antivirals also appear to be effective.

According to MDPH, this is the first case confirmed in the United States in 2022. In 2021, cases were reported in Texas and Maryland in two people who had recently traveled to Nigeria.

Officials said people should be tested if they: develop an unexplained rash; have traveled to a country where monkeypox has been reported in the last 30 days; have been in contact with those with confirmed or suspected cases of monkeypox; or are men who have sex with other men.

With Post Wires

NOVEMBER 2021

Strengthening Global Systems to Prevent and Respond to High-Consequence Biological Threats

*Results from the 2021 Tabletop Exercise Conducted in
Partnership with the Munich Security Conference*

SUMMARY

In March 2021, NTI partnered with the Munich Security Conference to conduct a tabletop exercise on reducing high-consequence biological threats. The exercise examined gaps in national and international biosecurity and pandemic preparedness architectures—exploring opportunities to improve prevention and response capabilities for high-consequence biological events. This report summarizes the exercise scenario, key findings from the discussion, and actionable recommendations for the international community.

Jaime M. Yassif, Ph.D.
Kevin P. O'Prey, Ph.D.
Christopher R. Isaac, M.Sc.

We are grateful to Open Philanthropy. The exercise and report would not have been possible without their generous support.



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Contents

Acknowledgments 3

Foreword 4

Executive Summary 6

About the Exercise 8

Summary of Exercise Discussion and Findings..... 14

Recommendations 22

Appendix A. Expert Contributors to Scenario Development 27

Appendix B. Epidemiological Model Summary..... 28

About the Authors 32

Acknowledgments

The authors gratefully acknowledge the support of those who were instrumental in the development and execution of this senior-level tabletop exercise. First, we would like to thank our partners at the Munich Security Conference, who jointly hosted this exercise with NTI. We are also grateful to the exercise participants whose valuable insights, expertise, and engagement were crucial to the success of this project. We also thank Talus Analytics for developing the epidemiological model underpinning this exercise, our expert advisors who informed the design of the exercise scenario early in the process, and Long Story Short for producing the exercise videos.

At the Nuclear Threat Initiative (NTI), we would like to thank members of the project team, who were instrumental to the success of this project. Dr. Andrew Hebbeler, who is now serving in government at the White House Office of Science and Technology Policy, jointly led the development and planning of this exercise with Dr. Jaime M. Yassif. Dr. Kevin P. O’Prey facilitated the scenario-based exercise, in addition to advising on exercise planning and jointly authoring this report. Christopher R. Isaac provided valuable research assistance for this project, and Amanda Cogan was instrumental in organizing the exercise event. From NTI’s Communications team, Rachel Staley Grant led the development of video production for this exercise, and along with Mimi Hall, provided valuable comments on this manuscript and led the report publication process.

We are grateful to Open Philanthropy for their support for this project as part of their ongoing support of our work to reduce Global Catastrophic Biological Risks.

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Foreword

Over the past two years, the world has faced the devastating impact that a biological event can have on human health, economies, and political stability. As of this writing, the SARS-CoV-2 virus has infected more than 250 million people, killed more than five million, and caused trillions of dollars in economic losses. COVID-19 has revealed that national governments and the international community are woefully unprepared to respond to pandemics—underscoring our shared vulnerability to future catastrophic biological threats that could meet or exceed the severe consequences of the current pandemic.

Although national and global leaders are appropriately focused on the immediate demands of the COVID-19 response, the international community cannot postpone implementing the steps necessary to protect against future biological threats. This must include the recognition that while naturally emerging

pandemics continue to pose a significant threat, the next global catastrophe could be caused by the deliberate misuse of the tools of modern biology or by a laboratory accident. Fundamentally, strengthening the preparedness of every nation to meet these challenges is a humanitarian imperative in the collective self-interest of the international community. Even the most prepared nations will remain vulnerable as long as significant biosecurity and pandemic preparedness gaps remain in countries around the world. We are only as safe as our weakest link.

Scientific and political leaders must take bold action to safeguard the global bioscience and biotechnology research and development enterprise to ensure that catastrophic accidents or deliberate misuse do not lead to the next global pandemic.

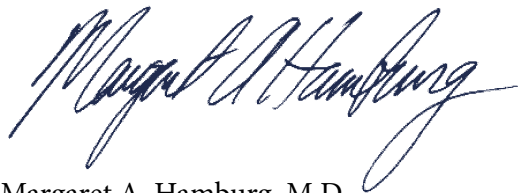
The world has witnessed how global travel, trade, urbanization, and environmental degradation can fuel the emergence and spread of infectious disease threats. However, the serious risks embedded in the very bioscience research and technology advances that offer vital opportunities to counter these risks remain less understood. Bioscience and biotechnology advances, while offering tremendous potential benefits, also present opportunities for accidental release or deliberate abuse of biological agents that could cause as much or more harm than COVID-19. Scientific and political leaders must take bold action to safeguard the global bioscience and biotechnology research and development enterprise to ensure that catastrophic accidents or deliberate misuse do not lead to the next global pandemic.

To strengthen international capabilities to respond to the next pandemic, national and global leaders must build stronger public health and medical response capabilities that can scale to address very high-consequence biological events—potentially orders of magnitude more severe than what we have experienced during the past two years. We cannot afford to be reactive. We must build our public health and medical systems to be anticipatory, responding energetically and proactively in the face of uncertainty—taking what humanitarian and crisis response communities describe as a “no regrets” approach.

NTI recognizes the critical importance of strengthening the global biosecurity and pandemic preparedness architecture. To that end, NTI is focused on catalyzing the development of stronger international biosecurity and pandemic preparedness capabilities so the world is better able to prevent and respond to future biological risks. To address important gaps in key areas, NTI is working with international partners:

- To establish a new global biosecurity entity dedicated to reducing emerging biological risks that can accompany certain technology advances. Its mission will be to reduce the risks of catastrophic consequences due to accidents, inadvertent misuse, or deliberate abuse of bioscience and biotechnology by promoting stronger global biosecurity norms and developing tools and incentives to uphold them.
- To explore the possibility of establishing a new Joint Assessment Mechanism to investigate high-consequence biological events of unknown origin. This new mechanism would operate at the “seam” between existing mechanisms—including World Health Organization (WHO) outbreak investigation capabilities and the United Nations Secretary-General’s Mechanism for investigating alleged deliberate bioweapons use—thereby strengthening UN system capabilities to investigate pandemic origins.
- To advocate for establishing a catalytic, multilateral financing mechanism for global health security and pandemic preparedness. The goal is to accelerate sustainable biosecurity and pandemic preparedness capacity-building in countries where resources are most needed.

To further examine these issues, NTI has partnered with the Munich Security Conference (MSC) over the past three years to host annual tabletop exercises focused on reducing high-consequence biological threats. NTI and MSC have jointly convened international leaders and experts to explore gaps in the global biosecurity and pandemic preparedness architecture, and to identify opportunities to address urgent needs. This report shares the lessons of our 2021 exercise.



Margaret A. Hamburg, M.D.
Interim Vice President, Global Biological Policy and Programs
Nuclear Threat Initiative

Executive Summary

In March 2021, the Nuclear Threat Initiative (NTI) partnered with the Munich Security Conference (MSC) to conduct a tabletop exercise on reducing high-consequence biological threats. Conducted virtually, the exercise examined gaps in national and international biosecurity and pandemic preparedness architectures and explored opportunities to improve capabilities to prevent and respond to high-consequence biological events. Participants included 19 senior leaders and experts from across Africa, the Americas, Asia, and Europe with decades of combined experience in public health, biotechnology industry, international security, and philanthropy.

The exercise scenario portrayed a deadly, global pandemic involving an unusual strain of monkeypox virus that emerged in the fictional nation of Brinia and spread globally over 18 months. Ultimately, the exercise scenario revealed that the initial outbreak was caused by a terrorist attack using a pathogen engineered in a laboratory with inadequate biosafety and biosecurity provisions and weak oversight. By the end of the exercise, the fictional pandemic resulted in more than three billion cases and 270 million fatalities worldwide.

Discussion among exercise participants led to the following key findings:

- **Weak global detection, assessment, and warning of pandemic risks.** The international community needs a more robust, transparent detection, evaluation, and early warning system that can rapidly communicate actionable information about pandemic risks.
- **Gaps in national-level preparedness.** National governments should improve preparedness by developing national-level pandemic response plans built upon a coherent system of “triggers” that prompt anticipatory action, despite uncertainty and near-term costs—in other words, on a “no-regrets” basis.
- **Gaps in biological research governance.** The international system for governing dual-use biological research is neither prepared to meet today’s security requirements, nor is it ready for significantly expanded challenges in the future. There are risk reduction needs throughout the bioscience research and development life cycle.
- **Insufficient financing of international preparedness for pandemics.** Many countries around the world lack financing to make essential national investments in pandemic preparedness.

To address these findings, the authors developed the following recommendations.

1 Bolster international systems for pandemic risk assessment, warning, and investigating outbreak origins

- The WHO should establish a graded, transparent, international public health alert system.
- The United Nations (UN) system should establish a new mechanism for investigating high-consequence biological events of unknown origin, which we refer to as a “Joint Assessment Mechanism.” (More about the Joint Assessment Mechanism is found on page 22.)

2 Develop and institute national-level triggers for early, proactive pandemic response

- National governments must adopt a “no-regrets” approach to pandemic response, taking anticipatory action—as opposed to reacting to mounting case counts and fatalities, which are lagging indicators.
- To facilitate anticipatory action on a no-regrets basis, national governments should develop national-level plans that define and incorporate “triggers” for responding to high-consequence biological events. (More about “triggers” is found on page 17.)

3 Establish an international entity dedicated to reducing emerging biological risks associated with rapid technology advances

- The international community should establish an entity dedicated to reducing the risk of catastrophic events due to accidents or deliberate abuse of bioscience and biotechnology.
- To meaningfully reduce risk, the entity should support interventions throughout the bioscience and biotechnology research and development life cycle—from funding, through execution, and on to publication or commercialization.

4 Develop a catalytic global health security fund to accelerate pandemic preparedness capacity building in countries around the world

- National leaders, development banks, philanthropic donors, and the private sector should establish and resource a new financing mechanism to bolster global health security and pandemic preparedness.
- The design and operations of the fund should be catalytic—incentivizing national governments to invest in their own preparedness over the long term.

5 Establish a robust international process to tackle the challenge of supply chain resilience

- The UN Secretary-General should convene a high-level panel to develop recommendations for critical measures to bolster global supply chain resilience for medical and public health supplies.

This report is organized into three parts: the first is a description of the exercise design and scenario; the second is a summary of the exercise discussions and related findings; and the third is a set of recommendations developed by the authors to address the identified gaps and requirements. NTI developed these recommendations after the event concluded; participants were not involved in their development and have not been asked to endorse them. The appendices provide a list of the experts who supported the exercise development process (Appendix A) as well as technical details about the epidemiological model (Appendix B) used to inform this fictional monkeypox pandemic scenario.

About the Exercise

In March 2021, NTI conducted a Tabletop Exercise on Reducing High-Consequence Biological Threats, the third in a series of annual collaborations between NTI and the Munich Security Conference. The exercise examined gaps in national and international biosecurity and pandemic preparedness architectures and explored opportunities to improve capabilities to prevent and respond to high-consequence biological events. The exercise included 19 senior leaders and experts from across Africa, the Americas, Asia, and Europe with decades of combined experience in public health, biotechnology industry, international security, and philanthropy. (See the box on page 9 for the list of exercise participants.)

Exercise Scenario

Developed in consultation with technical and policy experts, the exercise scenario portrayed a deadly, global pandemic involving an unusual strain of monkeypox virus that first emerges in the fictional country of Brinia and eventually spreads globally. Later in the exercise, the scenario reveals that the initial outbreak was caused by a terrorist attack using a pathogen engineered in a laboratory with inadequate biosafety and biosecurity provisions and weak oversight. The exercise scenario concludes with more than three billion cases and 270 million fatalities globally. As part of the scenario development process, NTI conducted a virtual consultation with experts in December 2020. (See Appendix A for the list of participating experts.)



The fictional exercise scenario unfolded in a series of short news videos that participants reacted to.

The exercise was designed for participants to:

- Discuss requirements for international architectures related to science-based, early assessment of emerging pandemic risks and timely international warning and alerts for potential pandemics.
- Explore conditions that should trigger national pandemic response actions and discuss strategies and challenges for scaling public health interventions.
- Consider options to reduce biotechnology risks and strengthen oversight of dual-use bioscience research.
- Explore opportunities to strengthen international financing mechanisms to bolster global health security preparedness.

2021 NTI-MUNICH SECURITY CONFERENCE TABLETOP EXERCISE PARTICIPANTS

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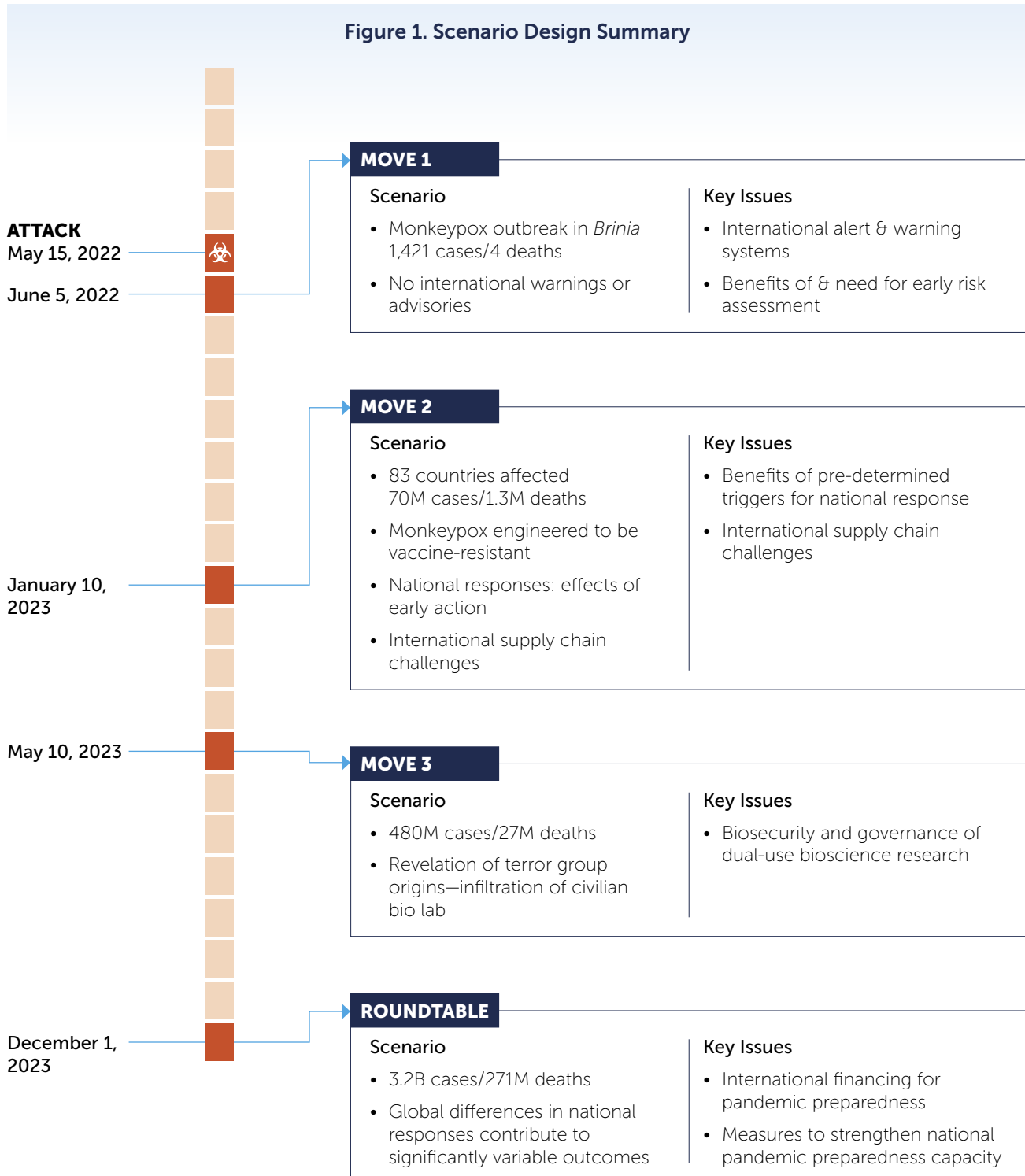
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The discussion was organized into three sequential “moves” corresponding with scenario developments, followed by a roundtable discussion of broader biosecurity and pandemic preparedness issues. The step-by-step approach to revealing scenario developments reflected the limitations of information available to real-world decision makers, as well as the resulting uncertainty associated with a pandemic of unknown origin (see Figure 1).



Move 1 (occurring on June 5, 2022, in scenario time) starts with an unusual outbreak of monkeypox in Brinia (population 250 million), with reports of 1,421 cases and four fatalities. There is no immediate evidence of international spread, but the outbreak takes place during a national holiday with extensive domestic and international travel by Brinians. Because monkeypox is not naturally found in Brinia, local and international experts consider this outbreak to be unusual. The Brinian government welcomes international outbreak investigations and requests medical support from the WHO. Genome sequencing of monkeypox patient samples reveals that the strain in Brinia contains mutations that make it resistant to existing vaccines.

The discussion that followed considered how the international system is postured to analyze initial indicators of pandemic risk and to communicate appropriate warnings.

Move 2 (January 10, 2023) occurs six months later, at which point the virus has spread to 83 countries with 70 million reported cases, causing more than 1.3 million fatalities. With no known effective therapies or vaccines, countries have had to rely principally on non-pharmaceutical interventions (NPIs) to mitigate the impacts of the pandemic. Highlighting significantly different national outcomes in managing the pandemic, some governments, including the fictional Republic of Dranma, promptly adopted aggressive measures to slow virus transmission by shutting down mass gatherings, imposing social-distancing measures, and implementing mask mandates. These countries have also established large-scale testing and contact-tracing operations and scaled-up their health care systems to support anticipated growing case numbers. By contrast, the scenario depicts another group of countries, including fictional Cardus, that have prioritized keeping their economies open, undertaking little-to-no NPIs, and downplaying the virus and its potential impacts. These countries have experienced much worse outcomes in terms of illness and mortality (Figure 2) than those that responded early and energetically. As Figure 3 shows, Dranma experienced far fewer cases and fatalities than Cardus.

Participant discussion in Move 2 focused on exploring the conditions that should trigger national pandemic response actions and discussing strategies and challenges for scaling public health interventions.

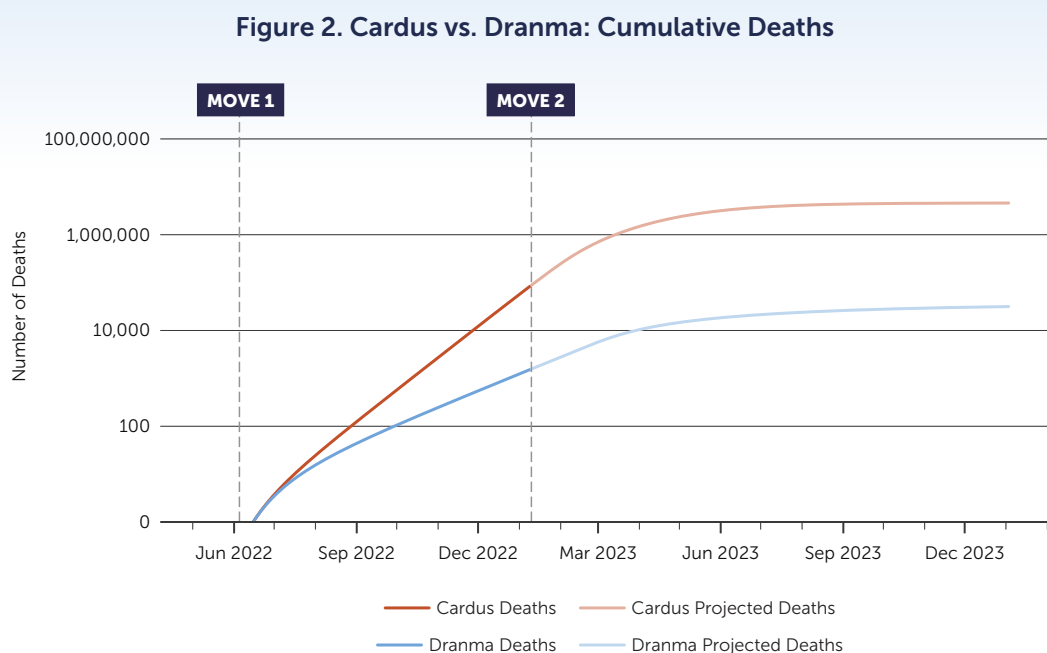
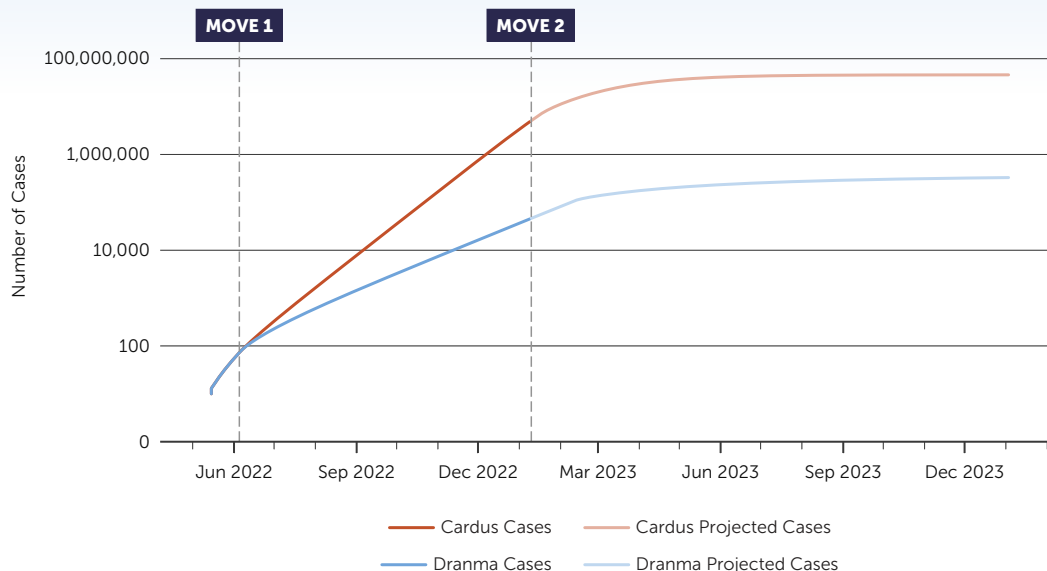
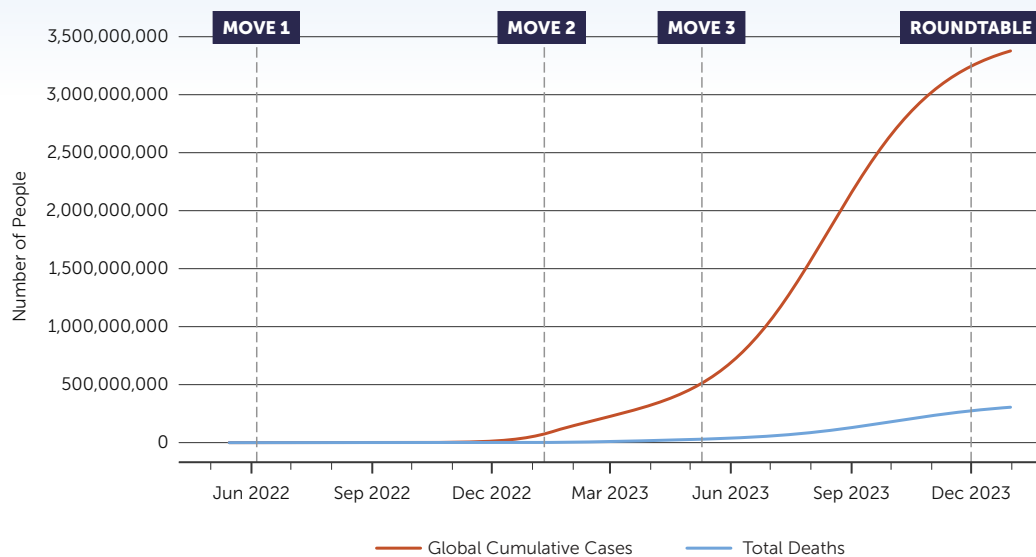


Figure 3. Cardus vs. Dranma: Cumulative Cases


Move 3 (May 10, 2023) occurred 12 months after the initial outbreak, with more than 480 million cases and 27 million fatalities globally (Figure 4). At this stage, participants learn that the pandemic was caused by a regional bio-terror attack that far exceeded the perpetrators' goals.

Figure 4. Global Cumulative Cases and Deaths


Specifically, Brinian intelligence reveals that the engineered monkeypox virus was developed illicitly at the fictional country of Arnica's leading institute for virology. Arnica (population 75 million) has a history of conflict with neighboring Brinia (see map in Figure 5). An independent Arnican terrorist group—the SPA—had worked with sympathetic laboratory scientists to engineer a highly contagious, deadly pathogen and disperse it at crowded train stations in Brinia during the national holiday, when much of the population was travelling domestically and internationally.

The SPA had exploited the Arnican government's weak oversight of its bioscience research laboratories. SPA sympathizers working in Arnica's leading virology institute used publicly available scientific publications to guide their work to modify the monkeypox virus to make it more transmissible and resistant to currently available vaccines.

The discussion in Move 3 focused on governance of dual-use bioscience research as well as current weaknesses in biosafety and biosecurity systems that exacerbate biological risks.

The final phase of the exercise was a **roundtable discussion** that considered disparities in public health preparedness around the globe and the resulting need for more effective financing mechanisms to accelerate pandemic preparedness capacity building. Recognizing that pandemic preparedness requires costly investments that lower- and lower-middle income countries cannot afford to make, participants were asked to discuss strategies to catalyze these investments in sustainable ways.

Figure 5. Map of the Fictional Country of Brinia, the Geographic Origin of the Outbreak



Summary of Exercise Discussion and Findings

The discussions throughout the tabletop exercise generated a wide range of valuable insights and key findings. Most significantly, exercise participants agreed that, notwithstanding improvements following the global response to COVID-19, the international system of pandemic detection, analysis, warning, and response is woefully inadequate to address current and anticipated future challenges.

Exercise participants agreed that gaps in the international biosecurity and pandemic preparedness architecture are extensive and fundamental, undermining the ability of the international community to mount effective responses to future biological events—and they noted that robust preparedness will require fundamental transformation across a number of fronts. Given the inherent latency in acquisition of definitive data on pandemic threats—e.g., geographic distribution, transmission rates, and lethality—and the very serious consequences of delay in pandemic response, participants observed that the international system and national governments must be transformed to emphasize pre-determined “no-regrets” anticipatory actions. Such a system requires significant improvements in the international community’s ability to detect, assess, and warn about pandemic threats as well as to develop proactive, national-level response plans and decision-making bodies. They agreed that the international community also must bolster its system of governance for dual-use life-science research, and they concluded that governments globally are severely underinvesting in pandemic preparedness—especially in low- and lower-middle income countries. These consensus findings frame the more detailed conclusions discussed below.

FINDING 1

The international community needs a more robust, transparent detection, evaluation, and early warning system that can rapidly communicate actionable warnings about pandemic risks.

Exercise participants found that the world continues to lack a coherent system for pandemic detection and assessment that would be effective across the full range of plausible scenarios. In this exercise, the scenario arguably depicted a “best case” where the country of origin reported what it knew to the WHO in a timely manner and welcomed international investigation. Yet even in this case, exercise participants expressed concern that it would be extremely challenging to discern warning signals early enough to contain or at least mitigate the effects of the initial outbreak.

Consequently, several participants stressed that the international community requires a more coordinated international biosurveillance network, which also incorporates pathogen genome sequencing. In scrutinizing disease outbreaks for pandemic potential, exercise participants identified a number of key indicators for an effective risk assessment system based on biosurveillance data.

Participants stressed that the most important indicators for analyzing the pandemic potential of an outbreak are its epidemiology and the geographic distribution of cases. A novel virus that is assessed to be

highly virulent and transmissible—either based on direct epidemiological observations or other evidence-based predictions—will warrant significant attention. Analyzing additional virus characteristics will also be important. For example, is the virus changing and/or is it different from previously detected variants? One participant observed that the number of fatalities would not be a good measure to track in the early period of a pandemic because it is a lagging indicator at a time of exponential growth in cases.

Participants also suggested that considering the social, political, and economic context of the country of origin or initial detection could be valuable for risk assessment. Key factors include the degree of societal openness of the country and the extent of international travel across its borders—both features that could contribute to faster spread. Another consideration is the strength of the country’s public health system and whether the population is reducing the risk of spread by using NPIs and avoiding mass gatherings.

In the sequence of events after detection and analysis, the next step is warning. All participants agreed that the principal means of international pandemic risk warning now in place—the WHO Director General’s declaration of a Public Health Emergency of International Concern (PHEIC)—requires significant reform. Among the shortfalls they identified in the current PHEIC approach is that it is a binary tool for a world where pandemic risks are characterized by different levels of risk that evolve over time. The current PHEIC approach potentially lumps risks like a limited regional Ebola outbreak with a globally catastrophic biological event. Both are concerning, but to very different degrees, and they warrant different responses. The binary nature of the PHEIC also unintentionally creates incentives to delay warnings. In effect, if analysts and decision makers only have two choices, they are likely to err on the side of certainty before activating an international alert system.

Participants stressed that a graded pandemic warning system—analogue to graded systems used for hurricanes and other natural disasters—would arguably provide a more flexible, informative, and actionable system for communicating risk. Under the current International Health Regulations (IHR 2005), the WHO could be empowered to provide more detailed risk assessments to member states. One participant noted that formally shifting the WHO PHEIC to a graded system might require a change to the IHR, which could pose significant political challenges.

Exercise participants observed that regardless of the particular institutional arrangements chosen for international systems of pandemic detection, analysis, and warning, these systems must be transparent. In particular, deliberations that currently occur behind closed doors—the WHO Emergency Committee, for example—would benefit if, at a minimum, an outside expert group could analyze the data and reach conclusions in parallel. Arguably, this would help validate and lend independent weight to official findings, or could challenge findings if they are inconsistent with available evidence.¹

“We face the simultaneous challenge of responding to this pandemic and preparing for the next one. The international community has an opportunity, if not an obligation, to improve the situation.”

—Exercise Participant

¹ For an excellent discussion of reported politicization of PHEIC deliberations and decisions, see Clare Wenham, Alexandra Phelan, Mark Eccleston-Turner, and Sam Halabi, “Reforming the Declaration Power for Global Health Emergencies,” International Law Impact and Infectious Disease (ILIAID) Consortium IHR Reform White Paper Series (1), (November 2020): 8.

Evaluating Outbreak Origins

Participants noted that biological incidents of unknown origin fall into a gap in the UN system. The WHO, as one participant highlighted, is the outbreak equivalent of a firefighter, not a police officer; the organization is best suited to public health and medical response, not security investigations. In cases where an outbreak is deliberately caused, a security investigation by the UN Secretary-General's Mechanism (UNSGM) would be appropriate. However, the means by which the WHO and the UN Secretary-General operate in parallel, if not in coordination, are still unclear. More problematic still are those cases where the origin of an incident is unclear or suspicious. In these cases, the respective roles of the UN Secretary-General and WHO must be clearly defined.²

Participants discussed additional international political challenges that could pose obstacles to effective investigation of an outbreak. First, the international community requires cooperation and transparency from the putative country of origin. Second, although the Secretary-General has the authority to use its investigative mechanism in response to a request from any member state, the mechanism has never been used to investigate a biological incident, and tensions among UN member states could cause delays. Similarly, objections by any of the WHO principal member state donors could hamper the organization's effectiveness in coordinating prompt detection and assessment.

FINDING 2

Governments should improve preparedness by developing national-level pandemic response plans built upon a coherent system of “triggers” that prompt anticipatory action on a “no-regrets” basis.

“It will be chaotic and frightening, but you can’t wait until you have certainty. You have to act with no regrets.”

—Exercise Participant

Tabletop exercise participants agreed that the exercise scenario and the larger lessons from the global COVID-19 response highlight the need to establish national response plans with a series of planning “triggers,” or threshold conditions, that ensure anticipatory steps early in a potential pandemic. Both the exercise scenario and the COVID-19 response demonstrate that early actions by national governments have significant, positive impacts in managing the impact of the disease. Because the nature of exponential disease transmission severely punishes even modest delays, slow responses by national governments lead to higher caseloads, worse mortality rates, and potentially even the collapse of the public health and medical system.

The Benefits of Early Action

One participant observed that the exercise outcomes were consistent with national performance during the COVID-19 response; governments that

² The UN Secretary-General's Mechanism and the need for a Joint Assessment Mechanism were key discussion points in the 2019 and 2020 NTI-MSG tabletop exercises. Reports from these exercises are available at [nti.org](https://www.nti.org).

responded early and energetically to pandemic warnings were much more successful in protecting their populations. As is widely recognized, a number of wealthier countries with strong public health systems were not proactive and timely in their responses and therefore experienced significantly worse outcomes than those nations that are less wealthy but responded more proactively.

What Is a Trigger?

In national pandemic response plans, specific readiness measures would be “triggered” based on factors related to the potential severity of the outbreak, expected delays in situational awareness, and the time it would take to implement response measures and see results.

Participants stressed that national-level decision makers must build trigger-based plans that emphasize a “no-regrets” bias toward early action. Although there is inevitably a risk of false-alarm responses, participants deemed the risk of delay as far more consequential. Action, one participant argued, must be the “default pathway” because “you will not have the luxury of waiting for certainty.”

Although triggered actions would vary depending upon the particular needs of the country, in most cases the goals are the same: slow the spread of disease to buy time and flatten the epidemiological curve, while using that time to scale up public health and medical systems to keep up with growing caseloads and save lives. NPIs such as mask mandates and ceasing mass gatherings were deemed to be critical for blocking chains of disease transmission. Participants generally did not endorse travel restrictions such as border closures, but travel health screening measures were viewed as valuable.

With the time bought by NPIs, participants argued for scaling up various capacities. The highest priority is implementing testing at scale and increasing health system capacity in terms of facilities and personnel. In addition, nations should ramp up production of the range of critical supplies that could otherwise cause bottlenecks in response operations, including masks, personal protective equipment (PPE) for health workers, testing reagents, oxygen tanks, and ventilators.

The triggers should not be limited just to actions; they should address institutional relationships as well. Indeed, a number of participants stressed that the whole-of-government decision-making process for national-level pandemic response must be planned and exercised as soon as possible, before the next pandemic. Several participants argued that most national governments have too many “silos” of decision making that must be swiftly integrated for a successful pandemic response. An effective, “no-regrets” national response will demand that the whole-of-government engage early, so internal bureaucratic hurdles do not cause critical delays.

“We want to focus the triggers on a large health response so we can find the disease, understand it, slow the spread, and eventually understand what it is and how to stop it from moving.”

—Exercise Participant

Bolstering Pandemic Supply Chain Resilience

All participants agreed that bolstering supply-chain resilience would be critical in future pandemic responses, but they differed on how to address the challenge. In particular, a debate ensued about whether the right approach for ensuring the availability of critical items is stockpiling or maintaining “warm” production capacity,³ or a mixture of both. For those items with long shelf lives—such as masks and other PPE—some participants argued that it is prudent for national governments and international institutions to stockpile.

Others argued that governments and/or international organizations should provide incentives to keep dual-use supply lines open or at least, “warm”—which could, for example, assist with large-scale ventilator production during an international public health emergency. An even more advanced scientific and engineering solution, where possible, would be to develop platform technologies—tools to rapidly develop diagnostics, vaccines, and other medical countermeasures for the wide range of pathogens with pandemic potential.

One participant offered a related vaccine supply recommendation that strikes a balance between national stockpiling and global coordination: selecting and empowering leading governments in each of the globe’s regions. In particular, this participant argued for the creation of a global network of small-population countries that would be charged with manufacturing at scale for their respective regions.⁴ Such an approach would require regional agreement and cooperative financing to build the capabilities in the selected countries.

FINDING 3

The international system for governing dual-use biological research is neither prepared to meet today’s security requirements, nor is it ready for significantly expanded challenges in the future. There are risk reduction needs throughout the bioscience research and development life cycle.

Exercise participants discussed the importance of strengthening biosecurity for bioscience research and development. Emerging biological risks associated with rapid technology advances are not new, but participants recognized that the COVID-19 pandemic has exacerbated these risks. They pointed out that the international community should expect to see a rapid expansion of high-containment laboratories (biosafety level 3 and 4 labs) as a number of countries expand their bioscience research capabilities and engage in more dual-use research on SARS-CoV-2 and other pathogens with pandemic potential.

Participants agreed that, although it is essential to avoid restricting legitimate biological research, it also is critically important to incorporate stronger biosafety and biosecurity measures into bioscience research

³ A warm production capacity would involve maintaining the production line, human expertise, and supply lines for a product even if there is no current market demand.

⁴ In the case of vaccines, for example, these countries would be expected to provide for their own populations first. But because their populations are small relative to their production capacity, they would be able to turn to support the needs of their region in short order.

and development processes—from project design and funding, through research execution, and on to publication or technology commercialization.

Funders

At the beginning of the research and development life cycle, government, philanthropic, and industry funders can play a role in early review of proposed research projects, thereby creating a stronger framework for biosecurity and responsible research. Participants argued that these activities will need to encompass both public and private funders, while recognizing that incorporating the latter may be particularly challenging. During this discussion, several participants argued that the funders cannot be the only arbiter and that implementing a biosecurity review as part of the evaluation process for funding new projects will need to be part of a more comprehensive solution.

Institutional Oversight

Institutional oversight—addressing both academic and industrial research institutions—is an important step in the middle of the research and development life cycle. Some participants argued that in the industry context, boards of directors should take responsibility for biosecurity much as they are increasingly addressing cybersecurity as a corporate governance issue. Participants acknowledged that biosecurity measures would likely add costs to operations—which may be considered high or even prohibitive for small biotechnology companies. However, at least one participant argued that the downside risk for a company involved in a biosecurity incident warrants this kind of executive-level attention and investment.

Some participants also argued that education can play an important role in bolstering private sector biosecurity, observing that many in the sector are ignorant of the security risks.

Providers of Goods and Services

The middle of the bioscience research and development life cycle also involves numerous private-sector entities, including providers of goods and services. For example, a number of companies provide DNA synthesis services to research laboratories. Exercise participants noted that approximately 80 percent of DNA providers are members of the International Gene Synthesis Consortium, which screens customers and DNA order sequences to prevent the building blocks of dangerous pathogens from falling into the hands of malicious actors.⁵ However, screening is costly, time-consuming, and requires human expertise, so non-

“Responsible stewardship of biotechnology and biomedical research is not going to be solved at any one institution. It will require a multifaceted approach that includes norms and standards, national regulations, and regional strategies. Companies, professional societies, funders, and publishers can all play an important role.”

—Exercise Participant

⁵ Formed in 2009, International Gene Synthesis Consortium (IGSC) members screen synthetic gene orders to identify regulated pathogen sequences and other potentially dangerous sequences. By screening the sequences of ordered DNA fragments and vetting customers, IGSC members help to ensure that researchers and the synthetic biology community realize the many benefits of gene synthesis technology while minimizing risk. See genesynthesisconsortium.org.

participants have an economic advantage over Consortium members. A sustainable system must include either incentives to participate or other ways to drive toward 100 percent participation.

Benchtop synthesis devices—smaller machines that individual research facilities can use to print DNA locally, as opposed to ordering from centralized DNA providers—create additional challenges. Participants observed that the entrance of benchtop DNA synthesis machines into the market poses greater risks of dangerous research with no traceability if effective biosecurity provisions are not incorporated.

International Efforts

All participants agreed that at the international level, the system for biosecurity and biosafety in bioscience research is fragmented, although they offered a range of possible remedies.

Recognizing that no comprehensive international solution exists, several participants argued for establishing a new entity that would work with a wide range of international stakeholders to develop biosecurity norms and standards and develop tools to promote compliance. It could provide both general biosecurity education as well as targeted technical assistance to companies, governments, and/or regional organizations. Several participants pointed to an example of a successful normative entity in the World Institute for Nuclear Security,⁶ which performs similar functions in the nuclear security field. At least one participant stressed the importance of bolstering existing mechanisms and institutions, as opposed to creating new ones.

Participants also discussed various biosecurity approaches at national and regional levels. Short of unified international guidelines, one participant argued that opportunities exist for international approaches to encourage national-level biosecurity regulation. In particular, this participant observed that existing international agreements or frameworks—such as the Biological Weapons Convention (BWC)—might facilitate or even require member nation adoption of biosecurity legislation. Others pointed to the promise of progress at the regional level. Described by one participant as a “sea change,” Africa, the Caribbean, and Europe all have developed or are developing regional biosecurity frameworks. For example, the Africa Centers for Disease Control (CDC) is developing a continent-wide biosafety and biosecurity framework. For dual-use research, Africa CDC is proposing a legal framework to establish a requirement for all institutions handling high-risk materials to conduct risk assessment and install mitigation measures and a requirement for all institutions and labs to report their cases of Dual-Use Research of Concern (DURC) to the government. The European Union has a dual-use research framework that is designed to facilitate information exchange. The Caribbean Public Health Agency has developed and implemented an ethical framework through a network of research ethics committees and is working to strengthen standards for bioscience labs.

⁶ See <https://wins.org/>.

FINDING 4

Many countries around the world currently lack financing to make essential national investments in pandemic preparedness.

Exercise participants discussed the need for substantially increased international financing for pandemic preparedness. Although they agreed that faulty policy choices and leadership failures had contributed profoundly to poor national outcomes in the COVID-19 response, they also agreed that pre-pandemic investments in preparedness are essential. Surveying the global landscape of public health spending, one participant stressed that “we have been trying to stop a tsunami with a teaspoon.” Participants noted that the challenge of financing is aggravated by significant problems of international inequity, recognizing that not all countries have the resources to make these investments. Because pandemics do not respect borders, participants agreed that a failure to bolster preparedness across all countries would inevitably pose significant risks for even the best prepared nations.⁷

Participants highlighted the need to create a sustainable financing mechanism for improving pandemic preparedness. The new mechanism should incentivize recipient governments to develop priorities and plans for domestic pandemic preparedness capacity building and to budget for these activities on an ongoing basis.

Participants argued for creating a single pot of funding with real executive authority over its disposition. At least one participant stressed that the funding should come from a larger cross-section of the global community than the limited number of countries that currently contribute. Another participant highlighted the role of the private sector as a contributor, noting that the COVID vaccine market will exceed \$150 billion in 2021. A small fraction of returns reinvested by industry would make a difference.

“We have been trying to stop a tsunami with a teaspoon.”

—Exercise Participant

⁷ According to the UN, approximately 70 countries worldwide have been identified as “aid-dependent.” Countries like Liberia, South Sudan, and Tuvalu depend upon external financing for more than 50 percent of their GDP. See “Are Developing Countries Getting the COVID-19 Funding They Need?” World Economic Forum, [weforum.org](https://www.weforum.org).

Recommendations

NTI developed the following recommendations based on key findings from the exercise, discussed above. These recommendations were developed after the exercise and do not necessarily reflect the views of participants.

1 Bolster International Systems for Assessing Pandemic Risk, Issuing Warnings, and Investigating Outbreak Origins

The NTI-MSR tabletop exercise and other studies have made a compelling case that a radically strengthened global biosurveillance system is needed. However, data gathering and analytical elements are only part of the task of prompt and effective pandemic response; risk evaluation, warning, and assessment of pandemic origins also are critical for success.

The WHO must establish a graded, transparent, international public-health alert system.

- The WHO must upgrade the PHEIC system to provide more actionable alerts and warnings. The system should include graded or incremental thresholds with clear specification of different levels of risk supported by data, to allow for prompt decisions at the national level. Risk gradations should be built explicitly on thresholds of pandemic potential—i.e., the potential of a disease outbreak to spread globally and yield high case counts—as well as estimated severity, such as case fatality rate.
- If reforming the PHEIC system proves too difficult, given the politics of changing the IHRs, the WHO should establish a graded alert system to complement its current PHEIC tool.
- Either way, the criteria for the graded alert system should be public and fully transparent, along with any epidemiological data used to make a determination. Transparency of data and criteria will allow independent assessment and vetting by other experts and organizations.

The UN system should establish a new Joint Assessment Mechanism to investigate high-consequence biological events of unknown origin.

- The experience of SARS-CoV-2's emergence demonstrates the importance of early international investigation to aid the public health and medical response, to minimize unproductive finger-pointing, and to clearly establish an outbreak's origin so that future outbreaks might be better mitigated or even prevented.
- In addition to bolstering existing capabilities to conduct international public health investigations, a new Joint Assessment Mechanism is needed. This mechanism would use transparent, evidence-based approaches to investigate events of unknown, or even suspicious, origin. It would address gaps between existing mechanisms—specifically the WHO outbreak investigation capabilities and the United Nations Secretary-General's Mechanism—while also incorporating and building upon these existing systems.

- To ensure its legitimacy and effectiveness, UN member states should establish the authority for the new mechanism through a vote at the UN General Assembly, with support from a broad international coalition of member states.
- The mechanism should be based within the UN Secretary-General's office and under its authority.
- The Joint Assessment Mechanism must possess significant analytical and investigatory capabilities and expertise, and make use of advanced biotechnology and bioinformatics tools.

2 Develop and Institute National-Level Triggers for Early, Proactive Pandemic Response

Success in preventing or mitigating the effects of future pandemics will depend fundamentally on actions at the national level. Although international institutions can provide timely warnings, advice, and coordination, the power of national sovereignty means that the choices made by individual nations may have the most decisive impacts—both positive and negative. Moreover, the significant variability in effectiveness of national responses to COVID-19 demonstrates that public health and medical capacity alone is not a good predictor of pandemic response performance. Rather, early decisive action has been the main determinant by which countries have managed their COVID-19 outbreaks most effectively.

National governments must adopt a “no-regrets” approach to pandemic response, taking anticipatory action—as opposed to reacting to mounting case counts and fatalities, which are lagging indicators.

- Simply put, national governments and their leaders must err on the side of taking early action. Recognizing that situational awareness of pandemic threats lags behind on-the-ground reality, national leaders cannot wait for cases or fatalities to accumulate before responding. If there is a significant chance that the outbreak could turn into a pandemic, national leaders should lean forward to scale up response efforts and capabilities.

To facilitate anticipatory action on a “no regrets” basis, national governments should develop national-level plans that incorporate “triggers” for responding to high-consequence biological events.

- Triggered national-level pandemic response actions should support the strategy of flattening the epidemiological curve while rapidly scaling up health system capacity to prevent collapse in the face of growing caseloads. Triggered actions should serve three major goals: slowing pathogen transmission, saving lives, and improving situational awareness about the pathogen's spread to enable effective targeting of resources. Triggered actions should include a range of NPIs, including proactive social distancing and mask-wearing guidelines; large-scale testing and contact tracing; large-scale production of PPE and medical equipment; expansion of the pool of deployable medical personnel and space to treat patients; and comprehensive risk communication.
- National-level triggers should include adjustments to institutional relationships and decision making processes to facilitate rapid, whole-of-government response to emerging pandemic threats. Decision making bodies with whole-of-government authorities and information should be stood-up early,

and bureaucratic stovepipes that hamper information-sharing should be eliminated. Additionally, relevant waivers, emergency declarations, clarifications of authorities, and legal determinations should be identified for each phase of these triggers.

- National governments should codify triggers in plans that are routinely exercised, and the results should be systematically evaluated to identify and implement corrective actions.
- The WHO should issue guidance that encourages or requires national governments to develop national-level pandemic response triggers that are pathogen-agnostic and that scale up across multiple levels with escalating pandemic risk.

3 Establish an International Entity Dedicated to Reducing Emerging Biological Risks Associated with Rapid Technology Advances

Bioscience advances offer significant promise for the future, but they also pose risks of accidents or deliberate misuse. Despite this concern, no international entity has a specific mandate to strengthen biosecurity and bioscience governance and to reduce emerging biological risks associated with technology advances.

The international community should establish an entity dedicated to reducing the risk of catastrophic events due to accidents or deliberate abuse of bioscience and biotechnology.

- A UN agency or credible non-governmental institution should partner with experts from the scientific, philanthropic, security, and public health communities to create an international entity dedicated to identifying and reducing emerging biological risks associated with technology advances.
- The mission of this entity should be to strengthen global biosecurity norms and to develop tools and incentives to support adherence.
- The entity should be agile, innovative, and free to engage with a diverse range of stakeholders—including industry, academia, and governments—to keep up with rapid bioscience advances and quickly develop effective approaches to address emerging risks. It should work in close coordination with the Biological Weapons Convention, the WHO, and other international institutions.

To meaningfully reduce risk, the entity should support interventions throughout the bioscience and biotechnology research and development life cycle—from funding, through execution, and on to publication or commercialization. It should:

- Support comprehensive and systematic DNA synthesis screening to prevent the building-blocks of dangerous pathogens from falling into the hands of malicious actors. The new entity should support more effective and comprehensive screening internationally, while also reducing risks associated with benchtop synthesis.
- Support the development of biosecurity standards for use by bioscience funders, who are uniquely positioned to incentivize incorporation of biosecurity measures in grant or investment proposals. This could include developing more rigorous prefunding review processes to reduce the risk that

fundings will support work that lacks important safeguards or is otherwise risky from a biosecurity perspective.

- Guide universities and industry in developing effective approaches to strengthen oversight of dual-use bioscience research conducted within their laboratories.
- Support effective pre-publication biosecurity review. The entity could collaborate with editors and publishers to improve biosecurity review of manuscripts and reduce the risks of public release of information hazards (i.e., information that may increase risks of intentional misuse of bioscience knowledge and biotechnology capabilities).

4 Develop a Catalytic Global Health Security Fund to Accelerate Pandemic Preparedness Capacity Building in Countries around the World

The COVID-19 pandemic has exacerbated inequalities in international pandemic preparedness.⁸ Before the pandemic, experts assessed the gap in preparedness financing for low- and lower-middle income countries to be approximately US\$4.5 billion per year; a gap that has only grown since that time.⁹ The G20 High Level Panel concluded that governments must dedicate at least US\$75 billion over the next five years to finance pandemic prevention and preparedness. A new, catalytic financing mechanism that is able to draw together resources from a wide variety of sources would transform the global system, driving resources and attention to the countries that need it most, and addressing critical gaps in the global health security architecture.¹⁰

National leaders, development banks, philanthropic donors and the private sector should establish and resource a new financing mechanism to bolster global health security and pandemic preparedness.

- This mechanism must mobilize at least US\$10 billion annually over the next 10 years. The mechanism should be oriented toward countries with the greatest need and be based on clear metrics through rigorous assessment, such as the Joint External Evaluation and other resources like the Global Health Security Index.
- This new financing mechanism should catalyze investments across sectors, drawing in funding from governments, multilateral organizations, non-governmental organizations, private sector donors, philanthropies, and individual donors.
- The funds should be disbursed transparently, driving resources to eligible countries to accelerate progress toward specific, measurable pandemic preparedness benchmarks.

⁸ See, for example, Second Report on Progress, Prepared by the Independent Panel for Pandemic Preparedness and Response for the WHO Executive Board, January 2021, pp. 5–6.

⁹ *Financing Pandemic Preparedness and Response*, Background Paper 14, Independent Panel for Pandemic Preparedness and Response, May 2021, p. 16.

¹⁰ See Pandemic Action Network Policy Brief, *A New Multilateral Financing Mechanism for Global Health Security and Pandemic Preparedness*, August 2021, <https://pandemicactionnetwork.org/wp-content/uploads/2021/08/A-New-Multilateral-Financing-Mechanism-for-Global-Health-Security-and-Pandemic-Preparedness.pdf>. NTI strongly supports the additional recommendations and priorities laid out in this brief, which align with and support recommendations made in this paper.

The design and operations of the fund should be catalytic, incentivizing national governments to invest in their own preparedness over the long term.

- Loans and grants through the mechanism should be managed within a country's national budget to increase accountability, incentivize domestic resource mobilization, and promote a sustainable way to shift accounting lines away from donor balance sheets to national budgets.
- To overcome the problem of dependence upon assistance, the mechanism should set various match levels by recipients, adjusted for their unique needs and means.
- The mechanism should complement existing mechanisms, such as the WHO Contingency Fund for Emergencies and other funding available through the UN and the World Bank.
- Funds disbursed should prioritize preparedness activities, strengthening countries' long-term capacity and ensuring that preparedness remains a political and budget priority.

5 Establish a Robust International Process to Tackle the Challenge of Supply Chain Resilience

As highlighted by exercise participants, the COVID pandemic has revealed significant weaknesses in global supply chains for critical medical and public health supplies. Robust systems for ensuring availability of PPE, testing supplies, and biomedical equipment are an international public good, which will be critical for responding to future pandemics. Achieving this goal will require energetic, focused planning and coordination, which must take place before the urgent need arises. To be effective, such an initiative should build upon lessons learned from the efforts of the UN COVID-19 Supply Chain Task Force and the Access to COVID-19 Tools Accelerator.

The UN Secretary-General should convene a high-level panel to develop recommendations for critical measures to bolster global supply chain resilience for medical and public health supplies, including:

- Developing more robust distributed production capabilities, which can provide needed supplies across the globe,
- Facilitating supply distribution, with a focus on transportation resources and pre-designated supplier-distributor-recipient relationships,
- Focused support on improving capabilities to deliver supplies over the “last mile” in developing countries.

Appendix A. Expert Contributors to Scenario Development

NTI convened a diverse group of experts in December 2020 to advise on the tabletop exercise scenario. These experts participated as individuals—not as representatives of their respective organizations—and they do not necessarily endorse the recommendations in this report.

Dr. Hillary Carter

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Appendix B. Epidemiological Model Summary

Developed by Dr. Ellie Graeden Trae Wallace, Talus Analytics

The epidemiological elements of the exercise scenario were developed using a standard Susceptible–Exposed–Infectious–Recovered (SEIR) compartmentalized model. The model assumes no asymptomatic spread. The structure of the model is summarized in Figure B-1. A lab-modified version of monkeypox was intentionally released via aerosols in train stations in the fictional country of Brinia (population 250 million) by agents of a terrorist group operating in neighboring Arnica (population 75 million).

Through intentional modifications made by Arnican virology lab scientists sympathetic with the Arnican terrorists, this monkeypox strain is assumed to be more contagious than naturally occurring monkeypox—with a basic reproductive number (R_0) for the modified strain of 3, as compared to 2.13 for the wildtype strain.¹¹ The lab-modified strain is also engineered to be resistant to the smallpox vaccine. Vaccine resistance is assumed to be driven by the introduction of the Interleukin-4 gene, as demonstrated in previous mousepox studies.¹² We assume a case fatality rate of approximately 10 percent, which is consistent with previously described monkeypox outbreaks.¹³

Modeling State Descriptions

The following bullet points summarize the states of the SEIR model and how individual model agents progress through them. (Additional details on each parameter are provided in Tables B-1 and B-2 on pages 30 and 31.)

- **Susceptible.** Initial state for all individuals in a fully predictive run. In cases where the model run is initiated based on prior cases, the susceptible group includes the proportion of individuals not previously exposed.
- **Exposed.** Individuals move from Susceptible to Exposed when they come into contact with infectious individuals at a rate that is determined by the number of contacts individuals have with one another. All exposed individuals transition to mild cases (Infected1) after eight days.

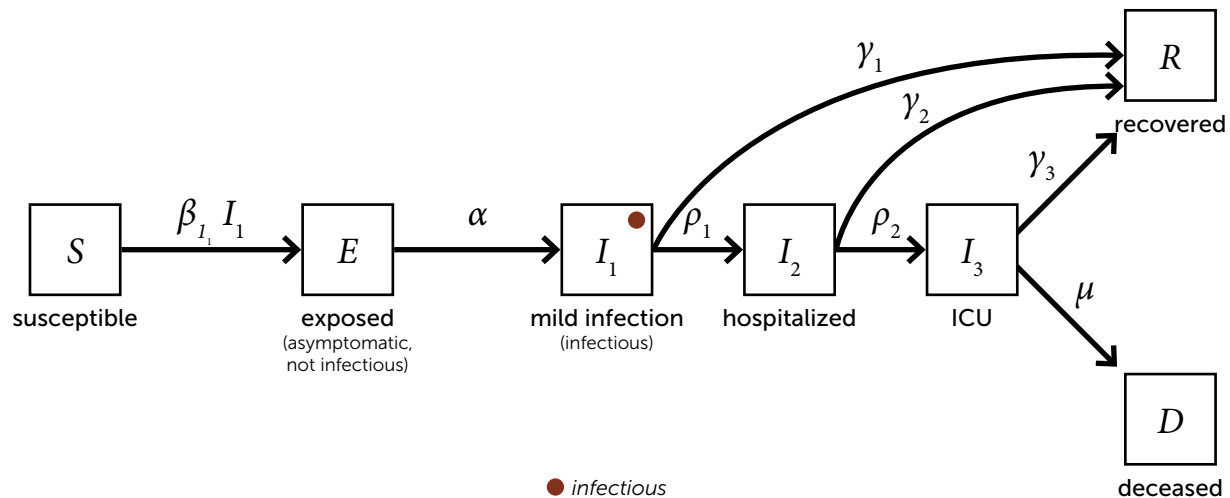
¹¹ Rebecca Grant, Liem-Binh Luong Nguyen, & Romulus Breban, “Modelling Human-to-Human Transmission of Monkeypox,” *Bulletin of the World Health Organization* 98, no. 9 (September 1 2020): 638–640, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7463189/>.

¹² R.J. Jackson, A.J. Ramsay, C.D. Christensen, S. Beaton, D.F. Hall, & I.A. Ramshaw, “Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox,” *J Virol* 75, no. 3 (February 2001): 1205–10. doi: 10.1128/JVI.75.3.1205-1210.2001. PMID: 11152493; PMCID: PMC114026.

¹³ WHO, “Monkeypox–Democratic Republic of the Congo,” *Disease Outbreak News* (October 1, 2020), <https://www.who.int/emergencies/disease-outbreak-news/item/monkeypox-democratic-republic-of-the-congo>.

- **Infected1.** These are mild cases. After approximately one week, 50 percent of these cases worsen, and require hospitalization (the Infected2 state) whereas the remaining 50 percent progress to the Recovered state.
- **Infected2.** These are severe, hospitalized cases, requiring non-ICU treatment. After approximately one week, 40 percent of these cases worsen, thus requiring ICU (Infected3), whereas the remaining 60 percent progress to the Recovered state.
- **Infected3.** These are critical cases requiring ICU treatment. This model assumes all deaths must first pass through this category. After approximately one week, 50 percent of these cases lead to death, whereas the remaining 50 percent progress to Recovered.
- **Recovered.** This compartment includes all individuals who have already had the disease (excluding those who died). For the purposes of the model, recovered individuals are considered to be immune from future infection.
- **Deceased.** Individuals who have died as a result of the disease. All deaths result from ICU (Infected3) cases and make up approximately 10 percent of all cases.

Figure B-1. SEIR Compartmental Model Structure



Associated parameters for each are described in Table B-1, below.

Table B-1. Key Parameters

Parameter	Symbol	Value	Source
Transmission rate	Beta (β)	0.175	scenario assumption
Pre-symptomatic period	–	8 days	¹⁴
Mild infection duration	–	14 days	¹⁵
Hospital stay (recovery/death)	–	18 days	ibid.
Asymptomatic cases	–	0%	¹⁶
Hospitalization rate	Rho1 (ρ_1)	50%	¹⁷ and scenario assumption
ICU need for hospitalized	Rho2 (ρ_2)	40%	ibid.
Death for ICU cases	Mu (μ)	50%	ibid.
Total Case Fatality Rate (CFR)	–	10%	¹⁸

The release in Brinia results in 150 initial infections on May 15, 2022, and 10 inadvertently infected Arnicans. By June 1, travel from Brinia has seeded infections in the rest of the world. Elements of national-level response were also included in the model using a basic framework of adjusting the contact rate, Beta (which impacts R), to represent the effects of social distancing on transmission (including lockdowns and stay-at-home orders). The global population, excluding those living in Arnica and Brinia, were divided into three categories, reflecting the quality of public health response at the national level—designated as “Effective,” “Modest,” or “Poor.” The population of countries with “Poor” responses represent 4.4 billion people, whereas those with “Modest” and “Effective” responses represent 1.5 billion people each. Brinia’s response is defined as “Poor”; and Arnica’s response is defined as “Moderate.” Additionally, the fictional countries of Cardus and the Republic of Dranma have “Poor” and “Effective” responses respectively, and each have populations of 60 million and 10 initial cases. The specific dates and impacts on transmission of each response are listed in Table B-2 page 31.

All countries react to the emerging outbreak in Brinia after Move 1 on June 5, 2022. These actions impact the transmission rate but do not bring the total effective reproductive number of the virus below 1. All countries act again in early 2023. For the countries with a “Poor” response, this action is still too small

¹⁴ Ellen M. Beer & V. Bhargavi Rao, “A Systematic Review of the Epidemiology of Human Monkeypox Outbreaks and Implications for Outbreak Strategy,” *PLOS Neglected Tropical Diseases* (October 16, 2019), <https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007791>.

¹⁵ Andrea M. McCollum & Inger K. Damon, “Human Monkeypox,” *Clinical Infectious Diseases* 58, no. 2 (January 2014): 260–7, <https://academic.oup.com/cid/article/58/2/260/335791>.

¹⁶ Daniel B. Di Giulio & Paul B. Eckburg, “Human Monkeypox: An Emerging Zoonosis,” *Lancet Infect Dis* 4, no. 1 (January 2004):15–25, <https://pubmed.ncbi.nlm.nih.gov/14720564/>.

¹⁷ Estimated from moderate/hospitalized and severe cases to achieve case fatality rate. Inger K. Damon, “Status of Human Monkeypox: Clinical Disease, Epidemiology and Research,” *Vaccine* 29 (2011): D54–D59, <https://www.sciencedirect.com/science/article/pii/S0264410X1100524X>.

¹⁸ WHO, “Monkeypox,” 2019, <https://www.who.int/news-room/fact-sheets/detail/monkeypox>.

and leaves the R well above 1. The “Moderate” response countries open up in January, increasing R to approximately 2.2, before locking down in the summer of 2023 when the outbreak is undeniable. Finally, the “Effective” response countries lock down aggressively in February 2023 and keep R below 1 throughout the remainder of the exercise.

The combined global pandemic leads to more than three billion cumulative cases and more than 270 million deaths by the end of December 2023. At the peak of the pandemic, nearly 500 million individuals are infected at the same time, and there are 161 million people simultaneously in need of hospitalization.

The model was written in Python, with configuration and visualization through Jupyter notebooks.

Table B-2. Non-Pharmaceutical Intervention Dates and Impacts

Effective National Response		
Date	Beta	R
6/6/22	0.09	1.89
2/7/23	0.01	0.77
Modest National Response		
Date	Beta	R
6/6/22	0.08	1.75
1/11/23	0.11	2.17
3/11/23	0.08	1.75
7/15/23	0.007	0.728
Poor National Response		
Date	Beta	R
6/6/22	0.15	2.73
1/15/23	0.085	1.82

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Dr. Jaime M. Yassif is Senior Fellow for Global Biological Policy and Programs at NTI, where she is leading several major biosecurity projects focused on strengthening governance of dual-use bioscience and reducing global catastrophic biological risks. Yassif previously served as a Program Officer at Open Philanthropy, where she led the Biosecurity and Pandemic Preparedness initiative. In this role, she recommended and managed approximately \$40 million in biosecurity grants, which rebuilt the field and supported work in several key areas, including developing new biosecurity programming at several leading think tanks, establishing the Global Health Security Index, initiating new biosecurity work in China and India, and framing a new public discourse about global catastrophic biological risks. Prior to this, Yassif served as a Science and Technology Policy Advisor at the U.S. Department of Defense and worked on the Global Health Security Agenda at the U.S. Department of Health and Human Services.

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Peter Daszak

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Peter Daszak



Daszak speaking in 2017

Nationality British

Education [Bangor University](#) (B.Sc.)
[University of East London](#) (Ph.D.)

Occupation Zoologist

Employer [Kingston University](#)
[University of Georgia](#)
[Centers for Disease Control and Prevention](#)
[Columbia University](#)

Peter Daszak is a British [zoologist](#), consultant and public expert on [disease ecology](#), in particular on [zoonosis](#). He is the president of [EcoHealth Alliance](#), a [nonprofit non-governmental organization](#) that supports various programs on [global health](#) and pandemic prevention.^{[1][2]} He is also a member of the Center for Infection and Immunity at the [Columbia University Mailman School of Public Health](#).^{[2][3]}

Daszak was involved in investigations into the initial outbreak which eventually developed into the [COVID-19 pandemic](#)^[4] and became a member of the [World Health Organization](#) team sent to [investigate the origins of the COVID-19 pandemic](#) in China. This became controversial due to Daszak's previous activities with the [Wuhan Institute of Virology](#), perceived by some^{[5][6]} as a conflict of interest.



Contents

- [1 Education](#)
- [2 Career](#)
 - [2.1 COVID-19 pandemic](#)
- [3 Awards and honors](#)
- [4 References](#)
- [5 External links](#)

Education

Daszak earned a [B.Sc.](#) in zoology in 1987, at [Bangor University](#) and a Ph.D. in [parasitic infectious diseases](#) in 1994 at [University of East London](#).^[2]

Career

Daszak worked at the School of Life Sciences, [Kingston University](#), in Surrey, England in the 1990s. In the late 1990s Daszak moved to the United States and was affiliated with the [Institute of Ecology](#) at the [University of Georgia](#) and the [National Center for Infectious Diseases, Centers for Disease Control and Prevention](#), in [Atlanta, Georgia](#). Around 2001 he became executive director at a collaborative [think-tank](#) in [New York City](#), the Consortium for Conservation Medicine.^[7] He has adjunct positions at two universities in the U.K. and three universities in the U.S., including the [Columbia University](#) Mailman School of Public Health.^{[2][8]}

He was one of the early adopters of [conservation medicine](#).^[9] The [Society for Conservation Biology](#) symposium in 2000, had focused on the "complex problem of emerging diseases".^[9] He said in 2001 that there were "almost no examples of emerging wildlife diseases not driven by human environmental change...[a]nd few human emerging diseases don't include some domestic animal or wildlife component." His research has focused on investigating and predicting the impacts of new diseases on wildlife, livestock, and human populations, and he has been involved in research studies on epidemics such as the [Nipah virus infection](#), the [Australian Hendra outbreaks](#), the [2002–2004 SARS outbreak](#), [Avian influenza](#), and the [West Nile virus](#).^[10]

Starting in 2014, Daszak was [Principal Investigator](#) of a six-year NIH project which was awarded to the [EcoHealth Alliance](#) and which focused on the emergence of novel zoonotic coronaviruses with a bat origin.^[11] Among the aims of the project was to characterize the diversity and distribution of [Severe acute respiratory syndrome–related coronavirus](#) (SARSr-CoV) in bats, viruses with a significant risk of spillover, in southern China, based on data from spike protein sequences, infectious clone technology, infection experiments (both in vitro and in vivo), as well as analysis of receptor binding.^[12] The six 1-year projects received \$3.75 million in funding from the [National Institute of Allergy and Infectious Diseases](#) (NIAID), part of the U.S. [National Institutes of Health](#) agency.^[11]

Daszak has served on committees of the [International Union for Conservation of Nature](#), [World Health Organization](#) (WHO), [National Academy of Sciences](#), and [United States Department of the Interior](#).^[2] He is a member of the [National Academy of Medicine](#) and Chair of the [National Academies of Sciences, Engineering, and Medicine](#) (NASEM)'s Forum on Microbial Threats and sits on the supervisory board of the [One Health](#) Commission Council of Advisors.^[13]

During times of large virus outbreaks Daszak has been invited to speak as an expert on epidemics involving diseases moving across the species barrier from animals to humans.^{[13][14][15]} At the time of the [Ebola](#) outbreak in West Africa in 2014, Daszak said "Our research shows that new approaches to reducing emerging pandemic threats at the source would be more cost-effective than trying to mobilize a global response after a disease has emerged".^[16]

In October 2019, when the U.S. federal government "quietly" ended the ten-year old program called [PREDICT](#),^[17] operated by [United States Agency for International Development](#) (USAID)'s emerging threats division,^[18] Daszak said that, compared to the \$5 billion the U.S. spent fighting Ebola in West Africa, PREDICT—which cost \$250 million—was much less expensive. Daszak further stated, "PREDICT was an approach to heading off pandemics, instead of sitting there waiting for them to emerge, and then mobilizing."^[18]

As of 2021, Daszak is the president of the New York-headquartered NGO EcoHealth Alliance.^[19] His research focuses on global emergent diseases such as [Severe Acute Respiratory Syndrome](#) (SARS), [Nipah virus](#), [Middle East Respiratory Syndrome](#) (MERS), [Rift Valley fever](#), [Ebola virus](#), and [COVID-19](#).^{[2][20][21]} The organization has administered more than \$100 million in U.S. federal grants to fund overseas laboratory experiments.^{[22][23]}

COVID-19 pandemic

After the outbreak of the [COVID-19 pandemic](#), Daszak noted in [The New York Times](#) that he and other disease ecologists had warned the WHO in 2018 that the next pandemic "would be caused by an unknown, novel pathogen that hadn't yet entered the human population", probably in a region with significant human-animal interaction.^[24] The group had named this hypothetical pathogen "[Disease X](#)"; it was included on a list of eight diseases which they recommended should be given highest priority in regard to research and development efforts, such as finding better diagnostic methods and developing [vaccines](#).^[25] He said, "As the world stands today on the edge of the pandemic precipice, it's worth taking a moment to consider whether Covid-19 is the disease our group was warning about."^[24]

Prior to the pandemic, Daszak and EcoHealth Alliance were the only U.S.-based organization researching coronavirus evolution and transmission in China,^[26] where they partnered with the [Wuhan Institute of Virology](#), among others. On 1 April 2020, following the beginning of the [COVID-19 pandemic in the United States](#), the [USAID](#) granted \$2.26 million to the EcoHealth program for a six-month emergency extension of the program whose funding has expired in September 2019.^{[27][28]} The [University of California](#) announced that the extension would support "detection of [SARS-CoV-2](#) cases in Africa, Asia and the Middle East to inform the public health response" as well as investigation of "the animal source or sources of SARS-CoV-2 using data and samples collected over the past 10 years in Asia and Southeast Asia."^[28]

An [open letter](#) co-authored by Daszak, signed by 27 scientists and published in [The Lancet](#) on 19 February 2020, stated: "We stand together to strongly condemn [conspiracy theories suggesting that COVID-19 does not have a natural origin](#)...and overwhelmingly conclude that this coronavirus originated in wildlife." It further warned that blaming Chinese researchers for the virus' origin jeopardised the fight against the disease.^[29] The letter has been criticized by [Jamie Metz](#) for "scientific propaganda and thuggery", and by Katherine Eban of [Vanity Fair](#) as having had a "chilling effect" on scientific research and the scientific community by

implying that scientists who "bring up the lab-leak theory... are doing the work of conspiracy theorists".^{[30][31][32]} According to emails obtained by FOIA, Daszak was the primary organizer of the letter, and had communicated with colleagues while drafting and signing the letter to "conceal his role and creat[e] the impression of scientific unanimity."^[32] It also caused controversy since Daszak did not disclose that his EcoHealth Alliance group had an existing relationship with the [Wuhan Institute of Virology](#), with some alleging that this was an apparent conflict of interest.^{[33][34]} In June 2021, *The Lancet* published an addendum in which Daszak listed his cooperation with researchers in China,^[35] and he also recused himself from *The Lancet's* inquiry commission focused on COVID-19 origins.^[36]

EcoHealth Alliance's project funding was "abruptly terminated" on 24 April 2020, by the [National Institutes of Health](#). The move met with criticism,^{[20][37][38]} including by a group of 77 [Nobel Prize](#) laureates who wrote to NIH Director [Francis Collins](#) that they "are gravely concerned"^[39] by the decision and called the funding cut "counterintuitive, given the urgent need to better understand the virus that causes COVID-19 and identify drugs that will save lives."^[40] An article on 8 May 2020 in the journal *Science* stated that the unusual 24 April decision to cut EcoHealth's funding had occurred shortly after "President Donald Trump alleged – without providing evidence – that the pandemic virus had escaped from a Chinese laboratory supported by the NIH grant, and vowed to end the funding."^[41]

In May 2020, Daszak "said there was 'zero evidence' that the virus" was created in the [Wuhan Institute of Virology](#) during an appearance on "60 Minutes."^[42]

In 2020 Daszak was named by the [World Health Organization](#) as the sole U.S.-based representative on a team sent to [investigate the origins of the COVID-19 pandemic](#),^[43] a team that also included [Marion Koopmans](#), Hung Nguyen, and Fabian Leendertz.^[43] Daszak had previously collaborated for many years with [Shi Zhengli](#), the director of the [Wuhan Institute of Virology](#),^[44] on efforts to trace [SARSr-CoV](#) viruses to bats after the [2002–2004 SARS outbreak](#).

Awards and honors

In 1999, Daszak received a meritorious service award from the [Centers for Disease Control and Prevention](#).^[45] In 2018, he was elected to the [National Academy of Medicine](#).^{[45][46]} He is commemorated in the names of the centipede *Cryptops daszaki*,^[47] as well as the [apicomplexan](#) parasite *Isospora daszaki*.^[48]

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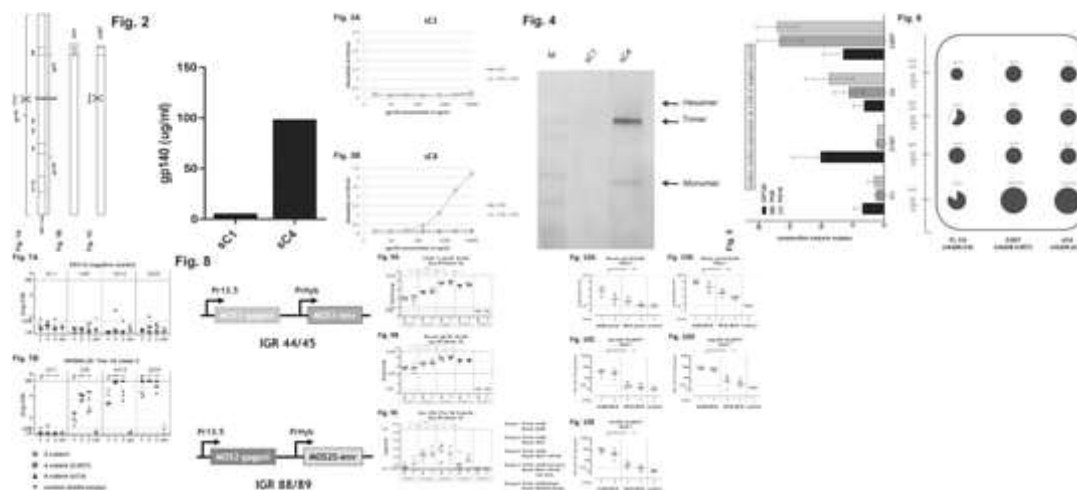
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Poxvirus vectors encoding HIV antigens, and methods of use thereof

Abstract

Poxvirus vectors encoding a synthetic HIV envelope antigen and other HIV antigens, as well as compositions containing such poxvirus vectors and uses of such poxvirus vectors as vaccines to provide improved immunity against HIV, are provided. Also provided are vaccine combinations containing the disclosed poxvirus vectors, adenovirus vectors encoding one or more HIV antigens, and one or more isolated HIV antigenic polypeptides, and methods of using the vaccine combinations to provide improved immunity against HIV.

Images (10)



Classifications



SIGA Announces Health Canada Regulatory Approval of Oral TPOXX®

December 1, 2021

NEW YORK, Dec. 01, 2021 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that Health Canada has approved oral TPOXX® (tecovirimat) as an extraordinary use new drug. Specifically, Health Canada has authorized the use of oral TPOXX for the treatment of human smallpox disease in adults and pediatric patients weighing at least 13 kg.

"This is an important milestone in our partnership with the Canadian Department of National Defence (DND) that provided support to SIGA for the submission and regulatory review of its application. The approval ensures that we can continue to supply oral TPOXX to both the DND and the Public Health Agency of Canada (PHAC) for stockpiling as a key countermeasure," said Dr. Phil Gomez, CEO of SIGA Technologies.

ABOUT SIGA TECHNOLOGIES, INC. and TPOXX®

SIGA Technologies, Inc. is a commercial-stage pharmaceutical company focused on the health security market. Health security comprises countermeasures for biological, chemical, radiological and nuclear attacks (biodefense market), vaccines and therapies for emerging infectious diseases, and health preparedness. Our lead product is TPOXX®, also known as tecovirimat and ST-246®, an orally administered and IV formulation antiviral drug for the treatment of human smallpox disease caused by variola virus. TPOXX is a novel small-molecule drug and the US maintains a supply of TPOXX under Project BioShield. The oral formulation of TPOXX was approved by the FDA for the treatment of smallpox in July 2018. The full label is available by clicking here [clicking here](#). For more information about SIGA, please visit www.siga.com.

In June 2019, SIGA entered into an international promotion agreement with Meridian Medical Technologies, Inc. ("Meridian"), a Pfizer company. Under the agreement, Meridian will promote the sale of oral tecovirimat for the treatment of smallpox in all international markets outside of the United States. SIGA will continue to own all rights to the product and its related intellectual property.

ABOUT MERIDIAN MEDICAL TECHNOLOGIES, INC.

Meridian Medical Technologies, Inc., a Pfizer company, has been putting emergency care treatment options into the hands of military and civilian defenders for more than 50 years. Meridian is committed to help defend against critical, time-sensitive, life-or-death situations by providing medical countermeasures to the United States Department of Defense, Emergency Medical Services, Homeland Security, and more than 30 nations around the world.

On November 1, 2021, Pfizer entered into an agreement with Altaris Capital Partners, LLC (collectively with its affiliates, "Altaris"), a healthcare investment firm based in New York, for Altaris to purchase Meridian. The transaction is expected to close in the coming months, subject to customary closing conditions including the receipt of regulatory approvals.

About Smallpox¹

Smallpox is a contagious, disfiguring and often deadly disease that has affected humans for thousands of years. Naturally occurring smallpox was eradicated worldwide by 1980, the result of an unprecedented global immunization campaign. Samples of smallpox virus have been kept for research purposes. This has led to concerns that smallpox could someday be used as a biological warfare agent. A vaccine can prevent smallpox, but the risk of the current vaccine's side effects is too high to justify routine vaccination for people at low risk of exposure to the smallpox virus.

FORWARD-LOOKING STATEMENTS

This press release contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Such forward-looking statements are subject to various known and unknown risks and uncertainties, and SIGA cautions you that any forward-looking information provided by or on behalf of SIGA is not a guarantee of future performance. More detailed information about SIGA and risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this press release, is set forth in SIGA's filings with the Securities and Exchange Commission, including SIGA's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, and in other documents that SIGA has filed with the SEC. SIGA urges investors and security holders to read those documents free of charge at the SEC's web site at <http://www.sec.gov>. Interested parties may also obtain those documents free of charge from SIGA. Forward-looking statements are current only as of the date on which such statements were made, and except for our ongoing obligations under the United States of America federal securities laws, we undertake no obligation to update publicly any forward-looking statements whether as a result of new information, future events, or otherwise.

The information contained in this press release does not necessarily reflect the position or the policy of the Government of Canada and no official endorsement should be inferred.

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¹ <http://www.mayoclinic.org/diseases-conditions/smallpox/basics/definition/con-20022769>



Source: SIGA Technologies Inc.



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Source: SIGA Technologies Inc.

SIGA Receives Approval from the FDA for Intravenous (IV) Formulation of TPOXX® (tecovirimat)

May 19, 2022 at 7:30 AM EDT

[PDF Version](#)

- FDA approval provides an important option for those unable to take oral formulation of TPOXX -

NEW YORK, May 19, 2022 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that the U.S. Food and Drug Administration (FDA) approved the intravenous (IV) formulation of TPOXX for the treatment of smallpox. The IV formulation is an important option for those who are unable to swallow the oral capsules of TPOXX.

“We are grateful to the FDA for their work leading to approval of IV TPOXX, which will provide access to a broader patient population,” said Dr. Dennis Hruby, CSO of SIGA. “We are also appreciative to our colleagues at BARDA who have been working with us for many years to include oral and IV TPOXX in U.S. preparedness efforts and look forward to continuing to work with them on our liquid pediatric formulation.”

The oral formulation of TPOXX (tecovirimat) is approved in the US, Canada and Europe for the treatment of smallpox. The European approval also includes the treatment of monkeypox, cowpox, and complications from immunization with vaccinia. The IV formulation of TPOXX was cited in the recent U.S. president’s budget request as being used to treat a patient in the U.S. with monkeypox.

ABOUT SIGA TECHNOLOGIES, INC. and TPOXX®

SIGA Technologies, Inc. is a commercial-stage pharmaceutical company focused on the health security market. Health security comprises countermeasures for biological, chemical, radiological and nuclear attacks (biodefense market), vaccines and therapies for emerging infectious diseases, and health preparedness. Our lead product is TPOXX®, also known as tecovirimat and ST-246®, an orally administered and IV formulation antiviral drug for the treatment of human smallpox disease caused by variola virus. Funding and technical support for this work is provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. 75A50118C00019 (19C). For more information about BARDA, refer to <https://www.medicalcountermeasures.gov/>. TPOXX is a novel small-molecule drug and the US maintains a supply of TPOXX under Project BioShield. The oral formulation of TPOXX was approved by the FDA for the treatment of smallpox in 2018. The full label is available by [clicking here](#). In September 2018, SIGA signed a contract with the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services,

for additional procurement and development related to both oral and intravenous formulations of TPOXX. For more information about SIGA, please visit www.siga.com.

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FORWARD-LOOKING STATEMENTS

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements relating to the progress of SIGA’s development programs and timelines for bringing products to market, as well as the impact of COVID-19 on SIGA’s business. Forward-looking statements may be identified by words or phrases such as “believes,” “estimates,” “expects,” “may,” “will,” “would,” “can,” “could,” and similar words and phrases. Such forward-looking statements are based on current expectations and assumptions and subject to various known and unknown risks and uncertainties, and SIGA cautions you that any forward-looking information provided by or on behalf of SIGA is not a guarantee of future performance. SIGA’s actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond SIGA’s control, including, but not limited to, (i) the risk that the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) elects, in its sole discretion as permitted under the BARDA Contracts (as defined below), not to exercise all, or any, of the remaining unexercised options under those contracts, (ii) the risk that SIGA may not complete performance under its contracts with BARDA (the “BARDA Contracts”) on schedule or in accordance with contractual terms, (iii) the risk that the BARDA Contracts are modified or canceled at the request or requirement of the U.S. government, (iv) the risk that the nascent international biodefense market does not develop to a degree that allows SIGA to successfully market TPOXX internationally, (v) the risk that potential products, including potential alternative uses or formulations of TPOXX that appear promising to SIGA or its collaborators, cannot be shown to be efficacious or safe in subsequent pre-clinical or clinical trials, (vi) the risk that SIGA or its collaborators will not obtain appropriate or necessary governmental approvals to market these or other potential products or uses, (vii) the risk that SIGA may not be able to secure or enforce sufficient legal rights in its products, including intellectual property protection, (viii) the risk that any challenge to SIGA’s patent and other property rights, if adversely determined, could affect SIGA’s business and, even if determined favorably, could be costly, (ix) the risk that regulatory requirements applicable to SIGA’s products may result in the need for further or additional testing or documentation that will delay or prevent SIGA from seeking or obtaining needed approvals to market these products, (x) the risk that the volatile and competitive nature of the biotechnology industry may hamper SIGA’s efforts to develop or market its products, (xi) the risk that changes in domestic or foreign economic and market conditions may affect SIGA’s ability to advance its research or may affect its products adversely, (xii) the effect of federal, state, and foreign regulation, including drug regulation and international trade regulation, on SIGA’s businesses, (xiii) the risk that the COVID-19 pandemic could impact

SIGA's operations by disrupting SIGA's supply chain for the manufacture of TPOXX, causing delays in SIGA's research and development activities, causing delays or the re-allocation of funding in connection with SIGA's government contracts, or diverting the attention of government staff overseeing SIGA's government contracts, (xiv) the risk that the U.S. or foreign governments' responses (including inaction) to national or global economic conditions or infectious diseases such as COVID-19 are ineffective and may affect SIGA's business adversely, and (xv) other risk factors discussed in Item 1A. "Risk Factors" of SIGA's Annual Report on Form 10-K for the year ended December 31, 2021, and in SIGA's subsequent filings with the U.S. Securities and Exchange Commission. These documents are publicly available at the SEC's website at <http://www.sec.gov> and SIGA's website at <https://investor.siga.com>. Forward-looking statements are current only as of the date on which such statements were made, and except as may be otherwise required by law, we undertake no obligation to update publicly any forward-looking statements whether as a result of new information, future events, or otherwise.

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¹ <http://www.mayoclinic.org/diseases-conditions/smallpox/basics/definition/con-20022769>

• The WHO To Discuss Global Pandemic Treaty At World Health Assembly May 22-28

- [Bruce Y. Lee](#)
- Senior Contributor
-



• • The World Health Organization (WHO) will be discussing a possible Global Pandemic Treaty at the ... [+]

POOL/AFP via Getty Images

You know the 1996 movie *Independence Day*, where much of the World united to defeat a common enemy? Well, during the Covid-19 pandemic that started in 2020, pretty much the opposite happened. The World was about as organized as all-cat produced and directed episode of *Dancing with the Stars* or rather *Dancing with the Stars Who are Also Cats*. The global pandemic response had relatively little coordination, little unity. In fact, it was more like the 1983 and 2009 TV miniseries *V*, where many politicians, personalities, social media accounts and others seemed like they were actually trying to help the enemy, in this case, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). That allowed the virus to kill over 6.27 million people and counting, leave potentially millions upon millions more with long Covid, and cost society boatloads of money. That's why the World Health Organization (WHO) will be discussing a possible Global Pandemic Treaty at the upcoming 75th World Health Assembly in Geneva, Switzerland, from May 22 to 28. Yet, despite the clear need for more global coordination, some politicians, some celebrities, and a bunch of social media accounts have been trying to, guess what, argue against such a treaty. They even started a hashtag #StopTheTreaty.

Yeah, having no global agreement in place before the next pandemic is going to work out real well, right? Picture a football team running on to the field for a championship game with no real plan, no real strategy, no real agreement to play together, and players saying, “I will do whatever I want with the ball, because you know, freedom.” Things don’t go well when people do whatever they want with their balls, meaning the kind that you kick and throw, during a team sporting event. Similarly, having each country or even each faction within each country do whatever they want is going to end up in disaster. This is essentially what’s ended up happening in the U.S., which has suffered over a million dead since the start of the pandemic.

[In a commentary published in *The Lancet* on May 16](#), a team of authors, most of whom are from the U.K., wrote that “the Covid-19 pandemic has highlighted profound weaknesses in the global governance of health; inadequate preparation, coordination, and accountability hampered the collective response of nations at each stage.” They asserted that “Changes to the global health architecture are necessary to mitigate the health and socioeconomic damage of the ongoing pandemic, and to prepare for the next major global threat to health.” They indicated that “success will require clear demarcations of responsibility with a parsimonious role for international institutions. Although a pandemic treaty or alternative new instrument or process cannot solve all that is wrong with global health, it can deliver targeted improvements if supported by effective and clear global governance.”

- [How to follow Davos 2022](#)

What's this year's meeting about?

The meeting is centered around the theme **History at a Turning Point: Government Policies and Business Strategies**. It happens at the most consequential geopolitical and geo-economic moment of the past three decades and against the backdrop of a once-in-a-century pandemic.

The war in Ukraine and the resulting tragedy calls for global moral action. Leaders will address urgent humanitarian and security challenges as they simultaneously advance long-standing economic, environmental and societal priorities – all while reinforcing the foundations of a stable global system.

Clarity of vision and unity of purpose will be crucial for making progress against the unprecedented complexity of a multipolar world.

The meeting provides a unique environment in which to reconnect, exchange insights, gain fresh perspectives and advance solutions.

Davos 2022: #WEF22

What's the conversation and where's the impact?

The philosophy of collective action has endured for more than 50 years and it has never been more needed than now. The meeting is the starting point for a new era of global responsibility and cooperation. The moment demands it.

Sessions address: global cooperation; economic rebalancing; society, equity and global health; nature, food and climate; industry transformation; and innovation, governance and cybersecurity.

See the full programme [here](#).

The focus is on setting strategies for impact, building new frontiers, creating viable future scenarios and providing ambitious solutions to the world's biggest issues.



Davos 2022: #WEF22

Over the past two years, the World Economic Forum has strengthened its impact initiatives, which deal with issues ranging from COVID-19 and climate change to education as well as technology and energy governance.

These include the Reskilling Revolution, an initiative to provide 1 billion people with better education, skills and jobs by 2030; an initiative on universal environmental, social and governance (ESG) metrics and disclosures to measure stakeholder capitalism; and the 1 Trillion trees initiative, 1t.org, to protect our trees and forests and restore the planet's ecosystems.

Monkeypox

19 May 2022

[العربية](#)

[中文](#)

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[Русский](#)

[Español](#)

Key facts

- Monkeypox is caused by monkeypox virus, a member of the Orthopoxvirus genus in the family Poxviridae.
- Monkeypox is a viral zoonotic disease that occurs primarily in tropical rainforest areas of Central and West Africa and is occasionally exported to other regions.
- Monkeypox typically presents clinically with fever, rash and swollen lymph nodes and may lead to a range of medical complications.
- Monkeypox is usually a self-limited disease with the symptoms lasting from 2 to 4 weeks. Severe cases can occur. In recent times, the case fatality ratio has been around 3-6%.
- Monkeypox is transmitted to humans through close contact with an infected person or animal, or with material contaminated with the virus.
- Monkeypox virus is transmitted from one person to another by close contact with lesions, body fluids, respiratory droplets and contaminated materials such as bedding.
- The clinical presentation of monkeypox resembles that of smallpox, a related orthopoxvirus infection which was declared eradicated worldwide in 1980. Monkeypox is less contagious than smallpox and causes less severe illness.
- Vaccines used during the smallpox eradication programme also provided protection against monkeypox. Newer vaccines have been developed of which one has been approved for prevention of monkeypox
- An antiviral agent developed for the treatment of smallpox has also been licensed for the treatment of monkeypox.

Introduction

Monkeypox is a viral zoonosis (a virus transmitted to humans from animals) with symptoms very similar to those seen in the past in smallpox patients, although it is clinically less severe. With the eradication of smallpox in 1980 and subsequent cessation of smallpox vaccination, monkeypox has emerged as the most important orthopoxvirus for public health. Monkeypox primarily occurs in Central and West Africa, often in proximity to tropical rainforests and has been increasingly appearing in urban areas. Animal hosts include a range of rodents and non-human primates.

The pathogen

Monkeypox virus is an enveloped double-stranded DNA virus that belongs to the *Orthopoxvirus* genus of the *Poxviridae* family. There are two distinct genetic clades of the monkeypox virus – the Central African (Congo Basin) clade and the West African clade. The Congo Basin clade has historically caused more severe disease and was thought to be more transmissible. The geographical division between the two clades has so far been in Cameroon - the only country where both virus clades have been found.

Natural host of monkeypox virus

Various animal species have been identified as susceptible to monkeypox virus.. This includes rope squirrels, tree squirrels, Gambian pouched rats, dormice, non-human primates and other species. Uncertainty remains on the natural history of monkeypox virus and further studies are needed to identify the exact reservoir(s) and how virus circulation is maintained in nature.

Outbreaks

Human monkeypox was first identified in humans in 1970 in the Democratic Republic of the Congo in a 9-year-old boy in a region where smallpox had been eliminated in 1968. Since then, most cases have been reported from rural, rainforest regions of the Congo Basin, particularly in the Democratic Republic of the Congo and human cases have increasingly been reported from across Central and West Africa.

Since 1970, human cases of monkeypox have been reported in 11 African countries – Benin, Cameroon, the Central African Republic, the Democratic Republic of the Congo, Gabon, Cote d'Ivoire, Liberia, Nigeria, the Republic of the Congo, Sierra Leone, and South Sudan. The true burden of monkeypox is not known. For example, in 1996–97, an outbreak was reported in the Democratic Republic of the Congo with a lower case fatality ratio and a higher attack rate than usual. A concurrent outbreak of chickenpox (caused by the varicella virus, which is not an orthopoxvirus) and monkeypox was found which could explain real or apparent changes in transmission dynamics in this case. Since 2017, Nigeria has experienced a large outbreak, with over 500 suspected cases and over 200 confirmed cases and a case fatality ratio of approximately 3%. Cases continue to be reported until today.

Monkeypox is a disease of global public health importance as it not only affects countries in West and Central Africa, but the rest of the world. In 2003, the first monkeypox outbreak outside of Africa was in the United States of America and was linked to contact with infected pet prairie dogs. These pets had been housed with Gambian pouched rats and dormice that had been imported into the country from Ghana. This outbreak led to over 70 cases of monkeypox in the U.S. Monkeypox has also been reported in travelers from Nigeria to Israel in September 2018, to the United Kingdom in September 2018, December 2019, May 2021 and May 2022, to Singapore in May 2019, and to the United States of America in July and November 2021. In May 2022, multiple cases of monkeypox were identified in several non-

endemic countries. Studies are currently underway to further understand the epidemiology, sources of infection, and transmission patterns.

Transmission

Animal-to-human (zoonotic) transmission can occur from direct contact with the blood, bodily fluids, or cutaneous or mucosal lesions of infected animals. In Africa, evidence of monkeypox virus infection has been found in many animals including rope squirrels, tree squirrels, Gambian poached rats, dormice, different species of monkeys and others. The natural reservoir of monkeypox has not yet been identified, though rodents are the most likely. Eating inadequately cooked meat and other animal products of infected animals is a possible risk factor. People living in or near forested areas may have indirect or low-level exposure to infected animals.

Human-to-human transmission can result from close contact with respiratory secretions, skin lesions of an infected person or recently contaminated objects. Transmission via droplet respiratory particles usually requires prolonged face-to-face contact, which puts health workers, household members and other close contacts of active cases at greater risk. However, the longest documented chain of transmission in a community has risen in recent years from six to nine successive person-to-person infections. This may reflect declining immunity in all communities due to cessation of smallpox vaccination. Transmission can also occur via the placenta from mother to fetus (which can lead to congenital monkeypox) or during close contact during and after birth. While close physical contact is a well-known risk factor for transmission, it is unclear at this time if monkeypox can be transmitted specifically through sexual transmission routes. Studies are needed to better understand this risk.

Signs and symptoms

The incubation period (interval from infection to onset of symptoms) of monkeypox is usually from 6 to 13 days but can range from 5 to 21 days.

The infection can be divided into two periods:

- the invasion period (lasts between 0-5 days) characterized by fever, intense headache, lymphadenopathy (swelling of the lymph nodes), back pain, myalgia (muscle aches) and intense asthenia (lack of energy). Lymphadenopathy is a distinctive feature of monkeypox compared to other diseases that may initially appear similar (chickenpox, measles, smallpox)
- the skin eruption usually begins within 1-3 days of appearance of fever. The rash tends to be more concentrated on the face and extremities rather than on the trunk. It affects the face (in 95% of cases), and palms of the hands and soles of the feet (in 75% of cases). Also affected are oral mucous membranes (in 70% of cases), genitalia (30%), and conjunctivae (20%), as well as the cornea. The rash evolves sequentially from macules (lesions with a flat base) to papules (slightly raised firm lesions), vesicles (lesions filled with clear fluid), pustules (lesions filled with yellowish fluid), and

crusts which dry up and fall off. The number of lesions varies from a few to several thousand. In severe cases, lesions can coalesce until large sections of skin slough off.

Monkeypox is usually a self-limited disease with the symptoms lasting from 2 to 4 weeks. Severe cases occur more commonly among children and are related to the extent of virus exposure, patient health status and nature of complications. Underlying immune deficiencies may lead to worse outcomes. Although vaccination against smallpox was protective in the past, today persons younger than 40 to 50 years of age (depending on the country) may be more susceptible to monkeypox due to cessation of smallpox vaccination campaigns globally after eradication of the disease. Complications of monkeypox can include secondary infections, bronchopneumonia, sepsis, encephalitis, and infection of the cornea with ensuing loss of vision. The extent to which asymptomatic infection may occur is unknown.

The case fatality ratio of monkeypox has historically ranged from 0 to 11 % in the general population and has been higher among young children. In recent times, the case fatality ratio has been around 3-6%.

Diagnosis

The clinical differential diagnosis that must be considered includes other rash illnesses, such as chickenpox, measles, bacterial skin infections, scabies, syphilis, and medication-associated allergies. Lymphadenopathy during the prodromal stage of illness can be a clinical feature to distinguish monkeypox from chickenpox or smallpox.

If monkeypox is suspected, health workers should collect an appropriate sample and have it transported safely to a laboratory with appropriate capability. Confirmation of monkeypox depends on the type and quality of the specimen and the type of laboratory test. Thus, specimens should be packaged and shipped in accordance with national and international requirements. Polymerase chain reaction (PCR) is the preferred laboratory test given its accuracy and sensitivity. For this, optimal diagnostic samples for monkeypox are from skin lesions – the roof or fluid from vesicles and pustules, and dry crusts. Where feasible, biopsy is an option. Lesion samples must be stored in a dry, sterile tube (no viral transport media) and kept cold. PCR blood tests are usually inconclusive because of the short duration of viremia relative to the timing of specimen collection after symptoms begin and should not be routinely collected from patients.

As orthopoxviruses are serologically cross-reactive, antigen and antibody detection methods do not provide monkeypox-specific confirmation. Serology and antigen detection methods are therefore not recommended for diagnosis or case investigation where resources are limited. Additionally, recent or remote vaccination with a vaccinia-based vaccine (e.g. anyone vaccinated before smallpox eradication, or more recently vaccinated due to higher risk such as orthopoxvirus laboratory personnel) might lead to false positive results.

In order to interpret test results, it is critical that patient information be provided with the specimens including: a) date of onset of fever, b) date of onset of rash, c) date of specimen collection, d) current status of the individual (stage of rash), and e) age.

Therapeutics

Clinical care for monkeypox should be fully optimized to alleviate symptoms, manage complications and prevent long-term sequelae. Patients should be offered fluids and food to maintain adequate nutritional status. Secondary bacterial infections should be treated as indicated. An antiviral agent known as tecovirimat that was developed for smallpox was licensed by the European Medical Association (EMA) for monkeypox in 2022 based on data in animal and human studies. It is not yet widely available.

If used for patient care, tecovirimat should ideally be monitored in a clinical research context with prospective data collection.

Vaccination

Vaccination against smallpox was demonstrated through several observational studies to be about 85% effective in preventing monkeypox. Thus, prior smallpox vaccination may result in milder illness. Evidence of prior vaccination against smallpox can usually be found as a scar on the upper arm. At the present time, the original (first-generation) smallpox vaccines are no longer available to the general public. Some laboratory personnel or health workers may have received a more recent smallpox vaccine to protect them in the event of exposure to orthopoxviruses in the workplace. A still newer vaccine based on a modified attenuated vaccinia virus (Ankara strain) was approved for the prevention of monkeypox in 2019. This is a two-dose vaccine for which availability remains limited. Smallpox and monkeypox vaccines are developed in formulations based on the vaccinia virus due to cross-protection afforded for the immune response to orthopoxviruses.

Prevention

Raising awareness of risk factors and educating people about the measures they can take to reduce exposure to the virus is the main prevention strategy for monkeypox. Scientific studies are now underway to assess the feasibility and appropriateness of vaccination for the prevention and control of monkeypox. Some countries have, or are developing, policies to offer vaccine to persons who may be at risk such as laboratory personnel, rapid response teams and health workers.

Reducing the risk of human-to-human transmission

Surveillance and rapid identification of new cases is critical for outbreak containment. During human monkeypox outbreaks, close contact with infected persons is the most significant risk factor for monkeypox virus infection. Health workers and household members are at a greater risk of infection. Health workers caring for patients with suspected or confirmed monkeypox virus infection, or handling specimens from them, should implement standard infection control precautions. If possible, persons previously vaccinated against smallpox should be selected to care for the patient.

Samples taken from people and animals with suspected monkeypox virus infection should be handled by trained staff working in suitably equipped laboratories. Patient specimens must be safely prepared for transport with triple packaging in accordance with WHO guidance for transport of infectious substances.

The identification in May 2022 of clusters of monkeypox cases in several non-endemic countries with no direct travel links to an endemic area is atypical. Further investigations are underway to determine the likely source of infection and limit further onward spread. As the source of this outbreak is being investigated, it is important to look at all possible modes of transmission in order to safeguard public health. [Further information on this outbreak can be found here](#)

Reducing the risk of zoonotic transmission

Over time, most human infections have resulted from a primary, animal-to-human transmission. Unprotected contact with wild animals, especially those that are sick or dead, including their meat, blood and other parts must be avoided. Additionally, all foods containing animal meat or parts must be thoroughly cooked before eating.

Preventing monkeypox through restrictions on animal trade

Some countries have put in place regulations restricting importation of rodents and non-human primates. Captive animals that are potentially infected with monkeypox should be isolated from other animals and placed into immediate quarantine. Any animals that might have come into contact with an infected animal should be quarantined, handled with standard precautions and observed for monkeypox symptoms for 30 days.

How monkeypox relates to smallpox

The clinical presentation of monkeypox resembles that of smallpox, a related orthopoxvirus infection which has been eradicated. Smallpox was more easily transmitted and more often fatal as about 30% of patients died. The last case of naturally acquired smallpox occurred in 1977, and in 1980 smallpox was declared to have been eradicated worldwide after a global campaign of vaccination and containment. It has been 40 or more years since all countries ceased routine smallpox vaccination with vaccinia-based vaccines. As vaccination also protected against monkeypox in West and Central Africa, unvaccinated populations are now also more susceptible to monkeypox virus infection.

Whereas smallpox no longer occurs naturally, the global health sector remains vigilant in the event it could reappear through natural mechanisms, laboratory accident or deliberate release. To ensure global preparedness in the event of reemergence of smallpox, newer vaccines, diagnostics and antiviral agents are being developed. These may also now prove useful for prevention and control of monkeypox.

WHO response

WHO supports Member States with surveillance, preparedness and outbreak response activities for monkeypox in affected countries. More information can be found [here](#).

News

[WHO working closely with countries responding to monkeypox 20 May 2022](#)

Events

[WHO Monkeypox Research: What are the knowledge gaps and priority research questions? 2 June 2022 13:00 – 19:30 CET](#)

Documents

[Monkey Pox Data Collection Toolbox final - Inis 20 November-update June 2021 \(111 KB\)](#)

World Economic Forum Annual Meeting

Davos-Klosters, Switzerland, 22 - 26 May 2022

As of 18 May 2022

List of confirmed Public Figures

Ministerial Portfolio / Category	# of Registered PFs
Heads of State and Government	50
Foreign Affairs	30
Finance / Economy	43
Trade / Commerce / Industry	27
Central Bank	7
International Organizations	36
Digital / Information, Communication and Technology	11
Energy and Resources	11
Environment	17
Health	6
Labor / Social Affairs / Education	6
Transport and Infrastructure	5
Defence and Intelligence Chiefs	3
Others	58
TOTAL	310

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Martín Guzmán	Minister of Economy of Argentina	Argentina
Matías Kulfas	Minister of Productive Development of Argentina	Argentina
Vahagn Khachaturyan	President of Armenia	Armenia
Karl Nehammer	Federal Chancellor of Austria	Austria
Alexander Schallenberg	Federal Minister for European and International Affairs of Austria	Austria
Magnus Brunner	Minister of Finance of Austria	Austria
Mikayil Jabbarov	Minister of Economy of Azerbaijan	Azerbaijan
Khalid Bin Ahmed Al Khalifa	Adviser on Diplomatic Affairs to the King of Bahrain	Bahrain
Salman bin Khalifa Al Khalifa	Minister of Finance and National Economy of Bahrain	Bahrain
Zayed Rashid Al Zayani	Minister of Industry and Commerce of Bahrain	Bahrain
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Andrzej Duda	President of Poland	Poland
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Waldemar Buda	Minister of Economic Development and Technology of Poland	Poland
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Mohammed Bin Abdulrahman Al Thani	Deputy Prime Minister and Minister of Foreign Affairs of Qatar	Qatar
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Mohammed bin Hamad bin Qassim Al Abdulla Al Thani	Minister of Commerce and Industry of Qatar	Qatar
Saad bin Sherida Al Kaabi	Minister of Energy of Qatar	Qatar
Lolwah AlKhater	Assistant Minister of Foreign Affairs of Qatar	Qatar
Kyung-Won Na	Special Envoy of the President of the Republic of Korea	Republic of Korea
Stevo Pendarovski	President of North Macedonia	Republic of North Macedonia
Bogdan Aurescu	Minister of Foreign Affairs of Romania	Romania
Paul Kagame	President of Rwanda	Rwanda
Clare Akamanzi	Chief Executive Officer, Rwanda Development Board (RDB)	Rwanda

Paula Ingabire	Minister of Information Communication Technology and Innovation of Rwanda	Rwanda
Vincent Biruta	Minister of Foreign Affairs and International Cooperation of Rwanda	Rwanda
John Rwangombwa	Governor of the National Bank of Rwanda	Rwanda
Abdulaziz Bin Salman Bin Abdulaziz Al Saud	Minister of Energy of Saudi Arabia	Saudi Arabia
Abdullah AlSwaha	Minister of Communications and Information Technology of Saudi Arabia	Saudi Arabia
Faisal Alibrahim	Minister of Economy and Planning of Saudi Arabia	Saudi Arabia
Faisal bin Farhan Al Saud	Minister of Foreign Affairs of Saudi Arabia	Saudi Arabia
Khalid Al-Falih	Minister of Investment of Saudi Arabia	Saudi Arabia
Mohammed Al-Jadaan	Minister of Finance of Saudi Arabia	Saudi Arabia
Haifa Bint Mohammed Al Saud	Assistant Minister for Strategy and Executive Affairs, Ministry of Tourism of Saudi Arabia	Saudi Arabia
Abdoulaye Diouf Sarr	Minister of Health and Social Action of Senegal	Senegal
Aleksandar Vučić	President of Serbia	Serbia
Tharman Shanmugaratnam	Senior Minister, Government of Singapore	Singapore
Josephine Teo	Minister for Communications and Information of Singapore	Singapore
S Iswaran	Minister for Transport; Minister-in-Charge of Trade Relations of Singapore	Singapore
Eduard Heger	Prime Minister of the Slovak Republic	Slovakia
Enoch Godongwana	Minister of Finance of South Africa	South Africa
Grace Naledi Mandisa Pandor	Minister of International Relations and Cooperation of South Africa	South Africa
Mmamoloko Kubayi-Ngubane	Minister of Human Settlements of South Africa	South Africa
Pedro Sánchez	Prime Minister of Spain	Spain
Teresa Ribera	Deputy Prime Minister and Minister for the Ecological Transition of Spain	Spain
José Manuel Albares Bueno	Minister of Foreign Affairs, European Union and Cooperation of Spain	Spain
Reyes Maroto Illera	Minister of Industry, Commerce and Tourism of Spain	Spain
Khashayar Farmanbar	Minister for Energy and Digital Development of Sweden	Sweden
Mikael Damberg	Minister for Finance of Sweden	Sweden
Anna König Jerlmyr	Mayor of Stockholm, Sweden	Sweden
Ignazio Cassis	President of the Swiss Confederation and Federal Councillor for Foreign Affairs of Switzerland	Switzerland
Alain Berset	Vice-President of the Swiss Confederation and Federal Councillor of Home Affairs	Switzerland
Guy Parmelin	Federal Councillor for Economic Affairs, Education and Research of Switzerland	Switzerland
Simonetta Sommaruga	Federal Councillor for the Environment, Transport, Energy and Communications of Switzerland	Switzerland
Ueli Maurer	Federal Councillor of Finance of Switzerland	Switzerland
Viola Amherd	Federal Councillor of Defence, Civil Protection and Sports of Switzerland	Switzerland
Thomas Hefti	President of the Council of States of Switzerland, 2021-2022	Switzerland
Walter Thurnherr	Federal Chancellor of the Swiss Confederation	Switzerland

Philip Isdor Mpango	Vice-President of the United Republic of Tanzania	Tanzania
Hussein Mohamed Bashe	Minister of Agriculture of Tanzania	Tanzania
Mwigulu Nchemba Madelu	Minister of Finance of Tanzania	Tanzania
Saada Mkuya Salum	Minister of State, Finance and Planning of Tanzania	Tanzania
Sethaput Suthiwartnarueput	Governor of Bank of Thailand, Bank of Thailand, Thailand	Thailand
Najla Bouden	Prime Minister of Tunisia	Tunisia
Siheem Boughdiri Nemsia	Minister of Finance of Tunisia	Tunisia
Marouane El Abassi	Governor of the Central Bank of Tunisia, Central Bank of Tunisia, Tunisia	Tunisia
Mykhailo Fedorov	Deputy Prime Minister, Minister of Digital Transformation of Ukraine	Ukraine
Yuliia Svyrydenko	First Deputy Prime Minister, Minister of Economy of Ukraine	Ukraine
Dmytro Kuleba	Minister of Foreign Affairs of Ukraine	Ukraine
Kyrylo Shevchenko	Governor of the National Bank of Ukraine	Ukraine
Alona Shkrum	Member of Parliament (Verkhovna Rada) of Ukraine	Ukraine
Anastasia Radina	Member of Parliament (Verkhovna Rada) of Ukraine	Ukraine
Ivanna Klympush-Tsintsadze	Member of Parliament (Verkhovna Rada) of Ukraine	Ukraine
Yevheniia Kravchuk	Member of Parliament (Verkhovna Rada) of Ukraine	Ukraine
Yulia Klymenko	Member of Parliament (Verkhovna Rada) of Ukraine	Ukraine
Vitaliy Klitschko	Mayor of Kyiv, Ukraine	Ukraine
Volodymyr Zelenskyy (virtual participation)	President of Ukraine	Ukraine
Maktoum bin Mohammed bin Rashid Al Maktoum	Deputy Prime Minister and Minister of Finance	United Arab Emirates
Abdulla Bin Touq Al Marri	Minister of Economy of the United Arab Emirates	United Arab Emirates
Mariam Mohammed Saeed Al Mheiri	Minister of Climate Change and the Environment of United Arab Emirates	United Arab Emirates
Mohammad Abdullah Al Gergawi	Minister of Cabinet Affairs of the United Arab Emirates	United Arab Emirates
Ohoud Bint Khalfan Al Roumi	Minister of State for Government Development and the Future of the United Arab Emirates	United Arab Emirates
Shamma bint Suhail Faris Al Mazrui	Minister of State for Youth Affairs of the United Arab Emirates	United Arab Emirates
Thani Ahmed Al Zeyoudi	Minister of State for Foreign Trade of the United Arab Emirates	United Arab Emirates
Mohamed bin Hadi Al Hussaini	Minister of State for Financial Affairs, Ministry of Finance of the United Arab Emirates	United Arab Emirates
Omar Sultan Al Olama	Minister of State for Artificial Intelligence, Digital Economy and Remote Work Applications of the United Arab Emirates	United Arab Emirates
Sarah Al Amiri	Minister of State for Advanced Technology, Ministry of Industry and Advanced Technology of the United Arab Emirates	United Arab Emirates
Shakhboot bin Nahyan AlNahyan	Minister of State of the United Arab Emirates	United Arab Emirates
Alok Sharma	President, 26th Conference of the Parties (COP26) to the United Nations Framework Convention on Climate Change	United Kingdom

Gerry Grimstone of Boscobel	Minister for Investment of the United Kingdom	United Kingdom
Vincent Keaveny	Lord Mayor, City of London Corporation, United Kingdom	United Kingdom
Gina Raimondo	Secretary of Commerce of USA	USA
John F. Kerry	Special Presidential Envoy for Climate of the United States of America	USA
Bill Keating	Congressman from Massachusetts (D), 9th District, U.S. House of Representatives, USA	USA
Daniel Meuser	Congressman from Pennsylvania (R), 9th District, U.S. House of Representatives, USA	USA
Madeleine Dean	Congresswoman from Pennsylvania (D), 4th District, U.S. House of Representatives, USA	USA
Ted Lieu	Congressman from California (D), 33rd District, U.S. House of Representatives, USA	USA
Ann Wagner	Congresswoman from Missouri (R), 2nd District, USA	USA
Christopher A. Coons	Senator from Delaware (D), USA	USA
Darrell Issa	Congressman from California (R), 50th District, USA	USA
Dean Phillips	Congressman from Minnesota (D), 3rd District, USA	USA
Debra Fischer	Senator from Nebraska (R), USA	USA
Eric Holcomb	Governor of Indiana, USA	USA
Gregory W. Meeks	Congressman from New York (D), 6th District, USA	USA
John W. Hickenlooper	Senator from Colorado (D), USA	USA
Larry Hogan	Governor of Maryland, USA	USA
Michael McCaul	Congressman from Texas (R), 10th District, USA	USA
Pat Toomey	Senator from Pennsylvania (R), USA	USA
Patrick J. Leahy	Senator from Vermont (D), USA	USA
Robert Menendez	Senator from New Jersey (D), USA	USA
Roger F. Wicker	Senator from Mississippi (R), USA	USA
Seth Moulton	Congressman from Massachusetts (D), 6th District, USA	USA
Sheldon Whitehouse	Senator from Rhode Island (D), USA	USA
Ted Deutch	Congressman from Florida (D), 22nd District, USA	USA
Francis Suarez	Mayor of Miami, USA	USA
Al Gore	Vice-President of the United States (1993-2001); Chairman and Co-Founder, Generation Investment Management, USA	USA
Peter Kodwo Turkson	Chancellor, Pontifical Academy of Sciences and the Pontifical Academy of Social Sciences of the Holy See	Vatican City State
Le Minh Khai	Deputy Prime Minister of Viet Nam	Viet Nam
Thanh Nghi Nguyen	Minister of Construction of Viet Nam	Viet Nam
Hakainde Hichilema	President of Zambia	Zambia
Situmbeko Musokotwane	Minister of Finance and National Planning of Zambia	Zambia
Emmerson Mnangagwa	President of Zimbabwe	Zimbabwe
Frederick Shava	Minister of Foreign Affairs of Zimbabwe	Zimbabwe
Mthuli Ncube	Minister of Finance and Economic Development of Zimbabwe	Zimbabwe

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* This designation is without prejudice to positions on status, and is in line with United Nations Security Council resolution 1244 (1999) and the International Court of Justice Opinion on the Kosovo declaration of independence.