



BRIEFER

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Key U.S. Initiatives for Addressing Biological Threats Part 3: The Biological Threat Reduction Program

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INTRODUCTION

The first case of COVID-19 identified outside of China occurred on January 13, 2020, in Thailand. This early detection can in large part be credited to a little-known yet essential U.S. Department of Defense (DoD) program, the Biological Threat Reduction Program (BTRP), which equipped partners in Thailand with disease surveillance technologies and trained experts on their use.¹

This is just one of countless examples of the BTRP's successes stemming back to the immediate post-Cold War years when the program helped guide the world through one of the more tumultuous periods of technology-related risk in modern history.

Between 1972 and 1991 the Soviet Union amassed the largest biological weapons stockpile in history--sufficient to end all life on Earth. This included the annual production of twenty tons of smallpox, a disease that kills thirty percent of those infected and spreads just as easily as SARS-CoV-2.² The Soviet

¹ Andrea Chaney, "<u>Strong International Relationships Enabled DTRA to Provide COVID-19 Support to Partners</u> <u>Abroad</u>," Office of the Deputy Assistant Secretary of the Army for Defense Exports and Cooperation, February 2, 2021.

² Milton Leitenberg, Raymond A. Zilinskas, and Jens H. Kuhn, *The Soviet Biological Weapons Program*, Harvard University Press, 2012; Donald A. Henderson, "The eradication of smallpox-an overview of the past, present, and

program included up to 65,000 employees in 50 to 60 facilities.³ Then, in 1991, the Soviet Union disbanded. The weapons, equipment, facilities, raw materials, and people involved in this program became one of the top weapons of mass destruction risks in the world. The United States stepped in and worked hand-in-hand with Soviet successor states to keep countries such as Iran from inheriting Soviet biological weapons capabilities. Originally called the Cooperative Biological Engagement Program, BTRP work helped to destroy these biological weapons facilities, secure dangerous pathogens, and put experts to work in peaceful pursuits.

BTRP has grown and changed over its approximate twenty-five years of protecting the world from biological threats, and it must be resourced and led to continue evolving as biological threats do. The scale, geographic spread, and irresponsibility of the activities of the Soviet biological weapons program were an intimidating problem. The unrestrained growth in the number of high-containment research labs throughout the world including in countries like China poses similar biosafety and security problems. Dangerous activities such as gain-of-function research and efforts to discover new viruses from nature pose dangerous pandemic and potentially biological weapons threats, even if they may provide some public health benefits. Developments in biotechnology are making it easier for actors to engineer biological weapons; viruses or bacteria engineered to slip by existing pathogen early warning systems and countermeasures are well within reach of the majority of countries today and are poised as a serious potential asymmetric threat to U.S. and allied forces.

Fully leveraging the historic BTRP program and all the assets it holds will require realignment of resources and policy instruction. BTRP enjoys the support of several, cross-party Congressional champions. White House guidance in April 2021 indicated that top DoD priorities should include "biological threat reduction in cooperation with global partners, emerging infectious disease surveillance, biosafety and biosecurity, and medical countermeasure research and development."⁴ BTRP is one of the core programs to advance such work. Yet in the final administration budget submitted to Congress, BTRP funding was slashed by 45% from the prior year.⁵

This briefer is part of a Council on Strategic Risks series on improving the U.S. biodefense enterprise and its ability to address and deter biological weapons threats. As a key program in this regard, it provides several recommendations to help ensure the BTRP is sufficiently robust and effective in the coming years. It concludes by recommending that BTRP resources be increased to up to \$400 million per year, a level of effort more commensurate with the threats the program addresses and sufficient to position BTRP as a key contributor to the U.S. bioeconomy as a strategic asset of the nation.

future," *Vaccine* 29 (2011): D7-D9. This quantity can be compared to the estimated amount of SARS-CoV-2 in all human hosts in the world: a maximum of 22 lbs. Ron Sender, Yinon M. Bar-On, Shmuel Gleizer, Biana Bernshtein, Avi Flamholz, Rob Phillips, and Ron Milo, "<u>The total number and mass of SARS-CoV-2 virions</u>," *Proceedings of the National Academy of Sciences* 118, no. 25, 2021.

³ Ibid.

⁴ U.S. White House, "<u>Summary of the President's Discretionary Funding Request</u>," Letter to the Senate, April 9, 2021.

⁵ Department of Defense, Office of the Undersecretary of Defense (Comptroller), <u>Fiscal Year 2022 President's</u> <u>Budget: Cooperative Threat Reduction Program</u>, accessed July 25, 2021.

MAXIMIZE BTRP'S LONG-TERM CONTRIBUTIONS TO U.S. SECURITY STRATEGY

It is in the strategic interest of the United States to be the most attractive partner for countries seeking cooperation and support in enhancing their capacities to mitigate biological threats. If the United States does not play this role, other countries will do so, including Russia and China.

China and Russia in particular target audiences in Central Asia, Southeast Asia, the Middle East, Africa, and elsewhere to cast their respective nations as an ideal partner. This can generally have a negative effect on U.S. interests. It increases the odds of such nations adopting norms and worldviews that may not align with those of the United States. In concrete terms, it also means that audiences in these regions receive misinformation conveyed by these nations---for example, Russian accusations that U.S. threat reduction programs are hiding bioweapons activities, and Chinese misinformation surrounding COVID-19. The long-term trust produced through BTRP and other bio cooperation programs is critical for countering this.

In many cases, trust-building requires sustaining relationships and cooperative efforts over the long term, just as BTRP has facilitated partnerships with former Soviet states such as Kazakhstan and Georgia for decades. Yet in recent years, the Defense Threat Reduction Agency (DTRA, which implements the program) has faced pressure to build capacity and then mostly exit countries with which it has invested. These nations take on more programmatic responsibility over time (e.g., sustainment costs for laboratories and personnel), yet too-steep reductions in U.S. presence would undercut the nation's ability to understand Russia's behavior in the region and effectively deter Russian aggression. Via persistent, long term cooperative partnerships, BTRP both directly reduces biological risks and supports broader U.S. security imperatives.

Ensuring high-level Executive Branch and Congressional support for BTRP will require that key leaders regularly, effectively communicate how this program helps to enact U.S. strategy on the ground in important regions. For example, those in positions like the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs and the DTRA Director can help ensure this work is tied into the national security strategy, and inform the highest-level defense leaders about the importance of these programs continually to help increase support for strong budgets during annual planning cycles. Too often, defense and diplomatic leaders with regional focuses are unaware of how functional programs like BTRP can support their goals. It is incumbent on BTRP leaders and those that oversee the program to communicate its benefits effectively to these audiences.

While partner nations need to bring their own resources to sustaining capabilities so that U.S. contributions can shrink over time, maintaining relationships built and awareness of the bio activities of these partners is invaluable for the United States. Given that biological threats grow exponentially and spread across borders, close, consistent relationships allow the United States far better early knowledge of emerging biological threats that can inform DoD and the nation in implementing appropriate precautions and mitigation strategies---for example, developing and deploying diagnostic tests for specific pathogens around U.S. bases and embassies.

BTRP strengthens ties to key partners and allies and enhances the U.S. position vis-a-vis countries like China and Russia---in addition to direct successes in mitigating biological threats. The program also directly helps to protect U.S. forces, allies, and the public. The following, specific areas of effort all support these national goals.

REDUCE GAPS AT HIGH-RISK HOTSPOTS

Governments in many countries lack strong, central knowledge of what researchers may be doing with especially dangerous pathogens within their own borders. Until recently there was no public accounting of high-containment labs (those designated at biosafety levels 3 and 4) dealing with dangerous pathogens globally, though such labs have proliferated in number recently.⁶ BTRP's work includes promoting consolidation of dangerous pathogens at such labs and training their personnel to improve safety and security. This should be one of the top priorities of the Department of Defense and the U.S. government more broadly.

BTRP should focus additional resources on high-risk hotspots like these high-containment laboratories in the years ahead. The open question (as of this writing) on whether COVID-19 was initiated via a lab accident from a facility conducting work on the pathogen shows the critical importance of work to reduce the risks of such accidents.

Cooperative biosafety and biosecurity activities can have the added benefit of increasing transparency regarding countries' biodefense programs. The Biological and Toxin Weapons Convention (BWC) does not effectively distinguish between allowable biodefense activities and prohibited bioweapons work, making insights from programs like BTRP regarding the nature and intention of bio work conducted around the world invaluable.

LEVERAGE BTRP TO ADVANCE PATHOGEN EARLY WARNING

One of the great successes of BTRP to date has been in building biosurveillance capacity with key partner nations around the world---including those proximate to nations for which the United States is concerned about biological weapons activities such as North Korea and Russia.⁷ BTRP is therefore ideally positioned to help implement the vision coalescing across the international community of transforming biosurveillance (by which disease threats are often detected and tracked days, weeks, or longer after they emerge) into a real-time pathogen early warning system.

Implementation will entail wider use of tools like next-generation genomic sequencing (especially metagenomic sequencing) which can help in finding and characterizing a vast range of pathogens within hours, coupled with big-data analytics and machine learning systems that can rapidly warn of potential emerging threats. This could significantly increase global capacity for halting natural outbreaks. Yet some of its greatest promise is for quickly identifying deliberately-introduced biological threats. Pathogen early warning tools, including those that have just come into use in the past few years, offer incredible promise against biological weapons---think, for example, of the benefit to further improving pathogen early warning in South Korea, where tens of thousands of U.S. defense personnel and their families reside and for which the stakes for understanding an outbreak fast are incredibly high. Indeed, such systems can be an effective deterrent against the development and use of biological weapons.

Not all of today's biosurveillance capabilities are useful in detecting the signs of a biological event that may stem from a deliberate attack or involve engineered pathogens. Some are slower than is helpful in

⁶ A new resource on the highest containment labs in the world and their locations is now being led by renowned experts Gregory D. Koblentz and Filippa Lentzos. See <u>www.globalbiolabs.org</u>, accessed July 20, 2021.

⁷ U.S. Department of State, "<u>Adherence and Compliance with Arms Control, Nonproliferation, and Disarmament</u> <u>Agreements and Commitments</u>," August 2019, p. 45-50.

terms of keeping defense forces safe. Others are capable of only detecting specific, known pathogens and are not useful for novel diseases such as COVID-19 was.

One of the most important ways in which BTRP should expand in the coming years is in building on its rich history of collaboration and existing, trusted relationships around the world to deploy cutting-edge early warning capabilities that will be maximally useful in catching and characterizing deliberate biological threats and new, novel pathogens that may pose serious risks to U.S. and allied personnel. As technologies such as metagenomic sequencing are deployed more broadly, BTRP should be at the forefront of providing them to existing and new partners and ensuring training for their use, as it has done with longer-standing genomic surveillance approaches with partners in the former Soviet Union, Southeast Asia, and elsewhere.⁸

EXPAND BTRP AUTHORITIES & EXERCISE THEM MAXIMALLY

One of the most important aspects of BTRP is that the program is designed with flexibility to either perform its work directly or to fund other, non-defense entities to execute projects, depending on what is best for each threat reduction circumstance. Given the sensitive nature of biological threats and solutions, at times progress with a specific country or laboratory is most likely via universities, nongovernmental organizations, or the U.S. Centers for Disease Control and Prevention (CDC). In other cases, having a defense agency presence at the forefront is best.

Various BTRP authorities, as well as its collaboration with non-defense agencies, also help provide significant insights for understanding how potential biological weapons threats may manifest and how nefarious actors may misuse synthetic biology in the future, and otherwise improve defense force health protection.

Several examples stem from work on orthopoxviruses, which are highly concerning given their presence in the former Soviet Union's biological weapons programs, the focus on these viruses by other nations, and recent trends in experimenting with them. In 2018, Canadian scientists published an article based on work to synthesize horsepox virus, further raising concerns regarding nefarious actors synthesizing the Variola virus which causes smallpox.⁹ Human monkeypox is also rising in parts of Africa where it is endemic and which coincide with areas of longstanding conflict, and symptoms of ill patients are nearly clinically indistinguishable from smallpox. Partnerships in Africa have allowed DoD to understand trends related to monkeypox rising and mutating---insights useful to understanding potential smallpox threats as well.¹⁰

BTRP's ability to work with diverse partners directly provides windows into trends in this genus of viruses, and also allows the defense community to find efficiencies in solutions based on such knowledge. For example, the deployment of genomic sequencing in key parts of Africa has facilitated our

⁸ The technologies discussed in our briefer "Pathogen Early Warning: New Technologies and Approaches," would enable a biological weapons early warning system that is so difficult to engineer around that it would significantly help deter countries from developing or releasing biological weapons.

⁹ Tom Inglesby, "<u>Horsepox and the need for a new norm, more transparency, and stronger oversight for experiments</u> that pose pandemic risks," *PLoS Pathogens* 14(10), 2018.

¹⁰ Zygmunt F. Dembeck (COL, USA, Ret.), "<u>USAMRIID's Medical Management of Biological Casualties</u> <u>Handbook, Seventh Edition</u>," United States Army Medical Research Institute of Infectious Diseases, September 2011; Jeffrey R. Kugelman, et al., "<u>Genomic Variability of Monkeypox Virus among Humans, Democratic Republic</u> <u>of the Congo</u>," *Emerging Infectious Diseases*, Volume 20, Number 2, February 2014.

understanding of how the smallpox vaccine can be highly effective against monkeypox, which may help guide how it is used for protecting U.S. personnel in the region.

Developing trusted relationships before crises strike is likewise important. Today this is hindered by BTRP being authorized to work only in specific regions, not globally.

Acting on an urgent threat like a quickly-spreading outbreak requires working within legal and regulatory bounds, and normally requires contracts and agreements to dictate terms of providing donations and assistance. This takes time and knowledgeable personnel, which the United States can only maintain through regular, sustained activities and partnerships over time. For example, a 2020 National Academies report noted that in 2014, as an Ebola crisis was spreading in West Africa, "BTRP was in place well before the declaration by WHO of a Public Health Emergency of International Concern and a vigorous international response could be organized."¹¹

Other unique BTRP authorities also make it a powerful tool for the United States in this regard. In particular, its co-mingling authority, by which it can bring in funds from other governments and partners and spend them alongside DoD funds, facilitates rapid responses to emerging threats. The BTRP team should be sure to exercise its co-mingling authority on a regular basis to both ensure its staff can use this ability quickly in crises and benefit from the partnerships it can create.

In the years ahead, BTRP needs leadership---from DoD, other U.S. agencies, and Congress---to expand upon its operational authorities as needed, and exercise them robustly. Providing the program with the ability to operate globally, for example, can be fixed with a straightforward authorization from Congress, as recommended by the 2020 National Academies report.¹²

BTRP activities are still at times hindered by those who view its mission too narrowly and believe it should focus entirely on biological weapons threats. This is a false distinction. COVID-19 has shown the strategic effects and operational issues that a natural outbreak can cause. This perspective reduces DoD's ability to use bio engagement to gain knowledge in key regions and advance partnerships. Such collaboration directly allows DoD to leverage the investments of other governments and philanthropies, and promote capacities that will benefit biodefense and the advancement of defense-relevant technologies. Most importantly, early in an outbreak it is nearly impossible to tell if its cause is natural, deliberate, or the result of an accident. Outreach and coordination across U.S. agencies can help promote better understanding of these and other reasons why BTRP efforts must extend across the full range of biological threats.

As such, expanding the range of pathogens under BTRP's focus is an important step. Every new pathogen that is discovered or created that has pandemic potential is a national security concern. As has been seen during the SARS-CoV-2 pandemic, pathogens that are deadly and spread quickly can kill millions even with the contemporary medical care available.

BTRP generally prioritizes work to lower risks from especially dangerous pathogens (EDPs) as set by the U.S. Select Agents and Toxins List.¹³ However, this can lead to under-valuing or under-utilizing

¹¹ National Academies of Sciences, Engineering, and Medicine, "<u>A Strategic Vision for Biological Threat</u> <u>Reduction: The U.S. Department of Defense and Beyond</u>," The National Academies Press, 2020, p. 31. ¹² *Ibid*, p. 126-27.

¹³ U.S. Centers for Disease Control and Prevention and U.S. Department of Agriculture, <u>Select Agents and Toxins</u> <u>List</u>, accessed July 25, 2021.

pathogen-agnostic tools that are ideal for detecting and understanding novel pathogens, including those that may be engineered. Such a posture could contribute to missed opportunities to stop outbreaks with the potential to do significant harm to the general public and defense forces. It is also important for BTRP work to touch on pathogens related to those already considered EDPs, given that work surrounding them and access to samples could help confer tacit knowledge and materials that could be used for nefarious purposes. It is crucial for DoD to remain aware of such work as much as possible.

ATTRACT AND MAINTAIN TALENT

The future success of BTRP in mitigating biological threats will depend on the ability of the Defense Threat Reduction Agency (DTRA) to attract and retain talented people. For 2020, in the Partnership for Public Service's annual survey of best places to work in the federal government, DTRA ranked 213 of 411 agencies.¹⁴ This is actually a significant improvement over its performance in prior years, yet shows the need for continued effort. Countering weapons of mass destruction threats (and bio threats in particular) is a highly attractive mission for talented people, in particular for early-career individuals. DTRA and BTRP program leaders need to continue improving their ability to tap into this interest.

In addition to attracting talented workers to BTRP, the agency will need to keep them. Reducing turnover will be critical. Retention is especially important for threat reduction given how important long-term relationships with international and U.S. interagency partners are to success. Military personnel typically rotate every 2-3 years. Civilian turnover is also affected by the demanding nature of the work itself, among other factors.

These issues can be managed in several ways. For example, pay bands can be altered so that people can remain in the same general job and still have opportunities to grow professionally and obtain good pay increases, as other federal agencies have implemented successfully. This will allow for improvement in the high-payoff, longer term relationship-building described above as critical to understanding and addressing biological threats. An increased budget for BTRP would also allow growth in the program's staff, which would help spread out the high workload.

ALIGN INVESTMENTS

Over the coming years, DoD leaders should bring the BTRP budget up to a healthy level and plan to sustain it, for all the reasons this briefer identifies. Biological threats are rising. Addressing them via cooperative partnerships will help in realizing broader U.S. security goals. BTRP is a proven asset, and expanding it can be done with a relatively small investment.

As noted above, after several years of budget cuts, the fiscal year 2022 President's Budget Request has included significant further cuts to BTRP: at \$124 million, an astonishing 45% cut below the enacted prior year budget.

At minimum, U.S. leaders should raise the BTRP budget to \$400 million per year and plan to sustain roughly that level over the next decade. This is slightly above the program's highest funding level in the past decade (\$320 million in FY2014). Based on the current President's Budget Request, this would represent under .06% of the 2022 U.S. defense budget---yet pay an incredible return in mitigating and deterring threats. Moreover, the White House has already indicated policy support in this direction.

¹⁴ Partnership for Public Service, "2020 Best Places to Work in the Federal Government Rankings," <u>Defense Threat</u> <u>Reduction Agency</u>, accessed July 20, 2021.

A common question from Executive Branch and Congressional leaders is how to ensure BTRP activities are not redundant to biological threat reduction programs of other U.S. agencies. As the National Academies recommended in 2020, this should be addressed via a strong White House-led interagency process for coordination and identifying new threats and opportunities.

While rising budgets for other agencies such as the U.S. Agency for International Development are critical for addressing global health security writ large, that will not be sufficient for covering defense equities such as reducing risks from especially dangerous pathogens or understanding and addressing trends related to deliberate biological threats. Without significant BTRP contributions, the United States will not have the capacity it needs to deter actors' potential interests in biological weapons or strengthen U.S. defense alliances.

CONCLUSION

The stakes are high for appropriately resourcing BTRP in the years ahead. If its investments are not returned to a strong level, relationships with key partners will weaken or sever. The United States will obtain less information about how biological threats are evolving around the world, and the nation will be less effective in deterring actors who may consider the COVID-19 pandemic as proof of the strategic benefits of weaponizing diseases. It is urgent to expand this program as a cornerstone of DoD's efforts to address biological risks.

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