

Balancing Security and Transparency: Policy Considerations

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Objectives

- What are some domestic and international policies and/or agreements relevant to communication regarding enhanced PPP research?
- How are issues regarding research transparency and security addressed in the U.S. and other countries?
- What can we learn from different policy frameworks that exist, in the U.S. or elsewhere, for managing transparency and security when conducting, communicating about, or engaging public(s) on issues surrounding high consequence pathogen research?

International Agreements



Biological Weapons Convention

- **Entered into force in 1975, Review Conferences every 5 years**
- **Article 1:** “Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.”
- **Confidence Building Measures:** “in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions and in order to improve international cooperation in the field of peaceful biological activities”
 - research centers and laboratories; biological defense research and development programs; past offensive biological research and development programs; vaccine production facilities; legislation, regulation, and related measures; encouragement of publication of results and promotion of use of knowledge; and outbreaks of infectious disease.
 - **Classified research has been controversial**

UNSCR 1540 (2004)

- “affirms that the proliferation of nuclear, chemical and biological weapons and their means of delivery constitutes a threat to international peace and security. The resolution obliges States, inter alia, to refrain from supporting by any means non-State actors from developing, acquiring, manufacturing, possessing, transporting, transferring or using nuclear, chemical or biological weapons and their means of delivery.
- “imposes binding obligations on all States to adopt legislation to prevent the proliferation of nuclear, chemical and biological weapons, and their means of delivery, and establish appropriate domestic controls over related materials to prevent their illicit trafficking. It also encourages enhanced international cooperation in this regard.”

Domestic frameworks



National Security Decision Directive 189

- 1985, President Ronald Reagan, focused on Eastern Bloc, reaffirmed during Bush Administration after 9/11
- Directly stemmed from a 1982 NAS report “Scientific Communication and National Security” chaired by Dale Corson, President Emeritus, Cornell University, nuclear physicist

“Current proponents of stricter controls advocate a strategy of security through secrecy. In the view of the Panel security by accomplishment may have more to offer as a general national strategy. The long-term security of the United States depends in large part on its economic, technical, scientific, and intellectual vitality, which in turn depends on the vigorous research and development effort that openness helps to nurture... Controls on scientific communication could adversely affect U.S. research institutions and could be inconsistent with both the utilitarian and philosophical values of an open society.”

JASON report on Openness and Fundamental Research

- December, 2019, funded by NSF, focused on foreign engagement
- JASON: independent group of elite scientists who perform advisory function to USG, established in 1960
- “National Security Decision Directive (NSDD) 189, established in 1985 a clear distinction between fundamental research and classified research. This remains a cornerstone to the fundamental-research enterprise, as officially reaffirmed in 2001 and 2010 and it continues to inform policy today”
- “NSF should support reaffirmation of the principles of NSDD-189, which make clear that fundamental research should remain unrestricted to the fullest extent possible, and should discourage the use of new CUI (controlled unclassified information) definitions as a mechanism to erect intermediate-level boundaries around fundamental research areas.”

There are places for classified research

National Biodefense Analysis and Countermeasures Center

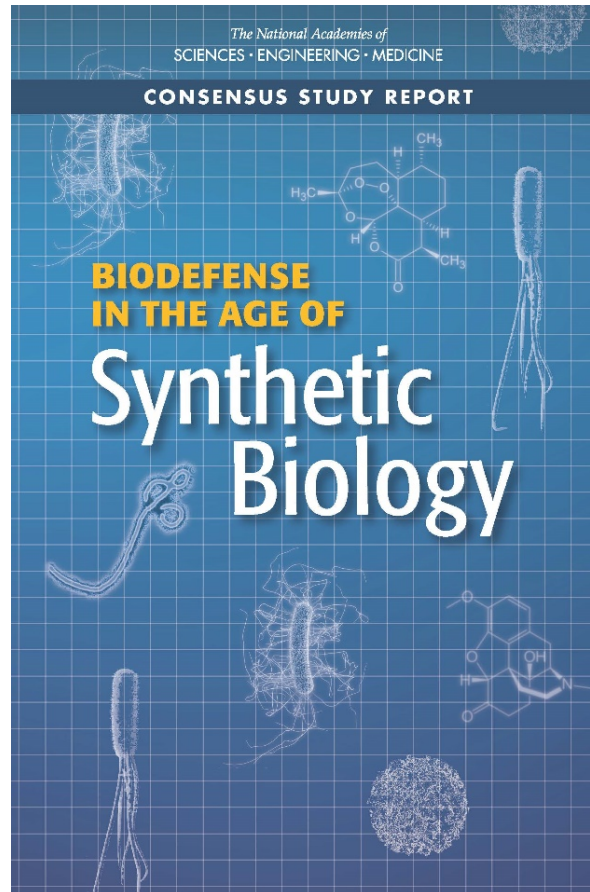
Location: Fort Detrick, MD

The National Biodefense Analysis and Countermeasures Center (NBACC) is a one-of-a-kind facility dedicated to defending the nation against biological threats. Its work supports intelligence assessments, preparedness planning, response, emerging threat characterization and bioforensic analyses. It is the first national laboratory created by DHS and the capabilities within the facility did not exist prior to the Amerithrax attacks of 2001.

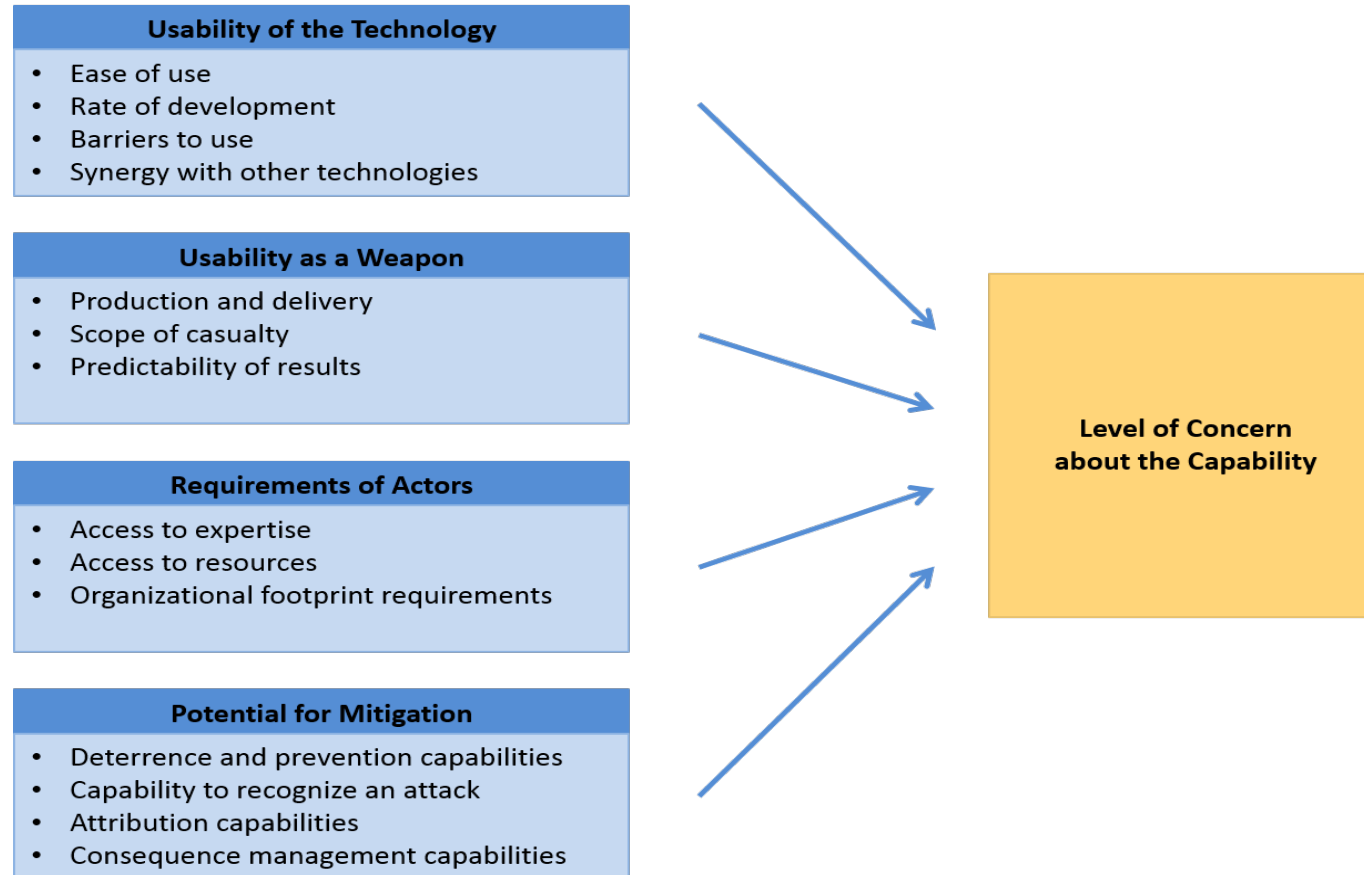
Since its inception, NBACC and its staff of more than 150 dedicated employees have filled critical shortfalls in our scientific knowledge of biological agents needed to defend the public from acts of terrorism.



Biodefense in the Age of Synthetic Biology



Framework for Assessing Relative Concern



A Holistic Assessment of the Risks and Benefits of the Synthesis of Horsepox Virus

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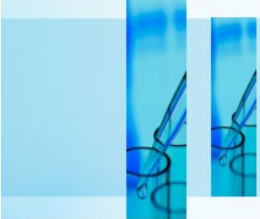
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ABSTRACT The re-creation of horsepox virus, an extinct orthopoxvirus with similarity to smallpox virus, has caused concerns in the biosecurity and biodefense communities that the technical capabilities achieved could advance the re-creation of smallpox virus by nefarious actors. The work is now published. While the authors went through due biosecurity diligence at their research institution and with the proper Canadian federal authorities, now that the experiments have been published, there is an opportunity to discuss the dual use risks and benefits of the research itself, as well as those associated with publication of such research—all of which challenge current policies. Here, an analytical framework is used to assess the risks and benefits of such dual use research, and relevant components of biosecurity policy and the biodefense enterprise (including the acquisition of medical countermeasures) in the United States are discussed. The authors emphasize the need to use such risk/benefit assessments at the onset of research and throughout its development, followed by an assessment for its responsible communication.

KEYWORDS biodefense, biosecurity, horsepox, smallpox

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Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide



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Reflections from GOF discussions

1. Safety and security should be separate discussions. Initially, NSABB focused on security, then on safety, but these are often muddled.
2. The debate over whether the work is valuable has flourished in spite of thousands of hours of discussion, high level meetings, and access to the same information.
3. Decision-making and policy making for the next DURC case will be influenced by the specifics of the research in question, the researchers involved, the urgency of the threat that the research is trying to address, and assessment of the danger that the information could be applied toward a biological weapon.
4. A framework policy that can be broadly disseminated would be helpful— but the question of “Who Decides?” will always be controversial.

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FIFTY-EIGHTH WORLD HEALTH ASSEMBLY

WHA58.29 Enhancement of laboratory biosafety

The Fifty-eighth World Health Assembly,

Considering that release of microbiological agents and toxins may have global ramifications;

Acknowledging that the containment of microbiological agents and toxins in laboratories is critical to preventing outbreaks of emerging and re-emerging diseases such as severe acute respiratory syndrome (SARS);

Recognizing the work of WHO in promoting laboratory biosafety;

Acknowledging that a number of Member States do have in place effective laboratory biosafety controls and guidelines for laboratory practice in order to manage the risks to laboratory workers and the community from microbiological agents and toxins;

Recognizing that some Member States may not have adequate biosafety controls in place;

Noting that an integrated approach to laboratory biosafety, including containment of microbiological agents and toxins, promotes global public health,

1. URGES Member States:

(1) to review the safety of their laboratories and their existing protocols for the safe handling of microbiological agents and toxins, consistent with WHO's biosafety guidance;

Further information

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