NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

Working Group on Communication of Dual Use Research Results, Methods, and Technologies





Communication Working Group Charge

- Identify issues and examine options and strategies for the responsible communication of dual use research information
- Develop principles and tools to facilitate careful, consistent decisions about how to responsibly communicate information with biosecurity implications



Working Group Roster

Voting Members:

- P. Keim (Chair)
- A. Casadevall
- L. Enquist
- D. Franz
- J. Gordon
- D. Kasper
- S. Lemon
- M. Nance
- T. Shenk
- A. Sorensen
- S. Ehrlich

Federal Agency Representatives:

B. Cuccherini (VA)

D. Dixon (NIH)

T. Lomax (NASA)

B. Lushniak (FDA)

S. Nightingale (HHS)

S. Steele (DoJ)

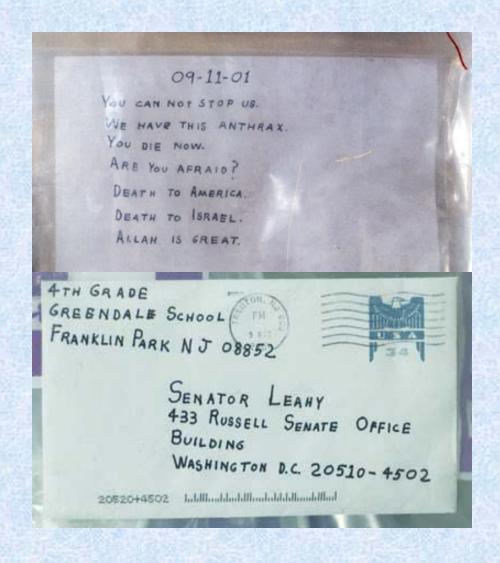
M. Schmolesky (State)

R. Walters (Intel.)



What's The Problem?

 Increasing concerns about the potential for misuse of life science research information for bioterrorism purposes





Calls to Action

Science

RESEARCH ARTICLE

Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus

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 Increasing calls for consideration of the security implications of dual use research findings

Journal Editors and Authors Group statement on the consideration of biodefense and biosecurity

We recognize that the prospect of bioterrorism has raised legitimate concerns about the potential abuse of published information, but also recognize that research in the very same fields will be critical to society in meeting the challenges of defense.

Fundamental is a view, shared by nearly all, that there is information that, although we cannot now capture it with lists or definitions, presents enough risk of use by terrorists that it should not be published.

Scientist and their journals should consider the appropriate level and design of processes to accomplish effective review of papers that raise such security issues.

Editorial Nature 421:771 (2003)

"Do no harm: reducing the potential for the misuse of life science research"

Research institutions and funding agencies need to consider how to build on existing processes for reviewing research projects to ensure that risks of misuse are assessed in an appropriate and timely manner.

"Science and Security in an Age of Terrorism"

The scientific, engineering, and health research community should work closely with the federal government to determine which research may be related to possible new security threats and to develop principles for researchers in each field.

Alberts, Wulf and Fineberg Presidents of the National Academies October 18, 2002

"US officials urge biologists to vet publications for bioterror risk"

"The science community ought to come up with a process before the public demands the government do it for them."

Parney Albright (OSTP)

Report on NAS meeting 'Scientific Openness and National Security' *Nature* 421:197 (2003)

"Risks and benefits of dual-use research"

"It is important to develop clear guidelines about what research is considered sensitive, what is expected of researchers whose work produces dualuse outcomes, and how the government should in practice respond without losing the priceless virtue of open scientific scrutiny."

Nature 435:7044 (2005)



How Does One Know If There Are Security Concerns?

"I'll know it when I see it" vs.

Systematic and comprehensive evaluation

- Guidance and tools will:
 - Facilitate consistent and well-considered approach
 - Demonstrate to the public that scientists recognize, and are being responsive to, concerns about the security implications of their work



Current Tasks

- Develop for consideration by the NSABB:
 - Principles for the responsible communication of dual use research findings
 - Statement regarding the importance of communicating findings from life sciences research



Current Tasks

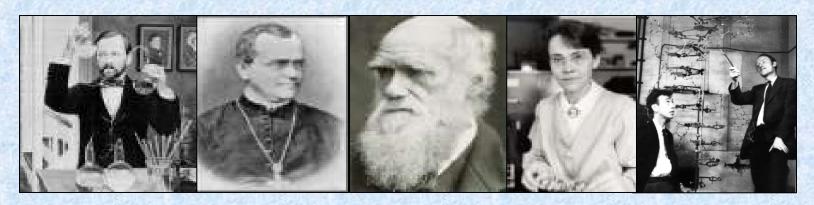
- Framework for identifying and assessing the security implications of communicating dual use research information
- Options for how and when to communicate information
- Elements of a comprehensive plan for communicating dual use research findings that have security implications



Principles that underpin the responsible communication of dual use research findings



Communication is vital for scientific progress



- 1. The open and unfettered sharing of information and technologies has been a hallmark of the life sciences and has fostered a steady stream of scientific advances that underpin public health and safety, a strong and safe food supply, and a healthy environment.
- 2. Progress in the life sciences relies heavily upon the communication of research findings, so that they can be both validated, and built upon.



- Communicate research to the fullest extent possible
 - Restriction of scientific communication is a <u>rare exception</u>
- 3. To ensure the continued advancement of human, animal, plant, and environmental health, life sciences research should be communicated to the fullest extent possible. Consequently, any restriction of scientific communication should be the rare exception rather than the rule.



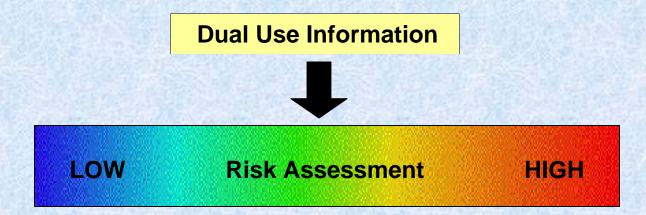
Need for Balance



4. There is, however, a need for reasonable balance in decisions about the communication of dual use research. It is important to recognize the potential for deliberate and malevolent misuse of dual use research findings and to consider whether the disclosure of certain information might pose a significant threat to national security.



 Need to assess risks and benefits of communicating information



5. If the communication of dual use research <u>does</u> pose potential security risks, the logical next step is a risk-benefit analysis of communicating the information.



- Consider a range of communication options
 - The decision to communicate information is not necessarily binary
 - 6. After weighing the risks and benefits of communicating dual use research, the decision regarding communication is not necessarily a binary (yes/no) one. Rather, a range of options for communication should be identified and considered.

 These options could range from full and immediate communication, to delayed and/or modified communication, to restricted/no communication, and could be recommended singly or in appropriate combinations on a case-by-case basis, depending on the nature of the dual use finding and the potential risks associated with its communication.



 Communication occurs throughout the research process

Project Concept and Design Funding application and award process

Institutional Approval Ongoing Research

Development of Manuscript or Research Product Publication of Manuscript or Research Product

7. Paradigms for the responsible communication of dual use research should also take into consideration that the communication of dual use research occurs at multiple points throughout the research process, i.e. at points well upstream of the publication stage.

Thus it is important to apply principles and practices of responsible communication at these early stages as well.



- Need to consider <u>what</u> is communicated, and the <u>way</u> in which it is communicated
 - Potential for public concern and misunderstanding should be minimized
 - 8. It is important to consider not only <u>what</u> is communicated, but also the <u>way</u> in which it is communicated. Investigators and sponsors of potentially dual use research should recognize that the communication of dual use information is likely to raise biosecurity concerns, not only within the general public, but also within the scientific community. Consideration should be given to the potential for public concern and misunderstanding and sensationalism. Thought should be given to the need for the inclusion of contextual and explanatory information that might minimize such concerns and misunderstanding.



Communication Tools

- Framework
 - Identifying and assessing the risks and benefits of communicating dual use research information
- Options
- Communication Plan



Possible uses:

- Review
 - Research proposals
 - Manuscripts
 - Presentations (oral, abstract, posters)
 - Internet postings

Education tool

- Raise awareness of DUR issues within the scientific community
- Ethics training



Possible users:

- Investigators
- Students
- Institutional biosecurity review entity
- Proposal and manuscript reviewers (pre and/or post submission)
- Government policy makers



Key Elements

- General Overview of Information
- Risk Analysis
- Benefit Analysis
- Risk vs. Benefit Assessment
- Formulation of Recommendation Regarding Communication



General Overview of Information

- What information is provided and to what extent is it novel?
 - E.g., is the information already publicly available?



Risk Analysis

- Are there potential <u>risks to public health</u> from application or utilization of this information? (E.g., does the information point out a vulnerability in public health preparedness?
- Could this information be intentionally misused to pose a threat to national security (other than public health)? (E.g., is novel scientific information provided that could be intentionally misused to threaten plant or animal health?
- If a risk has been identified, in what time frame (e.g., immediate, near future, years from now) might this information be used to pose a threat?



Risk Analysis (cont.)

- If the information were to be broadly communicated "as is," what is the potential for:
 - Public misunderstanding
 - What might be the implications of such misunderstandings, e.g., psychological, social, health/dietary decisions, economic, commercial etc.?
 - Sensationalism
 - In what way might it result in widespread concern or even panic about public health or other safety/security issues?



 If no risk is identified, further communication review is not necessary

 If a risk has been identified, complete the benefit analysis



Benefit Analysis

- Are there potential benefits to public health from application or utilization of this information?
- Are there potential benefits of the information for national security?
- Will this information be useful to the scientific community?
- If a benefit has been identified, in what time frame (e.g., immediate, near future, years from now) might these benefits be realized?



- Risk vs. Benefit Assessment
 - Based on the risks and benefits identified, and considering the time frame in which these might be realized:
 - Do the benefits of communicating the information outweigh the risks?
 - Do the risks outweigh the benefits?



 Formulation of Recommendation Regarding Communication

What are the recommendations with respect to the content, timing and extent of distribution of the information?



Communication Tools

Framework

Options



Options for Communication

Spectrum of options – can be used in combination

	Communicate as is	1			1		
Content	Addition of contextual Information		1	1			1
	Modify or remove substantive information			1		1	
	Communicate immediately	1	1	1			1
Timing	Delay communication				1	1	
Distribution	No limit on distribution	1	1	1	1	1	
	Limit distribution on a 'need to know basis'						1
	Don't communicate						



Communication Tools

- Framework
- Options
- Communication Plan a critical part of decision to communicate
 - Not only what is said, but how it is said
 - Promotes public understanding and trust



- Elements of a communication plan
 Important to speak to:
 - The public health significance of the research findings
 - How the new information or technology will be useful to the scientific community
 - The biosafety measures in place as the research was carried out
 - The dual use aspects of the information and that careful consideration was given to the biosecurity concerns in the decision to communicate



- Vehicles for addressing these points:
 - Editorials
 - Scientific journals
 - Popular press
 - Press release
 - Opportunity to provide:
 - Contextual information regarding issues that may be of concern to the public and
 - Scientific perspectives on the importance of the findings



- Vehicles (cont.):
 - Press conference
 - Usually for the most significant and/or sensitive findings
 - Opportunity for direct interaction with the media
 - Qs & As / Talking points
 - Helpful tool for scientists and communications staff

Concerns

Scientific Community

Public





Next Steps

- Seek broader input on communication tools, revise as necessary
 - Possible fora:
 - Focus groups
 - Workshops at professional meetings
- Promote acceptance of the communication tools
 - Scientific community
 - General public



Challenges

- Requires comprehensive education about dual use research concerns
 - Need to coordinate efforts with other working groups
 - Need to clearly explain how the tools fit into the oversight paradigm. E.g.,:
 - Purpose of the tools
 - Who are the users of the tools
 - How will the tools be used
 - When will the tools be used



Still to Come

- Strategies for review of work products containing information with national security implications
 - Where and how should dual use research communications be reviewed?
 - E.g., Institutional or regional committee with appropriate expertise
 - Oversight of research not initially identified as dual use